Medical Policy

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Title: Spinal Surgery-Minimally Invasive Lumbar Interbody Fusion (-LIF)

Description/Background

A variety of minimally invasive/minimal access procedures are being investigated to perform interbody fusion, with the intent of limiting iatrogenic damage to muscular, ligamentous, neural, and vascular structures. Minimally invasive (MI) techniques are being studied for anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), lateral interbody fusion (e.g., extreme lateral interbody fusion [XLIF] or direct lateral interbody fusion [DLIF]), and para-axial interbody lumbar fusion (AxiaLIF).

Interbody fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction. Anterior or posterior lumbar interbody fusions (ALIF/PLIF) are traditionally performed with an open approach (long incision with wide retraction of the musculature) but can also be performed through minimally invasive/minimal access procedures. Procedures described as minimally invasive (MI) range from percutaneous techniques to minimal open access approaches that decrease the size of the incision and reduce muscle retraction. For example, minimally invasive/minimal access PLIF uses tubular retractors (e.g., METRx™, Luxor™) to allow access and open visualization of the surgical area. (PLIF is differentiated from instrumented or non-instrumented posterolateral intertransverse fusion, which fuses the transverse processes alone). Additional MI approaches that use specialized retractors are lateral transpsoas interbody fusion (LTIF), lateral interbody fusion (e.g., XLIF, DLIF), and transforaminal interbody fusion (TLIF). An axial approach (AxiaLIF), which is performed perpendicular to the long axis of the spine with access through the sacrum, is also being investigated.

Interbody fusion surgeries may also include decompression of the spinal canal, use of interbody cages, bone grafts and osteoinductive agents (e.g., recombinant human bone morphogenetic protein [BMP]), and insertion of pedicle screws and rods to increase stability of the spine. Minimally invasive procedures may include percutaneous placement of pedicle screws and rods and/or use of BMP in place of autograft bone harvested from the iliac crest.

Open and Minimally Invasive (MI) Approaches to Lumbar Interbody Fusion (LIF)

Procedure	Access	Approach	Visualization
Anterior (ALIF)	Open, MI, or laparoscopic	Transperitoneal or retroperitoneal	Direct, endoscopic or laparoscopic, with fluoroscopic guidance
Posterior (PLIF)	Open or MI	Incision centered over spine with laminectomy/ laminotomy and retraction of nerve	Direct, endoscopic or microscopic, with fluoroscopic guidance
Transforaminal (TLIF)	Open or MI	Offset from spine, through the intervertebral foramen via unilateral facetectomy	Direct, endoscopic or microscopic, with fluoroscopic guidance
Lateral Extreme lateral (XLIF) Direct lateral (DLIF)	MI	Retroperitoneal through transpsoas	Direct, with neurologic monitoring and fluoroscopic guidance
Para-axial (AxiaLIF)	MI	Small incision via the pre-sacral space	Indirect, percutaneous, fluoroscopic guidance
Oblique Lateral (OLLIF)/ATP (Anterior to psoas)	MI	Lateral and paramedian incision between the peritoneum and psoas muscle	Indirect, biplanar fluoroscopic guidance, electrophysiological monitoring

Anterior Lumbar Interbody Fusion (ALIF)

Anterior access provides direct visualization of the disc space, potentially allowing a more complete discectomy and better fusion than lateral or posterior approaches. An anterior approach avoids trauma to the paraspinal musculature, epidural scarring, traction on nerve roots, and dural tears. However, the retraction of the great vessels, peritoneal contents and superior hypogastric sympathetic plexus with a peritoneal or retroperitoneal approach places these structures at risk of iatrogenic injury. Access to the posterior space for the treatment of nerve compression is also limited. Laparoscopic ALIF has also been investigated.

Posterior Lumbar Interbody Fusion (PLIF)

PLIF can be performed through either a traditional open procedure with a midline incision or with a MI approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision to facilitate wide muscle retraction and laminectomy. In minimally invasive PLIF, tubular retractors may be used to open smaller central bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum), as well as stabilization of the spine through interbody fusion.

Transforaminal Lumbar Interbody Fusion (TLIF)

TLIF is differentiated from the more traditional bilateral PLIF by a unilateral approach to the disc space through the intervertebral foramen. In MI TLIF, a single incision approximately 2-3 cm in length is made approximately 3 cm lateral to the midline. A tubular retractor is docked on the facet joint complex and a facetectomy with partial laminectomy is performed. Less dural retraction is needed with access through the foramen via unilateral facetectomy, and contralateral scar formation is eliminated. TLIF provides access to the posterior elements along with the intervertebral disc space.

Lateral Lumbar Interbody Fusion-LLIF (e.g., extreme lateral interbody fusion [XLIF] or direct lateral interbody fusion [DLIF])
Lateral interbody fusion uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas musculature. In comparison with ALIF, the lateral approach does not risk injury to the peritoneum or great vessels. The target of this approach is the vertebral body and anterior interspace utilizing a lateral rather than a ventral incision. After access has been obtained, the surgeon performs the anterior procedure (either decompression and/or Arthrodesis and/or anterior instrumentation) using standardized techniques. Therefore, the surgeon has performed and anterolateral procedure. Because exposure to the spine may be more limited, and dissection of the psoas major places the nerves of the lumbar plexus at risk, electromyographic monitoring and dissection predominantly within the anterior psoas major may be utilized to reduce the risk of nerve root injury. The MI-LIF approach allows for a discectomy from the lateral border of the anterior spine through an approximately 90 degree off midline, retroperitoneal, transpsoas corridor, which leaves the anterior and posterior longitudinal (A/PLL) intact. This is followed by placement of a larger-aperture interbody spacer (similar to an anterior lumber interbody fusion (ALIF) spacer) which spans the cortical bone of the ring apophysis. Various supplemental internal fixation options can be used for fixation without patient repositioning. Anatomically, passage to the lateral disc space through the psoas muscle, and then guided passage through the psoas muscle adjacent to the lumbar plexus.

Axial Lumbar Interbody Fusion (AxiaLIF)
Axial lumbosacral interbody fusion (also called pre-sacral, trans-sacral or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion, while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

The procedure for one level axial lumbosacral interbody fusion (axial LIF) is as follows: Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15- to 20-mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators are advanced over the guide pin, and a dilator sheath attached to the last dilator is left in place to serve as a working channel for the passage of instruments. A cannulated drill is passed over the guide pin into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors, and the nucleus pulposus is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod is placed over the guide pin and advanced through the sacrum into L5. The implant is designed to distract the vertebral bodies and restore disc and neural foramen height. Additional graft material is injected into the rod, where it enters into the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws may be used to provide supplemental fixation. The axial LIF may allow preservation of the annulus and all paraspinous soft tissue structures. However, there is an increased need for fluoroscopy and an inability to address intracanal pathology or visualize the discectomy procedure directly. Complications of the axial approach may include perforation of the bowel and injury to blood vessels and/or nerves.

Oblique Lateral Lumbar Interbody Fusion (OLLIF)/ATP (Anterior to psoas)
The OLLIF or ATP approach was first described by Michael Mayer in 1977 and involves minimally invasive surgical approach to the disc space via a corridor between the peritoneum and psoas muscle. OLLIF (also known as OLIF) does not require posterior surgery, laminectomy, facetectomy or stripping of spinal or paraspinal musculature. However, in contrast to the lateral

transpsoas approach, the OLIF technique does not dissect or pass through the psoas muscle. For this technique, the patient is positioned laterally, either left or right side up depending on the surgeon's preference and ease of access. A lateral and paramedian incision is performed based on position and angulation of the disc on image intensification when the patient is positioned. Neuromonitoring is not necessary as the anatomical corridor anterior to the psoas muscle is used for access. The OLIF technique is suitable for levels L1-S1. Indications for OLIF include all degenerative indications. Similar to LLIF, OLIF may be an option for sagittal and coronal deformity correction, especially lumbar degenerative scoliosis with latero-listhesis. The OLIF approach is contraindicated in patients with severe central canal stenosis and high grade spondylolisthesis.

Possible advantages of the OLIF approach include facilitation of rapid postoperative mobilization, the ability to aggressively correct deformities, and the ability to attain high fusion rates with comprehensive disc space clearance. Lumbar plexus and psoas injury are unlikely as dissection is performed anterior to the psoas. However, potential risks involved with OLIF surgery include sympathetic dysfunction and vascular injury.

Regulatory Status

The AxiaLIF® and AxiaLIF II Level systems were developed by TranS1® and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5-S1 or L4–S1 vertebral bodies. (In 2013, TranS1 acquired Baxano and changed the company name to Baxano Surgical.) The U. S. Food and Drug Administration (FDA) 510(k) marketing clearance summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to assist in the treatment of degeneration of the lumbar disc; to perform lumbar discectomy; or to assist in the performance of interbody fusion. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor, or trauma. The devices are not meant to be used in patients with vertebral compression fractures or any other condition in which the mechanical integrity of the vertebral body is compromised. Their usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with legally marketed facet or pedicle screw systems. FDA product code: KWQ

Other approaches may also use customized instrumentation, and several tubular retractor systems and pedicle screw-rod instrumentation are cleared for marketing through the FDA 510(k) pathway. These include the MAST QUADRANT™ Retractor System, METRx X-tube and Sextant pedicle screw system, all from Medtronic, and the Viper pedicle screw system from DePuy. XLIF uses specialized retractors (MaXcess) and NeuroVision EMG nerve monitoring by NuVasive, while DLIF utilizes specialized instrumentation from Medtronic.

Orthotic	Manufacturer	Date Cleared	510(k) No.
• TranS1® AxiaLIF™ SystemFor patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L5-S1 in conjunction with legally marketed pedicle screws	TranS1	12/04	K040426

• TranS1® AxiaLIF™ SystemIndication modified to include facet screws	TranS1	06/05	K050965
• TranS1® AxiaLIF® II SystemFor patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L4-S1 in conjunction with legally marketed facet and pedicle screws	TranS1	04/08	K073643
• TranS1® AxiaLIF® 2L SystemIndication unchanged, marketed with branded bone morphogenetic protein	TranS1	01/10	K092124
• TranS1® AxiaLIF® Plus SystemIntended to provide anterior stabilization of the L5-SI or L4-Sl spinal segment (s) as an adjunct to spinal fusion • This device's instruments are used for independently distracting the L5-S1 or L4-S1 vertebral bodies and inserting bone graft material (Dt3M, autograft or autologous blood) into the disc space. • Use limited to anterior supplemental fixation of the lumbar spine at L5-SI or L4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF	TranS1	03/11	K102334

Adapted from the U.S. Food and Drug Administration (2007, 2008).[95]
FDA: Food and Drug Administration.

Medical Policy Statement

The safety and effectiveness of specific minimally invasive interbody fusions of the lumbar spine have been established. They are considered useful therapeutic options for carefully selected patients who would otherwise be eligible for a conventional spinal fusion procedure.

Inclusionary and Exclusionary Guidelines

Inclusions:
The following minimally invasive (MI) lumbar interbody fusion techniques are considered established:

- Anterior lumbar interbody fusion (ALIF)
- Posterior lumbar interbody fusion (PLIF)
- Transforaminal lumbar interbody fusion (TLIF)
- Minimally invasive *lateral* lumbar interbody fusions [LLIFs] (e.g., XLIF, DLIF)

The following minimally invasive (MI) lumbar interbody fusion techniques are considered to be experimental/investigational:

- Laparoscopic ALIF (LALIF) lumbar interbody fusion
- Axial anterior lumbar interbody fusion (AxiaLIF)
- Oblique lateral lumbar interbody fusion (OLLIF)

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

Established codes:

22558	22585	22845	22899*	63052	63053

***When used for PLIF and TLIF)**

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

22586	22899**

****When used for OLLIF**

RATIONALE

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

Anterior Lumbar Interbody Fusion (ALIF)

In a 2005 review of the literature on laparoscopic ALIF, Inamasu and Guiot identified 19 studies which described the outcome of a L5-S1 laparoscopic ALIF, 9 studies which described the outcome of the L4-L5 laparoscopic ALIF, and 8 studies which described the outcome of a 2-level laparoscopic ALIF.[39] The review concluded that there was no marked difference between laparoscopic ALIF and the open or mini-open ALIF in terms of short-term efficacy (operative time, blood loss, and length of hospital stay), but there was a higher incidence of complications. In addition, the conversion rate to open surgery was considered to be high. It was noted that at the time of the review article, some spine surgeons were abandoning the laparoscopic approach and switching to mini-open ALIF.

The largest trial on laparoscopic ALIF was a prospective multicenter (19 surgeons from 10 U.S. centers) investigational device exemption (FDA-regulated) trial, published in 1999, that compared short-term outcomes from laparoscopic fusion of the spine (240 consecutive patients) and open

ALIF (earlier cohort of 591 similar patients).[79] Inclusion criteria were painful degenerative disc disease consisting of disc space narrowing at 1 or 2 contiguous levels (L4-L5 and L5-S1). Single level fusion was performed in 215 patients using laparoscopy and in 305 patients using the open procedure; 2-level fusions were performed in 25 patients via laparoscopy and 286 patients with the open procedure. In all surgeries, autologous bone graft from the iliac crest was used in conjunction with an interbody cage, and a general or vascular surgeon assisted with the surgery. In 25 (10%) of the laparoscopy patients, conversion to an open procedure was required due to bleeding (n=6), anatomic considerations (n=5), adhesions or scar tissue limiting access to the spine (n=8), and technical difficulties in placing the threaded cage (n=6). The hospital stay was modestly shorter for the single-level laparoscopy group (3.3 vs. 4 days, respectively) but not for patients undergoing 2-level laparoscopy. Operative time was increased (201 vs. 142 minutes, respectively) for the single-level laparoscopic approach (243 minutes for the 25 cases converted to open). For 2-level laparoscopy, the procedure time was 146 minutes longer than for the open approach. The reoperation rate for single-level procedures was 4.7% in the laparoscopy group compared with 2.3% in the open group (not significantly different). Major complications (implant migration, great vessel damage, and pulmonary embolism) were significantly lower in the laparoscopy group (0% vs. 2%, respectively). Postoperative complications were similar in the 2 groups, with an occurrence of 14.1% in the open approach and 19.1% for the laparoscopic approach.

A prospective comparison of 50 consecutive patients (25 in each group) with disabling discogenic pain who underwent 1 or 2 level ALIF at L4-L5 with either a laparoscopic or mini-open approach was reported by Zdeblick and David in 2000.[103] The reasons for assignment to the different procedures were not described. There was no difference between the laparoscopic and mini-open approaches in operating time (125 vs. 123 minutes), blood loss (50 cc vs. 55 cc), or length of hospital stay (1.4 vs. 1.3 days – all respectively) for single-level fusion. For 2-level fusion, the operating time was increased for the laparoscopic procedure (185 vs. 160 minutes, respectively). There was a 20% rate of complications in the laparoscopic group (disc herniation, ureter injury, iliac vein laceration, transient retrograde ejaculation, deep vein thrombosis) compared with 4% in the mini-open group (ileus). Exposure was considered inadequate in the laparoscopic group, with only a single interbody cage placed in 16% of patients in the laparoscopic group. All patients in the mini-open group had 2 interbody cages placed. Due to reports of a potentially a higher rate of complications with laparoscopic ALIF, this procedure is considered investigational.

A retrospective comparison between a cohort of 48 consecutive patients with spondylolisthesis who underwent mini-open ALIF and 46 patients who underwent minimally invasive (MI) transforaminal lumbar interbody fusion (TLIF) during the same period of time was reported by Kim and colleagues in 2009.[46] Patients had persistent radiculopathy, progressive neurologic deficits and lower-back pain for more than 6 months. Both groups underwent percutaneous pedicle screw fixation; however, only the TLIF group had decompression with removal of the ligamentum flavum. The mean time to return to work was significantly shorter in the ALIF group (6.1 months) than in the TLIF group (10.9 months). At an average of 33 (ALIF) and 30 (TLIF) months' follow-up, independent assessment showed successful radiologic fusion in 94% of the ALIF group and 98% of the TLIF group. There was no significant difference in disc height, listhesis, or lordosis between the 2 groups. Clinical outcomes, measured by visual analog scores (VAS) for pain and the Oswestry Disability Index (ODI), were similar for the 2 groups.

In 2010, the same group of investigators reported minimum 5- to 7-year follow-up of 63 patients from a cohort of 73 patients (86%) with isthmic spondylolisthesis who had undergone mini-open ALIF combined with percutaneous pedicle screw fixation.[45] The patients had a mean age of 50.6

years (range of 19–77 years). The MI ALIF was performed with an abdominal retroperitoneal approach, using a robotic arm retractor and endoscope-assisted ballooning. The mean operating time was 210 minutes, and there was a mean blood loss of 135 mL. No blood transfusions were needed. There were 6 cases of complications from the ALIF procedure (3 iliac vein injuries, 2 wound hematomas, and 1 deep vein thrombosis) and 6 cases of complications from the percutaneous pedicle screw/rod procedure (2 breakages of cortical walls of the vertebral body, 3 malpositions of screws, and 1 transient thigh numbness). Twenty-six patients (36%) were reported to have excellent results, 43 (59%) had good results, 3 (4%) were reported to have had fair results, and 1 patient (1%) had a poor result. Sixty-three patients (86%) were available for follow-up at a mean 72 months after the procedure. From this cohort, 89% had a good to excellent outcome, 8% had a fair outcome, and 3% had a poor outcome.

Minimally Invasive Posterior Lumbar Interbody Fusion (PLIF)

In 2007, Park and Ha reported minimum 12-month follow-up from a prospective cohort study that compared MI (n=32) and open (n=29) single-level PLIF.[70] The choice of procedure was determined by the ability to pay for the MI approach, which was not covered by medical insurance in Korea during that time period (Oct 2003–Oct 2004). Indications for surgery were segmental instability at the level of spinal stenosis, lumbar disc herniation, and low-grade spondylolisthesis. Patients who had previous spinal surgery or who needed multiple levels of decompression were excluded. In the MI group, microscopic visualization was used with the aid of tubular retractors (METRx-MD) that created a working channel through 2 small paramedian skin incisions. Percutaneous pedicle screw-rod fixation (Sextant system) of the motion segment was completed through the same incisions after removal of the tubular retractors. The preoperative diagnosis of the groups was comparable at baseline; there was a trend toward greater severity on the American Society of Anesthesiologists (ASA) score in the MI group (69% vs. 48% class 2, respectively). Although surgical time increased from 149 to 192 minutes, all other intraoperative variables were improved by the MI procedure. These included mean intraoperative blood loss (433 vs. 738 mL), postoperative drainage (175 vs. 483 mL), days before ambulation (1.2 vs. 3.0), and days of hospital stay (5.3 vs. 10.8 – all respectively). Postoperative back pain was lower at all times after surgery, with a VAS for pain of 2.1 versus 3.8 in the open group at the final (>12 month) follow-up. Good to excellent results were obtained in 91% of the MI group and 90% of the traditional open group. Radiographic outcomes were similar in the 2 groups. The MI group had one case of screw malposition and one case of cage migration. The authors noted that there is a steep and prolonged learning curve for MI spine surgery, and prudent attention is needed to lower the risk of technical complications.

In 2010, Ghahreman et al. reported a prospective study comparing MI versus open PLIF in 47 patients with spondylolisthesis and radicular pain who met inclusion criteria and agreed to participate in the study.[27] The study was performed as part of a quality assurance audit with independent assessment of outcomes 12 months after treatment. Patients chose the MI or open procedure after explanation that the effectiveness of the traditional approach was known but involved more extensive surgery, while the outcomes of the new MI approach were unknown. For the MI approach, bilateral hemilaminectomies and facetectomies were performed through 3 cm paramedian incisions. The pedicle screws were placed with direct visualization down the tubular retractor. For all but 3 patients in the MI group, the fusion was single level. Generally, the 2 groups of patients were similar at baseline; there was a significant difference in the percent of patients with listhesis and a difference in baseline disc height; these were adjusted for in the statistical analysis. With the MI approach, there were trends toward increased operating time (median of 220 vs. 203 minutes, respectively; p=0.08) but decreased percentage of patients requiring transfusion (4% vs. 21%, respectively; p=0.09). Radiologic outcomes were similar in the

2 groups at 12-month follow-up, and only one patient who underwent the open procedure had failure of fusion. The patients who had the MI approach had a shorter time to independent mobility (median of 2 vs. 4 days) and a shorter hospital stay (median of 4 vs. 7 days – both respectively). Clinical outcomes (e.g., back pain, leg pain, bodily pain, functioning) were similar for the 2 groups.

Kasis and colleagues published a comparative study of a procedure they called limited exposure PLIF (a small central incision and use of bone marrow aspirate, n=209 consecutive patients) and standard open PLIF (single surgeon, 114 historical controls) in 2009.[42] All patients had chronic low back pain for a minimum of 2 years that was unresponsive to conservative treatment, had magnetic resonance imaging (MRI) evidence of disc degeneration, and an ODI greater than 30. The limited access procedure was performed with a smaller central incision and direct visualization. In the standard open procedure, bone graft was harvested from the iliac crest; in the limited access procedure, the laminectomy was partial, and bone graft was obtained from the facetectomy and mixed with bone marrow aspirate from the iliac crest. All screws were inserted by direct vision. At baseline, and at 6 weeks, 3 months, and 6 months, then at 6-month intervals thereafter, patients completed an Internet-based self-assessment questionnaire (Global Patient Outcome System, GPOS), which included automatically assessed values for the ODI, short-form 36 (SF-36), and VAS for pain. The duration of follow-up averaged 6.4 years for the standard approach and 3.4 years for the limited access approach. Follow-up was available for 114 of 126 patients (90%) treated with the standard open approach and 209 of 223 patients (94%) undergoing limited access PLIF. Limited access was found to reduce the hospital stay from 4.0 days to 2.2 days and result in improved clinical outcomes at the latest follow-up. For example, the ODI improved by 22.5 points with the standard open approach and by 28.8 points with the limited access approach. VAS back pain improved from 6.4 to 2.7 with the standard approach and from 7.2 to 1.9 with limited access. VAS leg pain improved from 6.5 to 2.5 with the standard approach and from 6.3 to 1.2 with limited access. The limited access procedure was found to reduce bone-graft-donor-site pain without increasing other adverse events. Although limited by the longer follow-up in the patients treated with the standard open access (i.e., confounded by the potential for adjacent level disease over time), these results do suggest that a limited access approach to PLIF does not result in poorer outcomes than a standard open procedure.

Other publications from the U.S. report the use of open and MI PLIF for different patient populations. For example, a retrospective comparative review by Bagan et al. found that more procedures in their open cohort were revisions, and there was a higher prevalence of diabetes mellitus and hypertension in the open cohort.[7] Another retrospective analysis reported that patients presenting with bilateral neurologic symptoms were treated with open surgery, while those with unilateral symptoms were treated with MI PLIF. Although the complication profile is reported to be favorable with MI PLIF in comparison with open PLIF, the different patient populations in these retrospective studies limits direct comparison of results.

Minimally Invasive Transforaminal Lumbar Interbody Fusion (TLIF)

A meta-analysis of MI and open TLIF, published in 2010, identified 23 studies (1,028 patients) that met the study inclusion criteria.[101] All patients in the studies presented with spondylolisthesis, herniated nucleus pulposus, stenosis, or other degenerative lumbar disease. The included studies were all considered class III evidence (observational); no randomized controlled trials (RCTs) that compared MI and open TLIF were identified. The meta-analysis included 312 patients (8 studies) who underwent MI TLIF and 716 patients (16 studies) who underwent open TLIF. Mean clinical follow-up ranged from 9 to 46 months. After adjustment for publication bias, the fusion rate for the MI procedure was 94%, compared to 91% for open TLIF. Use of structural

allograft and bone morphogenetic protein (BMP) was more frequent in the MI procedure (54% and 50%, respectively) than the open procedure (14% and 12%, respectively). The percentage of single-level fusions was higher in the MI than open TLIF (84% vs. 68%, respectively). Complication rates, after adjustment for publication bias, were 18% for open TLIF and 8% for MI TLIF. The type of complications reported included dural tear/cerebrospinal fluid leak (n=34), new onset radiculopathy (n=32), infection (n=16), and misplaced screws (n=14).

Other clinical outcomes were not assessed in this meta-analysis due to variability in assessment tools and reporting. Given reports of symptomatic ectopic bone formation with off-label application of BMP in posterior and transforaminal interbody fusion, it is notable that BMP was used in as many as 84% of patients in the studies reviewed. As indicated by this meta-analysis, there are a number of publications describing the use of MI TLIF. Also identified in the 2010 literature update were prospective and retrospective cohort studies that compared outcomes from MI and open TLIF without the use of BMP; the largest of these comparative studies are described below.

A prospective pseudo-randomized study comparing MI and open TLIF in 62 patients was reported by Shunwu et al in 2010.[89] Patients diagnosed with discogenic low back pain, intervertebral space stenosis with unilateral huge lumbar disc herniation, foraminal stenosis, separation of the posterior ring apophysis at the level of spinal stenosis, low-grade spondylolisthesis, or single segmental instability were assigned to the MI group (n=32) if admitted on even-numbered days or to the open group (n=30) if admitted on odd-numbered days. The 2 groups were generally similar at baseline and had comparable follow-up (92%). Following the MI unilateral or bilateral paravertebral incisions, tube retractors were expanded to provide an operative field diameter of 2.5 to 4.0 cm (pedicle to pedicle). Pedicle screws and rods were inserted percutaneously, and the pedicle screw and rod system was distracted to achieve distraction of the intervertebral space. Decompression was achieved by cutting the inferior portion of the lamina, hypertrophied articular processes, and ligamenta flava. Interbody cages and iliac crest bone graft were used for interbody fusion. The operative duration was slightly longer for the MI group (159 vs. 142 min), and intraoperative blood loss was slightly reduced (400 vs. 517 mL – both respectively). Time-to-ambulation (3.2 days) and length of hospital stay (9.3 days) were reduced compared to patients who underwent the open procedure (5.4 and 12.5 days, respectively). At 24-month follow-up, radiographic outcomes were similar for the 2 groups. The ODI for the MI and open groups were 27.2 and 24.7, respectively. VAS for pain was 2.3 for the MI group and 3.2 for the open group. Complications were observed in 6 patients who underwent MI TLIF (including 2-screw malposition) and 5 patients who underwent the open procedure.

A prospective comparison of MI (n=42) and open (n=43) TLIF was reported by Wang et al. in 2010.[98] Eighty-five consecutive patients with single-level degenerative or isthmic spondylolisthesis were treated by different surgeons (one surgeon performed MI TLIF, the other performed open TLIF) at the same hospital during the same period of time. For the MI procedure, a retractor system with a 3-cm incision was used for placement of autologous bone graft, obtained from the facetectomy, in conjunction with an interbody cage. Percutaneous pedicle screws were implanted with palpation and fluoroscopic guidance. Comparison of the MI with the open procedure showed similar operating time (156 vs. 145 minutes), reduced blood loss (264 vs. 673 mL) and less blood transfusion (0.12 vs. 1.47), but an increase in x-ray time (84 vs. 37 minutes – all respectively). Hospital stay was reduced in the MI group (10.6 vs. 14.6 days, respectively). Follow-up at an average 26 months (range, 13-35 months) showed no difference in VAS or ODI between the 2 groups. Reported complications in the MI group were 2 small dural

tears and 2 new radiculopathies that resolved with reoperation. In the open group, there were 2 dural tears and 1 pedicle screw malposition that required revision surgery. Each group had 1 case of nonunion without complaint of back pain.

In 2010, Villavicencio and colleagues compared their first 76 consecutive patients undergoing MI TLIF with a matched cohort of 63 patients who had undergone open TLIF.[95] Patients were matched based on diagnosis (painful degenerative disc disease, spondylolisthesis, and/or stenosis), number of spinal levels (75% of both groups had 1 level and 25% had 2 level), and history of previous lumbar surgery (28% of the MI group and 40% of the open group). All patients underwent placement of interbody structural allografts with locally harvested autograft. In some cases, cancellous bone substitute was utilized, and use of BMP was slightly, but not significantly, higher with the MI procedure (80% vs. 68%, respectively, of cases). The operative time was similar for the 2 procedures (223 for MI and 215 for open); blood loss (163 vs. 367 mL) and hospital stay (3.0 vs. 4.2 days – both respectively) were reduced. The overall complication rate was similar in the 2 groups (31.6% vs. 31.7%), but there were more major complications in the MI group (18.4% vs. 9.5%). Six of 8 of the observed nerve injuries were noted to have occurred in the authors' first 15 MI cases, indicating a steep learning curve for this procedure. The rate of minor complications, including cerebrospinal fluid leak and anemia, was higher for the open procedure (22.2% vs. 13.2% of patients, respectively). At a mean 38-months follow-up (range 26-52), radiographic fusion was considered successful in all patients. VAS improved from 7.4 to 3.4 for the group that underwent MI TLIF and from 8.0 to 3.2 for the open group; these scores were not statistically different.

Clinical outcomes from 25 matched pairs of patients were reported by Peng et al in 2009.[74] The 25 patients were out of 29 who underwent MI TLIF and included the surgeon's learning cases; these were compared by retrospective review of patients matched based on age, sex, and level operated (reasons for excluding 4 patient pairs were not described). Indications for surgery were grade 1 or 2 spondylolisthesis and degenerate discs presenting with mechanical low back pain and radicular symptoms. Patients undergoing the MI TLIF had longer fluoroscopy time (105 vs. 35 sec) and longer surgery time (216 vs. 170 min) but a reduction in blood loss (150 vs. 681 mL) and need for transfusion (0 vs. 14% - all respectively). Time to ambulation (1.4 vs. 3.0 days), length of hospitalization (4.0 vs. 6.7 days), VAS on discharge (1.7 vs. 2.8), and total morphine (17.4 mg vs. 35.7 mg) were also reduced compared to the standard open group. The complication rate for the MI patients (6.9%, from 2 iliac crest bone graft site infections) was lower than for patients who underwent open TLIF (13.8%, 1 atelectasis, 2 urinary tract infections, and 1 wound infection). Outcomes (prospectively collected with independent evaluation) at a minimum of 24 month follow-up showed no significant difference between groups in North American Spine Society (NASS) scores (back pain/disability and neurogenic symptoms), the ODI, or the SF-36. No significant differences were observed in fusion rates (80% of MI, and 87% of open procedures achieved grade 1 fusion).

Rouben and colleagues assessed 49 month (range, 36 to 60 months) outcomes of single-level or 2-level MI TLIF in a retrospective review of prospectively collected data.[85] To be included in the study, patients had to have preoperative and minimum 3 years' postoperative ODI and VAS pain scores and imaging studies. Excluded from the study were patients with scoliosis greater than 10 degrees, spondylolisthesis greater than grade II, preoperative lumbar segment disease in excess of 2 levels, prior lumbar infection, failed lumbar fusion, or psychological factors preventing follow-up. All patients had failed a minimum 3 months of conservative medical management before surgery. A total of 169 patients met the study inclusion criteria with either isolated single-level (n=124) or 2-level (n=45) lumbar intervertebral segment pain. The primary diagnosis was

degenerative spondylolisthesis (n=35), central herniated disc (n=41), central stenosis (n=9), foraminal-lateral herniation of disc (n=53), foraminal/lateral stenosis (n=12), or isolated degenerative disc or joint disease (n=19). The hospital stay averaged 15 hours, and the median return to work time was 8 weeks. Data collection, which included patient reported outcomes, was conducted preoperatively and at 3, 12, and 24 months and then at yearly visits. Fusion rates (cages were filled with locally harvested autologous bone and off-label use of BMP) were 96% at 1-year follow-up. The overall rate for repeat surgery was 14.2%, with the most common reason being removal of painful pedicle screws. At the last follow-up, 86% of patients reached a 20% clinical improvement in ODI. The average improvement in VAS pain scores was 31% at the initial follow-up and was maintained at each subsequent follow-up. Patients with 2-level fusions improved similarly in both ODI and VAS scores as 1-level fusion patients (e.g., range of 66 to 77 at baseline and 26 to 30 at last follow-up. This study has an indeterminate potential for bias, due to the restrictive inclusion criteria (for a retrospective study) and lack of reporting of patients in the series who were lost to follow-up before 3 years.

Neal and Rosner studied the learning curve for MI TLIF for a single U.S. medical resident during his postgraduate year 5.[66] The resident performed 28 procedures with an attending surgeon present during a 19-month period. The accuracy of pedicle screw placement, as determined on postoperative computed tomography (CT) scans, was 97% for the first 14 patients and 94% for the next 14 patients (the latter group of patients were believed to include more difficult cases). The 3 misplaced screws were not symptomatic and did not require revision. Excluding 2 cases with grade III spondylolisthesis, the average operating time was 121 minutes for the first 13 cases and 105 minutes for the second group of cases. A plot of the operative time per level indicated that the operative time plateaued (i.e., time to learn the procedure) at about 15 cases. Additional studies are planned to evaluate a larger number of trainees and to assess the effect of the learning curve on long-term patient outcomes.

Lateral Lumbar Interbody Fusion (LLIFs) (e.g., XLIF, DLIF)

In a 2009 report, Knight and colleagues compared complications from a series of 58 patients who underwent XLIF or DLIF (1- to 3-level) with a historical cohort of patients who underwent open posterolateral lumbar fusion.[47] Thirteen patients (22.4%) experienced a mild or major complication. Nine of the complications were approach-related (2 L4-nerve root injuries, 6 cases of meralgia paresthetica, and 1 case of significant psoas muscle spasm). In 4 additional cases, the procedure was aborted because of concerns about nerve proximity. Compared with the historical cohort, there was less blood loss (136 vs. 489 mL), a shorter operative time (161 vs. 200 mins.), similar hospital stay (5 days), and a similar percentage of complications (22.4 vs. 22.5% - all respectively). Approach-related complications in the open cohort included wound infection and dural tears.

In 2010, Isaacs et al reported perioperative outcomes from a prospective multicenter (14 sites) observational study of the XLIF procedure for adult patients with degenerative scoliosis.[19] A total of 107 patients (mean age, 68 years, range, 45-87) underwent XLIF either with or without supplemental posterior fusion. A mean of 4.4 levels (range, 1-9) were treated per patient. The addition of supplemental instrumentation (anterior, lateral, or posterior), the use of direct decompression, the addition of a posterior approach, and the inclusion of L5-S1 was left to the choice of the surgeon. Supplemental pedicle screw fixation was used in 75.7% of patients, 5.6% had lateral fixation, and 18.7% had stand-alone XLIF. The mean operative time was 58 min/level, and the mean blood loss was 50 to 100 mL. Nine patients (8.4%) had greater than 300 mL blood loss. The mean hospital stay was 3.8 days (2.9 days for unstaged procedures and 8.1 days for staged procedures). Of the 36 patients (33.6%) with some evidence of weakness after surgery,

86.2% had transient weakness that was thought to be related to passage of retractors through the psoas muscle. Major complications occurred in 12.1% of patients overall. In patients who had XLIF alone or with percutaneous instrumentation, major complications occurred in 9% of patients. In patients with supplemental open posterior instrumentation, 20.7% had one or more major complications. The strongest independent predictor of complications was the total number of levels operated per patient. The authors concluded that the rate of major complications compares favorably to that reported from other studies of surgery for degenerative deformity.

In 2010, Rodgers et al published a retrospective review of a database for all patients treated with the XLIF procedure by a single surgeon (between 2006 and 2008), focusing on early complications (<3 months) in obese and non-obese patients.[82] Of a total of 432 patients treated with XLIF during this period, 313 (72%) met the inclusion criteria for the study and had complete data; 156 were obese (>30 kg/m2), and 157 were not obese. Patients who were obese were slightly younger (58.9 vs. 62.9 years of age) and had a higher incidence of diabetes mellitus (48 vs. 17 – both respectively) than patients who were not obese but were otherwise comparable at baseline. There were 27 complications (8.6%) in the entire group, which included cardiac and wound complications, vertebral body fractures (1 requiring reoperation), nerve injuries, gastrointestinal tract injuries (1 requiring reoperation), and hardware failures (1 requiring reoperation for recurrent stenosis after cage subsidence). The complication and reoperation rates were not significantly different between the obese and non-obese groups. There were no cerebrospinal fluid leaks, no infections, and no patient-required transfusion. The average length of hospital stay was 1.2 days. The authors noted that reliable automated neurologic monitoring and fluoroscopic guidance, and meticulous attention to operative technique are required but that the early outcomes compare well with traditional interventions.

In 2011, Rodgers and colleagues reported a retrospective analysis of intraoperative and perioperative complications from all consecutive patients (600 procedures, 741 levels) treated by 2 surgeons since the XLIF procedure was introduced at their institution.[83] Of these, 485 procedures were single level, 90 were 2 level, and 25 involved 3 or more levels. The hospital stay averaged 1.2 days. There were 37 complications (6%), classified into medical (60%) and surgical (40%). Surgical complications included 4 transient postoperative neurologic deficits and 1 subcutaneous hematoma. There were no wound infections, no vascular injuries, and no intraoperative visceral injuries in this series. At a minimum 1-year follow-up, VAS pain scores had decreased from an average 8.8 to 3.1.

The incidence of cage overhang following XLIF or DLIF was reported by Regev and colleagues in 2010.[80] Of a total of 152 MI lateral fusion procedures performed at the author's institution between 2005 and 2008, postoperative MRI or CT scans were available from 37 patients (14 DLIF and 23 XLIF). Reasons for imaging included the need for an additional posterior decompression following the anterior procedure or to evaluate patients with recurrent back or radicular pain. Of the 37 cases with post-operative imaging, 8 (22%) were found to be hanging outside of the intervertebral space. Six of the interbody cages (15%) had an anterior overhang, which placed them in the vicinity of the retroperitoneal great vessels. The study concluded that the risk of an excessively long interbody cage is high when relying on antero-posterior fluoroscopy for cage insertion in the anterior third of the disc space. The proportion of cases with an excessively long interbody cage out of the total number of procedures cannot be determined from this report.

A retrospective study by Formica et al in 2014 was done on 39 patients being treated for degenerative and post-traumatic lumbar diseases.[25] Functional status, leg and back pain and

radiological outcomes were evaluated pre- and post-operatively using the Oswestry disability index score, VAS, and X-ray studies. Mean follow-up was 16 months (range 12-24 months). Mean improvement in back and leg pain on VAS was 6.08 ($p<0.01$) and 2.77 (<0.01), respectively. Mean improvement in the ODI score was 38 ($p<0.01$). Increases in lumbar lordosis (32.8°-39.2°, $p < 0.05$) and disc height (3.6-4.8 mm, $p < 0.05$) were noted in the post-operative period. Mild, transient strength deficit of the quadriceps muscle was also noted in ten cases with complete regression. The authors concluded that XLIF proved to be a safe, effective, minimally invasive technique that allows valid arthrodesis to be carried out. Patients achieved positive clinical outcomes and satisfactory fusion rates, with sustained restoration of lordosis, spinal alignment and disc height.

A study by Alimi et al (2015) reviewed 23 patients, among whom 61% had degenerative scoliosis. These patients has single-level unilateral vertical foraminal stenosis and corresponding radicular pain and all underwent XLIF.[3] Postoperatively, the foraminal height on the stenotic side was significantly increased (<0.001) and remained significantly increased at the last follow-up of 11 ± 3.7 months ($p<0.0001$). Additionally, VAS buttock and leg as well as Oswestry Disability Index (ODI) scores were significantly improved. The conclusion was the in deformity patients with radicular pain caused by nerve compression at a single level, when not associated with other symptoms attributable to general scoliosis, treatment with single-level XLIF can result in short- and mid-term satisfactory outcome.

Another study done in 2015 by Berjano et al followed 77 patients between 2009 and 2013 at a single institution.[11] All patients received the XLIF procedure. A clinical evaluation and a CT scan of the involved spinal segments were performed with at least a 1 year follow-up following the standard clinical practice in the center. Fifty-three of the patients were available for review with a mean follow-up of 34.5 (12-62) months. A total of 68 (87.1%) of the 78 operated levels were considered as completely fused, 8 (10.2%) were considered as stable, probably fused, and 2 (2.6%) of the operated levels were diagnosed as pseudarthrosis. The authors concluded that the results of this series confirm that anterior interbody fusion by means of XLIF approach is a technique that achieves high fusion rate and satisfactory clinical outcomes.

Oblique Lateral Lumbar Interbody Fusion (OLLIF)

The most common complication following XLIF or DLIF surgery is nerve injury. It has been reported that 30% of patients show paresthesias in the leg and 27% of patients show thigh pain after DLIF surgery. Rates as high as 62.7% of patients have transient anterior thigh symptoms despite real-time electromyography (EMG) monitoring during these surgeries. In order to avoid these side effects, mini-open anterior retroperitoneal lumbar interbody fusion methods, such as oblique lateral interbody fusion (OLIF), have been developed. With this method, a 4-cm skin incision is made 6-10 cm anterior from the mid portion of an intervertebral disc; the retroperitoneal space is accessed by blunt dissection; and the peritoneal content is mobilized anteriorly. The psoas muscle is then identified and reclined posteriorly, revealing the intervertebral disc.

A 2015 article by Abbasi reported on a study on the oblique lumbar lateral interbody fusion (OLLIF) procedure performed on 69 consecutive OLLIF surgeries on 128 levels with a control group of 55 consecutive open transformational lumbar interbody fusions (TLIFs) on 125 levels.[2] For a single level OLLIF, the mean surgery time was 69 minutes (min) and blood loss was 29 ml. Surgery time was approximately twice as fast as open TLIF (mean: 135 min) and blood loss was reduced by over 80% compared to TLIF (mean: 355 ml). All procedures were done by the same surgeon as single surgeon procedures. The TLIF control group was selected

from patients who underwent surgery before the surgeon started performing OLLIF to eliminate selection bias. All 124 procedures were performed in two Minnesota hospitals. All surgeries were performed between March 2012 and December 2013. Unfortunately, this study is limited because it is a retrospective study which biases the data because clinical practices change over time. However, the data on perioperative measures, such as blood loss and OR time, was collected almost completely and clearly shows that OLLIF improves on TLIF. OLLIF justifies further study as it has the potential to significantly improve the outcomes of patients with lumbar fusions. It is not standard of care at this time.

Another 2015 study, this time by Ohtori and colleagues, reported on 35 patients with degenerated spondylolisthesis, discogenic pain, and kyphoscoliosis who underwent OLIF surgery (using a cage and bone graft from the iliac crest) with or without posterior decompression, without real-time electromyography monitoring. Posterior screws were used in all patients. Visual analog scale (VAS) score and Oswestry Disability Index (ODI) were evaluated before and 6 months after surgery. Surgical complications were also evaluated. The authors stated that they did not conduct real-time EMG monitoring during the OLIF procedure, and few patients showed any motor or sensory nerve injury or symptoms from the psoas muscle. In this regard, this OLIF method is useful for avoiding the complications reported for the XLIF procedure. However, they admitted that their study had some limitations in that it was a small-sized prospective study and the number of patients was restricted. Second, the duration of follow-up was short. Finally, we did not evaluate bone fusion or correction rates. Further study is required to clarify these points.

In 2016 Mehren and colleagues performed a chart review of intra- and perioperative complications of all patients who had undergone minimally invasive anterior lumbar interbody fusion through a lateral psoas-sparing approach from L1 to L5 during a 12-year period (1998-2010).[105] During the study period, the oblique, psoas-sparing approach was the preferred approach of the participating surgeons in this study, and it was performed in 812 patients, all of whom had complete data for assessment of the short-term (inpatient-only) complications. Complications were evaluated by an independent observer who was not involved in the decision-making process, the operative procedure, nor the postoperative care by reviewing the inpatient records and operative notes. A total of 3.7% (30/812) of patients who underwent the oblique lumbar interbody fusion experienced a complication intraoperatively or during the hospital stay. During the early postoperative period there were two superficial (0.24%) and three deep (0.37%) wound infections and five superficial (0.62%) and six deep (0.86%) hematomas. There were no abdominal injuries or urologic injuries. The percentage of vascular complications was 0.37% (n = 3). The percentage of neurologic complications was 0.37% (n = 3). The authors concluded that the risk of vascular complications after oblique lumbar interbody fusion seemed to be lower compared with reported risk for anterior midline approaches, and the risk of neurologic complications after oblique lumbar interbody fusion seemed to be lower than what has been reported with the extreme lateral transpsoas approach; however, they cautioned readers that head-to-head studies needed to be performed to confirm their very preliminary comparisons and results with the oblique psoas-sparing approach. Similarly, future studies will need to evaluate this approach in terms of later-presenting complications, such as infection and pseudarthrosis formation, which could not be assessed using this inpatient-only approach.

Axial Lumbar Interbody Fusion (AxiaLIF)

The literature on axial lumbosacral interbody fusion (axial LIF) consists of case series and one retrospective comparison of axial LIF versus anterior lumbar interbody fusion (ALIF). No controlled trials have been identified that compare outcomes of axial LIF with other approaches to lumbosacral interbody fusion.

Clinical Context and Therapy Purpose

The purpose of axial lumbosacral interbody fusion in individuals who have L4-S1 disc space diseases 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 axial lumbosacral interbody fusion improve net health outcome in individuals who have L4-S1 disc space diseases?
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals who have degenerative spine disease at the L4-S1 disc spaces.

Interventions

The therapy being considered is axial lumbosacral interbody fusion (also called presacral, transsacral, or paracoccygeal interbody fusion). Axial lumbosacral interbody fusion is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion while minimizing damage to muscular, ligamentous, neural, and vascular structures.

The procedure for 1-level axial lumbosacral interbody fusion is as follows[89]: Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15- to 20-mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators are advanced over the guide pin, and a dilator sheath attached to the last dilator is left in place to serve as a working channel for the passage of instruments. A cannulated drill is passed over the guide pin into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors, and the nucleus pulposus is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod is placed over the guide pin and advanced through the sacrum into L5. The implant is designed to distract the vertebral bodies and restore disc and neural foramen height. The additional graft material is injected into the rod, where it enters into the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws may be used to provide supplemental fixation.

Comparators

The following practice is currently being used to treat degenerative spine disease: standard lumbosacral interbody fusion and conservative therapy.

Outcomes

The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Follow-up was up to 24 months.

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.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Single-Level Axial Lumbosacral Interbody Fusion

The literature on axial lumbosacral interbody fusion includes a systematic review of case series and a retrospective comparison of axial lumbosacral interbody fusion with anterior lumbar interbody fusion. No prospective randomized controlled trials have been identified comparing outcomes of axial lumbosacral interbody fusion with other approaches to lumbosacral interbody fusion.

In 2012, Gerszten et al reported a series of patients who had a minimum 2-year follow-up after axial LIF with percutaneous posterior fixation with pedicle screws for the stabilization of grade 1 or grade 2 lumbosacral isthmic spondylolisthesis.[26] (Treatment of grade 2 spondylolisthesis is an off-label indication.) There were no perioperative procedure-related complications. The spondylolisthesis grade in the 26 consecutive patients was significantly improved at follow-up, with 50% of patients showing a reduction of at least 1 grade. Axial pain severity improved from a VAS score of 8.1 to 2.8, and 81% of patients were considered to have excellent or good results by Odom criteria. At 2 years post-treatment, all patients showed solid fusion.

The largest case series published to date is a 2011 retrospective analysis of 156 patients from 4 clinical sites in the U.S.[91] Patients were selected for inclusion if they underwent a L5-S1 interbody fusion via the axial approach and had both presurgical and 2-year radiographic or clinical follow-up. The number of patients who underwent axial LIF but were not included in the analysis was not reported. The primary diagnosis was degenerative disc disease (61.5%), spondylolisthesis (21.8%), revision surgery (8.3%), herniated nucleus pulposus (8.3%), spinal stenosis (7.7%) or other (8.3%). Pain scores on a numeric rating scale improved from a mean of 7.7 to 2.7 (n=155), while the Oswestry Disability Index (ODI) improved from a mean of 36.6 preoperatively to 19.0 (n=78) at 2-year follow-up. Clinical success rates, based on an improvement of at least 30%, were 86% for pain (n=127/147) and 74% for the ODI (n=57/77). The overall radiographic fusion rate at 2 years was 94% (145 of 155). No vascular, neural, urologic, or bowel injuries were reported in this study group. Limitations of this study include the retrospective analysis, lack of controls, and potential for selection bias by only reporting on the patients who had 2 years of follow-up.

Zeilstra et al conducted a retrospective review of 131 axial LIF procedures (L5-S1) performed at their institution over a period of 6 years.[104] All patients had undergone a minimum of 6 months (mean, 5 years) of unsuccessful nonsurgical management and had magnetic resonance imaging (MRI), radiographs, provocative discography and anesthetization of the disc. MRI of the sacrum and coccyx was performed to identify vascular anomalies, tumor, or surgical scarring that would preclude safe access through the presacral space, and patients followed a bowel preparation protocol the night before surgery. Percutaneous facet screw fixation was used in all patients beginning mid-2008. No intraoperative complications were reported. At a mean follow-up of 21 months (minimum 1 year), back pain had decreased by 51% (from a visual analog score [VAS] of 70 to 39), leg pain decreased by 42% (from 45 to 26), and back function scores (ODI) improved by 50% compared with baseline. With clinical success defined as improvement of 30% or more, 66% of patients were improved in back and leg pain severity. Employment increased from 47% to 64% at follow-up. The fusion rate was 87.8%, with 9.2% indeterminate on

radiograph and 3.1% showing pseudoarthrosis. There were 8 reoperations (6.1%) at the index level.

Whang et al reported a multicenter retrospective comparison of axial LIF versus ALIF of L5-S1 in 96 patients with a minimum of 2 years of follow-up.[99] Most of the procedures were performed for degenerative disc disease or spondylolisthesis and included the use of bilateral pedicle screws. A variety of graft materials was used, including the use of recombinant human bone morphogenetic protein-2 (in 29 axial LIF and 11 ALIF procedures. Fusion, assessed at 24 months by 2 independent evaluators based on radiographs and multiplanar CT images, was similar for the 2 procedures (85% for axial LIF, 79% for ALIF, p>0.05). The incidence of adverse events was also similar, with no cases of rectal perforation. Interpretation of this study is limited by the retrospective nature of the study, variability in procedures, absence of validated clinical outcome measures, and lack of randomization.

In 2010, Patil and colleagues reported a retrospective review of 50 patients treated with axial LIF.[71] Four patients (8%) underwent 2-level axial LIF, and 16 patients (32%) underwent a combination of axial LIF with another procedure for an additional level of fusion. There were 3 reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-up, visual analog scale (VAS) scores had decreased from 8.1 to 3.6 (n=48). At an average 12-month follow-up, 47 of 49 patients (96%) with postoperative radiographs achieved solid fusion. There were no significant differences between pre- and postoperative disk space height and lumbar lordosis angle.

Duan and colleagues (2009) reviewed the feature, biomechanics, and clinical application of percutaneous 360 degree AxiaLIF technique, which is different from other lumbar interbody fusion techniques due to its capability in maintaining the integrity of the bilateral facet joints, the anterior/posterior longitudinal ligament, and the annulus fibrosus.[23] The 3-dimensional AxiaLIF Rod provided axial support and fixation, thus relieving stenosis of the lumbar intervertebral foramen and restoring the intervertebral disc height and the whole height and physiological curvature of the lumbar spine. The recovery of the intervertebral disc height could restore the folded or crumpled flavum, the posterior longitudinal ligament, and the herniated annulus, resulting in the improvement of stenosis symptoms of nerve root canal or central vertebral canal. The authors concluded that percutaneous 360 degree AxiaLIF technique achieves satisfying therapeutic effects, although it has fairly narrow indication and needs long-term follow-up observation.

Aryan and colleagues reported on a series of 35 patients with average follow-up of 17.5 months in 2008.[5] These patients had pain secondary to lumbar degenerative disc disease, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the axial LIF procedure was followed by percutaneous pedicle screw-rod fixation; 2 patients had extreme lateral interbody fusion (XLIF) combined with posterior instrumentation, and 10 had a standalone procedure. Two patients had axial LIF as part of a larger construct after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar fusion. Radiographic evidence of stable cage placement and fusion was found in 32 patients at last follow-up.

Marchi and colleagues reported prospective 2-year follow-up on 27 patients who underwent 2-level (L4-5 and L5-S1) axial LIF.[57] Average back pain improved from a VAS score of 8.08 to 4.04 and the ODI improved from 51.7 to 31.4. Although no intraoperative complications occurred, the authors reported that the rod was malpositioned in 3 cases due to difficulty in attaining an adequate route for the double-level access, and in one of these cases, the rod

eventually migrated and perforated the bowel. Five patients (18.5%) underwent additional surgery for malpositioned rods, broken posterior screws, failure of the rods, and collapse of spine levels. Total complications observed at follow-up included screw breakage (14.8%), trans-sacral rod detachment (11.1%), radiolucency around the trans-sacral rod (52%), and disc collapse with cephalic rod migration (24%). A gain in disc height was observed 1 week after surgery, but by the 24-month follow-up, the disc space was reduced compared to the preoperative state. Only 22% of levels had solid fusion at the 24-month radiologic evaluation, and only 2 patients had solid fusion at both levels.

Adverse Events

An industry-sponsored 5-year voluntary post-marketing surveillance study of 9,152 patients was reported by Gundanna et al. in 2011.[28] A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a 2-level (L4-S1) fusion was performed in 1,118 patients (12%). A pre-defined database was designed to record device- or procedure-related complaints through spontaneous reporting. Several procedures, including the presence of a TransS1 representative during every case, were implemented to encourage complication reporting. The complications that were recorded included bowel injury, superficial wound and systemic infections, transient intraoperative hypotension, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury, and ureter injury, (pseudoarthrosis was not included). The follow-up period ranged from 3 months to 5 years 3 months. Complications were reported in 120 patients (1.3%) at a median of 5 days (mean, 33 days; range, 0-511 days). Bowel injury was the most commonly reported complication (0.6%), followed by transient intraoperative hypotension (0.2%). All other complications had an incidence of 0.1% or lower. There were no significant differences in complication rates for single-level (1.3%) and 2-level (1.6%) fusion procedures. Although this study includes a large number of patients, it is limited by the dependence on spontaneous reporting, which may underestimate the true incidence of complications.

Lindley and colleagues found high complication rates in a retrospective review of 68 patients who underwent axial LIF between 2005 and 2009.[54] Patient diagnoses included degenerative disc disease, spondylolisthesis, spinal stenosis, degenerative lumbar scoliosis, spondylolysis, pseudoarthrosis, and recurrent disc herniation. Ten patients underwent 2-level axial LIF (L4-S1), and 58 patients underwent a single-level axial LIF (L5-S1). A total of 18 complications in 16 patients (23.5%) were identified with a mean 34 months' follow-up (range 17-61 months). Complications included pseudoarthrosis (8.8%), superficial infection (5.9%), sacral fracture (2.9%), pelvic hematoma (2.9%), failure of wound closure (1.5%), and rectal perforation (2.9%). Both of the patients with rectal perforation underwent emergency repair and were reported to have no long-term sequelae. The patients with non-union underwent additional fusion surgery with an anterior or posterior approach. The 2 patients with sacral fractures had pre-existing osteoporosis; one was treated with long iliac screws. Because of the potential for these complications, the authors recommend full bowel preparation and preoperative magnetic resonance (MR) imaging prior to an axial LIF procedure to assess the size of the presacral space, determine rectal adherence to the sacrum, rule out vascular abnormalities, and determine a proper trajectory.

At the time this policy was created, the published literature reporting patient outcomes for percutaneous axial anterior lumbar interbody fusion was limited to a technical report with presentation of 2 cases and 1 retrospective case series with patients who received AxiaLIF at L5-S1. The AxiaLIF 2-level system received premarket notification in April 2008. Aryan and colleagues report on their series of 35 patients with average follow-up of 17.5 months.[5] These patients had pain secondary to lumbar degenerative disc disease, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the AxiaLIF procedure was followed by percutaneous

pedicle screw-rod fixation; 2 patients had extreme lateral interbody fusion combined with posterior instrumentation, and 10 had a standalone procedure. Two patients had axial LIF as part of a larger construct after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar fusion. Radiographic evidence of stable cage placement and fusion was found in 32 patients at last follow-up.

In a 2007 review of MI techniques for lumbar interbody fusion, Shen et al. note that experience with the technique is limited and complication rates are unknown.[88] Complications may include perforation of the bowel and injury to blood vessels and/or nerves, as well as infection. They also voiced concerns about the increased need for fluoroscopy and the inability of the surgeon to address intracanal pathology or visualize the discectomy procedure directly. In 2010, Patil and colleagues reported a retrospective review of 50 patients treated with AxiaLIF. Four patients (8%) underwent 2-level AxiaLIF, and 16 patients (32%) underwent a combination of AxiaLIF with another procedure for an additional level of fusion. There were 3 reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-up, VAS scores had decreased from 8.1 to 3.6 (n=48). At an average 12-month follow-up, 47 of 49 patients (96%) with postoperative radiographs achieved solid fusion. There were no significant differences between pre- and postoperative disk space height and lumbar lordosis angle. The 2011 literature update also identified a small case series (n=6) using intraoperative 3-dimensional navigation with AxiaLIF, a case report of removal of the AxiaLIF fixation rod due to pseudoarthrosis, and a case report of high rectal injury during AxiaLIF.

SUMMARY OF EVIDENCE

Current evidence for some minimally invasive/minimal access approaches includes systematic reviews and non-randomized comparative studies. The available evidence suggests that after an initial training period, short- to mid-term health outcomes (including complication and fusion rates, pain and function) following minimally invasive anterior, posterior, and transforaminal approaches are comparable to standard open approaches for single-level interbody fusion of the lumbar spine. Intra- and perioperative health outcomes (blood loss and hospital stay) have been shown to be improved. Therefore, the following approaches may be considered established for interbody fusion of the lumbar spine:

- Minimally invasive anterior interbody fusion (ALIF)
- Minimally invasive posterior lumbar interbody fusion (PLIF)
- Minimally invasive transforaminal lumbar interbody fusion (TLIF)
- Minimally invasive lateral lumber interbody fusion (LLIF), which may be called extreme lateral interbody fusion (XLIF) or direct lateral interbody fusion (DLIF)

The available evidence suggests the possibility of an increased risk of complications with *laparoscopic* ALIF. Therefore, this procedure is considered investigational for lumbar interbody fusion of one or more levels.

There is insufficient published evidence to evaluate whether percutaneous axial lumbar interbody fusion (AxiaLIF). In addition, there are a relatively large number of adverse event reports in the MAUDE database for percutaneous axial lumbar interbody fusion, which raises the possibility of an increased risk of complications. Therefore, the AxiaLIF interbody fusion procedure is considered investigational.

Although initial outcomes for the oblique lateral lumbar interbody fusion technique (OLLIFF) appear promising, there have been postoperative neurologic complications in some patients

which have required an alteration in technique. Further studies are needed to determine longer term outcomes of this novel procedure.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute for Health and Clinical Excellence (NICE)

In July 2018, the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. The recommendation, based on a literature review conducted in December 2017, states, "Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor."[65,66]

North American Spine Society

In 2014, the North American Spine Society published guidelines on the treatment of degenerative spondylolisthesis.[106] The North American Spine Society gave a grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guidelines discussed posterolateral fusion, 360º fusion, and minimally invasive fusion; it did not address axial lumbosacral interbody fusion.

Ongoing and Unpublished Clinical Trials

A search of Clinicaltrials.gov in March 2023 did not identify any ongoing trials that would influence this review.

Government Regulations

National:

No National Coverage Determination was found for AxiaLIF or lumbar fusion (CMS, 2017). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Local:

No CMS Local Coverage determination (LCD) on this topic.

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

Related Policies

- Artificial Intervertebral Discs-Cervical Spine
- Artificial Intervertebral Discs-Lumbar Spine
- Interspinous/Interlaminar Stabilization/Distraction Devices (Spacers)
- Spinal Surgery-Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD, MELD) for Spinal Stenosis
- Spinal Surgery Percutaneous, Endoscopic, Laser and/or Radiofrequency DecompressionStem Cell transplant for Spinal Cord Injury

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 2024 the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/08	5/19/08	7/1/08	Joint policy established
9/1/09	6/16/09	6/16/09	Routine review. CPT codes updated. Policy statement unchanged
9/1/10	6/15/10	6/29/10	Updated references; no change in policy statement
5/1/12	2/21/12	2/21/12	Policy name changed from "Axial Lumbo-Sacral (L5-S1) Interbody Fusion Using the Paracoccygeal Approach and Specialized Instrumentation" to "Minimally Invasive Lumbar Interbody Fusion." Expanded policy to include other LIF procedures. Code 22558 added to policy. Rationale reformatted. References updated.
5/1/13	2/19/13	3/4/13	Codes updated. Added codes 0309T and 22586 as experimental/ investigational . References added. Policy status unchanged.
7/1/14	4/8/14	4/15/14	References updated. No change to policy position.
1/1/16	10/13/15	10/27/15	References updated. No change to policy position.
7/1/16	4/19/16	4/19/16	Routine review
7/1/17	5/4/17	5/3/17	Change in status of XLIF and DLIF from experimental/investigational to established. Use CPT codes 22558, 22585 and 22845. 22845 added o policy. Added oblique LIF to policy, (OLIF or OLLIF). Additional references added to support policy positions.
5/1/18	4/17/18	4/17/18	Routine policy maintenance. Deleted code 0309T. No change in policy status.

7/1/19	4/16/19		Routine policy update. No change in policy status.
11/1/19	8/20/19		Codes 0195T and 0196T removed from policy. No change in policy status.
11/1/20	9/1/20		Routine policy maintenance, no change in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
5/1/22	2/15/22		Added codes 63052 and 63053 as established effective 1/1/22.
5/1/23	2/21/23		Removed reference #1, added reference #107. Routine policy maintenance, no change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance (jf) Vendor managed: Turning Point No change in policy status. Title Update: added “Spinal Surgery” for clarity to find on router. Previous title was Minimally Invasive Lumbar Interbody Fusion (-LIF). • Final title: Spinal Surgery-Minimally Invasive Lumbar Interbody Fusion (-LIF)Nomenclature updated per Optum Encoder Pro for codes 63052 and 63053 • Added under the regulation section FDA Table • Added PICO under Axial Lumbosacral Interbody Fusion from BCBSA • Added clinical trial review

Next Review Date: 1st Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPINAL SURGERY- MINIMALLY INVASIVE LUMBAR INTERBODY FUSION (-LIF)

I. Coverage Determination:

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

II. Administrative Guidelines:

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