# Decompression alone or decompression with fusion for lumbar spinal stenosis: a randomized clinical trial with two-year MRI follow-up

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## Aims

**The aims of this study were first, to determine if adding fusion to a decompression of the lumbar spine for spinal stenosis decreases the rate of radiological restenosis and/or proximal adjacent level stenosis two years after surgery, and second, to evaluate the change in vertebral slip two years after surgery with and without fusion.**

## Methods

**The Swedish Spinal Stenosis Study (SSSS) was conducted between 2006 and 2012 at five public and two private hospitals. Six centres participated in this two-year MRI follow-up. We randomized 222 patients with central lumbar spinal stenosis at one or two adjacent levels into two groups, decompression alone and decompression with fusion. The presence or absence of a preoperative spondylolisthesis was noted. A new stenosis on two-year MRI was used as the primary outcome, defined as a dural sac cross-sectional area ≤ 75 mm$^2$ at the operated level (restenosis) and/or at the level above (proximal adjacent level stenosis).**

## Results

**A total of 211 patients underwent surgery at a mean age of 66 years (69% female): 103 were treated by decompression with fusion and 108 by decompression alone. A two-year MRI was available for 176 (90%) of the eligible patients. A new stenosis at the operated and/or adjacent level occurred more frequently after decompression and fusion than after decompression alone (47% vs 29%; p = 0.020). The difference remained in the subgroup with a preoperative spondylolisthesis, (48% vs 24%; p = 0.020), but did not reach significance for those without (45% vs 35%; p = 0.488). Proximal adjacent level stenosis was more common after fusion than after decompression alone (44% vs 17%; p < 0.001). Restenosis at the operated level was less frequent after fusion than decompression alone (4% vs 14%; p = 0.036). Vertebral slip increased by 1.1 mm after decompression alone, regardless of whether a preoperative spondylolisthesis was present or not.**

## Conclusion

**Adding fusion to a decompression increased the rate of new stenosis on two-year MRI, even when a spondylolisthesis was present preoperatively. This supports decompression alone as the preferred method of surgery for spinal stenosis, whether or not a degenerative spondylolisthesis is present preoperatively.**

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## Introduction

Degenerative lumbar spinal stenosis, in which the spinal canal is constricted, causes back pain, leg pain, and restricted walking ability. Surgical decompression of the neural structures is generally considered more successful in the long term than conservative treatment:[1-4] lumbar spinal stenosis has become the most common indication for spinal surgery.[5-7] However, there is an ongoing debate as to whether decompression

**Table I.** Inclusion criteria and exclusion criteria.

| |
|---|
| **Inclusion criteria** |
| Age 50 to 80 years |
| Pseudoclaudication in one or both legs and back pain score, score > 30 on visual analogue scale range from 0 to 100, with higher scores indicating more pain |
| 1 or 2 adjacent stenotic segments (cross-section area of the dural sac ≤ 75 $mm^2$) between L2 and the sacrum on MRI |
| Duration of symptoms > 6 months |
| Written informed consent |
| **Exclusion criteria** |
| Spondylolysis |
| Degenerative lumbar scoliosis (Cobb angle > 20°) |
| History of lumbar spinal surgery for spinal stenosis or instability |
| Stenosis not caused by degenerative changes |
| 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 |

alone is sufficient, or if adding a lumbar fusion results in a better outcome.[8-11]

The clinical evidence for adding fusion to a decompression for lumbar spinal stenosis is weak.[8] There are unresolved concerns that decompression alone can result in restenosis at the same level, and conversely concerns that adding fusion would result in adjacent level stenosis above the fusion. Moreover, coexisting degenerative spondylolisthesis, where one vertebra has slipped forward in relation to the vertebra below, has traditionally been regarded as a risk factor for developing intervertebral instability and a worse clinical outcome after decompressing the slipped level alone. [12] Spinal stenosis with concomitant spondylolisthesis has therefore been thought to require the addition of fusion.[13,14]

In our first report from the Swedish Spinal Stenosis Study (SSSS), adding fusion to a decompression did not result in a better clinical outcome after two years, regardless of spondylolisthesis. Operating time, blood loss, operation costs, and length of hospital stay were higher for the fusion group.[8]

In the current report we compare decompression alone to decompression with fusion in relation to the risk of developing radiological restenosis and/or proximal adjacent level stenosis two years after surgery. In addition, the increase in degeneration at the proximal adjacent level two years after surgery is evaluated.

## Methods

**Study design.** The Swedish Spinal Stenosis Study (SSSS) (NCT01994512) was a multicentre open-label clinical superiority trial.[8] Patients who met the inclusion criteria (Table I) were randomized to decompression with fusion or decompression alone. The research sites were Uppsala University Hospital, four regional public health hospitals and two private centres for spine surgery in Sweden. The data presented in this paper are the radiological findings from the six (five public and one private) centres that scheduled patients for a two-year MRI as part of follow-up. Randomization was carried out using a web-based system for computer-generated random treatment assignment in a 1:1 ratio. Block sequences were used. Patients were stratified for the presence or absence of degenerative spondylolisthesis ≥ 3 mm on supine lateral conventional radiographs.[15] Patients, surgeons, radiologists, research nurses, and statisticians were not masked to allocation. The trial surgeons at each centre were highly experienced in the two trial interventions. The SSSS trial was approved by the regional ethical review board in Uppsala, Sweden. The study protocol in Swedish has been publicly available at the Swespine website since August 2006.[16]

**Procedures.** The methods for decompression surgery and fusion surgery were determined by the surgeon. Decompression alone was carried out either as central decompression resecting the midline structures or as bilateral laminotomies preserving the midline structures. Fusion methods used were instrumented posterolateral fusion, instrumented posterior lumbar interbody fusion (PLIF), and posterolateral uninstrumented fusion. All fusions were combined with central decompression (Table II). No minimal invasive surgery was used.

A routine MRI was obtained at baseline and two years after surgery. The axial T2-weighted images were evaluated at the operated level(s) and at the level cranially proximal to the operated level(s). Degenerative spondylolisthesis (in mm) was assessed from conventional lateral radiography at baseline and two years after surgery.[15] Flexion-extension radiographs were not obtained. Radiological data were assessed by an experienced spine surgeon (TK, KP) using the integrated digital measurements tools of Carestream VuePACS (Carestream Health, USA). The two-year MRI was independently re-evaluated for new stenosis by an experienced neuroradiologist (MS) for all 176 patients in the MRI follow-up. The main outcome results are those produced by the spinal surgeon (TK); the radiologist's measurements were used for sensitivity analysis. The two radiology evaluators (TK, MS) met in person to coordinate definitions before they started reading. All implants were made of titanium: artefacts compromising the morphology and measurement of the dural sac area were not seen. MRI scanners were at this time in clinical routine set to minimize blurring from titanium. Furthermore, the narrowest level is almost always at the disc, which is 5 to 10 mm cranially to the pedicle screws.

**Table II.** Baseline characteristics of the patients.*

| **Characteristic** | **Without spondylolisthesis** | | **With spondylolisthesis** | |
|---|---|---|---|---|
| | **Fusion** | **Decompression alone** | **Fusion** | **Decompression alone** |
| Patients, n | 44 | 48 | 59 | 60 |
| Mean age, yrs (SD) | 65 (9) | 65 (8) | 67 (7) | 67 (7) |
| Female sex, n (%) | 26 (59) | 25 (52) | 44 (75) | 50 (83) |
| Smoker, n (%) | 7 (16) | 8 (17) | 9 (16) | 8 (14) |
| **ASA grade, n (%)** | | | | |
| 1 or 2 | 36 (82) | 40 (87) | 48 (83) | 45 (76) |
| 3 | 8 (18) | 6 (13) | 10 (17) | 14 (24) |
| Mean ODI (SD) | 43 (16) | 40 (15) | 41 (13) | 41 (13) |
| Mean EQ-5D score (SD) | 0.39 (0.32) | 0.37 (0.31) | 0.37 (0.31) | 0.36 (0.29) |
| Mean VAS score for back pain (SD)† | 60 (25) | 59 (25) | 64 (21) | 64 (23) |
| Mean VAS score for leg pain (SD)† | 65 (19) | 60 (24) | 64 (22) | 65 (23) |
| Mean vertebral slip, mm (SD)‡ | 1.7 (2.3) | 0.6 (1.4) | 7.4 (2.8) | 7.4 (3.1) |
| **Levels of surgery, n (%)** | | | | |
| 1 | 22 (50) | 27 (56) | 41 (69) | 39 (65) |
| 2 | 22 (50) | 21 (44) | 18 (31) | 21 (35) |
| **Stenosis grade operated level(s)‡** | | | n = 58* | |
| Area ≤ 75, n (%) | 40 (91) | 46(96) | 56 (97) | 57 (95) |
| Schizas C-D, n (%) | 38 (88) (n = 43)** | 41 (85) | 51 (88) | 51 (85) |
| Mean dural sac area, mm$^2$ (SD) | 43 (18) | 41 (18) | 38 (15) | 41 (17) |
| **Disc degeneration adjacent level** | | | n = 58* | |
| Type I, n (%) | 0 (0) | 1 (2) | 0 (0) | 0 (0) |
| Type II, n (%) | 3 (7) | 4 (8) | 2 (3) | 6 (10) |
| Type III, n (%) | 20 (45) | 18 (38) | 23 (40) | 24 (40) |
| Type IV, n (%) | 19 (43) | 20 (42) | 29 (50) | 30 (50) |
| Type V, n (%) | 2 (5) | 5 (10) | 4 (7) | 0 (0) |
| **Method of surgery, n (%)§** | | | | |
| Bilateral laminotomies | | 10 (21) | | 12 (20) |
| Central decompression | | 38 (79) | | 48 (80) |
| Uninstrumented PLF | 2 (5) | | 4 (7) | |
| Instrumented PLF | 41 (93) | | 51 (86) | |
| PLIF | 1 (2) | | 4 (7) | |
| **Stenosis grade adjacent level (186 pts)¶** | n = 40 | n = 44 | n = 51 | n = 51 |
| Area ≤ 75 mm, n (%) | 3 (8) | 4 (9) | 2 (4) | 3 (6) |
| Schizas C-D, n (%) | 1 (3) (n = 39)** | 3 (7) | 0 (0) | 2 (4) |
| Mean dural sac area, mm$^2$ (SD) | 126 (38) | 123 (37) | 130 (34) | 138 (46) |

*1 missing patient. Baseline MRI could not be localized.
†Scores on the VASs for back pain and leg pain range from 0 to 100, with higher scores indicating more severe pain.
‡Only the narrowest/most slipped level is analyzed in cases of two level surgery.
§All fusion patients also had central decompression. PLIF means Instrumented PLF+interbody fusion, posterior approach.
¶MRI axial cut lines of adjacent level were missing for 25 patients.
**1 missing value. T2 axial not available. Area assessed from T1.
ASA, American Society of Anesthesiologists; EQ-5D, EuroQol five-dimension index; ODI, Oswestry Disability Index; PLF, posterolateral fusion; PLIF, posterior lumbar interbody fusion; SD, standard deviation; VAS, visual analogue scale.

**Patients.** Between 26 September 2006 and 14 February 2012, 222 patients were enrolled. Of the 211 who received the assigned treatment (103 decompression with fusion and 108 decompresion alone) the mean age was 66 (SD 7.6): 145 (69%) were women. The baseline characteristics did not differ between the trial arms (Table II). Two years after surgery, two patients had died, two were too ill to participate in the radiological follow-up, two had initially been operated on at the wrong level, and ten had already undergone subsequent lumbar surgery and could not, therefore, be evaluated (Figure 1). Of the remaining 195 patients, 176 (90%) had a two-year MRI with T2 axial and sagittal images covering the operated levels(s) and the proximal adjacent level (Figure 1). Two-year conventional lateral radiographs were available for 192 of the 195 patients above.

**Outcomes.** The primary outcome was a new spinal stenosis on two-year MRI, either restenosis at the operated level(s), a proximal adjacent level stenosis, or both. Stenosis was defined as a dural sac cross-sectional area of ≤ 75 mm$^2$. The cut-off of ≤ 75 mm$^2$, which was also used as an inclusion criteria, is commonly used for preoperative evaluation and based on experimental studies.[2,17] Secondary outcomes from MRI for stenosis were dural sac morphology according to Schizas (grades C-D regarded as stenosis)[18] and absolute dural sac area (mm$^2$). Disc

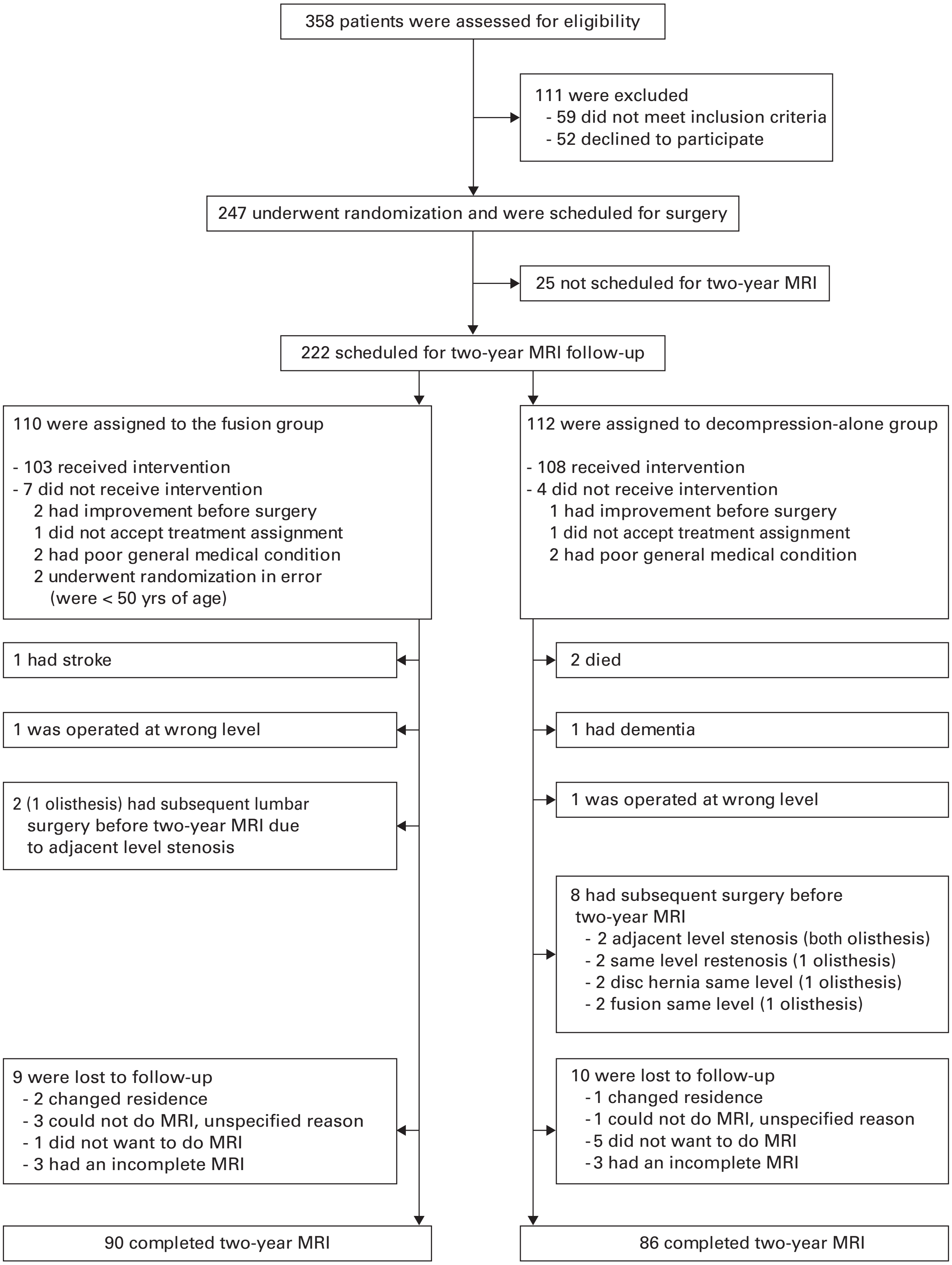


Fig. 1

Enrollment, randomization, treatment, and two-year MRI follow-up.

**Table III.** Radiological outcomes at two years.

| Variable | All patients | | p-value | Without spondylolisthesis | | p-value | With spondylolisthesis | | p-value |
|---|---|---|---|---|---|---|---|---|---|
| | | | | B0 | A0 | | B1 | A1 | |
| | Fusion | Decompression alone | | Fusion | Decompression alone | | Fusion | Decompression alone | |
| **MRI, n** | 90 | 86 | | 38 | 40 | | 52 | 46 | |
| **Restenosis and/or adjacent level stenosis*** | | | | | | | | | |
| Dural sac area ≤ 75 mm, n (%) | 42 (47) | 25 (29) | 0.020§ | 17 (45) | 14 (35) | 0.488§ | 25 (48) | 11 (24) | 0.020§ |
| Dural sac morphology (Schizas) C-D, n (%) | 36 (40) | 20 (23) | 0.023§ | 16 (42) | 12 (30) | 0.346§ | 20 (38) | 7 (15) | 0.013§ |
| **Proximal adjacent level stenosis** | | | | | | | | | |
| Dural sac area ≤ 75 mm, n (%) | 40 (44) | 16 (17) | < 0.001¶ | 17 (45) | 6 (15) | 0.009¶ | 23 (44) | 10 (22) | 0.033¶ |
| Dural sac morphology (Schizas) C-D, n (%) | 36 (40) | 13 (15) | < 0.001¶ | 16 (42) | 7 (18) | 0.033¶ | 20 (38) | 6 (13) | 0.009¶ |
| **Restenosis at operated level†** | | | | | | | | | |
| Dural sac area ≤ 75 mm, n (%) | 4 (4) | 12 (14) | 0.036§ | 0 (0) | 9 (22) | 0.004§ | 4 (8) | 3 (7) | 1.00§ |
| Dural sac morphology (Schizas) C-D, n (%) | 1 (1) | 7 (8) | 0.032§ | 0 (0) | 6 (15) | 0.026§ | 1 (2) | 2 (4) | 0.599§ |
| **Mean dural sac area, mm$^2$ (SD)** | | | | | | | | | |
| Operated level† | 196 | 128 | < 0.001** | 199 | 121 | < 0.001** | 193 | 134 | < 0.001** |
| Proximal adjacent level | 94 | 123 | < 0.001** | 91 | 123 | 0.002** | 96 | 124 | 0.006** |
| Operated level(s) and proximal adjacent level* | 92 | 99 | 0.236** | 90 | 94 | 0.622** | 94 | 104 | 0.227** |
| Increase in adjacent level disc degeneration‡ | 0.067 | -0.058 | 0.20** | 0.079 | -0.15 | 0.012** | 0.058 | 0.022 | 0.783** |
| **Plain radiographs, n** | 98 | 94 | | 41 | 43 | | 57 | 51 | |
| Mean degree of vertebral slip, mm (SD)* | 4.4 (3.7) | 5.5 (4.4) | 0.062** | 1.9 (2.6) | 2.0 (2.6) | 0.861** | 6.2 (3.2) | 8.3 (3.5) | 0.002** |

*Only the narrowest of the two or three levels is analyzed.
†Only the narrowest/most slipped level is analyzed in cases of two level surgery.
‡Degeneration according to Pfirrman (grade I to V, V being worst). Increase from baseline. Decrease is reported as negative increase.
§Fisher's exact test.
¶Chi-squared test with Yates' continuity correction.
**Independent-samples *t*-test.
SD, standard deviation.

degeneration at the proximal adjacent level was also assessed on MRI (Pfirrmann grade I to V, V being worst).[19] The grade of vertebral slip (mm), was assessed for operated level(s) using conventional lateral radiographs. Negative spondylolisthesis ('retrolisthesis') was considered equal to no spondylolisthesis and registered as 0 mm. Using negative values would have underestimated the spondylolisthesis on a group level.

Patient-reported outcome measures included the Oswestry Disability Index (ODI), Euro-Qol five-dimension health questionnaire (EQ-5D), and visual analogue scales (VAS) for leg and back pain.[20] The ODI (range 0 to 100, with 100 being worst) measures the degree of disability and quality in life in patients with low back pain. The EQ-5D (range 0 to 1, with 0 being worst) measures quality of life. The VAS ranged from 0 to 100, with 100 being worst. ODI, EQ-5D, and VAS scores were patient-reported data obtained from validated questionnaires collected from Swespine.[8]

**Statistical analysis.** There were four groups: fusion with spondylolisthesis, fusion without spondylolisthesis, decompression alone with spondylolisthesis, and decompression alone without spondylolisthesis. The number of patients needed in each group to achieve sufficient power was estimated for the primary clinical outcome, not for the radiological outcome. Since the distribution of patients with and without spondylolisthesis was more even than expected, the total sample size could be revised to a lower number than initially calculated. At follow-up, differences between the treatment groups were analyzed by independent-samples *t*-test for continuous variables (Welch's two-sample *t*-test, independent-samples *t*-test) and by dichotomized standard summary measures for ordinal variables (Fisher's exact test, Pearson's chi-squared test with Yates' continuity correction). Analyses were performed both with and without stratification for preoperative degenerative spondylolisthesis. We evaluated interobserver reliability between orthopaedic surgeon and radiologist using paired *t*-tests and confidence intervals (CIs). Pfirrmann disc degeneration, which is really an ordinal variable (I, II, III, IV, V), was analyzed as a quantitative variable (1, 2, 3, 4, 5) for the sake of simplicity. Analyses were done using SAS v. 9.4. (USA) and R v. 3.1 (R Foundation for Statistical Computing, Austria). Statistical considerations

**Table IV.** Characteristics of patients with and without a new stenosis.

| Variable | No new stenosis | New stenosis | | |
|---|---|---|---|---|
| | All patients | All patients | Fusion | Decompression alone |
| Patients, n | 109 | 67 | 42 | 25 |
| **Baseline characteristics** | | | | |
| Age, yrs (SD) | 67 (7) | 66 (8) | 66 (8) | 67 (8) |
| Female sex, n (%) | 78 (72) | 47 (70) | 31 (74) | 16 (64) |
| **Clinical two-year outcomes** | | | | |
| Mean ODI (SD) | 26 (19) | 24 (17) | 27 (18) | 20 (14) |
| EQ-5D score (SD) | 0.60 (0.34) | 0.70 (0.24) | 0.68 (0.25) | 0.72 (0.24 |
| Mean VAS score for back pain (SD)* | 35 (31) | 37 (29) | 38 (30) | 35 (28) |
| Mean VAS score for leg pain (SD)* | 35 (33) | 28 (27) | 29 (26) | 27 (30) |

*Scores for back pain and leg pain range from 0 to 100, with higher scores indicating more severe pain.
EQ-5D, EuroQol five-dimension index; ODI, Oswestry Disability Index; SD, standard deviation; VAS, visual analogue scale.

before and during inclusion are fully described in our two-year clinical report.[8]

## Results

**Outcomes at two years.** Our results are presented in Table III. Slightly fewer patients met the stenosis criteria using dural sac morphology Schizas C-D than using dural sac area, but the proportions were similar in all groups. On two-year MRI, 56 patients (32%) had an adjacent level stenosis and 16 (9%) had a restenosis at operated level ($p < 0.001$, Fisher's exact test).

The rate of new spinal stenosis (restenosis or/and proximal adjacent level stenosis) was higher in the fusion group than in the decompression-alone group (47% vs 29%; p = 0.020, Fisher's exact test). Proximal adjacent level stenosis was more common in the fusion group than in the decompression-alone group (44% vs 17%; $p < 0.001$, chi-squared test with Yates' continuity correction). In contrast, restenosis at the operated level was less common for patients in the fusion group (4% vs 14%; p = 0.036, Fisher's exact test).

Patients randomized to fusion had a higher rate of new spinal stenosis than patients in the decompression-alone group even in those with coexisting spondylolisthesis (48% vs 24%; p = 0.020, Fisher's exact test). There was no difference in the rate of new spinal stenosis between the fusion and decompression-alone groups among patients without a spondylolisthesis (45% vs 35%; p = 0.488, Fisher's exact test). Proximal adjacent level stenosis after fusion was more common than restenosis at the operated level after decompression alone (40 patients (44%) vs 12 (14%; $p < 0.001$, Fisher's exact test).

Overall, changes in Pfirrmann disc degeneration at the proximal adjacent level between the baseline and two-year MRI were similar in the fusion and decompression groups. Among spondylolisthesis patients, however, the fusion group showed more degeneration than the decompression-alone group (0.079 to -0.15; p = 0.012, independent-samples *t*-test): in the decompression-alone group slightly less degeneration than before surgery was recorded. In the decompression-alone groups with (n = 51) and without (n = 43) preoperative spondylolisthesis, the mean vertebral slip (in mm) increased from baseline to two-year follow-up from 7.2 (standard deviation (SD) 3.2) to 8.3 (SD 3.5) ($p < 0.001$, independent-samples *t*-test) and from 0.9 (SD 1.7) to 2.0 (SD 2.6) (p = 0.002, independent-samples *t*-test). The increase did not differ between the groups (p = 0.911).

Two-year MRI results were not available for patients who had undergone early reoperation. The missing data were unevenly distributed, with eight patients from the decompression-alone group and two from the fusion group (Figure 1). In a sensitivity analysis, we used the results of the ten clinical MRIs made prior to early reoperation, resulting in a group of 186 patients with overall proportions of any new radiological stenoses at 48% (44 patients) in the fusion group and 29% (27 patients) in the decompression-alone group (p = 0.010, Fisher's exact test). In an alternative sensitivity analysis, these ten patients were hypothetically considered to have a stenosis ≤ 75 $mm^2$ on a two-year MRI, resulting in 44 instances (48%) of new stenoses for fusion and 33 (35%) for decompression alone (p = 0.101, Fisher's exact test).

Small differences in results between the two examiners emerged for the evaluation of MRI variables. Dural sac area on the two-year MRI was evaluated at the level(s) of surgery and the cranial adjacent level; in total 417 levels on 176 patients. A paired analysis of the difference between observers resulted in a mean difference of 1.35 $mm^2$ and a 95% confidence interval (CI) of -0.6 to 3.3 (p = 0.185, paired *t*-test). The spinal surgeon found adjacent level stenosis or/and restenosis (≤ 75 $mm^2$) in 42 patients (47%) in the fusion group and in 25 patients (29%) in the decompression-alone group, whereas the neuroradiologist found stenosis in 44 (49%) and 25 (29%), respectively. In terms of dural sac morphology, the spine surgeon found stenosis in 36 patients (40%) in the fusion group and in 19 patients (22%) in the decompression-alone group, whereas the neuroradiologist found stenosis in 39 (43%) and 17 (20%), respectively.

The baseline characteristics and clinical outcomes of patients with and without new stenosis on two-year MRI are briefly compared in Table IV; it does not indicate any major differences.

## Discussion

This two-year radiological follow-up of a randomized controlled trial (RCT) of surgery for spinal stenosis showed that a new stenosis, defined as a stenosis at the operated level or/and the cranially adjacent level, occurred more frequently in the decompression and fusion group than in those who had undergone decompression alone. The increased rate of new stenosis after fusion was also significant in the subset of patients with a degenerative spondylolisthesis, a condition for which fusion has previously been regarded as particularly beneficial.

The increase of vertebral slip from baseline to two-year follow-up in the decompression-alone group was statistically significant, but by only 1.1 mm and, in our view, probably clinically insignificant. The increase in slip did not differ between patients with and without a preoperative spondylolisthesis. In our opinion, this indicates that the presence of degenerative spondylolisthesis, defined as a slip of more than 3 mm, can hardly be used as an indicator of instability.

Proximal level degeneration (Pfirrmann) in patients without a spondylolisthesis increased more after decompression and fusion than after decompression alone (here degeneration inexplicably decreased rather than increased). Although the difference is statistically significant, the absolute numbers are very small. Minor measurement errors may have affected the results, and we regard the findings as probably of little clinical relevance.

Radiological distal adjacent level stenosis was not evaluated in this study, since this is considered a lesser clinical problem than restenosis and proximal, adjacent stenosis. Furthermore, L5-S1, which was a distant level in 82% of the patients, is an unusual level for spinal stenosis.

We have found no other studies of two-year MRI follow-up after spinal stenosis surgery, but several with clinical follow-up. The evidence for the need for fusion is weak and based on older studies[13,14] with questionable validity.[21,22] Several recent studies and reviews have found minimal or no benefit from adding fusion, regardless of whether there is a coexisting degenerative spondylolisthesis.[8,9,11,23–31] Minimally invasive surgical techniques have shown comparable results to open decompression.[32,33] A scoring system was recently published to guide decision-making when choosing decompression with fusion or minimally invasive decompression for degenerative spondylolisthesis.[34] Our results suggest that decompression with fusion might even be inferior to decompression alone, by worsening the radiological outcome. Other disadvantages of adding fusion include longer operating times, more perioperative bleeding, extended hospitalization, an increased risk of severe complications in elderly patients, and higher operation costs.[5,8,23] Spinal fusion is, in fact, the surgical procedure connected with the highest costs in the USA.[35] There are also large regional differences in the use of spinal fusion that cannot be explained by differences in patient populations.[28,36] In Scandinavia, there is currently a trend towards less fusion in surgery for lumbar spinal stenosis with spondylolisthesis,[7] while fusion rates are high in the USA, and increased between 2004 and 2015.[37]

Some surgeons add fusion to decompression for spinal stenosis to minimize the risk of increased slippage postoperatively and restenosis at the operated level, especially if a spondylolisthesis is present preoperatively. This is weighed against the risk of causing proximal adjacent level stenosis from the stiffness of a fused segment. According to our results, adding a fusion increases the risk of a new stenosis at the adjacent level more than it prevents restenosis and increased slippage at the operated level. The presence of a preoperative spondylolisthesis is, according to our findings, not a predictor of the need for fusion. Patients with contraindications to fusion, such as older age, are a particular problem and may even be denied surgery when the need for fusion is overestimated. Our results, which present further evidence for the non-inferiority of decompression alone, make this less complex surgery a non-controversial alternative.

This study includes a large number of patients and has a high follow-up rate. The results, providing further evidence to support the use of decompression alone rather than decompression with fusion, may affect the choice of treatment. Furthermore, this is, to the best of our knowledge, the first two-year MRI follow-up after spinal stenosis surgery, and provides new basic data on the expected radiological outcome after such surgery.

A potential weakness of the present study is that we did not use standing or flexion-extension radiographs, which means that we may have underestimated the spondylolisthesis and included patients with so called intervertebral instability who would have been excluded from other studies.[3,9,13] However, the concept of vertebral instability has been deemed to be ill-defined, and the usefulness of flexion-extension radiographs has been questioned, as the relationship between imaging instability and symptoms is far from clear-cut.[38] Nevertheless, dynamic radiographs are commonly used and having them in the protocol might have been of interest for the reader. Another possible limitation is that the cut-offs for radiological stenosis, dural sac area ≤ 75 $mm^2$, and dural sac morphology (Schizas) grades C-D are validated for preoperative MRI but not for two-year MRI. Same-level restenosis on two-year MRI may in some cases have been caused by inadequate primary decompression rather than actual recurrent stenosis. If so, we have no reason to believe this to be more common in the decompression with fusion group, therefore it should not have affected our results and conclusions. Generalizability is limited by inclusion and exclusion criteria excluding, for example, foraminal stenosis, degenerative scoliosis, and patients who have undergone previous spinal surgery. Apart from degenerative spondylolisthesis, possible predictors for the need for fusion have not been analyzed, so there may be unidentified subgroups that would benefit from fusion. Developmental lumbar spinal stenosis, for example, a condition with pre-existing short pedicles and a narrow bony spinal canal at many levels, was not assessed on MRI. [39,40] This study presents only radiological outcomes from the SSSS, as a complement to clinical results that are presented elsewhere.[8] The correlation between baseline parameters, two-year MRI findings, and two-year clinical outcomes will be evaluated in separate reports. There is a delay in presenting the MRI results. We awaited the five-year clinical results intending to include them in the paper, however this proved too complex so the clinical results will be presented separately.

In this RCT of patients with lumbar spinal stenosis, new stenosis on two-year MRI was less common after decompression alone than after decompression and fusion, even for patients with a preoperative degenerative spondylolisthesis. Adding fusion seems to worsen the radiological outcome by increasing adjacent level stenosis more than it prevents same-level restenosis. Our results support decompression without fusion as the surgical treatment of choice for lumbar spinal stenosis, even for patients with a degenerative spondylolisthesis.

## Take home message

- This randomized clinical trial provides the first published two-year MRI follow-up after surgery for lumbar spinal stenosis.
- Patients who had a fusion had a significantly higher rate of new stenosis on two-year MRI, even when a preoperative degenerative spondylolisthesis was present.
- These findings provide support for the argument that decompression without fusion is the surgical treatment of choice for lumbar spinal stenosis, even for patients with a degenerative spondylolisthesis.

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