



Evaluation of Interspinous Spacer Outcomes in Degenerative Lumbar Canal Stenosis: Clinical Study

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■ **BACKGROUND:** Lumbar spinal stenosis is a common diagnosis in elderly individuals, and the rates of surgery have risen all over the world. The optimal approach to provide satisfactory decompression and minimize complications for lumbar spinal stenosis remains controversial.

■ **OBJECTIVE:** The purpose of this study was to evaluate the surgical outcome of interspinous spacers versus decompressive laminectomy in the management of degenerative lumbar canal stenosis.

■ **PATIENTS AND METHODS:** Our prospective, comparative study included 2 groups of patients who were operated on in Ain Shams University Hospitals between January 2010 and December 2014. In the first group, 28 patients underwent decompression and additional implantation of an interspinous spacer (ISP). In the second group, 25 patients underwent decompressive laminectomy (DL).

■ **RESULTS:** Our statistical results revealed no significant difference in outcome between the 2 groups regarding visual analog scale score for leg pain and Oswestry Low Back Pain Disability Index. However, the improvement (visual analog scale score) for back pain was better in the DL group. Complication and reoperation rates were higher in the ISP group.

■ **CONCLUSION:** Although decompression and additional implantation of an ISP are safe procedures, they do not

show better improvement in clinical outcome as compared with decompressive laminectomy.

INTRODUCTION

Spinal stenosis is one of the most common conditions in the elderly. It is defined as a narrowing of the spinal canal.¹ The main cause of lumbar spinal stenosis is progressive degeneration. From a pathoanatomic and pathophysiologic point of view, disk degeneration leads to loss of segmental height, with disk protrusion and narrowing of the spinal canal. The loss of segmental height also narrows the neural foramina and causes increasing protrusion of the dorsal ligamentous structures into the spinal canal. The altered biomechanical situation promotes progressive arthrosis of the intervertebral joints. Reactive hypertrophy of the ligamenta flava additionally narrows the spinal canal and lateral recesses so that, in the end, the spinal canal is hemmed in on all sides.²

Narrowing of the spinal canal can occur in the central portion, lateral recess, or foramen, leading to compression of the neural structures in those locations. The symptoms produced vary by location of neural compression. Patients with central canal stenosis typically present with neurogenic claudication, whereas those with lateral recess and foraminal stenosis present with radicular pain.³ Clinical examination in spinal stenosis is most often remarkably normal.⁴

Surgery for lumbar spinal stenosis (LSS) is generally accepted when conservative treatment has failed or if the stenosis

Key words

- Claudication
- Interspinous spacer
- Laminectomy
- Lumbar canal stenosis
- Radiculopathy

Abbreviations and Acronyms

- DL:** Decompressive laminectomy
- ISP:** Interspinous spacers
- LBP:** Low back pain
- LSS:** Lumbar spinal stenosis
- ODI:** Oswestry Disability Index

SD: Standard deviation

VAS: Visual analog scale

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substantially impacts on the patients' activities of daily living.⁵ Decompressive laminectomy without fusion is the most commonly used surgical treatment.⁶

The morbidity associated with surgical treatment of lumbar stenosis in the elderly is an important aspect as those patients often present with a number of preexisting cardiovascular, pulmonary, or metabolic comorbidities.⁷ An increased complication rate has also been shown to be associated with spinal fusion performed for lumbar stenosis in elderly patients. Therefore less invasive surgical approaches may be of particular interest.⁸

Also, there is some evidence that fusion may increase the biomechanical stresses imposed on the adjacent segments leading to transitional disease, which may occur at an earlier rate in instrumented fusion cases.⁹ That is why the need arises for less invasive strategies that provide a balance between safety and effectiveness.¹⁰

In this study, we focused on the interspinous spacers which are used to treat degenerative lumbar canal stenosis (Coflex device, Paradigm Spine, LCC, New York, New York, USA) and (X-Stop, St. Francis Medical Technologies, Inc., Alameda, California, USA).

The aim of this study is to evaluate the efficacy of the interspinous spacers in the management of degenerative lumbar spinal canal stenosis.

PATIENTS AND METHODS

From January 2010 to December 2014, a prospective study was conducted involving 53 patients complaining of low back pain with neurogenic intermittent claudication secondary to LSS and not responding to conservative measures.

Patients were divided as follows:

- Group 1: underwent decompression and additional implantation of an interspinous spacer (ISP).
- Group 2: underwent decompressive laminectomy (DL).

Patients were randomly selected on the basis of their insurance coverage level; those whose insurance coverage did not permit instrumentation were assigned to laminectomy. And those whose insurance coverage permitted instrumentations were assigned to the ISP group.

All patients were operated on in Ain Shams University Hospitals. All patients had:

- At least moderate degenerative spinal stenosis on the imaging studies with constriction of the central spinal canal, hypertrophy of the facet joints, and lateral recess stenosis or stenosis of the foramen at 1 or 2 adjacent segments in the region from L2–L5.

Table 1. Distribution of Sex, Level of Implantation, and Implant Used

	Number of Patients	Percentage %
Sex		
Male (n %)	22	78.6%
Female (n %)	6	21.4%
Level		
L3-4	1	3.6%
L3-4, L4-5 (n %)	5	17.9%
L4-5 (n %)	19	67.9%
L4-5, L5-S1 (n %)	2	7.1%
L5-S1 (n %)	1	3.6%
Implant used		
Coflex (n %)	21	75.0%
X stop (n %)	7	25.0%

- Radiologic confirmation of no translatory instability in the main segment, as well as in adjacent segments (dynamic translatory instability ≤ 3 mm).
- Neurogenic claudication pain that improves with leaning forward (lumbar flexion).
- Minimum of 4 months' conservative therapy without improvement of symptoms.
- Patients were randomly selected for each procedure.
- Recurrent cases and isthmic spondylolysis (pars fracture) are not included in our study.
- Ain Shams University Ethical Committee approval for the study design, informed consent, and statistical methodology was obtained.

Patient Evaluation

Each patient in this study was carefully assessed clinically in the form of detailed clinical history and a thorough general and local examination.

A thorough history was taken from all patients. The location, duration, relation to various activities, quality, and severity of low back pain and lower extremity complaints were documented, and bowel, bladder control, and sexual function were questioned. It also aimed at defining the degree of pain and patient disability. This was carried out using the Oswestry Low Back Pain Disability Index questionnaire (ODI)¹¹ and visual analog scale (VAS).¹²

Table 2. Description of Preoperative and Postoperative Oswestry Disability Index (ODI) Among Group 1 Patients

	Mean	±Standard Deviation	Minimum	Maximum	Median	Interquartile Range
Preoperative ODI	54.43	6.49	42.00	67.00	54.00	48.00–60.00
Postoperative ODI	30.67	13.28	16.00	64.00	26.00	22.00–42.00
Change in ODI	23.74	13.43	–4.00	47.00	28.00	14.00–32.00

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