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Clinical outcome in decompression alone versus decompression and instrumented fusion in patients with isthmic spondylolisthesis: a prospective cohort study

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OBJECTIVE In the surgical treatment of isthmic spondylolisthesis, it is debatable whether instrumented fusion is mandatory in addition to decompression. The objective of this prospective cohort study was to assess the long-term effect of decompression alone compared with decompression and instrumented fusion in patients who underwent the intervention of their own preference. The results were compared with those in patients who underwent randomly assigned treatment.

METHODS The authors performed a prospective observational multicenter cohort study, including 91 patients with isthmic spondylolisthesis assigned to undergo either decompression alone (n = 44) or decompression and fusion (n = 47). The main outcomes were the Roland-Morris Disability Questionnaire (RDQ) scores and the patient's perceived recovery at the 2-year follow-up. Secondary outcomes were visual analog scale (VAS) leg pain and back pain scores and the reoperation rate. A meta-analysis was performed for data from this cohort study (n = 91) and from a randomized controlled trial (RCT) previously reported by the authors (n = 84). Subgroup analyses were performed on these combined data for age, sex, weight, smoking, and Meyerding grade.

RESULTS At the 12-week follow-up, improvements of RDQ scores were comparable for the two procedures (decompression alone [D group] 4.4, 95% CI 2.3–6.5; decompression and fusion [DF group] 5.8, 95% CI −4.3 to 1.4; p = 0.31). Likewise, VAS leg pain scores (D group 35.0, 95% CI 24.5–45.6; DF group 47.5, 95% CI 37.4–57.5; p = 0.09) and VAS back pain scores (D group 23.5, 95% CI 13.3–33.7; DF group 34.0, 95% CI 24.1–43.8; p = 0.15) were comparable. At the 2-year follow-up, there were no significant differences between the two groups in terms of scores for RDQ (difference −3.1, 95% CI −6.4 to 0.3, p = 0.07), VAS leg pain (difference −7.4, 95% CI −22.1 to 7.2, p = 0.31), and VAS back pain (difference −11.4, 95% CI −25.7 to 2.9, p = 0.12). In contrast, patient-perceived recovery from leg pain was significantly higher in the DF group (79% vs 51%, p = 0.02). Subgroup analyses did not demonstrate a superior outcome for decompression alone compared with decompression and fusion. Nine patients (20.5%) underwent reoperation in total, all in the D group. The meta-analysis including both the cohort and RCT populations yielded an estimated pooled mean difference in RDQ of −3.7 (95% CI −5.94 to −1.55, p = 0.0008) in favor of decompression and fusion at the 2-year follow-up.

CONCLUSIONS In patients with isthmic spondylolisthesis, at the 2-year follow-up, patients who underwent decompression and fusion showed superior functional outcome and perceived recovery compared with those who underwent decompression alone. No subgroups benefited from decompression alone. Therefore, decompression and fusion is recommended over decompression alone as a primary surgical treatment option in isthmic spondylolisthesis.

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KEYWORDS spondylolisthesis; isthmic; decompression; laminectomy; fusion; spondylodesis; degenerative; surgical technique

ABBREVIATIONS MD = mean difference; RCT = randomized controlled trial; RDQ = Roland-Morris Disability Questionnaire; VAS = visual analog scale.

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In isthmic spondylolisthesis, a defect in the pars interarticularis (i.e., isthmus) results in the anterior slippage of one vertebral body in relation to the adjacent inferior vertebral body.[1–3] The prevalence of isthmic spondylolisthesis varies between 4% and 8.2%, although patients are asymptomatic in the majority of cases.[2,4,5] Fibrocartilaginous tissue is usually formed at the isthmic site, and in combination with the listhesis, this tissue may lead to compression of nerve tissue, resulting in radicular symptoms caused by foraminal compression of exiting nerve roots. Patients may subsequently experience leg pain and/or low-back pain and loss of mobility. These complaints may result in disability that affects the performance of daily activities, with a significant adverse impact on patient quality of life.

The management of isthmic spondylolisthesis varies from conservative treatment to surgical treatment options, with the latter generally yielding better outcomes.[6,7] Conservative treatment consists of pain management, physical therapy, and lumbar bracing. Several options exist regarding surgical treatment, including nerve root decompression alone and nerve root decompression and instrumented fusion with or without interbody cages. In decompression alone (Gill's procedure), the exiting nerve root is decompressed through a laminectomy that includes the inferior articular process, which opens the complete foraminal canal, in combination with removal of the fibrocartilaginous tissue compromising the nerve root.[8] Another treatment option is to add instrumented interbody fusion to the decompression to prevent the upper body from further slippage and to increase the foraminal height, avoiding recurrent compromise of the nerve root and/or cauda.[9,10] Furthermore, blocking the mobility at this degenerated segment may reduce low-back pain.[11] In addition, adding instrumented fusion to decompression may have more drawbacks, such as a higher complication risk, higher costs, and more pain because of a larger wound. Patients also may fear instrumented fusion because it is a more invasive surgical technique with complications associated with spondylodesis.[12]

We recently published the outcome data of a randomized controlled trial (RCT) comparing decompression alone with decompression and fusion and demonstrated that while short-term results were comparable, long-term results for decompression and fusion were superior. Additionally, fewer reoperations were performed in patients who underwent decompression and fusion (13% vs 47%).[13] It is interesting to evaluate whether outcomes were different when patients intentionally chose a particular intervention. When RCT participation was offered to eligible patients, a substantial number of patients declined but agreed to be in an observational cohort study. The results of the patient analysis in the cohort study are reported here. Furthermore, the results of this study were compared with the RCT results. Moreover, in this larger patient group, subgroup analyses were performed to assess for relevant parameters that could influence outcome, as planned in the original protocol.

Methods

A multicenter, prospective comparative study was conducted among patients with lumbosacral radiculopathy and/or neurogenic claudication secondary to lumbar isthmic spondylolisthesis (Sciatica-Gill trial) between June 2008 and January 2015. The protocol was approved in all 10 participating centers by the Medical Ethics Committee of Leiden University Medical Center. Written informed consent was obtained from all patients. Details of the design and study protocol have been published previously.[14]

In this study, the outcome of the prospective observational cohort arm was compared with the results of the previously published RCT (no. NL1254, www.trialregister.nl/).

Participants

Patients were eligible if they fulfilled the inclusion criteria, which consisted of patients who 1) were 18 to 70 years of age, 2) had radiologically proven low-grade isthmic spondylolisthesis (Meyerding grade 1 or 2),[28] 3) had received a diagnosis from a neurosurgeon of lumbar radicular syndrome and/or neurogenic claudication, and 4) had complaints that lasted > 3 months.

Patients were excluded from eligibility if one of the following criteria were applicable: patients with high-grade isthmic spondylolisthesis (Meyerding grade 3 or 4), disc herniation at the affected segment requiring discectomy, low-back pain only, abnormal instability on dynamic radiographs (> 3 mm), and progressive spondylolisthesis. Other exclusion criteria were severe obesity (BMI > 35), previous spine surgery, severe osteoporosis, chronic use of steroids, severe comorbidity, contraindication for surgery, short-term planned migration, no or limited understanding of the Dutch language, and pregnancy. Patients were first offered randomization to one of the two arms, and patients who objected to being randomized were asked to be included in the observational cohort study while receiving the treatment (decompression alone or decompression and fusion) of their preference.

Intervention

Patients received either nerve root decompression achieved by removing the floating lamina and the fibrocartilaginous mass of the pseudojoint according to Gill (decompression alone [D group]), or comparable nerve root decompression combined with instrumented spondylodesis (decompression and fusion [DF group]). In the D group, a lumbosacral midline incision was performed and the paravertebral muscles were dissected unilaterally or bilaterally, depending on the patient's symptoms. The floating lamina (due to the fracture at the isthmus) and inferior articular process were removed, together with the fibrocartilaginous mass of the pseudojoint. In case of a unilateral procedure (hemi-Gill), a vertical hemilaminectomy was performed. The affected nerve roots were decompressed adequately, implicating an additional reduction of the superior articular process if necessary. The wound was closed in layers with a suction drain if necessary. Decompression with instrumented spondylodesis was performed bilaterally as described above. Subsequently, pedicle screws were placed in the affected segment under fluoroscopic control. O-arm navigation was not routinely used during the inclu-

sion period. If the intervertebral space was accessible, the disc tissue was removed and the intervertebral space was filled with two PEEK or titanium cages. Sagittal realignment was achieved if possible, and screws were fixed to the rods under slight compression. The wound was closed in layers with a suction drain if necessary.

Postoperatively, all patients were encouraged to mobilize as soon as possible. No orthoses were prescribed.

Outcomes

The primary outcomes were scores on the 23-item Roland-Morris Disability Questionnaire (RDQ) for sciatica[29] and a 7-point Likert scale of perceived recovery in global health and leg pain.

Secondary outcomes were the 100-mm visual analog scale (VAS) scores for leg pain and back pain, respectively; the SF-36 score;[15] and the reoperation frequency.

Follow-Up

Patients were followed up for 2 years, with assessments of outcome at 3 weeks, 6 weeks, 12 weeks, 26 weeks, 1 year, and 2 years. Questionnaires were sent to patients, and in-person interviews were performed by research nurses/surgeons in an outpatient setting. Patients were not informed on the results of earlier assessments.

Statistical Analysis

The patients for the observational cohort arm were included during the inclusion period of the RCT. The primary outcome measure was the RDQ. It was hypothesized that at the short-term follow-up the treatment outcomes after decompression alone would be superior to those after decompression and fusion, whereas at the long-term follow-up decompression alone was not inferior compared with decompression and fusion. Treatment at the 12-week follow-up was considered successful in cases of RDQ score improvement of at least 7. Furthermore, a clinically relevant difference between the groups was deemed present if the values at the 12-week follow-up differed by at least 20% in the RDQ score. Equal effectiveness at the 2-year follow-up was defined as a maximum 4-point difference in the RDQ score between the D and DF groups, and a superior clinically relevant outcome was deemed to be present if the difference in the RDQ score was > 4. With a power of 90% and a two-tailed significance level of 0.05, 220 patients with symptomatic isthmic spondylolisthesis Meyerding grades 1 and 2 were calculated to be needed (110 patients in both treatment groups, including 10% loss to follow-up) for both the 12-week and the 2-year outcome data. The numbers used for this calculation were retrieved from the 1- and 5-year results of the Maine Lumbar Spine Study.[16,17]

The primary and secondary outcome measures, together with 95% CIs, were calculated using a linear mixed model containing the interaction of treatment group and follow-up time. Improvement of the outcome compared with baseline was used in the linear mixed model. Multiple imputation for missing outcome measurements was not performed because of the robust nature of mixed modeling for missing data, which provided valid inferences.[18] Paired-samples t-tests were used to analyze within-group improvement. Risk of reoperation over time was estimated for both treatment groups using Kaplan-Meier curves and compared with log-rank tests. Mean differences (MDs) with corresponding standard errors (SEs) and 95% CIs used in the meta-analysis were retrieved from the mixed-model analyses, with the present observational cohort study and the previously published RCT considered as two separate studies. A random-effects model was used to pool effect sizes. Subgroups were patients < 50 years or ≥ 50 years of age, male or female, normal weight or overweight, smoker or nonsmoker, and Meyerding grade 1 or 2. Results were pooled separately for each subgroup and were given as delta values compared with baseline. The DerSimonian and Laird method was used to calculate the heterogeneity variance τ^2, and p values < 0.05 were considered significant. Statistical analyses were performed using Review Manager (RevMan) and IBM SPSS version 22 (IBM Corp.).[19]

Results

Participants

In the Sciatica-Gill study,[14] 226 patients were assessed for eligibility and 39 patients were excluded based on the criteria listed in Fig. 1. In total, 187 patients were potentially eligible for the study, of whom 84 patients were randomized and analyzed in the Sciatica-Gill trial. This resulted in 103 patients being included in the observational cohort study. Of these patients, 12 patients were excluded on secondary assessment because of instability on dynamic radiograph > 3 mm (n = 6), age older than 70 years (n = 3), no surgery received (n = 1), other pathology (n = 1), and Meyerding grade ≥ 3 (n = 1). Therefore, 91 eligible patients were included in the cohort analysis, 44 patients in the D group and 47 patients in the DF group. Twelve weeks of follow-up data were available for 41 patients (93.2%) in the D group and 45 patients (95.7%) in the DF group. Two-year follow-up was available for 33 patients (75%) and 39 patients (83.0%) in the D and DF groups, respectively. Reasons for loss to follow-up were no response to questionnaires (n = 28), withdrawal from study due to pain (n = 1), withdrawal from study due to cerebrovascular event (n = 1), withdrawal from study due to knee surgery (n = 1), death (n = 1), and no response to questionnaires due to absence of health complaints (n = 1). A complete flowchart of participants can be found in Fig. 1.

Demographics

The two study groups were similar in terms of baseline characteristics (Table 1).

Data were available for 42 patients in the D group and 46 patients in the DF group. The mean age was 53.5 ± 10.4 years in the D group compared with 51.1 ± 8.8 years in the DF group (95% CI –1.6 to 6.5, p = 0.232), with a mean BMI of 27.7 ± 4.5 in the D group and 26.7 ± 3.8 in the DF group (95% CI –0.72 to 2.85, p = 0.241). There were 26 patients (59.1%) in the D group who were male and 23 (48.9%) in the DF group. The grade of spondylolisthesis did not differ between the two groups (31 and 38 participants with Meyerding grade 1 spondylolisthesis in the D

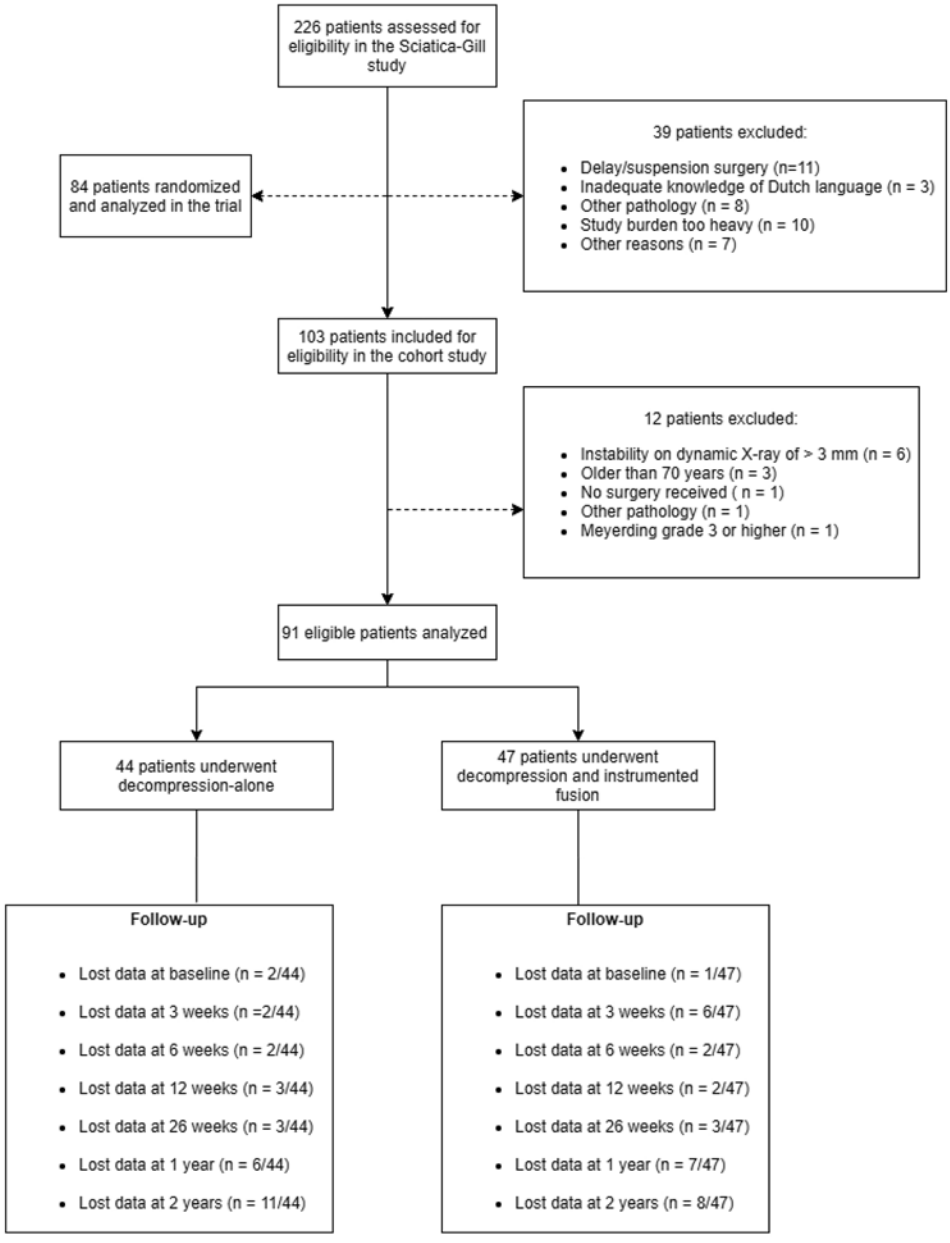

FIG. 1. Overview of patient enrollment and follow-up. All patients were analyzed according to the surgical treatment they received. Randomized patients (n = 84) were analyzed according to the intention-to-treat principle, and the results were reported in the Sciatica-Gill trial.[13] Other reasons (n = 7) for exclusion were that the patient could not be reached (n = 1), the patient was not enrolled in the study protocol in time (n = 5), and the patient was older than 70 years (n = 1).

and DF groups, respectively; p = 0.437). There were no statistically significant differences in operated segments in the two groups, and the L5–S1 segment was the surgical site in most patients (26 vs 33 patients in the D and DF groups, respectively).

Also, there were no statistically significant differences in preoperative outcome parameters between the two groups. The mean RDQ scores were 13.7 ± 5.3 in the D group and 14.0 ± 4.9 in the DF group (p = 0.821). The mean VAS leg pain scores were 70.4 ± 18.0 and 66.3 ± 21.6 in the D and DF groups, respectively (p = 0.332). The mean VAS back pain scores were 50.0 ± 30.1 and 54.9 ± 27.6 in the D and DF groups, respectively (p = 0.430).

Main Outcome

Within-group analyses showed that at the 12-week and 2-year follow-ups, scores for patients in both groups improved compared with their baseline scores.

At the 12-week follow-up, between-group analyses showed comparable improvement in RDQ scores in the D group (4.4, 95% CI 2.3–6.5) and the DF group (5.8, 95%

TABLE 1. Patient baseline characteristics

Characteristic	Study Group*		p Value
	D (n = 44)	DF (n = 47)	
Age, yrs	53.5 ± 10.4	51.1 ± 8.8	0.232
Age ≥60 yrs	13	7	0.125
No. of male pts	26	23	0.289
BMI†	27.7 ± 4.5	26.7 ± 3.8	0.241
BMI ≥30	12	8	0.309
Smoking status, often	16	15	0.421
Daily no. of cigarettes‡	18.4 ± 8.6	16.5 ± 7.4	0.500
Symptom duration, mos			
Leg pain	52.0 (26.0–136.5)	65.0 (30.0–156.0)	0.394
Low-back pain§	156.0 (39.0–520.0)	104.0 (47.0–520.0)	0.979
Nature of symptoms			0.448
Neurogenic claudication	11	17	
Pseudoradicular pain	0	1	
Radicular syndrome	14	14	
Radicular syndrome & neurogenic claudication	13	7	
Radicular syndrome & pseudoradicular pain	1	2	
Radicular syndrome, neurogenic claudication, & pseudoradicular pain	3	5	
Motor deficit¶	2	3	>0.999
SF-36 scores**			
Physical functioning	42.7 ± 19.4	43.1 ± 19.8	0.929
Role physical	73.2 ± 35.5	77.8 ± 35.0	0.548
Role emotional	49.2 ± 45.5	42.2 ± 45.7	0.478
Vitality	47.7 ± 20.6	44.8 ± 20.8	0.477
Mental health	62.2 ± 21.9	66.0 ± 20.6	0.411
Social functioning	57.1 ± 27.6	61.9 ± 24.7	0.395
Bodily pain	37.9 ± 15.8	38.3 ± 19.4	0.912
General health	57.9 ± 18.7	55.7 ± 21.5	0.614
Physical component summary	39.2 ± 5.4	39.2 ± 6.2	0.890
Mental component summary	41.6 ± 7.7	41.7 ± 7.0	0.923
Preop RDQ score††	13.7 ± 5.3	14.0 ± 4.9	0.821
Preop VAS leg pain score	70.4 ± 18.0	66.3 ± 21.6	0.332
Preop VAS back pain score‡‡	50.0 ± 30.1	54.9 ± 27.6	0.430
Operated levels§§			
L3–4	4	1	
L4–5	11	10	
L4–S1	1	0	
L5–S1	26	33	
L6–S1	0	2	
Meyerding grade			0.437
1	31	38	
2	11	8	
Flexion-extension movement at listhesis, mm¶¶			0.796
0–1	27	27	
2–3	11	9	

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TABLE 1. Patient baseline characteristics

Pt = patient.
Data are presented as number of patients, mean ± SD, or median (range) unless otherwise indicated.
* Baseline data were available for 42 patients in group D and 46 in group DF.
† BMI data were available for 42 patients in group D and 45 in group DF.
‡ Data were available for 41 patients in group D and 46 in group DF.
§ Data were available for 33 patients in group D and 43 in group DF.
¶ Motor deficit defined as measured weakness in motor function detected on neurological examination. Data were available for 43 patients in group D and 41 in group DF.
** The SF-36 questionnaire has been used frequently and is validated in surgical studies on spinal column pathology.[26,27] Data were available for 42 patients in group D and 45 in group DF.
†† Data were available for 41 patients in group D and 46 in group DF.
‡‡ Data were available for 42 patients in group D and 45 in group DF.
§§ Fisher's exact test based on dichotomized values (L5–S1 vs rest).
¶¶ Data were measured from preoperative dynamic flexion-extension radiographs.

CI 3.9–7.8) (p = 0.31). Similarly, at the 2-year follow-up, the D group showed comparable improvement in RDQ scores (6.0, 95% CI 3.5–8.4) relative to the DF group (9.1, 95% CI 6.8–11.4), with a difference of 3.1 (p = 0.07). These results revealed no statistically significant interaction in the mixed model between the study groups and RDQ over the follow-up time (p < 0.163) (Fig. 2A). However, a decrease of at least 7 in the RDQ score applied only to the DF group.

At the 12-week follow-up, patient-perceived recovery in global health was comparable in both groups, with 16 patients (39%) reporting recovery in the D group compared with 25 patients (55%) in the DF group (p = 0.14). Similarly, reported recovery of global health did not differ between the D group (n = 17, 51%) and the DF group (n = 28, 71%) at the 2-year follow-up (p = 0.09).

Both groups showed similar perceived recovery from leg pain at the short-term follow-up: 18 patients (43%) in the D group compared with 28 patients (62%) in the DF group (p = 0.13). However, at the long-term follow-up significantly more patients in the DF group than in the D group had perceived recovery of leg pain (31 vs 17, respectively; p = 0.02). The results of the primary and secondary outcomes are summarized in Tables 2 and 3.

Secondary Outcomes

Both the D group and the DF group showed comparable improvement in VAS leg pain at both short-term (–12.4, 95% CI –27.0 to 2.1, p = 0.09) and long-term (–7.4, 95% CI –22.1 to 7.2, p = 0.31) follow-ups. These results revealed no statistically significant interaction effects between the study groups and the VAS leg pain score over the follow-up time (p = 0.274) (Fig. 2B).

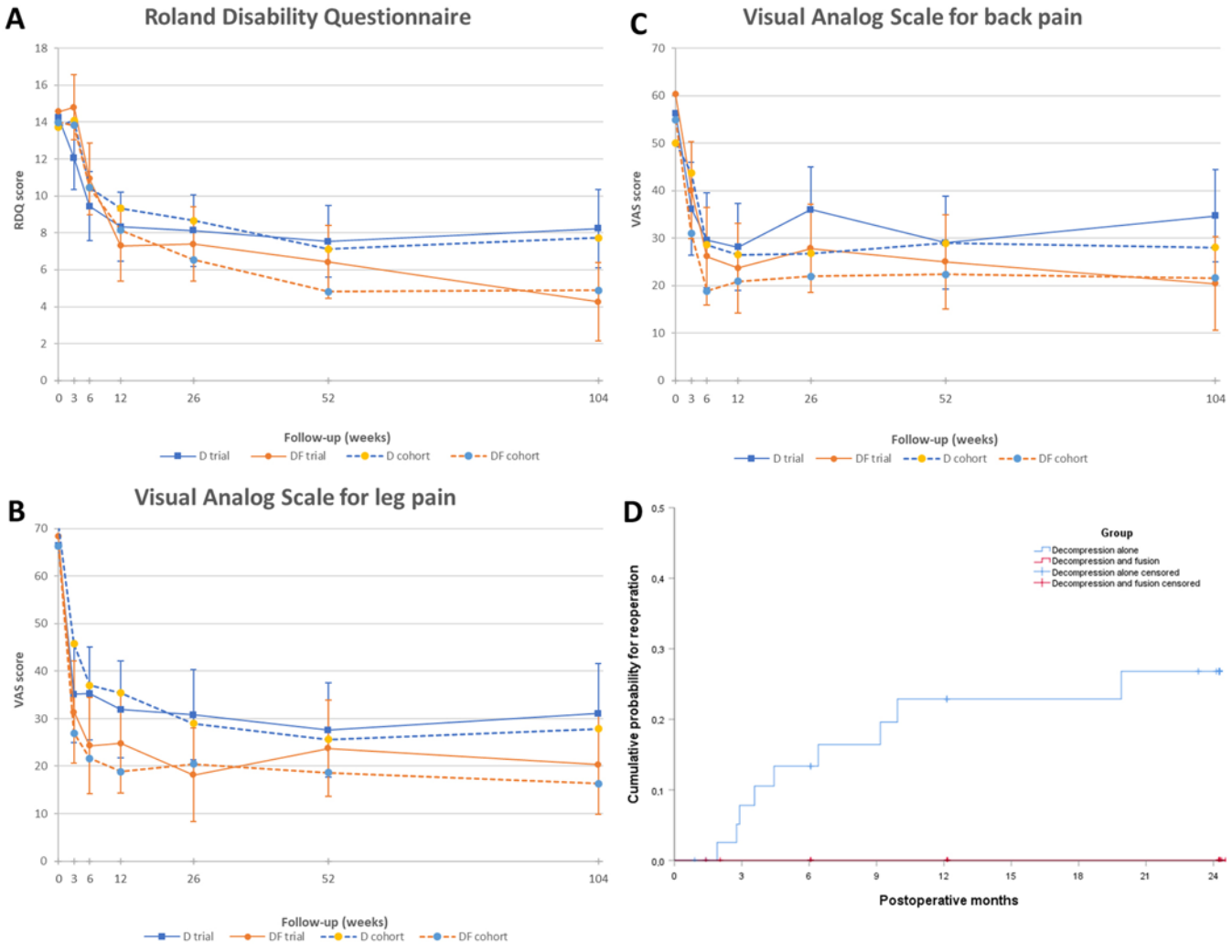

FIG. 2. A–C: Courses of primary outcomes and Kaplan-Meier curves for risk of reoperation in the D and DF groups. Shown are the courses of the RDQ score (A), VAS leg pain score (B), and VAS back pain score (C) over time, for which outcome at 0 weeks was set as the mean value at baseline. *Dashed lines* represent results found in the Sciatica-Gill trial. **D:** The cumulative risk of reoperation over time for the two study groups. Patients lost to follow-up or patients who did not undergo reoperation within 2 years after the primary operation were censored. The cumulative probability for reoperation at the 2-year follow-up was 23.5% in the D group and 0% in the DF group ($p < 0.001$). Figure is available in color online only.

Improvements in VAS back pain were comparable in the D and DF groups at both the 12-week (–10.5, 95% CI –24.7 to 3.7, $p = 0.15$) and 2-year (–11.4, 95% CI –25.7 to 2.9, $p = 0.12$) follow-ups. In addition, the mixed model did not find a statistically significant interaction effect between the study groups and VAS back pain over the follow-up time ($p = 0.392$) (Fig. 2C).

Surgical Outcomes and Complications

Surgery time differed significantly between the study groups: median of 69 (range 47.5–97.50) minutes versus median of 190 (range 170.0–207.5) minutes in the D group and DF group, respectively ($p < 0.001$). Also, blood loss was higher in the DF group (median 450 [range 300.0–850.0] ml) compared with the D group (median 150 [range 75.0–300.0] ml) ($p < 0.001$). Additionally, patients in the DF group had lengths of hospital stay that were significantly longer than those for patients in the D group: median of 4.0 (range 3.75–4.0) days compared with a median of 1.0 (range 1.0–2.0) day ($p < 0.001$).

One perioperative complication (pedicle breach) occurred in the DF group and none in the D group ($p = 0.485$). With regard to postoperative complications, the DF group had 1 patient with a postoperative hemorrhage, 4 patients with temporary micturition disorders, 1 patient with motor dysfunction in the form of a unilateral foot drop, and 1 patient with fever of unknown origin. In the D group, only 1 patient had a temporary micturition disorder, and 1 patient received a pacemaker due to second-degree atrioventricular block. The surgical outcomes and complications are summarized in Table 4.

Reoperations

No patients in the DF group underwent reoperation,

TABLE 2. Primary outcomes at short-term follow-up

Variable	Comparison at 12-Wk FU					
	D Group		DF Group			
	Score	Diff Compared w/ Baseline (95% CI)	Score	Diff Compared w/ Baseline (95% CI)	Improvement w/ D vs DF (95% CI)	p Value*
RDQ	9.2 ± 6.6	4.4 (2.3 to 6.5)	8.7 ± 6.9	5.8 (3.9 to 7.8)	–1.4 (–4.3 to 1.4)	0.31
VAS leg pain	26.5 ± 27.1	35.0 (24.5 to 45.6)	22.2 ± 25.2	47.5 (37.4 to 57.5)	–12.4 (–27.0 to 2.1)	0.09
VAS back pain	36.7 ± 31.2	23.5 (13.3 to 33.7)	20.5 ± 29.5	34.0 (24.1 to 43.8)	–10.5 (–24.7 to 3.7)	0.15
Perceived recovery in global health†‡	16 ± 39	NA	25 ± 55	NA	NA	0.14
Perceived recovery in leg pain†‡	18 ± 43	NA	28 ± 62	NA	NA	0.13
SF-36‡						
Physical functioning	61.5 ± 22.9	17.7 (9.7 to 25.6), p < 0.001	62.3 ± 21.9	19.7 (11.6 to 27.8), p < 0.001	–0.81 (–10.4 to 8.8)	0.87
Role physical	63.4 ± 42.2	–9.0 (–23.6 to 5.6), p = 0.220	69.1 ± 38.4	–10.3 (–21.2 to 0.7), p = 0.066	–5.7 (–22.9 to 11.6)	0.52
Role emotional	36.6 ± 44.6	–11.1 (–28.3 to 6.1), p = 0.200	34.8 ± 44.9	–6.2 (–20.6 to 8.2), p = 0.389	1.8 (–17.5 to 21.0)	0.86
Vitality	62.0 ± 16.4	13.3 (7.4 to 19.2), p < 0.001	59.7 ± 21.8	16.0 (9.2 to 22.9), p < 0.001	2.3 (–6.1 to 10.6)	0.59
Mental health	73.5 ± 19.6	11.3 (4.9 to 17.7), p = 0.001	43.6 ± 7.1	8.4 (3.3 to 13.5), p = 0.002	–1.2 (–10.1 to 7.7)	0.79
Social functioning	73.8 ± 25.9	16.3 (5.8 to 26.9), p = 0.003	72.2 ± 26.0	9.6 (1.3 to 17.9), p = 0.025	1.6 (–9.6 to 12.7)	0.78
Bodily pain	53.6 ± 24.2	14.9 (5.9 to 23.9), p = 0.002	61.2 ± 23.2	23.4 (16.4 to 30.5), p < 0.001	–7.7 (–17.8 to 2.5)	0.14
General health	61.1 ± 20.1	2.2 (–2.4 to 6.8), p = 0.345	66.1 ± 21.6	10.1 (4.5 to 15.8), p = 0.001	–5.0 (–14.0 to 4.0)	0.27
Physical component summary	43.7 ± 6.6	4.1 (1.9 to 6.3), p = 0.001	46.0 ± 8.3	6.6 (4.1 to 9.1), p < 0.001	–2.3 (–5.5 to 1.0)	0.17
Mental component summary	44.6 ± 6.2	3.2 (0.7 to 5.6), p = 0.012	43.6 ± 7.1	1.9 (–0.6 to 4.5), p = 0.127	1.0 (–1.9 to 3.9)	0.49

Diff = difference; FU = follow-up; NA = not applicable.
Data are presented as mean ± SD unless otherwise indicated.
* p value of difference in improvement between the D and DF groups at 12 weeks.
† Likert scores "complete recovery" and "almost complete recovery" were defined as good results and were used to dichotomize data. A Likert-perceived recovery evaluation was performed for the recovery of overall health and recovery of leg pain separately.
‡ Summary data were based on available cases.

whereas 9 patients in the D group underwent reoperation after a median time period of 4 (range 2–9) months. All reoperations were performed due to persisting radicular complaints. Performed reoperations, RDQ scores, VAS scores, and Likert scores are listed in Table 5. The cumulative probability of reoperation in the D group at the 2-year follow-up was 23.5% (p < 0.001, log-rank test) (Fig. 2D). An overview of reoperated patients can be found in Table 5.

Meta-Analysis

A meta-analysis was performed that included the data for the patient populations analyzed in the present study (n = 91) and the previously published RCT study (n = 84) (175 patients total: 87 patients in the D group and 88 patients in the DF group). The combined results showed no difference in the pooled estimates between both groups at the 12-week follow-up (MD –1.39, 95% CI –3.29 to 0.50, p = 0.15) (Fig. 3). However, at the 2-year follow-up, the meta-analysis showed a significant difference in RDQ scores in favor of decompression and fusion (MD –3.74, 95% CI –5.94 to –1.55, p = 0.0008) (Fig. 3). Although the pooled estimate of VAS leg pain was favorable for decompression and fusion at the 12-week follow-up (MD –10.77, 95% CI –20.93 to –0.60, p = 0.04), this difference was diminished at the 2-year follow-up (Fig. 3). The pooled estimate of VAS back pain score improvement was more in favor of decompression and fusion at the 2-year follow-up (MD –14.96, 95% CI –24.77 to –5.16, p = 0.003). With regard to the defined subgroups, in this study we found no significant differences between the treatment groups in pooled estimates of all outcome measures for both the 12-week and 2-year follow-ups (Supplemental Figs. 1–6).

Discussion

This study demonstrated that in patients with symptomatic isthmic spondylolisthesis, adding instrumented fusion to decompression provides treatment results superior to those for decompression alone at the 2-year follow-up. At the short-term follow-up, no superior results were obtained for the less-invasive decompression-alone surgery. Moreover, no subgroups were identified with results in favor of decompression alone.

Previously, we presented the results of an RCT in which we studied decompression alone versus decompression and fusion in the same type of patients. Two years after randomized patient treatment, the outcome was convincingly in favor of decompression and fusion.[13] However, patients who consented to be randomized may not represent

TABLE 3. Primary outcomes at long-term follow-up

Variable	Comparison at 2-Yr FU					
	D Group		DF Group			
	Score	Diff Compared w/ Baseline (95% CI)	Score	Diff Compared w/ Baseline (95% CI)	Improvement w/ D vs DF (95% CI)	p Value*
RDQ	7.4 ± 7.7	6.0 (3.5 to 8.4)	5.2 ± 7.3	9.1 (6.8 to 11.4)	–3.1 (–6.4 to 0.3)	0.07
VAS leg pain	25.6 ± 26.4	42.6 (31.9 to 53.2)	22.6 ± 25.0	50.0 (40.0 to 60.0)	–7.4 (–22.1 to 7.2)	0.31
VAS back pain	26.7 ± 29.5	21.9 (11.6 to 32.3)	18.2 ± 27.5	33.3 (23.4 to 43.2)	–11.4 (–25.7 to 2.9)	0.12
Perceived recovery of global health†‡	17 ± 51	NA	28 ± 71	NA	NA	0.09
Perceived recovery of leg pain †‡	17 ± 51	NA	31 ± 79	NA	NA	0.02
SF-36‡						
Physical functioning	65.9 ± 27.5	24.4 (15.7 to 33.0), p < 0.001	72.2 ± 28.5	29.3 (19.0 to 39.7), p < 0.001	–6.3 (–19.5 to 6.9)	0.35
Role physical	35.6 ± 45.1	–42.7 (–62.3 to –23.2), p < 0.001	33.3 ± 44.5	–44.6 (–59.8 to –29.4), p < 0.001	2.3 (–18.9 to 23.4)	0.83
Role emotional	26.3 ± 40.6	–22.6 (–41.6 to –3.5), p = 0.022	19.7 ± 36.4	–17.1 (–30.4 to –3.9), p = 0.013	6.6 (–11.5 to 24.7)	0.47
Vitality	59.2 ± 21.1	11.3 (4.7 to 17.8), p = 0.001	18.2 ± 27.5	16.4 (8.7 to 24.0), p < 0.001	–2.4 (–12.8 to 8.0)	0.64
Mental health	70.9 ± 21.6	9.2 (2.8 to 15.6), p = 0.007	28 ± 71	7.1 (1.2 to 12.8), p = 0.019	–3.6 (–13.6 to 6.5)	0.48
Social functioning	77.7 ± 24.8	23.8 (12.8 to 34.8), p < 0.001	31 ± 79	15.2 (3.0 to 27.4), p = 0.016	0.1 (–12.6 to 12.7)	0.99
Bodily pain	63.3 ± 22.9	26.6 (17.7 to 35.5), p < 0.001	73.2 ± 23.0	36.3 (29.0 to 43.6), p < 0.001	–9.9 (–20.7 to 0.9)	0.07
General health	58.8 ± 23.8	1.9 (–4.2 to 8.1), p = 0.527	62.7 ± 26.7	6.9 (0.1 to 13.7), p = 0.046	–3.9 (–15.9 to 8.1)	0.52
Physical component summary	43.8 ± 7.0	4.5 (2.2 to 6.8), p < 0.001	46.5 ± 8.2	7.2 (5.0 to 9.4), p < 0.001	–2.7 (–6.3 to 0.9)	0.14
Mental component summary	42.7 ± 7.5	1.7 (–0.9 to 4.3), p = 0.198	42.2 ± 6.4	0.5 (–2.2 to 3.3), p = 0.707	0.6 (–2.7 to 3.9)	0.72

Data are presented as mean ± SD unless otherwise indicated.

* p value of difference in improvement between the D and DF groups at 2 years.

† Likert scores "complete recovery" and "almost complete recovery" were defined as good results and were used to dichotomize data. A Likert-perceived recovery evaluation was performed for the recovery of overall health and recovery of leg pain separately.

‡ Summary data were based on available cases.

the average patient who presents with neurological symptoms due to an isthmic spondylolisthesis. To that end, in the present study we evaluated patients who underwent the surgical intervention of their preference. Prior to the start of the RCT, we hypothesized that decompression alone would be found to be advantageous at the short-term follow-up because decompression alone has a shorter duration with a smaller wound, which allows patients to mobilize faster postoperatively and leads to more satisfaction. However, in both the RCT and the present study cohort, no such outcome was observed. On the contrary, in all analyses we observed at least a tendency for better results in the DF group. For the long-term follow-up, we hypothesized that decompression and fusion would yield better results, which is indeed what we demonstrated in both the RCT and the cohort study patients. The results from the RCT were more convincing, but the trend in the cohort study was certainly toward a better outcome in the DF group.

Several authors have considered both RCT and observational cohort study results in comparing treatment protocols and combined these data in a meta-analysis.[20,21] Therefore, we combined the RCT results and the present study data in a meta-analysis. Although the number of patients was limited in both the RCT and the cohort study, the combined data convincingly indicate an advantage with decompression and fusion compared with decompression alone for symptomatic isthmic spondylolisthesis.

Theoretically, there may be a subgroup of patients who would benefit more from decompression alone. In the present study, we evaluated whether the outcomes would be different in a subgroup of elderly patients, because their spinal columns could be "naturally fused" with spondylophytes and they may do better with a short surgical intervention. However, this hypothesis was not demonstrated in the present study. Another subgroup that could theoretically benefit from decompression alone are patients with a high BMI. In these patients, instrumented fusion is more challenging, and therefore they may have an increased complication rate. However, in this group an advantageous outcome after decompression alone was not demonstrated.

Furthermore, it could be hypothesized that if patients have a preference for a type of operation, they may be more satisfied with the intervention they undergo. In support of this hypothesis, the cumulative reoperation rate was lower in the cohort study than in the RCT (23.5% vs 47%), illustrating that fewer reoperations may be needed in patients who are able to choose decompression alone than in those who are randomly assigned to this treatment.

TABLE 4. Surgical outcomes and complications

Characteristic	Study Group*		p Value
	D (n = 44)	DF (n = 47)	
Surgery time, mins†	69 (47.5–97.50)	190 (170–207.5)	<0.001
Blood loss, ml	150 (75.0–300.0)	450 (300.0–850.0)	<0.001
Length of stay, days‡	1 (1–3)	4.0 (3.75–4.0)	<0.001
Perop complications	0	1	0.485
Dural tear	0	0	
Pedicle breach	0	1	
Postop complications	2	7	0.427
Postop hemorrhage	0	1	
CSF leak§	0	0	
Micturition disorder¶	1	4	
Sensible dysfunction**	0	0	
Motor dysfunction	0	1	
Other††	1	1	

Values are presented as number or median (range) unless otherwise indicated.
* Data were available for 42 patients in group D and 46 patients in group DF.
† Data were available for 13 patients in group D and 16 patients in group DF.
‡ Data were available for 15 patients in group D and 22 patients in group DF.
§ CSF leakage requiring prolonged bed rest.
¶ Temporary micturition problems requiring urinary catheter.
** Numbness in the dermatome of the decompressed nerve root.
†† Other postoperative complications consisted of pacemaker insertion due to postoperative second-degree atrioventricular block in group D and fever of unknown origin in group DF.

The reoperation rate of the D group in the present study is in line with the previously reported reoperation rate in a study of the clinical outcomes of decompression alone in isthmic spondylolisthesis.[22] However, in the present study this difference in reoperation rates may have been biased by the fact that some of the study patients had a strict preference not to undergo instrumented fusion, illustrated by the observation that even though fewer patients had recovered from their leg pain (as measured by the Likert score) in the D group than in the DF group, these patients still did not undergo a reoperation. This difference in perceived recovery in favor of the DF group has implications regarding clinical care and patient information. Patients can be informed not only that decompression alone leads to a higher reoperation rate, but also that decompression and fusion leads to a significantly better perceived recovery of leg pain.

In the cohort study, patients in the D group underwent reoperation after a median of 4 months, compared with 7.3 months for patients in the RCT. Interpretation of the clinical outcome data of these reoperated patients was significantly influenced by intention-to-treat analysis, because treatment effects of fusion might cloud the results in the D group. Also, reoperated patients may not have had enough time to recover after surgery compared with the non-reoperated patients and thus were not in the same follow-up time frame. To reduce these influences, we chose to define long-term follow-up at 2 years to allow enough time for reoperated patients to recover after secondary fusion. Nevertheless, taking these factors into consideration is important when interpreting the results.

Fewer patients underwent reoperation in the DF group than the D group. This finding was present in both the RCT (n = 5) and this cohort study (n = 0). This result may be clouded by the fact that in patients who have persisting leg pain after decompression alone, secondary decompression and fusion is more accessible, whereas revision surgery is performed more hesitantly in patients who have already had a primary decompression and fusion.

Decompression and fusion is a more invasive surgical technique than decompression alone and is associated with fusion-related complications,[23–25] as confirmed by our findings that patients in the DF group had more postoperative complications, significantly longer surgery time and length of stay, and significantly more blood loss. The risk of these outcomes is a disadvantage of instrumented

TABLE 5. Reoperations

Pt No.	Reason for Reop	Outcome						
		RDQ Score		VAS Leg Pain Score*		VAS Back Pain Score*		Likert Score†
		Preop	Postop	Preop	Postop	Preop	Postop	
1	Additional fusion	21	21	83	53	81	47	Unsatisfied
2	Additional fusion	8	NA	56	NA	78	NA	
3	Additional fusion	21	23	88	90	87	100	Unsatisfied
4	Additional fusion	6	NA	57	NA	13	NA	Unsatisfied
5	Additional fusion	5	0	76	5	61	7	Satisfied
6	Contralateral hemi-Gill procedure	9	1	76	13	32	6	Satisfied
7	Additional fusion	18	1	81	0	0	0	Satisfied
8	Additional fusion	19	16	75	73	36	57	Unsatisfied
9	Additional fusion	19	NA	85	NA	64	NA	Unsatisfied

Preop = baseline; postop = 2-year follow-up.
* Data are numbers within the referred outcome measurement.
† The Likert score is for perceived recovery of global health, whereas the scores "complete recovery" and "almost complete recovery" were defined as satisfied. All patients who underwent reoperation rated preoperative global health as "unsatisfactory."

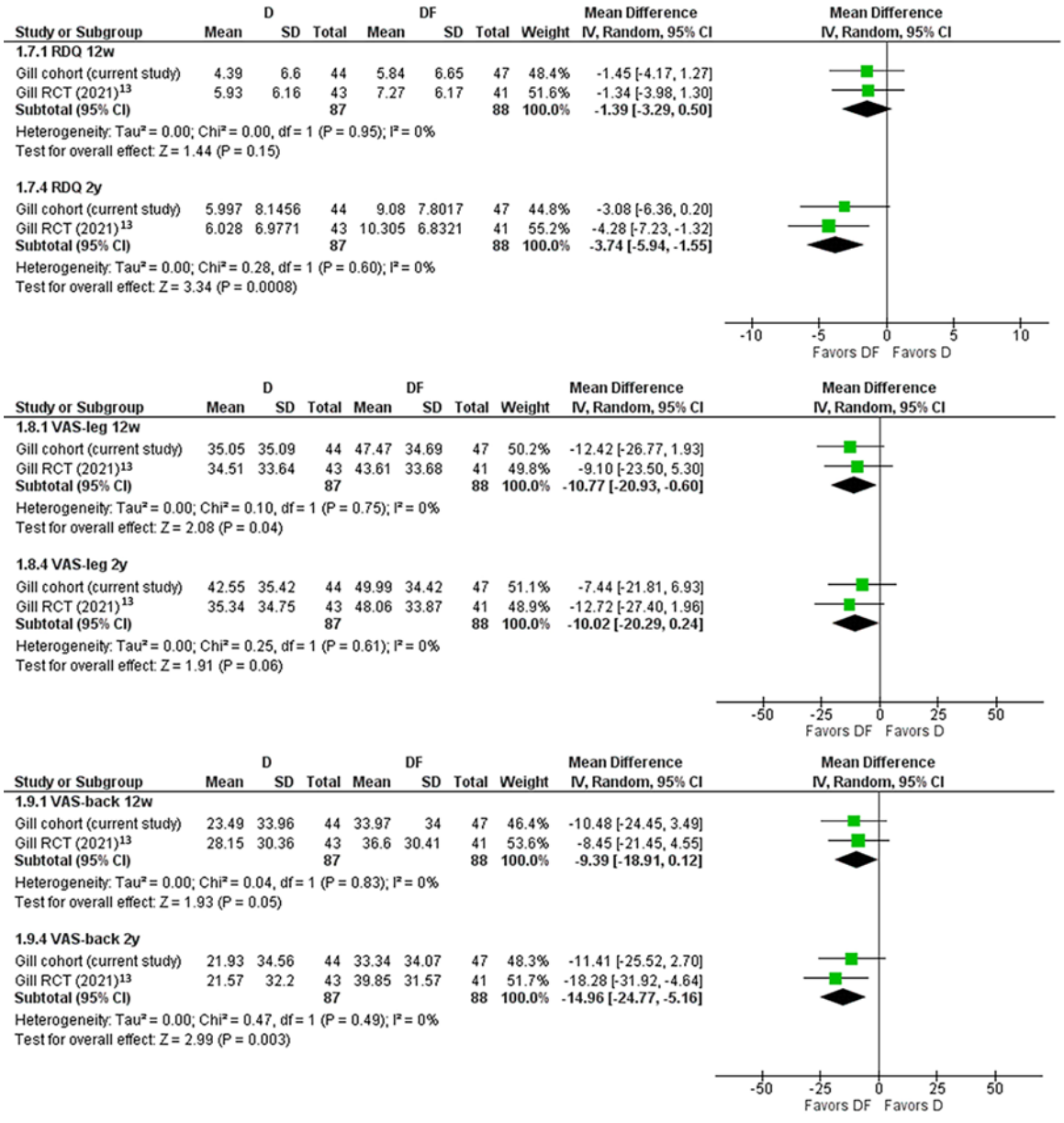

FIG. 3. Forest plots of primary outcomes at the 12-week and 2-year follow-ups. The forest plots compare the differences of improvement from baseline between the D and DF groups in terms of scores for RDQ, VAS leg pain, and VAS back pain. IV = inverse variance; 12w = 12-week follow-up; 2y = 2-year follow-up. Figure is available in color online only.

fusion. However, the increasing use of intraoperative CT navigation may shorten the surgical time and thereby limit the complication rate. Furthermore, complication rates may also be lower in the future due to a gradual increase in technical proficiency and the ongoing learning curve of neurosurgeons.

Our study has several limitations. First, the intended sample size was not reached: the inclusion rate was low, and because of this, we evaluated results in a preliminary state.[13] This study was not powered on the basis of patients' perceived recovery, defined as one of our primary outcomes, which has an impact on the reliability of the results. Even though some of our findings are statistically significant, the estimates on which the significant findings are based are wide and therefore might not be replicated in other contexts. Second, in the present observational cohort study, patients were not randomized and therefore the treatment groups may be subject to selection bias. However, roughly the same number of patients were represented in each treatment group, and baseline characteristics between both groups did not differ at baseline. Third, loss to follow-up was higher in the D group. This may be explained by a higher threshold for the patients with no spondylodesis materials in situ to contact their surgeon, even though our study protocol specified similar postoperative and outpatient follow-up for all patients. Another explanation could

be that satisfied patients tend to be more reluctant to fill in study questionnaires because follow-up may be burdensome.

Conclusions

Our RCT and cohort data demonstrate that adding instrumented fusion to decompression leads to superior functional outcome and recovery from leg pain and fewer reoperations in patients with symptomatic isthmic spondylolisthesis at the 2-year follow-up. No subgroup of patients was identified as having a superior outcome with decompression alone. Therefore, we recommend decompression and fusion over decompression alone as a primary surgical treatment option in isthmic spondylolisthesis.

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Supplemental Information

Online-Only Content

Supplemental material is available with the online version of the article.

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