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Decompression alone or decompression with fusion for lumbar spinal stenosis: five-year clinical results from a randomized clinical trial

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Aims

We compared decompression alone to decompression with fusion surgery for lumbar spinal stenosis, with or without degenerative spondylolisthesis (DS). The aim was to evaluate if five-year outcomes differed between the groups. The two-year results from the same trial revealed no differences.

Methods

The Swedish Spinal Stenosis Study was a multicentre randomized controlled trial with recruitment from September 2006 to February 2012. A total of 247 patients with one- or two-level central lumbar spinal stenosis, stratified by the presence of DS, were randomized to decompression alone or decompression with fusion. The five-year Oswestry Disability Index (ODI) was the primary outcome. Secondary outcomes were the EuroQol five-dimension questionnaire (EQ-5D), visual analogue scales for back and leg pain, and patient-reported satisfaction, decreased pain, and increased walking distance. The reoperation rate was recorded.

Results

Five-year follow-up was completed by 213 (95%) of the eligible patients (mean age 67 years; 155 female (67%)). After five years, ODI was similar irrespective of treatment, with a mean of 25 (SD 18) for decompression alone and 28 (SD 22) for decompression with fusion (p = 0.226). Mean EQ-5D was higher for decompression alone than for fusion (0.69 (SD 0.28) vs 0.59 (SD 0.34); p = 0.027). In the no-DS subset, fewer patients reported decreased leg pain after fusion (58%) than with decompression alone (80%) (relative risk (RR) 0.71 (95% confidence interval (CI) 0.53 to 0.97). The frequency of subsequent spinal surgery was 24% for decompression with fusion and 22% for decompression alone (RR 1.1 (95% CI 0.69 to 1.8)).

Conclusion

Adding fusion to decompression in spinal stenosis surgery, with or without spondylolisthesis, does not improve the five-year ODI, which is consistent with our two-year report. Three secondary outcomes that did not differ at two years favoured decompression alone at five years. Our results support decompression alone as the preferred method for operating on spinal stenosis.

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Introduction

In degenerative lumbar spinal stenosis (LSS), the spinal canal is constricted by bulging of the disc and hypertrophy of the ligaments and facet joints, causing compression of neural structures. Patients typically have leg pain, back pain, and a reduced walking distance. Surgical decompression is considered more successful than conservative treatment,[1-4] and LSS has become the most common indication for spinal surgery.[5-7]

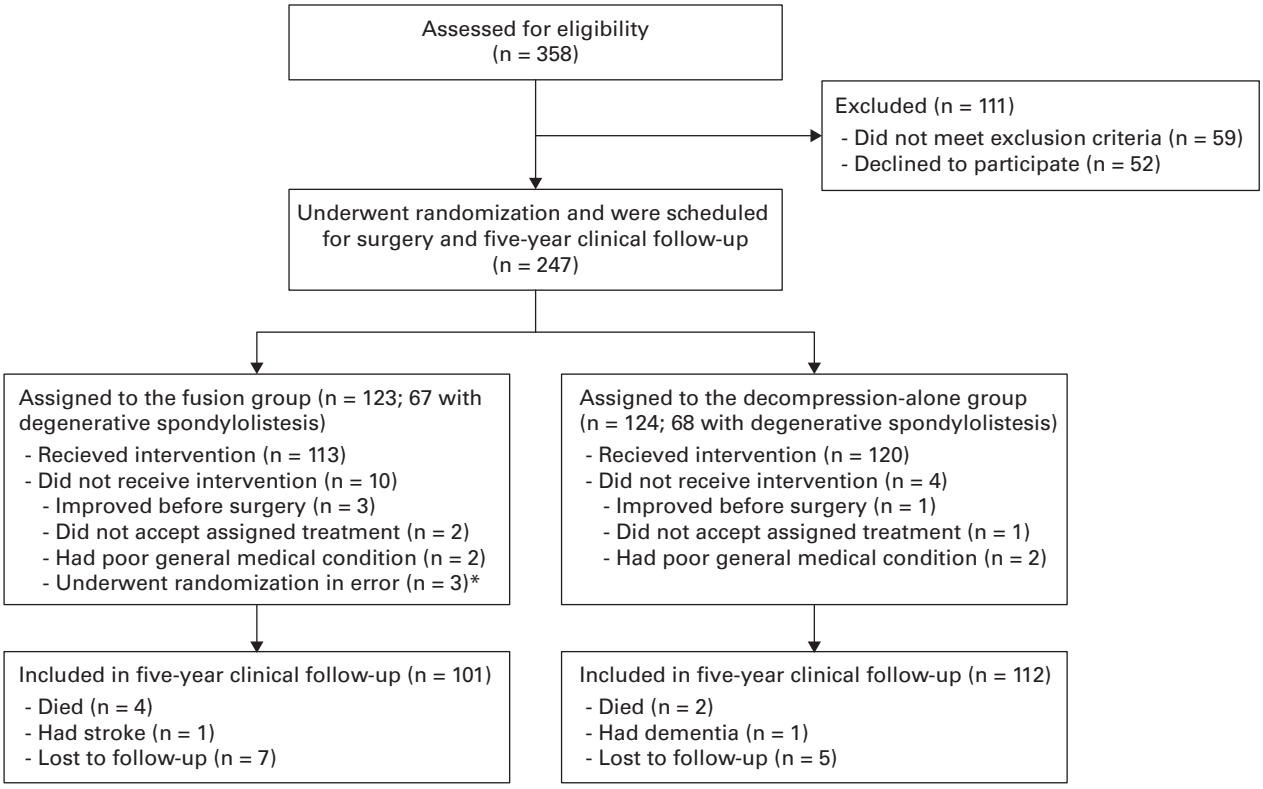

Fig. 1

Enrolment, randomization, treatment, and five-year clinical follow-up.

Table I. Inclusion criteria and exclusion criteria.

Inclusion criteria	Exclusion criteria
Aged 50 to 80 years	Spondylolysis
Pseudoclaudication in one or both legs and back pain, score > 30 on visual analogue scale range from 0 to 100 with higher scores indicating more pain	Degenerative lumbar scoliosis (Cobb angle > 20°)
1 or 2 adjacent stenotic segments (cross-section area of the dural sac ≤ 75 mm^2) between L2 and the sacrum on MRI	History of lumbar spinal surgery for spinal stenosis or instability
Duration of symptoms > 6 months	Stenosis not caused by degenerative changes
Written informed consent	Stenosis caused by a herniated disc
	Other specific spinal conditions (e.g. ankylosing spondylitis, cancer, or neurological disorders)
	History of vertebral compression fractures in affected segments
	Psychological disorders (e.g. dementia or drug abuse) that caused the surgeon to consider participation to be inappropriate

Degenerative spondylolisthesis (DS), defined as slippage of a vertebral body over the vertebral body below, may be present at the level of stenosis. In the Swedish Spinal Stenosis Study (SSSS),[8] DS was assessed from supine radiographs, which was common practice when the study was created. The sagittal alignment issue was less appreciated then, and the reliability of standing and flexion-extension films was questioned.[9–12]

Traditionally, fusion has often been added to decompression to prevent instability and recurrent stenosis at the decompressed segment, particularly in the presence of DS.[13–15] The disadvantage of fusion is thought to be increased stress above the fusion, with a potentially higher rate of cranial adjacent level degeneration and stenosis.[16] Furthermore, adding fusion incurs longer operating times, more bleeding, extended hospitalization, increased risk of severe complications in older patients, and higher operation costs.[5,8,17] Since the late 1990s, fusion rates have increased as have the mean patient age, comorbidity burden, and the rate of some perioperative complications.[18] In 2011, spinal fusion was the surgical procedure with the highest societal costs for the USA, and the proportion of spinal stenosis patients without spondylolisthesis that had fusion added to decompression increased from 17.8% in 2004 to 26.2% in 2009.[19-21]

Since 2015, several studies have scrutinized the need for fusion.[8,16,17,22–35] A recent meta-analysis concluded that there is now high-quality evidence of no difference in function between decompression alone and decompression with fusion in patients with LSS and DS at two years of follow-up. However, further studies of long-term outcomes are needed.[36] Two-year clinical results from the SSSS showed no advantage of decompression with fusion over decompression alone, regardless of DS.[8]

Table II. Baseline characteristics of the patients (n = 233).

Characteristic	Without spondylolisthesis		With spondylolisthesis	
	Fusion	Decompression alone	Fusion	Decompression alone
Patients, n	46	52	67	68
Mean age, yrs (SD)	66 (9)	66 (8)	68 (7)	67 (7)
Female sex, n (%)	19 (41)	29 (56)	51 (76)	56 (82)
Smoker, n (%)	7 (15)	9 (17)	9 (13)	10 (15)
ASA grade, n (%)[39]				
I or II	38 (83)	46 (88)	57 (85)	53 (78)
III	8 (17)	6 (12)	10 (15)	15 (22)
Mean ODI score (SD)	43 (15)	41 (15)	41 (13)	41 (14)
Mean EQ-5D score (SD)	0.40 (0.31)	0.37 (0.31)	0.39 (0.31)	0.36 (0.30)
Mean VAS score for back pain (SD)*	59 (24)	61 (25)	64 (20)	63 (24)
Mean VAS score for leg pain (SD)*	65 (19)	61 (24)	64 (21)	65 (22)
Mean vertebral slip, mm (SD)	N/A	N/A	7.3 (2.8)	7.3 (3.1)
Method for surgery, n†				
Bilateral laminotomies		11		12
Central decompression		41		56
Uninstrumented PLF	2		4	
Instrumented PLF	43		59	
PLIF	1		4	
Stenosis grade operated level(s) (232 pts)‡	(n = 46)	(n = 52)	(n = 66)	(n = 68)
Area ≤ 75, n (%)	41 (89)	50 (96)	63 (95)	65 (96)
Schizas C-D, n (%)	40 (87)	45 (87)	57 (86)	59 (87)
Mean dural sac area, mm^2 (SD)	44 (21)	41 (18)	39 (16)	40 (16)

*Higher scores indicate more severe pain.
†All fusion patients also had central decompression.
‡MRI was missing for one patient. Only the narrowest level is analyzed in cases of two-level surgery.
ASA, American Society of Anesthesiologists; EQ-5D, EuroQol five-dimension questionnaire; N/A, not applicable; ODI, Oswestry Disability Index; PLF, posterolateral fusion; PLIF, posterior lumbar interbody fusion; SD, standard deviation; VAS, visual analogue scale.

Radiological outcome was even better in the decompression alone group, with a lower rate of new stenosis than in the fusion group.[16,35] The present study investigated whether the five-year clinical outcomes were superior for any treatment group.

Methods

The SSSS (clinicaltrials.gov NCT01994512) is a multicentre open-label clinical superiority trial randomizing patients with LSS to either decompression alone or decompression with fusion.[8] Patients were sub-grouped for DS ≥ 3 mm on supine lateral conventional radiographs.[37] Patients who met the inclusion criteria (Table I) were randomized using a computer-generated random treatment assignment in a 1:1 ratio. Block sequences were stratified for the presence or absence of DS (Figure 1). Patients, treating surgeons, radiologists, research nurses, and statisticians were not blinded to allocation. The research sites, all in Sweden, were Uppsala University Hospital, four regional public health hospitals, and two private centres for spinal surgery. Patients were recruited in the outpatient clinics by the participating surgeons. Written and oral informed consent was a prerequisite to participate in the study. The trial surgeons at each centre were highly experienced in the two trial interventions. The Regional Ethical Review Board in Uppsala, Sweden, approved the SSSS trial. The study protocol in Swedish has been publicly available on the National Swedish Register for Spine Surgery (Swespine) website since August 2006.[38]

Procedures. The recruiting surgeon evaluated a preoperative MRI and conventional radiographs for stenosis ≤ 75 mm^2, DS ≥ 3 mm, and radiological exclusion criteria at inclusion. However, a dedicated spine surgeon (TK) assessed the radiological measures in Table II after completing the study as part of a radiological evaluation.[16]

Patients were randomized to a surgical procedure (decompression alone or decompression with fusion), and the surgeon then determined how to operate. The method for decompression alone was mostly central decompression resecting midline structures, sometimes midline-preserving bilateral laminotomies. Fusion methods used were posterolateral instrumented fusion, instrumented posterior lumbar interbody fusion (PLIF), and posterolateral uninstrumented fusion. Those were the most widely used fusion methods at the time the SSSS was created, and there is to our knowledge no clear evidence for the superiority of any fusion technique: differences are minor and vary between studies.[40–47] All fusions were combined with central decompression (Table I).

Clinical patient-reported data were collected from the Swespine questionnaire,[48] sent out from Swespine at baseline, one year, two years, and five years after surgery. If necessary, we reminded the patients to answer the questionnaires. Procedural settings, health economy, surgical details, and complications are further described in our two-year report from the SSSS and its supplementary appendix.[8]

Outcomes. The primary outcome was the Oswestry Disability Index (ODI)[49] at five-year follow-up. The index ranges from 0 to 100: 0 to 20 reflects minimal disability, 21 to 40 moderate disability, 41 to 60 severe disability, 61 to 80 crippled, and

Table III. Clinical outcomes at five years.

Outcome measure	All patients			Without spondylolithesis			With spondylolisthesis		
	Fusion	Decompression alone	p-value	Fusion	Decompression alone	p-value	Fusion	Decompression alone	p-value
Patients, n	101	112		42	49		59	63	
Mean ODI score (SD)	28 (22)	25 (18	0.226	27 (22)	27 (18)	0.839	28 (21)	23 (19)	0.152
Mean EQ-5D score (SD)	0.59 (0.34)	0.69 (0.28)	0.027	0.56 (0.38)	0.67 (0.28)	0.102	0.62 (0.31)	0.7 (0.28)	0.124
Mean VAS score for back pain (SD)	38 (32)	35 (29)	0.366	38 (33)	37 (29)	0.842	38 (33)	33 (29)	0.305
Mean VAS score for leg pain (SD)	34 (30)	32 (30)	0.672	34 (29)	32 (30)	0.751	34 (31)	32 (30)	0.776
			RR (95% CI)			**RR (95% CI)**			**RR (95% CI)**
Satisfied with surgery, % (n)*	61 (60)	66 (73)	0.91 (0.74 to 1.12)	60 (25)	67 (32)	0.89 (0.65 to 1.23)	61 (35)	66 (41)	0.93 (0.71 to 1.22)
Decrease in back pain, % (n)†	68 (64)	77 (83)	0.89 (0.75 to 1.05)	64 (25)	75 (36)	0.85 (0.64 to 1.14)	71 (39)	78 (47)	0.91 (0.73 to 1.12)
Decrease in leg pain, % (n)‡	66 (63)	78 (80)	0.85 (0.71 to 1.01)	58 (23)	80 (37)	0.71 (0.53 to 0.97)	73 (40)	77 (43)	0.95 (0.76 to 1.18)
Increased walking distance, % (n)§	53 (52)	58 (63)	0.92 (0.72 to 1.17)	50 (21)	57 (28)	0.88 (0.59 to 1.29)	55 (31)	58 (35)	0.95 (0.69 to 1.30)
	(n = 113)	**(n = 120)**		**(n = 46)**	**(n = 52)**		**(n = 67)**	**(n = 68)**	
Subsequent lumbar surgery, n (%)	27 (24)	26 (22)	1.1 (0.69 to 1.8)	11 (24)	10 (19)	1.2 (0.58 to 2.7)	16 (24)	16 (24)	1.0 (0.55 to 1.9)

*The question was: "How do you feel about the results of your back surgery?" Answer choices were, "I'm satisfied", "I'm doubtful", and "I'm dissatisfied". The data reflect the number of patients who answered "I'm satisfied".
†The question was: "How is your back pain today compared with before the operation?" The data reflect the number of patients who answered "completely gone", "greatly improved", or "somewhat improved".
‡The question was: "How is your leg or sciatic pain today compared with before the operation?" The data reflect the number of patients who answered "completely gone", "greatly improved", or "somewhat improved".
§The question was: "How far can you walk at a normal pace?" Answer choices were < 100 m, 100 to 500 m, 0.5 to 1 km, and > 1 km. The data reflect the number of patients reporting an increase from baseline.
CI, confidence interval; EQ-5D, EuroQol five-dimension questionnaire; ODI, Oswestry Disability Index; RR, relative risk; SD, standard deviation; VAS, visual analogue scale.

81 to 100 bedbound.[48] Secondary outcomes were the EuroQol five-dimension health questionnaire (EQ-5D), visual analogue scales for leg and back pain (VAS), and four global assessment questions.[48] The EQ-5D ranges 0 to 1, with higher scores denoting better quality of life. VAS ranges from 0 to 100, with the anchor points 'no pain' and 'worst possible pain', respectively. Global assessment questions are four single-item multiple choice questions regarding satisfaction with surgery, back pain, leg pain, and walking distance. Information about reoperations, defined as subsequent surgery on index and other lumbar levels, was collected from Swespine and patient medical records. The indications for reoperation were not standardized.

Statistical analysis. The study was powered to detect differences between the two treatment groups in ODI ≥ 12 and VAS ≥ 20. Statistical considerations before and during inclusion are fully described in our two-year report.[8] At follow-up, differences between treatment groups were analyzed by independent-samples *t*-test for continuous variables, dichotomized standard summary measures, and crude relative risk estimates for ordinal variables. Analyses were performed both with and without stratification for preoperative DS. Kaplan-Meier curves display the frequency of reoperations during follow-up by the allocated group. Analyses were done with SAS v. 9.4. and R 3.1 (SAS, USA).

Results

Between September 2006 and February 2012, 247 patients were enrolled in the trial. Of the 233 patients who underwent the assigned treatment, the mean age was 67 years (standard deviation (SD) 7.6), and 155 were female (67%). Baseline characteristics did not differ between the trial arms (Table II). Five years after surgery, six patients had died, and two were too ill to answer the questionnaires. Of the remaining 225 patients, 213 (95%) completed the five-year clinical follow-up (Figure 1).

Outcomes and reoperations. Clinical outcomes at the five-year follow-up are described in Table III. Patients treated with decompression alone had a trend towards a better clinical outcomes than the fusion group. However, the primary outcome (ODI) did not differ between the groups (mean 25 (SD 18), for the decompression alone group and 28 (SD 22), for the fusion group; p = 0.226, independent-samples *t*-test). ODI from baseline decreased by 16 units (95% confidence interval (CI)

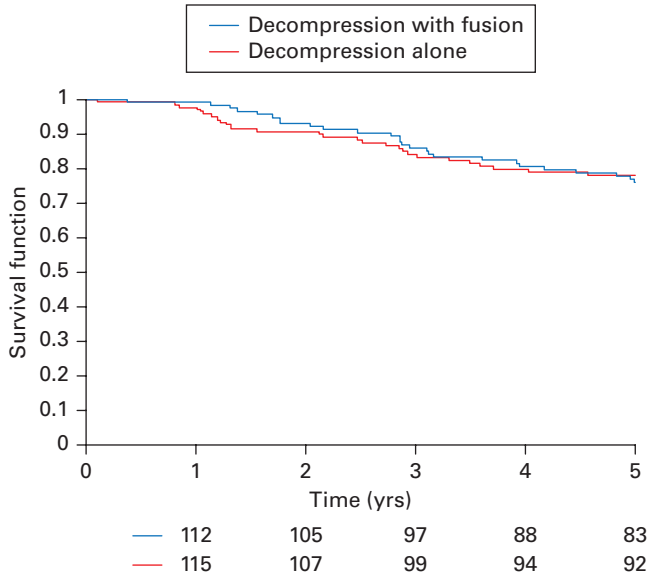

Fig. 2

Kaplan-Meier curve of subsequent surgery in the whole study population.

13 to 19) in the decompression alone group and by 14 (95% CI 10 to 17) in the fusion group, with 95% CI of -2 to 8 for the difference in change between the groups. Mean EQ-5D at five years was higher in the decompression alone group than in the fusion group (0.69 (SD 0.28) vs 0.59 (SD 0.34); p = 0.027, independent-samples *t*-test). The improvement in EQ-5D from baseline was also higher in the decompression alone group (0.32 (95% CI 0.26 to 0.39)) than in the fusion group (0.21 (95% CI 0.13 to 0.29)), 95% CI for the difference 0.01 to 0.21. In the subset of patients without a preoperative DS, fewer patients reported a decrease in leg pain in the fusion group (58%) than in the decompression alone group (80%); the relative risk for fusion group patients to report decreased leg pain was 0.71 (95% CI 0.53 to 0.97) when compared to the decompression alone group.

A total of 26 patients (22%) in the decompression alone group underwent subsequent surgery, with restenosis or foraminal stenosis at the index level being the most common cause (n = 19; 73%). Fusion of the primarily only decompressed level was performed in 14 cases. A total of 27 patients (24%) in the fusion group underwent further lumbar surgery, adjacent level stenosis being the most common cause (n = 23; 85%). Elongation of the fusion was carried out in nine (33%) of the reoperations in the fusion group. Stratification for the presence or absence of DS at baseline did not affect the results (Table III, Figure 2). No patients underwent reoperation for distal adjacent level stenosis. Six patients in the fusion group and three in the decompression alone group were revised for wound infections, eight of those nine within three months after surgery. These revisions are not included in the figures for reoperations.

A subgroup analysis was performed for patients with DS operated on at one level, with 82 of 91 (90%) available for follow-up. No differences were found between the decompression alone group (n = 41) and the fusion group (n = 41). At five-year follow-up, ODI was 22 in the decompression alone group and 28 in the fusion group (p = 0.165). ODI decreased from baseline by 18 units (95% CI 12 to 25) in the decompression alone group and by 11 (95% CI 5 to 17) in the fusion group; 95% CI for the difference in change was -1 to 16. EQ-5D was 0.72 in the decompression alone group and 0.64 in the fusion group (p = 0.208). The EQ-5D increase from baseline was 0.29 (95% CI 0.17 to 0.42) in the decompression alone group and 0.23 (95% CI 0.11 to 0.34) in the fusion group, 95% CI for the difference in change was -0.10 to 0.23. VAS for back pain was 31 in the decompression alone group and 39 in the fusion group (p = 0.225). VAS for leg pain was 29 in the compression alone group and 35 in the fusion group (p = 0.415).

Discussion

This five-year clinical follow-up of a randomized controlled trial (RCT) extends our previous results in that we found no benefits from adding fusion to lumbar decompression surgery. As in the previous two-year follow-up, the primary outcome (ODI) and secondary outcome change in ODI did not differ between the treatment groups. Three secondary outcomes – "EQ-5D at five years; entire group", "improvement in EQ-5D from baseline to five years; entire group", and "patient-reported decrease in leg pain at five years; DS subset of patients" – were better for the decompression alone group than for the fusion group. These differences were not present at two-year follow-up. However, no adjustments for multiple testing of the secondary outcomes were performed, and even if there was a difference in leg pain improvement in the Global Assessment domain, there was no difference in VAS for leg pain at five years.

The most common reasons for reoperation were adjacent level stenosis in the fusion group, and restenosis or foraminal stenosis in the decompression alone group. Reoperation rates did not differ between the groups, which is consistent with other studies.[36,50] No trend in the results suggests that patients with DS benefit more from fusion.

The results presented in this report concur with those reported in other recent studies which question the addition of fusion to decompression in surgery for spinal stenosis. Four recent RCTs which compared decompression alone with decompression and fusion for LSS surgery are the SLIP trial,[25] the Nordsten trial,[22] Inose et al's[26] study, and the SSSS,[8,16] the five-year results of which are presented in this paper. The SLIP trial on 66 patients, with one-level LSS and DS, a four-year follow-up, is the only one of the three that reported some benefits of adding fusion: fewer reoperations and more improvement from baseline to follow-up in the physical component summary score of the Medical Outcomes Study 36-Item Short-Form Health Survey. An associated editorial, however, interpreted the findings as no difference between the treatment groups.[25,30] In the Nordsten trial on 267 patients with one-level LSS and DS, two-year outcomes for decompression alone were non-inferior to decompression with instrumented fusion. Inose et al's[26] study on 85 patients with L4/L5 LSS with DS, a five-year follow-up, had a third trial arm, decompression with dynamic stabilization. No difference in outcomes was found between the groups. The SSSS trial (n = 233 patients) included one- and two-level stenosis, with or

without DS. In total, 91 of the patients had single-level LSS and DS (as in the SLIP and Nordsten trials). At two-year follow-up, we found no better clinical outcomes with added fusion, and new stenosis on MRI was less common after decompression alone than after decompression with fusion.[8,16] In the current five-year clinical follow-up, we still found no better outcomes with fusion; three secondary outcomes were better after decompression alone than after fusion. In addition to these three RCTs, several recent non-randomized studies reported no better outcomes for decompression with fusion,[17,23,24,29,31–34,36,51] and few found benefits with added fusion.[52,53]

Adding fusion has increased the risk of major complications, mortality, and resource use after spinal stenosis surgery in older adults.[5] Elongating the fusion, which was performed in one-third of the reoperations after fusion, may cause multiple repeated adjacent segment disease which eventually requires corrective surgery.[54] The knowledge that decompression alone confers no inferior outcome at a lower risk, and cost, is beneficial both for patients and society.

This RCT has a large sample size and a high follow-up rate (i.e. a low dropout rate). Having a follow-up after five years helps to fill a gap in the relative lack of evidence about long-term results after LSS surgery.

A potential limitation is that standing or flexion-extension radiographs were not included in the present study. We may have underestimated the spondylolisthesis and inadvertently included patients with 'intervertebral instability' who would have been excluded from other studies.[3,13,25] However, dynamic imaging has methodological issues: the relationship between imaging instability and symptoms is uncertain, and the concept of intervertebral instability is ill defined.[11] In the two-year report of the Nordsten study, 21% had instability on dynamic radiographs; fusion was nonetheless not better than decompression alone, even in a subgroup analysis of the 21% with instability.[22,55] In our two-year report, patients with slip > 7.4 mm, which is reasonable to believe are those most prone to be 'unstable', had outcomes that differed little from those with less or no slip.[8] Nonetheless, dynamic radiographs are frequently used and would have added value for the reader. Generalizability is limited by inclusion and exclusion criteria; for example, our study does not include patients with purely foraminal stenosis and central stenosis caused only by a herniated disc. Alternative fusion and decompression techniques such as oblique lumbar interbody fusion, extreme lateral interbody fusion, anterior lumbar interbody fusion, indirect decompression, and minimally invasive/endoscopic decompression have not been evaluated. Apart from DS, criteria for the indication of fusion have not been analyzed. Developmental LSS, for example, a condition with pre-existing short pedicles and a narrow bony spinal canal at many levels, was not assessed on MRI.[56,57] Spinopelvic malalignment was not addressed.[58] Thus, unidentified subgroups that would benefit from fusion may be present. Future studies will hopefully clarify this.

In conclusion, five-year ODI did not differ between decompression alone and decompression with fusion for LSS, with or without DS. The result is consistent with our two-year report from the same RCT.[8] Three secondary outcomes equal at two years were, at five years, better in the decompression alone group. Our findings support decompression alone as the primary operative method for treating LSS, even for patients with DS.

Take home message

- Adding fusion to decompression in lumbar spinal stenosis surgery does not improve five-year clinical outcomes.
- The presence of preoperative degenerative spondylolisthesis (DS) did not affect the study results.
- These findings support decompression without fusion as the primary method for the operative treatment of lumbar spinal stenosis, even in patients with DS.

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