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RESEARCH

A randomized trial on three different minimally invasive decompression techniques for lumbar spinal stenosis. Five years follow-up from the NORDSTEN-SST

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Abstract

Purpose The short-term clinical outcome for midline-preserving posterior decompression techniques was comparable. The aim of this study was to evaluate long-term clinical results after three different midline-preserving posterior decompression techniques.

Material In the NORDSTEN spinal stenosis trial (NORDSTEN-SST) 437 patients were randomized to three different midline-retaining posterior decompression techniques: Unilateral laminotomy with crossover (UL), bilateral laminotomy (BL) and spinous process osteotomy (SPO). Primary outcome was the mean change in Oswestry disability index (ODI) score at five-years follow-up. Secondary outcomes were the proportion of patients classified as success, mean change in EQ-5D, ZCQ-score, NRS-score for leg and low back pain, a seven-point Global Perceived Effect (GPE) Scale and proportion of subsequential spinal surgery.

Results The number of patients that completed follow-up data after five years was 358 (82%): In the UL, BL and SPO group the numbers were 122, 119 and 117, respectively. Mean age at baseline was 66.7 (SD 8.2) years, mean BMI was 27.8 (SD 4.1), and 172/358 (48%) were female. In the UL group the mean change was −18.2 (95% CI −21.0 −5.4), in the BL group it was −19.0 (95% CI -21.9–16.1) and in the SPO it was −18.6 (95% CI −21.6–15.7) (p = 0.917). No significant differences in the secondary outcomes between the three surgical groups were found, also the subsequent spinal surgery rates were similar.

Conclusion There were no significant differences in patient reported outcomes and subsequent spinal surgery rates after the three different decompression techniques at five-year follow-up.

Keywords Lumbar spinal stenosis (LSS) · Randomized Controlled Trial (RCT) · Posterior decompression techniques · Unilateral laminotomy with crossover (UL) · Bilateral laminotomy (BL) · Spinous process osteotomy (SPO)

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Introduction

Lumbar spinal stenosis (LSS) affects a high proportion of the elderly population [1, 2], and posterior decompression is the most common procedure in the adult lumbar spine. In the US, over 600.000 surgical procedures for LSS are performed annually [2]. In Norway, the number of procedures has increased by 54% within the last fifteen years [3]. Many studies suggest that surgery yields better clinical results compared to non-surgical treatment [4–6].

Posterior decompression is the most frequently performed procedure for LSS. Laminectomy was considered to be the reference method, before a number of minimally invasive midline retaining procedures came into use in recent decades [7]. As far, no superior clinical results have been associated with any of the surgical techniques [8, 9]. In a former publication, we reported no difference in the clinical results between the three commonly used minimally invasive posterior decompression techniques are unilateral laminotomy with crossover (UL), bilateral laminotomy (BL) and spinous process osteotomy (SPO) after two years follow-up [8].

Most studies comparing different surgical methods present short term follow-ups [6, 7]. Long-term differences in efficacy and subsequent spinal surgery rates are not known, and the current study will thus contribute valuable information to the surgical community.

The main aim of the present study was to evaluate the five years clinical results after three minimally invasive posterior decompression techniques: UL, BL and SPO for treatment of LSS.

Material and methods

The NORwegian Degenerative Spondylolisthesis and spinal STENosis (NORDSTEN) study includes three parallel studies for patients with LSS [10].

In the present paper, we analyse the clinical outcome after five years from the NORDSTEN-SST (Clinicaltrial identifier: NCT02007083). The protocol was prepared according to the SPIRIT statement [11]. Ethical approval has been obtained from the Regional Committee for Medical and Health Research Ethics of Central Norway (REC Central, 2011/2034). The two-year clinical results were monitored in line with a modified version of the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP) [8], and the corresponding data management was used for the follow-up data after five years. The clinical results after two years have been published previously [8]. Eligibility criteria are given in Table 1.

Table 1 Criteria for participant selection and disqualification in the Spinal Stenosis Trial of the NORDSTEN-study

Inclusion criteria
Clinical symptoms of lumbar spinal stenosis: neurogenic claudication or bilateral radiating pain
Non-responding to at least 3 months of non-surgical treatment
Radiological findings corresponding to the clinical symptoms of LSS. Central-stenosis, or lateral recess-stenosis
Able to give informed consent and to answer the questionnaires
Over 18 years of age
Able to understand Norwegian, both spoken and written
Exclusion criteria
Degenerative lumbar spondylolisthesis, with a slip ≥ 3 mm verified on standing plain x-rays in lateral view
Not willing to participate in the trial
Former surgery at the level of stenosis
Fracture, or former fusion in the thoraco-lumbar region
Cauda equina syndrome (bowel or bladder dysfunction) or fixed complete motor deficit
ASA-classified 4 or 5
Over 80 years of age
Lumbosacral scoliosis > 20 verified on AP-view
Distinct symptoms in one or both of their legs due to other diseases, e.g. polynevropathy, vascular claudication or osteoarthtritis
Stenosis in > 3 levels
Not able to comply fully with the protocol, including treatment, follow-up or study procedures (psychosocially, mentally and physical)
Participating in another clinical trial that may interfere with the present trial

Inclusion of patients

Patients with symptomatic LSS and corresponding magnetic resonance imaging (MRI) findings were eligible for inclusion in the trial. The assessment and inclusion took place at orthopedic or neurosurgical departments at 16 public hospitals between February 2014 and October 2018. Patients with degenerative spondylolisthesis were excluded. Initially, from February 2014 to October 2015, patients with an Oswestry Disability Index (ODI) baseline score of less than 25 points were also excluded. The removal of this exclusion criterion aimed to enhance external validity and study pragmatism [8].

Randomization and masking

After informed consent patients were randomly assigned to treatment by one of three different posterior decompression techniques. The randomization (1:1:1 allocation) occurred within 6 weeks before surgery. We employed a randomized block design, stratified by hospital, with block sizes kept as small as possible (randomly selected block sizes of 3 and 6). The sequences were computer-generated and concealed for the investigators. The randomization process was managed by the NORDSTEN study coordination center at the Research and Communication Unit for Musculoskeletal Health (FORMI), Oslo University Hospital in Norway. Information regarding allocation was emailed to the local research coordinator, who was not involved in patient recruitment or treatment, and was recorded in the patient records. Patients were aware of their treatment group but were, during the inclusion process, informed that no treatment was documented as superior to the others. All statistical analyses were conducted by a statistician blinded for the randomization.

Surgical techniques

All participating surgeons reported proficiency or were trained in the three posterior decompression techniques before including patients in the study. See Fig. 1 for an overview of the surgical procedures, and previous publications for more detailed description [8].

Unilateral Laminotomy with Crossover (UL): Surgeons initiated decompression by performing ipsilateral flavectomy. Subsequently, they conducted a laminotomy on the lower part of the superior lamina and the upper part of the inferior lamina. Medial facetectomy was carried out laterally. To visualize the contralateral side, the patient was slightly rotated on the operation table. Decompression was performed contralaterally.

Bilateral Laminotomy (BL): Decompression of the spinal canal began with bilateral flavectomy. Surgeons then performed bilateral laminotomy on the lower part of the superior lamina and the upper part of the inferior lamina. Medial facetectomy was conducted laterally.

Spinous Process Osteotomy and Decompression (SPO): An osteotomy was performed at the base of the spinous process, either above or, sometimes, below the affected level. The spinous process(es) were retracted to the contralateral side, preserving supraspinal and interspinal ligaments. This allowed midline access to the spinal canal. Decompression was initially performed in the midline and subsequently laterally on both sides. Surgeons conducted a laminotomy on the lower part of the superior lamina and the upper part of

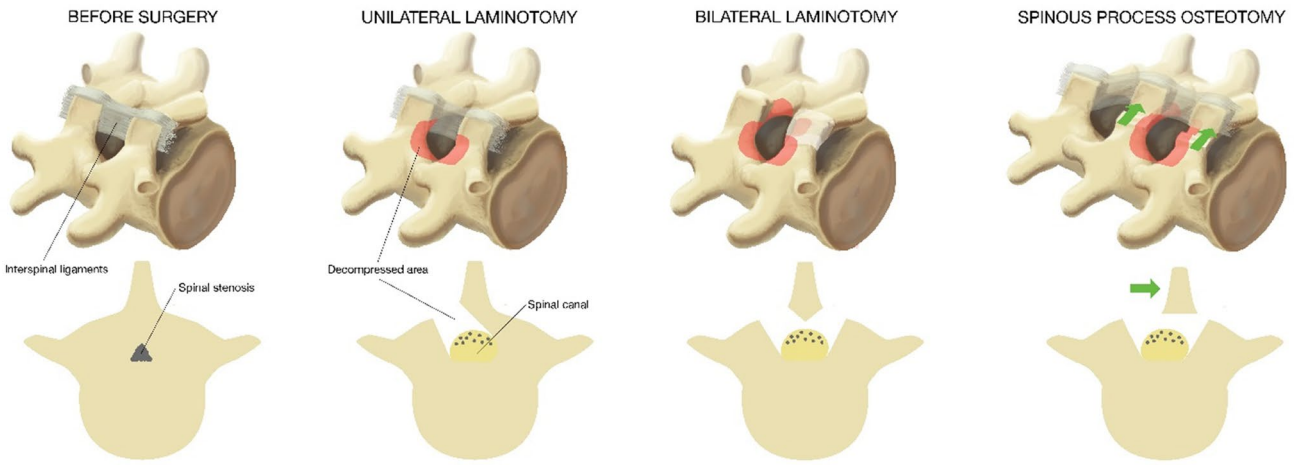

Fig. 1 Before surgery for lumbar spinal stenosis and after decompression with the three different minimal invasive techniques used in the in the Spinal Stenosis Trial of the NORDSTEN-study

the inferior lamina. Visualization of both nerve roots and decompression of lateral recesses were achieved. Multilevel decompression required special attention to retain at least one third of the lamina.

Outcome measurements

Primary outcome

The primary outcome in this study was change in functional capacity, as measured by the Oswestry Disability Index (ODI) version 2.0, from baseline to five years after surgery. The ODI is a well-established pain and function score [12], validated for the Norwegian patient population [13]. A score of 0 indicates asymptomatic status, and 100 represents complete disability. Patients reported outcome measures (PROMs) were completed before surgery (baseline) and at 3 months, one, two and five-years postoperatively. The mean score change over the five-year follow-up period was compared among three surgical technique groups. Only patients who had responded to the primary outcome questionnaires were included in the study.

Secondary outcomes

Patients were classified as a "success" if they achieved a 30% reduction of baseline ODI, and the proportion of successful patients in each group was determined at different follow-up time points [14].

-Mean change in EuroQol 5-Dimensional Questionnaire Utility Index (EQ-5D). A generic quality-of-life questionnaire ranging from −0.59 (worst possible) to 1.00 (best possible). Validated for the Norwegian population.

Mean change in Zurich Claudication Questionnaire (ZCQ-Score), a disease-specific questionnaire for lumbar spinal stenosis which includes symptom severity, physical activity, and patient satisfaction during follow-up; symptom severity scale: 1.0 to 5.0, physical activity scale: 1.0 to 4.0 and patient satisfaction scale (postoperatively): 1.0 to 4.0 (1.0 being the best).

Mean change in Numeric Rating Scale (NRS) for Leg Pain and Low Back Pain, validated parameters for clinical trials. Range: 0 (no pain) to 10 (worst pain imaginable).

Global Perceived Effect (GPE) Scale which is recommended for chronic pain condition trials and have seven response categories: completely recovered, much improved, slightly improved, no change, slightly worse, much worse, worse than ever.

Surgical Data (Secondary Outcomes): Number and type of subsequent spinal surgery after five years. This was registered as subsequent surgery as re-decompression same level, decompression adjacent level, or subsequent fusion. When data was missing for what specific subsequent surgical procedure that was performed, this was classified not specified subsequent surgery. When patients had more than one subsequent spinal surgery this was also noted.

All PROMs are validated in previous research [15–17].

Statistical analysis

Baseline data were summarized using standard descriptive statistics. For categorical variables, absolute and relative frequencies were reported. Continuous variables with a normal distribution, as assessed by visual inspection of histograms and qq-plots, were summarized using means and corresponding standard deviations (SD). Median and interquartile range (IQR) were used for continuous non-normal variables. Outcome measures were presented as means or proportions with 95% confidence intervals (CI).

To compare longitudinal outcomes between study arms, mixed models with random intercepts for study site and patient were estimated, including study arm and time (categorical) as covariates, as well as their interactions. Marginal means were predicted for each combination of study arm and time and illustrated graphically. To compare change from baseline to five years postoperatively, multivariable linear and logistic regression models were estimated, controlling for baseline measurement (continuous), DSCA of index level (continuous), sex, age, bmi, smoking (yes/no). Marginal means for each study arm were then predicted from these models, fixing the other covariates to their study average. Significance level was set to 5%. All analyses were done using Stata version 17.0.

Patient and public involvement

A representative from the Norwegian Back Society has been a member of both the NORDSTEN Scientific Steering Committee and the Working Committee.

Results

Baseline patient characteristics

Of the 437 patients included in the NORDSTEN-SST, 358 (81.9%) patients completed follow-up of the primary outcome after five years, meaning that they provided sufficient data to be able to calculate ODI at five years. A detailed account of the 79 patients lost to follow-up is provided in the flow chart (Fig. 2). In the present analysis, there were 122 patients in the UL group, 119 patients in the BL group and

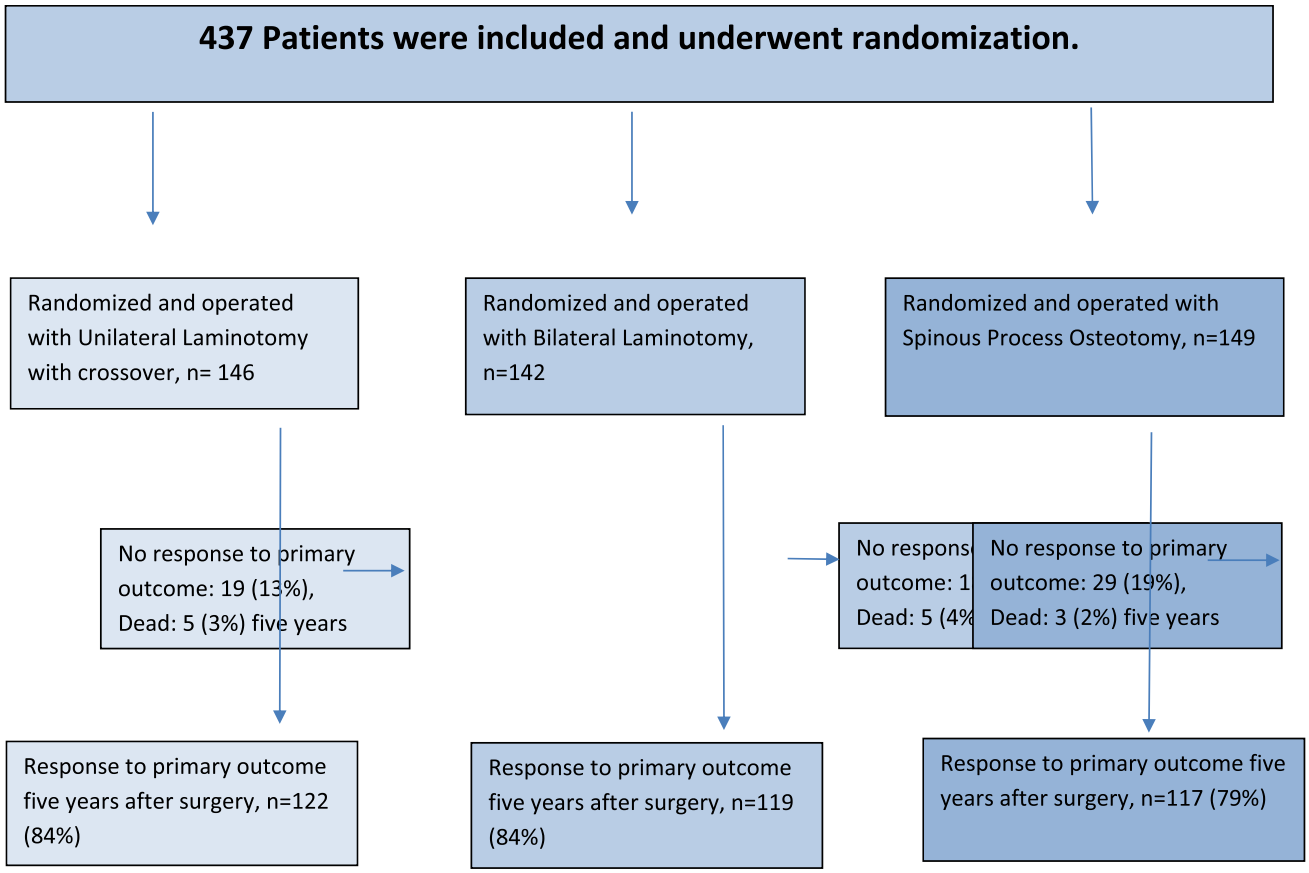

Fig. 2 Flow chart of the in the Spinal Stenosis Trial of the NORDSTEN-study according to the CONSORT-statement

117 patients in the SPO group. In the five-year follow-up cohort, mean age at baseline was 66.7 (SD 8.2) years, mean BMI was 27.8 (SD 4.1), 172/358 (48%) were female, and 70/358 (20%) smokers. A detailed overview of the baseline parameters is given in Table 2.

Primary outcome

There were no statistical differences between the mean changes in ODI scores between the three groups (Table 3). The ODI score did not deteriorate from 3 months to five years of follow-up (Fig. 3).

Secondary outcomes

The proportion of patients classified as successes was 70% for UL, 72% for BL and 70% for SPO, respectively. No group-differences were found for the secondary PROMs (p = 0.931) (Table 3). The subsequent spinal surgery rates after five years were about 9.6%, and there were not different between the three groups (p = 0,927), see Table 3. A detailed specification of subsequent spinal surgery is given in Table 4.

Discussion

After a five-year follow-up, clinically relevant or statistically significant differences were not found in clinical outcomes or subsequent spinal surgery rates among three different midline-retaining posterior decompression techniques used in lumbar spinal stenosis patients. Clinical outcomes remained stable from three months postoperatively through the observed five-year period. The consistency observed across all recorded outcome measures further reinforces these findings. Additionally, subsequent spinal surgery rates were similar across all three groups after five years (Fig. 4).

The findings here on clinical outcome align with previous trials and reviews reporting on various decompressive techniques, including full laminectomy [6–9, 17, 18]. Most of these reported on the first 2 years postoperatively. The present study's extended five year follow-up period further strengthens that different decompression techniques yield similar clinical outcomes, which remained stable also after

Table 2 Baseline characteristics, patient-reported outcome measures and number of levels of the patients included in the three study groups: UL = Unilateral laminotomy with crossover; BL = Bilateral Laminotomi; SPO = Spinous Process Ostetomy in the Spinal Stenosis Trial of the NORDSTEN-study

	UL (N = 122)	BL (N = 119)	SPO (N = 117)	p-value
Age, median (IQR)	68 (63–74)	67 (59–73)	68 (61–72)	0.382
Sex				0.003
Female	65/122 (53.3)	66/119 (55.5)	41/117 (35.0)	
Male	57/122 (46.7)	53/119 (44.5)	76/117 (65.0)	
Higher level of education	38/118 (32.2)	30/117 (25.6)	35/116 (30.2)	0.528
Smoking	19/118 (16.1)	28/118 (23.7)	23/116 (19.8)	0.340
BMI, mean(SD)	28.1 (4.1)	27.7 (3.8)	27.5 (4.4)	0.578
Former surgical procedure	9/113 (8.0)	10/113 (8.9)	6/110 (5.5)	0.606
Duration of leg pain > 1 yr	79/117 (67.5)	80/112 (71.4)	71/106 (67.0)	0.738
Duration of back pain > 1 yr	92/115 (80.0)	92/116 (79.3)	82/114 (71.9)	0.273
Use of analgesics	22/119 (18.5)	30/117 (25.6)	42/114 (36.8)	0.006
ASA score				0.063
1	8/117 (6.8)	22/116 (19.0)	11/113 (9.7)	
2	84/117 (71.8)	73/116 (62.9)	79/113 (69.9)	
3	25/117 (21.4)	21/116 (18.1)	23/113 (20.4)	
HSCL-25, median (IQR)	1.5 (1.2–1.9)	1.6 (1.3–1.8)	1.5 (1.3–1.8)	0.705
ODI, mean (SD)	38.3 (14.8)	40.2 (14.1)	35.6 (13.9)	0.046
ZCQ, mean (SD)				
Symptom severity	3.3 (0.5)	3.4 (0.6)	3.3 (0.5)	0.464
Physical activity	2.5 (0.5)	2.6 (0.5)	2.5 (0.5)	0.623
NRS, median (IQR)				
Leg pain	7 (5–8)	7 (5–8)	7 (5–8)	0.660
Back pain	7 (5–8)	7 (5–8)	7 (5–8)	0.492
EQ-5D, mean (SD)	0.38 (0.33)	0.34 (0.31)	0.42 (0.29)	0.174
Level of surgical procedure				0.506
1	73/115 (63.5)	70/115 (60.9)	73/111 (65.8)	
2	41/115 (35.7)	40/115 (34.8)	34/111 (30.6)	
3	1/115 (0.9)	5/115 (4.4)	4/11 (3.6)	

iqr:interquartile range; no: number of patients with data at baseline; ASA: American Society of Anesthesiologists, which ranges from 1 (no presence of disease) to 5 (life-threatening disease), BMI: Body Mass Index (calculated as weight in kilograms divided by height in meters squared), HSCL-25: Hopkins Symptom Checklist-25; ODI: Oswestry Disability Index, which ranges from 0 (no impairment) to 100 (the greatest impairment), ZCQ: Zurich Claudication Questionnaire, NRS: Numerical Rating Scale, which ranges from 0 (no pain) to 10 (worst pain imaginable), EQ-5D: EuroQol 5-dimensional questionnaire utility index

the 2 year mark. In another large RCT study on patients with lumbar spinal stenosis the clinical outcomes at five-year follow-up have been reported to be comparable to those in the present study [18]. In the study by Först et al. a significant proportion of patients had a degenerative spondylolisthesis, and further other types of posterior decompression techniques than in our study were included, why these studies are not fully comparable. Given that lumbar spinal stenosis is a condition typically developing gradually and slowly over several years [18–20], it is crucial to examine long-term data to fully understand the condition, both primarily and after surgical intervention.

The three decompression methods used in the present study each have been described to have advantages and disadvantages. For instance, regarding disadvantages, the unilateral decompression with crossover technique has been considered technically demanding in decompression of the contralateral recess. Unilateral techniques have been pointed out as somewhat more time-consuming and with difficulties to reach the recesses in patients with bulky facet joints and short distance to the spinal processes, while the spinal process osteotomy technique have been questioned as not being a fully midline structure preserving technique. While all these arguments and others may be valid, the results from the present study demonstrated that no single decompression technique can be considered superior, as the overall clinical outcomes remained stable over approximately five years, regardless of the methods used. In the NORDSTEN-SST it has previously been reported that there are no differences in obtained increase of the dural sac cross sectional area (DSCA) between the three different midline retaining posterior decompression techniques and further no difference

Table 3 Primary and secondary outcomes after five years of follow-up in the Spinal Stenosis Trial of the NORDSTEN-study. Means and corresponding 95% CI calculated by predicting marginal effects after fitting linear regression models for the difference between measurements at five years and preoperative measurements

	UL	BL	SPO	P-value
Primary outcome				
Mean change in ODI after five years (95% CI) (Number of patients)	−18.2 (−21.0—−15.4) (n = 114)	−19.0 (−21.9—−16.1) (n = 109)	−18.6 (−21.6—−15.7) (n = 109)	0.917
Secondary outcomes				
Proportion success (> 30% reduction in ODI) after five years (%) (Number of patients)	70.1 (62.0—78.2) (n = 114)	72.1 (64.0—80.2) (n = 109)	70.1 (61.5—78.8) (n = 109)	0.931
Mean change in global EQ5D-score (95% CI) (Number of patients)	0.33 (0.28—0.38) (n = 109)	0.34 (0.29—0.39) (n = 103)	0.32 (0.27—0.37) (n = 106)	0.889
Mean change in ZCQ symptom score (Number of patients)	−1.1 (−1.2—−0.9) (n = 113)	−1.1 (−1.3—−1.0) (n = 109)	−1.1 (−1.3—−1.0) (n = 105)	0.819
Mean change in ZCQ physical function score (Number of patients)	−0.8 (−0.9—−0.7) (n = 117)	−0.8 (−1.0—−0.7) (n = 108)	−0.8 (−1.0—−0.7) (n = 108)	0.759
Mean change in NRS leg pain score (Number of patients)	−3.1 (−3.6—−2.5) (n = 106)	−3.4 (−3.9—−2.9) (n = 105)	−3.6 (−4.1—−3.1) (n = 107)	0.378
Mean change in NRS low back pain score (Number of patients)	−2.6 (−3.1—−2.1) (n = 108)	−2.7 (−3.2—−2.2) (n = 106)	−2.6 (−3.2—−2.1) (n = 108)	0.952
Mean global perceived effect score after five years (Number of patients)	2.7 (2.4—2.9) (n = 122)	2.7 (2.4—3.0) (n = 119)	2.4 (2.1—2.7) (n = 116)	0.211
Proportion subsequent spinal surgery after five years (CI) n = number of patients	10.2 (4.8–15.6) (n = 114)	9.5 (3.5–13.5) (n = 109)	9.3 (3.6–15.1) (n = 109)	0.927

Proportions and corresponding 95% CI calculated by predicting marginal effects after fitting logistic regression. All outcomes are adjusted for baseline measurement and the following patient characteristics: preoperative DSCA at index level, sex, age, bmi, smoking (yes/no) and higher education (yes/no)

in clinical outcome in relation to DSCA change [8, 18, 19]. Furthermore, we have previously shown that decompression of adjacent levels with borderline stenosis seems unnecessary [21]. These findings, combined with the long-term stability of clinical outcomes and the similar rate of subsequent surgery reported in the present study across different decompression techniques, all are of importance for determining the best surgical decompression approach for this patient group. In clinical practice, the present findings, along with those from previous studies, suggest that if a surgeon is confident in the chosen method and can effectively decompress the neural structures at the affected level(s) without causing destabilization, any decompression technique may be utilized.

Another important consideration for patients is the risk of subsequent spinal surgery following different surgical procedures. In the present study, the subsequent spinal surgery rate was below 10% over the five-year follow-up period, with no observed differences between the three groups. The surgeries here primarily involved decompression of a previously treated level or addressing new level stenosis. Compared to existing literature, the subsequent spinal surgery rate in our study was relatively low. In the RCT by Försth et al., which compared decompression alone to decompression with fusion, the subsequent spinal surgery rate was 22% in the decompression group after five years [20]. In a similar study by Ghogawala et al. with a 4 year follow-up, the subsequent spinal surgery rate was even higher, 34% after decompressive surgery [21]. Both studies included patients with spondylolisthesis, which makes direct comparison with our study somewhat challenging. In the largest cohort study, we have found using an even less invasive method than in the present study, endoscopic surgery, a 10% subsequent spinal surgery rate after 19 months was reported. This should then be compared to the rate of 9.4% observed in our study over a five-year period.

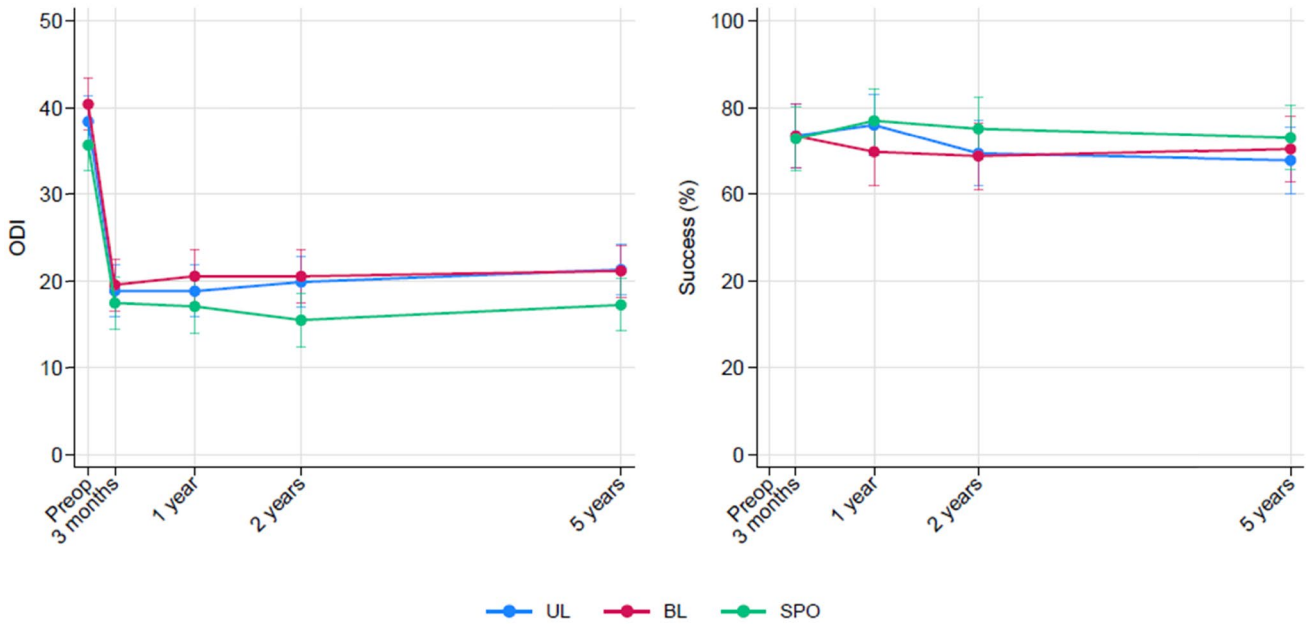

Fig. 3 The Spinal Stenosis Trial of the NORDSTEN-study (Left) Primary outcome, ODI-score at baseline and after 3 months, 1, 2, and 5 years of follow up after three posterior decompression techniques for lumbar spinal stenos given as mean score. (Right) The proportion of patients classified as success in the same follow up period. UL: Unilateral Laminotomy with crossover, BL: Bilateral Laminotomy and SPO: Spinous Process Ostetomy

Table 4 Total number of subsequent spinal surgery within five years registered in the three groups

	Ul	BL	SPO
Re-Decompression same level	6	1	10
Decompression adjacent level	9	7	1
Subsequent fusion	1	4	8
Not specified subsequent spinal surgery	7	1	1
Total	23	13	20

UL: Unilateral laminotomy with crossover. BL: Bilateral laminotomy. SPO spinous process osteotomy. In the UL-group eight patients had one subsequent spinal surgery, five patients had two surgeries, and one with five subsequent surgeries (infection revisions). In the BL-group eleven patients had one subsequent surgery and one patient had two surgeries. For the SPO-group six patients had one subsequent surgery, five with two surgeries and one with four surgeries

Two strengths of the present study, in addition to the long follow-up period, are the follow-up rate of over 80% and the large sample size. The NORDSTEN-SST has been identified as the study with the largest sample size in this field according to a recent review and meta-analysis [22].

The consistency observed across all recorded outcome measures further reinforces the findings of our study. A limitation of the study is the absence of strict criteria for subsequent spinal surgeries, which may have introduced bias into the reported numbers.

Conclusion

The five-year clinical outcomes and subsequent spinal surgery rates were similar among the three midline-retaining posterior decompression techniques for spinal stenosis in this RCT. This suggests that the choice of surgical decompression method for this patient group may be guided by the surgeon's personal experience and/or preference. Additionally, patients can be informed preoperatively of a high likelihood of maintaining a good clinical outcome over five years following lumbar spinal stenosis decompression, with a low risk of requiring any subsequent spinal surgery.

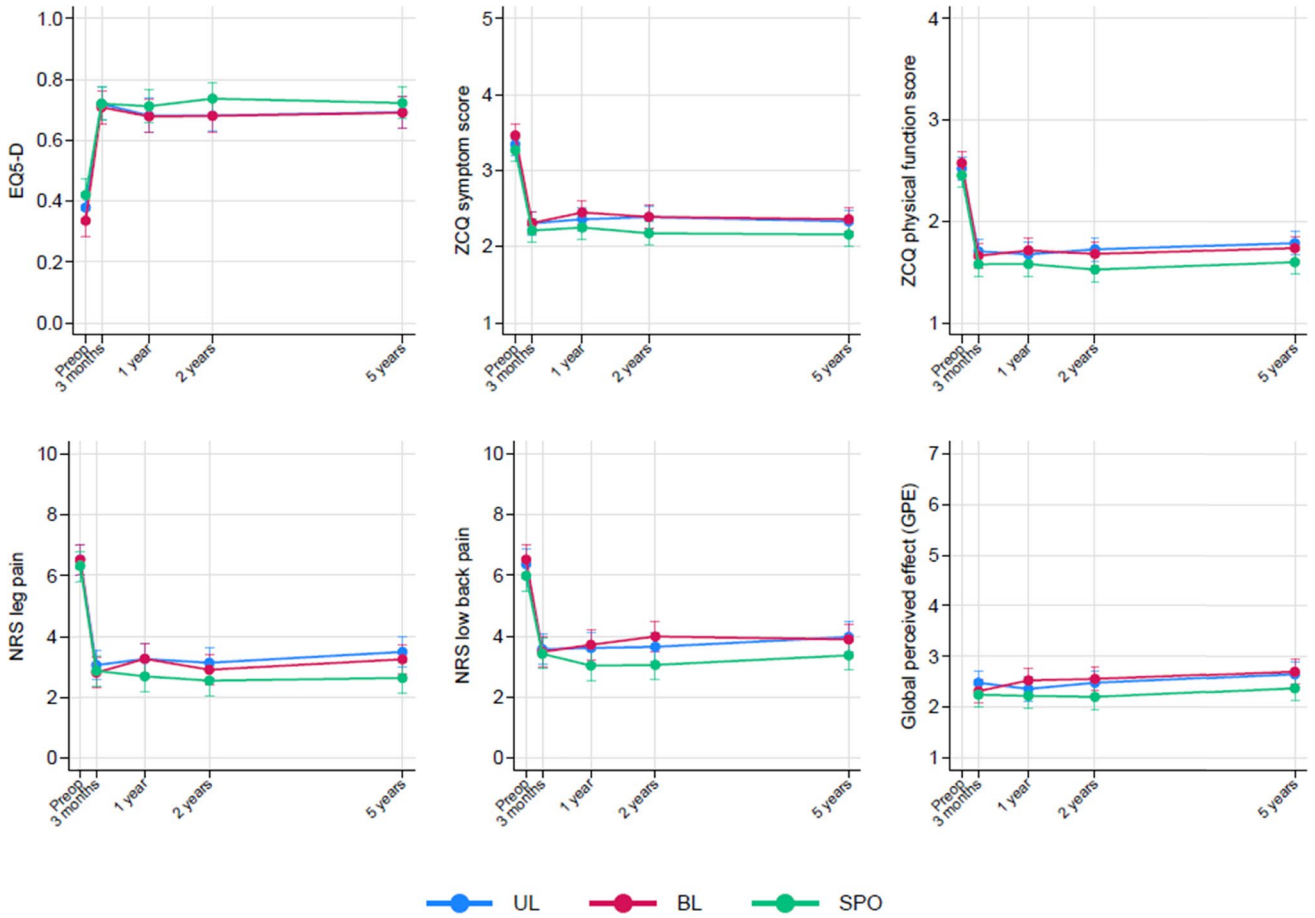

Fig. 4 The Spinal Stenosis Trial of the NORDSTEN-study Secondary outcome at baseline and after 3 months, 1, 2, and 5 years of follow up for EuroQol-5D 3L-score (EQ-5D), Zurich claudication questionnaire- score (ZCQ) of symptom severity and physical function, numeric rating scale-score (NRS) for leg pain and back pain. The Global perceived effect score (GPE) presented at the follow-up time points

Author contribution All authors whose names appear on the submission has made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; drafted the work or revised it critically for important intellectual content; approved the version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

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