The Likelihood of Reaching Substantial Clinical Benefit After an Interlaminar Dynamic Spacer for Chronic Low Back Pain: A Clinical and Radiologic Analysis of a Prospective Cohort

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OBJECTIVE: **Chronic low back pain (CLBP) often causes disabling pain that impairs a patient's quality of life. Surgical treatment is recommended for patients who do not respond to conservative treatments lasting more than 6 months. The purpose of this study is to present results after the use of an interlaminar dynamic spacer for CLBP.**

METHODS: **We enrolled consecutive patients with CLBP irresponsive to more than 6 months of conservative treatment into the present study. Included patients underwent an interlaminar dynamic spacer insertion without direct decompression. We assessed radiographic parameters and health-related quality of life (HRQoL) data included visual analog scale back/leg pain and Oswestry Disability Index scores. Substantial clinical benefit achievement was assessed.**

RESULTS: **Thirty-five patients (average age, 47.8 years; 21 female) were included. The mean preoperative symptom duration was 29.6 months. Surgeries involved 1-level (n = 18) and 2-levels (n = 17) procedures. Operative levels included L4-5 (n = 8), L5-S1 (n = 10), L3-4-5 (n-2), and L4-5-S1 (n = 15). The average follow-up period was 16.6 months. After the procedure, all radiographic parameters (including disc height, segmental extension angle, and foraminal area) improved significantly. All preoperative HRQoL parameters improved significantly at the final follow-up. Substantial clinical benefit achievement was observed in 75.8% of the cases on the Oswestry Disability Index, and in 72.7% and 84.8% of the cases on the visual analog scale back and leg pain, respectively.**

CONCLUSIONS: **An interlaminar dynamic spacer significantly improves HRQoL scores in patients with CLBP who do not respond to conservative treatment. Although encouraging, these results should be confirmed with studies assessing a larger cohort and a longer follow-up.**

INTRODUCTION

Chronic low back pain (CLBP) is a serious medical and social problem, and one of the most common causes responsible for musculoskeletal disability. In the literature, it is estimated that worldwide, an individual has an 80% probability of having low back pain (LBP) at some period during their lifetime, and about 18% of the population experiences LBP at any given moment.[1,2] According to the U.S. National Center for Health Statistics reports, 14% of new patients who go to a hospital for treatment are patients with low back pain. This figure represents 13 million people.[3] About 10% of these patients develop chronic persistent or recurrent LBP.[4,5]

To determine the cause of CLBP, the anatomic relationship of the spinal nerves in the neural foramen to the ligamentum flavum, and the intervertebral disk need to be evaluated. The sinuvertebral nerve at the posterior annulus and posterior longitudinal ligament, median branches at the facet joints, the dura mater, and the nerve root (especially the dorsal root, ganglion) are the main

Key words
- Chronic low back pain
- Degenerative disc disease
- Interlaminar device
- Interlaminar dynamic spacer
- Motion preservation

Abbreviations and Acronyms
CLBP: Chronic low back pain
HRQoL: Health-related quality of life
ILD: Interlaminar devices
ISD: Interspinous devices
LBP: Low back pain
MRI: Magnetic resonance imaging
ODI: Oswestry Disability Index
SCB: Substantial clinical benefit
VAS: Visual analog scale
VAS-LBP: Visual analog scale for low back pain
VAS-LP: Visual analog scale for leg pain

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contributors of CLBP. The progression of a degenerative cascade results in intervertebral space narrowing, osteophyte formation, end plate sclerosis, and gas formation within the disc space.[6] With this progressive mechanism, disc degeneration significantly increases the prevalence of spinal stenosis. A narrowed spinal canal or neural foramen impinges the dorsal root ganglion, causing back and neuropathic pain. At extension, the cross-sectional area of the neural foramen and its midsagittal and sagittal subarticular diameters are even more decreased in patients, both with and without retrolisthesis. In addition, extension of the trunk puts added pressure on facet joints.

Considering the complexity of the underlying mechanisms, the treatment of CLBP requires an interdisciplinary program to modulate pain and increase function.[4,7] Once conservative treatment options fail, surgical treatment options are the next step.[4] Although fusion surgery is still the gold standard for intractable back pain,[8,9] results vary considerably among the different studies, and the complication rate after fusion surgery in the lumbar spine cannot be overlooked. Recently, an alternative motion-preserving surgery has been introduced to treat CLBP to overcome fusion-related complications. Among the various types of motion-preserving modalities, interspinous devices (ISDs) are popular because of their favorable clinical outcomes with minimally invasive surgery and fewer overall complication rates.[10-16] Recently, a modification has been developed for ISD that lie in the posterior column, called interlaminar devices (ILDs). These new devices have been developed to support the lamina (i.e., the middle column), in which common pain generators, such as posterior annulus and facet joints, are located, and where it is closer to the rotational axis.[17,18] In the present study, we examine clinical and radiologic outcomes of ILD for treating CLBP.

METHODS

Patient Population

After receiving approval of the institutional review board, we performed a prospective study at a single institution between January 2014 and July 2015. Consecutive adult patients (>18 years old) with CLBP who did not respond to at least 6 months of conservative treatments, such as medication, physical therapy, core muscle strengthening exercise program, epidural steroid injection, or lumbar median branch block, were enrolled into our study for an interlaminar spacer implantation performed by 2 attending surgeons (J.B. and K.-H.K.). Patients with infection, tumor, spondylolisthesis, spondylolysis, trauma, medical compensation, radiculopathy caused by stenosis, or disc herniation requiring decompression, multilevel (>3) disc degeneration, ankylosing spondylitis, previous lumbar surgery, history of psychological symptoms (e.g., depression, anxiety, sleep disorder), and sacroiliac joint pain were excluded from our series. Radiologic inclusion criteria were 1 or more of the following: lumbar magnetic resonance imaging (MRI) showing 1-level or 2-level degenerated disc disease (higher than grade 3 Pfirrmann grade) with or without high intensity zone, facet arthropathy, or retrolisthesis.

Surgical Procedure

Surgery was performed under either general or local anesthesia in the prone position. After sterile surgical preparation, a 3-cm midline skin incision was made on the index level. Usually, a unilateral approach is used for placement of the device. Periosteal muscle dissection is carried out to expose the interspinous space and both cranial and caudal lamina. The lower two thirds of the interspinous ligament is resected with a monopolar coagulator and pituitary forceps. The opposite laminar space can be prepared for implantation using a monopolar and right-angled curette. The ligamentum flavum is preserved because this procedure is not intended to direct central decompression. The base of the spinous process should be cleaned before placing the nose part of the implant (Figure 1). Using the trial implant, surgeons decide on the size of the implant to be used. After insertion of the implant, large pituitary forceps hold the implant to push and pull, to confirm its secure placement. The surgical wound is closed in layers after irrigation. The patient is allowed to ambulate immediately after the procedure, wearing a soft brace. We recommend that patients avoid flexion, extension, and rotation for 2 weeks after

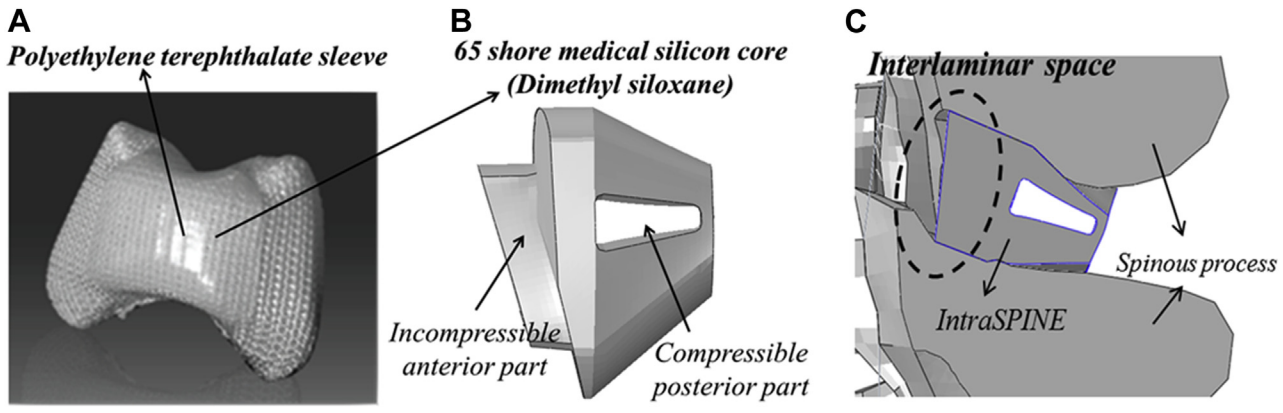

Figure 1. The interlaminar dynamic spacer (intraSPINE). (**A**) Perspective view. (**B**) Lateral view. (**C**) Sagittal view. The rigid incompressible anterior part positioned between the laminae (*dotted circle*), and the soft rear part (*tunneled*) is compressible. (Courtesy of Cousin Biotech, France.)

the surgery. Patients start walking regularly and completing core and stretching exercises 2 weeks after the procedure (Figure 2; case example).

Outcome Measurements

Patient-reported outcomes were measured with a visual analog scale (VAS) for low back pain (VAS-LBP) and leg pain (VAS-LP) and the Oswestry Disability Index (ODI) preoperatively and during the postoperative follow-up period. Substantial clinical benefit (SCB) thresholds for ODI were defined as a net improvement of 18.8 points, a 36.8% improvement, or a final raw score of 31.3 points. SCB thresholds for VAS-LBP and VAS-LP were defined as a net improvement of 2.5 points or a final raw score of <3.5 points. SCB thresholds for percent improvement were set as 41.4% for LBP and 38.8% for leg pain.[19]

Radiologic data were obtained at the preoperative and postoperative follow-up visits with plain radiographs (including standing posteroanterior, lateral, and flexion-extension dynamic views), computed tomography, and MRI of the lumbar spine. Radiologic measurements were taken using digitalized tools in PACS (picture archiving and communication system) (PiView STAR [Infinitt Co. Ltd., Seoul, Korea]). Segmental lordosis at standing and extension, lumbar lordosis, pelvic incidence, sacral slope, pelvic tilt, sagittal vertical axis (C7 plumb line), mean disc

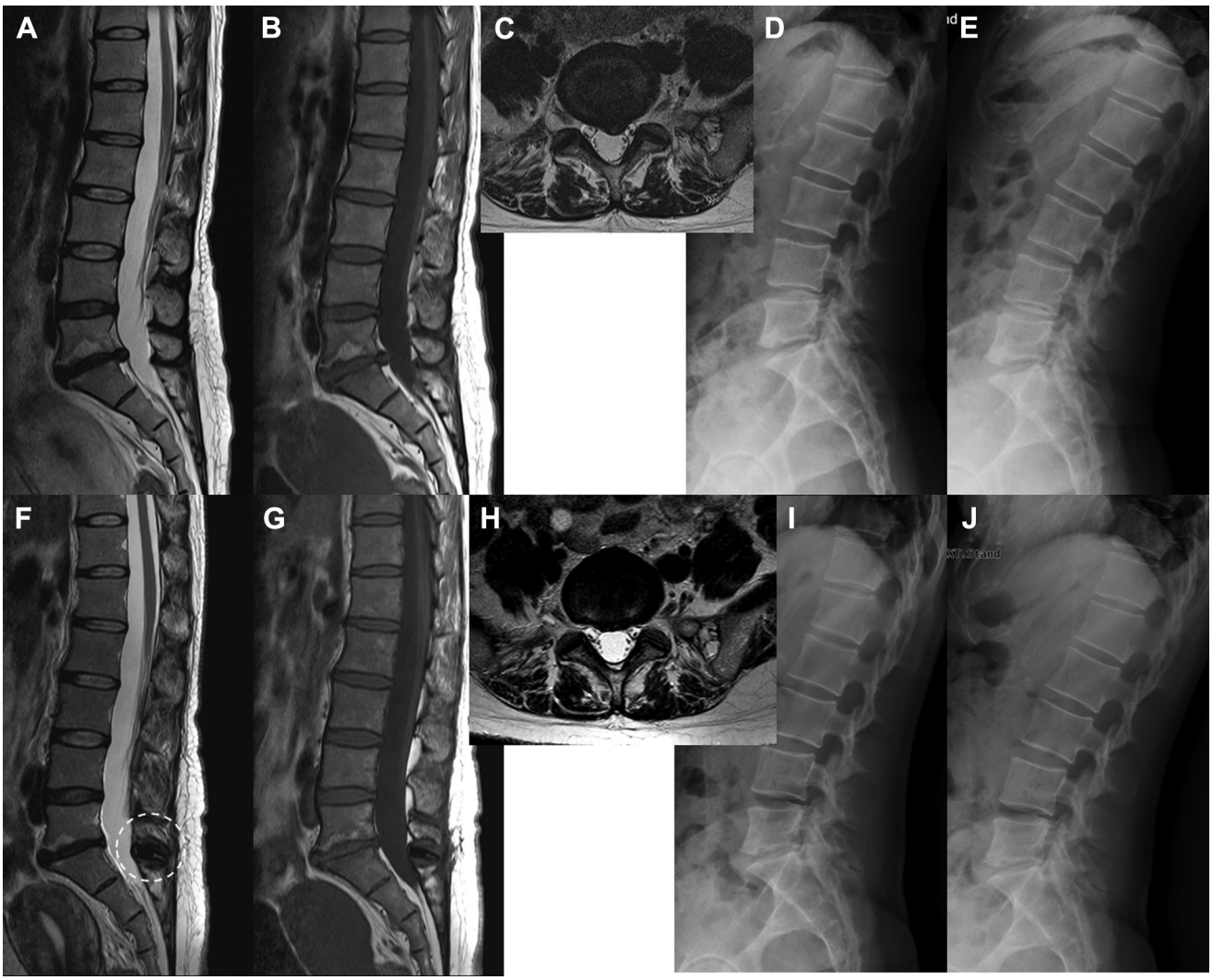

Figure 2. A case presentation of a 37-year-old woman with chronic low back pain for 18 months before surgery. Preoperative magnetic resonance imaging (**A**–**C**) and flexion-extension radiography (**D**, **E**) showing disc degeneration and central protrusion at the L5-S1 level. Modic change (type 1) at the L5 and S1 vertebra can be seen. At the 24-month postoperative follow-up, magnetic resonance imaging (**F**–**H**) and dynamic radiography (**I**, **J**) were performed, showing remodeling of the protruded disc at the L5-S1 and decreased bone edema at the vertebral body. Note the dynamic spacer is located within the laminar space (*round dot*). At the final follow-up, the visual analog scale for back and leg pain decreased from 7 to 1 and 5 to 1, respectively and the Oswestry Disability Index score decreased from 28% to 18%.

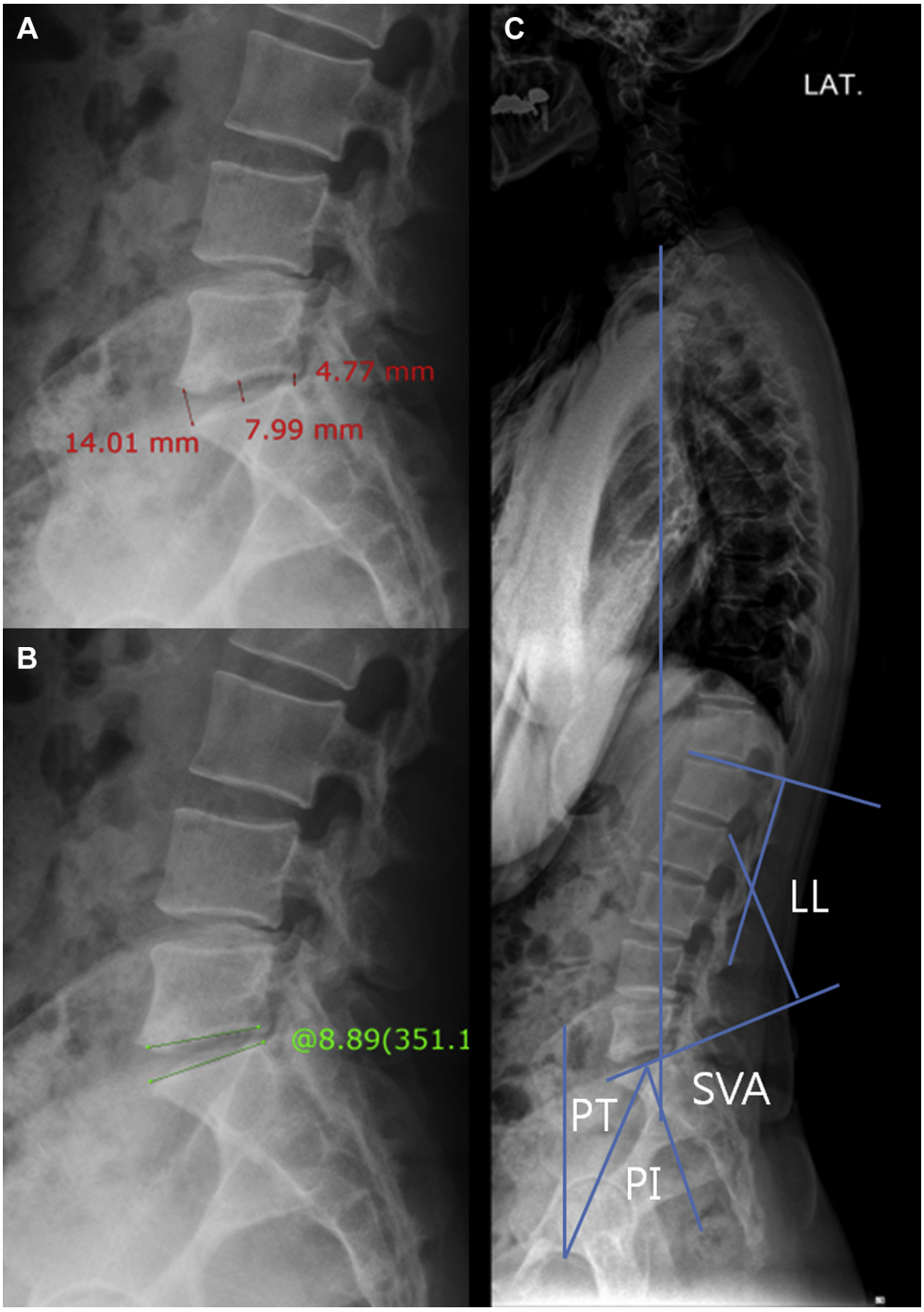

Figure 3. Spinal radiographic measurements. (**A**) Mean disc height was measured as the mean value of anterior, middle, and posterior disc height. (**B**) Segmental angle: sagittal Cobb angle between the lower end plate of the upper vertebra and the upper end plate of the lower vertebra. (**C**) C7-S1 sagittal vertical axis (SVA, plumb line from the center of the C7 vertebral body to the posterior sacral prominence on the lateral radiograph), lumbar lordosis (LL, sagittal Cobb angle between T12 inferior end plate and S1 superior end plate), pelvic incidence (PI, angle between a line perpendicular to S1 superior end plate and the line connecting S1 superior end plate to the bicoxofemoral axis), and pelvic tilt (PT, angle made between lines originating at the bicoxofemoral axis and extending vertically and to the middle of S1 superior end plate).

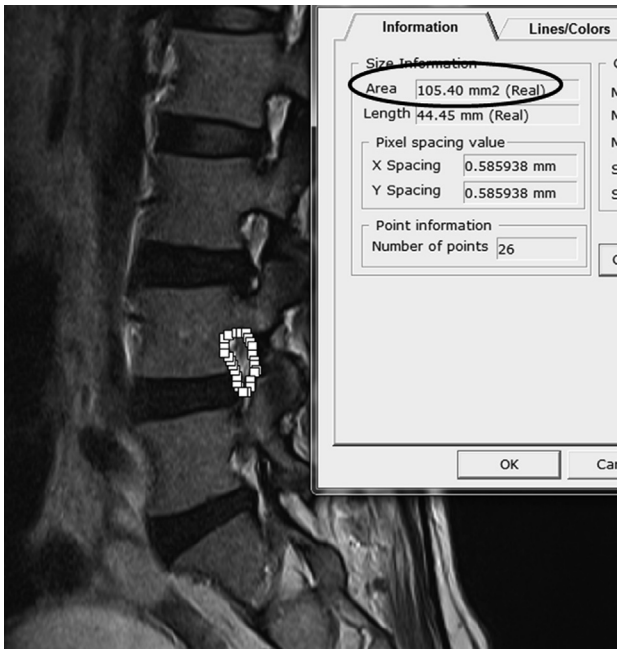

Figure 4. Foraminal dimension was calculated as the mean value of the right and left foraminal area measured within the regions of interest as outlined with a graphic cursor around the neural foramen at the midpedicular zone.

height, and posterior disc height were measured on the lateral radiographs. The segmental dynamic angle was measured on the dynamic radiograph by subtracting the flexion angle from extension angle (Figure 3). Foraminal dimension was measured on sagittal T2-weighted MRI at the midpedicular level (Figure 4). After free drawing the region of interest on both sides at the index level by 2 independent observers, the mean foraminal dimension was measured and preoperative and postoperative data were compared. Disc degeneration was classified according to the Pfirrmann classification system[20] (Table 1).

Statistical Analysis

We used the Student t test for parametric variables and Mann-Whitney U test for nonparametric variables. Pearson correlation coefficients were used to assess correlations between changes in VAS and ODI as well as the changes in radiographic measurements and demographic values. A P value <0.05 was defined as statistically significant. All analyses were performed using SPSS 14.0K (SPSS Inc., Chicago, Illinois, USA).

Table 2. Demographic and Clinical Data

Parameter	Value
Age (years)	47.8 ± 11.7
Sex, n	
Male	14
Female	21
Level, n (%)	
L4-5	8 (22.9)
L5-S1	10 (29.6)
L3-4, L4-5	2 (5.7)
L4-5, L5-S1	15 (42.9)
Preoperative symptom duration (months)	29.6 ± 42.1
Number of levels	
1	18
2	17
Follow-up period (months)	16.6 ± 6.5
Hospital stay (days)	6.9 ± 3.4
Body mass index (kg/m^2)	23.7 ± 2.8

RESULTS

Table 2 shows the demographic data of the patients included in the study. Thirty-five patients (21 females, 14 males; average age, 47.8 ± 11.7 years) met the inclusion criteria. The mean duration of back pain was 29.7 ± 42.1 months with a range of 6–180 months. The mean follow-up period was 16.6 ± 6.5 months with a range of 6–29 months. Of the 35 patients initially included in this study, a 49-year old male patient who had multiple contusion injuries as a result of a motor vehicle accident about 8 months after the surgery was later excluded from the study.

Table 1. Grading of Lumbar Disc Degeneration on T2-Weighted Sagittal Magnetic Resonance Images Proposed by Pfirrmann et al.

Grade	Structure	Distinction of Nucleus and Annulus	Signal Intensity	Height of Intervertebral Disc
I	Homogeneous, bright white	Clear	Hyperintense or isointense	Normal
II	Inhomogeneous with or without horizontal bands	Clear	Hyperintense or isointense	Normal
III	Inhomogeneous, gray	Unclear	Intermediate	Normal to slightly decreased
IV	Inhomogeneous, gray to black	Lost	Intermediate to hypointense	Normal to moderately decreased
V	Inhomogeneous, black	Lost	Hypointense	Collapsed disc space

Table 3. Preoperative and Postoperative Radiologic Outcome

	Preoperative	Postoperative	*P* Value*	Last Follow-Up	*P* Value*
Pelvic incidence (°)	49.1 ± 7.1	49.9 ± 8.2	0.476	49.0 ± 7.6	0.840
Pelvic tilt (°)	14.6 ± 6.8	17.2 ± 8.2	0.055	16.3 ± 7.7	0.049
Lumbar lordosis (°)	47.5 ± 10.3	46.1 ± 8.4	0.523	47.9 ± 8.2	0.780
Sagittal vertical axis (mm)	17.6 ± 13.6	4.0 ± 20.6	0.382	8.7 ± 10.1	0.404
Segmental flexion (°)	6.1 ± 5.0	6.3 ± 4.8	0.687	6.1 ± 4.9	0.971
Segmental extension (°)	14.2 ± 6.2	11.4 ± 6.4	0.000	11.7 ± 5.4	0.000
Segmental range of motion (°)	8.1 ± 6.8	5.1 ± 6.0	0.001	5.4 ± 6.6	0.017
Mean foraminal dimension (mm^2)	76.4 ± 17.1	112.3 ± 23.7	0.000	110.4 ± 24.8	0.000
Mean disc height (mm)	12.1 ± 3.1	12.9 ± 2.9	0.000	12.7 ± 3.1	0.014
Posterior disc height (mm)	7.7 ± 2.4	8.9 ± 2.5	0.000	8.7 ± 2.9	0.001
Modic change	1.9	1.9	1.000	1.9	0.317
Pfirrmann grade	3.9	3.9	0.083	3.9	0.157

**P* value compared with preoperative value.

Table 3 shows the comparison of radiographic parameters at the preoperative, early postoperative, and final follow-up. Global sagittal parameters such as pelvic incidence, pelvic tilt, lumbar lordosis, and sagittal vertical axis did not change significantly after surgery. Regarding regional sagittal parameters, segmental lordosis on the extension at the index level significantly decreased (14.2° ± 6.2° vs. 11.7° ± 5.4°; P = 0.000). The mean disc height (12.1 ± 3.1 vs. 12.7 ± 3.1 mm) and posterior disc height (7.7 ± 2.4 vs. 8.7 ± 2.9 mm) significantly increased after surgery (P = 0.014, P = 0.001, respectively). The range of motion at the index level decreased after surgery (8.1° ± 6.8° vs. 5.4° ± 6.6°; P = 0.017). The mean foraminal dimension significantly increased after surgery (76.4 ± 17.1 vs. 110.4 ± 24.8 mm^2; P < 0.05).

From the preoperative examination to the last follow-up (>6 months), ODI improved from 38.9% to 23.8% and VAS-LBP and VAS-LP improved from 6.8 to 3.6 and from 4.5 to 2.2, respectively (Table 4). Using ODI, 75.8% of patients reached the threshold for SCB. Using VAS-LBP and VAS-LP, 72.7% and 84.8% of patients reached SCB, respectively. 84.8% of patients reached SCB of either ODI or VAS-LBP. Table 5 shows the correlation of demographic and radiographic factors to the achievement of SCB in VAS-LBP, VAS-LP, and ODI. A 2-level surgery showed higher achievement of SCB in VAS-LBP than in a 1-level surgery (0.359, P = 0.040) and L4-5-S1 had superior achievement of SCB followed by L3-4-5, L5-S1, and L4-5 (0.045, P = 0.019) in VAS-LBP and VAS-LP (Figure 5). High body mass index and longer duration of symptoms before surgery showed a significant negative correlation to the achievement of SCB in VAS-LBP and ODI. Preoperative higher lumbar lordosis had an adverse impact on the improvement of VAS-LBP (−0.362, P = 0.038) and a postoperative greater segmental extension angle showed a significant negative correlation to ODI (−0.422, P = 0.016). Table 6 compares significant parameters between the reaching and nonreaching SCB groups, in more detail.

During the follow-up period, complications such as infection, spinous process fracture, allergic reaction, and implant migration were not observed in our series.

DISCUSSION

Because of the complexity of causes, treatment of CLBP is often challenging and consists of a wide array of treatment options ranging from physical therapy to spinal fusion. Although most of the preferred treatment options are conservative modalities so as not to interfere with existing structures, these treatments leave

Table 4. Clinical Outcomes

Variable	Total (n = 29) (Mean ± Standard Deviation)	*P* Value*
Visual analog scale back		
Preoperative	6.8 ± 1.6	
Postoperative	3.2 ± 1.8	0.000
Last follow-up	3.6 ± 2.3	0.000
Visual analog scale leg		
Preoperative	4.5 ± 2.7	
Postoperative	2.4 ± 2.1	0.000
Last follow-up	2.2 ± 2.3	0.000
Oswestry Disability Index (%)		
Preoperative	38.9 ± 14.3	
Postoperative	29.7 ± 12.1	0.001
Last follow-up	23.8 ± 11.9	0.000

**P* value compared with preoperative value.

Table 5. Correlation Coefficiency of Demographic and Radiographic Factors with Substantial Clinical Benefit in Visual Analog Scale for Low Back Pain, Visual Analog Scale for Leg Pain, and Oswestry Disability Index

	SCB VAS-LBP		SCB VAS-LP		SCB ODI	
	Correlation Coefficient	*P* Value	Correlation Coefficient	*P* Value	Correlation Coefficient	*P* Value
Age	0.019	0.917	0.060	0.738	−0.128	0.479
Gender	0.063	0.726	0.005	0.977	0.123	0.496
Level of surgery	0.405	0.019	0.356	0.042	0.016	0.930
Number of index level	0.359	0.040	0.266	0.134	0.017	0.925
Body mass index	−0.358	0.041	−0.275	0.121	−0.357	0.042
Symptom duration	−0.383	0.028	−0.085	0.637	−0.402	0.020
Hospital stay	0.186	0.300	−0.207	0.247	0.135	0.454
Smoking	0.259	0.146	0.179	0.320	0.042	0.817
Depression	0.156	0.387	0.107	0.552	0.144	0.425
Occupational status	−0.133	0.461	−0.146	0.418	−0.138	0.443
Follow-up period	0.161	0.371	−0.093	0.606	0.134	0.458
Preoperative						
Pelvic incidence	−0.118	0.512	0.093	0.605	−0.301	0.088
Pelvic tilt	−0.204	0.255	−0.102	0.571	−0.026	0.886
Lumbar lordosis	−0.362	0.038	−0.036	0.844	−0.086	0.635
Sagittal vertical axis	0.298	0.123	0.029	0.884	0.255	0.191
Segmental flexion	−0.155	0.526	−0.151	0.401	−0.149	0.409
Segmental extension	−0.122	0.500	−0.173	0.344	−0.316	0.073
Segmental range of motion	−0.072	0.692	−0.102	0.571	−0.238	0.182
Mean disc height	0.129	0.475	0.173	0.335	−0.186	0.301
Posterior disc height	0.139	0.439	0.049	0.787	−0.078	0.666
Mean foraminal dimension	0.207	0.247	0.355	0.043	0.223	0.213
Pfirrmann grade	0.072	0.700	−0.208	0.263	0.309	0.091
Postoperative						
Pelvic incidence	−0.235	0.196	−0.275	0.127	−0.029	0.876
Pelvic tilt	−0.149	0.416	−0.033	0.859	0.127	0.488
Lumbar lordosis	−0.290	0.108	−0.280	0.120	0.008	0.964
Sagittal vertical axis	0.312	0.232	0.302	0.726	0.457	0.345
Segmental flexion	−0.113	0.538	−0.154	0.400	−0.291	0.106
Segmental extension	−0.132	0.471	−0.313	0.081	−0.422	0.016
Segmental range of motion	−0.072	0.697	−0.168	0.358	−0.221	0.223
Mean disc height	0.168	0.350	0.186	0.299	−0.085	0.636
Posterior disc height	0.036	0.843	0.169	0.348	−0.249	0.162
Mean foraminal dimension	−0.049	0.790	0.051	0.781	−0.047	0.799
Pfirrmann grade	0.276	0.172	−0.047	0.819	0.239	0.240

SCB, substantial clinical benefit; VAS-LBP, visual analog scale for low back pain; VAS-LP, visual analog scale for leg pain; ODI, Oswestry Disability Index.

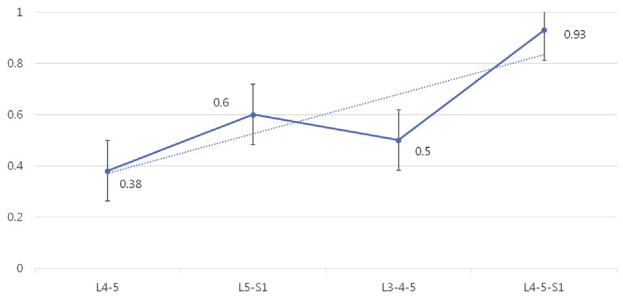

Figure 5. Correlation between the level of surgery and percentage of patients reaching substantial clinical benefit.

patients who still have mechanical instability. As degenerative cascade progresses, disc height (mainly posterior disc height) decreases, causing overloading on the posterior column such as facet joints and interspinous ligaments. Consequently, CLBP arises from multiple pain generators resulting from degenerative cascade, including mechanoreceptors in the vertebral end plates, the sinuvertebral nerves, and nociceptors in the posterior part of annulus fibrosis, the posterior longitudinal ligament, the capsule of facet joints and the dura mater.[21] Apart from spondylolisthesis or instability, which should already be treated by fusion, the loss of structural microstability in a normal spine caused by degeneration also needs to be stabilized.[22] Under these circumstances, it is recommended in the literature that dynamic stabilization systems be used and they are still being developed.

Table 6. Comparison of Significant Parameters Between Reaching and Nonreaching Substantial Clinical Benefit Groups in Visual Analog Scale for Low Back Pain and Oswestry Disability Index

	Substantial Clinical Benefit Reaching	Substantial Clinical Benefit Nonreaching	*P* Value
Visual analog scale for low back pain			
Body mass index (kg/m^2)	23.1 ± 2.8	25.1 ± 2.6	0.044
Symptom duration (months)	25.2 ± 38.6	46.2 ± 52.7	0.032
Level L45, 51, 345, 451	3/6/1/14	5/4/1/1	0.032
Number of levels	1.6 ± 0.5	1.2 ± 0.4	0.040
Oswestry Disability Index			
Body mass index (kg/m^2)	23.2 ± 3.1	25.1 ± 1.7	0.044
Symptom duration (months)	30.1 ± 48.9	33.4 ± 16.5	0.022
Postoperative segmental extension (°)	9.7 ± 5.7	15.7 ± 6.7	0.027

A pedicle screw-based system, arthroplasty such as disc replacement or facet joint replacement, and ISDs are common types of dynamic devices.[10,23] ISD is the most common nonfusion technique device that acts as spacers that can indirectly decompress neural tissue by means of distracting the spinous process.[24] As a minimally invasive surgery device, it compensates limitations of traditional fusion devices by preserving motion. Many of the early outcomes in the literature justified its effectiveness in treating CLBP.[21,25]

As proved in cadaver studies, ISD distracts the posterior part of the functional spinal unit, repositioning and unloading the facet joints and reducing intervertebral pressure, particularly on the posterior part of the end plates, to intervene in the pain-generating mechanism.[23,26,27] Buric et al.[16] reported a significant long-term improvement in pain and disability after surgery with the ISD (DIAM; Medtronic Inc., Memphis, Tennessee, USA) in patients with low back pain. In their study, at the 48-month follow-up examination, 67.3% of patients reached the minimum clinically important difference (>1.5 point improvement) in VAS-LBP. In the present study, our data show a better achievement of SCB in VAS-LBP (78.9%) at a higher point threshold (>2.5 point improvement). Although it may be imprecise to compare these 2 sets of results because of the different follow-up durations, it seems that the outcomes of the present study are in accordance with previous results. The outcomes after the DIAM application were best between 6 and 24 months postoperatively followed by an increase in VAS scores from 24 to 48 months. Despite this increase, VAS scores remained significantly lower than the baseline values. Buric et al. did not report their radiologic outcomes. We presume that the reason for pain deterioration in the later follow-up periods might be related to the loss of correction over time. Despite the many types of ISD, several studies of the biomechanical behavior of different ISDs showed a similar stabilizing effect and that significant postoperative radiologic changes have reverted back to their initial preoperative values during the course of the follow-up period. Complications that lead to the failure of the procedure such as a loss of constraint or a spinous process fracture, or overdistraction leading to segmental kyphosis that causes remodeling or fracture of the spinous process, are examples of loss of correction caused by the biomechanical characteristics of ISD.[28,29]

An ILD is designed to be used as an alternative to ISD because it is implanted more anteriorly in the interlaminar space compared with other ISDs, allowing better physiologic movements.[17] Because of differing elasticity between the anterior and posterior parts of the vertebral column, the posterior part of the spinous process can be deformed and compressed to allow for extension. In turn, ILD acts as an extension blocker at the interlaminar space to unload the posterior annulus and facet joints located in the middle column. Long-term reports of ILD show its clinical and radiologic efficacy in reducing or stopping the degenerative cascade without the loss of correction. Guizzardi et al.[18] reported a retrospective review of 281 patients after a minimum follow-up period of 52 months who underwent ILD implantation of >1 level. In that study, 91.1% of the patients showed excellent/good clinical results. In MRIs taken 18 months postoperatively, the investigators observed that 80% of the patients experienced an improvement or discontinuation of disc degeneration. A finite element analysis model[30] showed that ILD

is effective in reducing intradiscal pressure and facet loads as well as limiting extension, preserving spinal motion, and minimizing the adverse effects on adjacent segments. In an in vitro biomechanical study, ILD was also shown to be effective in decreasing intradiscal pressure and preserving spinal motion and normal axes of rotation.[17]

The overall achievement of SCB after the interlaminar spacer procedure in this study is highly satisfactory. Regarding ODI scores, 75.8% of the patients reached the threshold for SCB. In terms of VAS-LBP and VAS-LP scores, 72.7% and 84.8% of the patients reached SCB, respectively. 84.8% of the patients reached SCB in either ODI or VAS-LBP. Higher body mass index and longer duration of symptoms before surgery jeopardized clinical improvement, which suggests that multifactorial contributions including mechanical burden from obesity, neurophysiologic change,[31] and psychosocial factors[32] are also associated with CLBP. For obese patients, losing weight should be considered before or soon after the surgery. We recommend a multidisciplinary approach to treat patients with CLBP for more than 3 years. In our study, a 2-level procedure or surgery at the L5-S1 showed best overall outcomes. Although this finding does not imply that the L5-S1 level should always be included in the surgical treatment, proper presurgical planning is necessary in cases in which disc degeneration exists at the L5-S1, in addition to the L4-5 level surgery.

There are 2 major limitations of this study that should also be addressed. Although a positive result has been achieved and maintained for the given period postoperatively, definitive results need to be confirmed with longer follow-up periods. Because this is a motion-preserving surgery, it is less likely to develop adjacent segment degenerations to cause LBP. However, the longevity of ILD at the index level should be carefully evaluated with a longer postoperative follow-up period. Despite this limitation, our results are relevant because ILD showed consistent results with studies in the literature about ISD for CLBP. Our study showed even better outcomes at the midterm postoperative follow-up period without any major complications. This study is a level 3 study without a randomized control group. This limitation decreases the power of our result. Patients who underwent fusion surgery, which is a gold standard for intractable back pain, or patients who underwent conservative treatment, could be considered as possible control groups.

CONCLUSIONS

An ILD application significantly improves pain and functional status in patients with CLBP who do not respond to conservative treatment lasting more than 6 months. This finding may be attributable to disc height restoration and prevention of excessive extension, which decreases overloading on facet joints and reduces intervertebral pressure and indirectly decompresses nerve roots by increasing the foraminal area and preserving spinal motion. Although encouraging, these results should be confirmed by studies with larger cohorts and longer postoperative follow-up periods.

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