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Decompression surgery alone versus decompression plus fusion in symptomatic lumbar spinal stenosis: *A Swiss prospective multi-center cohort study with 3 years of follow-up*

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Abstract

Study Design. Retrospective analysis of a prospective, multicenter cohort study.

Objective. To estimate the added effect of surgical fusion as compared to decompression surgery alone in symptomatic lumbar spinal stenosis patients with spondylolisthesis.

Summary of Background Data. The optimal surgical management of lumbar spinal stenosis patients with spondylolisthesis remains controversial.

Methods. Patients of the LSOS with confirmed DLSS and spondylolisthesis were enrolled in this study. The outcomes of this study were Spinal Stenosis Measure (SSM) symptoms (score range 1-5, best-worst) and function (1-4) over time, measured at baseline, 6, 12, 24 and 36 months follow-up. In order to quantify the effect of fusion surgery as compared to decompression alone and number of decompressed levels, we used mixed effects models and accounted for the repeated observations in main outcomes (SSM symptoms and SSM function) over time. In addition to individual patients' random effects, we also fitted random slopes for follow-up time points and compared these two approaches with Akaike's Information Criterion (AIC) and the chi-squared test. Confounders were adjusted with fixed effects for age, gender, BMI, diabetes, CIRS musculoskeletal disorders and duration of symptoms.

Results. One hundred and thirty-one patients undergoing decompression surgery alone (n=85) or decompression plus fusion surgery (n=46) were included in this study. In the multiple mixed effects model the adjusted effect of fusion versus decompression alone surgery on SSM symptoms was 0.06 (95% confidence interval, CI: -0.16to 0.27) and -0.07 (95% CI: -0.25 to 0.10) on SSM function, respectively.

Conclusions. Among the patients with degenerative lumbar spinal stenosis and spondylolisthesis our study confirms that in the two groups, decompression alone and decompression plus fusion, patients distinctively benefited from surgical treatment. When

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adjusted for confounders, fusion surgery was not associated with a more favorable outcome in both SSM scores as compared to decompression alone surgery.

Key Words:decompression; degenerative lumbar spinal stenosis; fusion; laminotomy; laminectomy; mixed effects models; multi-center; multi-level; surgery; lumbar fusion
Level of Evidence: 3

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Introduction

Degenerative lumbar spinal stenosis (DLSS) is a narrowing of the spinal canal by surrounding bone and soft tissuesthat compromise neural structures. Radiographic findings of spinal stenosis are highly prevalent[1]and 85% of patients typically present with significant long-term symptoms of intermittentneurogenic claudicationlike gluteal and/or lower extremity pain and fatigue that may occur with or without back pain.[2,3] When conservative treatment fails, patients are usually referred to surgical treatment.The aim of surgery is to decompress the spinal canal and dural sac from degenerative bony and ligamentous overgrowth.

As a result, the number of surgical procedures performed for DLSS has increased steadily over the years (e.g., the rates of complex fusion surgeryhad a 15-fold increase between 2002 and 2007), with costs reaching USD $1.65 billion peryear.[4]For instance, in the metropolitan area of Zurich with around 1.5 million inhabitants approximately1750lumbar decompression surgeries and decompression withfusion surgeries are done every year.[5]

There is still a large variation in surgical management chosen by different surgeons and institutions,[6,7] and no strong superiority of one technique over the otherhas been identified yet.[8-11]Currently, surgicalmanagement for degenerative DLSS includes decompression with or without lumbar fusion.[12] Simple decompression surgery alone has been proven to be beneficial in patients with DLSS.[13-16]Otherstudiesshowed that the addition of fusion might bevaluable for patients' outcome.[17-19]

The aim of the study was to estimate the added effect of surgical fusion as compared to decompression surgery alone in symptomatic lumbar spinal stenosis patients with spondylolisthesis.

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Methods

Study design

For this retrospective analysis we did use data from the Lumbar Stenosis Outcome Study (LSOS). The LSOSisconducted as a prospective cohort study at eight medical centers (with approximately two million inhabitants in the over regional area) covered by Rheumatology and Spine Surgery Units in Switzerland.Patients with a history of neurogenic claudication and lumbar spinal stenosis verified by Magnetic Resonance Imaging (MRI) or Computer Tomography (CT)were eligible. Patients had no evidence of stenosis caused by tumor, fracture, infection, or significant deformity (>15° lumbar scoliosis, diagnosed on conventional x-ray with anterior-posterior and lateral views), and were aged 50 years or more. Furthermore, patients had no clinical peripheral artery occlusive disease (confirmed by a vascular specialist in patients without palpable pulses in the lower limb). The decision of the treatment strategy (conservative or surgical) was made by the patient and his attending physician.Patients were assessed for eligibility between December 2010 and December 2015, and will be followed up three years.

Patient population

All patients who met inclusion criteria, underwent surgery on one or two adjacent levelswithdegenerative spondylolisthesis (step > 3mm,evaluated in MRI, flexion–extensionradiographs were not obtained), and had at least twelve months follow-upwere eligible. Furthermore, none of the patients had prior lumbar spine surgery.

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Surgical interventions

All patients underwent either decompression alone (decompression alone group) or decompression with fusion (fusion group).Decompression surgery consisted of a standard open or microscopic posterior lumbar decompression of the affected level(s). Decompression of the lateral recess and the foramina was performed when necessary to decompress the exiting nerve roots. Fusion surgery consisted besides decompression surgery of additional implantation of pedicle screws with rods, plus intersomatic fusion and cage(s) at the affected level(s).The decisionto add fusionand to proceed with single versus multi-level procedures was based on the surgeon's discretion. The procedures were done or supervised by senior neuro- or orthopedic surgeons with more than 10 years of experience after board-certification.

Radiological classification

The MRI of each patient was evaluated by two senior radiologists. He categorized the severity of the central stenosis of each level into "no", "mild", "moderate", or "severe", and lateral recess and foraminal stenosis into Grade 0 to 3 according to the consensus paper on core radiological parameters of the LSOS-study.[20]

Data collection and follow-up

Parts of the basic data sheet were interview-administered and recorded by a study coordinator. All other questionnaires were self-administered and completed by the patients themselves. All data were collected at baseline, and at six months. Long-term outcome data was gathered after one, two, and three years.

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The study coordinator checked all questionnaires after receiving for completeness. In case of missing data, he called the patient and tried to collect the missing data.

Data was entered independently and in duplicate in two databases that were crosschecked. Any discrepancies were identified and rechecked in the original files.

Questionnaires

*Spinal Stenosis Measure (SSM):*The SSM, an instrument specifically developed for spinal stenosis patients by Stucki et al.,[21] targets to measure severity of symptoms and quantifies disability of the lumbar spinal stenosis population. It is recommended by the North American Spine Society (NASS) and used in different studies on lumbar spinal stenosis.[22-25] It consists of three different subscales; *the symptom severity subscale*, *the physical function subscale* and the *satisfaction subscale*. The symptom severity scale can be divided into a pain domain (severity, frequency and back pain) and a neuroischemic domain (leg pain, weakness, numbness and balance disturbance). Score range is from 1-5 and 1-4 (best-worst).

Feeling Thermometer (FT) and Numeric Rating Scale (NRS): General assessment of lumbar spinal stenosis symptoms such as lower extremity pain and discomfort are measured. Score range is from 0-100 and 0-10 (best-worst), respectively.

EQ-5D-3L: The EQ-5D-3L is an assessment tool to measure health-related quality of life. It measures general non-disease specific health-related quality of life, including physical, mental and social dimensions.[26] The health status measures five dimensions of health (*mobility, self-care, usual activities, pain/discomfort and anxiety/depression*) which can be calculated as a sum score (score range 0-100, worst-best).[26] The second part of the questionnaire estimates patient's *actual health* status (score range 0-100, worst-best).

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Roland and Morris Disability Questionnaire (RMDQ): The Roland and Morris Disability Questionnaire is a back pain specific, self-rated physical disability questionnaire developed by Roland and Morris in 1983.[27]Disability is measured respective to the following categories: physical function activities and activities of daily living including eating and sleeping. Score range is from 0-24 (best-worst).

Cumulative Illness Rating Scale (CIRS): Comorbidity is measured using CIRSthat rates the presence and severity of comorbid diseases in 14 organ systems (according to modified version by Miller et al.[28]). Score range is from 0-56 (best-worst).The musculoskeletal organ system (*CIRS musculoskeletal disorders*) was separately included in the analysis.Score range is from 0-4 (best-worst).

Outcomes

The outcomes of this study were SSM symptoms and SSM function over time. These outcomes were measured at baseline, 6, 12, 24, and 36 months follow-up.

Further outcomes of interest were NRS, FT, EQ-5D-EL sum score and actual health status, and RMDQ at 12 months follow-up.

Ethics

This multi-center cohort study was conducted in compliance with all international laws and regulations as well as any applicable guidelines.Written informed consent to participatein the study has been obtained from participants.The study was approved by the independent Ethics Committee of the Canton Zurich (KEK-ZH-NR: 2010-0395/0).

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Sample size considerations

We calculated that a minimum of 44 patients with baseline and twelve months follow-up in each treatment group − the decompression alone group and fusion group − would be required for the study to have 80% power to detect a clinical relevant difference in change in SSM symptoms of 0.48[21]at a significance level of 0.05. The standard deviation was assumed to be 0.8 (Ulrich et al., accepted for publication in Clinical Spine Surgery) in both treatment groups.Imbalance in baseline characteristics between treatment groups were adjusted for within the regression framework.

Statistical analyses

Analysis of data consisted of descriptive statistics of patient demographics and outcomes at baseline. Continuous variables were shown as mean and standard deviation, and categorical variables were shown as numbers and percentages of total, stratified by decompression alone and decompression plus fusion. Scatterplots were used to display changes in main outcomes over follow-up time and to display the correlation structure of the repeated measurements over time.

In order to quantify the effect of fusion surgery as compared to decompression alone and number of decompressed levels, we used mixed effects models and accounted for the repeated observations in main outcomes (SSM symptoms and SSM function) over time. In addition to individual patients' random effects, we also fitted random slopes for follow-up time points and compared these two approaches with Akaike's Information Criterion (AIC) and the chi-squared test. Confounders were adjusted for with fixed effects for age, gender, BMI, diabetes, CIRS musculoskeletal disorders, and duration of symptoms. Continuous

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confounders were centered prior to inclusion to simplify interpretation of the intercept term. Conservative p-values for the fixed effects were calculated as proposed by Kenward and Roger.[29] The level of significance was set to 5%.

All analyses were conducted with R for Windows.[30]

Results

Patient characteristics

Between December 2010 and December2015 1'716 patients were potentially eligible, 853patients agreed to participate, and 724 patients had no prior lumbar spine surgery (**Figure 1**, study flow). Of these, 443 patients underwent decompression surgery alone or decompression plus fusion surgery within the first six months after baseline. For this study, 131 patients met the inclusion criteria (see **Figure 1**).

In **Table 1** we present the patients' baseline characteristics;85 (65%) patientsunderwent decompression aloneand 46 (35%) patients underwent decompression plus fusion.Baseline characteristics wereremarkably similar; however, patients in the fusion group were slightly younger (mean age 68 years vs 75.4 years in the decompression alone group). There were no other statistically significant differences in baseline characteristics.

Overall, 76 of 131 patients (58%) were female, and mean body mass index was 26.8 kg/m^2 (standard deviation (SD)4.5).Seventeenpatients had diabetes (13%) and 23(17.6%) were current smokers.Fifty-two patients (61.2%) had previous lumbar epidural steroid injections in the decompression alone group, and 28patients (60.9%) in the fusion group.

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Four variables (duration of symptoms, EQ-5D-EL sum score and actual health status, and RMDQ) had a small percentage of missing values at baseline and/or 12 months follow-up (ranging from 0.75% to 1.5%).

Surgical characteristics

Most patients in both groupswere operated on the L4/L5 level (84.7% in the decompression alone and 82.6% in the fusion group, respectively). Furthermore, no patient had surgery on the level L1/L2. In the decompression alone group, 83.5% of the patients were operated microscopically whereas in the fusion group only 54.3% of the patients (**Table 2**).

In the decompression alone group, most patients had three or four moderate or severe level stenoses (31.8% and 30.6%, respectively), and 20% two. In the fusion group, 28.3% of the patients had three moderate or severe level stenoses, 26.1% two, and 28.3% one(**Table 2**).

In the fusion group, thirty-nine patients were treated with transpedicle screws with rods and intersomatic cages, andseven patients were treated the same way but without cage implantation.

Intra- and postoperative complications, reoperations

Two patients (2.4%) in the decompression alone group and onepatient (2.2%) in the fusion group suffered a durotomy during the surgery (**Table 3**). No patient in the decompression alonegroup and one patient (2.2%) in the fusion group had a postoperative wound infection. Other postoperative complications (e.g., urosepsis, hemorrhage, wound healing deficit) were seen in 6% and 6.6% of the patients, respectively. None of these differences were statistically significant. Furthermore, no patient died within three or six months postoperatively.

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Reoperations were performed in eight patients (9.4%) in the decompression alone group (one patient underwent two reoperations) and two patients (4.3%) in the fusion group(**Table 3**).Mean time to the second surgery was 192 days (range 8-565) in the decompression alone group and 280 days (range 33-527) in the fusion group. Six (75%) of the initially decompressed only patients underwent a fusion procedure during second surgery.

Further outcomes at 12 months follow-up

All patients improved from baseline to 12 months follow-up (**Appendix Table 1**). The patients of the fusion group improved more than the patients in the decompression alone group, however, factors influencing the treatment decisions were not accounted for these raw data.

Repeated measurements analysis for main outcomes

SSM symptoms

Graphical display of SSM symptoms from baseline to 36 months revealed a strong overall decrease from baseline to 6 months, a slighter decrease from 6 to 12 months, and remained fairly constanton the low level up to 36 months (**Figure 2a** left), as depicted by the corresponding loess curve. The pattern of the fusion group was similar to the overall trend, whereas there was a slight increase in the decompression group between 12 and 36 months **Figure 2a** (right and center).

The mixed effects model was fitted with random patient effects and with random slopes over time. When comparing the models, the AIC was in favor of the more complex random slopes model (chi-squared $p<0.001$). **Table 4a** shows the adjusted effect of fusion versus decompression alone surgery on SSM symptoms, which is estimated to be 0.06(95%

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confidence interval, CI: -0.16 to 0.27).On average, patients improved (decreased) by 1 point in SSM symptoms from baseline to 6 months follow-up. The improvement persisted at 12 months, 24 months, and 36 months (1.11, 1.10, 1.16 points, respectively). The improvement is larger than the established clinically meaningful change in SSM symptoms (0.48 points).[21]The confounders were2 versus 1 level decompression surgery, age, gender, body mass index (BMI) category, diabetes, cumulative illness rating scale (CIRS) musculoskeletal disorder subscore, and duration of symptoms before baseline in this model. Estimated random effects (bullet points) and slopes (small lines) were plotted against age at baseline in **Appendix Figure 1a**. It showed that older patients with higher levels of SSM symptoms developed slightly less favorable than the general decreasing trend.

SSM function

Graphical representation of SSM function showed an overall decrease from baseline to 36 months (**Figure 2b** left). A similar pattern as in SSM symptoms was visible in the clinical courses across patients with fusion and decompression alone surgery (**Figure 2b** right and center). When we fitted two mixed effects models, one with random patient effects and one with random slopes over time, we found that the AIC was smaller for the more complex model (chi-squared p = 0.048). The estimated effect of fusion versus decompression alone surgery on SSM function was -0.07 (95% CI: -0.25 to 0.10) (**Table 4b**) when adjusting for the confounders 2 versus 1 level decompression surgery, age, gender, body mass index (BMI) category, diabetes, cumulative illness rating scale (CIRS) musculoskeletal disorder subscore, and duration of symptoms before baseline. On average, patients improved (decreased) by 0.66 points in SSM function from baseline to 6 months follow-up. Improvement over time increased at 12 months, 24 months, and 36 months (0.79, 0.75, 0.71 points, respectively). The improvement considered clinically meaningful is 0.52 points for SSM function.[21]

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Estimated random effects (bullet points) and slopes (small lines) of this model were plotted against age at baseline in **Figure Appendix 1b**.

Discussion

This study examined the effect of decompression alone versus decompression plus fusion surgery in patients with symptomatic degenerative lumbar spinal stenosis (DLSS) and degenerative spondylolisthesis (DS). Our results demonstrated that both groups distinctly benefited from surgical treatment and thepositive effect persisted over three yearsfollow-up period. When adjusted for confounders, fusion surgery was not associated with a more favorableoutcome in both SSM scores as compared to decompression alone surgery.

Our results were in line with a quite recently published randomized controlled trial (RCT) by Försth et al.[16]In their trial the baseline SSM symptoms and function scores were comparable to our patient groups and after two years follow-up, they reported no significant differences in both scores between decompression surgery plus fusion and decompression alone surgeryin patients with degenerative spondylolisthesis. In a retrospective studyfrom 2013 with over 5390 patients (with and without spondylolisthesis) by Försth et al.,[31]the authorsidentified no patient-reported differences between the decompression only group and the fusion group two years postoperatively.Athiviraham et al.[32]came to a similar conclusion in their cohort study with 96 patientsat two years follow-up.

Ghogawala et al.,[19] on the other hand, reported in their RCT a significantly greater and clinically meaningful improvement in patients with degenerative spondylolisthesis who underwent decompression plus fusion compared to decompression alone. These results are in contrast to our findings, however, they reportedan improvement only in the physical-component summary of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The SF-36 is a generic outcome measure that doesnot measure specific

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neuroischemic features of DLSS which may be the dominant symptoms.[33] Furthermore, more patients underwent reoperation in the decompression alone group. Thismight have had a negative effect on thephysical-component summary score of SF-36 during the time from initial to secondary surgery.

Fusion surgery is associated with increased risk of major complications (i.e. acute myocardial infarct, respiratory failure, pneumonia)[4] as well as higher infection rates due to osteosynthesis material.Furthermore, the longer operating times of fusion compared to decompression alone surgery increase the risks of anesthesia and their consequences in the typical elderly lumbar spinal stenosis patient population.In these patients osteopenia or osteoporosis is also a common concomitant disease thatincreasesthe risk of screw loosening and sinking of the intersomaticcage.Nevertheless, surgeons use more and more fusion procedures[4] with the aim of preventing possible postoperative instability – especially if degenerative spondylolisthesis is present –despite the lack of a broadly accepted definition of this term.[34]The approach of treatingpatients with degenerative spondylolisthesiswith decompression and fusion is based on the results of a landmark study by Herkowitz and Kurz[18]from 1991 and subsequent long-term results of the same cohort.[35] However, this cohort was small (n=50), not randomized, did not address potential confounders or different techniques of fusion and did not use validated measures of treatment success. Moreover, only little new evidence has emerged to justify the increased risks and costs that are associated with fusionsince these studies.[36]

Fusion proceduresare also associated with increased resource use.[4] Costs of fusion surgery are twice as expensive in Switzerland (diagnosis related groups, SwissDRG standard treatment costs)and the estimated hospital stay is longer.

The main strength of this study was that only patients who underwent surgery on one or two adjacent levels anddegenerative spondylolisthesis were included. This study was designed to

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give us the opportunity to evaluate the effect of decompression alone versus decompression plus fusion surgery very specifically.The mixed models approach did adjust for the differences in age and other potential confounders at baseline which otherwise would have affected the results.Display of “raw” data might be useful for understanding differences in outcomes. However, as in non-randomized studies it does not account for systematic differences between treatment groups (with respect to covariates like age, BMI, etc.), it might also be misleading or even giving a biased impression. Further advantages of the LSOS-study include the multi-center setting and prospective collection of data, as well as the use of established questionnaires on degenerative lumbar spinal stenosis.

A limitation of this study wasthat that the treatment strategy (with or without fusion) was not randomized. If unaccounted for, this could have led to biased estimate of the effect of fusion. To account for this problem, adjustment for potential confounding was performed, however,only for measured covariates. Consequently, unmeasured confounders could have affected the difference between the two groups and hampereddirect comparisons with RCTs. Other limitations of the study were its small sample size and that only a third of the included patients have already reached 36 months follow-up. In addition, we do not have any data regarding operating time, length of hospital stay or the bone matrix density. These parameters might have influenced our results.

Conclusion

Among the patients with degenerative lumbar spinal stenosis our study confirms that in the two groups, decompression alone and decompression plus fusion, patients distinctively benefited from surgical treatment. When adjusted for confounders, fusion surgery was not associated with a more favorable outcome in both SSM scores as compared to decompression surgery alone.

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Figure Legends:

Figure 1. Study Flow

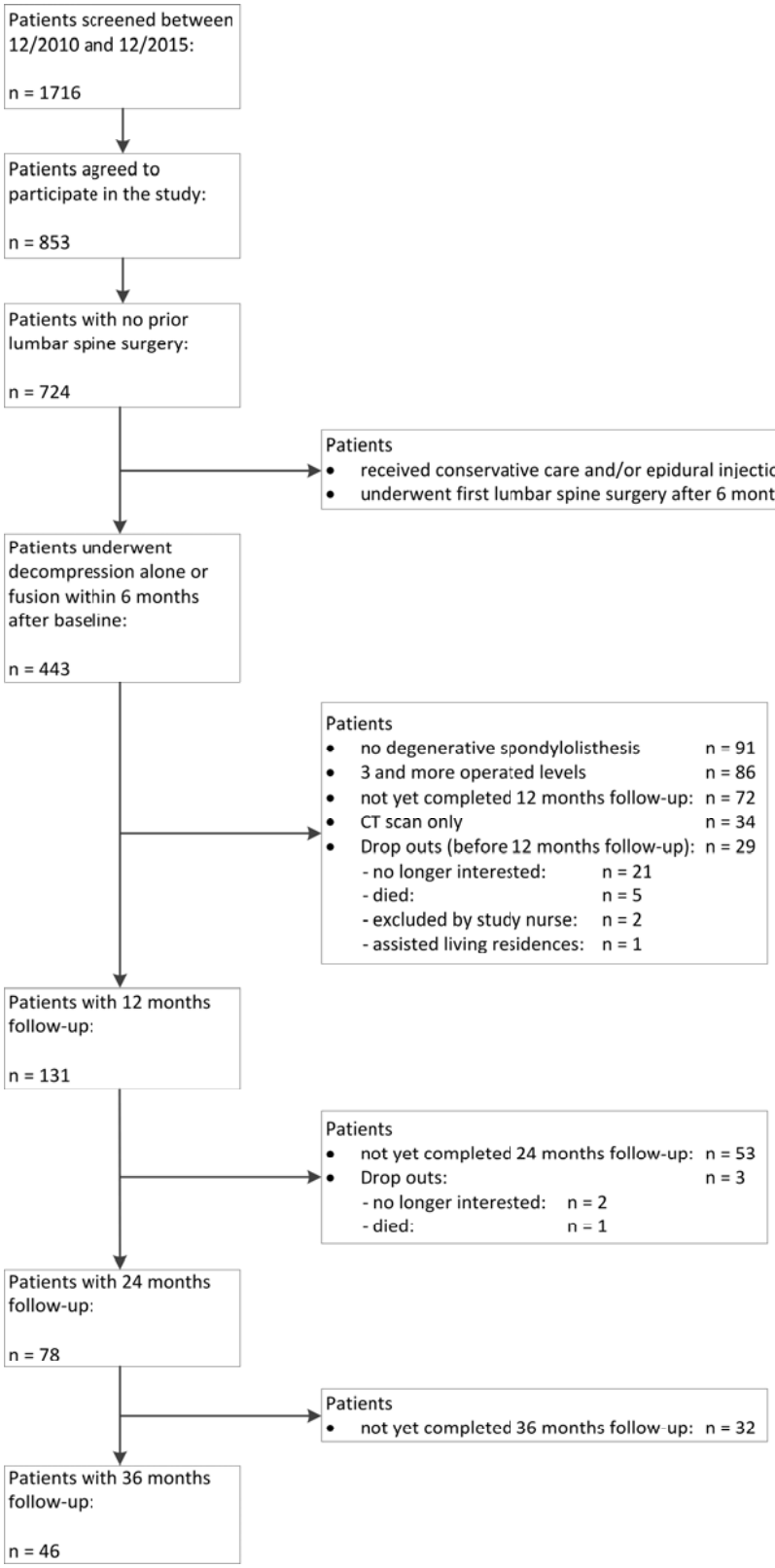

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Figure 2a. SSM symptoms score is displayed against time. The size of the bubbles represents the number of patients with the specific SSM symptoms score value. The overall trend is displayed by the solid black line, a smoothed estimate of the overall trend. The left most figure is based on all patients, the middle figure is based on patients with decompression alone, and the right most figure is based on patients with fusion.

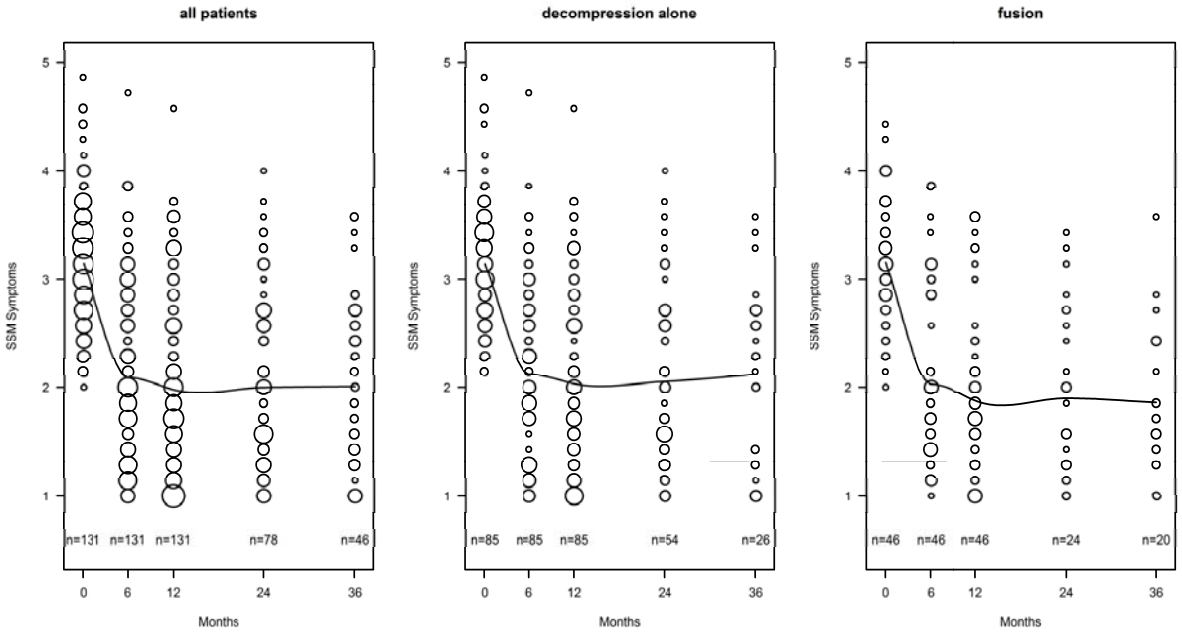

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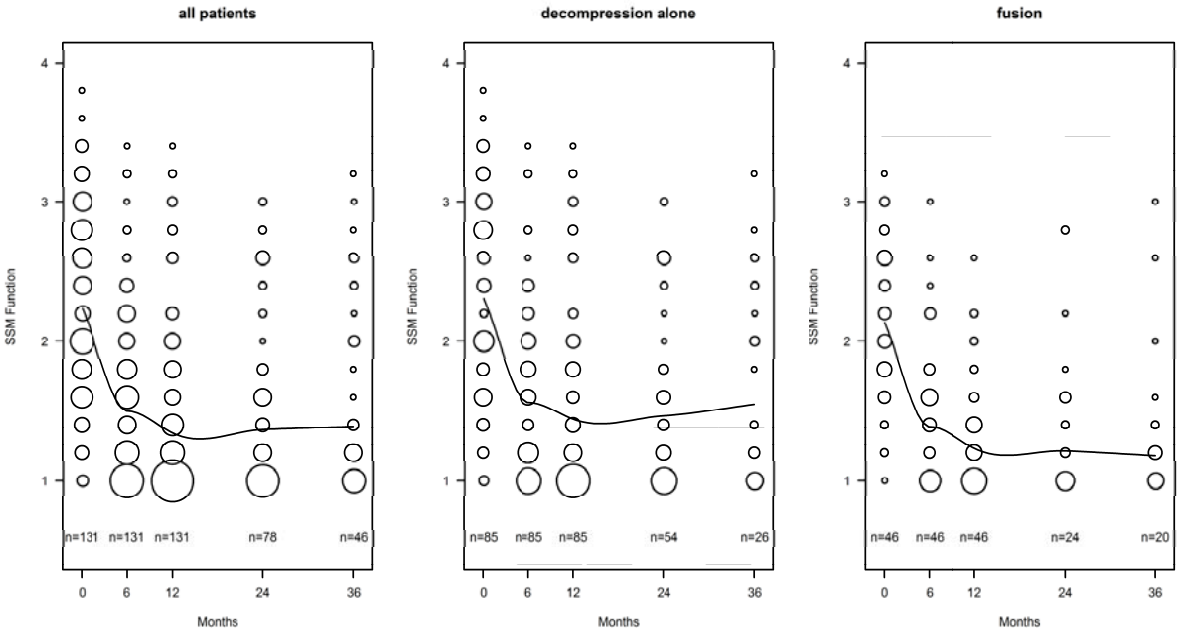
Figure 2b. SSM function score is displayed against time. The size of the bubbles represents the number of patients with the specific SSM function score value. The overall trend is displayed by the solid black line, a smoothed estimate of the overall trend. The left most figure is based on all patients, the middle figure is based on patients with decompression alone, and the right most figure is based on patients with fusion.



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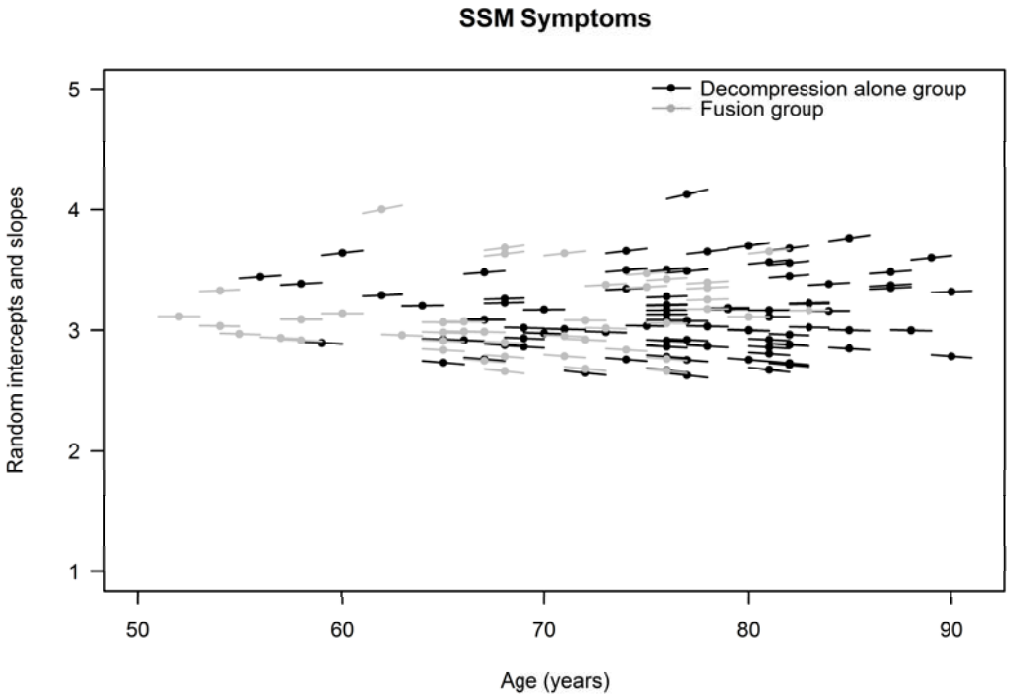
Appendix Figure 1a. Random intercepts and their slopes are displayed against age for the model with SSM symptoms as dependent variable. In general, a decreasing trend is visible, except for older patients aged 80 years and older. For them there seems to be a constant or slightly increasing trend, meaning stable or slightly increasing SSM symptoms values. Black intercepts and slopes are from patients in the decompression group, whereas grey intercepts and slopes are from patients in the fusion group.



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Appendix Figure 1b. Random intercepts and their slopes are displayed against age for the model with SSM function as dependent variable. There is no general trend visible. Black intercepts and slopes are from patients in the decompression group, whereas grey intercepts and slopes are from patients in the fusion group.

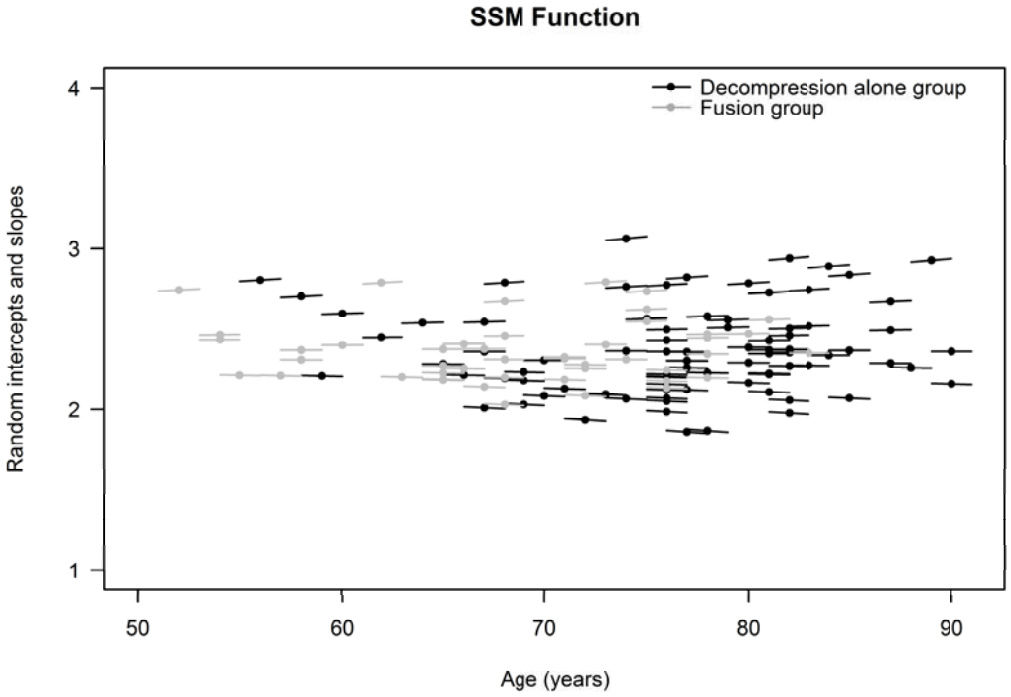

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Table 1: Patient characteristics at baseline

Characteristics	Decompression alone (n=85)	Fusion (n=46)	*p*
Age, mean (SD), y	75.4 (7.6)	68.0 (7.8)	<0.001
Female, n (%)	53 (62.4)	23 (50)	0.237
BMI, mean (SD), kg/m2	26.5 (4.7)	27.4 (4)	0.309
Diabetes, n (%)	14 (16.5)	3 (6.5)	0.179
Smoker, n (%)	12 (14.1)	11 (23.9)	0.244
Level of education, n (%)			0.521
compulsory education (1-9 years)	24 (28.2)	11 (23.9)	
Higher education/vocational training (no university) (10-12 years)	52 (61.2)	27 (58.7)	
University degree	9 (10.6)	8 (17.4)	
Work status, n (%)			0.065
Full- or part-time	7 (8.2)	11 (23.9)	
Retired	76 (89.4)	33 (71.7)	
Other	2 (2.4)	2 (4.4)	
Duration of symptoms, n (%)			0.138
< 3 months	6 (7.1)	3 (6.5)	
3 – 6 months	18 (21.2)	4 (8.7)	
6 – 12 months	16 (18.8)	5 (10.9)	
> 12 months	44 (51.8)	34 (73.9)	
Not available	1 (1.2)	0 (0)	
CIRS, mean (SD)	9.1 (3.7)	8.9 (3.9)	0.83
CIRS musculoskeletal disorders, mean (SD)	2.0 (0.5)	1.9 (0.4)	0.649
SSM symptoms, mean (SD)	3.2 (0.6)	3.2 (0.6)	0.986
SSM functions, mean (SD)	2.3 (0.7)	2.1 (0.5)	0.159
NRS, mean (SD)	6.6 (2.1)	6.6 (1.6)	0.917
FT, mean (SD)	66.2 (21.6)	65.5 (17.6)	0.842
EQ-5D-EL sum score, mean (SD)	66.9 (17.5)	66.7 (10.9)	0.924
EQ-5D-EL actual health status, mean (SD)	63.3 (26.4)	56.0 (19.3)	0.108
RMDQ, mean (SD)	12.5 (5.5)	12.1 (4.6)	0.679
Prior lumbar epidural steroid injection, n (%)	52 (61.2)	28 (60.9)	0.999

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BMI = body mass index; CIRS = Cumulative Illness Rating Scale; FT =Feeling Thermometer; HADS = Hospital Anxiety and Depression Scale; NRS = Numeric Rating Scale (NRS); RMDQ = Roland and Morris Disability Questionnaire;SSM = Spinal Stenosis Measure; *diagnosed in MRI

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Table 2: Comparison of perioperative outcomes and radiological parameters between the single-level and multi-level groups

Outcome	**Decompression alone (n=85)**	**Fusion (n=46)**	***p***
Decompression level, n (%)			
L2/L3	5 (5.9)	1 (2.2)	0.595
L3/L4	53 (62.4)	10 (21.7)	<0.001
L4/L5	72 (84.7)	38 (82.6)	0.95
L5/S1	6 (7.1)	5 (10.9)	0.674
Levels decompressed, n (%)			0.019
1	34 (40)	29 (63)	
2	51 (60)	17 (37)	
OP technique, n (%)			0.001
Conventional	13 (15.3)	21 (45.7)	
Microscopic	71 (83.5)	25 (54.3)	
Not available	1 (1.2)	0 (0)	
Number of moderate/severe levels, n (%)			<0.001
1	2 (2.4)	13 (28.3)	
2	17 (20)	12 (26.1)	
3	27 (31.8)	13 (28.3)	
4	26 (30.6)	4 (8.7)	
5	13 (15.3)	4 (8.7)	

n.a. = not available

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Table 3: Intra- and postoperative complications, reoperations

Outcome	Decompression alone (n=85)	Fusion (n=46)	*p*
Intraoperative complications, n (%)			
vascular injury	0 (0)	0 (0)	
durotomy	2 (2.4)	1 (2.2)	0.759
other	0 (0)	0 (0)	
none	83 (97.6)	45 (97.8)	
Postoperative complications, n (%)			
wound infection	0 (0)	1 (2.2)	0.302
osseous infection	0 (0)	0 (0)	
other	5 (6)	3 (6.6)	0.409
none	80 (84)	43 (93.4)	
postoperative mortality (death within 6 wk of surgery), n (%)	0 (0)	0 (0)	
postoperative mortality (death within 3 mo of surgery), n (%)	0 (0)	0 (0)	
Reoperation, indication for 2nd surgery			0.135
restenosis / foraminal stenosis (index level)	7 (8.2)	1 (2.2)	
adjacent segment stenosis	1 (1.2)	0 (0)	
infection	0 (0)	1 (2.2)	
back pain	1 (1.2)	0 (0)	

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Table 4a: Final random slopes model for SSM symptoms

Coefficients	Estimate	SE	*p*
(Intercept)	3.03	0.184	<0.001
Fusion	**0.06**	**0.107**	**0.599**
Change from baseline to …			
6 months	**-1.00**	**0.066**	**<0.001**
12 months	**-1.11**	**0.066**	**<0.001**
24 months	**-1.10**	**0.085**	**<0.001**
36 months	**-1.16**	**0.112**	**<0.001**

The estimated effects were adjusted for 2 versus 1 level decompression surgery, age, gender, body mass index (BMI) category, diabetes, cumulative illness rating scale (CIRS) musculoskeletal disorder subscore, and duration of symptoms before baseline.

On average, patients improved (decreased) by 1 point in SSM symptoms from baseline to 6 months follow-up. The improvement persisted, at 12 months, 24 months, and 36 months (1.11, 1.10, 1.16 points, respectively). The improvement is larger than the established clinically meaningful change in SSM symptoms (0.48 points). The estimated effect of fusion versus decompression surgery alone was small and non-significant,0.06 (p=0.599).

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Table 4b: Final random slopes model for SSM function

Coefficients	Estimate	SE	*p*
(Intercept)	2.30	0.15	<0.001
Fusion	**-0.07**	**0.087**	**0.414**
Changes from baseline to …			
6 months	**-0.66**	**0.057**	**<0.001**
12 months	**-0.79**	**0.056**	**<0.001**
24 months	**-0.75**	**0.068**	**<0.001**
36 months	**-0.71**	**0.086**	**<0.001**

The estimated effects were adjusted for 2 versus 1 level decompression surgery, age, gender, body mass index (BMI) category, diabetes, cumulative illness rating scale (CIRS) musculoskeletal disorder subscore, and duration of symptoms before baseline.

On average, patients improved (decreased) by 0.66 points in SSM function from baseline to 6 months follow-up. Improvement over time increased at 12 months, 24 and 36 months (0.79, 0.75, 0.71 points, respectively). The improvement considered clinically meaningful is 0.52 points for SSM function. Fusion versus decompression alone had a small and non-significant effect of -0.07 (p=0.414).

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Appendix Table 1: Further outcomes at 12 months follow-up

Outcomes	Decompression alone (n=85)	Fusion (n=46)	*p*
NRS, mean (SD)	2.5 (2.3)	2.3 (2.4)	0.662
FT, mean (SD)	27.1 (25.4)	23.2 (22.2)	0.386
EQ-5D-EL sum score, mean (SD)	84.4 (15.3)	86.3 (14.4)	0.478
EQ-5D-EL actual health status, mean (SD)	77.9 (18.3)	74.9 (24.7)	0.439
RMDQ, mean (SD)	7.0 (6.0)	6.3 (4.9)	0.469

FT =Feeling Thermometer; NRS = Numeric Rating Scale (NRS); RMDQ = Roland and Morris Disability Questionnaire

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