

Medical Policy



Title: Interspinous Fixation (Fusion) Devices

See Also: *Lumbar Spine Fusion*

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: • Who are undergoing spinal fusion	Interventions of interest are: • Interspinous fixation devices with interbody fusion	Comparators of interest are: • Interspinous fixation device with pedicle screw construct	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With spinal stenosis and/or spondylolisthesis	Interventions of interest are: • Interspinous fixation device alone	Comparators of interest are: • Decompression	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity

DESCRIPTION

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

OBJECTIVE

The objective of this evidence review is to determine whether use of an interspinous fixation device improves the net health outcome when used alone or in combination with interbody fusion to stabilize the spinal segment.

BACKGROUND

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. They are intended as an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an interspinous fixation device in combination with a unilateral pedicle screw system has also been proposed. Interspinous fixation devices are not intended for stand-alone use.

For use in combination with fusion, it has been proposed that interspinous fixation devices are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated that interspinous fixation devices may be similar to pedicle screw-rod constructs in limiting the range of flexion and extension, they may be less effective than bilateral pedicle screw-rod fixation for limiting axial rotation and lateral bending.¹ There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the interspinous fixation device. There is also a potential for spinous process fracture.

Unlike interspinous fixation devices, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process (see evidence review 7.01.107). In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas interspinous fixation devices are rigid. However, interspinous fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, interspinous fixation devices could 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.

REGULATORY STATUS

The following interspinous fixation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. This list may not be exhaustive.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec Spine)
- coflex-IF® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ (Spinal Simplicity)
- PrimalOK™ (OsteoMed Spine)
- Octave™ (Life Spine)
- Spire™ (Medtronic)
- SP-Fix™ (Globus)
- SP-Link™ System (Medical Designs LLC)
- ZIP® MIS Interspinous Fusion System (Aurora Spine).

FDA product code: PEK.

Interspinous fixation devices are intended for use as an adjunct to interbody fusion. For example, the indication for the coflex-IF® implant is as:

"a posterior, nonpedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies - with up to Grade 1 spondylolisthesis."

A number of interspinous plate systems have also been cleared for marketing by the FDA.

Use of an interspinous fixation device for a stand-alone procedure is considered off-label.

POLICY

- A. Interspinous fixation (fusion) devices are considered **experimental / investigational** for any indication, including, but not limited to, use:
1. in combination with interbody fusion, **OR**
 2. alone for decompression in patients with spinal stenosis.

Policy Guidelines

Clinical input has identified potential exceptions where the devices might be considered medically necessary, such as patients with small pedicles where pedicle screws could not be safely placed.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed though February 28, 2020.

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 the quality and credibility. To be relevant, studies must represent one or more intended clinical uses 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.

Clinical Context and Therapy Purpose

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does interspinous fixation improve the net health outcome in patients who are undergoing spinal fusion or who have spinal stenosis and/or spondylolisthesis?

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

Patients

The relevant population of interest is patients who are undergoing spinal fusion or who have spinal stenosis and/or spondylolisthesis.

Interventions

The therapy being considered is interspinous fixation (fusion) devices.

Comparators

The following therapies/tools/rules/practices are currently being used to make decisions about interspinous fixation (fusion) devices.

For individuals who are undergoing spinal fusion, comparators of interest are interspinous fixation devices with pedicle screw construct.

For individuals with spinal stenosis and/or spondylolisthesis, the comparator of interest is decompression.

Outcomes

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

Interspinous Fixation Device With Fusion

A systematic review by Lopez et al (2017) evaluated the literature on lumbar spinous process fixation and fusion devices.² Reviewers included both interspinous plates and fixation devices and excluded dynamic devices such as the X-Stop (see evidence review 7.01.107). Fifteen articles met 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 fixation devices with pedicle screws in patients undergoing interbody fusion and 2 included interspinous fixation device alone or pedicle screws plus an interspinous fixation device in patients undergoing interbody fusion. Use of an interspinous fixation device decreased surgical time and blood loss compared with pedicle screws. No study showed that interspinous fixation devices reduced the hospital length of stay compared with pedicle screw implantation.

Subsequent to the systematic review by Lopez et al (2017), 2 small RCTs (total N = 149) have been published in individuals with single-level lumbar degenerative diseases undergoing spinal fusion who receive an interspinous fixation device with interbody fusion as alternatives to pedicle screw and rod constructs (Table 1).^{3,4} The first was a single-center study by Huang et al (2017) that randomized 46 individuals to either an unknown type of interspinous fixation devices or pedicle screws and followed them for 24 months.³ The second was a multicenter study by Panchal et al (2018) that randomized 103 individuals to either the Aspen MIS Fusion System or pedicle screws and followed them for 12 months.⁴ Compared to the pedicle screw control groups (Table 2), similar or better fusion, disability, and quality of life outcomes were observed for the interspinous fixation device groups. Comparative complications rates were mixed across studies, but comparative treatment effects were not calculated. In the study by Panchal et al (2018), revisions were numerically lower in the interspinous fixation device group, but comparative treatment effects were not calculated. Interpretation of these findings is limited by important weaknesses, however. In the RCT by Panchal et al (2018), weaknesses included insufficient

follow-up duration, lack of control for selection bias, and data incompleteness (Tables 3 and 4). In the RCT by Huang et al (2017), weaknesses include unclear blinding of outcome assessors and potential use of a device that is not commercially available in the United States. Larger, longer-term and more rigorous multicenter RCTs are needed to confirm these findings.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Huang et al (2017) ³ ,	China	1	2013-2014	Single-level lumbar degenerative diseases, including lumbar disc herniation, lumbar spinal stenosis, or lumbar degenerative spondylolisthesis	PLIF+ISF, N=23	PLIF+pedicle screws, N=23
Panchal et al (2018) ⁴ ,	United States	9	NR	Single-level lumbar degenerative disc disease and/or spondylolisthesis (grade ≤ 2)	ALIF or LLIF +ISPF1, N=66	ALIF or LLIF + pedicle screws, N=37

RCT: randomized controlled trial; PLIF: posterior lumbar interbody fusion; ISF: interspinous fastener (Wego, Weihai, China); ALIF: anterior lateral lumbar interbody fusion; LLIF: lateral lumbar interbody fusion; ISPF: interspinous process fixation; NR: not reported

¹ Aspen MIS Fusion System, Zimmer Biomet Spine.

Table 2. Summary of Key RCT Results

Study	Fusion	Disability	Quality of life	Revisions	Overall Complications
Huang et al (2017) ³ ,	43	43	N/A	N/A	43
Outcome definition	24-mo: radiograph/CT-scan	% of patients achieved MCID on ODI ¹	N/A	N/A	
PLIF+ISP	17 (77%)/15 (68%)	33 (77%) overall ²	NR	NR	2 (9%)
PLIF+pedicle screws	17 (81%)/16 (76%)		NR	NR	1 (5%)
p-value	1.000/0.736	NR	N/A	N/A	NR
Panchal et al (2018) ⁴ ,	88	88	88	88	88
Outcome definition	12-mo radiographic fusion based on BSF-3/BSF-2/BSF-1 (95% CI)	ODI mean improvements ± SD at 12 mo	SF-36 physical component mean improvement ± SD at 12 mo	Required secondary surgical intervention	Rated as device-related / NOT device-related
ALIF or LLIF +ISP	45.5% (32.7%–59.6%)/45.5% (32.7%–59.6%) /9.1% (0.0%–23.2%)	25.97±4.23	10.87±2.79	1 (1.5%)	5 (7.5%) / 14 (21.2%)

Study	Fusion	Disability	Quality of life	Revisions	Overall Complications
ALIF or LLIF + pedicle screws	50% (33.3%–67.8%)/50% (3.3%–67.8%)/0% (0.0%–17.8%)	22.38±5.84	9.10±3.89	4 (10.8%)	6 (16.2%) / 7 (18.9%)
p-value	0.33	<0.01	≥0.22	NR	NR

PLIF: posterior lumbar interbody fusion; NR: not reported; CT: computed tomography; MCID: minimally clinically important difference; ODI: Oswestry Disability Index; RCT: randomized controlled trial; SD: standard deviation; BSF criteria: Brantigan, Stelfee, Fraser criteria: BSF-1, radiographic pseudoarthrosis with loss of intervertebral height with lucency around the implant; BSF-2, radiographic locked pseudoarthrosis with lucency within the cage but solid bone growth into the cage from each vertebral endplate; and BSF-3, radiographic fusion with bony bridges in at least half of the fusion area; CI: confidence interval; ALIF: anterior lateral lumbar interbody fusion; LLIF: lateral lumbar interbody fusion; ISPF: interspinous process fixation; NA: not available; SF-36: 36-Item Short Form Health Survey.

¹ MCID was prespecified as an 8-point difference.

² Did not stratify by group.

Table 3. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Huang et al (2017) ³		2. Version used unclear			
Panchal et al (2018) ⁴					1. Not sufficient duration for benefit; 2. Not sufficient duration for harms

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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.

Table 4. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Huang et al (2017) ³	3. Allocation concealment unclear; "using closed envelopes"	3. Blinding unclear	1. Not registered			
Panchal et al (2018) ⁴	4. Inadequate control for selection bias: More males (53% vs. 30%), on sick leave (23% vs.			1. High loss to follow-up or missing data (excluded 13% vs. 21% from 12-mo analysis); 6. Not intent to		

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
	5%) and with degenerative disk disease (55% vs. 43%)			treat analysis (per protocol for noninferiority trials)		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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. 3. Blinding unclear

^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

Section Summary: Interspinous Fixation Device With Fusion

The evidence for use of interspinous fixation device with interbody fusion for those undergoing spinal fusion consists of a systematic review of nonrandomized comparative studies and case series and 2 small RCTs. The randomized trials found comparable benefits for interspinous fixation device with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices compared with the established standard (pedicle screw with rod fixation). The evidence is insufficient to determine the effects of the technology on health outcomes.

Interspinous Fixation Device as a Stand-Alone

Sclafani et al (2014) reported on an industry-sponsored, retrospective series of the polyaxial PrimaLOK interspinous fusion device.⁵ Thirty-four patients were implanted with the interspinous fixation devices alone, 16 patients received the PrimaLOK plus an interbody cage, and 3 patients received the PrimaLOK plus pedicle screw instrumentation and an interbody cage. Evaluation at 6 weeks found no cases of fracture or device migration, although there were 4 cases of hardware removal and 2 cases of reoperation for adjacent-level disease during follow-up. At a mean 22 months after the index surgery, the average pain score had improved from 7.2 to 4.5 on a 10-point scale (method of collection, e.g., visual analog scale, were not specified). There was a statistically significant improvement in pain score for patients with degenerative disc disease with lumbar stenosis (2.8; n=25; p<0.001) and spondylolisthesis (4.6; n = 6; p = 0.01), but not for patients with lumbar disc herniation (2.2; n=10; p>0.05).

Section Summary: Interspinous Fixation Device as a Stand-Alone

There is a lack of evidence (only a retrospective series) on the efficacy of interspinous fixation devices as a stand-alone procedure for those who have spinal stenosis and/or spondylolisthesis.

RCTs are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression.

Summary of Evidence

For individuals who are undergoing spinal fusion who receive an interspinous fixation devices with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case series and 2 small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The randomized trials found comparable benefits for interspinous fixation devices with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices compared with the established standard (pedicle screw with rod fixation). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal stenosis and/or spondylolisthesis who receive an interspinous fixation device alone, the evidence includes a retrospective series. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There is a lack of evidence on the efficacy of interspinous fixation devices as a stand-alone procedure. RCTs are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

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.

In response to requests, input was received from 3 physician specialty societies (2 reviewers) and 2 academic medical centers while this policy was under review in 2012. Input was mixed. Some indications where the devices might be medically necessary were noted, such as patients with small pedicles where pedicle screws could not be safely placed.

Practice Guidelines and Position Statements

North American Spine Society

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion.⁶ The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction

with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that "No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this evidence review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01455805 ^a	Efficacy and Quality of Life Following Treatment of Lumbar Spinal Stenosis, Spondylolisthesis or Degenerative Disc Disease With the Minuteman Interspinous Interlaminar Fusion Implant Versus Surgical Decompression	50	March 2024
<i>Unpublished</i>			
NCT01560273 ^a	A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterolateral Fusion (PLF) in Patients With Spondylolisthesis	25	Sep 2015 (terminated)
01549366 ^a	System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)		

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 22840 Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
- 22853 Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)

- 22854 Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
- 22859 Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
- C1831 Personalized, anterior and lateral interbody cage (implantable) Effective 10-01-2021

Diagnoses

Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS

01-23-2015	Policy added to the bcbsks.com web site on 12-24-2014; effective 01-23-2015, 30 days after posting.
11-24-2015	Updated Description section.
	Updated Rationale section.
	Updated References section.
01-01-2017	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT codes: 22853, 22854, 22859 (<i>New codes, effective January 1, 2017</i>). ▪ Removed CPT code: 22851 (<i>Termed code, effective December 31, 2016</i>). ▪ Removed coding bullet.
05-24-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
06-06-2018	Updated Description section.
	Updated Rationale section.
06-05-2019	Updated Rationale section.
	Updated References section.
04-16-2021	Updated Rationale section.
	Updated References section.
10-01-2021	In Coding section: Added HCPCS code C1831 Effective 10-01-2021

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