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

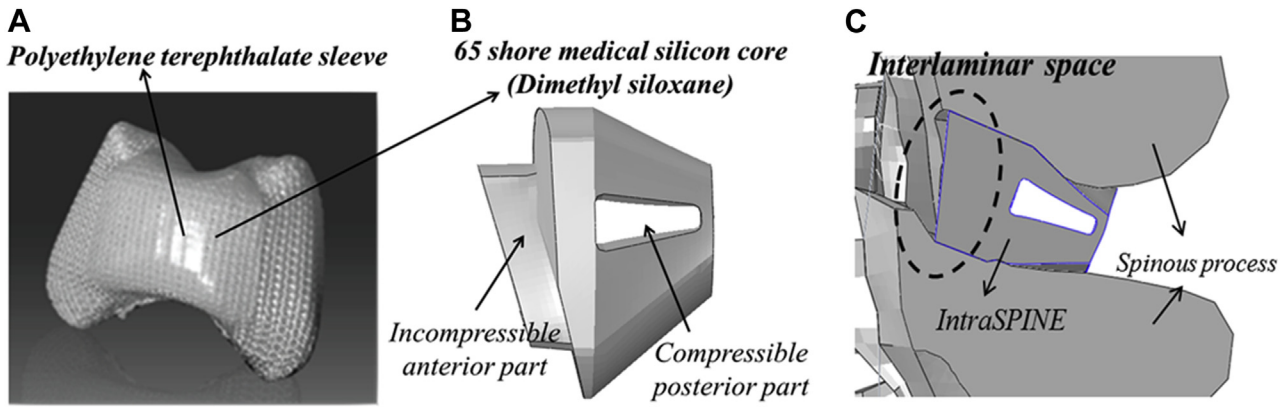

Figure 1. The interlaminar dynamic spacer (intraSPINE). (**A**) Perspective view. (**B**) Lateral view. (**C**) Sagittal view. The rigid incompressible anterior part positioned between the laminae (*dotted circle*), and the soft rear part (*tunneled*) is compressible. (Courtesy of Cousin Biotech, France.)