Original article

Effects of modified U-shaped interspinous distraction device on cadaveric intervertebral disc pressure

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Background: Adjacent syndrome is a widely concerned adverse outcome after spinal fusion. Interspinous distraction device (IDD) has become an interesting device and seems to be the solution by theoretically controlling loads to adjacent levels.
Objective: To analyze the effects of a modified U-shape IDD on the intervertebral disc (IVD) pressure at instrumented and adjacent level of a lumbar spine model.
Methods: Three cadaveric specimens using lumbar vertebrae level 1 - 5 (L1 - L5) spines were loaded in neutral, flexion and extension. Needle pressure sensor was applied to measure IVD pressure at anterior annulus, nucleus pulposus, and posterior annulus of the IVD at L2 - L3, L3 - L4, and L4 - L5. Cadaveric specimens were tested in 4 consecutive sequences including intact specimen, bilateral facetectomy at L3 - L4, insertion of the modified U-shape IDD at L3 - L4, and pedicle screw fixation at L3 - L4, respectively.
Results: By using the modified U-shape IDD, the IVD pressures at L2 – L3 were decreased when compared to both destabilized specimen and specimen with pedicle screw fixation especially IVD pressure at nucleus pulposus in flexion position of cadaveric specimen ($P = 0.021$). However, the IVD pressures at L3 – L4 and L4 – L5 were randomly affected by this device.
Conclusions: The modified U-shape IDD provides support for the upper adjacent IVD pressures but the effect for the instrumented and lower adjacent level are still unremarkable.

Keywords: Interspinous, distraction device, modified U-shape device, tension wire loop, intervertebral disc pressure, biomechanical cadaveric study.

Low back pain from degenerative spinal disease is a very common chief complain for patients who come to visit the orthopaedic clinics.[1, 2] The appropriate treatment ranges from non-operative treatment to the operative procedure. Standard operative option for most of the degenerative spinal diseases is a combination of decompression of stenosis and spinal fusion with or without instrument. Spinal fusion has increased the successful fusion rate but fails to improve the overall clinical success rate.[3 - 7] It also causes the problem of adjacent segment degeneration from increase motion and load transmission to the intervertebral disc above and below the fused segment. Moreover, in long-segment fusion, the overall range of motion is also decreased due to loss of mobile segment.

Motion preservation surgery of the spine is the new concept of surgery that provides the stability while preserve motion of functional spinal unit. This new concept is believed to reduce the disadvantage of the spinal fusion procedure. A modified U-shape interspinous distraction device (IDD) using this new concept has been designed to treat symptomatic degenerative lumbar disease especially for Thai

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patients who are different in size of bony anatomy and financial problem to use imported implants. It was designed and analyzed with finite element by Tantavisut S, *et al*.[8,9] This device is composed of a U-shaped spacer made of titanium located between two adjacent lumbar spinous processes and connected with titanium cable wire that looped around the spinous processes to prevent hyperflexion (Figure 1).

The objective of this biomechanical experimental study was to investigate the effects of modified U-shape IDD on the intervertebral disc (IVD) pressure at the instrumented and adjacent level of a lumbar spine cadaveric model compared in 4 sequential conditions including intact specimen, destabilized specimen simulated by bilateral facetectomy at L3 - L4, insertion of the modified U-shape IDD at L3 - L4, and pedicle screw fixation at L3 - L4 simulated spinal fusion condition, respectively.

Materials and methods

Three soft cadaveric lumbar spines were obtained and preserved from donors' age 68 to 80 years and separated into motion segments consisting of lumbar vertebrae level 1 - 5 (L1 - L5). Each specimen was debrided of muscle and fat tissues while preserved the ligament components. Standard screws and Polymethylmethacrylate (PMMA) were fixed to L1 and L5 vertebraes with the flat platforms. At the time of the study, the specimens were loaded onto a computer-controlled hydraulic machine (Figure 2) with axial load force generator (National instrument-labVIEW 8.5 and Force sensor Kistler model number-9345B).

Before beginning the experiment, the specimens were placed in neutral position while a 300-newton compressive force was applied for 15 minutes to each specimen. This procedure was performed only a single time for each model to precondition the specimens and decrease the postmortem superhydration effects of the corresponding IVD.[10] A pressure transducer with a diameter of 1.40 mm (Denton model number-6376) was stabilized in the holder and inserted into the IVD level with the tip in 3 areas including anterior annulus, nucleus pulposus and posterior annulus respectively to allow for pressure measurement of the L3 - L4 IVD and also the adjacent L2 - L3 and L4 - L5 IVD level (Figure 2).

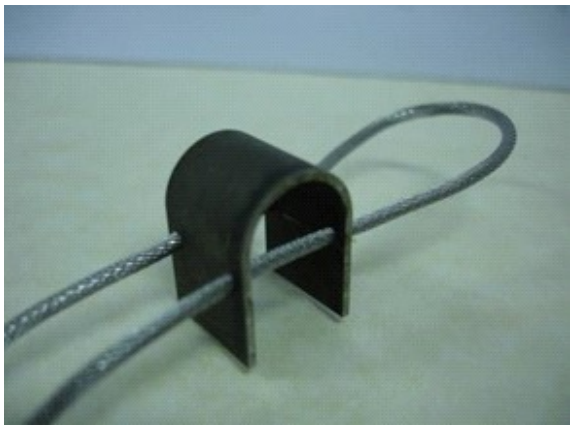

Figure 1. A prototype of modified U-shape interspinous distraction device.

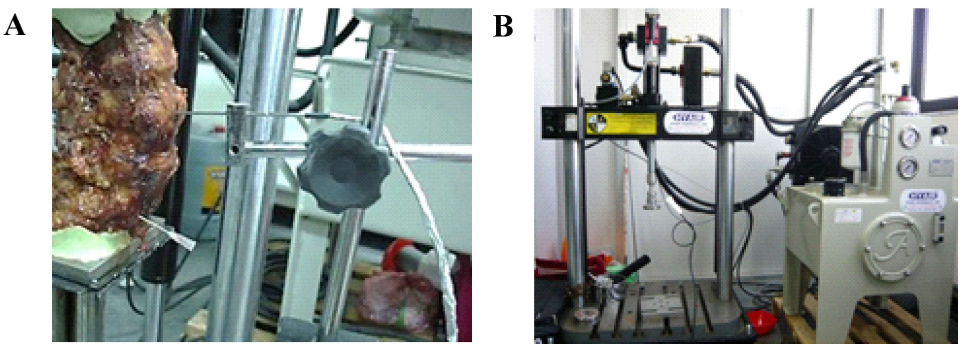

Figure 2. Needle pressure transducer with holder **(A)** and hydraulic loading machine **(B)**.

At the beginning, each specimen was placed in the neutral position to the loading frame and compressed by an axial force of 700 N for a half minute and the pressure transducer was simultaneously inserted along the mid-sagittal plane of the IVD. A 700-N force was chosen because it was approximately the magnitude of force in the lumbar spine during sitting.[11] Pressure measurement was performed for IVD at L2 - L3, L3 - L4, and L4 - L5 with the specimens in neutral, flexed, and extended positions. (See video, Supplemental Digital Content 1, which demonstrates 3 experimented positions) Flexion and extension were achieved by applying force on a wedge platform to produce the respective direction with the same superimposed 700-N compressive load (Figure 3).

Next, the spinal model was prepared for 3 other conditions consecutively. First, bilateral facetectomy was performed by removing both facet joints to create instability.[12] Second, insertion of the modified U-shape IDD at L3 - L4 was prepared by placing the device between the L3 and L4 spinous processes after creating a space through the interspinous ligament and dilating it until appropriated size was achieved without causing the specimen position in hyperflexion or hyperextension then secured with a cable wire. Third, pedicle screw fixation at L3 - L4 was prepared by inserting pedicle screws at L3 and L4 and connected with rod to simulate the fusion condition (Figure 4).

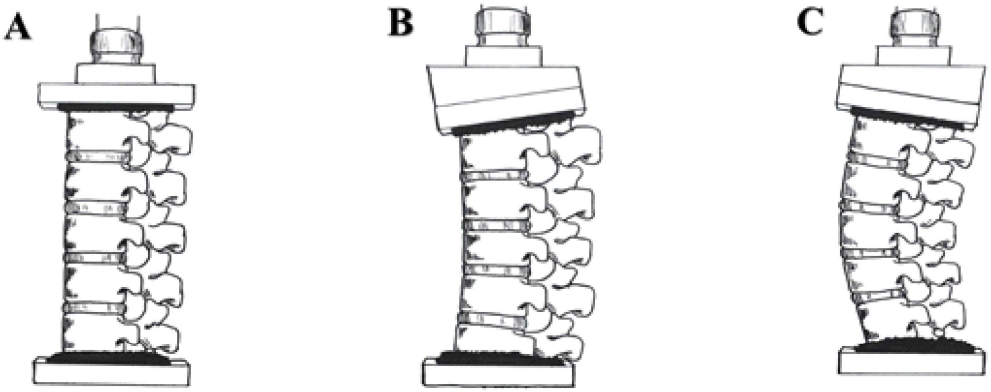

Figure 3. A diagram of 700-N-load applied to specimen in neutral **(A)** flexed **(B)** and extended **(C)** positions by using wedge platform.

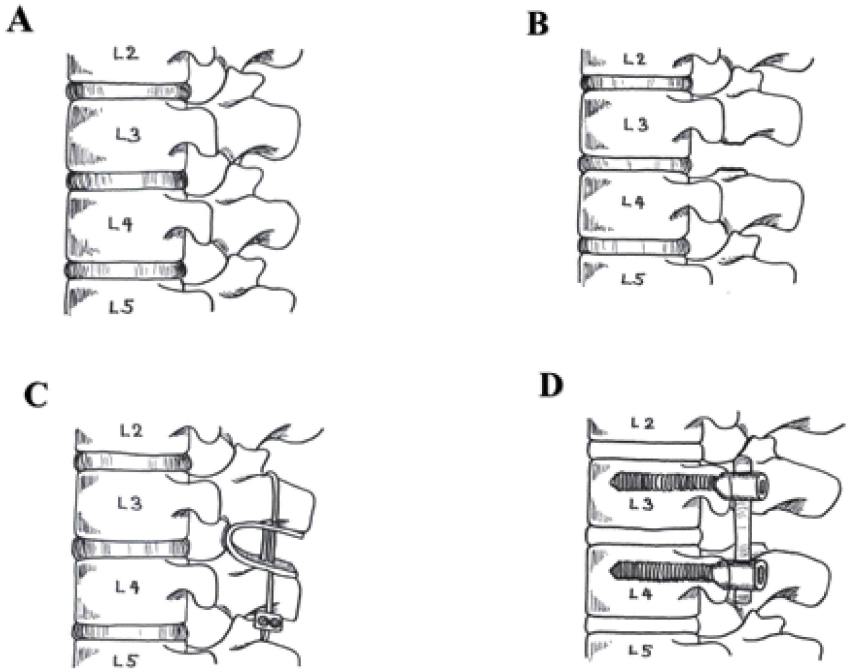

Figure 4. A diagram of cadaveric lumbar spinal specimens prepared in 4 conditions including intact specimen **(A)**, bilateral facetectomy at L3 - L4 **(B)**, insertion of the modified U-shape interspinous distraction device at L3 - L4 **(C)**, and pedicle screw fixation at L3 -L4 **(D)**.

After each condition was prepared, the specimen was placed once again in the loading frame and the aforementioned steps were repeated in each condition. The data were expressed as mean pressures and standard deviation (SD) and analyzed by using the Friedman test for a non-parametric data. *P* - value less than 0.05 was considered as significant difference.

This study has been approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand (IRB no. 442/53).

Results

IVD Pressures at the adjacent segment of L2 - L3 (Table 1)

Comparison in neutral position

There were no significant differences among those 4 specimen conditions in all sensor locations. However, there were few interesting trend of IVD pressure differences from these tests. First, bilateral facetectomy at L3 - L4 level caused higher IVD pressure at L2 – L3 level compared to intact specimen. Second, insertion of the modified U-shape IDD at L3 - L4 could reduce IVD pressure at L2 – L3 level after underwent bilateral facetectomy at L3 - L4. Third, insertion of the modified U-shape IDD at L3 - L4 caused lower IVD pressure at L2 – L3 level compared to the same level IVD pressure after pedicle screw fixation at L3 - L4.

Comparison in flexion position

There was a statistically significant difference of IVD pressure only at nucleus pulposus ($P = 0.021$) among those 4 specimen conditions. However, there were also the same correlations of IVD pressure differences from all sensor locations similar to the aforementioned result of neutral cadaveric specimen position.

Comparison in extension position

There were no significant differences among those 4 specimen conditions in all sensor locations. However, there were also the same interesting trend of IVD pressure differences from all sensor locations similar to the aforementioned result of neutral and flexion cadaveric specimen position.

IVD Pressures at the instrumented segment of L3 – L4 (Table 1)

Comparison in neutral position

There were statistically significant differences of IVD pressures at anterior annulus and nucleus pulposus ($P = 0.041$) among those 4 specimen conditions. The pressure at anterior annulus was higher when the modified U-shape IDD was inserted in comparison with the specimen after bilateral facetectomy. However, the pressures at nucleus pulposus was randomly affected among each specimen condition similar to the IVD pressures at posterior annulus.

Comparison in flexion position

There was a statistically significant difference of IVD pressure at posterior annulus ($P < 0.05$) among those 4 specimen conditions. The pressure at anterior annulus was higher when the modified U-shape IDD was inserted in comparison with the specimen after bilateral facetectomy. However, the pressures at other sensor locations were randomly affected among each specimen condition.

Comparison in extension position

There were no significant differences of IVD pressures among those 4 specimens in all sensor location. The pressure at anterior annulus was higher when the modified U-shape IDD was inserted in comparison with the specimen after bilateral facetectomy. However, the pressures at other sensor locations were randomly affected among each specimen condition.

IVD Pressures at the adjacent segment of L4 – L5 (Table 1)

In neutral, flexed, and extanded position, there were no significant differences of IVD pressures among those 4 specimens in all sensor location. Moreover, there was no trend or correlation among them as well.

Discussion

Many devices of posterior dynamic stabilization with varieties of biomechanical properties have been invented, with some of them having been used in clinical practice. These can be categorized into 4 different types: interspinous ligament, interspinous distraction, pedicle screw-based semimetallic, and pedicle screw-based ligament devices.[13] Among those devices, interspinous devices have increased popularity among orthopedic surgeons because they can be applied with minimal soft-tissue dissection.[14] Many previous in vitro studies of other design of interspinous devices showed that their devices could stabilize the intradiscal pressure on the implanted level without having a significant effect on the adjacent level. A decrease in posterior annular and nucleus pulposus pressure was identified in the implanted level.[15 - 20]

Table 1. Mean intervertebral disc pressures at the L2 - 3, L3 - L4, L4 - L5 level comparing among 4 conditions of spinal cadaveric pecimen.

Level	Spinal cadaveric specimen position	Sensor location	Spinal cadaveric specimen condition								*P*-value
			Intact specimen		Bilateral facetectomy at L3 - L4		Insertion of the modified U-shape IDD at L3 - L4		Pedicle screw fixation at L3 - L4		
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	
		Anterior annulus	275.19	119.01	414.70	329.92	279.13	156.28	513.79	37.65	0.160
	Neutral	Nucleus pulposus	64.85	25.37	112.33	102.74	85.07	37.41	139.19	19.94	0.077
		Posterior annulus	64.17	19.28	90.30	72.39	78.05	48.13	98.60	3.27	0.178
		Anterior annulus	347.01	185.06	475.45	364.45	270.32	109.02	771.83	309.38	0.062
L2 - L3	Flexion	Nucleus pulposus	68.85	10.78	158.54	169.61	98.42	51.15	292.85	134.38	0.021
		Posterior annulus	70.66	12.36	137.05	156.71	87.18	53.72	149.05	14.71	0.106
		Anterior annulus	206.10	101.28	487.87	585.77	199.42	163.02	317.86	263.18	0.472
	Extension	Nucleus pulposus	56.07	22.73	60.10	32.45	67.40	37.69	66.88	47.84	0.896
		Posterior annulus	48.78	19.68	55.21	30.47	59.99	58.27	56.86	36.96	0.564
		Anterior annulus	139.53	97.85	145.15	142.09	289.99	127.74	230.95	26.30	0.041
	Neutral	Nucleus pulposus	103.47	21.92	84.71	41.18	77.16	30.15	125.96	55.73	0.041
		Posterior annulus	100.22	14.56	104.99	110.36	63.68	31.45	105.18	43.88	0.077
		Anterior annulus	191.48	41.87	181.57	106.82	332.55	153.18	236.07	40.34	0.026
L3 - L4	Flexion	Nucleus pulposus	99.92	12.43	109.85	63.34	90.97	43.66	162.81	79.35	0.145
		Posterior annulus	111.15	11.69	107.07	99.82	98.50	53.62	-38.60	174.55	0.050
		Anterior annulus	89.89	130.53	97.58	126.17	210.92	118.86	111.92	72.51	0.323
	Extension	Nucleus pulposus	66.12	40.92	65.01	49.19	62.01	35.80	87.55	11.47	0.472
		Posterior annulus	80.36	51.51	73.67	71.32	36.83	27.85	76.75	18.89	0.095
		Anterior annulus	78.89	52.02	83.52	61.45	111.08	91.60	132.25	148.97	0.782
	Neutral	Nucleus pulposus	152.90	46.06	120.27	79.80	123.42	61.88	152.61	18.96	0.472
		Posterior annulus	229.02	212.60	117.71	28.59	138.12	86.32	127.28	54.98	0.062
		Anterior annulus	106.96	65.23	111.51	55.82	29.42	184.03	121.70	81.61	0.896
L4 - L5	Flexion	Nucleus pulposus	145.96	45.91	103.28	28.16	145.19	68.03	149.39	50.99	0.160
		Posterior annulus	220.69	182.24	130.44	39.56	134.42	73.36	149.28	69.14	0.062
		Anterior annulus	32.02	77.25	31.58	79.39	58.65	71.95	26.29	48.71	0.323
	Extension	Nucleus pulposus	79.06	37.72	54.09	57.11	80.73	14.73	82.65	9.69	0.724
		Posterior annulus	211.76	250.25	66.76	55.38	106.88	105.33	35.18	11.44	0.062

Explanatory legend: IDD = interspinous distraction device

The modified U-shape IDD is a prototype which combines a U-shape posterior dynamic stabilizer with a tensioning titanium wire loop and had been once tested by Singhatanadgige W, *et al*.[21] They performed a cadaveric biomechanical study of this device and it showed the efficacy of this device in controlling segmental motion and translation at implanted level without creating abnormal motion to the adjacent level.

The results of our study showed that this device could significantly decrease intradiscal pressure at nucleus pulposus of upper adjacent level compared to the specimen after bilateral facetectomy or after pedicle screw fixation at L3 - L4 in flexion position. Moreover, there were similar trends of IVD pressure differences without statistical significance at L2 – L3 level at other sensor locations and specimen positions. On the other hand, there were no significant differences of IVD pressures at lower adjacent level of L4 - L5 among those 4 specimen conditions in all sensor locations, cadaveric positions and there was no trend or correlation among them.

However, the IVD pressure at instrumented level of L3 – L4 was increased at anterior annulus when the modified U-shape IDD was inserted in comparison with the specimen after bilateral facetectomy or after pedicle screw insertion in all cadaveric positions. While the pressures at other sensor locations were randomly affected by each specimen condition. The unsatisfied increase in anterior annulus pressure of this device could be explained by either the size of this device might not match with the cadaveric interspinous space or losing of lordotic curve of lumbar spine during cadaveric setup that caused the system to be hyperflexed, therefore increased the load to the anterior structure of the spine.

In contrast, this modified U-shape IDD still had efficacy in decreasing intradiscal pressure of the upper adjacent level and also controlling the pressures at the nucleus pulposus and posterior annulus of instrumented level also with the lower adjacent level compared with the destabilized and pedicle screw fixation group. This was a supporting evidence that the modified U-shape IDD was intentionally designed to achieve the appropriate mechanical properties without over-rigidly stabilized the motion segment of the spine.

There were few limitations to this study. Firstly, aging of the cadaveric spine segment may result in decreasing of the bone mineral density that alter the modified U-shape IDD function. Secondly, IVD measurement during lateral bending, rotational motion and repetitive loading are lacking and should be further tested to add additional information to the biomechanics profile of the modified U-shape IDD. Thirdly, the statistical power of this study may not be enough for generalization to larger population as a result of small number of specimens.

Conclusion

The modified U-shape interspinous distraction device has a stabilizing effect on the adjacent segment from this *in vitro* study; however, the abnormal finding of increasing load in anterior annulus of the implanted level should be carefully considered and needs more experimental study.

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Conflict of interest

The authors, hereby, declare no conflict of interest.

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