Original Article

Preliminary experience with lumbar facet distraction and fixation as treatment for lumbar spinal stenosis

ABSTRACT

Objectives: To assess the properties of facet fixation with the Facet Wedge system in patients affected by lumbar spinal stenosis (LSS).

Summary of Background Data: Implant of intra-articular spacers is an emerging technique for lumbar degenerative disease.

Methods: This study included forty patients (Group 1) with symptomatic LSS in whom intra-articular spacers have been implanted along with microdecompression (MD) of the neural structures. Group 1 has been compared with a homogeneous group of patients with LSS treated with MD without intra-articular spacers implant (Group 2). Clinical findings have been observed preoperatively and 3, 6, 12 months postoperatively using dedicated questionnaires (Zurich Claudication Questionnaire, visual analog scale, and Oswestry disability index).

Results: One year following surgical treatment, 87% of the patients presented with good improvement of symptoms and 97% referred satisfaction for surgery. Overall, patients of Group 1 presented with significantly better clinical outcome when compared with the control group ($P < 0.01$).

Conclusions: Intra-articular spacers showed significant and clinically meaningful improvements in pain and disability for up to 1 year. These findings need further studies and a longer follow-up.

Keywords: Facet wedge, neurogenic intermittent claudication, spinal stenosis

INTRODUCTION

Lumbar spinal stenosis (LSS) is a degenerative, developmental, or congenital disorder where spine extension causes constriction of the nerve roots leaving the vertebral column. The degenerative type occurs most often, especially in those 50–60 years of age.[1] Arthritic invasion reduces the foraminal aperture resulting in the primary patient complaint of intermittent neurogenic claudication (INC). INC is the most specific symptom of spinal stenosis. It is defined as pain, paresthesia, and cramping of one or both lower extremities, due to neurologic compromise, appearing during walking or standing and relieved by sitting. People with the congenital type may complain earlier in life since the stenosis is a result of congenitally anatomic changes or malformations. Finally, in developmental spinal stenosis, the narrow spinal canal is caused by a growth disturbance of the posterior elements in the spinal canal.

LSS may occur at different localizations of the spinal canal. In central canal stenosis, nerve roots and the cauda equina are usually compressed. Lateral recess stenosis and foraminal stenosis produce compression of the nerve roots as they leave the spine. Besides INC, symptoms of LLS include lower back pain, unilateral or bilateral groin and leg pain, numbness, or weakness.

Because of the aging of the population, the medical community is facing a very wide variety of degenerative changes of the lumbar spine, and the treatment of symptomatic LSS is certainly among the major clinical challenges. As the available scientific

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evidence on the diagnosis and treatment of this entity is not completely consistent,[2] there is no currently a consensus for the treatment of LSS, especially for older patients. The optimum treatment for LSS is generally considered to be surgical intervention, as two randomized clinical trials comparing conservative treatment with conventional bony decompression resulted in treatment effects in favor of surgery.[3,4] Considering the destructive nature of bony decompressive surgery of the spinal column when performing lumbar spine laminectomy,[5] the resulting instability often requires subsequent instrumental spondylodesis.[6]

Recently, various microdecompression (MD) methods have been used for the treatment of LSS.[7,8] 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 an ongoing instability at the operational segment.

More than 10 years ago, Goel proposed an alternative method of treatment for spinal degeneration, which involved distraction of the facets by using the "Goel facet spacers."[9,10] (US Patent No. 9668783 B2 - Goel - Devices and method for spondylotic disease) Although the technique of introduction of the spacers into the facet joint varied in the lumbar spine, when compared to the cervical and dorsal spines, the basic concept and principle of its action was similar.[10,11] The process of facet distraction resulted in a remarkable reversal of almost the entire range of changes in the degeneration of the spine.[12] Recently, a facet fixation technique using the Facet Wedge® (FW) system has been reproposed.[13] Combining the principles of mechanical friction-based blockade and facet screws, FW offers a novel posterior approach in achieving primary stability in spinal fixation in a minimally invasive approach. Furthermore, considering that facet instability, rather than disc degeneration, could be the primary pathogenic factor that initiates a cascade of events, ultimately resulting in spinal canal stenosis,[14] facet distraction and fixation aims not only in maintaining spinal stability but also in reversal of several pathological events in the lumbar spine that are associated with degenerative/spondylotic lumbar canal stenosis.[14,15]

In this study, we have attempted to verify the properties of facet fixation with the FW system in patients affected by LSS.

METHODS

Patient populations and indications

In this study, forty consecutive patients with symptomatic LSS (Group 1) in whom FW device has been implanted along with MD of the spinal canal were prospectively analyzed. The surgical database at this institution was queried to identify forty patients with LSS as control (Group 2), corresponding to the same levels of operation with Group 1, where MD without FW implant was performed. Table 1 shows the demographic data for all the patients.

Inclusion criteria were age ≥45 years, persistent leg, buttock, or groin pain, with or without back pain, which was relieved by lumbar flexion, symptomatic and undergoing unsuccessful conservative treatment for at least 6 months, diagnosis of LSS (both central and lateral), defined as 25%–50% reduction in lateral/lumbar spinal canal diameter compared to adjacent levels, and radiographic evidence of thecal sac and/or cauda equine compression, nerve root impingement by either osseous or nonosseous elements, and/or hypertrophic facets with canal encroachment. Exclusion criteria included LSS at three or more levels, Grade II–V spondylolisthesis, significant lumbar instability, important systemic diseases, vertebral osteoporosis, or history of vertebral fracture.

For all patients, medical history was carefully investigated, physical examination along with neurological evaluation was achieved. X-rays (standing anteroposterior, lateral lumbar, flexion/extension lateral lumbar) and magnetic resonance imaging or computed tomography of the lumbar spine were performed in all the cases. The Zurich Claudication Questionnaire (ZCQ) was utilized to assess patient-reported measures of symptom severity, physical function, and patient satisfaction. Extremity and axial pain severity were measured with a 100 mm visual analog scale (VAS). The degree of back-specific functional disability was assessed with the Oswestry disability index (ODI).

The Facet Wedge system

FW is intended for the fixation of the spine through distraction and immobilization of the facet joints, at one or two levels, from L1 to S1.[13] It is a titanium implant configured to be placed in the plane of the facet joint, between the diarthrodial surfaces of the facet joint and as a mechanical spacer to distract the

Table 1: Demographic data

Characteristic	Value	
	Group 1	Group 2
Number	40	40
Sex		
Male	22	19
Female	18	21
Age (yrs)		
Mean±SD	60.3±3.2*	57.31±6.2
Range	50-74	55-76

SD - Standard deviation

facet faces. Following FW insertion, two self-locking screws strengthen the system in the facet joint [Figure 1].

Operative technique

Patients were operated on while under general anesthesia in a prone position and received an antibiotic prophylaxis before the surgery.

Briefly, a midline skin incision of approximately 3–4 cm was made above the spinous processes of the stenotic level. After the fascia was opened in a vertical way, blunt dissection of the muscle fibers in an oblique way, onto the lateral aspect of the facet joint, was performed. Upon facet joint identification, the capsule was opened to visualize the facet joint entry. In case of any osteophytes, they were removed to get a proper access into the joint. To ensure an optimal implant placement, a graft bed was prepared with a reamer. Following such a step, the FW was inserted into the facet joint and secured by screws insertion. The appropriate measure of the FW (small, medium, or large) and the following distraction were chosen with the aim to restore the normal alignments of the facets and dimensions of the canal.[14] Following FW implant, MD was carried out. 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. Under surgical microscope, the upper and lower lamina were partially removed in the area of the ligamentum flavum insertion. The basal part of the spinous process of the caudal half of the cranial lamina and a small cranial portion of the caudal lamina were removed with a high-speed drill. Following sufficient resection of the bony segment, the ligamentum flavum was removed. Radicular decompression in the foramen was also performed if required.

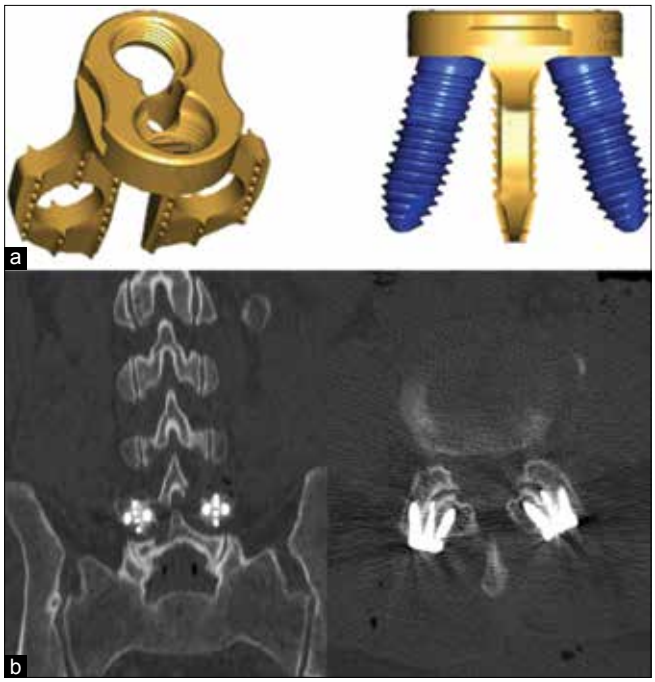

Figure 1: (a) Photograph showing the Facet Wedge system. It is a titanium implant tailored to be placed in the plane of the facet joint between the diarthrodial surfaces of the facet joint and as a mechanical spacer to distract the facet faces (left). Following Facet Wedge insertion, two self-locking screws strengthen the system in the facet joint (right); (b) postoperative computerized tomography scan showing the Facet Wedges implant in L4–L5 level (left coronal, right axial)

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. Rehabilitation was not generally recommended.

Clinical outcome measurement

We observed clinical findings preoperatively and 3, 6, 12 months postoperatively using dedicated questionnaires. The VAS, ODI, and ZCQ patient assessment scales were used to evaluate the outcome in this study. These assessments are reported for baseline and at 1 month, 6 months, and 1 year postoperatively. The VAS provides a numerical measurement of back and leg pain intensity on a 10-point continuum, with 1 denoting no pain and 10 indicating the worst pain possible. The ODI provides a measurement of functional disability resulting from chronic back pain. ODI scores range from 0 to 100, with higher scores signifying greater disability. The ZCQ is a validated patient-reported outcomes tool. ZCQ consists of symptom severity and physical function domains that are recorded at baseline and at each follow-up interval. In addition, ZCQ also contains a patient satisfaction domain that is completed only at follow-up. For each ZCQ domain, higher scores indicate worse patient condition. As a validated patient outcome tool is specific to LSS, ZCQ provides information specifically related to spinal disability.

Statistical analysis

Data were reported as mean ± standard deviation, and categorical data were reported as frequencies and percentages. The clinical results were analyzed using the analysis of variance Chi-square test, Fisher's exact test, Kruskal–Wallis test, and McNemar test.

RESULTS

Patient population

Patients were compared in terms of sex, symptoms, and age. Demographic differences among the groups were not statistically significant ($P > 0.05$).

A total of eighty FWs, two for each level, were inserted in Group 1. 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. None of the patients underwent re-exploration of the region or needed any additional surgical procedure for the lumbar spine.

The follow-up period ranged from 12 to 14 months (mean 12.3 months). One year following surgical treatment, 87% of the patients of Group 1 presented with a very good improvement of symptoms and 97% of patients referred satisfaction for surgery. Overall, the patients of Group 1 presented significantly better clinical outcome when compared with the control group (Group 2) ($P < 0.01$). ZCQ, VAS, and ODI score improved in all the groups at 6 months following surgery and at 1-year follow-up [Figure 2]. Significant statistical differences were noted in all the groups when comparing the clinical outcome measures from baseline to 1-year follow-up. A better clinical outcome was observed in Group 1 when compared with Group 2 ($P < 0.01$). The mean preoperative and postoperative ZCQ, VAS, and ODI scores are reported in Table 2.

DISCUSSION

Lumbar spinal degeneration leading to lumbar canal stenosis is a disabling clinical condition.

The most accepted pathogenetic mechanism is related to a cascade of processes starting with disc degeneration.[16] However, recently, Goel has suggested an alternative hypothesis identifying the facet damage as primum movens for spinal degeneration.[11,14] Reduction of the interfacet distance and the subsequent instability may play a role in the pathogenesis of the entire spectrum of spondylosis.[11] Facet degeneration would lead to the well-known events that ultimately result in stenosis of the spinal canal and intervertebral neural foramina such as reduction in disc height, bulge of the posterior anulus/posterior longitudinal ligament, invagination and hypertrophy of the ligamentum flavum. Accordingly, the frequently observed facet hypertrophy in lumbar canal stenosis could be the physical consequence of facet overload and back pain could be its symptomatic manifestation.

To date, treatment of degenerative spine disease encompasses decompression of the neural elements with or without instrumentation and fusion. Increasing in the understanding of spinal biomechanics, proliferation of sophisticated spinal devices, refinement of surgical approaches to the spine, and the development of microsurgical and minimally invasive methods have made it possible to successfully treat

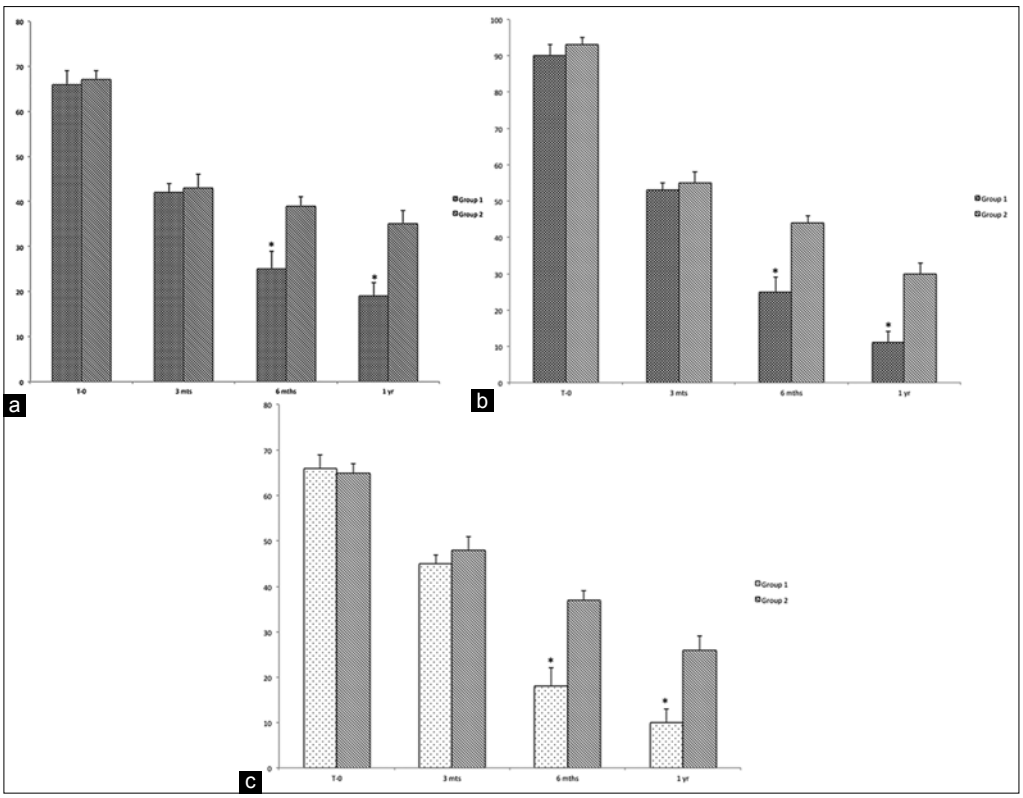

Figure 2: Bar graphs showing preoperative and postoperative Zurich Claudication Questionnaire (a), visual analog scale (b) and Oswestry Disability Index (c) outcomes between the groups. Overall, Zurich Claudication Questionnaire, visual analog scale, and Oswestry Disability Index score improved in all the groups at 1-year follow-up. Significant statistical differences were noted in all the groups when comparing the clinical outcome measures from baseline to 1-year follow-up. A better clinical outcome was observed in Group 1 when compared with Group 2 at 6-month and 1-year follow-up (*$P < 0.05$)

Table 2: Mean preoperative and postoperative ZCQ, VAS and ODI scores between the groups

	Preoperative		1-y follow-up	
	Group 1	Group 2	Group 1	Group 2
ZQR	66	67	19	35
VAS	90	93	11	30
ODI	66	65	10	26

several pathologies of the spine. When we examine the issue of posterior spinal disease and LSS, it is well known that it should be considered both the natural history of the disease process and the iatrogenic instability resulting from a surgical decompression. As in a large majority of these patients, the symptoms encompass from radicular to central canal compression; they can require decompression of the paramedian lamina and at least the medial third or half of the facet complex. This is often associated with microdiscectomy. Progressive resection of these structures can result in progressive spinal instability.[17]

In this scenario, a facet fixation technique with the FW system has recently been proposed.[13] Combining the principles of mechanical friction-based blockade and facet screws, FW offers a novel posterior approach in achieving primary stability in spinal fixation with a minimally invasive approach.[13] Furthermore, considering that facet instability, rather than disc degeneration, could be the primary pathogenic factor that initiates a cascade of events resulting in spinal canal stenosis,[11,14] facet distraction and fixation aims not only in maintaining spinal stability but also in reversal of several pathological events that are associated with degenerative/spondylotic LSS.

In this study, we prospectively analyzed patient data collected over 1 year to evaluate the properties of FW implant in patients with LLS in whom the FW system has been inserted along with MD of the neural structures. One year following surgical treatment, 87% of the patients presented a very good improvement of symptoms, and 97% of patients referred satisfaction for surgery as compared with patients treated by the solely MD.

No complications were associated with such a kind of surgery. In particular, FW systems showed significant and clinically meaningful improvements in pain and disability since the first 6-month postsurgery for up to 1 year. Our findings are in agreement with those of the previous studies that in shorter follow-up have shown the safety of the lumbar facet distraction and fixation.[11]

The results of this study lead to the overall conclusion that LLS treated with FW device is a safe treatment option to classic MD. The use of the FW system, however, does not preclude subsequent decompressive surgery and pedicle screw fixation if further required.

In the so-called "minimally invasive surgery," facet distraction and fixation takes the chance to gain in importance and popularity, especially if used in selected patients. It should be considered, however, that, similarly to other novel technologies and techniques in spine surgery developed in recent decades, the early optimism has since waned significantly as a result in exceeding indication thus causing unfavorable outcomes. The drawback of this study is the short follow-up. This, however, does not affect the value of the results of this preliminary report that adds new insight into the pertinent literature. FW implant and MD may be considered as an alternative treatment for LSS. Its effectiveness compared with laminectomy and fusion is unknown, and a direct comparison between the two procedures in a prospectively multicenter randomized controlled study would address an important issue. Furthermore, a longer follow-up, already ongoing, will provide new leading information.

CONCLUSIONS

Facet distraction and fixation with FW system along with MD of the neural structures has demonstrated to be a safe and effective alternative to other techniques. In addition, considering that facet instability could be involved in the cascade of events that ultimately result in spinal canal stenosis, FW implant offers the opportunity to directly counteract part of the pathogenetic mechanisms underlying LSS.

Acknowledgment

The results of this study were partially presented at the World Spine 7 meeting, April 15–17, 2016, Delhi, India.

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Conflicts of interest

There are no conflicts of interest.

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