07.01.35 Interspinous and Interlaminar Stabilization/Distraction Devices

Original Effective Date: January 2007

Review Date: June 2023

Revised: February 2023

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Summary

Description

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in individuals with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

Summary of Evidence

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes 2 randomized controlled trials (RCTs) of 2 spacers (Superion Indirect Decompression System, coflex

interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, the use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown high failure and complication rates. A pivotal trial compared the Superion Interspinous Spacer with the X-STOP Interspinous Process Decompression System (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion Interspinous Spacer on some measures. For example, the trial reported more than 80% of individuals experienced improvements in certain quality of life outcome domains. Interpretation of this trial is limited by questions about the number of individuals 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 (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind Foraminal Enlargement Lumbar Interspinous distraXion (FELIX) trial. Functional outcomes and pain levels were similar in the 2 groups at 1-year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For individuals 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 and 8% of the bony decompression group. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, the evidence includes 2 RCTs with a mixed population of individuals. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). For decompression with coflex versus decompression with lumbar spinal fusion, the pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. A secondary (unplanned) analysis of individuals with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; $p<.001$) and blood loss (106 vs. 336 mL, $p<.001$). There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual analog scale, and Zurich Claudication Questionnaire scores after 2 years. In that analysis, 62.8% of coflex patients and 62.5% of fusion patients met the criteria for operative success. The efficacy of the comparator in this trial is uncertain because successful fusion was obtained in only 71% of the control group, leaving nearly a third of individuals with pseudoarthrosis. The report indicated no significant differences in Oswestry Disability Index or visual analog scale between the individuals with pseudoarthrosis or solid fusion, but Zurich Claudication Questionnaire scores were not reported. There were 18 (18%) spinous process fractures in the coflex group, of which 7 had healed by the 2-year follow-up. Reoperation rates were 6% in the fusion group and 14% in the coflex group ($p=.18$), including 8 (8%) coflex cases that required conversion to fusion. This secondary analysis is considered hypothesis-generating, and a prospective trial in individuals with grade 1 spondylolisthesis is needed. In an RCT conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the Oswestry Disability Index, between the individuals treated with coflex plus decompression versus decompression alone. Composite clinical success, defined as a minimum 15-point improvement in Oswestry Disability Index 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 was used to assess superiority. A greater proportion of individuals who received coflex plus decompression instead of decompression alone achieved the composite endpoint. However, the superiority of coflex plus decompression is uncertain because the difference in the composite clinical success was primarily driven

by a greater proportion of individuals in the control arm who received a secondary rescue epidural steroid injection. Because the trial was open-label, surgeons' decision to use epidural steroid injection could have been affected by their knowledge of the individual's treatment. Consequently, including this component in the composite clinical success measure might have overestimated the potential benefit of treatment. Analysis was not reported separately for the group of individuals who had grade 1 spondylolisthesis, leaving the question open about whether the implant would improve outcomes in this population. 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 evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, the evidence includes RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, in addition to concerns about the efficacy of fusion in this study, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in individuals with no spondylolisthesis. 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 as the standard of care for individuals 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 individuals represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study, and the Spinal Laminectomy versus Instrumented Pedicle Screw study, 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. Therefore, demonstrating the noninferiority of coflex plus spinal decompression versus spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgroup of individuals without spondylolisthesis who received an interlaminar device with decompression in the pivotal Investigational Device Exemption trial have been published, but comparison with decompression alone in this population has not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Additional Information

2018 Input

Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery for individuals with spinal stenosis, predominant back pain and no or grade 1 spondylolisthesis who failed conservative treatment would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input 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.

- For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net

health outcomes. While some respondents considered the shorter recovery time and lower complication rate to be an advantage compared to fusion, others noted an increase in complications and the need for additional surgery with the device.

- For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, clinical input is not generally supportive of a clinically meaningful improvement in net health outcomes, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy alone.

Further details from clinical input are included in the Appendix.

OBJECTIVE

The objective of this evidence review is to determine whether the use of an interspinous distraction device or interlaminar stabilization device improves the net health outcomes in individuals with lumbar spinal stenosis.

PRIOR APPROVAL

Not applicable.

POLICY

Distraction Devices

Interspinous or interlaminar distraction devices are considered **investigational** for all indications to include:

- As a stand-alone procedure as a treatment of spinal stenosis

including but not limited to the following devices because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes:

- Coflex® Interlaminar Technology Implant
- Coflex® Intralaminar Stabilization Devices
- X-STOP® Interspinous Process Decompression (IPD®) System
- Vertiflex® Interspinous Decompression Spacer/Superion® InterSpinous Spacer

Stabilization Devices

Interspinous stabilization devices are considered **investigational** for all indications to include but not limited to when they are used:

- following decompression surgery
- in combination with interbody fusion

To include, but not limited to, the following devices because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes:

- Aerial™ Interspinous Fixation
- Affix™
- Aileron™
- Aspen™
- Axle™
- BacFuse®
- Benefix Interspinous Fixation System

- BridgePoint™
- CD HORIZON™ Spinal Fixation System
- Coflex-F®
- Inspan™
- InterBRIDGE® Interspinous Posterior Fixation System
- Minuteman™ G3 Interspinous Interlaminar Fusion Device
- Octave™ Posterior Fusion System
- PrimaLOK™ SP Interspinous Fusion System
- SP-Link™ System
- SP-Fix™ Spinous Process Fixation Plate
- Spire™
- StabiLink® MIS Interspinous Fixation System
- Zip Mis Interspinous Fusion System

POLICY GUIDELINES

Coding
See the Codes table for details.

BACKGROUND

Spinal Stenosis
Lumbar spinal stenosis, which affects over 200,000 people in the United States (U.S.), 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 U.S., spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis 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 lumbar spinal stenosis 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 individuals remain stable, some improve, and some deteriorate.

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

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

Surgical treatments for individuals 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 individuals with spinal deformity or moderate grade spondylolisthesis.

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities. The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. Professional societies recommend that surgery for lumbar spinal stenosis should be considered only after an individual 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 versus nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found individuals 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. A subgroup analysis of the SPORT trial found that only 37% of nonsurgically treated individuals 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. These findings provide some support for the view that, in clinical trials, individuals 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. Individuals with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery versus 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 individuals 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 individuals 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.

Diagnostic criteria for fusion surgery are challenging because individuals without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain. The SPORT trial did not provide guidance on which surgery is appropriate for individuals who do not have spondylolisthesis, because nearly all individuals 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 individuals at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to better surgical outcomes in individuals with spondylolisthesis than those with no spondylolisthesis.

Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis. However, in 2016, findings from 2 randomized trials of decompression alone versus decompression plus fusion were published. The Swedish Spinal Stenosis Study found no benefit of fusion plus decompression compared with decompression alone in individuals who had spinal stenosis with or without degenerative spondylolisthesis. 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 individuals who had spinal stenosis with grade 1 spondylolisthesis (3 – to 14 mm).18, The individuals in SLIP who had laminectomy alone had higher reoperation rates than those in Swedish Spinal Stenosis Study, and the individuals who underwent fusion had better outcomes in SLIP than in Swedish Spinal Stenosis Study. While some interpret the studies to reflect differences in patient factors-in particular, Swedish Spinal Stenosis Study but not SLIP included individuals with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns. As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the individuals before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings. 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 individuals with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the individuals also had dynamic instability. 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 individuals with lumbar spinal stenosis and neurogenic claudication.

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 – to 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 the adjacent lamina and spinous processes to provide dynamic stabilization either following 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.

Fixation Devices

The standard surgical procedure for rigid spinal fixation involves the use of pedicle screws, rods, and plates. Non-pedicle interspinous process fixation devices (with or without additional instrumentation) were developed as a minimally invasive rigid fixation alternative to standard rigid fixation instrumentation using pedicle screws and rods or interbody cages. The pedicle is a small area of bone that is the first to extend out from both sides of the back of the vertebral body and joins with broad flat plates of bone (laminae) to form a hollow archway that protects the spinal cord. Contemporary models of interspinous fixation devices have evolved from spinous process wiring with bone blocks and early device designs (e.g., Wilson plate, Meurig-Williams system, Daab plate). The newer devices range from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed either under direct visualization or percutaneously.

The interspinous fixation devices are being evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. According to the U.S. Food and Drug Administration (FDA) 510(k) clearance, interspinous process fixation devices are intended for use with bone graft material. Both of the following fixation techniques support fusion when used with bone graft material. One type of fixation involves pedicle screws that are inserted as anchors for rods that provide fixation. Another type of fixation is the interbody cage placed in the disc space. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

Interspinous fixation (fusion) devices are different from interspinous distraction devices (spacers), which are used alone for decompression and are typically not fixed to the spinous process In addition, interspinous distraction devices have been designed for dynamic stabilization, interspinous fixation devices are rigid. However, the fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, the fixation devices might be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If interspinous fixation devices are used alone as a spacer, there is a risk of spinous process fracture. For use in combination with fusion, it is proposed that interspinous fixation devices are less invasive and present fewer risks than pedicle or facet screws. However, while biomechanical studies indicate that interspinous fixation devices may be similar to pedicle screw-rod constructs in limiting the range of flexion-extension, they may be less effective than bilateral pedicle screw rod fixation for limiting axial rotation and lateral bending. There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the interspinous device. There is also a potential for spinous process fracture.

Regulatory Status

Distraction Devices

The following interspinous and interlaminar stabilization and distraction devices have been approved by the U.S. Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) (*This is not intended to be an all-inclusive list*)

Device	coflex Interlaminar Technology implant
Manufacturer	Paradigm Spine (acquired by RTI Surgical)
Approval Date	2012

Premarket Approval	P110008
Information	It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex (previously called the Interspinous U) is indicated for use in 1- or 2-level lumbar stenosis from the L1 to L5 vertebrae in skeletally mature individuals 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 nonoperative treatment. The coflex "is intended to be implanted midline between the adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s). The Coflex® device is not to be used accompanying a fusion at the treatment level. 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 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. o Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction." The FDA labeling also contains multiple precautions and the following warning: "Data has demonstrated that spinous process fractures can occur with coflex® implantation." At the time of approval, the FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the 5-year follow-up of the pivotal investigational device exemption trial. The second was a multicenter trial with 230 patients in Germany who were followed for 5 years, comparing decompression alone with decompression plus coflex®. The third, a multicenter trial with 345 patients in the U.S. who were followed for 5 years, compared decompression alone with decompression plus coflex, FDA product code: NQO.

Device	The Superion Indirect Decompression System (formerly InterSpinous Spacer)

Manufacturer	VertiFlex (acquired by Boston Scientific)
Approval Date	2015
Premarket Approval	P140004
Information	It is an H-shaped implant composed of titanium alloy and delivered percutaneously as a single-piece through a cannula after dilators have opened the interspinous space. The implant has superior and inferior cam lobes that rotate during deployment, so as to capture the superior and inferior spinous processes It is indicated to treat skeletally mature individuals 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 (MRI), and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for individuals with an 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 6 months of nonoperative treatment. FDA lists the following contraindications to use of the Superion® 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: o Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4) o An ankylosed segment at the affected level(s) o Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral). o Scoliosis (Cobb angle >10 degrees) • *Cauda equina* syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction. o 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."

Device	X Stop Interspinous Process Decompression System
Manufacturer	Medtronic Sofamor Danek
Approval Date	2005 (withdrawn 2015)

Premarket Approval	P040001
Information	It was approved for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis for those who have had a regimen of at least six months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at one or two lumbar levels in patients whose condition warrants surgery at no more than two levels. The X-STOP® PEEK IPD® System, a modified version of the original X-STOP system, received FDA approval in 2006. Medtronic has discontinued the distribution of the X-Stop system.

- The FDA recommended against approval for the following:
  - DIAM® Spinal Stabilization System: DIAM system (Medtronics) in an Orthopaedic & Rehabilitation Devices panel meeting in February 2016
- Other devices still undergoing study may include but are not limited to the following non-inclusive list:
  - Aperius PercLID System (Kyphon/ Medtronic Spine)
    CoRoent Extensure (Nuvasive)
    ExtenSure (Nuvasive)
    FLEXUS (Globus Medical)
    Falena Interspinous Decompression Device (Mikai Spine)
    Helifix Interspinous Spacer System (Alphatec Spine)
    In-Space (Synthes)
    NL-Prow Interspinous Spacer (Non-Linear Technologies)
    Stenofix (Synthes)
    Wallis System (Abbott Spine/ Zimmer Spine)

Fixation Devices

The following interspinous fixation devices have received clearance to market by the U.S. Food and Drug Administration (FDA). This is not intended to be an all-inclusive list.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Affix II (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- Benefix Interspinous Fixation System
- BridgePoint™ (Alphatec)
- CD HORIZON™ Spinal Fixation System (Medtronic Sofamor Danek)
- Coflex-F® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ G3 Interspinous Interlaminar Fusion Device (Spinal Simplicity)
- Octave™ Posterior Fusion System (Life Spine)
- PrimaLOK™ SP Interspinous Fusion System (OsteoMed)
- SP-Link™ System (Medical Designs LLC)
- SP-Fix™ Spinous Process Fixation Plate (Globus)

- Spire™ (Medtronic)
- StabiLink® MIS Interspinous Fixation System
- Zip Mis Interspinous Fusion System (Aurora Spine)

RATIONALE

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, 2 domains are examined: the relevance, and 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 largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated nonsurgically. At the other end of the spectrum are patients who have severe stenosis, concomitant back pain, and grade 2 or higher spondylolisthesis, spinal instability, or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

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® Interspinous Process Decompression System, coflex Interlaminar Stabilization, and Superion Interspinous Spacer devices had received the FDA approval for use in the U.S. Manufacturing of the X-STOP device stopped in 2015. This review focuses on devices currently available for use in the U.S.

Interspinous or Interlaminar Spacer as a Stand-Alone Treatment

Clinical Context and Test 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 PICO was 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 spinal stenosis with no spondylolisthesis or grade 1 spondylolisthesis: lumbar spinal decompression surgery and nonsurgical conservative therapy.

Outcomes
The general outcomes of interest are whether the placement of an interspinous or interlaminar spacer improves pain, function, and quality of life.

The visual analog scale for pain is a continuous scale that depicts pain intensity along a line that is anchored by 2 verbal descriptors. For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "worst imaginable pain" (score of 10) on 10 cm (100 mm) scale.

Function can be measured by a 15-point improvement in the Oswestry Disability Index scores.

Other measures such as 36-Item Short-Form (SF-36) Health Survey or 12-item Short-Form (SF-12) Health Survey to assess the quality of life, and the Zurich Claudication Questionnaire also to assess the quality of life for patients with lumbar spinal stenosis. The 12-item Short-Form (SF-12) and 36-Item Short-Form (SF-36) Health Survey is a measure of perceived health that describes the degree of general physical health status and mental health distress. The 12-item Short-Form (SF-12) is a shorter alternative to the 36-Item Short-Form (SF-36) and has at least 1 question from each of the SF-36's original 8 domains. Both scales are scored such that the adult population mean is 50, with a standard deviation of 10, and higher scores represent a better function.

Freedom from secondary interventions is also of interest to determine whether the 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 postprocedure.

Zurich Claudication Questionnaire
The Zurich Claudication Questionnaire was designed specifically for use in the evaluation of physical function in patients with lumbar spinal stenosis. Subscales of the questionnaire may be used separately. For example, the 5-item Physical Function Scale is used primarily to evaluate walking capacity. These 5 items assess the distance walked and activities of daily living that involve walking. The Physical Function Scale has been used to assess walking as an outcome for surgical and nonsurgical treatment in patients with lumbar spinal stenosis.

The Zurich Claudication Questionnaire consists of 3 subscales:

1. Symptom severity scale (questions I-VII) [further subdivided into pain domain (questions I-IV) and a neuro-ischemic domain (questions V-VII)]: Possible range of the score is 1 to 5.
2. Physical function scale (questions VIII-XII): Possible range of scores is 1 to 4.
3. Patient's satisfaction with treatment scale (questions XIII-XVIII): The range of the scale is 1 to 4.

Scoring Method/Interpretation

The result is expressed as a percentage of the maximum possible score. The score increases with worsening disability.

Oswestry Disability Index
The Oswestry Disability Index is a self-administered questionnaire used by clinicians and researchers to quantify disability for low back pain. The maximum score is 50. The Minimum Detectable Change (at 90% confidence) is 10 percentage points.

Interpretation of the Oswestry Disability Index:

1. 0% - to 20%: Minimal disability: This group can cope with most living activities. Usually, no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet. In this group, some patients have particular difficulty with sitting, and this may be important if their occupation is sedentary (eg, a typist or truck driver).

2. 20% - to 40% Moderate disability: This group experiences more pain and problems with sitting, lifting, and standing. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity, and sleeping are not grossly affected, and the back condition can usually be managed by conservative means.
3. 40% - to 60%: Severe disability: Pain remains the main problem in this group of patients, but travel, personal care, social life, sexual activity, and sleep are also affected. These patients require detailed investigation.
4. 60% - to 80%: Crippled: Back pain impinges on all aspects of these patients' lives, both at home and at work, and positive intervention is required.
5. 80% - to 100%: These patients would be bed-bound.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Superion Interspinous Spacer Device versus X-STOP Device (Interspinous)

Randomized Controlled Trials
(2015) Patel et al. reported on the results of a multicenter randomized noninferiority trial (10% margin) comparing the Superion interspinous spacer with the X-STOP. The participants had intermittent neurogenic claudication despite 6 months of nonsurgical management with the superion interspinous space. The primary outcome was a composite of a clinically significant improvement in at least 1 of 3 Zurich Claudication Questionnaire 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 endpoint was met, with a Bayesian posterior probability of 0.993. However, 111 (28%) patients (54 Superion interspinous spacer, 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 Oswestry Disability Index scores. Rates of complications and reoperations were similar between groups. Spinous process fractures, reported as asymptomatic, occurred in 16.4% of Superion interspinous space patients and 8.5% of X-STOP patients. Subsequently, long-term follow-up results were reported. At 3 years, 120 patients in the Superion interspinous process spacer 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 interspinous spacer 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 interspinous spacer 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 Zurich Claudication Questionnaire domains was observed in 84% of patients at years 4 and 5. The limitations noted it was not blinded to treatment assignment or outcome assessment. Outcomes were assessed by the treating physician. There was a high loss to follow-up and/or missing data.: 11% of patient were not randomized, and data from 28% missing at 2 years; 35% at 3 years. Additionally, it is unclear why there was a 10% noninferiority margin selected.

The purpose of the tables below is to display notable limitations 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.

Summary of Key Randomized Controlled Trial Characteristics

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

NCT00692276: Randomized Study Comparing the VertiFlex® Superion® interspinous process spacer to the X-STOP® Interspinous Process Decompression (IPD®) System in Patients With Moderate Lumbar Spinal Stenosis.

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)	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)	Superion	120	52.5%[c]	69/82	63/82	57/82		

	X-STOP	129	38.0%[c]	53/76	53/76	55/77		
4 years								
Nunley et al. (2017)	Superion	122	84.3%[d]	67/86	57/86	55/89		
5 years								
Nunley et al. (2017)	Superion	88	84%[d]	68/85	55/85	57/88		

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.

Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Patel et al. (2015)					

The study limitations 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. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Patel et al (2015)	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 study limitations 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.

Observational Studies

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 Superion interspinous spacer.35, Of the 199 patients included in the final analysis, 57 patients underwent minimally invasive lumbar decompression only, 124 patients underwent treatment with the Superion interspinous spacer only, and 18 patients underwent minimally invasive lumbar decompression followed by treatment with the Superion 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 Superion interspinous spacer. All patients who underwent subsequent surgery were noted to have severe lumbar spine stenosis.

(2019) Tekmyster et al. reported a registry of patients who had been treated with the Superion interspinous spacer for spinal stenosis and back and leg pain. Out of 2090 patients included at baseline, less than 25% provided data at 12 months. The low response rate raises the possibility of bias and is insufficient to derive any conclusions regarding the study.

Coflex Device (Interlaminar)

Randomized Controlled Trials

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 lumbar spinal stenosis. The primary outcome at 8-week and 1-year follow-ups was the Zurich Claudication Questionnaire score. The score increases with increasing disability. Trial characteristics and results are summarized in Tables below. 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 limitations was not done for this trial.

Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Moojen et al (2013) 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)

FELIX: Foraminal Enlargement Lumbar Interspinous distraXion.

Summary of Key Randomized Controlled Trial Outcomes

Study; Trial	Proportions of Patients Achieving ZCQ Success, [a] (95% CI), %		Reoperations, n (%)
	8 Weeks	*52 Weeks*	
Moojen et al (2013; 2014); FELIX (1-yr 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 (.44)	0.90 (.77)	p<.001
Moojen et al (2015)·; FELIX (2-yr follow-up)	145		Not reported
Coflex	69		23 (33)
Decompression alone	60		6 (8)
Odds ratio (p)	0.65 (.20)		p<.001

CI: confidence interval; FELIX: Foraminal Enlargement Lumbar Interspinous distraXion; ZCQ: Zurich Claudication Questionnaire.
[a] Reductions 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 Superion interspinous spacer for lumbar spinal stenosis includes a pivotal trial. This trial compared the Superion interspinous spacer with the X-STOP Interspinous Process Decompression System 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 the 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. This is an off-label use of the device. Use consistent with the FDA label is reviewed in the next section.

Interlaminar Stabilization Devices Used with Spinal Decompression Surgery in Individuals with Severe Spinal Stenosis and Grade 1 Spondylolisthesis or Instability

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in individuals with severe spinal stenosis and grade 1 spondylolisthesis or instability 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.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with severe spinal stenosis and grade 1 spondylolisthesis or instability 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.

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 Oswestry Disability Index and the Zurich Claudication Questionnaire, as well as the visual analog scale for back and leg pain. Other measures such as the SF-36 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.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Coflex Device Plus Decompression versus Decompression Plus Posterolateral Fusion

Randomized Controlled Trials
The FDA approved coflex on the basis of an open label, randomized, multicenter, noninferiority trial (-10% noninferiority margin) that compared coflex plus decompression to decompression plus posterolateral fusion in individuals who had stenosis, significant back pain, and either no spondylolisthesis or grade 1 spondylolisthesis. The control group was treated with pedicle screw and rod fixation with autograft but without an interbody (intervertebral) cage or bone morphogenetic protein. 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 endpoint. In the fusion group, 3 of 107 were lost to follow-up. Results of long-term follow-up to 5 years were reported subsequently.

Trial characteristics and results are summarized in the tables below. Composite clinical success (a minimum 15-point improvement in Oswestry Disability Index 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) at 24 months showed that coflex was noninferior to screw and rod fixation (-10% noninferiority margin). Secondary effectiveness criteria, which included Zurich Claudication Questionnaire score, visual analog scale scores for leg and back pain, SF-12 scores, time to recovery, patient satisfaction, and several radiographic endpoints, 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 were 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%.

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.

A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; p<.001) and blood loss (106 vs. 336 mL, p <.001). There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual analog scale, and Zurich Claudication Questionnaire scores after 2 years. In that analysis, 59 (62.8%) of 94 coflex patients and 30 (62.5%) of 48 fusion patients met the criteria for operative success. Fusion was obtained in 71% of the control group, leaving nearly a third of patients with pseudoarthrosis. The authors reported no significant differences in Oswestry Disability Index or visual analog scale between the patients with pseudoarthrosis or solid fusion, but Zurich Claudication Questionnaire scores were not reported. There were 18 (18%) spinous process fractures in the coflex group, of which 7 had healed by the 2-year follow-up. Reoperation rates were 6% in the fusion group (p=.18) and 14% in the coflex group, including 8 (8%) coflex cases that required conversion to fusion.

Another post-hoc analysis of the pivotal RCT evaluated the use of the device in patients 65 years or older. Clinical outcomes (e.g., Oswestry Disability Index, visual analog score, Zurich Claudication Questionnaire, epidural injections) were measured out to 60 months. Patients age 65 years or older who received the interlaminar implant with decompression (n=84) had clinical outcomes that were not significantly different to patients 65 years or older who received decompression and fusion (n=57), and to patients younger than 65 who received the interlaminar implant with decompression (n=131). In contrast, perioperative outcomes such as operative time (100 vs. 153 min ,; p<.001), blood loss (106 vs. 358 mL, p<.001), and hospital stay (2.1 vs. 3.3 days, p<.001) were improved with the interlaminar implant compared to posterolateral fusion.

Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Davis et al (2013), NCT00534235[a]	U.S.	21	2006-2008	Patients with spinal stenosis with up to grade 1 spondylolisthesis, 1 or 2 levels with VAS $\geq$ 50 and ODI $\geq$ 20 (N=344)	Decompression plus coflex (n=262)	Decompression plus pedicle screw and rod fixation (n=136)

NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients; ODI: Oswestry Disability Index; VAS: visual analog score
[a] Noninferiority study.

Summary of Key Randomized Controlled Trial 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)					
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)
% D (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)					
N	290	214	Unclear	NR	NR
Coflex	(62)	129 (90)	(76)	NR	NR
Fusion	(49)	53 (76)	(79)	NR	NR
% D (95% CI) or p	13.3(1.1 to 25.5)	.008	NR	NR	NR
4-year follow-up					
Bae et al (2015)					
N	274	181	NR	NR	NR
coflex	106 (58)	106 (86)	NR	NR	NR
Fusion	42 (47)	42 (72)	NR	NR	NR
% D (95% CI) or p	10.9(-1.6 to 23.5)	.038	NR	NR	NR
5-year follow-up					
Musacchio et al (2016)					
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)
% D (95% CI) or p	6.3 (NR); >.90	>.40	>.70	>.90	>.40

Values are n or n (%.)
CCS: composite clinical success; CI: confidence interval; D: decompression; ODI: Oswestry Disability Index (reported as mean score or percent with at least 15-point improvement); NR: not reported
[a] CCS 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%.

The tables below display notable limitations identified in each study.

Another limitation in the study, not listed in the limitation's 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 U.S. and elsewhere, there are few data on the performance of coflex plus decompression surgery other than in randomized trials. A retrospective cohort study Evaluation of the Clinical and Radiographic Performance of Coflex® Interlaminer Technology Versus Decompression With or Without Fusion (NCT03041896) trial, undertaken by the manufacturer was completed, but only limited descriptive results are published on Clinicaltrials.gov and a full publication of the trial is not available. Per the website, the proportion of participants undergoing secondary surgical interventions at 6 months was 8.8% (126/1428) with decompression, 6.1% (125/2058) with coflex, and 9.8% (99/1009) with fusion. Additionally, a large registry study, the Coflex® COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology (NCT02457468) trial, has been completed but results are not published.

Study Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Davis et al (2013)[,]; NCT00534235	4. Study population combines no and grade 1 spondylolisthesis		2. Noninferiority to a comparator whose benefit is uncertain does not permit meaningful interpretation of the net benefit.	1. Outcomes did not include success of the fusion procedure	
Davis et al (2013)[,]; NCT00534235			2. The benefit of the comparator is uncertain. Fusion was not obtained in 29% of cases. Intervertebral cages and BMP were not allowed in the FDA IDE study.		

BMP: bone morphogenetic protein; IDE: investigational device exemption; FDA: U.S. Food and Drug Administration; NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients. The study limitations 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. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Study Design and Conduct Limitations

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

Davis et al (2013) NCT00534235			3. Evidence of selective reporting. ZCQ scores were not reported for the comparison of pseudoarthrosis and solid fusion.			1. Secondary (unplanned) superiority testing in patients with grade 1 spondylolisthesis patients from the pivotal non-inferiority trial. 3. A non-inferiority margin for the subgroup analysis was not defined or discussed and confidence intervals were not reported.

NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients; ZCQ: Zurich Claudication Questionnaire.
The study limitations 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. 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 Versus Decompression Plus Posterolateral Fusion

The FDA's approval of coflex was based on an open label, randomized, noninferiority trial that compared the noninferiority of coflex plus decompression to decompression plus posterolateral fusion in patients who had spinal stenosis, significant back pain, and up to grade 1 spondylolisthesis. Use of the noninferiority framework by the 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, the Swedish Spinal Stenosis Study, and the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial assessing the superiority of adding fusion to decompression over decompression alone reported a lack of or marginal benefit. The Swedish Spinal Stenosis Study trial, which was adequately powered to detect a 12-point difference in Oswestry Disability Index score, showed

no difference in Oswestry Disability Index 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. A secondary (posthoc) comparison of the subgroup of patients with grade 1 spondylolisthesis, which may be a more relevant analysis, found similar outcomes between the coflex and fusion groups. However, almost a third of the fusion group had unsuccessful fusion with pseudoarthrosis which raises additional questions about the efficacy of the comparator. Oswestry Disability Index and visual analog scale did not significantly differ between the pseudoarthrosis and solid fusion groups, but the Zurich Claudication Questionnaire results were not reported. In addition, posthoc analysis is considered hypothesis-generating. Given the multiple concerns, a prospective trial that compares coflex to fusion in patients with severe spinal stenosis and grade 1 spondylolisthesis is needed.

Coflex Device Plus Decompression Versus Decompression Alone

Randomized Controlled Trials

Schmidt et al (2018) reported on results of an RCT in patients with moderate-to-severe lumbar spinal stenosis 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).[47,] 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=.017), with a treatment difference of 16.7% (95% confidence interval [CI], 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%) versus the decompression alone arm (14.8%; p=.010) at 24 months.

The proportion of patients with Oswestry Disability Index success among those censored for subsequent secondary interventions was not statistically significant between the treatment (75.6%) and the control arms (70.4%; p=.47). The difference in the proportion of patients overall who had Oswestry Disability Index success in the overall sample was also not statistically significant (55% vs. 44%, p=.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 Zurich Claudication Questionnaire (success was defined as an improvement in 2 or 3 Zurich Claudication Questionnaire criteria), success measured on a visual analog scale for pain (success defined as a >20-mm change from baseline), reduction in visual analog scale 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.

Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schmidt et al (2018)[,]; 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 alone (n=131)

Summary of Key Randomized Controlled Trial Outcomes

Study	CCS[a]	15-Point Improvement in ODI Score (all patients)	15-Point Improvement in 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)						
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)
%Δ (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	.017	.091	.470	.081	.655	.010

Values are n, n (%), or %.
CCS: composite clinical success; CI: confidence interval; D: decompression; ILS: interlaminar stabilization; ODI: Oswestry Disability Index;
[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 limitations in the tables below is to display notable limitations 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. 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 analysis, to handle 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 a 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 endpoint 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 Oswestry Disability Index for all patients, or Oswestry Disability Index 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.

Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Schmidt et al (2018)			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 2-y follow-up

The study limitations 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. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Schmidt et al (2018)		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		

The study limitations 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

(2021) Zhong et al. evaluated perioperative outcomes in a comparative study of 83 patients. Patients who had the coflex interlaminar implant in combination with laminectomy (n=46) had higher estimated blood loss (97.50 ± 77.76 vs 52.84 ± 50.63 mL, p = 0.004), longer operative time (141.91 ± 47.88 vs 106.81 ± 41.30 min, p = 0.001), and longer length of stay (2.0 ± 1.5 vs 1.1 ± 1.0 days, p = 0.001) compared to laminectomy alone (n=37). Total perioperative complications (21.7% vs 5.4%, p = 0.035) and instrumentation related complications (10.9% vs 0% p = 0.039) were also higher in the interlaminar implant cohort.

(2015) Röder et al (2015) reported on a small cross-registry study that compared lumbar decompression plus coflex (SWISS spine Registry) with lumbar decompression alone (Spine Tango Registry) in 50 pairs matched by a multifactorial propensity score. The 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 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 numeric rating scale back pain score (3.8 vs. 2.5; p=.014), numeric rating scale leg pain score (4.3 vs. 2.5; p<.001), numeric rating scale maximum pain score (4.1 vs. 2.3; p=.002), and greater improvement in Core Outcome Measures Index score (3.7 vs. 2.5; p=.029). Back pain improved by the minimum clinically relevant change in about 60% of patients in the decompression alone group versus 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 et al (2015) 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.

(2016) Lee et al. 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. 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.

(2013) Some radiologic findings with the coflex device require additional study to determine their clinical significance. Tian et al. reported a high rate (81.2%) of heterotopic ossification at follow-up (range, 24-57 months) in patients who had received a coflex device. 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 9.

(2010) Richter et al. reported on a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery. Richter et al (2014) also published a 2-year follow-up. 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 the 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.

Subsection Summary: Coflex Device Plus Decompression Versus Decompression Alone

One RCT, conducted in a patient population who had moderate-to-severe lumbar spinal stenosis with or without spondylolisthesis, showed that a greater proportion of patients who received coflex plus

decompression achieved the primary endpoint of composite clinical success compared with decompression alone. This composite endpoint 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 Oswestry Disability Index 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 this trial and an ongoing RCT, 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® (NCT02555280) on decompression with and without the coflex implant in the U.S. are published. 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. Limitations of the published evidence preclude determining the effects of the technology on net health outcomes.

Interlaminar Stabilization Devices Used With Spinal Decompression Surgery in Patients With No Spondylolisthesis or Instability

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in patients with spinal stenosis and no spondylolisthesis or spinal instability 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. 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 PICO was used to select literature to inform this review.

Populations

Individuals with spinal stenosis and no spondylolisthesis or instability 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 alone.

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 Oswestry Disability Index and the Zurich Claudication Questionnaire as well as a visual analog scale for back and leg pain. Other measures such as the SF-36 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Coflex Device Plus Decompression Versus Decompression Plus Posterolateral Fusion

Gilbert et al. (2022) retrospectively evaluated interlaminar stabilization with coflex following decompressive laminectomy in 20 patients with lumbar stenosis without instability or spondylolisthesis. The average visual analog scale score for low back pain preoperatively was 8.8, which improved postoperatively to 4.0, 3.7, and 3.9 at 2 months, 6 months, and 1 year, respectively ($p<.001$). The average visual analog scale score for lower extremity pain preoperatively was 9.0, which improved postoperatively to 2.7, 2.5, and 2.5 at 2 months, 6 months, and 1 year, respectively ($p<.001$). Furthermore, the average Oswestry Disability Index scores significantly improved from 66.6 preoperatively to 23.8, 23.3, and 24.5 at 2 months, 6 months, and 1 year postoperatively, respectively ($p<.001$). The difference in visual analog scale or Oswestry Disability Index scores between 2 months, 6 months, and 1 year did not reach statistical significance. The retrospective nature of the study and short follow-up period after surgery limit conclusions on the role of coflex interlaminar stabilization.

Abjornson et al. (2018) reported outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal investigational device exemption trial, but comparison with decompression alone in this population has not been reported. The major weakness in this trial was its use of lumbar spinal fusion as a comparator for patients with no spondylolisthesis. 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 Oswestry Disability Index success rate for decompression alone in the European Study of Coflex And Decompression Alone trial was comparable to the Oswestry Disability Index success rate for decompression plus fusion in the pivotal trial.

Section Summary: Interlaminar Stabilization Devices Used With Spinal Decompression Surgery in Individuals with No Spondylolisthesis or Instability

The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires a longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed as 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 and 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. Therefore, demonstrating the noninferiority of coflex plus spinal decompression versus spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal investigational device exemption trial have been published, but comparison with decompression alone in this population has not been reported. Limitations of the published evidence preclude determining the effects of the technology on the net health outcomes.

Miscellaneous Spacer/Distraction Devices

(2021) Hayes Inc. published an evolving evidence review in 2021 and they reported there is no evidence to inform if outcomes related with the Superion Interspinous Spacer are superior when comparing the Superion Interspinous Spacer with other minimally invasive interventions or other more well-known surgeries involving spinal fusion. They also noted the guidance on the use of spacers is mixed.

(2021) Aggarwal and Chow completed a review on the real-world adverse events of interspinous spacer using manufacturer and user facility device experience data. They noted the following methodically; disproportionality analysis was conducted to determine whether a statistically significant signal exists in the three interspinous spacers and the reported adverse events using the Manufacturer and User Facility Device Experience (MAUDE) database maintained by the US Food and Drug Administration. The results noted a statistically significant signals were found with each of the three interspinous spacer devices (Coflex, Vertiflex, and X-Stop) and each of the following adverse events: fracture, migration, and pain/worsening symptoms. In conclusion further studies such as randomized controlled trials are needed to validate the findings.

(2021) Welton et al. completed a retrospective review on the comparison of adverse outcomes follow placement of Superion interspinous spacer device vs. laminectomy and laminotomy. The purpose of this study is to compare the short-term complications of the SISS with laminectomy or laminotomy and highlight device-specific long-term outcomes with SISS. Having no differences in adverse events between laminectomies or laminotomies and SISS plus evidence of substantial device-specific long-term adverse outcomes and reoperation should be given consideration when deciding on surgical intervention of 1-2 level lumbar spinal stenosis. 89 patients who received lumbar level SISSs were compared with 378 matched controls who underwent primary lumbar spine laminectomy or laminotomy; data were collected from the American College of Surgeons National Surgical Quality Improvement Program database. Complications analyzed included rates of wound infection, pulmonary embolism, deep venous thrombosis, urinary tract infection, sepsis, septic shock, cardiac arrest, death, and reoperation within 30 days of index surgery. Differences between groups were analyzed using the $\chi 2$test. Device-specific complication (DSC) rates included device malfunction or misplacement (DM), device explantation (DE), spinous process fracture (SPF), and subsequent spinal surgery (SSS). The noted results included no differences in demographics or comorbidities existed between groups. There was no significant difference in rates of complications between groups. A total of 44.4% of patients in the SISS group experienced DSCs with 11.1% of patients experiencing DM, 21.1% experiencing an SPF, 20.1% requiring DE, and 24.3% requiring SSS. Having at least 1 DSC significantly increased odds of SSS, odds ratio >120, $P < .0001$. In conclusion, the rates of 30-day complications in the SISS group were not significantly different from patients undergoing laminectomy or laminotomy. Rates of 2-year DSC within SISS and cumulative

risk associated with these complications should be considered further as they likely represent need for additional procedures for patients and substantial cost to the healthcare system.

(2020) Merkow et al. completed a literature review on minimally invasive lumbar decompression and interspinous process device for the management of symptomatic lumbar spinal stenosis. The authors' findings noted, the available evidence for MILD and Superion has been continuously debated. Overall, it is considered that while the procedures are safe, there is only modest evidence for effectiveness. For both procedures, we have reviewed 13 studies. Based on the available evidence, MILD and Superion are safe and modestly effective minimally invasive procedures for patients with symptomatic LSS. It is our recommendation that these procedures may be incorporated as part of the continuum of treatment options for patients meeting clinical criteria.

(2020) Tram et al. completed a retrospective review examined the literature on the efficacy and complications associated with decompression and interspinous devices (ISDs) used in surgeries for LSS. LSS is a debilitating condition that affects the lumbar spinal cord and spinal nerve roots; however, a comprehensive report on the relative efficacy and complication rate of ISDs as they are compared to traditional decompression procedures is currently lacking. The PubMed database was queried to identify clinical studies that exclusively investigated decompression, those that exclusively investigated ISDs, and those that compared decompression with ISDs. Only prospective cohort studies, case series, and RCTs that evaluated outcomes using the VAS, ODI, or JOA scores were included. A random-effects model was established to assess the difference between pre-operative and the 1- to 2-year post-operative VAS scores between ISD surgery and lumbar decompression. This study included 40 papers that matched the selection criteria. A total of 25 decompression-exclusive clinical trials with 3,386 patients and a mean age of 68.7 years (range of 31 to 88 years) reported a 2.2 % incidence rate of dural tears and a 2.6 % incidence rate of post-operative infections. A total of 8 ISD-exclusive clinical trials with 1,496 patients and a mean age of 65.1 (range of 19 to 89 years) reported a 5.3 % incidence rate of post-operative leg pain and a 3.7 % incidence rate of spinous process fractures; 7 studies that compared ISDs and decompression in 624 patients found a re-operation rate of 8.3 % in ISD patients versus 3.9 % in decompression patients; they also reported dural tears in 0.32 % of ISD patients versus 5.2 % in decompression patients. A meta-analysis of the RCTs found that the differences in pre-operative and post-operative VAS scores between the 2 groups were not significant. Both decompression and ISD interventions were unique surgical interventions with different therapeutic efficacies and complications. The authors concluded that the collected studies did not consistently demonstrate superiority of either procedure over the other but understanding the differences between the 2 techniques could help tailor treatment regimens for patients with LSS. These researchers stated careful patient selection remains crucial for either surgical procedure to ensure optimal surgical outcomes tailored to each patient. They stated that more diverse studies are needed to determine the superiority of one technique over the other for different patient populations. The authors stated that limitations of this study included inconsistent reporting of measurements among studies. Inconsistencies were also found in the extent of complications reported, with more exhaustive studies reporting unique complications, while some studies simply stated that no major complications were encountered. Another limitation of this paper was the variation in post-operative care, which was important for long-term complications such as re-operation rates.

(2020) Grinberg et al. completed a prospective, multicentered, randomized controlled trail on the interlaminar stabilization for spinal stenosis in the Medicare population. Patients from 21 sites in the United States underwent surgery for moderate stenosis with up to a grade 1 degenerative spondylolisthesis and failure of conservative treatment with low back pain at 1 or 2 contiguous levels from L1-L5. Preoperatively, patient-reported assessment had to meet the criteria of significant pain and disability (Visual Analog Scale [VAS back pain] $\geqslant$50 mm on a 100 mm scale; Oswestry Disability Index

[ODI] of ⩾20/50). The primary outcome was overall Composite Clinical Success (CCS) as determined by ODI scores, incidence of postoperative epidural injections and/or reoperations, incidence of device-related complications, and persistent or progressive neurological deficit. Secondary outcomes included patient satisfaction as measured by VAS for back and worse leg pain and Zurich Claudication Questionnaire scores. Narcotic usage data and radiographic assessment of changes in postoperative posterior disc height and foraminal height were also evaluated. At 1- or 2-levels, 84 patients ⩾age 65 underwent decompression with ILS, 57 patients ⩾age 65 underwent decompression with fusion, and 131 patients <age 65 underwent decompression with ILS. Comparisons were made between ⩾age 65 ILS patients and ⩾age 65 fusion patients and between <age 65 and ⩾age 65 ILS patients. The patients were assessed before and after surgery at 6 weeks and 3, 6, 12, 18, 24, 48, and 60 months. They resulted, at 24 and 60 months, there were no statistically significant differences in CCS or any of the individual components of CCS between the ⩾ age 65 ILS and fusion groups or between the < age 65 and ⩾ age 65 ILS groups. ILS Medicare patients experienced significantly shorter surgeries (p<.001), less blood loss (p<.001), and a shorter hospital stay (p<.001) than fusion patients. There were no significant differences radiographically or with regards to postoperative narcotic usage. In conclusion, clinically, ILS patients ⩾ age 65 performed as well as both those receiving fusion and those <age 65 who received ILS. Importantly, however, for this older population, ILS Medicare patients experienced less blood loss, a shorter operation and shorter hospital stay than fusion Medicare patients.

(UpToDate 2020; Last updated January 2022) Levin et al. completed a review on “Lumbar spinal stenosis: Treatment and prognosis” states that “Intraspinous spacer implantation -- A potentially less invasive treatment option involves implanting a device between the spinous processes at one or two vertebral levels, relieving compression. This procedure is said to be appropriate for those patients with spinal stenosis without spondylolisthesis who have intermittent claudication symptoms that are exacerbated in extension and relieved in flexion. A randomized, multicenter study in 191 patients compared the implantation of the X STOP implant, a titanium alloy device, with nonoperative treatment. At 6 months, symptoms were relieved in 52 % of treated patients, compared with 9 % of controls. Benefit was maintained at 2 and 4 years of follow-up and was associated with reduced disability and improved quality of life. Subsequent uncontrolled observations have found that implantation of the X STOP device has been efficacious in many patients, if not in as large a proportion as was found in the clinical trial. While radiologic improvement in spinal canal and neuroforaminal narrowing can be measured after surgery, these changes are not correlated with clinical benefit and are not maintained over time in most patients. These procedures appear to be associated with higher rates of subsequent surgery than patients initially treated with laminectomy. Adverse effects also appear to be more commonly reported in general clinical experience; these include discitis/osteomyelitis, device dislocations, spinous process fractures, recurrent disc herniation, hematoma, cerebrospinal fluid fistula, and foot drop. It is unclear how this newer procedure compares with the standard surgical procedure, decompressive laminectomy, in terms of effectiveness, side effects, recovery time, and long-term outcomes. This treatment does not appear to be helpful in patients who have spondylolisthesis”. Furthermore, intraspinous spacer implantation is not listed in the “Summary and Recommendations” section of this review. (*Accessed February 2023*)

(2018) Simon et al. reviewed the two-level experience of interlaminar stabilization with a five-year follow-up of a prospective, randomized clinical experience compared to fusion for the sustainable management of spinal stenosis. This is the first 5-year analysis of the 2-level ILS experience, which supplements previous studies that describe the advantages of ILS by extending such advantages to 2-level cases. They had 322 patients enrolled in the Investigational Device Exemption clinical trial, 116 required surgical treatment at 2 levels. The ILS group consisted of 77 patients, and the fusion group consisted of 39 patients. Efficacy was measured using composite clinical success (CCS). Patients achieve CCS if they achieve all 4 of the following outcomes: ⩾15-point improvement from baseline Oswestry Disability Index

(ODI); no reoperation or epidural injections; no persistent, new, or increasing neurological deficits; and no major device-related complications. The results noted there was a 91% rate of follow-up within the participant population in the 5-year data. There was a difference trending toward significance between groups for the absence of reoperation or epidural injection, with 68.8% of ILS patients and only 51.3% of fusion patients meeting this criterion (P = .065); 13.0% of ILS patients and 25.7% of fusion patients required secondary surgery. The percentage of patients achieving overall CCS was much greater in the ILS group than the fusion group, with 55.1% (38/69) of ILS patients and only 36.4% (12/33) of fusion patients achieving CCS at month 60 (P = .077). With regard to the ODI, the visual analog scale back and worse leg pain, the Short Form-12, and the Zurich Claudication Questionnaire, both groups had significantly better results at every follow-up time point when compared to their respective baseline scores. In conclusion, the 2-level ILS patient group performed as well as, if not better than, the 2-level fusion group across almost all outcome measures, demonstrating both clinical outcome success and favorably low reoperation rates in patients who received ILS surgery.

(2016) Bae et al. completed a randomized controlled trail on the three-year follow-up of the prospective randomized, controlled trail of coflex interlaminar stabilization vs. instrumented fusion in patients with lumbar stenosis. The results noted composite clinical success at 36 months was achieved by 62.2% among 196 coflex Interlaminar Stabilization patients and 48.9% among 94 fusion patients (difference = 13.3%, 95% confidence interval, 1.1%-25.5%, P = .03). Bayesian posterior probabilities for noninferiority (margin = -10%) and superiority of coflex Interlaminar Stabilization vs fusion were >0.999 and 0.984, respectively. Substantial and comparable improvements were observed in both groups for patient-reported outcomes, although the percentage with a clinically significant improvement ($\geqslant$15) in the Oswestry Disability Index seemed larger for the coflex Interlaminar Stabilization group relative to the fusion group (P = .008). Radiographic measurements-maintained index level and adjacent level range of motion in coflex Interlaminar Stabilization patients, although range of motion at the level superior to fusion was significantly increased (P = .005). The author's concluded Coflex Interlaminar Stabilization for stenosis is proven to be effective and durable at improving overall composite clinical success without altering normal spinal kinematic motion at the index level of decompression or adjacent levels. The limitations noted, the main limitation for this study is that the duration of follow-up is limited to 36 months at this time. In this trial, patients with lumbar stenosis with and without spondylolisthesis were studied. They acknowledge that the need for post decompression stabilization in patients without spondylolisthesis has not been thoroughly studied or proven as necessary. The results of this trial suggest that these patients without spondylolisthesis benefit from stabilization with ILS after decompression, but a further study to compare decompression with ILS stabilization to decompression alone will help to determine the appropriateness of ILS in these patients. A second phase multicenter prospective, randomized, controlled trial comparing decompression and ILS to decompression alone will commence in the very near future

(2016) Musacchio et al. prospective, randomized, controlled trial was conducted at 21 centers. Patients with moderate to severe lumbar stenosis at one or two contiguous levels and up to Grade I spondylolisthesis were randomized (2:1 ratio) to decompression and interlaminar stabilization (D+ILS; n=215) using the coflex® Interlaminar Stabilization® device (Paradigm Spine, LLC) or decompression and fusion with pedicle screws (D+PS; n=107). Clinical evaluations were made preoperatively and at 6 weeks and 3, 6, 12, 18, 24, 36, 48, and 60 months postoperatively. Overall Food and Drug Administration success criteria required that a patient meet 4 criteria: 1) > 15-point improvement in Oswestry Disability Index (ODI) score; 2) no reoperation, revision, removal, or supplemental fixation; 3) no major device-related complication; and 4) no epidural steroid injection after surgery. The results noted at 5 years, 50.3% of D+ILS vs. 44% of D+PS patients (p>0.35) met the composite success criteria. Reoperation/revision rates were similar in the two groups (16.3% vs. 17.8%; p >0.90). Both groups had statistically significant improvement through 60 months in ODI scores with 80.6% of D+ILS patients and 73.2% of D+PS patients demonstrating > 15-point improvement (p>0.30). VAS, SF-12, and ZCQ scores followed a similar pattern of maintained significant improvement throughout follow-up. On the SF-12 and

ZCQ, D+ILS group scores were statistically significantly better during early follow-up compared to D+PS. In the D+ILS group, foraminal height, disc space height, and range of motion at the index level were maintained through 5 years. In conclusion, both treatment groups achieved and maintained statistically significant improvements on multiple outcome assessments throughout 5-year follow-up. On some clinical measures, there were statistically significant differences during early follow-up favoring D+ILS. At no point were there significant differences favoring D+PS. Results of this 5-year follow-up study demonstrate that decompression and interlaminar stabilization with coflex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels. The study did have some limitations. The study was not blinded during follow-up. Clinically, this would be very difficult to achieve, but may have introduced a bias. There is always difficulty in determining how to address patients who undergo additional surgery or injections after the study surgery, as their outcome measures may then be reflecting the effect of the additional intervention rather that the index procedure. In the current protocol, these patients were classified outcome failures in the composite assessment of success and excluded from the analyses of individual outcome assessments such as VAS and ZCQ.

(2015) Hirsch et al. stated that lumbar spinal stenosis is a major public health issue. Interspinous devices implanted using minimally invasive techniques may constitute an alternative to the reference standard of bony decompression with or without intervertebral fusion. However, their indications remain unclear, due to a paucity of clinical and biomechanical data. These investigators evaluated the effects of four interspinous process devices implanted at L4 to L5 on the intervertebral foramen surface areas at the treated and adjacent levels, in flexion and in extension. Six fresh frozen human cadaver lumbar spines (L2 to sacrum) were tested on a dedicated spinal loading frame, in flexion and extension, from 0 to 10 N·m, after preparation and marking of the L3 to L4, L4 to L5, and L5 to S1 foramina. Stereoscopic 3D images were acquired at baseline then after implantation at L4 to L5 of each of the 4 devices (Inspace®, Synthes; X-Stop®, Medtronic; Wallis®, Zimmer; and Diam®, Medtronic). The surface areas of the 3 foramina of interest were computed. All 4 devices significantly opened the L4 to L5 foramen in extension. The effects in flexion separated the devices into 2 categories. With the 2 devices characterized by fixation in the spinous processes (Wallis® and Diam®), the L4 to L5 foramen opened only in extension, whereas with the other 2 devices (X-Stop® and Inspace®), the L4 to L5 foramen opened not only in extension, but also in flexion and in the neutral position. None of the devices implanted at L4 to L5 modified the size of the L3 to L4 foramen. X-Stop® and Diam® closed the L5 to S1 foramen in extension, whereas the other 2 devices had no effect at this level. The authors concluded that these findings demonstrated that interspinous process devices modified the surface area of the interspinous foramina in-vitro. They stated that clinical studies are needed to clarify patient selection criteria for interspinous process device implantation. They also noted several limitations. They performed in vitro measurements of cadaver specimens of lumbar spine segments after excision of all the muscles, which act as spinal stabilizers in vivo. Therefore, the data provides only indications about in vivo biomechanical behavior, as is the case for all biomechanical studies. Furthermore, the advanced mean age of the donors does not reflect the mean age of the patients who might benefit from IPD implantation. Also, they did not measure the degree of kyphosis induced by the IPDs, which might vary across devices and would be a parameter of interest to further categories the two IPD categories. They saw two main methodological limitations to the study: the small sample size limits the statistical power of the analysis, and the differences in IPD size precluded randomization of the order of IPD implantation. Although the biomechanical effects documented in vitro seem indisputable, no information is available on whether the foraminal size increase correlates linearly with the clinical benefits. Thus, they do not know the foraminal opening cut-off above which an improvement in the clinical symptoms can be expected. Thus, the biomechanical study must be completed by a clinical study to confirm the efficacy of IPD implantation and to determine the best criteria for selecting patients likely to benefit from this procedure.

(2015) Lauryssen et al. compared the 2-year clinical outcomes of a prospective, RCT of an FDA-approved interspinous spacer with the compilation of published findings from 19 studies of decompressive laminectomy for the treatment of LSS. Back and leg pain, ODI, and ZCQ values were compared between spacer- and laminectomy-treated patients pre-operatively and at 12 and 24 months. Percentage improvements between baseline and 24 months uniformly favored patients treated with the spacer for back pain (65 % versus 52 %), leg pain (70 % versus 62 %), ODI (51 % versus 47 %) and ZCQ symptom severity (37 % versus 29 %) and physical function (36 % versus 32 %). The authors concluded that both treatments provided effective and durable symptom relief of claudicant symptoms. This stand-alone interspinous spacer offered the patient a minimally invasive option with less surgical risk. This study provided short-term follow-up data (24 months).

(2015) Lee et al. conducted a systematic literature review of interspinous dynamic stabilization, including Diam®, Wallis®, Coflex, and X-STOP®, to assess its safety and efficacy. A literature search was done in Korean and English, by using eight domestic databases which included KoreaMed and international databases, such as Ovid Medline, Embase, and the Cochrane Library. A total of 306 articles were identified, but the animal studies, preclinical studies, and studies that reported the same results were excluded. As a result, a total of 286 articles were excluded and the remaining 20 were included in the final assessment. Two assessors independently extracted data from these articles using predetermined selection criteria. Qualities of the articles included were assessed using Scottish Intercollegiate Guidelines Network (SIGN). The complication rate of interspinous dynamic stabilization has been reported to be 0% to 32.3% in 3- to 41-month follow-up studies. The complication rate of combined interspinous dynamic stabilization and decompression treatment (32.3%) was greater than that of decompression alone (6.5%), but no complication that significantly affected treatment results was found. Interspinous dynamic stabilization produced slightly better clinical outcomes than conservative treatments for spinal stenosis. Good outcomes were also obtained in single-group studies. No significant difference in treatment outcomes was found, and the studies compared interspinous dynamic stabilization with decompression or fusion alone. The authors of the systematic review concluded that no particular problem was found regarding the safety of the technique. Its clinical outcomes were similar to those of conventional techniques, and no additional clinical advantage could be attributed to interspinous dynamic stabilization. However, few studies have been conducted on the long-term efficacy of interspinous dynamic stabilization. Thus, the authors suggest further clinical studies be conducted to validate the theoretical advantages and clinical efficacy of this technique.

(2014) Puzzilli et al. evaluated patients who were treated for symptomatic lumbar spinal stenosis with interspinous process decompression (IPD) implants compared with a population of patients managed with conservative treatment. A total of 542 patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial; 422 patients underwent surgical treatment consisting of X-STOP device implantation, whereas 120 control cases were managed conservatively. Both patient groups underwent follow-up evaluations at 6, 12, 24, and 36 months using the Zurich Claudication Questionnaire, the visual analog scale (VAS) score and spinal lumbar X-rays, CT scans and MR imaging. One-year follow-up evaluation revealed positive good results in the 83.5% of patients treated with IPD with respect to 50% of the non-operative group cases. During the first 3 years, in 38 out of the 120 control cases, a posterior decompression and/or spinal fixation was performed because of unsatisfactory results of the conservative therapy. In 24 (5.7%) of 422 patients, the IPD device had to be removed, and a decompression and/or pedicle screw fixation was performed because of the worsening of neurological symptoms. The authors concluded that these findings supported the effectiveness of surgery in patients with stenosis; IPD may offer an effective and less invasive alternative to classical microsurgical posterior decompression in selected patients with spinal stenosis and lumbar degenerative disk diseases.

Miscellaneous Fixations Devices

Clinical Context and Test Purpose

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with spinal stenosis and/or spondylolisthesis and those who might undergo a spinal fusion.

The question addressed in this policy is: Does the use of interspinous fixation improve the net health outcome in patients who are undergoing spinal fusion?

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are the following individuals:

- Those who have spinal stenosis and/or spondylolisthesis.
- Those who are undergoing spinal fusion.

Interventions

The therapy being considered are the following:

- interspinous fixation device alone
- interspinous fixation devices with interbody fusion

Comparators

The following practice is currently being used to treat spinal stenosis and/or spondylolisthesis: decompression.

The following practice is currently being used for individuals who are undergoing spinal fusion: interspinous fixation devices with pedicle screw construct.

Outcomes

The general outcomes of interest include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

(2020) Chen et al. completed a single center on BacFuse in the treatment of lumbar spinal stenosis with 5 years follow-up study. The authors concluded, BacFuse, as a new type of IPD, avoided the disadvantages of previous IPD and increased the fusion characteristic. It was an effective alternative treatment option for LSS. The best indication for BacFuse treatment was the lateral moderate type. For lateral severe patients, distraction combined with decompression was suggested for higher satisfaction rate. Severe central spinal stenosis was a relative contraindication for BacFuse. The authors also noted the study was limited due to the single-center and small sample size set up, especially for some types of LSS. In addition, they only took a scoring scale which may be partially biased.

(2019) Wei et al. published the results of a retrospective study that included 95 subjects with lumbar disc herniation (LDH). The subjects were treated with inter-spinal distraction fusion (ISDF) using the BacFuse® Spinous Process Fusion Plate (RTI Surgical, Inc., Marquette, MI). Symptoms and imaging were evaluated prior to surgery, immediately following surgery, 6 months post-op, and a single final visit (average was 15.4 ± 3.4 months). Follow-up assessment reported improvements from baseline in VAS from 6.7 ± 1.3 to 2.1 ± 1.4 ($p<0.001$) at final follow-up, and ODI of 33.3 ± 6.2 to 12.5 ± 5.7 ($p<0.001$) at final follow-up. Imaging showed the anterior disc height was not statistically different at the post-operative follow-up ($p=0.502$). The imaging results showed initial improvement in imaging for both posterior disc

height (18.3%) and foramina height (9.7%), only to have decreases of 2.4% and 5.1% respectively, at the final follow-up. Only 1 subject suffered a spinous process fracture as a result of a post-operative complication; it did not cause significant back discomfort and was treated non-operatively. Long-term studies with a robust sample size are needed to show the product is durable and subjects experience long-term improvement with use of the BacFuse implant for LDH.

(2018) Panchal et. al completed a multicenter, prospective, randomized, noninferiority controlled study on the anterior and lateral lumbar interbody fusion with supplemetal interspinous process fixation. All patients received single-level ALIF or LLIF with supplemental ISPF (n = 66) or pedicle screw fixation (PSF; n = 37) for degenerative disc disease and/or spondylolisthesis (grade ⩽2). The randomization patient ratio was 2:1, ISPF/PSF. Perioperative and follow-up outcomes were collected (6 weeks, 3 months, 6 months, and 12 months). The results noted for ISPF patients, mean posterior intraoperative outcomes were blood loss, 70.9 mL; operating time, 52.2 minutes; incision length, 5.5 cm; and fluoroscopic imaging time, 10.4 seconds. Statistically significant improvement in patient Oswestry Disability Index scores were achieved by just 6 weeks after operation (P < .01) and improved out to 12 months for the ISPF cohort. Patient-reported 36-Item Short Form Health Survey and Zurich Claudication Questionnaire scores were also significantly improved from baseline to 12 months in the ISPF cohort (P < .01). A total of 92.7% of ISPF patients exhibited interspinous fusion at 12 months. One ISPF patient (1.5%) required a secondary surgical intervention of possible relation to the posterior instrumentation/procedure. In conclusion, ISPF can be achieved quickly, with minimal tissue disruption and complication. In supplementing ALIF and LLIF, ISPF supported significant improvement in early postoperative (⩽12 months) patient-reported outcomes, while facilitating robust posterior fusion. The authors acknowledge that heterogeneity in footprint size is a potential limitation; however, this remains an inherent limitation of any interbody fusion clinical study in which patient anatomy is variable. A perceived limitation of ISPF is that it cannot afford the same degree of lordotic correction as PSF and could potentially introduce local kyphosis by distracting the interspinous space. However, although PSF may provide greater mechanical leverage to induce lordosis, this may incur facet violation and again predispose to ASD. Although no definitive evidence exists differentiating PSF as a more effective posterior fixation modality with respect to sagittal balance maintenance, the diminished rates of ASD with ISPF provide compelling evidence that ISPF, despite the perceived limitations, can provide effective sagittal correction and preservation. Furthermore, the use of large anterior/lateral lordotic angled intervertebral cages can provide a source lordosis induction without necessitating significant induction via posterior manipulation. The authors do acknowledge that local kyphosis may occur if the ISPF device is oversized or inappropriately placed within the interspinous space; however, proper device trialing and placement mitigates this risk. The authors acknowledge that limitations did exist within this study, including the heterogeneity of PSF techniques. However, as emphasized, the use of a PSF control group significantly marginalizes any posterior technique selection bias. Accordingly, outcomes with ISPF should be considered within the context of what is clinically meaningful, with comparison to PSF outcomes contemplated only when appropriate. Heterogeneity also existed in the use of anterolateral plating; however, use of randomization and statistical controlling demonstrated a marginalized effect. Furthermore, standardization of concomitant medication(s) and intraoperative use of biologics were not performed; however, randomization of cohorts resulted in comparable distributions between cohorts that align with routine standard of care.

(2017) Huang et al. completed a randomized controlled trial to investigate the clinical feasibility and validity of interspinous fastener (ISF) for lumbar degenerative diseases. From October 2013 to March 2014, a total of 46 patients suffering from lumbar degenerative diseases underwent posterior lumbar interbody fusion (PLIF) randomly augmented by ISF or pedicle screws. The clinical outcome was primarily measured by Oswestry Disability Index (ODI) score. The minimal clinical important difference (MCID) was defined as an eight-point decrease in ODI. The second clinical outcome measurement was Japanese Orthopedic Association (JOA) score. Interbody fusion rates were evaluated by lumbar plain radiograph

and computed tomography (CT) scan. Complications were also compared between groups. Statistical analyses were performed by SPSS version 13.0. Sample size calculation was performed before the study. The type I error α was set at 0.05 and the type II error β at 0.1. Based on these assumptions and adding 10% for possible dropouts, sample size calculations indicated that a total of 46 patients were required for the study. Parametric data was compared by independent t-test and categorical variables were compared using χ2 -tests or Fisher exact tests depending on the sample size. A P-value of less than 0.05 was considered significantly statistically different. Fleiss kappa coefficients were calculated for intra-observer and inter-observer reliability. The results noted a total of 43 patients completed the follow-up, with 22 cases in the ISF group and 21 patients in the pedicle screws group, respectively. Less intraoperative blood loss and shorter operation time were observed in the ISF group. The mean ODI significantly declined in both groups, with the ISF group's decreasing from preoperative 43.3 ± 8.2 to 21.4 ± 3.5 at 24-month follow-up and the pedicle screws group's decreasing from preoperative 42.9 ± 7.9 to 22.5 ±3.8 at 24-month follow-up, respectively. The ODI changes between groups had no statistical difference (P > 0.05). Of the 43 patients, 33 patients achieved an MCID. The bone fusion rate was 77.3% according to X-rays and 68.2% according to CT scans in the ISF group, and 81.0% according to X-rays and 76.2% according to CT scans in the pedicle screws group at the final follow-up. The intra-observer and inter-observer reliability assessed by the kappa value were 0.93 and 0.89, respectively. One patient in the pedicle screws group demonstrated screw loosening at the 6-month follow-up but was asymptomatic. One patient with spondylolisthesis in the ISF group demonstrated cage subsidence during the follow-up but also without related symptoms. In conclusion, the less invasive ISF combined with PLIF provided comparable clinical outcome and a similar bone fusion rate to pedicle screws. The ISF could potentially serve as a new alternative for lumbar degenerative diseases. Several limitations should be noted. First, despite no statistical difference, heterogeneity in baseline characteristics, including diagnosis, smoking and index levels, do exist between groups and may potentially generate bias. Second, it is well established that the most accurate standard to determine fusion is surgical exploration. Despite improvement in CT scans in fusion assessment, neither radiographs nor CT scans can demonstrate the same accuracy as surgical exploration. The third potential weakness of the study is the relatively short follow‐up period.

(2017) Lopez et al. systematically evaluated the literature on lumbar spinous process fixation and fusion devices (excluding dynamic fixation and spinous process spacer devices). A total of 15 articles met the inclusion and exclusion criteria, including 4 comparative studies (level III evidence), 2 case series (level IV evidence), and 9 in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous process fixation devices to pedicle screws in individuals undergoing interbody fusion and two other studies included interspinous process fixation devices alone or pedicle screws plus an interspinous process fixation device in individuals undergoing interbody fusion. Use of an interspinous process fixation device decreased surgical time and blood loss compared to pedicle screw implantation procedures, however, study designs were methodologically flawed and biased when reporting outcomes of reduced spinal instability at 1 year, rates of device failure, bony fracture, and complications. No comparative studies exist that report either complication rates of interspinous process fixation devices to other treatment modalities or length of hospital stay for interspinous process fixation devices compared to pedicle screw implantation procedures.

(2014) Sclafani et al. retrospectively reviewed medical records to evaluate postoperative clinical outcomes in 53 individuals who were implanted with a second generation polyaxial PrimaLOK™ SP Interspinous Fusion System (OsteoMed, Addison, TX). All subjects reached the 1-year postoperative time point. Subjects had a mean age of 60 years (range, 34-89 years) at the time of surgery. The most common primary surgical indications were degenerative disc disease with stenosis (45.3%), herniated disc (18.9%) and spondylolisthesis (11.3%). A total of 34 subjects were implanted with the PrimaLOK SP device, 16 subjects received both a polyetheretherketone interbody cage and the PrimaLOK SP device, and 3 subjects received pedicle screw instrumentation, a polyetheretherketone interbody cage and the

PrimaLOK SP device. Complications included intraoperative dural tear (n=1) and readmission for intractable pain after a post-discharge mechanical fall (n=1). There were no cases of fracture or migration of the device observed at the 6-week postoperative time point; however, there were 4 cases of hardware removal and 2 cases of re-operation for adjacent level disease during the follow-up period. The pain index score improved from 7.17 ± 1.68 to 4.48 ± 2.8 (p=0.0001, 22 months average follow-up) for the overall study group. There was no difference in Macnab classification score between different primary surgical indication groups ($\chi 2$ p>0.05). Limitations of this review include the retrospective study design and lack of data collection on preoperative VAS scores of low back and leg pain and validated quality of life of life data to distinguish if the postoperative improvement was predominantly in axial low back pain, radicular lower extremity pain or neurogenic claudication.

(2012b) Kim et al. retrospectively compared 40 individuals who underwent single level spinal fusion with the CD HORIZON® SPIRE™ (Medtronic Sofamor Danek, Inc., U.S.A., Memphis, TN) interspinous fusion device (IFD) for lumbar spine disease (n=12, degenerative spondylolisthesis; n=2, intervertebral disc herniation; n=26, spinal stenosis) to 36 individuals with similar lumbar spinal disorders (n=10, degenerative spondylolisthesis; n=7, foraminal stenosis; n=1, intervertebral disc herniation; n=18, spinal stenosis) who underwent spinal fusion with pedicle screw fixation. All individuals in both groups underwent posterior lumbar interbody fusion with a polyetheretherketone cage or a titanium alloy cage. Both groups were evaluated using dynamic lateral radiographs, visual analogue scale (VAS), and a Korean version of the Oswestry Disability Index (K-ODI) scores. The mean follow-up period was 14.2 months in the IFD group and 18.3 months in pedicle screw group. At 1-year follow-up, there was an improvement in the mean preoperative to postoperative VAS scores from 7.16 (± 2.1) to 1.3 (± 2.9) and 8.03 (± 2.3) to 1.2 (± 3.2) (p<0.05) in the IFD and pedicle screw groups, respectively. The K-ODI was reduced significantly in an equal amount in both groups 1 year postoperatively (p<0.05); however, no statistical difference in clinical outcomes was noticed between the 2 groups. Postoperative radiographs in the IFD group showed less improvement of instability at the instrumented level compared with the pedicle screw group. A higher incidence of adjacent segmental degeneration was reported in the pedicle screw group (n=13, 36.1%) than in the IFD group (n=5, 12.5%; p=0.029). In the IFD group, 1 individual had sustained back pain, and lumbar CT revealed fusion failure and inferior articular process fracture. There were no major surgery-related complications such as deep infection, nerve root injury, and cerebral spinal fluid (CSF) leakage in the IFD group; however, in the pedicle screw group, 3 individuals developed deep infection, 2 individuals experienced CSF leakage, and 1 individual required re-operation for a postoperative epidural hematoma. Limitations of this study include the retrospective, nonrandomized design, the heterogeneous population of participants in terms of preoperative diagnoses, and a relatively short-term follow-up period.

(Kaibara, 2012; Kim, 2012a and Karahalios, 2010 et al.) The available evidence in the peer-reviewed published medical literature comparing the Aspen® Spinous Process Fixation System (Zimmer Biomet Spine, Inc, Westminster, Colorado) to standard pedicle fixation includes two articles describing the biomechanical effect of the device on cadaver spines and a small prospective study evaluating individuals with a primary diagnosis of lumbar spinal stenosis (with pain) treated with the Aspen device or an interspinous process spacer. Of the 6 individuals implanted with the Aspen device (as a stand-alone procedure), 2 (33%) had postoperative spinous process fractures observable on computed tomography (CT). Limitations of this study include the small sample size, heterogeneous population, and lack of outcome measures reporting a change in Oswestry Disability Index (ODI) or a reduction in pain medication usage.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input from 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.

2018 Input

Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery for individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input 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.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net health outcome. While some respondents considered the shorter recovery time and lower complication rate to be an advantage compared to fusion, others noted an increase in complications and the need for additional surgery with the device.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, clinical input is not generally supportive of a clinically meaningful improvement in net health outcomes, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy alone.

Further details from clinical input are included in the Appendix.

2011 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 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 technology investigational, stating that it has a role in the treatment of selected patients with neurogenic intermittent claudication.

2009 Input

In response to requests, 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 indicated data were sufficient to demonstrate improved outcomes.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or

National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience (ASPN)

(2022) The ASPN published a consensus guidance on the best practices for minimally invasive lumbar spinal stenosis treatment 2.0 (MIST) which stated the following information:

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
    - In conclusion, there are many studies in the literature supporting the use of interspinous spacers for pain relief, improved mobility, and decreased opiate utilization. However, most of the studies are retrospective, albeit some have protracted follow-up of 5 years. There is a void of prospective RCTs comparing the efficacy of interspinous spacers to CMM or open surgery.

The Australian Medical Services Advisory Committee (MSAC)

(2017) The Australian Medical Services Advisory Committee provided a public summary document for minimally invasive, lumbar decompression and dynamic stabilization using an interlaminar device, with no rigid fixation to the vertebral pedicles, of one or two lumbar motions which noted the following information: MSAC considered a submission to include a service using the Coflex Interlaminar Stabilization device (hereafter the device) in the MBS. The proposed service involves use of 2 the device to stabilize the spine following decompression, without the need for fusion, in patients with lumbar spinal stenosis and mild degenerative instability of one or two lumbar motion segments.

- MSAC noted that the submission only compared use of the device to decompression with fusion for people with lumbar spinal stenosis. MSAC noted that the PICO Sub-Committee (PASC) had asked that use of the device also be compared with decompression alone because of uncertainty about whether outcomes in people undergoing decompression and fusion were any better than outcomes in people undergoing decompression alone. Studies published around the time the protocol was written had compared decompression and fusion with decompression alone in people with lumbar spine stenosis (with or without spondylolisthesis). Two years post-surgery, these studies reported similar levels of disability due to back pain.
- MSAC questioned the applicant's claim that decompression and fusion, rather than decompression alone, was the appropriate comparator for use of the device. In addition to the two studies identified above, MSAC noted that a Cochrane review of spinal surgery for lumbar spinal stenosis was unable to identify any clear benefit of surgery compared to nonsurgical treatment.
- MSAC noted that the submission did not provide a valid reason for failing to compare use of the device with decompression alone and as a result, the committee was unable to determine the relative safety and effectiveness of using the device compared with decompression alone. With respect to the comparator of decompression and fusion, MSAC noted that the evidence to support listing of the device relied upon a single, low-quality trial in people with moderate spinal stenosis with low back pain (>5/10) and with or without up to Meyerding grade I spondylolisthesis (the Investigational Device Exemption (IDE) trial).
- MSAC had several concerns about the quality of the IDE trial including that the study was unblinded and that study outcomes may have been selectively reported. MSAC also noted that in the analysis of disability due to back pain five years post-surgery, 30% of patients were excluded from the analysis because they had had a secondary surgical procedure or epidural injection.

- Given the uncertainty around clinical effectiveness, MSAC was unable to support the listing of the use of this device. MSAC requested this advice be provided to PLAC. MSAC noted that any resubmission required new high quality trial evidence comparing use of the device with decompression alone and comparing use of the device with decompression and fusion and for each of the indications requested (lumbar spinal stenosis with or without mild instability and mild instability alone).
- Given MSAC's concerns as to whether decompression and fusion was any better than decompression alone, MSAC queried whether decompression and fusion should be funded on the MBS. MSAC suggested that a review of the current evidence for decompression and fusion in people with lumbar spine stenosis be undertaken. MSAC noted that the MBS Review of Spinal Surgery is currently reviewing available MBS items for spinal surgery. However, MSAC considered that an in-depth review of the evidence for decompression and fusion in this population was still warranted. MSAC noted that it would be helpful if the review considered utilization and provider level data from the Department. MSAC foreshadowed that if there was insufficient evidence for decompression and fusion in lumbar spinal stenosis then a wider review including decompression and/or fusion for other conditions may be recommended.

International Society for the Advancement of Spine Surgery (ISASS)

(2016) The International Society for the Advancement of Spine Surgery published recommendations and coverage criteria for decompression with interlaminar stabilization. The Society concluded that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Criteria included coverage rationale only pertains to patients with moderate lumbar spinal stenosis at 1 or 2 contiguous levels who do not present with gross instability because interlaminar stabilization has only been used and tested in this patient group:

- At least moderate lumbar stenosis (>25% reduction of the anteroposterior dimension) at 1 or 2 contiguous levels between L1 and L5.
- Absence of gross angular or translatory instability of the spine at index or adjacent levels.
- 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.
- Only experienced surgeons who have undergone training on use of the device should perform the procedure.
- This ISASS policy does not formally address coverage rationale for interspinous distraction devices without decompression pending further data and review of this type of procedural approach in treating LSS.

The National Institute for Health and Care Excellence (NICE)

(2010) The National Institute for Health and Care Excellence (NICE) published a guideline on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication which indicated:

> "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® Interspinous Process Decompression System.)

The North American Spine Society (NASS)

(2018) The North American Spine Society (NASS) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression, 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."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
	22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
	22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
	22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
	22899	Unlisted procedure, spine *[when specified as insertion of an interspinous process distraction or fixation device]*
HCPCS		
	C1821	Interspinous process distraction device (implantable)
ICD10-PCS		ICD-10-PCS codes are only used for inpatient services

Codes	Number	Description
	0RH008Z, 0RH038Z,0RH048Z, 0RH108Z,0RH138Z, 0RH148Z, 0RH408Z, 0RH438Z,0RH448Z, 0RH608Z,0RH638Z, 0RH648Z,0RHA08Z, 0RHA38Z,0RHA48Z	Surgical, upper joints, insertion, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)
	0SH008Z, 0SH038Z,0SH048Z, 0SH308Z, 0SH338Z, 0SH348Z	Surgical, lower joints, insertion, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)
	0RP008Z, 0RP038Z,0RP048Z, 0RP108Z,0RP138Z, 0RP148Z, 0RP408Z, 0RP438Z,0RP448Z, 0RP608Z,0RP638Z, 0RP648Z,0RPA08Z, 0RPA38Z,0RPA48Z	Surgical, upper joints, removal, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)
	0SP008Z, 0SP038Z,0SP048Z, 0SP308Z, 0SP338Z, 0SP348Z	Surgical, lower joints, removal, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)
Type of Service	Surgery	
Place of Service	Inpatient	

POLICY HISTORY

Date	Action	Action
June 2023	Annual Review	Policy Renewed
February 2023	Annual Review	Policy Revised

Date	Action	Action
February 2022	Annual Review	Policy Revised
February 2021	Annual Review	Policy Revised
October 2020	Interim Review	Policy Revised
February 2020	Annual Review	Policy Renewed
February 2019	Annual Review	Policy Revised
February 2018	Annual Review	Policy Renewed
February 2017	Annual Review	Policy Revised
February 2016	Annual Review	Policy Revised
March 2015	Annual Review	Policy Renewed
April 2014	Annual Review	Policy Renewed
May 2013	Annual Review	Policy Revised
May 2012	Annual Review	Policy Renewed
June 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.

Appendix

2018 Clinical Input

Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain and no or grade 1 spondylolisthesis who failed conservative treatment would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. 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.

Respondents

Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)
- International Society for Advancement of Spine Surgery (ISASS)
- Patrick W. Hitchon, MD, Professor of Neurosurgery and Bioengineering, Department of Neurosurgery, identified by University of Iowa Hospitals & Clinics
- Anonymous, MD, Professor of Neurosurgery and Chairman, identified by an academic medical center
- Thiru Annaswamy, MD, Physical Medicine and Rehabilitation, Veterans Administration North Texas Health Care System, identified by the American Academy of Physical Medicine and Rehabilitation
- Anonymous, MD, Physical Medicine and Rehabilitation, identified by the American Academy of Physical Medicine and Rehabilitation

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by a specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a specialty society and/or physician member designated by a specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA nor any Blue Plan.

Clinical Input Ratings

Indication	Respondent	Specialty	Identified by	Confidence Level That Clinical Use Expected to Provide Clinically Meaningful Improvement in Net Health Outcome: Yes or No	NO: High 5	NO: Intermediate 4	NO: Intermediate 3	NO: Intermediate 2	NO: Low 1	YES: Low 1	YES: Intermediate 2	YES: Intermediate 3	YES: Intermediate 4	YES: High 5	Confidence Level that Clinical Use is Consistent with Generally Accepted Medical Practice: Yes or No	NO: High 5	NO: Intermediate 4	NO: Intermediate 3	NO: Intermediate 2	NO: Low 1	YES: Low 1	YES: Intermediate 2	YES: Intermediate 3	YES: Intermediate 4	YES: High 5
Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	AANS/CNS	Neurosurgery		Yes								■			Yes									■
	ISASS	Spine Surgery		NR											No	■									
	Dr. Hitchon	Neurosurgery	U Iowa	Yes						■					Yes						■				
	Anonymous	Neurosurgery	AMC	No					■						No					■					
	Dr. Annaswamy	Phys Med & Rehab	AAPM&R	No			■								No			■							
	Anonymous	Phys Med & Rehab	AAPM&R	No				■							No			■							

NR=not reported; grey shaded=not reported

Respondent Profile

	Specialty Society	
#	Name of Organization	Clinical Specialty

1	American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)		Neurosurgery		
2	International Society for Advancement of Spine Surgery (ISASS)		Spine surgery		
	Physician				
#	**Name**	**Degree**	**Institutional Affiliation**	**Clinical Specialty**	**Board Certification and Fellowship Training**
Identified by University of Iowa Hospitals & Clinics					
3	Patrick W. Hitchon	MD	Professor of Neurosurgery and Bioengineering, Department of Neurosurgery University of Iowa Hospitals & Clinics	Neurosurgery	American Board of Neurological Surgery; Fellowship - Cardiovascular Physiology, University of Iowa Hospitals & Clinics, Iowa City, Iowa
Identified by an Academic Medical Center					
4	Anonymous	MD		Neurosurgery	American Board of Neurological Surgery
Identified by American Academy of Physical Medicine and Rehabilitation					
5	Thiru Annaswamy	MD	Veterans Administration North Texas Health Care System	Physical Medicine and Rehabilitation	Physical Medicine and Rehabilitation
6	Anonymous	MD		Physical Medicine and Rehabilitation	FAAPMR, Pain Medicine, Sports Medicine

Respondent Conflict of Interest Disclosure

#	1) Research support related to the topic where clinical input is being sought	2) Positions, paid or unpaid, related to the topic where clinical input is being sought	3) Reportable, more than $1,000 healthcare-related assets or sources of income for myself, my spouse, or my dependent children related to the topic	4) Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical

					where clinical input is being sought		input is being sought	
	YES/NO	***Explanation***	***YES/NO***	***Explanation***	***YES/NO***	***Explanation***	***YES/NO***	***Explanation***
1	No		No		No		No	
2	No		No		No		No	
3	No		No		No		No	
4	No		No		No		No	
5	No		No		No		No	
6	No		No		No		No	

Individual physician respondents answered at an individual level.Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.
NR = not reported.

Responses

- We are seeking your opinion on whether using the interventions for the below indications provide a clinically meaningful improvement in net health outcome. Please respond based on the evidence and your clinical experience. Please address these points in your response
    - Relevant clinical scenarios (e.g., a chain of evidence) where the technology is expected to provide a clinically meaningful improvement in net health outcome;
    - Any relevant patient inclusion/exclusion criteria or clinical context important to consider in identifying individuals for this indication;
    - Supporting evidence from the authoritative scientific literature (please include PMID).

#	Rationale
1	Interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade I spondylolisthesis who failed conservative treatment provides a clinically meaningful improvement in net health outcomes. The rationale is that the addition of interlaminar spacer may provide the additional stability for patients with micro-instability, or decrease the chance of iatrogenic micro-instability when extensive facet joint resection is needed for decompression. The addition of interlaminar spacer might also help with pain from facet arthropathy at the treated level from unloading the facet joint. Patients with back pain predominant lumbar spinal stenosis with and without grade I spondylolisthesis represent a challenging clinical scenario. A valid comparator in this predominant back pain population would be spinal decompression surgery with fusion. As mentioned in the evidence summary, the shorter recovery time and lower complication rate associated with decompression and interlaminar spacer when compared with decompression and fusion would be expected to and does demonstrate a clinically meaningful improvement in net health outcomes. The assertion that Swedish Spinal Stenosis Study and SLIP results would remove the decompression and fusion comparator is not valid. The study groups in those two studies were not identical and SLIP did show clinical benefit of decompression and fusion. We believe that this question is beyond the scope of this query, and should be addressed in a wider evidence-based review. There is now increasing evidence of the durable noninferiority of spinal decompression with interlaminar spacer versus spinal decompression and fusion in appropriately selected patients. • Musacchio MJ, Lauryssen C, Davis RJ, et al. Evaluation of decompression and interlaminar stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. *Int J Spine Surg*. 2016;10:6. PMID 26913226

2	The "Population" is now described as a Stenosis patient with "predominant back pain."The ILS (coflex) population has never been defined as having "predominant back pain." and the population described by the PICO does not comply with the PMA approval by the FDA or with the ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage, Indications, Limitations, and/or Medical Necessity on Decompression with Interlaminar Stabilization (D+ILS). We believe the inclusion of "predominant back pain" for the population undermines a functional and fair clinical review as this is not an indication for ILS. Lumbar Spinal Stenosis patients do not typically have "predominant back pain". We believe it is clinically inappropriate to include this in the patient population description and recommend removal. The ILS PRCT's did not study this patient, lumbar spinal stenosis with "predominant back pain," but rather, the PRCT's conducted were on lumbar spinal stenosis patients with neurogenic claudication, leg pain and with back pain. Never is it contemplated that the primary symptom is "predominant back pain" nor is this the patient ("Population") defined in any of the studies referenced in the Evidence Review. It appears these changes were made without clinical input from spine surgeons or without consideration of the Davis publication or the ILS FDA approved Indications for Use. Limiting the population for ILS devices with decompression to those patients with "predominant back pain" is inconsistent with the clinical use of ILS and the FDA approved label. The US FDA label for ILS indications states: "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" This label paints a clear picture of a patient with symptoms of moderate to severe lumbar spinal stenosis. ***ILS (coflex) is actually contraindicated in patients with "axial pain only, with no leg, buttock, or groin pain." *** The IDE trial included patients with an average Oswestry Disability Index of 61 and an MRI with severe or moderate radiographic stenosis. Patients enrolled in the trial had similar visual analog scale back and visual analog scale leg scores at baseline. Surgery for "predominant back pain" is a complex topic distinct from the evidence for lumbar spinal stenosis. Surgical treatment of lumbar spinal stenosis is uncontroversial, and we do not believe it is appropriate for ES to conflate/confuse this with "predominant back pain" surgery. We also are having difficulty understanding why ES is having such difficulty determining the net health benefits of the ILS procedure. ISASS believes the current evidence is overwhelming as reflected in the ISASS statement and position, as well as the North American Spine Society (NASS) from May 2018.
3	Interspinous non-fusion devices (IPD) such as X-Stop, Coflex, Diam, have been shown to be equally effective in the short term, as non-fusion laminectomy in the treatment of lumbar stenosis and neurogenic claudication without instability. A meta-analysis (Deyo et al, Interspinous Spacers Compared to Decompression or Fusion for Lumbar Stenosis: Complications and Repeat Operations in the Medicare Population, Spine2013 May 1; 38(10)) using Medicare inpatient claims between 2006 and 2009 data, compared comorbidity for patients with spinal stenosis having surgery (n=99,084) with (1) an interspinous process spacer alone; (2) laminectomy and a spacer; (3) decompression alone; or (4) lumbar fusion (1-2 level).Patients receiving a spacer alone had fewer major medical complications than those undergoing decompression or fusion surgery (1.2% versus 1.8% and 3.3% respectively) but had higher rates of further inpatient lumbar surgery (16.7% versus 8.5% for decompression and 9.8% for fusion at 2 years). Hospital payments for spacer surgery were greater than for decompression alone but less than for fusion procedures. Their conclusion was that "Compared to decompression or

	fusion, IPD pose a trade-off in outcomes: fewer complications for the index operation, but higher rates of revision". A second meta-analysis from Australia (Phan et al, Interspinous process spacers versus traditional decompression for lumbar spinal stenosis: systematic review and meta-analysis, J Spine Surg 2016;2(1):31-40) reviewed 11 published studies comparing interspinous devices with decompression alone. The conclusion of the analysis showed "no superiority for mid- to long-term patient-reported outcomes for IPD compared with traditional bony decompression, with lesser surgical complications (4% vs. 8.7%, P=0.03) but at the risk of significantly higher reoperation rates (23.7% vs. 8.5%, P<0.00001). A third review of the literature in 2017 showed that though the initial hospital stay may be shorter with the devices than laminectomy alone, a higher percentage of instrumented patients will require additional surgery with time (6-85%, Ravindra, Ghogawala, Neurosurg Clin N Am 28 (2017) 321-330). This will add to the cost, superseding laminectomy, and undermining any benefits of these implants.
4	We do not use these devices in our neurosurgery practice. Based on findings from the literature, and experiences gained from caring for patients who had these devices implanted by outside surgeons, we are not convinced they are in the patient's best interest.
5	No response
6	No response

NR = not reported

- Based on the evidence and your clinical experience for each of the clinical indications described in Question 1:
    - Respond YES or NO for each clinical indication whether the intervention would be expected to provide a clinically meaningful improvement in net health outcome; AND
    - Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	Indications	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	Yes			X		
2	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1	NR					

	spondylolisthesis who failed conservative treatment.						
3	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	Yes	X				
4	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No	X				
5	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No			X		
6	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No		X			

NR = not reported

- Based on the evidence and your clinical experience for each of the clinical indications described in Question 1:
    - Respond YES or NO for each clinical indication whether this intervention is consistent with generally accepted medical practice; AND
    - Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

#	Indications	YES / NO	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5

1	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	Yes				X	
2	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No					X
3	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	Yes	X				
4	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No	X				
5	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No				X	
6	Use of interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment.	No				X	

NR = not reported

- Additional narrative rationale or comments regarding clinical pathway and/or any relevant scientific citations (including the PMID) supporting your clinical input on this topic.

#	Additional Comments

1	Interlaminar spacer with spinal decompression surgery in individuals with spinal stenosis, predominant back pain, and no or grade I spondylolisthesis who failed conservative treatment provides a clinically meaningful improvement in net health outcomes also when compared directly to those patients who underwent spinal decompression alone. The pivotal RCT, conducted in a patient population who had moderate-to-severe lumbar spinal stenosis with or without spondylolisthesis, showed that a greater proportion of patients who received coflex plus decompression achieved the primary endpoint of composite clinical success compared with decompression alone. The difference in success was in part attributed to a larger number of patients receiving "rescue" epidural and facet injections. Although there is potential bias from the unblinded decision of committing certain patients (more in the decompression arm) to injections without a clear algorithm there is also very clearly the potential for a confounding or masking effect of these interventions with respect to back pain. The increased use of these measures in the postoperative period could be interpreted as a failure to address the underlying pain generator and their increased use may represent a failure of the study treatment to address low back pain. More long-term results are expected. • Schmidt S, Franke J, Rauschmann M, et al. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. *J Neurosurg Spine*. Apr 2018;28(4):406-415. PMID 29372860
2	ISASS has previously reviewed the ILS evidence and has determined that there is a net health benefit with the use of an ILS (coflex being the only one currently marketed) and have issued a coverage recommendation. We have reviewed the BCBS Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) Evidence Summary. In general, this is a comprehensive review, but we have the following comments for consideration. • Interspinous Spacers (ISP) versus Interlaminar Stabilization (ILS) devices: We feel that it is confusing to include these two classes of devices in the same context. The US FDA labels and IDE trials for current and previous interspinous process (ISP) devices are for implantation without direct surgical decompression (ie, stand-alone). The US FDA label and IDE trial for the Interlaminar Stabilization (ILS) device are for implantation with direct surgical decompression. ISP and ILS devices are biomechanically different, have different mechanisms of action and are intended for distinctly different patient populations with significant differences in disease severity. ISP devices are placed between the spinous processes without direct decompression, with their only point of contact being the spinous process. ILS devices, although also placed between the spinous processes are combined with a direct decompression and their main point of contact and fixation is on the vertebral lamina. It is unfortunate that these two types of devices are being confounded, particularly considering the poor historic clinical outcomes associated with the ISP devices. The ILS devices have a much stronger long-term (5 years published) clinical evidence. • Please note that our Coverage Recommendation, issued November 2016, is applicable to ILS devices and is silent on the ISP devices. By combining these two types of devices Evidence Street (ES) is blurring the distinction between them. This is further confounding in that ES is citing an off-label use ILS study which has no relevance to ILS evidence and coverage recommendations. Moojen et al. reported on a study of coflex, used off-label, functionally as an ISP without a direct decompression and not as an ILS is intended to be used with direct decompression. As expected when using a device inappropriately the results of the Moojen trial are unfavorable, and unjustly is a poor reflection on the proper clinical use of the ILS device. The use of the ILS in the Moojen study is not consistent with the FDA Approved Indications for Use for coflex, which is the only ILS available in the U.S. In order to

avoid this confusion and misrepresentation we recommend removing Moojen from this evidence review.

PICO Table

- With regards to the PICO Table ES provided for clinical input, we feel the new addition of the Population which now includes "predominant back pain" confuses and confounds the interpretation of the evidence. ES has newly and wrongly changed the population of patients by adding with "predominant back pain" to the Population category of the PICO table. In April 2018, ISASS submitted our response to your request for Clinical Input. We agreed with the Population in the PICO Table that was submitted at that time. We are perplexed by the change of the Population definition in the current PICO table. The ILS intended population was changed to include an inappropriate qualifier as having "predominant back pain." The addition of "predominant back pain" is an improper clinical indication for ILS.ILS is not intended for this patient population nor does any of the evidence cited utilize this indication. It appears these changes were arbitrary and made without clinical input from spine surgeons or without consideration of the Davis publication or the ILS FDA approved Indications for Use. It is clear that the PRCT's conducted using the ILS were on lumbar spinal stenosis patients with neurogenic claudication, leg pain and with concomitant back pain but never is it contemplated that the primary symptom is "predominant back pain".
- It is inappropriate and not productive to evaluate the published evidence in the context of an arbitrarily defined PICO, in which the studies conducted did not include the patient population that is now suddenly being defined in the PICO.
- The surgical treatment of patients with "predominant back pain" is a complex and controversial topic, the discussion of which cannot be subordinated to a policy on stenosis. Surgical treatment of stenosis is evidence-based, and ES cannot confuse or confound this with the controversies surrounding "predominant back pain" surgery. Lumbar spinal stenosis causes claudication and radicular pain, and its surgical treatment targets those symptoms. Secondarily, patients with stenosis may have concomitant back pain which may respond to surgery in some circumstances.
- The addition of "predominant back pain" is inconsistent with the clinical use of ILS and the FDA approved label. The US FDA label for ILS states it is indicated for:
- "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"
- ILS is actually contraindicated in patients with "axial pain only, with no leg, buttock, or groin pain." This label paints a clear picture of a patient with symptoms of moderate to severe lumbar spinal stenosis.
- The IDE trial included patients with an average Oswestry Disability Index of 61 and an MRI with severe or moderate radiographic stenosis. Patients enrolled in the trial had similar visual analog scale back and visual analog scale leg scores at baseline.
- Regarding the Overview by Evidence-Review Indications section, again it is not surprising that ES has concluded that the evidence is "Uncertain" considering that Indication 2 has inserted the "predominant back pain" language, which makes uninterpretable all the evidence supporting the use of the ILS device.

With regards to the discussion of the SPORT study on page 3 of the ES Evidence Summary we offer the following:

- Evidence Street is correct in citing that one rationale for "surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Trial (SPORT), which found that patients

who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated non-operatively." However, Evidence Street has selectively interpreted the many follow-up and subset analyses of this landmark trial. This appears to be due to a mistaken attempt to make isolated "predominant back pain" as the primary diagnostic criterion for fusion surgery. Evidence Street stated that "nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone". This was the structure of separate studies of patients with stenosis but with and without spondylolisthesis in the trial.

- However, Evidence Street fails to note that the results for patients undergoing fusion are much more nuanced than Evidence Street's mistaken attempt to isolate predominant back pain as a diagnostic criterion. Evidence Street cites Pearson et al.1 to support the statement that "patients without spondylolisthesis and with grade 1 spondylolisthesis are equally likely to have predominant back pain and predominant leg pain." However, Evidence Street fails to note that the authors' conclusion that "patients with predominant leg pain had baseline scores indicative of less severe symptoms", which is a serious confounder in the interpretation of these results. Also, only about a quarter of patients were classified as predominant back pain, and a mixed pain profile was most common. These findings limit the use of this classification as an isolated criterion.
- Evidence Street cites Pearson et al. 2 to support the assertion that "back pain improved to the same degree for the fused spondylolisthesis patients than for the unfused spinal stenosis patients at 2 years," but fails to note that patients who were fused improved more with surgery on multiple outcome measures including Oswestry Disability Index, physical function, bodily pain despite similar baseline characteristics, confounding the back pain outcomes as an isolated finding. In both the fusion and non-fusion groups, multiple univariate predictors of treatment effect have been identified that do not include back pain.3,4 Taken as a whole, the results from multiple publications of the SPORT data show that Evidence Street's attempt to isolate predominant back pain as a primary diagnostic criterion for fusion is misguided. The actual clinical reality is more nuanced.

With regards to the Inose study described on page 3 of the ES evidence summary.

- As ES noted the sample size is very small and further distributed between three treatments yielding group sizes of approximately 20 patients. The study was limited to only for one level lumbar spinal stenosis and excluded patients with foraminal stenosis. Additionally, no baseline clinical data is provided to be able to assess the severity of the lumbar spinal stenosis in these patients. For these reasons, we would suggest caution in over-interpreting this clinical report.

General comment of the ES evidence review

- In general, we would like to comment that when reviewing the evidence for the treatment of lumbar spinal stenosis is important to understand the extent of baseline pain and disability of the patient populations, rather than if they have spondylolisthesis or not. The type of treatment and the response to treatment is very dependent on the extent of stenosis and the severity of the symptoms. An lumbar spinal stenosis patient who has mild stenosis and solitary leg pain and a modest Oswestry Disability Index (<40) can be treated with a simple decompression whereas a moderate to severe stenotic patient with a high Oswestry Disability Index (>60) would require a more extensive decompression which usually requires some concomitant stabilization (fusion or ILS). For example, your Evidence Review cites two pieces of literature that question the use of fusion as an effective treatment for lumbar spinal stenosis and therefore question if it is an appropriate comparator for the ILS studies; the Forsth and Ghogawala studies. This is an apples and oranges comparison. Both of these

studies enrolled patients with far less severe disease and disability than the patients in the Davis study. The Forsth and Ghogawala studies did not have a minimum Oswestry Disability Index as part of the patient inclusion criteria. This resulted in a patient population in both studies with significantly less severe disease than those in the Davis publication. The average patient in the Forsth and Ghogawala studies (Oswestry Disability Index=42/100, 37/100 respectively) would not have been enrollable in either the Davis or the Schmidt clinical trials which had Oswestry Disability Index inclusion criteria of a minimum of 40/100 and an actual baseline average of Davis=61/100 and Schmidt= 53/100. The patients in the Forsth and Ghogawala studies are not the typical lumbar spinal stenosis patient that would be candidates for decompression with fusion and it is not surprising that decompression alone in those patients did as well as the fusion patients.

- On page 9 of the ES evidence summary under the coflex device (Interlaminar) heading there is a review of the Moojen study.
- We feel it is inappropriate to cite or highlight this study as it severely biases against ILS devices. The US FDA labels and IDE trials for current and previous interspinous process (ISP) devices are for implantation without direct surgical decompression (ie, stand-alone). The US FDA label and IDE trial for the Interlaminar Stabilization (ILS) device is for implantation with direct surgical decompression. These devices are biomechanically different, have different mechanisms of action and are intended for distinctly different patient populations with significant differences in disease profile. ISP devices are placed between the spinous processes with their only point of contact being the spinous process. ILS devices although also placed between the spinous processes their main point of contact and fixation is on the lamina.
- ISASS has a Coverage Recommendation, issued November 2016, that is applicable to ILS devices and is silent on the ISP devices. Please note that NASS also has two separate payer coverage policies, one covering ISP devices, issued in May 2014 and the other covering ILS devices, issued in May 2018.
- Evidence Street is blurring the distinction between these devices by citing of an off-label use study which has no relevance to ILS clinical evidence and coverage recommendations. Moojen et al. reported on a study of coflex, used off-label, specifically being used as an ISP without a direct decompression and not as an ILS is intended to be used with direct decompression. As would be expected the Moojen study yielded unfavorable results. It is not surprising that any device used outside of its intended use would not perform as expected. The use of ILS in the Moojen study is not consistent with the FDA Approved Indications for Use for coflex, the only ILS available in the United States. ISASS gave ES this specific feedback on this point in a previous review in March 2018 which apparently has been ignored. In order to avoid confusion in the Indications for Use of ILS devices, due to the inappropriate use in the Moojen study, we would recommend it be removed from the ES evidence review or at a minimum be disclaimed as to the off-label use.
- In the introductory paragraph headed INTERLAMINAR STABILIZATION DEVICES USED WITH SPINAL DECOMPRESSION SURGERY, page 11, the symptom of "predominant back pain" appears again.
- The ILS patient described in the Population category of the PICO would not normally have predominant back pain. Significant back pain many times is a component of the patient's presentation but if the primary disease was lumbar spinal stenosis we would not expect back pain to be the predominant symptom. The predominant symptoms would be the classic lumbar spinal stenosis symptoms of leg and buttock pain, neurogenic claudication with or without back pain. A patient with predominant back pain would have a differential diagnosis which included Degenerative Disc Disease (DDD).

	• Also on page 11, under the heading CLINICAL CONTEXT AND THERAPY PURPOSE, the first sentence states: "Coflex is not intended for patients who are not candidates for lumbar decompression or decompression with fusion". • We feel this is a very misleading statement. It would be more clinically accurate and less misleading to state that: coflex is not intended for ALL patients who are not candidates for lumbar decompression or decompression with fusion. It is shortsighted to think of all lumbar spinal stenosis patients only fitting into the decompression alone or the decompression with fusion categories. There are patients whom coflex is ideally suited who are too severe (pain, function, instability) for decompression alone but not severe enough to require a decompression with fusion. This is the ideal coflex patient, allowing a decompression while providing stabilization without having to go to the extreme highly invasive fusion surgery. Coflex provides the opportunity to avoid the extreme binary treatment for lumbar spinal stenosis that you are describing and allow an intermediate treatment for a subset of patients. • Further on this page, in the PICO, under the category PATIENTS, again the introduction of the "predominant back pain" is a new insertion which as described above makes no clinical sense and defies the designs of the studies used as evidence in this review. • The statement is made "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". We do not feel this is an accurate statement. The ideal coflex patient may have significant back pain that is concomitant with the other classic lumbar spinal stenosis symptoms such as leg/buttock pain, neurogenic claudication, relief on postural flexion and MRI evidence of central, lateral and foraminal stenosis. There is no requirement for the back pain to exceed the leg pain. Reviewing the baseline data from the Davis publication of the U.S. IDE PRCT clinical trial it can be seen from the Inclusion criteria there was no requirement for back pain to be greater than leg pain for inclusion in the study. visual analog scale back pain was required to be minimum 50/100 but no requirement for back pain to be greater than leg pain. Again if back pain were required to be greater than leg pain it would be defining a patient population more typical of DDD than lumbar spinal stenosis. The actual data from the study shows that the visual analog scale back and visual analog scale leg pain scores for patients were on average, nominally the same. • On page 12 under the OUTCOMES section, we would also suggest including Composite Clinical Success under outcomes. We believe the composite clinical success outcomes which consider several aspects of a patient's outcome, (Oswestry Disability Index, the need for subsequent intervention, neurologic status, and adverse events) give a more meaningful assessment of the net health benefit of an intervention. Looking at these outcomes individually can give a myopic and skewed perspective on a patient's clinical outcome. For example, how do you assess net health benefits if a patient has had a good Oswestry Disability Index outcome at 2 years but has had a subsequent surgery or 3 epidural injections in the interim period? Or if a patient has had a major improvement in leg pain but suffers from a neurologic drop foot. Or if at 2 years the Oswestry Disability Index has improved but immediately post-surgery they had several months of treatment for an adverse event? Using a composite clinical success that combine these possibilities in a robust endpoint and gives the clearest evidence of a net health benefit when comparing two treatments. • Under the SETTING heading also on page 12, the setting is described as "inpatient". One of the big advantages of ILS surgery particularly considering the age of the lumbar spinal stenosis population is the ability to perform the surgery in the outpatient or ASC setting. The outpatient setting can be much less stressful for these patients and usually implies a shorter anesthesia time, again which is critical for this aged population. Outpatient setting also provides less exposure to nosocomial infections which in many cases is life-threatening for the older patient.

- Under the heading COFLEX DEVICE PLUS DECOMPRESSION VS DECOMPRESSION PLUS POSTEROLATERAL FUSION on page 12, first paragraph the coflex indication is stated as "patients who have stenosis, significant back pain, and up to grade 1 spondylolisthesis".
- This is generally correct but it potentially wrongly implies that the patients must have a spondylolisthesis up to grade 1. The authors reported that 46% of the patients had a spondylolisthesis while 54% did not.
- Also in this section, you note a 14% incidence of spinous process fractures but fail to report the comparison to the fusion group which had an 11.9% spinous fracture rate which puts the 14% in clinical perspective.
- In Table 8 on page 12 the Participants column indicates N=344, Active N=262, and Comparator N=136. These are different "N's" then you report in the paragraph above. It appears by review of the SSED that the text in the paragraph is correct.
- On page 13 you note "The major weakness in this trial was its use of lumbar spinal fusion as a comparator".
- We disagree that fusion is not an appropriate comparator for this study and population.
- The Davis publication, which was conducted using fusion as the control group is considered by ISASS, our surgeon membership and other spine specialty societies as a landmark study. It was a multi-center, long-term (5 years) PRCT with a large number of patients that we consider the most compelling evidence for the clinical benefit of the ILS treatment. Conversely, your Evidence Review concludes that this study cannot be considered or at best discounted, on what is a critical piece of ILS clinical evidence.
- Rather than conclude based on the 5-year clinical outcomes data that coflex in combination with direct decompression yields a net health benefit, your Evidence Review has questioned whether decompression with fusion is an established treatment and thus whether it was an appropriate comparator to coflex. As practicing spine surgeons we do not understand, based on all available clinical and coverage information on lumbar spinal stenosis, how Evidence Street came to this conclusion. Decompression with fusion is a widely recognized and well-established treatment for a subset of lumbar spinal stenosis patients.
- Interestingly, and to our knowledge, decompression with spinal fusion for lumbar spinal stenosis is widely covered by all major commercial insurance providers including BCBS. Additionally, decompression with fusion for certain lumbar spinal stenosis patients is supported by the Coverage Policy Recommendations from the major spine specialty societies, the North American Spine Society (NASS), the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) and the International Society for the Advancement of Spine Surgery (ISASS).
- There is little clinical or practical rationale for not accepting decompression with fusion as an accepted treatment for lumbar spinal stenosis patients. The draft Evidence Review cites two pieces of literature that question the use of fusion as a comparator; the Forsth and Ghogawala studies. This is an apples and oranges comparison. Both studies enrolled patients with far less severe disease and disability than the patients in the Davis study. These studies did not have a minimum Oswestry Disability Index as part of the patient inclusion criteria. This resulted in a patient population in both studies with significantly less severe disease than those in the Davis publication. The average patient in the Forsth and Ghogawala studies (Oswestry Disability Index=42/100, 37/100 respectively) would not have been enrollable in either the Davis or the Schmidt clinical trials which had Oswestry Disability Index inclusion criteria of a minimum of 40/100 and an actual baseline average of (Davis=61/100, Schmidt= 53/100). The patients in the Forsth and Ghogawala studies are not the typical lumbar spinal stenosis patient that would be a candidate for decompression with

fusion and it is not surprising that the decompression alone patients in those studies did as well as the fusion patients.

- Another study design issue in these two studies is that the decompression and the decompression plus fusion surgical technique were not pre-specified or standardized. The Forsth study allowed surgeons to solely determine the decompression and decompression plus fusion procedures that would be performed without including any description of the procedures nor any stratification in the results of the various surgical techniques utilized. This likely had a large effect on the outcomes as various fusion techniques can have an impact on the degree of decompression that can be performed resulting in differences in outcome.
- The Davis study had a primary endpoint of composite clinical success which included four individual safety and efficacy endpoints, Oswestry Disability Index improvement (15pt), no significant adverse events, no subsequent interventions, and neurological maintenance or improvement. In order for a patient to be a success, the patient had to be successful in all four endpoints. Composite clinical success has become the standard for large PRCT's. It is preferred over a single success endpoint as it measures a patient's outcome for multiple criteria. For example, if the sole criteria for success were Oswestry Disability Index improvement and a patient had a 15 point Oswestry Disability Index improvement but also exhibited neurologic deterioration, this patient would erroneously be considered a success. In a composite clinical success endpoint study, this patient would be correctly considered a failure due to not maintaining neurologic status. An additional advantage of utilizing a composite clinical success as the success endpoint in a clinical trial is that it is a practical way of handling the survivorship bias that usually exists in these studies. In these studies, there are times when patients receive intervention subsequent to the initially assigned surgical treatment (subsequent intervention) ie, epidural steroid injections or additional surgery. Without utilizing a composite clinical success it is difficult to account for the outcomes at the final endpoint for these patients. If they have a subsequent intervention it is not appropriate to take for example their 24-month Oswestry Disability Index score knowing that it does not represent the result of the primary treatment but rather is confounded by the subsequent intervention. By using a composite clinical success that included subsequent intervention as a study failure would prevent all data collected after the subsequent intervention from confounding the patient's data who have survived to the terminal time-point without subsequent intervention.
- The use of composite clinical success as study success criteria is a comprehensive and robust methodology. By contrast, the Forsth and Ghogawala studies each had only a single success endpoint (for Forsth, Oswestry Disability Index and Ghogawala, SF-36 PCS). Additionally, in these studies, there is no description in the publications as to how the primary endpoint (Oswestry Disability Index or SF-36 PCS) was calculated at the terminal 24 months for the patients that received subsequent interventions.
- Using these two studies as evidence that decompression plus fusion is not an appropriate treatment for a subset of lumbar spinal stenosis patients is overreaching from the clinician's perspective and could withhold the clinically-appropriate treatment to many lumbar spinal stenosis patients. For these reasons, we believe decompression plus fusion is an accepted treatment for lumbar spinal stenosis patients and therefore an appropriate comparator to assess the net health benefit of an ILS treatment.
- Additionally, we find it troubling that you fail to apply the same rigorous criticisms to the two studies mentioned above and other studies used as counter-evidence throughout your review that you apply to the studies conducted with the ILS device.
- In sum, Evidence Street's negative opinion concerning the evidentiary support for coflex's net health benefit depends first upon disqualifying the rigorous Level I PRCT PMA approved by the FDA that utilized decompression with fusion as the established alternative for the relevant

population. It further depends upon disregarding that decompression with fusion is widely recognized by government agencies, Spine Specialty Societies, expert physicians, commercial insurers, and other health care stakeholders as a medically necessary and effective treatment for a subset of lumbar spinal stenosis patients. It requires doing so based on two studies that do not represent the intended population, that are methodologically flawed, and that fail to meet FDA's or Evidence Street standards for the evaluation of evidence.

- In the last sentence on page 13, which states "In addition, the underlying premise that patients with back pain and spinal stenosis do not respond well to decompression (alone or followed by non-surgical treatments for back pain) has been challenged" is inconsistent with spine clinical knowledge and practice and not substantiated with a reference. We would also reiterate that to discuss in these general terms lumbar spinal stenosis patients without clinically defining where they are on the disease continuum (mild to severe) makes it difficult and adds confusion to the broad conclusions you are drawing.
- On page 14 you indicate that the non-spondylolisthesis group analysis from the U.S. IDE PRCT IDE Study has not been published. In fact has been published: Spinal Stenosis in the Absence of Spondylolisthesis: Can Interlaminar Stabilization at Single and Multiple-levels Provide Sustainable Relief? International Journal of Spine Surgery, Vol. 12, No. 1, 2018, pp. 64-69.
- On page 14 the review states: "Another gap in evidence, not listed in the gaps table, 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." We find this statement perplexing, particularly in the area of spine. These are very difficult and challenging trials to conduct. We should encourage this level of clinical evidence commitment with a large and long-term clinical trial. It would be welcome if all devices being used in spine had such rigorous clinical evidence. We would also point out that many of the products that have received coverage recommendations from ES have an equal evidentiary basis as coflex, (ie, Minimally Invasive SI Joint Fusion.
- With regards to Table 10 on page 14 Relevance limitations: We have the same comments made relative to fusion as an appropriate comparator as above.
- With regards to Table 11 on page 14 Study Design and Conduct limitations, under Allocation 3. Allocation Concealment Unclear. In a review of the SSED study arm allocation was specified stating "The study was a prospective, randomized, multicenter, concurrently controlled clinical study. Surgeons were blinded prior to patient randomization, and patients were blinded until after surgery".
- With regards to Table 11 on page 14 Study Design and Conduct limitations, under Blinding 4. "No independent adjudication or preset criteria for subsequent intervention". We do not feel the use of independent blinded adjudication presents a potential surgeon bias in this study and a priori objective criteria would not have been possible in this study or any study of this type. In this study, the protocol with regards to subsequent intervention study reflects the usual and customary practice of clinical medicine, including the treatment of recurrent intractable pain or neurologic deterioration. It is not clinically realistic or real-world that a list of preset criteria could account for all the possible clinical circumstances that could be encountered when contemplating a subsequent treatment for a patient who has recurrent pain or a deteriorating neurologic condition.
- It is reasonable to believe that a treating surgeon would not consider performing a subsequent intervention in consultation with a patient unless it was absolutely necessary. Any other inference would suggest that spine surgeons are willing to perform an unnecessary procedure in order to bias the outcome of a study, frankly an absurd proposition.

- Additionally, when looking at the reoperation rates of this study, specifically, the Adverse Events and Secondary Surgical Procedures section on page 1535 of the publication it can be seen that the authors state that 10.7% (23/215) and 7.5% (8/115)1) were the reoperation rates for coflex and fusion respectively. This indicates a higher reoperation rate for coflex compared to fusion, which if you suspected a surgeon bias would only be biased against coflex.
- In our opinion the use of independent blinded adjudication and a priori objective criteria is ethically and practically not possible in these types of studies and based on the data does not suggest any surgeon bias related to subsequent interventions was introduced in favor of ILS.
- On page 15 under Subsection summary, ES again discounts fusion and subsequently discounts the entire IDE/PMA clinical as an appropriate comparator on the basis that 2 RCT's (Forsth and Ghogawala) showed no difference in Oswestry Disability Index scores between decompression alone and decompression with fusion. We reiterate as above our position that these studies, due to the study design and statistical flaws do not serve as a credible basis to discount decompression with fusion as an appropriate lumbar spinal stenosis treatment for this population. Among the other issues discussed, the Swedish Spinal Stenosis Study trial used a 12-point Oswestry Disability Index difference as the study's primary endpoint. Besides being a solitary endpoint, which has the disadvantages relative to composite clinical success, already discussed the use of 12 point Oswestry Disability Index difference in lieu of a 15 point Oswestry Disability Index difference is highly unusual and possibly unprecedented in spine clinical trials. On page 1416 of the publication, the authors even state that "We chose a difference of 12 conservatively since a decrease in the Oswestry Disability Index score of 15 had been suggested by the Food and Drug Administration to indicate minimally important improvement after spinal fusion surgery".ES emphasizes that the study was powered to detect a 12 point Oswestry Disability Index difference but it is interesting to note that if the more usual and accepted 15 point Oswestry Disability Index difference was used the study would be underpowered. It is unclear whether the 12 point Oswestry Disability Index difference was prescribed a priori or was it a posthoc analysis to insure adequate power in the study. Regardless, using a 12 point Oswestry Disability Index difference in lieu of the accepted 15 point lowers the success bar and biases the study outcome in favor of the more conservative procedure. Combined with the fact that based on the low baseline Oswestry Disability Index scores, the patients in these 2 studies had only mild lumbar spinal stenosis and would not have even met the enrollment inclusion criteria of the more severe lumbar spinal stenosis disease in the coflex PMA study.

Regarding the ES review of the coflex device plus decompression versus decompression alone:

- On page 17 of the ES coflex evidence summary Table 14. Relevance limitations under the category Comparator it is stated: "In the control arm, nonsurgical treatment for back pain after decompression should be described."
- The patients in this trial have already been shown to have failed conservative care for a minimum of 3 months. It does not make clinical sense that after the initial surgery to then put the patient thru another course of non-surgical treatment. Recurrence of pain after the initial procedure is an indication that the primary surgery has failed. It is unlikely that a patient that has recurrent pain after their initial treatment is going to respond to additional conservative care, and even if they did it would still indicate a failure of the initial surgical treatment and their 24-month outcome could not be attributed solely to the initial treatment.
- On page 17 of the ES coflex evidence summary Table 14. Relevance limitations under the category Outcomes it is stated: "No CONSORT reporting of harms".

- Although not in CONSORT format the authors do describe Adverse Events in the publication that show no significant differences between groups.

Regarding Table 15. Study Design and Conduct limitations under the Blinding category it is stated that: "Not blinded to treatment assignment".

- The Schmidt article clearly states that the study was randomized and the surgeon and patient did not know the treatment assignment until the time of surgery. Therefore it is unclear why "not blinded to treatment assignment "would be considered a limitation in this study.
- Additionally, in Table 15, under the Blinding category, it is stated that "No independent adjudication or preset criteria for subsequent intervention". We offer the same comment for this proposed limitation as that described in our comments on ES Table 11 regarding the coflex versus fusion PMA study.
- Table 15 indicates a limitation under Data Completeness indicating a high loss to follow-up, use of LOCF, no intent to treat analysis and power not calculated for primary outcome.
- We disagree with the statement that this study has a high loss to follow-up. We believe this is a misrepresentation or misunderstanding by ES of the study design and data presentation. The authors state that "the analysis set (mitt) consisted of 225 patients" which "at 24 months 204 patients were evaluable for analysis representing an overall 91% follow-up rate".
- Also, ES states that: "LOCF" may not be the most appropriate approach for missing data".
- We do not see any reference or discussion of an LOCF analysis in the Schmidt publication, therefore, we are unsure of the source of this comment.
- Evidence Street states that power was not calculated for primary outcome
- The Schmidt authors include a discussion on statistical analysis which includes the power calculation and rationale.
- On page 17 of the ES review, it is stated that: "The inclusion of epidural and facet joint injections in the endpoint may be inappropriate in this trial."
- Admittedly, in clinical practice, there are scenarios although not ideal, where a surgeon may need to perform an epidural steroid injection to assist a patient through an ongoing or recurrent pain episode. But in the case of performing a clinical trial, in order to objectively compare two surgical treatments and to develop the most clinically meaningful scientific evidence, we believe epidural injections should be used as a study endpoint. A surgical treatment that required fewer post-operative epidural(s) to be successful in the long-term would be considered clinically superior to one that required post-operative epidurals to maintain pain relief. This outcome data is important clinical information for a surgeon in which to choose between two surgical treatments. Therefore, a clinical trial study design for stenosis that classified an epidural as a patient failure is a preferred protocol. It gives the surgeon a true picture of what outcome to expect when utilizing either of the two surgical treatments. It would be misleading to report two-year outcomes in a study, without being clear that to achieve those outcomes it required subsequent interventions (including) epidural injections. Additionally, the fact that the same criteria (epidural constitutes a failure) are used for both study arms, does not inherently bias the study towards one or the other treatment. For these reasons, in clinical trials, we consider the use of a post-operative epidural as a patient failure appropriate.
- With regards to the Schmidt study, there are some findings not in the primary endpoint that are clinically important. First, is the finding that the ILS group showed a 5x improvement in walking distance compared to decompression alone patients which had a 2x improvement. For many patients, the ability to walk is their primary presenting complaint and restoring their ability to walk leads to significant patient satisfaction. This is particularly important in the aged

	lumbar spinal stenosis patient population in that immobility can lead to and exacerbate other comorbidities. Secondly, the ILS group had a decreased need for compensatory pain management (opioids) at every time point. Currently, the elderly are the fastest-growing demographic identified in the "opioid epidemic" and anything a surgeon can do to decrease opioid use is significant.
3	Interspinous devices may have short term benefits, with shorter hospital stays. These benefits, however, are outweighed with the need for additional surgery, exceeding that in patients undergoing decompression without such devices. These conclusions are consistent across several peer-reviewed publications.
4	Per the section above, the limitations of these devices appear so significant, compared to more standard surgical treatment approaches that we do not use them.
5	No response
6	Clinically, these devices have utility in patients that do not want to consider decompression and fusion, or those that cannot move forward with general anesthesia.

NR = not reported

- I**s there any evidence missing from the attached draft review of evidence that demonstrates clinically meaningful improvement in net health outcome?**

#	YES / NO	Citations of Missing Evidence
1	No	
2	Yes	Richard Guyer, MD; Michael Musacchio, MD; Frank P. Cammisa, Jr., MD; and Morgan P. Lorio, MD, FACS. ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage Indications, Limitations, and/or Medical Necessity. November 10, 2016. http://www.isass.org/public-policy/isass-policy-statement-decompression-with-interlaminar-stabilization/
3	No	
4	No	
5	No	
6	No	