Interspinous implants: are the new implants better than the last generation? A review

Michael Pintauro¹ · Alexander Duffy¹ · Payman Vahedi^{1,2} · George Rymarczuk^{1,3} · Joshua Heller¹

Published online: 22 March 2017
© Springer Science+Business Media New York 2017

Abstract

Purpose of review Interspinous process devices (IPDs) are used in the surgical treatment of lumbar spinal stenosis. The purpose of this review is to compare the first generation with the next-generation devices in terms of complications, device failure, reoperation rates, symptom relief, and outcome.

Recent findings Thirty-seven studies were included from 2011 to 2016. Device failure occurred at a mean of 3.7%, with a lower tendency to happen with next-generation IPDs. Reoperations occurred at a lower rate with the next-generation devices, with a mean follow up of 24 months (3.7% vs. 11.1%). The clinical outcome is not influenced by the type of IPD.

Summary The long-term functionality of these devices is questionable, with radiologic changes and recurrence of symptoms often seen by 2 years following implantation. Next-generation devices do not appear to be subject to the same “bounce back” effect of symptom re-emergence after several years.

Keywords Interspinous device · Lumbar · Spine · Canal stenosis · Coflex · X-Stop

This article is part of the Topical Collection on *Motion Preserving Spine Surgery*

✉ Payman Vahedi
payman.vahedi@gmail.com

¹ Department of Neurological Surgery, Thomas Jefferson University, 909 Walnut St, 3rd Floor, COB Bldg, Philadelphia, PA 19107, USA

² Department of Neurosurgery, Tehran Medical Sciences Branch, Islamic Azad University, Tehran, Iran

³ Division of Neurosurgery, Walter Reed National Military Medical Center, Bethesda, MD, USA

Introduction

Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal and can be of either congenital or acquired etiology. Within the aging population, the latter has become common due to spondylosis [1]. Altered biomechanics of the segmentally degenerating spine are thought to trigger compensatory hypertrophic changes of the facet joints and ligamentum flavum. The cumulative effect is further superimposed narrowing of the spinal canal, which may result in impingement of both the thecal sac and nerve roots as they traverse the lateral recess and exit the intervertebral foramina. LSS typically manifests as lower back pain, lower extremity radiculopathy and paresthesia, and neurogenic intermittent claudication (NC). NC is the most common symptom of the disease process and occurs in part as a consequence of segmental epidural venous stasis secondary to buckling of ligamentum flavum in extension. Symptoms in LSS are characteristically relieved by flexion, which functions to increase cross-sectional area of the spinal canal.

Conservative treatment for LSS often precedes surgical intervention. Typical conservative measures involve physical therapy for paravertebral muscle strengthening and posture correction, pharmacotherapy with NSAIDs, and epidural injections of corticosteroids and anesthetics. However, given the degenerative nature of LSS, evidence supporting the long-term efficacy of such treatment methods is lacking [2].

Surgical intervention for LSS classically consisted of spinal decompression, with or without vertebral fusion. Urgent surgery may be required if neurological deficits progress rapidly or if bladder or bowel dysfunction emerges (cauda equina syndrome). Treatment aims include decompression of neural structures at the level of stenosis

and correction of instability. A single- or multi-level decompressive laminectomy is performed; indications for additional segmental fusion include observed instability on preoperative X-rays or if the spine is found to be unstable intraoperatively. Although most studies have shown benefit to surgical intervention, others have shown the benefits diminish over time, particularly for more subjective patient-centered outcomes including low back pain and satisfaction measures [3–6]. A systematic review of surgical studies showed limited evidence supporting the effectiveness of some aspects of surgical intervention [7].

Recently, minimally invasive approaches have been developed to combat LSS using implantable interspinous process devices (IPDs) or intralaminar devices as alternatives or adjuncts to traditional decompressive surgery. In order to relieve nerve compression, IPDs are placed between adjacent spinous processes at the level of stenosis. The distractive force applied by the device, and the subsequent height restoration, is believed to be the main mechanism through which it functions. IPDs can further be subdivided into interspinous distraction devices (IDDs) and interspinous stabilizers (ISSs). IDD act to separate adjacent spinous processes, thereby reducing compression of nerves during spinal extension. In the case of ISSs, the implant is also felt to confer some degree of dynamic stability to adjacent levels, particularly in instances of non-isthmic spondylolisthesis. ISSs involve fixing adjacent spinous processes to one another with a bracing component between them. This reduces movement of the vertebrae and decompresses impinged nerves.

The first IPD, the WALLIS device (Abbott Spine, Austin, Texas), was developed in 1986, and since then, many devices have emerged on the market from a variety of manufacturers. Figure 1 illustrates some of the more well-known IPDs. Despite initial promising results, these devices were found to have relatively high complication and failure rates and thus did not garner wide appeal among spine surgeons. As a result, newer or “next-generation” devices have been developed and implemented. Here, we will evaluate the success of current-generation IPDs including X-STOP (IDD; Kyphon, Sunnyvale, California), WALLIS (ISS; Abbott Spine, Austin Texas), DIAM (ISS; Medtronic, Memphis, Tennessee), and Aperius PercLID (IDD; Medtronic, Memphis, Tennessee) and compare them to the next-generation technologies of Coflex (ISS; Paradigm Spine, New York, New York), Superior (IDD; VertiFlex, San Clemente, California), Helifix (IDD; Alphatec Spine, Carlsbad, California), and In-Space (IDD; DePuySynthes, West Chester, Pennsylvania). We will explore and elucidate the latest literature pertaining to these IPDs over the last 5 years and examine their successes and failures in the context of LSS treatment.

Fig. 1 Currently FDA approved IPDs available for commercial use in the USA. **a** X-STOP (Medtronic, Minnesota, USA and Tolochenaz, Switzerland). **b** Coflex (Paradigm Spine, USA). **c** Superior (Vertiflex, San Clemente, CA, USA). Image credit to FDA

First-generation technologies

X-STOP (Medtronic, Minnesota, USA and Tolochenaz, Switzerland)

The X-STOP device, known also as the “interspinous process decompression system,” is an FDA-approved, titanium device used to treat lumbar spinal stenosis (Fig. 1a). In a study comparing conservative treatment versus surgical intervention with X-STOP, symptom severity, physical function, and patient satisfaction were all found to be significantly greater in the X-STOP group at 1-, 6-, and 12-month follow-up periods

[8]. Significantly improved visual analog scale (VAS) scores were seen in the X-STOP group over a 7-year follow-up period. Intraoperative complications in 4.9% of patients included spinous process fracture and CSF leak, while postoperative complications including superficial infection, device dislocation, and spontaneous spinal process fracture were found in 11.1% of patients. Another study with 30 X-STOP patients saw significantly improved Oswestry Disability Index (ODI) and Japanese Orthopedic Association (JOA) scores throughout a 24-month follow up period, with one device dislocation and subsequent removal noted during the follow-up period [9]. A 2015 study compared minimally invasive decompression (MID) surgery to X-STOP and found improved postoperative Zurich Claudication Questionnaire (ZCQ) and Oswestry Disability Index (ODI) scores for both groups, with no difference noted in improvement between the two interventions [10]. Mean surgery time for MID and X-STOP was 113 and 47 min, respectively. Reoperation rates due to recurrent symptoms were significantly higher for X-STOP than MID, however [11].

WALLIS (Zimmer, Warsaw, IN, USA)—IDE only

The Wallis device was the first clinically approved interspinous distraction device (IDD) originally made from titanium. It may be used for preservation or restoration of lumbar motion or as an adjunct to traditional decompressive surgery [12]. The second-generation Wallis device is a dynamic interspinous device consisting of one polyetheretherketone (PEEK) spacer that limits extension and two Dacron ribbons that limit flexion. The spacer is placed between spinous processes, and the ribbons are wrapped around and secured to adjacent spinous processes. Studies investigating the implantation of second-generation Wallis devices following lumbar decompression found short- and medium-term improved ODI and VAS scores, which was comparable to success rates of first-generation Wallis devices [13]. The Wallis device has seen postoperative short- and medium-term radiologic success regarding intersegmental stabilization, and investigators believe that patients with the Wallis implant can maintain positive outcomes over periods greater than 24 months [14]. Regarding the long-term viability of the Wallis device, significant radiologic changes from postoperative measurements have occurred without any associated clinical deterioration, including increase in VAS scores. Investigators hypothesize that the PEEK material's modulus of elasticity, which is more physiologic, may be responsible for these changes over time.

DIAM (Medtronic, Memphis, TN, USA)—not FDA approved, IDE only

The Device for Intervertebral Assisted Motion (DIAM) is made of a polyester mesh material. The implant has a central

component that is placed between adjacent spinous processes and two associated tethers to secure the device longitudinally. In the past, DIAM has been successful in long-term treatment of lower back pain caused by degenerative disc disease. A 2010 study found that over two thirds of patients achieved and maintained significant, clinically apparent differences in both VAS scores and Roland-Morris Disability Questionnaire (RMDQ) scores over a 48-month period [15]. Recently, the DIAM device has been explored as a potential therapy following posterior lumbar interbody fusion (PLIF) in the treatment of degenerative lumbar disease to prevent the development of adjacent segment degeneration (ASD) [16]. Patients that received both PLIF and DIAM saw significantly improved VAS and ODI scores at 24 months, as well as a significant reduction in the development of radiographic ASD, compared to those that received PLIF alone.

Aperius (Medtronic, Memphis, TN, USA)

Introduced in 2007, Aperius was the first percutaneous IPD available on the market. It is made of a titanium alloy core surrounded by pure titanium shell. The device was designed to be used as a stand-alone implant, requiring only local anesthesia and approximately 7 min for implantation [17]. Surgical exposure and implantation site preparation does not require removal of the interspinous ligament; instead, the spine is thought to be decompressed via interspinous process distraction.

Masala et al. noted an initial improvement in VAS scores from 8.292 to 4.250 at 6 months and a decrease in ODI from 26.08 to 10.96 at 6 months [18]. However, both VAS and ODI rose to 5.083 and 16.08, respectively, by the 12-month follow-up. During the study, perioperative complications were not observed. A similar pattern of short-term pain relief followed by return of symptoms has been shown in other studies, as well. One study indicated that, at 2 year follow-up, ODI and VAS levels even exceeded those reported preoperatively, indicating failure of the device [19].

Next-generation technologies

Coflex (paradigm spine, New York, NY, USA)

The Coflex device is a dynamic ISP that is placed between adjacent lamina (Fig. 1b). Approved for use in 2012, this U-shaped device is made of titanium and is inserted between adjacent laminae and spinous processes following decompression surgery. Coflex has been shown to stabilize adjacent vertebrae while preserving both flexion and extension in LSS patients (Fig. 2).

In a study comparing patients receiving Coflex ILS or posterolateral spinal fusion after decompression surgery, there was no significant difference in the number of secondary

Fig. 2 Dynamic interlaminar stabilization with two Coflex interspinous devices. Postoperative lateral standing X-ray (a), Flexion (b), and extension (c) studies confirm the stability after multilevel lumbar decompression surgery

interventions or in time from index surgery and secondary intervention between the two cohorts [20•]. Patients undergoing ILS utilizing Coflex found greater clinical composite success (CCS), with no difference between adverse events compared to fusion patients, in a 48-month follow-up period. Another study found a significantly greater improvement in ODI score, as well as VAS back and leg pain scores, among Coflex patients compared to those receiving standard decompression alone [21]. Surgical complications among the Coflex group included one durotomy, while the decompression-only group experienced four durotomies and one surgical site infection. Postoperatively, the Coflex device has been noted to erode bone that is immediately in contact with the device. A study found that in 14 of 30 Coflex patients, erosion resulted from a lack of engagement between the device and vertebrae [22]. Patients that did not experience such bony erosion were found to have a greater postoperative decrease in index range of motion (ROM) than those that experienced erosion. Erosion can be considered a failure of the Coflex device, and the investigators hypothesize that certain preoperative radiologic parameters may serve as predictors for its success in LSS patients.

Superion (VertiFlex, San Clemente, CA, USA)

Approved by the FDA in 2015, the Superion InterSpinous Spacer became the second stand-alone interspinous device approved by the FDA for lumbar spinal stenosis. It is composed of a central segment of titanium which rests between spinous processes (Fig. 1c). Wings extend cranially and caudally, to prevent lateral displacement. Patel et al. found the results from implantation of Superion to be not inferior to implantation of X-STOP interspinous spacer at 2-year

follow-up [23]. Both groups saw decreases in leg pain severity by 70%, and an ODI reduction of 15% was noted in 65% of patients. By 3 years, Patel et al. found that the Superior cohort showed more subjects maintaining the primary endpoints of statistically significant reduction in pain than those in the X-Stop cohort [24•].

Other studies have shown improved ODI scores, ZCQ scores, and decreased VAS levels after implantation of the device [25]. Some studies have shown minor increases in ODI and VAS at 2-year time points after initial drop following surgery [19, 26].

HeliFix (Alphatec spine, Carlsbad, CA, USA)

The HeliFix device is an interspinous process decompression device first introduced in 2010 and is currently available only in Europe. It is a percutaneously implanted device that may be used to treat patients suffering from symptomatic 1- or 2-level lumbar spinal stenosis. The device is constructed of PEEK and is available in various sizes. Its unique spiral shape requires it to be “screwed” into place between adjacent spinous processes, aiding the implant to maintain appropriate positioning.

One study looked at the outcomes of 100 patients who received HeliFix for the subsequent 12 months following implantation [26]. Overall, pain was reduced from 8 to 4 on a VAS scale, and lower back pain, which was initially present in 62 patients, was noted to have resolved in 25 individuals and decreased in a further 35. Neurogenic intermittent claudication, initially present in 84 patients, resolved in 29 individuals and improved in a further 37. Of the 100 patients who underwent implantation, two patients underwent reoperation due to recurrence of symptoms. However, this study was limited in that it followed patients for only 12 months.

In-Space (Synthes, Umkirch, Germany)—IDE only

The In-Space device is a percutaneous interspinous spacer designed for treatment of LSS. Similar to other devices, it is composed of PEEK with titanium wings extending from the lateral edges of the main cylinder.

As of yet, the In-Space device lacks a significant amount of published data compared to the other IPDs presented in this review. Yingsakmongkol et al. found that VAS scores for back pain and leg pain decreased from 6.56 to 2.64 at 1 week post-operatively [27]. Over the subsequent 2 years, patients experienced no significant worsening in VAS for back or leg pain. Radiographic evaluation revealed significant improvement in foraminal area; however, no improvement in intervertebral disc height was noted.

Discussion

Literature search

Interspinous process spacer devices have been developed as a less-invasive potential alternative to standard posterior lumbar decompression, with or without fusion procedures. The latter directly addresses spinal disease by removing hypertrophied posterior elements including enlarged facet joints and ligamentum flavum; however, longer operation time, higher estimated blood loss (EBL), longer time of hospitalization, higher complication rates, need for revision surgery, and lack of cost effectiveness are all considerations that must be kept in mind. IPDs were first introduced with the potential to minimize these occurrences.

Although the development and use of interspinous spacers has become more common in the treatment of LSS, the data supporting the use of these devices in place of decompressive surgery is largely inconclusive. Meta-analyses comparing standard decompression to IPDs have shown that IPDs are not as efficacious. Al-Min Wu et al. conducted a retrospective study of IPD and laminectomy patients and found no significant difference between VAS and ODI improvements between the two groups but encountered a higher risk for reoperation in the IPD group during the 12- to 24-month follow-up period [28]. Patil et al. compared IPD using X-STOP to laminectomy patients and found an increased risk of reoperation (12.6 vs. 5.8%, RR = 2.07) in the IPD cohort [29]. The authors noted however that the laminectomy cohort showed significantly greater 90-day complication rates, and there was no significant difference in costs over a period of 18 months.

For this review, the authors conducted a thorough Medline-based search of studies on IPDs over the past 5 years, from 2011 to 2016. MeSh terms included “interspinous process device(s),” “interspinous distraction device(s),” “interspinous device(s),” “interspinous spacer(S),” “interspinous fusion

device(s),” “Interlaminar device(s),” “lumbar,” and “Spine.” A total of 42 studies were returned, and after excluding meta-analyses, review studies, and biomechanical studies, 37 original studies were included in our review (Table 1). This encompasses 18 retrospective, 12 prospective (comparative or non-comparative), and 7 randomized controlled trials (RCTs). Thirty-four (92%) studies cited the brand of interspinous device used, while three studies did not disclose the brand of IPD used [29, 32, 47].

Demographics

The mean age of the patients ranged from 42.7 to 79 years. Patel et al. [23] and Fabrizio et al. [17] recruited the largest number of patients in RCT and retrospective studies, respectively (391 and 1315 patients). The main inclusion criteria were lumbar spine stenosis (LSS) at one or multiple levels, while some studies also recruited patients with lumbar disk herniation (LDH) with or without Myerding Grade I spondylolisthesis [10, 12, 14, 27, 36, 37, 38, 40, 41, 45].

Surgical intervention

The consensus for surgical treatment of LSS has been to include patient refractory to conservative treatment; however, the length of conservative therapy preceding surgical intervention is a matter of controversy. Some studies required a period of conservative treatment to be at least 6 months [7, 8, 10, 13, 21, 35, 36, 38, 44, 45], whereas other studies [3, 6, 27, 35, 36, 37] resorted to surgery after 3 months of unsuccessful conservative therapy. One study recruited patients after only 6 weeks of unsuccessful conservative treatment [14].

Complications

Device failure or intraoperative device-related complications occurred in a mean of 4.26% of patients (Table 2), with a trend towards decreasing failure rates in next-generation IPDs (2.9 vs. 4.8%). Due to discrepancy between available studies covering next-generation versus older implants (Table 1), this finding needs to be verified in a meta-analysis.

The main reason for device failure was spinous process fracture. Osteoporosis, over-distraction, inappropriately sized device selection, and poor surgical technique are all potential sources of this complication.

One long-term cross-sectional study [40] estimated the clinical failure of IPDs to be as high as 33.8% after 60 months. According to this study, which has one of the longest follow-up periods of any study in this area, device-related problems such as loosening, breakage, or migration occurred in 3.7%, deep infection in 0.9%, spinous process fracture in 5.1%, wound complications in 14%, and new or worsening pain in 33% of patients.

Table 1 Characteristics of selected studies (2011–2016)

Author	Year	No. of patients	Mean age (years)	Study type	Device used
Postacchini et al. [30]	2011	71	68	Cohort/comparative	Aperius
Shabat et al. [25]	2011	53	70	Retrospective	Superion
Buric and Pulidori [15]	2011	52	–	Prospective	DIAM
Fabrizi et al. [17]	2011	1315	–	Retrospective	DIAM
Meirhaeghe et al. [31]	2012	156	65	Retrospective	Aperius
Beyer et al. [19]	2012	45	64	Prospective/non-randomized	Aperius
Surace et al. [32]	2012	37	64	Retrospective	Aperius
Miller and Block [33]	2012	168	67	Prospective/randomized	Superion and X-STOP
Heyrani et al. [34]	2012	50	79	Retrospective	X-STOP
Kim and Choi [35]	2013	14	78	Retrospective	X-STOP
Strömqvist et al. [36•]	2013	50	60	RCT	X-STOP
Nandakumar et al. [37]	2013	57	71	Prospective	X-STOP
Patil et al. [29•]	2014	ISD:174 Lami:174	73	Retrospective/comparative	N/A
Yingsakmongkol et al. [27]	2014	56	44	Prospective	In-Space
Pan et al. [38]	2014	50	52	Retrospective	Second-gen Wallis (PEEK)
Grasso et al. [39]	2014	100	65	Retrospective	X-STOP: 50, Impala (SIGNUS Medizintechnik GmbH, Germany): 50
Alexandre et al. [26]	2014	100	56	Prospective/non-comparative	Helifix
Kumar et al. [21]	2014	46	58	Prospective/Cohort	Coflex
Schmier et al. [40]	2014	Coflex:215 PLIF + PSI:107	62	Retrospective	Coflex
Marsh et al. [13]	2014	60	60	, RCT	Wallis
Puzzilli et al. [8]	2014	422	–	Retrospective	X-STOP
Gazzeri et al. [41]	2015	1108	59	Retrospective	X-STOP, DIAM, and Viking
Patel et al. [23]	2015	391	–	Prospective/randomized	Superion and X-STOP
Lu et al. [16]	2015	49	65	Retrospective	DIAM
Liu et al. [42]	2015	62	–	Retrospective	Coflex
Huang et al. [9]	2015	28	61	Prospective	X-STOP
Huddleston et al. [43]	2015	40	–	RCT	X-STOP
Lonne et al. [44•]	2015	X-Stop:40 MIS:41	67	RCT	X-STOP
Lonne et al. [10]	2015	40	67	RCT	X-STOP
Jiang et al. [14]	2015	26	48	Retrospective	Wallis
Wang et al. [45]	2015	44	43	Retrospective	Wallis
Yue et al. [46]	2015	66	53	Prospective	Wallis
Van den Akker-van Marle et al. [47]	2016	ISD:80 Lami:79	–	Double blind RCT	N/A
Masala et al. [18]	2016	24	65	Retrospective	Aperius Falena
Bae et al. [20•]	2016	222	62	RCT	Coflex
Lee et al. [22]	2016	30	62	Retrospective	Coflex
Daentzer et al. [12]	2016	10	64	Prospective	Wallis

Interestingly, two next-generation devices, Helifix and In-Space, are composed of the same PEEK material as the second-generation Wallis device. Studies following Wallis devices longitudinally have found that radiologic changes occur over time, and multiple authors have theorized that

differences in the device's fabrication material may be implicated. Future research can be directed to examine the durability of the next-generation PEEK devices, and whether they will suffer the same consequence as their predecessor.

Reoperations

Overall, reoperations occurred at a mean of 13.35% during the postoperative follow-up period (mean 24 months) (Table 2). A comparison between next- and last-generation IPDs revealed the rate to be lower with next-generation IPDs (3.7 vs. 11.1%) during the same follow-up period (24 months). However, due to the paucity of studies on next-generation IPDs, this finding also needs to be verified in a meta-analysis of matched studies. Main reasons for reoperation included late spinous process fracture, device dislocation, new radicular deficit, and recurrent or persistent symptoms postoperatively. In an attempt to minimize this rate, patient selection should occur with scrutiny. Reoperations can potentially be avoided by seeking options other than IPDs for patients with marked osteopenia, adjacent segment disease, severe canal or foraminal stenosis, or isthmic spondylolisthesis [48].

One RCT [41] found the reoperation rate for IPDs to be significantly higher than for minimally invasive decompressive surgery in a 2-year follow-up time due to persistent or recurrent symptoms. The high rate of reoperation led to the early termination of the trial. An interesting randomized prospective study by Miller et al. [33] found similar complications and failure rate in a 6-month follow-up of patients

operated with next- (Superion) versus last-generation (X-TOP) IPDs. Nevertheless, another RCT evaluating the same IPDs found increased reoperation rate with last-generation versus next-generation IPDs after the second year [23].

Symptom relief

When used as an adjunct to decompressive surgery, patients undergoing IPD implantation typically experience initial reduction in symptomatology. Postoperatively, a steady rise in VAS has been reported to occur after 6 months [8], 1 year [19, 39], and 2 years [18, 34] of follow-up. Other studies have reported the maintenance of initially improved VAS up to 2 years [21, 27, 36•, 38] or even 3 years [13, 23]. Of the latter studies, three are with next-generation products [23, 27, 38] and three correspond to last-generation [13, 21, 36•] IPDs. In the preparation of this manuscript, the authors could only find two RCTs in the literature comparing the success of pain reduction between next- vs. last-generation IPDs [23, 33]. Although Miller et al. [33] showed equal results of back and leg pain reduction in terms of VAS during a 6-month follow-up, Patel et al. [23] found that the success to decrease leg VAS is significantly higher after the second year with next-generation IPDs.

Table 2 Reported rates of failure and reoperation for interspinous devices

Reference	Immediate device failure (%)	Reoperation rate (%)	Follow up (months)
Patil et al. [29•]	3.45	23.1	18
Van den Akker-van Marle et al. [47]	–	21	12
Gazzeri et al. [41]	4.8	–	44.8
Yingsakmongkol et al. [27]	–	5.3	24
Beyer et al. [19]	0.6	42	24
Surace et al. [32]	2.8	5.6	18
Alexandre et al. [26]	0	2	12
Shabat et al. [25]	3.7	3.7	24
Miller et al. [33]	5.3	7.5	6
Buric and Pulidori [15]	–	11.5	48
Fabrizi et al. [17]	–	3	12
Lu et al. [16]	–	2	41.2
Bae et al. [20•]	8.8	7.4	36
Kumar et al. [21]	2.1	–	24
Heyrani et al. [34]	8	–	24
Huddleston et al. [43]	–	25	24
Lønne et al. [10]	7.5	32.5	24
Nandakumar et al. [37]	–	15	24
Puzzilli et al. [8]	4.9	11.1	24
Strömqvist et al. [36•]	2	26	24
Daentzer et al. [12]	10	10	24
Marsh et al. [13]	0	0	36

In terms of clinical outcome measure, most studies have employed Oswestry Disability Index (ODI) or Zurich Claudication Questionnaire (ZCQ). There is a general agreement on immediate decreased ODI or ZCQ with the use of IPDs. Some studies have demonstrated a “bounce back” effect after 1 or 2 years for both ODI [12, 18, 25] and ZCQ [33, 37]. Although outcome in terms of ODI or ZCQ appear similar between last- and next-generation IPDs, the literature lacks sufficient randomized trials recruiting both types. We could only find one RCT with this criterion for ODI during the last 5 years [23], which showed no difference in outcome between the Superion and X-STOP devices. Similarly, with regard to ZCQ, two recent clinical trials showed no statistically significant difference between the Superion and X-STOP devices.

Costs

With regard to cost, IPDs are more expensive compared to standard decompression surgery at index hospitalization, the difference being mainly attributable to implant cost. One retrospective study [29•] did, however, find no significant difference in overall cost at a period of 12 months postoperatively between those surgically treated with IPDs versus decompression. Two recent RCTs [44•, 47] have shown that after 12 months of follow-up, IPDs are no more cost-effective than decompression surgery. According to the results found in the latter studies, the authors have questioned the cost utility of IPDs in the long-term due to observed higher rates of reoperation. To overcome the bias of short-term follow-up, further RCTs with long-term follow up are recommended to examine this trend.

Conclusion

Interspinous devices offer a simple, minimally invasive alternative to standard decompression for the treatment of lumbar stenosis. Although their use has been reported for a spectrum of different spinal pathologies, careful patient selection is an absolute requirement for successful clinical outcome. Current evidence supports their consideration for use in patients who cannot tolerate lengthy procedures or general anesthesia due to medical concerns; however, these devices should be used with caution in osteoporotic patients due to increased risk of intraoperative and postoperative complications. Positive results of the procedure are immediately apparent and are similar to those of laminectomy or other decompressive surgery. However, the long-term functionality of these devices is questionable, with radiographic changes and recurrence of symptoms frequently noted following surgical intervention. The previous generation of devices features implants constructed of titanium. The newest devices incorporate PEEK into their design. The durability of such polymer-based devices over the

long term warrant further investigation. Additionally, next-generation devices do not appear to be subject to the same “bounce back” effect that has been documented with previous iterations of these implants. Moreover, the latest generation of devices offers stand-alone functionality, not requiring additional decompression or other surgical procedures, thus reducing cost for the patient.

Compliance with ethical standards

Conflict of interest Joshua Heller reports professional relationships with Nuvasive, Providence Medical, and Convatec.

The other authors declare that they have no conflict of interest.

Human and animal rights and informed consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Papers of particular interest, published recently, have been highlighted as:

- Of importance

1. Sapico FL, Montgomerie JZ. Pyogenic vertebral osteomyelitis: report of nine cases and review of the literature. *Rev Infect Dis*. 1979;1(5):754–76.
2. Ammendolia C, Stuber K, de Bruin LK, Furlan AD, Kennedy CA, Rampersaud YR, et al. Nonoperative treatment of lumbar spinal stenosis with neurogenic claudication: a systematic review. *Spine*. 2012;37(10):E609–16. doi:10.1097/BRS.0b013e318240d57d.
3. Chang Y, Singer DE, Wu YA, Keller RB, Atlas SJ. The effect of surgical and nonsurgical treatment on longitudinal outcomes of lumbar spinal stenosis over 10 years. *J Am Geriatr Soc*. 2005;53(5):785–92. doi:10.1111/j.1532-5415.2005.53254.x.
4. Atlas SJ, Keller RB, Robson D, Deyo RA, Singer DE. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the Maine lumbar spine study. *Spine*. 2000;25(5):556–62.
5. Weinstein JN, Tosteson TD, Lurie JD, Tosteson A, Blood E, Herkowitz H, et al. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the spine patient outcomes research trial. *Spine*. 2010;35(14):1329–38. doi:10.1097/BRS.0b013e3181e0f04d.
6. Malmivaara A, Slätis P, Heliövaara M, Sainio P, Kinnunen H, Kankare J, et al. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. *Spine*. 2007;32(1):1–8. doi:10.1097/01.brs.0000251014.81875.6d.
7. Gibson JNA, Waddell G. Surgery for degenerative lumbar spondylosis. *Cochrane Database Syst Rev*. 2005;19(4):CD001352. doi:10.1016/j.spinee.2015.01.003.
8. Puzilli F, Gazzeri R, Galarza M, Neroni M, Panagiotopoulos K, Bolognini A, et al. 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*. 2014;124:166–74. doi:10.1016/j.clineuro.2014.07.004.
9. Huang W, Chang Z, Zhang J, Song R, Yu X. Interspinous process stabilization with rocker via unilateral approach versus X-Stop via bilateral approach for lumbar spinal stenosis: a comparative study.

- BMC Musculoskelet Disord. 16:328. doi:[10.1186/s12891-015-0786-9](https://doi.org/10.1186/s12891-015-0786-9).
10. Lønne G, Johnsen LG, Rossvoll I, Andresen H, Storheim K, Zwart JA, et al. Minimally invasive decompression versus X-Stop in lumbar spinal stenosis: a randomized controlled multicenter study. *Spine*. 2015a;40(2):77–85. doi:[10.1097/BRS.0000000000000691](https://doi.org/10.1097/BRS.0000000000000691).
 11. Verhoof OJ, Bron JL, Wapstra FH, et al. High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. *Eur Spine J*. 2008;17(2):188–92.
 12. Daentzer D, Hurschler C, Seehaus F, Noll C, Schwarze M. Posterior dynamic stabilization in the lumbar spine—24 months results of a prospective clinical and radiological study with an interspinous distraction device. *BMC Musculoskelet Disord*. 2016;17:90. doi:[10.1186/s12891-016-0945-7](https://doi.org/10.1186/s12891-016-0945-7).
 13. Marsh GDJ, Mahir S, Leyte A. A prospective randomised controlled trial to assess the efficacy of dynamic stabilisation of the lumbar spine with the Wallis ligament. *Eur Spine J*. 2014;23(10):2156–60. doi:[10.1007/s00586-014-3487-4](https://doi.org/10.1007/s00586-014-3487-4).
 14. Jiang Y, Che W, Wang H, Li R, Li X, Dong J. Minimum 5 year follow-up of multi-segmental lumbar degenerative disease treated with discectomy and the Wallis interspinous device. *J Clin Neurosci*. 2015;22(7):1144–9. doi:[10.1016/j.jocn.2014.12.016](https://doi.org/10.1016/j.jocn.2014.12.016).
 15. Buric J, Pulidori M. 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*. 2011;20(8):1304–11. doi:[10.1007/s00586-011-1697-6](https://doi.org/10.1007/s00586-011-1697-6).
 16. Lu K, Liliang P-C, Wang H-K, Liang C-L, Chen J-S, Chen T-B, et al. Reduction in adjacent-segment degeneration after multilevel posterior lumbar interbody fusion with proximal DIAM implantation. *J Neurosurg Spine*. 2015;23(2):190–6. doi:[10.3171/2014.12.SPINE14666](https://doi.org/10.3171/2014.12.SPINE14666).
 17. Fabrizio AP, Maina R, Schiabello L. Interspinous spacers in the treatment of degenerative lumbar spinal disease: our experience with DIAM and aperiis devices. *Eur Spine J*. 2011;20(Suppl 1):S20–6. doi:[10.1007/s00586-011-1753-2](https://doi.org/10.1007/s00586-011-1753-2).
 18. Masala S, Marcia S, Taglieri A, Chiaravalloti A, Calabria E, Raguso M, et al. Degenerative lumbar spinal stenosis treatment with aperiis™ PerCLID™ system and Falena® interspinous spacers: 1-year follow-up of clinical outcome and quality of life. *Interv Neuroradiol*. 2016;22(2):217–26. doi:[10.1177/1591019915622163](https://doi.org/10.1177/1591019915622163).
 19. Beyer F, Yagdiran A, Neu P, Kaulhausen T, Eysel P, Sobottke R. Percutaneous interspinous spacer versus open decompression: a 2-year follow-up of clinical outcome and quality of life. *Eur Spine J*. 2013;22(9):2015–21. doi:[10.1007/s00586-013-2790-9](https://doi.org/10.1007/s00586-013-2790-9).
 20. Bae HW, Lauryssen C, Maislin G, Leary S, Musacchio MJ. Therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. *Int J Spine Surg*. 2015;9:15. doi:[10.14444/2015](https://doi.org/10.14444/2015). **Four-year RCT demonstrating the viability of the Coflex interlaminar device for the treatment of lumbar spinal stenosis.**
 21. Kumar N, Shah SM, Ng YH, Pannierselvam VK, DasDe S, Shen L. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. *Asian Spine J*. 2014;8(2):161. doi:[10.4184/asj.2014.8.2.161](https://doi.org/10.4184/asj.2014.8.2.161).
 22. Lee N, Shin DA, Kim KN, Yoon DH, Ha Y, Shin HC, et al. Paradoxical radiographic changes of coflex interspinous device with minimum 2-year follow-up in lumbar spinal stenosis. *World Neurosurg*. 2016;85:177–84. doi:[10.1016/j.wneu.2015.08.069](https://doi.org/10.1016/j.wneu.2015.08.069).
 23. Patel VV, Whang PG, Haley TR, Bradley WD, Nunley PD, Davis RP, et al. Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. *Spine*. 2015a;40(5):275–82. doi:[10.1097/BRS.0000000000000735](https://doi.org/10.1097/BRS.0000000000000735).
 24. Patel VV, Nunley PD, Whang PG, Haley TR, Bradley WD, Davis RP, et al. Superion® Interspinous spacer for treatment of moderate degenerative lumbar spinal stenosis: durable three-year results of a randomized controlled trial. *J Pain Res*. 2015b;8:657–62. doi:[10.2147/JPR.S92633](https://doi.org/10.2147/JPR.S92633). **A 3-year RCT demonstrating the Superion device to provide clinical improvement in patients with lumbar spinal stenosis.**
 25. Shabat S, Miller LE, Block JE, Gepstein R. Minimally invasive treatment of lumbar spinal stenosis with a novel interspinous spacer. *Clin Interv Aging*. 2011;6:227–33. doi:[10.2147/CIA.S23656](https://doi.org/10.2147/CIA.S23656).
 26. Alexandre A, Alexandre AM, De Pretto M, Coro L, Saggini R, et al. One-year follow-up of a series of 100 patients treated for lumbar spinal canal stenosis by means of HeliFix interspinous process decompression device, one-year follow-up of a series of 100 patients treated for lumbar spinal canal stenosis by means of HeliFix interspinous process decompression device. *Biomed Res Int*. 2014;2014:e176936. doi:[10.1155/2014/176936](https://doi.org/10.1155/2014/176936).
 27. Yingsakmongkol W, Chaichankul C, Limthongkul W. Percutaneous interspinous distraction device for the treatment of lumbar spinal canal stenosis: clinical and radiographic results at 2-year follow-up. *Int J Spine Surg*. 2014;8:32. doi:[10.14444/1032](https://doi.org/10.14444/1032).
 28. Wu AM, Zhou Y, Li QL, et al. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: a systematic review and meta-analysis. *PLoS One*. 2014;9(5):e97142. doi:[10.1371/journal.pone.0097142](https://doi.org/10.1371/journal.pone.0097142).
 29. Patil CG, Sarmiento JM, Ugiliweza B, Mukherjee D, Nuno M, Liu JC, et al. Interspinous device versus laminectomy for lumbar spinal stenosis: a comparative effectiveness study. *Spine J*. 2014;14(8):1484–92. doi:[10.1016/j.spinee.2013.08.053](https://doi.org/10.1016/j.spinee.2013.08.053). **A retrospective comparative study analyzing complication rates, reoperation rates, and costs in patients receiving an IPD vs. laminectomy.**
 30. Postacchini R, Ferrari E, Cinotti G, Menchetti PPM, Postacchini F. Aperiis interspinous implant versus open surgical decompression in lumbar spinal stenosis. *Spine J*. 2011;11(10):933–9. doi:[10.1016/j.spinee.2011.08.419](https://doi.org/10.1016/j.spinee.2011.08.419).
 31. Meirhaeghe JV, Franssen P, Morelli D, Craig NJA, Godde G, Mihalyi A, et al. Clinical evaluation of the preliminary safety and effectiveness of a minimally invasive interspinous process device APERIUS®. *Eur Spine J*. 2012;21(12):2565–72. doi:[10.1007/s00586-012-2330-z](https://doi.org/10.1007/s00586-012-2330-z).
 32. Surace MF, Fagetti A, Fozzato S, Cherubino P. Lumbar spinal stenosis treatment with aperiis perclid interspinous system. *Eur Spine J*. 2012;21(1):69–74. doi:[10.1007/s00586-012-2222-2](https://doi.org/10.1007/s00586-012-2222-2).
 33. Miller LE, Block JE. Interspinous spacer implant in patients with lumbar spinal stenosis: preliminary results of a multicenter, randomized, controlled trial. *Pain Res Treat*. 2012;2012:823509. doi:[10.1155/2012/823509](https://doi.org/10.1155/2012/823509).
 34. Heyrani N, Picinic Norheim E, Elaine Ku Y, Nick SA. Interspinous process implantation for the treatment of neurogenic intermittent claudication. *Anesth Pain Med*. 2012;2(1):36–41. doi:[10.5812/aapm.5173](https://doi.org/10.5812/aapm.5173).
 35. Kim H-Y, Choi B-W. Change of radiological parameters after interspinous implantation (X-stop®) in degenerative spinal stenosis. *Eur J Orthop Surg Traumatol*. 2012;23(3):281–5. doi:[10.1007/s00590-012-0986-z](https://doi.org/10.1007/s00590-012-0986-z).
 36. Strömquist BH, Berg S, Gerdhem P, Johnsson R, Möller A, Sahlstrand T, et al. X-Stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year follow-up. *Spine*. 2013;38(17):1436–42. doi:[10.1097/BRS.0b013e31828ba413](https://doi.org/10.1097/BRS.0b013e31828ba413). **This study compared X-STOP with decompressive surgery and found a greater need for reoperation in patients receiving X-stop.**

37. Nandakumar A, Clark NA, Smith FW, Wardlaw D. Two-year results of X-stop interspinous implant for the treatment of lumbar spinal stenosis: a prospective study. *J Spinal Disord Tech*. 2013;26(1):1–7. doi:[10.1097/BSD.0b013e318227ea2b](https://doi.org/10.1097/BSD.0b013e318227ea2b).
38. Pan B, Zhang Z-J, Lu Y-S, Xu W-G, Fu C-D. Experience with the second-generation Wallis interspinous dynamic stabilization device implanted in degenerative lumbar disease: a case series of 50 patients. *Turk Neurosurg*. 2014;24(5):713–9. doi:[10.5137/1019-5149.JTN.9465-13.0](https://doi.org/10.5137/1019-5149.JTN.9465-13.0).
39. Grasso G, Giambardino F, Iacopino DG. Clinical analysis following lumbar interspinous devices implant: where we are and where we go. *Spinal Cord*. 2014;52(10):740–3. doi:[10.1038/sc.2014.100](https://doi.org/10.1038/sc.2014.100).
40. Schmier J, Halevi M, Maislin G, Ong K. Comparative cost effectiveness of Coflex & interlaminar stabilization versus instrumented posterolateral lumbar fusion for the treatment of lumbar spinal stenosis and spondylolisthesis. *Clinicoecon Outcomes Res*. 2014;6:125–31. doi:[10.2147/CEOR.S59194](https://doi.org/10.2147/CEOR.S59194).
41. Gazzeri R, Galarza M, Neroni M, Fiore C, Faiola A, Puzzilli F, et al. Failure rates and complications of interspinous process decompression devices: a European multicenter study. *Neurosurg Focus*. 2015;39(4):E14. doi:[10.3171/2015.7.FOCUS15244](https://doi.org/10.3171/2015.7.FOCUS15244).
42. Liu X, Liu Y, Lian X, Xu J. Magnetic resonance imaging on disc degeneration changes after implantation of an interspinous spacer and fusion of the adjacent segment. *Int J Clin Exp Med*. 2015;8(4):6097–102.
43. Huddleston P. X-stop resulted in a higher reoperation rate than minimally invasive decompression, but both decreased symptoms of neurogenic intermittent claudication in patients with lumbar spinal stenosis. *J Bone Joint Surg Am*. 2015;97(22):1889. doi:[10.2106/JBJS.9722.ebo101](https://doi.org/10.2106/JBJS.9722.ebo101).
44. Lønne G, Johnsen LG, Aas E, Lydersen S, Andresen H, Rønning R, et al. Comparing cost-effectiveness of X-Stop with minimally invasive decompression in lumbar spinal stenosis: a randomized controlled trial. *Spine*. 2015b;40(8):514–20. doi:[10.1097/BRS.0000000000000798](https://doi.org/10.1097/BRS.0000000000000798). **This randomized clinical trial was terminated early because of high complication rate in the X-STOP group (33%).**
45. Wang K, Zhu Z, Wang B, Zhu Y, Liu H. Bone resorption during the first year after implantation of a single-segment dynamic interspinous stabilization device and its risk factors. *BMC Musculoskelet Disord*. 2015;16:117. doi:[10.1186/s12891-015-0561-y](https://doi.org/10.1186/s12891-015-0561-y).
46. Yue Z-J, Liu R-Y, Lu Y, Dong L-L, Li Y-Q, Lu EB. Middle-period curative effect of posterior lumbar intervertebral fusion (PLIF) and interspinous dynamic fixation (Wallis) for treatment of L4/5 degenerative disease and its influence on adjacent segment degeneration. *Eur Rev Med Pharmacol Sci*. 2015;19(23):4481–7.
47. Van den Akker-van Marle ME, Moojen WA, Arts MP, Vleggeert-Lankamp CLAM, Peul WC. Interspinous process devices versus standard conventional surgical decompression for lumbar spinal stenosis: cost-utility analysis. *Spine J*. 2016;16(6):702–10. doi:[10.1016/j.spinee.2014.10.017](https://doi.org/10.1016/j.spinee.2014.10.017).
48. Epstein NE. A review of interspinous fusion devices: high complication, reoperation rates, and costs with poor outcomes. *Surg Neurol Int*. 2012;3:7. doi:[10.4103/2152-7806.92172](https://doi.org/10.4103/2152-7806.92172).