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Interspinous dynamic fixation for lumbar spinal stenosis: a trade-off or an option?

O.G. Prudnikova, M.V. Khomchenkov

Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics, Kurgan, Russia

Introduction Currently, there is no single concept of interspinous process stabilization. Some authors consider the procedures to be a trade-off for the elderly population with vague morphological changes and neurogenic claudication whereas others do not support the practice, and still others offer it as an alternative to conservative and conventional surgical treatment for lumbar spinal stenosis (LSS). **Material and methods** The study included 22 patients with LSS. The patients were followed for 6 months. The clinical outcomes measures were neurological assessment, the Wong-Baker pain rating scale, Oswestry Disability Index (ODI). Radiographic evaluation and statistical analysis were also used. Surgical treatment included distraction laminoplasty and placement of interspinous dynamic fixator. **Results** Interspinous dynamic fixation and distraction laminoplasty resulted in regression of neurological deficiency and did not lead to deterioration of segmental and local imbalance. Clinical assessment of pain, radicular motor and sensory deficit and intermittent neurogenic claudication was performed. Morphological evaluation showed relative central spinal canal stenosis, foraminal stenosis and enduring degenerative spondylolisthesis (grades I and II). **Conclusion** Interspinous dynamic fixation is the method of choice for patients with lumbar spinal stenosis in presence of specific morphological and clinical manifestations.
Keywords: lumbar spinal stenosis, distraction laminoplasty, dynamic interspinous fixator, segmental lordosis, local lumbar lordosis

INTRODUCTION

Interspinous process fixation implants are used for posterior spinal stabilization in patients with lumbar spinal stenosis (LSS). Interspinous fixation is produced either with dynamic systems or interspinous fusion devices [1]. The implantation can be performed with/without decompression of the spinal canal depending on the type of the device used.

Biomechanical considerations of the implantation are based on pathogenesis of degenerative changes in the spine. According to the concept of segmental instability primary changes in intervertebral disc result in unstable lumbar segment, inflammatory reaction in the surrounding tissues, hypertrophy and different types of LSS [1, 2]. Some authors report restricted segment movement due to progressive disc degeneration [3] followed by position pains and changes in the surrounding tissues including hypertrophy of the ligamentum flavum [4].

Interspinous devices are designed to distract the posterior elements of adjacent vertebral bodies unloading the intervertebral disc, limiting spinal extension and improving neuroforaminal stenosis [5, 6]. Those embracing the concept of lumbar segmental instability observe further degeneration and spinal stenosis resulting in alterations of the sagittal balance [1]. Various authors suggest that the implants unload facet joints [7] and reduce intradiscal pressure and have positive impact on clinical symptoms causing no action on the movements of adjacent segments [8] and alterations of the sagittal balance [9].

The advent of minimally invasive interspinous devices has potentially revolutionised the management of LSS without subjecting the patient to a major surgery [10] and also can be used as a preventive measure in patients necessitating rigid fusion [11, 12]. The treatment of LSS has to be strictly linked to the concept of vertebral instability as a basic pathological condition, and dynamic stabilisation is unacceptable in the case [1].

Therefore, the usage of interspinous stabilisation remains extremely controversial. Interspinous fixation devices can be used stand-alone, in combination with decompression procedures and interspinous fusion. Some authors consider the procedures to be a trade-off for the elderly population with vague morphological changes and neurogenic claudication whereas others do not support the practice, and still others offer it as an alternative to conservative and conventional surgical treatment for LSS.

Objectives. The primary aim of the study was to review dynamic interspinous fixation and distraction laminoplasty in patients with lumbar spinal stenosis to determine indications for the usage.

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MATERIAL AND METHODS

The study included outcomes of 22 patients with LSS. The patients were followed up preoperatively and at 6 months clinically and preoperatively, postoperatively and at 6 months radiologically.

Mean age of the patients was 57.0 ± 1.9 years. Male to female ratio was 1.7:1. The prevailing interference level was L4–L5 segment (n = 17), stenosis at L3–L4 level was observed in 5 cases. Interlaminar approach of the adjacent segment was used for additional decompression in 6 patients including 4 above and 2 below stabilisation level. Two patients had undergone earlier surgery of removing herniated disc from low-lying segment and decompression stabilizing procedure at superior lumbar spine for LSS.

Operative treatment included distraction laminoplasty (O'Leary's type) to enlarge spinal canal area due to excision of hypertrophied ligamentum flavum, hypertrophied facet joints and foraminal decompression [13, 14]. Dynamic interspinous implant was inserted between adjacent spinous processes after decompression (**Fig. 1**). The size of an implant was patient-specific depending on interspinous space measuring from 8 to 12 mm.

Intervertebral discs herniation as one of the factors causing LSS was removed in five cases.

The clinical outcomes measures were neurological assessment, the Wong-Baker pain rating scale (2011), Oswestry Disability Index (ODI).

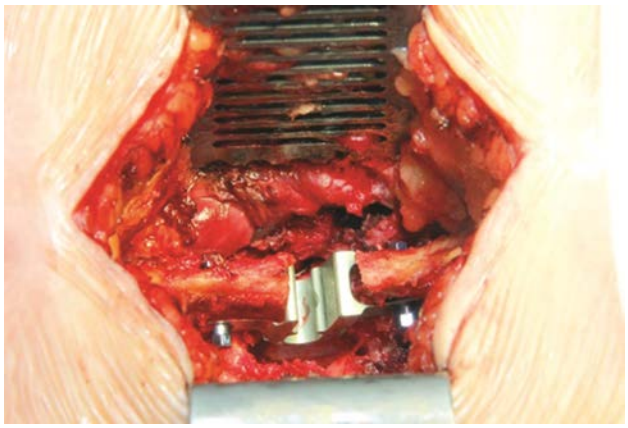


Fig. 1 Photograph of surgical wound showing distraction laminoplasty performed and dynamic interspinous device placed

Radiological parameters included evaluation of spinal stenosis using CT to determine a type of stenosis, segment mobility with functional assessment and diagnosis of segmental and local lumbar lordosis. Wiasis v.2.03 (Medical viewer) software was used for radiometric measurements.

Statistical analysis of variance was used to calculate the arithmetic mean (M), error of the arithmetic mean (±m), the Pearson correlation coefficient r and estimate using the Chaddock scale.

RESULTS

Preoperative clinical manifestations showed lumbalgia in 27 % of the patients and radicular pain in 63 % of the cases. Neurogenic intermittent claudication was observed in 12 (54.5 %) patients. Preoperative pain intensity measured 6.3 ± 1.2 with ODI being 43.4 ± 0.8.

Mean sagittal spinal canal dimension radiologically measured 12.1 ± 0.4 mm on CT scans. Decrease in the canal dimensions due to disc degeneration and spondylolisthesis measured 4.0 ± 0.3 mm on average. Central stenosis was observed in 19 cases and foraminal stenosis diagnosed in 3 patients. Degenerative spondylolisthesis was observed in 2 patients including 1 retrolisthesis and 1 anterolisthesis. Disc herniation with spinal stenosis was diagnosed in 5 patients. No pathological mobility at the involved level was noted in the cases. Degenerative scoliosis of lumbar spine was diagnosed in 6 patients presenting with local frontal imbalance and mean curve angle of 8.3 ± 0.9°.

Relative central or foraminal spinal stenosis was indication to operative treatment [15] with clinical manifestations, ineffective 6-month conservative treatment or progressive neurological symptoms developing during the treatment.

Contraindications to the implantation of interspinous device included spondylolytic anterolisthesis, unstable degenerative spondylolisthesis, absolute spinal stenosis and compression.

Six-month follow-up of 15 patients showed persistent pain of considerably less intensity (n = 1), intermittent pain (n = 7), complete regression of pain (n = 7). Pain intensity measured 1.8 ± 0.2 with ODI being 16.3 ± 1.6 at the time. Neurogenic intermittent claudication was arrested in all the patients.

Intervertebral disc inclination angle and lumbar lordosis were shown to decrease radiologically by 1° and 2° on average, correspondingly, with no progression of the frontal component of the curve (scoliosis angle measuring 8.33 ± 0.9° preoperatively and 8.38 ± 0.9° postoperatively) (**Fig. 2**). Mobility of 0.1 mm was observed at the level of intervention in one case (**Table** 1).

Statistical analysis of preoperative pain intensity and segmental lordosis, pain intensity and lumbar lordosis using the Pearson correlation coefficient showed medium positive correlations between the variables. Coefficient values between pain intensity and segmental lordosis, and between pain intensity and lumbar lordosis

were 0.1 (**Fig. 3**) and 0.2 ($p < 0.05$) (**Fig. 4**), correspondingly. This indicated to a greater preoperative impact of lumbar lordosis on pain intensity in the patients.

Correlation between pain intensity and segmental and lumbar lordosis was negative after the treatment with r = -0.1 (VAS and segmental lordosis) (**Fig. 5**) and r = -0.2 (VAS and local lordosis) (**Fig. 6**) that indicated no relationship existed between the variables.

Pain was found to have no relationship with segmental and local lordosis.

Postoperative CT scans showed enlarged spinal canal due to decompression performed (**Fig. 7**).

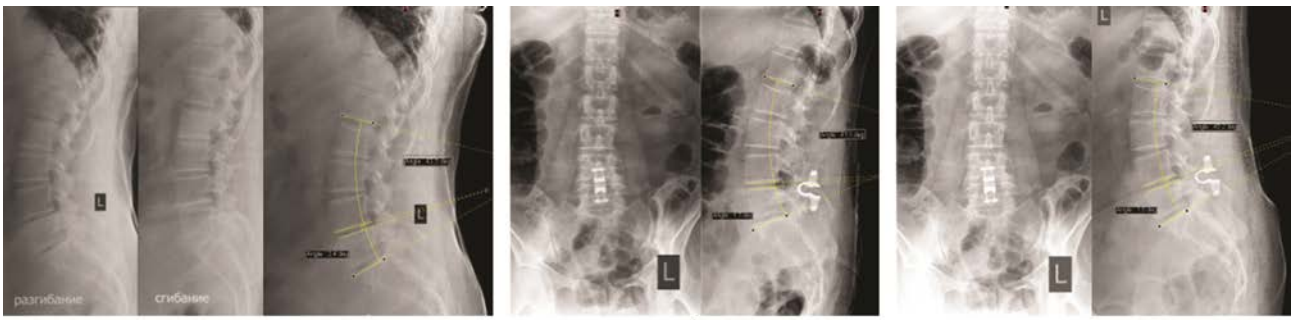
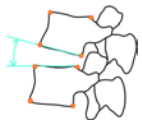
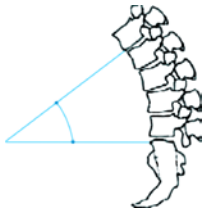


Fig. 2 Spondylography of a female patient P. with LSS at L4–L5 level showing radiological manifestations (a) preoperatively, (b) postoperatively, (c) at 6-month follow-up

Table 1

Radiological spine evaluation at stages of treatment

Evaluation parameters		preoperatively (n = 22)	postoperatively (n = 22)	6-month follow-up (n = 15)
	Segmental lordosis	6.4 ± 0.6	5.5 ± 0.5	5.9 ± 0.7
	Lumbar lordosis	45.7 ± 2.3	43.8 ± 2.1	44.7 ± 2.4
Mobility with functional radiology, mm		0	–	0.01 ± 0.015

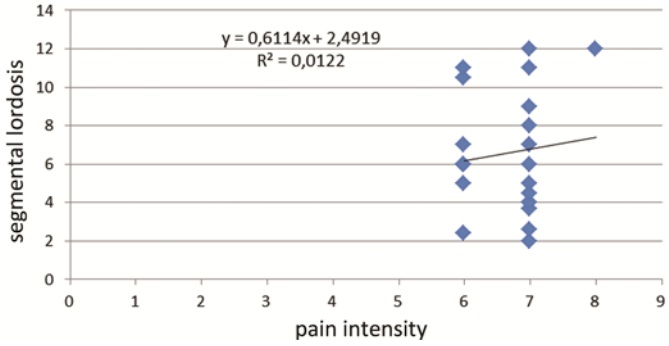


Fig. 3 Preoperative relationship between pain and segmental lordosis

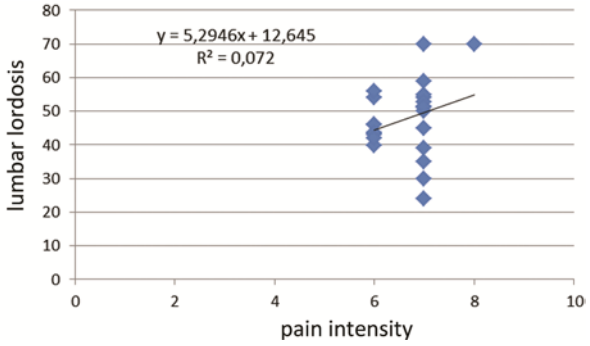


Fig. 4 Preoperative relationship between pain and lumbar lordosis

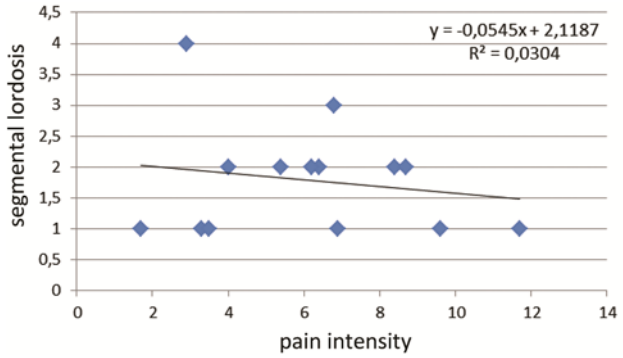


Fig. 5 Relationship between pain and segmental lordosis after treatment

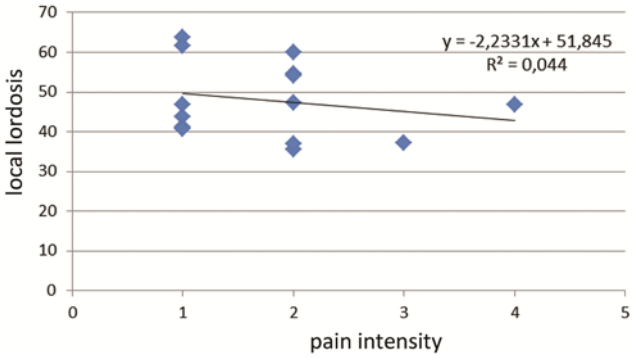
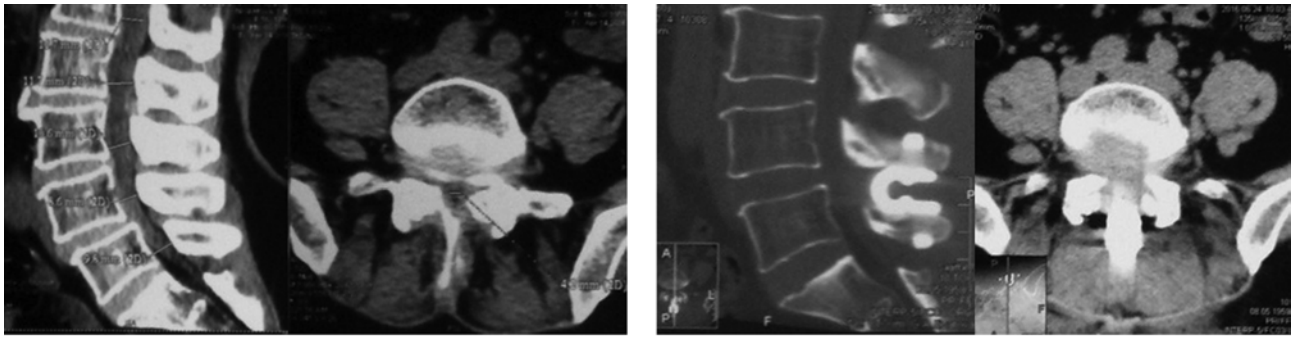


Fig. 6 Relationship between pain and local lumbar lordosis after treatment



a b

Fig. 7 CT scans of a female patient T. with combined LSS due to stable degenerative anterolisthesis of L4 showing (a) preoperative manifestations, (b) spinal canal enlarged postoperatively

COMPLICATIONS

Unintended durotomy with intraoperative SCF extravasation was observed in one case. The tear was sealed and no more SCF leak noted. One month after the surgery the patient developed infection and the superjacent spinous process fractured and the implant was removed.

DISCUSSION

Assessment of local sagittal balance following distraction laminoplasty, interspinous fixation and fusion showed a slight decrease in inclination angle and lumbar lordosis of 1° to 2° at 24-month follow-up [14]. A. Ploumis et al. (2012) reported segmental lordosis decreased by 2.4° and lumbar lordosis increased by 0.6° with interspinous stabilization and microsurgical decompression [16]. Our findings showed intervertebral disc inclination and lumbar lordosis decreased by 1° and 2°, correspondingly, following dynamic fixation. Intervertebral disc inclination and lumbar lordosis increased by 0.5° and 1°, correspondingly, at 6-month follow-up as compared to preoperative values (**Fig. 8**).

Functional radiology demonstrated instability of 0.1 cm in one case and was not informative. No progression of the frontal component was observed. Postoperative correlation of pain intensity and segmental and local lumbar lordosis was negative and showed no relationship between the variables. So, changes in segmental and local lumbar sagittal balance being minimal did not result in spine imbalance and had no impact on clinical manifestations of the disease.

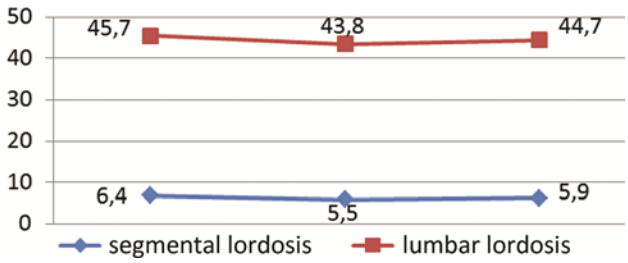


Fig. 8 Diagram showing changed parameters of segmental and local lumbar lordosis

Positive results of interspinous fixation without decompression were observed in 60 % of moderate stenosis and 31 % of severe cases [17]. This cohort of patients developed less complications and more reoperations hospitalisation related expenses [18, 19, 20]. The overall complication rate was 38 %, and the ultimate failure rate requiring additional spinal surgery was 85 % [5]. Most common complications included fractures of spinous processes and fixators ranging from 6 % [20, 21] to 23 % [5].

Decompression performed during fixator placement allowed us to visualise spinal canal, minimise bone re-

section and considerably improve treatment results [13, 14, 15]. The improved clinical symptoms were reported to decrease ODI scores from 37 to 14 and pain scores from 6 to 1.7 [14, 16]. Our series showed regression of pain and ODI scores from 6.3 to 1.8 and from 43.4 to 16.3, correspondingly. Considerably improved clinical symptoms, neurological manifestations and quality of life indicated to efficacy of the technique used.

Decompression was shown to considerably improve outcomes providing less complication and reoperation rate. J.M. *Cuélla*r et al. (2016) reported very few complications including dural tear (1/37), implant failure (1/33), seroma (1/37), postoperative urinary incontinence (1 /33) and postoperative neurological deficiency (1/33) [14]. A. Ploumis et al. (2012) performed a study of 22 patients who underwent decompressive surgery for LSS and developed a fracture of spinous process (n = 1), postoperative radiculopathy above the decompressed level (n = 2) and asymptomatic migration of interspinous device with no need of reoperation (n = 2) [16].

Additional procedure was performed for the broken spinous process and infection in one case of our series. Complication and reoperation rate was 4.5 % and 4.5 %, correspondingly.

CONCLUSIONS

Dynamic interspinous fixation and distraction laminoplasty is the method of choice for patients with lumbar spinal stenosis who presented with pains, radicular motor and sensory deficits and neurogenic intermittent claudication. Morphological evaluation showed relative central spinal canal stenosis, foraminal stenosis and enduring degenerative spondylolisthesis (grades I and II).

The decompression involving resection of hypertrophic ligamentum flavum, sparing resection of articular processes and foraminal decompression allows for the practice to be used for relative central or foraminal spinal stenosis with clinical manifestations and failed conservative treatment. Insertion of a lumbar interspinous implant is contraindicated by conditions with prognostic progression of segment mobility including spondylolytic anterolisthesis, unstable degenerative spondylolisthesis, extensive decompression in expressed spinal stenosis with resection of articular processes. Implantation of interspinous fixation is helpful in prophylaxis of scarry deformity of dural sac caused by decompressive resection of the ligament maintaining enlarged intervertebral foramen. Interspinous dynamic fixation results in minimal changes in segmental and local lumbar lordosis. Therefore, interspinous dynamic fixation with distraction laminoplasty is the method of choice for patients with LSS in presence of specific morphological and clinical manifestations.

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Information about the authors:

1. Oksana G. Prudnikova, M.D., Ph.D., Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics, Kurgan, Russia, Scientific Clinical-and-experimental Laboratory of Axial Skeletal Pathology and Neurosurgery, senior researcher; Email: pog6070@gmail.com
2. Maksim V. Khomchenkov, M.D., Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics, Kurgan, Russia, Scientific Clinical-and-experimental Laboratory of Axial Skeletal Pathology and Neurosurgery, junior researcher