Minimally Invasive Spine Surgery Procedures (for New Mexico Only)

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➲ Instructions for Use

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- Total Artificial Disc Replacement for the Spine (for New Mexico Only)
- Vertebral Body Tethering for Scoliosis (for New Mexico Only)

Application

This Medical Policy only applies to the state of New Mexico.

Coverage Rationale

The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy:

- Axial Lumbar Interbody Fusion (AxiaLIF®), a percutaneous Presacral access route to the L5-S1 vertebral bodies
- Percutaneous Image-Guided Lumbar Decompression (PILD)
- Percutaneous sacral augmentation (Sacroplasty) with or without a balloon or bone cement
- Automated percutaneous and percutaneous Endoscopic Discectomy (APLD) for intervertebral disc decompression
- Minimally invasive lumbar decompression (mild ®)
- Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)
- Transforaminal lumbar Interbody Fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization)

Definitions

Automated Percutaneous Lumbar Discectomy (APLD): Is a minimally invasive surgical technique for treatment of herniated lumbar intervertebral discs. For this procedure, a thin, blunt-tipped suction and cutting probe is inserted through the skin, and the end of the probe is placed into the middle of the herniated disc under fluoroscopic guidance. This device is then used to remove some or all of the degenerated portion of the center of the disc. The goal of this procedure is to relieve pressure on nerve roots without damaging surrounding tissues, thereby minimizing postoperative complications and morbidity. APLD is intended as an alternative to chemonucleolysis, open discectomy, or other types of percutaneous discectomy for individuals who have a relatively small degree of lumbar disc protrusion without fragmentation or complete extrusion of disc material and who have failed conservative therapy (Vertos Medical, 2018).

Axial Lumbar Interbody Fusion (AxiaLIF): Also called trans-sacral, transaxial, or para-coccygeal Interbody Fusion, is a minimally invasive technique used in L5-S1 (presacral) spinal fusions. The technique provides access to the spine along the long axis of the spine, as opposed to anterior, posterior, or lateral approaches. The surgeon enters the back through a very small incision next to the tailbone and the abnormal disc is taken out. Then a bone graft is placed where the abnormal disc was and is supplemented with a large metal screw. Sometimes, additional, smaller screws are placed through another small incision higher on the back for extra stability (Cragg, et al., 2004).

Endoscope: A thin, fiberoptic tube with a light and lens, used to examine the interior of the patient's body; provides minimally invasive access for diagnostic and surgical procedures (AANS, 2022).

Endoscopic Discectomy: Involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an Endoscope, and aspiration of disc material (Vertos Medical, 2018).

Fluoroscopy: Imaging technique to obtain real-time moving images of the internal structures of the body; this imaging uses an x-ray source and fluorescent screen; modern fluoroscopes couple the screen to an x-ray image intensifier and video camera allowing the images to be recorded and shown on a monitor (Vertos Medical, 2018).

Image-Guided Minimally Invasive Lumbar Decompression (mild®): A percutaneous procedure for decompression of the central spinal canal in individuals with lumbar spinal stenosis. In this procedure, a specialized cannula and surgical tools are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal (Vertos Medical, 2018).

Interbody Fusion: A surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar Interbody Fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis following a discectomy, or for adjacent-level disc disease (Ortho Info, 2021).

Interlaminar Lumbar Instrumented Fusion (ILIF): During the ILIF procedure, the surgeon makes an incision in the lower back and an opening is created through the ligaments. This allows access to the spinous processes. The bone, ligament, or disc that is causing compression is removed to release pressure on the nerves. Allograft bone may be placed in the disc space. Bone, either autograft and/or allograft, is placed between the spinous processes and on the remaining lamina. An implant is inserted to stabilize the spine and secure the spinous processes until the fusion takes place (Veritas Health, 2022).

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF): Minimally invasive alternative to an open surgical approach to spinal fusion. The vertebrae are reached through an incision in the lower abdomen or side. This method employs a laparoscope to remove the diseased disc and insert an implant (i.e., rhBMP, autogenous bone, cages, or fixation devices) into the disc space intended to stabilize and promote fusion (Veritas Health, 2022).

Nucleoplasty: Also known as percutaneous disc decompression (PDD) or percutaneous plasma discectomy, uses x-ray images (Fluoroscopy) for guidance to insert a specialized catheter to reach the disc nucleus. Radiofrequency energy is used to ablate nuclear material and create small channels within the disc. This is thought to decompress the disc, reducing the pressure both inside the disc and on nerve roots.

Open Spine Surgery: Unlike the minimally invasive approach, traditional Open Spinal Surgery relies on longer skin incisions and more extensive tissue dissection to expose the surgical field.

Percutaneous Endoscopic Lumbar Diskectomy (PELD): PELD is a minimally invasive procedure in which indirect access to the herniated disc is made under fluoroscopic guidance using an Endoscope and specialized instruments; removal of the disc occurs using laser or other mechanical means (Veritas Health, 2022).

Percutaneous or Endoscopic Lumbar Fusion: During a percutaneous endoscopic procedure the surgeon does not have direct visualization of the operative field, in contrast to an open approach. Visual guidance is obtained using either Fluoroscopy or a video monitor. Specialized instruments are typically used and advanced through a retractor, avoiding major soft tissue injury. The approach is associated with a steep learning curve, risk of radicular trauma with insertion of cages, and in some cases postoperative migration of the devices (Veritas Health, 2022).

Percutaneous Image-Guided Lumbar Decompression (PILD): A posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area (Veritas Health, 2022).

Posterior Lumbar Spine Surgery: Performed by approaching the spine through the individual's back by a traditional back midline incision or transforaminally through the opening between two spinal vertebrae (i.e., the foramen) where the nerves leave the spinal canal to enter the body [i.e., transforaminal lumbar Interbody Fusion (TLIF)] (Veritas Health, 2022).

Presacral: Anterior to the sacrum (Ortho Info, 2021).

Sacroplasty: A minimally invasive surgical treatment that attempts to repair sacral insufficiency fractures using bone cement. Sacral insufficiency fractures have traditionally been treated with conservative measures, including bed rest, analgesics, orthoses/corsets, and physical therapy. In some cases, pain persists and is refractory to these measures. For this procedure, two thin, hollow tubes are placed in the lower back, over the left half and right half of the sacrum, guided by images from x-rays or computed tomography scans. The surgeon then advances a needle through each tube to the site of the sacral fracture and injects 2 to 5 mL of bone cement (Hayes, 2018; updated January 2021).

Spinal Decompression: Spinal stenosis, which is a narrowing of the vertebral canal, is a common condition that can result in compression of the nerves. This can produce a variety of symptoms, including pain, numbness and muscle weakness. If surgery is recommended, it may be possible to remove the bone and soft tissues causing the nerve compression through an MIS approach using tubular dilators and a microscope or Endoscope. The more common decompressive procedures include laminectomy and foraminotomy (AANS, 2022).

Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems: The TESSYS® approach focuses on the endoscopic visualization of the foramen and a transforaminal approach in order to resect the herniated disc. The surgeon performs a foraminoplasty through which neural elements can be decompressed. Disc material is removed completely and directly through the foramen, which is gradually widened using specialized reamers and instruments. The iLESSYS® method uses endoscopic interlaminar access for the removal of herniated discs or the treatment of lumbar spinal stenosis. Generally, all lumbar levels can be treated with either approach.

Tubular Retractor: This technique involves progressive dilation of the soft tissues, as opposed to cutting directly through the muscles. By using tubes to keep the muscles out of the way, the surgeon works through the incision without having to expose the area widely. Sometimes, the surgeon will also utilize an Endoscope or microscope focused down the tube to assist with performing the surgery Once the procedure is complete, the Tubular Retractor can be removed, allowing the dilated tissues to come back together. Depending on the extent and type of surgery necessary, incisions can often be small (AANS, 2022).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar

CPT Code	Description
22899	Unlisted procedure, spine
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

HCPCS Code	Description
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

Description of Services

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, a surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy, in which the extruding disc material is excised. When performed with an operating microscope the procedure is known as microdiscectomy. Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material.

In an attempt to alleviate many of the limitations of previous techniques, a Presacral approach to the lumbosacral junction has been investigated. Transaxial anterior lumbar Interbody Fusion is an emerging minimally invasive spinal fusion procedure used to treat patients with chronic lower back pain. This procedure is an alternative to traditional fusion techniques that utilize anterior or posterior approaches to directly expose the lumbosacral spine. In the case of transaxial anterior lumbar Interbody Fusion the spine is accessed percutaneously via the anterior surface of the sacrum (Ollendorf, et al., 2011).

Clinical Evidence

Automated Percutaneous Lumbar Discectomy (APLD)

Systematic reviews have assessed automated percutaneous discectomy compared to other interventions; however, the majority of these reviews contained observational studies published more than a decade ago with generally small patient populations and inconsistent results. There is insufficient evidence obtained from well-designed and executed randomized controlled trials to evaluate the impact of automated percutaneous discectomy on net health outcome.

Feng et al. (2017) conducted a meta-analysis of randomized controlled trials (RCTs) to evaluate the clinical results of 7 surgical interventions for the treatment of lumbar disc herniation. The eligible RCTs were identified and data from 3 outcomes (success, complications, and reoperation rate) were independently extracted by 2 authors. A total of 29 RCTs including 3,146 participants were included in this meta-analysis. For the success rate the rank probability (from best to worst) included: percutaneous endoscopic lumber discectomy (PELD) > standard open discectomy (SOD) > standard open microsurgical discectomy (SOMD) > chemonucleolysis (CN) > micro endoscopic discectomy (MED) > percutaneous laser disc decompression (PLDD) > automated percutaneous lumber discectomy (APLD). The limitations of this network meta-analysis include the range of study populations and inconformity of the follow-up times and outcome measurements. The authors concluded that this meta-analysis provides evidence that PELD might be the best choice to increase the success rate and decrease the complication rate, moreover SOMD might be the best option to drop the reoperation rate. APLD might lead to the lowest success rate and the highest complication and reoperation rate. Higher quality RCTs and direct head-to-head trials are needed to confirm these results.

Manchikanti et al. (2013c) conducted a systematic review of APLD for the contained herniated disc. Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, opioid intake, and return to work. Short-term effectiveness was defined as one year or less, whereas long-term effectiveness was defined as greater than one year. Nineteen observational studies and no randomized controlled trial were included and met inclusion criteria for methodological quality assessment. Overall, 5,515 patients were studied with

4,412 patients (80%) showing positive results lasting one year or longer. Based on USPSTF criteria, the indicated evidence for APLD is limited for short- and long-term relief. A study limitation is the paucity of RCTs in the literature describing APLD.

A number of systematic reviews (SRs) have been published since 2007. A review of these trials suggested that APD produced inferior results to either of the established procedures. The authors of the systematic reviews reached similar conclusions, that while there is considerable evidence of efficacy for conventional surgical discectomy, there is insufficient evidence on percutaneous discectomy techniques including APD to draw firm conclusions. Large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to establish the safety and efficacy of automated percutaneous and percutaneous endoscopic discectomy compared with open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous and endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

The 2005 National Institute for Health and Clinical Excellence guidance for automated percutaneous mechanical lumbar discectomy concluded, “There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomized controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research”.

The 2002 Lumbar Automated Percutaneous Discectomy Outcomes Group (LAPDOG) trial, (Haines et al.) is a RCT to compare automated percutaneous discectomy with open discectomy in patients with lumbar disc herniation. No additional RCTs have been identified since the 2002 LAPDOG trial. The trial was designed to recruit 330 patients but enrolled 36 patients for reasons not readily apparent. Twenty-seven patients were available at follow-up, with efficacy reported by 41% of those undergoing automated percutaneous discectomy and by 40% of those undergoing conventional discectomy. The trialists concluded that "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation".

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In the section on percutaneous disc decompression in the evidence-based guideline, the ASIPP found limited evidence for the use of automated percutaneous lumbar discectomy for the treatment of lumbar disc compression (Manchikanti et al., 2013).

North American Spine Society (NASS)

The 2014 practice guidelines from the NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (poor quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

Axial Lumbar Interbody Fusion (AxiaLIF)

Although this method may be considered an emerging minimally invasive surgical approach, no randomized controlled trials evaluating axial LIF as a minimally invasive or percutaneous surgical procedure for the treatment of L5-S1 conditions were found in the peer-reviewed, published, scientific literature supporting safety and efficacy. Improvement in net health outcomes has not been clearly demonstrated when compared to standard surgical methods, and it remains unclear whether this surgical technique results in clinical benefits that are as good as or superior to standard surgical techniques. The evidence is insufficient to allow any conclusions regarding short- or long-term clinical benefits, possible complications, failure rates, relief of symptoms, improvement in functional levels, and the need for further surgery is as beneficial as other surgical approaches to lumbosacral interbody fusion.

An ECRI report for the AxiaLIF Plus System indicated that the evidence from case series in one systematic review and one additional case series (not in the systematic review) is at too high a risk of bias to support conclusions on safety and effectiveness of one-level lumbar interbody fusion or L5-S1 spondylolisthesis or spondylosis with AxiaLIF. Randomized controlled trials (RCTs) comparing patient-oriented outcomes (e.g., pain, functional status, reoperation rates) of AxiaLIF with other interbody fusion surgical approaches are needed to assess AxiaLIF’s comparative effectiveness (ECRI, 2020).

Balsano et al. (2020) conducted a retrospective analysis to evaluate the radiographic and clinical results of patients treated with AxiaLIF® Technique (AxiaLIF®, AMSGroup, Italy) using a minimally invasive pre-sacral approach. From 2013

to 2018, a total of 52 patients have been treated (12 M, 40 F; mean age 46.3 years). Diagnosis included L5 isthmic spondylolisthesis low-grade dysplasia, primary and secondary degenerative disc disease. Forty-three patients have been followed for at least 2 years. Fusion assessment was based on plain radiographs and Brantigan fusion criteria at 1, 6, 12 and 24 months after surgery. All patients completed the VAS and ODI at baseline through last follow-up. Results: Clinical results showed good pain resolution. VAS back demonstrated an average reduction over baseline of 50%, 57%, 71%, 77% at 3, 6, 12 and 24 months, respectively ($p < 0.001$). ODI demonstrated an average reduction over baseline of 38%, 51%, 67%, and 72% at the same time points ($p < 0.001$). Complete fusion was demonstrated in 65% of cases, 30% partial fusion and 5% in the absence of bony bridges visible radiographically. We had two major complications, as 1 retroperitoneal hematoma and 1 spondylodiscitis, and one minor complication, as a superficial infection of the surgical wound. The authors concluded that the surgical treatment of degenerative disc disease at L5-S1 with minimally invasive technique AxiaLIF showed good radiographic and clinical outcomes with an acceptable rate of complications. Moreover, shorter hospitalization and faster functional recovery are adding factors to the choice of this technique. This study is limited by its small sample size and retrospective observations. Although the results are promising, the small sample size and lack of a comparison group limit the generalizability of the findings.

Anand et al. (2018) conducted a single-center retrospective study to compare the fate of the lumbosacral junction in ALIF versus AxiaLIF patients in terms of clinical and radiographic outcomes. Adult spinal deformity patients, treated with CMIS techniques, with at least 2-year follow-up who underwent AxiaLIF or ALIF at the lumbosacral junction were included. Patients were separated into two groups: AxiaLIF (56 patients) and ALIF (38 patients). Outcome measures included segmental lordosis, sagittal vertical alignment, lumbar lordosis (LL), pelvic incidence-LL mismatch, and pseudarthrosis, major complication, and revision surgery rates. The ALIF group achieved greater postoperative and delta segmental lordosis, higher delta sagittal vertical alignment, higher delta LL, and lower postoperative pelvic incidence-LL mismatch. The pseudarthrosis, major complication, and revision surgery rates were higher in the AxiaLIF group. Five cases of pseudarthrosis at L5-S1 were seen, all in the AxiaLIF group. The authors concluded ALIF patients showed more favorable radiographic correction parameters and lower rates of pseudarthrosis, major complications, and revision surgeries. ALIF is the preferred strategy for L5-S1 arthrodesis at a bottom of a long construct. This study is limited by its small sample size and retrospective observations. In addition, the ALIF vs AxiaLIF surgeries were not randomized. Further research with randomized controlled trials is needed to validate these findings.

Schroeder et al. (2015) performed a systematic review of seventy-four articles discussing safety profile of axial interbody arthrodesis, but only 15 (13 case series and 2 retrospective cohort studies) met the study inclusion criteria. The authors concluded that review of the literature indicates that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). However, these results are based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicate that the actual fusion rate may be lower, and the complication rate may be higher than currently reported.

Zeilstra et al (2013) reported their 6-year single-center experience with L5-S1 axial lumbar interbody fusion (AxiaLIF). A total of 131 patients with symptomatic degenerative disc disease refractory to non-surgical treatment were treated with AxiaLIF at L5-S1 and were followed for a minimum of 1 year. Main outcomes included back and leg pain severity, Oswestry Disability Index score, working status, analgesic medication use, patient satisfaction, and complications. Back and leg pain severity decreased by 51% and 42%, respectively, during the follow-up period. Back function scores improved 50% compared to baseline. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve lumbosacral fusion in patients with symptomatic degenerative disc disease. Moreover, they noted that “Our study is limited by the retrospective nature of the analysis. Additionally, all patients underwent fusion at L5 to S1 and, therefore, no conclusions can be drawn regarding the effectiveness or safety of 2-level AxiaLIF from this report. Lastly, mean patient follow-up was 21 months. Although this represents one of the longest follow-up reports following AxiaLIF surgery, long-term clinical and radiographic outcomes are unknown”.

In a 5-year post-marketing surveillance study, Gundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9,152 patients. A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a two-level L4-S1 fusion was performed in 1,118 patients (12%). Complications were reported in 1.3% of patients with the most commonly reported complications being bowel injury (0.6%) and transient intraoperative hypotension (0.2%). Other complications noted include superficial wound and systemic infections, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury and ureter injury. The overall complication rate was similar between single-level (1.3%) and two-level (1.6%) fusion procedures, with no significant differences noted for any single complication. The authors concluded that the overall complication rates compare favorably with those reported in trials of open and minimally invasive lumbar fusion surgery.

Clinical Practice Guidelines

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)

AANS and CNS have jointly published a series of guidelines addressing fusion for degenerative disease of the lumbar spine (2014). Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention. In the absence of deformity or instability, lumbar fusion has not been shown to improve outcomes in patients with isolated stenosis, and therefore it is not recommended.

National Institute for Health and Clinical Excellence (NICE)

The National Institute for Health and Clinical Excellence (NICE) guidance stated that the evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into transaxial interbody lumbosacral fusion (NICE, 2018).

North American Spine Society (NASS)

NASS published guidelines on the treatment of degenerative spondylolisthesis in 2014. NASS has stated that there is insufficient evidence to make a recommendation for or against the cost-effectiveness of minimal access-based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis. This guideline did not specifically address axial lumbosacral interbody fusion (AxiaLIF).

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)

Evidence in the peer-reviewed scientific literature evaluating laparoscopic anterior lumbar interbody fusion is primarily in the form of prospective and retrospective case series, comparative trials, and nonrandomized trials. The average sample size of these studies varies but range on average from 40 to more than 200 patients. Many studies are outdated with average being over twenty years ago. Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic approach compared to open spinal fusion.

Minimally Invasive Lumbar Decompression (MILD)

Available studies have limitations that include: non-controlled trials, case series, non-blinded studies, and small number of participants. Well-designed studies that include: a larger number of participants at multi-centers, use of clear patient selection criteria, measures of outcome using standardized tools, comparison to conservative management, comparison with and without an anesthetic agent and longer-term outcomes are needed to validate the use/safety/effectiveness of this technology.

Hayes (2023) completed a Health Technology Assessment to evaluate the effectiveness and safety of the minimally invasive lumbar decompression (MILD) procedure, an approach that uses a proprietary surgical kit (mild®; Vertos Medical Inc.) to treat lumbar spinal stenosis (LSS) in adult (≥ 18 years old) patients. Patients had statistically significant and clinically significant improvements in pain, disability, and function after treatment with MILD compared with baseline that lasted for up to 1 to 2 years, but it is uncertain whether there is a longer durability of effect or whether MILD improved quality of life. The MILD procedure was associated with a reduction in use of pain medications in over half of patients, although some patients started their use de novo at some point during follow-up. A small number of patients required surgical reintervention within 1 to 5 years after MILD. A single study on the comparative efficacy of MILD with the Superion Indirect Decompression device only reported rates of surgical reintervention and provided no data on other outcomes, such as pain and disability. While finding that MILD led to a higher percentage of surgical reinterventions, the statistical significance of the difference between groups was not analyzed. The authors concluded Vertos mild® procedure may have the potential to provide greater improvement in pain and symptoms compared with epidural steroid injection and with conventional medical management, however, there are too few studies to draw definitive conclusions. Substantial uncertainty exists due to individual study limitations and the lack of long-term follow-up. Additional well-designed good-quality studies with follow-up durations > 2 years are needed to better establish the safety, effectiveness, and comparative effectiveness of this technology.

ECRI (2021) performed a literature review of the Vertos mild® device kit. Evidence from studies synthesized in systematic reviews shows the mild® procedure is safe and relieves LSS symptoms at up to one-year follow-up. Evidence from additional studies suggests the mild® procedure may be as effective but safer than laminectomy (three nonrandomized studies) and may be more effective than epidural steroid injections (one randomized controlled trial), but these findings need validation in additional RCTs to permit conclusions. Despite the large amount of available data, some evidence gaps

remain. Additional RCTs are needed to verify findings and assess mild®'s effectiveness compared with other decompression procedures. Large, multicenter studies that assess the mild® procedure's long-term effectiveness (i.e., five years or longer) are also needed.

Mekhail and associates (2021) published the results of a retrospective observational cohort study evaluating mild® for treatment of lumbar spinal stenosis, with hypertrophic ligamentum flavum as a contributing factor (n = 75). The primary outcome measure was the incidence of open lumbar decompression surgery at the same level(s) as the MILD procedure during a five-year follow-up period. Secondary outcome measures included change in patient reported pain levels using the Numeric Rating Scale (NRS), and opioid medication use using the Morphine Milligram Equivalent dose per day from baseline to 3, 6, and 12 months post procedure. The mean patient age was 74.4 years, all had continued pain despite conservative management for an average of 6.8 years. Nineteen subjects had MILD performed at two levels, all others had single level surgery with the most frequent level treated being L4-L5. No major complications were reported, minor complications included post procedural soreness and ecchymosis, with one case of allergic dermatitis at the surgical site. The authors reported a significant difference in the NRS pain scores from baseline and all three time points, 73.8%, 69.5% and 60.3% respectively for 3, 6 and 12 months post-procedure. Within five years nine subjects required open surgical decompression (2.4% annually), women had an odds ratio of 0.175 of having subsequent surgery compared with men. Only three had surgery at the exact same level as the MILD procedure, seven had surgery which involved more levels than the MILD. Only two subjects reported improvement in neurogenic claudication following the open procedure, three reported no improvement following open surgery, and three subjects did not have follow-up visits. In the author opinion MILD was durable over five years and may allow elderly patients the avoidance of open lumbar surgery. The study is limited by its retrospective design, lack of control group, and small sample population.

Merkow and colleagues (2020) published results of a systematic review evaluating outcomes of both mild® and Superion (intraspinous process device) separately, as treatment of lumbar spinal stenosis. Regarding mild® the authors review included eight studies; two RCTs, three prospective observational trials, and three retrospective observational trials. The authors concluded that mild® is modestly safe and effective for treatment of lumbar spinal stenosis, based primarily on the study by Staats, et al. 2018 showing two year outcomes.

Aldahshory et al. (2020) evaluated and compared the clinical outcomes of two different treatment modalities for degenerative lumbar canal stenosis (LCS): the classic laminectomy with posterolateral transpedicular screw fixation and mild®. This was a randomized study of 50 patients with degenerative LCS. The study compared two cohorts: Group A – 25 patients underwent classic lumbar laminectomy with posterolateral transpedicular fixation and Group B – 25 patients underwent mild®. There were no statistically significant differences between both treatment modalities in the Visual Analogue Score (VAS) for leg pain and back pain, the patient satisfaction index, and the Oswestry Disability Index after 1 year. The fusion operations were associated with higher estimates of blood loss and longer hospital stay. The authors concluded that mild® has the same satisfactory results as classic laminectomy with posterolateral fixation for the treatment of degenerative LCS with less bleeding loss and shorter hospitalization. The study limitations included a one-year follow-up that is not sufficient to assess the reoperation rate in case of adding fusion. Other limitations include small sample size and lack of information about the body mass index of each patient and the associated comorbidities.

In 2018, Deer and associates published consensus guidelines for minimally invasive spine treatment (MIST) for lumbar spinal stenosis. The United States Preventive Task Force (USPTF) criteria for evidence level and degree of recommendation was used along with strength of consensus for development of the guidelines. Within this guideline regarding percutaneous image guided lumbar decompression, the authors concluded the available evidence is level 1 and is supportive of PILD. In addition to retrospective and prospective studies reviewed by the consensus group, there were two comparative prospective trials that led to reimbursement approval by CMS, noted as being both Level 1 (Brown, et al., 2012; Staats, et al., 2016, detailed below), both compare PILD to lumbar ESI and not to open decompression. The recommendation by the authors is Grade A (good evidence the measure is effective and that benefits outweigh harms), Level 1 (at least 1 controlled and randomized trial, properly designed), Consensus strong (> 80% consensus).

Staats et al. (2018, included in ECRI above) reported results of a prospective, multicenter, randomized controlled clinical study. This study evaluated the long-term durability of the minimally invasive lumbar decompression (MILD) procedure in terms of functional improvement and pain reduction for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only. Oswestry Disability Index, Numeric Pain Rating Scale, and Zurich Claudication Questionnaire were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events. The authors concluded that mild showed excellent long-term durability, and there was no evidence of spinal instability through 2-year follow-up. Given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, mild® is an excellent choice for first-line therapy for select patients with central spinal stenosis suffering from neurogenic claudication symptoms with hypertrophic ligamentum flavum. Despite the above

findings that study did have the following limitations, lack of a control group at 2-year follow-up. The randomized controlled portion of the study concluded at the primary end point of 1 year, and supplementary follow-up through 2 years was conducted for the mild patient group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, or spacers.

In another study, Chopko (2013) evaluated the long-term effectiveness and safety of mild® as a treatment of neurogenic claudication associated with lumbar spinal stenosis. The 2-year data are reported for 45 participants that were treated with mild® at 11 U.S. facilities. Outcome measurements included the VAS, ODI, and ZCQ. Interim data on the participants are included for 1 week, 6 months, and 1-year follow-up. The authors reported that at 2 years, the subjects demonstrated a statistically significant reduction of pain as measured by VAS, and significant improvement in physical function and mobility as measured by ZQC and ODI. The authors also reported major improvement occurred by 1-week follow-up and showed no difference between each subsequent follow-up, suggesting considerable stability and durability of the initial result over time. There were no major adverse events or complications related to the procedure. Limitations of this study include its uncontrolled design and small size.

Brown et al. (2012) reported the results of a double-blind, randomized, prospective study of epidural steroid injections (ESI) and the mild® procedure at a single pain management center. A total of 38 individuals with symptomatic lumbar spinal stenosis (LSS) participated in the study and were randomized into two treatment groups: 21 participants in the mild® arm and 17 individuals in the ESI arm. Outcome measures were reported using the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI) and Zurich Claudication Questionnaire (ZCQ) patient satisfaction score. The authors reported that at 6 weeks, the mild® participants improved from an average VAS baseline of 6.3 to a mean of 3.8. The ESI group had a mean VAS score of 6, at baseline compared with 6.3 at 6 weeks follow-up. Using the ODI, at 6 weeks follow-up, participants in the mild® group demonstrated a decrease from a baseline mean ODI from 38.8 to 27.4. In the ESI group, the initial ODI was 40.5 and at 6 weeks follow-up, the ODI was 34.8. In the mild® group, there was no significant change in the VAS and ODI scores from weeks 6 to 12. Participants in the ESI group were not measured at week 12. Participants were allowed to cross over from the ESI group to the mild® group before 12 weeks and eventually, all of the participants in the ESI group had the mild® procedure. A total of 14 of the 17 participants in the cross-over ESI group experienced an improvement in their VAS scores after the mild® procedure. Limitations of the study include its small size and short follow-up.

In 2010, Chopko et al., reported on a one-year follow-up from an industry-sponsored multicenter study, with patients who were treated with mild® devices. All 78 patients had failed conservative medical management, with 75.9% of patients treated with conservative therapy for more than 6 months. Twenty-nine patients (50%) were discharged from the surgical facility on the same day as the procedure, and none of the patients stayed longer than 24 hours. There were no reports of major intraoperative or postoperative procedure-related adverse events. The primary outcome of patient success was defined as a 2-point improvement in VAS pain, but the percentage of patients who achieved success was not reported. VAS for pain improved from a mean of 7.4 at baseline to 4.5 at 1-year follow-up. The ODI improved from 48.6 to 36.7, and there was significant improvement on all domains of the Zurich Claudication Questionnaire and the SF-12 physical component score (from 27.4 to 33.5). The small number of study participants and its industry sponsorship limit the conclusions that can be drawn from this study.

Clinical Practice Guidelines

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations for decompression with interlaminar stabilization. ISASS concluded, based in part on a conference presentation of a study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Recommended indications and limitations were described in the article. The document did not address interspinous and interlaminar distraction devices without decompression (Guyer et al., 2016).

National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence states that current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication (such as the X-STOP prosthesis) shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur, and further surgery may be needed. There are no major safety concerns. Therefore, these procedures may be used provided that normal arrangements are in place for clinical governance, consent, and audit. Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options (NICE, 2010).

North American Spine Society (NASS)

The 2014 revised NASS clinical guideline on interspinous process spacing devices concluded that there is insufficient evidence to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis (LSS).

Percutaneous Image-Guided Lumbar Decompression (PILD, PLDD)

This evidence review addresses posterior decompression of lumbar spinal stenosis with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression includes a large RCT, a small RCT, and a number of prospective and retrospective cohort studies and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high-risk of bias. The available evidence is insufficient to determine the efficacy of MILD compared with placebo or to determine the efficacy of image-guided minimally invasive lumbar decompression compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

In a health technology assessment, a small body of very limited low-quality evidence is considered insufficient to determine the safety and efficacy of PLDD for lower back disc herniation (Hayes 2018, updated 2021). The assessment also suggests uncertainty regarding the comparative and long-term effectiveness of PLDD and the need for subsequent surgeries.

Brouwer and colleagues (2015, included in Hayes report above) conducted a RCT with non-inferiority study design (n = 115) to evaluate PLDD compared with conventional surgery for the treatment of LBP. The non-inferiority analysis showed that PLDD resulted in non-inferior outcomes compared with conventional surgery; however, the number of reoperations required was significantly higher in the PLDD group (38%) compared with conventional surgery group (16%). At the two year follow up, Brower and his colleagues (2017) demonstrated that although the rate of reoperation in the PLDD group was higher than expected, surgery could be avoided in 48% of those patients that were original candidates for surgery. The authors concluded the results justify the need for additional studies into the value of PLDD as an alternative to conservative treatment.

In a retrospective observational study, Klessinger (2018c) reported on the re-surgery frequency of 73 patients that received percutaneous lumbar disc decompression (PLDD) using Dekompressor. Patient data were drawn from an electronic medical record system of patients receiving PLDD between January 2005 and December 2007. A history of pain for a minimum of 3 months was mandatory. Patients had either low back pain or radicular pain with or without a sensory loss. Patients with a lumbar spine surgery in their history were excluded. All patients were seen in the practice one month after the operation for follow-up and subsequent follow up was according to the needs of the patient. In 22 patients (30.1%), the follow-up was longer than 5 years, and in five patients (6.8%) it was longer than 10 years. The mean follow-up time was 35.6 months. The results showed that one month after the intervention, excellent results were achieved in 17 patients and good results, in 32 patients, giving a short-term success rate of 67.1%; however, subsequent open surgery at the index level was necessary in 19 patients (26.0%). Most reoperations (15 patients) had to be performed during the first year after PLDD (20.5% of all patients, 78.9% of all resurgeries). These patients had a statistically significant worse outcome (26.7% versus 75.0% satisfied patients). Radicular pain was present in all patients with an early subsequent surgery, but only in 50% of patients with late surgery. The mean time between PLDD and the additional surgery was at 10.8 ±17.9 months. The author concluded that despite an initial success rate of 67%, the resurgery rate of 26% offsets that, and suggests that PLDD is not a replacement for open discectomy. Further studies are needed to compare the outcome and rate of subsequent surgery in patient populations with and without radicular symptoms to find the ideal indications for PLDD.

In a prospective cohort study, McCormick et al. (2016) determined long-term outcomes of Dekompressor percutaneous lumbar disc decompression (PLDD) for discogenic radicular pain. Consecutive patients (n = 70) with discogenic lumbosacral radicular pain who underwent PLDD with Dekompressor were included in the study. Numerical Rating Scale (NRS) leg pain score and Oswestry Disability Index (ODI) score data were collected at 6 months and 1 year. These 2 measures, 5-point Likert scale patient satisfaction, and surgical rate data were also collected at 8 years when possible. Forty and twenty-five patients were successfully contacted at 1-year and 8-year follow-up, respectively. At 1 year and 8 years, NRS leg pain scores were reduced greater than 50% in 47% and 29% of patients, respectively; ODI score improved greater than 30% in 43% and 26% of patients, respectively. Of the patients who were followed-up at 8 years, 36% had undergone surgery and the median satisfaction was "4" (interquartile range of 2 to 5). The authors concluded that while limited by loss-to-follow-up, the findings of this study suggested that treatment of discogenic lumbosacral radicular pain with Dekompressor resulted in decreased leg pain and disability and favorable satisfaction at long-term

follow-up. They stated that further study with adequate follow-up retention is needed to confirm that Dekompressor spares open spinal surgery. The findings are limited by lack of comparison group and large loss to follow up.

Cong et al. (2016) conducted a systematic review to compare the effectiveness and safety of endoscopic discectomy (ED) with open discectomy (OD) for the treatment of symptomatic LDH. A search was used to identify all published RCTs up to August 2014. Cochrane methodology was used for the results of this meta-analysis. Nine relevant RCTs involving 1,092 patients were identified. Compared with OD, ED results in slightly better clinical outcomes which were evaluated by the Macnab criteria without clinical significance (ED group: 95.76%; OD group: 80%; p = 0.10), a significantly greater patient satisfaction rate (ED group: 93.21%; OD group: 86.57%; p = 0.03), lower intraoperative blood loss volume, and shorter length of hospital stay. The authors concluded that from the existing outcomes, ED surgery could be viewed as a sufficient and safe supplementation and alternative to standard open discectomy. The cost-effectiveness analyses still remain unproved from the existing data. More independent high-quality RCTs using sufficiently large sample sizes are needed.

Manchikanti et al. (2013b) conducted a systematic review on patients with radicular pain to determine effectiveness of mechanical lumbar disc decompression with nucleoplasty. Fifteen studies met the inclusion criteria, but only one was an RCT thus no meta-analysis could be performed. A total of 2,429 patients were evaluated with at least 50 patients in each study and a follow up period of one year. Patients had an average improvement of 62% in pain relief. In this limited to fair evidence, the authors concluded nucleoplasty may provide relief in patients with disc herniation. Limitations included lack of RCTs, patient loss, publication bias and a large number of placebo-control groups where utilization of local anesthetic injection was performed thus mimicking a facet joint injection.

Nucleoplasty

Klessinger (2018a) conducted a retrospective case series to investigate the frequency of an additional open surgery after percutaneous cervical nucleoplasty (PCN) up to 10 years. The follow-up time was longer than 5 years in 31.6% of patients and longer than 10 years in 6.0% of patients. One hundred thirty-three patients who underwent PCN between 2005 and 2007, were included. Patient satisfaction was evaluated using McNab's outcome criteria. The necessity of an additional open surgery at the cervical spine, the period between PCN and the fusion, and the treated levels were analyzed. The results showed a short-term success rate (1 month) of 70.7%; however, subsequent surgery was performed in 19.5% of patients. Overall, 57.7% of reoperations were performed during the first year after PCN. In patients with a good result after PCN, subsequent surgery was less frequent, and the interval between PCN and additional surgery was longer. The data from this study suggest that PCN is a poor replacement for conventional open surgery. Degeneration of the disc is progressive despite or because of PCN. Findings are limited by the lack of comparison group.

Klessinger (2018b) conducted a retrospective observational study of 203 patients who underwent percutaneous disc nucleoplasty (PDN) using the Perc-DLG Spine Wand (Arthrocare Corporation, Austin, Texas), to report the frequency of re-operation at the same level. Patient data were drawn from an electronic medical record system of patients who underwent PDN at a single level (L4-5 or L5-S1) in an outpatient procedure. The indications for PDN was either a discogenic low back pain, or a contained disc herniation with back pain with or without radiating pain and with or without a sensory loss. All patients had a history of pain for a minimum of three months. Level L4-5 was treated in 117 patients (57.6%), and level L5-S1 was treated in all other patients. In 43.3% of patients, the left side was treated, in 46.3% of the patients, the right side was treated; and in 21 patients (10.3%), both sides were treated. There were no PDN-related complications. Patients were seen one month after the procedure and subsequent follow up was dependent on patients complaints of pain. In 41 patients (20.2%), the follow-up was longer than 5 years, and in 16 patients (7.9%), it was longer than 10 years with a mean follow up time of 28.8 months. One month after the PDN, the success rate was 63.5%, and subsequent surgery at the index level was required in 18.7% of patients. These patients either had poor pain relief after PDN or a new onset of similar pain. 50% of the re-surgeries had to be performed during the first three months after the PDN. In a five-year follow-up of 172 patients, excellent or good patient satisfaction was achieved in 87.9% of patients after one week, and 63.4% was achieved at the last follow-up. The authors concluded that while the initial patients satisfaction rate appears good, this is offset by the high re-surgery rate, and Indications for nucleoplasty should be reconsidered.

Nie et al. (2018) reported in a retrospective cohort study 5-year outcomes from a comparison of therapeutic efficacy of radiofrequency target disc decompression and nucleoplasty for LDH. Two hundred sixty patients with LDH were divided into two groups: target disc decompression group (group T, n = 147) and nucleoplasty group (group N, n = 113). VAS and functional rating index (FRI) were measured at one, three, six, 12, 24, and 60 months after the surgery. Hospitalization time, operation time, complications, and recurrence/invalid were compared between the two groups. Compared with the pre-operation, the VAS and FRI in both groups were significantly decreased in post-operation ($p < 0.01$). There was no significant difference of the occurrence of complications and disease recurrence/invalid during the follow-up between the two groups. Logistic regression analysis showed that operation time was an independent factor in the prognosis. The authors concluded there was no significant difference between the two methods used and that both can significantly alleviate pain and improve quality of life. The study is limited by lack of randomization and a retrospective design.

Wu et al. (2015) conducted a RCT to compare CT-guided nucleoplasty, CT-guided nucleoplasty combined with nerve root injection, and CT-guided transforaminal lumbar epidural injections in 97 patients with lumbar disk herniation and leg pain. Results of the study demonstrated that the combination of nucleoplasty with nerve root injection produced a significantly greater reduction in the pain score and disability score when compare with only nucleoplasty in the short term, at 1 week, as well at 1 month. The study limitations included lack of blinding and relatively small patient populations.

Ren et al. (2015) evaluated the efficacy of percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific LBP after 5 years of follow-up. Forty-one patients who underwent percutaneous nucleoplasty for chronic LBP were assessed preoperatively and at 1 week, 1 year, 3 years, and 5 years postoperatively in this case series. Pain was graded using a 10 cm VAS and the percentage reduction in pain score was calculated at each postoperative visit. The ODI was used to assess disability related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria. There were significant differences between the preoperative, 1-week postoperative, and 3-year postoperative VAS and ODI scores, but not between the 3-and 5-year postoperative scores. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up. The authors concluded although previously published short and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, the long-term follow-up results showed a significant decline in patient satisfaction over time. This is an uncontrolled study with a small sample size.

In a retrospective review, Liliang et al. (2016) reported outcomes from a case series of 47 patients who underwent nucleoplasty for degenerative LBP using VAS scores. At 10-months, 21 patients (67.7%) experienced substantial pain relief. The most common side effects following nucleoplasty were soreness at the needle puncture site (64.5%), numbness in the lower leg (12.9%), and increased intensity of back pain (9.7%). All side effects were transient. Multivariate analysis revealed that the discography results were the most critical predictor for substantial pain relief of nucleoplasty ($p = 0.03$). The sensitivity and specificity of discography were 92.8% and 62.5%, respectively. Limitations of this study include lack of comparison to a different intervention, non-randomization, small sample size, and short follow-up period.

Kumar et al. (2014) evaluated the safety and efficacy of annul-nucleoplasty using Disc-FX for the treatment of lumbar disc pathology ($n = 24$). All patients in this case series were non-responsive to non-operative treatment measures. A total of 12 patients had degenerative disc disease and 12 patients had contained LDH. Health outcomes included the VAS, ODI, and the SF-36 scores evaluated before and after the procedure. Study authors reported significant improvement in outcomes relative to baseline. The overall rate of re-intervention for symptoms that continued to persist was about 18%; in the group of patients with LDH, the rate was about 36%. The study was limited by lack of appropriate comparator groups, lack of randomization, and relatively limited follow-up.

Zhu et al. (2011) evaluated longer-term efficacy over a 2-year follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc in a case series. A total of 42 cases of protruded lumbar intervertebral disc treated by coblation nucleoplasty followed-up for 2 years were analyzed. Relief of LBP, leg pain and numbness after the operation were assessed by VAS. Function of lower limb and daily living of patients were evaluated by the ODI. The authors concluded that coblation nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as 2-year follow-up, but longer-term benefit still needs verification. The findings are limited by lack of relevant comparison group.

NICE (2016a) evaluated percutaneous coblation of the intervertebral disc for LBP and concluded that this procedure may be used for patients with pain caused by contained herniated discs that have not responded to conservative treatment, when open surgery is not suitable.

Percutaneous Endoscopic Discectomy (PELD)

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to establish the safety and efficacy of percutaneous endoscopic discectomy compared with open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

Xu et al. (2020) conducted a meta-analysis on the efficacy of percutaneous endoscopic lumbar discectomy (PELD) versus micro endoscopic discectomy (MED); the authors specifically focused on the midterm and long-term outcomes. A total of 487 studies were identified with only 9 articles meeting the inclusion criteria and high-quality standards. Only one of these was a randomized controlled trial, the other were observational studies. In the results analysis, both PELD and MED

obtained satisfactory midterm and long-term clinical efficacy, however, the PELD group obtained better outcomes in scores for low back pain after 2 years postoperatively compared with the MED group. The authors concluded that the PELD patients exhibited overwhelming superiority in length of incision, postoperative time in bed and hospital length of stay which supported PELD as less invasive and faster rehabilitation. Further well-defined large, randomized trials are needed to validate and increase the strength of these findings. Limitations included lack of randomization in most included studies, lack of detailed surgical methods for several studies thus limiting additional subgroup analysis and high heterogeneity.

Ruan et al. (2016) conducted a systematic review and meta-analysis to compare PELD and open lumbar microdiscectomy (OLM) for the treatment of LDH. A total of 7 studies (1,389 patients) were included (2 RCTs and 5 observational studies). The authors concluded that existing evidence indicates that no superiority exists between the two surgical approaches for the treatment of LDH in terms of functional outcome, complication rate and reoperation rate, in spite of the PELD surgical group can achieve shorter operation time and hospital stay than OLM surgical group. This review is limited by a low number of RCTs, and unknown follow-up periods.

The results of a recent meta-analysis investigating the effect of PELD in comparison to other surgeries for treatment of lumbar disc herniation supports that similar complications occurred with PELD in comparison, however, it was also associated with a significantly higher rate of recurrent disc herniation (Bai, et al., 2021). The author's analysis included 14 studies involving 2,528 subjects (ten cohorts, four RCTs), the other surgeries for comparison included open lumbar microdiscectomy, microendoscopic discectomy, minimally invasive transforaminal lumbar interbody fusion, and percutaneous endoscopic lumbar discectomy. Success rates in the PELD and other surgical intervention groups were 90.1% and 88.0%, respectively, recurrence rates in the PELD and other surgical intervention groups were 7.57% and 4.38%, respectively. The authors acknowledged additional large-scale, well-performed randomized trials are needed to verify their findings.

An ECRI report for the Vertebris System for Interlaminar Endoscopic Lumbar Discectomy indicated that the interlaminar endoscopic lumbar discectomy with the Vertebris system reduces pain and improves functional status in patients with lumbar disc herniation, based on evidence from three nonrandomized comparison studies and four before-and-after studies; however, the studies are at too high a risk of bias to be conclusive about how well the system works or how it compares with other lumbar discectomy approaches (ECRI, 2021).

Within a Health Technology Brief document published by Hayes, eight studies were reviewed evaluating safety and efficacy of PELD as treatment of primary lumbar disc herniation. Hayes concluded that although overall the body of evidence was low-quality, the evidence consistently suggests PELD performs similarly to other surgical alternatives for decompression when there was failure of conservative management. However, Hayes acknowledged "substantial uncertainty exists due to the overall quality of the body of evidence and additional studies are needed to evaluate comparative effectiveness and determine patient selection criteria when employed for primary disc herniation." In a second Health Technology Brief document Hayes evaluated PELD as treatment of recurrent lumbar disc herniation. A total of six studies were included in the review. According to the report, a low quality body of evidence suggests PELD may be inferior to comparison treatments for decreasing back pain and that PELD may have higher recurrence rates than comparison treatments (Hayes, 2019c).

Alvi (2018) conducted a meta-analysis which included 14 RCTs or quasi-randomized trials and compared open discectomy (OD), with microdiscectomy (MD) to minimally invasive procedures including percutaneous discectomy, percutaneous endoscopic discectomy (PED), and tubular discectomy (TD) for lumbar disc herniation. All of the studies were determined to have a serious risk of bias and were judged to be of low or very low quality. No differences were seen between groups for VAS score. Open procedures were also associated with longer hospital stays and greater blood loss.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In 2013, a task force of the ASIPP published updated guidelines for interventional techniques in the management of chronic spinal pain. The evidence for percutaneous lumbar discectomy was rated as limited for short- and long-term relief based on all observational studies. An evidence rating of "limited" is defined as evidence insufficient to assess effects on health outcomes because of limited number or inadequate power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or execution, gaps in the chain of evidence, or lack of information on important health outcomes. The ASIPP concluded that this technique may be performed when indicated but did not provide patient selection criteria. Nor was the recommendation graded; the authors indicated only that this recommendation was based on "individual experience and the large amount of literature." Therefore, this recommendation is not considered evidence-based.

North American Spine Society (NASS)

The 2014 practice guidelines from the NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that endoscopic percutaneous discectomy or automated percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (poor quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

Percutaneous Sacroplasty

A Hayes report for percutaneous sacroplasty for treatment of sacral insufficiency fractures published in 2018, indicates that the literature search identified a nonrandomized controlled study and a few uncontrolled studies of percutaneous sacroplasty. Results of these studies provide preliminary evidence that percutaneous sacroplasty improves outcomes for patients who have sacral insufficiency fractures. The best evidence supporting use of this treatment was obtained in the nonrandomized controlled study and the largest available uncontrolled trial. Both of these studies enrolled patients who could not tolerate or failed to respond to conservative nonsurgical therapy. Comparing pre-surgery with post-surgery, percutaneous sacroplasty provided statistically significant reductions in pain and improvements in mobility and activities of daily living. Two smaller uncontrolled studies of percutaneous sacroplasty do not provide reliable evidence of efficacy since the investigators did not report whether patients underwent nonsurgical treatments for sacral insufficiency fractures before sacroplasty. Further controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures. The January 2021 Hayes update indicates that the evidence regarding efficacy is unchanged since publication of the 2018 Health Technology Brief (Hayes, 2018; updated January 2021).

Frey et al. (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs. nonsurgical management. This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up. However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post; posttreatment through 2 weeks; 12 weeks through 24 weeks; 24 weeks through 1 year. Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score − at the 2-week follow-up post-treatment. One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.

Dougherty et al. (2014) retrospectively evaluated outcomes of consecutive patients with SIF treated by percutaneous sacroplasty in an electronic database. The study included 57 patients (75% women; age 61 to 85 years, median 74 for men or 75 for women; duration of pain 2 to 5 weeks. Pain was measured at rest and, sometimes, during activity on an 11-point NRS (higher values = greater pain) or described by patients, opioid use was also evaluated before and at 1 to 5 weeks (median, 2.5) after sacroplasty. The study is limited by retrospective design, small sample size, lack of a control group, subjective outcome measures, inconsistent evaluation of pain, and short follow-up.

Kortman et al. (2013, included in Hayes report above) retrospectively examined outcomes of patients with painful SIF or symptomatic sacral lesions treated by percutaneous sacroplasty at any of six participating U.S. centers. Patients were included in the study if they had severe sacral pain refractory to standard conservative management (defined as any combination of bed rest, analgesics, partial weight bearing, and orthosis), imaging evidence of bilateral or unilateral SIF or focal or infiltrating sacral lesions, and symptoms attributable to sacral pathology. The SIF group consisted of 204 patients. The group with sacral lesions (SL group) included 39 patients. Sacroplasty entailed the long- or short-axis approach and PMMA or bioceramic cement, but the rate of each approach and the trade names for cement and other devices were not reported. Pain was evaluated by self-report, a VAS, and analgesic use before and at 1 month after sacroplasty. All patients with SIF were followed for ≥ 1 year. Compared with pretreatment values, mean VAS scores improved significantly after sacroplasty in patients with bilateral SIF, patients with unilateral SIF, and patients with sacral lesions. In the entire group with SIF and the group with sacral lesions, respectively, 31% and 18% experienced complete pain relief and 3.0% and 10% experienced no significant pain relief. Use of narcotic, non-narcotic, and over-the-counter analgesics decreased markedly after versus before sacroplasty in both groups but data for analgesic use were not reported. The study is limited by retrospective design, lack of a control group, and use of subjective outcome measures.

Percutaneous Endoscopic Transforaminal Discectomy (PETD)

Jiang et al. (2021) conducted a retrospective analysis of 48 patients with recurrent lumbar disc herniation (RLDH) to compare the clinical efficacy of percutaneous transforaminal endoscopic discectomy (PTED) and traditional laminectomy

(TL). Perioperative evaluation indicators included operation time, the intraoperative blood loss, length of incision and hospitalization time. Clinical outcomes were measured preoperatively, and at 1 day, 3 months, and 12 months postoperatively using the Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) scores. The results showed that compared with the TL group, the operation time, postoperative bed-rest time, and hospitalization time of the PTED group were significantly shorter, and the intraoperative blood loss was also reduced. There were no significant differences in VAS or ODI scores between the two groups before or after surgery. The authors concluded that PTED and TL have similar clinical efficacy in the treatment of RLDH, but PTED can shorten the operation time, postoperative bedrest time and hospitalization time, and reduce intraoperative blood loss, and PTED is a safe and effective surgical method for the treatment of RLDH. but more randomized controlled trials are still required to further verify these conclusions. This study is limited by the retrospective design and a small number of participants.

Tacconi et al. (2020) compared surgical invasiveness between two procedures: transforaminal full endoscopic lumbar discectomy (FELD) and open discectomy (OD). 50 patients with a single-level lumbar foraminal herniation were randomly assigned to either have a FELD or OD procedure. Pre- and post-operative leg and back pain data were collected using a visual analog scale (VAS). A satisfactory postoperative outcome was defined by a decrease in the leg pain score by ≥ 3 points from the preoperative leg VAS score. The VAS scores for back pain were recorded ≥ 6 hours after the procedure or at mobilization. Additional assessment of back pain was not performed later during follow-up period due to potential risk of back pain occurring secondarily to spinal instability or a degenerative disc. There were no intraoperative or postoperative surgical complications. For the OD group, the median VAS score for leg pain had decreased from 7 preoperatively to 2 at six months postoperatively. In the FELD group, the median VAS score for leg pain had decreased from 8 preoperatively to 2 at six months postoperatively. The authors concluded even though the VAS scores for leg pain were not significantly different between the two groups, the period for patient mobilization along with the VAS scores for back pain immediately postoperatively were significantly lower for the FELD group. Limitations included a relatively small number of participants.

In a 2019 meta-analysis, Huang et al. sought to systematically review and compare the safety and effectiveness of PETD versus percutaneous endoscopic interlaminar discectomy (PEID) for the treatment of LDH. A total of 13 studies with 974 cases consisting of 3 RCTs, 3 prospective studies and 7 retrospective studies were included. The aggregate results, based on observational studies and randomized controlled trials, suggest that patients treated with PEID experienced significant advantages with shorter operation time, less intraoperative blood loss and less intraoperative fluoroscopy times but more complications than those treated with PETD; however, the two operative approaches did not significantly differ in terms of LDH recurrence, hospital stay, ODI scores, VAS scores, Japanese Orthopedic Association (JOA) scores and MacNab criteria at the final follow-up. The authors concluded that PEID may be superior to PETD in certain ways, some of its advantages have yet to be verified and the two interventions were not significantly different in terms of relief of symptoms and functional recovery. They also concluded that PEID would be recommended for treating LDH especially at L5/S1 under certain conditions, but a prudent attitude is necessary to choose between the two operative approaches before a large sample and high quality RCTs have been performed. Limitations included lack of separation between randomized and non-randomized studies in the aggregate estimates, which could introduce biases, clinical heterogeneity and short-term follow-up.

Mo et al. (2019) evaluated percutaneous endoscopic transforaminal diskectomy (PETD) in comparison with percutaneous endoscopic interlaminar diskectomy (PEID) for herniation at L5-S1. 80 participants were recruited and randomly assigned to two different groups - either PETD or PEID. All procedures were performed by the same physician. Even though the operation time in the PEID group was significantly shorter than the PETD group, no significant differences were noticed during the postoperative period. All patients were followed for 9-22 months, with an average follow-up of 16.59 ±4.10 months in the PETD group and 16.71 ±3.72 months in the PEID group. The Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) scores were similar with no significant differences between the two groups. The authors concluded PETD has a similar clinical effect to that of PEID. Limitations included single-center study, low number of participants and analysis based on as-treated rather than intent-to-treat approach. Larger sample size and tracking of long-term results are still warranted.

Yu et al. (2019) compared the clinical outcomes for percutaneous transforaminal endoscopic discectomy (PTED) and micro-endoscopic discectomy (MED) as alternative minimally invasive procedures for lumbar disc herniation. A literature search provided eight studies in the final analysis totaling 805 patients. Only one of these studies was a randomized controlled trial, while the others were observational studies. From the data extracted, Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) were considered the primary outcomes. The author's analysis concluded that PTED resulted in a shorter hospital length of stay, but MED was superior for intraoperative fluoroscopy and total cost. Significant lower back pain was found in the PTED group short term and at one year postoperatively. No differences were found regarding the pain score or ODI. The authors' meta-analysis concluded that both the PTED and MED are safe and effective in treating lumbar disc herniation. Limitations included small number of studies included for review and findings

based mainly on observational studies. Furthermore, different methodologies contributed to heterogeneity in the analyses and the surgeon skill level may have introduced bias.

Chen et al. (2018) conducted a systematic review and meta-analysis to compare efficacy and safety between PETD and PEID for L5-S1 LDH. Nine studies involving 621 patients met inclusion criteria. Only three of these studies were reported to be randomized controlled trials. The results indicated that PETD was significantly associated with greater fluoroscopy times (mean difference 9.28 times); and longer operative time (mean difference 16.51 minutes) compared with PEID. However, there were no distinct differences between PETD and PEID in estimated blood loss ($p = 0.24$), bed time after surgery ($p = 0.32$), hospitalization time ($p = 0.27$), or MacNab evaluation ($p = 0.78$). Similarly, no obvious differences were detected between PETD and PEID regarding VAS, JOA score, or ODI when measured preoperatively, 1 day postoperatively, 3 months postoperatively, or at the last follow up. In addition, no significant difference was found regarding overall incidence of complications between PETD and PEID ($p = 0.14$). Nevertheless, a significantly lower incidence rate of dural tear was observed in PETD compared with PEID ($p = 0.04$). The authors concluded that PETD had comparable clinical efficacy and safety compared with PEID; however, PEID was superior to PETD regarding fluoroscopy times and operative time. Therefore, PEID might be a better surgical procedure for L5-S1 LDH. The findings are limited by lack of separation in the analysis between randomized controlled trials and observational studies.

Liu et al. (2018, included in the Yu systematic review cited above) evaluated the clinical outcomes of PETD, micro endoscopic discectomy (MED), and microdiscectomy (MD) for treatment of symptomatic LDH. One hundred ninety-two patients with symptomatic LDH at L3-4 and L4-5 were included in this retrospective cohort study. The patients were divided into groups as follows: group A was treated with PETD and included 60 patients (31 men and 29 women) with a mean age of 36.2 years; group B was treated with MED and included 63 patients (32 men and 31 women) with a mean age of 33.1 years; and group C was treated with MD and included 69 patients (36 men and 33 women) with a mean age of 34.0 years. There were no significant differences in mean preoperative ODI score, and VAS scores for LBP and leg pain among groups A, B, and C. Incision length, duration of the operation, blood loss, creatine phosphokinase, length of hospital stay, and postoperative incision pain according to the VAS were best in the PETD group ($p < 0.05$). Fifty-five (91.6%), 59 (93.7%), and 62 patients (89.9%) had at least 2 years of follow-up in groups A, B, and C, respectively. At the last follow-up, VAS scores of LBP and leg pain, and ODI scores were significantly better than preoperative correlates in all groups. The authors concluded that PETD, MED, and MD were all reliable techniques for the treatment of symptomatic LDH. With a restricted indication, PETD can result in rapid recovery and better clinical results after at least 2 years of follow-up. Findings are limited by the observational and retrospective design of the study. Additional studies with randomization, longer outcomes, and larger patient populations are needed to further evaluate PETD.

Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems

A 2019 ECRI clinical evidence assessment on Transforaminal Endoscopic Spine System (TESSYS) (Joimax, Inc.) for Treating Lumbar Disc Herniation concluded that low-quality studies at high risk of bias and RCTs provide mixed evidence on efficacy and compared different procedures at different time points, which prevents drawing efficacy conclusions for percutaneous transforaminal endoscopic discectomy (PTED) with TESSYS or determining how it compares with other minimally invasive surgeries for lumbar hernia repair. TESSYS appears to be safe, with no AE differences between groups for most comparisons and a lower TESSYS event rate in one RCT.

In a prospective cohort study of 80 patients who underwent TESSYS for LDH, Wu et al. (2018, included in 2019 ECRI assessment above) evaluated outcome predictors in 36 men and 44 women with a mean age of 48.76 ±15.60 years (range: 24-78 years). The mean follow-up time was 25.15 ±9.76 months (range: 12-48 months). LDH with older age [odds ratio (OR): 6.621; 95% confidence interval (CI), 0.632-20.846; $p = 0.019$], high-intensity zone (HIZ) (OR: 8.152; 95% CI, 0.827-4.380; $p = 0.003$), and larger disk herniation (OR: 6.819; 95% CI, 0.113-4.825; $p = 0.017$) were the most significant negative outcome predictors. The study is limited by its lack of randomization and small patient population.

In a retrospective case series, Kosztowski et al. (2018) evaluated the risk for reherniation in the first year after transforaminal endoscopic decompression in 46 consecutive male and 38 female patients. Four patients required microdiscectomy due to reherniation at 5 months, 8 months, 9 months, and 10 months postoperatively. All the patients in the series reportedly improved immediately following their endoscopic procedures, and no patients presented with symptoms suggestive of reherniation until 5 months after their initial endoscopic surgery. Patients with reherniation tended to be young: 31, 45, 48, and 49 years of age: all less than the average patient age who underwent endoscopic surgery. The 1-year reherniation rate in this study is 4.7%. According to the authors, this suggests that the benefit of this technique may be that it is ultra-minimally invasive, but it may only be equal, not superior to microdiscectomy in its rate of reherniation. The study was limited by lack of comparison group and loss to follow up. RCTs with larger patient populations and longer follow-up periods are needed to further evaluate this technique in the treatment of LDH.

Pan et al. (2016, included in 2019 ECRI assessment above) performed a prospective case series to investigate the clinical outcomes of transforaminal endoscopic system (TESSYS) for discogenic lLBP (DLBP). Consecutive patients (n = 62) with one-level DLBP underwent TESSYS from January 2010 to December 2013, with a mean follow-up of 26.8 ±4.2 months. The VAS was used for back pain, the ODI for lumbar function, and the modified MacNab criteria for clinical global outcomes. Twenty-four patients showed only inflammatory granuloma on annulus tear tissues (Group A), 16 patients showed no annulus tear but adhesion and inflammatory granuloma among the intracanal annulus fibrous posterior longitudinal ligament and the abdomen side of the dura sac (Group B) and 22 patients showed both (Group C). The success rate of group C was much higher than A and B. The whole success rate was 75.8%. Of the 4 patients with poor result, 2 refused further surgical treatment and showed either no improvement or worsening. The remaining 2 patients had spinal fusion surgery and achieved better results. VAS and ODI had significantly improved after surgery ($p < 0.01$). No unexpected complications were seen. The authors concluded that TESSYS is an effective method in treating DLBP. The findings of this study need to be validated by well-designed studies and are limited by lack of comparison group.

Sanusi et al. (2015) conducted a two-year retrospective case series of patients (n = 201) who underwent transforaminal endoscopic discectomy at a tertiary neurosurgical center in the United Kingdom by a single surgeon. Mean time of onset of symptoms was 5.5 months and the most common level was L4/5 (53%). All endoscopic discectomies were performed under local anesthesia. The VAS of the pain dropped from an average of 7/10 pre-operatively to 0-1/10 in 95% of patients two weeks post operatively. Eighty-seven percent of the patients went back to their normal daily activities within two weeks. There were no cases of cerebrospinal fluid leak, hematoma formation or wound infection. One percent of patients developed a nerve root injury. 6% of patients had recurrent herniation and required microdiscectomy. The authors concluded that endoscopic discectomy can be an alternative approach to microdiscectomy, and the data shows that the far lateral endoscopic discectomy using the TESSYS technique has comparable outcomes to microdiscectomy. The study is limited by its retrospective observations and lack of comparison group.

Transforaminal Lumbar Interbody Fusion (TLIF)

Evidence in the peer-reviewed scientific literature evaluating percutaneous endoscopic fusion is limited to case series involving small sample populations. Published trials comparing this approach to open conventional approaches are lacking and strong conclusions regarding safety and efficacy cannot be made. Further studies are needed to establish safety and efficacy of this approach to lumbar fusion.

Yang et al. (2022) conducted a randomized controlled trial (RCT) to evaluate the effectiveness, safety, and usability of a novel minimally invasive surgery (MIS) bone graft delivery device. Seventy-three consecutive patients with lumbar spondylosis, degenerative disc disease, spondylolisthesis, scoliosis or trauma were enrolled in this RCT. Group 1 comprised 39 patients treated with the novel MIS bone graft delivery device. Group 2 consisted of 34 patients treated with the conventional system. The primary objective of the study was the assessment of the amount of bone graft delivery using the device. The secondary objectives were the effect of the device on operative time, pain relief, disability improvement, and bone fusion grade. Bone delivery amount was higher in the MIS device group (6.7 ±2.9 mL) compared to the conventional group (2.3 ±0.5 mL), $p < 0.001$. Regarding the operation time, the MIS device group was associated lower duration than the conventional group ($p < 0.001$). After a 3-month follow-up, 39.5% of the patients in the MIS device group and 3.5% of the patients in the conventional group were observed to achieve grade I fusion (complete fusion). There was a notable difference in fusion success rates ($p < 0.01$). The authors concluded that the novel MIS bone graft delivery device was associated with successful bone delivery stating the MIS device provides a promising modality with less operative time and higher bone fusion rates than conventional modalities. Long-term evaluations of the results and prospective randomized studies are still needed.

Song et al. (2022) conducted a meta-analysis to compare the safety and clinical effectiveness of PE-TLIF and MIS-TLIF in treating LDD. Based on inclusion criteria, the authors selected 8 studies for meta-analysis. There are a total of 229 patients who underwent PE-TLIF and 258 patients who underwent MIS-TLIF. MIS-TLIF and PE-TLIF have similar effectiveness in relieving leg pain and improving the Oswestry Disability Index. However, PE-TLIF is superior in relieving back pain. The pooled data of fusion rates, postoperative analgesic, and complication rates are comparable between the 2 groups. The pooled operation and intra-operative fluoroscopic time are both higher in the PE-TLIF group than the MIS-TLIF group. The pooled intra-operative blood loss, incision length, duration from surgery to ambulation, and hospital stay are significantly lower in the PE-TLIF group than the MIS-TLIF group. Most of the endpoints reveal significant heterogeneity. The endpoints of operation time and intra-operative blood loss reveal significant publication bias. Both PE-TLIF and MIS-TLIF are safe and effective interventions for patients with LDD. The authors concluded that when compared, although MIS-TLIF results in reduced operative time, less intra-operative blood loss and enhanced post-operative recovery can be achieved by PE-TLIF. The findings of this study need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of this procedure is proven.

Luan et al. (2022) conducted a single-center retrospective study to analyze the clinical efficacy of transforaminal lumbar interbody fusion (TLIF) in the treatment of continuous double-level lumbar spondylolisthesis with sagittal imbalance. The clinical data of 36 patients with double-level spondylolisthesis treated with TLIF were included and divided into L3/L4 double spondylolisthesis group and L4/L5 double spondylolisthesis group according to the site of spondylolisthesis. The sagittal parameters of the patients were measured by standing anteroposterior and lateral X-rays of the whole spine, and the visual analogue scale (VAS) for lumbar and lower limb pain, Japanese Orthopaedic Association (JOA), and Oswestry Disability Index (ODI) were recorded. The imaging parameters and clinical parameters of the patients before surgery, after surgery, and at the last follow-up were compared and statistically analyzed. A total of 36 patients were included in the study and all had sagittal imbalance. Among them, there were 21 cases of L3 and L4 spondylolisthesis, 6 males and 15 females, with an average age of 64.7 ±9.4 years; there were 15 cases of L4 and L5 spondylolisthesis, 4 males and 11 females, with an average age of 66.5 ±8.0 years. 36 patients completed the operation, the operation time was 190.28 ±6.12 min, and intraoperative blood loss was 345 ±11 ml. Compared with preoperative, there were differences in SVA, TPA, T1-SPi, LL, PT, SS, PI-LL, SD, SA, and SP between patients after surgery and at the last follow-up ($p < 0.05$). Compared with preoperative, VAS score, JOA score, and ODI index of waist and lower limbs were improved after the operation and at the last follow-up, and there was a difference ($p < 0.05$). The authors concluded TLIF can effectively relieve the symptoms of patients with continuous double-level lumbar spondylolisthesis, restore lumbar lordosis and sagittal spinal sequence, and improve the quality of life of patients. Limitations include a small sample size and lack of control. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

Giordan et al. (2021) performed a systematic review and meta-analysis to assess transforaminal endoscopic lumbar foraminotomy (TELF) outcomes in the treatment of lumbar foraminal stenosis consequent to bony stenosis or lateral disc herniation. Multiple databases were searched for studies published in the English language, involving patients older than 18 years old who underwent endoscopic foraminotomy. Outcomes included the rate of patients who showed "excellent" and "good" postoperative improvement, decreased leg pain, and improved Oswestry Disability Index (ODI) scores. A total of 14 studies that included 600 patients, were included in the analysis. Approximately 85% of patients improved significantly after TELF, without significant differences among different groups and with almost negligible adverse events rates. Mean leg pain decreased an average of 5.2 points, and ODI scores improved by 41.2%. Patients with previous spine surgery or failed back surgery syndrome had higher postoperative leg dysesthesia rates after TELF (14% vs. 1%, respectively). The investigators concluded that TELF is a useful and safe method to achieve decompression in foraminal stenosis. According to the investigators, the main limitation in this analysis is the lack of individual patient data, making predictive analysis subject to confounding bias. Also, six studies were estimated to have an elevated risk of bias. The investigators indicated that this systematic review and meta-analysis lacks randomized studies and that the level of evidence is relatively low (mostly level III), but that this is the best that is currently available from the literature.

In a systematic review and meta-analysis, Kou et al. (2021) compared clinical efficacy and safety of endoscopic lumbar interbody fusion (Endo-LIF) and minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) in treatment of lumbar degenerative diseases. A literature search was performed using multiple databases. Studies published up to November 15, 2020, that compared Endo-LIF with MIS-TLIF for treating lumbar degenerative diseases were retrieved. Data were extracted according to predefined clinical outcome measures. Primary outcomes were preoperative and postoperative visual analog scale for leg and back pain and Oswestry Disability Index scores. Secondary outcomes were operative time and intraoperative blood loss; length of hospitalization; and complication, reoperation, and fusion rates. Data analysis was conducted with statistical software. The meta-analysis included 6 studies comprising 480 patients. Results of the merged analysis revealed similar complication, reoperation, and fusion rates and preoperative and postoperative visual analog scale for leg and back pain and Oswestry Disability Index scores for Endo-LIF and MIS-TLIF. Nevertheless, with the exception of longer operative time, Endo-LIF compared favorably with MIS-TLIF, with less intraoperative blood loss, shorter hospital stay, and better long-term functional outcome. Based on the evidence provided by this study, the investigators concluded that there is no significant difference in clinical efficacy and safety between Endo-LIF and MIS-TLIF in the treatment of lumbar degenerative diseases. Although Endo-LIF has a longer operative time, it has the advantages of less tissue trauma and rapid recovery after operation. This systematic review and meta-analysis has some limitations. First, it included 6 articles, and several of these articles had methodological defects. Therefore, the validity of the available data may lead to unsatisfactory results. Second, the total number of patients included is relatively small, which may have an impact on the study results owing to the limited statistical capacity of the data. Third, because of the small number of current relevant studies, with most of the follow-up periods lasting about 12 months, a comparison of the long-term clinical outcomes of the 2 surgical techniques could not be obtained. Therefore, more studies with longer follow-ups are needed to compare the long-term clinical outcomes of Endo-LIF with MIS-TLIF.

Zhu et al. (2021) conducted a systematic review and meta-analysis to compare clinical outcomes and complications of percutaneous endoscopic transforaminal lumbar interbody fusion (PE-TLIF) and minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) in treating degenerative lumbar disease. A comprehensive search of multiple databases was

performed to identify related studies reporting the outcomes and complications of PE-TLIF and MIS-TLIF for degenerative lumbar disease. The clinical outcomes were assessed by the Visual Analog Scale and Oswestry Disability Index. In addition, the operative time, intraoperative blood loss, time to ambulation, length of hospital stay, fusion rate, and surgery-related complications were summarized. Forest plots were constructed to investigate the results. A total of 28 studies involving 1,475 patients were included in this meta-analysis. PE-TLIF significantly reduced operative time, intraoperative blood loss, time to ambulation, and length of hospital stay compared to MIS-TLIF. Moreover, PE-TLIF was superior to MIS-TLIF in the early postoperative relief of back pain. However, there were no significant differences in medium to long-term clinical outcomes, fusion rate, and incidence of complications between PE-TLIF and MIS-TLIF. The investigators concluded that medium to long-term clinical outcomes and complication rates of PE-TLIF were similar to MIS-TLIF for the treatment of degenerative lumbar disease. However, PE-TLIF shows advantages in less surgical trauma, faster recovery, and early postoperative relief of back pain. This systematic review and meta-analysis has some limitations. First, there is a high degree of statistical heterogeneity among the included studies. Another limitation is that most of the included studies are nonrandomized controlled trials. Randomized controlled trials are needed to confirm the results of this analysis.

Zhao et al. (2021) compared the clinical efficacy of percutaneous full-endoscopic transforaminal lumbar interbody fusion (Endo-TLIF) with percutaneous pedicle screws (PPSs) performed by using a visualization system with that of minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) for the treatment of degenerative lumbar spinal stenosis (LSS). From June 2017 to May 2018, the data of 78 patients who met the selection criteria were retrospectively reviewed and were divided into the Endo-TLIF group (40 cases) and the MIS-TLIF group (38 cases) according to the surgical method used. The Visual Analog Scale (VAS) and the Japanese Orthopaedic Association (JOA) scale were administered preoperatively and at the 1-week, 3-month, and 1-2-year follow-ups. The fusion rate and major complications, including revision, were also recorded. All the patients were followed up for 24 to 34 months, with an average follow-up of 30.7 months. The intraoperative blood loss and length of hospital stay for the Endo-TLIF group were statistically significantly lower than those for the MIS-TLIF group. The VAS and JOA scores of the patients in the two groups at postoperative 1 week, 3 months, 1 year, 2 years were statistically significantly improved from the preoperative scores. The VAS and JOA scores of the Endo-TLIF group were statistically significantly better than those of the MIS-TLIF group at 3 months and 1 year after surgery. There were no statistically significant differences in the scores between the two groups at any of the other time points. There was no significant difference in the intervertebral altitude between the two groups at the 3-month or final follow-up. Dural tears, cerebrospinal fluid leakage, infection, and neurologic injury did not occur. Both groups showed good intervertebral fusion at the last follow-up. The intervertebral fusion rate was 97.5% in the Endo-TLIF group and 94.7% in the MIS-TLIF group, with no statistically significant difference between the two groups. The authors concluded that endo-TLIF with percutaneous pedicle screws performed by using a visualization system for lumbar degenerative disease may be regarded as an efficient alternative surgery for degenerative lumbar spinal stenosis. It is a safe and minimally invasive way to perform this surgery and has shown satisfactory clinical outcomes. This is a retrospective study with a small sample size. Long-term follow-up and multicenter, randomized controlled clinical trials are needed to verify the results of this study.

Chang et al. (2021) conducted a systematic review and meta-analysis aimed to compare oblique lumbar interbody fusion (OLIF) with transforaminal interbody fusion (TLIF) as an interbody fusion technique in lumbar fusion surgery for patients with degenerative spondylolisthesis (DS). Among the 3,022 articles, three studies were identified and met the inclusion criteria. In terms of radiological outcome, the amount of disc height restoration was greater in the OLIF group than in the TLIF group, but there was no difference between the two surgical techniques ($p = 0.18$). In the clinical outcomes, the pain improvement was not different between the two surgical techniques. In terms of surgical outcomes, OLIF resulted in a shorter length of hospital stay and less blood loss than TLIF ($p < 0.0001$ and $p = 0.02$, respectively). This meta-analysis indicated no difference in clinical, radiological outcomes, and surgical time between TLIF and OLIF for DS, but the lengths of hospital stay, and blood loss were better in OLIF than TLIF. Though encouraging, these findings were based on low-quality evidence from a small number of retrospective studies that are prone to bias. The findings of this study need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of this procedure is proven.

Kang et al. (2021) conducted a retrospective comparison study on biportal endoscopic lumbar interbody fusion. The clinical and radiological outcomes of biportal endoscopic TLIF were analyzed. There are 3 biportal endoscopic TLIF techniques. In the available literature, the postoperative 1-year outcomes of biportal endoscopic TLIF were comparable to those of posterior lumbar interbody fusion (PLIF) and minimally invasive (MIS)-TLIF. Clinical parameters were improved after biportal endoscopic TLIF. Compared to PLIF or MIS-TLIF, biportal endoscopic-TLIF may have the advantage of a faster recovery. Biportal endoscopic TLIF showed no inferiority in fusion rates compared to PLIF or MIS-TLIF. The postoperative complications were usually minor. The authors concluded that the postoperative 1-year clinical and radiological outcomes of biportal endoscopic TLIF were favorable compared to those of PLIF and MIS-TLIF. However, long-term outcomes need to be investigated through prospective, randomized controlled trials in the future.

ECRI (2019) conducted a clinical evidence review of the Transforaminal Endoscopic Spine System. They concluded that low-quality studies at high risk of bias and RCTs provide mixed evidence on efficacy and compared different procedures at different time points, which prevents drawing efficacy conclusions for percutaneous transforaminal endoscopic discectomy (PTED) with TESSYS or determining how it compares with other minimally invasive surgeries for lumbar repair. The nonrandomized comparisons are at high risk of bias due to lack of randomization, retrospective design, and/or single-center focus; the case series and cohort study are at high bias due to lack of randomization, small size, and single-center focus. Studies primarily measured efficacy using subjective measures of pain relief and disability.

Lan et al. (2018) compared the efficacy and safety in the management of lumbar diseases performed by either posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). Sixteen studies involving 1,502 patients were included in the metanalysis. The authors found that while TLIF was superior to PLIF, both achieved similar outcomes. While interbody fusion is considered the gold standard, both PLIF and TLIF have been promoted as promising techniques however the authors indicate these techniques remain controversial. Limitations of the study identified additional well-designed RCTs with long-term outcomes and larger sample sizes are warranted.

A retrospective study by Price et al. (2017) compared clinical results and radiographic outcomes of minimally invasive surgery (MIS) versus open techniques for transforaminal lumbar interbody fusion (TLIF). A consecutive series of 452 1- or 2-level TLIF patients at a single institution between 2002 and 2008, were analyzed. A total of 148 were MIS patients and 304 were open. Oswestry disability index (ODI) and visual analog (VAS) pain scores were documented preoperatively and postoperatively. Fusion was at a minimum of 1 year follow-up. The author's concluded MIS TLIF produces comparable clinical and radiologic outcomes to open TLIF with the benefits of decreased intraoperative blood losses, shorter operative times, shorter hospital stays and fewer deep wound infections. Results are limited by study design, and lack of a control. Further prospective studies investigating long-term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.

Villavicencio et al. (2010) conducted a retrospective study comparing minimally invasive and open approaches for transforaminal lumbar interbody fusion (TLIF) in patients with painful degenerative disc disease with or without disc herniation, spondylolisthesis, and/or stenosis at one or two spinal levels. Outcomes were measured using visual analog scale (VAS), patient satisfaction, and complications. Average follow-up was 37.5 months. Postoperative change in mean VAS was 5.2 in the open group and 4.1 in the minimally invasive group. Overall patient satisfaction was 72.1% in the open group versus 64.5% in the minimally invasive group. The total rate of neurological deficit was 10.5% in the minimally invasive TLIF group compared to 1.6% in the open group. The authors concluded that open and minimally invasive approaches for transforaminal lumbar interbody fusion have equivalent outcomes; however, the rate of neural injury related complications in the minimally invasive approach must be considered when selecting patients for surgery.

Clinical Practice Guidelines

American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)

The AANS/CNS published a guideline update in 2014 on the performance of fusion procedures for degenerative disease of the lumbar spine, with part of the guideline update focused on. This guideline did not offer any specific recommendations pertaining to TLIF in general or MITLIF specifically. The authors indicated that there was no conclusive evidence of superior clinical or radiographic outcomes based on technique when performing interbody fusion. Therefore, no general recommendations were offered regarding the technique that should be used to achieve interbody fusion. The authors also noted that they did not analyze any comparisons of minimally invasive surgery (MIS) versus traditional open surgery in this report (Mummaneni et al., 2014).

North American Spine Society (NASS)

NASS published clinical guidelines for treatment of adult isthmic spondylolisthesis (Kreiner et al., 2014) and degenerative spondylolisthesis (Matz et al., 2014). These guidelines did not offer any specific recommendations pertaining to the use of MITLIF versus OTLIF procedures. However, both guidelines recommend the development of randomized controlled trials or prospective comparative studies comparing MIS versus traditional open surgical techniques in adult patients with these conditions.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A variety of endoscopes and associated surgical instruments and devices have received marketing clearance through the FDA's 510(k) process. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

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Policy History/Revision Information

Date	Summary of Changes
07/01/2024	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.