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Comparison of Decompression, Decompression Plus Fusion, and Decompression Plus Stabilization for Degenerative Spondylolisthesis

A Prospective, Randomized Study

Hiroyuki Inose, MD, PhD, Tsuyoshi Kato, MD, PhD,* Masato Yuasa, MD, PhD,* Tsuyoshi Yamada, MD, PhD,* Hidetsugu Maehara, MD, PhD,† Takashi Hirai, MD, PhD,* Toshitaka Yoshii, MD, PhD,* Shigenori Kawabata, MD, PhD,* and Atsushi Okawa, MD, PhD**

Study Design: This is a prospective, randomized controlled trial.

Objective: To prospectively assess the long-term clinical results of decompression alone, decompression plus fusion, and decompression plus stabilization for degenerative spondylolisthesis.

Summary of Background Data: Symptoms of lumbar spinal stenosis due to degenerative spondylolisthesis originate from compression of the dural sac or nerve root. Essentially, this condition is treated by performing a decompression of neural structures. Posterolateral lumbar fusion and posterior pedicle-based dynamic stabilization are additional techniques performed to ensure improved prognosis. However, to date, the selection of a surgical procedure for lumbar spinal stenosis due to degenerative spondylolisthesis remains debatable, especially in terms of the addition of instrumentation because of the few available prospective, randomized studies.

Materials and Methods: We randomly assigned patients who had 1 level lumbar spinal stenosis due to degenerative spondylolisthesis at the L4/5 level to undergo either decompression alone (decompression group), decompression plus fusion (fusion group), or decompression plus stabilization (stabilization group). Outcomes were assessed using the Japanese Orthopaedic Association and Visual Analogue Scale scores.

Results: In total, 85 patients underwent randomization. The follow-up rate at 5 years was 86.4%. The fusion and stabilization groups showed higher blood loss and a longer operative time than the decompression group. The fusion group showed longer postoperative hospital stay than the decompression group. In terms of clinical outcomes, all scores significantly improved postoperatively, and these outcomes were maintained at 5 years postoperatively in each group. There were no significant differences among the groups at 1 and 5 years postoperatively.

Conclusions: Additional instrumentation operation for low-grade (< 30%) degenerative spondylolisthesis did not result in superior results to decompression alone at 1 and 5 years postoperatively.

Level of Evidence: Level II.

Key Words: lumbar canal stenosis, degenerative spondylolisthesis, decompression, fusion, stabilization, randomized controlled trial

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Lumbar spinal stenosis due to degenerative spondylolisthesis is a widespread condition and has become one of the most common indications for spinal operation.[1] In early surgical practice, only the decompression of neural structures was performed. Further developments, such as spinal instrumentation using pedicle screws to fix the unstable spine, have been shown to improve surgical outcomes and inhibit progression of listhesis.[2] More recently, posterior pedicle-based dynamic stabilization was developed to prevent instability from joint degeneration and decompression procedure and to combat postoperative adjacent segmental stenosis.[3–5] In fact, the use of the stabilization method (the Graf system) maintained lordosis and preserved segmental motion in 80% of patients with symptomatic degenerative spondylolisthesis.[4] As the symptoms of lumbar spinal stenosis originate from compression of the dural sac or nerve root, the need for decompression of neural structures is apparent. In fact, a prospective, randomized study showed that patients with lumbar spinal stenosis who underwent operation showed significantly more improvement than patients who were treated nonsurgically.[6] However, to date, the selection of a surgical procedure for lumbar spinal

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From the *Department of Orthopaedics, Graduate School, Tokyo Medical and Dental University; and †Department of Orthopaedics, Suwa central Hospital, Nagano, Japan.
H.I. and T.K. contributed equally.
The authors declare no conflict of interest.
Reprints: Hiroyuki Inose, MD, PhD, Department of Orthopaedics, Graduate School, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8519, Japan (e-mail: inose.orth@tmd.ac.jp).

stenosis due to degenerative spondylolisthesis remains debatable, especially in terms of the addition of instrumentation because of the few available prospective, randomized studies.[7,8] Regardless, the results of prospective, randomized studies are inconsistent; for example, one study showed a superior outcome in patients who underwent decompression with fusion,[8] whereas another study showed no difference in clinical outcomes between decompression alone and decompression with fusion.[7] In 2007 in the United States, decompression alone was performed in 20.6% of patients with spondylolisthesis, whereas instrumentation operation was performed in 79.4% of patients.[1] Although decompression alone was suggested for the treatment of low-grade (<20%) degenerative spondylolisthesis in the clinical guidelines of the North American Spine Society,[9] in the United States, over 95% of patients with degenerative spondylolisthesis undergoing surgery now undergo a decompression with fusion regardless of the severity of the spondylolisthesis.[10] These facts indicate that a concrete procedure for patients with degenerative spondylolisthesis has yet to be established. Furthermore, no prospective studies have compared the clinical outcomes of these 3 procedures. Thus, to establish a consensus regarding whether it is better to fuse, stabilize, or neither, the purpose of this study was to prospectively assess the clinical results of decompression alone, decompression plus fusion, and decompression plus stabilization for degenerative spondylolisthesis.

MATERIALS AND METHODS

Patient Selection

This prospective, randomized trial was approved by our institutional research ethics committee and was registered with the University Hospital Medical Information Network clinical trials registry (UMIN000028114). Written informed consent was obtained from all enrolled patients. Between May 2003 and April 2012, 87 patients who underwent spinal operation for 1 level lumbar spinal stenosis with degenerative spondylolisthesis at the L4/5 level from 2 hospitals were screened. We excluded patients with a previous lumbar spinal operation, multilevel stenosis, or foraminal stenosis. Physicians explained to each patient the pathologic condition and the surgical indication, and upon patient approval of undergoing surgery, each patient was invited to participate in this study. Two patients refused to undergo randomization; therefore, the remaining 85 patients were randomly assigned to undergo decompression alone (decompression group), decompression and posterolateral fusion with autogenous iliac bone graft and pedicle screw fixation (fusion group), or decompression plus stabilization using the Graf system (stabilization group using a braided polypropylene tension band to link the titanium pedicle screws) in a 1:1:1 allocation by an independent doctor, according to computer-generated random number tables. Among the 85 patients, 2 had a major stroke, 1 had lumbar compression fracture, and 1 had severe dementia; the remaining 81 patients were eligible for the 5-year follow-up assessment. Of these 81 patients, 70 (86.4%) provided information on outcomes.

The diagnosis of lumbar spinal stenosis was based on the presence of typical symptoms, such as neurogenic claudication or radicular leg pain with associated neurological signs and the findings from magnetic resonance imaging scans and/or myelograms of stenosis at L4/5 level. Degenerative spondylosis was defined as the presence of >3 mm of spondylolisthesis of the L4 vertebra on a plain lateral radiograph. Dynamic instability was defined as a change of >10 degrees of angulation or >4 mm of translation of the vertebrae between flexion and extension of the spine.[6]

All trial surgeons routinely performed the 3 trial interventions.

Preoperative and Perioperative Patient Data

The following data were collected: age, sex, duration of operation, blood loss, duration of postoperative hospital stay, and major intraoperative and perioperative complications.

Clinical Follow-up

The following data were collected: the Japanese Orthopaedic Association (JOA) score (the score ranges from −6 to 29 based on 3 subjective symptoms, 3 clinical signs including straight-leg raising, 7 activities of daily living, and bladder function) and Visual Analogue Scale (VAS) scores for lower back pain and leg pain (ranging from 0 to 100 mm, with higher scores indicating more severe pain) before the operation, at 1 year postoperatively, and 5 years postoperatively.[11,12] The primary outcome measure was the VAS score for lower back pain with secondary outcomes including the JOA score and the VAS score for leg pain. The JOA score was obtained by the operator or other spinal surgeons. The VAS scores were completed without the assistance of the medical staff involved in this study. As for the radiographic evaluation, we investigated the degree of progression of slippage at postoperative year 5. Postoperative slip progression was defined as a change of >5% of slip progression in comparison to the preoperative neutral lateral radiograph.

Power Analysis

On the basis of the results of a previous prospective study,[2] a power analysis with a significance of 0.05, power of 0.80, an assumed SD of 2.0, and expected change in pain score for the lower back of 1.6 was identified to calculate the sample size for this study. A minimum number of 25 subjects was required to detect a significant change in the VAS score for lower back pain between the decompression and fusion groups. Assuming a 10% loss to follow-up, we decided to enroll >28 patients into each arm, yielding a minimum of 84 patients in total.

Statistical Analysis

Statistical analysis was performed with the assistance of a computer statistics program (JMP version 12.1.0; SAS Institute, Cary, NC). $P < 0.05$ were considered statistically significant. Clinical results were analyzed using the Fisher exact test with Bonferroni correction for categorical variables, and the Steel-Dwass multiple comparison test for nonparametric continuous variables. Data are presented as mean ± SD.

TABLE 1. Baseline Characteristics of the Patients

Characteristic	Decompression Group (N = 29)	Fusion Group (N = 31)	Stabilization Group (N = 25)	*P* (P_{D-F}/P_{D-S}/P_{F-S})
Age (y)	63.4 ± 8.6	61.2 ± 6.7	65.9 ± 5.7	0.93/0.71/0.47*
Female sex [n (%)]	12 (41)	20 (65)	17 (68)	0.36/0.18/0.99†
Degree of vertebral slip (mm)	6.5 ± 2.2	8.1 ± 3.8	6.5 ± 2.5	0.98/0.98/0.96*
Dynamic instability [n (%)]	12 (41)	13 (42)	10 (40)	> 0.99/> 0.99/> 0.99†

Plus-minus values are means ± SD.

*P_{D-F}, P_{D-S}, and P_{F-S} represent the comparisons between the decompression and fusion groups, the decompression and stabilization groups, and the fusion and stabilization groups, respectively, using the Steel-Dwass test.

†P_{D-F}, P_{D-S}, and P_{F-S} represent the comparisons between the decompression and fusion groups, the decompression and stabilization groups, and the fusion and stabilization groups, respectively, using the Fisher exact test with Bonferroni correction.

RESULTS

Baseline characteristics of the patients are shown in Table 1. There were no significant differences among the 3 groups in any of the preoperative variables. Regarding perioperative variables, mean blood loss was significantly higher and operative time was longer in the fusion and stabilization groups than in the decompression group ($P < 0.001$). In addition, mean blood loss was significantly higher and operative time was longer in the fusion group than in the stabilization group ($P = 0.013$ and 0.016, respectively). The duration of postoperative hospital stay was significantly longer in the fusion group than in the decompression group ($P = 0.005$) (Table 2). Concerning intraoperative and perioperative complications, dural tears occurred in 2 patients in the fusion group. Postoperative delusion occurred in 1 patient in the stabilization group. Meralgia paresthetica due to compression of the lateral femoral cutaneous nerve occurred in 5 patients in the fusion group and in 1 patient in the stabilization group. A postoperative symptomatic hematoma that required bed rest, but not reoperation, occurred in 1 patient in the decompression group and in 1 patient in the stabilization group. Pulmonary embolism occurred in 1 patient in the fusion group and in 1 patient in the stabilization group. Misplacement of pedicle screw occurred in 1 patient in the stabilization group (Table 2). Follow-up rates at 1 and 5 years postoperatively were 96.6% and 82.1% in the decompression group, 96.8% and 93.3% in the fusion group, and 100% and 82.6% in the stabilization group, respectively (Fig. 1). During the follow-up period, revision operation was performed in 1 patient in the fusion group because of nonunion of the fused segments and in 1 patient in the stabilization group because of misplacement of a pedicle screw. Regarding radiographic evaluation, postoperative slip progression was significantly higher in the decompression group and the stabilization group than in the fusion group ($P = 0.02$, 0.02, respectively). Interestingly, preoperative dynamic instability was not associated with postoperative slip progression in this study ($P > 0.99$). In terms of clinical outcome, all scores improved postoperatively in all groups (Fig. 2). Moreover, all outcome measures showed no statistical differences among the groups at 1 and 5 years postoperatively (Fig. 2).

DISCUSSION

In this prospective, randomized study, although decompression alone, decompression plus fusion, and decompression plus stabilization resulted in no statistical differences in terms of the subjective and patient-based

TABLE 2. Surgical Complications

Variable	Decompression Group (N = 29)	Fusion Group (N = 31)	Stabilization Group (N = 25)	*P* (P_{D-F}/P_{D-S}/P_{F-S})
Estimated blood loss	80.3 ± 62.5	334.8 ± 206.3	209.8 ± 111.8	< 0.001*/< 0.001*/0.013*†
Operation time	148 ± 46	244 ± 50	205 ± 39	< 0.001*/< 0.001*/0.016*†
Duration of hospital stay after surgery	11.6 ± 2.5	14.1 ± 3.6	13.9 ± 6.5	0.007*/0.16/0.74†
Postoperative slip progression (%)	26.1	0	26.3	0.02*/> 0.99/0.02*‡
Complications				
Any	1	8	5	0.08/0.26/> 0.99‡
Dural tear	0	2	0	—
Delusion	0	0	1	—
Hematoma	1	0	1	—
Meralgia	0	5	1	—
Pulmonary embolism	0	1	1	—
Misplacement of pedicle screw	0	0	1	—

Plus-minus values are means ± SD.

*Statistically significant.

†P_{D-F}, P_{D-S}, and P_{F-S} represent the comparisons between the decompression and fusion groups, the decompression and stabilization groups, and the fusion and stabilization groups, respectively, using the Steel-Dwass test.

‡P_{D-F}, P_{D-S}, and P_{F-S} represent the comparisons between the decompression and fusion groups, the decompression and stabilization groups, and the fusion and stabilization groups, respectively, using the Fisher exact test with Bonferroni correction.

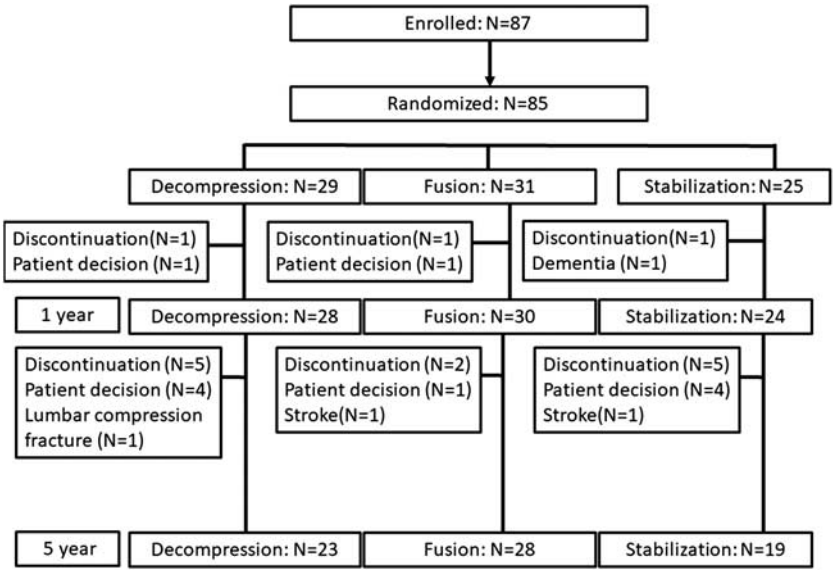

FIGURE 1. Consolidated standards of reporting trials flow diagram showing patient disposition.

outcomes at 1 and 5 years postoperatively, the amount of blood loss and duration of operation were least and shortest in the decompression group.

Some spinal surgeons consider degenerative spondylolisthesis with a 3 mm translation as a sign of instability,[13] leading some facilities to perform instrumentation operation for all patients with degenerative spondylolisthesis. In fact, decompression with fusion surgery has become the standard treatment for degenerative spondylolisthesis, and in the United States, over 95% of patients with degenerative spondylolisthesis undergoing surgery now undergo a decompression with fusion, regardless of the severity of the spondylolisthesis.[10] However, while the use of pedicle screws may lead to a higher

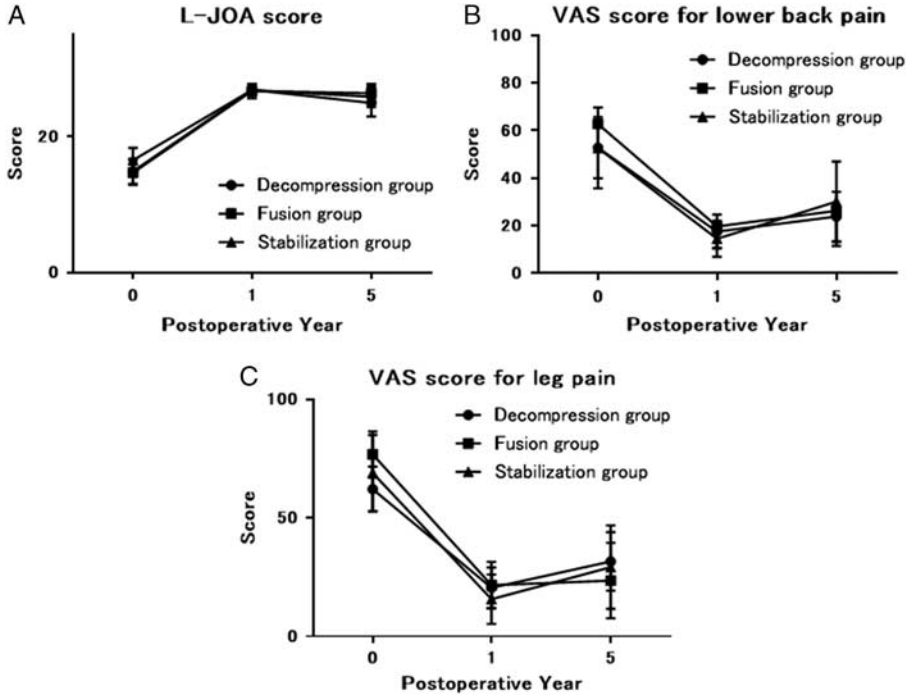

FIGURE 2. JOA scores (full mark, 29 points) (A), VAS (scores range from 0 to 100 mm, with higher scores indicating more severe pain) scores for lower back pain (B) and leg pain (C). Error bars indicate the 95% confidence intervals. JOA indicates Japanese Orthopaedic Association; VAS, Visual Analogue Scale.

fusion rate, it did not always lead to improvements in pain in the back and lower limbs.[14] Moreover, in line with the investigation of Forsth et al,[7] instrumentation of the slipped spine showed no superior results compared with nonfusion in the VAS scores for lower back pain and leg pain, as well as the JOA score in our study. These results may again raise the question of whether local spinal instability due to degenerative spondylolisthesis causes lower back pain and/or lower quality of life. In fact, a prospective comparative study showed no statistical differences between decompression with fusion and microendoscopic decompression measured using the JOA Back Pain Evaluation Questionnaire, which scores pain-related disorders, lumbar spine dysfunction, walking ability, social life dysfunction, and psychological disorders.[15] In addition, decompression without fusion for stable grade 1 spondylolisthesis patients with leg-dominant pain is significantly more cost-effective than instrumented fusion.[16]

Interestingly, the results of the present study were partially inconsistent with the findings of a previous randomized comparative study.[8] In their report, the addition of lumbar spinal fusion to laminectomy was associated with a greater increase in SF-36 physical component summary scores at 2 and 4 years postoperatively, whereas our results did not show this association in the JOA scores. Although both studies utilized different evaluation tools as an outcome measure, the JOA score was significantly correlated with the subscales of the SF-36, especially physical functioning.[17] This difference may arise from the operative procedures and reoperation rate between the studies. Although Ghogawala et al[8] performed complete laminectomy with partial removal of the medial facet joint, we performed wide fenestration, a procedure in which only the medial parts of the inferior facets and the adjoining ligamentum flavum are removed[18] for decompression to minimize damage to the facet joint and preserve the spinous process. Thus, postoperative instability caused by the decompression procedure may have occurred less in our study. In addition, the trial by Ghogawala and colleagues had a higher reoperation rate during the follow-up period in the decompression group than in the fusion group (34% vs. 14%), whereas our trial had overall low reoperation rates (0%, 3%, and 3%, respectively) as reoperation is a risk factor for poor surgical results.[19]

In our study, mean blood loss was significantly higher and operative time was longer in the fusion and stabilization groups than in the decompression group. Many studies have shown that prolonged operative time and blood loss correlated with higher intraoperative and postoperative complications.[20,21] Moreover, most spinal surgeons found that patients who underwent laminectomy alone required fewer blood transfusions compared with those who underwent instrumentation operation.[20] In this study, the 4 patients who required autologous blood transfusions were in the additional instrumentation groups. Additional instrumentation resulted in higher blood loss, leading to the higher possibility of blood transfusions. It scarcely needs to be said that blood transfusions are associated with their own risk of complications, such as infection and anaphylactic shock.[22] Even autologous blood transfusion poses the risk of contamination of blood with bacteria and hemolysis that result in massive loss of blood.[23]

Although the duration of postoperative hospital stay was longer in the fusion group compared with the decompression group, there was no difference between the decompression and stabilization groups. This difference may be due to the level of surgical invasiveness; decompression only requires a small incision and exposure to the lamina, whereas posterolateral fusion requires a larger skin incision and exposures to the lamina, facet joints, transverse processes, and intertransverse spaces. Interestingly, the overall duration of postoperative hospital stay was longer in this study compared with previous reports.[7,8] This difference may be influenced by Japanese customs; for example, Japanese patients prefer to be discharged after their stitches are removed.

Furthermore, instrumentation operation has more potential/theoretical risks compared with decompression alone because of higher bleeding and longer operative time, as well as pedicle screw-related complications, such as misplacement of the pedicle screw, nonunion, and future adjacent stenosis. In fact, a prospective study for isthmic spondylolisthesis showed that the risk of additional surgery on the lumbar spine was markedly higher when the fusion was performed with instrumentation.[24]

Within the instrumentation group, while the addition of fusion effectively inhibited the postoperative slip progression, the addition of stabilization could not inhibit postoperative slip progression in this study because there were no significant differences between decompression and stabilization in terms of occurrence of postoperative slip progression. Considering that most of patients enrolled in this study had a low-grade slip ($< 30\%$), the addition of fusion might be considered for the patients with high-grade slip ($> 30\%$) and/or high risk for postoperative slip progression.

To our knowledge, this study is the first prospective, randomized study to compare clinical outcomes of decompression alone, decompression plus fusion, and decompression plus stabilization for lumbar spinal stenosis due to degenerative spondylolisthesis. Methodological strengths of this investigation are that we used original surgical reports, discharge summaries, and outpatient medical records to extract accurate information, and we only chose patients with 1 level lumbar canal stenosis due to degenerative spondylosis at the L4/5 level to accurately compare the effects of surgical interventions. Another strength is the predefined analysis plan using validated subjective and patient recorded outcome measures to evaluate neurological recovery and pain.[12,17]

This study has several limitations. First, most of the study patients had a low-grade slip ($< 30\%$). As some authors defined greater instability as Meyerding grade $\geq$ II (slip $\geq 25\%$),[25,26] it would be necessary to prospectively compare the surgical outcomes of patients with greater instability only in future studies. Second, the operative procedures involved in this study did not contain recently developed, less invasive procedures, such as microendoscopic laminectomy or

minimally invasive interbody fusion. It would also be interesting to compare the outcomes of these procedures prospectively in the future. Third, the 5-year follow-up rate of the fusion group (93.3%) was higher than the decompression (82.1%) and stabilization (82.6%) groups. This factor could potentially threaten the validity of our conclusions. Although there is no consensus on the introduction of bias based on follow-up, most estimates suggest that <5% loss will have no effect, whereas >20% may pose serious threats to validity.[27] Thus, we do not believe that this difference had a serious effect on the study conclusions, as our follow-up rates were between these levels. Fourth, the sample sizes in the groups were small and the possibility of a type II error cannot be excluded. However, the values in all outcome measures were highly similar between groups. A post hoc sample size calculation showed that to detect a statistically significant between-group difference in VAS score for lower back pain of 2.4 mm, using the SDs from our trial, 1560 patients would be required in each treatment group. Therefore, we consider that the between-group difference in VAS score for lower back pain of 2.4 mm, even if statistically significant, are unlikely to be of clinical significance based on current evidence.[28]

Despite these limitations, we believe that the addition of instrumentation for low-grade (<30%) degenerative spondylolisthesis should be carefully considered until further prospective, randomized studies show obvious advantages of additional instrumentation over decompression alone.

In summary, decompression plus fusion or stabilization did not result in superior results to decompression alone at 1 and 5 years postoperatively in this prospective, randomized study of patients with 1 level lumbar spinal stenosis with low-grade (<30%) degenerative spondylolisthesis at the L4/5 level.

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