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ORIGINAL ARTICLE

IPD without bony decompression versus conventional surgical decompression for lumbar spinal stenosis: 2-year results of a double-blind randomized controlled trial

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Abstract
Purpose Interspinous process devices (IPDs) are implanted to treat patients with intermittent neurogenic claudication (INC) based on lumbar spinal stenosis. It is hypothesized that patients with lumbar spinal stenosis treated with IPD have a faster short-term recovery, an equal outcome after 2 years and less back pain compared with bony decompression.
Methods A randomized design with variable block sizes was used, with allocations stratified according to center. Allocations were stored in prepared opaque, coded and sealed envelopes, and patients and research nurses were blind throughout the follow-up. Five neurosurgical centers (including one academic and four secondary level care centers) included participants. 211 participants were referred to the Leiden–The Hague Spine Prognostic Study Group. 159 participants with INC based on lumbar spinal stenosis at one or two levels with an indication for surgery were randomized into two groups. Patients and research nurses were blinded for the allocated treatment throughout the study period. 80 participants received an IPD and 79 participants underwent spinal bony decompression. The primary outcome at long-term (2-year) follow-up was the score for the Zurich Claudication Questionnaire. Repeated measurement analyses were applied to compare outcomes over time.
Results At two years, the success rate according to the Zurich Claudication Questionnaire for the IPD group [69 % (95 % CI 57–78 %)] did not show a significant difference compared with standard bony decompression [60 % (95 % CI 48–71 %) p value 0.2]. Reoperations, because of absence of recovery, were indicated and performed in 23 cases (33 %) of the IPD group versus 6 (8 %) patients of the bony decompression group ($p < 0.01$). Furthermore, long-term VAS back pain was significantly higher [36 mm on a 100 mm scale (95 % CI 24–48)] in the

Trial registration: Dutch Trial register number: NTR1307.

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IPD group compared to the bony decompression group [28 mm (95 % CI 23–34) p value 0.04].
Conclusions This double-blinded study could not confirm the advantage of IPD without bony decompression over conventional 'simple' decompression, two years after surgery. Moreover, in the IPD treatment arm, the reoperation rate was higher and back pain was even slightly more intense compared to the decompression treatment arm.

Keywords Lumbar spinal stenosis · Interspinous implants · Bony decompression · Randomized trial

Background

Intermittent neurogenic claudication (INC) caused by lumbar spinal stenosis (LSS) is common in the elderly [1–3]. Concomitant with progressive spinal canal narrowing over the years, patients start to develop the typical symptoms due to compression of the roots of the cauda equina: leg pain (frequently both legs) exacerbated by walking, prolonged standing or lumbar extension, and sometimes associated back pain [3–7]. Surgical treatment is considered to be superior to non-surgical treatment [8, 9]. Patient's satisfaction after treatment is successful in 65 % [8–10]. Open decompression may not provide satisfactory outcome due to the somewhat destructive nature of bony decompression [11–13]. Nowadays, some centers even opt for combining bony decompression with instrumented spondylodesis (pedicle screws and/or intercorporal cages) as the golden standard for treatment of patients with INC caused by LSS [14–16]. Many different new treatment options were, therefore, developed in the 80s and 90s, including less invasive procedures. In particular, in (elderly) patients with LSS due to arthrosis of the facet joints, implantation of interspinous process device (IPD) is regularly offered instead of conventional bony decompression [17, 18]. Neurogenic claudication treatment with IPD has been demonstrated to be superior compared with conservative care [19–23]. The IPD was developed to increase the interspinous distance with indirect decompression of the dural sac and nerve roots due to flexion of the involved segments, and to widen the entry of the spinal root canal at the same time [17–19, 24–30]. Additionally, patients are hypothetically expected to have less postoperative pain, a shorter hospital stay, a faster short-term recovery and less back pain at long-term follow-up.

We previously published the short-term 1-year results of a double-blind randomized trial comparing treatment with IPDs to bony decompression in patients with intermittent neurogenic claudication due to LSS. [31] Patients who were treated with an IPD without bony decompression showed similar rates of recovery at 8 weeks and at 1 year compared to patients treated with bony decompression, although the repeat surgery rate in the interspinous implant group was substantially higher (29 %) in the early post-surgical period compared with the decompression group (8 %; p value <0.001). The 2-year results of the aforementioned trial are presented in the current paper.

Methods

A prospective, randomized double-blind multicenter trial was conducted among patients with INC based on LSS after failed conservative treatment (Foraminal Enlargement Lumbar Interspinosus distraXion: Felix trial). Minimal invasive therapy with placement of an IPD, without any attempt to decompress the spinal canal was compared to the usual care being conventional bony decompression. The medical ethics committees at the five participating hospitals approved the protocol, including an approval for randomization after anesthetic induction. Written informed consent was obtained from all patients. The design and study protocol were published previously [32]. Dutch Trial Register Number: NTR1307.

Eligibility and randomization

Patients between 40 and 85 years with at least three months of INC due to single- or two-level degenerative lumbar canal stenosis and an indication for surgery were eligible. All patients were diagnosed with INC by a neurologist in one of the participating hospitals. If MRI demonstrated a lumbar spinal canal stenosis, patients could be included as surgical candidates for the study by the consulting neurosurgeon. At the time of enrollment, an independent research nurse verified the persistence of the symptoms. Patients with a cauda equina syndrome, moderate and severe degenerative olisthesis, a herniated disc needing discectomy, history of lumbar surgery or those with significant scoliosis (Cobb angle >25 °) or other spinal deformities were excluded.

A randomized design with variable block sizes was used, with allocations stratified according to center. Allocations were stored in prepared opaque, coded and sealed envelopes. The key was only accessible to the ProMISe data management system of the Department of Medical Statistics and BioInformatics of the Leiden University Medical Center. All patients gave informed consent. After induction of anesthesia, the prepared envelope was opened and randomized allocation to one of the treatment arms was performed. Patients, nursery department and research nurses remained blind for the allocated treatment during the follow-up period of two years. The surgical report was kept separately from the regular clinical patient forms and was

only available for the neurosurgeons in case of complications or reoperations.

Interventions

Patients allocated to the experimental group were operated on general anesthesia in knee-elbow position; no bony decompression was performed and an IPD was implanted by a posterior midline approach using x-ray data for localization of the proper level.

Patients in the standard bony decompression group underwent surgery in the same knee–elbow position using a similar incision length as the IPD group to keep all caregivers blind for the allocated treatment. A partial resection of the adjacent laminae was executed, followed by a flavectomy with bilateral opening of the lateral recess. A limited or, if judged necessary, an extensive medial facetectomy was performed. Patients of both groups received the same standard postoperative care. Patients and research nurses who were following these patients were asked after every visit if they were still blind for the allocated treatment [32].

Outcomes

The primary outcome measure was a disorder-specific functional score, obtained by the Zurich Claudication Questionnaire (ZCQ) [33–35]. The primary outcome score was assessed at baseline, direct postoperatively (2 weeks) and at 4, 8, 12, 26, 52, and 104 weeks. The ZCQ consists of three domains (symptom severity, physical function and patient satisfaction) in which, respectively, seven, five and six questions had to be answered on a five-point (symptom severity) or a four-point (physical function and patient satisfaction) scale. The subscale scores were the averages of the points obtained for every question of the subscale, and were maximized to five (symptom severity) or four (physical function and patient satisfaction). The score increases with increasing disability. The average subscale scores were obtained at every follow-up moment by blinded research nurses [32]. The overall ZCQ score was considered to be a 'successful recovery' when two domain subscales at least were judged as 'success' [36]. 'Success' on the symptom severity scale and on the physical function scale was defined as a decrease of at least 0.5 points. A score of less than 2.5 on the patient satisfaction subscale was defined as 'success' [34, 35].

Secondary outcome measures were the Modified Roland Disability Questionnaire for sciatica (scores range from 0 to 23, with higher scores indicating worse functional status), [37–45] 100 mm visual analog scale (VAS) back and leg pain (with 0 representing no pain and 100 the worst pain ever experienced), [46] Medical Outcome Study 36-item short-form Generated Health Survey (SF-36) scale (based on eight scaled scores, which are the weighted sums in their sections) [47, 48], McGill pain questionnaire (with 0 representing minimum pain score and 78 maximum pain score) [49, 50], and a 7-point Likert self-rating scale of global perceived recovery as given by the question whether the patient experienced recovery (dichotomized in 1–2 recovery and 3–7 no recovery) compared to the baseline status [51]. Furthermore, a Hospital Anxiety Depression Scale (HADS) consists of a 7-item depression scale and a 7-item anxiety scale (four-point scale from 0 to 3) were obtained [52]. The seven items of the HADS depression scale are related (if more than 8 points) to depression and the seven items on the HADS anxiety scale are related (if more than 8 points) to generalized anxiety disorder [53]. Most studies report a cutoff point at eight points [53]. Last, patients underwent a Shuttle Walking Test (SWT) with a predefined maximum distance and timeframe (1,200 m or 15 min) [54]. Patients were scored "success" when they walked 1,200 m within 15 min or demonstrated an increase of more than 80 m compared to baseline walking distance [32, 51, 55, 56]. Secondary outcome scores were assessed at baseline (VAS scores) and at 2 (only VAS back and leg pain), 8, 12, 26, 52 and 104 weeks. The HADS anxiety and depression were obtained at baseline and after 52 and 104 weeks.

Sample size

The aim of this study was to assess whether the experimental surgical technique of IPD without bony decompression would be comparable to conventional surgery for patients with INC due to LSS at the time point of 2 years after surgery. Based on our primary outcome score (ZCQ) and an assumed minimal clinically important change (MCIC) of 20 % difference in the overall success rate between the two groups at 8 weeks and 10 % loss to follow-up, it was calculated that a sample size of 80 per treatment group would be required to provide a statistical power of 0.80 and a two-sided alpha of 0.05 [33–36]. This difference of 20 % in success rate was decided based on the assumption that this level of superiority would be convincing enough to change the surgical guidelines and reimburse (in our case the commercial health insurance companies) the costs of the IPD implant. Data from the 104 weeks follow-up were only accessible for the researchers after completion of the full 2-year follow-up period.

Statistical analysis

Groups were compared based on an intention-to-treat analysis. Differences between groups at all follow-up (2, 4,

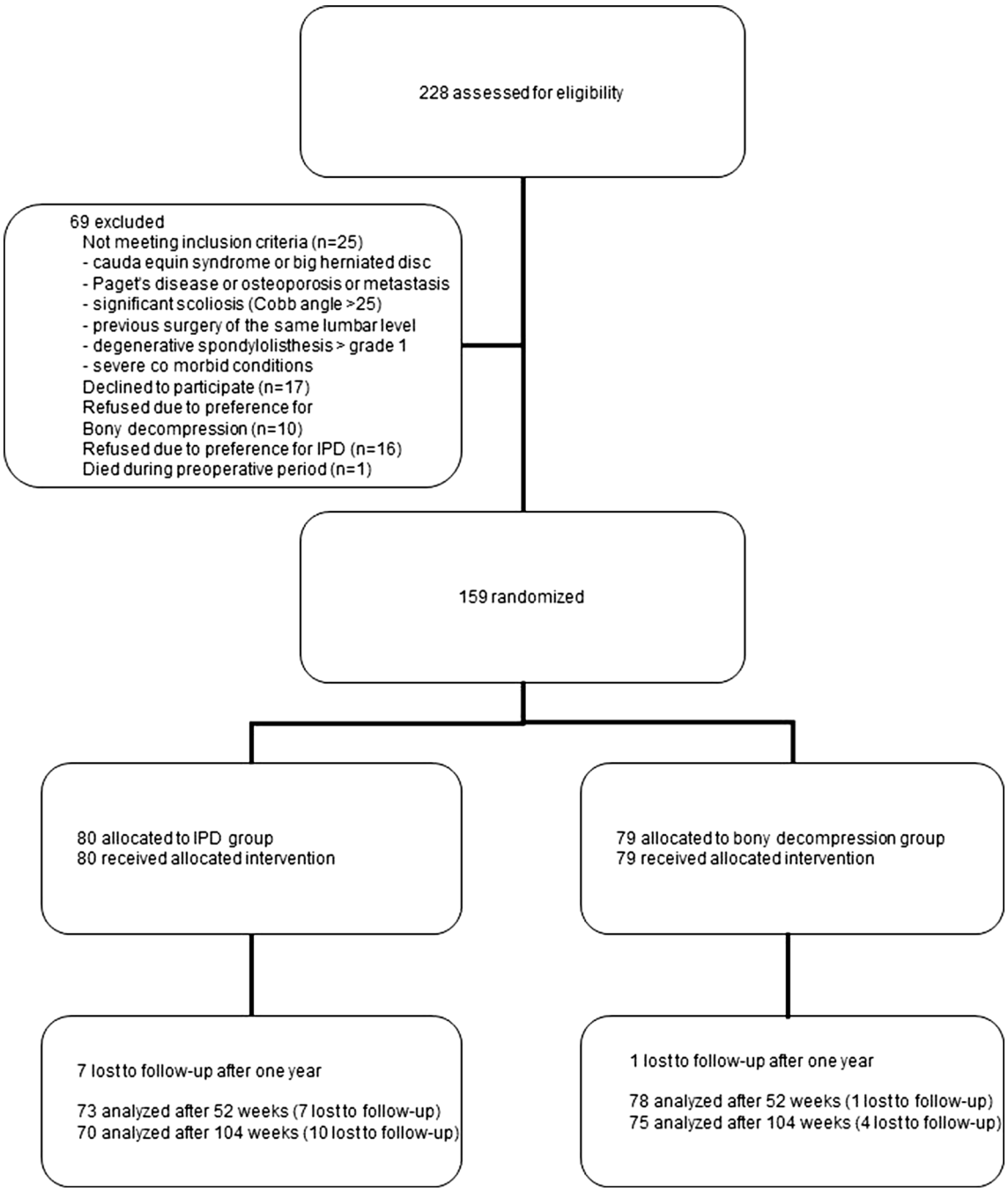

Fig. 1 Enrollment and follow-up

8, 12, 26, 52, 104 weeks) time points were analyzed with repeated measurement analysis. To account for the correlation between repeated measurements of the same individual, generalized estimating equations (GEE) were used. The difference between the results for the two groups was presented as an Odds Ratio (OR) for binary outcome variables and as mean differences for continuous outcome variables. To address potential bias due to loss to follow-up, a sensitivity analysis was performed for the primary outcome by assigning a poor outcome to all missing cases and a second analysis was performed for the primary outcome by assigning a favorable outcome to all missing cases.

At randomization, the study was stratified by the (administrative) center for the purpose of analyzing possible heterogeneity among centers and attempting a clinical interpretation of such heterogeneity. Data collection and checking for quality were performed with the ProMISe

data management system of the Department of Medical Statistics and BioInformatics of the Leiden University Medical Center. IBM SPSS software, version 20.0, was used for all statistical analysis.

Results

Between October 2008 and September 2011, 205 patients with INC due to spinal stenosis were referred to the participating hospitals. Patients with a single or two-level, MRI confirmed, degenerative lumbar stenosis and INC according to their referring neurologists were screened for inclusion by the including neurosurgeon. For 162 patients, signed informed consent was obtained and the patients were enrolled in the felix trial (Fig. 1). One patient died during the time waiting for the operation. Two patients revealed a severe spondylolysis of the L5-S1 segment at final preoperative check-up and were excluded from the study. The remaining patients were randomly assigned to

Table 1 Characteristics of the patients at baseline

Characteristic	IPD group ($n = 80$)	Decompression group ($n = 79$)
Median age–years (range)	66 (45–83)	64 (47–83)
Male sex–no. (%)	49 (60)	37 (47)
Median duration of INC–months (range)*	12 (2–120)	22 (1–204)
Median BMI (range)[#]	27 (20–48)	28 (20–37)
Duration of back-pain (categorized)	1–3 years	1–3 years
IPD was patient's preferred treatment (%)[##]	49 %	46 %
Bony decompression patient's preferred treatment (%)[##]	0 %	4 %
No preference for specific treatment (%)[##]	52 %	50 %
Mild paresis or sensory loss (%)	67 %	71 %
Localization of stenosis–no. (%)	$n = 80$	$n = 79$
L2–L3	2 (3)	3 (4)
L3–L4	25 (31)	22 (28)
L4–L5	53 (66)	54 (68)
Operated on two levels–no. (%)	21 (26)	16 (18)
L2-L3-L4	2 (3)	3 (4)
L2–L3 and L4–L5	1 (1)	0 (0)
L3-L4-L5	17 (16)	13 (16)
ZCQ[$]	Mean (SD)	Mean (SD)
Mean subscale symptom severity 0–5 scale (SD)[$]	3.1 (0.5)	3.2 (0.5)
Mean subscale physical function 0–4 scale (SD)[$]	2.6 (0.5)	2.6 (0.5)
Roland disability questionnaire 23 points (SD)[$]	13.0 (5.2)	14.4 (4.5)
Mean mm VAS leg pain (95 % CI)[$$]	52 (47–59)	58 (52–64)
Mean mm VAS back pain (95 % CI)[$$]	50 (43–56)	52 (46–58)
	($n = 70$)	($n = 70$)
Median meters SWT (range)[^]	180 (20–1,260)	140 (10–1,220)
Percentage of patients completing SWT[^]	8 (10 %)	13 (17 %)

SD standard deviation

* Duration of intermittent neurogenic claudication (INC) in months

[#] Bodily mass index is the weight in kilograms divided by the square of the heights in meters

[##] The question was asked if the patient had any treatment preference (no preference, IPD, or bony decompression)

[$] Zurich Claudication Questionnaire (ZCQ) is a disease specific outcome score. At baseline the score was reported in two sub domains: symptom severity (range 0–5) and physical function (range 0–4)

[$$] The intensity of pain was measured by a horizontal 100 mm visual analog scale (VAS), with 0 representing no pain and 100 the worst pain ever

[^] Shuttle walking distance was obtained before operation. Patients were asked to walk as many meters until the got complaints. The test was scored 'complete' when the patients walked 1,200 m in 15 min without stopping for complaints

Table 2 Primary and secondary Outcome

Variable	8 weeks			52 weeks			104 weeks		
	IPD	BD	OR (p value)	IPD	BD	OR (p value)	IPD	BD	OR (p value)
Primary outcome									
Success ZCQ- % (CI)	63 $N = 73$ (51–73)	72 $N = 78$ (60–81)	0.73 (0.44)	67 $N = 73$ (54–74)	68 $N = 78$ (57–78)	0.90 (0.77)	69 $N = 70$ (57–79)	60 $N = 75$ (48–71)	0.65 (0.20)
Secondary outcome	IPD	BD	Mean difference	IPD	BD	Mean difference	IPD	BD	Mean difference
Mean MRDQ (23 points) score–mean (CI)	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)***
VAS back pain (0–100 mm)–mean (CI)	24 (19–30)	23 (17–28)	1	23 (17–29)	31 (24–37)	8	36 (24–48)	28 (23–34)	18 (0.26)***
VAS leg pain (0–100 mm)–mean (CI)	26 (20–32)	22 (18–27)	4	23 (17–30)	26 (20–33)	3	21 (15–27)	26 (20–32)	5 (0.22)***
	IPD	BD	OR p value	IPD	BD	OR p value	IPD	BD	OR p value
Likert percentage of successful perceived–mean (CI)[#]	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)

The outcomes were analyzed with generalized estimating equations (GEE). Outcome was reported with an (RC) regression coefficient (beta) on a better success rate when treated with IPD versus bony decompression, and overall p value (based on GEE) of the interaction between two groups based on a continuous outcome scale (MRDQ and VAS)

N stands for number of patients analyzed. *CI* denotes 95 % confidence interval, *ZCQ* Zurich claudication questionnaire, *MRDQ* modified roland disability questionnaire, *VAS* visual analog scale, *Dashes* denote tests not administrated ***Overall score in the continuous outcome scales were not significant (MRDQ and VAS)

[#] Likert global perceived recovery is defined by a seven point scale from "worse" to "complete" recovery. The score was dichotomized between (1–2) good recovery and bad recovery (3–7)

IPD without bony decompression or conventional decompression. In effect, 159 patients received the allocated treatment. All patients were suffering from INC for an average period of 23 (IPD group) and 22 (decompression group) months. No significant differences were noted in baseline characteristics between patients in the two treatment arms (Table 1). Ten patients were lost to follow-up in the IPD group and five patients in the bony decompression group at two years after surgery.

Successful recovery according to ZCQ at long-term follow-up (two years) was achieved in 69 % of the patients in the IPD group versus 60 % of the patients in the bony decompression group (OR 0.65; $p = 0.20$). Overall, ZCQ analysis revealed no differences between the two treatment arms (Table 2; Fig. 2). MRDQ values at long-term (two years) decreased with 5.5 points for patients treated with IPD and with 6.3 points for patients treated with bony decompression ($p = 0.65$). MRDQ values at 104 weeks were equal compared with the 52 week's value in the bony decompression group and slightly—not significant—higher (0.6 on a 23 point scale) in the IPD group. GEE analysis showed no differences between the two treatment arms (Table 2; Fig. 2). Analysis of all other subscales, VAS back pain ($p = 0.26$), VAS leg pain ($p = 0.22$), ($p = 0.52$), did not show any differences between treatments at all-time points during the complete follow-up (Tables 2, 3; Fig. 2). However, the back-pain in the IPD group increased in the second year after surgery in comparison to the one year time point (from 23 mm at 52 weeks to 36 mm VAS back pain at 104 weeks). In contrast, the back pain in the bony decompression group remained equal (31 mm at 52 weeks and 28 at 104 weeks), (p value 0.04). GEE analysis on SF36 and McGill pain scores showed no differences (Tables 2, 3). The dichotomized Likert perceived recovery scores showed 54 % successful in IPD group and 46 % successful in bony decompression group (OR 1.21, p value 0.52). GEE analysis on HADS scores showed no differences. Primary outcome scores were not adjusted for HADS depression due to the small percentage of participants with an HADS depression of 8 or more (indicating depression). There was no difference in walking distance in the SWT at 104 weeks

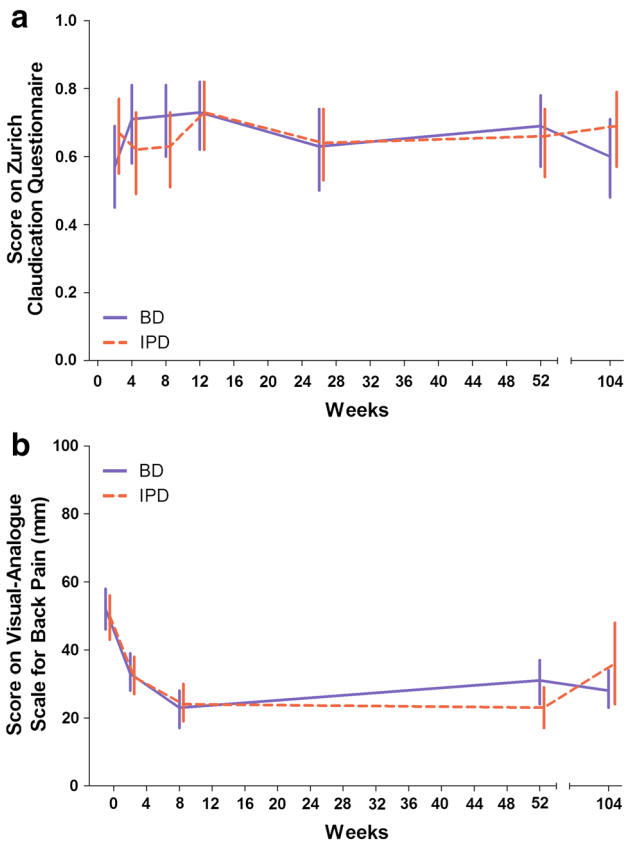

Fig. 2 **a** Shows the percentage of patients which experiences success based on the Zurich Claudication Questionnaire over time. **b** Shows the mean VAS back pain score (0–100 mm) over time

between the two treatment groups (ORs 0.90 p values 0.76) and no difference at 104 weeks in both groups compared with the walking distance at 52 weeks (p value 0.54).

Direct (post)operative complications occurred in six patients in the bony decompression group: two patients with direct epidural hematoma needing reoperation, four patients with dural tears without further consequences. Five patients had complications after IPD treatment: three patients with spinous process fractures, and one patient was explored at the wrong level which was corrected during the same procedure. Reoperations, because of the absence of recovery, were indicated and performed in 23 cases (33 %) of the IPD group versus 6 (8 %) patients of the bony decompression group ($p < 0.01$). One patient underwent second surgery with pedicle screw fixation in the IPD group due to progressive olisthesis. All other patients underwent laminotomy (and removal of the implant in the IPD group) as described in the study protocol [32]. No complications were described in the re-operated patients. This is also, compared with the one-year results (17 reoperations in the IPD group and five in the bony decompression group), a bigger increase in the IPD group without bony decompression in the second year of follow-up. Average hospital stay was similar in both groups: 1.83 days for the IPD group per patient (without hospital stay when operated for the second time) and 1.89 days for the bony decompression group ($p = 0.753$). After reoperations, patients were no longer blind for the type of treatment after reoperation.

Sensitivity analysis was performed to assess the impact of the missing values on our primary outcome. First, all missing values were replaced by unfavorable outcomes. This did not affect our results in any substantial way. Next, all missing values were replaced by favorable outcomes. Again, there were no substantial changes to our results. The results concerning the primary outcome were, therefore, not sensitive to loss to follow-up. There was no clinically significant heterogeneity found in the outcomes between the five centers (supplementary appendix). The small difference will support that the sample of hospitals is a good representation of the Dutch Health Care system with high-complex patients' centers and less-complex patient's centers.

Discussion

The long-term follow-up did not show important differences in results (based on the ZCQ) comparing treatment with IPD without bony decompression and conventional bony decompression in patients with INC based on LSS. Previously published short-term results did not show any short-term benefit (based on the ZCQ) of treatment of IPD compared with bony decompression, and at long follow-up, the ZCQ rate of success was slightly higher for the IPD group, but not significantly [31]. These results were similar compared with other prospective and randomized studies comparing IPDs with bony decompression [57–60]. Furthermore, similar to the published one-year analysis, the reoperation rate was significantly higher (overall and in the period between 52 and 104 weeks) in the IPD group compared with the bony decompression group. Back pain was hypothesized to be less in the group that underwent an operation with less tissue damage, namely the IPD without bony decompression group. However, this was not the result that was encountered: the long-term back pain in IPD group was significantly—though not clinically relevant—higher compared with the conventional bony decompression group.

The recently published randomized trial comparing wide laminectomy combined with posterior and intercorporal fusion, to bony decompression with IPD showed comparable back pain in both groups (104 week VAS back pain of 27 mm and 24 mm, respectively) (Table 4) [14]. In addition, it had already been demonstrated in a non-randomized study that patients suffering from INC treated with bony decompression and adjuvant IPD placement (to

Table 3 Secondary outcome

	IPD	Decompression	(p value)
Percentage success on SWT	Success- % (CI)	Success- % (CI)	OR (p value)‡
8 weeks (increase of 80 or complete)	($n = 73$)	($n = 72$)	0.75 (0.33)
	57 (45–68)	59 (47–0.88)	
52 weeks (increase of 80 or complete)	($n = 66$)	($n = 70$)	1.25 (0.54)
	57 (43–69)	51 (40–62)	
104 weeks (increase of 80 or complete)	($n = 60$)	($n = 59$)	0.90 (0.76)
	63 (52–75)	62 (50–73)	
	Mean (95 % CI)	Mean (95 % CI)	(overall p value)***
McGill pain questionnaire (0–78 points)			
8 weeks	11 (9–12)	10 (8–12)	
52 weeks	11 (9–13)	10 (9–12)	
104 weeks	9	11	(0.37)
	$N = 70$	$N = 75$	
Reoperations (%)	23 (33 %)	6 (8 %)	(<0.01)#
Operated on two levels–no. (%)	21 (26 %)	16 (18*)	
reoperations in patients operated on two levels	8	1	(0.03)#
Duration of operation–minutes (95 % CI)	24 (22-26)	43 (39-47)	(<0.001)
Blood loss–categorized**	10–50 mL	50–100 mL	(<0.001)
Complications during hospital stay	4	6	
Of which spinous process fractures	3	#	#
Hospital stay	1.83 (SD 0.9)	1.89 (SD 1.2)	(0.753)
After reoperation	2.41 (SD 2.1)	3.00 (SD 1.9)	
	($N = 23$)	($N = 6$)	
Blinded to allocated treatment	67 %	86 %	

The outcomes were analyzed with Generalized Estimating Equations (GEE)

CI denotes confidence interval, *SF-36* the medical outcomes study 36-Item, and McGill pain questionnaire, *N* stands for the number of patients analyzed

*** Overall p value (based on GEE) of the interaction between two groups based on a continuous outcome scale (SF-36 and McGill)

** Blood loss 0–10 mL, 10–50 mL, 50–100 mL, 100–200 mL

Spinous process fractures were not registered as relevant complications in the bony decompression group, therefore also no comparison (or p value); p value with Fisher's exact test and Pearson Chi-square, *95 % CI* was 95 % confidence intervals

‡ The odds ratio (beta) on a better success rate when treated with IPD versus bony decompression based on generalized estimating equations (GEE)

maintain posterior dynamic stabilization) had the same long-term VAS back pain as patients treated with bony decompression alone (Table 4) [58, 59]. In the present study, treatment with IPD without bony decompression (operation with less tissue damage) did not result in less back pain as well.

The first interspinous device was designed to damp the motion of extension [17, 18]. A few years later, implants were hypothesized to achieve indirect decompression [61]. In theory, both properties should lead to less back and leg pain. Furthermore, devices were also designed with more rigidity to achieve a long-lasting effect [17]. In the current study, the VAS leg pain was comparable in both groups, even after long-term (two-year) follow-up. In both groups, all success rates (MRDQ, Likert and ZCQ) stabilized, or even increased in the second year of follow-up, without fixation techniques. Indirect decompression with stand-alone device can be achieved and with long-lasting effect. However, the number of reoperations in the IPD treatment arm is worrisome. Especially because re-operated patients

Table 4 Literature comparison of VAS back-pain

Variable	Baseline Mean mm VAS (SD)	104 weeks Mean mm VAS (SD)
Primary outcome		
IPD without bony decompression	60 (44)	36 (23)
Moojen et al.	$n = 79$	$n = 72$
Bony decompression	49 (25)	28 (25)
Moojen et al.	$n = 80$	$n = 76$
Bony decompression	60*	30*
Richter et al.	$n = 30$	*
IPD with bony decompression	60*	30*
Richter et al.	$n = 30$	*
IPD with bony decompression	80 (15)	24 (26)
Davis et al.	$n = 215$	$n = 162$
Bony decompression with fixation	79 (14)	27 (29)
Davis et al.	$n = 106$	$n = 86$

N stands for number of patients analyzed, *SD* stands for standard deviation from means, *VAS* visual analog scale, *Dashes* denote tests not administrated

* No precise values available in abstracts

do not reach the success rate of primary surgeries, it is suggested that use of IPD prevents recovery in 20 % of the patients [31].

One of the strengths of this study is that this is the first blinded randomized study on this subject. Furthermore, due to blinding of patient information during data analysis, we excluded as much as possible bias. However, the present study has also features that may limit the generalizability of its findings. First, selection bias could have been introduced by the opinion of the including neurosurgeon that patients with severe spinal stenosis on the MRI should not be offered an IPD and were thus not included in the Felix Trial. However, clinical features of the patients included in this study demonstrated baseline values (mean VAS (leg and/or back) of 60 mm at baseline) comparable to those of other large trials [8, 61]. Another limitation might be the fact that, because of lack of power, a difference was not found that might exist. As the 2-year results do not show a significant difference, one cannot say that the outcomes were similar or equal. The intention of this study was to find evidence to present strong superiority in favor of IPD, to create arguments to reimburse the expensive implants. This evidence in favor of IPD, however, was not found and the investigators did not find any suggestion in the data that a larger sample size would lead to a different study result. To the contrary, the higher reoperation rate and the higher intensity of LBP in the IPD group do suggest inferiority compared to classical decompression.

Conclusion

This double-blinded study could not confirm advantage of IPD without body decompression over conventional 'simple' decompression. Since the introduction thirty years ago, there is a lack of proof of the superiority of this expensive implants in the treatment of LSS as a stand-alone decompressive device.

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Conflict of interest All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure and declare that The Felix trial was funded by Paradigm Spine/InSpine and was carried out by The Leiden–The Hague SIPS group. Paradigm Spine had no role in data collection, design of the study, data analysis, interpretation of data, writing the report or had any influence whether to submit the manuscript or not. No other relationships or activities that could appear to have influenced the submitted work. All the researchers were individual independent from funders.

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