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ORIGINAL ARTICLE

Does surgical technique influence clinical outcome after lumbar spinal stenosis decompression? A comparative effectiveness study from the Norwegian Registry for Spine Surgery

Erland Hermansen[1,2,3] · Ulla Kristina Romild[4] · Ivar Magne Austevoll[2,3] · Tore Solberg[5,6] · Kjersti Storheim[7] · Jens Ivar Brox[8] · Christian Hellum[9] · Kari Indrekvam[2,3]

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Abstract
Introduction The aim of this study was to compare the clinical outcome of spinal process osteotomy with two other midline-retaining methods, bilateral laminotomy and unilateral laminotomy with crossover, among patients undergoing surgery for lumbar spinal stenosis.
Methods This cohort study was based on data from the Norwegian Registry for Spine Surgery (NORspine). Patients were operated on between 2009 and 2013 at 31 Norwegian hospitals. The patients completed questionnaires at admission for surgery, and after 3 and 12 months. The Oswestry Disability Index (ODI) was the primary outcome. Secondary outcomes were duration of surgery and hospital stay, Numeric Rating Scale (NRS) for back pain and leg pain, and EQ-5D and EQ-VAS. The patients were classified into one of three treatment groups according to the surgery they had received, and a propensity score was utilized to minimize bias. The three treatment groups were divided into subgroups based on Propensity Scores, and the statistical analyses were performed with and within the Propensity Score stratified subgroups.
Results 103 patients had spinal process osteotomy, 966 patients had bilateral laminotomy, and 462 patients had unilateral laminotomy with crossover. Baseline clinical scores were similar in the three groups. There were no differences in improvement after 3 and 12 months between treatment groups. At 12 months, mean ODI improvement was 15.2 (SD 16.7) after spinous process osteotomy, 16.9 (SD 17.0) after bilateral laminotomy, and 16.7 (SD 16.9) after unilateral laminotomy with crossover. There were no differences in the secondary clinical outcomes or complication rates. Mean duration of surgery was greatest for spinal process osteotomy ($p < 0.05$). Length of stay was 2.1 days (SD 2.1) in the bilateral laminotomy group, 3.5 (SD 2.4) days for unilateral laminotomy, and 6.9 days (SD 4.1) for spinous process osteotomy group ($p < 0.05$).
Conclusion In a propensity scored matched cohort, there were no differences in the clinical outcome 12 months after surgery for lumbar spinal stenosis performed using the three different posterior decompression techniques. Bilateral laminotomy had shortest duration of surgery and shortest length of hospital stay. Surgical technique does not seem to affect clinical outcome after three different midline-retaining posterior decompression techniques.

Keywords Lumbar spinal stenosis · Laminotomy · Posterior decompression · Spinal process osteotomy

✉ Erland Hermansen
Erland.hermansen@helse-bergen.no

1 Department of Orthopedic Surgery, Ålesund Hospital, Møre and Romsdal Hospital Trust, Ålesund, Norway

2 Kysthospitalet in Hagevik, Orthopedic Clinic, Haukeland University Hospital, Bergen, Norway

3 Department of Clinical Medicine, University of Bergen, Bergen, Norway

4 Department of Research, Levanger Hospital, Nord-Trøndelag Hospital Trust, Levanger, Norway

5 Department of Neurosurgery, University Hospital of North Norway, Tromsø, Norway

6 Norwegian National Registry for Spine Surgery, University Hospital of North Norway, Tromsø, Norway

7 Communication and Research Unit for Musculoskeletal Disorders (FORMI), Oslo University Hospital, University of Oslo, Oslo, Norway

8 Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Oslo, Norway

9 Department of Orthopedics, Oslo University Hospital, Oslo, Norway

Introduction

Several posterior decompression techniques are used for decompression of lumbar spinal stenosis (LSS), but there is neither evidence to recommend one particular technique nor to suggest how extensive the decompression should be [1–3]. To our knowledge, there are no objective scientific criteria that can guide the extent of decompression needed. Neither radiological parameters, neuromonitoring, nor epidural pressure monitoring have been useful in deciding surgical technique or the extent of decompression needed. Bilateral laminotomy has been compared to a full laminectomy in some trials. One study found superior clinical results after bilateral laminotomy compared to laminectomy [4], but these findings have not been confirmed by subsequent studies [5–8]. Unilateral laminotomy with crossover has also been presented as a minimally invasive surgical technique, but clinical results have been reported to be equal to bilateral laminotomy [9–11]. Both bilateral laminotomy and unilateral laminotomy with crossover have gained popularity as midline-preserving methods, and are considered to reduce the risk of iatrogenic post-operative instability, as compared to laminectomy, but scientific evidence is lacking.

Another midline-preserving method is spinal process osteotomy, which was first introduced in 1978 by Yong-Hing and Kirkaldy-Willis [12]. Theoretically, this method may have some advantages over other midline-preserving methods, including better visualization of the spinal canal and the lateral recesses, facilitating a more extensive decompression. Studies of spinal process osteotomy have shown good clinical results [13–15], but the effectiveness has not been compared with the other midline-preserving methods. Takaso et al. reported in 2011 [16] that a modified version could be performed with a minimally invasive surgical technique with good results.

While the proposed advantages of posterior decompression techniques that limit the extent of bony decompression or avoid removal of posterior midline structures regarding iatrogenic instability and post-operative low back pain are plausible, the scientific evidence documenting these advantages is lacking. A recently published Cochrane review evaluated 10 trials and 733 patients, treated with different midline-preserving and conventional techniques, concluded that the studies were of very low quality, and that further research is necessary to compare the safety and effectiveness of these decompression techniques [3].

The aim of this study was to investigate the clinical outcome after spinal process osteotomy and compare them to bilateral laminotomy and unilateral laminotomy with crossover.

Methods

Study population

This cohort study is based on data from the Norwegian Registry for Spine Surgery (NORspine). During the given period 31 of 36 (86 %), hospitals in Norway were reporting to the NORspine register. Patients with lumbar spinal stenosis who had midline-retaining decompression in the period from 1/1-2009 to 11/3-2013 at 31 Norwegian hospitals were included. The NORspine register does not record spinal process osteotomy in the register forms. The bilateral laminotomy and unilateral laminotomy with crossover groups were identified from the register from 27 hospitals not performing spinal process osteotomy. In three other hospitals, spinal process osteotomy is performed occasionally, and patients from these hospitals were excluded. The spinal process osteotomy group was identified manually by reviewing the operative protocol for all patients who had surgery for LSS at one large hospital (the Coastal Hospital in Hagevik), performing this type of surgery on a regular basis. Patients missing exact data about the surgical method or who had a unilateral decompression were excluded. Informed consent was obtained from all participants. The registry protocol was approved by the Norwegian board of ethics, REC Central (2014/98).

Patient-reported outcome measures

The patient questionnaires were self-administered and identical at admission for surgery (baseline) and at 3 and 12 months follow-up; they contained established patient-reported outcome measures. At baseline, the forms include additional questions about demographics and lifestyle issues. During the hospital stay data, concerning comorbidity; radiological classifications; American Society of Anesthesiologists (ASA) grade; perioperative complications; operation method; duration of surgery; and hospital stay were recorded by the surgeon.

Primary outcome

Pain-related function was assessed by the Oswestry Disability Questionnaire, Norwegian version 2.0, (ODI) [17], and change in the ODI score was chosen as the primary outcome measure. ODI scores range from 0 (no disability) to 100 (worst possible).

Secondary outcomes

Secondary outcome measures were duration of surgery, length of stay, health related quality of life, measured by the EQ-5D (ranging from −0.59 to 1), EQ-VAS, leg pain and back pain numeric rating from 0 (no) to 10 (worst possible), and a seven point global perceived effect scale (1 = completely recovered, 2 = much improved, 3 = slightly improved, 4 = no change, 5 = slightly worse, 6 = much worse, and 7 = worse than ever).

The NRS pain scales, ODI, and EQ-5D have shown good validity and reliability, and the Norwegian versions of these instruments have shown good psychometric properties [18–20].

We also analyzed differences between patients who were excluded and those included in the trial, both at baseline and during follow-up.

Statistics

Propensity score matching (PSM) [21] is frequently used in orthopedic research [22, 23] to reduce selection bias and confounding caused by a non-random treatment assignment. The patients are then divided into subgroups according to their propensity scores, and the statistical analysis is performed within these subgroups. The purpose is to balance prognostic factors in different patients in order. A propensity score is calculated by summarizing a score generated by logistic regression analysis from different baseline parameters to balance groups with respect to factors that may influence clinical outcome.

The Propensity Score was performed by three logistic regression models for each combination of treatment groups, using the following baseline variables: age, gender, smoking, education, hip/knee arthritis, ischemic heart disease, vascular claudication, osteoporosis, hypertension, diabetes, and the number of levels operated on. All variables, except gender, differed significantly between at least two groups in the unadjusted sample. The individuals from each comparison were then stratified into three or five subgroups (three when spinal process osteotomy was involved, due to the smaller number in this group) based on their Propensity Score. Statistical analysis was performed between the PSM subgroups with the two-way ANOVA. Unmatched comparisons between the three treatments groups were made by the one-way ANOVA for continuous variables, Kruskal–Wallis test for ordinal variables, and Pearson's Chi-square test for categorical variables. A p value <0.05 was regarded statistically significant without adjustment for multiple comparisons.

Results

Of 2935 patients screened, 1531 patients fulfilled the inclusion criteria, and were included in the study. Follow-up response rates varied from 71.4 to 86.4 % (Fig. 1).

Baseline data

There were small differences in baseline data between patients who were excluded and those included in the study (Table 1). The mean age of the excluded patients [61.9 years (SD 12.0)] was almost 4 years younger ($p < 0.05$) than those included in the study [65.7 years (SD 10.7)]. Number of levels operated on were 1.3 (SD 0.6) for the excluded versus 1.4 (SD 0.5) for those included ($p < 0.05$). There were 27 % smokers in the excluded group and 24 % in the included group. Otherwise, there were no differences between excluded and included patients (Table 1).

We identified 103 patients treated by spinal process osteotomy, 966 by bilateral laminotomy, and 462 by unilateral laminotomy with crossover. There were small differences in clinical scores between the groups at baseline. Patients who underwent bilateral laminotomy with crossover were younger ($p < 0.05$), and the spinal process osteotomy group had more patients with multilevel surgery ($p < 0.05$) (Table 1).

Primary outcome

Analysis of primary and secondary outcome measures after 12 months showed no differences between the patients excluded from the study versus the patients included.

The clinical improvement was most pronounced at 3 months, and then slightly reduced at 12 months after surgery for the whole cohort (Table 2; Fig. 2). The mean unadjusted improvement in ODI points at 12 months was 15.2 (SD 16.7) in the spinous process osteotomy group, 16.9 (SD 17.0) in the bilateral laminotomy group, and 16.7 (SD 16.9) in the unilateral laminotomy with crossover group (Table 2). Differences between the three groups were not statistically significant. The adjusted mean improvement in ODI in the propensity scores stratified subgroups was not significantly different.

Secondary outcomes

There were no significant differences in patient-reported outcome measures between the three surgical groups (Table 2).

The chosen operation method had no impact on self-assessed improvement, which was reported in 84.8 % in the spinous process osteotomy group, 80.8 % in the bilateral laminotomy group, and 80.1 % in the unilateral laminotomy with crossover group. A worse outcome was reported by 8.2, 10.2, and 9.5 %, respectively (Table 3).

When summarizing Table 3, 80.8 % of the included patients report that they are "slightly improved," "much improved," or "completely recovered". If one uses a

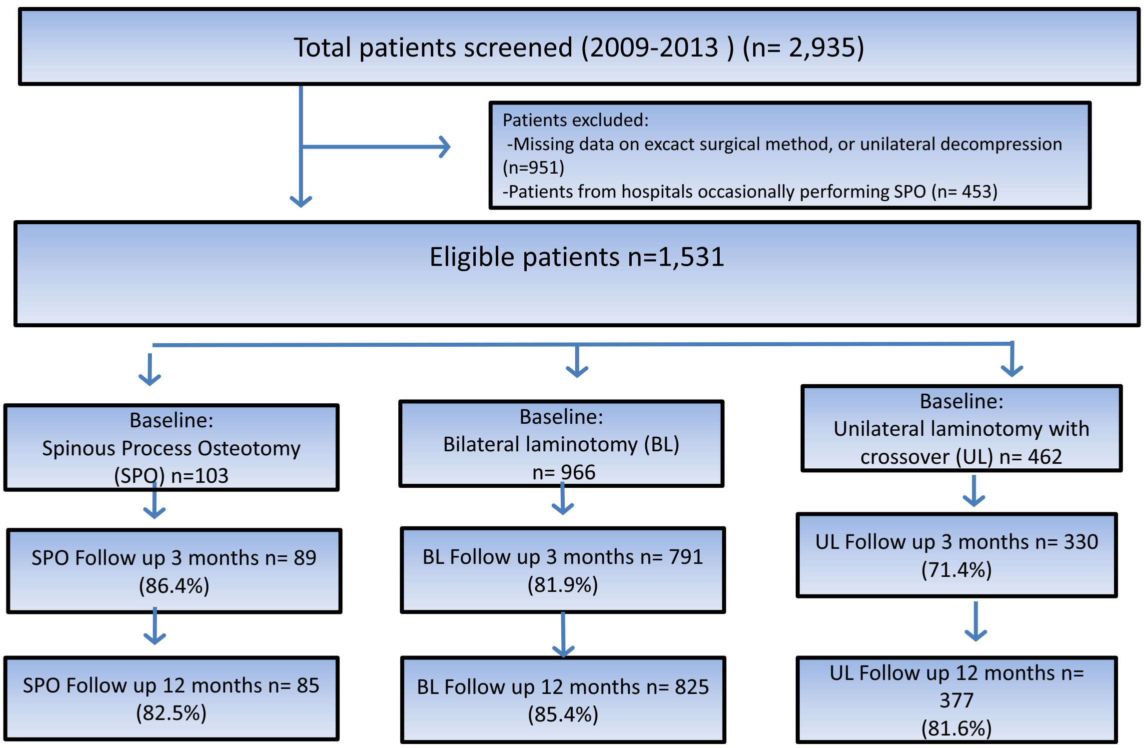

Fig. 1 Of 2935 patients 1404 patients were excluded. In the included group, there were 103 in the spinous process osteotomy group, 966 patients in the bilateral laminotomy group, and 462 in the unilateral with crossover group

Table 1 Demographic and baseline characteristics from the patients included vs the patients excluded and the three study groups

Characteristic	All patients included ($n = 1531$)	All patients excluded ($n = 1404$)	p value	Spinal process osteotomy ($n = 103$)	Unilateral laminectomy ($n = 462$)	Bilateral laminectomy ($n = 966$)	p value
Age	65.7 (10.7)	61.9 (12.0)	<0.05	66.8 (10.6)	64.1[c] (11.3)	66.4[b] (10.2)	<0.05
Men (%)	51	48	0.17	55	51	50	0.60
Smoking (%)	24	27	0.05	18	27	23	0.12
BMI	27.3 (4.2)	27.1 (4.3)	0.23	27.8 (3.6)	27.3 (4.3)	27.2 (4.3)	0.82
ODI	39.1 (15.5)	38.7 (14.8)	0.48	40.6 (15.9)	39.5 (14.5)	38.7 (14.9)	0.27
EQ-5D	0.37 (0.32)	0.39 (0.32)	0.17	0.40 (0.31)	0.37 (0.31)	0.38 (0.32)	0.62
EQ-VAS (0–100)	49.2 (20.6)	49.5 (21.3)	0.69	47.8 (19.6)	50.3 (20.3)	48.8 (20.8)	0.52
Back pain	6.4 (2.1)	6.3 (2.2)	0.12	6.3 (2.1)	6.4 (2.2)	6.4 (2.1)	0.66
Leg pain	6.6 (2.1)	6.5 (2.2)	0.15	6.5 (2.0)	6.6 (2.1)	6.6 (2.1)	0.65
Number of levels	1.4 (0.5)	1.3 (0.6)	<0.05	1.7 (0.8)[b,c]	1.3 (0.6)[a]	1.4 (0.6)[a]	<0.05

Values are mean (SD) unless stated otherwise

[a] Unilateral laminotomy with crossover vs spinal process osteotomy

[b] Bilateral laminotomy vs unilateral laminotomy with crossover

[c] Bilateral laminotomy vs spinal process osteotomy

Table 2 Clinical outcome 3 and 12 months after surgery, unmatched cohort

Improvement from baseline	Spinous process osteotomy ($n = 103$)		Bilateral laminotomy ($n = 966$)		Unilateral laminotomy with crossover ($n = 462$)		p value	
	3 months	12 months	3 months	12 months	3 months	12 months	3 months	12 months
ODI	16.1 (16.0)	15.2 (16.7)	17.6 (17.3)	16.9 (17.0)	17.5 (16.8)	16.7 (16.9)	0.76	0.62
EQ-5D	0.25 (0.28)	0.21 (0.29)	0.30 (0.36)	0.27 (0.36)	0.29 (0.35)	0.25 (035)	0.54	0.13
Back pain	2.8 (2.7)	2.4 (2.5)	2.9 (2.8)	2.8 (2.9)	2.8 (3.0)	2.5 (3.1)	0.87	0.20
Leg pain	3.3 (3.0)	3.1 (3.0)	3.5 (3.1)	3.4 (3.1)	3.5 (3.2)	3.0 (3.4)	0.87	0.15
EQ-VAS	16.5 (24.9)	17.4 (23.0)	19.7 (25.0)	18.9 (26.5)	16.2 (26.4)	16.2 (25.7)	0.26	0.39
Complications (%)	6.8		5.3		3.7		0.22	
Duration of operation (min)	121 (41)[b,c]		85 (37)[a,b]		104 (40)[a,c]		<0.05	
Length of stay (days)	6.9 (4.1)[b,c]		2.1 (2.1)[a,b]		3.5 (2.4)[a,c]		<0.05	

All patients reported outcome measures were similar in all three groups. Bilateral laminotomy had the shortest duration of surgery. Spinous process osteotomy had the longest length of stay. No significant differences in complication between the three surgical groups. Values are mean (SD) unless stated otherwise

[a] Unilateral laminotomy with crossover vs bilateral laminotomy

[b] Spinal process osteotomy vs bilateral laminotomy

[c] Spinal process osteotomy vs Unilateral laminotomy with crossover

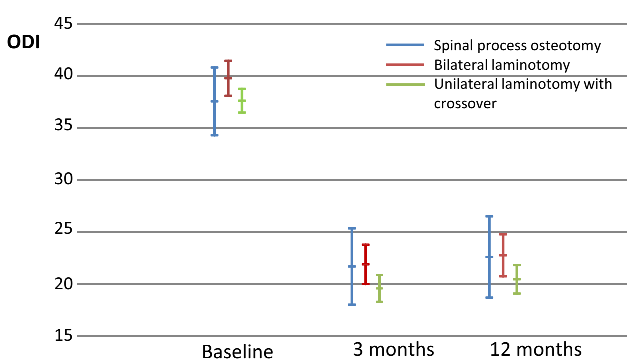

Fig. 2 Mean ODI (95 % CI) at baseline, 3, and 12 months after surgery

success criteria that is "much improved" or "completely recovered" 59.5 % of the included patients report clinical success.

A complete overview of the improvement in clinical scores (ODI, EQ-5D, NRS leg pain, NRS back pain, and EQ-VAS) within the global perceived effect scale subgroups is shown in Table 4.

The bilateral laminotomy procedure lasted shorter than unilateral laminotomy with crossover and spinal process osteotomy. Bilateral laminotomy lasted 85 min (SD 37), unilateral laminotomy with crossover 104 min (SD 40), and spinous process osteotomy 121 min (SD 41), whereas length of hospital stay was 2.1 days (SD 2.1) following bilateral laminotomy, 3.5 days (SD 2.4) following

Table 3 Global perceived change

Improvement from baseline	Spinal process osteotomy ($n = 85$)	Bilateral laminotomy ($n = 764$)	Unilateral laminotomy with crossover ($n = 366$)	Total ($n = 1215$)
Completely recovered	18.9 (16)	23.0 (176)	17.5 (64)	21.0 (256)
Much improved	34.1 (29)	38.3 (293)	39.9 (146)	38.5 (468)
Slightly improved	31.8 (27)	19.5 (149)	22.7 (83)	21.3 (259)
No change	7.1 (6)	9.0 (69)	10.4 (38)	9.3 (113)
Slightly worse	4.7 (4)	5.4 (41)	4.9 (18)	5.2 (63)
Much worse	2.4 (2)	2.6 (20)	3.0 (11)	2.7 (33)
Worse than ever	1.2 (1)	2.1 (16)	1.6 (6)	1.9 (23)

Percentage (number) of patients are given

The distribution in the three surgical groups showed no differences in the global perceived effect scale. A Kruskal–Wallis test was used, and the p value = 0.20

Table 4 Clinical outcome scores 12 months after surgery within the global perceived effect score subgroups

Improvement from baseline (*n*)	ODI 12 months	Back pain 12 months	Leg pain 12 months	EQ-5D 12 months	EQ-VAS 12 months
Completely recovered ($n = 256$)	32.0 (15.3)	5.4 (2.5)	6.0 (2.5)	0.49 (0.32)	37.0 (23.6)
Much improved ($n = 468$)	21.2 (13.8)	3.2 (2.5)	3.8 (2.7)	0.32 (0.31)	23.0 (23.1)
Slightly improved ($n = 259$)	8.7 (12.5)	1.3 (2.1)	1.7 (2.4)	0.17 (0.33)	6.4 (20.7)
No change ($n = 113$)	0.5 (9.8)	0.1 (1.8)	0.3 (2.1)	0.01 (0.31)	−2.5 (20.7)
Slightly worse ($n = 63$)	0.5 (11.7)	−0.2 (1.9)	−0.1 (2.3)	0.01 (0.31)	−2.3 (21.0)
Much worse ($n = 33$)	−3.4 (10.8)	−0.4 (2.1)	−0.2 (2.6)	−0.19 (0.33)	−6.7 (27.0)
Worse than ever ($n = 23$)	−10.1 (15.6)	−1.0 (1.7)	−0.3 (2.9)	−0.17 (0.38)	−1.7 (27.0)

Values are given as improvement from baseline. Negative values indicate worsening reported in the patient-reported questionnaires. Values are mean (SD)

unilateral laminotomy with crossover, and 6.9 days (SD 4.1) days following spinal process osteotomy. These findings were significantly different between groups in both the analyses (Table 2).

Complications included accidental dural tears, nerve root injury, wrong level surgery, peri-operative bleeding requiring transfusion, respiratory, or cardiac complications. There were no significant differences in the number of reported complications (Table 2).

We also analyzed the clinical data for the three methods at the single institution, where the spinous process osteotomy group was operated. There were no significant differences in the baseline data or clinical outcome, complications, duration of surgery, or length of stay between the three groups at this particular hospital.

Discussion

In the present study, clinical outcomes were similar in patients treated with three posterior decompression techniques for lumbar spinal stenosis, both regarding improvement and worsening. In total, 80.8 % of the patients reported improvement, and few patients reported a worse outcome (9.8 %).

These findings are in accordance with a previous study from the Spine Tango register [23], in which no differences in the patient-reported outcome measures after 24 months were reported following four different surgical methods (laminectomy with fusion, laminectomy, hemi-laminectomy, and laminotomy). A recent publication from NORspine reported similar results when comparing laminectomy to micro-decompression [24]. Most of the studies evaluating different surgical techniques have a relatively short (less than 3 years) follow-up [4–8, 11, 23]. In this study, the clinical outcome deteriorated slightly from 3 to 12 months of follow-up. This suggests that longer time for follow-up is warranted. In addition, Overdevest et al. who recently published a Cochrane review on posterior decompression techniques concluded that studies with longer follow-up are warranted [3].

Baseline data regarding pain and function were similar in the three groups. The patients in the unilateral laminotomy with crossover group were younger, and more levels were operated in the spinal process osteotomy group. When adjusting for these differences by the propensity score matching method, we found no differences in primary outcome. Two recent publications concluded that smoking was associated to less improvement after surgery, while increased age was not [25, 26]. In this trial, these factors were incorporated in the propensity score matching, and would, therefore, not confound the comparison of treatment groups.

Although differences at baseline and in outcome measures between the included and excluded patients were small, (Table 1), the included patients were somewhat older, and were operated on at more levels than excluded patients. Both groups reported improved clinical scores after surgery (Table 3). Given these small differences between included and excluded patients, the trial has a high external validity.

When generally accepted definitions of minimally clinical important differences are used [27–29], 80.8 % of the included patients reported a clinically meaningful improvement at follow-up. These results are in accordance with previous reports of minimally important clinical differences in spine surgery [27, 29–32]. Of the patients, 9.8 % reported deterioration after the surgery; this number is also in correspondence with previous trials [33]. Recent year's clinical success or substantial improvement has been considered as more important than minimal change by several authors [33–36]. In the present study, 59.5 % of the patients altogether had a substantial improvement, when the success criteria "completely recovered" or "much improved" in the global perceived effect scale were applied. No major differences between the surgical groups were found in the global perceived effect scale (Table 3).

A limitation of the present study is that all the spinal process osteotomy procedures were performed at one single orthopedic educational institution. This is considered to be the only high-volume hospital, where orthopedic consultants and residents are performing spinous process osteotomy on a regular basis. This may lead to selection bias and reduce the validity for the findings concerning process osteotomy, even in the propensity score matched cohorts. This single institution had longer duration of surgery and hospital stay, also when performing bilateral laminotomy and unilateral laminotomy with crossover, probably due to local traditions. The effectiveness of all procedures should, therefore, preferably be assessed in a high-quality clinical trial. The NORspine register collects clinical data from follow-up at 3 and 12 months. Not having data for 24 months follow-up, in comparison to the Spine Tango-based paper by Munting et al. [23], is, therefore, another limitation of the present study.

Unilateral laminotomy with crossover is by some considered to be the most technically challenging surgical method with a longer learning curve, and one might expect a longer duration of the operation and a higher rate of complications. The present study only partly confirms these assumptions. Although unilateral laminotomy with crossover lasted longer than bilateral laminotomy, the three operations had similar complication rates. On the other hand, complications may have been underreported [37]. Since unilateral laminotomy with crossover is considered to be more technically challenging, possibly the most experienced surgeons perform this procedure. However, data on surgeon's experience are not recorded in the NORspine register.

The bilateral laminotomy procedure had shorter duration of surgery compared to the unilateral laminotomy with crossover and spinous process osteotomy procedures. The patients who had a bilateral laminotomy procedure also had a shorter hospital stay than the unilateral laminotomy with crossover group and the spinous process osteotomy group. Despite the fact that all patients in the spinous process osteotomy group were treated in a single institution, which might have influenced the length of hospital stay, the large difference suggests that the spinous process osteotomy is more expensive.

The main goal of surgery for LSS is to reduce pain and disability by relieving the actual stenosis in the affected level of the spine. The amount of bony and ligamentous structures that is removed varies between the posterior decompression techniques applied in this study. It is, however, still unclear how much of the bony and ligamentous structures outside and inside the spinal canal needs to be removed to achieve satisfactory long-term results with minimal iatrogenic complications. To date, we are lacking objective criteria of how extensive the surgical procedure needs to be.

Conclusion

In this prospective study from the Norwegian Registry for Spine Surgery, no differences in clinical outcome 12 months after decompression of the spinal canal by spinal process osteotomy, bilateral laminotomy, or unilateral laminotomy with crossover were found. Bilateral laminotomy had the shortest duration of surgery and the shortest length of hospital stay. Surgical technique does not seem to affect clinical outcome after three different midline-retaining posterior decompression techniques. A randomized study is needed to assess the relative efficacy of these surgical procedures.

Compliance with ethical standards

Conflict of interest None.

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