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Interspinous process device versus conventional decompression for lumbar spinal stenosis: 5-year results of a randomized controlled trial

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OBJECTIVE Interspinous process distraction devices (IPDs) can be implanted to treat patients with intermittent neurogenic claudication (INC) due to lumbar spinal stenosis. Short-term results provided evidence that the outcomes of IPD implantation were comparable to those of decompressive surgery, although the reoperation rate was higher in patients who received an IPD. This study focuses on the long-term results.

METHODS Patients with INC and spinal stenosis at 1 or 2 levels randomly underwent either decompression or IPD implantation. Patients were blinded to the allocated treatment. The primary outcome was the Zurich Claudication Questionnaire (ZCQ) score at 5-year follow-up. Repeated measurement analysis was applied to compare outcomes over time.

RESULTS In total, 159 patients were included and randomly underwent treatment: 80 patients were randomly assigned to undergo IPD implantation, and 79 underwent spinal bony decompression. At 5 years, the success rates in terms of ZCQ score were similar (68% of patients who underwent IPD implantation had a successful recovery vs 56% of those who underwent bony decompression, p = 0.422). The reoperation rate at 2 years after surgery was substantial in the IPD group (29%), but no reoperations were performed thereafter. Long-term visual analog scale score for back pain was lower in the IPD group than the bony decompression group (p = 0.02).

CONCLUSIONS IPD implantation is a more expensive alternative to decompressive surgery for INC but has comparable functional outcome during follow-up. The risk of reoperation due to absence of recovery is substantial in the first 2 years after IPD implantation, but if surgery is successful this positive effect remains throughout long-term follow-up. The IPD group had less back pain during long-term follow-up, but the clinical relevance of this finding is debatable.

Dutch Trial Register no.: NTR1307

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KEYWORDS lumbar spinal stenosis; interspinous implants; bony decompression; randomized trial

Lumbar spinal stenosis (LSS) may cause patients to suffer from neurogenic claudication,[1] in which compression of the roots of the cauda equina triggers leg pain that is aggravated by prolonged walking, standing, or lumbar extension. Symptoms are sometimes accompanied by back pain.[2,3] Surgical treatment may be offered if conservative treatment fails. Lumbar decompressive surgery without instrumentation is the standard treatment.[4,5] Patient satisfaction after surgery is relatively low,[4–6] and one of the reasons may be the destructive nature of bony decompression.[7,8] Interspinous process distraction devices (IPDs) were developed as a less destructive alternative to standard bony decompression. The IPD simultaneously increases the interspinous distance via in-

ABBREVIATIONS Felix = Foraminal Enlargement Lumbar Interspinous distraXion; INC = intermittent neurogenic claudication; IPD = interspinous process distraction device; LSS = lumbar spinal stenosis; LTFU = lost to follow-up; OR = odds ratio; RMDQ = modified Roland-Morris Disability Questionnaire; VAS = visual analog scale; ZCQ = Zurich Claudication Questionnaire.

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TABLE 1. Inclusion and exclusion criteria

Criteria
Inclusion
Signed informed consent
Age 40–85 yrs
Diagnosis of INC, as noted by leg/buttock/groin pain w/ or w/o back pain
≥3 mos conservative treatment
Regular indication for surgical intervention for INC
Narrowed lumbar spinal canal, nerve root canal, or intervertebral foramen at 1 or 2 levels, confirmed w/ MRI
Physically & mentally willing & able to comply w/ postop evaluations (or has a caregiver willing to comply)
Exclusion
Cauda equina syndrome
Herniated disc at the same level, necessitating lumbar discectomy
Paget's disease, severe osteoporosis, or metastasis to vertebrae
Significant scoliosis (Cobb angle >25°)
Previous surgery at the same lumbar level
Degenerative spondylolisthesis > grade 1 (scale 1–4) at affected level
Significant instability of lumbar spine
Severe comorbid conditions
Fused segment at indicated level

direct decompression of the dural sac and nerve roots owing to flexion of the involved segments and widens entry to the spinal root canal.[9–18] This device can be implanted in patients with symptomatic LSS instead of performing conventional bony decompression.[9,10] The less invasive nature of IPD surgery could lead to decreased postoperative pain, shorter hospital stay, faster recovery, and less back pain at follow-up compared with bony decompression.[19]

We previously published the 1- and 2-year results of a double-blind randomized trial that compared treatment with stand-alone IPD (without bony decompression) to standard bony decompression in patients with INC due to LSS.[20,21] At 8 weeks, 1 year, and 2 years, the success rates according to the Zurich Claudication Questionnaire (ZCQ) were not significantly different between the IPD group and standard bony decompression group. However, the reoperation rates of the IPD group were substantially higher than those of the decompression group after 1 year (29% vs 8%) and 2 years (33% vs 8%). Back pain was comparable between treatment groups at 1 and 2 years after surgery.[20,21] Other outcome parameters for pain and functioning did not show significant differences between groups.

The 5-year follow-up data are now available, and a similar analysis was conducted to compare the long-term results of IPD implantation with those of conventional decompressive surgery.

Methods

Study Population

The enrolled patients had participated in the multicenter randomized controlled trial, Foraminal Enlargement Lumbar Interspinous distraXion (Felix). This prospective double-blind trial enrolled patients with neurogenic claudication due to LSS. Stand-alone treatment with insertion of an IPD without bony decompression was compared to standard bony decompression. The study protocol was approved by the medical ethics committees of the five participating hospitals. Specifically, we obtained approval to randomly assign treatment after induction of anesthesia. The design and study protocol were published previously (Dutch Trial Register no.: NTR1307).[21] The trial was performed using a randomized design with variable block sizes.

All patients met the inclusion and exclusion criteria of the Felix trial (Table 1).[21] Written informed consent was obtained from all patients. All patients were diagnosed with INC on the basis of lumbar spinal canal stenosis at 1 or 2 levels with MRI confirmation and underwent at least 3 months of failed conservative treatment. The patient was excluded if preoperative MRI also showed a herniated disc that required discectomy or other deformities such as spondylolisthesis grade > 1 at the affected level (Table 1).

Allocations were stored in prepared, opaque, coded, sealed envelopes that were opened only after induction of anesthesia. The patients, clinical nurses, and research nurses remained blinded to the allocated treatment for 1 year of follow-up. The preoperative MR images of the lumbar spine of each patient were analyzed in a previous study of the Felix trial, which showed that the included patients presented with varying degrees of stenosis according to the Schizas scale, including the most severe degree.[22]

Interventions

Patients in the IPD group underwent operations under general anesthesia in the knee-elbow position. Under fluoroscopic control, the IPD was implanted with a posterior midline approach and no bony decompression was performed. Patients in the standard bony decompression group underwent surgery in the same position with a similar incision length as that used for the IPD group in order to ensure that all caregivers were blind to the allocated treatment. At the stenotic level(s), limited reduction of the adjacent laminae was executed, followed by flavectomy with bilateral opening of the lateral recess. Medial facetectomy was performed if necessary. No patients underwent laminectomy, discectomy, or a combination of these procedures. Patients in both groups received the same standard postoperative care. Patients, and the research nurses who were observing these patients, were asked after every visit if they were still blind to the allocated treatment.[20]

Outcomes

The primary outcome measure was a disorder-specific functional score provided by the ZCQ.[23,24] The primary outcome score was assessed at baseline, immediately postoperatively (2 weeks), and at 4, 8, 12, 26, 52, 104, and 260 weeks postoperatively. The ZCQ has three domains (symptom severity, physical function, and patient satisfaction). Domain scores were calculated as the average num-

ber of points obtained on the subsets of questions, with high scores of 5 (symptom severity) or 4 (physical function and patient satisfaction). The score increases with increasing disability. Average subscale scores were determined at every follow-up evaluation by the blinded research nurses. In terms of the overall ZCQ score, the patient was considered to have had a successful recovery if at least two domain subscales of the ZCQ were considered successful.[25] Success was defined as a decrease of at least 0.5 points on the symptom severity scale and the physical function scale.[20,23,24] A score of less than 2.5 on the patient satisfaction subscale was also defined as successful.[23,24]

Secondary outcome measures were scores on the modified Roland-Morris Disability Questionnaire (RMDQ) for sciatica (score range 0 to 23, with higher scores indicating worse functional status),[26–34] 100-mm visual analog scale (VAS) for back and leg pain (with 0 representing no pain and 100 representing the worst pain ever experienced),[35] McGill Pain Questionnaire (with 0 representing the minimum pain score and 78 representing the maximum),[36,37] and 7-point Likert self-rating scale of global perceived recovery (based on whether the patient experienced recovery compared with baseline status; 1–2 points were considered recovery and 3–7 points were considered no recovery).[38]

Sample Size

A sample size of 80 patients per treatment group would be required to provide a statistical power of 0.80 and a 2-sided alpha of 0.05.[23–25] A difference of 20% between success rates was considered clinically significant on the basis of the assumption that this level of superiority would be convincing enough to change surgical guidelines and to warrant reimbursement for the costs of the IPD implant.

Statistical Analysis

An intention-to-treat analysis was used to compare treatment groups. Repeated measurement analysis was used to compare groups at all follow-up evaluations (2, 4, 8, 12, 26, 52, 104, and 260 weeks postoperatively), and generalized estimating equations were used to account for correlations between repeated measurements of the same individual. Odds ratios (ORs) were reported for binary outcome variables and mean differences for continuous outcome variables.

To analyze and interpret possible heterogeneity between treatment centers, the study was stratified at randomization. The ProMISe data management system was used for data collection and quality control. SPSS version 20.0 (IBM Corp.) was used for all statistical analysis. The Department of Medical Statistics and Bioinformatics of Leiden University Medical Center assisted and advised in the steps of the statistical analysis.

Results

Between October 2008 and September 2011, a total of 205 patients with INC due to spinal stenosis were referred to the participating hospitals and screened for inclusion by the neurosurgeon. In total, 162 patients were enrolled in the trial and gave informed consent (Fig. 1). However, 1 patient died waiting for the operation, and 2 patients appeared to have severe spondylolysis at the L5–S1 level at the final preoperative checkup. Both patients were excluded. Therefore, 159 patients received the allocated treatment. At baseline, there were no significant differences in characteristics between treatment groups (Table 2).

Five-Year Results

Primary Outcome Measure

Five years after randomization, 25 patients in the IPD group and 24 in the bony decompression group were lost to follow-up (LTFU), which brought both groups to a size of 55 patients. The proportions of patients with successful recovery according to ZCQ score were similar between treatment groups: mean (95% CI) 68% (56%–78%) of patients in the IPD group versus 56% (95% CI 44%–68%) in the bony decompression group ($p = 0.422$). During the 5-year follow-up period, the ZCQ success rates were similar between treatment arms (Table 3; Fig. 2). The ZCQ scores of the IPD group showed an upward trend, increasing from 63% of patients with successful recovery at 8 weeks to 68% at 260 weeks ($p = 0.55$). The ZCQ scores of the bony decompression group showed a downward trend, decreasing from 72% of patients with successful recovery at 8 weeks to 56% at 260 weeks ($p = 0.07$).

To evaluate whether this trend was biased by the absence of data from patients who were LTFU, the 2-year follow-up ZCQ scores were compared between the LTFU and non-LTFU patients. There were no significant differences in the 2-year ZCQ scores between those who were LTFU and those who remained in the follow-up cohort after 5 years in either treatment group. Fifty-four percent of patients who were LTFU in the IPD group had a 2-year ZCQ score indicative of successful recovery compared with 69% of patients who remained in the follow-up cohort after 5 years ($p = 0.14$). Among the patients in the bony decompression treatment group, 58% had ZCQ scores indicative of successful recovery at 2 years compared with 64% at 5 years ($p = 0.71$).

Secondary Outcome Measures

Neither the bony decompression group nor the IPD group showed statistically significant changes in RMDQ values between 104 and 260 weeks ($p = 0.65$ for both groups), with respective averages of 8.6 and 7.0 points at 260 weeks. The VAS score for back pain was lower in the IPD group than the bony decompression group at 260 weeks (mean 26 vs 38 mm, $p = 0.02$). Similar to ZCQ values, the VAS score for back pain showed a downward trend in the IPD group and an upward trend in the bony decompression group (Fig. 3).

The mean VAS score for leg pain at 260 weeks was 24 mm in the IPD group and 32 mm in the bony decompression group, and the VAS score for leg pain did not show any significant differences between treatment groups during the 5-year follow-up ($p = 0.12$) (Table 3; Fig. 4). The McGill Pain Questionnaire scores showed no significant differences between groups at 260 weeks or over time ($p = 0.48$; Table 3).

The dichotomized Likert scores for perceived recov-

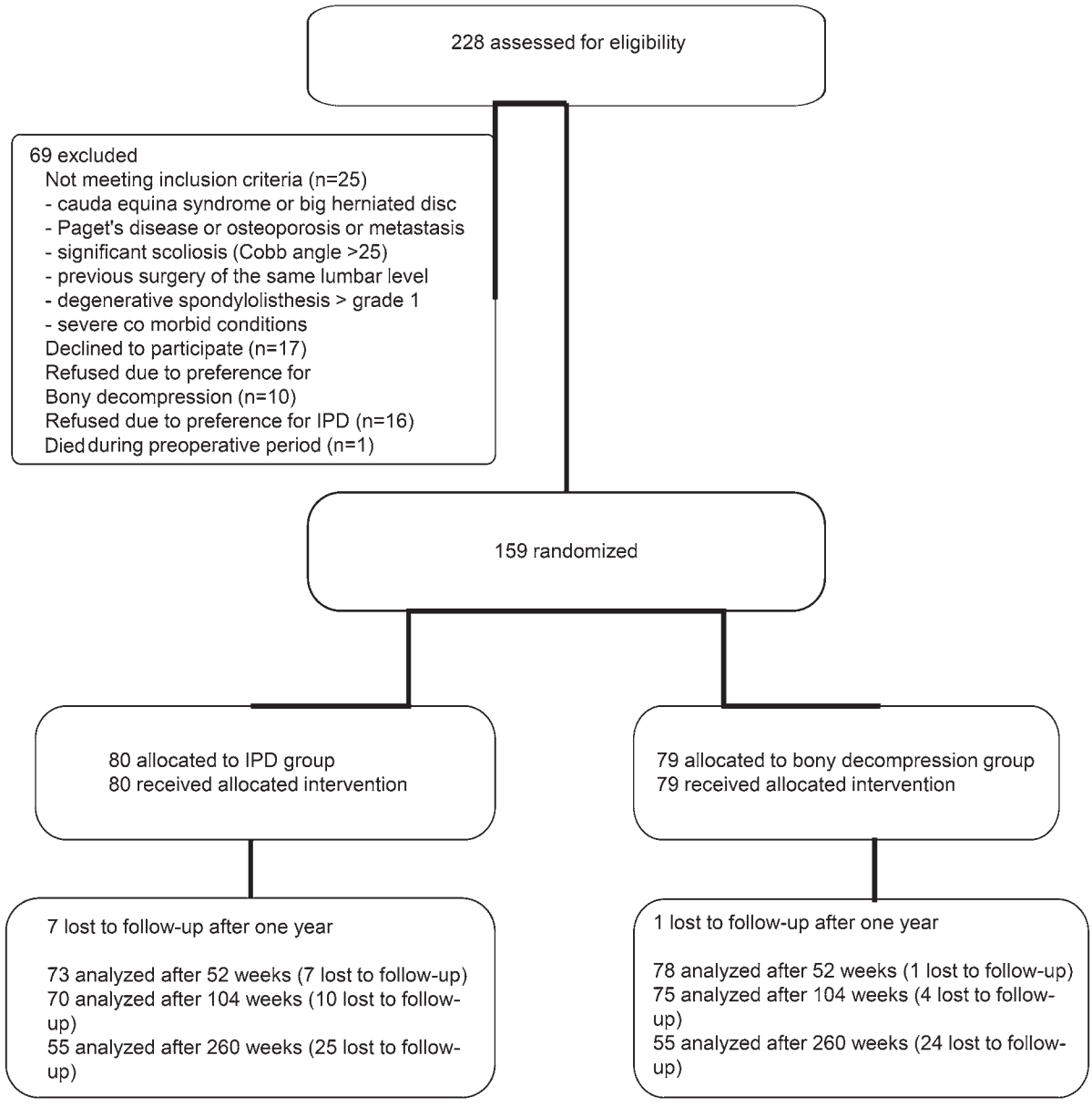

FIG. 1. Enrollment and follow-up.

ery at 5 years were comparable between groups: namely, 65% of patients in the IPD group reported successful recovery versus 63% of the bony decompression group (OR 0.847, p = 0.718). This was a positive trend in comparison with the 2-year follow-up Likert scores, which showed that 54% of patients in the IPD group (p = 0.22) and 46% of those in the bony decompression group (p = 0.06) had a successful recovery (Fig. 5).

Complications and Reoperations

Direct postoperative complications were minor and described in the 1-year follow-up study.[25] Reoperations were indicated and performed on 23 patients (29%) in the IPD group versus 10 patients (13%) in the bony decompression group (p = 0.04). This means that 4 additional patients in the bony decompression group underwent a reoperation since the 2-year analysis,[26] while no additional patients in the IPD group underwent a reoperation. All 23 patients in the IPD group who needed a reoperation had the implant removed and underwent standard surgery with bony decompression at the same level. Of the patients in the bony decompression group who needed a reoperation, 4 underwent a reoperation on the previously operated level. Two of these 4 patients underwent a fusion procedure. The remaining patients in the bony decompression group who needed a reoperation underwent operations on directly adjacent levels.

The ZCQ scores showed that 41% (21%–64%) of the

TABLE 2. Baseline characteristics

Characteristic	IPD Group (n = 80)	Decompression Group (n = 79)
Age, median (range), yrs	66 (45–83)	64 (47–83)
Male sex, no. (%)	49 (61)	37 (47)
Duration of INC, median (range), mos	12 (2–120)	22 (1–204)
BMI, median (range), kg/m^2	27 (20–48)	28 (20–37)
Duration of back pain, range, yrs	1–3	1–3
IPD was preferred treatment, no.	49	46
Mild paresis or sensory loss, no.	67	71
Level of stenosis, no.		
L2–3	2	3
L3–4	25	22
L4–5	53	54
2-level op, no. (%)	21 (26)	16 (20)
ZCQ score, mean ± SD		
Symptom severity subscale (range 0–5)	3.1 ± 0.5	3.2 ± 0.5
Physical function subscale (range 0–4)	2.6 ± 0.5	2.6 ± 0.5
23-item RMDQ score	13.0 ± 5.2	14.4 ± 4.5
VAS, mean (95% CI)		
Leg pain	52 (47–59)	58 (52–64)
Back pain	50 (43–56)	52 (46–58)

reoperated patients in the IPD group had a successful recovery at 5 years, compared with 68% of the total IPD group. ZCQ scores showed that 60% (22%–94%) of the reoperated patients in the bony decompression group had successful recovery at 5 years, compared with 56% of the total bony decompression group.

Discussion

Functionality, as represented by successful recovery according to the ZCQ score, did not show any differences at any evaluation throughout the 5-year follow-up period in this comparison of IPD without bony decompression to conventional bony decompression in patients with symptomatic LSS. In the 1- and 2-year follow-up studies of this trial, it was stressed that the high reoperation rate of the IPD group disqualified this treatment as a suitable alternative to standard decompression. Remarkably, no extra patients in the IPD group underwent operations between 2 and 5 years of follow-up, in contrast to 4 extra operations in the bony decompression group. Reoperations for recurrence of symptoms after conventional decompression may be attributed to secondary collapse of the operated segments due to progressive depression of the intervertebral disc and/or progressive degeneration of the facet joints. Therefore, the results presented here tend to legitimize the rationale for IPD implantation, which tries to achieve indirect decompression and stabilization of the lumbar spine after decompression.

Because stand-alone IPD implantation is a less destructive surgical intervention than bony decompression, it was hypothesized that its use would lead to less postop-

TABLE 3. Primary and secondary outcomes

Variable	8 wks			52 wks			104 wks			260 wks		
	IPD	BD	OR (p value)	IPD	BD	OR (p value)	IPD	BD	OR (p value)	IPD	BD	OR (p value)
Primary outcome												
ZCQ												
No. of patients	73	78	0.73 (0.44)	73	78	0.90 (0.77)	70	75	0.65 (0.20)	55	55	0.717 (0.422)
% successful	63 (51–73)	72 (60–81)		67 (54–74)	68 (57–78)		69 (57–79)	60 (48–71)		68 (56–78)	56 (44–68)	
Secondary outcome												
RMDQ score	7.5 (6.1–9.0)	6.5 (5.3–7.8)	1.0	6.9 (5.4–8.5)	8.1 (6.6–9.7)	1.2	7.5 (5.6–9.5)	8.1 (6.6–9.6)	0.6 (0.65)*	7.0 (5.5–8.5)	8.6 (6.8–10.3)	
VAS score												
Back pain	2.4 (19–30)	23 (17–28)	1	23 (17–29)	31 (24–37)	8	36 (24–48)	28 (23–34)	8 (0.26)*	26 (20–32)	38 (30–46)	12 (0.02)
Leg pain	26 (20–32)	22 (18–27)	4	23 (17–30)	26 (20–33)	3	21 (15–27)	26 (20–32)	5 (0.22)*	24 (17–30)	32 (24–40)	8 (0.12)
Likert scale, % successful	51 (40–63)	53 (41–64)	0.94 (0.85)	56 (45–67)	49 (38–60)	1.37 (0.37)	54 (45–69)	46 (32–55)	1.21 (0.52)	65 (51–77)	63 (50–75)	0.847 (0.718)
McGill Pain Questionnaire score	11 (9–12)	10 (8–12)		11 (9–13)	10 (9–12)		9	11	0.37	10 (8–12)	11 (9–12)	0.48

BD = bony decompression.
Values are shown as mean (95% CI) unless indicated otherwise.
* Overall scores with continuous outcome scales (RMDQ and VAS) were not significantly different.

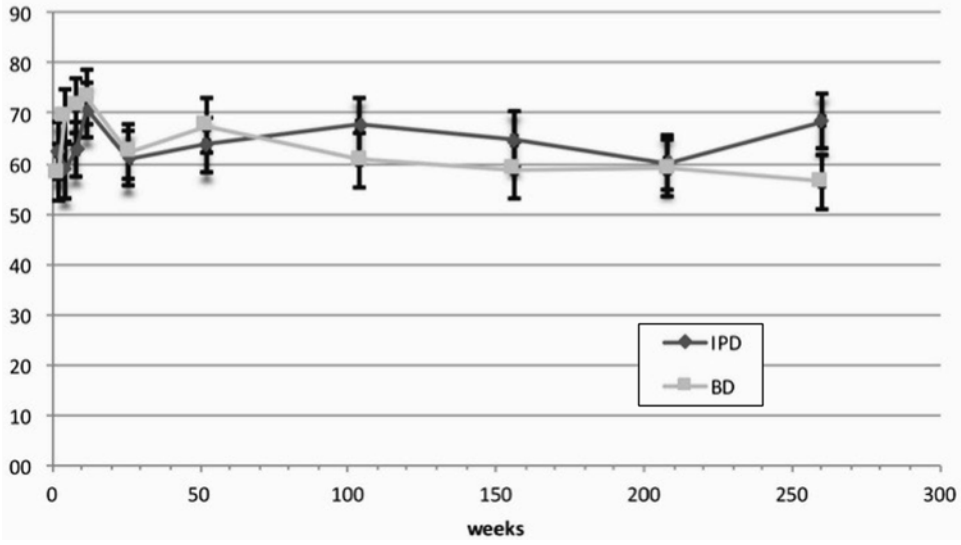

FIG. 2. Proportions of patients with successful recovery over time according to ZCQ score. The *whiskers* indicate 95% CIs. BD = bony decompression.

erative pain, shorter hospital stay, faster recovery, and less low-back pain during the postoperative phase. The 1-year follow-up results could not confirm this hypothesis.[20] The long-term results demonstrated less back pain in the IPD group. This may be the result of the stabilizing effect of the IPD on the target level in the lumbar spine. However, the relevance of this low-back pain score is debatable. The minimal clinically important difference in VAS score for pain is generally between 10 and 20 mm or a decrease of more than 30%.[39] In our study, the baseline VAS score for back pain was 50, which leads to a minimal clinically important difference of 15 between groups. A difference in back pain of 12 mm was demonstrated here. Moreover, a VAS score of 40 mm is usually considered the threshold for clinical relevance.[5,40] Thus, the low-back pain score of the IPD group can be considered clinically irrelevant.

Our study showed improvements in Likert scores between 2 and 5 years after surgery in both treatment groups. Subjective satisfaction scores generally decrease as study populations age. Positive trends could be due to a higher rate of LTFU in patients who were not satisfied. However, in both groups of this study, patients who were LTFU did not have significantly different 2-year ZCQ scores compared with patients who remained in the follow-up cohort. A favorable outcome in 63%–65% of patients, as reported at 5-year follow-up, is in line with the satisfaction scores for LSS surgery reported by other studies.[4–6]

In agreement with our results, Nunley et al. reported ZCQ scores and a reoperation rate of 25% at 5 years after interspinous spacer implantation.[41] Moreover, they also demonstrated that many revisions (20%) took place during the first 2 years after device implantation. They included patients with symptomatic "moderate" LSS, which was not further defined, whereas we included patients with all

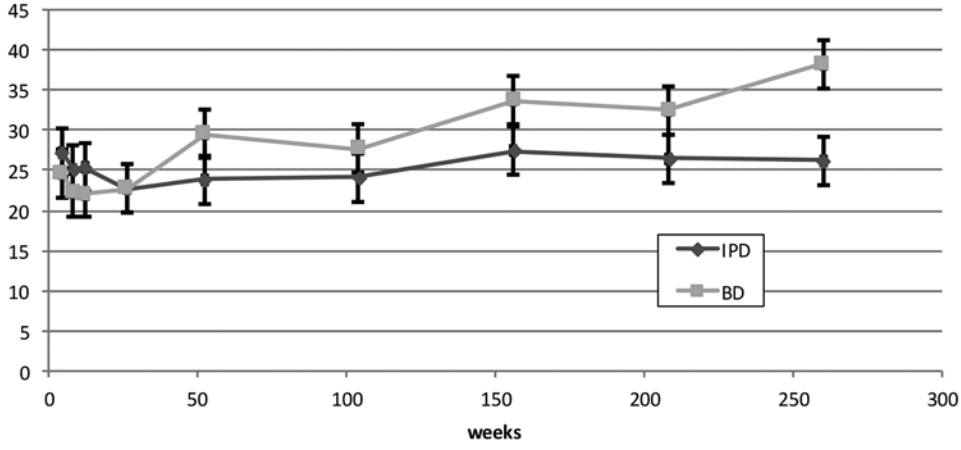

FIG. 3. Mean VAS scores for back pain (in millimeters) over time. The *whiskers* indicate 95% CIs.

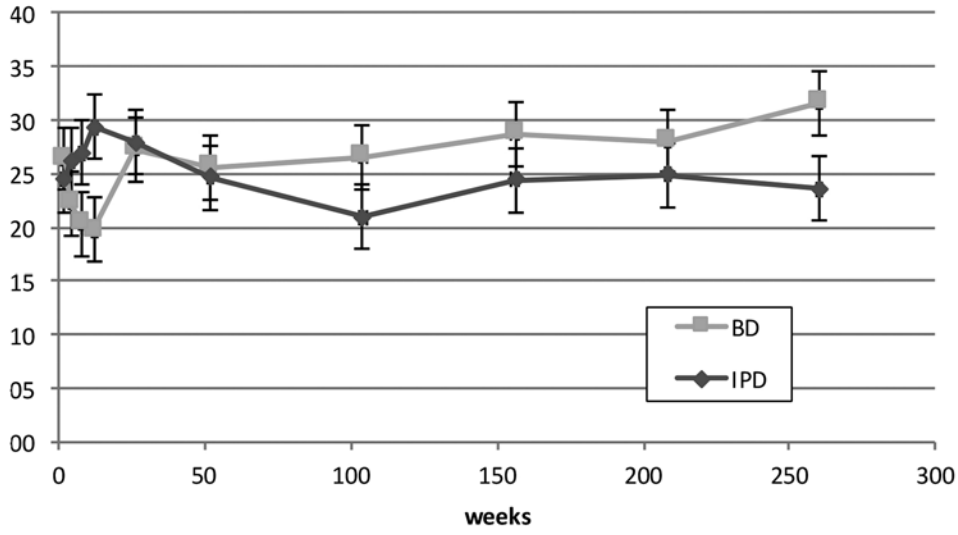

FIG. 4. Mean VAS scores for leg pain (in millimeters) over time. The *whiskers* indicate the 95% CIs.

degrees of narrowing (according to the Schizas scale). In a previously published study of the Felix trial, we reported no correlation between grade of stenosis and clinical outcome.[22,42]

Likewise, Strömqvist et al. showed comparable 2-year ZCQ outcomes, as well as similar secondary outcomes, between patients who underwent IPD and those who underwent bony decompression for symptomatic LSS.[43] They also reported significantly more reoperations in the IPD group than the bony decompression group after 2 years, which is in concordance with our 2-year results. Unfortunately, they did not publish their 5-year results, so a comparison with our 5-year results is lacking.

The blinded randomized controlled design and the long follow-up period are the major strengths of this study because the majority of studies on this subject present a follow-up period of only 2 years.[43–45] The clinical features and baseline pain scores of the patients included in this study are comparable to those of other large trials.[4,5] The elderly population and the long follow-up period pose extra challenges for patient tracing because these patients are more likely to die or move away to retirement or nursing homes over the years. Although the LTFU rate of 30% is relatively high, we considered these losses reasonable given the patient population. Another weakness is that the power of the study was based on ZCQ scores, which prevents us from drawing strong conclusions about other outcome parameters.

There is a subpopulation of LSS patients who thrive well with an IPD, but the number of patients in this study was too small to perform a subgroup analysis in order to identify in which patients IPD is successful. Nonetheless, it is unlikely that the size of the favorable effect would outweigh the higher costs of the implant.

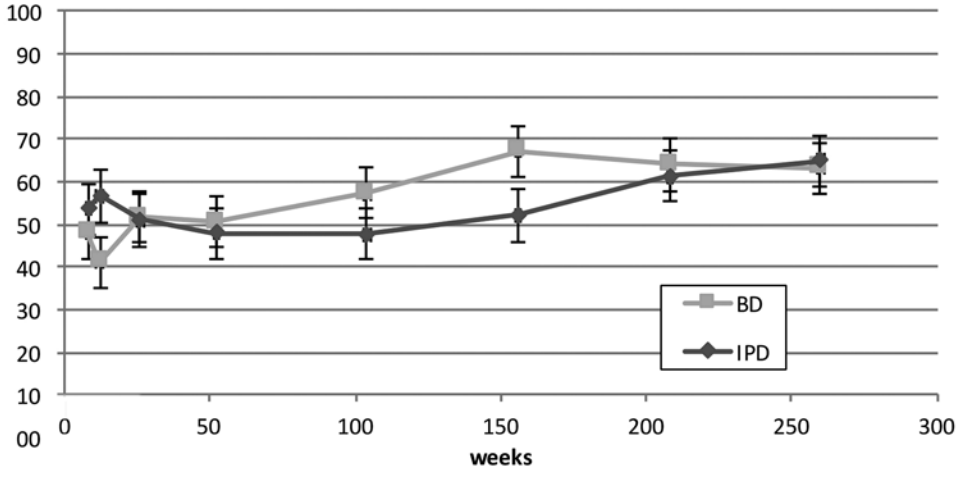

FIG. 5. Proportions of patients with successful recovery over time according to Likert scores. The *whiskers* indicate the 95% CIs.

Conclusions

The present study shows that bony decompression should remain the gold standard treatment of neurogenic claudication because the reoperation rate during the first years after surgery was higher in the IPD group and IPD costs are substantial. Despite these drawbacks, once beneficial, IPD implantation remains successful over long-term follow-up.

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Disclosures

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Author Contributions

Conception and design: Moojen. Analysis and interpretation of data: Schenck, Terpstra, Vleggeert-Lankamp. Drafting the article: Schenck, Terpstra, Vleggeert-Lankamp. Critically revising the article: Schenck, Moojen, Peul, Vleggeert-Lankamp. Reviewed submitted version of manuscript: Arts. Approved the final version of the manuscript on behalf of all authors: Schenck. Statistical analysis: Terpstra, van Zwet. Study supervision: Moojen, Peul.

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