Decompression of lumbar canal stenosis with a bilateral interlaminar versus classic laminectomy technique: a prospective randomized study

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OBJECTIVE The aim of this study was to compare the radiological and clinical results of bilateral interlaminar canal decompression and classic laminectomy in lumbar canal stenosis (LCS).

METHODS Two hundred eighteen patients with LCS were randomized to surgical treatment with classic laminectomy (group 1) or bilateral interlaminar canal decompression (group 2). Low-back and leg pain were evaluated according to the visual analog scale (VAS) both preoperatively and postoperatively. Disability was evaluated according to the Oswestry Disability Index (ODI) preoperatively and at 1 month, 1 year, and 3 years postoperatively. Neurogenic claudication was evaluated using the Zurich Claudication Questionnaire (ZCQ) preoperatively and 1 year postoperatively. The two treatment groups were compared in terms of neurogenic claudication, estimated blood loss (EBL), and intra- and postoperative complications.

RESULTS Postoperative low-back and leg pain declined as compared to the preoperative pain. Both groups had significant improvement in VAS, ODI, and ZCQ scores, and the improvements in ODI and back pain VAS scores were significantly better in group 2. The average EBL was 140 ml in group 2 compared to 260 ml in group 1. Nine patients in the laminectomy group developed postoperative instability requiring fusion compared to only 4 cases in the interlaminar group ($p = 0.15$). Complications frequency did not show any statistical significance between the two groups.

CONCLUSIONS Bilateral interlaminar decompression is an effective method that provides sufficient canal decompression with decreased instability in cases of LCS and increases patient comfort in the postoperative period.

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KEYWORDS lumbar canal stenosis; bilateral interlaminar; spinal decompression; minimally invasive surgery

LUMBAR canal stenosis (LCS) is common in the elderly as a result of hypertrophy of the ligamentum flavum, spine aging, disc degeneration, facet joint growth, and osteophytes constricting the spinal canal and resulting in nerve root compression.³ The main symptoms are low-back pain and leg pain and numbness that increase with exertion (neurogenic claudication).³¹ When patients do not respond to conservative treatment, surgery is indicated.² As technology advances, minimally invasive approaches are increasing. One of these minimally invasive methods is bilateral interlaminar canal decompression.⁴⁰ In this study, we compare the radiological and clinical results obtained in classic decompressive laminectomy cases and those achieved in bilateral interlaminar decompression cases.

A classic decompressive laminectomy is the most common surgical approach for LCS decompression. It permits maximal operative decompression of the neural canal and/or bilateral foramina, but there is damage to the paraspinal muscles, the posterior bone compartment, the supraspinous ligament, the interspinous ligament, and occasionally the capsular facet.^{2,3,31,40}

Many techniques have been described for LCS decompression including microhemilaminotomy, interlaminar microdecompression, intersegmental microdecompression, recapturing microlaminoplasty, and segmental microsublaminoplasty.²⁸ In particular, unilateral¹³ and bilateral laminotomy have been described for bilateral canal decompression.^{20,23}

The microsurgical method is ideal for sufficient bilat-

ABBREVIATIONS EBL = estimated blood loss; LCS = lumbar canal stenosis; ODI = Oswestry Disability Index; VAS = visual analog scale; ZCQ = Zurich Claudication Questionnaire.

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eral decompression of the spinal canal or foramen, with minimal paraspinal muscle separation. Thus, it helps to stabilize the spine while the vital bones and soft tissues are secured and at the same time decompressing the spinal canal and/or foramen.¹³

Success rates of the microsurgical methods are as high as 90%; however, studies reporting these rates were without a control group, had few patients with not necessarily the same symptoms, or were retrospective.³⁴ Some investigators did not find a significant advantage to the microsurgical methods over the classic laminectomy.²⁷ Moreover, in the few qualified studies, investigators reported a higher incidence of preoperative neurological morbidity.

As a result, some authors of a systematic review concluded that laminectomies should be reserved for severe LCS cases.⁶ This study had a sufficiently sized population with comparative data; however, it was not a prospective trial. Our aim in the current prospective study was to compare the clinical outcomes and safety between bilateral interlaminar decompression and classic laminectomy in patients with LCS.

Methods

Ethics committee approval to perform this study was obtained. Among 597 patients with LCS who were seen in the neurosurgery department throughout a 24-month period, 218 (mean age 53.5 years, range 41–63 years) were unresponsive to conservative measures, fit our study inclusion criteria, and were randomized to treatment with classic laminectomy (109 patients) or bilateral interlaminar canal decompression (109 patients) (Fig. 1). The following inclusion criteria were used: 1) neuroimaging findings of degenerative LCS, 2) symptoms of radiculopathy or neurogenic claudication, 3) absence of other pathology such as instability or disc herniation, 4) no history of lumbar fusion or LCS surgery, and 5) no history of arthritis or heavy smoking (20 cigarettes/day). All patients had undergone a trial of nonsteroidal antiinflammatory drugs and physical therapy for at least 12 weeks without enough improvement.

Spinal instability was defined as 5 mm or more of translation on sagittal flexion-extension radiographs.⁸

Preoperative Assessment

On admission, all patients underwent full neurological and clinical assessment, and average pain in the last month prior to admission was self-assessed for the low back and legs according to a 10-point visual analog scale (VAS).²⁹ Disability was self-assessed according to the Oswestry Disability Index (ODI) questionnaire,⁹ and neurogenic claudication was assessed using the Zurich Claudication Questionnaire (ZCQ).³²

Radiological examination involved MRI (Fig. 2) for all patients and postoperative CT scanning (Fig. 3) for confirmation of adequate decompression of the involved segments.

Randomization Plan

Informed consent was obtained from every patient. A blinded person from the study (resident) gave every pa-

tient who met the inclusion criteria a number according to their sequence on admission, which was used for the randomization. The even-number group was operated on via bilateral interlaminar decompression, and the odd-number group was operated on via classic laminectomy.

Operations

Surgery was performed with the patient under general anesthesia and in the prone position for both procedures and using the operating microscope in the bilateral interlaminar decompression procedure. Undercutting of the facet joints was used in both groups to diminish the facet joint resection. To evaluate the adequacy of decompression, postoperative CT scans were obtained in all patients.

Classic Laminectomy: Group 1

The laminae and spinous process of the stenotic segment(s) and the medial end of the facet joint were resected.⁷

Bilateral Interlaminar Canal Decompression: Group 2

A midline skin incision was sharply made over the intended levels through subcutaneous tissue. The lumbar fascia was then encountered and incised bilaterally. In a subperiosteal fashion, the musculature was elevated off the lamina without disturbing the facet capsule. The microscope was brought into the field, and the remainder of the procedure was done with microscopic visualization. Resection of the lower end of the superior lamina and a small part of the superior end of the inferior lamina was followed by excision of the ligamentum flavum to expose the canal. To expand the lateral recess, resection of the medial end of the facet joint was also done. The spinous process, a considerable percentage of the lamina, and the supra- and interspinous ligaments were conserved.^{4,20,23}

Assessment of the Surgical Procedure

Intraoperative factors such as duration of the technique, estimated blood loss (EBL), and other intraoperative issues were noted. Perioperative morbidity included the occurrence of nerve injury and any reoperations in the 3 years since surgery.

Outcome Evaluation

For the proper assessment of pain in the back and legs, VAS scores were recorded at follow-ups 1 month, 1 year, and 3 years after surgery. The ODI scores were recorded at 1 month, 1 year, and 3 years after surgery, and neurogenic claudication (ZCQ) scores were recorded at 1 year. The results were evaluated by a statistician. MRI and flexion-extension radiography were performed in patients showing recurrent symptoms or substantial residual stenosis. In cases of residual or adjacent-level stenosis and instability, surgical intervention occurred and was documented.

Statistical Analysis

The unpaired Student t-test, Fisher exact test, and chi-square test were used as appropriate to analyze differences

FIG. 1. Flow process: enrollment, randomization, treatment, and 3-year follow-up.

in the preoperative demographic characteristics (age, sex, weight, and spinal levels involved), clinical presentations (preoperative ODI, ZCQ, and VAS scores), and clinical outcomes (postoperative complications and ODI, ZCQ, and VAS scores) between the two groups. The paired Student t-test was used to analyze variations in each group over a period of time. Statistical significance was established at $p < 0.05$.

Results

There were no significant preoperative dissimilarities between the two groups of patients (Table 1). Preoperative low-back and leg pain scores (VAS) were recorded (Table 2); there were no significant variances in the preoperative

pain features between the groups. The mean preoperative neurogenic claudication duration was 26.4 months.

Pain Assessment

Surgical canal decompression led to a marked decrease in total pain compared to the preoperative pain in both groups ($p < 0.001$). Preoperative average back pain scores on the VAS were 6.82 ± 1.18 in group 1 and 6.56 ± 1.08 in group 2, and preoperative average leg pain scores were 8.06 ± 0.94 and 7.91 ± 0.94 , respectively (Table 2 and Fig. 4A). These preoperative scores were not significantly different between the groups. The remaining overall average back pain scores on the VAS were 5.85 ± 1.37 , 5.35 ± 0.99 , and 3.08 ± 1.02 in group 1 at 1 month, 1 year, and 3 years,

FIG. 2. Preoperative MRI of the lumbar spine: sagittal (A) and axial (B) views.

respectively, compared with 3.02 ± 1.12 , 1.92 ± 0.85 , and 1.37 ± 0.6 , respectively, in group 2. With regard to back pain, compared to the preoperative pain, both groups had significant improvement on the VAS ($p < 0.001$), and the improvements were significantly better in group 2 ($p < 0.001$), which may have been attributable to less muscle dissection and less bony removal. The remaining overall average leg pain scores on the VAS were 2.35 ± 1.01 , 1.39 ± 0.82 , and 1.08 ± 0.31 in group 1 at 1 month, 1 year, and 3 years, respectively, compared with 2.3 ± 0.95 , 1.37 ± 0.54 , and 1.17 ± 0.38 , respectively, in group 2 ($p > 0.05$). With regard to the leg pain, compared to the preoperative pain, both groups had significant improvement on the VAS ($p < 0.001$), and there was no significant difference between the two groups ($p > 0.05$; Fig. 4B).

Disability Assessment

There was a marked decrease in total disability after surgical canal decompression in both groups, as compared to the preoperative disability ($p < 0.001$). The preoperative average disability scores on the ODI were 33.77 ± 5.65 in group 1 and 32.22 ± 5.37 in group 2. The remaining overall average disability scores on the ODI were 16.6 ± 7.03 , 14.73 ± 6.36 , and 14.06 ± 6.27 in group 1 at 1 month, 1 year, and 3 years, respectively, compared with 13.62 ± 5.75 , 11.63 ± 4.82 , and 10.98 ± 5.17 , respectively, in group 2. There was no significant difference in preoperative dis-

ability between the groups (Table 2). Improvements on the ODI were significantly better in group 2 ($p < 0.001$).

Neurogenic Claudication

Neurogenic claudication, which is the most common symptom of LCS, improved after surgery in both groups according to the ZCQ ($p < 0.001$). Preoperative mean symptom severity and physical function on the ZCQ were not significantly different between the groups (Table 2). Symptom severity and physical function scores improved at the 1-year postoperative visit in both groups. The mean patient satisfaction scores according to the ZCQ were 2.25 ± 0.69 in group 1 and 2.1 ± 0.7 in group 2 ($p = 0.11$). There was no significant difference between the groups except in postoperative symptom severity, which was higher in group 1 ($p < 0.001$) mainly due to high scores in the back pain questions.

Levels Involved

We detected multisegmental stenosis in the majority of patients, with an overall mandatory decompression of 414 levels (Table 1). The L3–4 and the L4–5 levels were most commonly involved (96 [23%] and 95 [23%] of cases, respectively). The maximum number of levels decompressed was four in each group. The mean number of levels decompressed was 1.92 ± 0.58 in group 1 and 1.88 ± 0.59 in group 2.

FIG. 3. Postoperative CT of the lumbar spine: sagittal (A), axial (B), and coronal (C) views.

Intraoperative Parameters

The planned technique was followed in all patients, and lumbar canal decompression was sufficiently attained in all surgical cases. The operation's mean time per level was significantly longer for group 2 (112 vs 64 minutes in group 1, $p < 0.001$; Fig. 4C). The mean EBL was lower in patients in group 2 (140 vs 260 ml/level in group 1; Fig. 4D). No patient in group 2 required a blood transfusion, whereas 1 patient in group 1 required a blood transfusion because of intraoperative blood loss.

Intraoperative Complications

Unintended durotomy occurred in 9 cases in group 1 and 4 cases in group 2 ($p = 0.15$; Table 3 and Fig. 4E). Dural tears were associated with an increased duration of surgery. The tears were managed by direct stitching, and no subsequent postoperative CSF fistula was detected. Seven cases in group 2 had an epidural hematoma needing reoperation ($p = 0.007$), which was recognized on MRI. Three cases in group 1 and 1 case in group 2 had a postoperative radicular deficit ($p = 0.31$).

Four wound infections were noted in group 1 (3 deep

and 1 superficial) and 11 cases in group 2 (all superficial; $p = 0.06$; Fig. 4F). We did not have any perioperative deaths.

Follow-Up

Follow-ups were conducted 1 month, 1 year, and 3 years after the operation. In that period, 1 patient died of unrelated reasons 26 months after surgery and 1 patient was lost to follow-up within 3 years after surgery (both were in group 2); therefore, 216 patients were followed up for 3 years.

Necessary Reoperations

All the patients had adequate canal decompression, which was seen on the postoperative CT scan and was reported by the radiologist. Reoperation was required for recurrent or residual LCS in the same segment within 3 years in 1 patient in group 1 and 2 cases in group 2. Postoperative instability necessitated fusion surgery in 9 patients in group 1 and 4 patients in group 2. Overall, the reoperation rate between the groups was nearly the same ($p = 0.15$; Fig. 4G).

TABLE 1. Demographic and clinical characteristics of patient groups

Variable	Group 1 (classic laminectomy)	Group 2 (bilat interlaminar decompression)	p Value
No.	109	107	
Age in yrs	52.88 ± 4.19	54.21 ± 4.54	0.0256
Males	55%	52.3%	0.68
Weight in kg	89.75 ± 7.4	88.65 ± 6.9	0.26
No. of levels decompressed	209	205	0.49
Mean no. of levels decompressed	1.92 ± 0.58	1.88 ± 0.59	
Mean EBL/level in ml	260 ± 75	140 ± 44	<0.001
Mean surgical time/level in mins	64 ± 10.4	112 ± 29.6	<0.001

Discussion

Following our experience and with the aid of previous studies that have reported on the effectiveness of bilateral interlaminar decompression, we report the results of the first randomized prospective study comparing bilateral

TABLE 2. Clinical outcomes: VAS, ODI, and ZCQ scores

Scale	Group 1	Group 2	p Value
VAS low back			
Preop	6.82 ± 1.18	6.56 ± 1.08	0.091
Postop			
1 mo	5.85 ± 1.37	3.02 ± 1.12	<0.001
1 yr	5.35 ± 0.99	1.92 ± 0.85	<0.001
3 yrs	3.08 ± 1.02	1.37 ± 0.6	<0.001
VAS leg			
Preop	8.06 ± 0.94	7.91 ± 0.94	0.24
Postop			
1 mo	2.35 ± 1.01	2.3 ± 0.95	0.71
1 yr	1.39 ± 0.82	1.37 ± 0.54	0.83
3 yrs	1.08 ± 0.31	1.17 ± 0.38	0.057
ODI			
Preop	33.77 ± 5.65	32.22 ± 5.37	0.0391
Postop			
1 mo	16.6 ± 7.03	13.62 ± 5.75	<0.001
1 yr	14.73 ± 6.36	11.63 ± 4.82	<0.001
3 yrs	14.06 ± 6.27	10.98 ± 5.17	<0.001
ZCQ			
Preop			
Symptom severity	3.5 ± 0.63	3.38 ± 0.66	0.17
Physical function	2.66 ± 0.7	2.61 ± 0.62	0.58
Postop (1 yr)			
Symptom severity	2.85 ± 0.8	2.05 ± 0.66	<0.001
Physical function	1.74 ± 0.7	1.7 ± 0.71	0.68
Patient satisfaction	2.25 ± 0.69	2.1 ± 0.7	0.11

TABLE 3. Perioperative complications

Complication	Group 1	Group 2	p Value
Dural tear	9 (8.3%)	4 (3.7%)	0.15
Epidural hematoma	0 (0%)	7 (6.5%)	0.007
Radicular deficit	3 (2.8%)	1 (0.9%)	0.31
Wound infection	4 (3.7%)	11 (10.3%)	0.06

interlaminar decompression with laminectomy in 218 patients with LCS.

Demographics

Degenerative LCS is seen more often in people ages 60 and above.¹⁴ The most common surgery for LCS is laminectomy and bilateral partial facetectomy. While this approach is satisfactory in alleviating the symptoms of neurogenic claudication, the risk of new-onset spondylolisthesis is reported to be as high as 31%.¹⁰ Progression of spondylolisthesis is evident on radiography if resection of greater than 50% of the facet joint was done at any level.¹

Surgical Approach

The benefit of classic laminectomy is the adequate working space that it offers through the removal of the posterior elements, including the spinous process, interspinous ligament, and supraspinous ligament, which enables good visibility. A disadvantage of the classic laminectomy includes resection of the osteoligamentous complex, which may cause trunk extensor weakness and secondary spinal instability. The classic laminectomy has a success rate of only 64%, significant intraoperative bleeding, and perioperative complications such as incisional pain after surgery, longer recovery time, disturbance of the normal anatomy, and perhaps failed back syndrome.³⁸

The benefit of minimally invasive methods is the possible preservation of the osteoligamentous complex; however, these methods still involve disturbance of the paraspinal musculature and the risk of neural injury especially in patients with tight LCS.^{17,33,38} The advantage of bilateral canal decompression over classic laminectomy is preservation of the posterior ligamentous complex, which stabilizes lumbar motion and acts as a tension band. The disadvantage of bilateral canal decompression is the smaller operational space encountered and the possible prolongation of operative time because of technical difficulty. In addition, if unintended durotomy occurs, a complete laminectomy may be obligatory to adequately visualize and repair the dural defect.³⁴ In 1993 Postacchini et al. recommended bilateral laminotomy as acceptable for mild to moderate stenosis, whereas laminectomy was favored for severe stenosis or spondylolisthesis.²⁷ These authors maintained that bilateral laminotomy must not be routinely done with severe stenosis. The clinical decision is affected by the severity of stenosis,³⁵ medical comorbidity,¹⁸ the liquid inside the facets,¹ facet tropism,²¹ and segmental mobility before surgery.²⁴

More modified techniques have been planned by numerous authors, especially unilateral and bilateral laminotomy for bilateral canal decompression, with reported

FIG. 4. Bar graphs depicting mean preoperative back and leg pain scores (VAS, **A**); mean postoperative back and leg pain scores (VAS) at 1 month, 1 year, and 3 years after surgery (**B**); mean operative time (**C**); mean EBL (measured in ml; **D**); number of unintended durotomies (**E**); number of superficial and deep wound infections (**F**); and number of patients needing reoperation (**G**).

success rates of 60%–80%. The advantage of unilateral and bilateral laminotomy over classic laminectomy is reduced pain postoperatively, improved health-related quality of life, and no need for fusion surgery later on.^{25,33,39} The interlaminar decompression has the benefit of conserving the inferior levels of the paraspinal muscle from atrophy due to the reduction of muscle injury.¹⁵

Clinical Outcome

Thomé et al. reported a randomized study of 120 patients who underwent LCS decompression.³³ The patients were randomized to three treatment groups: unilateral laminotomy, bilateral laminotomy, and laminectomy. The bilateral laminotomy group had the lowest total complication rate. Ninety-four percent of patients had at least 12 months of follow-up. Residual pain was lowest in the bilateral laminotomy group (VAS score 2.3 ± 2.4 and 4 ± 1 in laminectomy group, $p = 0.05$; and 3.6 ± 2.7 in unilateral

laminotomy group, $p < 0.05$). In most of the cases, bilateral laminotomy produced major advantages, and it proved to be a possible treatment substitute in cases of LCS.

In reviewing the literature on the bilateral interlaminar canal decompression technique,²² we found clinical case series showing good results in 91%⁴ of cases in 1 year; 82%,²³ 87%,¹² 78%,⁴¹ and 68%⁵ of cases in 2 years; 85%⁷ of cases in 3 years; and 74%⁵ of cases in 6 years. Moreover, in a 54-patient prospective outcome study, Kleeman et al. showed patient satisfaction at 100% and good outcomes at 88% after 4 years without any deterioration.²⁰

In our randomized study, the outcomes confirm that bilateral interlaminar decompression is superior to laminectomy in terms of less postoperative back pain. Fusion was indicated less often in group 2 patients. Long-term analysis of the follow-up data showed that bilateral interlaminar decompression is more beneficial for LCS patients and may reduce the need for further fusion surgery, but

there was no statistically significant difference in the reoperation rate between the groups ($p = 0.3$).

Comparative preoperative and postoperative imaging showed adequate decompression in both groups. A comparison of both decompression on imaging and postoperative leg pain (VAS) indicated no significant differences between the groups, which reveals that bilateral canal decompression is sufficient. Furthermore, postoperative low-back pain was statistically worse in the laminectomy group ($p < 0.001$).

Intraoperative Parameters

Although bilateral canal decompression's longer operative time seems to be a disadvantage compared to the classic laminectomy, it is believed that the operative time will decline for the bilateral decompression group as the surgeon learning curve improves, as in our study. To avoid complications during surgery, surgeons use fine Kerrison rongeurs instead of a high-speed drill, the latter contributing to a longer operative time. Prolonged surgery time has always been associated with bilateral interlaminar canal decompression²⁷ compared to the classic laminectomy.³⁹ In our study, the mean operative time was 64 minutes/level for group 1 compared to 112 minutes/level for group 2. The longer time was attributed to a lack of experience with the bilateral interlaminar canal decompression approach, which decreased in the cases performed later in our series because of the learning curve. Only 6 surgeons with 4–9 years of neurosurgical experience were involved in these operations. Khoo and Fessler described a surgical time of 109 minutes/level for microendoscopic unilateral laminectomy and 88 minutes/level for classic laminectomy.¹⁹ Other studies have described less surgical time per level for classic laminectomies.¹¹ Although the unfavorable blood loss that necessitates transfusion is infrequent in all lumbar canal decompression procedures, EBL was less in the bilateral interlaminar group.^{19,26}

Perioperative Complications

A spine surgeon's main concern is to decompress the LCS in a minimally invasive manner; however, there has been an increased rate of neural injury.^{6,27} Verbiest reported that there was increased radicular deficit postoperatively in 5% of laminectomy patients.³⁶ Postacchini et al. reported an increase in radiculopathy postoperatively in 3 (11.5%) of 26 bilateral interlaminar canal decompression patients compared with 1 (3.1%) of 32 classic laminectomy patients;²⁷ however, other studies have reported that radicular deficit occurs in only 1% of cases when using the bilateral interlaminar canal decompression approach.⁵ Referring to our data, there was no definite injury to the nerve root. Intraoperative compression and/or manipulation of the nerve roots, however, may be the cause of the radicular deficit. We had 3 patients in the classic laminectomy group who had a radicular deficit compared to only 1 patient in the bilateral interlaminar canal decompression group ($p = 0.31$).

In general, incidental durotomy rates for bilateral interlaminar decompression range from 2% to 6%,^{20,34,42} while classic laminectomy may cause dural tears in 5%–15% of cases.^{30,37} In our series, 9 incidental durotomies occurred in group 1 and 4 in group 2, all of which were primarily

repaired. When the rates of durotomies were compared, the difference was not statistically significant ($p = 0.15$).

All spinal surgery cases have a 2% risk of wound infection,^{16,30} but this complication was more frequent in our study (3.7% in group 1, three deep and one superficial; and 10% in group 2, all superficial).

The occurrence of postoperative epidural hematoma ranges from 1% to 3%.^{30,42} The incidence of postoperative hematoma after bilateral interlaminar decompression in our study was 6.4%, and there were no cases in the classic laminectomy group.

According to our results, we recommend bilateral interlaminar decompression as a good treatment option for patients with LCS, regardless of the severity of illness or patient age.

Study Limitations

Among the limitations of this study is the lack of computerized randomization of the patients; however, it was solved by the randomization of patients by a blinded study person. Also, we compared only the classic laminectomy and the bilateral interlaminar canal decompression; bilateral canal decompression through a unilateral approach was not included in this study.

Conclusions

Bilateral interlaminar decompression permits safe and acceptable spinal canal decompression in patients with LCS. The procedure was associated with increased postoperative comfort and sufficient canal decompression with minimal effect to stability during a long follow-up period of 3 years. Surgeon experience with this approach will help to reduce operation time and complications.

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Disclosures

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Author Contributions

Conception and design: both authors. Acquisition of data: both authors. Analysis and interpretation of data: both authors. Drafting the article: both authors. Critically revising the article: both authors. Reviewed submitted version of manuscript: both authors. Approved the final version of the manuscript on behalf of both authors: Soliman. Statistical analysis: Soliman. Administrative/technical/material support: Ali. Study supervision: Ali.

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