

Navigated minimally invasive unilateral laminotomy with crossover for intraoperative prediction of outcome in degenerative lumbar stenosis

ABSTRACT

Background: Different surgical techniques have been described for treatment of degenerative lumbar stenosis (DLS). Only postoperative measures have been identified as predictors of efficacy of decompression. The objective of this study is to assess the role of navigated unilateral laminotomy with crossover to achieve and predict a satisfying decompression and outcome in DLS.

Materials and Methods: We enrolled patients with DLS who underwent navigation-assisted unilateral laminotomy with crossover. The extent of decompression was evaluated during surgery using neuronavigation. The outcome was assessed through the Oswestry disability index (ODI) and visual analog scale (VAS) for leg pain. Outcome correlation with the extent of the intraoperative bone decompression was analyzed. Finally, the outcome, surgical time, and in-hospital length-of-stay were compared with a control group treated through standard unilateral laminotomy.

Results: Twenty-five patients were treated using the navigated technique (Group A), 25 using the standard unilateral laminotomy (Group B). In Group A, a cut-off value ≥ 0.9 cm for bone decompression revealed to be an intraoperative predictor of good outcome, both regarding the ODI and VAS scores ($P = 0.0005$; $P = 0.002$). As compared with Group B, patients operated using the navigated technique showed similar operative times, in-hospital length-of-stay, ODI scores, but improved VAS scores for leg pain ($P = 0.04$).

Conclusions: The intraoperative navigated evaluation of the bone decompression could predict the outcome allowing satisfactory results in unilateral laminotomy for DLS. The navigated technique also could lead to an improved decompression of lateral recesses resulting in better control of leg pain as compared to standard unilateral laminotomy.

Keywords: Lumbar stenosis, minimally invasive spine surgery, navigation, unilateral laminotomy

INTRODUCTION

Background

Simple posterior decompression represents one of the most used techniques for surgical treatment of degenerative lumbar spine stenosis.^[1-14] Different surgical techniques have been described,^[4,7-14] but a clear superiority of one technique over the others regarding pain and functional outcome has not been identified.^[2,10,15,16]


Several attempts to obtain quantitative measurements to assess the degree of decompression achieved and to predict the functional outcome have been made. The dural sac cross-sectional area (DSCSA) of the lumbar spinal canal, as measured on the postoperative computed

tomography (CT) or magnetic resonance imaging (MRI) scans, turned out to be a reliable predictor of clinical and functional outcome.^[2,17-21] On the other hand, the DCSA

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is a postoperative measurement and cannot be used to change the surgical strategy.^[22] Till date, no intraoperative parameter has been identified as a predictor of good functional outcome.

Objectives

The aim of this study is to describe a new technique for the qualitative and quantitative intraoperative evaluation of the extent of decompression using intraoperative three-dimensional (3D) fluoroscopy and navigation. These measurements were used to guide the surgical procedure in unilateral laminotomy with bilateral decompression of the spinal canal used as decompressive procedure for the treatment of degenerative lumbar stenosis (DLS). We also analyzed the efficacy of the navigated technique by comparing the outcome with patients treated using standard microsurgical unilateral laminotomy.

MATERIALS AND METHODS

Study design

We collected clinical and outcome data from patients operated on for DLS using the navigated minimally invasive posterior decompression. We analyzed the association between the extent of intraoperative decompression, as evaluated through the navigated technique, and the postoperative outcome. Finally, we compared the operative times, in-hospital length of stay, and 6-month outcome with that of a historical control group composed of patients operated using the standard microsurgical unilateral laminotomy.

Selection and description of participants

We reviewed and collected the clinical data of patients operated on for single-level DLS between January and October 2016.

Inclusion criteria were as follows: Age ≥ 18 years old; the presence of a single-level lumbar degenerative stenosis; failure of symptoms relief with non-surgical treatment after a 6 months period. Exclusion criteria were as follows: Age < 18 years old; lumbar stenosis associated with spinal instability requiring instrumented fusion; the presence of multilevel stenosis; previous lumbar spine surgery; refuse to sign the informed consent. The historical control group included the last 25 consecutive patients matching the inclusion criteria and operated during the same timeframe without using the navigated technique. The study was conducted according to the Declaration of Helsinki and its later amendments. The informed consent was obtained from all individual participants included in the study.

Data sources

Demographic and clinical data of patients including age, sex, pre- and post-operative Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) scores, extent of bone decompression, operative time, and in-hospital length of stay were collected from our Institutional database including: clinical charts, PACS, outpatients' clinic records.

Measurements

The functional outcome was evaluated by comparing the preoperative versus post-operative ODI (version 1)^[23,24] and VAS score^[25] for leg pain after 6 months from surgery in both groups. The length of surgery and the in-hospital staying were also recorded. Finally, 6 months after surgery, patients underwent MRI scan and dynamic X-rays (during flexion and extension) of the lumbar spine to assess neural decompression or postoperative instability. In Group A patients, a correlation analysis between the extent of bone decompression and the outcome (ODI and VAS scores) was performed. The ability of the quantitative evaluation of the bone decompression to predict the functional outcome was also assessed.

Surgical technique

The navigated minimally invasive posterior decompression consisted of a unilateral laminotomy with crossover. The patient is placed in prone position with flexion of the thigh and legs.^[26] The skin incision is performed over the spinous processes of the interested level. Unilateral incision of the muscular fascia and subperiosteal dissection of paravertebral muscles are performed up to visualize the spinous processes of the two interested vertebrae, the corresponding laminae, and the interlaminar space. The side of the access is defined according to clinical signs/symptoms and/or neuroradiological findings. A Williams retractor is positioned, and a small contralateral incision of the muscular fascia is performed just to visualize the contralateral surface of the spinous process of the upper vertebra. The navigation optical reference is clamped over the spinous process of the upper vertebra and positioned with an inclination toward the head of the patients to avoid interference with the microscopic view and surgical instruments. A baseline intraoperative low-dose 3D fluoroscopy is performed to acquire imaging for neuronavigation (O-arm Surgical Imaging, Medtronic Navigation, USA). At this point, the microsurgical technique is employed, and neuronavigation is ready to be used (Spine software, StealthStation S7, Medtronic Navigation, USA) [Figure 1]. A unilateral laminotomy is performed by a partial removing of the lower part of the upper lamina and the upper part of the inferior lamina using Kerrison rongeurs. The medial facet joint is slightly undercut

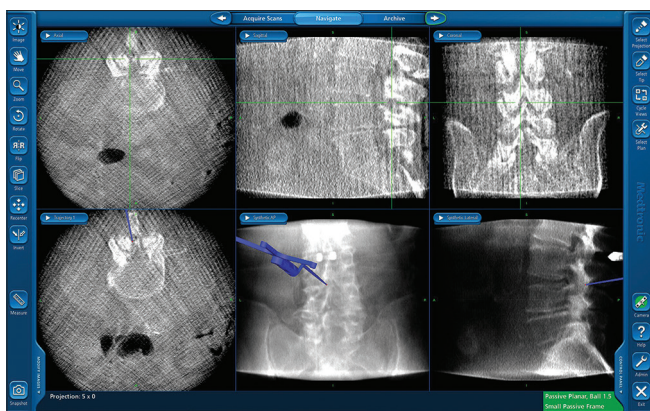


Figure 1: An example of the intraoperative use of neuronavigation for the minimally invasive unilateral laminotomy with crossover in a case of lumbar degenerative stenosis. The blue stick and the green crosshair represent the navigation probe tip visualized in different planes and projections

as well as the basis of the spinous process on the midline. The ipsilateral ligamentum flavum is visualized and removed using rongeurs up to identify the dural sac. The ipsilateral radicular recess is identified with a navigated probe. This helped to qualitatively assess the entity of ipsilateral decompression. In case of non-satisfying unilateral decompression, a further lamina and ligamentum flavum resection is performed. At this point, the surgical table is tilted contralaterally to gain an appropriate working angle to visualize the contralateral recess. The contralateral ligamentum flavum is then removed with the use of rongeurs. The basis of the spinous process and the medial facet can be further undercut to better visualize the contralateral recess, the contralateral border of the dural sac and the corresponding emerging spinal nerve root. The extent of the contralateral decompression is then qualitatively verified with the navigated probe. If the tip of the probe can successfully reach the contralateral recess, the decompression is considered satisfying. If not, further resection of the ligamentum flavum and undercutting of the medial portion of the contralateral facet are performed. The progressive decompression of the contralateral recess is therefore evaluated under direct view and for the more lateral portion that is not accessible to the sight, through the progression and the degree of mobility of the navigated probe tip along and across the recess and the foramen. The more is the removed ligamentum flavum and the soft tissue contralateral decompression, the easier will be to reach the contralateral recess using the tip of the navigated probe. This will be evaluated also through the visual feedback on the neuronavigation screen [Figure 2]. At the end of the procedure, a second low-dose 3D fluoroscopy is performed. The entity of decompression is now qualitatively and quantitatively evaluated using the neuronavigation probe on the post-decompression scan, and the extent of the unilateral bone removal in a lateromedial direction is measured at the level of the larger portion of the laminotomy [Figure 2].

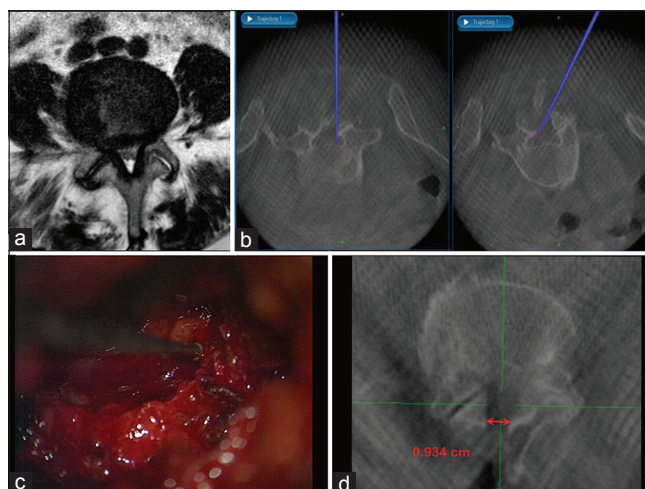


Figure 2: Case illustration of a patient affected by L4-L5 degenerative stenosis in Group A. (a) Preoperative axial MRI scan showing a narrowing of the spinal canal. (b) Intraoperative qualitative verification of the decompression of the ipsilateral (on the right) and contralateral (on the left) recesses. (c) Microscopic view of the neuronavigation probe used to verify decompression. (d) Three-dimensional fluoroscopy after decompression showing the maximal extent of the laminotomy that is intraoperatively quantified as 0.934 cm

Patients in the control group were operated using the same microsurgical technique but without using intraoperative navigation.

Statistics

The comparison between pre- and post-operative ODI and VAS scores was performed by using the paired Student *t*-test. The correlation between the extent of the bone decompression and the functional outcome (ODI and VAS scores) was assessed through the Pearson correlation and linear regression analysis. The accuracy of the quantitative measure of the bone decompression in predicting the functional outcome was analyzed using the Fisher's test and defined through computation of the sensitivity (ST), specificity (SP), positive and negative predictive values (PPV and NPV). The comparison of operative times, in-hospital length of stay, and outcome between the study group and controls was performed using the unpaired Student *t*-test. Statistical significance was defined as a $P < 0.05$. Data analysis was performed using GraphPad Prism version 6.00 for Windows, GraphPad Software, La Jolla, California, USA, www.graphpad.com.

RESULTS

Participants

Fifty patients were enrolled in the study. Twenty-five patients (14 males, 11 females, mean age 64.2 ± 5.2 years old) were operated using the navigated technique (Group A).

The control group included 25 patients operated using the standard non-navigated unilateral laminotomy (13 males, 12 females, mean age 64.3 ± 3.7) (Group B).

Descriptive data

At the admission, in Group A, the median ODI score was 46% (range 36–50), and the median VAS score for leg pain was 7 (range 5–9). The mean surgical time was 75.88 ± 11.07 min. The mean in-hospital stay was 2.44 ± 0.71 days.

In Group B, the median preoperative ODI score was 46% (range 38–50), the median VAS score for leg pain was 7 (range 6–9), the mean surgical time 74.52 ± 8.84 min, and the mean in-hospital stay was 2.48 ± 0.58 days.

No significant differences were observed between the two groups [Table 1].

In Group A, the intraoperative evaluation of decompression was considered satisfying in all cases. The contralateral decompression through crossover (resection of the ligamentum flavum, undercutting of the medial aspect of the facets) was stopped when it was considered satisfying under the direct microscopic view, and for the more lateral portion, when the navigation probe tip could be moved without obstacles along and across the contralateral

recess and foramen on the neuronavigation screen, thus demonstrating a satisfying decompression. The mean bone decompression as measured on the navigation screen was 0.927 ± 0.118 cm.

In Group B, the qualitative evaluation of the decompression was performed under the microscopic view, even tilting the operating table, without any quantitative assessment of the achieved decompression. The decompression was stopped in all cases when the qualitative microscopic assessment of the decompression was considered satisfying.

Outcome data

After 6 months from surgery, we observed an overall improvement of the functional independence (ODI score) and leg pain (VAS score) in both groups.

In particular, in Group A, we observed a significant reduction of the median ODI score to 21% (range 8%–40%, $P < 0.0001$). The median VAS score for leg pain was significantly reduced to 4 (range 2–6, $P < 0.0001$) [Figure 3].

Interestingly, we observed a significant negative correlation between the entity of the bone decompression and the functional outcome expressed as ODI ($r = -0.926$, $P < 0.0001$) and VAS scores ($r = -0.885$, $P < 0.0001$). A cutoff value for

Table 1: Clinical characteristics of patients and main findings of the study

Characteristics	Measurements		Group A vs. B (P)
	Group A (Navigated Technique)	Group B (standard technique)	
n of patients	25	25	NA
Sex			
Males	14	13	NA
Females	11	12	
Age (mean±SD)	64.2 ± 5.2 years old	64.3 ± 3.7 years old	$P=0.9$ ns
Operative time (mean±SD)	75.88 ± 11.07 min	74.52 ± 8.84 min	$P=0.6$ ns
In-hospital length of stay (mean±SD)	2.44 ± 0.71 days	2.48 ± 0.58 days	$P=0.8$ ns
Extent of bone decompression (mean±SD)	0.927 ± 0.118 cm	NA	$P=NA$
Median ODI score (range)			
Preoperative	46 (36-50)	46 (38-50)	$P=0.6$ ns
Postoperative	21 (8-40)	23 (14-40)	$P=0.3$ ns
Pre vs. post	$P < 0.0001$	$P < 0.0001$	
Median VAS score (range)			
Preoperative	7 (5-9)	7 (6-9)	$P=0.8$ ns
Postoperative	4 (2-6)	5 (3-6)	$P=0.04$
Pre vs. post	$P < 0.0001$	$P < 0.0001$	
Correlation between outcome and extent of bone resection			
ODI score	$r = -0.926$, $P < 0.0001$	NA	NA
VAS score	$r = -0.885$, $P < 0.0001$		
Accuracy of the extent of bone resection as predictor of outcome			
ODI score ≤ 20	ST=100%, SP=71.4%, PPV=73.3%, NPV=100%, $P=0.0005$	NA	NA
VAS score < 5	ST=86.6%, SP=80%, PPV=86.6%, NPV=80%, $P=0.002$		

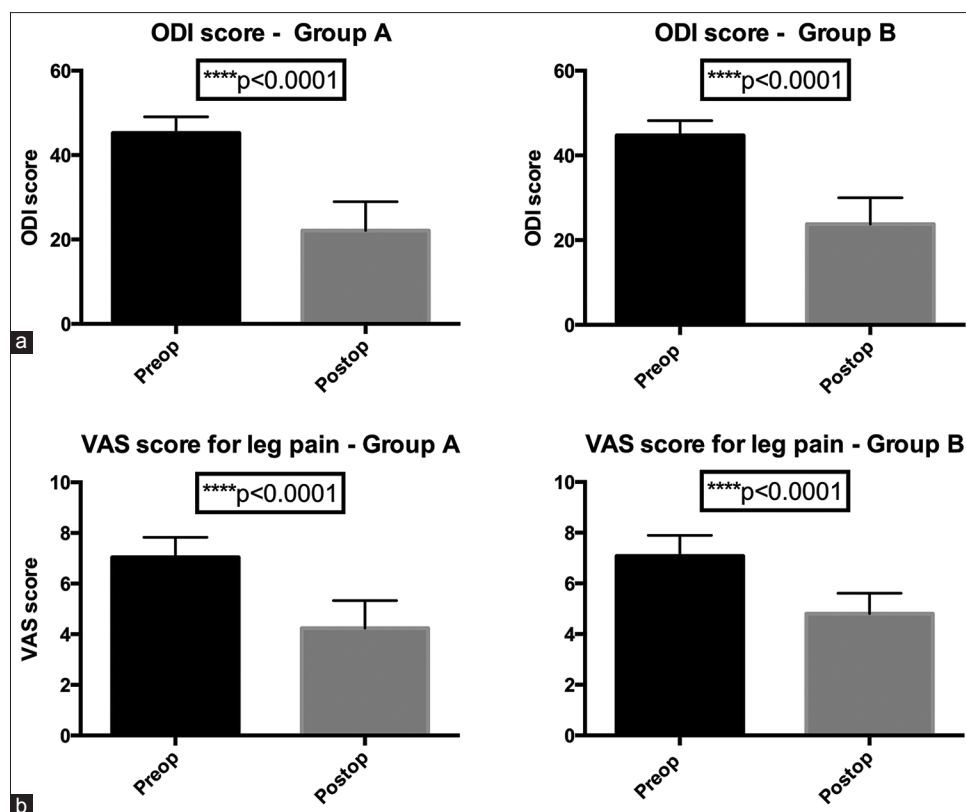


Figure 3: Assessment of outcome after 6 months from surgery. (a) The Oswestry disability index score is significantly reduced as well as the (b) visual analog scale score for leg pain compared to the admission in both groups

bone decompression ≥ 0.9 cm was identified as a predictor of good outcome both for the ODI and VAS scores [Figure 4].

As well, in Group B, we observed a significant improvement of the ODI score to 23% (range 14%–40%, $P < 0.0001$) and of the VAS score for leg pain to 5 (range 3–6, $P < 0.0001$) as compared to the preoperative period.

Interestingly, we observed a significantly better improvement of the median VAS score for leg pain in Group A vs. Group B ($P = 0.04$) [Figure 5]. No differences were observed for the ODI score.

Other analyses

The best accuracy for intraoperative bone decompression was observed for a cut-off ≥ 0.9 cm, with a sensitivity of 100%, a specificity of 71.4%, a PPV of 73.3%, and a NPV of 100% in predicting good outcome expressed as ODI ≤ 20 (minimal disability) ($P = 0.0005$) [Figure 4a]. The same cut-off value revealed a sensitivity of 86.6%, a specificity of 80%, a PPV of 86.6%, and an NPV of 80% in predicting a good relief from leg pain expressed as a VAS < 5 ($P = 0.002$) [Figure 4b].

No case of metameric instability caused by decompression was observed after 6 months from surgery in both groups.

DISCUSSION

Key results

In this study, we assessed qualitatively and quantitatively the entity of decompression during surgery using intraoperative 3D fluoroscopy and navigation. Our results suggest that this procedure is associated with a satisfactory outcome. Furthermore, the extent of the bone decompression, as measured intraoperatively, was actually correlated to the improvement in ODI and VAS scores. We also identified a cut-off value ≥ 0.9 mm (as measured at the largest portion of the laminotomy) as an intraoperative predictor of a good postoperative functional outcome. Finally, in this series, the use of the navigated technique was associated with a better control of the radicular pain as compared to the standard microsurgical decompression. Nevertheless, the use of the navigated technique did not result in a reduced length of surgery or in-hospital staying, neither to an improvement of the postoperative ODI as compared to the standard microsurgical laminotomy.

Interpretation

Despite several surgical techniques for decompression of the spinal canal in lumbar degenerative stenosis are well established, routinely used all over the world, and often

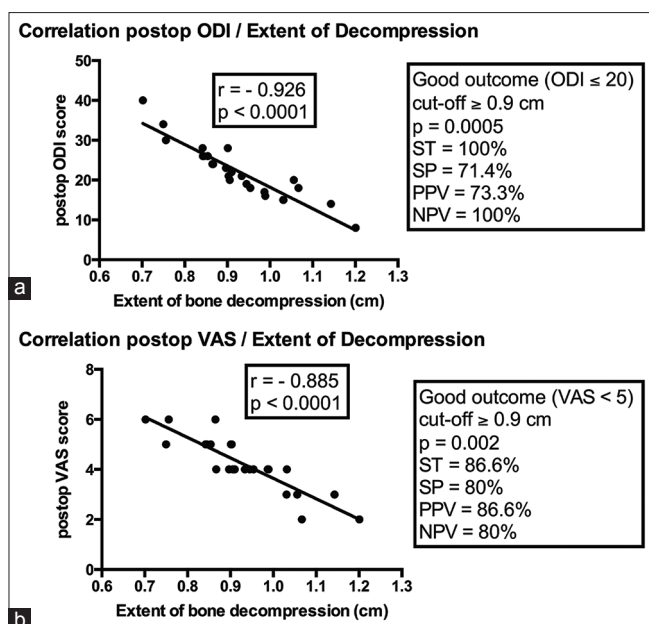


Figure 4: Analysis of correlation between the extent of bone decompression and the postoperative outcome after 6 months in Group A. (a) The postoperative Oswestry disability index and (b) visual analog scale scores show a significant negative correlation with the extent of bone decompression that is quantified during surgery through the neuronavigation. A cut-off value ≥ 0.9 cm is significantly associated to a good functional outcome intended as an Oswestry disability index score ≤ 20 and a visual analog scale score < 5

considered a simple surgical gesture, the postoperative outcome is considered satisfactory by patients in the only 63.4%–81.9% of cases.^[27-29] Different percentages of satisfaction are reported for different techniques, but the common result is that surgical treatment for spinal stenosis could be considered unsatisfactory in up to 36.6% of patients. This aspect is usually neglected, especially by experienced spine surgeons who consider surgical decompression for lumbar stenosis a straightforward surgical procedure that could not be suitable for/does not need further technical improvement. Another important aspect that is usually neglected is the role that the bone narrowing of the spinal canal plays in the prediction of postoperative outcome. Adamova *et al.*, in a retrospective cohort of 53 patients affected by lumbar stenosis, reported the lowest transverse diameter of spinal canal < 13.6 mm measured at the CT scan was the only independent predictor of unsatisfactory clinical outcome;^[30] moreover, Choi *et al.* in a series of 144 patients with lumbar stenosis treated by unilateral approach for bilateral decompression, reported that the satisfactory rate after surgery was reduced in cases of trefoil stenosis as compared to cases with a round or oval spinal canal.^[28] This could reflect the role of narrowed lateral recesses in radicular compression. Nevertheless, in DLS, it is well known that also soft tissues, such as the ligamentum flavum, play an important role in compression. Such effect can be assessed

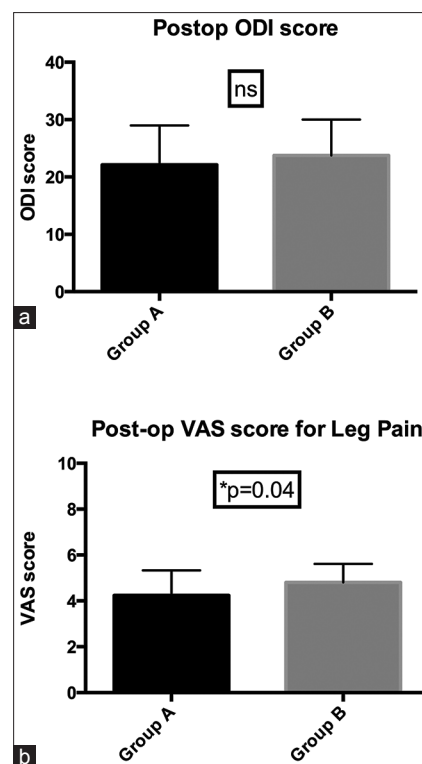


Figure 5: Comparison of the outcome between Group A and Group B. (a) Patients treated with the navigated technique (Group A) showed a similar postoperative Oswestry disability index score as compared to patients treated through standard microsurgical unilateral laminotomy with crossover (Group B). (b) Conversely, patients in Group A showed a significant improvement of the postoperative visual analog scale score for leg pain as compared to patients in Group B

through the evaluation of the DSCSA at the MRI scan. The DSCSA evaluation has been suggested as a method to assess the compression (before surgery) and decompression (after surgery) of the dural sac by measuring the area of the spinal canal on pre-operative and post-operative imaging.^[2,17-21] Actually, an increase of the DSCSA has been described as positively correlated to a better functional outcome,^[31] but the postoperative nature of this measurements limits its clinical relevance.^[22] Collectively, these data suggest that no other imaging methodologies apart from preoperative and postoperative CT/MRI scans have been identified so far to assess the compression and the decompression of the spinal canal after surgery for lumbar degenerative stenosis.

To the best of our knowledge, there are no studies reporting intraoperative imaging data that can positively influence the surgical procedure (i.e., suggesting changes in the size or location of the decompression) and therefore predict patients' outcome.

Despite the unilateral laminotomy with crossover has been already described as effective to achieve a bilateral decompression,^[4,8,32] there are no studies in which the extent

of decompression was intraoperatively quantified. This is a relevant point as the efficacy of unilateral approaches has been questioned because considered inadequate for bilateral decompression of the spinal canal.^[12,29,33,34] Actually, using a standard microsurgical technique, there is no way other than a qualitative visual inspection to achieve a proof that sufficient decompression has been achieved. This does actually lead to a wide intra- and inter-operator variability of decompression results. Nevertheless, this aspect is often neglected. The navigated technique with intraoperative imaging provides objective quantification eventually extending the span of decompression while preserving the facet joints. As expected, larger bone decompression was associated to a better outcome, especially using a cut-off value ≥ 0.9 cm. To the best of our knowledge, this is the first intraoperative parameter associated to outcome in posterior decompression for lumbar stenosis.

This value can be measured during surgery, eventually suggesting an extension of bone resection while intraoperative imaging may help to preserve critical structures, such as the facet joints.

It can be argued that bone decompression alone is not able to predict the postoperative functional outcome since it mainly depends on the soft-tissue decompression (i.e., flavectomy). In the present study, the quantitative evaluation of bone removal was associated to a qualitative evaluation of contralateral soft-tissue decompression. Although this can be achieved by the direct microscopic view, the visual feedback provided by the navigated probe tip [Figure 3] of the most lateral portion of the recess and the foramen that is not available to the direct view of the surgeon appears to us extremely useful. The free movement without the obstacle of the navigated tip along and across the contralateral recess is perceived through tactile feedback but also by visual feedback on the navigation screen. Moreover, our technique allowed the visualization of the contralateral recess and the navigated probe tip in the three planes of the space including the axial plane.

The improved visualization and decompression of the most lateral portion of the recesses resulted in an improvement of the post-operative radicular pain. This is witnessed by the significant improvement of the VAS score for leg pain in the group treated by using the navigated technique (Group A) as compared with patients operated using the standard microsurgical unilateral laminotomy (Group B). Nevertheless, the improvement of the radicular pain did not result also in an improvement of the overall disability of patients, since no significant differences in the ODI scores between the two

groups were recorded. Moreover, similar findings regarding the operative time and in-hospital staying were observed using the two different techniques.

Thus, a combination of a qualitative and quantitative intraoperative data represents the strength of this navigated unilateral laminotomy with crossover, especially for the decompression of the most lateral portion of the recesses.

At the same time, the navigated technique prevents from an excessive decompression that could lead to postoperative instability, a possible side effect of standard decompressive surgery,^[35] since no cases of postoperative instability were recorded. Although unilateral laminotomy with crossover is less frequently associated to postoperative instability,^[10,33] it could be speculated that the real-time visualization of the facet joints obtained by using the navigated technique could better guide the undercutting of the medial facet joints, ensuring an increased but not harmful decompression.

Limitations

This study, as the majority of studies evaluating the outcome after spinal surgery, suffers from bias related to the evaluation of patient-reported functional outcome. This could lead to potential errors and bias such as the response-shift.^[1]

One important difference with other surgical techniques is the use of X-ray based intraoperative imaging and the consequent increase of X-ray exposure for the patients. Nevertheless, we used a low dose 3D fluoroscopy and limited the intraoperative imaging to only two scans (at the beginning and the end of surgery).

Finally, it must be underlined that the retrospective nature of the study limits the strength of our findings.

Nevertheless, the aim of this study was to shed a light on the need to further investigate new operative techniques and strategies for the improvement of the satisfaction rate of patients operated for lumbar degenerative stenosis. Despite all the above-mentioned limitations, the description of our small experience with the use of the navigated unilateral laminotomy goes in that direction.

CONCLUSIONS

Our results suggest that the 3D fluoroscopy-based navigation could be a useful intraoperative tool for the surgeon to increase its confidence with the extent of

bone decompression in an already described minimally invasive technique (unilateral laminotomy with crossover) for bilateral decompression in lumbar degenerative stenosis. This intraoperative imaging could reassure the surgeon about an adequate decompression, or suggest to extend bone removal undercutting of the medial facet joint, or even the necessity of instrumentation when an extended decompression is required. The identification of a quantitative cutoff of bone decompression (0.9 cm) predicting the outcome further supports the use of intraoperative image-guidance. Finally, the navigated technique could be associated with a better decompression of the lateral recesses as compared to the standard microsurgical unilateral laminotomy, thus improving the control of postoperative leg pain. Further prospective studies in larger cohorts of patients are warranted.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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