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REVIEW ARTICLE

Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: a systematic review and meta-analysis

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Abstract
Introduction Despite an increasing implantation rate of interspinous process distraction (IPD) devices in the treatment of intermittent neurogenic claudication (INC), definitive evidence on the clinical effectiveness of implants is lacking. The main objective of this review was to perform a meta-analysis of all systematic reviews, randomized clinical trials and prospective cohort series to quantify the effectiveness of IPDs and to evaluate the potential side-effects.
Methods Data from all studies prospectively describing clinical results based on validated outcome scales and reporting complications of treatment of patients with INC with IPD placement. We searched MEDLINE, EMBASE, Web of Science, Cochrane (CENTRAL), CINAHL, Academic Search Premier, Science Direct up to July 2010. Studies describing patients with INC caused by lumbar stenosis, reporting complication rate and reporting based on validated outcome scores, were eligible. Studies with only instrumented IPD results were excluded.
Results Eleven studies eligible studies were identified. Two independently RCTs and eight prospective cohorts were available. In total 563 patients were treated with IPDs. All studies showed improvement in validated outcome scores after 6 weeks and 1 year. Pooled data based on the Zurich Claudication Questionnaire of the RCTs were more in favor of IPD treatment compared with conservative treatment (pooled estimate 23.2, SD 18.5–27.8). Statistical heterogeneity after pooled data was low (I-squared 0.0, $p = 0.930$). Overall complication rate was 7%.
Conclusion As the evidence is relatively low and the costs are high, more thorough (cost-) effectiveness studies should be performed before worldwide implementation is introduced.

Keywords Degenerative · Lumbar spinal · Stenosis · IPD · Effectiveness · Meta-analysis · Complications

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Introduction

Intermittent neurogenic claudication (INC) is a complex of symptoms, the most important being leg pain and numbness (frequently in both legs) with possibly associated back pain [1–4]. The symptoms can be diminished by flexion of the lumbar spine [5–8]. Lumbar spinal arthrosis inducing arthrosis of the facet is associated with INC [8, 9]. Traditionally, bony decompression of the canal and the lateral recessus seems to be the golden standard in the treatment of INC [3, 4]. There is some evidence that bony decompression is a proven superior therapy compared with non-surgical therapy, such as steroid injections or physiotherapy [10, 11]. Less invasive strategies have been developed to

minimize the perioperative damage, such as unilateral laminotomy or endoscopic procedures [12]. Although surgery is frequently offered, detailed outcome results are not available and spine surgeons try to develop innovative less invasive surgical approaches to gain better outcome than the results observed in daily practice.

Parallel to these developments, interspinous implants for interspinous process distraction devices (IPD) have been developed to achieve indirect decompression [13, 14]. The design of the implants aims at limitation of lumbar extension and increasing the interlaminar space of the affected level [15–19]. Nowadays, the technique is widely used. Kyphon Inc. had a worldwide X-STOP™ net sale, in the first quarter of 2007, of 18.1 million USD. Paradigm Spine Inc. reported in May 2010 a worldwide sale of 13,128 Coflex™ devices in 2009 [20]. The existing evidence seems to be poor; almost no comparative studies between conventional surgical decompression and surgery with IPD are done [17, 21–24]. Some claim, performing IPD placement in day surgery and with local anesthesia will lower the costs. However, a thorough cost-analysis has never been performed.

The main objective of this systematic review was to evaluate if surgery with IPD is more effective compared with bony decompression in the treatment of patients with INC or at least more effective compared with conservative (e.g. steroid injections) treatment.

Methods

This systematic review was performed according to the Cochrane systematic review methodology, up-dated by Furlan and Van Tulder and the Meta-analysis of Observational Studies in Epidemiology (MOOSE) criteria [25–27].

Search strategies

On July 1, 2010, a search of relevant systematic reviews on IPD in the Cochrane Library and, in addition, observational cohort studies (with and without control group), systematic reviews and randomized clinical trials was conducted in MEDLINE, EMBASE, Web of Science, Cochrane (CENTRAL), CINAHL, Academic Search Premier, Science Direct. Keywords used for the search were: interspinous implant surgery, interspinous implants, interspinous distraction devices, interspinous decompression device, interspinous process decompression, intermittent neurogenic claudication, neurogenic claudication, lumbar stenosis, or spinal stenosis. The full search strategy is available upon request from the corresponding author. References of retrieved articles and relevant overview articles were checked to identify additional studies.

Inclusion criteria

Prospective cohort studies, systematic reviews and/or RCTs written in English were considered eligible for inclusion if they fulfilled all of the following:

1. The study population consists of patients with INC caused by lumbar stenosis.
2. Patients with INC without or with degenerative spondylolisthesis to a maximal grade I.
3. One of the treatments consists of non-instrumented IPD for treating symptoms of INC (excluding pedicle screw fixations combined with IPD).
4. A validated outcome score is used to evaluate the outcome after surgery, the Zurich Claudication Questionnaire or the Modified Roland Disability Questionnaire for Sciatica, Oswestry Disability Index, VAS leg and back pain [28–39].

Studies, in which subgroups met our inclusion criteria, were included in our results if the results for these subpopulations were reported separately.

Study selection

Two reviewers independently applied the inclusion criteria to select potential relevant studies from the titles and abstracts or if necessary the complete publication of the references retrieved by the literature search. Where necessary, a third reviewer was consulted to resolve a disagreement.

Categorization of the relevant literature

Relevant literature was categorized under three different headers: systematic reviews, RCTs, and prospective cohort studies of high quality. The header '*systematic reviews*' describes all systematic reviews. The header '*RCTs*' contains all published RCTs on the same intervention comparing IPD with decompression or conservative treatment. Additional prognostic cohort studies were included. The header '*observational cohort studies*' contains all prospective cohorts with adequate description of the follow-up period and validated outcome measurements. When, due to lack of evidence, pooling data was not possible a descriptive review would be performed based on RCTs and prospective observational cohort studies.

Methodological quality assessment

Systematic reviews were validated using the steps defined by Furlan and Van Tulder [27, 40]. To identify potential risks of bias of the included RCTs two reviewers independently assessed the methodological quality of each

RCT according to the Cochrane quality measurements adapted by Furlan and Van Tulder [25, 27, 41, 42]. Each item was scored as "yes", "no", or "don't' know". High quality was defined as a score of 50% or more on the methodological quality assessment. The Dutch Cochrane Centre Quality Assessment (DCCQA) scale was used for the validation process for observational studies. According to the Dutch Cochrane Centre Quality Assessment scale, a score below six was defined as low methodological quality on the DCCQA scale. A third reviewer could be consulted to solve disagreement between the reviewers.

Data extraction

Independently, data were extracted by two reviewers. Information was collected on the study population, intervention(s) performed, outcome measures and outcome. The follow-up time was categorized into short-term outcome (6 weeks after intervention) and long-term outcome (at least 1 year). Furthermore, complication rate and device failure (a re-intervention or other surgical technique was necessary) were recorded. Despite the often mentioned spinal process fractures, all other causes for surgical re-interventions were also recorded [43–46].

Outcome measurements

There are various classifications to describe neurological and functional outcome of patients with intermittent neurogenic claudication. Articles were filtered on presence of one of the four mostly used outcome scales. Firstly, articles were included on the Zurich Claudication Questionnaire (ZCQ), also known as the Brigham Spinal Stenosis Questionnaire and Swiss Spinal Stenosis Questionnaire [35, 38, 39]. The ZCQ scale consists of three subscales: symptom severity, physical function and patient satisfaction. Domain scores ranges from 1 to 5, 1 to 4, and 1 to 4, respectively. Like in the study of Tuli in 2006, we chose threshold scores for each scale based on prior work [35, 38, 39, 47]. In the symptom severity scale and in the physical function scale the minimal clinically important difference (MCID) is 0.5 [38, 39]. A mean patient satisfaction score of less than 2.5 has been shown previously to represent a satisfied patient [38, 39]. Secondly, articles were used on the Modified Roland Disability Questionnaire for Sciatica (MRDQ). The 23-points MRDQ is the most widely used patient-assessed measure of health for low back pain and leg pain [29–34, 36]. This questionnaire consists of 23 questions with higher scores indicating increased disability [48]. The Visual Analog Scale (VAS) is one of the most used follow-up measurement tools for back pain and leg pain [49]. This parameter will measure the experienced back and leg pain intensity in the week before visiting the research nurse. Pain will be assessed on a horizontal 100 mm scale varying from 0 mm, "no pain", to 100 mm, "the worst pain imaginable" [49]. This parameter has a MCID of two points on a scale of 0 to 10 [50]. Finally, the Oswestry disability index (ODI), where 0 indicates no disability and 100 indicates worst possible disability, was included for our analysis [51]. This parameter has a MCID of 10.0–12.4 points [50, 52, 53].

Data synthesis

A meta-analysis was performed if two or more RCTs were available with clinical homogeneous patient groups and statistical homogeneous results. When not possible, due to small amount of studies or heterogeneity, a best-evidence synthesis was used. Best-evidence synthesis was performed stratified for studies meeting 50% or more opposed to those meeting less than 50% of the quality criteria of the Van Tulder list [27]. The study was only included in the best-evidence synthesis if a comparison was made between the groups (IPD placement vs. conservative treatment or IPD placement vs. surgical decompressive treatment). When meta-analysis or best-evidence synthesis based on RCT is not possible, a data extraction based on observational studies (with or without control group) will be performed. Although a high risk of bias is possible, if possible we performed a data extraction from observational studies based on the "best-of-the-rest" principle.

Results

Study selection

The search revealed 253 references. 222 articles were excluded on the basis of the abstract, title and keywords. 20 articles were excluded after reading the complete articles because of the following reasons: the reports did not consist original patient data (4) [17, 23, 54, 55], articles were not written in English (2) [56, 57], there were no outcome results given (9) [24, 58–65], studies with a retrospective study design (5) [43, 66–69]. As a result, only three RCTs and eight prospective cohorts were included for methodological quality assessment in this review (Fig. 1, Flowchart) [17, 21–23, 70–76].

Description of study characteristics

No systematic reviews could be found. Three reports of randomized clinical trials (RCTs) and eight prospective cohorts were found. Three reports described two RCTs comparing non-operative treatment to treatment with IPD; one observational cohort described IPD treatment versus

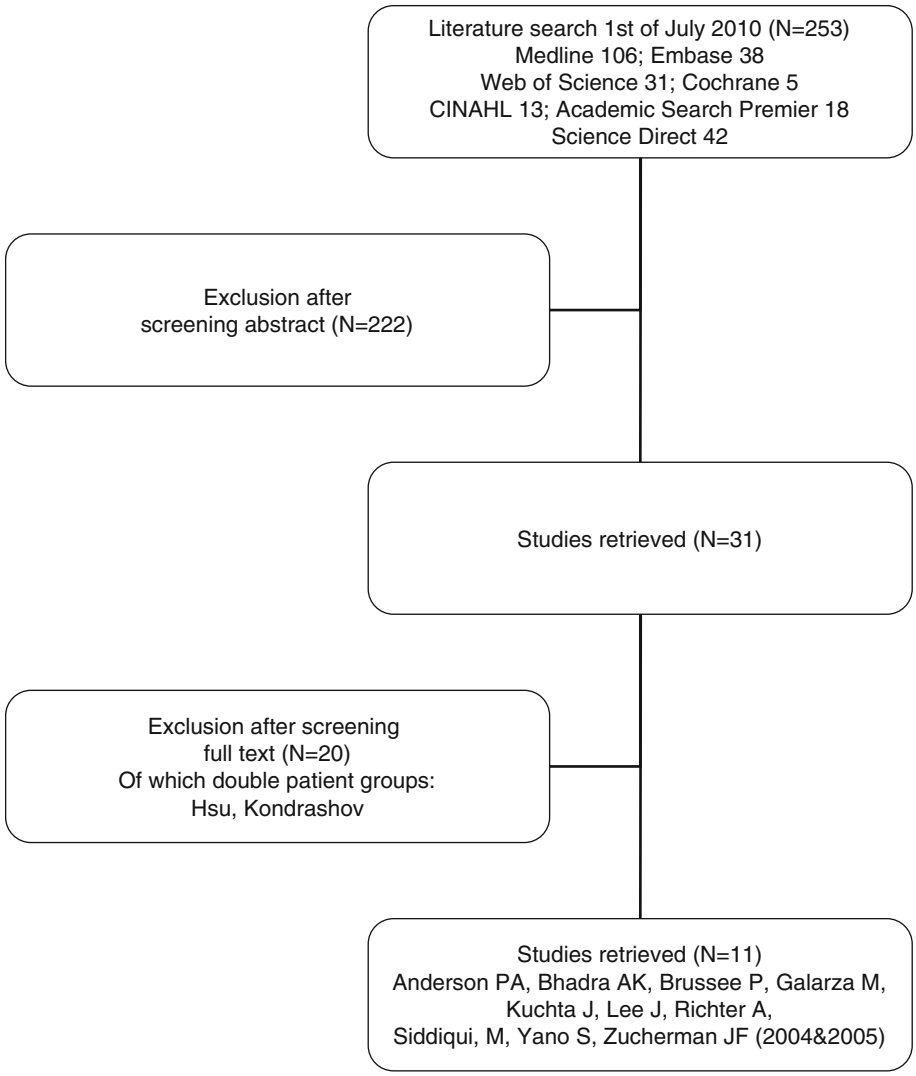

Fig. 1 Flowchart

non-operative treatment after bony decompression in both groups; seven cohorts described treatment with IPD only. Two RCTs described the results of the same patient sample. The first study published follow-up data after 1 year and the last published study after 2 years, both are shown in Table 1 [17, 23].

Methodological quality assessment

The methodological quality of the studies is summarized in Tables 1 and 2. Two reports of one RCT (of the three RCTs) had a methodological quality score of 5 (low quality) and one RCT had a quality of 6 (a high quality study) according to the Furlan and Van Tulder criteria [25, 27]. Only one observational study had a methodological quality of 6 out of 8 (reflecting high quality) [76], thus the remaining 7 observational studies are of low methodological quality and with high risk of bias [22, 70–75].

Data extraction

In Tables 3, 4 and 5, relevant data on the selected studies is shown with the baseline and postoperative follow-up scores at 6 weeks and 1 year. Two RCTs with different patients samples (the two RCTs of Zucherman were conducted on the same patient sample), Anderson et al. and Zucherman et al. [17, 21], could be used for best evidence synthesis. Both RCTs compared conservative treatment with IPD placement (Fig. 2, meta-analysis). Both studies measured follow-up data on the ZCQ. In the study by Zucherman et al., however, overall success rates and standard deviation (SD) values were not shown. A calculation was made, based on the ZCQ values of symptom severity and physical function ZCQ. SD values were calculated estimated from the SD values of Anderson et al. Both studies favored treatment with IPD placement, pooled ZCQ improvement by 23.2 (SD 18.5–27.8). Statistical heterogeneity after pooled data was low (I-squared 0.0, $p = 0.930$). According

Table 1 RCT validation according to Van Tulder validation scale

		Adequate randomization	Allocation concealment	Baseline comparability	Blinding of patient	Blinding of care provider	Blinding outcome assessor	Cointerventions were avoided	Acceptable compliance between groups	Drop-out rate is described	Similar timing of outcome assessment	Intention-to-treat analysis	Overall quality (max 11)
1	Anderson PA	No	No	Yes	No	No	Don't know	Yes	Yes	Yes	Yes	Yes	6
2	Zucherman JF 2004	No	No	Yes	No	No	Don't know	Yes	Yes	Yes	Yes	Don't know	5
3	Zucherman JF 2004	No	No	Yes	No	No	Don't know	Yes	Yes	Yes	Yes	Don't know	5

Max maximal points available

Table 2 Prospective cohort validation according to Dutch Cochrane validation scale

		Patients defined	Absence of selection bias	Treatment defined	Appropriate outcome measurements	Blinded outcome	Sufficient follow-up time	No selective loss to follow-up	Groups comparable confounding factors	Overall quality (max 8)
1	Bhadra AK	+	+	+	+	−	+	−	−	5
2	Brussee P	+	−	+	+	−	−	+	−	4
3	Galarza M	−	−	+	+	−	+	−	−	3
4	Kuchta J	+	+	+	+	−	+	−	−	5
5	Lee J	+	−	+	+	−	−	+	−	4
6	Richter	+	−	+	+	−	+	−	−	4
7	Siddiqui M	+	−	+	+	−	+	−	−	4
8	Yano S	+	+	+	+	−	+	+	−	6

Max maximal points available

Table 3 RCTs—outcome measurements and complications

RCT	Sample size	Control sample size	FU	Age (years)	ZCQ baseline IPD (SD)	ZCQ baseline control (SD)	ZCQ short-term IPD (%)	ZCQ short-term control (%)	ZCQ 1 year term IPD (SD)	ZCQ 1 year term control (SD)	Complications (%)	Device failure (%)
Anderson PA	42	33	99/92	71.4/68.5	50.40 (±2.04)	51.26 (±2.39)	46[a]	27[a]	23.05[a] (±3.14)	47.40[a] (±3.18)	2	2
Zucherman JF	100	91	88/68	69.9/68.6	SS 3.14	SS 3.12	47	10	45.4%	7.4%	2	6
					PF 2.48	PF 2.49	50	10	44.3%	−0.4%		
						Overall success	52[a]	10[a]	48.4%[a]	4.9%[a]		

Age patients' age in years, *FU* complete follow-up, *ZCQ* Zurich Claudication Questionnaire, *SS* ZCQ symptom severity domain, *PF* ZCQ physical function domain

[a] Values of ZCQ overall success domain

to the statistical heterogeneity, baseline criteria in both studies showed a good clinical homogeneity. Richter et al. [22] compared two surgical decompression cohorts: one group with surgical decompression and no IPD placement, one group with surgical decompression with IPD placement. Both groups showed clinical improvement in the ODI, MRDQ and VAS. At 6 weeks and at 1 year follow-up there were no statistical significantly differences between both groups. The remaining seven prospective cohort studies showed improvement from baseline after treatment with IPD [70–76]. However, these groups did not compare other treatment modalities (such as conservative treatment) with IPD follow-up results. Due to the use of multiple follow-up scales, pooling of data was not possible (Tables 4, 5, prospective cohort studies).

In our search of literature, 563 patients underwent implantation with IPD. Complication rates and device failure rates were available from 513 patients (Table 3, RCT, Tables 4, 5, prospective cohorts). A total of 31 devices failed (6%) and had to be replaced or were re-operated with bony decompression and stabilization. Six (1%) other complications were also reported (infections and postoperative leakages).

Discussion

The literature has been systematically reviewed to evaluate the outcome for patients with intermittent neurogenic claudication treated with IPD versus bony decompression or conservative non-surgical treatment. To our knowledge, this is the first systematic review and meta-analysis on this subject. After a literature search, two independent RCTs and eight prospective cohorts, one with a control group, were eligible for validation and data extraction. The methodological quality of the RCTs were 5 (Zucherman) and 6 (Anderson) [17, 21]. The methodological quality of the remaining prospective cohort studies was relatively low (only one reached 6 out of 8) [22, 70–76]. In total 563 patients were treated with IPD. All studies showed improvement in validated outcome scores after 6 weeks and 1 year. Pooled data of the RCTs were more in favor of IPD treatment compared with conservative treatment.

The review of the literature showed that very little is known about treatment with IPD. Only one comparative study with good methodological quality fulfilling our selection criteria was found [21]. Different indications are used for these devices, such as described by Richter who used an IPD in combination with surgical decompression [22]. Some studies show beneficial effect of surgical technique compared to conservative treatment for patients with degenerative lumbar spinal stenosis and neurogenic intermittent claudication [10, 11]. More centers, however,

Table 4 Prospective cohorts comparing conservative treatment with surgery with IPD—outcome measurements and complications

	Sample size	Device	FU (%)	Age	Follow-up	VAS baseline	VAS follow-up	ODI baseline	ODI follow-up 1	ODI follow-up 2	ZCQ baseline SS/PF	ZCQ follow-up 1 SS/PF/PS	ZCQ follow-up 2 SS/PF/PS	Complications (%)	Device failure (%)
Bhadra AK	45	X-Stop	100	61.5		69	28	42	16					4	2
Brussee P	65	X-Stop	95	64.4										0	9
Galarza M	40	Aperius	100	72.7	1 year	71	22					90%			
Kuchta J	175	X-Stop	100	69.4	6 weeks/1 year	61	39	33	23	15				0	5
Lee J	10	X-Stop	100	71.0	9–18 months							50%		0	
Siddiqui M	37	X-Stop	65	71.5	3 months/1 year			48	35	37	3.37/2.45	2.42/2.05/1.90	2.83/2.19/2.12	0	11
Yano S	19	Ceramic	95	70.1	Mean 37.4 months	69	30				2.94/2.51	1.92/1.73		0	11

Age patients' age in years, *FU* complete follow-up, *Follow-up* follow-up periods, *ZCQ* Zurich Claudication Questionnaire, *ODI* Oswestry Disability Index, *VAS* Visual Analog Scale, *SS* ZCQ symptom severity domain, *PF* ZCQ physical function domain, *PS* ZCQ patient satisfaction domain

Table 5 Prospective cohorts comparing decompressive surgery with decompressive surgery combining IPD—Outcome measurements and complications

	Sample size	Device	Control sample	FU (%)	Age	Follow-up	VAS baseline	VAS follow-up 1	VAS follow-up 2	ODI baseline	ODI follow-up 1	ODI follow-up 2	Complications (%)	Device failure (%)
Richter	30	Coflex	30	100	68.0	3 months/1 year	63	25	22	48	23	18	3	10

Age patients' age in years, *FU* complete follow-up, *Follow-up* follow-up periods, *ODI* Oswestry Disability Index, *VAS* Visual Analog Scale

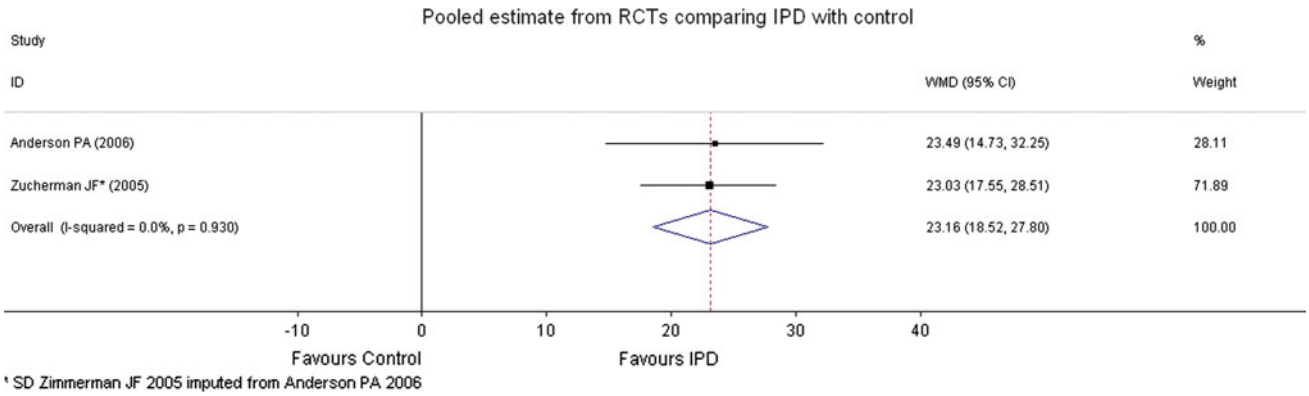

Fig. 2 Meta-analysis. *IPD* interspinous process decompression, *SD* standard deviation, *WMD* weighted mean difference

perform complex techniques rather than only a decompression technique. Between 2002 and 2007, complex fusion procedures showed a 15-fold increase in the USA. Furthermore, the overall procedure rate slightly decreased with 1.4% [77–79]. Coflex worldwide implants increased from 1,717 in 2005 to 13,128 in 2009. Even without evidence of implantation of an IPD as a treatment strategy for INC, some centers use it in a combination with other techniques [22]. Despite the fact that no arguments exist in the literature about the effectiveness of treatment with IPD versus bony decompression, many centers throughout the world use IPD for the treatment of INC.

Overall complication and failure rate of (7%, including 6% reoperations rate after device failure) tended to be relatively low compared to the complication rate of standard bony decompression. For example, Weinstein and Malmivaara [10, 11] reported a complication rate of 17–24% in the standard bony decompression operation cohorts. The most frequently reported complications in these series are dural tears and wrong level surgery. Due to the use of standard X-rays in the operation theater with IPD treatment, wrong level surgery in interspinous decompression surgery is rare. Most techniques of interspinous decompression are indirect and with some distance from the dura, therefore causing a dural tear is difficult by regular surgical methods. Despite the large numbers of case reports on complications after IPD treatment, complication rates tends to be low [43, 44, 80, 81]. This, however, might be induced by selection bias of published studies. Despite the relatively low complication rate, device failure rate needing reoperation is high (6%). This number can be higher because of the publication bias, but also the lack of long-term follow-up. This conclusion is difficult to confirm due to the fact that no comparative studies are done on this subject. Combined with the 6% device failure rate complication rate, the IPD complication rate is 7%. In the literature, implantation surgery is associated with complication rate of 8% (2–6% failure rate) [79]. The complication rate would be possible higher when complications would be monitored 30 days after discharge. Not all studies included in our review reported complication rate 30 days after hospital stay. Prospective reporting of complication should be made standard in future trials.

The most important limitation of this review concerned the methodological weaknesses and selection biases of the included studies: the vast majority was observational, without independent outcome assessment, and without complications well defined. Additionally, we combined two different RCTs for our meta-analysis [17, 21]. Both studies did not mention a thorough power or sample size design, resulting in a 191 patients in one RCT and 75 in the other. Furthermore, only one study was of relatively high methodological quality. Therefore, possible information bias could be introduced. Furthermore we excluded 242 studies, introducing selection bias. Due to the retrospective design of some of these studies, possible interesting patient data had to be excluded. Studies that were published in abstract or poster format only were excluded. The present study was aimed at identifying published peer-reviewed literature, so that influence of publication bias cannot be ruled out. Due to the small number of studies, possible publication bias (using e.g. funnel plot) could not adequately be assessed. Due to the anticipated low number of RCTs, prospective studies were also included. Most of these studies were of low methodological quality (Table 2, Validation). Due to the inclusion of studies of low methodological quality, information bias is easily introduced. Furthermore, methodological quality assessment does not take into account the author's disclosure. For example, two studies in our review stated that one of the authors is a consultant and, in one article, stockholder of the company manufacturing the IPD device they were using for their study [21, 70]. The remaining studies did not mention any conflict of interest or disclosure. Seven studies did not even describe the possible conflicts of interest. Assessing possible conflict of interest is not incorporated in both

validation scales [25, 27]. Standard adjusting both scales based on possible conflict of interest is advisable.

This review of the literature shows that surgical decompression with interspinous process devices is superior to conservative non-surgical treatment in patients with lumbar degenerative spinal stenosis with INC. However, the level of evidence for this conclusion is debatable due to the low quality of some of the included studies. Furthermore, no data is presently available comparing interspinous process decompression with standard bony decompression. We suggest that more studies will be done on this subject comparing the surgical treatment with IPD versus bony decompression. Despite the fact that we could give a Grade A recommendation, according to the Oxford-Centre for Evidence Based Medicine, we suggest that further studies have to be performed before a thorough recommendation can be given regarding the treatment of INC with IPDs [82]. These studies should also include analysis on complication rate and device failure rate. As the evidence is relatively low and the costs are high, more thorough cost-effectiveness studies should be performed before worldwide implementation is introduced. Because the golden standard for surgical decompression seems to be absent, patients with lumbar spinal stenosis should be guarded against instrumented surgery or the use of IPD on the basis of the current evidence.

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Conflict of interest The authors have no conflict of interest.

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