Invasive Treatments for Low Back Disorders

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Objective: This abbreviated version of the American College of Occupational and Environmental Medicine's Low Back Disorders guideline reviews the evidence and recommendations developed for invasive treatments used to manage low back disorders. **Methods:** Comprehensive systematic literature reviews were accomplished with article abstraction, critiquing, grading, evidence table compilation, and guideline finalization by a multidisciplinary expert panel and extensive peer-review to develop evidence-based guidance. Consensus recommendations were formulated when evidence was lacking and often relied on analogy to other disorders for which evidence exists. A total of 47 high-quality and 321 moderate-quality trials were identified for invasive management of low back disorders. **Results:** Guidance has been developed for the invasive management of acute, subacute, and chronic low back disorders and rehabilitation. This includes 49 specific recommendations. **Conclusion:** Quality evidence should guide invasive treatment for all phases of managing low back disorders.

This is the third article summarizing findings for low back disorders from the ACOEM's Low Back Disorders Guideline. This article focuses on the invasive treatment sections from the 862-page ACOEM Low Back Disorders Guideline (2456 references). The first article[1] addresses assessment and diagnostic evaluation and the second article[2] addresses non-invasive and minimally invasive treatments. Three algorithms are provided as figures to a prior publication.[2]

The ACOEM's Low Back Disorders Guideline is designed to provide health care providers with evidence-based guidance for management of low back disorders among working-age adults. Guidance in this report has been developed for acute (up to 1 month duration), subacute (1 to 3 months' duration), and chronic (more than 3 months' duration) clinical timeframes. Evidence for, and guidance development, was sought for the treatment of several spine disorders including: low back pain (LBP), sciatica/radiculopathy, spondylolisthesis, facet arthrosis, degeneration of the disc, failed back surgery syndrome, and spinal stenosis. This guideline does not address several broad categories including congenital disorders or malignancies. It also does not address specific intraoperative procedures. This article includes addressing the following multi-part questions by treatment phase (acute, subacute, chronic, postoperative) by the Evidence-based Practice Spine Panel:

- When, and for what conditions are invasive procedures recommended?
- When, and for what conditions is surgery recommended?
- Which surgeries are recommended for which conditions?
- What management options are recommended for delayed recovery?

The following topics which may be relevant to patients with low back disorders are addressed in the Chronic Pain Guideline[3] and thus are not reviewed below: rehabilitation for delayed recovery; biofeedback; behavioral interventions for chronic pain; work conditioning, work hardening, early intervention programs and back schools for chronic pain; tertiary pain programs: interdisciplinary pain rehabilitation programs, multidisciplinary rehabilitation programs, chronic pain management programs, and functional restoration programs; and participatory ergonomics programs for patients with chronic pain.

The search strategies used 10 databases (PubMed, Scopus, Google Scholar, Medline, EBM Online, Cochrane, TRIP, CINAHL, AMBASE, and PEDro). A total of 309,035 articles were screened, with all potentially relevant study abstracts reviewed and evaluated against specified inclusion and exclusion criteria. A total of 1128 articles were included in these guidelines that addressed invasive treatment of low back disorders, with 368 moderate- or high-quality. Low-quality studies are cited elsewhere.[4] Evidence-based recommendations were developed and graded from (A) to (C) in favor and against the specific invasive procedures, with (A) level recommendations having the highest quality literature. Expert consensus was employed for insufficient evidence (I) to develop consensus guidance. This guideline achieved 100% Panel agreement for all developed guidance with two exceptions noted below.

Guidance was developed with sufficient detail to facilitate assessment of compliance (Institute of Medicine [IOM]) and auditing/monitoring (Appraisal of Guidelines for Research and Evaluation [AGREE]).[5] Alternative options to manage conditions are provided when comparative trials are available.[3] All AGREE,[6] IOM,[5] AMSTAR,[7] and GRADE[8] criteria were adhered to.[9] In accordance with the IOM's Standards for Developing Trustworthy Clinical Practice Guidelines, this guideline underwent external peer review, and detailed records of the peer review processes are kept, including responses to external peer reviewers.[5]

The Evidence-based Practice Spine Panel and the Research Team have complete editorial independence from ACOEM and Reed Group, which have not influenced the guideline. The literature is continuously monitored and formally appraised for evidence that would materially affect this guidance. This guideline is planned to be comprehensively updated at least every 5 years or more frequently should evidence require it. Focused updates occur approximately annually as evidence requires. All treatment recommendations are guidance based on synthesis of the evidence plus expert consensus. These are recommendations for practitioners, and decisions to adopt a particular course of action must be made by trained practitioners on the basis of available resources and the particular circumstances presented by the individual patient.

PSYCHOLOGICAL EVALUATION

The patient presenting with acute, subacute, and chronic pain should generally be evaluated psychologically to explore factors either affecting the presentation of pain and/or maintaining subacute/chronic pain and disability and to facilitate recovery and restoration of function. In the acute phase, this is usually a cursory evaluation of prior psychosocial issues. Yet, psychological evaluations should be considered in all pain presentations as analogous to other diagnostic methods. This is despite the implications of requesting a psychological evaluation that are often misconstrued to imply that the purpose is to rule out or affirm a mental disorder. Though such diagnoses may be rendered, this does not necessarily imply a ''psychological'' or ''mental'' cause for the symptoms. Reports of pain and functional problems are usually maintained by a variety of medical, physical, social, psychological, and occupational factors; and the general purpose of psychological evaluation is to comprehensively evaluate these influences. However, most pain and functional deficits arising from musculoskeletal injuries resolve spontaneously or respond adequately to initial conservative treatment.

The general purpose of the psychological evaluation is to: (1) describe and diagnose the current psychological and psychosocial dysfunctions; (2) elucidate the current psychological and behavioral factors which are salient in maintaining the symptoms and dysfunction; (3) assess the likely premorbid factors which may be contributory; and (4) recommend treatment, management, and/or occupational/vocational options.

Psychological evaluation for chronic LBP disorders is Recommended (I), Low Confidence as part of the evaluation and management of patients with chronic pain in order to assess whether psychological factors will need to be considered and treated as part of the overall treatment plan. Indications, frequency and components of a psychological evaluation in these patients is provided in Table 1. Psychological evaluation is also Recommended (I), Moderate Confidence prior to consideration of back surgery in patients with chronic benign pain, with indications particularly including: patients' responses to prior therapeutic interventions and/or their level of disability (given objective findings) suggests that psychological factors may affect the clinical course postoperatively; histories of excessive numbers of prior health care providers; prior history of substance(s) use/abuse; and prior psychiatric disorders.

Invasive Clinical Treatment Recommendations Overview

Quality evidence indicates that patient outcomes are not adversely affected by delaying non-emergent surgery for weeks or a few months and continued nonoperative care is encouraged in patients with stable or improving deficits who desire to avoid surgery.[16] In the absence of red flags,[1,4] patients with radicular pain and other potential surgical conditions are treated with non-invasive treatments for typically at least 4 to 6 weeks. However, patients with either moderate to severe neurological deficits that are either not improving or not trending to improvement at 4 to 6 weeks may benefit from earlier surgical intervention. Those with progressive neurological deficit(s) are believed to have indications for immediate surgery. Those with severe deficits that do not rapidly improve are also candidates for earlier testing and surgery.

INJECTIONS

There are several types of injections including epidural injections (caudal, interlaminar, and transformal), intradiscal injections, ketamine, clonidine, chemonucleolysis, tender or ''trigger point'' injections, facet joint injections, sacroiliac joint injections, intrathecal drugs, ligamentous injections (prolotherapy), and botulinum injections.

LUMBAR EPIDURAL INJECTIONS

A total of 18 high-quality and 41 moderate-quality studies were included in this analysis.[17–41] Epidural glucocorticosteroid injections (ESIs) have long been used to deliver glucocorticosteroid close to the herniated disc or area of spinal stenosis.[42] The three approaches most commonly used are caudal, interlaminar, and transforaminal.[43–46] The technical performance including precise placement of these injections is reportedly related to the efficacy.[47] Interlaminar ESIs are the least technically demanding to perform and place the steroid immediately adjacent to the dural sac in the posterior spinal column. Fluoroscopic guidance improves the placement accuracy of injection, as blind targeting has been shown to be 77% accurate.[48] Transforaminal ESIs most closely target the herniated disc and neurological impingement with the least volume of agent,[43,49] but are technically more difficult and fluoroscopic or computed tomography (CT) guidance is usually used.[50] Transforaminal ESIs also necessitate better diagnostic precision to ensure proximity to the affected level.[46] As ESIs are most frequently performed as a combination of a glucocorticoid with an anesthetic, they are considered both diagnostic and therapeutic.[51]

Evidence is consistent that ESIs result in up to 6 weeks of modest improvement compared with placebo injections.[52] The combination of minimal, short-term benefits, and risks[53] has resulted in the American Academy of Neurology Guideline recommending against the routine performance of ESIs.[54] As the main alternative is surgery, this Spine Panel's opinion is that an ESI is Recommended (I), Moderate Confidence for select circumstances as an option for treatment of acute or subacute radicular pain syndromes, typically after treatment with NSAID and waiting at least 3 weeks. Its purpose is to provide a few weeks of partial pain relief while awaiting spontaneous improvement and remaining as active as practical. Effects of an injection should be assessed, and there should not be a series of injections (eg, three) ordered. Epidural glucocorticosteroid injections are Moderately Not Recommended (B), Moderate Confidence for treatment of spinal stenosis.[36] Epidural glucocorticosteroid injections are Not Recommended, Evidence (C), High Confidence for treatment of acute, subacute, or chronic low back pain in the absence of significant radicular symptoms.

INTRADISCAL STEROIDS

A total of five moderate-quality studies were included in this analysis.[55–59] Injections of glucocorticoids into the intervertebral disc, often performed under fluoroscopy or other imaging modalities, are classified as ''intradiscal steroids.''[41,60,61] These injections are theorized to help reduce the degree to which the disc is both herniated and/or producing an inflammatory response. For radicular pain and herniated discs, one study is available but it did not include a placebo group, thus there is no quality evidence regarding efficacy.[58] For chronic LBP, two moderate-quality trials suggest lack of efficacy[55,59] and one suggests efficacy.[57] Thus, there is no clear evidence that these injections improve on the natural history of acute LBP. Benefits have not been demonstrated compared with epidural injections or to no treatment. Thus, intradiscal steroid injections are Not Recommended (I), Moderate Confidence for treatment of acute LBP and are Not Recommended, (C), Moderate Confidence for treatment of subacute or chronic LBP.

KETAMINE

There are two high-quality[62,63] and three moderate-quality[64–66] studies incorporated into this analysis. Ketamine infusions do not have quality evidence of efficacy and are Not Recommended (I), High Confidence for treatment of chronic LBP.[62–66]

TABLE 1. Indications, Frequency, and Components of Psychological Evaluation in Patients With Chronic Pain

A psychological evaluation is recommended as part of the evaluation and management of patients with chronic pain in order to identify psychosocial barriers that are contributing to disability and inhibiting function and to assess whether psychological factors will need to be considered and treated as part of the overall treatment plan. Psychological evaluation should be considered for patients with moderate to severe chronic pain. Indications are:

1. Cases in which significant psychosocial dysfunction is observed or suspected.
2. The provider has need to understand psychosocial factors contributing to the patient's pain reports and disability behaviors.
3. Inadequate recovery: This includes continued dysfunctional status despite a duration which exceeds the typical course of recovery; failure to benefit from indicated therapies or to return to work when medically indicated; or a persistent pain problem which is inadequately explained by the patient's physical findings.
4. Medication issues and/or drug problems: This includes any suspicion of drug overuse or misuse, aberrant drug behavior, substance abuse, addiction, or use of illicit substance, or for consideration of chronic use of opioids.
5. Current or premorbid history of major psychiatric symptoms or disorder.
6. Problems with compliance/adherence with prescribed medical treatment or rehabilitation program: For evaluation of candidacy for or potential benefit from a proposed functional restoration program, for example, comprehensive occupational rehabilitation or interdisciplinary pain rehabilitation (see Functional Restoration).
7. Evidence of possible cognitive impairment which is associated with related significant activities of daily living (ADL) dysfunction: This may be secondary to injury and/or possible adverse effects of medical therapies initiated for the chronic pain.
8. Catastrophic injuries with significant pain related or other dysfunction, for example, spinal cord injury.[10]
9. Cases for which certain procedures are contemplated, for example, back surgery or spinal cord stimulation.

There are various known styles and components to a comprehensive psychological evaluation of a patient with chronic nonmalignant pain.[11] However, the following are the key components which should be addressed in any such evaluation.

1. Appropriate review of records: The referring provider should assist in providing medical record documentation. Other information is sometimes reviewed, as necessary, for example, from a family assessment, job description, etc.
2. Clinical interview with the patient: The following parameters should be described from this interaction and other data obtained: history (including mental health, physical health, work, educational, legal, and substance use history), description of the pain, disability and/or other clinical problem, analysis of medication usage, social history, mental status, and behavioral assessment (including, as necessary, ADL, functional issues, and operant parameters, eg, pain/illness, behavior, and environmental influences).
3. Psychologic testing: A battery of appropriate diagnostic psychological tests should be administered and interpreted, as necessary. This should include instruments with evidence of validity and/or appropriate normative data for the condition or problems being assessed and have known value in differential diagnosis or treatment planning.[12] In selecting test instruments, the clinician should consider: (1) the appropriateness of the test(s) for the patient's presenting complaints and condition; (2) the appropriateness of a test(s) given the degree to which the patient's medical, sex, race/ethnicity, age, educational, and other group status was represented during the test(s) development; (3) how a patient's performance in comparison to normative data will be useful in diagnosis or treatment planning; (4) the prognostic value of interpreted test data for certain treatments; and/or (5) whether the sensitivity and specificity will enhance the accuracy of a diagnosis (more specific test information may be found in Chronic Pain Guideline[3]). Indications for psychological test may include circumstances when:
    Understanding factors contributing to the patient's pain reports and disability behaviors;
    ● A mental disorder is suspected;
    ● Evaluating for a functional restoration program;
    ● The evaluation is part of a presurgical assessment;
    ● There is suspicion of cognitive impairment;
    ● The veracity of the complaint is at issue.

The test battery for evaluation of patients with chronic nonmalignant pain includes, but is not limited to:
1. Test(s) for assessment of the presenting pain, and/or other related health disorders or dysfunction;
2. Test(s) of personality and psychopathology;
3. Brief cognitive testing, when there is suspicion of central nervous system (CNS) impairment;
4. Diagnostic impressions: These should be inferred according to the ICD-10;
5. Summary: The psychological evaluation should provide both cogent explanations for the identified complaints and dysfunction, and recommendations for management.

More detailed descriptions of a psychological evaluation for patients with chronic pain and report format recommendations can be found elsewhere.[13] Clinical and forensic standards for psychological evaluations of patient with pain have been recently reviewed, and those should be noted.[14,15]

Standardized psychological testing should be done as a part of a comprehensive mental health evaluation. In addition, a review of appropriate records should be completed. Properly performed psychological testing enhances the reliability and value of a psychological evaluation. Psychometric testing conducted outside the context of a qualified mental health evaluation has not been evaluated in quality studies and is believed to either provide little if any helpful information for the treating provider, may be potentially misleading, and psychological test results outside settings comparable to those used for standardization may be uninterpretable. Tests used in isolation provide questionable clinically useful diagnoses or prognostic information for various procedures.[3]

CLONIDINE

There are one high-quality[67] and one moderate-quality[68] RCTs incorporated into this analysis. Clonidine is an α-agonist most typically used as an anti-hypertensive, yet as an α_2 adrenoceptor agonist, it may affect nociceptive processing,[69] and has been used to treat complex regional pain syndrome (see Chronic Pain Guideline[3]). There is evidence epidural clonidine is inferior to epidural steroid injection for radicular pain,[68] and thus, epidural clonidine is Not Recommended (C), Moderate Confidence for treatment of radicular pain. There is No Recommendation (I), Low Confidence for or against the use of epidural clonidine for treatment of chronic LBP. There is No Recommendation (I), Low Confidence for or against the use of intramuscular clonidine for treatment of pyriformis syndrome or other low back conditions.

CHEMONUCLEOLYSIS (CHYMOPAPAIN AND COLLAGENASE)

Chymopapain is an enzyme that has long been used to successfully treat herniated discs.[70–72] While collagenase has been

utilized more recently,[73] both enzymes are injected into the disc. Chymopapain is no longer available in the United States due to reimbursement problems. Caution is warranted in those increasingly limited numbers of countries that allow this procedure.[74]

TRIGGER AND TENDER POINT INJECTIONS

There is one high-quality,[75] and five moderate-quality studies[76–80] incorporated into this analysis. Trigger points involve an examiner's opinion that the degree of tenderness on palpating a muscle is abnormally great.[81] Ideally, examiners seek a palpable ''knot'' or nodule of muscle tissue with palpation both reproducing the patient's symptoms and distal radiation of symptoms, such as tingling in the extremity denoting a trigger point. However, most patients have tender points which are defined as tenderness without radiating symptoms. In common usage, the terms ''trigger'' and ''tender'' are often used interchangeably. Studies have attempted to address both findings, although research methods have not been particularly clear on distinguishing these conditions from each other. Tender and trigger points are primarily diagnosed in the periscapular area, although some may be found in the lumbosacral area. These points are integrally involved in ''myofascial pain syndrome'' and ''fibromyalgia.'' Most practitioners believe these are two distinct entities, while others believe that these are related conditions on a continuum of the same basic disorder.[81] Robust epidemiological and descriptive studies are lacking. It appears that many people are tender to palpation, thus what differentiates normal from abnormal is unclear. There are multiple weaknesses in these theories, including a lack of identification of how common these findings are in normal people, the lack of purely objective findings, subjectivity involved on the part of the examiner, and weaknesses in the pathophysiological theories.

Trigger and tender point injections into muscle ''knots'' may consist of an anesthetic with or without glucocorticoid.[81,82] The goals of injection are generally thought to involve anesthesia, anti-inflammatory medication, and allowing deep-tissue massage of the area to work out the muscle knot. There is one high-quality[75] and five[76–80] moderate-quality RCTs or crossover trials incorporated into this analysis. Trigger and/or tender point injections are Not Recommended (I), Moderate Confidence for treatment of acute LBP.[75] Trigger and/or tender point injections may be Recommended (C), Low

Confidence as a reasonable second or tertiary option for treatment of subacute or chronic LBP that is not resolving with progressive aerobic exercise, and other exercises and NSAIDs. These injections are recommended to consist either solely of a topical anesthetic (eg, bupivacaine) or dry needling without an injection. Repeated injections should be linked to subjective and objective improvements. The use of therapeutic injections without participation in an active therapy program or in the context of maintaining employment is not recommended. An alternative option to these injections is acupuncture. It is recommended to allow at least 3 to 4 weeks between injections. If results are not satisfactory after first set of injections, a second set is reasonable. If there are not subjective and objective improvements at that point, further injections are not recommended. Glucocorticosteroids are Not Recommended (C), Moderate Confidence for use in trigger point injections.[83]

DIAGNOSTIC FACET JOINT INJECTIONS (INTRAARTICULAR AND NERVE BLOCKS)

There are zero high-quality and six moderate-quality studies incorporated into this analysis.[84–89] Facet (zygapophysial) joints are prone to degenerative joint disease, particularly osteoarthrosis, and become ubiquitous with age.[90–92] These joints are also theorized by some to be pain-generating sources.[93–106] Facet joint pain prevalence estimates vary from 5% to 90%.[97] Because of the overlapping innervation of the facet joints themselves (each is served by two medial branch nerves—a given medial branch nerve innervates the caudal portion of the facet joint at its level, and the rostral portion of the next lower facet joint) there has been considerable debate regarding whether these injections are truly diagnostic of underlying pathology. Moreover, careful skin mapping shows that the area of skin served by the cervical and lumbar medial branch nerves is more cephalad (in the neck) and more lateral and caudad (in the low back) than the location of the joint itself. Thus, it is often difficult to correlate degenerative joint disease changes seen on imaging studies with the actual nerve involved.

Two types of diagnostic facet injections are performed, intra-articular and medial nerve branch block. Intra-articular injections are performed by injecting a local anesthetic under fluoroscopic or other imaging guidance directly into the facet joint. A medial nerve branch block is performed by injecting anesthetic along the nerves supplying the facet joints.[107] Either

can be used to attempt to diagnose facet syndrome, but a medial branch block has been used when rhizotomy procedures have been considered.[96,101,108] A positive block is considered to occur when there is complete, or nearly complete, relief of the pain the patient has been experiencing for the length of time expected for the anesthetic used.[109–111] Intra-articular blocks are sometimes combined with a glucocorticosteroid injection and thus, they are potentially a combined diagnostic and therapeutic intervention.[112] Nerve root blocks are often performed prior to attempts at radiofrequency lesioning.[113] The peri-procedure administration of sedatives reportedly may confound the results of facet joint pain[114] and contribute to suboptimal results. Some have suggested a small minority of patients fulfill diagnostic criteria.[87]

There are six moderate-quality RCTs incorporated into this analysis.[84,85,87–89,115] Most quality studies now suggest a lack of utility of diagnostic facet joint injections.[84,85,89] Few studies suggest diagnostic utility of facet joint injections.[86] One study of medial branch blocks reported equal value of those blocks compared with peri-capsular blocks raising some question as to the efficacy versus inefficacy of either.[88] The results of a three-arm trial comparing intra-articular injection with periarticular injection with saline injection also raises concerns about the validity of this construct,[89] although the resulting short-term improvements in all three groups could be argued to be worth the intervention in select significantly affected patients with chronic LBP thought to be facet mediated. Diagnostic facet joint injections are Not Recommended (C), Low Confidence for evaluation of patients with chronic LBP, including that which is significantly exacerbated by extension and rotation or associated with lumbar rigidity. Diagnostic facet joint injections are Not Recommended (I), Low Confidence for acute or subacute LBP or radicular pain syndromes. Diagnostic medial branch blocks are Not Recommended (C), Low Confidence for acute or subacute LBP or radicular pain syndromes.[88]

THERAPEUTIC FACET JOINT INJECTIONS

There are one high-quality[116] and 16 moderate-quality studies incorporated into this analysis.[84,85,87,89,102,117–128] Therapeutic facet joint injections involve a combination of a local anesthetic with glucocorticosteroids to attempt to relieve pain from the facet.[84,94,96,106,112,113,129–132] They may be accomplished using various techniques either as an intra-articular or as a

pericapsular injection.[88,89,133] They also have been performed to address a purported cause of segmental rigidity.[87,134]

High- and moderate-quality studies suggest lack of efficacy of therapeutic facet joint injections for treatment of chronic LBP,[89,102,118,119,135] although one study suggested modest efficacy.[116] One comparative trial found comparable (in)efficacy with radiofrequency injections which also appear ineffective (see below).[136,137] Another moderate-quality trial found comparable (in)efficacy with intramuscular compared with facet joint injections with steroids for treatment of LBP.[122]

Both the American Pain Society and NICE guidelines recommend against these injections.[138,139] These injections are invasive, have relatively low adverse effects, but are costly. Most of the quality studies available on this topic do not support these injections. If they are performed highly selectively, there should be evidence of enduring reductions of pain plus objective functional benefits along with a lack of needing to repeat the treatment other than rarely.

Therapeutic facet joint injections are Not Recommended (I), Low Confidence for treatment of chronic LBP (62% Panel agreement; 19% agreed with Recommended and 19% agreed with No Recommendation.) Indications are nevertheless provided for the potential to seek approval from a workers' compensation carrier for highly select patients with chronic LBP thought to be isolated to one or at most two facet joints, generally with increased pain with extension and axial rotation; and failure to gain sufficient relief with non-invasive treatment options including at least multiple NSAID(s), aerobic exercise, and strengthening exercise. A trial of manipulation to assess functional gain is also generally warranted before consideration of therapeutic facet joint injection(s). If there is 80% relief and objective improvement in function, yet symptoms recur, a second injection may be reasonable; however, repeated, recurrent injections are not recommended.

Therapeutic facet joint injections are Not Recommended (I), Moderate Confidence for treatment of acute, subacute LBP or for any radicular pain syndrome. Therapeutic facet joint injections are Moderately Not Recommended (B), Moderate Confidence for routine treatment of chronic non-specific axial pain. Repeat use of intra-articular therapeutic facet joint injections are Moderately Not Recommended (B), Moderate Confidence for patients who have failed to achieve lasting functional improvements with a prior injection.

FACET JOINT HYALURONIC ACID INJECTIONS

There is one moderate-quality RCT incorporated into this analysis.[140] Facet joint injections with hyaluronic acid have been attempted for treatment of facet degenerative joint disease. These injections are theoretically analogous to similar injections in the knee and other arthritic joints, although whether facet joints are pain generating sources is unclear (see above). There are no placebo- or sham-controlled trials in facet joints. Weekly injections of hyaluronic acid involving 18 injections at three levels have been studied in one moderate-quality study and appear to be largely ineffective compared with facet steroid injections that appear no more effective than placebo.[140] Thus, facet joint injections with hyaluronic acid are Not Recommended (I), Low Confidence for treatment of facet degenerative joint disease.

SACROILIAC JOINT INJECTIONS

There are zero high-quality and nine moderate-quality RCTs incorporated into this analysis.[117,141–148] The sacroiliac joints (SIJs) are believed to cause a minority of chronic LBP cases, with estimates ranging from 10% to 26.6% and have been treated with SIJ injections either with or without fluoroscopic or other imaging guidance.[106,149] The injection typically targets the most tender area with a combination of a glucocorticosteroid and a local anesthetic, resulting in both a diagnostic and therapeutic injection. However, the diagnostic precision of these injections is likely limited by factors that include the inability to inject the joint directly without fluoroscopic or other imaging, as well as, the infiltration and diffusion of medication into surrounding tissues that could be potential pain generators.[150] The use of fluoroscopically guided, CT guided, or unguided SI joint corticosteroid injections have been suggested by some to be effective for LBP and spondyloarthropathy.[151–153] Other resources have found that evidence to be limited or poor.[154–156]

There are four moderate-quality RCTs incorporated into this analysis.[117,145–147,157] SIJ corticosteroid injections are Recommended (C), Low Confidence as a treatment option for patients with a specific known cause of sacroiliitis, that is, proven rheumatologic inflammatory arthritis (eg, rheumatoid arthritis, ankylosing spondylitis) involving the SIJs with symptoms of at least 1 to 2 months and prior treatment that has included NSAIDs. Each injection should be evaluated before additional injections

are scheduled, rather than scheduling a series of injections.

Regarding non-inflammatory pain, one study reported a short-term response to glucocorticoid injection into the soft tissue above the joint.[147] In limb joints, injection outside a joint has not been demonstrated to improve pain coming from a joint, so the mechanism for this finding is unclear. The other two quality studies were of spondyloarthropathy patient populations, thus applicability to working populations is unclear. Whether fluoroscopic guidance is needed is unclear and controversial.[154] Without fluoroscopic guidance, the joint itself is usually not injected as this is a difficult joint on which to perform arthrocentesis without imaging guidance. It is not clear if actual joint injection results in appreciably higher success rates as an injection in the local proximity may be just as effective. Injection in the local proximity should perhaps be classified as a tender point injection and not a sacroiliac joint injection. There are no quality studies showing a long-term improvement in pain or function in those receiving SIJ injections for chronic non-specific LBP. SIJ injections are Not Recommended (I), Low Confidence for treatment of acute LBP including LBP thought to be SIJ related; subacute or chronic non-specific LBP, including pain attributed to the sacroiliac joints, but without evidence of inflammatory sacroiliitis (rheumatologic disease); or any radicular pain syndrome.

INTRATHECAL DRUGS

This subject has been reviewed in the Opioids Guidelines.[158] The body of quality literature does not support revising the prior guidance against use of these devices for treatment of LBP.

PROLOTHERAPY INJECTIONS

There are two high-quality[159,160] and five moderate-quality[117,161–164] studies incorporated into this analysis. Prolotherapy injections attempt to address a theoretical cause for chronic LBP.[161,165–170] It involves repeated injections of irritating, osmotic, and chemotactic agents (eg, dextrose, glucose, glycerin, zinc sulphate, phenol, guaiacol, tannic acid, pumice flour, sodium morrhuate), combined with an injectable anesthetic agent to reduce pain, into back structures, especially ligaments, with the theoretical construct that they will strengthen these tissues.[171,172] There are two high-quality[159,160] and five moderate-quality[117,161–164] RCTs incorporated into this analysis; the highest quality studies in this considerably heterogeneous literature failed to show benefits.[159–162] Thus, prolotherapy injections are Strongly Not

Recommended (A), High Confidence for treatment of acute, subacute, or chronic LBP or radicular pain syndromes.

BOTULINUM INJECTIONS

There are two high-quality[173,174] and two moderate-quality[175,176] studies incorporated into this analysis. Botulinum injections have been used to produce muscle paresis and have anti-nociceptive properties.[177] Adherents beliefs include that this ''rest through weakness'' is useful as a treatment for a number of musculoskeletal disorders including LBP,[178,179] upper back pain, myofascial pain,[160,180,181] LBP,[179,182–184] and piriformis syndrome.[173,175,178,185] There are two high-[173,174] and two moderate-quality[106,175,176,186–188] RCTs incorporated into this analysis.[185,189] Two high-quality studies directly conflict, with one suggesting benefits[174] while the other suggesting no benefits.[173] One moderate-quality trial suggested benefits.[175] Thus, the quality data conflict and there are no sizable quality studies with long-term follow-up. It is concerning that these injections induce weakness, yet many of the most successful interventions identified in systematic reviews in other sections of this guideline build strength and/or endurance. Botulinum injections are invasive, have adverse effects that include fatalities,[174] are costly and with conflicting data, there is thus No Recommendation (I), Low Confidence for or against the use of botulinum injections for treatment of acute, subacute, or chronic LBP or radicular pain syndromes or other low back-related problems.

RADIOFREQUENCY NEUROTOMY, NEUROTOMY, AND FACET RHIZOTOMY

There are four high-quality[190–193] and 23 moderate-quality studies incorporated into this analysis.[88,102,136,137,194–212] Facet joints are thought by some to be the source of pain for some patients with chronic LBP.[203,213–217] Patients who experience pain relief from the injection of anesthetic along the nerve roots innervating the joints (''diagnostic blocks'') have been considered candidates for various neurotomy procedures.[218] However, many patients thought to be candidates for the procedure do not have successful blocks (43.5%[219] to 54.3%).[192] Surgical neurotomy involves the transecting or cutting of the nerves supplying the facet joints. Radiofrequency neurotomy has largely replaced the surgical procedure and involves the use of a radiofrequency electrode to create a heat lesion to coagulate the nerve supplying the joint. If the theory is correct and the patient is correctly

diagnosed, the procedure will result in complete relief of LBP. If there are other sources of pain that have other nerves for conduction of pain impulses or the radiofrequency lesion does not encompass the nerve due to either anatomic variants or technical errors, the procedure is thought to be less successful or not at all successful.[95,220]

The theoretical basis of cutting or ablating nerve fibers seems sound as procedures that eliminate the pathway to conduct pain sensations should be effective for the treatment of chronic pain syndromes. However, the history of cutting or otherwise ablating nerves to treat numerous pain conditions throughout the body is suboptimal, with a not infrequent increased risk for developing additional chronic pain problems that were only widely recognized after long-term follow-up studies were reported.[221] There have been many attempts at this type of procedure over several decades. However, perhaps due to pain fiber regeneration, alternate pathways for conduction, phantom pain, ongoing neurological stimulation, and/or conduction from the transected or ablated nerve fibers, no procedure to date has been shown to be effective for the treatment of pain that involves cutting or ablating nerve fibers.

The highest quality, sham-controlled studies are largely negative.[190,192] A moderate-quality study of radiofrequency added to steroid injection also found nearly all measures were negative between groups.[195] The largest sized trial found neurotomy ineffective compared with an exercise program for treatment of LBP, SI joint pain or intervertebral disc pain.[207] The next lower quality study is more favorable, but used unconventional statistical testing with 90% confidence intervals, rendering it unusable,[194] and the next study suffered an apparent randomization failure.[198] Two comparative trials found comparable (in)efficacy with intraarticular glucocorticoid injections which also appear ineffective, which suggests the procedure may have no significant benefit (see above).[136,137] The lowest quality study had worrisome results in the placebo.[199] There is a poor correlation between pain relief from a block and relief from radiofrequency neurotomy.[142] Available systematic reviews also discuss additional significant methodological concerns.[222] These concerns further limit the robustness of conclusions. As results are permanent, there should be good evidence of long-term benefit prior to recommending this procedure. Permanently denervated joints in the appendicular skeleton are known as Charcot joints, and over long-term follow-up they do not do well. There are no long-term results reported for those potential adverse effects. All studies suggested the need for further research.

Radiofrequency neurotomy, neurotomy, or facet rhizotomy are Not Recommended (C), Low Confidence for treatment of patients with chronic LBP including that confirmed with diagnostic blocks[190,192,195,207] (64% panel agreement, while 36% agreed with limited indications). Indications are nevertheless provided as a potential appeals process for workers' compensation carriers: chronic LBP without radiculopathy with failure of conservative treatments including NSAIDs and a quality exercise program, and who have had a confirmed diagnosis by medial branch blocks.[223] There is no recommendation for repeated procedures. It is reasonable to attempt a second lesion after 26 weeks in patients who had greater than 80% improvement in pain from first procedure for the first 8 weeks with a late return of pain.[224] There is no recommendation for a third or for additional procedures. There is logically a limit as to how many times it is possible to permanently destroy the same nerve. Radiofrequency neurotomy, neurotomy, or facet rhizotomy are Not Recommended (C), Low Confidence for treatment of all other lumbar spinal conditions.

DORSAL ROOT GANGLIA RADIOFREQUENCY LESIONING

There is one high-quality RCT incorporated into this analysis.[225] Radiofrequency lesioning of the dorsal root ganglia has been attempted for treatment of chronic sciatica and some other pain syndromes.[213,216,226] There is one high-quality RCT incorporated into this analysis and suggests lack of efficacy.[225] Thus, radiofrequency lesioning of the dorsal root ganglia is Moderately Not Recommended (B), Moderate Confidence for treatment of chronic sciatica.

INTRADISCAL ELECTROTHERMAL THERAPY (IDET)

There are two high-quality studies incorporated into this analysis.[227,228] Intradiscal electrothermal therapy (IDET) involves the heating of an intradiscal probe through electrical current. The goal is to coagulate tissue and theoretically result in improvement in pain thought to be derived from the disc or surrounding structures.[229–231] There are two high-quality RCTs incorporated into this analysis[227,228] that conflict regarding whether IDET has any value in treating chronic LBP. It is unclear whether heterogeneity of patients' clinical findings may in part explain these differences. Another problem is the reliance on discography as the primary diagnostic

requirement for IDET, as it has low diagnostic value.[4,232] As IDET has not been clearly shown to be beneficial, there is not adequate evidence to recommend IDET and it is Not Recommended (I), Low Confidence for treatment of acute, subacute, or chronic LBP or any other back-related disorder.

PERCUTANEOUS INTRADISCAL RADIOFREQUENCY THERMOCOAGULATION (PIRFT)

There are one high-quality[233] and two moderate-quality[234,235] studies incorporated into this analysis. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) involves the same principle as that of IDET.[233,235,236] However, the heating of an intradiscal probe is through radiofrequency instead of electrical current. There is one high-[233] and two moderate-quality[234,235] RCTs incorporated into this analysis. There is no evidence of efficacy in two quality studies, including one high-quality study.[233,234] Thus, PIRFT is Moderately Not Recommended (B), Moderate Confidence for treatment of acute, subacute, or chronic LBP particularly including discogenic LBP.

SURGICAL CONSIDERATIONS

This guideline addresses only the non-emergent surgical treatment of the most common acute, subacute, and chronic back problems. This guideline discusses recognition of red flag conditions that require expedited referral to a surgeon qualified to deal with spine emergencies (see Red Flags[4,232]). The indications for emergent surgery for red flag conditions are outside the scope of this guideline, including spinal cord compereession, cauda equina syndrome, unstable fractures, epidural abscess, or hematoma, as are other indications for surgery (eg, neoplasms).

Within the first 3 months after onset of acute low back symptoms, surgery is considered only for serious spinal pathology or nerve root compression not responsive to an adequate trial of conservative therapy. Disc herniation may impinge on a nerve root typically causing mostly lower extremity and sometimes lumbosacral symptoms accompanied by nerve root dysfunction. However, the presence of a herniated disc on an imaging study does not necessarily imply nerve root dysfunction. Studies of asymptomatic adults commonly demonstrate intervertebral disc herniations that apparently do not cause symptoms.[237–260] Some studies show spontaneous disc resorption without surgery. Many patients with strong clinical findings of nerve root

compression due to disc herniation and/or spinal stenosis recover activity tolerance within 1 month. There is no quality evidence that delaying surgery for this period worsens outcomes in the absence of progressive nerve root compromise.[261] With or without surgery, more than 70% of patients with apparent surgical indications eventually recover to their premorbid activity level, including those with severe initial presenting signs of neurological compromise.[262,263] Spine surgery for patients with clear indications appears to speed short- to mid-term recovery. However, surgery results in pain improvements in fewer than 40% of patients with questionable physiologic findings, which is the rate of response of pain to placebo surgery.[264,265] Surgery generally increases the risk for future spine procedures with higher complication rates especially associated with more invasive procedures such as fusion.[266–269] Yet, reoperation rates are reportedy lower after fusion compared with decompressive surgery for spinal spondylolisthesis.[268] In older patients and repeat procedures, the rate of complications is higher.[270,271] Patients with comorbid conditions such as cardiac or respiratory disease, diabetes, or mental illness, may be poor candidates for surgery. Comorbidity should be weighed and discussed carefully with the patient.

If surgery is a consideration, counseling regarding likely outcomes, risks, and benefits and especially expectations is important. Patients with acute LBP alone (in the absence of objective findings of radiculopathy), without findings of serious spinal pathology (such as tumor, fracture, infection, hematoma), rarely benefit from surgery, although a second opinion from a spine surgeon to the effect that surgery is not recommended and is unlikely to be helpful may be reassuring to the patient.

Before surgery, physicians may consider referral for psychological screening to improve surgical outcomes, possibly including standard tests such as the second edition of the Minnesota Multiphasic Personality Inventory (MMPI-2).[272] In addition, physicians may seek non-organic signs (eg, Waddell) during the physical examination as these have been shown to correlate with poorer surgical outcome.

Nerve root decompression is performed for symptomatic nerve root compression by disc herniation and/or spinal stenosis. Direct methods of nerve root decompression include standard open discectomy, laminotomy, foraminotomy, facetectomy, and laminectomy. The only indirect method of nerve root decompression shown to be potentially effective is chemonucleolysis with chymopapain.

Endoscopic removal of a herniated disc fragment, while performed percutaneously, is a similar operation to standard open discectomy and is considered below. Standard open discectomy can be done with or without the use of an operating microscope or loop magnification and with or without endoscopic "tubes" to minimize the size of the skin incision and muscle dissection.

DISCECTOMY, MICRODISCECTOMY, SEQUESTRECTOMY, ENDOSCOPIC DECOMPRESSION

There are three high-quality and 31 moderate-quality studies incorporated into this analysis.[16,72,261,273–302] There are multiple surgical techniques that have been used to surgically relieve pressure on lumbosacral nerve roots causing radicular pain syndromes.[285,303–306] Techniques attempted include open discectomy (with or without microscope),[307–312] automated percutaneous discectomy,[313–315] epidural percutaneous discectomy,[316] sequestrectomy, and endoscopic procedures.[317–321] More recent techniques include percutaneous laser disc decompression,[322] automated percutaneous discectomies (also known as nucleoplasty),[323,324] disc coblation, and endoscopic approaches.[325] The same surgical approaches are also sometimes used to address less common spinal pathology (eg, facet joint arthropathy with consequent nerve root impingement). This section reviews the indications for discectomy for a herniated lumbar disc.

There are no sham-controlled discectomy trials. All moderate-quality comparative trials demonstrate short- to intermediate-benefits, but not long-term benefits from nerve root decompression surgery compared with nonoperative treatment for patients with radicular symptoms from disc herniation unresponsive to prior nonoperative treatment.[16,261,273,274] However, as up to 75% of patients with radicular symptoms from herniated discs may become minimally symptomatic or asymptomatic without surgery,[16,261,273,274,326] sufficient time should pass prior to considering surgery.

As there is consistent, moderate-quality evidence that lumbar discectomy is an effective operation to speed recovery in patients with radiculopathy due to ongoing nerve root compression who have not improved significantly after 4 to 6 weeks of time and appropriate conservative therapy, it is thus Moderately Recommended (B), High Confidence. Quality literature is insufficient on the comparative values of open discectomy, microdiscectomy, or

endoscopic discectomy. As open discectomy, microdiscectomy, and endoscopic discectomy are all potentially appropriate ways to perform discectomy, the decision as to which of these procedures to choose should be left to the surgeon and the patient until quality evidence becomes available to provide evidence-based guidance. Indications for discectomy are all of: (1) radicular pain syndrome with current dermatomal pain and/or numbness, or myotomal muscle weakness all consistent with a herniated disc; (2) imaging findings by MRI, or CT with or without myelography that confirm persisting nerve root compression at the level and on the side predicted by the history and clinical examination; and (3) continued significant pain and functional limitation after 4 to 6 weeks of time and appropriate nonoperative therapy that usually includes NSAID(s). Progressive neurological deficits are considered a separate indication for urgent surgery.

For patients who are candidates for discectomy (other than for cauda equina syndrome and the rare progressive major neurologic deficit), there is evidence that there is no need to rush patients into surgery as there is consistent evidence of a lack of differences in long-term functional recovery whether the surgery is performed early or delayed.[16,261,273,274] Other procedures such as laser discectomy and/or PERC involve indirect procedures with limited access to the disc contents.

Discectomy is Not Recommended (B), High Confidence for treatment of acute, subacute, or chronic LBP without radiculopathy. There is no quality evidence that automated percutaneous discectomy, laser discectomy, or coblation therapy are effective treatments for any back or radicular pain problem, and thus they are Not Recommended (I), Low Confidence.

ADHESIOLYSIS

There is one high-quality[327] and four moderate-quality[328–331] studies incorporated into this analysis. Epidural adhesiolysis attempts to use hypertonic saline and glucocorticoids with a catheter and/or endoscopy to address adhesions that particularly develop after surgery and are proposed by some to be related to postoperative pain and failed back surgery syndrome.[332,333] Epidural adhesiolysis is also known as percutaneouslysis of epidural adhesions, epidural neurolysis, epidural decompressive neuroplasty, and Racz neurolysis.[334–338] There is one high-quality[327] and four moderate-quality[328–331] RCTs incorporated into this analysis.[339] There are no sham-controlled trials. All studies comparing different adhesiolysis techniques were conducted by the same research group. The only other trial was an unblinded comparison of adhesiolysis with physiotherapy.[329] Complications include dural puncture, spinal cord compression, infection, catheter shearing, hematoma, cardiac dysrhythmias, myelopathy, paralysis, and blindness.[328,336,339–342] Independent, large-scales replication of the suggested modest benefits is needed before a recommendation may be made, and thus adhesiolysis is Not Recommended (I), Low Confidence for treatment of acute, subacute, or chronic LBP, or spinal stenosis or radicular pain syndromes.

DECOMPRESSIVE SURGERY FOR SPINAL STENOSIS (LAMINOTOMY/ FACETECTOMY, LAMINECTOMY)

There are three high-quality and 22 moderate-quality studies incorporated into this analysis.[343–366] Spinal stenosis involves insufficient room for neural elements in the spinal canal and/or neural foramina, whether it is congenital (eg, short pedicles, narrow canal diameter), acquired (degenerative enlargement of facets and ligaments and in addition the formation of osteophytes), or both. Stenosis can be in the central canal, in the lateral recess, or in the neural foramen. These degenerative changes are referred to as lumbar spondylosis. The typical symptom of lumbar spinal stenosis is neurogenic claudication, or leg pain that develops during walking and that is promptly relieved by rest. Standing may exacerbate the pain. Acquired lumbar spondylosis is a natural aging phenomenon with a strong genetic component that may become symptomatic.

Decompressive surgery for spinal stenosis involves various techniques that remove bone from one or more structures to expand a narrowed spinal canal/neural foramen that impinges on neural structures.[367–378] Laminotomy is removal of a portion of the lamina, usually to permit access to the central spinal canal to gain access to another structure such as a herniated disc or a neural foramen. Laminectomy refers to the complete removal of the lamina. It was traditionally performed as part of a discectomy, but is not performed any longer for that sole indication. Hemilaminectomy refers to removal of the left half or the right half of the lamina.[379,380] Facetectomy is removal of part or all of a facet joint. Posterior decompression is a term usually used to include any of the above surgeries for spinal stenosis. Fusion is sometimes recommended at the same time as a spinal stenosis decompression (see below for fusion indications).[381] These procedures are commonly performed in settings of either central canal stenosis, lateral recess, or neuroforaminal stenosis.

The highest of the moderate-quality trials reported comparable results from physical therapy (PT) consisting of flexion exercises plus aerobic exercises versus decompressive surgery over 2 years,[344] although it is noteworthy that 57% of the PT group crossed over to surgery. One trial found no significant differences between a decompressive device and epidural steroid injection.[37] One moderate-quality trial comparing decompressive surgery with nonoperative management found superiority of decompression surgery for patients with symptomatic spinal stenosis (neurogenic claudication) that is intractable despite conservative management.[343,346] There is no quality evidence of benefit to adding lumbar fusion to decompression.[354] Fusion has no role in the surgical treatment of spinal stenosis, rather the role of fusion is to treat instability if proven to be present (see Fusion below).

Decompression surgery is thus Moderately Recommended (B), Moderate Confidence for treatment of patients with symptomatic spinal stenosis (neurogenic claudication) that is intractable to nonoperative management. Caution is warranted among elderly with multiple comorbidities.[382] Indications are all of: (1) radicular-type pain involving usually multiple dermatomes with pain and/or numbness, or myotomal muscle weakness all consistent with the nerve root levels affected; (2) imaging findings by MRI, or CT with or without myelography that confirm spinal stenosis and corroborate the dermatomal and myotomal findings predicted by the history and clinical examination; and (3) continued significant pain and functional limitation after at least 4 to 6 weeks of time and appropriate nonoperative therapy that usually includes flexion exercises plus aerobic exercise (walking or cycling),[344] and NSAIDs. Progressive neurological deficits are considered a separate indication for earlier surgery.

SPINAL FUSION

There are one high-quality and 77 moderate-quality studies included in this analysis.[128,280,290,347,383–451] Lumbar fusion involves the surgical fusion of one or more vertebral segments by inserting bone grafts (with or without instrumentation) so that the previously mobile involved segment(s) heal together to form a single bone mass. The proposed goal of lumbar fusion is similar to that in fusing other joints in the body—that instability and pain will be significantly improved, if not resolved through preventing joint movement.[452–486]

The United States has the highest rate of lumbar fusion surgery in the world (twice that of Norway, 5-fold that of England). There has been a 55% increase in spine surgery rates in the 1980s, a 6-fold variation in spine surgery rates among US cities, and 10-fold variation in spine fusion rates[487] without evidence of beneficial outcomes. Compared with matched non-surgical controls, patients on workers' compensation reportedly have worse outcomes with over 5.5-fold greater permanent disability status, greater opioid use, greater than 3.6-fold days of work lost and 26% of surgical patients underwent a second surgery.[456] Risks of increased opioids use among those with prior use and 13% without preoperative use becoming chronic users after fusion surgery suggest risks are considerable.[488] Following lumbar fusion, reoperation rates within 2 years have been estimated to range from 5.4% to 22% in the recent well-designed RCTs.[387,439] A 1990s population-based study found the reoperation rate following lumbar fusion was 17% to 21% when assessed at 11-year follow-up.[489] There appears to be an increased risk of reoperation if the initial diagnosis is herniated disc, degenerative disc disease, or spinal stenosis. Patients subjected to more invasive procedures have increased blood loss, longer operative times, and/or poorer outcomes in all higher quality studies where such data have been reported.[385,387,402,407,414,437,490,491] Overall, reported complication rates range from 1.4% to 40% (excluding scoliosis).[387,395,490,492]

The terms "degenerative disc disease," "discogenic back pain," "black disc disease," "micro instability," and "lumbar spondylosis" are used interchangeably to describe the same group of patients with chronic LBP in whom the pain generating structure is not defined. Discography has been used to attempt to define the lower back disc structures as the pain source, but has been largely unsuccessful in so doing.[4,232] Chronic back pain theorized to arise from degeneration of the discs is complex and can be difficult to treat. Current surgical treatments are controversial. Since there is no reliable method to identify the source of a patient's pain, surgery for pain would presumably be unlikely to be helpful. Nevertheless, there have been attempts to test this theory.

There are numerous methodological issues affecting the quality of the literature on this subject and these methodological issues impair the ability to draw robust evidence-based conclusions. For example, chronic LBP patients can be extremely difficult to manage, particularly when the pain is severe, narcotics, and other drug issues are present, adherence to exercise regimens is weak, psychosocial stressors are present, and coping skills are poor.[493] Patients without indications often come to view these surgical procedures as potential cures. These difficulties have been widely noted,[452,458,483,492,494-498] and these quality problems in the underlying original research are underscored by the sharply differing conclusions in the systematic reviews. Many of these conflicts likely originate from the problem that case series tend to show benefits while subsequent RCTs may or may not support the original impressions from the uncontrolled or less well designed studies. Although there are no quality studies, there are some diagnoses for which fusion is either non-controversial or less controversial, including unstable vertebral fractures or where surgery is being done for tumor, infection (osteomyelitis and/or discitis), or other disease processes that have led to spinal motion segment instability. There are many trials showing equivalent outcomes in nonoperatively managed, neurologically-intact patients with thoracolumbar burst fractures compared with various surgeries.[349,499-501] Treatment of those conditions is outside the scope of these guidelines.

There is controversy in the medical literature about the definition of proven spinal instability. The Evidence-based Practice Spine Panel recognizes the controversy[502] and recommends the following definition be used with flexion-extension bending films done standing with a 72 in. tube to film distance: these films should be taken digitally, and a CD with the films and the software to permit viewing and computer measurement of the translation distance should be retained and kept available for review. The first criterion is more than or equal to 5 mm of translation of the superior vertebral body on the inferior body from the full extension film to the full flexion films. The other criterion is having a total angular movement during flexion and extension at the unstable level that is at least 20° greater than the motion present at an adjacent disc.

For isthmic spondylolisthesis, there is one moderate-quality trial comparing fusion with nonoperative care that reported benefits of surgery.[394] The literature available pertains to lumbar fusion for treatment of Grade 1 and Grade 2 spondylolisthesis. There is no quality evidence on Grade 3, Grade 4, and Grade 5 spondylolisthesis, but these are rare conditions, and when nerve roots are compromised, fusion is indicated. Regarding isthmic spondylolisthesis, lumbar fusion is thus Recommended (C), Moderate Confidence.[394] Indications are: LBP with documented instability, with either: (1) more than or equal to 5 mm of translation of the superior vertebral body on the inferior body from the full extension film to the full flexion films; and/or (2) a total angular movement during flexion and extension at the unstable level that is at least 20° greater than the motion present at an adjacent disc. Lumbar fusion is also indicated for grades 3, 4, and 5 spondylolisthesis; (2) a decompressive laminectomy at an area of degenerative instability as in the case of a coexisting spondylolisthesis or scoliosis when a discectomy is performed at the same level; (3) a decompressive laminectomy performed at an area of degenerative instability, as in the case of a coexisting spondylolisthesis or scoliosis where there is gross movement on flexion-extension radiographs; and (4) a decompressive laminectomy at an area of degenerative instability as in the case of a coexisting spondylolisthesis or scoliosis where an adequate decompression requires the removal of greater than 50% of both facets or the complete removal of a unilateral facet complex.[503]

Regarding degenerative spondylolisthesis, there is one moderate-quality trial comparing fusion with nonoperative care. This trial reported negative results. However, the trial reported approximately 40% crossovers and so it may have inadvertently negated the value of the trial as there were no differences in the intention to treat analysis, but better outcomes for fusion in the "as treated" analysis.[395] One comparative trial of spinal fusion with spinal fusion plus decompressive surgery for treatment of adult spondylolisthesis found no additive benefits of the decompressive surgery.[396] Another trial of unilateral compared with bilateral fusion found no significant differences.[398] Thus, the highest quality evidence suggests there may be a beneficial effect of fusion surgery for treatment of isthmic spondylolisthesis and it is also believed to be true for degenerative spondylolisthesis and thus it is recommended (see indications above).

There are three moderate-quality comparative trials of fusion versus rehabilitation programs for treatment of chronic LBP and two suggest fusion is inferior to rehabilitation.[383-385,387-390,392,490,504,505] The third study reported surgical fusion improved upon standard conservative care[385,389]; however, the wait-listed control group's treatment consisted of "more of the same" that previously failed,[506] while anticipating surgery and thus using a biased design. In addition, Fritzell's patients were highly selected (each surgeon did on average two fusions for chronic back pain each year). They had a lower incidence of depressive symptoms than is seen in typical chronic LBP populations. Benefits from fusion were on average small (on average 30% improvement), and about one in six

patients became pain free. The study was not blinded and improvement in outcomes from fusion over nonoperative treatment decreased over time.[488] These studies demonstrate that if there is a benefit from fusion, it is not much.[383,390,392] A meta-analysis of RCTs found that at an average 11 years after surgery/randomization, there is no demonstrable benefit for fusion surgery among these patients and there was more adjacent segment disease among those undergoing fusion surgery although it was not clinically significant.[505,507–511] In a pooled study, the surgical group incurred reoperations (23%), worse disability (53% vs 32% disability pensions) and greater fear avoidant beliefs.[391] There are no published RCTs of lumbar fusion in a US workers' compensation population. There are four retrospective cohort studies in workers' compensation systems, and these show the results of fusion are significantly worse than in a non-workers' compensation population.[456,512–514] In summary, there is not quality evidence to support fusion for chronic non-specific LBP in any population, while there is evidence of considerably worse outcomes among workers. Thus, lumbar fusion is Moderately Not Recommended (B), Moderate Confidence as a treatment for chronic non-specific LBP.[383,384,390,392,504,505]

There are no quality trials of fusion in patients with radiculopathy from disc herniation. Without other indications for more extensive surgery, far less invasive surgical options (eg, nonoperative management, discectomy, etc) are available. Thus, lumbar fusion is Not Recommended (I), Moderate Confidence to treat radiculopathy from disc herniation or for most patients with chronic LBP after lumbar discectomy. Exceptions are rare but include large foraminal herniations with need to remove the facet joint to access the disc.

There are no quality trials of patients treated with spinal fusion while undergoing a third discectomy on the same disc. If there is a second herniation of the same disc, repeat discectomy results in comparable outcomes and is recommended.[515–518] However, among those having undergone two prior discectomies, it is believed to be a reasonable option to attempt fusion to avoid the theoretical need for a fourth discectomy and thus, spinal fusion is Recommended (I), Low Confidence as an option at the time of discectomy if a patient is having the third lumbar discectomy on the same disc.

Decompressive surgery (see above), is a less extensive surgical approach that resolves spinal stenosis without concomitant instability or deformity. One moderate-quality trial reported no advantage of fusion over decompression for foraminal stenosis.[399] In the absence of proven instability

or deformity, lumbar fusion is Not Recommended (C), Moderate Confidence for treatment of spinal stenosis.[343,346]

DISC REPLACEMENT

There are zero high-quality and 16 moderate-quality studies included in this analysis.[128,290,301,302,434,438–440,519–524] Artificial disc replacement was devised as an alternative to fusion for the patient with chronic non-specific LBP thought to be disc-related[480,525–528] as well as for focal lumbar stenosis.[529] Its theoretical advantage is that it preserves motion in the involved vertebral segment thus purportedly decreasing the chances of degenerative changes developing at the adjacent motion segments. The term "adjacent segment disease" is used to describe patients with degenerative changes (that are presumed to be painful) at the spinal level above or below a spinal motion segment that has been treated, for example, by spinal fusion. Currently, two manufacturers have FDA approval to sell disc replacement prostheses, CHARITÉ® and ProDisc.[530]

There is one moderate-quality trial comparing disc replacement with only ~2 weeks of a rehabilitation program, showing some evidence of superiority over 2 years based on Oswestry Disability Index (ODI) scores. However, the study reported worse adjacent segment disease and facet degeneration in the surgical arm[519–521] and no significant advantage in range of motion.[302] The rehabilitation was so short that it may likely be susceptible to both undertreatment and attention biases. A few comparative RCTs suggest potential superiority of disc replacement to fusion over short to intermediate terms.[128,438–440,522–524] Results from trials are not generalizable to those with multi-level degenerative disc disease. One trial has now been reported to 5 years of follow up, suggesting superiority over fusion,[128] but no longer-term quality studies have been reported.

Available RCTs compare disc replacement to fusion[128,524,531] and as noted in the fusion section of this Guideline, fusion has not been shown to improve the outcomes over modern nonoperative care. The follow-up in the published RCTs is now up to 5 years. Some may consider this too short to be considered standard treatment for a permanent appliance. There is evidence that higher volume surgical centers have shorter hospital stays and lower complication rates.[532] Complication rates are not inconsiderable and include 2.8 adverse events per patient, 5% device failures, 5% neurological deteriorations at 24 months compared with baseline, and 33.3% failure to have at least a 25% decrease in the ODI at 24 months compared

with baseline. Additional research including demonstrated long-term safety and efficacy is needed prior to a recommendation in support. Thus, artificial disc replacement is Not Recommended, Insufficient Evidence (I) for treatment of chronic non-specific LBP and any other spinal pain syndrome. There is also No Recommendation (I), Low Confidence regarding artificial disc replacement as a treatment for subacute or chronic radiculopathy or myelopathy.

VERTEBROPLASTY

There are four high-quality and 13 moderate-quality studies incorporated into this analysis.[533–548] Vertebroplasty involves an injection of polymethylmethacrylate within the vertebral body, in order to stabilize vertebral fractures caused by osteoporosis,[549–556] vertebral osteonecrosis, or malignancies of the spinal column.[557–565] This procedure is most common among elderly osteoporotic patients who have delayed healing of compression fractures of the vertebral body(ies),[566] but it is sometimes performed on younger patients with acute vertebral fractures due to osteoporosis.

There are multiple high-quality, sham-controlled RCTs that evaluated the efficacy of vertebroplasty and failed to find significant improvements in the patients who underwent vertebroplasty compared with a sham procedure.[492,533,534,536] These results are in contrast with two moderate-quality RCTs,[537,539] and other low-quality studies that had reported pain relief and other functional improvements that had appeared promising.[562,567–575] There is one other quality trial which reported pain relief and increased mobility. However, that trial is of lower quality, was short term (2 weeks), and had a substantially lower sample size than both of the high-quality RCTs, and appears biased against pain treatment.[538] In addition, substantial complications occur with this procedure including deaths[536,562,576,577] and subsequent fractures.[578,579] Thus, vertebroplasty is Strongly Not Recommended (A) [Subacute, Chronic], High Confidence; Not Recommended (C) [Acute], Moderate Confidence as a routine treatment for patients with low back or thoracic pain due to vertebral compression fractures.[533,536]

It remains unclear whether there are highly selected unusual patients—such as severely affected patients, patients with three or more simultaneous compression fractures, or patients with pathologic fractures due to neoplasms[580]—who were outside the scope of these two quality trials, who might still derive benefit from this procedure. Thus, there is No Recommendation (I), Low Confidence for or against

the use of vertebroplasty for treatment of highly select patients with low back or thoracic pain due to unusual vertebral compression fractures, that is, for highly select patients with severe pain lasting over 2 months who have failed other interventions (including quality medical management) and for whom there are no other options available, whose significant pain is not resolving, pathological fractures due to neoplasias, multiple simultaneous compression fractures (three or more), and especially for those having failed bisphosphonate therapy.

KYPHOPLASTY

There are one high-quality and 14 moderate-quality studies incorporated into this analysis.[219,581–594] Kyphoplasty has been used similarly to vertebroplasty to restore vertebral body height and improve sagittal alignment of the spine.[560,576,595–605] It involves injection of polymethylmethacrylate within a cavity in the vertebral body that has been created by the percutaneous insertion of a balloon through the involved pedicle(s).[582] It has been suggested that kyphoplasty may be appropriate as a prophylactic procedure.[606]

There are no quality studies comparing kyphoplasty with a sham procedure. There is one moderate-quality study comparing kyphoplasty with an unstructured, unblinded, non-interventional control that included cancer patients.[584] This study also differentially utilized passive treatments between the two groups, such as bed rest and braces that may have confounded the results. There are comparative clinical trials and other low-quality studies suggesting benefit.[597,607,608] These have been compiled into meta-analyses with a conclusion of efficacy (as well as efficacy of vertebroplasty).[609–611] Yet, as kyphoplasty is similar to vertebroplasty, and two high-quality, sham-controlled trials for vertebroplasty show a lack of benefit,[533,536] and despite the Wardlaw study which included patients with neoplasia, it appears reasonable to assume the same lack of benefit will eventually be shown for kyphoplasty for treatment of non-cancer patients. It remains unclear whether there are highly selected, unusual patients such as those severely affected, patients with three or more simultaneous compression fractures, or patients with pathologic fractures due to neoplasms,[580] who may derive benefit from this procedure. Kyphoplasty has also been found to be associated with subsequent, adjacent vertebral compression fractures.[578,579,591,612–617] Thus, there is No Recommendation (I), Low Confidence for or against the use of kyphoplasty for the treatment of low back or thoracic pain due

to vertebral compression fractures. Potential indications for unusual clinical scenarios are the same as those for vertebroplasty above.

SACROILIAC SURGERY

There are zero high-quality and nine moderate-quality studies incorporated into this analysis.[143,144,148,618–621] Two trials with several reports compare SI joint fusion surgery with nonoperative management.[143,144,618,620] Both trials excluded patients with workers' compensation.[144] Patients included in the larger US-based study had either SI joint disruption or degenerative SI joints,[618] but only had degenerative disease in the European study.[620] Neither of the two trials included a control arm consisting of a functional restoration program with progressive aerobic and strengthening exercises combined with cognitive behavioral therapy (CBT) or sham-control.[383,390,391] Yet, in treatment of LBP, the analogous procedure of lumbar fusion has been shown to be ineffective compared with a quality rehabilitation program (see Lumbar Fusion section above). There also are SI joint fusion case series.[619] Prior studies of SI joint fusion reported relatively poor results (one study found that 18% of patients operated on were "satisfied" and 65% required additional surgery)[622] but used different techniques than the more recent studies. Other surgical series have reported better results with unpublished results as high as 90% good or excellent.[623–625] Thus, as there are no quality trials comparing SI joint fusion with a quality rehabilitative program, sacroiliac joint fusion surgery and other sacroiliac joint surgical procedures are Not Recommended (I), Low Confidence for treatment of any LBP disorder. SI fusion is a reasonable option for treatment of severe pelvic fractures with or without instability.[626] There may be limited uses for posttraumatic, unstable SI joints that requires further definition in quality studies.

IMPLANTABLE SPINAL CORD STIMULATORS

There are zero high-quality and seven moderate-quality studies incorporated into this analysis.[627–633] Spinal cord stimulators (SCSs) deliver electrical impulses to the spinal cord area through electrodes that are implanted by laminotomy or percutaneously.[634–637] Proponents believe that this device is successful via the gate-control theory in which stimulating nerve fibers closes other paths of pain conduction[638]; however, this mechanism is poorly understood.[639]

There are few quality studies evaluating SCS for the treatment of LBP, none of

which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or a sham procedure.[628,631] Problems with study design have been noted for many years,[640,641] but to date have not been addressed in quality studies.

One moderate-quality study showed reduced pain ratings by 6 and 12 months after implantation, but improvements diminished over time.[628] A more recent RCT found better efficacy with high-frequency stimulation than with traditional SCS, but had no sham- or functional restoration-controlled arm, similar to the weaknesses of prior studies.[197] A non-RCT of 40 patients with chronic LBP with intractable leg pain attempted to determine whether operating when the patient was awake and able to provide feedback would improve outcomes[642]; however, there appeared to be a lack of lasting benefit (Fig. 1).

Reports with workers' compensation patients include a controlled, 2-year cohort study of workers' compensation patients in Washington State which found a low success rate, lack of long-term benefits, and increased opioid use among those receiving stimulators.[640] Cost effectiveness was also not shown in Washington State,[643] resulting in a decision to not cover the procedure for workers' compensation patients.[640]

Spinal cord stimulators are costly,[629*] invasive, have reported serious complications (including surgical procedures for loose leads, repairs, and surgical removal of the devices), and have a significant revision rate.[644,645] Without quality evidence of enduring efficacy compared with either sham-control or a quality functional restoration program, they are Not Recommended (I), Low Confidence for treatment of acute, subacute, chronic low back pain, radicular pain syndromes or failed back surgery syndrome. Potential indications are provided in Table 1 in the event that there is a patient with predominant radicular pain, unamenable to surgery, with

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*A cost-effectiveness analysis from Canada has been used to support cost-effectiveness of SCS. The cost analyses for conservative care included annual, 3-day hospitalizations for breakthrough pain [$9405 total], 24 annual visits with a family physician, and physician therapy charges over 5 years [estimated at $8680]. Five-year costs were estimated at $28,123 SCS vs $38,029 for conservative care. Hospitalization for breakthrough pain [$9405] is highly unusual in the United States, and without that expense [without consideration of the other unusual numbers of visits], the fiscal advantage of SCS completely disappeared. As the study contains unusual assumptions and elimination of hospitalization causes the purported fiscal advantage of the SCS to disappear, the conclusions of this study do not appear applicable to typical US patients. A second cost-effectiveness estimate in the United Kingdom reported approximately 4.8-fold higher costs in those receiving SCS.
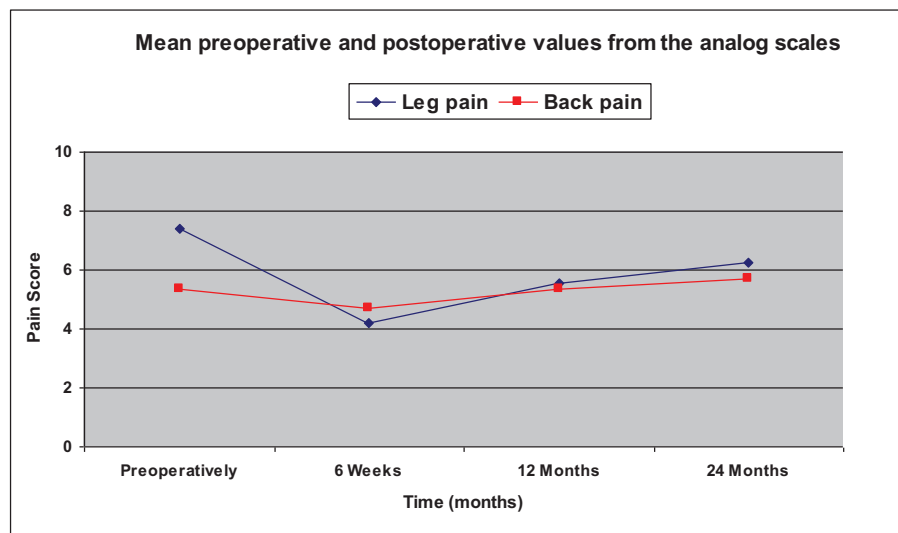
FIGURE 1. Spinal cord stimulator mean preoperative and postoperative analog pain scale ratings. Adapted from Ohnmeiss et al.[642]

TABLE 2. Selection Criteria for Implantable Spinal Cord Stimulator in a Chronic Radiculopathy Patient[*]

1. Clear diagnosis of chronic radiculopathy including supportive evidence on electrodiagnostic study. Leg pain should predominate over axial back pain.[646]
2. Poor or inadequate response to surgical treatment such as discectomy.
3. Poor or inadequate response to functional restoration program with treatment generally for at least 6 months.[**] Program shoud have been in an experienced interdisciplinary clinic with proven good outcomes that included core, emphasized elements of progressive aerobic exercise, strengthening, and cognitive behavioral therapy, and for which the patient demonstrated good compliance.
4. Remedial surgery inadvisable or not feasible.
5. Major psychiatric disorders have been treated with expected responses. Somatization disorder not amenable to treatment disqualifies the patient for use of invasive procedures, as the risk of the procedure is higher than the expected success rate. The candidate should have a successful independent, psychological evaluation and a structured interview performed by a psychologist specialized in chronic pain management including appropriate psychometric testing (see Chronic Pain guideline,[3] Appendix 1). The psychological evaluation should be performed by a practitioner who is not employed by the requesting or treating physicians.[***]
6. Willingness to stop inappropriate drug use before implantation.
7. No indication that secondary gain is directly influencing pain or disability complaints.
8. Ability to give informed consent for the procedure.
9. Successful results of at least 50% pain reduction from a trial of a temporary external stimulator of approximately 2 to 3 days and reduction of use of opioid medication or other medication with significant adverse effects or functional improvement such as return to work that may be evaluated by an occupational or physical therapist prior to and before discontinuation of the trial.

[*]Adapted from Kumar et al,[647] Lee et al,[648] Segal et al.[649,650]
[**]Some authors advocate earlier intervention[651,652];however, quality evidence is lacking.
[***]Presence of depression is common in patients with chronic pain, requires evaluation and may require treatment. Depression that is particularly severe may require treatment prior to assessing appropriateness of SCS, however, the presence of depression does not preclude SCS.

inadequate function after complying with functional restoration program components for at least 6 months who wishes to seek potential approval from a workers' compensation insurer (Table 2).

CONCLUSION

Evidence-based recommendations have been developed for invasive treatments to manage low back disorders. We have included psychological screening in this guideline as, while necessary for all low back disorder cases, that is especially needed prior to invasive treatments. Most common invasive treatments have quality RCTs to address either efficacy and/or

comparable efficacy. A total of 47 high-quality and 321 moderate-quality trials were identified for invasive management of low back disorders. This guideline includes 49 specific recommendations. Quality evidence should guide the treatment of all phases of managing low back disorders, including invasive treatments.

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