Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis

Description

Image-guided minimally invasive lumbar decompression (IG-MLD) describes a novel percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis (LSS). In this procedure, a specialized cannula and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

Background

In LSS, the space around the spinal cord narrows, compressing the spinal cord and the nerve roots. The most common symptom of LSS is back pain with neurogenic claudication, i.e., pain, numbness, or weakness in the legs that worsens with standing or walking and is alleviated with sitting or leaning forward. Compression of neural elements generally occurs from a combination of degenerative changes including ligamentum flavum hypertrophy, bulging of the intervertebral disc, and facet thickening with arthropathy. Spinal stenosis is often linked to age-related changes in disc height and arthritis of the facet joints. LSS is one of the most common reasons for back surgery and the most common reason for lumbar spine surgery in adults over 65 years of age. The goal of surgical treatment is to "decompress" the spinal cord and/or nerve roots.

For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life. Less invasive surgical procedures have been developed, such as open laminotomy and microendoscopic laminotomy. Limited evidence on the comparative efficacy of these procedures suggests that less invasive procedures may achieve a roughly similar benefit with less adverse effects. The present policy addresses posterior decompression of central LSS with a percutaneous treatment that is performed under fluoroscopic guidance.

Percutaneous IG-MLD using a specially designed tool kit (mild®) has been proposed as an ultra-minimally invasive treatment of central LSS. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a 6-gauge cannula that is clamped in place with a back plate, single-use tools (portal cannula, surgical guide, bone rongeur, tissue sculpter, and trocar) are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting is conducted entirely under fluoroscopic guidance, with additional contrast media added throughout the
procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal. The devices are not intended to be used near the lateral neural elements and are contraindicated for disc procedures.

Alternative posterior decompressive surgical procedures include:

- Decompressive laminectomy, the classic treatment for LSS, which unroofs the spinal canal by extensive resection of posterior spinal elements, including the lamina, spinous processes, portions of the facet joints, ligamentum flavum, and the interspinous ligaments. Wide muscular dissection and retraction is needed to achieve adequate surgical visualization. The extensive resection and injury to the posterior spine and supporting muscles can lead to instability with significant morbidity, both post-operatively and longer-term. Spinal fusion, performed at the same time as laminectomy or after symptoms have developed, may be required to reduce the resultant instability. Laminectomy may be used for extensive multi-level decompression.

- Hemilaminotomy and laminotomy, sometimes termed laminoforaminotomy, are less invasive than laminectomy. These procedures focus on the interlaminar space, where most of the pathologic changes are concentrated, minimizing resection of the stabilizing posterior spine. A laminotomy typically removes the inferior aspect of the cranial lamina, superior aspect of the subjacent lamina, ligamentum flavum, and the medial aspect of the facet joint. In contrast to laminectomy, laminotomy does not disrupt the facet joints, supra- and interspinous ligaments, a major portion of the lamina or the muscular attachments. Muscular dissection and retraction are required to achieve adequate surgical visualization.

- Microendoscopic decompressive laminotomy (MEDL) is similar to laminotomy, but utilizes endoscopic visualization. The position of the tubular working channel is confirmed by fluoroscopic guidance, and serial dilators (METRx™ lumbar endoscopic system, Medtronic) are used to dilate the musculature and expand the fascia. For MEDL, an endoscopic curette, rongeur, and drill are used for the laminotomy, facetectomy, and foraminotomy. The working channel may be repositioned from a single incision for multilevel and bilateral dissections.

Regulatory Status

The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the U.S. Food and Drug Administration (FDA) in 2006, with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.

Vertos’ mild® instructions for use state that the devices are not intended for disc procedures but rather for tissue resection at the perilaminar space, within the interlaminar space, and at the ventral aspect of the lamina. These devices are not intended for use near the lateral neural elements and remain dorsal to the dura using image guidance and anatomical landmarks.

Note: The abbreviation MILD has also been used for microscopic muscle-preserving interlaminar decompression, which involves a small skin incision at the interspinous level and partial drilling of the spinous process, with decompression performed under microscopic visualization.
Related Policies

7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Image-guided minimally invasive lumbar decompression for central stenosis without nerve root compression or disc herniation is considered **medically necessary**.

For all other conditions image-guided minimally invasive lumbar decompression is considered **investigational**.

Rationale

Conventional Posterior Decompressive Surgery

A 2009 systematic review of surgery for back pain, commissioned by the American Pain Society (APS), was conducted by the Oregon Health Sciences University Evidence-Based Practice Center. (1,2) Four higher-quality randomized trials were reviewed that compared surgery to nonsurgical therapy for spinal stenosis, including two studies from the multicenter Spine Patient Outcomes Research Trial (SPORT) evaluating laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). (3, 4). All 4 trials found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (e.g., average 8- to 18-point difference on the 36 item Short-Form Health Survey [SF-36] and Oswestry Disability Index [ODI]). There was insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (i.e., with or without fusion, and instrumented vs. non-instrumented fusion) in patients with or without degenerative spondylolisthesis.

Image-Guided Percutaneous Minimally Invasive Lumbar Decompression (IG-MLD)

Primary literature on IG-MLD consists of 1 small controlled trial and a number of prospective and retrospective cohort studies and case series. Members of the Standards Division of the International Spine Intervention Society (ISIS) published a systematic review of the IG-MLD literature in 2014. (5) Included in the review were 1 randomized controlled trial (described next) and 12 cohort studies/series. Pain measurements using a visual analog score (VAS) or Zurich Claudication Questionnaire (ZCQ) showed a weighted mean improvement of 41% in the short-term (4 to 6 weeks), 46% at 3 months, 42% at 6 months, and 49% at 1 year. However, mean VAS remained greater than 3 at all times after treatment. Ten studies assessed function using the Oswestry Disability Index (ODI) or Roland-Morris Disability Questionnaire (RMDQ). With a baseline ODI score of 47.0, the ODI improved by a weighted mean of 16.5 at 6 weeks, 16.2 at 12 weeks, 15.4 at 6 months, and 14.0 at 1 year. One study that reported 2-year outcomes was considered to be of questionable validity and the data were not accepted. (6) The mean final ODI was greater than 30 in the majority of studies, which would not meet one author’s definition of a minimally acceptable outcome. No direct procedure-related complications were identified in the included studies, although the possibility of damage to dura and nerve roots while
performing this procedure was noted. Overall, the body of evidence addressing the IG-MLD procedure was of low quality.

The single randomized trial included in the systematic review was a small (n=38) double-blind study of mild® compared to epidural steroid injections. (7) The study included patients with painful lower limb neurogenic claudication and hypertrophic ligamentum flavum as a contributing factor. Patients with a history of recent spinal fractures, disabling back or leg pain from causes other than LSS, fixed spondylolisthesis greater than grade 1, disk protrusion or osteophyte formation, or excessive facet hypertrophy were excluded from the study. To maintain blinding, patients receiving steroid injection also received skin anesthesia with a small incision, followed by trocar placement under fluoroscopy. The primary efficacy endpoint was pain measured by VAS at 6 weeks' post-treatment. Results showed that 76.2% of mild® treated patients had a 2-point or greater improvement in pain scores, compared with 35.3% of steroid-treated patients. ODI score improved significantly from 38.8 to 27.4 after mild®, while the steroid-treated patients showed a non-significant improvement from 40.5 to 34.8. There was no significant difference between groups on ZCQ (2.2 for mild® vs 2.8 for steroid) at 6 weeks. After the 6-week assessment, patients were unblinded and allowed to cross over to the other treatment. Fourteen (82%) of the steroid-treated patients crossed over to mild®. Follow-up at 12 weeks in patients treated with mild® showed no significant change in mean VAS from 6 to 12 weeks (6.3 at baseline, 3.8 at 6 weeks, and 3.4 at 12 weeks). There were no major procedure-related or device-related complications. The study was continued with cross-over allowed for the epidural steroid group until 26-week results. The study was completed in 2013. The 26-week results have been posted on the online site www.clinicaltrials.gov (NCT00995371).

MiDAS I (NCT00956631) is an industry-sponsored multi-center study of IG-MLD at 14 centers. In 2010, Chopko and Caraway reported 6-week results of this study. (8) Included were patients with symptomatic LSS that was caused primarily by dorsal element hypertrophy with a hypertrophic ligamentum flavum greater than 2.5 mm and central canal sectional area of 100 square mm or less and had failed conservative therapy. Of 78 patients treated, 6-week follow-up was available for 75 (96%). Thirty-nine of the patients (52%) were discharged from the hospital on the same day, and 36 patients (48%) stayed for one night. No major device or procedure-related complications (e.g. dural tears, nerve root injury, post-operative infection, hemodynamic instability, or post-operative spinal structural instability) were reported. The average VAS pain score improved from 7.3 at baseline to 3.7 at the 6-week follow-up. Scores on the ODI improved from 47.4 to 29.5, a 38% improvement. Scores on the ZCQ improved 26.8% on the symptom severity subscale and 17.5% for physical function. Scores on all subscales of the SF-12 health survey were improved. At 1-year follow-up, VAS for pain from 58 patients was 4.5. (9) The ODI improved from 48.6 to 36.7, and there was significant improvement on all domains of the ZCQ and the SF-12 Physical Component Summary score (from 27.4 to 33.5). Functional and self-reported outcomes were also reported for 40 of the 78 patients at 1 year. (6) In 2013, Chopko reported 2-year outcomes with 45 patients from this trial. (6) Validity of the longer-term results is uncertain due to the high loss to follow-up.

Chopko also reported on IG-MLD in 14 patients who were considered at high risk for complications from open spine surgery and general anesthesia. (10) Comorbidities included obesity, diabetes mellitus, hypertension, chronic obstructive pulmonary disease, chemotherapy, and coronary artery disease. Nine of the 14 patients (64%) reported an improvement in VAS pain scores of 3 points or
more. The average VAS score improved from 7.6 to 3.6 (53% improvement) at a mean follow-up of 23.5 weeks (range: 4 to 72 weeks). Scores on the ODI were 50% at baseline and 43.9% at follow-up; this change was not statistically significant. Two post-operative complications (calf deep venous thrombosis and pulmonary embolism) related to the procedure were observed in a single patient. One patient subsequently received open lumbar decompressive laminectomy due to continued decline in function.

Several other reports on IG-MLD have been published by Deer et al. A 2012 report by Deer et al describes a prospective study of mild® in 46 consecutive patients with neurogenic claudication related to lumbar spinal stenosis that was caused primarily by ligamentum flavum hypertrophy (NCT01076244). (11) Complete follow-up to 1 year was available for 35 patients (76%). VAS improved from 6.9 at baseline to 4.0 at 1 year, ODI improved from a mean of 49.4 to 32.0, and the ZCQ improved for all ZCQ domains. A 2010 publication by Deer and Kapural describes a chart review of 90 consecutive patients treated in the U.S. (14 physicians in 12 facilities) with mild® devices under fluoroscopic guidance. (12) No major adverse events (dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, hematoma) were found in the chart review. The safety review was updated in 2012 by Levy and Deer with a total of 373 patients treated with IG-MLD. (13)

Another retrospective review from 2010 reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by interventional pain specialists. (14) All patients met MRI criteria (spinal stenosis and ligamentum flavum hypertrophy) for IG-MLD and had undergone previous conservative treatment to include lumbar epidural steroid injections, opioid and non-opioid medication and physical therapy. Most of the patients were considered non-surgical candidates in consultation with or referral from a spine surgeon (no further details were provided). All patients had bilateral IG-MLD with most (n=26) at 2 levels. VAS pain scores averaged 9.6 at baseline and 5.8 at 30 days after the procedure, with 80% of patients reporting a change in VAS of 3 or more. Thirty patients (71%) reported an improvement in function following IG-MLD. No major adverse events were identified.

**Section Summary.** There is one small randomized trial with short-term follow-up that reports improved outcomes from mild® compared with epidural steroid injections. Evidence from prospective case series in patients who have failed conservative management reports that pain is reduced and functional status is improved following treatment with mild®.

This evidence is insufficient to determine the efficacy of mild® compared with placebo and is also insufficient to determine the comparative efficacy of IG-MLD in relation to alternative surgical approaches. Because of the variable natural history of back pain and the subjective nature of the outcomes of pain and functional status, RCTs are necessary to determine which surgical approach to lumbar spinal stenosis achieves the best outcomes. Further trials with larger numbers of subjects, longer follow-up, and relevant control groups are needed to determine the effect on health outcomes with greater certainty.

**Ongoing and Unpublished Clinical Trials**

A search of online site ClinicalTrials.gov in March 2014 found several trials on IG-MLD. Two studies are phase 4 open label with mild® (NCT01082159, NCT01315145), and 1 is a small RCT (NCT01129921).
NCT01129921 is an independently-sponsored (Grigsby, PI) double-blind sham-controlled trial with 40 patients. The study was completed in 2012. Results have been posted; no peer-reviewed publications have been identified to date.

NCT01082159 (MiDAS II) – This is a Vertos-sponsored multicenter study with 55 patients. Caraway and Chopko are principle investigators (PI). The study is listed as completed as of February 2013. Results have been posted; no peer-reviewed publications have been identified to date.

NCT01315145 (MiDAS III) - This is a multicenter Vertos-sponsored trial (Mekhail, PI) that was initially designed as a randomized trial with an active comparator (epidural steroid injection). Due to difficulty of enrollment, the study was amended and converted to an observational comparative study with study arm being self-selected by the patient. This study has completed recruiting with 138 patients enrolled and study completion expected May 2014.

Practice Guidelines and Position Statements

The American Pain Society (APS) published clinical practice guidelines in 2009 on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. (2) The guidelines were based on a systematic review commissioned by the APS and conducted at the Oregon Health Sciences University Evidence-Based Practice Center. (1) APS provided a strong recommendation (high-quality evidence) that clinicians discuss risks and benefits of surgery as an option for patients with persistent and disabling radiculopathy due to spinal stenosis. This recommendation was based on evidence showing that decompressive laminectomy is associated with moderate benefits compared with nonsurgical therapy through 1 to 2 years for persistent and disabling leg pain due to spinal stenosis, either with or without degenerative spondylolisthesis. There was insufficient evidence to determine if laminectomy with fusion was more effective than laminectomy without fusion. APS recommended that shared decision making regarding surgery include a specific discussion about average benefits, which appear to decrease over time in patients who undergo surgery. It should be noted that this recommendation was based on randomized trials of laminectomy. Evidence for more recent decompressive surgical procedures was not reviewed.

Summary

Posterior decompression for lumbar spinal stenosis has been evolving toward increasingly minimally invasive procedures in an attempt to minimize post-operative morbidity and spinal instability. In general, the literature comparing surgical procedures is limited. The evidence available suggests that less-invasive surgical decompression may reduce perioperative morbidity without impairing long-term outcomes when performed in appropriately selected patients.

In contrast to surgical decompression, the mild® procedure is a percutaneous decompressive procedure performed solely under fluoroscopic guidance (e.g., without endoscopic or microscopic visualization of the work area). This procedure is indicated for central stenosis only, without the capability of addressing nerve root compression or disc herniation, should it be required. Therefore, image-guided minimally invasive lumbar decompression for central stenosis without nerve root compression or disc herniation is considered medically necessary.
Due to the unknown impact of these limitations on health outcomes, randomized controlled studies in appropriate patients are needed and are being conducted to compare this novel procedure with the established alternatives; therefore, for all other conditions image-guided minimally invasive lumbar decomposition procedure is considered investigational.

**Medicare National Coverage**

There is no national coverage decision.

**References**


**Policy History**

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<tr>
<th>Date</th>
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<td>December 2011</td>
<td>New Policy</td>
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<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, references added, reordered and renumbered. No change in policy statement.</td>
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<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 5-6 added. Policy statement unchanged.</td>
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**Keywords**

Lumbar spinal stenosis
MILD®
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Posterior lumbar decompression
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 12, 2014 and is effective October 15, 2014.

Signature on File
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