

Lumbar Interspinous Spacers

A Systematic Review of Clinical and Biomechanical Evidence

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Study Design.

Systematic review.

Objective. To evaluate the current biomechanical and clinical evidence available on the use and effectiveness of lumbar interspinous devices and to recommend indications for their use.

Summary of Background Data. Lumbar interspinous spacers (ISPs) have recently become popular as an alternative treatment for lumbar degenerative disease. Several spacers are currently available in the market and there have been various proposed indications. The relevant biomechanical and clinical papers are analyzed.

Methods. A systematic review of clinical and biomechanical studies was done using the following key words: interspinous implants, interspinous devices, interspinous spacers, dynamic stabilization, X-STOP, Coflex, Wallis, DIAM. The database inclusions were MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and PubMed. The main outcome measure was clinical outcome assessment based on validated patient-related questionnaires. Biomechanical studies were analyzed to evaluate the effects of ISPs on the kinematics of the spine. The methodology of the clinical studies was also analyzed.

Results. Largest number of studies has been with the X-STOP device. The biomechanical studies with all the devices showed that ISPs have a beneficial effect on the kinematics of the degenerative spine. Apart from 2 randomized controlled trials, the other studies with the X-STOP device were not of high methodologic quality. Nevertheless, analysis of these studies showed that X-STOP may improve outcome when compared to nonoperative treatment in select group of patients aged 50 or over, with radiologically confirmed lumbar canal stenosis and neurogenic claudication, who have improvement of their symptoms in flexion. Studies on the other devices show satisfactory outcome to varying degrees. However, due to small number and poor design of the studies, it is difficult to clearly define indications for their use in lumbar degenerative disease.

Conclusion. Lumbar ISPs may have a potential beneficial effect in select group of patients with degenerative disease of the lumbar spine. However, further good quality trials are needed to clearly outline the indications for their use.

Key words: interspinous spacers, interspinous devices, X-STOP, interspinous implants. **Spine 2010;35:E1499–E1506**

Several interspinous spacers (ISPs) are currently available in the market. Though they vary in design and composition, their common mechanical goal is distraction between adjacent spinous processes and thus blocking intervertebral extension at that level. There has been several proposed indication for their use including lumbar canal stenosis, Grade 1 degenerative spondylolisthesis, discogenic low back pain, nontraumatic instability, lumbar disc herniation, and facet syndrome.^{1–4} However, proper evidence for such widespread use is currently lacking. The main aim of this paper is to critically analyze the current biomechanical and clinical evidence available about ISPs.

Materials and Methods

Inclusion Criteria

Population of interest: Adult patients with degenerative disease of the lumbar spine.

Types of studies included: Clinical and biomechanical studies including cadaveric studies.

Types of interventions: Treatment of degenerative disease of the lumbar spine by insertion of interspinous spacers.

Types of outcome measures: For the clinical studies, outcome assessment was based on patient-related outcome measures with regards to pain and quality of life using various validated questionnaires, *e.g.*, Oswestry disability index (ODI), Zurich claudication questionnaire (ZCQ), Short Form 36 (SF-36), SSSQ (Swiss spinal stenosis questionnaire), *etc.* For the biomechanical studies, the main outcome measure was to see if insertion of ISPs significantly affected the kinematics of the lumbar spine and spinal canal and neural foramina diameter (with or without concomitant decompression).

Exclusion Criteria

Articles describing novel techniques, nonconventional techniques *e.g.*, endoscopic decompression and case reports were excluded. A minimum follow-up of 1 year was needed for clinical studies.

Search Strategy

Relevant biomechanical and clinical studies meeting the above criteria were identified as follows:

1. A computerized database search of MEDLINE (1966 to January 2009), CINAHL (Cumulative Index to Nursing

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Table 1. Biomechanical Studies on the X-STOP Device

Author	Type of Study	Sample Size	Parameter Assessed	Results
X-STOP Wilke <i>et al</i> ⁶	Cadaveric	24	Compare all 4 different implants in terms of their 3-dimensional flexibility and intradiscal pressure	All 4 stabilized and reduced intradiscal pressure in extension, but had almost no effect in flexion, lateral bending and axial rotation
Siddiqui <i>et al</i> ⁶	Case series	26	Sagittal kinematics <i>in vivo</i> at the instrumented and adjacent levels (MRI assessment)	No significant changes in disc heights, segmental and total lumbar spine movements postoperatively
Siddiqui <i>et al</i> ⁷	Case series	26	Kinematics of lumbar spine at the instrumented levels in various postures.	Significant increase in the dimensions of the neural foramen and canal area after surgery
Fuchs <i>et al</i> ⁸	Cadaveric	7	Kinematics following graded facetectomies	BTF significantly increase ROM UMF and UTF did not affect the ROM
Wiseman <i>et al</i> ⁸	Cadaveric	7	Facet loading	Implant significantly reduced the mean peak pressure, average pressure, contact area, and force at the implanted level
Zucherman <i>et al</i> ¹⁰	Multicenter, prospective, randomized trial	191	X-ray assessment of: spinous process distance, anterior disc height, posterior disc height, foraminal height, angulation	No significant difference between implanted patients and control at 12 and 24 mo
Richards <i>et al</i> ¹¹	Cadaveric	8	Dimensions of the spinal canal and neural foramina during flexion and extension	In extension, canal area increased 18%, canal diameter 10%, the foraminal area 25% and foraminal width 41%
Lee <i>et al</i> ¹²	Case series	10	Cross-sectional areas of the dural sac and intervertebral foramina at the stenotic level (MRI assessment)	Cross-sectional area of the dural sac increased 22.3% Intervertebral foramina increased 36.5%
Swanson <i>et al</i> ¹³	Cadaveric	8	Measurement of intradiscal pressure	No significant change at adjacent levels Significant unloading of the intervertebral disc at the instrumented level in neutral and extended positions

UTF indicates unilateral total facetectomy; UMF, unilateral medial facetectomy; BTF, bilateral total facetectomy; ROM, range of movement; PLIF, posterior lumbar interbody fusion; ASD, adjacent segment degeneration; MRI, magnetic resonance imaging.

and Allied Health Literature), and PubMed was performed.

- The following keywords were used: interspinous implants, interspinous devices, dynamic stabilization, interspinous spacer, X-STOP, Coflex, Wallis, DIAM.
- For the selected articles, the reference list was also reviewed.

Method of Review

The abstracts were initially reviewed to ensure that there were no exclusion criteria. If no clear exclusion criteria were identified, the full journal article was subsequently obtained. The biomechanical and clinical papers were analyzed. The following effects of the ISPs were specifically noted when analyzing the biomechanical papers: stability at instrumented level, distraction, spinal canal and neural foramen dimension, intradiscal pressure, effect on facet joints, adjacent level degeneration/instability, and concomitant lumbar surgery. The methodology of the clinical papers was also reviewed.

Results

The relevant biomechanical and clinical articles are outlined in Tables 1–4. The relevant features of the currently available spacers are outlined in Table 5. Let us briefly discuss the relevant articles regarding each type of spacer.

X-STOP

Biomechanical Studies

A total of 10 studies were found, which reported the effect of X-STOP on the kinematics of the lumbar spine.^{5–12,38} Six were cadaveric studies. Analysis of the studies shows that X-STOP has some beneficial effects on the kinematics of the spine. The important biomechanical findings of the studies are as follows: (1) decrease in flexion-extension range of movement at instrumented level; (2) significant increase in neural foramen and spinal canal dimension; (3) decrease in intradiscal pressure at instrumented level in neutral and extended position; (4) decrease in mean peak pressures, average pressures, contact area and force at the facets; (5) no significant alteration of kinematics or accelerated disc degeneration at adjacent levels; (6) no significant change in intervertebral angle, posterior disc height, and interspinous process distance.

The clinical as well as the laboratory studies available on the X-STOP have mainly focused on its use as a “stand-alone” device. In a cadaveric study by Fuchs *et al*,⁸ X-STOP was additionally evaluated in combination with graded facetectomies. Their study suggested that the implant may be used in conjunction with a unilateral

Table 2. Biomechanical Studies on the Other Devices

Author	Type of Study	Sample Size	Parameter Assessed	Results
DIAM Bellini <i>et al</i> ⁴	FEM analysis	N/A	Biomechanics of instrumented and adjacent levels	ROM decreased at instrumented level by 17% in flexion, 43% in extension. Adjacent levels, no significant changes. Decrease in intradiscal pressure at instrumented level
Kim <i>et al</i> ⁵	Case control study	62	Disc height and sagittal alignment following DIAM insertion after simple lumbar surgery	No significant change in disc height or sagittal alignment at the mean 12-mo follow-up interval
Phillips <i>et al</i> ⁶	Cadaveric	6	Kinematics after partial facetectomy and discectomy	Reduces the increased segmental flexion-extension and lateral bending motions observed after discectomy
Coflex Trautwein <i>et al</i> ⁷	Case series	176	Determine the actual <i>in vivo</i> loading environment (radiographic analysis)	Implant fatigue strength significantly higher than the measured median force
Tsai <i>et al</i> ⁸	Cadaveric	8	Biomechanics under following conditions: (1) intact; (2) partial destabilization; (3) stabilization with the Coflex device; (4) complete destabilization with total laminectomy; and (5) stabilization with pedicle screws and rods	Insertion of coflex returns a partially destabilized specimen back to the intact condition in terms of motion in flexion/extension and axial rotation
Kong <i>et al</i> ⁹	Case series	42	Adjacent segment motion in spinal stenosis with mild segmental instability, comparing PLIF with Coflex	Range of motion at upper adjacent segments increased significantly after surgery in the PLIF group, which was not manifested in the Coflex group during the follow-up
Wallis Korovessis <i>et al</i> ²⁰	Case-control study	45	Effect of implantation cephalad to short lumbar and lumbosacral instrumented fusion on incidence of ASD	Lowered the radiographic ASD incidence until to 5 yr postoperatively
Lafage <i>et al</i> ²¹	Cadaveric/FEM	6	Biomechanical effect on lumbar spine: Intact, injured (simulated herniectomy and partial discectomy), and instrumented	Reduce motion at instrumented injured segment compared to uninstrumented injured and intact segment level Lower stress in the disc fibers and annulus matrix

ROM indicates range of motion; FEM, finite element analysis; ASD, adjacent segment degeneration; PLIF, posterior lumbar interbody fusion.

medial facetectomy or unilateral total facetectomy but not with a bilateral total facetectomy. However, it is worth noting that use of X-STOP with concomitant lumbar surgery is not one of the indications advocated by the developer.

Clinical Evidence

There have been 2 prospective randomized controlled trials with the X-STOP device. Zucherman *et al* were the first to publish results of a prospective, comparative, multicenter, randomized trial, in which 100 patients were treated with the X-STOP and 91 patients received nonoperative management.^{10,28,31} Patients had to be at least 50 years old and have leg, buttock, or groin pain with or without back pain that was relieved during flexion. Eligible patients had to be able to sit for 50 minutes without pain, walk 50 feet or more, and have completed at least 6 months of nonoperative therapy. Stenosis was confirmed by CT or MRI scans at 1 or 2 levels. Results at 1 year were analyzed using the ZCQ and the SF-36.

However, only the ZCQ was used for the 2-year follow-up. They observed a significantly greater improvement in clinical symptoms in the X-STOP group compared with controls (nonoperative) at all time points. At 2 years, 60.2% patients reported a clinically significant improvement in the Symptom Severity domain and 57% reported clinically significant improvement in the Physical function. Though a direct comparison with laminectomy was not done, the authors felt that the success rate observed in this study is comparable to the good outcome following laminectomy (55%–70%) in the existing literature.^{39–41} However, some of the concerns raised by the FDA (Food and Drug Administration) with this trial were as follows⁴²: (1) the block randomization used could potentially be used to select patients more likely to respond to the device, (2) outcomes in both groups were significantly worse than expected, which calls into question the validity of the power calculations, and (3) results from 1 particular center were clearly superior to results

Table 3. Clinical Studies on the X-STOP Device

Series	Patients	Type of Study	Follow-up	Evaluation	Results
Barbagallo <i>et al</i> ²²	69	Retrospective, case series	23 mo	n/a	8 complications, 7 needing revision
Sobottke <i>et al</i> ²³	129	Retrospective, case series	200/300 d	VAS Radiological	Good symptom control Very weak correlation between VAS and radiological improvement
Kuchta <i>et al</i> ²⁴	175	Prospective, noncomparative	2 yr	VAS ODI	Mean VAS 39% Mean ODI 20.3%
Brussee <i>et al</i> ²⁵	65	Prospective, noncomparative	12 ± 8 mo	Self-rated questionnaires SF-36, ZCQ	Good outcome—31% No relief/recurrent symptoms—9% Need for second surgery—9%
Verhoof <i>et al</i> ²⁶	12	Retrospective, case series	30 mo	Relief/recurrent pain (objective criteria not described)	Early postoperative relief—67% No relief/recurrent symptoms—58% Need for second surgery—58%
Siddiqui <i>et al</i> ²⁷	40	Prospective study, noncomparative	1 yr	ODI SF-36 ZCQ	Satisfied with procedure—71% Recurrence of symptoms—29% Need for second surgery—8%
Hsu <i>et al</i> ²⁸	191	Prospective, comparative, randomized, multicenter	2 yr	SF-36	Mean domain scores significantly better in X-STOP group at all post-treatment point times.
Kondrashov <i>et al</i> ²⁹	18	Prospective, noncomparative	51 mo	ODI	Successful outcome at 51 mo—78%
Anderson <i>et al</i> ³⁰	75	Prospective, comparative, randomized, multicenter	24 mo	SF-36 ZCQ Radiographic	Clinical success in implant group 63%, control 13% Spondylolisthesis and kyphosis unaltered
Zucherman <i>et al</i> ¹⁰	191	Prospective, comparative, randomized, multicenter	2 yr	ZCQ Radiographic	Significant better outcome in X-STOP group compared to control
Lee <i>et al</i> ¹²	10	Prospective, noncomparative	11 mo	SSSQ Radiographic	At least somewhat satisfied—70%
Zucherman <i>et al</i> ¹¹	191	Prospective, comparative, randomized, multicenter	1 yr	ZCQ SF-36	Success rate at 1 yr in implant group 59%, control 12%

VAS indicates Visual Analogue Scale; ODI, Oswestry Disability Index; ZCQ, Zurich Claudication Questionnaire; SSSQ, Swiss Spinal Stenosis Questionnaire.

from other centers. Four-year follow-up on 18 of the X-STOP patients showed that 78% of patients had a successful outcome by measurement using the ODI.²⁹ However, this study has significant shortcomings. Only 18 of the original 100 patients who had insertion of X-STOP were included. Also, in the 4-year results, the ODI scores were reported instead of ZCQ scores, as were documented in the pivotal study. The reason for this is unclear. This makes it very difficult to draw any definite conclusions from the 4-year study. It is worth mentioning here that the 2-year follow-up SF-36 data of 82 of the 100 X-STOP-treated patients and 53 of 91 nonoperatively treated patients were published separately.²⁸ The findings were as follows: (1) mean domain scores in X-STOP-treated patients were significantly greater than those in patients treated nonoperatively, with the exception of the mean General Health, Role Emotional, and Mental Component Summary scores at 2 years; and (2) mean post treatment domain scores documented in X-STOP-treated patients were significantly greater than mean pretreatment scores, with the exception of mean General Health scores at 6, 12, and 24 months.

The application of X-STOP in patients with Grade I spondylolisthesis was specifically studied in a prospective, comparative, multicenter, randomized trial in a cohort of 75 patients by Anderson *et al*, using SF-36 and ZCQ.³⁰ They reported clinical success of 63% in implant

group compared to 13% in nonsurgical group. These results were, however, not replicated by Verhoof *et al*. In their cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis and treated with the X-STOP, there was a second need for surgery in 58% of the patients. The authors felt that any grade of degenerative spondylolisthesis be considered a contraindication for X-STOP placement.²⁶ Further trials are needed to look into the effect of X-STOP in patients with degenerative spondylolisthesis.

Other single center noncomparative studies on the effect of X-STOP in lumbar canal stenosis (Table 2) suggest varying degrees of satisfactory outcome.^{12,25,27}

In a recent publication on X-STOP, Barbagallo *et al*²² looked into the complications of X-STOP. Of a total of 69 patients, 8 had complications. These included 4 device dislocations and 4 spinous process fractures. Of these 8, 7 patients (10.14%) required revision surgery. In another recent paper, Sobottke *et al*²³ did not find any significant correlation between radiologic parameters and clinical outcome. It is also worth noting that only 175 (17.5%) of a total of more than 1000 patients seen in their outpatients clinic with symptoms of intermittent claudication due to spinal stenosis were suitable for X-STOP insertion.

Table 4. Clinical Studies on the Other Devices

Series	Patients	Type of Study	Follow-up	Evaluation	Results
DIAM					
Taylor <i>et al</i> ⁶²	104	Retrospective study, noncomparative	18 mo	Chart review unverified patient questionnaire	Analgesic usage decreased in 63.1%, activities of daily living improved in 46.2%, decreased in 30.8%
Kim <i>et al</i> ¹⁵	62	Case-control study	12 mo	VAS MacNab serial imaging	Improvement in pain scores significant in both Changes in ant/posterior disc heights not significant
Mariottini <i>et al</i> ⁶³	43	Microsurgical nerve root decompression followed by implantation of DIAM			Results satisfying—97%
Schiavone and Pasquale ³⁴	22	Non-English literature	10 mo		Outcome 16/22 Excellent (4/22) Good
Coflex					
Richter <i>et al</i> ⁶⁵	60	Prospective controlled study 30 patients with laminectomy and Coflex, 30 laminectomy alone	1 yr	ODI VAS	No significant difference between groups
Kong <i>et al</i> ⁹	42	Retrospective-prospective, Comparative comparing 18 patients undergoing Coflex placement (and concomitant lumbar decompression) with 24 patients undergoing PLIF. All patients in the study had mild segmental instability	1 yr	ODI VAS serial imaging	Improvement in ODI, VAS, significant in both Significant increase in ROM in upper segments in PLIF patients
Wallis					
Floman <i>et al</i> ⁶⁶	37	Retrospective-prospective, noncomparative only latter 14 evaluated for pain/disability scores (no charts used for initial 23 patients) All patients underwent concomitant Lumbar disc excision	16 mo	ODI SF-36 VAS	Wallis implant is probably incapable of reducing the incidence of recurrent herniations
Senegas <i>et al</i> ⁶⁷	107	Retrospective, noncomparative	13 yr	ODI SF-36 VAS	Good outcome in 80% patients Implant removed and fusion performed in 20%

VAS indicates visual analogue scale; ODI, Oswestry disability index; ROM, range of movement; PLIF, posterior lumbar interbody fusion; SF-36, short-form 36.

■ Wallis Implant

Biomechanical Studies

The initial studies were limited to the titanium prototype.^{43–45} The published biomechanical data on the second generation implant is scanty. In 2007, the developer along with coworkers published a combined *in vitro* and finite-element model analysis of the second generation implant. *In vitro* study results showed that the device placement after a simulated herniectomy and partial discectomy reduced the instrumented level range of movement to near intact levels. Finite-element model analysis indicated a decrease in disc stresses and increase in loads transmitted through the spinous processes.⁴⁶

Korovessis *et al*²⁰ conducted a prospective controlled study to see if Wallis implant reduces adjacent segment degeneration (ASD) above lumbosacral instrumented fusion. Their study concluded that Wallis interspinous implant changed the natural history of ASD and saved the 2 cephalad adjacent unfused vertebrae from fusion, while it lowered the radiographic ASD incidence until up to 5 years after surgery.

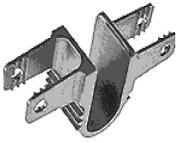
Clinical Evidence

Senegas *et al* has recently published his results of a 13-year mean follow-up of 107 patients.³⁷ All patients had initially been scheduled for decompression and fusion for

canal stenosis, herniated disc, or both. In 20 patients, the implant had to be removed, and fusion was performed. The other 87 still had the dynamic stabilizer. Satisfaction, Oswestry disability index, visual analog scales for back and leg pain, short-form (SF-36) quality-of-life physical composite score, physical function, and social function were significantly better ($P \leq 0.05$) in the patients who still had the dynamic stabilization device. The study showed that the device provided a good 13-year clinical outcome and obviated arthrodesis in around 80% of the total 107 patients. However, this is a retrospective study with no control. It is, therefore, difficult to say whether the good results are due to the decompression alone or not.

Floman *et al* (2007) published a retrospective study evaluating the new implant.³⁶ The aim was to assess whether implant placement resulted in a subsequent lower incidence of recurrent disc herniation and further surgery. Thirty-seven patients underwent primary lumbar disc excision followed by fixation of the segment with the Wallis implant. After an average follow-up of 16 months, 13% of patients had recurrent herniations. This is in comparison to an independently published figure showing that 14% of primary lumbar discectomies require additional surgical intervention.⁴⁷ They concluded that the Wallis implant is probably incapable of

Table 5. Relevant Features of the Interspinous Devices

Implant	Wallis	X-STOP/X-STOP ^{PK}	Coflex ("Interspinous U")	DIAM
Company	Abbott spine	Kyphon Inc.	Paradigm spine	Medtronic
Launch	2002 (new)	2002	1994 (The U)	2001
Developer	Senegas J	St Francis Inc.	Samani J	Taylor J
FDA Status	Approved for clinical trial	Approved for clinical use	Approved for clinical trial	Approved for clinical trial
Composition	Blocker—PEEK	Titanium alloy body and PEEK spacer (X-STOP ^{PK})	Titanium alloy	Silicone Core with polyester sleeve
Technique	Removal of supraspinous ligaments necessary	Preserves supraspinous ligament	Removal of supraspinous ligaments necessary	Preserves supraspinous ligament
Implant				

FDA indicates Food and Drug Administration; PEEK, polyether ether ketone.

reducing the incidence of recurrent herniations. They also attempted to evaluate the clinical benefits after implant placement. However, only 14 of the total 37 patients were evaluated for pain/disability scores. The average ODI and VAS dropped and SF-36 scores improved significantly in these 14 implanted patients. It is probably inappropriate to attribute these clinical gains to the implant alone as the concomitant decompressive surgery is likely to significantly contribute to the outcome.

■ Coflex

Biomechanical Studies

Biomechanical studies on the coflex device shows the following effects on the kinematics of the spine: (1) significant reduction in flexion-extension range of motion at instrumented level; (2) stabilization of a partially destabilized cadaveric specimen to intact condition in terms of motion in flexion/extension and axial rotation; (3) no significant increase in range of motion at adjacent level when compared to PLIF (posterior lumbar interbody fusion).¹⁷⁻¹⁹

Trautwein *et al*¹⁷ did a study to determine the *in vivo* posterior loading environment of the Coflex. The average loads exerted by the Coflex implant on the spinous process and lamina are 11.3% and 7.0% of their respective static failure load. As the implant fatigue strength is significantly higher than the measured median force, they concluded that Coflex fatigue failure is extremely rare.

Clinical Evidence

In a clinical study on Coflex by Kong *et al*,¹⁹ 18 patients undergoing Coflex placement and concomitant lumbar decompression were compared with 24 patients undergoing PLIF.¹⁹ The study was retrospective and nonrandomized. All patients in the study had mild segmental instability. Clinical evaluation was done using VAS and ODI which improved significantly in both the patient groups. However, the range of motion at the upper adjacent segments (L3-L4) increased significantly after surgery in the PLIF group, which was not manifested in the

Coflex group during the follow-up. The authors assumed that interspinous implantation can be an alternative treatment for the spinal stenosis with segmental instability in selected conditions posing less stress on the superior adjacent level than PLIF. In a recent prospective controlled study, Richter *et al*³⁵ evaluated the surgical outcome of decompressive surgery in comparison to decompressive surgery and additional implantation of the Coflex interspinous device in patients with lumbar spinal stenosis. A total of 60 patients were divided into 2 groups. Of them, 30 patients were treated with decompression surgery alone and in the other 30 patients a Coflex device was additionally implanted. At 1-year follow-up, there were no statistically differences between both groups in all ascertained parameters including patient satisfaction and subjective operation decision.

■ DIAM

Biomechanical Studies

Analysis of the biomechanical studies revealed the following: (1) decrease range of motion at instrumented level with no significant change at adjacent level, (2) decrease in intradiscal pressure at instrumented level, (3) no significant change in disc height or sagittal alignment, and (4) after discectomy, the angular motion was restored to below the level of the intact segment in flexion-extension but failed to stabilize in rotation.¹⁴⁻¹⁶

Clinical Evidence

In one of the earliest clinical series, Mariottini *et al* implanted DIAM in 43 patients following nerve decompression. They reported "satisfying" results in 97% of cases.³³ In the series by Kim *et al*, there was statistically no difference in radiculopathy or low back pain VAS or McNab outcomes in patients with or without placement of implant after decompressive surgery.¹⁵ A retrospective analysis of 104 patients operated as far back as 2001 were published in 2007 by Jean Taylor, the developer of the implant.³² The implant was placed in a "wide variety of lumbar disorders." A retrospective evaluation was

performed based on chart review and patient questionnaire. The questionnaire revealed that at 18 months after surgery, analgesic usage was decreased in 63.1%, increased in 12.3%, and unchanged in 24.6% of patients, and activities of daily living were improved in 46.2%, decreased in 30.8%, and unchanged in 23.1%. Specific outcomes measures for sitting, standing, physical activity, and psychosocial functioning revealed similar results.

■ Conclusion

There has been a deluge of ISPs currently available in the market. There have been several indications proposed by the developers as well. Current biomechanical evidence suggests a beneficial effect of interspinous devices on the kinematics of the degenerate spine. The trial by Zucherman *et al*¹⁰ shows that X-STOP may be beneficial when compared to nonoperative treatment in select group of patients aged 50 years or over with radiologically confirmed lumbar canal stenosis whose symptoms improve on flexion. Despite the trial by Anderson *et al*,³⁰ the use of X-STOP in degenerative spondylolisthesis is controversial. Other studies on X-STOP and other devices have shown promising clinical results. But these studies are mostly retrospective and do not provide us with high level of evidence. Therefore, it is very difficult to reach a firm conclusion regarding the widespread use of spacers for all the proposed indication. There is also very little in the literature regarding long-term follow-up, including revisional surgery, complications and failure rate. Several randomized controlled trials are currently under way. The results of these trials are keenly awaited based on which the indications for insertion of ISPs may be revised.

■ Key Points

- Lumbar ISPs may be beneficial for a select group of patients.
- However, prospective randomized controlled trials are lacking.
- Further good quality trials are needed to clearly outline the indications for their use.

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