Original Article

Lumbar facet distraction and fixation in patients with lumbar spinal stenosis: Long-term clinical outcome and reoperation rates

ABSTRACT

Objective: Symptomatic lumbar spinal stenosis (LSS) unresponsive to conservative therapy is commonly treated by surgical decompression. In this study, we compared clinical outcomes after decompressive surgery for LSS in patients implanted with interarticular spacers along with microdecompression (MD) with those receiving only MD.

Methods: A retrospective study was analyzed 40 patients (Group A) affected by LSS treated by MD and implant of interarticular spacers comparing the outcome with a homogeneous group of 40 patients with LSS treated with MD alone (Group B). Clinical outcome was evaluated using the Oswestry Disability Index (ODI) and visual analog scale (VAS) scores, as well as Macnab's criteria.

Results: At 1-year follow-up, ODI improved in both groups with statistically significant differences as compared to baseline and both Groups ($P < 0.05$). Statistically significant differences were observed at 3-year follow-up ($P < 0.05$), without further variation at 5-year follow-up. At 1-year follow-up, VAS for back and leg pain scores was significantly better than that of Group B ($P < 0.05$). At 3-year follow-up, back and leg pain scores were no longer significantly improved ($P > 0.01$), resulting almost the same at 5-year follow-up. A comparison of functional outcomes between the groups showed significant improvements in Group A as compared to Group B ($P < 0.05$). The reoperation rate was 10% in Group A and 30% in Group B. In implanted patients, successful fusion was obtained in 90% of the cases.

Conclusions: Interarticular spacers showed significant and clinically meaningful improvements in pain and disability, even in a long follow-up.

Keywords: Facet wedge, neurogenic intermittent claudication, spinal stenosis

INTRODUCTION

Lumbar spinal stenosis (LSS) is a highly prevalent condition often resulting from a gradual, degenerative aging process. Symptomatic LSS unresponsive to conservative therapy is commonly treated using direct surgical decompression.[1] Current guidelines recommend additional arthrodesis in patients with LSS and preexisting spondylolisthesis.[2-7] However, when the instability of the lumbar spine is not identified, a wide range of surgical approaches have been proposed, including laminectomy, hemilaminectomy, and laminotomy.

However, wide laminectomies violating stabilizing bony, and ligamentous structures may provide iatrogenic instability.[8]

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Minimally invasive laminectomy through tubular or similar retractors is a recently introduced alternative procedure for decompression of LSS.[9] This technique avoids detachment of the paraspinal muscles and may promote the preservation of stabilizing ligamentous and bony spinal structures.[10,11] Biomechanical studies indicate that compared with open laminectomy, minimally invasive laminectomy may result in less postoperative instability.[12,13] Common characteristics of these techniques are smaller incisions, preservation of stabilizing ligamentous and bony spinal structures, and preservation of paraspinal muscles. However, despite the many advantages, MD can lead to ongoing instability in the operational segment.[8]

Recently, various microdecompression (MD) methods have been used for the treatment of LSS.

All these surgical treatments, however, are based on the general concept that the main pathogenetic mechanism underlying LSS is strictly related to a cascade of processes starting with disc degeneration.[14] Indeed, evidence accumulated over time has suggested that facet can be directly addressed as a possible cause of lumbar stenosis.[15,16] This well-established theorem, entrenched by decades of peer-reviewed literature, has been recently spotlighted by Goel, who has argued that facet damage could start and foster spinal degeneration.[17,18] According to this intriguing hypothesis, reduction of the interfacet distance, and the subsequent instability, may play a role in the pathogenesis of the entire spectrum of spondylosis[18] including stenosis of the spinal canal and intervertebral neural foramina, reduction in disc height, bulge of the posterior anulus/posterior longitudinal ligament, invagination, and hypertrophy of the ligamentum flavum. The plastic representation of this degenerative cascade is the frequently observed lumbar facet hypertrophy seen in canal stenosis, which may reflect the facet overload and the consequent back pain.

In agreement with this pathogenetic mechanisms,[17] and on the heels of successful results accumulated[18] the current study had two main goals: first to extend the preliminary observation[19] of clinical and radiological outcomes in patients with LSS who underwent MD of the neural structures along with the implant of interarticular spacers as compared with those receiving MD alone. The second aim was to compare the reoperation rate in both groups.

METHODS

Patient populations and indications

The study was approved by the institutional review board. Informed consent requirements were waived due to the retrospective study design. The Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines were followed for this manuscript.[20]

Between 2014 and 2015, 40 consecutive patients with symptomatic LSS (Group A), in whom the interarticular spacers Facet Wedge (FW) device has been implanted following MD of the spinal canal were sought. These patients were compared with 40 patients with LSS as control recruited from our surgical database (Group B), corresponding to the same levels of operation with Group A, where MD without interarticular spacers implant was performed. The control group was also matched for demographic and constitutional patient characteristics, smoking habit, steroid use, and comorbidities considered to be of importance for the outcome of surgery in LSS.[21]

Inclusion and exclusion criteria have been previously reported.[19] Briefly, patients with age ≥45 years, presenting with clinical symptoms of LSS, such as intermittent claudication, low back pain, and radiating lower extremity pain, unresponsiveness to conservative treatment were included. In addition, imaging findings on a cross-section of the spinal canal (magnetic resonance imaging/computed tomography) showing compression of the dural sac or nerve roots, such as thickening of the ligamentum flavum and hypertrophy of the joints were considered. Exclusion criteria included LSS at three or more levels, Grade II to V spondylolisthesis, significant lumbar instability, systemic diseases, vertebral osteoporosis or history of vertebral fracture, spinal stenosis caused by tumors, inflammation, or other diseases, inadequate accurate follow-up data.

Outcome measures

The preoperative and latest available follow-up Oswestry Disability Index (ODI)[22] and visual analog scale (VAS) scores for back and leg pain were collected and compared. These assessments are reported for baseline and at 1 month, 6 months, and every year till the last follow-up. The functional outcome was evaluated using Macnab's criteria.[23] Four levels were defined according to Macnab's criteria to assess the functional outcome as following: (1) excellent (no pain; no restriction of activity); (2) good (sporadic back or leg pain without interfering with the daily activities); (3) fair (reduced functional capacity by intermittent pain); (4) poor, (insufficient improvement to allow daily activities thus suggesting the need for further interventions).[23]

The evaluation was conducted by in-person interviews with all participants before surgery and at each follow-up examination, asking also if they had undergone any further

lumbar spine surgery in other medical centers. The patients who required a second surgery were identified. The indication for the second operation and a description of the procedure were recorded.

In all the patients, radiographic investigations were performed to evaluate the fusion of the spinal segment, defined as the absence of motion on flexion-extension radiographs obtained at each follow-up for up to 5 years.

Surgical procedures

Procedures were MD of the spinal canal with or without the implant of the FW system. The latter is a titanium implant intended for the fixation of the spine through distraction and immobilization of the facet joints, at one or two levels, from L1 to S1.[24] As previously described,[19] it is constructed to be inserted into the facet joint after the cartilage removal, acting as a mechanical spacer to distract the facets. On its positioning, two self-locking screws secure the system, previously filled of bone graft, in the facet joint.

All the procedures were performed under general anesthesia and in a prone position following a surgical technique described elsewhere.[19]

In both groups, optimal lumbar canal decompression was achieved under a surgical microscope. Briefly, laminotomy was performed, preserving as much of the facet joints as possible. If bilateral lateral recess stenosis was present, laminotomy was performed on both sides. Following sufficient resection of the bony segment, the ligamentum flavum was removed. Radicular decompression in the foramen was also performed if required. In Group A, the appropriate measure of the FW (small, medium, or large) and the following distraction was chosen with the aim to restore the normal alignments of the facets and dimensions of the canal.[17]

Patients were generally allowed to walk with a corset brace the day following the surgery, and corset brace use was recommended for 4–6 weeks. Discharge was on the 2nd postoperative day in almost the cases and rehabilitation was not generally recommended.

Statistical analysis

Values are expressed as means ± standard deviation. The clinical results were analyzed using the analysis of variance Chi-square test, Fisher exact test, Kruskal–Wallis test, and McNemar test. All analyses were performed using appropriate statistical software (SPSS, version 18.0.0.1, SPSS Inc., IBM, Armonk, New York, USA). A value of $P < 0.05$ was considered statistically significant.

RESULTS

Patient demographics

Eighty consecutive patients, 41 males and 39 females, with isolated LSS who had undergone minimally invasive surgery for decompression, were included in our study. In forty cases, FW system was implanted following MD (Group A). The mean age at surgery was 58.8 years (range 50–76 years). The mean BMI was 27.3 kg/m^2 in Group A and 27.8 kg/m^2 in Group B, respectively. A positive history for smoking was present in 17.5% of Group A and 20% In Group B. Assumption of steroid drugs was reported in 35% of Group A and 37% in Group B. Diabetes and high blood pressure were present in 15% and 37.5% of Group A, and 12.5% and 32.5% of Group B, respectively. Overall, there were no statistically significant differences in the demographic and constitutional patient characteristics, smoking habit, steroid use, and comorbidities between the groups ($P > 0.05$). The main preoperative characteristics are shown in Table 1.

Surgical features

A total of 40 FWs, two for each level, were inserted in Group A. Only one stenotic level was treated. The most common level of insertion was L4–L5. The most common device size used was the medium size. No infections were observed in all the patients. In Group B, a satisfactory MD was performed. All the patients were discharged on the 1st postoperative day.

Table 1: Main preoperative characteristics

Characteristic	Group A	Group B	All patients
Number	40	40	80
Sex			
Male	22 (55)	19 (47.5)	41 (51.25)
Female	18 (45)	21 (52.5)	39 (48.75)
Age (years)			
Mean±SD	60.3±3.2	57.31±6.2	58.8±3.8
Range	50–74	55–76	50–76
BMI (kg/m^2)			
Mean±SD	27.3±4.8	27.8±4.6	27.5±4.8
Smoking (%)			
Yes	17.5	20	18.75
No	82.5	80	81.25
Steroid use (%)			
Yes	35	37.5	36.25
No	65	62.5	63.75
Diabetes (%)			
Yes	15	12,5	13.75
No	75	87.5	86.25
HBP (%)			
Yes	37.5	32.5	35
No	62.5	67.5	65

There are no statistically significant differences in the demographic characteristics between the groups ($P>0.05$). SD - Standard deviation, HBP - High blood pressure, BMI – Body mass index

None of the patients underwent re-exploration of the region or needed any additional surgical procedure for the lumbar spine during the 1-year follow-up. However, reoperation was necessary in two cases (10%) of Group A at 3 years and 4 years of follow-up evaluation, respectively. In the first case, reoperation was necessary due to the right facets of fracture and system dislocation. In the second case, inter-articular fusion was not observed. In Group B, a new surgical treatment was undertaken in 6 cases (30%) at 2- (2 cases), 3- (2 cases), and 4-year (2 cases) follow-up evaluation overall for preoperative symptoms resurgence. Analysis for the reoperation rate showed a statistically significant difference between the Groups ($P < 0.05$). In each case, patients underwent additional/revision decompression and posterior lumbar interbody fusion (PLIF) with final satisfactory results.

Clinical outcome

The follow-up period ranged from 57 to 71 months (mean 61.45 months). As reported in the preliminary analysis,[19] 1 year following surgical treatment, statistically significant differences were noted between the groups when comparing the clinical outcome measures from baseline to 1 year follow-up. At 1-year follow-up, analysis between the groups showed that patients of Group A presented significantly better clinical outcomes when compared with the control group (Group B) ($P < 0.01$).

The mean preoperative ODI was 66 ± 15.3 in Group A and 65 ± 13.1 in Group B. At 1 year follow-up, ODI decreased to 10 ± 16.6 and 26 ± 18.2, respectively ($P < 0.05$) showing statistically significant differences between the groups. At 3-year follow-up, ODI was 12 ± 10.2 and 28 ± 14.6, respectively, without significant statistical differences ($P > 0.01$) and resulting almost the same at 5-year follow-up [Figure 1a].

The median preoperative VAS back, and leg pain scores were 90 ± 12.3, and 67.0 ± 20.5 in Group A and 93 ± 18.6, and 66.3 ± 19.7 in Group B, respectively. At 1 year follow-up, significant statistical differences were noted in VAS for back and leg pain scores between the groups being 11 ± 12.4 and 21 ± 13.7 in Group A, and 30 ± 15.4 and 33 ± 24.8 in Group B. At 3-year follow-up, back, and leg pain scores were no longer significantly improved ($P > 0.01$) resulting almost the same at 5-year follow-up [Figure 1b and c].

Functional outcome, as assessed using Macnab's criteria, showed that at 1-year follow-up it was excellent and good in 90.6% in Group A and 90.2% in Group B ($P > 0.05$), lowering to 87.4% and 71.2% at 3-years follow-up, respectively, thus showing statistically significant differences between the groups ($P < 0.05$). In the late follow-up, Macnab's criteria showed excellent and good score in 85% of patients of Group A

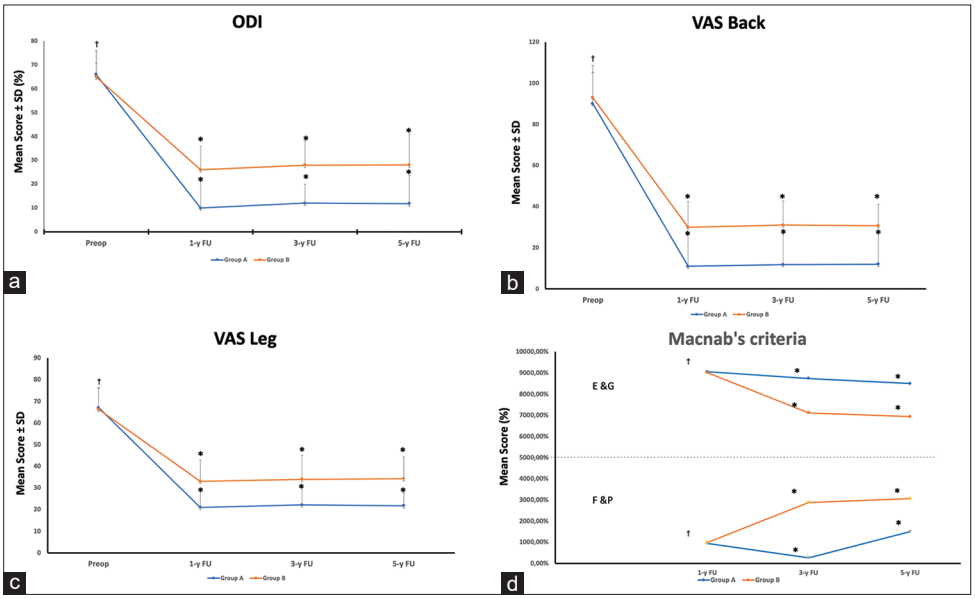

Figure 1: Graphs showing changes in clinical outcomes over time: (a) ODI score. At 1-year follow-up ODI decreased to 10 ± 16.6 and 26 ± 18.2, respectively ($P < 0.05$) showing statistically significant differences between the groups. At 3-year follow-up, ODI was 12 ± 10.2 and 28 ± 14.6, respectively without significant differences ($P > 0.01$) and resulting almost the same at 5 year follow-up. (b and c) VAS back and leg. At 1-year follow-up, statistically significant differences were noted in VAS for back and leg pain scores between the groups being 11 ± 12.4 and 21 ± 13.7 in Group A, and 30 ± 15.4 and 33 ± 24.8 in Group B. At 3-year follow-up, back, and leg pain scores were no longer significantly improved ($P > 0.01$) resulting almost the same at 5 year follow-up. (d) Macnab score. At 1-year follow-up it was excellent and good in 90.6% in Group A and 90.2% in Group B ($P > 0.05$), lowering to 87.4% and 71.2% at 3-year follow-up, respectively, thus showing statistically significant differences between the groups ($P < 0.05$). In the late follow-up, Macnab's criteria showed excellent and good score in 85% of patients of Group A and 69.4% in Group B ($P > 0.05$). An overall comparison of Macnab's results between the groups, showed significant improvements in Group A compared to Group B since the 3-year follow-up till the late evaluation ($P < 0.05$). ODI – Oswestry Disability Index; VAS – Visual analog scale; E and G – Excellent and good; F and P – Fair and poor

and 69.4% in Group B ($P > 0.05$). An overall comparison of Macnab's results between the groups, showed significant improvements in Group A compared to Group B since the 3-year follow-up till the late evaluation ($P < 0.05$) [Figure 1d]. Clinical outcome measures between the groups are summarized in Table 2.

Radiographic features

Fusion of the spinal segment was investigated in patients of Group A and was defined as the absence of all kinds of motion in the interlaminar and intervertebral body distances on flexion-extension radiographs obtained at each follow-up for up to 5 years. Evidences of neo-bone formation across the facets and laminae were suggestions of bone fusion.

Successful fusion was obtained in 90% of the cases. In 1 case facets fracture and device dislocation was observed. In the second case, FW failed in providing fusion.

DISCUSSION

As the global population ages, an increasing number of spinal disorders specific to the elderly will require management. The elderly population poses a particular challenge to health care systems and physicians because this age group of patients is associated with peculiar spine disorders, where spinal degeneration, reduced bone mass density and osteoporosis, decreased mobility, and multiple medical comorbidities are the main features.[25] In this scenario, the treatment of symptomatic LSS is one of the major challenges. As the available scientific evidence on the diagnosis and treatment of this entity is not very reliable,[26,27] there is no currently valid overall assessment of treatment strategies especially for older patients.

To date, treatment of degenerative spine disease encompasses decompression of the neural elements with or without instrumentation and fusion since releasing the nerve root, dural sac, and restoring stability of the spine is key for a successful treatment. Decompression of the neural structures can be obtained by a simple laminectomy with or without discectomy, or bilateral fenestration and unilateral fenestration with undercutting contralateral decompression. However, all these procedures have been shown to provide iatrogenic spinal instability in most of the cases[28] and to increase the pressure on the intervertebral discs.[29] In recent years, numerous mini-invasive surgical techniques have been introduced to minimize injury to paraspinal ligaments and muscles and maintains stabilization of the motion segment.

Among patients with LSS, facet joint hyperplasia and hypertrophy of the ligamentum flavum are the main causes of spinal stenosis, due to biomechanical changes and compensatory activities of the body.[30-32] In contrast to disc degeneration,[14] in recent years new evidence has suggested the role of facet degeneration in the onset of LSS.[17,18] Reduction of the interfacet distance, and the subsequent instability could give the start to the entire spectrum of spondylosis[18] that ultimately result in stenosis of the spinal canal and intervertebral neural foramina, reduction in disc height, bulge of the posterior anulus/posterior longitudinal ligament, invagination, and hypertrophy of the ligamentum flavum. Considering that facet instability, rather than disc degeneration, could be the primary pathogenic factor that initiates the cascade of events resulting in spinal canal stenosis,[17,18] facet distraction and fixation could solve the spinal stability and reverse the pathological events underlying LSS. FW system offers a novel posterior approach in achieving primary stability in spinal fixation with a minimal invasive approach[24] and has been shown to be effective in LSS-affected patients.[19]

In the present study, we extended our preliminary observation[19] on patients with LSS who underwent MD of the neural structures along with the implant of interarticular spacers (Group A) as compared with those receiving MD alone (Group B) with a follow-up up to 5 years.

Overall, we found that at 1-year follow-up, patients of Group A presented significantly better clinical outcome when compared with the control group (Group B) ($P < 0.01$). At 1-year follow-up ODI improved in both groups with

Table 2: Clinical outcome measures with preoperative and postoperative data

	Preoperative		1-year FU		3-years FU		5-years FU	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
ODI	66±15.3	65±13.1	10±16.6*	26±18.2*	12±10.2†	28±14.6†	11.8±9.4†	28.1±12.2†
VAS back	90±12.3	93±18.6	11±12.4*	30±15.4*	11.8±10.5†	31±14.7†	12±10.5†	30.7±15.2†
VAS leg	67±20.5	66.3±19.7	21±13.7*	33±24.8*	22.1±16.7†	34±21.3†	21.7±14.7†	34.3±16.6†
Macnab's criteria (%)								
E and G			90.6†	90.2†	97.4*	71.2*	85*	69.4*
F and P			9.4†	9.8†	2.6*	28.8*	15*	30.6*

*Statistically significant, †No statistically significant. FU - Follow-up, ODI - Oswestry disability index, VAS - Visual analog scale; ODI: E - Excellent, G - Good, F - Fair, P - Poor

statistically significant differences as compared to baseline in both Groups ($P < 0.05$). Statistically significant differences were observed at 3-year follow-up, since ODI was 12 ± 10.2 in Group A and 28 ± 14.6 in Group B, respectively ($P < 0.05$), without further variation at 5-year follow-up. At 1 year follow-up, VAS for back and leg pain scores was significantly better than that of Group B ($P < 0.05$). At 3-year follow-up, back, and leg pain scores were no longer significantly improved ($P > 0.01$) resulting almost the same at 5 year follow-up. At 1-year follow-up, functional outcome, as assessed using Macnab's criteria,[23] was excellent and good in 90.6% of the patients of Group A, 97.4 at 3 years follow-up and 85% at 5-years follow-up. A comparison between the groups, showed significant improvements in Group A compared to Group B ($P < 0.05$). Reoperation was necessary in two cases (10%) of Group A at 3 years and 4 years postsurgery, respectively. While a new surgical treatment was undertaken in 6 cases (30%) of Group B at 2 (2 cases), 3 (2 cases), and 4-year (2 cases) follow-up evaluation. Analysis for the reoperation rate showed statistically significant differences between the Groups ($P < 0.05$). In each case, patients underwent new decompression and PLIF with final satisfactory results. Overall, FW implant provided a successful fusion rate in 90% of the cases.

Our results are in agreement with those of previous studies that in shorter follow-up have shown the safety of the lumbar facet distraction and fixation.[18,19]

The results of this study expand our previous observations suggesting that FW device can be considered a safe and effective treatment option to classic MD even in a long follow-up.

The main limitation was the small sample size of patients recruited from a single hospital, which indicates that the data might not be representative of the majority of patients with LSS. Second, this was a case series with retrospective data collection potentially leading to multiple biases, including sampling bias, and recall bias. Finally, another limitation lies in the absence of a comparison with a group of patients treated with laminectomy and fusion. In this regard, the current study can provide plenty information that can be used to tailor addressing studies. A major strength of this study is that we assessed outcome measurements both before and after the treatment with a follow-up spanning 5 years.

CONCLUSIONS

Facet distraction and fixation with FW system along with MD of the neural structures is an effective procedure to treat LSS and shows better results when compared to the decompression alone. This procedure presents with low reoperation rates and has the benefits of minimally invasive surgery such as less blood loss and shorter hospital stay. In light of this and other studies demonstrating the potential benefit of FW implant along with decompression surgery, the need for routine decompression surgery in LSS patients should be critically reevaluated.

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Conflicts of interest

There are no conflicts of interest.

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