

# Surgical outcomes of patients with degenerative lumbar disc disease post-IntraSPINE® device fixation: Three-year prospective study

*Running title:* IntraSPINE® device in patients treated for degenerative spinal pathologies

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## Abstract

**Background:** Lumbar degenerative disc disease is one of the most common conditions associated with chronic low back pain. IntraSPINE® is a novel inter-laminar device that allows more physiological rocking-type movements in flexion and extension.

**Aim:** To evaluate the results of patients with symptomatic Lumbar degenerative disc disease treated with an IntraSPINE® device and followed up over a 3-year period.

**Materials and Methods:** A Prospective longitudinal research study involving patients with imaging-confirmed Lumbar degenerative disc disease in whom conservative treatment was unsuccessful. Outcome measures were changes over baseline score on the Oswestry Disability Index (ODI), and low back and radicular pain assessed at 6, 12, 24 and 36 months postoperatively. Overall success, a composite outcome that included key safety and clinical considerations, was assessed. Secondary outcomes included satisfaction with symptoms, employment status and post-surgery medical interventions. To compare differences in longitudinal clinical score patterns over 36 months, a mixed-effect model ANCOVA with repeated measurements was performed, with adjustment for low back and radicular pain score and ODI score at baseline.

**Results:** 231 patients were recruited and 180 completed the study. A significant improvement in ODI score ( $p=0.0597$ ), as well as in VAS (Visual Analogue Scale) scores for back ( $p= 0.0228$ ) and leg pain ( $p<0.0001$ ) was observed during the follow-up. For ODI score, the mean percentage decrease from inclusion to month 36 was 64.5%. These scores were respectively 66.2% for radicular pain and 46.4% for low back pain. In 73% of cases, surgery was considered successful. 89% of working patients returned to work and 68% of patients were very satisfied at month 12. Only four patients presented intraoperative complications.

**Conclusion:** Patients treated with IntraSPINE® showed significant and clinically meaningful improvements in disability and pain for up to 36 months. The results of this study also demonstrated very satisfactory safety data.

**Keywords:** spine surgery, IntraSPINE®, interlaminar device, degenerative lumbar disc disease, low back pain

## Introduction

A variety of diseases can cause low back pain (LBP), one of which is degenerative lumbar disc disease (DDD)[1]. When conservative treatment fails, surgery may be considered. Although the rationale for surgery is often unclear, and despite the lack of convincing evidence regarding the effectiveness of surgery in the treatment of symptomatic DDD, the number of surgical procedures performed is continually increasing [2,3]. Yet the presence of LBP and DDD can support the placement of an interspinous device (ISD) [4–8].

The reported indications for ISDs are diverse and include degenerative spinal stenosis, discogenic LBP, facet syndrome, disc herniation and instability [9,10].

IntraSPINE® is a novel device that, unlike interspinous positioned implants, is unique in being placed more anteriorly in an interlaminar position, closer to the normal center of rotation of the motion segment [11,12]. Mechanical advantages are thus conferred over more posteriorly positioned devices through the possibility of more physiological ‘rocking’ type movements in flexion and extension [13,14]. This enables IntraSPINE® to off-load the facet joints in extension without blocking movement. Having a more anteriorly placed fulcrum also helps control excessive flexion movements by virtue of an improved lever arm in conjunction with an intact posterior tension band [15].

The aim of this three-year prospective study is to report the results of patients with symptomatic DDD who were treated using an IntraSPINE® device. After a follow-up period of 36 months, we evaluated the clinical and safety results of the IntraSPINE® device in the treatment of DDD patients.

## Materials and Method

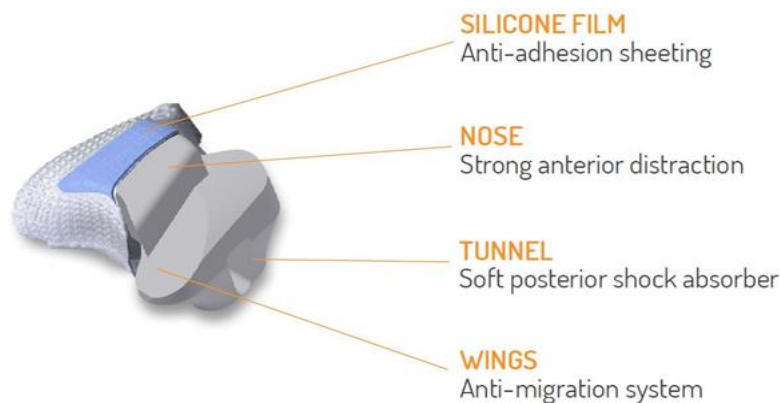
A prospective study was performed throughout the period from November 21, 2012 to December 20, 2017. It was conducted at 4 French clinics specializing in spinal surgery and involved one surgeon at each clinic. Patients were recruited from November 21, 2012 to December 1, 2014.

Patients with symptomatic LBP and / or radicular pain, with imaging confirmed DDD at one or two levels in whom conservative treatment was unsuccessful, and who had undergone surgery using IntraSPINE® were included. Inclusion diagnoses were: lumbar disc herniation (LDH), foraminal stenosis and facet joint syndrome. Non-inclusion criteria were: aged < 18 years, allergy to one of the components of the implant, pregnancy, infected site and patients with known isthmus spondylolisthesis or spinal dysraphism.

Eligible patients with a diagnosis of DDD were informed about the study and, after providing written consent, each patient was enrolled. Patients were evaluated at 6, 12, 24 and 36 months postoperatively and all underwent a postoperative MRI.

**Investigational Device:** The IntraSPINE® is a dynamic interlaminar device made of medical dimethyl siloxane and covered with pure polyethylene terephthalate. The front surface is coated with a silicone film to prevent the formation of adhesions in the region of the yellow ligament or dura mater [16,17] (Figure 1). The device is available in five sizes (8, 10, 12, 14 and 16 mm) for optimal accommodation of the interlaminar space. IntraSPINE® is CE marked (March 2007) and made of materials allowing it a permanent duration of use or contact with the body.

The implant is compressed within the interlaminar space resulting in an immediate stable interference-type fit. Soft tissue in- and on-growth further secures the implant over time.



**Figure 1:** Image of the IntraSPINE® device (Source: Cousin Biotech).

**Surgical Technique:** All the participating clinics performed comparable routine spine surgical procedures as described on the manufacturer’s guidelines. All operations were performed under general anesthesia in the prone position with appropriate positioning precautions and hips and knees flexed.

Implanting IntraSPINE® is performed according to the following technique: incision of the interspinous ligament, trying to preserve the supraspinatus ligament. The distractor provided is used to improve access to the interlaminar space. Metal trials that are also available in 5 sizes are used to accurately size the interlaminar space.

The selected implant is briefly immersed in saline and then compressed with a simple holder which narrows the cranio-caudal dimension of the implant to facilitate simple lateral insertion.

## Data collection

All data were collected using Quanta view eCRF and the Evamed database. Baseline evaluations, including basic demographic data and employment status, were conducted before surgery. Disc degeneration was assessed using the Pfirrmann grading system.

Furthermore, surgical data were collected. Variables of interest including discharge disposition, length of stay and post-surgical complication were also obtained from patient’s charts and physician’s notes.

## Clinical Outcome Measures

### Assessments of disability status and pain

Disability functional assessment was measured using the Oswestry disability index (ODI)[18], both preoperatively and at 6, 12, 24 and 36 months of postoperative follow-up.

Low back and radicular pain were also assessed on a visual analogue scale (VAS)[19] at each visit on a horizontal 100-mm scale ranging from 0 mm, “no pain”, to 100 mm, “the worst pain imaginable”. Patients were not shown the records of their earlier assessments.

Success was achieved if postoperative improvement at month 36 in terms of ODI score was at least 30%, and in the absence of complications, including revision surgery (reoperation) at the treated level, removal of the implant, infection or re-herniation or any other adverse event related to surgery or the device.

### Post-surgery and satisfaction data

Secondary measures included patient work status and return-to-work data. Other medical interventions, including medication use and physical therapy were collected. The Likert scale was used to assess the grade of satisfaction with current symptoms and with care (1: Not satisfied at all, 4: Very satisfied).

### Complications

A systematic assessment of complications including infection, hematoma, deep venous thrombosis, vascular injury, was carried out. Moreover, surgeons were asked to record intraoperative complications such as cerebrospinal fluid leakage. Throughout the entire course of the study,

information was also collected on Adverse Events (AEs) and Serious Adverse Events (SAEs) occurring at any time point. Recurrent lumbar disc herniation (at the operated level) was also taken into account. Recurrent herniation was confirmed using MRI and classified as either symptomatic re-herniation (painful and requiring surgery) or non-symptomatic re-herniation (confirmed by MRI but not requiring reintervention).

### Statistical analysis

Data analyses were performed using SAS Version 9.4 (SAS Institute, Cary, NC USA software). Data are presented as median and interquartile ranges (25th-75th percentiles) for continuous variables and number (percentage) for categorical variables.

To compare differences in longitudinal clinical score patterns over 36 months, a mixed-effect model ANCOVA with repeated measurements was performed, with adjustment for low back and radicular pain score and ODI score at baseline.

Safety data were described over the study period (number, seriousness, outcomes, and causal relationship with IntraSPINE® implant). Two-sided tests with type I error  $\alpha = 0.05$  were applied to all analyses.

### Results

A total of 231 patients were included in the study. Of these, 180 (78%) completed the study with an average follow-up of 2.7 years (Figure 2: study flow chart).

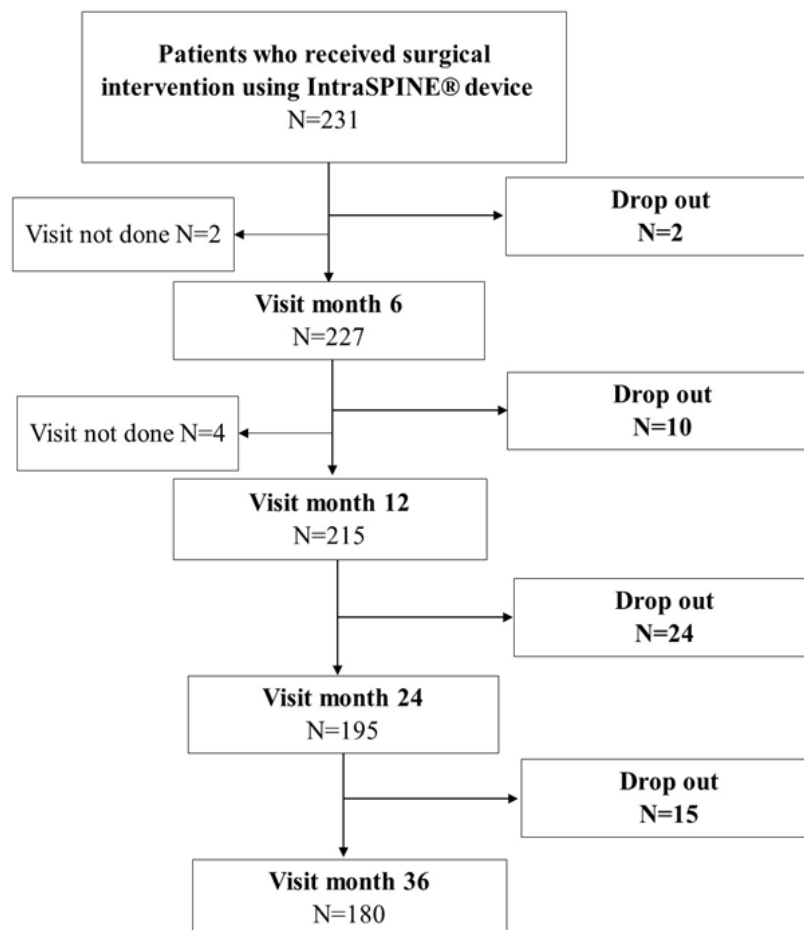


Figure 2: Patient flow chart

Baseline characteristics of the 231 included patients are shown in **Table 1**. Median age was 49 years (Q1; Q3: 40; 61). The majority of patient being male (58.9%) and employed (62 %). A median work stoppage of 30 days (Q1; Q3: 30; 90) was prescribed for 71/139 (51 %) employed patients. Disc herniation was the most common reported diagnosis (63%).

About 83% of the patients had degenerative disc disease at a single level, with L4/5 being most commonly affected (59%). Among patients, 59 (31%) were classified as Pfirrmann Grade II. Drug therapy before surgery was prescribed for 99 % of patients and 76 % had physical therapy.

Characteristics		Missing data
<b>Age (years), Median [Q1; Q3]</b>	49 [40 ;61]	
<b>Age at onset of symptoms (years), Median [Q1; Q3]</b>	48 [38 ; 59]	
<b>Symptom duration (years), Median [Q1; Q3]</b>	1 [0.9; 2]	
<b>Sex N (%)</b>		
Male	136 (59)	
Female	95 (41)	
<b>BMI (Kg/m<sup>2</sup>), Mean (SD)</b>	25 [16 ;42]	
<b>Employment status, N (%)</b>		8
Retired	61 (27)	
Without employment	23 (10)	
Hard physical work	84 (38)	
Sedentary work	55 (25)	
<b>Diagnosis, N (%)</b>		
Disc herniation	146 (63)	
Foraminal stenosis	36 (16)	
Facet syndrome	6 (3)	
Mixed pathology	33 (14)	
Other	10 (4)	
<b>Number of Level affected, N (%)</b>		
One	191 (83)	
Two	40 (17)	
<b>Level of degenerative disc disease, N (%)</b>		
<b>Level 1</b>		
L1-L2	0 (0)	
L2-L3	6 (3)	
L3-L4	37 (16)	
L4-L5	136 (59)	
L5-S1	52 (22)	
<b>Level 2 (N=40)</b>		
L3-L4	3 (8)	
L4-L5	18 (45)	
L5-S1	19 (47)	
<b>Pfirrmann Grade, N (%)</b>		39
Grade I	36 (19)	
Grade II	59 (31)	
Grade III	46 (24)	
Grade IV	28 (14)	
Grade V	23 (12)	
<b>Surgical history at spinal level, N (%)</b>		4
Surgical history on the affected level	5/17 (29)	
<b>Clinical symptomatology<sup>(a)</sup>, N (%)</b>		
Low back pain or radicular pain	217 (94)	
Nerve Root pain	225 (97)	
Intermittent neurogenic claudication	25 (11)	
Deficit signs	36 (16)	
<b>Conservative treatment applied<sup>(a)</sup>, N (%)</b>		3
Drug therapy	226 (99)	
Physical therapy	174 (76)	
Rigid or semi-rigid lumbar belt	80 (35)	
Infiltration	158 (69)	

(a) The total percentage may exceed 100% because some patients can have more than one category.

**Table 1:** Baseline characteristics of study participants (N=231)

Surgical data are presented in **Table 2**. 87% of patients had single-level surgery and implantation, and the remaining 13% had two-level surgery with two devices being implanted.

The median operating time was 40 minutes (Q1, Q3: 35, 60). Median blood loss was 50 ml (Q1, Q3: 20,100).

Hospitalization was required in 97% of patients, with a median hospital

stay of 4 days (Q1, Q3: 3, 5). Day case surgery was achieved in 6 patients (3%).

Most patients (220, 96%) were discharged home with routine postoperative care. Routine drug therapy, comprising analgesics, psychotropics or non-steroidal anti-inflammatory drugs, was prescribed for 174 (79 %) of these patients during the immediate postoperative period.

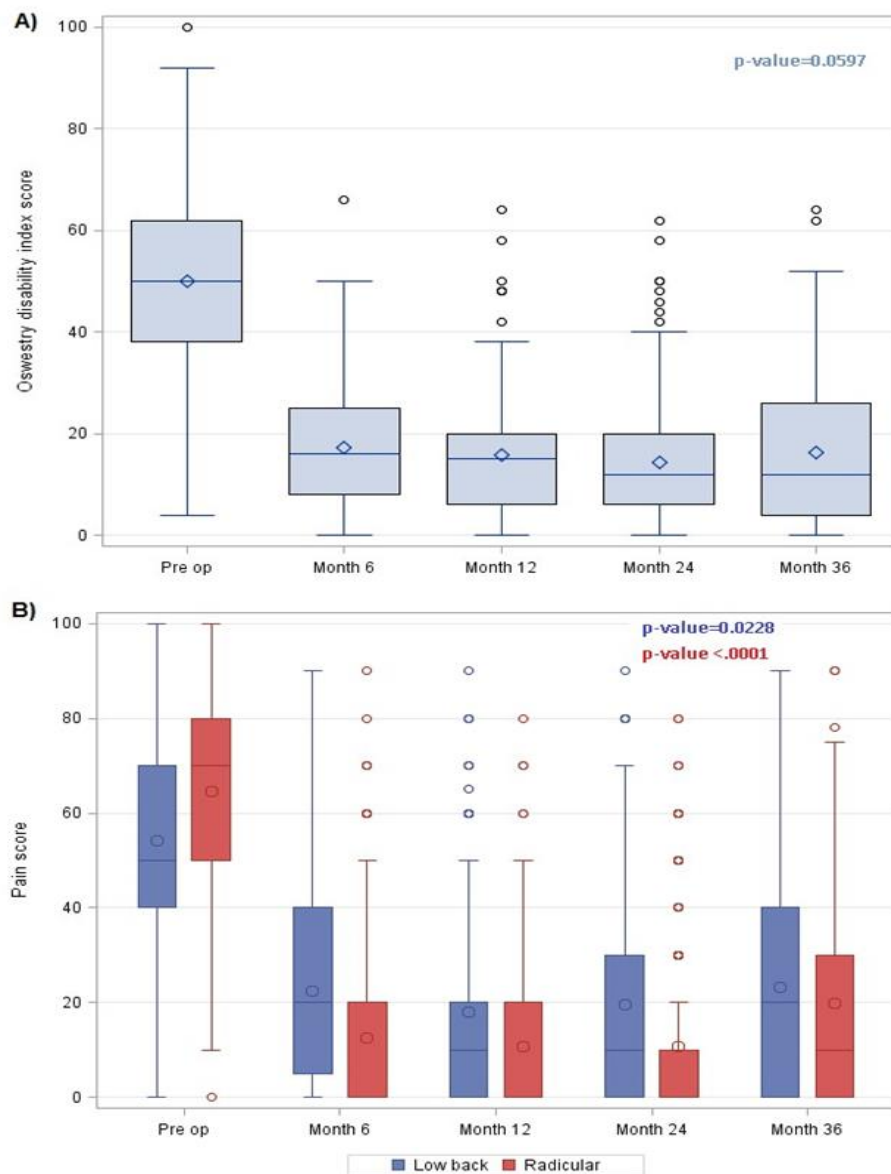
Characteristics		Missing data
<b>Instrumentation level, N (%)</b>		
One	201 (87)	
Two	30 (13)	
<b>Operation time, minutes, Median [Q1; Q3]</b>	40 [35 ; 60]	
<b>Length of stay (days), Median [Q1; Q3]</b>	4 [3 ; 5]	
<b>Estimated Blood Loss (ml), Median [Q1; Q3]</b>	50 [20,100]	
<b>Type of caring after surgery, N (%)</b>		
Hospitalization	224 (97)	1
Ambulatory	6 (3)	
<b>Implant size, N (%)</b>		
8 mm	161 (70)	
10 mm	41 (18)	
12 mm	20 (9)	
14 mm	7 (3)	
16 mm	1 (0)	
<b>Immediate postoperative care, N (%)</b>		
Not required	10 (4)	1
Required <sup>(a)</sup>	220 (96)	
Drug therapy	174 (79)	
Rigid or semi-rigid lumbar belt	100 (45)	
Physical therapy	20 (9)	

(a) The total percentage may exceed 100% because some patients can have more than one category.

**Table 2:** Surgical data

Success was observed in 73 %, CI95% [66 %; 79 %] of the patients completing 36 months of follow-up. The observed mean scores over time for the individual efficacy variables, including ODI, low back pain and radicular pain, are shown in **Figure 3**. A significant improvement over baseline was observed for all of these variables. A decrease in scores between 6 and 24 months postoperatively was followed by an

increase from 24 to 36 months. Radicular pain showed a greater improvement over time compared to low back pain (mean percentage decrease from inclusion to month 36 was respectively 66 % and 46 %). Regarding the ODI score, the mean percentage decrease from inclusion to month 36 was 64 %.



Mixed effects models with repeated measures were constructed to compare differences in longitudinal clinical score patterns over 36 months, with adjustment for Oswestry Disability Index score and low back/radicular pain scores at baseline

**Figure 3:** Evolution of A) Oswestry Disability Index score, and B) low back pain score and radicular pain score from pre-operative time to month 36 post surgery.

Of the 139 working patients, 89% returned to work after surgery. Median time to return to work was 3 months (Q1; Q3: 2; 5). There was no difference regarding time to return to work between sedentary and hard physical workers (respectively 3 months and 3.6 months, p-value=0.2).

At 6 months, 41 (19%) patients required concomitant treatment, while respectively 34 (18%), 22 (14%) and 20 (20%) required concomitant therapy at 12, 24 and 36 months.

As for global satisfaction, 51 (29%) and 118 (68%) patients were respectively satisfied and very satisfied with their current symptoms and with care at month 12. Levels of satisfaction were very similar at 36 months (31% and 64%).

**Table 3:** summarizes the safety data. Four patients had an intraoperative complication comprising cerebrospinal fluid leakage. 138 (60%) patients

presented at least one AE. Of a total of 226 reported AEs, 7 were related to the surgical procedure and 5 to the IntraSPINE® device itself, consisting of adjacent segment degeneration.

In 47 patients (20%), at least one SAE was reported. Of a total of 58 reported SAEs, causal relationship with the IntraSPINE® device or the surgical procedure was reported for only 3 SAEs: one case required arthrodesis following removal of the implant, one case involved suspected deep infection, and one case comprised neuropathic pain. In the latter two cases, the implant was removed. Only one proven case of infection was reported. A single reoperation occurred in 26 (11%) patients, with one patient requiring 2 operations. Of the 146 patients with disc herniation, 24 (16%) presented re-herniation or persistent herniation at the level of the device. 16 / 146 patients (11%) required further surgery.

Characteristics	
<b>AE</b>	
<b>Total AEs, N</b>	226
<b>Classification, N</b>	
<i>Reoperation</i>	26
<i>Recurrence*</i>	24
<i>Pain related to the instrumented level</i>	72
<i>Neurological signs related to the instrumented level</i>	4
<i>Surgery on a different level</i>	3
<i>Discopathy on a different level</i>	6
<i>Pain related to a different level</i>	4
<i>Surgery on another spine level</i>	4
<i>Discopathy on another spine level</i>	1
<i>Pain related to another spine level</i>	19
<i>Surgery on another organ than spine</i>	6
<i>Pathology related to another organ than spine</i>	17
<i>Pain related to another organ than spine</i>	19
<i>Other</i>	
<b>SAEs</b>	22
<b>Total SAEs, N</b>	58
<b>Patients with ≥ 1 SAE, N (%)</b>	47 (20)
<b>Number of SAEs, Moy (SD)</b>	1 (1)
Min, max	
<b>Safety outcomes</b>	1, 3
<b>Reoperation, n/N (%)</b>	26/321 (11)
<b>Reherniation, n/N (%)</b>	24/146 <sup>a</sup> (16)
Symptomatic reherniation	16/24 (67)
Non symptomatic reherniation	8/24 (33)

AE: Adverse Event, SAE: Serious adverse Event, a: 146 patients with disc herniation

\*1 patient whose recurrence and reintervention were reported as a single AE

**Table 3:** Safety endpoints

## Discussion

We report a national multicenter observational prospective study on the effects of a novel interlaminar device, "IntraSPINE<sup>®</sup>", in a cohort of patients presenting DDD.

Our study found that complications related to surgery or to the device were very few, with only four patients presenting intraoperative complications (spinal fluid leak) which were unrelated to specific use of IntraSPINE<sup>®</sup>. This is consistent with the results of Leet al who reported no complications such as myocardial infarction, pulmonary embolism, cerebrovascular accident, acute renal failure, mortality, deep venous thrombosis, ileus or urinary tract infection[20].

It is widely accepted that lumbar degenerative disc disease (DDD), as characterized by disc dehydration and loss of disc height, is one of the most common conditions associated with and predisposing to chronic low back pain [21,22].

Among options in treating symptomatic DDD, the inter-spinous devices ISD may be used to try and restrict painful motion. Inter-spinous space distraction may contribute to indirect decompression of the neural foramen and spinal canal but at the expense of lordosis. Theoretically, this enlarges the neural foramen in patients with spinal stenosis and neurogenic claudication [23]. However, inducing segmental kyphosis with any form of instrumentation would generally be considered a disadvantage and to be avoided. Also, a posteriorly placed interspinous implant is at a mechanical disadvantage in controlling abnormal flexion

movement and is therefore less likely to be effective in 'protecting' the disc and reducing discogenic back pain.

The limitations of ISDs led to the development of the interlaminar device IntraSPINE<sup>®</sup> with its unique anterior positioning in the inter-laminar space [24]. IntraSPINE<sup>®</sup> provides both a fulcrum and support through the middle column of the spine, thereby contributing to the spine's passive subsystem of stability. This unique positioning closer to the instant axis of rotation and nearer the sagittal axis of the facet joints allows the implant to more effectively off-load the facet joints in extension[13,20–26].

Also, an intact posterior tension band enables control of abnormal or excessive flexion movement, thereby 'protecting' the degenerate disc. In this way, IntraSPINE<sup>®</sup> has the potential to mitigate both facet and discogenic pain [24,27].

In this study, IntraSPINE<sup>®</sup> showed very good results, with an improvement in ODI score and in VAS back and leg pain scores during follow-up. The reduction in pain appeared to persist for two years, although scores increase slightly from 24 to 36 months, but nevertheless remained lower than baseline values. These results were also observed in the systematic review by Parker et al. in which the short-term and long-term incidence of recurrent back pain after primary single-level lumbar discectomy ranged from 3% to 34% and 5% to 36%, respectively[28].

These results appear consistent with those in studies about ISD. Buric et al. showed that the outcomes after surgery using DIAM device were best between 6 and 24 months postoperatively followed by an increase in VAS scores from 24 to 48 months [29]. Despite this increase, VAS scores

remained significantly lower than the baseline values. Considering these results, ILD could very well be proposed as an alternative to ISD.

The efficacy of this interlaminar device, in addition to standard microdiscectomy, in preventing recurrence of LBP has already been published[15]. The rationale for using this interlaminar device in conjunction with discectomy to reduce the incidence of post-discectomy back pain is the ability of the prosthesis to slow down disk-space collapse and control abnormal patterns of movement or micro-instability [30].

Our results show that 89% of active patients returned to work after surgery within an average of 3 months. Moreover, day case surgery was achieved in almost 3% of cases. Healthcare costs for LBP are increasing rapidly[31]. Direct and indirect costs of LBP associated with loss of earnings or changes in productivity are very high [32,33]. Hence, it is essential to develop treatments that are both clinically effective and, no less importantly, cost effective.

In this study, 16/146 (11%) of patients with disc herniation experienced symptomatic postoperative disc re-herniation. This result is consistent with the literature, which reports re-herniation rates of between 5 and 18% [34–36]. Regarding this aspect, since the IntraSPINE® maintains close to normal movement of the affected segment, it behaves just like a “normal” segment and thus with the same probability of recurrences. Although in theory IntraSPINE® has the potential to reduce disc re-herniation by abolishing excessive flexion movement and protecting the disc [37], a study in a significantly larger patient population is needed to achieve the requisite statistical power to provide proof. In addition, some experts are of the opinion that re-herniation occurred due to the relatively small size of the implants (8 mm), but this hypothesis remains to be confirmed too.

Regarding the further surgery, IntraSPINE® did not manage to rule out this factor. According to the experience of the surgeons who took part in the study, in the rare event that removal of the IntraSPINE® is necessary to gain access to the spinal canal, the device is easily removed without damaging the surrounding soft tissues, bone or dura mater. This is because IntraSPINE® is coated with a film of non-adherent silicone on the surface in contact with the dura mater or yellow ligament, effectively preventing the formation of adhesions to these layers.

The material composition of IntraSPINE®, comprising a silicone core and an outer shell reinforced by continuous wound PET fiber, is similar to ISP devices such as DIAM[29] or synthetic intervertebral disc prostheses [38]. According to the authors of the latter report, the combination of these materials represents a composite that mimics the architecture of the intervertebral disc and presents similar viscoelastic properties, making the device able to support/replace the function of the disc itself [38].

One limitation of our study was possible bias related to the fact that this was an observational study. The absence of a control group receiving standard care (surgery) without device insertion prevented us from confirming that the improvement in patient outcome post-operatively is related to the IntraSPINE® device alone. However, our results are consistent with the comparative study of Corriero et al. showing the absence of low back pain during the follow-up period in 74% of patients who received the IntraSPINE® implant, compared with only 41% of patients treated by simple stand-alone microdiscectomy who remained pain-free [15]. Moreover, numerous randomized studies assessing the efficacy of ISD found a significantly greater improvement in ODI score, as well as VAS back and leg pain scores, among patients with an ISD compared with those treated with stand-alone surgery[39,40]. These results suggest that the use of an implant may confer additional benefits over un-instrumented surgery in terms of patient outcome. Although some studies reports that Interspinous process decompression is still considered investigational and poor clinical results in the medical literature will continue to limit the appeal of these devices to many surgeons in the future [41]

Another limitation was that some patients would be inevitable lost to follow-up since this was a study with multiple follow-up appointments over three years, it. This potentially introduces a bias in the final analysis that could lead to under- or over-estimation of the outcomes following surgery. However, despite a long follow-up period, 78% of patients completed the study, which is relatively acceptable and reduces this potential bias [42].

Another limitation consists in the absence of radiological data. It would have been interesting to measure post-operative lordosis using standing X-rays to assess sagittal balance and segmental alignment following IntraSPINE® insertion. Previous radiological studies of IntraSPINE® devices suggest that the implant does not affect sagittal balance [24,43] and that it also maintains the biomechanics of the spine in an effective manner with slowing down or partial reversal of the natural progression of the degenerative cascade[26]. Radiological enlargement of the neural foramen has also been reported previously [23,24].

Supporting this, in vitro studies have shown that ISDs distract the posterior part of the functional spinal unit, reposition and unload the facet joints, and reduce intervertebral pressure, particularly on the posterior part of the disc [44].

In summary, the findings of this study are promising and demonstrate that successful patient outcomes can be achieved using the IntraSPINE® device for a range of degenerative diseases, with improvements in both back/leg pain and disability, sustained at 3 years. Implantation of the IntraSPINE® device was straightforward and there were no device-specific complications. Use of the IntraSPINE® in the treatment of degenerative disease of the lumbar spine has been evaluated and discussed in published papers.

The findings of this study coupled with other published research results suggest that IntraSPINE® may confer additional benefits in terms of back pain reduction and disability outcomes when used in conjunction with decompression or microdiscectomy in comparison to stand-alone decompressive procedures. A helpful future trial would single-blindly randomize the implantation of IntraSPINE® to patients undergoing a decompressive procedure so as to produce a matched control group. In addition, economic evaluation will be conducted in future trials to assess the cost effectiveness of using IntraSPINE®. The results of such follow-up trials are expected to establish a robust clinical basis for the effects of IntraSPINE® in this patient population.

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### Research Ethics Committee:

This study received a favorable opinion from ethical committee of Clinique d'Argonay

### Author contributions

D.C, C.V, L.M and M.L performed patient's recruitment and data collection. N.W performed data monitoring. R.B, H.R, and O.Z. analysed the data. All authors discussed the results and commented on the manuscript. R.B wrote the paper with input from all authors. C.A worked on the manuscript and correct it.

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## References

1. Errico TJ. (2005) Lumbar disc arthroplasty. *Clin Orthop*.106-117.
2. Van den Eerenbeemt KD, Ostelo RW, van Royen BJ, Peul WC, van Tulder MW. (2010) Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature. *Eur Spine J Off Publ Eur Spine Soc Eur Spinal Deform Soc Eur Sect Cerv Spine Res Soc*. 19:1262-1280.
3. Freeman BJC, Davenport J. (2006) Total disc replacement in the lumbar spine: a systematic review of the literature. *Eur Spine J Off Publ Eur Spine Soc Eur Spinal Deform Soc Eur Sect Cerv Spine Res Soc*. 15(S3): 439-447.
4. Puzilli F, Gazzeri R, Galarza M, Neroni M, Panagiotopoulos K, Bolognini A, et al. (2014) Interspinous spacer decompression (X-STOP) for lumbar spinal stenosis and degenerative disk disease: a multicenter study with a minimum 3-year follow-up. *Clin Neurol Neurosurg*. 124:166-174.
5. Bellini CM, Galbusera F, Raimondi MT, Mineo GV, Brayda-Bruno M. (2007) Bio mechanics of the lumbar spine after dynamic stabilization. *Clin Spine Surg*. 20:423-429.
6. Christie SD, Song JK, Fessler RG. (2005) Dynamic interspinous process technology. *Spine*. 30:73-78.
7. Grasso G, Giambardino F, Iacopino DG. Clinical analysis following lumbar interspinous devices implant: where we are and where we go. *Spinal Cord*. 52:740-743.
8. Strömquist BH, Berg S, Gerdhem P, Johnsson R, Möller A, Sahlstrand T, et al. (2013) X-stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year follow-up. *Spine*. 38:1436-1442.
9. Deyo RA, Martin BI, Ching A, Tosteson AN, Jarvik JG, Kreuter W, et al. (2013) Interspinous spacers compared to decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. *Spine*. 38 (10):865-872.
10. Kong D-S, Kim E-S, Eoh W. (2007) One-year outcome evaluation after interspinous implantation for degenerative spinal stenosis with segmental instability. *J Korean Med Sci*. 22:330-335.
11. Aylott Caspar, Cabezudo Jose Manuel, Guizzardi Giancarlo, Morichi Riccardo, Lopes Manuel. The IntraSPINE® in the Treatment of L5-S1 Degenerative Disc Disease. Preliminary Report n.d.
12. Darwono A. (2014) The new dynamic interlaminar device for the treatment of early and late lumbar degenerative problems. *Glob Spine J*.
13. Guizzardi G, Persohn S, Campana S, Aylott C, Petrini P, Skalli W. (2015) Biomechanical effect of an interlaminar device on ranges of motion, intradiscal pressure, and centers of rotation. *Open Access J Sci Technol*.
14. Guizzardi G, Petrini P. (2011) Biomechanical consideration on posterior motion preservation systems. Interspinous versus interlaminar devices. *Columna*. 1:31-38.
15. Corriero OV, Morichi R, Aless, Vagaggini R, Paoli L, Guizzardi G. (2014) Lumbar Herniated Disc Treated by Microdiscectomy Alone or Microdiscectomy Plus an Interlaminar Shock Absorbing Device: Retrospective Study with Minimum 3-Years Follow-Up. *J Spine*.
16. Guizzardi G. (2016) Looking at the future of motion preservation surgery in the lumbar spine with the experience of the past. *Glob Spine J*.
17. Feng S, Fan Z, Ni J, Yang Y, Fei Q. (2020) New combination of IntraSPINE device and posterior lumbar interbody fusion for rare skipped-level lumbar disc herniation: a case report and literature review. *J Int Med Res*.
18. Fairbank JCT, Couper J, Davies JB, O'brien JR. (1980) The Oswestry low back pain disability questionnaire. *Physiotherapy*. 66:271-273.
19. Crichton N. (2001) Visual analogue scale (VAS). *J Clin Nurs*. 10:706-716.
20. Lee S-H, Seol A, Cho T-Y, Kim S-Y, Kim D-J, Lim H-M. (2015) A systematic review of interspinous dynamic stabilization. *Clin Orthop Surg*. 7:323-329.
21. Borenstein DG. (2001) Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain. *Curr Opin Rheumatol*. 13:128-134.
22. Livshits G, Popham M, Malkin I, Sambrook PN, MacGregor AJ, Spector T, et al. (2011) Lumbar disc degeneration and genetic factors are the main risk factors for low back pain in women: the UK Twin Spine Study. *Ann Rheum Dis*.
23. Khiami F, Brèque C, Pascal-Mousselard H, Ragot S, Hirsch C, Richer JP, et al. (2013) Intervertebral Foramen Variation Following Dynamic L4-L5 Interspinous Device Implantation: Foramen Size After Interspinous Device Implantation. *Clin Spine Surg*. 26:215-220.
24. Bae J, Lee SM, Lee S-H, Shin S-H, Kim H-J, Kim KH. (2017) The likelihood of reaching substantial clinical benefit after an interlaminar dynamic spacer for chronic low back pain: a clinical and radiologic analysis of a prospective cohort. *World Neurosurg*. 101:589-598.
25. Giancarlo Guizzardi , Piero Petrini. Biomechanical consideration on posterior motion preservation systems.
26. Giancarlo G, Morichi R. (2015) Clinical Results with IntraSPINE®. *EC Orthop*. 101-106.
27. Mostofi K, Moghadam BG, Peyravi M. (2018) Interlaminar lumbar device implantation in treatment of Baastrup disease (kissing spine). *J Craniovertebral Junction Spine*.
28. Parker SL, Mendenhall SK, Godil SS, Sivasubramanian P, Cahill K, Ziewacz J, et al. (2015) Incidence of Low Back Pain After Lumbar Discectomy for Herniated Disc and Its Effect on Patient-reported Outcomes. *Clin Orthop*. 473:1988-1999.
29. Buric J, Pulidori M. (2011) Long-term reduction in pain and disability after surgery with the interspinous device for intervertebral assisted motion (DIAM) spinal stabilization system in patients with low back pain: 4-year follow-up from a longitudinal prospective case series. *Eur Spine J*. 20:1304-311.
30. Martin MD, Boxell CM, Malone DG. (2002) Pathophysiology of lumbar disc degeneration: a review of the literature. *Neurosurg Focus*. 13:1-6.
31. Lin C-WC, Haas M, Maher CG, Machado LA, van Tulder MW. (2011) Cost-effectiveness of guideline-endorsed treatments for low back pain: a systematic review. *Eur Spine J*. 20:1024-1038.
32. Dagenais S, Caro J, Haldeman S. (2008) A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J*. 8:8-20.
33. Maniadakis N, Gray A. (2000) The economic burden of back pain in the UK. *Pain*. 84:95-103.
34. Crock H. (1976) Observations on the management of failed spinal operations. *Bone Jt J*. 58:193-199.
35. Ebeling U, Kalbarczyk H, Reulen H. (1989) Microsurgical reoperation following lumbar disc surgery: timing, surgical findings, and outcome in 92 patients. *J Neurosurg*. 70:397-404.
36. Law JD, Lehman RA, Kirsch WM. Reoperation after lumbar intervertebral disc surgery. *J Neurosurg* 1978;48:259-263.
37. Gelder CL, Drozda M, Spink G. (2020) Lumbar Microdiscectomy With IntraSPINE®—A Case Series. *Coluna/Columna*. 19:201-204.
38. Gloria A, De Santis R, Ambrosio L, Causa F, Tanner KE. (2011) A multi-component fiber-reinforced PHEMA-based hydrogel/HAPEXTM device for customized intervertebral disc prosthesis. *J Biomater Appl*. 25:795-810.

39. Pintauro M, Duffy A, Vahedi P, Rymarczuk G, Heller J. Interspinous implants: are the new implants better than the last generation? A review. *Curr Rev Musculoskelet Med.* 10:189-198.
40. Galarza M, Gazzeri R, De la Rosa P, Martínez-Lage JF. (2014) Microdiscectomy with and without insertion of interspinous device for herniated disc at the L5–S1 level. *J Clin Neurosci.* 21:1934-1939.
41. Gazzeri R, Galarza M, Alfieri A. (2014) Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future. *BioMed Res Int.*
42. Kristman V, Manno M, Côté P. (2004) Loss to follow-up in cohort studies: how much is too much? *Eur J Epidemiol.* 19:751-760.
43. Bistazzoni S, De Angelis M, D'ercole M, Chiaramonte C, Carotenuto A. (2017) Evaluation of Effect of Posterior Dynamic Stabilization IntraSPINE System on Sagittal Spinal Balance using EOSR X-Ray Imaging System. *J Neurol Neurophysiol.*
44. Lindsey DP, Swanson KE, Fuchs P, Hsu KY, Zucherman JF, Yerby SA. (2003) The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. *Spine.* 28:2192-2197.



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