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Are There Differences Between Patients with Extreme Stenosis and Non-extreme Stenosis in Terms of Pain, Function or Complications After Spinal Decompression Using a Tubular Retractor System?

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Abstract

Background Micro-tubular decompression in extreme lumbar spinal stenosis is challenging because it is technically difficult to achieve adequate decompression. Whether the results of micro-tubular decompression related to pain, function, and complications in lumbar spinal stenosis of the extreme and non-extreme varieties are different has not yet been conclusively established.

Questions/purposes Are there differences between patients with extreme stenosis and non-extreme stenosis in terms of (1) VAS back or leg pain, (2) Oswestry Disability Index (ODI), or (3) complications when they were treated with spinal decompression using a tubular retractor system?

Methods Between January 2007 and January 2017, one surgeon performed 325 single-level lumbar micro-tubular decompressions without fusion. Of those, 43% (140 of 325) had extreme stenosis (defined as the absence of cerebrospinal fluid signal and a grey homogeneous dural sac with unrecognizable rootlets and posterior epidural fat in T2 weighted axial MRI image) and the rest had non-extreme stenosis. During this time, we used tubular retractors for these procedures in patients with simple lumbar spinal stenosis who had persistent symptoms despite conservative treatment for neurogenic claudication. No alternate form of decompression was performed in the study period. Patients with complex lumbar spinal stenosis associated with a deformity or instability who were treated with instrumented fusion were excluded. A total of 14% (20 of 140) patients in the extreme stenosis group and 15% (28 of 185) patients in the non-extreme stenosis group were lost to follow-up before 2 years; the remaining 120 patients with extreme stenosis and 157 patients with non-extreme stenosis were analyzed at a mean follow-up of 33 ± 5 months in this retrospective, comparative study. The groups were not different at baseline in terms of preoperative VAS score for back pain, age, gender, BMI or the percentage who had diabetes or who smoked. However, patients with extreme stenosis had higher preoperative ODI scores and higher preoperative VAS score for leg pain compared with the non-extreme group. There was a higher proportion of men in the non-extreme stenosis group (56% [104 of 185] versus 50% [71 of 140]; p = 0.324). Study

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endpoints were VAS score for leg and back pain, ODI, and complications, all of which were ascertained by chart review. With the numbers available, we could detect with 80% power at $p < 0.05$ a difference of 0.93 cm of 10 cm on a 10-cm VAS scale for VAS leg pain; a difference of 1.00 cm of 10 cm on a 10-cm VAS scale for VAS back pain and a difference of 2.12 cm of 100 cm on a 100-cm ODI scale.

Results In terms of pain, both groups improved after surgery, but there was no between-group difference in terms of the VAS scores at the most recent follow-up. VAS back pain improved from a mean of 3 ± 1 to 2 ± 1 in the extreme stenosis group and from 3 ± 1 to 1 ± 1 in the non-extreme stenosis group ($p = 0.904$); VAS leg pain improved from 7 ± 1 to 1 ± 1 versus 6 ± 1 to 1 ± 1, respectively ($p = 0.537$). ODI scores likewise improved in both groups, with no between-group difference in the ODI scores at latest follow-up (66 ± 7 to 19 ± 2 in the extreme stenosis group versus 59 ± 5 to 19 ± 2 in the non-extreme stenosis group ($p = 0.237$). Complications in the group with extreme stenosis occurred in six patients (incidental dural tears in two patients, urinary retention in three patients, and Syndrome of Inappropriate Anti Diuretic Hormone secretion (SIADH) in one patient); complications in the non-extreme stenosis occurred in two patients (incidental dural tears in two patients).

Conclusions The results in terms of improvement in VAS for leg and back pain and ODI scores were not different between patients with extreme and non-extreme stenosis. Micro-tubular decompression can be thus considered an alternative for patients with extreme stenosis. Future studies, ideally multicentre, comparative trials, are needed to confirm our preliminary results.

Level of Evidence Level III, therapeutic study.

Introduction

No studies to our knowledge have compared the results of spinal decompression in extreme and non-extreme stenosis using tubular retractors. We believe the reason is that it is very difficult to reliably categorize patients into groups of extreme and non-extreme stenosis using guidelines based on the available imaging tools. In general, this classification has been subjective, although we think that the landmark work of Schizas et al. [31] (validated by Weber et al. [34]) makes it somewhat more objective and allows us to make a more rigorous comparison. It is important to scientifically compare the outcomes of different techniques for the same or different degrees of spinal stenosis, to compare outcomes of the same technique for different degrees of spinal stenosis, and intraoperatively for the surgeon, to be conscious and aware of the complexity of the procedure when dealing with severe stenosis.

Micro-tubular decompression is a challenging, less-invasive procedure in which spinal stenosis is addressed through ports with narrow corridors. We believe this has potential advantages, perhaps including a shorter recovery period [3, 7, 13, 16, 23], but it also is technically demanding (especially in patients with more severe stenosis), and so it may carry an increased complication risk. Using the above-mentioned classification system [31], we wanted to determine whether there would be important differences in outcomes scores or complications after micro-tubular decompression performed in patients with extreme and non-extreme lumbar spinal stenosis.

Therefore, we asked: Are there any differences between patients with extreme stenosis and non-extreme stenosis in terms of (1) VAS back or leg pain, (2) Oswestry Disability Index (ODI), or (3) complications when they were treated with spinal decompression using a tubular retractor system?

Patients and Methods

Between January 2007 and 2017, one surgeon (AGK) performed micro-tubular decompression in 325 patients with single-level lumbar spinal stenosis without fusion using the METRx™ system (Medtronic Sofamor Danek, Memphis, TN, USA) with 18- and 16-mm-diameter tubular retractors. Of those, 43% (140 of 325) had extreme stenosis, which was defined as the absence of a cerebrospinal fluid signal and a grey homogeneous dural sac with unrecognizable rootlets and posterior epidural fat in T2 weighted axial MRI (Type D according to Schizas et al. [31]). The rest (57%; 185 of 325) had non-extreme stenosis (Types A-C) (Fig. 1).

For all patients, the lead author (AGK) and a certified radiologist (RP) analyzed the MR images; interobserver reliability was assessed with Cohen's kappa statistics test ($\kappa = 0.879$), which demonstrated high reproducible accuracy in categorizing extreme stenosis on MRI.

We included patients with simple, single-level lumbar spinal stenosis with neurogenic claudication as their predominant complaint in the study. We excluded patients with multi-level involvement, complex lumbar spinal stenosis (associated with deformity or instability) [10] and congenital causes of lumbar spinal stenosis such as dwarfism, Paget's disease, epidural lipomatosis. There were no instances of conversion to an open procedure. No alternate form of decompression procedure was performed.

A total of 14% (20 of 140) patients in the extreme-stenosis group and 15% (28 of 185) patients in the non-extreme stenosis group were lost to follow-up before 2 years; the remaining 120 patients with extreme stenosis and 157 with non-extreme stenosis were analyzed at a mean follow-up of 32 ± 5 months in this retrospective, comparative study. Mean operative time and blood loss in both

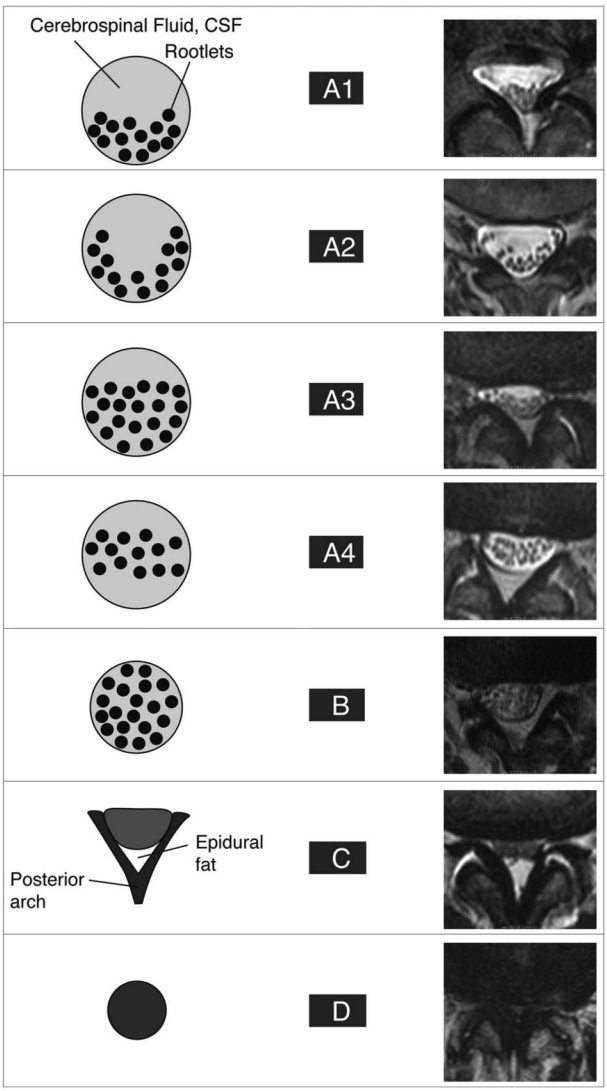

Fig. 1 Description of the morphologic classification of lumbar spinal stenosis combining graphic and MRI examples.

the groups were extracted. The mean operative time for patients with extreme stenosis was 80 ± 13 minutes and 65 ±11 minutes for those with non-extreme stenosis. The mean blood loss was 68 ± 25 mL for patients with extreme stenosis and 55 ± 20 mL for those with non-extreme stenosis.

The groups were not different at baseline in terms of preoperative VAS score for back pain, age, gender, BMI, or the percentage who had diabetes or who smoked cigarettes. However, patients with extreme stenosis had higher preoperative Oswestry Disability Index (ODI) scores and VAS score for leg pain compared with the non-extreme group. There was a higher proportion of men in the non-extreme stenosis group (50% [71of 140] versus 56% [104 of 185]; p = 0.324) (Table 1).

Operative Procedure

Patients were positioned prone on a radiolucent table with bolsters below the chest and the iliac crest. The abdomen was free, the head-end was raised, and pressure points were well-padded.

Under lateral fluoroscopy control, the surgeon inserted a 20-gauge spinal needle approximately 0.8 cm to 1.2 cm, depending on an assessment of the patient's morphometry on MRI, lateral to the midline at the involved level, so that the trajectory of the needle was collinear with the disc space and bisected it. This step helped guide the tubular retractor so that it docked with the intervertebral disc in the center of the field, allowing the surgeon to perform decompression from the cranial to the caudal pedicle encompassing the length of the lateral recess. An 18-mm to 20-mm-long incision (based on the diameter of the tube used; an 18-mm incision for a 16-mm-diameter tube and a 20-mm incision for an 18-mm-diameter tube) was centered over the needle and deepened beyond the fascia. The target site was the inferior lamina of the superior vertebra at the junction of the lamina and medial facet.

The surgeon inserted an initial dilator to sweep off the paraspinal muscle mass and palpate the bony landmarks, and then confirmed the target site under fluoroscopy and insertion of sequential dilators. The marking on the final dilator at skin level indicated the depth of the tubular retractor. The surgeon docked the final tubular retractor by fixing the flexible arm as the final working channel. The operating microscope was advanced into the operating field, and the soft tissue was separated using a long cautery tip until the lamina could be visualized. The surgeon drilled the ipsilateral lamina with a 4-mm high-speed cutting burr until he encountered the junction of the inner cortex and ligamentum flavum, and then he performed an ipsilateral laminotomy using a Kerrison rongeur. The central canal and opposite lateral recess were decompressed using the "over the top" decompression technique. Decompression of the contralateral side was technically easier because of the diagonal view. Hence, if one side was more stenotic morphologically, it was easier to decompress from the opposite side (Fig. 2). If the compression was a result of facet hypertrophy, then drilling under direct vision was easier if performed from the opposite side.

To appropriately visualize the contralateral sublaminar structures, the surgeon tilted the operating table away from him and wanded the tubular retractor. Next, the base of the spinous process and the inner blade of the contralateral lamina was initially undercut using the burr and then rongeurs. The surgeon exposed the ligamentum flavum bilaterally. The central natural cleft in the ligamentum flavum was opened with a number 4 Penfield dissector, and the flavum was excised medially and laterally using numbers 2 and 3 Kerrison rongeurs.

Table 1. Demographics and preoperative scores

Parameter	Extreme stenosis (n =140)	Non-extreme stenosis (n =185)	p value
Preoperative ODI	66 ± 7	59 ± 5	< 0.001
Preoperative VAS-Back	3 ± 1	3 ± 1	0.15
Preoperative VAS-Leg	7 ± 1	6 ± 1	< 0.001
Female	n = 69 (49%)	n = 81 (43%)	0.324
Mean age in years	61 ± 9	62 ± 12	0.61
Mean BMI (kg/m^2)	26 ± 5	25 ± 4	0.212
Diabetes mellitus	11% (15)	11% (21)	0.856
Smoking	13% (18)	10% (18)	0.373
Steroid use	6% (9)	7% (13)	0.831

ODI = Oswestry Disability Index.

The surgeon performed meticulous and complete decompression of the contralateral recess after excising the ligamentum flavum, hypertrophied medial facet, and medial border of the superior facet. When there was severe soft compression as a result of ligamentum flavum hypertrophy, the surgeon created a cleft in the meat of the flavum with a Penfield dissector so that a thinner Kerrison's rongeur could be introduced into the cleft (Fig. 3). Then, the superficial part of the flavum was excised, after which the canal on the opposite side widened. Next, the deeper part of the flavum was excised and the lateral recess on the contralateral part was decompressed, which allowed for complete visualization and decompression of the contralateral traversing nerve root. Using a curved Kerrison's rongeur to decompress the ipsilateral lateral recess and the foramen is critical to achieve adequate decompression without violating the facet joint. The curved Kerrison's punch digs into the lateral recess without biting the medial facet (Fig. 4).

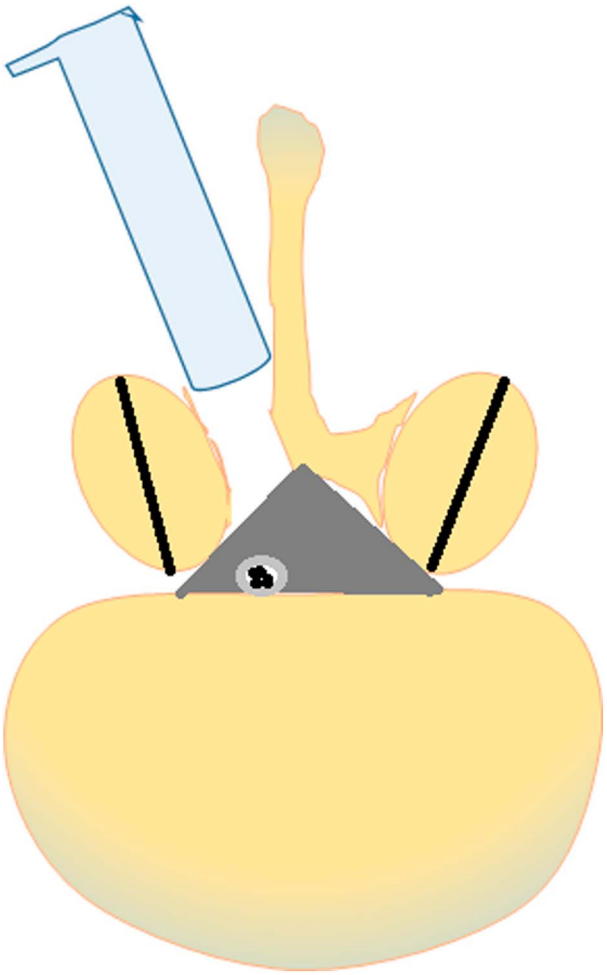

Fig. 2 This schematic axial image shows tube docking for decompression from the contralateral side in a patient with unilateral extreme stenosis.

Finally, the surgeon returned the table and retractor to the initial position, and then he performed decompression of the ipsilateral lateral recess. We recommend using Kerrison's rongeurs with thinner foot-plate, such as number 2 and even number 1, to prevent dural or nerve root injuries at the interface of stenosis components and the neurological structures.

Epidural bleeding was controlled using a combination of bipolar cautery, bone wax, and gelatine sponge (STERISPON®, Gujarat, India). The thoracolumbar fascia and the subcutaneous layers were closed using 2-0 Vicryl (Ethicon, Johnson and Johnson, Aurangabad, India) and the skin was closed using 3-0 Monocryl (Johnson and Johnson Int, Aurangabad, India) for cosmetic reasons.

Outcome Measures

Study endpoints were the VAS score for leg and back pain, ODI scores; all scores were ascertained by a chart review performed by the operating surgeon (AGK). We compared the difference between the most recent and preoperative

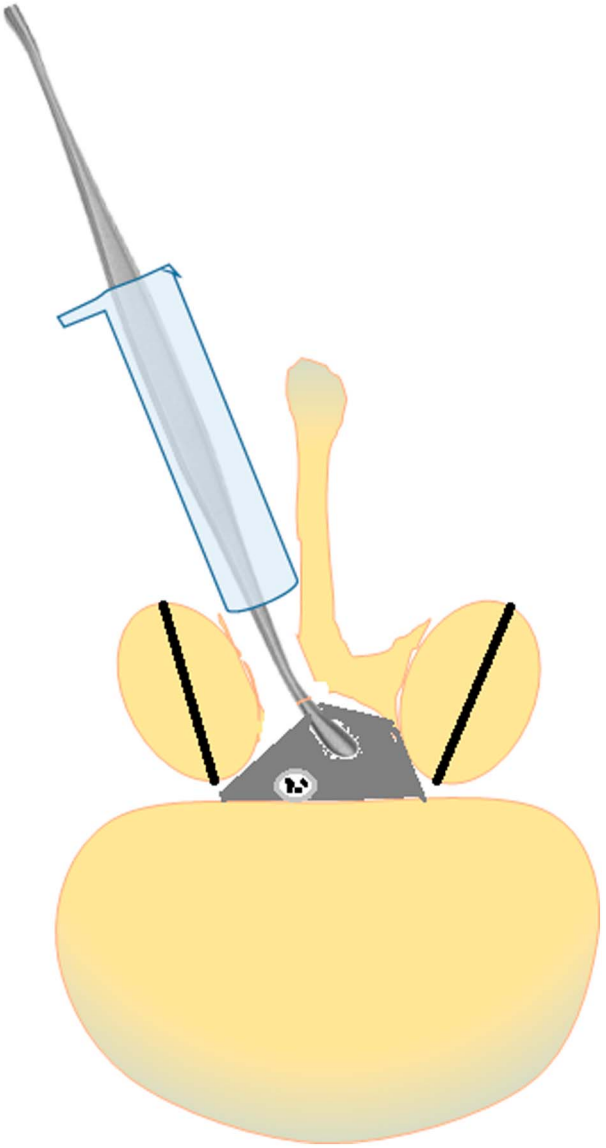

Fig. 3 This schematic axial image shows the creation of a cleft in the meat of the contralateral ligamentum flavum with a Penfield dissector.

scores, and secondarily, we compared only the most-recent scores between the groups We also compared the groups qualitatively in terms of complications. The study groups were patients with extreme stenosis and patients with non-extreme stenosis.

Statistical Analyses

Approval from the institutional review board was obtained before study initiation.

Descriptive analysis was performed to identify distribution of variables included in the study. Normal distribution

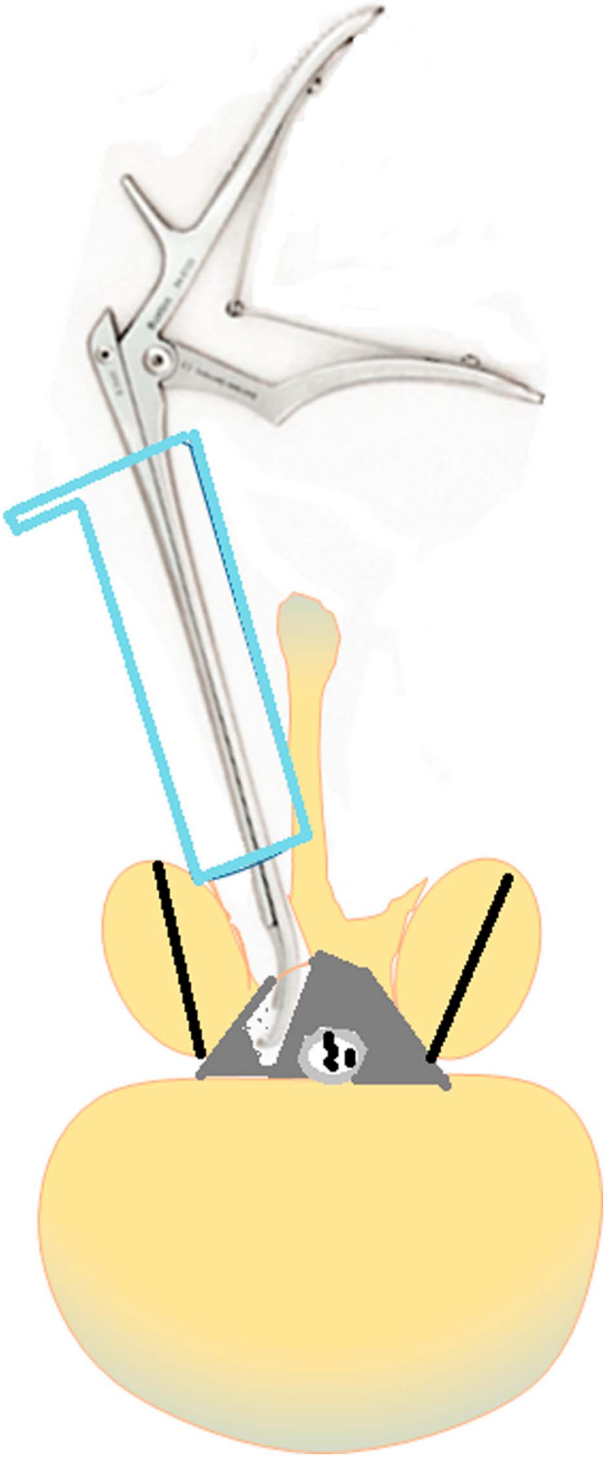

Fig. 4 This schematic axial image shows decompression of the ipsilateral lateral recess with a curved Kerrison rongeur, thereby minimizing facet violation.

of the scores was tested using the Kolmogorov-Smirnov test, and homogeneity of variance was tested using Levene's test. Categorical data were represented in the frequency form and

Table 2. ODI, VAS back pain, and VAS leg pain scores comparing patients with extreme and non-extreme stenosis

Latest follow-up	Extreme stenosis	Non-extreme stenosis	p value
ODI	19 ± 2	19 ± 2	0.237
VAS- Back	2 ± 1	1 ± 1	0.904
VAS-Leg	1 ± 1	1 ± 1	0.537

ODI = Oswestry Disability Index.

continuous data were presented as the mean ± SD. Interobserver reliability was ascertained by using the Cohen's kappa statistical test. A non-parametric mixed method for repeated measures were made of each of the outcome measures, with group and time entered as fixed effects and the outcome measures as dependent variables.

All analyses were tested with two-sided hypothesis testing and significance was considered at a p value of 0.05. Statistical analyses were performed using SPSS, the statistical package for social sciences (IBM Corp, Armonk, NY, USA) and RStudio version 1.0.136 (R. RStudio Inc, Boston, MA, USA) with R package "nparLD."

Results

In terms of pain, both groups improved after surgery, but there was no between-group difference in the pain scores at most recent follow-up. VAS back pain improved from a mean of 3 ± 1 to 2 ± 1 in the extreme stenosis group and from 3 ± 1 to 1 ± 1 in the non-extreme stenosis group (p = 0.904); VAS leg pain improved from 7 ± 1 to 1 ± 1 versus 6 ± 1 to 1 ± 1, respectively (p = 0.537).

Likewise, ODI scores improved in both groups, with no between-group difference in the most recent ODI scores (66 ± 7 to 19 ± 2 in the extreme stenosis group versus 59 ± 5 to 19 ± 2 in the non-extreme stenosis group (p = 0.237).

Incidental dural tears occurred in two patients with extreme stenosis and two patients with non-extreme stenosis; all were managed successfully with watertight closure of muscles, fascia, and skin. There were no postoperative complications attributable to the dural tears, such as pseudomeningocele or infection. Urinary retention in three patients (two in extreme stenosis) and Syndrome of Inappropriate Anti Diuretic Hormone secretion (SIADH) in one patient (in extreme stenosis) occurred. These conditions were managed nonoperatively.

Discussion

Numerous studies have evaluated a host of approaches for the surgical management of lumbar spinal stenosis, from open decompression to micro-lumbar decompression to micro-tubular decompression [2, 3, 14, 22, 23, 26, 28]. Potential problems with open procedures include muscle atrophy, damage to the native anatomic supports, and problems related to future instability; by contrast, procedures involving smaller approaches have their own drawbacks, mainly related to technical difficulty and a steep

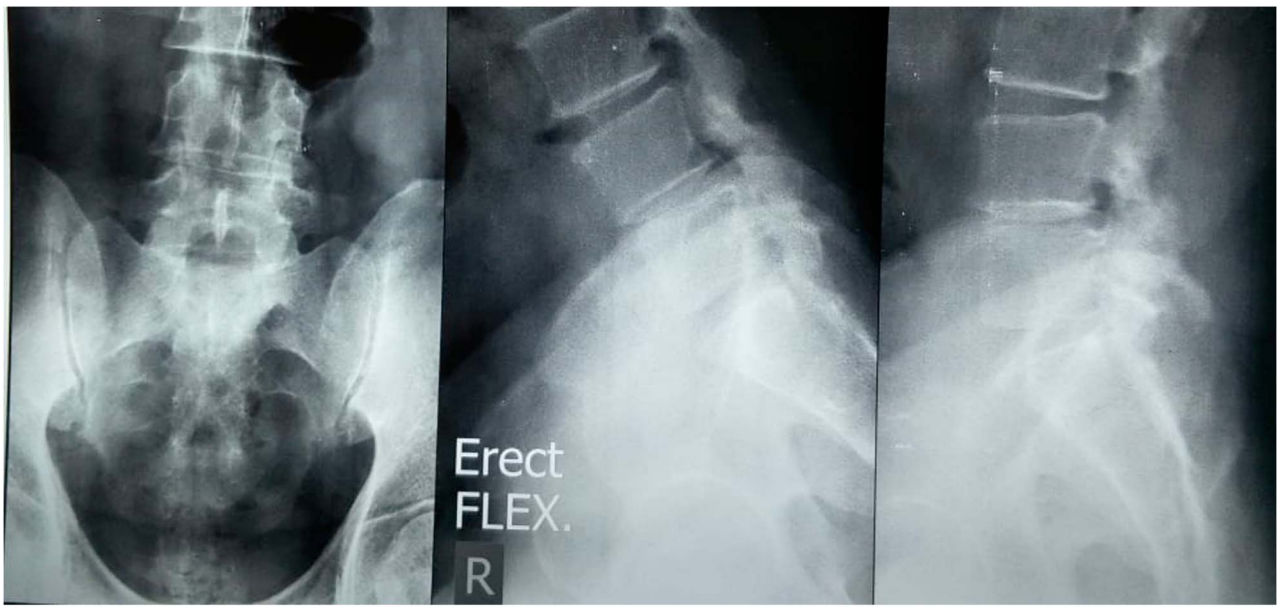

Fig. 5 At 2 years follow-up, AP and lateral dynamic radiographs show sufficient unilateral laminotomy with maintenance of stability at L4-L5.

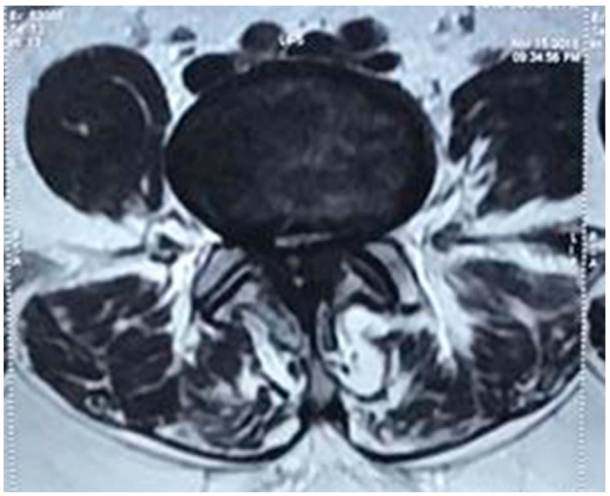

Fig. 6 A preoperative T2 axial image of a 65-year-old man shows extreme L4-L5 stenosis.

learning curve [7, 13, 16, 18, 19]. We have favored less invasive approaches because of the perceived advantages of reduced morbidity and a shorter convalescence when compared with an open procedure; we believe these are especially noteworthy in older patients and patients with obesity [32]. However, to our knowledge, no studies have compared micro-tubular decompression in patients with extreme versus non-extreme stenosis. We sought to do so and found no differences in the magnitude of improvement in pain or ODI scores, and no differences in complications in this single-surgeon, retrospective study.

This study had several limitations. Firstly, this was a retrospective study, and as a single-surgeon series, may be susceptible to selection bias and assessment bias, which can inflate the apparent benefits of treatment. We believe selection bias was mitigated by the fact that the study surgeon used the same approach in all patients meeting the study indications, regardless of stenosis severity. Assessment bias may have been partially mitigated by longitudinal data collection rather than retrospective data collection; in addition, validated outcomes scores (VAS and ODI) were used. Transfer bias was a concern, in that some patients in each group were lost to follow-up; this was somewhat diminished by the fact that the proportion of patients lost in each group was not different (that is, there was no differential loss to follow-up). In general, though, one ought to consider that the health status of the missing generally is inferior to that of the accounted-for, and so the apparent benefit of treatment in both groups here may be inflated, and the proportion of patients with complications or reoperations somewhat underestimated. The mean follow-up period of this study was 33 months, and so sequelae and complications that may appear over longer follow-up could not be recorded; longer-term follow-up studies are necessary.

We found no difference in the magnitude of improvement in pain between patients with extreme and non-extreme stenosis who underwent micro-tubular decompression. This finding is supported by studies concerning lumbar spinal stenosis managed with tubular retractors [5, 6, 14, 20, 23]. Nomura et al. [18] noted improvement in leg pain in 78% and improvement in back pain in 64% of patients who underwent micro-tubular decompression for lumbar spinal stenosis. In their study, Alimi et al. [3] described reduction in both back and leg pain. Jones et al. [12] also observed reduction in back pain along with pain related to claudication. These findings support the idea that less invasive approaches can be used in this setting, but available evidence suggests that these approaches are associated with a challenging learning curve [7, 13, 16, 18, 19] and specific risks [27, 30], which we urge surgeons to take seriously. The current series was performed by a surgeon who has taken specific training in the use of micro-tubular decompression.

Likewise, we found improvement in function (as measured by ODI) in both groups after surgery, but no difference in the ODI score at latest follow-up between patients with extreme and non-extreme stenosis (Table 2). This supports the idea that micro-tubular decompression can be performed even in patients with more severe stenosis with good improvement in function. The overall amount of improvement in ODI score and VAS leg pain was higher in the extreme group compared with the non-extreme group, but we attribute this to the fact that the extremely stenotic patients were relatively more disabled before surgery compared with the non-extreme group. Earlier studies by Pao et al. [24], Parikh et al. [25] as well as Alimi et al. [3] have shown comparable improvements in patient's function after tubular decompression. Although many authors [3, 5, 12, 19, 22, 24] have demonstrated good functional results with the tubular technique, the sample sizes were smaller and follow-up periods were relatively shorter compared with the present study. Furthermore, none of these studies compared the results according to the severity of stenosis measured objectively. The prospect of providing an equally favorable functional result in an extremely stenotic canal compared with lesser degrees of morphological stenosis as established in this study is revealing and can inform preoperative patient counseling.

There were no major complications such as iatrogenic instability (Fig. 5) or neurological deficits. Surgeons know that there could be excess bone removal in the lamina, pars, and the medial facets during decompression of severe stenosis. This is to prevent an access-related neurodeficit in a constricted narrow canal by the operating surgeon, where the surgeon would attempt to carve a wider and bigger laminotomy to allow easy passage of instruments

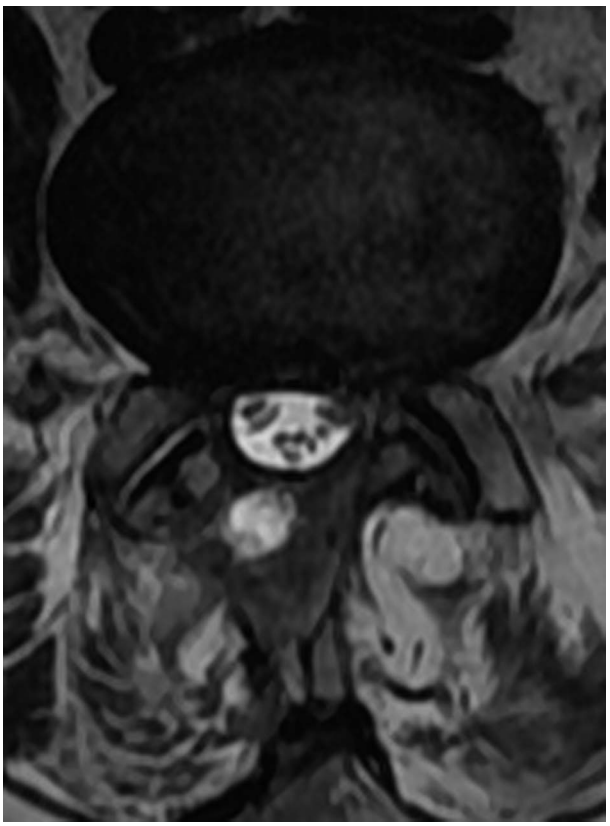

Fig. 7 A postoperative T2 axial image of the same patient shows adequate decompression with minimal collateral damage.

using multiple trajectories with minimal manipulation of neurological structures. While excessive bony excision of the lamina, facets, and the pars can result in iatrogenic instability and its consequences, manipulation of neurological structures in the limited space provided by smaller laminotomies can result in neurological complications. Meticulous anatomical orientation is an important practice to strike a balance. Given the morphology of the spinal canal in extreme stenosis (Fig. 6), performing micro-tubular decompression may be intimidating for surgeons who are unfamiliar with the technique. In those patients, open surgery, meaning decompressive laminectomy with or without fusion, may be an option. This may relieve clinical symptoms but may inadvertently lead to patients with iatrogenic spinal instability, resulting in additional surgical intervention for stabilization [26]. Radiographic studies, cadaver models, and finite element analyses have demonstrated the benefits of open laminectomies in widening the dimensions of the spinal canal [4, 8, 35, 29]. However, these studies also reveal the possibility of damage in terms of disruption of the native anatomic support structures (supraspinous ligament, interspinous ligament, spinous process, lamina, facet joints, ligamentum flavum, and the paraspinal musculature) leading to muscular atrophy and potential long-term spinal instability [1, 6, 26, 34]. By contrast, successful micro-tubular decompression with unilateral laminotomy and bilateral decompression as shown in the current study may offer some benefits. Quantitative studies have demonstrated an increase in spinal canal dimensions in the postoperative MRI after micro-tubular decompression and have found them comparable to open approaches [5]. As seen in the preoperative (Fig. 6) and postoperative axial images (Fig. 7), a thorough decompression of the spinal canal, comparable to an open decompressive laminectomy, is achievable using the tubular retractors with a unilateral approach. A low risk of postoperative instability [1, 6, 11, 21, 26, 33], minimal damage to paraspinal musculature [1, 26], and reduced postoperative back pain when compared with open procedures [12] are other potential benefits of tubular decompression. The technique may be of added benefit in patients with stable degenerative spondylolisthesis [17], patients with obesity, and older patients [9]. Podichetty et al. [27] studied surgical complications in 220 patients with lumbar spinal stenosis treated with a micro-tubular decompression and reported a durotomy rate of 4.5%. In our study, the durotomy rate was low. Water-tight closure of the wound in all layers was successful in the management of all postoperative leaks. This is related to the absence of dead space after removing the tubular retractor and the tamponade effect produced by the collapse of the operating corridor. We believe the forgiving nature of the micro-tubular decompression technique with regard to extreme stenosis is an added advantage because of the increased likelihood of incidental durotomies in critically compromised spinal canals [15]

In conclusion, the results in terms of improvement in VAS for leg and back pain and ODI scores were not different between patients with extreme and non-extreme stenosis. Micro-tubular decompression can be thus considered an alternative for patients with extreme stenosis. Future studies, ideally multicenter, comparative trials, are needed to confirm our preliminary results here.

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