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Postoperative Dural Sac Cross-Sectional Area as an Association for Outcome After Surgery for Lumbar Spinal Stenosis

Clinical and Radiological Results From the NORDSTEN-Spinal Stenosis Trial

Erland Hermansen, MD, PhD,[a,b,c] Tor Å. Myklebust, PhD,[d,e] Clemens Weber, PhD,[f,g] Helena Brisby, PhD,[h,i] Ivar M. Austevoll, PhD,[b] Christian Hellum, PhD,[j] Kjersti Storheim, PhD,[k] Jørn Aaen, MD,[a,l] Hasan Banitalebi, MD,[m,n] Jens I. Brox, PhD,[o] Oliver Grundnes, PhD,[p] Frode Rekeland, MD,[b,c] Tore Solberg, PhD,[q,r] Eric Franssen, MD,[s] and Kari Indrekvam, PhD[b,c]

From the [a]Department of Orthopedic Surgery, Ålesund Hospital, Møre and Romsdal Hospital Trust, Ålesund, Norway; [b]Kysthospitalet in Hagevik, Orthopedic Clinic, Haukeland University Hospital, Bergen, Norway; [c]Department of Clinical Medicine, University of Bergen, Bergen, Norway; [d]Department of Research and Innovation, Møre and Romsdal Hospital Trust, Ålesund, Norway; [e]Department of Registration, Cancer Registry Norway, Oslo, Norway; [f]Department of Neurosurgery, Stavanger University Hospital, Stavanger, Norway; [g]Department of Quality and Health Technology, University of Stavanger, Stavanger, Norway; [h]Department of Orthopedics, Sahlgrenska University Hospital, Gothenburg, Sweden; [i]Department of Orthopedics, Institute for Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; [j]Division of Orthopedic Surgery, Oslo University Hospital Ullevål, Oslo, Norway; [k]Communication and Research Unit for Musculoskeletal Health (FORMI), Oslo University Hospital Oslo, Norway; [l]Department of Circulation and Medical Imaging, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway; [m]Department of Diagnostic Imaging, Akershus University Hospital, Nordbyhagen, Norway; [n]Institute of Clinical Medicine, University of Oslo, Oslo, Norway; [o]Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Oslo, Norway; [p]Department of Orthopedics, Akershus University Hospital, Oslo, Norway; [q]Department of Neurosurgery and the Norwegian Registry for Spine Surgery (NORspine), University Hospital of Northern Norway, Tromsø, Norway; [r]Institute of Clinical Medicine, The Arctic University of Norway, Tromsø, Norway; and [s]Department of Orthopedic surgery, Stavanger University Hospital, Stavanger, Norway.

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Address correspondence and reprint requests to Erland Hermansen, MD, PhD, Department of Orthopedic Surgery, Aalesund Hospital, Ålesund 6026, Norway; E-mail: erland.hermansen45@gmail.com

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Study Design. Prospective cohort study.

Objective. The aim was to investigate the association between postoperative dural sac cross-sectional area (DSCA) after decompressive surgery for lumbar spinal stenosis and clinical outcome. Furthermore, to investigate if there is a minimum threshold for how extensive a posterior decompression needs to be to achieve a satisfactory clinical result.

Summary of Background Data. There is limited scientific evidence for how extensive lumbar decompression needs to be to obtain a good clinical outcome in patients with symptomatic lumbar spinal stenosis.

Materials and Methods. All patients were included in the Spinal Stenosis Trial of the NORwegian Degenerative spondylolisthesis and spinal STENosis (NORDSTEN)-study. The patients underwent decompression according to three different methods. DSCA measured on lumbar magnetic resonance imaging at baseline and at three months follow-up, and patient-reported outcome at baseline and at two-year follow-up were registered in a total of 393 patients. Mean age was 68 (SD: 8.3), proportion of males were 204/393 (52%), proportion of smokers were 80/393 (20%), and mean body mass index was 27.8 (SD: 4.2). The cohort was divided into quintiles based on the achieved DSCA postoperatively, the numeric, and relative increase of DSCA, and the association between the increase in DSCA and clinical outcome were evaluated.

Results. At baseline, the mean DSCA in the whole cohort was 51.1 mm^2 (SD: 21.1). Postoperatively the area increased to a mean area of 120.6 mm^2 (SD: 46.9). The change in Oswestry disability index in the quintile with the largest DSCA was −22.0 (95% CI: −25.6 to −18), and in the quintile with the lowest DSCA the Oswestry disability index change was −18.9 (95% CI: −22.4 to −15.3). There were only minor differences in clinical improvement for patients in the different DSCA quintiles.

Conclusion. Less aggressive decompression performed similarly to wider decompression across multiple different patient-reported outcome measures at two years following surgery.

Key words: lumbar spinal stenosis, surgical treatment, dural sac cross-sectional area, patient, reported outcome measures, randomized controlled trial
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Symptomatic lumbar spinal stenosis (LSS) is a condition that results in pain in the lower back and the lower extremities, especially while walking, is associated with radiological narrowing of the lumbar spinal canal.[1] Surgery is often considered when conservative treatment fails.[2–7] Surgery addressing LSS is the most common procedure performed on the spine in adult patients and usually consists of a posterior decompression. There are several posterior decompression techniques performed today. According to the latest Cochrane review evaluating the different surgical techniques for LSS, there is insufficient scientific evidence to conclude that one method is superior to another.[8]

Degenerative changes in the lower spine commonly lead to a reduction in the dural sac cross-sectional area (DSCA) at one or more of the lumbar levels.[9] The rationale for performing a posterior decompression is therefore to relieve the stenosis. When stenosis at any particular level is successfully decompressed, the DSCA at that level increases. There is little evidence regarding how extensive the posterior decompression needs to be, or how much the DSCA needs to increase after surgery, to achieve a significant clinical improvement for the patient. One study reported an association between the increase in DSCA in mm^2 and the patient-reported result of the procedure,[10] while other studies have not confirmed these findings.[11,12] All these studies are performed on rather limited patient samples. In the NORDSTEN Spinal Stenosis Trial (SST) it was found that three commonly used minimally invasive midline-retaining posterior decompression techniques resulted in a similar increase in DSCA.[13] In the present study, our sample is more than four times greater than those considered in previous studies, and our analyses focused specifically on the increase in DSCA following surgical decompression.

Our study aimed to determine to what extent the actual postoperative DSCA, or the increase in DSCA, is associated with clinical outcomes after surgery for LSS. We also sought to determine whether a minimum threshold is required to achieve a satisfactory clinical outcome.

MATERIALS AND METHODS

Data were collected as part of the NORwegian Degenerative spondylolisthesis and spinal STENosis (NORDSTEN) study, which is a multicenter study with 16 participating Norwegian hospitals. The NORDSTEN study consists of two randomized trials, the SST and Degenerative Spondylolisthesis Trial, and an Observational Cohort.[14,15] The present study involves patients with LSS without degenerative spondylolisthesis (the NORDSTEN-SST cohort). These patients were randomized to decompressive surgery using one of three minimally invasive methods. The three techniques used were unilateral laminotomy with bilateral decompression, bilateral laminotomy, and spinous process osteotomy. All three surgical techniques are considered minimally invasive and midline retained. Unilateral laminotomy with bilateral decompression is performed through unilateral access, and bilateral decompression is performed using a crossover technique. Bilateral laminotomy requires bilateral access, and the decompression is performed from both sides. Bilateral decompression after spinous process osteotomy gives the advantage of midline access with unilateral muscle release. Unilateral laminotomy with bilateral decompression is considered to be the least invasive of the three procedures. No difference in clinical outcomes were found between the three techniques in prior work,[16] and all three resulted in the same increase in DSCA.[13] The trial protocol (supplement appendix 1) was approved by The Regional Committee for Medical and Health Research Ethics of Central Norway (REC Central), project identifier 2011/2034.

Inclusion Criteria and Patient Recruitment

A detailed description of the patients included in the NORDSTEN-SST, with inclusion and exclusion criteria, is available in a previous publication[16] and in the study protocol.[14] All patients included in the NORDSTEN-SST who had representative magnetic resonance imaging (MRI) at baseline and at three months follow-up, as well as who had completed the patient-reported outcome measures (PROMs) at baseline and after two years, were eligible for inclusion in the present study.

Radiological Investigations

All patients underwent an MRI of the lumbosacral region during the six months prior to surgery, as well as at three months after surgery. An MRI three months after surgery was considered the best time point for a true postoperative evaluation, allowing any hematomas or other postoperative changes to resolve. Radiological images were imported into a Picture Archiving and Communication System, Sectra Sweden, IDS7. The investigators performed the measurements using integrated software tools for area measurements included in the Picture Archiving and Communication System. DSCA (Fig. 1) was measured in square millimeters before and after surgery by a minimum of three readers (two orthopedic surgeons and one musculoskeletal radiologist). Three levels (L2/L3, L3/L4, L4/L5) were evaluated in each patient. At the most stenotic level on MRI (defined as the index level), the smallest area was noted. The following parameters were measured and calculated for each level: the actual postoperative DSCA in mm^2, the absolute change in DSCA from baseline to follow-up in mm^2 and the relative change in DSCA (as a percentage) from baseline to follow-up.

For all three parameters the cohort was divided into quintiles. The analysis based on actual postoperative DSCA in mm^2 is given as the primary result. The analysis from the two other parameters based on actual change (in mm^2) are

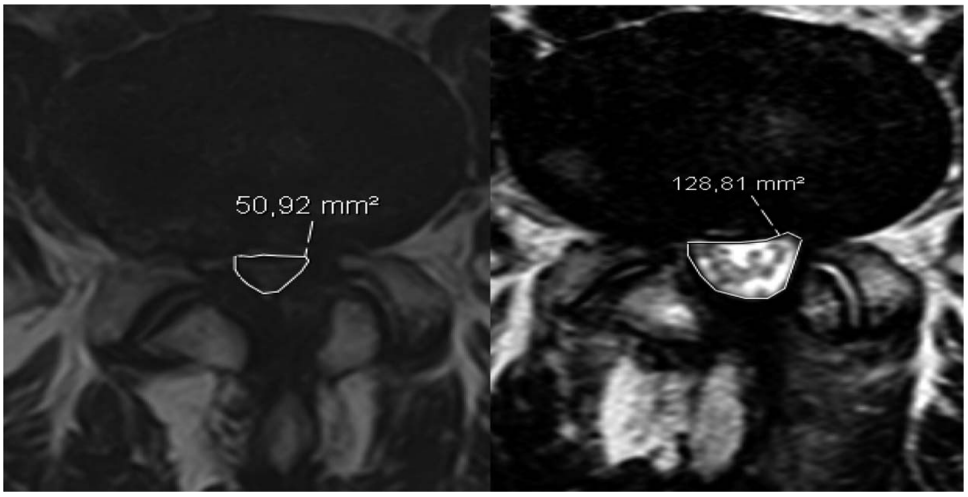

Figure 1. Measurement of dural sac cross-sectional area before (left) and after decompressive surgery (right) in lumbar spinal stenosis patients.

given in "Supplemental Data File 1, Supplemental Digital Content 1, http://links.lww.com/BRS/C11" and relative change (as a percentage) are given in the "Supplemental Data File 2, Supplemental Digital Content 1, http://links.lww.com/BRS/C11."

Clinical Outcome Measures

The patients completed a series of questionnaires, before and 24 months after surgery. Change in disability was measured with the Oswestry disability index (ODI, version 2.0) between baseline and 24 months after surgery, as the

TABLE 1. The demographics, smoking status, randomization arm, and preoperative measurements for LSS patients waiting for decompressive surgery

Variables	First Quintile	Second Quintile	Third Quintile	Fourth Quintile	Fifth Quintile
Demographics, n (%)					
Female	42 (54.5)	37 (47.4)	42 (56.0)	34 (42.0)	30 (38.5)
Male	35 (45.5)	41 (52.6)	33 (44.0)	47 (58.0)	48 (61.5)
Age (mean/SD)	66.9 (8.3)	67.3 (8.0)	66.2 (8.8)	65.8 (8.2)	66.0 (8.5)
BMI (mean/SD)	27.1 (4.3)	27.5 (3.8)	27.9 (4.3)	28.2 (4.4)	27.7 (4.2)
Smoking status, n (%)					
No	60 (81.1)	58 (75.3)	60 (81.1)	67 (82.7)	59 (75.6)
Yes	14 (18.9)	19 (24.7)	14 (18.9)	14 (17.3)	19 (24.4)
Randomization arm, n (%)					
UL	21 (27.3)	32 (41.0)	22 (29.3)	28 (34.6)	25 (32.1)
BL	29 (37.7)	26 (33.3)	25 (33.3)	24 (29.6)	25 (32.1)
SPO	27 (35.1)	20 (25.6)	28 (37.3)	29 (35.8)	28 (35.9)
Preoperative measurements					
DSCA	65.1 (23.6)	55.0 (21.5)	51.1 (18.2)	46.8 (16.8)	41.5 (15.7)
ODI	39.1 (15.4)	39.8 (14.0)	37.2 (13.2)	35.4 (15.3)	42.2 (13.2)
ZCQ symptom score	3.3 (0.6)	3.4 (0.5)	3.3 (0.5)	3.3 (0.6)	3.5 (0.5)
ZCQ physical function	2.5 (0.5)	2.5 (0.6)	2.4 (0.5)	2.5 (0.6)	2.6 (0.5)
EQ5D score	0.4 (0.3)	0.4 (0.3)	0.4 (0.3)	0.4 (0.3)	0.3 (0.3)
NRS leg pain	6.0 (2.2)	6.7 (1.8)	6.6 (2.0)	6.4 (2.1)	6.8 (1.9)
NRS back pain	6.3 (2.3)	6.5 (2.1)	6.5 (1.9)	6.0 (2.4)	6.3 (2.2)

The patients were divided into five quintiles based on actual achieved postoperative dural sac cross-sectional area (DSCA). First quintile has the largest postoperative DSCA, and the fifth quintile has the smallest postoperative DSCA. Baseline parameters are given in the five different quintiles with SD in brackets for the continuous variables, and percent (%) for the categorical variables.

BL indicates bilateral laminotomy; BMI, body mass index; DSCA, dural sac cross-sectional area; EQ-5D, EuroQol Questionnaires; LSS, lumbar spinal stenosis; NRS, numeric rating scale; ODI, Oswestry disability index; SPO, spinous process osteotomy; UL, unilateral laminotomy with crossover; ZCS, Zurich Claudication Scale.

primary outcome. ODI is a widely used and validated score of back pain related disability, ranging from 0 (no disability) to 100 (completely disabled).[17] Further analysis included the EuroQol five-dimensional questionnaire utility index (EQ-5D-3L), the Zurich Claudication Questionnaire (ZCQ-score), the 10-point numeric rating scale (NRS) for low back pain and leg pain, and the global perceived effect scale.

EQ-5D is a generic questionnaire measuring quality of life. It ranges from –0.59 (worst possible) to 1.00 (best possible). This questionnaire has been validated for the Norwegian population.[18] To calculate scores, the three-level version of EQ-5D and the corresponding UK value set were used. The ZCQ is a disease-specific questionnaire for LSS.[19] It includes symptom severity, physical activity, and patient satisfaction during follow-up. In the symptom severity-scale the score ranges from 1.0 to 5.0. In the physical activity scale, the range is from 1.0 to 4.0. The patient satisfaction scale was only answered postoperatively and ranges from 1.0 to 4.0. For all scales, 1.0 is the best option. The NRS scores for leg pain and low back pain are validated parameters for clinical trials.[20] The range is from 0 to 10, where 0 is no pain and 10 is the worst pain imaginable. The global perceived effect scale is a seven-point score, which is recommended for clinical trials of chronic pain conditions.[21] It has seven response categories: 1 = completely recovered, 2 = much improved, 3 = slightly improved, 4 = no change, 5 = slightly worse, 6 = much worse, and 7 = worse than ever.

Statistical Analysis

The cohort was divided into quintiles based on the actual postoperative DSCA (Table 1). Descriptive statistics are given for each quintile, using frequencies and percentages for categorical variables, and means and SDs for continuous variables. For each quintile we also calculated the mean change in each outcome with corresponding 95% CI (Table 2). To identify any association between postoperative DSCA and clinical improvement, we developed multivariate regression models using restricted cubic splines to model nonlinear effects. The models were adjusted for sex, age (continuous), body mass index, smoking status, randomization arm, preoperative DSCA (continuous), and baseline measurement of the outcome (continuous). We then calculated predicted means, with corresponding 95% CI, for all values of postoperative DSCA, giving a smooth, nonlinear curve depicting the estimated association. In case of a positive association between DSCA and clinical improvement was found, one should expect to find a curve that was decreasing/increasing until a threshold value was detected (a dose-response curve).

All analyses were repeated for absolute (numeric increase in mm^2) and relative increases (percentage increase) in DSCA. The results from these analyses are included in the "Supplemental Data File 1, Supplemental Digital Content 1, http://links.lww.com/BRS/C11" and "Supplemental Data File 2, Supplemental Digital Content 1, http://links.lww.com/BRS/C11". All analyses were done using Stata 16 Stata

TABLE 2. Patient-reported outcome measures related to postoperative dural sac cross-section area (DSCA) in mm^2 for LSS patients operated with decompressive surgery

	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
Postoperative DSCA (range, mm^2)	185 (155–276)	141 (127–154)	118 (108–126)	96 (83–108)	64 (26–82)
Change ODI	−22.0 (−25.6, −18.4)	−21.1 (−24.5, −17.8)	−19.4 (−22.9, −15.9)	−15.9 (−19.3, −12.6)	−18.9 (−22.4, −15.3)
Change physical function (ZCQ)	−1.0 (−1.1, −0.8)	−0.8 (−0.9, −0.6)	−0.9 (−1.0, −0.7)	−0.8 (−0.9, −0.6)	−0.8 (−1.0, −0.7)
Change symptoms (ZCQ)	−1.1 (−1.3, −0.9)	−1.0 (−1.2, −0.8)	−1.1 (−1.3, −0.9)	−0.9 (−1.1, −0.7)	−1.0 (−1.2, −0.8)
Change QoL (EQ5D)	0.4 (0.3, 0.5)	0.3 (0.3, 0.4)	0.3 (0.2, 0.4)	0.3 (0.2, 0.4)	0.3 (0.2, 0.4)
Leg pain (NRS)	−3.9 (−4.6, −3.2)	−3.4 (−4.1, −2.8)	−3.6 (−4.3, −3.0)	−3.0 (−3.6, −2.3)	−3.6 (−4.3, −3.0)
Back pain (NRS)	−3.1 (−3.7, −2.4)	−2.8 (−3.4, −2.2)	−3.1 (−3.7, −2.5)	−2.0 (−2.6, −1.4)	−2.4 (−3.0, −1.7)

Based on the postoperative DSCA, the cohort was divided into quintiles. Quintile 1 has the largest postoperative DSCA, and quintile 5 has the smallest postoperative DSCA. Change of the different outcome parameters for each quintile of postoperative DSCA (SD in brackets).

DSCA indicates dural sac cross-sectional area; EQ-5D, EuroQol Questionnaires; LSS, lumbar spinal stenosis; NRS, numeric rating scale; ODI, Oswestry disability index; QoL, quality of life; ZCS, Zurich Claudication Scale.

(StataCorp. Stata Statistical Software: Release 16. StataCorp LLC, College Station, TX). All analyses were performed on the full sample (n = 393) and also on the subgroup without additional surgery between 3 and 24 months (n = 368). The level of significance was set to 5%.

RESULTS

Baseline Data

Of 437 patients included in the NORDSTEN-SST, 393 (89.9%) had an MRI both preoperatively and postoperatively, and completed the PROMs at follow-up after 24 months and were included in the present study (Fig. 2).

Baseline demographic characteristics for the total cohort showed a mean age of 68 (SD: 8.3) years; there were 204/393 (52%) males, 80/393 (20%) were smokers and the mean body mass index was 27.8 (SD: 4.2).

The mean pain and function scores at baseline for the total cohort were ODI 38.4 (SD: 14.5), EQ-5D 0.38 (SD: 0.32), ZCQ Symptoms 3.4 (SD: 0.6), ZCQ Function 2.5 (SD: 0.5), NRS Leg Pain 6.5 (SD: 2.0) and NRS Low Back Pain 6.3 (SD: 2.2).

The specific baseline parameters, both demographic and baseline measurements, for the different quintiles are given in Table 1.

Among the cohort of 393 patients, 25 underwent a reoperation due to a variety of reasons (*e.g.* hematoma, deep or superficial infection, wrong level, disc herniation, incomplete decompression, or spondylolistheses) between 3 and 24 months postoperatively. Of the 25 patients that required a reoperation 4/25 had a revision decompression procedure. A flow chart of the original inclusion for the NORDSTEN-SST are given in "Supplemental Data File 5, Supplemental Digital Content 1, http://links.lww.com/BRS/C11".

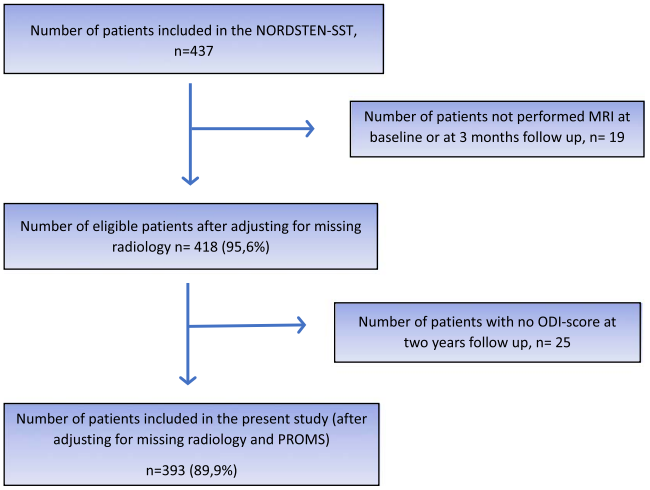

Figure 2. Flow chart of patients included in the study from inclusion to two years of follow-up. MRI indicates magnetic resonance imaging; NORDSTEN-SST, NORwegian Degenerative spondylolisthesis and spinal STENosis-Spinal Stenosis Trial; ODI, Oswestry disability index; PROMs, patient-reported outcome measures. full color online

Radiological Data

Of all patients, we included 393 of the eligible 437 (89.9%) who had MRI suited for radiologic analysis preoperatively and at follow-up three months after surgery. At baseline, the mean DSCA in the whole cohort was 51.1 mm^2 (SD: 21.1), increasing by 68.6 mm^2 (SD: 39.9) to a mean area of 120.6 mm^2 (SD: 46.9) postoperatively.

Outcome Measures

The mean change in ODI between baseline and the two-year follow-up for the whole cohort was –19.1 (95% CI: –20.8 to –17.5). For EQ-5D there was an improvement of 0.32 (95% CI: 0.28–0.36), whereas the mean change in ZCQ was 1.02 (95% CI: 0.94–1.11) for symptom severity and 0.85 (95% CI: 0.78–0.92) for physical function. The mean improvement from baseline in NRS for leg pain was 3.5 (95% CI: 3.2–3.8) and for NRS back pain 2.7 (95% CI: 2.4–3.0).

For the quintiles based on actual postoperative DSCA, the clinical improvement is given in Table 2. There were only minor differences in the clinical outcome scores between the different quintiles.

No association between postoperative DSCA and clinical improvement using the multivariable regression model was found (Fig. 3). This model could not detect any association or threshold value in terms of a minimum DSCA needed or DSCA minimum change needed to significantly improve the clinical outcome (Fig. 3). The figures presented in the "Supplemental Data File 1, Supplemental Digital Content 1, http://links.lww.com/BRS/C11" for absolute change (increase in mm^2) and "Supplemental Data File 2, Supplemental Digital Content 1, http://links.lww.com/BRS/C11" for relative change (percentage change), confirm the findings for actual achieved DSCA postoperatively.

For the quintiles based on absolute and relative increase of DSCA, the unadjusted and adjusted values are given in the "Supplemental Data File 3, Supplemental Digital Content 1, http://links.lww.com/BRS/C11" and "Supplemental Data File 4, Supplemental Digital Content 1, http://links.lww.com/BRS/C11." The results from these two parameters were consistent with the results from the achieved postoperative DSCA. Only minor differences in the clinical outcome scores were found. No threshold value was detected in terms of a minimum increase of DSCA needed to improve the clinical outcome significantly. An analysis of the subgroup which excluded patients with additional surgery 3 to 24 months postoperatively, demonstrated essentially similar results.

DISCUSSION

Among patients undergoing surgery for LSS, we found no association between the extent of decompression, measured by early postoperative DSCA and DSCA change at three months, and PROMs at the two years' time point. This may indicate that even patients in the quintile with the lowest postoperative DSCA had achieved a sufficient decompression, and that other factors were more important

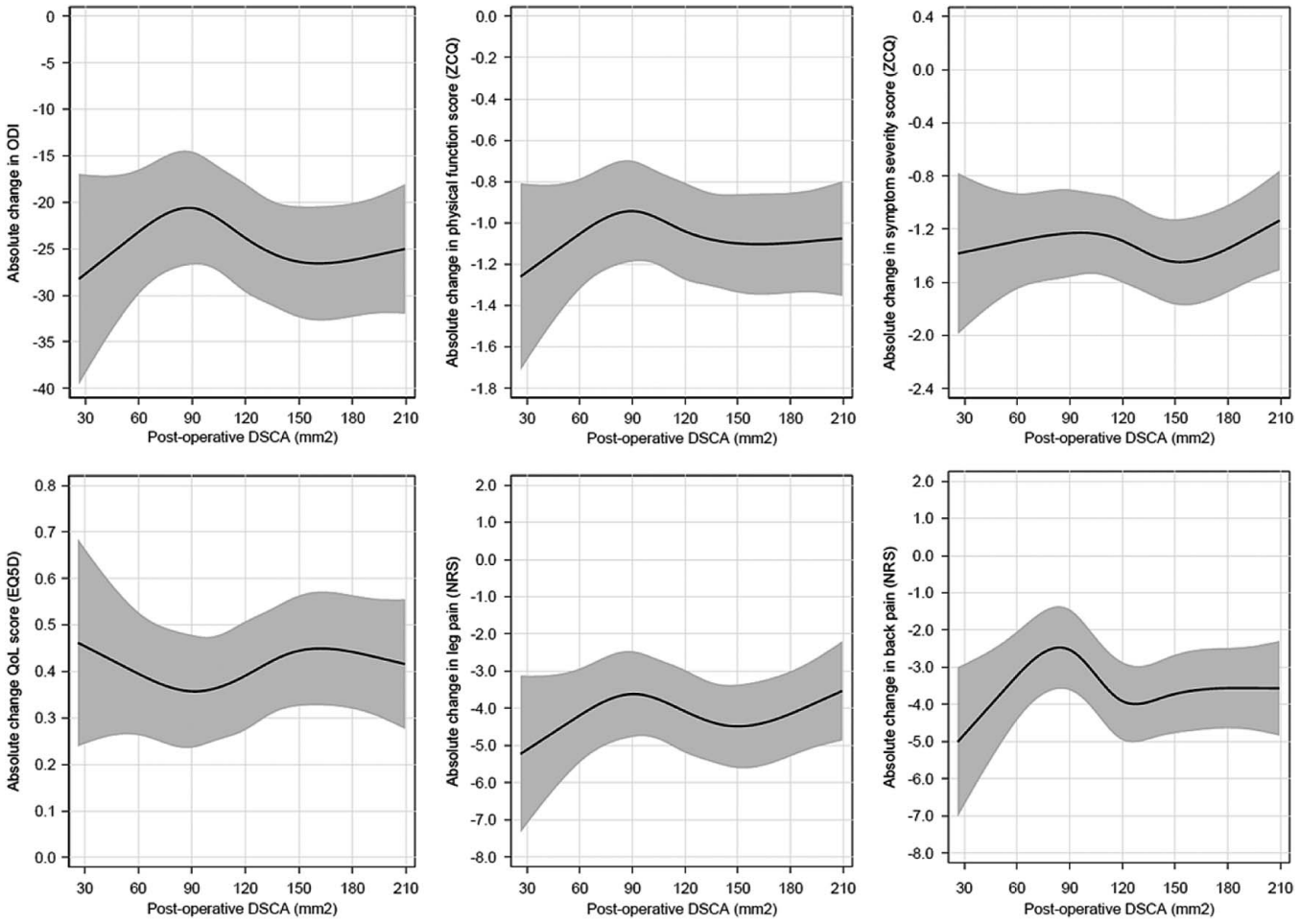

Figure 3. Association between dural sac cross-sectional area (DSCA) and patient-reported outcome measures. Absolute change in outcomes as a function of postoperative DSCA. Estimates are generated on the basis of a multivariable regression model using restricted cubic splines to model nonlinear effects of postoperative DSCA and change in outcome is predicted at the mean of other covariates. No association between postoperative DSCA and clinical improvement was found. No minimal threshold value for postoperatively DSCA was detected. EQ-5D indicates EuroQol Questionnaires; NRS, numeric rating scale; ODI, Oswestry disability index; ZCS, Zurich Claudication Scale.

determinants of the variation in clinical results observed. We were not able to detect a threshold value or a minimum value for increase in DSCA that resulted in an adequate clinical improvement. In the quintile of patients with the lowest DSCA, the clinical results were equal to the results for the quintile with the most extensive decompression. This suggests that a less comprehensive decompression could be effective, at least up to two years after surgery.

The rationale for decompressing the spinal canal is to relieve nerve roots and neurovascular structures. This study indicates that this can be achieved by a moderate increase in the DSCA. Our findings are in accordance with other publications which have not shown an association between increase in DSCA and clinical improvement.[11,22] Whether these clinical findings, after two years follow-up, will remain after a longer postoperative observation period remains to be investigated. Our ongoing 5 and 10-year follow-up of the patients in the present study with MRI and PROMS may contribute to this debate.

Several clinical studies on the effectiveness of using interspinous devices have shown a clinical improvement despite only a small increase in DSCA.[23,24] This is in accordance with the findings in the present study, in which even the quintile with the smallest postoperative area or the least increase in area had a comparable improvement in PROMs at follow-up. This may suggest that a minor area increase can result in a significant improvement in clinical symptoms. Whether these results will persist over a longer time than two years is not possible to predict. One can speculate that a small increase in area could potentially lead to a faster recurrence of narrowing of the canal and a return of symptoms, and perhaps a second intervention might be required in such scenarios.

Strengths and Limitations

The high numbers of participants and the prospective design are strengths of the present study. Further, the fact that patients were recruited from a multicenter RCT with a pragmatic design indicates a high internal and external validity.

The DSCA measurements are focused on the central component of LSS. This measurement does not cover the lateral recess stenosis component in LSS. This is a possible

bias of our work. The reason for not including measurements of the lateral recess stenosis in this study is that there are no reliable scientific methods to assess lateral recess stenosis.[25] However, the mean DSCA preoperatively was 51.1 mm^2, indicating that this central component of the stenosis was the most important stenotic factor in this cohort. Further, the question about how large a central decompression is needed to relieve claudication symptoms, prevent restenosis, and still not increase the risk of segmental instability, might not just involve the size of the DSCA but also involve other structures that are removed and to what extent the facet joints are compromised. This is difficult to evaluate based on standard MRI and was not considered in the present work.

CONCLUSION

Less aggressive decompression performed similarly to wider decompression across multiple different PROMs at two years following surgery.

➢ Key Points

- ❑ A cohort of 393 patients operated for lumbar spinal stenosis was divided into five quintiles based on achieved postoperative dural sac cross-sectional area.
- ❑ There were no differences in clinical outcomes among the different quintiles.
- ❑ Less aggressive decompression fair similar to more wide decompression with regard to multiple different patient-reported outcome metrics at the two years follow-up.

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