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Original Investigation

Dynamic Radiographic Results of Different Semi-Rigid Fusion Devices for Degenerative Lumbar Spondylolisthesis: “Dynamic Rod” vs. “Dynamic Screw Head”

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ABSTRACT

AIM: To assess the clinical outcomes and compare the segmental range of motion (ROM) at the implanted L4-L5 level, the cranial and caudal adjacent levels, and the ROM of the whole lumbar spine after semi-rigid lumbar fusion with 2 different devices.

MATERIAL and METHODS: Patients with neurogenic claudication, due to grade 1 spondylolisthesis and spinal stenosis at levels L4-L5, were treated either Bio-flex® (n = 28) and Cosmic® (n = 23); discectomy was not performed at any level. The clinical outcomes were compared between the 2 groups. All patients underwent neutral, flexion, and extension radiography before the surgery and after 2 years postoperatively. ROM was assessed at the level of L4-L5, L3-L4, L5-S1, and at the whole lumbar spine.

RESULTS: According to clinical outcomes, 82% and 78% of patients in the BioFlex and Cosmic groups, respectively, had a good or excellent result. In both groups, there was significant reduction of the segmental ROM at the implanted L4-L5 level (p = 0.039 and 0.011).

CONCLUSION: These outcomes may play a role in decreasing the risk of ASD after dynamic stabilization, at least 2 years after surgery.

KEYWORDS: Adjacent segment disease, Adjacent segment degeneration, Bioflex, Cosmic, Dynamic stabilization, Lumbar fusion surgery

INTRODUCTION

Lumbar fusion surgery in the treatment of degenerative lumbar diseases is a widely accepted treatment modality. Conventional rigid fusion devices lead to excess axial load and acceleration of adjacent segment degeneration (ASD). In some cases of ASD, further treatments are often required for adjacent segment disorders such as spinal stenosis, herniated nucleus pulposus, and spinal instability. Rates of radiographic ASD after conventional lumbar spinal fusion surgery have been reported to be between 0% and 36% (12).

Recently, a semi-rigid stabilization system has been implemented in the surgical treatment of lumbar degenerative dis-

ease to prevent adjacent segmental degenerations. Some investigators report that dynamic stabilization systems can prevent ASD in clinical and radiological studies (8,11,21), while others suggest that the ratios of ASD after conventional systems or dynamic stabilization procedures are not different statistically (2,6). Among these devices, pedicle screw-based systems are used in more lumbar fusion procedures because of the good clinical outcomes associated with conventional surgical techniques (2,6,8,13,20,21). We performed 2 different dynamic stabilization procedures using a dynamic rod-rigid screw device (BioFlex System; Biospine Corp., Seoul, Korea) and a dynamic rod-dynamic screw device (Cosmic System; Ulrich Medical, Ulm, Germany). The former used flexible Ni-



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tinol spring rods and the latter is secured by a hinged screw head (Figure 1A, B). The 2 systems can theoretically preserve the motion of the implanted segment (1,4,7,11).

The purpose of this study was to assess the clinical outcomes and the range of motion (ROM) changes of the adjacent and implantation segments after 2 different pedicle screw-based dynamic stabilization systems using dynamic plain X-rays.

■ MATERIAL and METHODS

Patients

From 2008 to 2012, we performed dynamic stabilizations on patients with degenerative spondylolisthesis (Meyerding Grade 1) with instability and neurogenic intermittent claudication, using the BioFlex and Cosmic systems. Lumbar degenerative instability was defined as 10 degrees of sagittal rotation and 4 mm of sagittal translation of functional segmental units in dynamic radiographs (5).

Forty-six and 28 patients were treated with the BioFlex and Cosmic system, respectively. All patients had a minimum of 24-months follow-up with dynamic plain X-rays. We excluded patients with multilevel dynamic stabilizations, lumbosacral and L2-L3 or L3-L4 segment stabilizations, and previous lumbar surgeries. We selected patients with only L4-L5 segment dynamic stabilization without discectomy because for more accurate and precise radiologic results, the groups must have similar biomechanical status. Finally, 28 and 23 patients were enrolled in the BioFlex® and Cosmic® system groups, respectively.

All investigations were performed in accordance with our institutional guidelines, which comply with all international laws and policies.

Instruments and Surgical Procedure

The BioFlex® posterior dynamic system (Biospine Corp., Seoul, Korea) is a dynamic rod-rigid screw system (FDA approval; K072321). Stability is assured by a titanium pedicle screw similar to conventional screws, and a coiled-shaped Nitinol rod allows physiological stability during flexion, extension, and lateral bending (Figure 1A).

The Cosmic® posterior dynamic system (Ulrich Medical, Ulm, Germany) is a dynamic rod-dynamic screw device system (FDA approval; K080841). Stability is assured by the threaded rod, and motion preserving is assured by a hinged screw head (Figure 1B). The threaded part of the screw is coated with bioactive calcium phosphate to induce adequate bone healing. The hinged screw allows the same rotation stability as a healthy motion segment, while motion in flexion-extension shows a 65% reduction, and motion in lateral bending shows a 90% reduction compared to intact spine values (17).

In all patients, we performed an optimal neural decompression surgery, such as subtotal laminectomy and foraminotomy, and preserved the facet joint with a midline incision. Discectomy was not performed in any of the patients. After adequate neural decompression, we performed “pedicle screw-based dynamic stabilization” using fluoroscopy.

Clinical Data and Treatment Outcomes

We investigated the clinical parameters, such as age, sex, weight, and body mass index by reviewing the patients’ medical records. The visual analogue scale (VAS) and the modified Macnab criteria were used to compare the clinical outcomes between the 2 groups.

Radiologic Measurement

Dynamic plain X-ray films were obtained using a standard

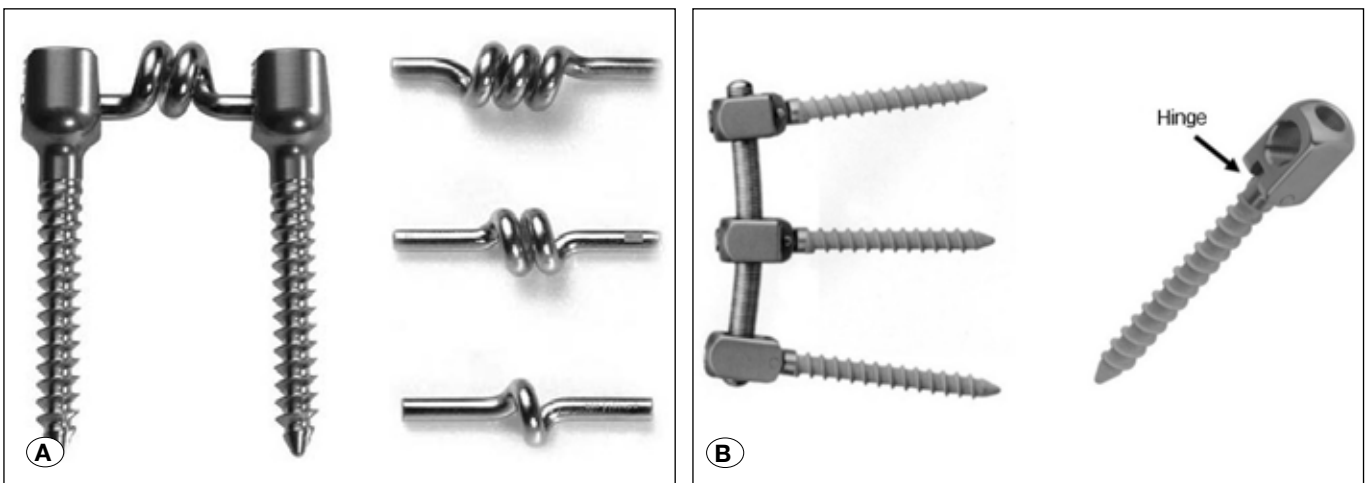


Figure 1: A) The BioFlex dynamic stabilization system. (Permission was obtained from the editor and corresponding author of Adjacent Segment Degeneration After Lumbar Dynamic Stabilization Using Pedicle Screws and a Nitinol Spring Rod System With 2-Year Minimum Follow-up. *Journal of Spinal Disorders and Techniques* 25(8):409-14., 2012). **B)** The Cosmic dynamic stabilization system. The pedicle screw features a hinge joint between the head and the threaded part (arrow). (Permission was obtained from the editor and corresponding author of Pedicle Screw-based Dynamic Stabilization with a Hinged Screw Head System in the Treatment of Lumbar Degenerative Disorders. *Korean Journal of Spine* 8(2):102-105, 2011).

radiographic technique preoperatively, and at more than 24 months postoperatively. The implanted segmental angulation at the level L4-L5 was determined from the upper vertebral endplate of L4 to the upper endplate of L5 on the flexion/extension radiographs. The cranial segmental angulation (L3-L4) was measured from the upper endplate of L3 to the upper endplate of L4, and the angulation of the caudal adjacent segment (L5-S1) was analyzed from the upper endplate of L5 to the superior endplate of S1. The ROM of the whole lumbar spine was also measured from the upper endplate of L1 to the lower endplate of L5. ROM was calculated as the difference of the angulation in extension and flexion. All radiologic measurements were calculated on a personal computer by one independent spine surgeon and one neuroradiologist.

Statistical Analysis

Preoperative data were evaluated using the Mann-Whitney test in case of metric data and Fisher’s exact test in case of nominal data to ensure that both groups of patients were comparable before surgery. With 2 independent radiologic measurements, we calculated the average of all numerical values. The differences in preoperative and postoperative segmental ROM within each group were assessed using the Wilcoxon matched-pairs signed-rank test. Radiologic results of comparison between the 2 groups were assessed using a linear mixed model. Null hypotheses with no differences were rejected if p-values were less than 0.05. Data were analyzed using SPSS 12.0 statistical software (SPSS V12.0K, SPSS Inc., Chicago, Illinois, USA).

RESULTS

Demographic and Clinical Treatment Outcomes

Both groups were similar in age, body weight, body mass index, and preoperative VAS score. Sex was statistically different between both groups (p = 0.004) (Table I). At 2-years

follow-up, the mean VAS score for treatment outcome was 2.1 and 2.3 in the BioFlex and Cosmic groups, respectively. In addition, according to the modified Macnab criteria, 82% and 78% of patients in the BioFlex and Cosmic groups, respectively, had a good or excellent result. There were no statistically significant differences in clinical outcomes between the 2 groups (Table II). Within 24 months, there were no reported instrument-related complications, such as screw loosening and broken screw, in either group.

Radiologic Results (Figures 2,3; Table III)

The mean preoperative ROM of the cranial adjacent segment (L3-L4) was 5.7° ± 2.7° in the BioFlex group and 4.2° ± 3.0° in the Cosmic group. The mean preoperative caudal adjacent segment ROM (L5-S1) was 5.4° ± 4.6° in the BioFlex group and 6.7° ± 5.0° in the Cosmic group. There were no statistically significant postoperative changes in either group.

The mean preoperative whole lumbar ROM (L1-S1) was 31.8° ± 13.3° in the BioFlex group and 33.2° ± 12.7° in the Cosmic group. The postoperative whole lumbar ROM did not significantly change in both groups. The mean preoperative ROM of the implanted segment (L4-L5) was 9.2° ± 6.2° in the BioFlex and 8.5° ± 6.1° in the Cosmic group. The mean dynamic stabilized L4-L5 ROM decreased significantly in both groups (p < 0.05).

Between the 2 devices, there were no statistically significant differences in segmental motion changes at the adjacent levels, implanted level, and in the whole lumbar ROM postoperatively (Table IV).

DISCUSSION

Lumbar fusion surgery is a commonly accepted treatment for degenerative lumbar disease such as stenosis, spondylolisthesis, and instability. However, after lumbar fusion surgery several complications have been reported, including intraop-

Table I: Demographic Characteristics and Preoperative VAS Score

	Bio-flex	Cosmic	p
Age	59.8 ± 8.9	66.0 ± 10.7	0.093
Weight	25.0 ± 3.8	23.8 ± 2.0	0.314
BMI (kg/m ²)	60.0 ± 7.9	61.6 ± 8.8	0.587
Gender (female/n)	15/28	8/23	0.004*
Preop.VAS score	8.4	7.9	0.365

Value given as mean ± standard deviation for “age”, “weight”, “BMI (body mass index)”, and VAS (visual analogue scale).

Table II: Comparison of Clinical Outcomes of the BioFlex and Cosmic Groups

	Postop. VAS score (p<0.05)	Modified Macnab Criteria			
		Excellent (%)	Good (%)	Fair (%)	Poor (%)
Bioflex	2.1	47	35	9	9
Cosmic	2.3	46	32	16	6

VAS: Visual analogue scale.

Table III: Preoperative and Postoperative Range of Motions of each Segments in Degrees After Cosmic and BioFlex Instrumentation at L4-L5 Level

	Bio-flex		p-value	Cosmic		p-value
	Preop.	Postop.		Preop.	Postop.	
ROM L3-L4	5.7 ± 2.7	5.7 ± 4.6	0.795	4.2 ± 3.0	5.5 ± 3.8	0.087
ROM L4-L5	9.2 ± 6.2	3.1 ± 3.2	0.011*	8.5 ± 6.1	4.5 ± 4.5	0.039*
ROM L5-S1	5.4 ± 4.6	6.2 ± 4.0	0.523	6.7 ± 5.0	6.3 ± 5.7	0.807
ROM L1-S1	31.8 ± 13.3	24.7 ± 9.1	0.075	33.2 ± 12.7	26.4 ± 12.2	0.152

Value given as mean ± standard deviation.

Table IV: Results of the Linear Mixed Model Test for Comparisons Between the Cosmic and BioFlex groups

	f	p-value
Preop. x Postop. ROM x group		
L3-L4	0.372	0.408
L4-L5	0.612	0.821
L5-S1	0.413	0.526

ROM: Range of motion.

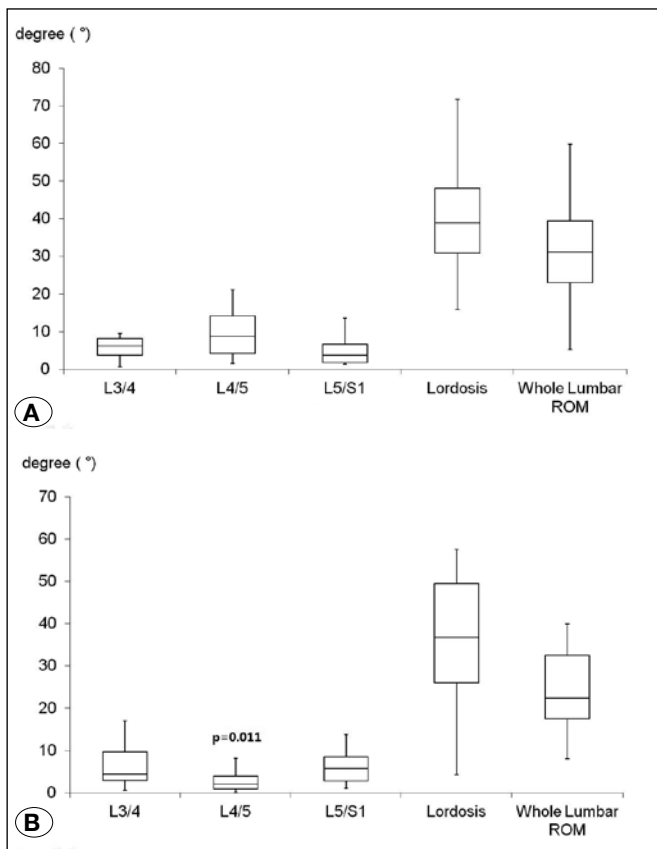


Figure 2: The preoperative (A) and postoperative (B) flexion-extension ranges of motion (ROMs) of the implanted segments, adjacent segments, and the whole lumbar spine in the BioFlex group. The mean preoperative ROM of the implanted segment (L4-L5) was 9.2° ± 6.2° and the postoperative ROM was 3.1° ± 3.2°. The BioFlex system controlled the ROM of L4-L5 significantly (p = 0.011) with preservation of adjacent segment motion.

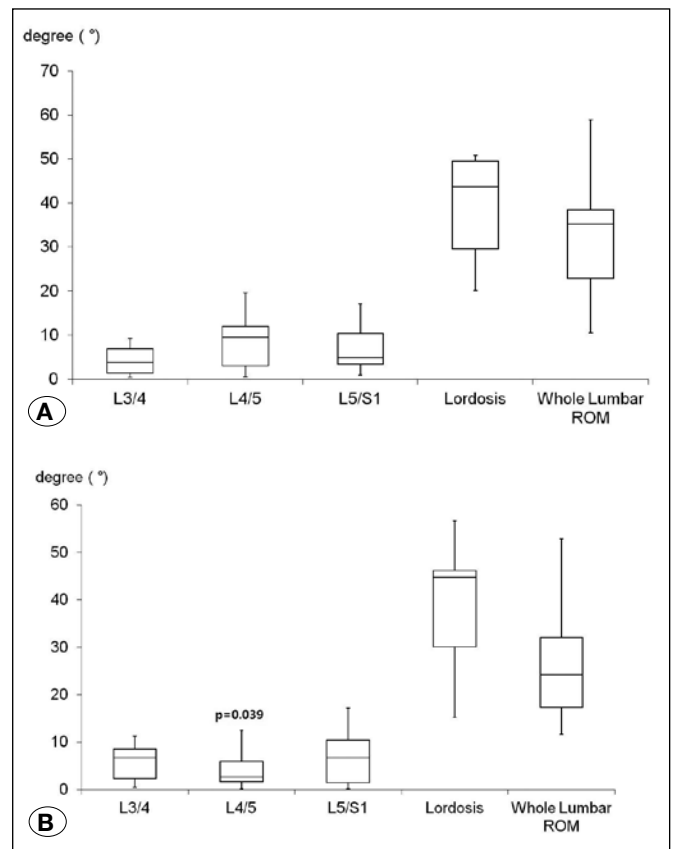


Figure 3: The preoperative (A) and postoperative (B) flexion-extension ranges of motion (ROMs) of implanted segments, adjacent segments, and the whole lumbar spine in the Cosmic group. The mean preoperative ROM of the implanted segment (L4-L5) was 8.5° ± 6.1° and the postoperative ROM was 4.5° ± 4.5°. The Cosmic system controlled the ROM of L4-L5 significantly (p = 0.039) with preservation of adjacent segment motion.

erative neural structure injury, implant migration, dural tearing, infection, heterotopic ossification, osteolysis, subsidence, and acceleration of ASD. Among these complications, acceleration of ASD is common and can lead to significant stenotic lesion, instability, and disc rupture, requiring an additional surgical modality. It has been proposed that lumbar fusion surgery may induce hyper-mobility with increasing intradiscal pressure at adjacent segments and alterations in axial loading distribution (15).

William et al. reported that the mean incidence of additional surgery for symptomatic ASD is 2.5% over the first 10 years in all patients; the 5-, 10-, and 15-year prevalence rates of asymptomatic ASD were found to be 13.6%, 22.2%, and 27.3%, respectively (19). Okuda et al. reported that at the 2-year follow-up, the incidence of ASD without neurologic symptoms was 29% in patients who underwent posterior lumbar interbody fusion (14). In their systemic literature review of 271 articles, Park et al. predicted the incidence of asymptomatic and symptomatic ASD after posterior lumbar fusion to be 100% and 5.2%–18.5%, respectively (16). Therefore, motion-preserved fusion systems, such as interspinous devices, facet replacement systems, artificial disc replacement systems, and pedicle screw-based systems, were applied on the implantation level to prevent ASD. Among those, pedicle screw-based devices are commonly used in the treatment of lumbar degenerative disorders (10), and these are divided into dynamic rod-rigid screw devices and dynamic rod-dynamic screw devices, according to the biomechanical design.

Similar to the BioFlex system, the Dynesys system (dynamic rod-rigid screw device, Zimmer spine Inc., Warsaw, IN) may be generally used for the treatment of lumbar degenerative disorders with many clinical results (10,18); the BioFlex system (dynamic rod-rigid screw device, Biospine Corp., Seoul, Korea) was also proven to be a useful device for dynamic stabilization (9,21). Some investigators have reported good clinical and radiologic outcomes of the BioFlex dynamic stabilization system using dynamic plain x-ray films (3,9,21).

Using postoperative magnetic resonance imaging (MRI), others demonstrated that this system may not completely prevent adjacent level degeneration and speculated that the Nitinol spring rods may be more rigid during extension than flexion; therefore, during extension, the additional axial loading may be transferred to the adjacent levels (6,10) and then, hyper-mobility of the adjacent segment can lead to the acceleration of degeneration. There is need for postoperative MRIs to provide more accurate radiological findings related to ASD after semi-rigid stabilization. In this study, we focused on the motion-preserved result of dynamic stabilization systems that may lead to reduced ASD aggravation. Therefore, we used dynamic plain radiographs to evaluate the ROM of lumbar vertebral segments. The preliminary results of a few studies conducted on this system found that the Cosmic dynamic stabilization system did not influence adjacent segment motion and improved clinical symptoms (3,17).

For similar conditions in both groups, we selected patients with the same preoperative diagnosis of L4 degenerative spondylolisthesis (Grade I) and performed a simple laminectomy preserving the intervertebral disc. Regarding the L3-L4 and L5-S1 segment ROM and the whole lumbar spine ROM, no differences could be observed in both groups preoperatively and postoperatively, which is consistent with previous reports. Motion of the implanted level decreased in both groups, and this outcome may improve back pain caused by hyper-mobility. The rate of decreased implanted segment ROM did not differ statistically between the 2 groups. We suggest that pedicle screw-based dynamic stabilizations in the treatment of lumbar degenerative spondylolisthesis (Grade 1) could maintain the ROM in adjacent segments and control the ROM in implanted segments after the procedure.

We found that previous comparative reports on the incidence rates of ASD after rigid or semi-rigid (dynamic stabilization) systems included subjects who underwent multilevel stabilization and those receiving single level stabilization with discectomy on the implanted segment. Risk factors for ASD after posterior lumbar interbody fusion have been described, including facet sagittalization, facet tropism, and laminar inclination (14). Lee et al. found that pre-existing facet degeneration may be a high risk factor following lumbar fusion surgery (11). Cakir et al. reported adjacent level disc pressure and adjacent level facet joint pressure as other factors contributing to the risk of ASD after fusion of the lumbar spine (2). Park et al. suggested putative risk factors associated with ASD in lumbar or lumbosacral fusion groups, such as facet violation, fusion length, pre-existing degenerated disc at the adjacent level, lumbar stenosis, age, osteoporosis, and post-menopausal state (15). We suggest that risk factors of additional stress on adjacent segments after fusion surgery were related to possible multiple conditions, and not only to fusion device difference as stated in previous reports.

Our study had some limitations. The number of enrolled patients in both groups was small. Therefore, the results of our study cannot be generalized to all pedicle screw-based systems. Further, we did not have a control group that underwent rigid lumbar fusion surgery.

■ CONCLUSION

Lumbar dynamic stabilizations, using pedicle screws with a Nitinol spring rod system and a hinged screw head system, may control the motion of instability level, and both device systems may maintain the ROM of adjacent segments. We suggest that these radiographic outcomes may play a role in decreasing the risk of ASD after dynamic stabilization, at least 2 years after surgery, with favorable clinical results.

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