
Medical Policy



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Title: Interspinous/Interlaminar Stabilization/Distraction Devices (Spacers)

Description/Background

Spinal Stenosis

Lumbar spinal stenosis (LSS), which affects over 200,000 people in the United States, involves a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, resulting in pain as well as limitation of activities such as walking, traveling, and standing. In adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of LSS is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Some sources describe the course of LSS as “progressive” or “degenerative,” implying that neurologic decline is the usual course. Longer term data from the control groups of clinical trials as well as from observational studies suggest that, over time, most patients remain stable, some improve, and some deteriorate.^{1,2}

The lack of a valid classification for LSS contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each patient.^{3,4} This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.⁵

Treatment

Appropriate surgical treatments for patients with spinal stenosis not responding to conservative treatments include decompression with or without spinal fusion. There are many types of decompression surgery and types of fusion operations. In general, spinal fusion is associated with more complications and a longer recovery period and, in the past, was generally reserved for patients with spinal deformity or moderate grade spondylolisthesis. Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities.⁶ The terms “nonsurgical” and “nonoperative” have also been used

to describe conservative treatment. Professional societies recommend that surgery for LSS should be considered only after a patient fails to respond to conservative treatment, but there is no agreement about what constitutes an adequate course or duration of treatment.

The term “conservative management” may refer to “usual care” or to specific programs of nonoperative treatment, which use defined protocols for the components and intensity of conservative treatments, often in the context of an organized program of coordinated, multidisciplinary care. The distinction is important in defining what constitutes a failure of conservative treatment and what comparators should be used in trials of surgical vs nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found that patients who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated nonoperatively. The SPORT investigators did not require a specified program of nonoperative care but rather let each site decide what to offer.⁷ A subgroup analysis of the SPORT trial found that only 37% of non-surgically treated patients received physical therapy in the first 6 weeks of the trial and that those who received physical therapy before 6 weeks had better functional outcomes and were less likely to cross over to surgery later.⁸ These findings provide some support for the view that, in clinical trials, patients who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time, but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise.⁹ Patients with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery vs an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of patients assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after 2 years of follow-up. The main implication is that about one-third of patients who were deemed candidates for decompression surgery but instead entered an intensive program of conservative care achieved outcomes similar to those of a successful decompression.¹⁰

Diagnostic criteria for fusion surgery are challenging because patients without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain.¹¹ The SPORT trial did not provide guidance on which surgery is appropriate for patients who do not have spondylolisthesis, because nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, patients with predominant back pain have more severe symptoms, worse function, and less improvement with surgery (with or without fusion). Moreover, because back pain improved to the same degree for the fused spondylolisthesis patients as for the unfused spinal stenosis patients at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to the better surgical outcomes in patients with spondylolisthesis than those with no spondylolisthesis.^{12,13}

Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis.¹⁴⁻¹⁶ However, in 2016, findings from two randomized trials of decompression alone vs. decompression plus fusion were published. The Swedish Spinal Stenosis Study (SSSS) found no benefit of fusion plus decompression compared with decompression alone in patients who had spinal stenosis with or without degenerative spondylolisthesis.¹⁷ The Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial found a small but clinically meaningful improvement in the Physical Component Summary score of the 36-Item Short-Form Health Survey but no change in Oswestry Disability Index scores at 2, 3, and 4 years in patients who had spinal stenosis with grade 1 spondylolisthesis (3-14 mm).¹⁸ The patients in SLIP who had laminectomy alone had higher reoperation rates than those in SSSS, and the patients who underwent fusion had better outcomes in SLIP than in SSSS. While some interpret the studies to reflect differences in patient factors-in particular, SSSS but not SLIP included patients with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns.¹⁹⁻²⁴ As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the patients before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings.²⁵ A small trial conducted in Japan, Inose et al (2018) found no difference in patient-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the patients also had dynamic instability.²⁶ Certainty in the findings of this trial is limited because of its size and methodologic flaws.

Spacer Devices

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; they are not discussed in this evidence review.

Interspinous Implants

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a spacer between the spinous processes, maintaining flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar Spacers

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either with decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers)

distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication.

Regulatory Status

In November 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon-now part of Medtronic Spine LLC) was approved by the U.S. Food and Drug Administration (FDA) for “treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis.” It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment and who have relief of their pain when in flexion. In 2015, Medtronic discontinued sales and distribution of the implant.

In 2015, the Superior® Interspinous Spacer (ISS VertiFlex) was approved by FDA through the premarket approval process. The Superior® ISS, as stated in the premarket approval, is to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, and/or central canal or foraminal narrowing. The Superior® ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least six months of nonoperative treatment. The Superior® ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated and at no more than two levels, from L1 to L5.

FDA lists the following contraindications to use of the Superior® Indirect Decompression System:

- “An allergy to titanium or titanium alloy.
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as:
 - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
 - An ankylosed segment at the affected level(s)
 - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
 - Scoliosis (Cobb angle >10 degrees)
- *Cauda equina* syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction.
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normal.
- Active systemic infection, or infection localized to the site of implantation.
- Prior fusion or decompression procedure at the index level.
- Morbid obesity defined as a body mass index (BMI) greater than 40.”

The coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in 2012 (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. This device was previously called the Interspinous U.

The coflex® is indicated for use in 1- or 2-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The coflex® is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed in conjunction with decompression of stenosis at the affected level(s).

The FDA lists the following contraindications to use of the coflex®:

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal, which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 25 degrees).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index >40.
- Active or chronic infection – systemic or local.
- Known allergy to titanium alloys or magnetic resonance imaging (MRI) contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

Continued FDA approval of the coflex® is contingent on annual reports of 2 post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study will provide 5-year follow-up of the cohort in the pivotal investigational device exemption (IDE) trial. The second will be a multi-center trial with 230 patients with follow-up at 5 years that compares decompression alone versus decompression plus coflex®. FDA product code: NQO.

Medical Policy Statement

Interspinous/interlaminar distraction devices are considered established as a treatment of neurogenic intermittent claudication and/or lumbar spinal stenosis resulting in leg/buttock/groin pain, with or without back pain, or when used as a stabilization device with or without decompressive surgery. They may be considered useful therapeutic options for patients meeting specified patient selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions Superior® (Vertiflex) (must meet all criteria):

- Age greater than 40 years
- Vertiflex should be used only when the individual is not a candidate for a decompression procedure due to significant comorbid conditions
- Vertiflex is not intended for use in conjunction with laminectomy for treatment of spinal stenosis
- Degenerative lumbar stenosis when **ALL** of the following criteria are met:
 - Neurogenic claudication interferes with daily activities and is relieved by lumbar flexion
 - Able to sit for 50 minutes and walk for at least 50 feet
 - Moderate stenosis* is confirmed by imaging at 1-2 adjacent levels from L1-L5 and correlates with symptoms
 - Imaging confirms no more than 10 degrees of degenerative scoliosis and no more than grade 1 (8mm) of degenerative spondylolisthesis
 - Failure of at least 6 months of non-operative treatment including all of the following (unless contraindicated due to severity of pain or progressive neurological deficit)
 - NSAIDs
 - Physical therapy-- should include a trial of 6 weeks of physical therapy or a documented and supervised home therapy program
 - Trial of epidural steroid injection(s)

*Moderate stenosis is defined as 25-50% reduction in the central and/or nerve root canal (spinal or subarticular/neuroforaminal) compared to the adjacent levels, including **one** of the following:

- Thecal sac and/or cauda equina compression
- Nerve root impingement (displacement or compression caused by either osseous or non-osseous structures)
- Hypertrophic facets with canal encroachment

Exclusions (Superior® [Vertiflex])

- Age less than 40 years
- An allergy to titanium or titanium alloy.
- Mainly axial back pain that is not related to activity
- Lumbar flexion does not relieve symptoms
- Back or leg pain of unknown etiology
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as:
 - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (greater than 25%, or 8mm)
 - An ankylosed segment at the affected level(s)
 - Acute fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
 - Scoliosis (Cobb angle >10 degrees)
- *Cauda equina* syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction. Diagnosis of severe osteoporosis, defined as bone mineral density

(from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normal.

- Active systemic infection, or infection localized to the site of implantation.
- Prior fusion or decompression/laminectomy procedure at the index level.
- Morbid obesity defined as a body mass index (BMI) greater than 40.

Inclusions Coflex ® (must meet all criteria):

- Skeletally mature patients with at least moderate impairment (determined by shared decision making between the patient and treating physician) in function experiencing leg/buttock/groin pain with or without back pain
- 6 months of non-operative treatment including non-steroidal therapy, comprehensive physical therapy to surgery
- Comprehensive therapy should include a trial of 6 week physical therapy or a documented and supervised home therapy program (not required if symptoms are severe causing forced bed rest, functionally limiting motor weakness or if there is evidence of progressive neurological deficit)
- Trial of epidural injection
- DEXA scan performed prior to surgical procedure
- A laminectomy at the time of Coflex device insertion is required

Exclusion (Coflex)

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle greater than 25°).
- Osteoporosis
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection - systemic or local.
- Known allergy to titanium alloys or MR [magnetic resonance] contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

22867 22868 22869 22870

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The literature is dominated by reports from non-U.S. centers evaluating devices not approved by the U.S. Food and Drug Administration (FDA), although a number of them are in trials at U.S. centers. As of April 2018, only the X-STOP, coflex, and Superior Interspinous Spacer (ISS) devices had received FDA approval for use in the United States. Manufacturing of the X-STOP device stopped in 2015. This review focuses on devices currently available for use in the United States.

Interspinous or Interlaminar Spacer as a Stand-Alone Treatment

Clinical Context and Therapy Purpose

The purpose of the interspinous or interlaminar spacer in individuals with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis is to provide a treatment option that is better than lumbar spinal decompression surgery. Although not tested in trials, another potential purpose could be to provide an alternative to conservative therapy in patients who are medically unsuitable for undergoing general anesthesia for more invasive lumbar surgery or nonsurgical conservative therapy.

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest is patients with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis.

Interventions

The treatment being considered is the placement of an interspinous or interlaminar spacer as a stand-alone treatment.

Comparators

The following practices are currently being used to treat with spinal stenosis with no spondylolisthesis or grade 1 spondylolisthesis: lumbar spinal decompression surgery and nonsurgical conservative therapy.

Outcomes

The general outcome of interest is whether placement of an interspinous or interlaminar spacer improves function as measured by a 15-point improvement in Oswestry Disability Index (ODI) scores. Other measures such as 36-Item Short-Form Health Survey to assess the quality of life, Zurich Claudication Questionnaire (ZCQ) also to assess quality of life for patients with lumbar spinal stenosis [LSS], and freedom from secondary interventions are also of interest to determine whether placement of an interspinous or interlaminar spacer improves the net health outcome. In addition, the adverse events of treatment need assessment.

The window to judge treatment success is a minimum of 2 years post procedure.

Superion® ISS Device vs. X-STOP Device

Patel et al (2015) reported on the results of a multicenter randomized noninferiority trial (10% margin) comparing the Superion ISS with the X-STOP.²⁸ Trial characteristics and results are summarized in Tables 2 and 3. The primary outcome was a composite of clinically significant improvement in at least 1 of 3 ZCQ domain scores compared with baseline; freedom from reoperation, epidural steroid injection, nerve block, rhizotomy, or spinal cord stimulator; and freedom from a major implant or procedure-related complications.

The results at 2 years of follow-up indicated that the primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 (28%) patients (54 Superion ISS, 57 X-STOP) withdrew from the trial during follow-up because they received a protocol-defined secondary intervention. Modified intention-to-treat analysis showed similar levels of clinical success for leg pain, back pain, and ODI scores. Rates of complications and reoperations were similar between groups. Spinous process fractures, reported as asymptomatic, occurred in 16.4% of Superion ISS patients and 8.5% of X-STOP patients. Subsequently, long-term follow-up results were reported. At 3 years, 120 patients in the Superion ISS group and 129 in the X-STOP group remained (64% [249/391]). Of them, composite clinical success was achieved in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group ($p=0.023$). The 36-month clinical outcomes were reported for 82 patients in the Superion ISS group and 76 patients in the X-STOP group (40% [158/391]). It is unclear from the reporting whether the remaining patients were lost to follow-up or were considered treatment failures and censored from the results. Also, trial interpretation is limited by questions about the efficacy of the comparator and lack of a control group treated with surgical decompression. At the 4-year and 5-year follow-ups, only data for the Superion arm were reported, which included data for 90% and 65% of originally randomized patients, respectively. Of these, success on at least 2 of 3 ZCQ domains was observed in 84% of patients at years 4 and 5.

The purpose of the gaps tables (see Tables 4 and 5) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following

each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Patel et al (2015) ²⁸ NCT00692276	U.S.	29	2008-2011	Patients with intermittent neurogenic claudication despite 6 mo. of nonsurgical management (n=440)	Superion ISS (n=218)	X-STOP spacers (n=222)

RCT: randomized controlled trial

Table 3. Results of Noninferiority Trials Comparing Superion With X-STOP

Study	Group	N	Success Rates	VAS Leg Pain ^a	VAS Back Pain ^a	ODI Scores ^b	Spinous Process Fractures	Reoperation Rates
2 years								
Patel et al (2015) ²⁸	Superion	136	75% ^c	76%	67%	63%	16.4%	44 (23.2%)
	X-STOP	144	75% ^c	77%	68%	67%	8.5%	38 (18.9%)
3 years								
Patel et al (2015) ²⁹	Superion	120	52.5% ^c	69/82	63/82	57/82		
	X-STOP	129	38% ^c	53/76	53/76	55/77		
4 years								
Nunley et al (2017) ³⁰	Superion	122	84.3% ^d	67/86	57/86	55/89		
5 Years								
Nunley et al (2017) ³¹	Superion	88	84% ^d	68/85	55/85	57/88		

Values are n, %, or n (%).

ODI: Oswestry Disability Index; VAS: visual analog scale.

^a Percentage achieving at least a 20 mm improvement on a 100-mm VAS score.

^b Percentage achieving at least a 15% improvement in ODI scores.

^c Composite outcome based on 4 components: improvement in 2 of 3 domains of the Zurich Claudication Questionnaire, no reoperations at the index level, no major implant/procedure-related complications, and no clinically significant confounding treatments.

^d Clinical success on at least 2 of 3 Zurich Claudication Questionnaire domains.

Table 4. Relevance Gaps

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Patel et al (2015) ²⁸					

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Gaps

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^e	Power ^e	Statistical ^f
Patel et al (2015) ²⁸	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. High loss to follow-up and/or missing data: 11% of patients not randomized; and data for 28% missing at 2 y; 36% at 3 y.	3. Unclear why a 10% noninferiority margin selected	

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Hagedorn et al (2022) conducted a retrospective study to determine the incidence of lumbar decompression surgery following minimally invasive lumbar decompression or treatment with the Superior interspinous spacer.³² Of the 199 patients included in the final analysis, 57 patients underwent minimally invasive lumbar decompression only, 124 patients underwent treatment with the Superior interspinous spacer only, and 18 patients underwent minimally invasive lumbar decompression followed by treatment with the Superior interspinous spacer. After 2 years of follow-up, subsequent spine surgery was received by 3 patients who initially underwent minimally invasive lumbar decompression and 1 patient who initially underwent treatment with the Superior interspinous spacer. All patients who underwent subsequent surgery were noted to have severe lumbar spine stenosis.

Coflex® Device

A European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar Interspinous distraXion: FELIX) assessed the superiority of coflex (without bony decompression) over bony decompression in 159 patients who had intermittent neurogenic claudication due to LSS.³³ The primary outcome at 8-week and 1-year follow-ups was the ZCQ score. The score increases with increasing disability. Trial characteristics and results are summarized in Tables 6 and 7. At 8 and 52 weeks, the primary outcome efficacy measure in the coflex arm was not superior to that for standard decompression. In addition, more coflex recipients required reoperation than the standard decompression patients at the 1- and 2-year follow-ups. Given the substantially higher frequency of reoperation in the absence of statistically significant improvements in the efficacy outcome, further summarization of study gaps was not done for this trial.

Table 6. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Moojen et al (2013) ³³ ; Felix	Netherlands	5	2008-2011	Patients with intermittent neurogenic claudication due to lumbar stenosis with an indication for surgery (n=159)	Coflex (n=80)	Decompression (n=79)

RCT: randomized controlled trial.

Table 7. Summary of Key RCT Outcomes

Study; Trial	Proportions of Patients Achieving ZCQ Success ^a (95% CI), %		Reoperations, n (%)
	8 Weeks	52 Weeks	
Moojen et al (2013; 2014) ^{33,34} (FELIX) (1-y follow-up)	142	144	Not reported
Coflex	63 (51 to 73)	66 (54 to 74)	21 (29)
Decompression alone	72 (60 to 81)	69 (57 to 78)	6 (8)
Odds ratio (p)	0.73 (0.44)	0.90 (0.77)	P<0.001
Moojen et al (2015) ³⁴ (FELIX) (2-y follow-up)	145		Not reported
Coflex	69		23 (33)
Decompression alone	60		6 (8)
Odds ratio (p)	0.65 (0.20)		P<0.001

RCT: randomized controlled trial; ZCQ: Zurich Claudication Questionnaire.

^aReductions in ZCQ scores were categorized as successful if at least 2 domain subscales were judged as "success." The ZCQ has 3 domains: symptoms severity, physical function, and patient's satisfaction. Success in the domains was defined as a decrease of at least 0.5 points on the symptom severity scale and on the physical function scale or a score of less than 2.5 on the patient's satisfaction subscale.

Section Summary: Interspinous or Interlaminar Spacer as Stand-Alone Treatment

The evidence for the Superior ISS for LSS includes a pivotal trial. This trial compared the Superior ISS with the X-STOP but did not include comparison groups for conservative treatment or standard surgery. The trial reported significantly better outcomes on some measures. For example, the percentage of patients experiencing improvements in certain quality of life outcome domains was reported at over 80%. However, this percentage was based on 40% of the original dataset. Interpretation of this trial is limited by uncertainty about a number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression.

The coflex interlaminar implant was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain levels between the 2 groups at 1-year follow-up did not differ statistically but reoperation rates due to lack of recovery were statistically higher with the coflex implant (29%) compared with bony decompression (8%). It is not clear whether patients with reoperations were included in pain and function assessments; if they were, this would have decreased assessment scores at 1 year. For patients with 2-level

surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group.

Interlaminar Stabilization Devices Used With Spinal Decompression Surgery

The largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated non-surgically. At the other end of the spectrum are patients who have severe stenosis, dominant back pain, and grade 2 or higher spondylolisthesis or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in individuals with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis is to provide a treatment option that is less invasive than lumbar spinal decompression surgery with fusion and more effective for back pain than lumbar spinal decompression surgery alone. Lumbar spinal stenosis has a broad clinical spectrum. Features that may affect the choice of the surgical procedure include the severity of leg pain, back pain, and instability; the presence of facet hypertrophy, diminished disc height, or deformity; the risk of general anesthesia, and the patient's preferences.¹⁰ The clinical feature that best distinguishes the target population for coflex is the severity of back pain, specifically, back pain that is worse than leg pain. The hypothesis underlying this use of coflex is that decompression alone, while effective for claudication and other symptoms of spinal stenosis, may be less effective for severe back pain than decompression plus a stabilizing procedure.

The following **PICOs** were used to select literature to inform this review.

Populations

Individuals with spinal stenosis, and no or grade 1 spondylolisthesis who have not responded to conservative treatment.

Interventions

The treatment being considered is the placement of an interlaminar spacer as an adjunct to spinal decompression.

Comparators

The comparators are lumbar spinal decompression with spinal fusion and lumbar spinal decompression surgery without fusion. Ideally, spinal decompression without fusion should be followed by additional nonsurgical treatment in patients who have persistent back symptoms.

Outcomes

The main outcomes of interest are (1) improvements in symptoms of spinal stenosis (e.g., claudication, leg pain), (2) reductions in back pain, and (3) reductions in limitations on activities related to symptoms. Symptoms can be measured by scores of validated instruments such as the ODI and the ZCQ as well as visual analog scales (VAS) for back and leg pain. Other measures such as the 36-Item Short-Form Health Survey to assess the quality of life are relevant. Other key outcome measures are reoperations, including fusion procedures, and adverse events.

The window to judge treatment success is a minimum of 2 years post procedure.

Coflex Device Plus Decompression vs. Decompression Plus Posterolateral Fusion

FDA approved coflex on the basis of an open-labeled, randomized, multicenter, noninferiority trial (-10% noninferiority margin) that compared coflex plus decompression with decompression plus fusion in patients who had stenosis, significant back pain, and up to grade 1 spondylolisthesis.³⁶⁻³⁸ A total of 398 patients were randomized, of whom 322 were included in the per-protocol analysis. Of 215 coflex patients in the per-protocol analysis, 11 were lost to follow-up at the 2-year end point. In the fusion group, 3 of 107 were lost to follow-up. Results of long-term follow-up to 5 years were reported subsequently.³⁷⁻⁴³

Trial characteristics and results are summarized in Tables 8 and 9. Composite clinical success at 24 months showed that coflex was noninferior to posterolateral fusion (-10% noninferiority margin). Secondary effectiveness criteria, which included ZCQ score, VAS scores for leg and back pain, 12-Item Short-Form Health Survey scores, time to recovery, patient satisfaction, and several radiographic end points, tended to favor the coflex group. The percentages of device-related adverse events (5.6%) did not differ statistically between the 2 groups. Wound problems were more frequent in the coflex group (14% vs. 6.5%), but all of these resolved by 3 months. There was a 14% incidence of spinous process fractures in the coflex arm, which were reported to be mostly asymptomatic. The reported follow-up rates through 5 years were at least 85%.⁴¹

In the subset of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients), there were no statistically significant differences between the coflex and fusion groups in ODI, VAS, and ZCQ scores after 2 years.³⁸ In that analysis, 59 (62.8%) of 94 coflex patients and 30 (62.5%) of 48 fusion patients met the criteria for operative success. Reoperation rates were 14% in the coflex group and 6% in the fusion group (p=0.18). Outcomes for the subset of patients with no spondylolisthesis who were treated with the Coflex device at 1 or 2 levels have been reported.⁴³ At 2 years, overall success was similar for patients treated with the coflex device at 1 or 2 levels (68.9% and 69.4%, respectively). At 60 months, the composite clinical success was achieved in 48.3% of 1 level and 60.9% of 2 level patients. However, the outcomes for patients without spondylolisthesis who underwent decompression plus fusion were not included in the publication.

Table 8. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Davis et al (2013) ³⁷ NCT00534235 ^a	U.S.	21	2006-2008	Patients with spinal stenosis with up to grade 1 spondylolisthesis, 1 or 2 levels (n=344)	Coflex plus decompression (n=262)	Decompression plus fusion (n=136)

RCT: randomized controlled trial

^a Noninferiority study

Table 9. Summary of Key RCT Outcomes

Study	CCS ^a	15-Point Improvement in ODI Score	No Secondary Surgical Intervention or Lumbar Injection	No Secondary Surgical Intervention	No Secondary Lumbar Injection
2-year follow-up					
Davis et al (2013) ³⁷					
N	308	248	322	215	215
Coflex	135 (66)	139 (86)	173 (81)	192 (89)	190 (88)
Fusion	104 (58)	66 (77)	89 (83)	99 (93)	94 (88)
% ▲ (95% CI)	8.5 ^b (-2.9 to 20.0)	9 (NR)	2 (NR)	-4 (NR)	0
3-year follow-up					
Bae et al (2016) ⁴¹					
N	290	214	Unclear	NR	NR
Coflex	(62)	129 (90)	(79)	NR	NR
Fusion	(49)	53 (76)	(79)	NR	NR
% ▲ (95% CI)	13.3 (1.1 to 25.5)	0.008	NR	NR	NR
4-year follow-up					
Bae et al (2015) ³⁹					
N	274	181	NR	NR	NR
Coflex	106 (58)	106 (86)	NR	NR	NR
Fusion	42 (47)	42 (72)	NR	NR	NR
% ▲ (95% CI)	10.9 (-1.6 to 23.5)	0.038	NR	NR	NR
5-year follow-up					
Musacchio et al (2016) ⁴⁰					
N	282	179	322	322	322
Coflex	96 (50)	100 (81)	148 (69)	179 (83)	173 (81)
Fusion	40 (44)	41 (75)	71 (66)	89 (83)	82 (77)
% ▲ (95% CI) or p	6.3 (NR); >0.90	>0.40	>0.70	>0.90	>0.40

Values are n or n (%).

CCS: composite clinical success; CI: confidence interval; FU: follow-up; NR: not reported; ODI: Oswestry Disability Index (reported as mean score or percent with at least 15-point improvement).

^a Composite clinical success was composed of a minimum 15-point improvement in ODI score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit.

^b The lower bound of Bayesian posterior credible interval for the device group difference in CCS was equal to -2.9%, which is within the prespecified noninferiority margin of -10%.

Tables 10 and 11 display notable gaps identified in each study. The major weakness in this trial was its use of lumbar spinal fusion as a comparator. Fusion after open decompression laminectomy is a more invasive procedure that requires longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and back pain; thus demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to result in a net benefit in health outcomes. However, the role of fusion in the population of patients represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study (SSSS) and the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP), 2 RCTs comparing decompression alone with decompression plus spinal fusion that were published in 2016. As a consequence, results generated from a noninferiority trial using a comparator whose net benefit on health outcome is uncertain confounds meaningful interpretation of trial results. In addition, the underlying premise that patients with back pain and spinal stenosis do not

respond well to decompression (alone or followed by nonsurgical treatments for back pain) has been challenged. For example, the ODI success rate for decompression alone in the European Study of Coflex And Decompression Alone trial⁴⁴ was comparable to the ODI success rate for decompression plus fusion in the pivotal trial.

There are also gaps in the reporting of the pivotal trial. For example, a subgroup analysis of patients with grade 1 spondylolisthesis has been published. A similar analysis of the subgroup of patients with no spondylolisthesis would be helpful, as would results by treatment group for single and multilevel spondylolisthesis.

Another gap in the evidence, not listed in the gaps tables, is that other published evidence about the use of coflex as an alternative to fusion is sparse. The results of a single randomized trial do not always correspond with the rates of treatment response, complications, and reoperations in actual practice. Although thousands of coflex operations have been performed in the United States and elsewhere, there are few data on the performance of coflex plus decompression surgery other than in randomized trials. A retrospective cohort study (NCT03041896) undertaken by the manufacturer has not been reported, and a large registry of studies is not yet complete (NCT02457468).

Table 10. Relevance Gaps

Study; Trial	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Davis et al (2013) ³⁷ (NCT00534235)			2.Noninferiority to a comparator whose benefit is uncertain does not permit meaningful interpretation of the net benefit. This may be particularly problematic in the subgroup of patients with no spondylolisthesis		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 11. Study Design and Conduct Gaps

Study; Trial	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Davis et al (2013) ³⁷ NCT00534235	3.Allocation concealment unclear	4.No independent adjudication or preset criteria for subsequent intervention	3.Evidence of selective reporting			

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.4 No independent adjudication or preset criteria for subsequent intervention.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intention-to-treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

Zheng et al (2021) retrospectively compared the long-term outcomes of coflex plus decompression to decompression plus fusion for lumbar degenerative disease.⁴⁵ The coflex group was comprised of 39 patients and the decompression plus posterior lumbar interbody fusion group (PLIF) was comprised of 43 patients. Both groups had a mean follow-up period of 104 months (about 8.7 years). Both the Oswestry disability index and visual analog scale leg and back pain scores of both groups significantly improved compared to the baseline ($p < .05$ for all), with no difference detected between groups. Compared to the PLIF group, the coflex group displayed preserved mobility ($p < .001$), shorter duration of surgery ($p = .001$), decreased amount of blood loss ($p < .001$), and shorter hospital stay ($p = .040$).

Subsection Summary: Coflex Device Plus Decompression vs. Decompression Plus Posterolateral Fusion

FDA’s approval of coflex was based on an open-labeled, randomized, noninferiority trial that compared the noninferiority of coflex plus decompression with decompression plus fusion in patients who had spinal stenosis, significant back pain, and up to grade 1 spondylolisthesis. Use of the noninferiority framework by FDA assumed that decompression plus fusion was the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and, because fusion is a more invasive procedure that requires longer operative time and has a potential for higher surgical and postsurgical complications, demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to demonstrate a net benefit in health outcomes. However, subsequent to the approval of coflex, 2 RCTs (SSSS, SLIP) assessing the superiority of adding fusion to decompression over decompression alone reported a lack of or marginal benefit. The SSSS trial, which was adequately powered to detect a 12-point difference in ODI score, showed no difference in ODI scores between the 2 treatment arms. Hence, the results generated from a noninferiority trial using a comparator whose net benefit on health outcomes is uncertain confound meaningful interpretation of its results.

Coflex Device Plus Decompression vs. Decompression Alone

Schmidt et al (2018) reported on results of an RCT in patients with moderate-to-severe LSS and back pain with or without spondylolisthesis randomized to open microsurgical decompression with interlaminar stabilization using the coflex device (n=110) or open microsurgical decompression alone (n=115).⁴⁴ Trial characteristics and results at 24 months are summarized in Tables 12 and 13. The proportion of patients who met the criteria for composite clinical success at 24 months was statistically and significantly higher in the coflex arm (58.4%) than in the decompression alone arm (41.7%; p=0.017), with a treatment difference of 16.7% (95% confidence interval, 3.1% to 30.2%). This result was driven primarily by the lower proportion of patients who received an epidural steroid injection in the coflex arm (4.5%) vs. the decompression alone arm (14.8%; p=0.010) at 24 months.

The proportion of patients with ODI success among those censored for subsequent secondary interventions was not statistically significant between the treatment (75.6%) and the control arms (70.4%; p=0.47). The difference in the proportion of patients overall who had ODI success in the overall sample was also not statistically significant (55% vs. 44%, p=0.091).

None of the other outcomes (data not shown) showed statistically significant differences between the treatment and control arms; outcomes included success measured on the ZCQ (success was defined as an improvement in 2 or 3 ZCQ criteria), success measured on a VAS for pain (success defined as a >20-mm change from baseline), reduction in VAS leg pain, success on a walking distance test (either ≥8-minute walk improvement or the ability to walk to the maximum 15-minute limit), the proportion of patients receiving secondary surgical interventions, or 1- and 2-year survival (Kaplan-Meier) estimates without secondary surgical interventions or survival curves for time to first secondary intervention.

Table 12. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schmidt et al (2018) ⁴⁴ NCT01316211	Germany	7	2008-2014	Patients with moderate to severe LSS with or without Spondylolisthesis and significant back pain (n=255)	Decompression with interlaminar stabilization (n=129)	Open microsurgical decompression along (n=131)

LSS: lumbar spinal stenosis; RCT: randomized controlled trial.

Table 13. Summary of Key RCT Outcomes

Study	CCS ^a	15-Point Improvement in ODI Score (all patients)	15-Point Improvement ODI Score (those not receiving a secondary intervention)	No Secondary Surgical Intervention or Lumbar Injection	No Secondary Surgical Intervention	No Secondary Lumbar Injection
Schmidt et al (2018) ⁴⁴						
N	204	255	132	225	225	225
D plus ILS	59 (58)	69 (55)	62 (76)	91 (83)	96 (87)	105 (96)
D alone	43 (42)	57 (44)	50 (70)	84 (73)	98 (85)	98 (85)
% ▲ (95% CI)	16.7 (3.1 to 30.2)	10.6 (-1.6 to 22.8)	5.2 (-8.9 to 19.3)	9.7 (-1.1 to 20.4)	2.1 (-6.9 to 11.0)	10.2 (2.7 to 17.8)
p	0.017	0.091	0.470	0.081	0.655	0.010

Values are n, n (%), or %.

CCS: composite clinical success; CI: confidence interval; D: decompression; ILS: interlaminar stabilization; ODI: Oswestry Disability Index; RCT randomized controlled trial.

^a CCS defined as meeting all 4 criteria: (1) ODI success with improvement >15 points; (2) survivorship with no secondary surgical intervention or lumbar injection; (3) neurologic maintenance or improvement without worsening; and (4) no device- or procedure-related severe adverse events.

The purpose of the gaps tables (see Tables 14 and 15) is to display notable gaps identified in each study. Major limitations are discussed below.

- Based on the reporting by Schmidt et al (2018), 254 patients were randomized but data for only 204 patients were analyzed for the primary outcome measure.⁴⁴ Thus, data of 20% of patients were excluded. While the proportion of patients excluded was comparable in both arms, the investigators did not explain the missing data of these 50 patients. Lack of a consistent approach in reporting and handling of missing data (patients who remained in the trial but for whom data for repeated longitudinal measures were missing), including describing methods to minimize missing data, reporting reasons for missing data, and using appropriate multiple imputation statistical techniques and sensitivity analysis⁴⁵ to manage missing data, makes interpretation of trial results challenging.
- The observed treatment effect on the primary composite outcome was primarily driven by a reduction in the use of rescue epidural steroid injection. One concern is bias that could have been introduced by the open-label design where the treating surgeon also made the assessment that additional intervention with lumbar steroid was needed. The trial design did not include features commonly used to address this problem, such as preset criteria for subsequent intervention, or independent blinded adjudication to verify that subsequent intervention was merited.
- The inclusion of epidural and facet joint injections in the end point may be inappropriate for this trial. Epidural injections are less invasive than reoperations, revisions, removal, and supplemental fixations. Nonsurgical therapy, including epidural or facet injections, would be an expected adjunct to decompression alone in patients with predominant back pain. In this context, epidural injections may be offered to provide temporary pain relief that allows a patient to progress with a rehabilitative stretching and exercise program. Censoring patients who undergo particular components of nonsurgical back care may be inappropriate in this context. A better approach would be to measure and report ODI for all patients, or ODI success in all patients except for those who have revisions or reoperations, at 24 months.

- Because of concerns about potential bias, inconsistent reporting of analysis as intention-to-treat, and a lack of critical discussion of the number, timing, pattern, and reason for and possible implications of missing values, the magnitude of difference might have been overestimated.

Table 14. Relevance Gaps

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Schmidt et al (2018) ⁴⁴			1. In the control arm, nonsurgical treatment for back pain after decompression should be described	3. No CONSORT reporting of harms	1, 2. Present study reports only on the first 2 y of the 5 y follow-up required by FDA

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

FDA: Food and Drug Administration.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 15. Study Design and Conduct Gaps

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Schmidt et al (2018) ⁴⁴		1. Not blinded to treatment assignment 4. No independent adjudication or preset criteria for subsequent intervention		1. High loss to follow-up or missing data 2. Inadequate handling of missing data. LOCF may not be the most appropriate approach 6. Not intention to treat analysis	2. Power not calculated for primary outcome	

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

LOCF: last observation carried forward.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. 4. No independent adjudication or preset criteria for subsequent intervention.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intention-to-treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

Röder et al (2015) reported on a small cross-registry study that compared lumbar decompression plus coflex (SWISSspine Registry) with lumbar decompression alone (Spine Tango Registry) in 50 pairs matched by a multifactorial propensity score.⁴⁶ SWISS spine is a governmentally mandated registry from Switzerland for coverage with evidence development. Spine Tango is a voluntary registry from the Spine Society of Europe. Both registries use the numeric rating scale (NRS) for back and leg pain, as well as the Core Outcome Measures Index as the patient-based outcome instrument. The Core Outcome Measures Index consists of 7 questions to evaluate pain, function, well-being, quality of life, and disability. At 7- to 9-month follow-up, the coflex group had greater reductions in NRS back pain score (3.8 vs. 2.5, $p=0.014$), NRS leg pain score (4.3 vs. 2.5, $p<0.001$), NRS maximum pain score (4.1 vs. 2.3, $p=0.002$), and greater improvement in Core Outcome Measures Index score (3.7 vs. 2.5; $p=0.029$). Back pain improved by the minimum clinically relevant change in about 60% of patients in the decompression alone group vs. 78% in the coflex plus decompression group.

Because of substantial baseline differences between the compared groups, small sample size, and short follow-up time, there is a high risk that the Röder study's estimate of the effect of decompression alone versus decompression plus coflex is biased. Decompression alone had better outcomes than those reported by Röder et al (2015) in a larger, well-conducted, 12-month European registry study of patients with spinal stenosis, significant back, and no spondylolisthesis.⁴⁷

Richter et al (2010) reported on a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery.⁴⁸ Richter et al (2014) also published a 2-year follow-up.⁴⁹ The surgeon determined whether the midline structures were preserved or resected and whether the coflex device was implanted (1 or 2 levels). The indications for the 2 groups were identical and use of the device was considered incidental to the surgery. At 1- and 2-year follow-ups, placement of a coflex device did not significantly improve the clinical outcome compared with decompression surgery alone.

Some radiologic findings with the coflex device require additional study to determine their clinical significance. Tian et al (2013) reported a high rate (81.2%) of heterotopic ossification at follow-up (range, 24-57 months) in patients who had received a coflex device.⁵⁰ In 16 (50%) of 32 patients, heterotopic ossification was detected in the interspinous space but had not bridged the space, while in 2 (6.3%) patients there was interspinous fusion. In the 9 patients followed for more than 3 years, class II (interspinous space but not bridging) and class III (bridging) heterotopic ossification were detected in all nine. Lee et al (2016) reported erosion around the spinous process and reductions in disc height and range of motion in patients treated with a coflex device plus spinal decompression and had at least 24 months of follow-up.⁵⁰ Erosion around the coflex device, which was observed in 47% of patients, has the potential to result in spinous process fracture or device malposition. Continued follow-up is needed.

Subsection Summary: coflex Device Plus Decompression vs. Decompression Alone

The pivotal RCT, conducted in a patient population who had moderate-to-severe LSS with or without spondylolisthesis, showed that a greater proportion of patients who received coflex plus decompression achieved the primary end point of composite clinical success compared with decompression alone. This composite end point was primarily driven by a greater proportion of patients who received a secondary rescue epidural steroid

injection in the control arm while there was no difference in the proportion of patients who achieved a meaningful reduction of 15 points in ODI score in the treatment and the control arms. However, the decision to use rescue epidural steroid injection introduced possible bias given that the trial was open label. No attempts were made to mitigate this potential bias using protocol-mandated standard objective clinical criteria to guide decisions about the use of secondary interventions and subsequent adjudication of these events by an independent blinded committee. Given these critical shortcomings, trial results might have been biased. Greater certainty about the net health outcome of adding coflex to decompression surgery might be demonstrated when results of 5-year follow-up of these trials and an ongoing RCT (NCT02555280) on decompression with and without the coflex implant in the United States are published.

Clinical input supplements and informs the interpretation of the published evidence. Clinical input respondents were mixed in the level of support of this indication. While some of the expert opinion supported a potential benefit in carefully selected individuals, other experts were not confident of a clinically meaningful benefit or use in generally accepted medical practice, citing long-term complications leading to removal of the device. Some clinical input suggested that spacers may have utility in patients who are high risk for general anesthesia. Consideration of existing studies as indirect evidence regarding the outcomes of using spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. The main source of uncertainty about the benefits versus risks of using coflex plus laminectomy in patients who are not able to have general anesthesia is whether revisions, removals, and other secondary surgical procedures can be conducted safely if they are needed.

SUMMARY OF EVIDENCE

Lumbar spinal stenosis has historically been treated with open decompressive surgery which is associated with significant morbidity and may give rise to various complications. Interspinous spacers (ISS) have been developed as a less invasive strategy which may serve to avoid many of these risks. The two current spacers that are FDA approved and commercially available are the Coflex and Superion devices.

The Coflex device has been shown to be analogous to decompression and fusion when treating moderate spinal stenosis. It provides dynamic stability after a decompression is performed, without the rigidity of pedicle-screw instrumentation. Recent results show improved outcomes in Coflex patients at 3 years of follow-up, as compared to decompression and fusion. The Superion implant is placed percutaneously in the interspinous space with minimal disruption of spinal anatomy. When compared to the X-Stop device (which is no longer available), the Superion implant shows improved outcomes at 3 years of follow-up. ISS are lesser invasive options as compared to formal decompression and fusion for the treatment of lumbar spinal stenosis.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 16.

Table 16. Summary of Key Active Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02555280 ^a	A 2 and 5 year comparative evaluation of clinical outcomes in the treatment of degenerative spinal stenosis with concomitant low back pain by decompression with and without additional stabilization using the Coflex® Interlaminar Technology for FDA real conditions of use study (post-approval ‘real conditions of use’ study)	406	Nov 2027
NCT02457468	The Coflex® Community Study: an observational study of Coflex® Interlaminar Technology	500	June 2023
NCT04563793 ^a	Postmarket outcomes study for evaluation of the superior spacer	3000	Sep 2026
Unpublished			
NCT01316211 ^a	Comparative evaluation of clinical outcome in the treatment of degenerative spinal stenosis with concomitant low back pain by decompression with and without additional stabilization using the Coflex® Interlaminar Technology—Active, not recruiting	245	Dec 2017
NCT03041896 ^a	Retrospective evaluation of the clinical and radiographic performance of coflex® interlaminar technology vs. decompression with or without fusion	5000	Oct 2017
NCT04087811 ^a	Postmarket Registry for Evaluation of the Superior® Spacer	1672	Mar 2021

NCT: national clinical trial

^a Denotes industry-sponsored or cosponsored trial

*Terminated January 2018 due to Medtronic’s voluntary withdrawal of PMA P040001 for X-STOP systems.

SUPPLEMENTAL INFORMATION

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009

In response to requests from BCBSA, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Differing input was received; several reviewers felt data were sufficient to demonstrate improved outcomes.

2011

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in March 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes including durability. Two reviewers did not consider this investigational but felt the technology had a role in the treatment of selected patients with neurogenic intermittent claudication.

2018

In response to requests, clinical input on the use of interlaminar spacer with spine decompression in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment was received from 6 respondents, including 2 specialty society-level responses and 4 physician-level responses, including 2 identified through a specialty society and 2 through an academic medical center, while this policy was under review in 2018. Evidence from clinical input is integrated within the Rationale section summaries and the Summary of Evidence.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute for Health and Care Excellence

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) published guidance in November 2010 stating that "Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur and further surgery may be needed. The evidence reviewed consisted mainly of reports on X-STOP®.⁵⁴

North American Spine Society

The North American Spine Society (NASS; 2018) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression.⁵³ NASS recommended that:

"Stabilization with an interspinous device without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:

1. Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.
2. A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the *NASS Coverage Recommendations for Lumbar Fusion*.
3. A lumbar laminectomy is indicated as recommended in the *NASS Coverage Recommendations for Lumbar Laminectomy*.
4. Previous lumbar fusion has not been performed at an adjacent segment.
5. Previous decompression has been performed at the intended operative segment.

Interspinous devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

1. Degenerative spondylolisthesis of Grade 2 or higher.
2. Degenerative scoliosis or other signs of coronal instability.
3. Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.
4. Iatrogenic instability or destabilization of the motion segment.
5. A fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the *NASS Coverage Recommendations for Lumbar Fusion*.

6. A laminectomy for spinal stenosis is otherwise not indicated as per the *NASS Coverage Recommendations for Lumbar Laminectomy.*"

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations and coverage criteria for decompression with interlaminar stabilization.⁵²

Criteria included:

1. Radiographic confirmation of at least moderate lumbar stenosis.
2. Radiographic confirmation of the absence of gross angular or translatory instability of the spine at index or adjacent levels.
3. Patients who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 12 weeks of non-operative treatment.

The document did not address interspinous and interlaminar distraction devices without decompression.

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience published a consensus guideline outlining best practices for minimally invasive lumbar spinal stenosis treatment.⁵⁶ The following recommendation was provided with regard to the use of interspinous spacers:

- "Interspinous spacers should be considered for treatment of symptomatic spinal stenosis at the index level with mild-to-moderate spinal stenosis, with less than or equal to grade 1 spondylolistheses, in the absence of dynamic instability or micro-instability represented as fluid in the facets on advanced imaging. Grade A; Level of certainty high; Quality of Evidence 1-A"

U.S. Preventive Services Task Force Recommendations

Not applicable.

Government Regulations

National:

There is no national coverage decision.

Local:

The following codes show as having a fee in the CMS fee schedule:

- 22867
- 22868
- 22869
- 22870

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Artificial Intervertebral Discs-Cervical Spine
 - Artificial Intervertebral Discs-Lumbar Spine
 - Spinal Surgery-Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD, MELD) for Lumbar Stenosis
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/07	5/14/07	6/30/07	Joint policy established
7/1/08	5/17/08	6/27/08	Routine maintenance
9/1/09	6/1/09	6/16/09	Routine maintenance
5/1/10	2/16/10	2/16/10	Review of information submitted by Michigan State Medical Society (MSMS).
3/1/12	12/13/11	12/21/11	Policy updated with literature review, additional references added, policy statement unchanged.
5/1/13	2/19/13	3/4/13	Policy updated with literature review, additional references added. Added information re: coflex device. Policy statement unchanged.
5/1/14	2/18/14	3/3/14	Routine review of experimental/ investigational service. Policy status unchanged.
7/1/15	4/21/15	5/8/15	Routine review of experimental/ investigational service. Policy status unchanged.
7/1/16	4/19/16	4/19/16	Routine review References and rationale updated
5/1/17	2/21/17	2/21/17	Add codes 22867-22870. Deleted 0171T and 0172T. Updated rationale adding information on Superior® Interspinous Spacer and added references # 27 & 29.
9/1/17	8/30/17	9/1/17	Policy status changed to established. Rationale updated to support policy status.
9/1/18	6/19/18	6/19/18	Routine policy maintenance. No change in policy status.
9/1/19	6/18/19		Routine policy maintenance, reformatted rationale, added references 6, 24, 26, 41-43. No change in policy status.
9/1/20	6/16/20		Routine policy maintenance, no changes in policy status.
9/1/21	6/15/21		Routine policy maintenance, no change in policy status.
3/1/22	12/14/21		Clarification of FDA guidelines for Superior vs. Coflex. No change in policy status.

3/1/23	12/20/22		Updated rationale section, added reference #44. No changes in policy status.
3/1/24	12/28/23		Updated rationale and supplemental section, added reference #32 and 56. Inclusion/exclusion section modified. Vendor managed: Turning Point (ds)

Next Review Date: 4th Qtr. 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INTERSPINOUS/INTERLAMINAR STABILIZATION/DISTRACTION DEVICES
(SPACERS)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	See policy criteria.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.