Systematic Review

# Perspective: A Proposed Diagnostic and Treatment Algorithm for Management of Lumbar Spinal Stenosis: An Integrated Team Approach

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**Background:** Newly-introduced minimally invasive interventions have filled a gap between conservative care and open surgical procedures in the treatment and management of lumbar spinal stenosis (LSS), allowing expanded access to patient care. This spectrum of care involves an important interplay between advanced practice providers, interventional pain physicians, and spine surgeons.

**Objectives:** Using an integrated team approach starting with history taking; static and dynamic imaging; and conservative care, we developed a simple, understandable clinical algorithm that serves as a foundation for physicians to confidently make objective decisions regarding diagnosing and treating LSS throughout the entire clinical course of the condition. We believe this could potentially lead to more efficient and effective care for patients suffering from LSS with neurogenic claudication.

**Methods:** A decision tree approach was utilized with "either/or" choices at each branch or node in the algorithm. Activities are divided into examination procedures and corresponding treatment interventions. Symptom and radiographic severity grading as well as assessing clinical status employed published validated standards. Commensurate treatment choices were selected based on published LSS-specific clinical practice guidelines and/or meta-analyses.

**Results:** This algorithm recommends a systematic rule set for LSS diagnostic and treatment options. Initially, LSS symptom severity is graded based on the patient's pain relief with spinal flexion. This is correlated with radiographic severity assessment graded as mild, moderate, or severe. Radiographic severity combined with dynamic imaging prescribes a choice of treatment options and a risk/benefit discussion with the patient. These options include conservative management, minimally invasive methods such as interspinous process decompression, and more invasive surgical procedures such as laminectomy for increasing grades of radiographic severity.

**Limitations:** Understanding that each patient with LSS is managed on a case-by-case basis, the treatment options recommended by this algorithm should be considered "soft guidance." As such, integrated team/patient consultation is recommended to ensure maximum clinical benefit. A risk/benefit assessment and discussion should be performed with each individual patient.

**Conclusions:** Our proposed algorithm offers an easy-to-use clinical tool and general foundation for identifying, evaluating, and treating patients with intermittent neurogenic claudication associated with LSS.

**Key words:** Lumbar spinal stenosis, neurogenic claudication, minimally invasive, interspinous spacer, decompression, algorithm

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The recent introduction of several minimally invasive interventions has substantially narrowed the treatment gap in the continuum of options for lumbar spinal stenosis (LSS). Previously, these were limited to conservative management, epidural steroid injections, and open decompressive

laminectomy when symptoms became severe and intractable (1-3). Patients with more moderate disease, both clinically and radiographically, in whom conservative care had failed, were left with few options (4). The current availability of interventions that provide evidence-based clinical benefit earlier in the treatment continuum is timely. Indeed, new studies suggest that prolonged neurological compression with LSS is associated with poor surgical outcomes, underscoring the need to intervene earlier in the disease process (5).

The commercial availability of minimally invasive, nonfusion treatment options for LSS, such as interspinous process decompression (IPD) which uses a standalone spacer, and percutaneous image-guided lumbar decompression (PILD), has broadened the practitioner base for these procedures to include interventionalists with specialties in pain medicine and neuroradiology. Consequently, a valuable recommendation has been proposed to establish a fundamental diagnostic and treatment algorithm to assist in guiding LSS procedural choices and options based on different clinical and radiographic severity stages of LSS (6).

In response to this recommendation, we employed an integrated team approach, merging expertise in musculoskeletal imaging, interventional pain management, and spine surgery to develop a simple, easy-to-use algorithm, facilitated by advanced practice providers, that would serve as a foundation for clinical decision making in managing LSS throughout the continuum of care.

## Methods

This report's primary purpose was to develop a simple, understandable clinical algorithm to serve as a foundation for physicians to confidently make objective decisions regarding diagnosing and treating LSS throughout the entire clinical course of the condition. To address the multifactorial clinical and biomechanical aspects of LSS, we assembled a team of specialists to integrate existing knowledge regarding LSS diagnosis and the full spectrum of interventional options with the objective of maximizing clinical benefit and efficiency of care.

Our proposed algorithm recommends a systematic rule set for LSS diagnostic and treatment decisions based on unambiguous alternatives and clear stopping rules (7). A decision tree approach was utilized with "either/or" choices at each branch or node in the algorithm which progresses logically in a temporal fashion (Fig. 1). Activities are divided into examination procedures and corresponding treatment interventions. Diagnostic and clinical assessment queries are represented in the algorithm as diamonds, with corresponding symptom severity grading and treatment options shown as rectangles.

Symptom and radiographic severity grading, as well as assessing clinical changes, employed published validated standards. Commensurate treatment choices were selected based on published LSS-specific clinical practice guidelines and/or meta-analyses to support each option.

## Results

### Diagnostic Characteristics

The objective of the initial patient encounter and team consultation is to undertake a thorough clinical assessment and examination to determine the likelihood and duration of possible LSS symptoms (Fig. 1, Box 1). The clinical hallmark of LSS is neurogenic claudication, defined as a constellation of symptoms that occur intermittently and involve the back, buttocks, groin, and anterior thigh, as well as radiating pain down the posterior aspect of the leg to the feet (8,9). Patient discomfort is often described as a cramping or burning feeling with symptoms distributed unilaterally or bilaterally. The patient may suffer concomitant back pain, although lower extremity pain and discomfort is usually the more bothersome clinical feature (10).

A distinguishing clinical attribute of neurogenic claudication with LSS is its relationship to the patient's posture, where prolonged lumbar extension increases and flexion decreases pain onset and severity. Symptoms progressively worsen when standing or walking and are relieved by sitting and bending forward (8). The "shopping cart sign" or "simian stance," with the patient walking in a flexed or stooped position to relieve or reduce symptoms, is a common neurogenic claudication indicator in LSS (11).

Patients may also complain of radicular symptoms, with sharp lower extremity pain. Leg pain is described as severe and radicular in distribution, and almost always presents with postural aggravation during lumbar extension (8,11). This can occur with peripheral spinal column stenosis, with impingement of transiting nerves in the lateral recess, or exiting nerves in the neural foramen.

Patients demonstrating the foregoing constellation of signs and symptoms for greater than 6 months can be classified diagnostically as exhibiting LSS (Fig. 1, Box 2).

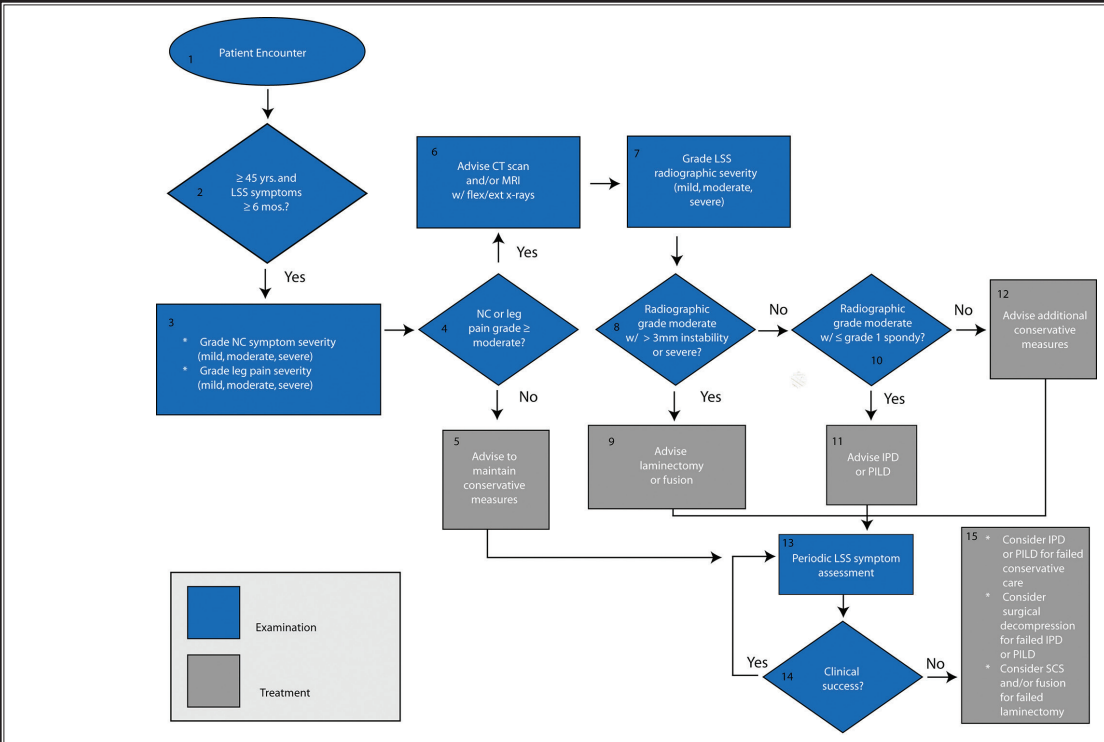


Fig.1: ***Diagnostic and treatment algorithm for lumbar spinal stenosis. Box 1: Patient Encounter.*** A patient encounter is defined as any interaction between a health care practitioner (generally a physician, nurse practitioner or physician assistant) that provides the opportunity to assess a patient's history and symptoms, and provide advice, counseling, or treatment (21). ***Box 2: ≥ 45 Years and LSS symptoms ≥ 6 Months.*** The practitioner seeks to determine that the patient exhibits or reports characteristics associated with acquired degenerative lumbar spinal stenosis (LSS). The patient should be ≥ 45 years of age and have experienced symptoms of sufficient duration (≥ 6 months) to consider surgical options (8,11). ***Box 3: Grade neurogenic claudication (NC) symptom severity (mild, moderate, severe); Grade leg pain severity (mild, moderate, severe).*** Neurogenic claudication (NC) symptom severity should be graded based on the top 3 criteria identified by the International Task Force on the Diagnosis and Management of LSS as defining the condition (13). Presence of at least one of these NC clinical signs is characteristic of LSS diagnosis (14): • Leg symptoms worsened by walking and relieved by sitting • Symptoms worsened by lumbar extension and relieved by flexion • Leg pain relieved by leaning forward on a shopping cart while walking. Mild: presence of 1 criterion; Moderate: presence of 2 criteria; Severe: presence of 3 criteria; Leg pain severity should be graded using either the Visual Analog Scale or the Numeric Rating Scale (0-10) as follows (15,16): Mild: ≤ 3; Moderate: > 3 to < 7; Severe: ≥ 7. ***Box 4: NC or leg pain grade ≥ moderate?*** Segregate patients that have mild NC and mild leg pain symptom severity from those that have at least moderate NC or moderate leg pain symptom severity. ***Box 5: Advise to maintain conservative measures.*** Patients with mild LSS clinical symptoms should be counseled to pursue a combination of manual therapy/individualized exercise (14). Consider local anesthetic injection (19). ***Box 6: Advise computed tomography scan and/or magnetic resonance imaging with flexion-extension x-rays.*** Patients with moderate LSS clinical symptoms should be referred for lumbar radiography with either MRI and/or CT (21,22,25). Dynamic flexion-extension radiographs should be undertaken to assess the degree of instability and spondylolisthesis. ***Box 7: Grade LSS radiographic severity (mild, moderate, severe).*** LSS radiographic severity should be graded using criteria similar to those proposed by the Lumbar Spinal Stenosis Outcome Study Working Group Zurich as follows (26): Mild: < 25% reduction in central canal and/or nerve root canal dimensions compared to the adjacent levels; Moderate: ≥ 25% to ≤ 50% reduction in central canal and/or nerve root canal dimensions compared to the adjacent levels; Severe: > 50% reduction in central canal and/or nerve root canal dimensions compared to the adjacent levels. ***Box 8: Radiographic grade moderate w/ > 3 mm instability or severe?*** Segregate patients with radiographically severe LSS from those with either mild or moderate LSS severity without instability. ***Box 9: Advise surgical decompressive laminectomy or fusion.*** Patients with radiographically moderate LSS with > 3 mm instability or severe LSS should consider surgical decompressive laminectomy which offers the best chance for symptom amelioration based on results of the SPORT randomized controlled trial (2,28) as well as several systematic reviews and evidence-based guidelines (3,22,27). Fusion may also be considered. ***Box 10: Radiographic grade moderate w/ ≤ grade 1 spondylolisthesis?*** Segregate patients with radiographically moderate LSS from those with mild LSS severity. ***Box 11: Advise interspinous decompression (IPD) or percutaneous image-guided lumbar decompression (PILD)*** Patients with radiographically moderate LSS should consider stand-alone IPD which offers symptom amelioration equivalent to surgical decompression based on the results of several systematic reviews (35-37), an evidence- based guideline (1), and a cost-effectiveness analysis (38). IPD not indicated: > grade 1 spondylolisthesis, > 3 mm instability, and/or > 2 treated levels. PILD may also be considered (32,33). ***Box 12: Advise additional conservative measures.*** Patients with radiographically mild LSS should be counseled to continue conservative approaches. If not undertaken previously, patients should pursue a combination of manual therapy/individualized exercise (14). Consider local anesthetic injection (19). ***Box 13: Periodic LSS symptom assessment.*** Patients should receive periodic monitoring (e.g., annually) of their LSS symptoms to assess degree of improvement/worsening and/or to identify new onset symptoms. ***Box 14: Clinical success?*** During periodic monitoring and following surgical interventions, practitioners should evaluate whether a patient has achieved a clinically significant clinical outcome. Success criteria for leg pain severity are improvements of either 2 units (0-10 scale) or 30% compared to the baseline value at initial clinical presentation (44,45). ***Box 15: Consider IPD or PILD for failed conservative care; consider surgical decompression for failed IPD or PILD; consider spinal cord stimulation and/or fusion for failed laminectomy.*** If the patient has not achieved a clinically successful outcome and/or exhibits worsening or new onset symptoms, additional surgical interventions should be considered. In general, a patient with an unsatisfactory clinical outcome would be offered a surgical intervention at the next level of invasiveness.

## Symptom Severity Assessment

Following an initial diagnosis of LSS, the subsequent clinical decision pathway involves evaluating the severity of LSS symptoms (Fig. 1, Box 3) as a means of guiding and recommending treatment options.

This algorithm recommends a simple 2-part symptom severity determination of neurogenic claudication and leg pain (12). Neurogenic claudication severity should be based on the top 3 diagnostic consensus criteria validated by the International Taskforce on the Diagnosis and Management of LSS (13). These cardinal features of LSS-associated neurogenic claudication include:

- Leg symptoms worsened by walking and relieved by sitting
- Symptoms worsened by lumbar extension and relieved by flexion
- Leg pain relieved by leaning forward on a shopping cart while walking.

The presence of at least one of these clinical signs is considered diagnostically characteristic of LSS (14). Neurogenic claudication severity should be graded as follows:

Mild: presence of 1 criterion

Moderate: presence of 2 criteria

Severe: presence of 3 criteria.

It should be emphasized that if a patient does not experience symptom relief upon lumbar flexion, they have clinically severe LSS and are not a candidate for minimally invasive interventions.

Coincident with the determination of neurogenic claudication severity, leg pain severity should be graded using either the Visual Analog Scale or the 11-point Numeric Rating Scale and based on current clinical guidance, the severity should be graded as follows (15,16):

Mild: ≤ 3

Moderate: > 3 to < 7

Severe: ≥ 7.

## Primary Interventions

After determining LSS symptom severity, patients can be dichotomized as those with mild neurogenic claudication and mild leg pain severity from those with at least moderate neurogenic claudication or moderate leg pain severity (Fig. 1, Box 4).

Patients with overall mild LSS clinical symptoms should be counseled to pursue conservative care, consisting of medications (e.g., nonsteroidal anti-inflammatory drugs), physical therapy, lifestyle modifications, localized spinal injections, and multidisciplinary rehabilitation (11). A systematic Cochrane Review of nonoperative management strategies for patients with neurogenic claudication and imaging-confirmed LSS concluded that there was insufficient evidence to recommend any specific type of nonsurgical treatment for LSS (17). However, recent trials suggest a structured and supervised conservative management regimen consisting of a combination of manual therapy and individualized exercises provide effective short-term clinical benefit and symptom amelioration (Fig. 1, Box 5) (14,18). Local anesthetic injection may also be considered (19,20).

Using advanced imaging modalities, such as magnetic resonance imaging (MRI) and/or computed tomography, should be reserved for patients with at least moderate LSS clinical symptoms (Fig. 1, Box 6) (21,22). In these patients, imaging provides definitive diagnostic confirmation of LSS as well as indirect visualization of the severity, location, and extent of anatomical degeneration (23,24). These studies are particularly helpful in procedural planning for patients considering invasive interventions for LSS (11). MRI, which allows examination of the size, shape, and anatomic associations between spinal and neural elements, is currently the recommended method for confirming an LSS diagnosis (23,24). Dynamic flexion and extension radiographs are also recommended for completely evaluating associated spondylolisthesis and instability and for procedural planning purposes, particularly with respect to the selection of and preparation for minimally invasive interventions (25). It is known that static imaging such as MRI may underestimate the degree of spondylolisthesis and while facet joint fluid may be an indicator of instability, a flexion-extension film provides necessary confirmation.

LSS radiographic severity should be graded using criteria similar to those proposed by the Lumbar Spinal Stenosis Outcome Study Working Group Zurich as follows (Fig. 1, Box 7) (26):

Mild: < 25% reduction in central canal and/or nerve root canal dimensions compared to the adjacent levels

Moderate: ≥ 25% to ≤ 50% reduction in central canal and/or nerve root canal dimensions compared to the adjacent levels

Severe: > 50% reduction in central canal and/or nerve root canal dimensions compared to the adjacent levels.

Following the determination of LSS radiographic severity, patients can be dichotomized as those with radiographically severe LSS from those with radiographically mild or moderate LSS severity without instability (Fig.1, Box 8).

Based on surgical consultation, patients with radiographically moderate LSS with instability or severe LSS may consider undergoing surgical decompressive laminectomy or fusion (Fig.1, Box 9). Laminectomy has long been recognized as the "gold standard" surgical treatment for LSS when symptoms become severe and intractable and anatomical degeneration is advanced (2,3,22,27,28). However, 2 Cochrane systematic reviews have challenged the purported effectiveness of this procedure (29,30). A recently-published, large observational study utilizing propensity score matching had a contrary finding: surgical treatment is superior to nonoperative care for patients with LSS (31). Surgical decompression can be achieved using an open procedure alone or with interlaminar stabilization as well as with numerous minimally invasive approaches, including with indirect imaging guidance (1,3).

Patients can be further dichotomized as those with radiographically moderate LSS from those with radiographically mild LSS severity (Fig.1, Box 10).

Patients with radiographically moderate LSS may consider undergoing IPD or PILD (Fig.1, Box 11) (32,33). IPD (Superion™ device, Boston Scientific) features a nonfusion, stand-alone, minimally invasive procedure that utilizes an interspinous spacer implanted with fluoroscopic guidance under monitored anesthesia care (1,6,34). IPD is indicated for use in patients suffering from neurogenic claudication with confirmed evidence of either a thickened ligamentum flavum, narrowed lateral recess, and central canal and/or foraminal narrowing. It is not indicated in patients where plain radiographs indicate > grade 1 spondylolisthesis, or where dynamic flexion-extension films show > 3 mm instability, and/or > 2 treated levels.

The published compendium of literature shows that IPD offers symptom amelioration equivalent to surgical decompression based on the results of several systematic reviews (35-37), an evidence-based guideline (1), and a cost-effectiveness analysis (38). Additionally, 5-year follow-up findings from an investigational device exemption randomized controlled trial of IPD demonstrated durable clinical benefit and a reduction in reoperation rates (39), a consistent decrease in the prevalence of opioid use (40), and an improvement in quality of life in patients with moderate LSS (41). Real-world registry data of commercial IPD usage have corroborated the clinical benefits achieved in the clinical trial setting (42). Quantitative imaging studies show no association of IPD with sagittal alignment that can occur with other devices such as fusion clamps, which can alter the natural biomechanics of the joint complex.

PILD (mild® procedure, Vertos Medical) is a minimally invasive outpatient procedure to treat central canal LSS related to a hypertrophied ligamentum flavum with good clinical results (43). However, PILD is not indicated for patients with foraminal or lateral recess LSS as a contributing factor.

Patients with radiographically mild LSS should be counseled to pursue a resumption of conservative care (Fig.1, Box 12). If not undertaken previously, these patients should be offered a structured and supervised conservative management regimen consisting of a combination of manual therapy and individualized exercises (14).

## Clinical Success Criteria

Irrespective of initial LSS symptoms and radiographic severity assessment or primary intervention, a concerted effort should be undertaken to periodically evaluate all patients to assess the magnitude of symptom changes and whether additional tests or procedures are warranted (Fig.1, Box 13). The treatment goal should be to realize clinically significant improvements within 12 months of the index intervention.

During periodic monitoring and following surgical interventions, practitioners should evaluate whether patients have achieved a clinically significant clinical outcome (Fig.1, Box 14). At a minimum, patients should be queried regarding the current severity of their leg pain. Patients who have a clinically significant positive response to leg pain severity demonstrate improvements of either 2 units (0-10 scale) or 30% compared to the baseline value at initial clinical presentation (44,45).

## Secondary Interventions

We recommend additional multidisciplinary team consultation for patients that fail to realize a clinically significant improvement and/or exhibit worsening or new onset symptoms. Additional surgical interventions may be recommended, proceeding to the next level of invasiveness in most cases (Fig.1, Box 15). Thus, a patient with continued unsatisfactory outcomes with conservative care would proceed to IPD or PILD, while those experiencing a lack of success with IPD or PILD would proceed to laminectomy, and so forth. One cave-

at to this pathway would be the revision of a previous laminectomy converted to fusion. Evidence is emerging to suggest that adding fusion to decompression alone does not offer additional clinical benefit and carries a higher risk of surgical complications (46-48).

## Discussion

The Pain Management Best Practices Inter-Agency Task Force was convened in 2019 by the US Department of Health and Human Services to address acute and chronic pain in response to the ongoing opioid crisis (49). Indeed, it has been demonstrated that opioids offer little clinical benefit by way of pain reduction or functional improvement in patients with neurogenic claudication associated with LSS (50,51). Consequently, the task force emphasized an individualized, patient-centered approach based on establishing a therapeutic alliance with a multidisciplinary team using a multimodal treatment approach focused on proper diagnosis and measurable outcomes in quality of life, functionality and activities of daily living.

We employed an integrated team approach to merge expertise in musculoskeletal imaging, interventional pain management, and spine surgery to develop a pragmatic LSS clinical algorithm to improve diagnostic efficiency and maximize clinical benefit. The LSS diagnostic and treatment algorithm presented herein provides a basic foundation for making procedural decisions related to the management of patients with LSS. We recognize that many decisions regarding the diagnosis and treatment of patients with LSS require subtle determinations about the appropriate clinical pathway that cannot be addressed via "black-and-white" choices in an algorithm. Indeed, many LSS patients tend to be older with multiple contributory spinal conditions that can act as pain generators. That said, the current algorithm specifically focuses on identifying those patients where the primary concern is intermittent neurogenic claudication, a symptom highly specific to LSS.

The approach taken in developing the current LSS algorithm was distinctly different than would be used in the formation of clinical practice guidelines, which are comprehensive dossiers and offer multiple options with graded levels of evidence (7). In comparison, we provide unambiguous alternatives and clear stopping points. As such, the proposed algorithm should be considered soft guidance, appreciating that the treatment trajectory for some patients may fall outside this definitive rule set. Indeed, while we advocate for objective criteria to grade clinical and radiographic LSS severity. each clinical decision should be a shared risk/benefit discussion between physician and patient. Factors that may influence decision making include medical comorbidities and patient preference.

A primary goal in developing this algorithm was to remain both pragmatic and parsimonious with respect to the choice of diagnostic and treatment procedures. The aim was to incorporate simple choices that were immediately understandable to the practitioner. For example, we included only leg pain severity for LSS symptom severity and outcome assessment, eschewing the use of condition-specific instruments such as the Zurich Claudication Questionnaire. We felt the direct assessment of leg pain severity on a standard 11-point scale was a universally understood metric, used in daily practice with well-accepted success criteria and can be queried in a phone interview. In contrast, the Zurich Claudication Questionnaire is rarely used outside of a controlled trial setting, requires a scoring algorithm, and provides metrics over 3 separate domains have little pertinence for clinicians.

We elected not to include epidural steroid injections as a treatment option for LSS. While there remains a limited group of proponents for this intervention (52), there is a growing body of evidence that epidural steroids provide no additional benefit over local anesthetic injections in the setting of LSS (19,20,53,54). Additionally, published findings of a randomized controlled trial comparing epidural steroid injections with PILD found almost no clinical benefit associated with steroid injections in patients with LSS (55).

The flexion/extension plain film as a foundational piece of the LSS workup is noteworthy, especially for the nonspine surgeon. Interventional pain management physicians participating in a multidisciplinary team may not be accustomed to this diagnostic tool being routinely utilized in their daily practice. In our algorithm, the presence of > 3 mm of motion between flexion and extension in spondylolisthesis, indicating a hypermobile segment, triages the patient to the surgical pathway. Thus, the presence of instability is a contraindication to IPD placement. The routine use of dynamic plain film imaging and evaluation of stability has allowed the interventional pain management physician to understand biomechanics at a higher level. We believe this will ultimately allow for better and earlier identification of appropriate surgical candidates.

## Conclusion

The operative treatment of spinal pathology in LSS

has traditionally been under the management purview of orthopedic spine surgeons and neurosurgeons. However, the recent commercial adoption of several minimally invasive LSS treatment options, such as IPD, that can be undertaken in an ambulatory surgical setting, has extended these interventions to an expanded group of physician subspecialties (6,56). Thus, we believe a team approach that integrates the knowledge base of imaging, interventional pain management, and orthopedic specialists provides the most comprehensive method for managing patients with the full array of available treatment and surgical options. This algorithm provides a straightforward clinical decision process for identifying, evaluating, and treating patients with intermittent neurogenic claudication associated with LSS.

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