

Medical Policy Manual

Topic: Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) **Date of Origin:** October 2006

Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Surgical decompression with or without fusion is the standard surgical treatment for patients with moderate to severe lumbar spinal stenosis. Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion.

- One type of interspinous process spacers are inserted between the spinous processes through a small (4–8 cm) incision. The supraspinous ligament is maintained and assists in holding the implant in place. No laminotomy, laminectomy or foraminotomy is performed. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.
- Interlaminar spacers are implanted midline between adjacent lamina and spinous processes following surgical decompression at the affected level(s). These implants have two sets of wings that are placed around the inferior and superior spinous processes.

These devices are intended to restrict painful motion while enabling otherwise normal motion. The devices theoretically enlarge the neural foramen, decompresses the cauda equina, and act as spacers between the spinous processes to maintain the flexion of the spinal interspace.

Proponents of these spacers list the advantages compared with standard surgical decompression techniques to be the option of local anesthesia, shorter hospital stay and rehabilitation period, preservation of local bone and soft tissue, reduced risk of epidural scarring and cerebrospinal fluid leakage, and reversibility that does not limit future treatment options. The potential complications of spacers are implant dislodgement, incorrect positioning of implant, fracture of the spinous process, foreign body reaction (e.g., allergic reaction to titanium alloy), and mechanical failure of the implant.

Regulatory Status

There are a number of interspinous process and interlaminar spacers that are under investigation:

Device name	Manufacturer	FDA Approved?
Aperius [™] -PercLID [™] System	Kyphon/Medtronic	No
Coflex® Interlaminar Stabilization Device* (formerly Interspinous U)	Paradigm Spine	<ul style="list-style-type: none"> As a stand-alone spacer – No As adjunct to fusion - No
CoRoent [™] System	NuVasive®	<ul style="list-style-type: none"> As a stand-alone spacer – No As adjunct to fusion - Yes
DIAM [™] Spinal Stabilization System	Medtronic Sofamor Danek	No IDE only
Falena [®] Interspinous Decompression Device	Mikai Spine	No
FLEXUS [™]	Globus Medical	No IDE only
Helifix [®] Interspinous Spacer System	Alphatec Spine [®]	No
In-Space	Synthes [®]	No IDE only
NL-Prow [™] Interspinous Spacer	Non-Linear Technologies	No
Stenofix	Synthes [®]	No
Superion [®] ISS Interspinous Spacer System	VertiFlex	No IDE only
Wallis [®] System	Zimmer Spine (formerly Abbott Spine)	No IDE only
X-STOP [®] Interspinous Process Decompression (IPD®) System	Kyphon/Medtronic Spine	Yes
X-STOP [®] PEEK (polyetheretherketone)	Medtronic	Yes

Note: This policy addresses only IPD devices. Dynamic stabilization devices across pedicle screws are considered in separate medical policies (see Cross References below). *The Coflex-F device is a fusion device and is not address in this policy.

MEDICAL POLICY CRITERIA

Interspinous process and interlaminar distraction/stabilization devices are considered **investigational**

for all indications.

SCIENTIFIC EVIDENCE

The primary beneficial outcomes of interest for treatment of low back pain are relief of pain and improved function. Both of these outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, data from large, blinded, randomized controlled trials (RCTs) with sufficient long-term follow-up are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from interspinous process and interlaminar distraction/stabilization spacers provides a significant advantage over conventional surgical decompression or nonsurgical treatment. In addition, adverse effects related to complications, such as spinous process fracture and implant dislodgement or breakage, must be considered in evaluating the net health impact of spacers compared with conventional surgical decompression with or without fusion.

Literature Appraisal

The focus of this literature appraisal is on systematic reviews and randomized trials. There are currently no long-term clinical trials for either interspinous process distraction or interlaminar stabilization spacers. The published clinical trial data are relatively sparse and consist largely of small, non-randomized, uncontrolled studies with short-term follow-up. Of the few studies with a control group, most compare spacers with conservative medical management.

Systematic Reviews

Two systematic reviews of spacers were published in 2010.^[1,2] Both noted that outcomes seem promising, but that the level of evidence is low. The authors call for well-designed, large randomized studies with long-term follow-up and consistent outcome measures.

Randomized Controlled Trials (RCTs)

Spacers Compared with Nonoperative Treatment

- The U.S. Food and Drug Administration (FDA) approval of the X STOP Interspinous Process Decompression System was based on laboratory, mechanical and cadaver studies, and a multi-center, prospective randomized controlled clinical study.^[3-5] In this clinical study, patients were randomized to either the XSTOP® at one (n=64) or two (n=36) levels or to a control group (n=91) which received continued non-operative therapy which included bed rest, a lumbar corset and a varied number of epidural injections. The Symptom Severity and Physical Function scores were measured at six weeks, six months, one year and two years. The scores for the X STOP patients were significantly higher than the scores for the control group at each follow-up point. At two years, the mean Symptom Severity score for the X-STOP and the control groups was 45.4% above baseline scores and 7.4 (p<0.001), respectively. The mean Physical Function score changes were 44.3% and -0.4% (p<0.001), respectively. While these short-term results are promising, the study precludes scientific conclusions related to long-term health outcomes.

The following are additional reports on various subsets of the participants in this RCT:

- A subsequent article was been published by the same authors using the 2-year quality of life date (SF-36) data from this trial.^[6] As with other reports, the X STOP group showed improvements (by single-factor ANOVA or t-test) in both physical and mental component scores compared to both baseline and control subjects. However, in this report the authors considered the patients from both treatment and control groups who went on to have laminectomy within the 2-year follow-up period as lost to follow-up rather than as treatment failures; thus, the beneficial outcomes reported are misleadingly inflated. The article also notes a conflict of interest for the two primary authors of these articles.
- Anderson and colleagues reported two year outcomes of a subset of patients in the original randomized trial reported above.^[7] This subset consisted of patients in the randomized trial whose symptoms were due to degenerative spondylolisthesis at one or two levels. The overall success was defined as a case in which all outcome measures (i.e., Zurich Claudication Questionnaire (ZCQ), Patient Satisfaction Survey, Short Form-36 (SF-36) scores, and additional surgery) were met. In the X-STOP® group (n=42) 63.4% of patients met success criteria while 12.9% of the control group (n=33) met success criteria. The difference was statistically significant. Five patients (12%) in the X-STOP® group and four patients (12%) in the control group underwent laminotomy during the follow-up period. Again, short-term results were encouraging but long-term outcomes are needed.
- In 2006, Kondrashov and Zucherman published the four year outcomes of another subset of patients in the randomized trial noted above.^[8] Eighteen patients from one center were selected from the original nine-center sample based on the availability of preoperative Oswestry Disability Index (ODI) scores and willingness to complete the ODI at four years following surgery. Using a 15 point improvement from baseline ODI score as a success criterion, 14 out of 18 patients (78%) had successful outcomes at the 4-year follow-up. The outcomes of the original control group were not included in this article. This intermediate-term study suffered from the same design flaws noted previously, specifically, the small size, lack of a control group for comparison, and lack of long-term health outcomes.

Spacers Compared with Decompression Surgery

- The 2-year outcomes of the pivotal investigational device exemption (IDE) trial for the coflex® Interlaminar Technology were published in 2013. This was a non-blinded randomized multi-center non-inferiority trial that compared implantation of the coflex spacer with decompression and posterolateral fusion with pedicle screw fixation.^[9,10] The condition treated was back pain due to spinal stenosis or low-grade degeneration spondylolisthesis. A total of 322 patients were randomized to undergo either laminectomy and coflex insertion (n=215) or laminectomy and fusion (n=107).

At a minimum of 2 years follow-up, non-inferiority was reported, with 66.2% success with coflex and 57.7% success with fusion (p=0.999). There was no statistically significant between-group differences in pain and function scores. The percentage of device-related adverse events was the same (5.6%) for both groups, and the rate of spinous process fractures was not significantly different between the groups (14% for coflex and 12% for fusion). The vast majority of spinous process fractures were asymptomatic. A separate article reported similar outcomes for the spondylolisthesis subgroup in the study.^[11] The overall reoperation rate was 10.7% in the coflex group and 7.5% in the fusion control (p=0.426). One limitation of this study was the lack of participant blinding to the treatment allocation; however, since the postoperative protocols are different for these procedures,

blinding can be difficult to maintain. In addition, the 2-year follow-up does not permit conclusion about long-term outcomes.

- In 2013, Stromqvist et al. reported the 2-year outcomes of a noninferiority randomized trial of 100 patients with symptomatic one- or two-level lumbar spinal stenosis with neurogenic claudication relieved on flexion.^[12] Patients were randomized in a 1:1 ratio to undergo either X-STOP implantation or conventional surgical decompression. At 6, 12, and 24 months follow-up, there was no significant difference in scores for symptoms and function, or for complication rates. Reoperation rates were significantly higher ($p<0.04$) in the X-STOP group ($n=13$; 26%) than in the decompression group ($n=3$; 6%). (The X-STOP patients who later underwent decompression were not considered to be treatment failures.) For the reasons noted above, longer-term data is needed to determine the durability of treatment effects and to compare the long-term reoperation rates.
- Richter et al. also published 2-year follow-up for 60 patients who underwent decompressive surgery with or without implantation of the Coflex device.^[13,14] Though comparative, this study was not a randomized trial; treatment was allocated at the discretion of the surgeon. The authors reported no significant between-group differences in any outcome measures, and concluded that “additional placement of a Coflex™ interspinous device does not improve the already good clinical outcomes after decompression surgery for LSS in this 24-month follow up interval.”

Comparisons Between Spacers

Preliminary results have been published from an FDA-regulated multicenter randomized IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP.^[15] Non-blinded results at 6-month follow-up showed similar efficacy for the two devices. Twenty percent of patients in the Superion group and 23% of patients in the X-STOP had complications. The FDA-mandated primary endpoint of this trial is non-inferiority to X-STOP at 2 years, with additional postmarket surveillance for 10 years. This trial is ongoing and over 300 patients are expected to be enrolled. Interpretation of this study is limited by the lack of blinding and lack of control groups treated by surgical decompression or medical management.

Clinical Practice Guidelines

- The 2011 revised clinical guidelines from the North American Spine Society concluded that “there is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis” (Grade of Recommendation I - Insufficient Evidence)^[16]
- In 2009, Chou and colleagues presented a review of evidence related to surgical treatments for low back pain.^[17] On the basis of the randomized trial data available at that time, the authors offered the conclusions noted below. Of note, although the Anderson report^[7] is a subset of the Zuckerman study^[5], these reviewers analyzed them as two separate studies.
 - The evidence was fair quality
 - Interspinous spacer device is superior to nonsurgical therapy for 1- or 2-level spinal stenosis with symptoms relieved with forward flexion, but that
 - Insufficient evidence exists to judge long-term benefits or harms.

The American Pain Society guidelines developed from this evidence review indicated that interspinous spacer devices, based on fair evidence, have a B recommendation (panel recommends

that clinicians consider offering the intervention).^[18] The net benefit was considered moderate through two years, with insufficient evidence to estimate the net benefit for long-term outcomes.

Summary

Current evidence is insufficient to permit conclusions about whether any beneficial effect from interspinous process distraction or interlaminar stabilization spacers provides a significant advantage over surgical decompression, which is the current standard of care for surgical treatment of lumbar spinal stenosis. In addition, the complication rates and reoperation rates for these spacers compared with those of decompression surgery is unknown. Therefore, use of interspinous process and interlaminar stabilization/distraction spacers is considered investigational.

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CROSS REFERENCES

[Dynamic Stabilization of the Spine](#), Surgery, Policy No. 143

[Total Facet Arthroplasty](#), Surgery, Policy No. 171

[Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172

[Image-Guided Minimally Invasive Lumbar Decompression \(IG-MLD\) for Spinal Stenosis](#), Surgery, Policy No. 176

CODES	NUMBER	DESCRIPTION
CPT	0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
	0172T	Insertion of posterior spinous process distraction device (including necessary

CODES	NUMBER	DESCRIPTION
		removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (list separately in addition to code for primary procedure)
HCPCS	C1821	Interspinous process distraction device (implantable)