Back Pain - Invasive Procedures

Number: 0016

Policy

*Please see amendment for Pennsylvania Medicaid

at the end of this CPB.

Aetna considers any of the following injections or procedures medically necessary for the treatment of back pain; provided, however, that only 1 invasive modality or procedure will be considered medically necessary at a time.

I. Facet joint injections

- An initial facet injection (intra-articular and medial branch block) from C2-3 to L5-S1 is considered medically necessary for the diagnosis of facet pain in persons with severe chronic neck and back pain that limits daily activities and has lasted more than 3 months despite six or more weeks of conservative treatment (including, systemic medications, and/or physical therapy), with symptoms suggestive of facet joint syndrome (symptoms of facet joint syndrome include absence of radiculopathy, pain that is aggravated by extension, rotation or lateral bending of the spine and is not typically associated with any neurological deficits), where facet mediated pain is confirmed by provocative testing on physical examination (to confirm that pain is exacerbated by extension and rotation), imaging studies suggest no other obvious cause of pain (such as fracture, tumor, infection, or significant extraspinal lesion), and radiofrequency facet neurolysis is being considered.

Injection of no more than three (3) facet joint levels are considered medically necessary during the same session/procedure. These may be performed bilaterally during the same session for a total of up to six injections.
A second diagnostic facet injection (intraarticular and medial branch block) is considered medically necessary to confirm the validity of the clinical response to the initial facet injection when it is administered at the same level as the initial facet injection, and where the initial facet injection produced a positive response (i.e., resulted in an 80% relief of facet mediated pain for at least the expected minimum duration of the effect of the local anesthetic). If the initial injection did not produce a positive response, a second diagnostic injection is considered not medically necessary.

Diagnostic facet joint injections are considered experimental and investigational for neck and back pain with untreated radiculopathy. Facet joint injections are considered experimental and investigational as therapy for back and neck pain and for all other indications because their effectiveness for these indications has not been established.

Facet joint injections (intra-articular and medial branch blocks) containing corticosteroids are considered therapeutic injections. Aetna considers diagnostic facet joint injections not medically necessary where radiofrequency facet neurolysis is not being considered.

Additional sets of facet injections or medial branch blocks at the same levels and side are considered experimental and investigational because they have no proven value.

Aetna considers ultrasound guidance of facet injections experimental and investigational because of insufficient evidence of its effectiveness.

II. Trigger point injections

of corticosteroids and/or local anesthetics are considered medically necessary for treating members with chronic neck or back pain or myofascial pain syndrome, when all of the following selection criteria are met:

A. Conservative treatment such as bed rest, exercises, heating or cooling modalities, massage, and pharmacotherapies such as non-steroidal anti-inflammatory drugs (NSAIDS), muscle relaxants, non-narcotic analgesics, should have been tried and failed, and
B. Symptoms have persisted for more than 3 months, and
C. Trigger points have been identified by palpation; and
D. Trigger point injections are not administered in isolation, but are provided as part of a comprehensive pain management program, including physical therapy, patient education, psychosocial support, and oral medication where appropriate.

Trigger point injections are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

Aetna considers ultrasound or electromyography (EMG) guidance of trigger point injections experimental and investigational because of insufficient evidence of its effectiveness.

A trigger point is defined as a specific point or area where, if stimulated by touch or pressure, a painful response will be induced. A set of trigger point injections means injections in several trigger points in one sitting. It is not considered medically necessary to repeat injections more frequently than every 7 days. Up to 4 sets of injections are considered medically necessary to diagnose the origin of a patient's pain and achieve a therapeutic effect; additional sets of trigger point injections are not considered medically necessary if no clinical response is achieved. Once a diagnosis is established and a therapeutic effect is achieved, it is rarely considered medically necessary to repeat trigger point injections more frequently than once every 2 months. Repeated injections extending beyond 12 months may be reviewed for continued medical necessity.

Aetna considers dry needling experimental and investigational for the treatment of low back pain because the effectiveness of this approach has not been established.

III. Sacroiliac joint injections

are considered medically necessary to relieve pain associated with lower lumbosacral disturbances in members who meet all of the following criteria:

. Member has sacroiliac joint (SIJ) pain for greater than 3 months; and
A. Member has pain at or close to the posterior superior iliac spine (PSIS) with possible radiation into buttocks, posterior thigh, or groin and can point to the location of pain (Fortin Finger Test); and

B. Member has at least 3 of 5 physical examination maneuvers specific for SI joint pain:

1. Compression
2. Posterior Pelvic Pain Provocation test - P4 (Thigh Thrust)
3. Patrick’s test (Fabere)
4. Sacroiliac distraction test
5. Geanslens test; and

C. Other causes of low back pain have been ruled out, including lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, and lumbar vertebral body fracture; and

D. Member has tried 6 weeks of adequate forms of conservative treatment with little or no response, including pharmacotherapy (e.g., NSAIDS), activity modification, and active therapy (including physical therapy where appropriate); and

E. The injections are not used in isolation, but are provided as part of a comprehensive pain management program, including physical therapy, education, psychosocial support, and oral medication where appropriate.

Sacroiliac joint injections are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

Up to 2 diagnostic sacroiliac injections are considered medically necessary to diagnose the member’s pain and achieve a therapeutic effect. It is not considered medically necessary to repeat these injections more frequently than once every 7 days. Additional therapeutic sacroiliac injections are considered medically necessary if the member has improvement in lower back pain numeric rating scale (NRS) of at least 70% of the pre-injection NRS score after fluoroscopic or CT controlled injection of local anesthetic into affected SI joint. If the member experiences less than a 70% reduction of pain for the expected duration of the anesthetic, additional sacroiliac joint injections are not considered medically necessary. Once the diagnosis is established, up to four therapeutic sacroiliac injections are considered medically necessary every 12 months. Ultrasound guidance of sacroiliac joint injections is considered not medically necessary.

IV. Interlaminar epidural injections
of corticosteroid preparations (e.g., Depo-Medrol), with or without added anesthetic agents, are considered medically necessary in the outpatient setting for management of persons with radiculopathy or sciatica when all of the following are met:

- Pain is radicular in nature (radicular signs may include, but are not limited to, a positive straight leg raise or a dermatomal pattern of sensory loss). **Note:** In low back pain, radicular means pain and/or numbness that radiates below the knee; in neck pain, it is pain, numbness or weakness in the shoulder, arm, wrist, or hand; **and**
  - A. Intraspinal tumor or other space-occupying lesion, or non-spinal origin for pain, has been ruled out as the cause of pain; **and**
  - B. Member has failed to improve after 4 or more weeks of conservative treatments (e.g., rest, systemic analgesics, and/or physical therapy); **and**
  - C. Interlaminar epidural injections are provided as part of a comprehensive pain management program, which includes physical therapy, patient education, psychosocial support, and oral medications, where appropriate.

Interlaminar epidural injections of corticosteroid preparations, with or without added anesthetic agents, are considered experimental and investigational for all other indications (e.g., non-specific low back pain [LBP] and failed back syndrome) because their effectiveness for indications other than the ones listed above has not been established.

Additional interlaminar epidural injections are considered medically necessary if the initial injection resulted in at least two of the following for at least two weeks:

- **D.** A 50% or greater relief in pain; **and**
- **E.** Increase in the level of function/physical activity (e.g., return to work); **and**
- **F.** Reduction in the use of pain medication and/or additional medical services such as physical therapy/chiropractic care; **and**
- **G.** The interlaminar epidural injections are provided as part of a comprehensive pain management program, which includes physical therapy, patient education, psychosocial support, and oral medications.

Additionally, when medical necessity criteria are met for an initial or repeat cervical or thoracic interlaminar epidural steroid injections, advanced diagnostic imaging should be performed within 24 months prior to the initial or repeat injection.
Additional epidural injections are not considered medically necessary if these criteria are not met. Repeat epidural injections more frequently than every two weeks are not considered medically necessary. No more than one interlaminar epidural injection is considered medically necessary per session; more than one interlaminar epidural injection in a single region per session is considered not medically necessary, and interlaminar epidural injection of more than one region per session is considered not medically necessary. A total of up to 3 interlaminar epidural injections per region, per episode of pain are considered medically necessary in 6 months, and up to four interlaminar epidural steroid injections per region (ie, cervical, thoracic, lumbar) per rolling 12-month period are considered medically necessary, only upon return of pain and/or deterioration in function and only when responsiveness to prior injections has occurred (ie, the individual should have at least a 50% reduction in pain and/or symptoms for two weeks). Additional interlaminar epidural injections per region per rolling 12-month period are considered not medically necessary and experimental and investigational because they have no proven value.

Aetna considers ultrasound guidance of epidural injections experimental and investigational because of insufficient evidence of its effectiveness.

For transforaminal epidural injections, see CPB 0722 - Transforaminal Epidural Injections.

V. Chymopapain chemonucleolysis

is considered medically necessary for the treatment of sciatica due to a herniated disc when all of the following are met:

A. Member has radicular symptoms reproduced by sciatic stretch tests; and
B. Member has only a single-level herniated disc with nerve root impingement at clinically suspected level demonstrated by MRI, CT, or myelography; and
C. Member has objective neurologic deficit (e.g., diminished deep tendon reflex, motor weakness, or hypalgesia in dermatomal distribution); and
D. Pain not relieved by at least 6 weeks of conservative treatments.
Chymopapain chemonucleolysis is considered experimental and investigational for all other indications, including the following because its effectiveness for these indications has not been established:

E. Acute LBP alone  
F. Cauda equina syndrome  
G. For herniated thoracic or cervical discs  
H. Multiple back operations (failed back surgery syndrome)  
I. Neurologic disease (e.g., multiple sclerosis)  
J. Pregnancy  
K. Profound or rapidly progressive neurologic deficit  
L. Sequestered disc fragment  
M. Severe spinal stenosis  
N. Severe spondylolisthesis  
O. Spinal cord tumor  
P. Spinal instability  
Q. When performed with chondroitinase ABC or agents other than chymopapain

VI. Percutaneous lumbar discectomy

, manual or automated, is considered medically necessary for treatment of herniated lumbar discs when all of the following are met:

A. Member is otherwise a candidate for open laminectomy; and  
B. Member has failed 6 months of conservative treatment; and  
C. Diagnostic studies show that the nuclear bulge of the disc is contained within the annulus (i.e., the herniated disc is contained); and  
D. Member has no previous surgery or chemonucleolysis of the disc to be treated; and  
E. Member must have typical clinical symptoms of radicular pain corresponding to the level of disc involvement.

Percutaneous lumbar discectomy is considered experimental and investigational for all other indications because its effectiveness for indications other than the one listed above has not been established.
**Note:** Clinical studies have not established any clinically significant benefit of use of a laser over use of a scalpel for percutaneous lumbar discectomy.

**VII. Non-pulsed radiofrequency facet denervation**

(Also known as facet neurotomy, facet rhizotomy, or articular rhizolysis) is considered medically necessary for treatment of members with intractable cervical or back pain with or without sciatica in the outpatient setting when all of the following are met:

. Member has experienced severe pain limiting activities of daily living for at least 6 months; and
  A. Member has had no prior spinal fusion surgery at the level to be treated; and
  B. Neuroradiologic studies are negative or fail to confirm disc herniation; and
  C. Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; and
  D. Member has tried and failed six or more weeks of conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics, and muscle relaxants); and
  E. The member has two positive diagnostic facet joint injections (intraarticular or medial branch blocks) at the level to be treated, as evidenced by at least 80% relief of facet mediated pain for at least the expected minimum duration of the effect of the local anesthetic used.

Non-pulsed radiofrequency facet denervation is considered experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

When performing radiofrequency joint denervations/ablations, it may be necessary to perform the procedure at the same level(s) bilaterally; however, radiofrequency ablation of no more than three levels are considered medically necessary during the same session/procedure.

Provided that greater than 50% pain relief is obtained for at least twelve weeks, further facet denervation procedures should be at intervals of at least six months per
level per side, at a maximum of twice per rolling calendar year. Only 1 treatment procedure per level per side is considered medically necessary in a 6-month period.

See also CPB 0735 - Pulsed Radiofrequency.

**VIII. Pedicle screws for spinal fixation**

are considered medically necessary for the following indications:

- Fusion adjacent to prior lumbar fusion
- A. Fusion after decompression
- B. Pseudoarthrosis repair
- C. Revision lumbar disc surgery requiring instrumentation because of instability at the previous level of surgery
- D. Scoliosis and kyphosis requiring spinal instrumentation
- E. Segmental defects or loss of posterior elements following tumor resection
- F. Spinal trauma of all types including fractures and dislocations
- G. Spondylolisthesis – grades I to IV
- H. Thoracic fractures

Pedicle screw fixation is considered experimental and investigational for all other indications, including the following because its effectiveness for indications other than the ones listed above has not been established:

- I. Decompressive laminectomy for spinal stenosis without evidence of instability
- J. Degenerative disc disease
- K. Failed lumbar surgery without documentation of instability pattern or pseudarthrosis
- L. First time intervertebral disc herniation
- M. Isolated LBP without spinal instability or neurologic deficits
- N. Single-level discectomy

**IX. Intervertebral body fusion devices**
(synthetic spine cages/spacers) (see appendix) are considered medically necessary for use with allograft or autogenous bone graft in members who meet criteria for lumbar spinal fusion as outlined in CPB 0743 - Spinal Surgery: Laminectomy and Fusion and for thoracic fusion. Synthetic spine cages/spacers for cervical fusion are considered medically necessary for members who meet criteria in CPB 0743 - Spinal Surgery: Laminectomy and Fusion with any the following indications for use of a synthetic cervical cage/spacer:

- Cervical corpectomy (removal of half or more of vertebral body, not mere removal of osteophytes and minor decompression) in the treatment of one of the following:
  1. For tumors involving one or more vertebrae, or
  2. Greater than 50% compression fracture of vertebrae, or
  3. Retropulsed bone fragments, or
  4. Symptomatic central canal stenosis caused by vertebral body pathology (such as due to fracture, tumor or congenital or acquired deformity of the vertebral body).
A. Cervical fusion for pseudarthrosis in persons with prior fusion; or
B. For adjacent level disease that has developed in persons with a prior cervical fusion involving a plate, in order to avoid dissection for plate removal; or
C. Cervical fusion where cervical kyphosis (reversal of lordosis) is documented and an implant with at least 7 degrees of lordosis is required by the surgeon.

Spine cages are otherwise not considered medically necessary for cervical fusion because they have not been proven more effective than bone graft for this indication.

Spine cages are considered experimental and investigational for indications other than fusion because their effectiveness for indications other than those listed above has not been established.

Expandable cages are considered medically necessary for persons who meet criteria for fusion in CPB 0743 - Spinal Surgery: Laminectomy and Fusion and who meet either of the following criteria:

1. At L2-S1; or
2. for persons with osseous defects at the fusion site (i.e., voids or gaps in bone due to trauma, surgical resection, or congenital defects). Expandable cages are considered experimental and investigational for all other indications.

X. Percutaneous polymethylmethacrylate vertebroplasty (PPV) or kyphoplasty

is considered medically necessary for members with persistent, debilitating pain in the cervical, thoracic, or lumbar vertebral bodies resulting from any of the following:

- Multiple myeloma; or
- A. Painful and/or aggressive hemangiomas; or
- B. Painful vertebral eosinophilic granuloma; or
- C. Painful, debilitating osteoporotic collapse/compression fractures (e.g., Kummell’s disease); or
- D. Primary malignant neoplasm of bone or bone marrow; or
- E. Secondary osteolytic metastasis, excluding sacrum and coccyx; or
- F. Steroid-induced fractures

AND all of the following criteria have been met:

- G. Other causes of pain such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging; and
- H. Severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g., acetaminophen, NSAIDS, narcotic analgesics, braces, physical therapy, etc.); and
- I. The affected vertebra has not been extensively destroyed and is at least 1/3 of its original height.

XI. Lateral (including extreme [XLIF], extra and direct lateral [DLIF]) interbody fusion

is considered an acceptable method of performing a medically necessary anterior interbody fusion. See CPB 0743 - Spinal Surgery: Laminectomy and Fusion.
XII. Coccygectomy

is considered medically necessary for individuals with coccygodynia who have tried and failed to respond to 6 months of conservative management.

XIII. Vertebral body replacement spacers

(e.g., AVS AL PEEK Spacer) are considered medically necessary for vertebral body replacement used in spine surgery for persons with a collapsed, damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures due to tumor or trauma (vertebral body replacement should not be confused with Interspinous distraction devices (spacers) (e.g., X-Stop)).

XIV. Minimally invasive transforaminal lumbar interbody fusion with direct visualization

is considered medically necessary when criteria are met in CPB 0743 - Spinal Surgery: Laminectomy and Fusion.

XV. Cementoplasty

is considered medically necessary for individuals with bone pain from pelvic bone metastases with reduced mobility and have failed conventional pain treatments (e.g., acetaminophen, non-steroidal anti-inflammatory drugs, and opioids). For "cementoplasty" for vertebral indications, see section on vertebroplasty.

XVI. Sacroiliac joint fusion
- minimally invasive arthrodesis of the sacroiliac joint (e.g., iFuse) is considered medically necessary for sacroiliac joint syndrome interfering with activities of daily living when all of the following criteria are met:

  . Adults 18 years of age or older with sacroiliac joint (SIJ) pain for greater than 6 months (or greater than 18 months for pregnancy induced pelvic girdle pain): and

A. Diagnosis of the SI joint as the primary pain generator based on all of the following:

  1. Member has pain at or close to the posterior superior iliac spine (PSIS) with possible radiation into buttocks, posterior thigh, or groin and can point to the location of pain (Fortin Finger Test); and

  2. Member has at least 3 of 5 physical examination maneuvers specific for SI joint pain:

     a. Compression
     b. Posterior Pelvic Pain Provocation test - P4 (Thigh Thrust)
     c. Patrick’s test (Fabere)
     d. Sacroiliac distraction test
     e. Geanslens test; and

  3. Other causes of low back pain have been ruled out, including lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, and lumbar vertebral body fracture;

  . Clinician has documented that other neighboring motion segments have been evaluated and ruled out as potential pain generators, including diagnostic testing with facet/medial branch blocks and or interlaminar epidural injections, as appropriate based on the member’s presentation; and

a. Member has had recent (within 6 months) diagnostic imaging studies that include all of the following:

   i. Plain X-rays and/or cross sectional imaging (CT or MRI) that excludes the presence of destructive lesions (e.g. tumor, infection), acute fracture or
inflammatory arthropathy that would not be properly addressed by SIJ fusion; and

ii. Plain X-rays of the pelvis including the ipsilateral hip to evaluate potential concomitant hip pathology; and

iii. Cross-sectional imaging (e.g. CT or MRI) of the lumbar spine to evaluate potential concomitant neural compression or other degenerative conditions; and

4. Sacroiliac pathology is not caused by autoimmune disease (e.g. ankylosing spondylitis) and/or neoplasia (e.g. benign or malignant tumor) and/or crystal arthropathy; and

5. Member has improvement in lower back pain numeric rating scale (NRS) of at least 70% of the pre injection NRS score after two separate fluoroscopic or CT controlled injection of local anesthetic into affected SI joint; and

B. Baseline lower back pain score of at least 5 on 0-10 point NRS; and

C. Member should have tried 6 months of adequate forms of conservative treatment with little or no response, including pharmacotherapy (e.g., NSAIDS), activity modification, and active therapy (including 3 or more months of physical therapy).

Open sacroiliac joint fusion is considered medically necessary for sacroiliac joint infection, tumor involving the sacrum, and sacroiliac pain due to severe traumatic injury where a trial of an external fixator is successful in providing pain relief.

Sacroiliac joint fusions are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

For intercostal nerve blocks, see CPB 0863 - Nerve Blocks.

**Experimental and Investigational Interventions**

Aetna considers any of the following injections or procedures experimental and investigational:

- AccuraScope procedure;
- AnchorKnot Tissue Approximation Kit (Anchor Orthopedics) for lumbar discectomy;
- Annulus repair devices (Xclose Tissue Repair System, Barricaid, Disc Annular Repair Technology (DART) System);
- BacFast HD for isolated facet fusion;
- Biomet Aspen fusion system (an interlaminar fixation device) (see Appendix);
- Chemical ablation (including but not limited to alcohol, phenol, or sodium morrhuate) of facet joints;
- Coccygeal ganglion (ganglion impar) block for coccydynia, pelvic pain, and all other indications;
- Cooled radiofrequency ablation (e.g., Coolief) for facet denervation;
- Cryoablation (cryoanesthesia, cryodenervation, cryoneurolysis, or cryosurgery) for the treatment of lumbar facet joint pain;
- Deuk Laser Disc Repair;
- Devices for annular repair (e.g., Inclose Surgical Mesh System);
- Direct visual rhizotomy (extradural transection or avulsion of other spinal nerve) for the treatment of chronic low back pain;
- DiscoGel (intradiscal alcohol injection) for the treatment of back and neck pain;
- Disceel procedure (regenerative spine procedure) for the treatment of back pain;
- Endoscopic disc decompression, ablation, or annular modulation using the DiscFX System;
- Endoscopic laser foraminoplasty, endoscopic foraminotomy, laminotomy, and rhizotomy (endoscopic radiofrequency ablation);
- Endoscopic transforaminal diskectomy;
- Epidural fat grafting during lumbar decompression laminectomy/discectomy;
- Epidural injections of lytic agents (e.g., hyaluronidase, hypertonic saline) or mechanical lysis in the treatment of adhesive arachnoiditis, epidural fibrosis, failed back syndrome, or other indications;
- Epidural steroid injections for the treatment of non-radicular low back pain;
- Epiduroscopy (also known as epidural myeloscopy, epidural spinal endoscopy, myeloscopy, and spinal endoscopy) for the diagnosis and treatment of intractable LBP or other indications;
- Facet chemodenervation/chemical facet neurolysis;
- Facet joint allograft implants (NuFix facet fusion, TruFuse facet fusion)
- Facet joint implantation (Total Posterior-element System (TOPS) (Premia Spine), Total Facet Arthroplasty System (TFAS) (Archus Orthopedics), ACADIA Facet Replacement System (Facet Solutions/Globus Medical);
- Far lateral microendoscopic diskectomy (FLMED) for extra-foraminal lumbar disc herniations or other indications;
- Hardware injections/blocks;
- Interlaminar lumbar instrumented fusion (ILIF);
• Interspinous and interlaminar distraction devices (see Appendix);
• Interspinous fixation devices (Benefix Interspinous Fixation System, CD HORIZON SPIRE Plate, PrimaLOK SP, SP-Fix Spinous Process Fixation Plate, and Stabilink interspinous fixation device) for spinal stenosis or other indications (see Appendix);
• Intracpect System (intra-osseous basivertebral nerve ablation) for the treatment of low back pain;
• Intradiscal injections of notochordal cell-derived matrix for the treatment of intervertebral disc disease;
• Intradiscal injection of platelet-rich plasma;
• Intradiscal, paravertebral, or epidural oxygen or ozone injections;
• Intramuscular steroid injection for the treatment of neck pain
• Intradiscal steroid injections;
• Intravenous administration of corticosteroids, lidocaine, magnesium, Toradol or vitamin B12 (cyanocobalamin) as a treatment for back pain and neck pain;
• Khan kinetic treatment (KKT);
• Laser facet denervation;
• Least invasive lumbar decompression interbody fusion (LINDIF);
• Microendoscopic discectomy (MED; same as lumbar endoscopic discectomy utilizing microscope) procedure for decompression of lumbar spine stenosis, lumbar disc herniation, or other indications;
• Microsurgical anterior foraminotomy for cervical spondylotic myelopathy or other indications;
• Microsurgical lumbar sequestrectomy for the treatment of lumbar disc herniation;
• Minimally invasive/endoscopic cervical laminoforaminotomy for cervical radiculopathy/lateral and foraminal cervical disc herniations or other indications;
• Minimally invasive lumbar decompression (MILD) procedure (percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements under indirect image guidance) for lumbar canal stenosis or other indications;
• Minimally invasive thoracic discectomy for the treatment of back pain;
• Minimally invasive endoscopic transforaminal lumbar interbody fusion (endoscopic MITLIF; same as endoscopic MAST fusion) for lumbar disc degeneration and instability or other indications;
• OptiMesh grafting system;
• Percutaneous cervical diskectomy;
• Percutaneous endoscopic discectomy with or without laser (PELD) (also known as arthroscopic microdiskectomy or Yeung Endoscopic Spinal Surgery System [Y.E.S.S.]);
• Piriformis muscle resection and other surgery for piriformis syndrome;
• Posterior intrafacet implants (e.g., DTRAX Cervical Cage) for posterior cervical fusion;
• Psoas compartment block for lumbar radiculopathy or myositis ossification;
• Racz procedure (epidural adhesiolysis with the Racz catheter) for the treatment of members with adhesive arachnoiditis, epidural adhesions, failed back syndrome from multiple previous surgeries for herniated lumbar disk, or other indications;
• Radiofrequency denervation for sacroiliac joint pain;
• Radiofrequency lesioning of dorsal root ganglia for back pain;
• Radiofrequency lesioning of terminal (peripheral) nerve endings for back pain;
• Radiofrequency/pulsed radiofrequency ablation of trigger point pain;
• Sacroplasty for osteoporotic sacral insufficiency fractures and other indications;
• SpineJack system for the treatment of osteoporotic vertebral compression fractures
• Tendon sheath injections for the treatment of back pain;
• Total Facet Arthroplasty System (TFAS) for the treatment of spinal stenosis;
• Vesselplasty (e.g., Vessel-X).

See also CPB 0411 - Bone and Tendon Graft Substitutes and Adjuncts, and CPB 0602 - Intradiscal Procedures.

Reimbursement Notes

• Laser: Clinical studies have not established a clinically significant benefit of use of a laser over a scalpel in spinal surgery. No additional benefit will be provided for the use of a laser in spinal surgery.
• Microscope and endoscope: Use of a microscope or endoscope is considered an integral part of the spinal surgery and not separately reimbursable.

Background

Epidural Steroids

An epidural steroid finjection is an injection of long lasting steroid in the epidural space – that is the area which surrounds the spinal cord and the nerves coming out of it. An epidural steroid injection is used to help reduce radicular spinal pain that may be caused by pressure on a spinal nerve root as a result of a herniated disc, degenerative disc disease or spinal stenosis. This treatment is most frequently used for low back pain, though it may also be used for cervical (neck) or thoracic (midback) pain. A combination of an anesthetic and a steroid medication is injected into the epidural space near the affected spinal nerve root with the assistance of fluoroscopy which allows the physician to view the placement of the needle.
Approaches to the epidural space for the injection include:

- **Caudal** -
  
  the epidural needle is placed into the tailbone (coccyx) allowing the treatment of pain which radiates into the lower extremities. This approach is commonly used to treat lumbar radiculopathy after prior surgery in the low back (post-laminectomy pain syndrome).

- **Cervical** -
  
  the epidural needle is placed in the midline in the back of the neck to treat neck pain which is associated with radiation of pain into an upper extremity (cervical radiculopathy).

- **Interlaminar** -
  
  the needle is placed between the lamina of two vertebrae directly from the middle of the back. Also called translaminar, this method accesses the large epidural space overlying the spinal cord, and is the most commonly used approach for cervical, thoracic, and lumbar epidural injections. Medication is delivered to the nerve roots on both the right and left sides of the inflamed area at the same time.

- **Lumbar** -
  
  the epidural needle is placed in the midline in the low back to treat back pain which is associated with radiation into a lower extremity (lumbar radiculopathy).
• Thoracic -

the epidural needle is placed in the midline in the upper or middle back.

• Transforaminal -

the needle is placed to the side of the vertebra in the neural foramen, just above the opening for the nerve root and outside the epidural space; this method treats one side at a time.

The goal of this treatment is to reduce inflammation and block the spinal nerve roots to relieve radicular pain or sciatica. It can also provide sufficient pain relief to allow the individual to progress with their rehabilitation program.

The efficacy of epidurally administered steroids has been demonstrated without adverse consequence in a large number of patients with reproducible results. In a large number of studies, long-term relief of pain (greater than 3 months) can be achieved in at least 10 to 30% of patients, while short-term relief (less than 1 month) can be achieved in 60 to 100% of patients. Results for cervical pain are somewhat lower than those for lumbar pain. Such therapy is considered under accepted guidelines to be indicated in patients with low back and cervical pain that has not resolved after only a short period of more conservative measures since studies have shown a better response to therapy in patients whose pain is of shorter duration. Even if pain relief is temporary, it may have long-term benefit because it allows initiation of physical therapy or other rehabilitative measures at an earlier stage. Most authors indicate that a limit on number of injections is appropriate, and that most patients will respond with 3 or fewer injections.

The American Academy of Neurology’s assessment on the use of epidural steroid injections in the treatment of radicular lumbosacral pain (Armond et al, 2007) concluded that:

• Epidural steroid injections may result in some improvement in radicular lumbosacral pain when determined between 2 and 6 weeks following the injection, compared to control treatment (Level C, Class I to III evidence). The average magnitude of effect is
small, and the generalizability of the observation is limited by the small number of studies, limited to highly selected patient populations, the few techniques and doses studied, and variable comparison treatments.

- In general, epidural steroid injections for radicular lumbosacral pain have shown no impact on average impairment of function, on need for surgery, or on long-term pain relief beyond 3 months. Their routine use for these indications is not recommended (Level B, Class I to III evidence).

- Data on use of epidural steroid injections to treat cervical radicular pain are inadequate to make any recommendation (Level U).

Guidelines from the American Pain Society (Chou et al, 2009) questioned the clinical value of epidural injection for long-term use or for use of non-radicular back pain. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis was not offered based on insufficient or poor evidence.

Langer-Gould et al (2013) discussed the American Academy of Neurology (AAN)'s top five recommendations in the “Choosing Wisely” campaign promoting high-value neurologic medicine and physician-patient communication. They noted that 1 of the 11 finalist recommendations was “Don’t perform epidural steroid injections to treat non-radicular low back pain”.

**Trigger Point Injections**

Trigger point injections (TPI) are injections of saline or a local anesthetic, with or without a steroid medication, into a painful area of a muscle that contains the trigger point. The purpose of a TPI is to relax the area of intense muscle spasm, effectively inactivate the trigger point and provide prompt symptomatic pain relief. TPI is the most common interventional technique used in pain medicine.

Trigger points have also been treated with dry needling. Dry needling is not to be confused with traditional Chinese acupuncture, even though it does make use of acupuncture-type needles. Acupuncture follows the principles of energy flow as a guide to where the needles will be inserted; in dry needling, needles are inserted directly into a myofascial trigger point, in an attempt to inactivate it, thereby decreasing the associated pain. Dry needling, even though it targets a trigger point, also differs from a trigger point injection, as there is no injection of medication or fluid.

A myofascial trigger point is a discrete focal tenderness, 2-5 mm in diameter that is located in distinct tight bands or knots of skeletal muscle (AHFMR, 2002). When
palpated, these hyper-irritable areas cause pain in distant areas, or referred pain zones, which are specific for each trigger point. Trigger point injection, or direct wet needling, involves injection of fluid directly into the trigger point located in the taut muscle band. The main objective of trigger point injection is fast pain relief and elimination of muscle spasm in order to break the pain cycle. This facilitates physical therapy aimed at reducing muscle contracture and increasing range of motion. Trigger point injection is rarely used in isolation but is generally part of a multi-disciplinary approach aimed at treating both the trigger points and reducing all contributing factors (Scott and Guo, 2005; AHFMR, 2002; Sanders et al, 1999). Thus, treatment may also include patient education, psychosocial support, oral medications, and physical therapy to improve the strength and flexibility of the affected musculoskeletal systems. An assessment conducted by the Alberta Heritage Foundation for Medical Research (Scott and Guo, 2005) found that the evidence for the effectiveness of trigger point injections when used as the sole treatment for patients with chronic head, neck, and shoulder pain and whiplash syndrome was inconclusive, regardless of whether sterile water, saline, or botulinum toxin is injected. The assessment found that the combined use of dry needling and trigger point injection with procaine offers no obvious clinical benefit in the treatment of chronic craniofacial pain, while the effectiveness of trigger point injection for the treatment of cervicogenic headache is unknown. In contrast, the assessment found that trigger point injection with lidocaine may be useful in the treatment of joint pain caused by osteoarthritis (Scott and Guo, 2005). The assessment found no proof that trigger point injection is more effective than other less invasive treatments, such as physical therapy and ultrasound, in achieving pain relief, and there is some suggestion that the only advantage of injecting anesthetic into trigger points is that it reduces the pain of the needling process (Scott and Guo, 2005). Usually, approximately 3 treatments are necessary to abolish a trigger point completely (AHFMR, 2002). A number of trigger points may be injected in 1 session, but rarely more than 5. Repeated injections in a particular muscle are not recommended if 2 or 3 previous attempts have been unsuccessful (Alvarez and Rockwell, 2002; Sanders et al, 1999). The pain relief may last for the duration of the anesthetic to many months, depending on the chronicity and severity of the trigger points and the concomitant treatment of perpetuating factors. According to available guidelines, use of trigger point injections should be short-term and part of a comprehensive rehabilitation program. Available guidelines indicate that, while there are a number of uncontrolled case studies using trigger point injections in more acute pain presentations, there is virtually no consistent evidence for its application with chronic non-malignant pain syndrome patients to date (Sanders et al, 1999; AHFMR, 2002).

Botwin and colleagues (2008) noted that myofascial pain is defined as pain that originates from myofascial trigger points in skeletal muscle. It is prevalent in regional
musculoskeletal pain syndromes, either alone or in combination with other pain generators. The myofascial pain syndrome is one of the largest groups of under diagnosed and under treated medical problems encountered in clinical practice. Trigger points are commonly seen in patients with myofascial pain which is responsible for localized pain in the affected muscles as well as referred pain patterns. Correct needle placement in a myofascial trigger point is vital to prevent complications and improve efficacy of the trigger point injection to help reduce or relieve myofascial pain. In obese patients, these injections may not reach the target tissue. In the cervico-thoracic spine, a misguided or misplaced injection can result in a pneumothorax. These researchers described an ultrasound-guided trigger point injection technique to avoid this potential pitfall. Office based ultrasound-guided injection techniques for musculoskeletal disorders have been described in the literature with regard to tendon, bursa, cystic, and joint pathologies. For the interventionalist, utilizing ultrasound yields multiple advantages technically and practically, including observation of needle placement in real-time, ability to perform dynamic studies, the possibility of diagnosing musculoskeletal pathologies, avoidance of radiation exposure, reduced overall cost, and portability of equipment within the office setting. To the authors' knowledge, the use of ultrasound guidance in performing trigger point injection in the cervico-thoracic area, particularly in obese patients, has not been previously reported. A palpable trigger point in the cervico-thoracic musculature was localized and marked by indenting the skin with the tip of a plastic needle cover. The skin was then sterile prepped. Then, using an ultrasound machine with sterile coupling gel and a sterile latex free transducer cover, the musculature in the cervico-thoracic spine where the palpable trigger point was detected was visualized. Then utilizing direct live ultrasound guidance, a 25-gauge 1.5 inch needle connected to a 3-ml syringe was placed into the muscle at the exact location of the presumed trigger point. This guidance helped confirm needle placement in muscle tissue and not in an adipose tissue or any other non-musculature structure. The technique was simple to be performed by a pain management specialist who has ultrasound system training. The authors concluded that ultrasound-guided trigger point injections may help confirm proper needle placement within the cervico-thoracic musculature. The use of ultrasound-guided trigger point injections in the cervico-thoracic musculature may also reduce the potential for a pneumothorax by an improperly placed injection.

Zhou and Wang (2014) stated that myofascial pain syndrome (MPS) is a common chronic pain condition that is characterized by distinct “trigger points”. Despite current treatments with physical therapy, analgesics, anti-depressants and trigger-point injections, myofascial pain remains a challenging chronic pain condition in clinical practice. Botulinum toxin A (BTX-A) can cause prolonged muscle relaxation through inhibition of acetylcholine release. It may offer some advantages over the current
treatments for MPS by providing a longer sustained period of pain relief. Despite numerous clinical trials, the efficacy of BTX-A in alleviating MPS is not well-established due to mixed results from recent clinical trials. Active trigger points are associated with referred pain and greatly impact many aspects of activities of daily living, mood, and health status. This review was designed to analyze the clinical trials regarding the efficacy of BTX-A injection of active trigger points as a treatment for MPS. The literature referenced was obtained via a computer search with Google Scholar, PubMed, Medline and Embase. Search terms included "Botulinum toxin", "myofascial pain", "trigger points", "myofascial trigger points", and "chronic pain". Additional references were retrieved from the reference list of the reports found via this search. Studies were considered eligible for inclusion if they were double-blinded, randomized, controlled trials evaluating the efficacy of BTX-A injections into trigger points for pain reduction, and if the trigger point selection in the trial included referred pain and/or local twitch response. Open-label studies, case reports, and other non-randomized studies were excluded. A total of 8 trials were found according to the above criteria. There are well-designed clinical trials to support the efficacy of trigger-point injections with BTX-A for MPS. However, further clinical trials with considerations of minimizing placebo effect, repeated dosing, adequate coverage of trigger points, and using ultrasound confirmation and guidance are required to provide conclusive evidence for BTX-A in the treatment of myofascial pain.

In a prospective, double-blinded, randomized controlled trial, Misirlioglu et al (2015) investigated the differences between local anesthetic (LA) and LA + corticosteroid (CS) injections in the treatment of piriformis syndrome (PS). A total of 57 patients having unilateral hip and/or leg pain with positive FAIR test and tenderness and/or trigger point at the piriformis muscle were evaluated. Out of 50 patients randomly assigned to 2 groups, 47 patients whose pain resolved at least 50% from the baseline after the injection were diagnosed as having PS. The 1st group (n = 22) received 5 ml of lidocaine 2% while the 2nd group (n = 25) received 4 ml of lidocaine 2% + 1 ml of betametazone under the guidance of ultrasound. Outcome measures included Numeric Rating Scale (NRS) and Likert Analogue Scale (LAS). No statistically significant difference (p > 0.05) was detected between the groups in NRS score values at resting (p = 0.814), night (p = 0.830), and in motion (p = 0.145), and LAS values with long duration of sitting (p = 0.547), standing (p = 0.898), and lying (p = 0.326) with evaluations at baseline, 1st week, and 1st and 3rd months after the injection. A statistically highly significant (p < 0.005) reduction of pain was evaluated through NRS scores at resting (p = 0.001), in motion (p = 0.001), and at night (p = 0.001) and LAS values with long duration of sitting (p = 0.001), standing (p = 0.001), and lying (p = 0.001) in both of the groups. The authors concluded that LA injections for the PS were found to be clinically effective. However,
addition of CS to LA did not give an additional benefit. The main drawback of this study was its relatively small sample.

Shinomiya et al (2016) examined if differences in corticosteroid injection site influence the therapeutic effect on trigger finger and thickness of local structures such as the A1 pulley and flexor tendons. Previously untreated trigger fingers were randomly assigned to receive either

I. a true intra-sheath (group I) or

II. an extra-sheath (group E) injection under ultrasonographic guidance.

1. a true intra-sheath (group I) or
2. an extra-sheath (group E) injection under ultrasonographic guidance.

Symptom remission and recurrence rates and recurrence timing did not significantly differ between the groups. Ultrasonography revealed mean (standard deviation) pre-injection A1 pulley thicknesses of 1.1 (0.3) and 1.1 (0.2) mm in groups I and E, respectively. One month after injection, these decreased to 0.7 (0.2) and 0.8 (0.2) mm, respectively (p < 0.05). Furthermore, mean (standard) pre-injection flexor digitorum tendon thickness was 4.1 (0.4) and 4.0 (0.5) mm in groups I and E, respectively, and, 1 mo after injection, decreased to 3.9 (0.3) and 3.8 (0.5) mm, respectively (p < 0.05). However, the difference at each time-point between the 2 groups was not statistically significant. The authors concluded that true intra-sheath injection offered no apparent advantage over extra-sheath injection for treating trigger fingers because both have the same effect on local structures.

UpToDate reviews on "Subacute and chronic low back pain: Nonsurgical interventional treatment" (Chou, 2018) and "Treatment of neck pain" (Isaac, 2017) do not mention ultrasound-guidance as an adjunct for trigger point injections.

**Dry Needling for the Treatment of Low Back Pain**

UpToDate reviews on "Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment" (Chou, 2020a) and "Treatment of acute low back pain" (Knight et al, 2020) do not mention dry needling as a management / therapeutic option.
Furthermore, an “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2020b) states that “Local or trigger point injection -- A systematic review found no clear differences between local or trigger point injections with a local anesthetic, with or without a corticosteroid, and control interventions (saline or dry needle injections, or ethyl chloride plus acupressure) for short-term (7 days to 2 months) pain relief in 3 trials of patients with subacute or chronic low back pain. All trials had methodological shortcomings and evaluated heterogeneous injection methods. One trial evaluated an injection over the iliac crest, one evaluated injections over the iliolumbar ligament, and one evaluated trigger point injections. The limited benefit observed in heterogeneous, low-quality studies does not support their widespread use”.

Lumbar Laminectomy with or without Fusion

Laminectomy and laminotomy involve removal of a small part of the bony arches of the spinal canal, called the lamina, which increases the size of the spinal canal. A laminectomy or laminotomy is most commonly performed for a diagnosis of spinal stenosis. During a laminectomy the entire lamina is removed while only a portion of the lamina is removed in a laminotomy. These procedures are also often done with either a discectomy or a foraminectomy/foraminotomy.

Most individuals with acute low back problems spontaneously recover activity tolerance within 4 to 6 weeks of conservative therapy (AHCPR, 1994). Conservative therapy for acute low back pain (LBP) includes:

- Avoidance of activities that aggravate pain
- Chiropractic manipulation in the first 4 weeks if no radiculopathy
- Cognitive support and reassurance that recovery is expected
- Education regarding spine biomechanics
- Exercise program
- Heat/cold modalities for home use
- Limited bed rest with gradual return to normal activities
- Low impact exercise as tolerated (e.g., walking, swimming, stationary bike)
- Non-narcotic analgesics
- Pharmacotherapy (e.g., non-narcotic analgesics, non-steroidal anti-inflammatory drugs [NSAIDs] (as second-line choices), avoid muscle relaxants, or only use during the first week, avoid narcotics).

If conservative therapy fails to relieve symptoms of sciatica and radiculopathy and there is strong evidence of dysfunction of a specific nerve root confirmed at the
corresponding level by findings demonstrated by CT/MRI, lumbar laminectomy may be proposed as a treatment option. The goal of lumbar laminectomy is to provide decompression of the affected nerve root to relieve the individual's symptoms. It involves the removal of all or part of the lamina of a lumbar vertebra. The addition of fusion with or without instrumentation is considered when there are concerns about instability.

**Decompression with or without Discectomy for Cauda Equine Syndrome**

Cauda equina ("horse's tail") is the name given to the lumbar and sacral nerve roots within the dural sac caudal to the conus medullaris. Cauda equina syndrome is usually the result of a ruptured, midline intervertebral disk, most commonly occurring at the L4 to L5 level. However, tumors and other compressive masses may also cause the syndrome. Individuals generally present with progressive symptoms of fecal or urinary incontinence, impotence, distal motor weakness, and sensory loss in a saddle distribution. Muscle stretch reflexes may also be reduced. The presence of urinary retention is the single most consistent finding (Perron and Huff, 2002).

In acute cauda equine syndrome, surgical decompression as soon as possible is recommended. In a more chronic presentation with less severe symptoms, decompression could be performed when medically feasible and should be delayed to optimize the patient's medical condition; with this precaution, decompression is less likely to lead to irreversible neurological damage (Dawodu, 2005).

**Cervical Laminectomy with or without Fusion**

A cervical laminectomy (may be combined with an anterior approach) is sometimes performed when acute cervical disc herniation causes central cord syndrome or in cervical disc herniations refractory to conservative measures. Studies have shown that an anterior discectomy with fusion is the recommended procedure for central or anterolateral soft disc herniation, while a posterior laminotomy-foraminotomy may be considered when technical limitations for anterior access exist (e.g., short thick neck) or when the individual has had prior surgery at the same level (Windsor, 2006).

Discectomy alone is regarded as a technique that most frequently results in spontaneous fusion (70 to 80%). Additional fusion techniques include the use of bone grafts (autograft, allograft or artificial) with or without cages and/or the use of an anterior plate. Based on the clinical evidence, autologous or cadaveric bone grafting, with or without plating, remains the gold standard for cervical fusion. Therefore, use of
an intervertebral cage for cervical fusion is considered experimental and investigational. A Cochrane systematic review (2004) reported the results of fourteen studies (n = 939) that evaluated three comparisons of different fusion techniques for cervical degenerative disc disease and concluded that discectomy alone has a shorter operation time, hospital stay, and post-operative absence from work than discectomy with fusion with no statistical difference for pain relief and rate of fusion. The authors concluded that more conservative techniques (discectomy alone, autograft) perform as well or better than allograft, artificial bone, and additional instrumentation; however, the low quality of the trials reviewed prohibited extensive conclusions and more studies with better methodology and reporting are needed.

An assessment by the BlueCross BlueShield Association Technology Evaluation Center (BCBSA, 2014) stated: "The choice of bone material for interbody fusion in [anterior cervical discectomy and fusion] ACDF has important clinical implications. Allograft bone has several drawbacks, including a minute (albeit unproven) risk of infectious disease transmission; possible immunological reaction to the allograft; and possible limited commercial availability of appropriate graft material. In contrast, the use of autograft bone in ACDF has potentially substantial morbidities at the harvest site, generally the iliac crest. These include moderate-to-severe, sometimes prolonged pain; deep infection; adjacent nerve and artery damage; and increased risk of stress fracture. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90%–100%) and satisfactory outcomes for single-level, anterior-plated ACDF using either bone source. Thus, the choice of graft material involves a trade-off between the risks specific to autograft harvest versus those specific to use of allograft material."

A systematic review of randomized controlled trials found no reliable evidence for use of cages over autograft for cervical spinal fusion (Jacobs et al, 2011). Noting that the number of surgical techniques for decompression and anterior cervical interbody fusion (ACIF) for cervical degenerative disc disease has increased, the investigators sought to determine which technique of ACIF gives the best outcome. From a comprehensive search, the investigators selected randomized studies that compared anterior cervical decompression and ACIF techniques, in patients with chronic single- or double-level degenerative disc disease or disc herniation. Risk of bias was assessed using the criteria of the Cochrane back review group. A total of 33 studies with 2,267 patients were included. The major treatments were discectomy alone and addition of an ACIF procedure (graft, cement, cage, and plates). The investigators stated, at best, there was very low-quality evidence of little or no difference in pain relief between the techniques. The investigators found moderate quality evidence for few secondary outcomes. The
investigators found that Odom’s criteria were not different between iliac crest autograft and a metal cage (risk ratio [RR]: 1.11; 95% confidence interval [CI]: 0.99-1.24). Bone graft produced more fusion than discectomy (RR: 0.22; 95% CI: 0.17-0.48). Complication rates were not different between discectomy and iliac crest autograft (RR: 1.56; 95% CI: 0.71-3.43). Low-quality evidence was found that iliac crest autograft results in better fusion than a cage (RR: 1.87; 95% CI: 1.10-3.17); but more complications (RR: 0.33; 95% CI: 0.12-0.92). The investigators concluded that, when fusion of the motion segment is considered to be the working mechanism for pain relief and functional improvement, iliac crest autograft appears to be the gold standard. The investigators stated that, when ignoring fusion rates and looking at complication rates, a cage as a gold standard has a weak evidence base over iliac crest autograft, but not over discectomy.

An evidence review by Epstein et al (2012) reached similar conclusions. These researchers (2012) noted that grafting choices available for performing anterior cervical diskectomy/fusion (ACDF) procedures have become a major concern for spinal surgeons, and their institutions. The "gold standard", iliac crest autograft, may still be the best and least expensive grafting option; it deserves to be reassessed along with the pros, cons, and costs for alternative grafts/spacers. Although single or multilevel ACDF have utilized iliac crest autograft for decades, the implant industry now offers multiple alternative grafting and spacer devices; (allografts, cages, polyether-etherketone (PEEK) amongst others). While most studies have focused on fusion rates and clinical outcomes following ACDF, few have analyzed the "value-added" of these various constructs (e.g. safety/efficacy, risks/complications, costs). Epstein (2012) found that the majority of studies document 95%-100% fusion rates when iliac crest autograft is utilized to perform single level ACDF (X-ray or computed tomography [CT] confirmed at 6-12 postoperative months). Although many allograft studies similarly quote 90%-100% fusion rates (X-ray alone confirmed at 6-12 postoperative months), a recent "post hoc analysis of data from a prospective multicenter trial" (Riew KD et. al., CSRS Abstract Dec. 2011; unpublished) revealed a much higher delayed fusion rate using allografts at one year 55.7%, 2 years 87%, and four years 92%. The author found no clinically significant differences in cervical spine fusion outcomes between autograft and cages, despite an up to 10-fold difference in cost among various constructs. The author concluded that iliac crest autograft utilized for single or multilevel ACDF is associated with the highest fusion, lowest complication rates, and significantly lower costs compared with allograft, cages, PEEK, or other grafts. As spinal surgeons and institutions become more cost conscious, we will have to account for the "value added" of these increasingly expensive graft constructs.

Kersten et al (2015) stated that polyetheretherketone (PEEK) cages have been widely used during the past decade in patients with degenerative disorders of the cervical
spine. Their radiolucency and low elastic modulus make them attractive attributes for spinal fusion compared with titanium and bone graft. Still, limitations are seen such as pseudoarthrosis, subsidence, and migration of the cages. The authors stated that limited evidence on the clinical outcome of PEEK cages is found in the literature other than noncomparative cohort studies with only a few randomized controlled trials. The authors conducted a systematic evidence review to assess the clinical and radiographic outcome of PEEK cages in the treatment of degenerative disc disorders and/or spondylolisthesis in the cervical spine. The systematic review included all randomized controlled trials and prospective and retrospective nonrandomized comparative studies with a minimum follow-up of 6 months and all noncomparative cohort studies with a long-term follow-up of more than 5 years. The primary outcome variable was clinical performance. Secondary outcome variables consisted of radiographic scores. The MEDLINE, EMBASE, and Cochrane Library databases were searched according to the Preferred Reporting Items of Systematic reviews and Meta-Analyses statement and Metaanalysis Of Observational Studies in Epidemiology guidelines. A total of 223 studies were identified, of which 10 studies were included. These comprised two randomized controlled trials, five prospective comparative trials, and three retrospective comparative trials. The authors found minimal evidence for better clinical and radiographic outcome for PEEK cages compared with bone grafts in the cervical spine. No differences were found between PEEK, titanium, and carbon fiber cages. The authors stated that future studies are needed to improve methodology to minimize bias. Publication of lumbar interbody fusion studies needs to be promoted because differences in clinical and/or radiographic scores are more likely to be demonstrated in this part of the spine.

The Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and Congress of Neurological Surgeons (Ryken et al, 2009) conducted a systematic review to determine the efficacy of cervical interbody grafting techniques. The National Library of Medicine and Cochrane Database were queried using MeSH headings and keywords relevant to cervical interbody grafting. Abstracts were reviewed and studies that met the inclusion criteria were selected. The guidelines group assembled an evidentiary table summarizing the quality of evidence (Classes I-III). Disagreements regarding the level of evidence were resolved through an expert consensus conference. The group formulated recommendations that contained the degree of strength based on the Scottish Intercollegiate Guidelines network. Validation was done through peer review by the Joint Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons. The authors found that autograft bone harvested from the iliac crest, allograft bone from either cadaveric iliac crest or fibula, or titanium cages and rectangular fusion devices, with or without the use of autologous graft or substitute, have been successful in creating arthrodesis after 1- or 2-level anterior cervical discectomy with fusion (Class
II). Alternatives to autograft, allograft, or titanium cages include polyetheretherketone cages and carbon fiber cages (Class III). Polyetheretherketone cages have been used successfully with or without hydroxyapatite for anterior cervical discectomy with fusion. Importantly, recombinant human bone morphogenic protein-2 carries a complication rate of up to 23-27% (especially local edema) compared with 3% for a standard approach. The authors concluded that current evidence does not support the routine use of interbody grafting for cervical arthrodesis. Multiple strategies for interbody grafting have been successful with Class II evidence supporting the use of autograft, allograft, and titanium cages.

The Congress of Neurological Surgeons assessment (Ryken et al, 2009) stated that “class II evidence indicates that either autograft bone harvested from iliac crest, allograft bone from either cadaveric iliac crest or fibula, or titanium cages and rectangular fusion devices, with or without autologous graft or substitute are excellent interbody treatment options for obtaining cervical arthrodesis. There is an expected autograft fusion rate for non-instrumented single-level fusions better than 80% and for 2-level fusion of better than 70%. With allograft, the expected fusion rate for non-instrumented single-level fusion is > 80%, and is > 50% for 2-level fusion. The use of titanium cages carries an expectation of a fusion rate of > 70%, and often > 90% with avoidance of donor site morbidity.” The CNS assessment stated: “In choosing a graft strategy, no single type of graft has not proven consistently superior to the other. Class III evidence suggests that the surgeon consider the increased rate of subsidence with allograft but also understand that subsidence does not correlate with clinical outcome. Class III evidence also suggests that the surgeon factor in the incidence of donor pain and decrease in patient satisfaction reported with the harvest of autograft iliac crest graft.” The assessment stated: “If alternatives to auto- and allograft are preferred, therapeutic options are as follows: PEEK may be considered with or without the use of hydroxyapatite after ACDF. There is an expectation of fusion rates > 90% with fewer complications due to the absence of graft harvesting (Class III). Carbon fiber cages may be considered as well with fusion rates ranging from 55 to 62% in the larger studies (Class III). Polymethyl-methylmethacrylate may be considered to preserve intervertebral distraction after discectomy, but is a poor fusion substrate (Class II). All of the above options appear to have similar clinical outcomes equivalent to the use of bone.” The CNS assessment concluded that, “Given the generally high rates of improved clinical outcome with anterior cervical discectomy and fusion, regardless of methodology, the evaluation of medical-economic factors may play an important role in future studies.”

A Senate Finance Committee Report (2012) focusing on Infuse, one substitute for bone graft, noted that company officials inserted language into studies that promoted the
substitute as a better technique than the autograft technique by emphasizing the pain associated with the autograft technique.

**Chemonucleolysis**

Chemonucleolysis is a procedure that involves the dissolving of the gelatinous cushioning material in an intervertebral disk by the injection of chymopapain or other enzyme. The AHCPR evidence-based guideline on the management of acute back pain and the medical literature supports the use of chemonucleolysis (CNL) with chymopapain as a safe and effective alternative to surgical disc excision in the majority of patients who are candidates for surgery for intractable sciatica due to herniated nucleus pulposus (HNP). Chemonucleolysis involves the enzymatic degradation of the nucleus pulposus, and has been shown to be more effective than percutaneous discectomy since it can be successfully performed for protruded and extruded discs, just as long as the herniated disc material is still in continuity with the disc of its origin. Following CNL, in many cases, relief of sciatica is immediate; however, in up to 30% of patients, maximal relief of symptoms may take up to 6 weeks. The overall success rate for CNL in long-term follow-up (7 to 20 years) in 3,130 patients from 13 contributors averaged 77% (range of 71 to 93%), the same as that reported for surgical discectomy. In the United States, CNL is approved by the Food and Drug Administration (FDA) for use in the lumbar spine only.

**Facet Joint Blocks and Medial Branch Blocks**

Facet injections, also known as facet blocks, are injections of a local anesthetic, with or without a steroid medication, into the facet joints or around the nerve supply (the medial branch nerve) to the joints. Facet injections may be given for diagnostic purposes to determine if the facet joint is the source of pain or it may be performed to treat facet pain that has previously been detected. The injections are fluoroscopically guided. If the pain is relieved, the physician will know that the facet joint appears to be the source of pain. This may be followed with therapeutic injections of anti-inflammatory (steroid) and/or local anesthetic medications to relieve pain for longer periods. Facet denervation may also follow a successful diagnostic facet block.

Degenerative changes in the posterior lumber facet joints have been established as a source of LBP that may radiate to the leg. Pain impulses from the medial branches of lumbar dorsal rami can be interrupted by blocking these nerves with anesthetic (facet block) or coagulating them with a radiofrequency wave (radiofrequency facet denervation). Typically, facet joint blocks are performed as a part of a work-up for back
or neck pain (Wagner, 2003). Pain relief following a precise injection of local anesthetic confirms the facet joint as the source of pain. Based on the outcome of a facet joint nerve block, if the patient gets sufficient relief of pain but the pain recurs, denervation of the facet joint may be considered.

A number of uncontrolled studies have suggested positive effects of facet injections on chronic back pain (Wagner, 2003). However, randomized controlled trials (RCTs) have failed to demonstrated a benefit. A well-designed trial (n = 101) of patients who responded to a local anesthetic injection into the facet joint published in the New England Journal of Medicine found no difference in the likelihood of pain relief following randomization to glucocorticoid or saline facet joint injection at either 1 or 3 months post injection (Carette et al, 1991). A higher proportion of patients in the steroid injection group reported marked improvement after 6 months (46% versus 15%), but the benefit was attenuated after controlling for co-interventions used in the steroid group, and there is no biologic explanation for a delayed benefit from steroids. A second, smaller trial found no differences between steroid and/or bupivacaine injection compared to placebo (Lilius et al, 1989).

A number of systematic evidence reviews and evidence-based guidelines have evaluated the literature on facet injections for chronic back pain. Guidelines from the American Pain Society (Chou et al, 2009) stated: "We found good or fair evidence that ... facet joint injection ... are not effective." Guidelines from the American Association of Neurological Surgeons (Resnick et al, 2005) state: "Facet injections are not recommended as long-term treatment for chronic low-back pain." Guidelines from the American College of Occupational and Environmental Medicine (Hegmann, 2007) state that therapeutic facet joint injections for acute, subacute, chronic low back pain or radicular pain syndrome are "not recommended". An assessment by the Canadian Agency for Drugs and Technologies in Health (Zakaria et al, 2007) concluded: "According to the RCTs [randomized controlled trials] completed to date, FJIs [facet joint injections] with local anesthetics or steroids have not been proven to be superior to placebo for the treatment of chronic LBP [low back pain]. Steroid FJIs have not been proven to be superior to local anesthetic FJIs in the treatment of chronic neck pain secondary to a motor vehicle accident. The studies are limited....." An assessment for BMJ Clinical Evidence (McIntosh and Hall, 2007) concluded that facet injections for chronic back pain are of "unknown effectiveness". A Cochrane systematic evidence review found no clear differences between facet joint glucocorticoid and placebo injections (Staal et al, 2008). A review in UpToDate (Chou, 2009) stated: "Evidence is unavailable, unreliable, or contradictory regarding the effectiveness of glucocorticoid injections for other sites, including ... facet joint injections ......We suggest not performing these procedures for chronic low back pain".
Sacroiliac Joint Injections

Sacroiliac (SI) joint injections are performed by injecting a local anesthetic, with or without a steroid medication, into the SI joints. These injections may be given for diagnostic purposes to determine if the SI joint is the source of the low back pain or it may be performed to treat SI joint pain that has previously been detected/diagnosed. If the pain is relieved, the physician will know that the SI joint appears to be the source of pain. This may be followed up with therapeutic injections of anti-inflammatory (steroid) and/or local anesthetic medications to relieve pain for longer periods.

In a prospective, single-blinded, randomized controlled trial, Jee and colleagues (2014) compared the safety and short-term effects of ultrasound (US)-guided SIJ injections with fluoroscopy (FL)-guided SIJ injections in patients with non-inflammatory SIJ dysfunction (n = 120). All procedures were performed using an FL or US apparatus. Subjects were randomly assigned to either the FL or US group. Immediately after the SIJ injections, fluoroscopy was applied to verify the correct placement of the injected medication and intravascular injections. Treatment effects and functional improvement were compared at 2 and 12 weeks after the procedures. The verbal numeric pain scale and Oswestry Disability Index (ODI) improved at 2 and 12 weeks after the injections without statistical significances between groups. Of 55 US-guided injections, 48 (87.3%) were successful and 7 (12.7%) were missed. The FL-guided SIJ approach exhibited a greater accuracy (98.2%) than the US-guided approach. Vascularization around the SIJ was seen in 34 of 55 patients. Among the 34 patients, 7 had vascularization inside the joint, 23 had vascularization around the joint, and 4 had vascularization both inside and around the joint; 3 cases of intravascular injections occurred in the FL group. The authors concluded that the US-guided approach may facilitate the identification and avoidance of the critical vessels around or within the SIJ. Function and pain relief significantly improved in both groups without significant differences between groups. The US-guided approach was shown to be as effective as the FL-guided approach in treatment effects. However, diagnostic application in the SIJ may be limited because of the significantly lower accuracy rate (87.3%).

Radiofrequency Facet Denervation

Radiofrequency ablation (may also be referred to as RFA, percutaneous radiofrequency neuroablation, radiofrequency coagulation, radiofrequency denervation, radiofrequency lesioning, radiofrequency neuroablation, radiofrequency neurotomy or rhizotomy [articular rhizolysis]) involves the use of radiofrequency energy to denervate a nerve. One of the most commonly performed neuroablative procedures is facet denervation,
which is the destruction or interruption of a facet joint nerve to relieve chronic pain in the cervical, thoracic or lumbar region of the spine.

Facet joints of the spine have joint capsules that are supplied by a branch of the posterior ramus of the spinal nerve. Percutaneous radiofrequency facet denervation, also known as radiofrequency facet joint rhizotomy or facet neurotomy, involves selective denervation using radiofrequency under fluoroscopic guidance. As a method of neurolysis, radiofrequency facet denervation has been shown to be a very safe procedure and can offer relief for many patients with mechanical LBP in whom organic pathology, most commonly a herniated lumbar disc, has been eliminated. According to the literature, it offers advantages over conventional neurolytic agents (e.g., phenol, alcohol, and hypertonic saline) because of its long lasting effects, the relative lack of discomfort, and its completely local action without any random diffusion of the neurolytic agent. Because there are no reliable clinical signs that confirm the diagnosis, successful relief of pain by injections of an anesthetic agent into the joints are necessary before proceeding with radiofrequency facet denervation. Results from many studies have shown that radiofrequency facet denervation results in significant (excellent or good) pain relief, reduced use of pain medication, increased return-to-work, and is associated with few complications. Success rate, however, depends on a careful selection of patients.

**Laser Facet Denervation**

Neuroablative techniques in pain management consist of several surgical and non-surgical methods to denervate a nerve. The goal of denervation is to "shut off" the pain signals that are sent to the brain from the joints and nerves. An additional objective is to reduce the likelihood of, or to delay, any recurrence by selectively destroying pain fibers without causing excessive sensory loss, motor dysfunction or other complications.

Laser ablation involves the use of laser to denervate a nerve. There is a lack of published evidence of laser facet denervation for lumbar facet pain.

**Facet Chemodenervation / Chemical Facet Neurolysis**

Chemical neurolysis (also referred to as chemical ablation, chemical denervation or chemodenervation) involves injection of neurolytic agents (e.g., phenol, alcohol or hypertonic saline) to denervate a nerve. The use of chemical facet injections such as alcohol, phenol and hypertonic saline has been proposed as an option for lumbar facet
pain. However, there is a lack of published data to support the safety and effectiveness of this technique.

**Pedicle Screw Fixation**

Pedicle screw fixation systems consist of steel or titanium plates that are longitudinally inter-connected and anchored to adjacent vertebrae using bolts, hooks, or screws. Pedicle screw fixation in the spine is used to produce a rigid connection between 2 or more adjacent vertebrae in order to correct deformity and to stabilize the spine, thereby reducing pain and any neurological deficits. It is most often used in the lumbosacral spine from L1 through S1, and may also be used in the thoracic spine. Excision of tissues compressing the spinal cord (posterior decompression) is a common treatment for patients with herniated or subluxed vertebrae (spondylolisthesis), degenerative intervertebral discs, certain types of vertebral fractures, or spinal tumors. Spinal instability following decompression may be sufficiently severe to require stabilization by bony fusion (arthrodesis) of affected and adjacent vertebrae using implanted autologous bone grafts. Following placement of the graft, sufficient mechanical stability to allow its incorporation may be provided by combinations of various surgically implanted hooks, rods, or wires. However, severe instability may require surgical implantation of plates or rods anchored to vertebral pedicles using screws (pedicle screw fixation systems) in order to provide rigid 3-column fixation and minimize the risk of incomplete fusion (pseudoarthrosis or pseudarthrosis) or loss of alignment during fusion. The current medical literature suggests that rigid fixation of the lumbar spine with pedicle screws improves the chances of successful fusion as compared with patients with lumbar spine fusion not supplemented with internal fixation. Internal fusion and fixation are major operative procedures with significant risks and according to the available literature should be reserved for patients with spinal instability associated with neurological deficits, major spinal deformities, spinal fracture, spinal dislocation or complications of tumor. Spinal fusion and pedicle screw fixation has been shown not to be effective for the treatment of isolated chronic back pain, and surgery is not advocated to treat this diagnosis in the absence of instability or neurological deficits. In July 1998, the FDA re-classified into Class II the pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute or chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Pedicle screw systems intended for any other uses are considered post-amendment Class III devices for which pre-market approval is required.
Intervertebral Body Fusion Devices (Spine Cages)

A spine cage, also known as an interbody cage, is a small hollow cylindrical device, usually made of titanium, with perforated walls. The device is placed in the disc space between 2 vertebrae to restore lost disc height resulting from a collapsed disc and to relieve pressure on nerve roots. Currently, there are 2 intervertebral body fusion devices approved by the FDA: the BAK Interbody Fusion System (Spine-Tech, Inc.), and the Ray Threaded Fusion Cage (Surgical Dynamics, a subsidiary of United States Surgical Corporation). The BAK (Bagley and Kuslich) Interbody Fusion System and the Ray Threaded Fusion Cage (TFC) are hollow cylinders made of titanium, which may be implanted by anterior or posterior approach. Unlike pedicle screws, both of these fusion devices are permanent implants, as the literature describes bone growing into and through the implant. The safety and effectiveness of these fusion devices have not been established in 3 or more levels to be fused, previous fusion attempt at the involved level(s), spondylolisthesis or retrolisthesis of Grade II or greater. Although the BAK has received FDA approval for implantation laparoscopically, studies performed for FDA approval demonstrated significantly greater incidence of complications from anterior spinal reconstructive surgery using a laparoscopic approach than using an open approach. Furthermore, patients with laparoscopically implanted BAK fusion devices were followed for only 6 months; thus, the long-term stability of laparoscopically implanted BAK cages is unknown. Thus, coverage of laparoscopic (endoscopic) implantation of the BAK should be denied as experimental and investigational. (See discussion of anterior endoscopic spinal reconstructive surgery above).

In a retrospective, database review, Pirkle and colleagues (2019) analyzed the rate of nonunion in patients treated with structural allograft and intervertebral cages in anterior cervical discectomy and fusion (ACDF). These investigators carried out a retrospective analysis of 6,130 patients registered in the PearlDiver national database through Humana Insurance from 2007 to 2016. All ACDF patients with anterior plating who were active in the database for at least 1 year were included in the study. Patients with a fracture history within 1 year of intervention, past arthrodesis of hand, foot, or ankle, or a planned posterior approach were excluded from the study. Patients were stratified by number of levels treated, tobacco use, and diabetic condition. Nonunion rates of structural allograft and intervertebral cage groups after 1 year were compared using Chi-squared analyses. A total of 4,063 patients were included in the allograft group, while 2,067 were included in the cage group. Overall nonunion rates were significantly higher in the cage group (5.32%) than in the allograft group (1.97%) (p < 0.01). When controlling for confounders, increased rates of nonunion were consistently observed in the cage group, achieving statistical significance in 25 of the 26 analyses. The authors
concluded that the increased rate of nonunion associated with intervertebral cages may suggest the superiority of allograft over cages in ACDF. Level of evidence = III.

The authors noted that with any large database, there are weaknesses. The reliability of the reporting and coding was dependent upon multiple sources in an administrative data registry. These researchers were unable to obtain radiographic evidence of nonunion for individual patients and instead relied on the diagnosis codes for nonunion, an important assumption they have made in this study. As this was an observational database study, these investigators were also unable to determine the constitution of each cage placed, whether that be PEEK, titanium, mesh, or porous material. In this analysis, the authors stratified their initial population to account for the 3 most likely confounding variables for nonunion. It was entirely possible that other confounding variables exist and this may affect the analysis. Even with this large database, the nonunion patients whittled down to less than 11 patients in some sub-analyses. One of the limitations of PearlDiver was when patient population size was less than 11, the true number was not revealed because of the potential for patient identification. The authors encountered this in some of their sub-analyses and this limited their ability to analyze the data, particularly where they attempted to control for multiple confounders. These researchers stated that future studies utilizing other data sources with sufficient sample size may be of value in further investigation. However, the PearlDiver data have been widely utilized in peer-reviewed publication. To-date, this study is the largest comparative study examining the fusion rates of ACDF using cages and structural bone graft. The authors’ practice, like the majority of spine surgeons in North America, is to utilize structural bone graft in ACDF. These data suggested that allograft, when available, may be a superior option than the use of a cage in achieving arthrodesis in the cervical spine.

Key points in this study: Both structural allograft and intervertebral cage groups experienced high fusion rates. When comparing nonunion rates, these data suggested the superiority of allograft in ACDF. While the use of a cage and non-structural bone graft material remains an important surgical option, the use of allograft, when donor bone is available, may be preferable in achieving solid arthrodesis.

**Vertebroplasty**

Percutaneous polymethylmethacrylate vertebroplasty (PPV) is a therapeutic, interventional radiologic procedure, which consists of the injection of an acrylic bone cement (usually methyl methacrylate) into a cervical, thoracic or lumbar vertebral body lesion for the relief of pain and the strengthening of bone. The procedure is performed
under fluoroscopic guidance with local anesthesia and moderate sedation. This procedure is being used for patients with lytic lesions due to bone metastases, aggressive hemangiomas, or multiple myeloma, and for patients who have medically intractable debilitating pain resulting from osteoporotic vertebral collapse.

Examples of PMMA include, but may not be limited to, Ascendx Cement, Cobalt HV, Cobalt V Radiopaque Vertebroplasty Bone Cement, Cohesion, Kyphx HV-R, Opacity+, Osteopal, Osteopal V, SPACE CpsXL, Spine-Fix Biomimetic Bone Cement, StabiliT ER, Vertecern and Vertefix Radiopaque Bone Cement. An alternative to traditional bone cement is Cortoss Bone Augmentation Material. Cortoss is an injectable, non-resorbable synthetic material that functions as a strengthening agent for injection into vertebral bodies with compression fractures.

Results from two uncontrolled prospective studies and several case series reports, including one with 187 patients, indicated that percutaneous vertebroplasty can produce significant pain relief and increase mobility in 70% to 80% of patients with osteolytic lesions in the vertebrae. In these reports, pain relief was apparent within 1 to 2 days after injection, and appeared to persist for at least several months up to several years. While experimental studies and preliminary clinical results suggest that percutaneous vertebroplasty can also strengthen the vertebral bodies and increase mobility, it remains to be proven whether this procedure can prevent additional fractures in the injected vertebrae. In addition, the duration of effect was not known; there were no long-term follow-up data on most of these patients, and these data may be difficult to obtain and interpret in patients with an underlying malignant process because disease progression may confound evaluation of the treatment effect. Complications were relatively rare, although some studies reported a high incidence of clinically insignificant leakage of bone cement into the paravertebral tissues. In a few cases, the leakage of polymer caused compression of spinal nerve roots or neuralgia. Several instances of pulmonary embolism were also reported.

The FDA (2004) notified healthcare professionals about complications related to the use of polymethylmethacrylate bone cement to treat osteoporotic compression fractures of the spine using vertebroplasty and kyphoplasty. Reported complications, such as soft tissue damage and nerve root pain and compression, are related specifically to the leakage of bone cement. Other reported complications include pulmonary embolism, respiratory and cardiac failure, and death.

Percutaneous vertebroplasty is an in-patient procedure because it may cause compression of adjacent structures and require emergency decompressive surgery. In addition, radiation therapy or concurrent surgical interventions, such as laminectomy,
may also be required in patients with compression of the spinal cord due to ingrowth of a tumor. An assessment of percutaneous vertebroplasty by the National Institute for Clinical Excellence (NICE, 2003) concluded that "current evidence on the safety and efficacy of percutaneous vertebroplasty appears adequate".

However, 2 subsequently published RCTs published in the *New England Journal of Medicine* have found no significant benefit with vertebroplasty. In the Investigational Vertebroplasty Safety and Efficacy Trial (INVEST), Kallmes et al (2009) reported that pain and disability outcomes at 1 month in a group of patients who underwent vertebroplasty were similar to those in a control group that underwent a sham procedure. In the other trial, Buchbinder et al (2009) measured pain, quality of life, and functional status at 1 week and at 1, 3, and 6 months after sham and active vertebroplasty and found there were no significant between-group differences at any time point. As in INVEST, patients in the 2 study groups had improvement in pain.

The Society for Interventional Radiology (SIR, 2009) had identified a number of issues in interpreting these studies, including potential biases in patient selection, the use of vertebroplasty in older (greater than 3 months) fractures, and a potentially inadequate amount of polymethylmethacrylate (PMMA) that was injected into the vertebrae. The SIR concluded: "We recognize the value of randomized controlled trials and evidence-based medicine. But based on the above-discussed weakness in the studies and the degree of discordance between the outcomes of these studies, prior studies and experience, we believe it is premature and possibly incorrect – to conclude that vertebroplasty is no better than a control sham procedure (trigger point, facet injection). We suggest waiting for the results of the VERTOSS 2 trial to be published and encourage larger clinical trials to address the weaknesses of the two *New England Journal of Medicine* articles".

In a retrospective study, He and colleagues (2008) examined if a repeat percutaneous vertebroplasty (PV) is effective on pain-relief at the vertebral levels in patients who had previously undergone PV. Of the 334 procedures of PV performed in 242 patients with osteoporotic vertebral compression fractures from October 2000 to June 2006 in the authors' institute, 15 vertebrae in 15 patients with unrelieved pain in 4 to 32 days after an initial PV were treated with a repeat vertebroplasty. The clinical outcomes were assessed by measurements of visual analog scale (VAS), and the imaging features were analyzed pre- and post-procedure. The mean volume of polymethylmethacrylate injected in each vertebra was 4.0 ml (range of 1.5 to 9 ml) in the repeat PV. During the first month of follow-up after repeat PV in this series, a mean VAS scores of the pain level was reduced from 8.6 (range of 7 to 10) pre-procedure to 1.67 points (range of 0 to 4) post-procedure, with a mean reduction of 6.93 points (range of 4 to 8). Complete and
Partial pain relief were reached in 11 (73%) and 4 patients (27%), respectively in a mean follow-up of 15 months. No serious complications related to the procedures occurred, however asymptomatic polymethylmethacrylate leakage around vertebrae was demonstrated on radiograph or computed tomography in 2 patients. The authors concluded that the outcomes of this series suggested that repeat PV is effective at the same vertebral levels in patients without pain-relief who underwent previous PV. Absent or inadequate filling of cement in the unstable fractured areas of the vertebral body may be responsible for the unrelieved pain after the initial PV.

An accompanying editorial by Kallmes (2008) of the afore-mentioned article stated that "[u]nfortunately, limitations in the current study likely preclude definitive answers, but still the series may help focus future studies". The editorialist also noted that while the authors found insufficient or absent filling in 100% of the failed cases, they did not provide any information regarding the frequency in which they had insufficient or absent filling in the other 227 (successful) cases. Furthermore, Kallmes is still somewhat concerned about the safety of the repeat procedure.

Absolute contraindications to percutaneous vertebroplasty or kyphoplasty (balloon-assisted vertebroplasty) include, but may not be limited to, the following:

- Allergy to bone cement or contrast media; or
- Asymptomatic vertebral compression fractures; or
- Individual is improving with medical therapy; or
- Nonfractured vertebral levels; or
- Ongoing local or systemic infection; or
- Osteomyelitis of the target vertebra; or
- Prophylactic treatment for osteoporosis to prevent future fractures; or
- Retropulsed bone fragment resulting in myelopathy; or
- Spinal canal compromise secondary to tumor resulting in myelopathy; or
- Uncorrected coagulation disorders.

Relative contraindications to percutaneous vertebroplasty include, but may not be limited to, the following:

- Asymptomatic retropulsion of a fracture fragment causing significant spinal compromise; or
- Asymptomatic tumor extension into the epidural space; or
- Radiculopathy in excess of vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse.
Kyphoplasty

Kyphoplasty (also known as balloon-assisted vertebroplasty) is a minimally-invasive orthopedic procedure, which has been developed to restore bone height lost due to painful osteoporotic compression fractures. It is a modification of the vertebroplasty procedure, and involves the insertion of 1 or 2 balloon devices into the fractured vertebral body. Once inserted, the surgeon inflates the balloon(s) to create a cavity and to compact the deteriorated bone with the intent to restore vertebral height. The balloon(s) are then removed and the newly created cavity is filled with the surgeon's choice of bone filler material, creating an internal cast for the fractured area.

The Kiva VCF Treatment System is an implantable device which has been proposed for use with a vertebroplasty or kyphoplasty procedure for reduction and treatment of spinal fractures. PMMA bone cement is used to fill the implant once it is placed.

An assessment of balloon kyphoplasty by the National Institute for Health and Clinical Excellence (NICE, 2006) concluded that "[c]urrent evidence on the safety and efficacy of balloon kyphoplasty for vertebral compression fractures appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance". The NICE assessment reviewed 3 non-randomized studies, 2 of which compared balloon kyphoplasty with conventional medical care (physical and analgesic therapy) and 1 which compared the procedure with vertebroplasty. All 3 studies found that patients who had undergone balloon kyphoplasty had improved pain scores compared with the control group at a maximum follow-up of 24 months. The assessment noted that the specialist advisors to NICE expressed uncertainties about whether the improvements following balloon kyphoplasty (reduced pain and height restoration) are maintained in the long term. In clinical studies, the most common complication following balloon kyphoplasty was cement leakage, occurring in up to 11% of patients. Other potential complications of kyphoplasty include infection, allergy, and spinal cord or nerve root injury caused by incorrect needle placement.

Based on the results of an assessment, the Ontario Ministry of Health and Long Term Care (2004) reached the following conclusions about balloon kyphoplasty: "There are currently two methods of cement injection for the treatment of osteoporotic VCFs. These are vertebroplasty and balloon kyphoplasty. Although no RCT has been conducted to compare the two techniques, the existing evidence shows that balloon kyphoplasty is a reasonable alternative to vertebroplasty, given the lower reported peri-operative and long-term complications of balloon kyphoplasty".
Wardlaw et al (2009) reported positive results with kyphoplasty compared with non-surgical care in a non-blinded, multi-center RCT. The investigators randomly assigned 300 adults with 1 to 3 acute vertebral fractures to kyphoplasty (n = 149) or non-surgical care (n = 151). At 1 month, mean SF-36 Physical Component Score (PCS) improved by 7.2 points (95% confidence interval [CI]: 5.7 to 8.8) in the kyphoplasty group, and by 2.0 points (95% CI: 0.4 to 3.6) in the non-surgical group, a difference between groups that was statistically significant (p < 0.0001). The investigators reported that the frequency of adverse events did not differ between groups. There were 2 serious adverse events related to kyphoplasty (hematoma and urinary tract infection); other serious adverse events (such as myocardial infarction and pulmonary embolism) did not occur peri-operatively and were not related to procedure.

The California Technology Assessment Forum (Karliner, 2009) concluded that balloon kyphoplasty meets CTAF criteria for safety, effectiveness and improvement in health outcomes for the treatment of recent (less than 3 month old) osteoporotic vertebral compression fractures confirmed by MRI.

**Sacroplasty**

Sacroplasty is a variation of the vertebroplasty technique, and involves the injection of polymethylmethacrylate cement into sacral insufficiency fractures for stabilization. Under fluoroscopic guidance, PMMA is injected into the sacrum at the fracture site, in an attempt to stabilize the fracture. Sacral insufficiency fractures (SIFs) can cause LBP in osteoporotic patients. Symptomatic improvement may require up to 12 months. Treatment includes limited weight-bearing and bed rest, oral analgesics, and sacral corsets. Significant mortality and morbidity are associated with pelvic insufficiency fractures. Percutaneous sacroplasty is being developed as an alternative treatment for SIF patients.

Frey et al (2007) reported on a prospective observational cohort study of the safety and efficacy of sacroplasty in consecutive osteoporotic patients with SIFs. Each procedure was performed under intravenous conscious sedation using fluoroscopy. Two bone trochars were inserted between the sacral foramen and sacroiliac joint through which 2 to 3 ml of polymethylmethacrylate was injected. A total of 37 patients, 27 females, were treated. Mean age was 76.6 years, and mean symptom duration was 34.4 days. All patients were available at each follow-up interval except 1 patient who died due to unrelated pulmonary disease before the 4-week follow-up. The investigators reported that mean VAS score at baseline was 7.7 and 3.2 within 30 mins, and 2.1 at 2, 1.7 at 4, 1.3 at 12, 1.0 at 24, and 0.7 at 52 weeks post-procedure. The investigators found that
improvement at each interval and overall was statistically significant using the Wilcoxon Rank Sum Test. One case of transient S1 radiculitis was encountered. The investigators concluded that sacroplasty appears to be a safe and effective treatment for painful SIF. Limitations of this study include its small size, limited duration of follow-up, and lack of control group.

Vesselplasty

Vesselplasty (Vessel-X, A-Spine Holding Group Corp., Taipei, Taiwan) is an image-guided procedure that attempts to solve the problem of cement leakage out of the vertebral body, which can happen during both vertebroplasty and kyphoplasty. Cement leakage, a common problem with vertebroplasty particularly in lytic lesions (Mathis and Wong, 2003), has been reported in up to 30% to 70% of cases. Most occurrences, however, are asymptomatic (Cortet et al, 1997). Vesselplasty uses a porous polyethylene terephthalate balloon to create both a cavity and contain the cement, thereby, allowing only a small amount of cement to permeate into the vertebral body.

Flors et al (2009) evaluated the use of vesselplasty to treat symptomatic vertebral compression fractures (VCFs) in 29 patients. All patients had been undergoing medical therapy for 1 or more painful VCFs. Pain, mobility, and analgesic use scores were obtained, and restoration of vertebral body height was evaluated. A 2-tailed paired Student's t test was used to compare differences in the mean scores for levels of pain, mobility, and analgesic use before and after the procedure and to evaluate changes in vertebral body height. Seven of the 29 patients had fractures in more than 1 level, for a total of 37 procedures. The cause of the vertebral collapse was osteoporosis in 27 (73%), high-impact trauma in 5 (13.5%), myeloma in 3 (8%), and metastatic fracture in 2 (5.4%). The average pain score before treatment was 8.72 +/- 1.25 (SD), whereas the average pain score after treatment was 3.38 +/- 2.35. The average mobility score before treatment was 2.31 +/- 1.94, whereas the average mobility score after treatment was 0.59 +/- 1.05 (p < 0.001). The average analgesic use score before treatment was 3.07 +/- 1.46, whereas it was 1.86 +/- 1.90 after treatment (p < 0.001). There was no evidence of clinical complications. The authors concluded that vesselplasty offers statistically significant benefits in improvements of pain, mobility, and the need for analgesia in patients with symptomatic VCFs, thus providing a safe alternative in the treatment of these fractures.

While vesselplasty appears to be a promising new technique for VCFs, there is insufficient evidence of its safety and effectiveness. Prospective, randomized, controlled studies with a larger number of patients and long-term follow-up are needed.
**Epiduroscopy**

Epiduroscopy involves insertion of a fiberoptic camera through the sacral hiatus into the lower epidural space, which is then guided upwards towards the lower lumbar discs and nerve roots. Epidural adhesions can be released and anesthetic and steroid injected around nerve roots. In September 1996, the epiduroscope (myeloscope) was cleared by the FDA for visualization of the epidural space. It has been used in the outpatient setting for the diagnosis and treatment of intractable LBP. Insertion of this miniature fiberoptic scope into the epidural space allows direct visualization of scarring and placement of a catheter through which fluid is injected under pressure to break down scar tissue and lyse adhesions. Although a number of pain treatment centers advertise the availability of this technique and claim it to be successful, there is insufficient scientific evidence in the peer-reviewed medical literature to support the clinical utility of this technique for diagnosis or therapy in patients with spinal pain syndromes, including those with failed back surgery syndromes. Moreover, currently available non-invasive technologies allow adequate visualization of the epidural space to confirm pathology contained therein. An assessment of epiduroscopy for the Australian Safety and Efficacy Register of New Intervventional Procedures (ASERNIP-S, 2003) concluded that "[t]here is little high-quality evidence available on the safety and efficacy of epiduroscopically guided surgery/drug delivery... More studies are needed to compare the safety and efficacy of epiduroscopy relative to other procedures". An assessment by the National Institute for Clinical Excellence (NICE, 2004) concluded that "current evidence on the safety and efficacy of endoscopic epidural procedures does not appear adequate for these procedures to be used without special arrangements for consent and for audit or research." The NICE assessment found that "The studies identified were small and uncontrolled. Some measures used in these studies to assess outcomes, such as scores of pain and function, were of unknown validity".

**Epidural Lysis of Adhesions**

Epidural lysis of adhesions is a pain management procedure that has been proposed as a method to relieve chronic back pain. This procedure may also be known as adhesiolysis, endoscopic adhesiolysis, epidurolysis, percutaneous adhesiolysis or percutaneous epidural neuroplasty. It differs from epidural injections as it attempts to treat the neural (nerve) adhesions that cause the pain. Epidural lysis of adhesions can be performed by use of a fiberoptic endoscope (epiduroscopy), percutaneously with the use of a catheter (flexible tube) or with the more specialized Racz catheter.
In epiduroscopy, normal saline is injected into the sacral canal to distend and decompress the epidural space; purportedly the fiberoptic endoscope can then directly disrupt the fibrosis, scar tissue or adhesions. This procedure is generally an outpatient procedure utilizing local anesthesia and light sedation.

In the percutaneous procedure utilizing the Racz catheter, the specialized epidural catheter is inserted under fluoroscopy via the sacral canal. The injection of dye (an epidurogram) may indicate the area of adhesions and provide a way to perform lesion-specific lysis utilizing the flexible wire embedded catheter. Local anesthetic, corticosteroid and hypertonic sodium chloride solution injections via the catheter are performed daily for three days. During this time the catheter is left in place and the individual is generally hospitalized.

A similar version of the procedure involves a single use catheter (instead of the Racz catheter) which is removed after the lysis is completed. The procedure may be repeated at a later date, but would require a new catheter placement.

The Racz catheter is a small caliber, flexible catheter that is introduced into the sacral hiatus and into the lumbro-sacral epidural space. The Racz catheter is used to release adhesions deliver steroids and anesthetics into the epidural space. There is no evidence from adequate well-designed RCTs in the peer-reviewed medical literature supporting the safety and effectiveness of manipulation of an indwelling epidural Racz catheter or epidural injections of hypertonic saline or hyaluronidase to relieve back pain in patients with epidural adhesions, adhesive arachnoiditis, or failed back syndrome from multiple previous surgeries for herniated lumbar disk. The Racz epidural catheter was cleared by the FDA based on a 510(k) pre-market notification (PMN) due to FDA's judgment that the device was "substantially equivalent" to devices that were marketed prior to the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act; thus, the manufacturer was not required to provide the evidence of effectiveness that is necessary to support a pre-market approval (PMA) application. Most of the reported studies of the Racz catheter are retrospective (Racz and Holubec, 1989; Manchikanti et al, 2001; Manchikanti et al, 1999) or lacking a control group (Racz et al, 1999). Manchikanti, founder and president of the American Society of Interventional Pain Physicians (ASIPP), is a leading advocate of the use of the Racz catheter (Manchikanti et al, 1999; Manchikanti and Bakhit, 2000; Manchikanti and Singh, 2002). He is lead author of ASIPP guidelines which incorporate the Racz catheter into the management of chronic spinal pain (Manchikanti et al, 2003). Manchikanti et al (2001, 2004) has reported the results of 2 controlled clinical studies of the Racz catheter in the ASIPP’s official journal Pain Physician. One of these studies involved 45 patients with chronic LBP, 30 of whom received Racz catheter treatment, and a control group of 15 patients who did not
receive Raczk catheter treatment. The study was unblinded and utilized a biased control group, as control group subjects were patients who refused Raczk catheter treatment, either because coverage was denied by their insurer or for other reasons (Manchikanti et al, 2001). In another study, subjects with chronic LBP were randomized to a sham control group or 2 treatment groups (n = 25 in each group). Nineteen of 25 subjects in the control group were unblinded or lost to follow-up before completion of the 12-month study (Manchikanti et al, 2004). Both of these controlled clinical studies involve small groups of patients and are from the same group of investigators from a single private practice, raising questions about the generalizability of the findings (Manchikanti et al, 2001; Manchikanti et al, 2004). The small sample sizes of these studies do not allow adequate evaluation of potential adverse outcomes that may occur with the procedure (Fibuch, 1999). A Joint Health Technology Assessment of the German Medical Association and the German National Association of Statutory Health Insurance Physicians (KBV, 2003) concluded that, "due to insufficient evaluation and lack of empirical data, at present there is no convincing evidence for the efficacy or effectiveness of the Raczk treatment procedure".

The National Institute for Clinical Excellence (NICE, 2004) assessed mobilization and division of epidural adhesions, and concluded that "[c]urrent evidence on the safety and efficacy of endoscopic division of epidural adhesions does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research". The assessment noted that studies of epidural lysis of adhesions are "small and uncontrolled". In addition, NICE noted that "[s]ome measures used in the studies to assess outcomes, such as scores of pain and function, were of unknown validity". NICE stated that the main safety concerns are infection, bleeding, neurological damage, epidural hematoma, and damage to the nerve roots or cauda equina.

Veihelmann et al (2006) examined if epidural neuroplasty is superior to conservative treatment with physiotherapy in treating patients with chronic sciatica with or without LBP. A total of 99 patients with chronic LBP were enrolled in this study and randomly assigned into either a group with physiotherapy (n = 52) or a second group undergoing epidural neuroplasty (n = 47). Patients were assessed before and 3, 6, and 12 months after treatment by a blinded investigator. After 3 months, the VAS score for back and leg pain was significantly reduced in the epidural neuroplasty group, and the need for pain medication was reduced in both groups. Furthermore, the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced until 12 months after the procedure in contrast to the group that received conservative treatment. The authors concluded that epidural neuroplasty results in significant alleviation of pain and functional disability in patients with chronic LBP and sciatica based on disc protrusion/prolapse or failed back surgery on a short-term basis as well as at 12 months
of follow-up. Moreover, these investigators stated that further prospective randomized double-blinded studies are needed to prove the effectiveness of epidural neuroplasty in comparison to placebo and in comparison to open discectomy procedures.

**Microsurgical Anterior Foraminotomy**

Microsurgical anterior foraminotomy has been developed to improve the treatment of intractable cervical radiculopathy. This new technique provides direct anatomical decompression of compressed nerve roots by removing the compressive spondylotic spur or disc fragments through the holes of unilateral anterior foraminotomies. Using microsurgical instruments, the surgical approach exposes the lateral aspect of the spinal column through a small incision at the front of the neck in a naturally occurring crease. The affected nerve root is exposed, and a herniated disc or bone spur is removed to decompress the nerve. By removing only the herniated portion of the disc, the procedure is intended to preserve normal disc function and avoid bone fusion. As it utilizes a microsurgical technique that minimizes laminectomy and facet trauma, this technique does not require bone fusion or post-operative immobilization. However, there is a paucity of clinical studies to validate the effectiveness of this approach. The studies reported in the medical literature involve a small number of patients, are published by just one author, and a considerable portion of each article discusses only the technical aspects of the procedure.

**Open Sacroiliac Fusion**

Sacroiliac fusion involves bony fusion of the sacroiliac joint for stabilization. Sacroiliac joint (SIJ) fusion has been suggested as a possible treatment option for individuals with low back pain due to sacroiliac joint dysfunction or syndrome. This procedure may be performed by an open surgical approach or as a minimally invasive procedure in order to place plates and/or screws to develop a bony fusion across the SIJ for stabilization. There is insufficient scientific evidence to support use of sacroiliac fusion in treating LBP due to sacroiliac joint syndrome.

In the 1920's, sacroiliac dysfunction was a common diagnosis and fusion of this joint was the most common form of back surgery. However, there is little evidence that the sacroiliac joint is a common source of back pain. European guidelines on the diagnosis and treatment of pelvic girdle pain (Vleeming et al, 2004) recommend against the fusion of sacroiliac joints. The guidelines note that severe traumatic cases of pelvic girdle pain can be an exception to this recommendation, but only when other non-operative treatment modalities have failed. In that case, pre-operative assessment with an external...
fixator for 3 weeks to evaluate longer lasting effects of fixation, is recommended (Wahlheim, 1984; Slatis and Eskola, 1989; Sturesson et al, 1999). The authors identified no controlled trials of sacroiliac fusion. Available evidence consists of cohort studies (level D evidence) (Smith-Petersen and Rogers, 1926; Gaenslen, 1927; Hagen, 1974; Olerud and Wahlheim, 1984; Waisbrod et al, 1987; Moore, 1995; Keating, 1995; Belanger and Dall, 2001; Berthelot et al, 2001; van Zwienen et al, 2004; Giannikas et al, 2004). The guidelines note that, in all reports of fusion surgery, an operation took place only on patients in whom non-operative treatment had been unsuccessful. The cohort studies included from 2 to 77 patients and the results were assessed by the authors as fair to excellent in 50 to 89% of the patients. However, controlled studies are necessary to reach firm conclusions about the effectiveness of this procedure in the treatment of back pain.

Guidelines on treatment of LBP from the Colorado Department of Labor and Employment (2005) state that sacroiliac joint fusion is of limited use in trauma and is considered to be under investigation for patients with typical mechanical LBP: "Until the efficacy of this procedure for mechanical low back pain is determined by an independent valid prospective outcome study, this procedure is not recommended for mechanical low back pain".

Microdiskectomy

Discectomy (diskectomy) is the most common surgical treatment for ruptured or herniated discs, particularly of the lumbar spine, though it may also be used on the cervical or thoracic spine. During a discectomy, the surgeon removes the section of the disc that is protruding from the disc wall and any other disc fragments that may be pressing on a nerve root or the spinal cord. A discectomy may be "open" or it may be performed microscopically (known as a microdiscectomy). Both procedures allow for direct visualization of the vertebra, disc and other surrounding structures. The microdiscectomy utilizes a special microscope or magnifying instrument to view the disc and nerves, which makes it possible to remove the disc material through a smaller incision. This smaller incision reduces the risk of damage to the surrounding tissues, which decreases the potential complications.

Endoscopic Diskectomy

There is insufficient evidence from clinical studies proving additional benefits from using an endoscope for performing disc decompression (such as in percutaneous endoscopic discectomy or endoscopic laser percutaneous discectomy (LASE)). At this time there are
no reliable clinical studies of endoscopic spinal surgery that have included an adequate comparison group of patients receiving open procedures. In addition, there is limited evidence on the long-term outcomes resulting from these endoscopic procedures. Gibson et al (2002), reporting on the results of a systematic review of studies on surgery for lumbar disc prolapse, explained that "[t]here is currently no evidence supporting endoscopic... treatment of disc prolapse".

**Yeung Endoscope Spine Surgery (Arthroscopic Microdiskectomy, Percutaneous Endoscopic Diskectomy with or without Laser (PELD))**

An arthroscopic microdiscectomy, also known as a percutaneous endoscopic discectomy (PED), has been proposed as another alternative to the traditional open procedure or the microdiscectomy. A cannula is inserted, with fluoroscopic guidance, near the spine through which an endoscope and very small surgical instruments are then inserted. The herniated portion of the disc can then be removed. This procedure does not allow direct visualization of the disc or surrounding tissues and is generally performed under conscious sedation, rather than general anesthesia. Examples of devices used in an arthroscopic microdiscectomy/percutaneous endoscopic discectomy include, but may not be limited to, the AccuraScope DND, Joimax iLESSYS, Joimax TESSYS or Yeung Endoscopic Spinal System (Y.E.S.S.).

Yeung Endoscopic Spinal Surgery (YESS) (also known as arthroscopic microdiskectomy or percutaneous endoscopic diskectomy (PELD)) is an endoscopic approach to lumbar disc surgery that involves a multi-channel scope and special access cannulae that allow spinal probing in a conscious patient, diagnostic endoscopy, and "minimally invasive surgery" (Yeung and Porter, 2002). The Yeung Endoscope Spine System (Y.E.S.S.) (Richard Wolf Surgical Instrument Corp., Vernon Hills, IL) or similar specialized instruments may be used to perform these procedures. The spinal endoscope is used to direct probing and targeted fragmentectomy of disc herniations. In addition, the approach may be used for foraminoplasty, where an endoscope-assisted laser is used to widen the exit route foramina of the lumbar spine and ablate any protruding portions of the intervertebral disk. Typically, procedures are performed at several levels of the spine, either simultaneously or in close temporal succession. Other adjunctive therapeutic procedures may be performed such as applying chemonucleolytic agents, lasers, radiofrequency technology, electrothermal energy, flexible mechanical instruments or intradiscal steroids. Supporters of arthroscopic microdiskectomy state that it provides visualization at the same time as application of therapeutic services. In addition, they argue that the ability to provoke pain while the patient is in the aware state and able to communicate during surgery allows the surgeon to better identify and treat the source.
of the patient's back pain. However, there is inadequate evidence to determine whether the results of arthroscopic microdiskectomy are as durable or as effective as open spinal surgery. A particular concern is whether this microendoscopic approach allows for adequate visualization of the spine during surgery. Literature to date on arthroscopic microdiskectomy has been limited to review articles and reports of retrospective case series. There are no published prospective, RCTs of arthroscopic microdiskectomy, and there are no prospective studies with long-term follow-up. In addition, the studies of Y.E.S.S. that have been published thus far have been from a single investigator group, raising questions about the generalization of the findings. Thus, arthroscopic microdiskectomy does not meet Aetna’s criteria.

**Minimally Invasive Lumbar Decompression Procedures**

Minimally invasive approaches for laminectomy, laminotomy, foraminectomy or foraminotomy have also been proposed as a newer treatment option by some surgeons. They may utilize either an endoscopic or laparoscopic approach for the procedure, which allows direct visualization of the surgical field.

Additionally, percutaneous procedures have been proposed as an alternative surgical approach for laminectomy, laminotomy, foraminectomy or foraminotomy. The percutaneous procedures are generally performed in an outpatient setting with the individual awake but sedated. Percutaneous spinal procedures do not allow direct visualization of the surgical field. Examples of percutaneous image-guided decompression procedures for lumbar spinal stenosis are the MILD procedure and decompression with the Totalis Direct system, both of which utilize trocars to access the area of stenosis (resection of the ligamentum flavum).

The North American Spine Society defines an open procedure done through an incision of approximately one inch or more. Minimally invasive lumbar decompression is performed through small incisions of less than 1 inch. Minimally invasive lumbar decompression procedures include those performed under direct visualization using specialized tubular retractors, and procedures performed under indirect visualization.

These approaches are not supported by reliable evidence in the peer reviewed published medical literature. These centers typically advertise their "unique" methods of performing spine surgery through very small portals using specialized instruments that often have been developed by the centers themselves. These procedures are often performed while the patient is conscious under moderate sedation. Typically, several surgical procedures are performed at multiple levels simultaneously or on successive
days until the patient reports pain relief or surgery is exhausted. Proponents argue that these procedures involve fewer anesthetic risks, a smaller incision, reduced blood loss, faster post-operative recovery and performance of surgery in an outpatient setting.

An important concern about this minimally invasive approach is the limited visualization of the spine, such that the surgeon cannot reliably identify and ensure complete removal all bone spurs and other structures impinging on nerves. In addition, the performance of several surgical procedures in close temporal succession does not allow adequate evaluation of the outcomes of one surgical procedure before subsequent surgical procedures are performed.

One center advertises that they manufacture special instruments and develop new techniques to perform complex microscopic laser spinal surgeries through portals of 1/4 to 1/2 of an inch under conscious sedation. They state that they have developed "unique" methods of performing endoscopic surgeries. The center states that they are the only facility that performs endoscopic spinal joint surgery, thoracic laser discectomy, endoscopic sacroiliac joint surgery, endoscopic hardware removal, or endoscopic bio-absorbable fusions or intradiscal stem cell therapy. The center also asserts that their unique minimally invasive spine surgery techniques are so advanced that patients who have failed other minimally invasive or conventional spine surgeries may benefit from their procedures. The center advertises that they have performed over 7,000 of these minimally invasive spinal surgeries. Although they state that they regularly publish their findings in peer-reviewed journals, what evidence they have published is limited to small, uncontrolled case series focusing on short-term followup (Haufe et al, 2008; Haufe and Mork, 2007; Haufe and Mork, 2006; Haufe and Mork, 2005; Haufe and Mork, 2004).

Another center makes similar claims for the effectiveness of unique endoscopic laser spinal surgical procedures performed under conscious sedation with patented instruments. The center performs spinal procedures using videoendoscopy and specially adapted surgical probes. Procedures include specialized methods of laser diskectomy, laser lumbar facet debridement, laser foraminoplasty, and laser debridement of spinal processes. The center's website includes testimonials and a list of abstracts presented at meetings, but the center has not published the results of their procedures in peer-reviewed publications. The center recently announced initiation of an outcome study to evaluate outcomes of their procedures in persons with failed back syndrome.

Another center offers unique endoscopic laser methods of performing surgery for back and neck pain. The primary procedures include foraminotomy, laminotomy, percutaneous endoscopic discectomy, and facet thermal ablation. The center advertises
the ability to complete all necessary evaluation, pre-operative preparation, surgery, and post-operative physical therapy within 1 week. The center advertises that advantages of their method of minimally invasive surgery includes no general anesthesia, no hospitalization, minimally invasive surgery, minimal scar tissue formation, and the availability of outpatient procedures. The center states that the most prominent difference between their techniques and that of other spinal centers is the endoscopic method in which they enter the body to minimize trauma, scar tissue formation, and healing times. The center states that their surgeons have performed approximately 10,000 surgeries collectively for over 10 years. Their website includes testimonials. However, they have not submitted their results for peer-review publication.

Minimally Invasive Lumbar Decompression (MILD)

MILD (Vertos Medical) is a new procedure for pain relief from symptomatic central lumbar canal stenosis. It entails limited percutaneous laminotomy and thinning of the ligamentum flavum in order to increase the critical diameter of the stenosed spinal canal.

In a retrospective study, Lingreen and Grider (2010) examined the minor adverse events and peri-procedural course associated with the MILD procedure. In addition, these researchers evaluated the effectiveness of the procedure with regard to pain relief and functional status. A total of 42 consecutive patients meeting MRI criteria for MILD underwent the procedure performed by 2 interventional pain management physicians working at the same center. The pre- and post-procedure VAS as well as markers of global function were recorded. Major and minor adverse events were tracked and patient outcomes reported. There were no major adverse events reported. Of the minor adverse events, soreness lasting 3.8 days was most frequently reported. No patients required over-night observation and only 5 required post-operative opioid analgesics. Patients self-reported improvement in function as assessed by ability to stand and ambulate for greater than 15 mins, whereas prior to the procedure 98% reported significant limitations in these markers of global functioning. Visual analog pain scores were significantly decreased by 40% from baseline; 86% of the patients reported that they would recommend the MILD procedure to others. The authors concluded that the MILD procedure appears to be a safe and likely effective option for treatment of neurogenic claudication in patients who have failed conservative therapy and have ligamentum flavum hypertrophy as the primary distinguishing component of the stenosis.
In a multi-center, non-blinded, prospective clinical study, Chopko and Caraway (2010) evaluated the clinical application and patient safety and functional outcomes of the MILD procedure in the treatment of symptomatic central canal spinal stenosis. A total of 78 patients were enrolled in the MiDAS I Study and treated with the MILD procedure for lumbar decompression. Of these patients, 6-week follow-up was available for 75 patients. Outcome measures were VAS, Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2 Health Survey. Outcomes were assessed at baseline and 6 weeks post-treatment. There were no major device or procedure-related complications reported in this patient cohort. At 6 weeks, the MiDAS I Study showed statistically and clinically significant reduction of pain as measured by VAS, ZCQ, and SF-12v2. In addition, improvement in physical function and mobility as measured by ODI, ZCQ, and SF-12v2 was statistically and clinically significant in this study. In this 75-patient series, and in keeping with a previously published 90-patient safety cohort, the MILD procedure proved to be safe. Further, based on near-term follow-up, the MILD procedure showed efficacy in improving mobility and reducing pain associated with lumbar spinal canal stenosis. Limitations of this study were:

I. this was a preliminary report encompassing only a 6-week follow-up, and

II. there was no control group.

1. this was a preliminary report encompassing only a 6-week follow-up, and
2. there was no control group.

Deer and Kapural (2010) assessed the acute safety of the MILD procedure. Manual and electronic chart survey was conducted by 14 treating physicians located in 9 states within the United States on 90 consecutive patients who underwent the MILD procedure. Patients requiring lumbar decompression via tissue resection at the peri-laminar space, within the inter-laminar space and at the ventral aspect of the lamina were treated. Data collected included any complications and/or adverse events that occurred during or immediately following the procedure prior to discharge. Of 90 procedures reviewed, there were no major adverse events or complications related to the devices or procedure. No incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, or hematoma were observed. Limitations of this study were:

I. data were not specifically collected; however, regardless of difficulty, in this series none of the procedures was aborted and none resulted in adverse events, and
The authors concluded that this study demonstrates the acute safety of the MILD procedure with no report of significant or unusual patient complications. They noted that additional studies are currently underway to establish complication frequency and longer-term safety profile associated with this treatment.

In a prospective, case-series study, Mekhail et al (2012) reported findings of consecutive LSS patients who presented with neurogenic claudication and were treated with percutaneous lumbar decompression. Efficacy was evaluated using the Pain Disability Index (PDI) and Roland-Morris Disability Questionnaire. Pre- and post-procedure standing time, walking distance, and VAS were also monitored. Significant device- or procedure-related AEs were reported. The MILD procedure was successfully performed on 40 patients. At 12 months, both PDI and Roland-Morris showed significant improvement of 22.6 points (ANOVA, p < 0.0001) and 7.7 points (ANOVA, p < 0.0001), respectively. Walking distance, standing time, and VAS improvements were also statistically significant, increasing from 246 to 3,956 feet (ANOVA, p < 0.0001), 8 to 56 mins (ANOVA, p < 0.0001), and 7.1 to 3.6 points (ANOVA, p < 0.0001), respectively. Tukey HSD test found improvement in all 5-outcome measures to be significant from baseline at each follow-up interval. No significant device- or procedure-related AEs were reported. The authors concluded that this study demonstrated significant functional improvement as well as decreased disability secondary to neurogenic claudication after the MILD procedure. Safety, cost-effectiveness, and QOL outcomes were best compared with comprehensive medical management in a randomized controlled fashion and, where ethical, to open lumbar decompression surgery.

The Centers for Medicare & Medicaid Services (CMS, 2014) concluded that percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS) is not reasonable and necessary. The scope of the CMS national coverage analysis (NCA) included a review of the evidence on whether percutaneous image-guided lumbar decompression for LSS provides improved health outcomes in Medicare beneficiaries. The analysis also included the proprietary procedure mild®. CMS identified a number of studies related to the PILD procedure for LSS. The majority of
studies were case series which have inherent limitations in providing a level of reliable evidence of benefit for a procedure, especially a procedure addressing pain. The case series for the PILD procedure suffered from additional limitations in failing to report information important for anyone to assess the clinical utility of this procedure for a particular patient. The one RCT had a small enrollment and major design flaws that called into question the results of the trial.

Zaina et al (2016) reported on a Cochrane review evaluating the effectiveness of different types of surgery compared with different types of non-surgical interventions in adults with symptomatic lumbar spinal stenosis. Low-quality evidence from one small study suggested no differences at six weeks in the Oswestry Disability Index for patients treated with minimally invasive mild decompression versus those treated with epidural steroid injections (MD 5.70, 95% CI 0.57 to 10.83; 38 participants). Zurich Claudication Questionnaire (ZCQ) results were better for epidural injection at six weeks (MD -0.60, 95% CI -0.92 to -0.28), and visual analogue scale (VAS) improvements were better in the mild decompression group (MD 2.40, 95% CI 1.92 to 2.88). At 12 weeks, many cross-overs prevented further analysis. The authors concluded that “we have very little confidence to conclude whether surgical treatment or a conservative approach is better for lumbar spinal stenosis, and we can provide no new recommendations to guide clinical practice. However, it should be noted that the rate of side effects ranged from 10% to 24% in surgical cases, and no side effects were reported for any conservative treatment. No clear benefits were observed with surgery versus non-surgical treatment.”

Benyamin et al (2016) concluded that 1-year results of a RCT demonstrated that MILD was statistically superior to epidural steroid injections (ESI) in the treatment of LSS patients with neurogenic claudication and verified central stenosis due to ligamentum flavum hypertrophy. Primary and secondary efficacy outcome measures achieved statistical superiority in the MILD group compared to the control group. With 95% of patients in this study presenting with 5 or more LSS co-factors, it is important to note that patients with spinal co-morbidities also experienced statistically significant improved function that was durable through 1 year. The main drawbacks of this study included the lack of patient blinding due to significant differences in treatment protocols between study arms, including multiple ESI procedures during the study period versus one MILD procedure. Also, adjunctive pain therapy within the lumbar region was restricted, and therefore responder rates may be lower for both study groups compared to those outside of study confines. Study enrollment was not limited to patients that had never received ESI therapy.
In a prospective, multi-center, randomized controlled clinical study, Staats and colleagues (2018) evaluated the long-term durability of the minimally invasive lumbar decompression (MILD) procedure in terms of functional improvement and pain reduction for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. This was a report of 2-year follow-up for MILD study patients. These investigators compared outcomes for 143 patients treated with MILD versus 131 treated with epidural steroid injections (ESI). Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only; ODI, NPS, and ZCQ were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related AEs. All outcome measures demonstrated clinically meaningful and statistically significant improvement from baseline through 6-month, 1-year, and 2-year follow-ups. At 2 years, ODI improved by 22.7 points, NPS improved by 3.6 points, and ZCQ symptom severity and physical function domains improved by 1.0 and 0.8 points, respectively. There were no serious device-/procedure-related AEs, and 1.3% experienced a device-/procedure-related AE. The authors concluded that MILD showed excellent long-term durability, and there was no evidence of spinal instability through 2-year follow-up. Re-operation and spinal fracture rates were lower, and safety was higher for MILD versus other lumbar spine interventions, including interspinous spacers, surgical decompression, and spinal fusion. These researchers stated that given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, MILD is an excellent choice for 1st-line therapy for select patients with central spinal stenosis suffering from neurogenic claudication symptoms with hypertrophic ligamentum flavum.

The authors stated that the limitations of this study included the lack of a control group at 2-year follow-up. The randomized controlled portion of the study concluded at the primary end-point of 1 year, and supplementary follow-up through 2 years was conducted for the MILD patient group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, or spacers. Other limitations included the lack of patient blinding due to considerable differences in treatment protocols, a potentially higher non-responder rate for both groups versus standard-of-care due to study restrictions on adjunctive pain therapies, and study enrollment was not limited to patients that had never received ESI therapy.

Deer et al (2019) noted that lumbar spinal stenosis (LSS) can lead to compression of neural elements and manifest as low back pain (LBP) and leg pain. LSS has traditionally been treated with a variety of conservative (pain medications, physical therapy, epidural spinal injections) and invasive (surgical decompression) options. Recently, several minimally invasive procedures have expanded the therapeutic options. The Lumbar Spinal Stenosis Consensus Group convened to examine the peer-reviewed literature as
the basis for making minimally invasive spine treatment (MIST) recommendations. A total of 11 consensus points were defined with evidence strength, recommendation grade, and consensus level using U.S. Preventive Services Task Force (USPSTF) criteria. The Consensus Group also created a treatment algorithm. Literature searches yielded 9 studies (2 randomized controlled trials [RCTs]; 7 observational studies, 4 prospective and 3 retrospective) of MISTs, and 1 RCT for spacers. The LSS treatment choice is dependent on the degree of stenosis; spinal or anatomic level; architecture of the stenosis; severity of the symptoms; failed, past, less invasive treatments; previous fusions or other open surgical approaches; and patient co-morbidities. There is Level I evidence for percutaneous image-guided lumbar decompression as superior to lumbar epidural steroid injection, and 1 RCT supported spacer use in a non-inferiority study comparing 2 spacer products currently available. The authors concluded that MISTs should be used in a judicious and algorithmic fashion to treat LSS, based on the evidence of efficacy and safety in the peer-reviewed literature. The MIST Consensus Group recommended that these procedures be used in a multi-modal fashion as part of an evidence-based decision algorithm.

Aldahshory et al (2020) stated that the classic laminectomy for spinal decompression was the treatment of choice of the degenerative lumbar canal stenosis (LCS). Many surgeons prefer to add instrumented lumbar fusion to avoid future instability after the removal of posterior elements. Adding fusion is associated with more bleeding and longer periods of hospitalization. Minimally invasive lumbar decompression (MILD) has been advocated for successful decompression with less bleeding loss and shorter hospitalization. These researchers compared the clinical outcomes of 2 different treatment modalities for degenerative LCS: the classic laminectomy with postero-lateral transpedicular screw fixation and the MILD. A total of 50 patients with degenerative LCS were randomized from 2 institutions: Ain Shams University Hospital and Arab Contractors Medical Center, who underwent surgeries for degenerative LCS between 2016 and 2018 with 1-year follow-up. The study compared 2 cohorts: Group A -- 25 patients underwent classic lumbar laminectomy with postero-lateral transpedicular fixation, and Group B -- 25 patients underwent MILD. There were no statistically significant differences between both treatment modalities in the VAS for leg pain and back pain, the patient satisfaction index, and the ODI after 1 year. The fusion operations were associated with higher estimates of blood loss, longer hospital stay, and more financial costs. The authors concluded that MILD had the same satisfactory results as classic laminectomy with postero-lateral fixation for the treatment of degenerative LCS with less bleeding loss and shorter hospitalization. Since the results were comparable, MILD was suggested in low-income countries as Egypt for economic reasons.

The authors stated that this study had limitations as 1-year follow-up was insufficient to
evaluate the re-operation rate in case of adding fusion. Other limitations included small sample size (n = 25 in the MILD group) and lack of information regarding the BMI of each patient and the associated co-morbidities.

Ricciardi et al (2020) noted that chronic LBP can be due to many different causes, including degenerative spondylolisthesis (DS). For patients who do not respond to conservative management, surgery remains the most effective treatment. Open laminectomy alone and laminectomy and fusion (LF) for DS have been widely investigated, however, no meta-analyses have compared minimally invasive decompression with posterior elements preservation (MID) techniques and LF. Minimally invasive techniques might provide specific advantages that were not recognized in previous studies that pooled different decompression strategies together. This was a systematic review and meta-analysis, according to the PRISMA statement, of comparative studies reporting surgical, clinical and radiological outcomes of MID and LF for DS. A total of 3,202 papers were screened and 7 were finally included in the meta-analysis. MID is associated with a shorter surgical duration and hospitalization stay, and a lower intra-operative blood loss and residual LBP; however, the residual disability grade was lower in the LF group; complication rates were similar between the 2 groups. The rate of adjacent segment degeneration was lower in the MID group, whereas data on radiological outcomes were heterogeneous and not suitable for data-pooling. The authors concluded that this meta-analysis suggested that MID might be considered as an effective alternative to LF for DS. Moreover, these researchers stated that further clinical trials are needed to confirm these findings, better investigate radiological outcomes, and identify patient subgroups that may benefit the most from specific techniques.

Fornari et al (2020) stated that degenerative LSS is a progressive disease with potentially dangerous consequences that affect QOL. Despite the detailed literature, natural history is unpredictable. This uncertainty presents a challenge making the correct management decisions, especially in patients with mild-to-moderate symptoms, regarding conservative or surgical treatment. This article focused on conservative treatment for degenerative LSS. To standardize clinical practice worldwide as much as possible, the World Federation of Neurosurgical Societies Spine Committee held a consensus conference on conservative treatment for degenerative LSS. A team of experts in spinal disorders reviewed the literature on conservative treatment for degenerative LSS from 2008 to 2018 and drafted and voted on a number of statements. During 2 consensus meetings, 14 statements were voted on. The Committee agreed on the use of physical therapy for up to 3 months in cases with no neurologic symptoms. Initial conservative treatment could be applied without major complications in these cases. In patients with moderate-to-severe symptoms or with acute radicular deficits, surgical treatment is
indicated. The efficacy of epidural injections is still debated, as it showed only limited benefit in patients with degenerative LSS. The authors concluded that a conservative approach based on therapeutic exercise may be the 1st choice in patients with LSS except in the presence of significant neurologic deficits. Treatment with instrumental modalities or epidural injections is still debated. These researchers stated that further studies with standardization of outcome measures are needed to reach high-level evidence conclusions. This review noted that there is low-quality level of evidence for minimally invasive surgical decompression provides better pain reduction and improves functional mobility versus epidural steroid injections (citing the study by Zaina et al, 2016). Zaina et al (2016) concluded that they had very little confidence to conclude whether surgical treatment or a conservative approach is better for LSS, and they could provide no new recommendations to guide clinical practice. However, it should be noted that the rate of side effects ranged from 10 % to 24 % in surgical cases, and no side effects were reported for any conservative treatment. No clear benefits were observed with surgery versus non-surgical treatment. These findings suggested that clinicians should be very careful in informing patients regarding possible therapeutic options, especially given that conservative treatments have resulted in no reported side effects. These researchers stated that high-quality research is needed to compare surgical versus conservative care for individuals with LSS. For the study by Deer et al (2019), this review noted that short- to intermediate-term benefit of epidural injections for symptomatic treatment of LSS. Benefit of caudal and interlaminar injections (local anesthetic only and local anesthetic with steroid) and transforaminal injections of local anesthetic with or without steroid. Patients exhibiting shorter-term relief of less than 3 months should not proceed with further injection therapy but rather continue down treatment algorithm to a therapeutic option directed at decompression.

Merkow et al (2020) noted that symptomatic LSS is a condition affecting a growing number of individuals resulting in significant disability and pain. Traditionally, therapeutic options have consisted of conservative measures such as physical therapy, medication management, epidural injections and percutaneous adhesiolysis, or surgery. There exists a treatment gap for patients failing conservative measures who are not candidates for surgery. Minimally invasive lumbar decompression (MILD) and interspinous process device (IPD) with Superion represent minimally invasive novel therapeutic options that may help fill this gap in management. These investigators carried out a literature review to separately evaluate these procedures and examined their safety and effectiveness. The authors concluded that the available evidence for MILD and Superion has been continuously debated. Overall, it is considered that while the procedures are safe, there is only modest evidence for effectiveness. For both procedures, these researchers have reviewed 13 studies. Based on the available evidence, MILD and Superion are safe and modestly effective minimally invasive
procedures for patients with symptomatic LSS. They stated that these procedures may be incorporated as part of the continuum of therapeutic options for patients meeting clinical criteria.

Furthermore, an UpToDate review on “Lumbar spinal stenosis: Treatment and prognosis” (Levin, 2021) states that “Minimally invasive decompression -- There is long-standing interest in the development of less invasive decompression procedures, such as percutaneous lumbar decompression and/or minimally invasive lumbar decompression, which appear in observational studies to have lower complication rates than traditional surgical techniques. It is unclear if these newer procedures offer benefit in terms of improved symptoms and function or fewer complications in routine practice compared with standard decompression with laminectomy”.

Laser Diskectomy

Laser discectomy is also known as laser-assisted discectomy, laser disc decompression or laser-assisted disc decompression (LADD). Though this procedure is called a discectomy, it does not actually remove the disc, but utilizes a laser to "vaporize" a small portion of the nucleus pulposus in order to purportedly decompress a herniated disc. Laser discectomy may be performed either laparoscopically or percutaneously.

Laser discectomy involves the use of a laser to vaporize a small portion of the nucleus pulposus in order to decompress a herniated disc. In laparoscopic laser discectomy, the procedure is done through a laparoscope, which allows visualization of the disc, disc space and other structures. The surgeon places a laser through a delivery device that has been directed under radiographic control to the disc. The annulus of the disc is opened and is then excised with a laser device which is inserted through the laparoscope. It uses many of the same techniques used in automated percutaneous discectomy. An endoscope may be used in conjunction with this procedure to visualize the disc space and nucleus pulposus, or the procedure may be done percutaneously. By contrast, percutaneous disc decompression uses an x-ray to localize the tip of the needle/trocar to ensure that it is in the appropriate level and location. Percutaneous laser discectomy is performed under a local anesthetic. Under x-ray (fluoroscopic) guidance, a needle is inserted through the skin into the disc. A flexible quartz fiber is then threaded through the needle and into the disc, which delivers the laser energy.

The mechanism of action for pain relief in LADD is not well understood; most believe that the primary mechanism of pain reduction after LADD is its decrease in intradiscal pressure. According to the literature, laser-assisted disc decompression appears to be a
safe procedure, but studies have not compared it to open surgical alternatives or other percutaneous methods. Randomized controlled trials are needed to compare current standard alternatives to both LADD and conservative treatment. A Cochrane review of surgical procedures for lumbar disc herniation concluded that "[t]here is currently no evidence supporting endoscopic (micro-suction) or laser treatment of disc prolapse" (Gibson et al, 2002). A systematic review of the literature on percutaneous endoscopic laser discectomy for the Royal Australasian College of Surgeons (Boult et al, 2000) reached similar conclusions: "Given the extremely low level of evidence available for this procedure it was recommended that the procedure be regarded as experimental until the results are available from a controlled clinical trial, ideally with random allocation to an intervention and control group".

An assessment of laser lumbar discectomy conducted for the National Institute of Clinical Excellence (NICE, 2003) concluded that current evidence on the safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. A systematic evidence review by Jordan et al (2003) similarly concluded that the effectiveness of laser discectomy is "unknown".

**Microdiscectomy**

Microdiscectomy refers to removal of protruding disc material, using an operating microscope to guide surgery. Dent (2001) recently assessed the evidence supporting the use of microdiscectomy for prolapsed intervertebral disc, and found no evidence of differences in clinical outcomes between microdiscectomy and standard open discectomy. A Cochrane review found evidence that microdiscectomy takes longer to perform than standard open discectomy (Gibson et al, 2002). The review found no evidence of difference in short- or long-term symptom relief or complications, or length of inpatient stay. Similarly, a systematic assessment of the literature by Jordan et al (2003) concluded that microdiskectomy has not been shown to be more effective than standard discectomy.

**Microendoscopic Discectomy**

Microendoscopic discectomy (MED) procedure combines conventional lumbar microsurgical techniques with endoscopy and is performed at an outpatient setting. It is employed for the treatment of lumbar spine stenosis and lumbar disc herniation. It has been suggested that MED is less invasive (no damage to muscle, bone or soft tissue) compared with traditional open microdiscectomy. Moreover, MED allegedly allows an
early return to work. However, this endoscopic procedure is difficult because of the limited exposure and 2-dimensional video display. The potential injury of the nerve root and prolonged surgical time remain as matters of serious concern. Currently, there is insufficient evidence to support the clinical value of this procedure especially its long-term effectiveness.

Muramatsu et al (2001) examined if MED was minimally invasive with respect to the nerve roots, cauda equina, and paravertebral muscles by comparing the post-operative magnetic resonance imaging findings in patients treated by MED and the conventional Love’s method. The authors concluded that MED had an effect on the nerve roots and cauda equina that was comparable with that of Love’s method. The magnetic resonance images of the route of entry failed to show that MED is appreciably less invasive with respect to the paravertebral muscles. Furthermore, in a review on the various minimally invasive procedures available for the treatment of lumbar disc disease, Maroon (2002) stated that although all percutaneous techniques (including MED) have been reported to yield high success rates, to date no studies have demonstrated any of these to be superior to microsurgical discectomy, which continues to be regarded as the standard with which all other techniques must be compared.

**Far Lateral Microendoscopic Diskectomy (FLMED)**

Extra-foraminal lumbar disc herniations (ELDHs) at the lumbo-sacral junction are an uncommon cause of L5 radiculopathy. The surgical anatomy of the extra-foraminal space at L5 to S1 is challenging for the various open surgical approaches that have been described for ELDHs in general. Reports specifically describing minimally invasive surgical approaches to lumbo-sacral ELDHs are lacking.

There is currently insufficient evidence to support the use of far lateral microendoscopic discectomy (FLMED). O'Toole and colleagues (2007) reported the novel use of far lateral microendoscopic discectomy (FLMED) to lumbo-sacral ELDH. To better define the unique anatomical features of extra-foraminal approaches to the lumbo-sacral junction as they apply to minimal access techniques. A cadaveric investigation a well as a clinical case were performed, and a thorough review of the literature was conducted. A single patient with an extra-foraminal disc herniation at the lumbo-sacral junction underwent evaluation and surgery. The patient's self-reported pain levels were documented. Physiologic outcome was judged on pre- and post-operative motor and sensory examinations. Functional capacity was assessed by work status and ability to perform activities of daily living. Far lateral microendoscopic discectomy was performed in 2 fresh human cadavers at the lumbo-sacral junction. Qualitative assessments of the
surgical anatomy were made, and intra-operative fluoroscopy and endoscopic photographs were obtained to document the findings. A patient with refractory pain and sensori-motor deficits from compression of the L5 nerve root by an ELDH underwent FLMED. The literature was carefully reviewed for the epidemiology of ELDHs at the lumbo-sacral junction and the surgical techniques used to treat them. The postero-lateral surgical corridor to the lumbo-sacral disc was consistently constrained by the sacral ala and to a lesser extent the lateral facet and L5 transverse process. Resection of the superior ala exposed the exiting nerve root and provided ample access to the disc. In the clinical case, the patient enjoyed immediate pain relief, was discharged in 3 hours, and returned to full work and social activities. Follow-up neurological examination revealed no sensory or motor deficit. The authors concluded that FLMED offers a safe and effective approach to ELDHs at the lumbo-sacral junction by combining satisfactory visualization for adequate resection of the sacral ala with the benefits of reduced tissue injury and faster recovery times that accompany minimally invasive techniques.

Pirris and colleagues (2008) noted that surgical access to ELDHs is complicated due to the unique anatomical constraints of the region. Minimizing complications during microdiscectomies at the level of L5 to S1 in particular remains a challenge. The authors reported on a small series of patients and provided a video presentation of a minimally invasive approach to L5 to S1 ELDHs utilizing a tubular retractor with microscopic visualization.

Dynamic Stabilization

Failed back surgery syndrome (FBSS) is reported to occur in 5 to 50% of cases of lumbar spine operation. A marked rise in the number of performed spinal procedures has also led to an increase in the number of FBSS cases, which is the consequence of biological, psychological, social, and/or economical causes. Patient selection and correct indications are of key importance for successful surgical intervention of this syndrome. Surgical interventions that have been used for FBSS treatment include decompression, stabilization and fusion, as well as dynamic stabilization/neutralization procedures (Chrobok et al, 2005).

Dynamic spinal stabilization devices are proposed as a way to provide immobilization and stabilization of spinal segments in skeletally mature individuals as an adjunct to fusion in the treatment of chronic instabilities or deformities of the thoracic, lumbar and sacral spine including, but not limited to, degenerative spondylolisthesis (with objective evidence of neurologic impairment) or previous failed spinal fusion. They are
also cleared by the US Food and Drug Administration (FDA) for individuals who are receiving fusions with autogenous graft only, those who are having the device fixed or attached to the lumbar or sacral spine and those who are having the device removed after the development of a solid fusion mass.

These devices attach to the spine by way of titanium alloy screws that have been implanted into the spinal bone. Two screws are implanted per vertebra in two or three adjacent vertebrae. The protruding ends of the screws are attached to polyethylene-terephthalate cords. These cords are surrounded by a set of solid polycarbonate-urethane spacers. The system is designed to stabilize the spine by the polyethylene cords pulling against the spinal motions that separate the vertebrae. At the same time, the polycarbonate spacers push against the spinal motions that compress the vertebrae. These devices differ from traditional instrumentation used during spinal fusion, as they are non-rigid and allow some movement of the spine segments. Examples of dynamic spinal stabilization devices include, but may not be limited to, the Dynesys Stabilization System, the BAR Posterior Pedicle Screw System and the N Fix II Pedicle Screw System.

The use of rigid instrumentation in the treatment of degenerative spinal disorders seems to increase the fusion rate of the lumbar spine. However, rigid devices are associated with adverse effects such as pseudoarthrosis and adjacent segment degeneration. The use of semi-rigid and dynamic devices has been advocated to decrease such adverse effects of rigid fixation and thereby to attain a more physiological bony fusion (Korovessis et al, 2004). Dynamic stabilization systems (e.g., the Dynesys Spinal System) are intended to restrict segmental motion and thus prevent further degeneration of the lumbar spine. The Dynesys, a non-fusion pedicle screw stabilization system (a flexible posterior stabilization system), was developed in an attempt to overcome the inherent disadvantages of rigid instrumentation and fusion. It uses flexible materials threaded through pedicle screws rather than rigid rods or bone grafts alone as an adjunct to fusion. The Dynesys is installed posteriorly, and does not require bone to be taken from the hip, as is required in other fusion procedures. It is designed to prevent over-loading the disc, but it restricts extension and loses lordosis (Sengupta and Mulholland, 2005; Putzier et al, 2005).

The Dynesys Spinal System (Centerpulse Spine-Tech, Inc., Minneapolis, MN) was cleared by the FDA via a 510(k) pre-market notification in March 2004. According to the product labeling, it is indicated to provide stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence or neurological impairment, kyphosis; and failed previous fusion
(pseudoarthrosis). In addition, the product labeling states that the Dynesys system is intended for use in persons who meet all of the following criteria:

- Patients who are receiving fusions with autologous graft only; and
- Patients who are having the device attached to the lumbar or sacral spine; and
- Patients who are having the device removed after the development of a solid fusion mass.

The Dynesys Stabilization System has also been proposed for immobilization and stabilization of spinal segments without a spinal fusion procedure; at this time the FDA has not approved this application. Although the Dynesys has been in clinical use for several years, there is insufficient evidence demonstrating that implantation of this device results in improved health outcomes compared to standard treatments.

A more recent development has been a hybrid device, the Zimmer DTO Implant, which combines the Dynesys Dynamic Stabilization System with the rigid stabilization of the OPTIMA ZS Spinal System. This device is an attempt to offer a new segmental solution for treating degenerative lumbar spine pathologies with different stages of degeneration at contiguous levels.

Dynamic spinal stabilization devices may also be semi-rigid in design. These devices purportedly allow less spinal movement than the non-rigid, but more than traditional spinal fusion instrumentation. Examples of semi-rigid devices include the CD HorizoN Agile Dynamic Spinal Stabilization Device and the Isobar Spinal System.

In a RCT, Korovessis et al (2004) examined the short-term effects of rigid versus semi-rigid and dynamic instrumentation on the global and segmental lumbar spine profile, subjective evaluation of the result, and the associated complications. The study did not examine objective functional outcomes. They compared 3 equal groups of 45 adult patients, who underwent primary decompression and stabilization for symptomatic degenerative lumbar spinal stenosis. Patients were randomly selected and received either the rigid (Group A), or semi-rigid (Group B), or dynamic (Group C) spinal instrumentation with formal decompression and fusion. The mean ages for the 3 groups were 65 +/- 9, 59 +/- 16, and 62 +/- 10 years, respectively. All patients had detailed roentgenographical study including computed tomography (CT) scan and magnetic resonance imaging (MRI) before surgery to the latest follow-up observation. The following roentgenographical parameters were measured and compared in all spines: lumbar lordosis (L1 to S1), total lumbar lordosis (T12 to S1), sacral tilt, distal lordosis (L4 to S1), segmental lordosis, vertebral inclination, and disc index. The SF-36 health survey and visual analog scale (VAS) was used before surgery to the latest evaluation. All
patients were evaluated after a mean follow-up of 47 +/- 14 months. Both lumbar and total lordosis correction did not correlate with the number of the levels instrumented in any group. Total lordosis was slightly decreased after surgery (3%, p < 0.05) in Group C. The segmental lordosis L2 to L3 was increased after surgery by 8.5% (p < 0.05) in Group C, whereas the segmental lordosis L4 to L5 was significantly decreased in Groups A and C by 9.8% (p = 0.01) and 16.2% (p < 0.01), respectively. The disc index L2 to L3 was decreased after surgery in Groups A and C by 17% (p < 0.05) and 23.5% (p < 0.05), respectively. The disc index L3 to L4 was increased after surgery by 8.5% (p < 0.05) in Group C, whereas the segmental lordosis L4 to L5 was significantly decreased in Groups A and C by 9.8% (p = 0.01) and 16.2% (p < 0.01), respectively. The disc index L2 to L3 was decreased after surgery in Groups A and C by 17% (p < 0.05) and 23.5% (p < 0.05), respectively. The disc index L3 to L4 was increased in Group C by 18.74% (p < 0.01). After surgery, the disc index L4 to L5 was decreased in all 3 groups: Group A by 21% (p = 0.01), Group B by 13% (p < 0.05), and Group C by 13.23% (p < 0.05). The mean pre-operative scores of the SF-36 before surgery were 11, 14, and 13 for Groups C, B, and A, respectively. In the first year after surgery, there was a significant increase of the pre-operative SF-36 scores to 65, 61, and 61 for Groups C, B, and A, respectively, that represents an improvement of 83%, 77%, and 79%, respectively. In the second year after surgery and thereafter, there was a further increase of SF-36 scores of 19%, 23%, and 21% for Groups C, B, and A, respectively. The mean pre-operative scores of VAS for LBP for Groups C, B, and A were 5, 4.5, and 4.3, respectively, and decreased after surgery to 1.9, 1.5, and 1.6, respectively. The mean pre-operative scores of the VAS for leg pain for Groups C, B, and A were 7.6, 7.1, and 6.9, respectively, and decreased after surgery to 2.5, 2.5, and 2.7, respectively. All fusions healed radiologically within the expected time in all 3 groups without pseudoarthrosis or malunion. Delayed hardware failure (1 screw and 2 rod breakages) without radiologically visible pseudoarthrosis was observed in 2 patients in Group C 1 year and 18 months following surgery. There was no adjacent segment degeneration in any spine until the last evaluation. These investigators concluded that all 3 instrumentations applied over a short area for symptomatic degenerative spinal stenosis almost equally maintained the pre-operative global and segmental sagittal profile of the lumbosacral spine and was followed by similarly significant improvement of both self-assessment and pain scores. Hardware failure occurred at a low rate following dynamic instrumentation solely without radiologically visible pseudoarthrosis or loss of correction. These researchers further noted that because of the similar clinical and radiological data in all 3 groups and the relative small number of patients that were included in each group, it is difficult to make any recommendation in favor of any instrumentation.

Putzier et al (2005) examined the effect of dynamic stabilization on the progression of segmental degeneration after nucleotomy. A total of 84 patients underwent nucleotomy of the lumbar spine for the treatment of symptomatic disc prolapse. Additional dynamic stabilization (the Dynesys system) was performed in 35 subjects. All patients showed signs of initial disc degeneration (Modic Type I - changes in the vertebral end plate are
frequently associated with degenerative disc disease. Type 1 changes include decreased signal intensity on T1-weighted and increased signal intensity on T2-weighted MRI). Evaluation was carried out before surgery, 3 months after surgery, and at follow-up. The mean duration of follow-up was 34 months. Examinations included radiographs, MRI, physical examination, and subjective patient evaluation using Oswestry score and VAS. Clinical symptoms, Oswestry score, and VAS improved significantly in both groups after 3 months. At follow-up, a significant increase in the Oswestry score and in the VAS was seen only in the non-stabilized group. In the dynamically stabilized group, no progression of disc degeneration was noted at follow-up, while radiological signs of accelerated segmental degeneration existed in the solely nucleotomized group. There were no implant-associated complications. These investigators concluded that the Dynesys system is useful to prevent progression of initial degenerative disc disease of lumbar spinal segments following nucleotomy. Moreover, the same group of researchers noted that the Dynesys system seems not to be indicated for treating marked deformities or if osseous decompression needs to be performed (Putzier et al, 2004).

In contrast to the observation of Korovessis et al (2004) and Putzier et al (2005), a number of investigators have questioned whether the Dynesys Spinal System offers any clinical advantages over rigid instrumentation (Hopf et al, 2004; Grob et al, 2005; Schwarzenbach et al, 2005).

In a clinical trial, Hopf et al (2004) compared the use of artificial disc replacement with dynamic stabilization procedure (Dynesys’ method) in the treatment of patients with LBP. Indications for the operation were unsuccessful conservative treatment for over 6 months, segmental pain, age of less than 45 years, evidence of mono- or bi-segmental disc degeneration, with or without disc prolapse, demonstrated by MRI, exclusion of psychogenic disease and positive pre-operative, diagnostic measures such as facet joint infiltration and discography. These investigators stated that in younger patients with mono- or bi-segmental disc degeneration there is an indication for the implantation of an artificial disc. Contraindications for the operation are facet joint arthrosis and age of over 45 years. The investigators commented that the indication in subjects with a classic FBSS is still unclear, the improvement of the instrumentation and a further adaptation of the systems to the known biomechanics of the lumbar spine are mandatory as is an intensive discussion of the operative procedure in the case of revision operations. These authors further noted that the Dynesys’ method, with the inherent danger of segmental kyphozitation, a published, significant revision quota combined with a reduction of motility, does not fulfill this criterion.
In a retrospective study, Grob and colleagues (2005) assessed patient-oriented outcome after implantation of the Dynesys Spinal System. A total of 50 consecutive patients instrumented with the Dynesys over the preceding 40 months were invited to complete a postal, patient-oriented follow-up questionnaire. The data from 31 of these subjects (11 men and 20 women; mean age of 50 years), with at least 2 years' follow-up, were analyzed. The primary indication for surgery was degenerative disease (disc/stenosis) with associated "instability"; 11 of 31 (35%) patients had had prior spinal surgery. One-level instrumentation was performed in 32% cases, 2-level instrumentation in 52% cases, 3-level in 13% cases, and 4-level in 3% cases. Thirteen of 31 (42%) patients underwent additional decompression. Within the 2-year follow-up period, 6 of 31 (19%) patients had needed or were scheduled for another surgical intervention. At follow-up, mean back and leg pain (0 to 10 VAS) were 4.7 and 3.8, respectively. The following global outcomes were reported:

I. back symptoms – 67% improved, 30% same, 3% worse;

II. leg symptoms - 64% improved, 21% same, 14% worse;

III. ability to do physical activities/sports - 40% improved, 33% same, 27% worse;

IV. quality of life - 50% improved, 37% same, 13% worse;

V. how much the operation helped - 29% helped a lot, 23% helped, 10% only helped a little, 35% didn't help, 3% made things worse.
These investigators concluded that their findings indicated that both back and leg pain are, on average, still moderately high 2 years following instrumentation with the Dynesys Spinal System. Only 50% of the patients declared that the operation had helped and had improved their overall quality of life; less than 50% reported improvements in functional capacity. The re-operation rate following implantation of the Dynesys was relatively high. The investigators concluded that these results provide no support for the notion that semi-rigid fixation of the lumbar spine resulted in better patient-oriented outcomes than those typical of fusion.

In a recent review on posterior dynamic stabilization systems, Schwarzenbach et al (2005) stated that their experience with the Dynesys has shown that this method has limitations in "elderly patients with osteoporotic bone or in patients with a severe segmental macro-instability combined with degenerative spondylolisthesis and advanced disc degeneration. Such cases have an increased risk of failure. Only future randomized evaluations will be able to address the potential reduction of accelerated adjacent segment degeneration. The few posterior dynamic stabilization systems that have had clinical applications so far have produced clinical outcomes comparable with fusion. No severe adverse events caused by these implants have been reported. Long-term follow-up data and controlled prospective randomized studies are not available for most of the cited implants but are essential to prove the safety, efficacy, appropriateness, and economic viability of these methods".

In a review on dynamic stabilization in the surgical management of painful lumbar spinal disorders, Nockels (2005) concluded that posterior dynamic stabilization systems may provide benefit comparable to fusion techniques, but without the elimination of movement. Moreover, the author also noted that further study (well-designed prospective, randomized, controlled trial) is needed to ascertain optimal design and clinical indications.

In a systematic evidence review on non-rigid stabilization procedures for the treatment of LBP, the National Institute for Health and Clinical Excellence (NICE, 2005) stated that "current evidence on the safety of these procedures is unclear and involves a variety of different devices and outcome measures. Therefore, these procedures should not be used without special arrangements for consent and for audit or research". Additionally, the specialist advisors to the Institute’s Interventional Procedures Advisory Committee noted that these procedures may be undertaken concurrently with disc decompression or discectomy. Thus, it is difficult to ascertain what clinical benefit is derived from the implants themselves. The specialist advisors noted that the reported adverse events include infection, malpositioned or broken screws leading to nerve root damage, cerebrospinal fluid leak, failure of the bone/implant interface, and failure to control pain.
The theoretical risks with the techniques include: device failure (particularly long-term), increased lordosis, and root damage caused by loose or misaligned screws.

Welch and colleagues (2007) presented the preliminary clinical outcomes of dynamic stabilization with the Dynesys spinal system as part of a multi-center randomized prospective FDA investigational device exemption (IDE) clinical trial. This study included 101 patients from 6 IDE sites (no participants were omitted from the analysis) who underwent dynamic stabilization of the lumbar spine with the Dynesys construct. Patient participation was based on the presence of degenerative spondylolisthesis or retrolisthesis (Grade I), lateral or central spinal stenosis, and their physician’s determination that the patient required decompression and instrumented fusion for 1 or 2 contiguous spinal levels between L1 and S1. Subjects were evaluated pre-operatively, post-operatively at 3 weeks, and then at 3-, 6-, and 12-month intervals. The 100-mm VAS was used to score both lower-limb and back pain. Patient functioning was evaluated using the Oswestry Disability Index (ODI), and the participants' general health was assessed using the Short Form-12 questionnaire. Overall, patient satisfaction was also reported. One hundred one patients (53 women and 48 men) with a mean age of 56.3 years (range of 27 to 79 years) were included. The mean pain and function scores improved significantly from the baseline to 12-month follow-up evaluation, as follows: leg pain improved from 80.3 to 25.5, back pain from 54 to 29.4, and ODI score from 55.6 to 26.3%. The authors concluded that the early clinical outcomes of treatment with Dynesys are promising, with lessening of pain and disability found at follow-up review. Dynesys may be preferable to fusion for surgical treatment of degenerative spondylolisthesis and stenosis because it decreases back and leg pain while avoiding the relatively greater tissue destruction and the morbidity of donor site problems encountered in fusion. However, long-term follow-up care is still recommended.

In a prospective case series, Kumar et al (2008) examined the radiological changes in the intervertebral disc after Dynesys dynamic stabilization. A total of 32 patients who underwent Dynesys procedure and have completed 2-year follow-up MRI scans were included in this study. Pre-operative and 2-year post-operative lumbar MRI scans were evaluated by 2 independent observers. T2-weighted mid-sagittal images were used and disc degeneration were classified according to the Woodend classification of disc degeneration. Anterior and posterior intervertebral disc heights were also measured. Of the 32 patients, 20 patients underwent Dynesys procedure alone and 12 underwent additional fusion at 1 or more levels. A total of 70 levels were operated on, of which 13 levels were fused. There was a statistically significant increase in the mean Woodend score at the operated levels in the Dynesys alone group, a change from 1.95 before surgery to 2.52 after surgery (p < 0.001). The mean Woodend scores changed from 1.27 pre-operative to 1.55 post-operative (p = 0.066) at the proximal adjacent levels, and
from 1.37 to 1.62 at the distal levels (p = 0.157). There was good inter-observer agreement (weighted k score of 0.819). The anterior intervertebral disc height reduced by 2 mm from 9.25 to 7.17 (p < 0.001). The posterior disc height increased by 0.14 mm but this change insignificant. The authors concluded that disc degeneration at the bridged and adjacent segment seems to continue despite Dynesys dynamic stabilization.

The Stabilimax NZ Dynamic Spinal Stabilization System is an investigational device that is being evaluated for the treatment of patients with symptomatic spinal stenosis. The Stabilimax NZ is inserted and fixed to the vertebra by means of pedicle screws in exactly the same manner a fusion device is inserted and attached. The only difference is that for the Stabilimax NZ no bone graft will be placed around or between the vertebra to promote bone growth for fusion. It should be noted that a clinical trial sponsored by Applied Spine Technologies to evaluate if the Stabilimax NZ is at least as safe and effective as the control therapy of fusion in patients receiving decompression surgery for the treatment of clinically symptomatic spinal stenosis at 1 or 2 contiguous vertebral levels from L1 to S1 has been suspended (Applied Spine Technologies, 2008); the reason for this suspension is unclear.

Graf artificial ligament stabilization (Graf) is primarily used to stabilize the unstable vertebral segment without rigid fusion (Noorani and Topfer, 2006). The Graf technique involves insertion of pedicle screws into each vertebra to be stabilized which are then attached to one another with Dacron loops. This method has the theoretical advantages of simplicity (to surgeons familiar with the insertion of pedicle screws), avoidance of bone graft donor site problems, and allowing a spinal fusion to be attempted at a later date if considered necessary (Noorani and Topfer, 2006). The concept of ligament stabilization was introduced by H. Graf in the early 1990s and performed in patients with chronic back pain as a less invasive technique than spinal or posterio-lateral fusion.

In a retrospective, long-term, follow-up study, Kanayama et al (2007) reported minimum 10-year follow-up results of posterior dynamic stabilization using Graf artificial ligament (Graf ligamentoplasty) and evaluated the role and limitations of this procedure in the treatment of degenerative lumbar disorders. A total of 56 consecutive patients who underwent Graf ligamentoplasty were reviewed at a minimum 10-year follow-up. Forty-three patients in the original cohort had sufficient clinical and radiographical follow-up for analysis. The pathologies included degenerative spondylolisthesis in 23 patients, disc herniation with flexion instability in 13 patients, spinal stenosis with flexion instability in 4 patients, and degenerative scoliosis in 3 patients. Single-level procedures were performed in 36 patients; multi-level procedures were performed in 7 patients. Radiographical and clinical assessments were performed before surgery and at the final
follow-up. Disability due to LBP and/or sciatic symptoms was significantly improved in the patients with degenerative spondylolisthesis or flexion instability. However, degenerative scoliosis and/or laterolisthesis were associated with poor clinical improvement. In radiographical assessment, segmental lordosis was maintained in 10.9 degrees, and flexion-extension motion was averaged 3.6 degrees at the final follow-up. Facet arthrodesis eventually occurred in 14 patients (32.6%) at an average of 82 months after surgery. Additional surgeries were required in 3 patients (7.0%) for adjacent segment pathologies. The authors concluded that long-term results showed that Graf ligamentoplasty is an effective treatment option for low-grade degenerative spondylolisthesis and flexion instability. However, this procedure has limitations to correct spinal deformity, and is not advocated for the treatment of degenerative scoliosis and laterolisthesis.

In a discussion of the afore-mentioned study, Fraser (2007) stated that "[p]erhaps the main value of this retrospective study is the finding that Graf ligamentoplasty is not effective in the treatment of patients with degenerative scoliosis, but the long-term efficacy of the Graf procedure for other lumbar conditions is yet to be proven".

Putzier et al (2010) compared dynamic fixation of a clinically asymptomatic initially degenerated segment adjacent to fusion (iASD), with circumferential lumbar fusion alone. A total of 60 patients with symptomatic degeneration of L5/S1 or L4/L5 (Modic greater than or equal to 2 degrees) and asymptomatic iASD (Modic = 1 degrees, confirmed by discography) were divided into 2 groups; 30 patients were treated with circumferential single-level fusion (SLF). In dynamic fixation transition (DFT) patients, additional posterior dynamic fixation of iASD was performed. Pre-operatively, at 12 months, and at a mean follow-up of 76.4 (60 to 91) months, radiological (MRI, X-ray) and clinical (ODI, VAS, satisfaction) evaluations assessed fusion, progression of adjacent segment degeneration (PASD), radiologically adverse events, functional outcome, and pain. At final follow-up, 2 non-fusions were observed in both groups. A total of 6 SLF patients and 1 DFT patient presented a PASD. In 2 DFT patients, a PASD occurred in the segment superior to the dynamic fixation, and in 1 DFT patient, a fusion of the dynamically fixated segment was observed. A total of 4 DFT patients presented radiological implant failure. While no differences in clinical scores were observed between groups, improvement from pre-operative conditions was significant (all p < 0.001). Clinical scores were equal in patients with PASD and/or radiologically adverse events. The authors do not recommend dynamically fixating the adjacent segment in patients with clinically asymptomatic iASD. The lower number of PASD with dynamic fixation was accompanied by a high number of implant failures and a shift of PASD to the superior segment.
In summary, despite some preliminary evidence that dynamic stabilization systems (e.g., the Dynesys) have produced clinical outcomes comparable to that of fusion, the clinical value of dynamic stabilization awaits the findings of prospective, RCTs, which are an essential requirement for practice of evidence-based medicine.

**Inter-Spinous Distraction and Interlaminar Stabilization Procedures**

Lumbar spinal stenosis (LSS) refers to narrowing of the lumbar spinal canal, lateral recess, or foramen resulting in neurovascular compression that may lead to pain. Spinal stenosis may be classified by etiology (e.g., congenital or acquired) or symptomatology (e.g., radiculopathy, neurogenic claudication, or mechanical back pain). It can also be classified radiographically, by the location of the stenosis (e.g., central canal, lateral recess, or intervertebral foramen) or by the presence of deformity such as spondylolisthesis or scoliosis. Overlapping in the classification of LSS can occur in that central stenosis with thecal sac compression usually leads to neurogenic claudication, while lateral recess compression is associated with compression of an individual nerve root, thus resulting in radiculopathy. Although symptoms may arise from narrowing of the spinal canal, not all patients with narrowing develop symptoms. The reason why some patients develop symptomatic stenosis and others do not is still unknown. Therefore, LSS does not refer to the pathoanatomical finding of spinal canal narrowing. It is a clinical syndrome of lower extremity pain caused by mechanical compression on neural elements or their vascular supply (Truumees, 2005).

Non-surgical treatments (e.g., activity modification, medications such as NSAIDs, physical therapy that focuses on flexion-based exercises, as well as epidural steroid injections) are usually the first treatment choice for patients suffering from neurogenic intermittent claudication (NIC) secondary to LSS. If symptoms failed to improve with non-surgical treatments, decompressive surgery (e.g., laminectomy, facetectomy, multi-level laminotomies, fenestration, distraction laminoplasty, and microscopic decompression), with or without fusion, may be necessary. Moreover, several studies reported that surgical treatment produces better outcomes than non-surgical treatment in the short-term; however, the results tend to deteriorate with time (Yuan et al, 2005).

While fusion operations have traditionally been used to manage many disorders of the lumbar spine related to instability, pain, or deformity, concern over the long-term effects of fusion on adjacent spinal segments has led to the development of new approaches such as inter-spinous distraction procedures.
Examples of US Food and Drug Administration (FDA) approved interspinous process spacers include, but may not be limited to, the Superion Interspinous Spacer, the X-Stop Interspinous Process Decompression (IPD) System and the X-Stop PEEK IPD System.

Interspinous process decompression is a minimally invasive surgical procedure that is proposed to relieve the symptoms of lumbar spinal stenosis in those patients who do not respond to conservative, nonsurgical treatment. The procedure involves implanting interspinous process decompression spacers between the spinous processes of the vertebrae which appear to be the source of the symptoms. The spacers can be implanted at one or two lumbar levels and are designed to remain in place without being permanently affixed to the bone or ligamentous structures of the spine.

The X-Stop Inter-Spinous Process Distraction/Decompression System (St. Francis Medical Technologies, Inc., Alameda, CA) was developed to provide an alternative therapeutic. The principal behind the X-Stop (eXtension-Stop) is that by decompressing the affected spinal segment and maintaining it in a slightly flexed position (and also preventing extension) the symptoms of LSS can be relieved. Additionally, it allows the patient to resume their normal posture rather than flex the entire spine. The X-Stop is made of titanium alloy and is available in 5 sizes – 6, 8, 10, 12, and 14 mm in diameter. It consists of 2 major parts:

I. the universal wing, and

II. the main body (with oval spacer and tissue expander).

1. the universal wing, and
2. the main body (with oval spacer and tissue expander).

The wings prevent anterior and lateral movement while the supraspinous ligament prevents posterior displacement. The oval spacer swivels, making it self-aligning relative to the uneven surface of the spinous process. This ensures that no sharp edges come into contact with the spinous process and that compressive loads are distributed equally on the surface of the bone.

The X-Stop Inter-Spinous Process Distraction/Decompression System gained FDA’s PMA in November 2005 for use in alleviating the symptoms of patients with LSS. The X-Stop
is intended to be used in patients with symptomatic LSS at 1 or 2 levels who have failed at least 6 months of conservative treatment. Under local anesthesia, the implant is inserted between the spinous processes of the affected level(s), and prevents extension at those levels. Talwar et al (2005) stated that patients with lower bone mineral density must be approached with more caution during insertion of the inter-spinous process implant.

According to SFMT Europe B.V., a subsidiary of St. Francis Medical Technologies, the X-Stop is indicated for any of the following conditions:

- Axial-load induced back pain; or
- Baasstrup’s syndrome (also known as kissing spines); or
- Contained herniated nucleus pulposus; or
- Degenerative and/or iatrogenic (post-discectomy) disc syndrome; or
- Facet syndrome; or
- Neurogenic intermittent claudication due to central and/or lateral-recess LSS; or
- Spondylolisthesis up to grade 1.5 (of 4) (about 35%), with NIC; or
- Unloading of disc adjacent to a lumbar fusion procedure, primary or secondary.

There is a scarcity of randomized controlled studies on the clinical value of the X-Stop for the indications listed above, especially its long-term (over 2 years) benefits. Currently, available evidence on this device is mainly from J.F. Zucherman and K.Y. Hsu (developers of this technology), and their associates.

Verhoof and colleagues (2008) stated that the X-Stop inter-spinous distraction device has been reported to be an alternative to conventional surgical procedures in the treatment of symptomatic degenerative lumbar spinal stenosis. However, the effectiveness of the X-Stop in symptomatic degenerative lumbar spinal stenosis caused by degenerative spondylolisthesis is not known. A cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis were treated with the X-Stop inter-spinous distraction device. All patients had LBP, neurogenic claudication and radiculopathy. Pre-operative radiographs revealed an average slip of 19.6%. Magnetic resonance imaging of the lumbo-sacral spine showed a severe stenosis. In 10 patients, the X-Stop was placed at the L4 to L5 level, whereas 2 patients were treated at both, L3 to L4 and L4 to L5 level. The mean follow-up was 30.3 months. In 8 patients, a complete relief of symptoms was observed post-operatively, whereas the remaining 4 patients experienced no relief of symptoms. Recurrence of pain, neurogenic claudication, and worsening of neurological symptoms was observed in 3 patients within 24 months. Post-operative radiographs and MRI did not show any changes in the percentage of slip or spinal dimensions. Finally, secondary surgical
treatment by decompression with postero-lateral fusion was performed in 7 patients (58%) within 24 months. The authors concluded that the X-Stop inter-spinous distraction device showed an extremely high failure rate, defined as surgical re-intervention, after short term follow-up in patients with spinal stenosis caused by degenerative spondylolisthesis. They do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis.

Lindsey et al (2003) examined the kinematics of the instrumented lumbar spine and adjacent levels due to the insertion of the X-Stop. Seven lumbar spines (L2 to L5) were tested in flexion-extension, lateral bending, and axial rotation. Images were taken during each test to determine the kinematics of each motion segment. The X-Stop was inserted at the L3 to L4 level, and the test protocol was repeated. These researchers found that the X-Stop does not significantly alter the kinematics of the motion segments adjacent to the instrumented level.

In a study using 7 cadaveric spines (L2 to L5), Fuchs et al (2005) noted that the X-Stop may be used in conjunction with a unilateral medial facetectomy or unilateral total facetectomy. However, it should not be used in conjunction with bilateral total facetectomy. In another cadaveric L2 to L5 spine study (n = 7), Wiseman et al (2005) reported that inter-spinous process decompression by placing the X-Stop between the L3 to L4 spinous processes will unlikely cause adjacent level facet pain or accelerated facet joint degeneration. Furthermore, pain induced from pressure originating in the facets and/or posterior anulus of the lumbar spine may be relieved by inter-spinous process decompression. Richards et al (2005) quantified the effect of the X-Stop on the dimensions of the spinal canal and neural foramina during flexion and extension. By means of a positioning frame, 8 specimens (L2 to L5) were positioned to 15 degrees of flexion and 15 degrees of extension. Each specimen was assessed using magnetic resonance imaging (MRI), with and without the X-Stop, placed between the L3 to L4 spinous processes. Canal and foramina dimensions were compared between the intact and implanted specimens. These investigators concluded that the X-Stop prevents narrowing of the spinal canal and foramina in extension.

Lee and colleagues (2004) reported their preliminary findings on the use of the X-Stop for LSS in elderly patients (n = 10). Subjects were evaluated post-operatively by MRI and the Swiss Spinal Stenosis Questionnaire. Cross-sectional areas of the dural sac and intervertebral foramina at the stenotic level were measured post-operatively and compared with the pre-operative values. After implantation of the X-Stop, the cross-sectional area of the dural sac increased 16.6 mm² (22.3%) and intervertebral foramina increased 22 mm² (36.5%). The intervertebral angle as well as the posterior disc height
changed significantly. A total of 70% of the patients stated that they were satisfied with
the surgical outcome.

In a multi-center, prospective, randomized, controlled trial, Zucherman and colleagues
(2005) compared the outcomes of X-Stop treated NIC patients (n = 100) with their non-
operatively treated counterparts (n = 91). The primary outcomes measure was the Zurich
Claudication Questionnaire (ZCQ) – a patient-completed, validated instrument for NIC.
At every follow-up visit, X-Stop treated patients had significantly better outcomes in
each domain of the ZCQ. At 2 years, the X-Stop treated patients improved by 45.4%
over the mean baseline Symptom Severity score compared with 7.4% in the control
group; the mean improvement in the Physical Function domain was 44.3% in the X-Stop
group and -0.4% in the control group. In the X-Stop group, 73.1% patients were
satisfied with their treatment compared with 35.9% of control patients.

Siddiqui et al (2007) reported on the one year results of a prospective observational
study of the X Stop interspinous implant for the treatment of lumbar spinal stenosis.
Forty consecutive patients were enrolled and surgically treated with X Stop implantation.
The X Stop device was implanted at the stenotic segment, which was either at 1 or 2
levels in each patient. Sixteen of 40 patients failed to complete all clinical questionnaires
at each of the specified time intervals and were excluded from the study. The
investigators reported that, by 12 months after surgery, 54% of the 24 remaining
patients reported clinically significant improvement in their symptoms, 33 reported
clinically significant improvement in their physical function, and 71% expressed
satisfaction with the procedure. Twenty-nine percent of patients required caudal
epidural after 12 months for recurrence of their symptoms of neurogenic claudication.
The investigators noted that, although this study indicates that the X Stop offers
significant short-term improvement, these results were less favorable than the previous
randomized clinical study. Limitations of this study include the lack of a control group,
short duration of follow-up, and high proportion of dropouts.

In a literature review, Christie et al (2005) evaluated the mechanisms of action and
effectiveness of inter-spinous distraction devices in managing symptomatic lumbar
spinal pathology. They stated that these devices continue to be evaluated in clinical
trials; and that although the use of inter-spinous implants is still experimental, the early
results are promising, and it is likely that future studies will establish a niche for them in
the management of lumbar spinal pathology.

Bono and Vaccaro (2007) reviewed interspinous process devices for the lumbar spine,
and stated that, although some clinical data exist for some of these devices, defining the
indications for these minimally invasive procedures will be crucial. "Indications should emerge from thoughtful consideration of data from randomized controlled studies".

Based upon a systematic evidence review on inter-spinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine, the National Institute for Health and Clinical Excellence (NICE, 2006) concluded that "evidence of efficacy is limited and is confined to the medium and short term. These procedures should only be used in the context of special arrangements for consent, audit and research". Additionally, the specialist advisors to the Institute’s Interventional Procedures Advisory Committee noted that given the fluctuating symptoms associated with this condition, the assessment of outcomes in clinical studies may be unreliable. Furthermore, some advisors questioned the long-term effectiveness of the procedure.

The questions regarding the long-term effectiveness of the X-Stop raised by Christie et al (2005) as well as some specialist advisors of the National Institute for Health and Clinical Excellence’s Interventional Procedures Advisory Committee (2006) are congruous with those raised by documents released by the FDA in 2004 prior to a public hearing on the product. The FDA’s PMA review stated that "although the device can be inserted with a minimally invasive operative technique as an outpatient procedure with generally a local anesthetic a decision as to the safety and effectiveness of this device is based solely on 24 month data because information on the patient outcomes after 24 months is not available. This information becomes important when looking at pain relief and return to function. Even though the goal of the study was accomplished showing a significant, statistical difference between the investigational and control groups, more patients report improvement at 12 months than at 24 months. Contrary to what has been observed in spinal fusion studies, in this study, a percentage of patients whose symptoms improved at 6 and 12 months show a trend of regression of pain and function symptoms toward baseline levels. There appears to be a trend with early pain relief but the data suggests that in about 15% of patients initially successfully treated by the X-stop had only temporary relief".

On August 31, 2004, the FDA’s Orthopaedic and Rehabilitation Devices Panel voted 5 to 3 to recommend a "not approvable" decision on the PMA for the X-Stop. The Panel cited concern with the need to identify the patient population that is most likely to benefit from the device, noting that overall effectiveness was not demonstrated in a majority of the clinical study population. The Panel also cited concerns with the longer term effectiveness of the device (longer than 2 years), with potential bias in the clinical study, and with the need for radiographic or other objective evidence of the device’s mechanism of effect on the spine in patients.
As a condition of approval, the FDA has required the manufacturer to conduct a post-marketing study of the long-term safety and effectiveness of the X-Stop in patients who received the X-Stop under the Investigational Device Exemption (IDE). The FDA has required the manufacturer to conduct an additional post-approval study involving 240 patients at up to 8 clinical sites.

Guidelines from the North American Spine Society (NASS, 2007) concluded that there was insufficient evidence to support the use of the XSTOP in persons with lumbar spinal stenosis. The NASS guidelines noted: "Although the study cited in support of this recommendation is a level I study, it is a single study. Therefore, until further evidence is published there remains insufficient evidence to make a recommendation [about the use of the XSTOP in lumbar spinal stenosis]". More recently, guidelines from the North American Spine Society (NASS, 2011) concluded: "there is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis."

In summary, the clinical value of X-Stop for patients with LSS is still uncertain. In particular, whether its reported benefit will decline over time will require more research with longer-term evaluation. Additionally, further randomized controlled studies are needed to compare these inter-spinous process implants with traditional surgical interventions such as laminectomy and/or fusion.

In December 2004, the FDA granted 510(k) approval for ExtenSure bone allograft inter-spinous spacer device, which is a cylindrically fashioned piece of allograft bone intended to effect distraction, restore and maintain the space between 2 adjacent spinous processes and indirectly decompress a stenotic spinal canal at 1 or 2 levels. The procedure promotes fusion of the allograft to the spinous process above, while allowing motion between the allograft and the spinous process below. It is thought that this would provide a long-term solution to implant stability while retaining segmental motion. It may also be used to facilitate fusion between 2 or more adjacent spinous processes. This is similar to the action of the X-Stop device. However, there is a lack of clinical studies demonstrating effectiveness of the ExtenSure device.

The TOPS System, a total posterior arthroplasty implant, is an alternative to spinal fusion that is designed to stabilize but not fuse the affected vertebral level following decompression surgery to alleviate pain stemming from lumbar spinal stenosis while maintaining range of motion. It is indicated for patients with lower back and leg pain resulting from moderate-to-severe lumbar spinal stenosis at a single level between L3 and L5 that may be accompanied by facet arthrosis or degenerative spondylolisthesis.
The TOPS System is not available for commercial use in the United States. Enrollment for an FDA investigational device exemption study commenced in May 2008.

In a review of the evidence on surgery for LBP for the American Pain Society's clinical practice guideline, Chou et al (2009) concluded that surgery for radiculopathy with herniated lumbar disc and symptomatic spinal stenosis is associated with short-term benefits compared to non-surgical therapy, though benefits diminish with long-term follow-up in some trials. For non-radicular back pain with common degenerative changes, fusion is no more effective than intensive rehabilitation, but associated with small-to-moderate benefits compared to standard non-surgical therapy. Moreover, they stated that although there is fair evidence that an inter-spinous spacer device is moderately more effective than non-surgical therapy for 1- or 2-level spinous stenosis, there are insufficient data to evaluate long-term benefits and harms.

The Coflex (Paradigm Spine) is an interlaminar spinal stabilization device for persons with lumbar stenosis that is implanted following laminectomy and decompression. The device is intended to provide benefits over fusion, including durable pain relief, maintenance of spinal motion, reduced hypermobility of adjacent segments resulting in reduced degeneration at adjacent levels. A pivotal randomized controlled clinical trial evaluated the noninferiority of the Coflex interlaminar stabilization with instrumented posterolateral spinal fusion (pedicle screw fixation) in subjects with back pain and spinal stenosis and no or mild instability (up to grade 1 spondylolisthesis) who had failed conservative management. The primary outcome of the study is improvements in Oswestry Disability Index (ODI) score, and secondary outcomes include the Visual Analog Scale (VAS) back and leg pain, and the Zurich Claudication Questionnaire (ZCQ) score. Other endpoints measured include range of motion at the level adjacent to the procedure, as range of motion has been found to be related to the development of adjacent level degeneration and disease. Subjects were followed over a two-year period. Limitations of the study include the lack of blinding and the intermediate duration of the study. In addition, the study compared the effectiveness of the Coflex device with spinal fusion in spinal stenosis subjects with no instability; however, the benefits of spinal fusion this group of patients is uncertain.

In a prospective, randomized, multi-center, FDA IDE trial, Davis et al (2013a) evaluated the safety and effectiveness of Coflex interlaminar stabilization compared with posterior spinal fusion (PSF) in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. A total of 322 patients (215 Coflex and 107 fusions) from 21 sites in the U.S. were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and postero-lateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a
15-point reduction in ODI, no re-operations, no major device-related complications, and no post-operative epidural injections. Patient follow-up at minimum 2 years was 95.3% and 97.2% in the Coflex and fusion control groups, respectively. Patients taking Coflex experienced significantly shorter operative times ($p < 0.0001$), blood loss ($p < 0.0001$), and length of stay ($p < 0.0001$). There was a trend toward greater improvement in mean ODI scores in the Coflex cohort ($p = 0.075$). Both groups demonstrated significant improvement from baseline in all VAS back and leg parameters. Patients taking Coflex experienced greater improvement in Short-Form 12 physical health outcomes ($p = 0.050$) and equivalent mental health outcomes. Coflex subjects experienced significant improvement in all ZCQ outcomes measures compared with fusion (symptom severity [$p = 0.023$]; physical function [$p = 0.008$]; satisfaction [$p = 0.006$]). Based on the FDA composite for overall success, 66.2% of Coflex and 57.7% of fusions succeeded ($p = 0.999$), thus demonstrating non-inferiority. The overall adverse event rate was similar between the groups, but Coflex had a higher re-operation rate (10.7% versus 7.5%, $p = 0.426$). At 2 years, fusions exhibited increased angulation ($p = 0.002$) and a trend toward increased translation ($p = 0.083$) at the superior adjacent level, whereas Coflex maintained normal operative and adjacent level motion. The authors concluded that Coflex interlaminar stabilization is a safe and effective alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.

In a prospective, randomized, multi-center FDA IDE trial, Davis et al (2013b) evaluated the safety and effectiveness of Coflex Interlaminar Stabilization compared with PSF to treat low-grade spondylolisthesis with spinal stenosis. A total of 322 patients from 21 sites in the U.S. were enrolled between 2006 and 2008 for the IDE trial. The current study evaluated only the subset of patients from this overall cohort with Grade 1 spondylolisthesis (99 in the Coflex group and 51 in the fusion group). Subjects were randomized 2:1 to receive decompression and Coflex interlaminar stabilization or decompression and PSF with spinal instrumentation. Data collected included peri-operative outcomes, ODI, back and worse leg VAS scores, 12-Item Short Form Health Survey, ZCQ, and radiographic outcomes at a minimum of 2 years. The FDA criteria for overall device success required the following to be met: 15-point reduction in ODI, no re-operations, no major device-related complications, and no post-operative epidural injections. At a minimum of 2 years, patient follow-up was 94.9% and 94.1% in the Coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. The average age was 63 years in the Coflex cohort and 65 years in the fusion cohort. Coflex subjects experienced significantly shorter operative times ($p < 0.0001$), less estimated blood loss ($p < 0.0001$), and shorter length of stay ($p < 0.0001$) than fusion controls. Both groups experienced significant improvements from baseline at 2 years in ODI, VAS back, VAS
leg, and ZCQ, with no significant group differences, with the exception of significantly
greater ZCQ satisfaction with Coflex at 2 years. The FDA overall success was achieved in
62.8% of Coflex subjects (59 of 94) and 62.5% of fusion controls (30 of 48) (p = 1.000).
The re-operation rate was higher in the Coflex cohort (14 [14.1%] of 99) compared with
fusion (3 [5.9%] of 51, p = 0.18), although this difference was not statistically significant.
Fusion was associated with significantly greater angulation and translation at the
superior and inferior adjacent levels compared with baseline, while Coflex showed no
significant radiographic changes at the operative or index levels. The authors concluded
that low-grade spondylolisthesis was effectively stabilized by Coflex and led to similar
clinical outcomes, with improved per-operative outcomes, compared with PSF at 2 years.
Re-operation rates, however, were higher in the Coflex cohort. Patients in the fusion
cohort experienced significantly increased superior and inferior level angulation and
translation, while those in the Coflex cohort experienced no significant adjacent or index
level radiographic changes from baseline. Coflex Interlaminar Stabilization is a less
invasive, safe, and equally effective clinical solution to PSF to treat low-grade
spondylolisthesis, and it appears to reduce stresses at the adjacent levels.

The major drawback associated with these 2 studies were:

I. lack of patient blinding,

II. these studies did not assess the effectiveness of a fusion group consisting of lumbar
intervertebral cages or BMP, and

III. it is possible a subset of patients with a stable slip and with minimal back pain may
benefit from decompression only, without the need for stabilization.

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Furthermore, long-term data are needed to ascertain if motion preservation with the Coflex device will lead to lower re-operation rates for adjacent level disease compared with fusion.

Also, an UpToDate review on "Subacute and chronic low back pain: Surgical treatment" (Chou, 2013) does not mention Coflex/interlaminar stabilization as a therapeutic option.

The pivotal investigational device exemption (IDE) trial for Coflex® Interlaminar Technology was a non-blinded, randomized, multi-center, non-inferiority trial of Coflex® compared to postero-lateral fusion with pedicle screw fixation. A total of 344 patients were randomized in a 2:1 ratio (215 Coflex® and 107 fusion controls, with 22 protocol violators). This study was conducted in a restricted population with numerous exclusion criteria. Compared to fusion, implantation of the Coflex® device required less operative time (98.0 versus 153.2 mins) and resulted in less blood loss (109.7 versus 348.6 cc) and a shorter hospital stay (1.9 versus 3.2 days). Composite clinical success (a combination of a minimum 15-point improvement in Oswestry Disability Index (ODI), no re-operations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months achieved non-inferiority compared to postero-lateral fusion (66.2% Coflex® and 57.7% fusion). Secondary effectiveness criteria, which included the ZCQ, visual analog score (VAS) for leg and back pain, Short Form-12 (SF-12), time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the Coflex® group by Bayesian analysis. In this analysis, non-overlapping confidence intervals imply statistically reliable group differences. For example, ZCQ composite success was achieved in 78.3% of Coflex® patients (95% confidence interval [CI]: 71.9% to 84.7%) compared to 67.4% of controls (95% CI: 57.5% to 77.3%). The percentage of device-related adverse events was the same for the 2 groups (5.6% Coflex® and 5.6% control), and a similar percentage of asymptomatic spinous process fractures were observed. The FDA considered the data in this non-blinded study to support reasonable assurance of safety and effectiveness for device approval, but approval is conditional on 2 additional studies that will provide longer-term follow-up (in the IDE cohort) and evaluate device performance under actual conditions of use (decompression alone versus decompression with Coflex®).

Wouter et al (2014) commented that the FDA does not demand that the experimental treatment for a device is compared with the "gold standard." The author noted that interspinous process device (IPD) treatment with bony decompression was approved in the United States, after the publication of an FDA study on IPD treatment (citing Davis, et al., 2013). However, this study did not compare the experimental treatment (IPD) with the "gold standard" (bony decompression) but with another experimental treatment (bony decompression with fixation techniques). Wouter, et al. (2014) noted that most
studies of interspinous process devices (IPD) did not compare the results with other interventions and most did not have prospective study designs. The authors stated that it took 30 years (from the introduction of the Wallis IPD in 1984 until 2013) until 2 prospective studies of IPDs were published that compared IPD treatment with conventional (surgical) care (citing Moojen, et al., 2013; Davis, et al., 2013; Moojen, et al., 2010; Stromqvist, et al., 2013). These studies showed that treatment with IPD was not superior to bony decompression without implants and that IPD treatment resulted in a higher reoperation rate (citing Moojen, et al., 2013; Stromqvist, et al., 2013). A third study of an IPD (X-Stop) was terminated because of the high number of reoperations (complications) in the experimental (IPD) group (Lønne, 2013).

Richter et al (2010) reported a prospective case control study of the Coflex® device in 60 patients who underwent decompressive surgery. The 2-year follow-up from this study was published in 2014 (Richter et al). These investigators prospectively evaluated the outcome of symptomatic lumbar spinal stenosis (LSS) treated with decompressive surgery alone in comparison with additional implantation of the Coflex® interspinous device. A total of 62 patients with symptomatic LSS were treated with decompressive surgery; 31 of these patients received an additional Coflex® device. Pre-operatively and post-operatively, disability and pain scores were measured using the ODI, the Roland-Morris Disability Questionnaire, the VAS, and the pain-free walking distance. Patients underwent post-operative assessments at 3, 6, 12, and 24 months including the above-mentioned scores and patient satisfaction. There was a significant improvement (p < 0.001) in the clinical outcome assessed in the ODI, the Roland-Morris Disability Questionnaire, the VAS, and the pain-free walking distance at all times of re-investigation compared with the base line in both groups. Up to 2 years after surgery, there were no significant differences between both groups in all ascertained parameters, including the patient satisfaction and subjective operation decision. The authors concluded that the results of this first prospective controlled study indicated that the additional placement of a Coflex® interspinous device does not improve the already good clinical outcome after decompressive surgery for LSS in the 24-month follow-up interval.

In a randomized controlled trial, Moojen et al (2013) examined if interspinous process device implantation is more effective in the short-term than conventional surgical decompression for patients with intermittent neurogenic claudication due to lumbar spinal stenosis. A total of 203 participants were referred to the Leiden-The Hague Spine Prognostic Study Group between October 2008 and September 2011; 159 participants with intermittent neurogenic claudication due to lumbar spinal stenosis at 1 or 2 levels with an indication for surgery were randomized. A total of 80 participants received an interspinous process device and 79 participants underwent spinal bony decompression.
The primary outcome at short-term (8 weeks) and long-term (1 year) follow-up was the Zurich Claudication Questionnaire score. Repeated measurements were made to compare outcomes over time. At 8 weeks, the success rate according to the Zurich Claudication Questionnaire for the interspinous process device group (63%, 95% confidence interval [CI]: 51% to 73%) was not superior to that for standard bony decompression (72%, CI: 60% to 81%). No differences in disability (Zurich Claudication Questionnaire; p = 0.44) or other outcomes were observed between groups during the 1st year. The repeat surgery rate in the interspinous implant group was substantially higher (n = 21; 29%) than that in the conventional group (n = 6; 8%) in the early post-surgical period (p < 0.001). The authors concluded that this double blinded study could not confirm the hypothesized short-term advantage of interspinous process device over conventional "simple" decompression and even showed a fairly high re-operation rate after interspinous process device implantation. Furthermore, for orthopedic studies with implanted device, 1 year follow-up would not be considered long-term.

Mohi Eldin (2014) evaluated the safety and effectiveness of the Coflex Dynamic Distraction Stabilization (DDS) device in treating patients with degenerative diseases of the lumbar spine (DDLS), especially lumbar canal stenosis (LCS), to confirm its indications for implantation and to evaluate the clinical outcomes of patients. This study was part of a multi-center prospective, case-controlled study in Egypt to determine the safety and efficacy of minimally invasive spinal procedures; of these, the Coflex implant, a functionally dynamic U-shaped titanium interspinous implant, was included in the present study. From June 2008 until July 2013, these researchers treated 42 patients with this Coflex procedure. Median follow-up was 22.5 months. At the time of follow-up, all patients completed questionnaires and underwent clinical examination and spinal radiography. A significant number of patients showed pain relief. Pre-operatively, 30/42 (71%) patients complained of moderate or severe low back pain (LBP). Post-operatively, the LBP in 6 (14%) patients did improve, 24 (57%) even showed no low back pain anymore. Mean pre-operative walking distance was less than 1,000m in 36 (86%) patients. Post-operatively, all 42 (100%) patients could walk greater than 1,000m. Significant pain relief (greater than 50%) in months was calculated. Radiological results showed that endplate angles when were acute pre-operatively, always became less acute post-operatively, and the foraminal height always increased. Segmental range of motion (ROM) showed maintenance of the dynamic movements at the operated level. Disc height showed significant changes after the procedure in both anterior and posterior disc heights. The authors noted that merging the clinical and radiological results of the current study suggested that these effects produce a clinical benefit for LCS patients treated with the Coflex spacer. Though this series has limitations of a smaller sample size, it nevertheless confirmed the satisfactory results. These researchers stated that they will continue to follow the patients enrolled in this study, together with
new cases and will report on the longer follow-up. This was a small study (n = 42) with mid-term follow-up (median of 22.5 months). There is a lack of data on durability; well-designed studies with more subjects and longer follow-up are needed.

Yuan et al (2017) retrospectively compared the at least 5-year clinical and radiological outcomes of Coflex stabilization and PLIF for lumbar degenerative disease. Eighty-seven consecutive patients with lumbar degenerative disease were retrospectively reviewed. Forty-two patients underwent decompression and Coflex interspinous stabilization (Coflex group), 45 patients underwent decompression and PLIF (PLIF group). Clinical and radiological outcomes were evaluated. Coflex subjects experienced less blood loss, shorter hospital stays and shorter operative time than PLIF (all p < 0.001). Both groups demonstrated significant improvement in Oswestry Disability Index and visual analogue scale back and leg pain at each follow-up time point. The Coflex group had significantly better clinical outcomes during early follow-up. At final follow-up, the superior and inferior adjacent segments motion had no significant change in the Coflex group, while the superior adjacent segment motion increased significantly in the PLIF group. At final follow-up, the operative level motion was significantly decreased in both groups, but was greater in the Coflex group. The reoperation rate for adjacent segment disease was higher in the PLIF group, but this did not achieve statistical significance (11.1% vs. 4.8%, p = 0.277). Both groups provided sustainable improved clinical outcomes for lumbar degenerative disease through at least 5-year follow-up.

In an extension of the study reported by Davis, et al. in 2013, Musacchio, et al. (2016) reported on five-year outcomes of a prospective, randomized, controlled trial conducted at 21 centers. Patients with moderate to severe lumbar stenosis at one or two contiguous levels and up to Grade I spondylolisthesis were randomized (2:1 ratio) to decompression and interlaminar stabilization (D+ILS; n=215) using the Coflex Interlaminar Stabilization device or decompression and fusion with pedicle screws (D+PS; n=107). Clinical evaluations were made preoperatively and at 6 weeks and 3, 6, 12, 18, 24, 36, 48, and 60 months postoperatively. Overall FDA success criteria required that a patient meet 4 criteria: 1) >15 point improvement in Oswestry Disability Index (ODI) score; 2) no reoperation, revision, removal, or supplemental fixation; 3) no major device-related complication; and 4) no epidural steroid injection after surgery. At 5 years, 50.3% of D+ILS vs. 44% of D+PS patients (p>0.35) met the composite success criteria. Reoperation/revision rates were similar in the two groups (16.3% vs. 17.8%; p >0.90). Both groups had statistically significant improvement through 60 months in ODI scores with 80.6% of D+ILS patients and 73.2% of D+PS patients demonstrating >15 point improvement (p>0.30). VAS, SF-12, and ZCQ scores followed a similar pattern of maintained significant improvement throughout follow-up. On the SF-12 and ZCQ, D+ILS group scores were statistically significantly better during early follow-up.
compared to D+PS. In the D+ILS group, foraminal height, disc space height, and range of motion at the index level were maintained through 5 years. This study compared the effectiveness of the Coflex device with spinal fusion in spinal stenosis subjects, some with low-grade spondylolisthesis; however, the benefits of spinal fusion in persons with spinal stenosis with low-grade spondylolisthesis are uncertain (see, e.g., Försth, et al., 2016; Puel & Moojen, 2016; Ghogawala, et al., 2016).

The Work Loss Data Institute's guideline on “Low back – lumbar & thoracic (acute & chronic)” (2013) listed interspinous decompression device (X-Stop) as one of the interventions/procedures that were considered, but was not recommended.

The North American Spine Society (NASS)'s clinical guideline on “Diagnosis and treatment of degenerative lumbar spondylolisthesis” (2014) stated that “There is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/interventional treatment in the management of degenerative lumbar spondylolisthesis patients. Grade of Recommendation: I (Insufficient Evidence).”

Puzzilli et al (2014) evaluated patients who were treated for symptomatic lumbar spinal stenosis with interspinous process decompression (IPD) implants compared with a population of patients managed with conservative treatment. A total of 542 patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial; 422 patients underwent surgical treatment consisting of X-STOP device implantation, whereas 120 control cases were managed conservatively. Both patient groups underwent follow-up evaluations at 6, 12, 24, and 36 months using the Zurich Claudication Questionnaire, the visual analog scale (VAS) score and spinal lumbar X-rays, CT scans and MR imaging. One-year follow-up evaluation revealed positive good results in the 83.5% of patients treated with IPD with respect to 50% of the non-operative group cases. During the first 3 years, in 38 out of the 120 control cases, a posterior decompression and/or spinal fixation was performed because of unsatisfactory results of the conservative therapy. In 24 (5.7%) of 422 patients, the IPD device had to be removed, and a decompression and/or pedicle screw fixation was performed because of the worsening of neurological symptoms. The authors concluded that these findings supported the effectiveness of surgery in patients with stenosis; IPD may offer an effective and less invasive alternative to classical microsurgical posterior decompression in selected patients with spinal stenosis and lumbar degenerative disk diseases.

Doulgeris et al (2015) compared an interspinous fusion device with posterior pedicle screw system in a lateral lumbar interbody lumbar fusion. These researchers biomechanically tested 6 cadaveric lumbar segments (L1 to L2) under an axial preload of
50N and torque of 5Nm in flexion-extension, lateral bending and axial rotation directions. They quantified range of motion, neutral zone/elastic zone stiffness in the following conditions: intact, lateral discectomy, lateral cage, cage with interspinous fusion, and cage with pedicle screws. A complete lateral discectomy and annulectomy increased motion in all directions compared to all other conditions. The lateral cage reduced motion in lateral bending and flexion/extension with respect to the intact and discectomy conditions, but had minimal effect on extension stiffness. Posterior instrumentation reduced motion, excluding interspinous augmentation in axial rotation with respect to the cage condition. Interspinous fusion significantly increased flexion and extension stiffness, while pedicle screws increased flexion/extension and lateral bending stiffness, with respect to the cage condition. Both posterior augmentations performed equivalently throughout the tests except in lateral bending stiffness where pedicle screws were stiffer in the neutral zone. The authors concluded that a lateral discectomy and annulectomy generated immediate instability. Stand-alone lateral cages restored a limited amount of immediate stability, but posterior supplemental fixation increased stability. Both augmentations were similar in a single level lateral fusion in vitro model, but pedicle screws are more equipped for coronal stability. They stated that an interspinous fusion is a less invasive alternative than pedicle screws and is potentially a conservative option for various interbody cage scenarios.

Hirsch et al (2015) stated that lumbar spinal stenosis is a major public health issue. Interspinous devices implanted using minimally invasive techniques may constitute an alternative to the reference standard of bony decompression with or without intervertebral fusion. However, their indications remain unclear, due to a paucity of clinical and biomechanical data. These investigators evaluated the effects of four interspinous process devices implanted at L4 to L5 on the intervertebral foramen surface areas at the treated and adjacent levels, in flexion and in extension. Six fresh frozen human cadaver lumbar spines (L2 to sacrum) were tested on a dedicated spinal loading frame, in flexion and extension, from 0 to 10 N·m, after preparation and marking of the L3 to L4, L4 to L5, and L5 to S1 foramina. Stereoscopic 3D images were acquired at baseline then after implantation at L4 to L5 of each of the 4 devices (Inspace®, Synthes; X-Stop®, Medtronic; Wallis®, Zimmer; and Diam®, Medtronic). The surface areas of the 3 foramina of interest were computed. All 4 devices significantly opened the L4 to L5 foramen in extension. The effects in flexion separated the devices into 2 categories. With the 2 devices characterized by fixation in the spinous processes (Wallis® and Diam®), the L4 to L5 foramen opened only in extension; whereas with the other 2 devices (X-Stop® and Inspace®), the L4 to L5 foramen opened not only in extension, but also in flexion and in the neutral position. None of the devices implanted at L4 to L5 modified the size of the L3 to L4 foramen. X-Stop® and Diam® closed the L5 to S1 foramen in extension, whereas the other 2 devices had no effect at this level. The authors concluded
that these findings demonstrated that interspinous process devices modified the surface area of the interspinous foramina in-vitro. They stated that clinical studies are needed to clarify patient selection criteria for interspinous process device implantation.

Lee et al (2015) conducted a systematic literature review of interspinous dynamic stabilization, including Diam®, Wallis®, Coflex, and X-STOP®, to assess its safety and efficacy. A literature search was done in Korean and English, by using eight domestic databases which included KoreaMed and international databases, such as Ovid Medline, Embase, and the Cochrane Library. A total of 306 articles were identified, but the animal studies, preclinical studies, and studies that reported the same results were excluded. As a result, a total of 286 articles were excluded and the remaining 20 were included in the final assessment. Two assessors independently extracted data from these articles using predetermined selection criteria. Qualities of the articles included were assessed using Scottish Intercollegiate Guidelines Network (SIGN). The complication rate of interspinous dynamic stabilization has been reported to be 0% to 32.3% in 3- to 41-month follow-up studies. The complication rate of combined interspinous dynamic stabilization and decompression treatment (32.3%) was greater than that of decompression alone (6.5%), but no complication that significantly affected treatment results was found. Interspinous dynamic stabilization produced slightly better clinical outcomes than conservative treatments for spinal stenosis. Good outcomes were also obtained in single-group studies. No significant difference in treatment outcomes was found, and the studies compared interspinous dynamic stabilization with decompression or fusion alone. The authors of the systematic review concluded that no particular problem was found regarding the safety of the technique. Its clinical outcomes were similar to those of conventional techniques, and no additional clinical advantage could be attributed to interspinous dynamic stabilization. However, few studies have been conducted on the long-term efficacy of interspinous dynamic stabilization. Thus, the authors suggest further clinical studies be conducted to validate the theoretical advantages and clinical efficacy of this technique.

The Australian Medical Services Advisory Committee (MSAC, 2017) found insufficient evidence to support the Coflex Interlaminar Stabilization device. MSAC considered that the evidence comparing use of the device with decompression and fusion, and with decompression alone, for LSS was too limited to support the listing and no evidence was presented comparing use of the device to other alternatives for mild degenerative instability alone. MSAC noted that any resubmission would require high quality trial evidence that compared the benefits, harms and cost-effectiveness of using the device with decompression alone, and with decompression and fusion. Such a resubmission should also clarify the appropriate patient population who need ‘stabilization’.
Patel et al (2015a) noted that interspinous spacers are a less-invasive treatment alternative compared with surgical decompression for patients with LSS unresponsive to conservative care. High-quality comparative data with these devices are lacking. In a prospective, multi-center, randomized, controlled, IDE non-inferiority trial, these researchers determined the 2-year outcomes in patients with intermittent neurogenic claudication secondary to moderate LSS who were treated with the Superion interspinous process spacer. Patients presenting with intermittent neurogenic claudication secondary to moderate LSS who failed at least 6 months of non-surgical management were randomly allocated to treatment with the Superion spacer or a control spacer (X-Stop) and followed for 2 years. A total of 391 randomized patients were implanted with Superion (n = 190) or control (n = 201) spacers at 29 sites in the U.S. between August 2008 and December 2011. Implants were successfully implanted in 99.5 % of patients with Superion and 99.0 % of control patients. The primary composite end-point of this study was met, which demonstrated that the Superion spacer was non-inferior to the X-Stop spacer. Leg pain, the predominant patient complaint, decreased in severity by 70 % during 2 years in each group. Most (77 %) patients achieved leg pain clinical success (improvement greater than or equal to 20 mm) at 2 years. Back pain clinical success (improvement greater than or equal to 20 mm) was 68 %, with no differences between groups; ODI clinical success (greater than or equal to 15 % point improvement) was achieved in 65 % of patients. The rates of complications and re-operations were similar between groups. The authors concluded that the Superion interspinous process spacer relieved symptoms of intermittent neurogenic claudication secondary to moderate LSS in the majority of patients through 2 years. These researchers stated that the Superion device may represent a reasonable therapeutic option for this patient population.

The authors stated that this study had several drawbacks. The long-term durability of interspinous process spacers is currently unknown and requires further investigation. In addition, the generalizability of these findings may only be applicable to patients with radiographically confirmed moderate LSS with no more than low-grade spondylolisthesis deformities. The finding that patients with a spinous process fracture yielded similar long-term clinical results to patients without a spinous process fracture brought into question the mechanisms of mechanical action of these devices. Finally, a comparison of interspinous process spacers with non-surgical treatment or surgical decompression was not performed; thus this randomized study provided no information on these interesting questions.

Patel et al (2015b) provided the 3-year clinical outcomes from the randomized, controlled FDA IDE trial of the Superion for the treatment of moderate degenerative LSS. The Superion was evaluated in the treatment of subjects aged 45 years or older.
suffering from symptoms of intermittent neurogenic claudication, secondary to a confirmed diagnosis of moderate degenerative LSS at 1 or 2 contiguous levels from L1 to L5. Patients were treated between June 2008 and December 2011 at 31 investigational sites. A total of 391 subjects were included in the randomized study group consisting of 190 Superion and 201 X-STOP control subjects. The primary composite end-point was individual patient success based on 4 components: improvement in 2 of 3 domains of the Zurich Claudication Questionnaire, no re-operations at the index level, no major implant/procedure-related complications, and no clinically significant confounding treatments. At 3 years, the proportion of subjects achieving the primary composite end-point was greater for Superion (63/120, 52.5 %) than for X-STOP (49/129, 38.0 %) (p = 0.023) and the corresponding success rates exceeded 80 % for each of the individual components of the primary end-point in the Superion group (range of 81 % to 91%). Improvements in back and leg pain severity as well as back- and disease-specific functional outcomes were also maintained through 36 months. The authors concluded that the 3-year outcomes from this RCT demonstrated durable clinical improvement consistently across all clinical outcomes for the Superion in the treatment of patients with moderate degenerative LSS.

These researchers stated that the durable clinical results achieved with the Superion in the current study were further reflected in a low conversion rate to surgical decompression of only 14 % (26/190) at 3 years. This finding may have a profound effect on the health economics and societal costs of treating the increasing number of patients suffering from spinal stenosis. Indeed, approximately 40 % of patients treated conservatively to alleviate early signs of spinal stenosis ultimately require decompression surgery within 10 years due to persistently worsening symptoms. They stated that the use of an InterSpinous Spacer at the appropriate juncture in the continuum of care may obviate the need for decompression surgery in the majority of patients carefully selected in accordance with the approved indications for use. This study provided short-term follow-up data.

Parker et al (2015) noted that LSS is a painful and debilitating condition resulting in healthcare costs totaling tens of billions of dollars annually. Initial treatment consists of conservative care modalities such as physical therapy, NSAIDs, opioids, and steroid injections. Patients refractory to these therapies can undergo decompressive surgery, which has good long-term efficacy but is more traumatic and can be associated with high post-operative AE rates. Interspinous spacers have been developed to offer a less-invasive alternative. These researchers compared the costs and quality adjusted life years (QALYs) gained of conservative care (CC) and decompressive surgery (DS) to a new minimally-invasive interspinous spacer. A Markov model was developed evaluating 3 strategies of care for LSS. If initial therapies failed, the model moved patients to more
invasive therapies. Data from the Superion FDA clinical trial, a prospective spinal registry, and the literature were used to populate the model. Direct medical care costs were modeled from 2014 Medicare reimbursements for healthcare services; QALYs came from the SF-12 PCS and MCS components. The analysis used a 2-year time horizon with a 3% discount rate. CC had the lowest cost at $10,540, while Spacers and DS were nearly identical at about $13,950. CC also had the lowest QALY increase (0.06), while Spacers and DS were again nearly identical (0.28). The incremental cost-effectiveness ratios (ICER) for Spacers compared to CC was $16,300 and for DS was $15,200. The authors concluded that both the Spacer and DS strategies were far below the commonly cited $50,000/QALY threshold and produced several times the QALY increase versus CC, suggesting that surgical care provided superior value (cost/effectiveness) versus sustained conservative care in the treatment of LSS.

The authors stated that the limitations inherent in this study had significant implications for its interpretation. As in many studies using economic models, the treatments were not all randomized against one another. If outcomes were related to patient characteristics, this could cause bias in the comparisons. To address differences in patients at baseline, these investigators modeled failure rates and QALYs gained as a function of baseline ODI, and adjusted when indicated. While small sample sizes, such as those used in this model, did not in themselves cause bias, they did lead to more variable estimates of each treatment's effectiveness, and thus more uncertainty in the comparisons. This may be especially true during the 2nd year after the procedure, when the original sample size was somewhat reduced. However, this base case failure rates were within the range of other studies. For DS, the failure rate was 9.2% over 2 years, somewhat higher than 6.8% from Burnett, but similar to 8.9% (35/394) reported from the SPORT study. In addition, results from the probabilistic sensitivity analysis (PSA) were similar to the base case analysis, showing higher cost and greater QALYs gained for the surgical strategies compared to the CC strategy. Utility was estimated as a function of age, sex, SF-12 MCS and PCS scores. These researchers did not recognize a utility decrement when a patient suffered an AE or incurred an inpatient rehabilitation facility (IRF) stay; but because these were short-term events, they would have had minor impact on 2-year utility. The QALYS gained by 2 years were also similar to previous studies. For Spacer, the QALY gained was 0.144 which compared to 0.14 from Skidmore and 0.15 from Burnett. Similarly, the DS QALY gained was 0.15, which compared to 0.08 from Skidmore and 0.16 from Burnett and 0.17 from Tosteson. Finally, the analysis was limited to a 2-year time horizon due to the available data. LSS is a lifetime condition, so longer time horizons may be of interest even in the commercial insurance market. It will be important to extend the time horizon of this and other studies as longer-term data become available on interspinous spacers.
Lonne et al (2015) noted that LSS is the most common indication for operative treatment in elderly. Laminectomy has been the "gold standard", but minimally invasive decompression (MID) is now widely used. Another minimally invasive surgery option is X-Stop showing good result compared with non-operative treatment, but showing higher re-operation rate than laminectomy. In a prospective, multi-center RCT, these researchers compared the effect of X-Stop with MID in patients with neurogenic intermittent claudication due to LSS. These researchers enrolled 96 patients aged 50 to 85 years, with symptoms of neurogenic intermittent claudication within 250-m walking distance and 1- or 2-level LSS, randomized to either MID or X-Stop. Primary outcome was ZCQ in this intention-to-treat (ITT) analysis. Secondary outcome was ODI, EuroQol 5-dimensional questionnaire, NRS 11 for LBP and leg pain, and risk for secondary surgery and complications. No significant differences were found in ZCQ between the groups at any follow-ups. Both groups had a statistical and clinical significant improvement at 6 weeks and throughout the 2-year observation period. The number of patients having secondary surgery due to persistent or recurrent symptoms was significantly higher in the X-Stop group (95 % CI: 6.5 (1.3 to 31.9). Complication rate was similar and low, but more severe for MID. The authors concluded that both MID and X-Stop led to significant symptom improvements. There were no significant clinical differences in effect between the methods at any of the follow-up time points. X-Stop had significant higher risk of secondary surgery. Complication was more severe for MID.

Lauryssen et al (2015) compared the 2-year clinical outcomes of a prospective, RCT of an FDA-approved interspinous spacer with the compilation of published findings from 19 studies of decompressive laminectomy for the treatment of LSS. Back and leg pain, ODI, and ZCQ values were compared between spacer- and laminectomy-treated patients pre-operatively and at 12 and 24 months. Percentage improvements between baseline and 24 months uniformly favored patients treated with the spacer for back pain (65 % versus 52 %), leg pain (70 % versus 62 %), ODI (51 % versus 47 %) and ZCQ symptom severity (37 % versus 29 %) and physical function (36 % versus 32 %). The authors concluded that both treatments provided effective and durable symptom relief of claudicant symptoms. This stand-alone interspinous spacer offered the patient a minimally invasive option with less surgical risk. This study provided short-term follow-up data (24 months).

Nunley et al (2017a) determined the 4-year clinical outcomes in patients with moderate LSS treated with minimally invasive stand-alone interspinous process decompression using the Superion device. The 4-year Superion data were extracted from a randomized, controlled FDA IDE. Patients with intermittent neurogenic claudication relieved with back flexion who failed at least 6 months of non-surgical management were enrolled. Outcomes included ZCQ symptom severity (ss), physical function (pf) and
patient satisfaction (ps) subdomains, leg and back pain VAS, and ODI. At 4-year follow-up, 89 of the 122 patients (73 %) provided complete clinical outcome evaluations. At 4 years after index procedure, 75 of 89 patients with Superion (84.3 %) demonstrated clinical success on at least 2 of 3 ZCQ domains. Individual component responder rates were 83 % (74/89), 79 % (70/89), and 87 % (77/89) for ZCQss, ZCQpf, and ZCQps; 78 % (67/86) and 66 % (57/86) for leg and back pain VAS; and 62 % (55/89) for ODI. Patients with Superion also demonstrated percentage improvements over baseline of 41 %, 40 %, 73 %, 69 %, and 61 % for ZCQss, ZCQpf, leg pain VAS, back pain VAS, and ODI. Within-group effect sizes all were classified as very large (greater than 1.0): 1.49, 1.65, 1.42, 1.12, and 1.46 for ZCQss, ZCQpf, leg pain VAS, back pain VAS, and ODI. The authors concluded that minimally invasive implantation of the Superion device provided long-term, durable relief of symptoms of intermittent neurogenic claudication for patients with moderate lumbar spinal stenosis.

Nunley et al (2017b) stated that lumbar spinal stenosis is the most common indication for spine surgery in older adults. Interspinous process decompression (IPD) using a stand-alone spacer that functions as an extension blocker offers a minimally invasive therapeutic option for intermittent neurogenic claudication associated with spinal stenosis. This study evaluated the 5-year clinical outcomes for IPD (Superion®) from a randomized controlled FDA non-inferiority trial. Outcome measures included Zurich Claudication Questionnaire (ZCQ) symptom severity (ss), physical function (pf), and patient satisfaction (ps) subdomains, leg and back pain visual analog scale (VAS), and Oswestry Disability Index (ODI). At 5 years, 84% of patients (74 of 88) demonstrated clinical success on at least 2 of 3 ZCQ domains. Individual ZCQ domain success rates were 75% (66 of 88), 81% (71 of 88), and 90% (79 of 88) for ZCQss, ZCQpf, and ZCQps, respectively. Leg and back pain success rates were 80% (68 of 85) and 65% (55 of 85), respectively, and the success rate for ODI was 65% (57 of 88). Percentage improvements over baseline were 42%, 39%, 75%, 66%, and 58% for ZCQss, ZCQpf, leg and back pain VAS, and ODI, respectively (all p < 0.001). Within-group effect sizes were classified as very large for 4 of 5 clinical outcomes (i.e., greater than 1.0; all p < 0.0001); 75% of IPD patients were free from re-operation, revision, or supplemental fixation at their index level at 5 years. The authors concluded that after 5 years of follow-up, IPD with a stand-alone spacer provided sustained clinical benefit. Financial support for this work was provided by VertiFlex, Inc. (Carlsbad, CA).

Zhao et al (2017) stated that IPD were widely used for the treatment of lumbar spinal stenosis (LSS). However, whether IPD was superior to bony decompression (DP) was still debated. These investigators compared the clinical outcomes of IPD to DP for LSS. PubMed, Cochrane library, Cochrane Central Register of Controlled Trials (CCTR), Ovid Medline, China national knowledge internet database, Wan Fang database were
searched on August 8, 2016. Studies were identified using selection criteria and analysis was performed with Review Manager Version 5.3. A total of 4 RCTs (7 articles) were included, with 200 patients in the IPD group and 200 patients in DP group. There was no significant difference in hospital stay time ($p = 0.36$), VAS leg pain scores ($p = 0.83$), and complication rates ($p = 0.20$) for IPD alone versus DP. However, IPD alone showed higher VAS low back pain scores ($p = 0.03$) and re-operation rates ($p < 0.0001$) between the 2 therapy groups. Two studies' results showed the IPD group had lower cost-effectiveness. The authors concluded that although patients who received IPD may obtain several benefits in the short-term, it was associated with higher costs, re-operation rates. These researchers stated that larger sample size studies and longer follow-up are needed to evaluate the IPD.

Poetscher et al (2018) noted that degenerative LSS is a condition related to aging in which structural changes cause narrowing of the central canal and intervertebral foramen. It is currently the leading cause for spinal surgery in patients over 65 years; IPDs were introduced as a less invasive surgical alternative, but questions regarding safety, efficacy, and cost-effectiveness are still unanswered. These researchers provided complete and reliable information regarding benefits and harms of IPDs when compared to conservative treatment or decompression surgery and suggested directions for forthcoming RCTs. They searched Medline, Embase, Cochrane Library, Scopus, and LILACS for randomized and quasi-randomized trials, without language or period restrictions, comparing IPDs to conservative treatment or decompressive surgery in adults with symptomatic degenerative LSS. Data extraction and analysis were conducted following the Cochrane Handbook. Primary outcomes were pain assessment, functional impairment, ZCQ, and re-operation rates. Secondary outcomes were quality of life (QOL), complications, and cost-effectiveness. The search strategy resulted in 17 potentially eligible reports. At the end, 9 reports were included and 8 were excluded. Overall quality of evidence was low; 1 trial compared IPDs to conservative treatment: IPDs presented better pain, functional status, QOL outcomes, and higher complication risk; 5 trials compared IPDs to decompressive surgery: pain, functional status, and QOL had similar outcomes; IPD implant presented a significantly higher risk of re-operation. These investigators found low-quality evidence that IPDs resulted in similar outcomes when compared to standard decompression surgery. Primary and secondary outcomes were not measured in all studies and were often published in incomplete form. Subgroup analysis was not feasible. Difficulty in contacting authors may have prevented us of including data in quantitative analysis. The authors concluded that patients submitted to IPD implants had significantly higher rates of re-operation, with lower cost-effectiveness. These researchers stated that future trials should improve in design quality and data reporting, with longer follow-up periods. They stated that until conclusive evidence becomes available, therapeutic options must be chosen very carefully on an
individual patient basis, with full disclosure of unproven clinical benefits and presumably higher risk of re-operation.

Nunley et al (2018a) noted that LSS causes significant pain and functional impairment, and medical management has increasingly included the prescription of opioid-based analgesics; IPD provides a minimally-invasive therapeutic option for LSS. This study estimated the type, dosage, and duration of opioid medications through 5 years of follow-up after IPD with the Superion Indirect Decompression System. Data were obtained from the Superion-treatment arm of a randomized controlled non-inferiority trial. The prevalence of subjects using opiates was determined at baseline through 60 months. Primary analysis included all 190 patients randomized to receive the Superion device. In a subgroup of 98 subjects, these investigators determined opioid-medication prevalence among subjects with a history of opioid use. At baseline, almost 50 % (94 of 190) of subjects were using opioid medication. Thereafter, there was a sharp decrease in opioid-medication prevalence from 25.2 % (41 of 163) at 12 months to 13.3 % (20 of 150) at 24 months to 7.5 % (8 of 107) at 60 months. Between baseline and 5 years, there was an 85 % decrease in the proportion of subjects using opioids. A similar pattern was also observed among subjects with a history of opiates prior to entering the trial. The authors concluded that stand-alone IPD was associated with a marked decrease in the need for opioid medications to manage symptoms related to LSS. In light of the current opiate epidemic, such alternatives as IPD may provide effective pain relief in patients with LSS without the need for opioid therapy.

The authors stated that this study had several limitations. In the absence of a non-surgical control, these researchers were unable to estimate the comparative natural history of opioid usage among LSS patients treated conservatively. Although medication prescribing was captured on a compulsory basis for all study subjects, the trial was not designed to evaluate opioid usage as a primary or secondary outcome. As an ancillary variable, data collection methods lacked a standardized methodology to quantify opioid usage. Consequently, this post-hoc analysis was constrained to prevalence estimates within specified post-operative follow-up intervals and limited only to those patients who remained implanted with the study device and who were free of a re-operation at the index surgical level.

Deer et al (2019a) stated that LSS can lead to compression of neural elements and manifest as LBP and leg pain. LSS has traditionally been treated with a variety of conservative (pain medications, physical therapy, epidural spinal injections) and invasive (surgical decompression) options. Recently, several minimally invasive procedures have expanded the therapeutic options. The Lumbar Spinal Stenosis Consensus Group convened to evaluate the peer-reviewed literature as the basis for making minimally
invasive spine treatment (MIST) recommendations. A total of 11 consensus points were clearly defined with evidence strength, recommendation grade, and consensus level using U.S. Preventive Services Task Force criteria. The Consensus Group also created a treatment algorithm. Literature searches yielded 9 studies (2 RCTs; 7 observational studies, 4 prospective and 3 retrospective) of minimally invasive spine treatments, and 1 RCT for spacers. The LSS therapeutic choice is dependent on the degree of stenosis; spinal or anatomic level; architecture of the stenosis; severity of the symptoms; failed, past, less invasive treatments; previous fusions or other open surgical approaches; and patient co-morbidities. There is Level I evidence for percutaneous image-guided lumbar decompression as superior to lumbar epidural steroid injection, and 1 RCT supported spacer use in a non-inferiority study comparing 2 spacer products currently available. The authors concluded that MISTs should be used in a judicious and algorithmic fashion to treat LSS, based on the evidence of safety and efficacy in the peer-reviewed literature. The MIST Consensus Group recommended that these procedures be used in a multi-modal fashion as part of an evidence-based decision algorithm.

In a review on “The emerging evidence for utilization of a percutaneous interspinous process decompression device to treat symptomatic lumbar adjacent-segment degeneration”, Deer et al (2019b) concluded that “Indirect lumbar decompression via interspinous spacer is an emerging minimally invasive technique for patients with a history of implanted spinal cord stimulators or spinal instrumentation who continue to experience symptoms due to progressive neurogenic claudication”.

Zini et al (2019) examined the literature regarding IPD that mainly focused on comparison with conservative treatment and surgical decompression for the treatment of degenerative LSS (DLSS). The authors noted that IPD are diverse mini-invasive devices placed with fluoroscopic guidance under local anesthesia between the spinal processes at the DLSS level in order to obtain nerve decompression. It has been demonstrated to be more effective than a conservative treatment for DLSS; treatment failure appeared to be significantly lower in the IPD group, while complications appeared to be more frequent for the implant group compared to the conservative treatment. These researchers stated that low quality evidence indicated that outcomes regarding pain, functional status and QOL were similar comparing IPD with surgical procedures; however, treatment failure was significantly higher in IPD group compared to decompressive surgery because of complication as dislocation of the device and erosion/fracture of the spinous process that could be avoided with spinoplasty or “lack of success” almost related to patient selection; cost-effectiveness of IPD is still being debated. The authors concluded that a prospective, randomized study to evaluate the efficacy of pure percutaneous IPD plus preventive spinoplasty versus spinal laminectomy
with long (greater than 24 months) term follow-up is highly desirable.

Merkow et al (2020) noted that symptomatic LSS is a condition affecting a growing number of individuals resulting in significant disability and pain. Traditionally, therapeutic options have consisted of conservative measures such as physical therapy, medication management, epidural injections and percutaneous adhesiolysis, or surgery. There exists a treatment gap for patients failing conservative measures who are not candidates for surgery. Minimally invasive lumbar decompression (MILD) and IPD with Superion represent minimally invasive novel therapeutic options that may help fill this gap in management. These researchers carried out a literature review to examine these procedures and evaluate their safety and effectiveness. The available evidence for MILD and Superion has been continuously debated. Overall, it is considered that while the procedures are safe, there is only modest evidence for effectiveness. For both procedures, these investigators have reviewed 13 studies. Based on the available evidence, MILD and Superion are safe and modestly effective minimally invasive procedures for patients with symptomatic LSS. It is the authors’ recommendation that these procedures may be incorporated as part of the continuum of therapeutic options for patients meeting clinical criteria.

In a retrospective review, Tram et al (2020) examined the literature on the efficacy and complications associated with decompression and interspinous devices (ISDs) used in surgeries for LSS. LSS is a debilitating condition that affects the lumbar spinal cord and spinal nerve roots; however, a comprehensive report on the relative efficacy and complication rate of ISDs as they are compared to traditional decompression procedures is currently lacking. The PubMed data-base was queried to identify clinical studies that exclusively investigated decompression, those that exclusively investigated ISDs, and those that compared decompression with ISDs. Only prospective cohort studies, case series, and RCTs that evaluated outcomes using the VAS, ODI, or JOA scores were included. A random-effects model was established to assess the difference between pre-operative and the 1- to 2-year post-operative VAS scores between ISD surgery and lumbar decompression. This study included 40 papers that matched the selection criteria. A total of 25 decompression-exclusive clinical trials with 3,386 patients and a mean age of 68.7 years (range of 31 to 88 years) reported a 2.2 % incidence rate of dural tears and a 2.6 % incidence rate of post-operative infections. A total of 8 ISD-exclusive clinical trials with 1,496 patients and a mean age of 65.1 (range of 19 to 89 years) reported a 5.3 % incidence rate of post-operative leg pain and a 3.7 % incidence rate of spinous process fractures; 7 studies that compared ISDs and decompression in 624 patients found a re-operation rate of 8.3 % in ISD patients versus 3.9 % in decompression patients; they also reported dural tears in 0.32 % of ISD patients versus 5.2 % in decompression patients. A meta-analysis of the RCTs found that the
differences in pre-operative and post-operative VAS scores between the 2 groups were not significant. Both decompression and ISD interventions were unique surgical interventions with different therapeutic efficacies and complications. The authors concluded that the collected studies did not consistently demonstrate superiority of either procedure over the other but understanding the differences between the 2 techniques could help tailor treatment regimens for patients with LSS. These researchers stated that careful patient selection remains crucial for either surgical procedure to ensure optimal surgical outcomes tailored to each patient. They stated that more diverse studies are needed to determine the superiority of one technique over the other for different patient populations.

The authors stated that limitations of this study included inconsistent reporting of measurements among studies. Inconsistencies were also found in the extent of complications reported, with more exhaustive studies reporting unique complications, while some studies simply stated that no major complications were encountered. Another limitation of this paper was the variation in post-operative care, which was important for long-term complications such as re-operation rates.

Furthermore, an UpToDate review on “Lumbar spinal stenosis: Treatment and prognosis” (Levin, 2020) states that “Intraspinous spacer implantation -- A potentially less invasive treatment option involves implanting a device between the spinous processes at one or two vertebral levels, relieving compression. This procedure is said to be appropriate for those patients with spinal stenosis without spondylolisthesis who have intermittent claudication symptoms that are exacerbated in extension and relieved in flexion. A randomized, multicenter study in 191 patients compared the implantation of the X STOP implant, a titanium alloy device, with nonoperative treatment. At 6 months, symptoms were relieved in 52 % of treated patients, compared with 9 % of controls. Benefit was maintained at 2 and 4 years of follow-up and was associated with reduced disability and improved quality of life. Subsequent uncontrolled observations have found that implantation of the X STOP device has been efficacious in many patients, if not in as large a proportion as was found in the clinical trial. While radiologic improvement in spinal canal and neuroforaminal narrowing can be measured after surgery, these changes are not correlated with clinical benefit and are not maintained over time in most patients. These procedures appear to be associated with higher rates of subsequent surgery than patients initially treated with laminectomy. Adverse effects also appear to be more commonly reported in general clinical experience; these include discitis/osteomyelitis, device dislocations, spinous process fractures, recurrent disc herniation, hematoma, cerebrospinal fluid fistula, and foot drop. It is unclear how this newer procedure compares with the standard surgical procedure, decompressive laminectomy, in terms of effectiveness, side effects, recovery time, and long-term
outcomes. This treatment does not appear to be helpful in patients who have spondylolisthesis”. Furthermore, intraspinous spacer implantation is not listed in the “Summary and Recommendations” section of this review.

Interspinous Fixation Devices

Spinous process fixation is promoted as a minimally invasive spine surgery technique that stabilizes the lumbar spine with less dissection and trauma to the vertebra than the current gold standard, pedicle screw (PS) fixation (Lopez, et al., 2016). Interspinous fixation devices (IFD) aim to provide rigidity comparable with PS fixation by bilaterally securing plates to the lateral aspects of 2 adjacent spinous processes, effectively clamping the motion segment together. IFD implantation has been applied to posterolateral and interbody fusion procedures. Certain IFD products are designed to achieve additional stability through interspinous bony fusion. Proponents have noted that IFD placement is a more expedient procedure that requires a single, less obtrusive midline incision. Multiple IFDs have been designed and are indexed in the literature using various terminology, including spinous process clamps, plates, and anchors. These are not to be confused with interspinous spacers” (X-Stop®, Wallis®, or Diam® devices), which reduce extension through dynamic stabilization with the aim of decreasing symptoms of lumbar spinal stenosis.

Lopez et al (2016) systematically reviewed the available literature on interspinous rigid fixation/fusion devices (IFD) to explore the devices’ efficacy and complication profile. A systematic review of the past 10 years of English literature was conducted according to PRISMA guidelines. The timeframe was chosen based on publication of the first study containing a modern IFD, the SPIRE, in 2006. All PubMed publications containing MeSH headings or with title or abstract containing any combination of the words “interspinous,” “spinous process,” “fusion,” “fixation,” “plate,” or “plating” were included. Exclusion criteria consisted of dynamic stabilization devices (X-Stop®, Diam®, etc.), cervical spine, pediatrics, and animal models. The articles were blinded to author and journal, assigned a level of evidence by Oxford Centre of Evidence-Based Medicine (OCEBM) criteria, and summarized in an evidentiary table. A total of 293 articles were found in the initial search, of which 15 remained after examination for exclusion criteria. No class I or class II evidence regarding IFDs was found. IFDs have been shown by methodologically flawed and highly biased class III evidence to reduce instability at 1 year, without statistical comparison of complication rates against other treatment modalities

Piriformis Muscle Resection
Piriformis syndrome is believed to be a condition in which the piriformis muscle, a narrow muscle located in the buttocks, compresses or irritates the sciatic nerve. There is debate within the medical community whether this is a discrete condition, since it lacks objective evidence, and thus can not be reliably evaluated. Pain associated with piriformis syndrome is exacerbated in prolonged sitting. Specific physical findings are tenderness in the sciatic notch and buttock pain in flexion, adduction, and internal rotation of the hip. Imaging modalities are rarely helpful. Physical therapy is a mainstay of conservative treatment; and is usually enhanced by local injections (Papadopoulos and Khan, 2004). There is insufficient evidence regarding the effectiveness of resection of the piriformis muscle as a treatment for piriformis syndrome.

**Endoscopic Laser Foraminoplasty**

Endoscopic laser foraminoplasty (decompression) is primarily employed to treat patients with back pain caused by a prolapsed intervertebral disc. This endoscope-assisted laser technique is used to widen the lumbar exit route foramina in the spine. A laser is inserted to ablate portions of the intervertebral disc that have protruded. Hafez and associates (2001) noted that laser ablation of bone and ligament for nerve root decompression using the Ho: YAG laser may offer substantial advantages, but the risk of serious complication may only be avoided if the technique is combined with saline irrigation.

Knight and colleagues (2001) reported that the complication rate of endoscopic laser foraminoplasty is significantly lower than that reported following conventional spinal surgery. From these results, these investigators concluded that endoscopic laser foraminoplasty as a treatment for chronic LBP and sciatica presents less risk to a patient than conventional methods of spinal surgery. On the other hand, the National Institute for Clinical Excellence's (2003) guidance on this procedure stated that current evidence on the safety and effectiveness of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Moreover, the Specialist Advisors believed the effectiveness of this procedure to be unproven; and they also noted a number of potential complications including nerve injury and infection. Takeno et al (2006) stated that percutaneous lumbar disc decompression is associated with significant risk of disc, end-plate, and nerve root injuries, contrary to the general belief that the procedure is minimally invasive. Their findings highlight the need for careful diagnosis and sufficient technical skill when selecting percutaneous lumbar disc decompression as a treatment option.

**Percutaneous Discectomy**
Percutaneous disc decompression is a procedure specifically for a herniated disc in which the core of the disc has not broken through the disc wall. Performed through a needle in the skin, it is a form of surgery in which small bits of disc are removed to relieve pressure on the nerves surrounding the disc. The procedure may be performed with a cutting instrument or laser. Although the literature indicates that open laminectomy is an acceptable and, at times, necessary method of treatment for herniated intervertebral discs, percutaneous discectomy has emerged as a method of treatment for contained and non-migrated sequestered herniated discs. It has taken on 2 different forms: the selective removal of nucleus pulposus from the herniation site with various manual and automated instruments under endoscopic control (percutaneous nucleotomy with discoscopy, arthroscopic microdiscectomy, percutaneous endoscopic discectomy); the other is the removal of nucleus pulposus from the center of the disc space with one single automated instrument (automated percutaneous lumbar discectomy) to achieve an intradiscal decompression.

Automated percutaneous lumbar discectomy (APLD), or automated percutaneous mechanical lumbar discectomy, is another newer approach for surgical treatment of herniated discs. In this procedure, under local anesthesia and fluoroscopic guidance, a cannula is inserted into the disc; an automated cutting and aspiration device is then inserted through the cannula and the disc material is removed. As with the arthroscopic microdiscectomy/PED, APLD does not allow direct visualization of the disc or surrounding tissues. An example of a device used for this type of procedure includes, but may not be limited to, the Stryker Dekompressor Lumbar Discectomy Probe.

Automated percutaneous discectomy refers to techniques using minimal skin incisions (generally several, all less than 3 to 5 mm) to allow small instruments to be inserted, using radiography to visualize these instruments, and using extensions for the surgeon to reach the operative site without having to dissect tissues. Lasers to vaporize the nucleus pulposus have become an additional percutaneous option. Proponents of percutaneous lumbar discectomy cite several potential advantages over open discectomy procedures, including reduced morbidity, less potential for perineural scarring, less intra-operative blood loss, fewer complications of epidural fibrosis, transverse myelitis or disc space infection, reduced patient recovery times, and a faster return to normal activity. Initial case series focusing on lumbar disc disease reported encouraging results and the technique was widely adopted (Onik, 1990; Fiume et al, 1994; Ohnmeiss et al, 1994; Kotilainen and Valtonen, 1998). However, controlled trials reported less impressive results.

An interventional guidance on laser lumbar discectomy issued by the National Institute for Health and Clinical Excellence (NICE, 2003) stated that “Current evidence on the
safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research”. The guidance noted that in an uncontrolled study of 348 patients with chronic back pain, 210 (60%) patients reported good or excellent results at 1 year, however, the validity of the studies on this procedure were compromised by high rates of loss to follow-up and the lack of long-term data on efficacy outcomes.

A review of minimally invasive procedures for disorders of the lumbar spine (Deen et al, 2003) stated that “Percutaneous lumbar disectomy techniques hold considerable promise; however, lumbar microdiskectomy is the gold standard for surgical treatment of lumbar disk protrusion with radiculopathy”.

A National Institute for Health and Clinical Excellence (NICE, 2005) guidance on automated percutaneous mechanical lumbar discectomy stated that “Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research”.

A Cochrane review on surgical interventions for lumbar disc prolapse (Gibson and Waddell, 2007) examined the evidence on automated percutaneous discectomy and laser discectomy. The reviewers found four trials on automated percutaneous discectomy that met their inclusion criteria: 2 trials that compared automated percutaneous discectomy with chymopapain (Revel, 1993; Krugluger, 2000) and 2 that compared automated percutaneous discectomy with microdiscectomy (Chatterjee, 1995; Haines, 2002). The reviewers reported that the results from these 4 trials suggested that automated percutaneous discectomy produced inferior results to either more established procedure. The reviewers found 2 trials that met their inclusion criteria on laser discectomy: 1 trial compared the effects of a Nd-YAG-laser with that of a diode laser (Paul and Hellinger, 2000) and reported slight vaporization with both lasers and excellent shrinkage of disc tissue, however, no comparative outcome results were published; the other trial compared chemonucleolysis with laser discectomy (Steffen and Wittenberg, 1997) and reported that the study results favored chemonucleolysis. The reviewers concluded that while microdiscectomy gives broadly comparable results to open discectomy, the evidence on other minimally invasive techniques remains unclear (with the exception of chemonucleolysis using chymopapain, which is no longer widely available).
Nezer and Hermoni (2007) reviewed the evidence for percutaneous discectomy and percutaneous intradiscal radiofrequency thermocoagulation from 4 leading evidence-based databases: the National Institute for Clinical Excellence (NICE), which is an independent organization responsible for providing national guidance on treatments, the Cochrane Library, which is the largest library world-wide for systematic reviews and randomized controlled trials, the Center for Review and Dissemination at the University of York, which undertakes reviews of research about the effects of interventions in health and social care and finally, a search via Medline. The authors concluded that "The results from those systematic reviews and randomized trials show that, at present, unless or until better scientific evidence is available, automated percutaneous discectomy and laser discectomy should be regarded as research techniques".

Goupille et al (2007) reviewed the literature on percutaneous laser disc decompression for treating lumbar disc herniation and stated that "[e]xperimental and clinical studies have investigated the modality of percutaneous laser disc decompression, but no consensus exists on the type of laser to use, the wavelength, duration of application, or appropriate energy applied. Studies have evaluated the impact of different techniques on the amount of disc removed, intradiscal pressure, and damage to neighboring tissue. Several open studies have been published, but their methodology and conclusions are questionable, and no controlled study has been performed". The authors concluded that "Although the concept of laser disc nucleotomy is appealing, this treatment cannot be considered validated for disc herniation-associated radiculopathy resistant to medical treatment".

A California Technology Assessment (2008) reviewed the scientific evidence for percutaneous laser disc decompression in the treatment of symptomatic lumbar disc herniation and found no published randomized, concurrently controlled, blinded trials comparing outcomes of percutaneous laser disc decompression with conventional conservative measures or open discectomy or laminectomy. The authors reported that the published articles concerning percutaneous laser disc decompression are almost all uncontrolled case series: 2 non-randomized comparative trials (Ohnmeiss et al, 1994, Tassi, 2006) and 1 systematic review (Boult et al, 2000) of percutaneous laser disc decompression have been published. The assessment stated that "The published data are not sufficient to conclude that the efficacy and safety of the percutaneous laser disc decompression procedure have been established in the investigational setting, let alone under conditions of usual medical practice. Percutaneous laser disc decompression requires further evaluation in a randomized controlled trial to assess its efficacy as an alternative treatment for symptomatic lumbar disc herniation".
An assessment by the National Institute for Health and Clinical Excellence (NICE, 2008) of percutaneous endoscopic laser lumbar discectomy concluded that "[c]urrent evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research". The specialist advisors to NICE considered theoretical adverse events to include a higher risk of nerve or dural injury because of the poor visual field and disorientation, and a higher probability of missed fragments. One specialist advisor stated that there had been cases of heat damage to the cauda equine when laser was used for lumbar discectomy with concomitant foraminoplasty.

An assessment by NICE (2008) reached similar conclusions about the unproven status of percutaneous endoscopic laser cervical discectomy. The NICE assessment concluded that "[c]urrent evidence on the safety and efficacy of percutaneous endoscopic laser cervical discectomy is inadequate in quantity and quality. Available evidence reviewed by NICE was limited to uncontrolled case series". The specialist advisors to NICE considered the most important theoretical risk of the procedure to be heat damage to nerve roots or to the spinal cord, potentially leading to quadriplegia. One specialist advisor stated that neurological damage had occurred in a patient as a result of using laser in the spine. The NICE review committee noted that the extent to which laser ablation was used instead of, or in addition to, mechanical methods of removing prolapsed disc material was unclear in much of the published evidence.

All of the trials reviewed above focused on lumbar disc herniation. There were no clinical trials of percutaneous discectomy of cervical or thoracic disc herniation.

**Xclose™ Tissue Repair System**

An annular (annulus) repair/closure may be performed following a spinal decompression (discectomy) surgery. It has been proposed that annular closure may reduce the risk of disc reherniation and the need for a fusion. Examples of devices used in an annular repair include the Inclose Surgical Mesh System and Xclose™ Tissue Repair System.

The Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) has received 510(k) clearance for use in soft tissue approximation for procedures such as general and orthopedic surgery. It is being investigated as a method of soft tissue re-approximation of the anulus fibrosus after a lumbar discectomy procedure. However, there is insufficient evidence of the clinical effectiveness of the Xclose™ Tissue Repair System following a lumbar discectomy procedure. Randomized controlled studies are
needed to determine whether closing the anulus following a lumbar discectomy procedure will result in improved clinical outcomes (i.e., decrease in re-herniation rates). To evaluate the benefits of anulus fibrosis repair utilizing the Xclose™ Tissue Repair system, Anulex is sponsoring a prospective, controlled, randomized study that will compare discectomy patients who receive anular repair using the Xclose™ Tissue Repair System to those who receive a standard discectomy without using the Xclose™. However, results from this study have not yet been published in the peer-reviewed medical literature.

**Barricaid Annular Closure Device**

An assessment of annulus fibrosus repair after lumbar discectomy by the Ludwig Boltzmann Institute for Heathlh Technology Assessment (Semlitsch & Geiger-Gritsch, 2019) found that the closure of anular defects after discectomy using the Barricaid device could be a meaningful intervention for a selected group of patients with a large anular defect to prevent reherniations and reoperations. However, a significant number of patients experienced problems with device integrity over a period of two years. In addition, these results are based on a few studies with a high risk of bias and published long-term results beyond a period of two years are missing. Similar results in terms of clinical effectiveness and safety were obtained for the Xclose™ system. However, only results from a single randomized controlled trial with a high risk of bias are available.

In a randomized, multi-center trial, Nanda et al (2019) examined if implanting an annular closure device (ACD) following lumbar discectomy in patients with large defects in the annulus fibrosus lowers the risk of re-operation after 4 years. Patients with large annular defects following single-level lumbar discectomy were intra-operatively randomized to additionally receive an ACD or no treatment (controls). Clinical and imaging follow-up were performed at routine intervals over 4 years of follow-up. Main outcomes included re-operations at the treated lumbar level, leg pain scores on a visual analog scale (VAS), Oswestry Disability Index (ODI), and Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36 questionnaire. Among 550 patients (ACD 272, control 278), the risk of re-operation over 4 years was 14.4% with ACD and 21.1% with controls (p = 0.03). The reduction in re-operation risk with ACD was not significantly influenced by patient age (p = 0.51), sex (p = 0.34), body mass index (BMI; p = 0.21), smoking status (p = 0.85), level of herniation (p = 0.26), leg pain severity at baseline (p = 0.90), or ODI at baseline (p = 0.54). All patient-reported outcomes improved in each group from baseline to 4 years (all p < 0.001). The percentage of patients who achieved the minimal clinically important difference without a re-operation was proportionally higher in the ACD group compared to controls for leg pain (p =
The authors concluded that the addition of a bone-anchored ACD following lumbar discectomy in patients with large post-surgical annular defects reduced the risk of re-operation and provided better long-term pain and disability relief over 4 years compared to lumbar discectomy only.

The authors stated that this study had several drawbacks. First, the results presented were applicable only to patients with large post-discectomy annular defects, who accounted for approximately 30% of all lumbar discectomy cases. Implantation of an ACD in patients with small annular defects cannot be justified clinically given the inherently low risk of symptom recurrence in these individuals. Additional patient characteristics that were crucial to achieving positive results included adequate disc height and non-osteoporotic bone mineral density (BMD) of the lumbar spine. Second, the decision to re-operate involved shared decision-making between the patient and surgeon and, thus, there was potential for bias in the reported re-operation rates. Finally, 5-year follow-up in this study is ongoing and these long-term outcomes are anxiously awaited to provide final comparative efficacy, safety, and cost-utility results of bone-anchored ACD implantation.

Radiofrequency Denervation for Sacroiliac Joint Pain

Cohen et al (2008) carried out a randomized placebo-controlled study in 28 patients with injection-diagnosed sacroiliac joint pain. Fourteen patients received L4 to L5 primary dorsal rami and S1 to S3 lateral branch radiofrequency (RF) denervation using cooling-probe technology after a local anesthetic block, and 14 patients received the local anesthetic block followed by placebo denervation. Patients who did not respond to placebo injections crossed-over and were treated with RF denervation using conventional technology. One, 3, and 6 months after the procedure, 11 (79%), 9 (64%), and 8 (57%) RF-treated patients experienced pain relief of 50% or greater and significant functional improvement. In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3 months after the procedure. In the cross-over group (n = 11), 7 (64%), 6 (55%), and 4 (36%) experienced improvement 1, 3, and 6 months after the procedure. One year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief. The authors concluded that these results provide preliminary evidence that L4 and L5 primary dorsal rami and S1-S3 lateral branch RF denervation may provide intermediate-term pain relief and functional benefit in selected patients with suspected sacroiliac joint pain. They stated that larger, multi-centered studies with long-term follow-up and comprehensive outcome measures are needed to confirm
these results, further establish safety and determine the optimal candidates and treatment parameters.

Drawbacks of this study, albeit a randomized controlled one, include small number of patients as well as "poor" long-term results (only 14% in the treatment group showed continued pain relief after 1 year). In addition, a systematic review on sacroiliac joint interventions (Hansen et al, 2007) concluded that the evidence for RF neurotomy in managing chronic sacroiliac joint pain is limited.

In an observational study, Karaman et al (2011) examined the safety and effectiveness of novel cooled RF application for sacral lateral-branch denervation. Patients experiencing chronic sacroiliac pain were selected for this study. Fluoroscopy guidance cooled RF denervation was applied on the L5 dorsal ramus and the S1 to S3 lateral branches on patients who had twice undergone consecutive joint blockages to confirm the diagnosis and obtained at least 75% pain relief. At the 1st, 3rd and 6th month post-operatively, the patients’ pain was evaluated using a VAS, and their physical function was evaluated with the ODI. Cooled RF was applied on a total of 15 patients. Prior to the procedures, the median VAS score (interquartile range) was 8 (7 to 9), but at the 1st, 3rd and 6th month, this had fallen to 3 (1 to 4), 2 (1 to 3) and 3 (2 to 4). The baseline median ODI score (interquartile range) was 36 (32 to 38), while at the 1st, 3rd and 6th month, it was 16 (8 to 20), 12 (9 to 18) and 14 (10 to 20), respectively. At the final control, while 80% of the patients reported at least a 50% decline in pain scores, 86.7% of those reported at least a 10-point reduction in ODI scores. The authors concluded that the cooled RF used for sacroiliac denervation was an effective and safe method in the short-to-intermediate term. The major drawbacks of this study were its small sample size (n = 15) and short follow-up period (6 months). The authors stated that RCTs with longer follow-up period are needed.

Stelzer et al (2013) retrospectively evaluated the use of cooled RF lateral branch neurotomy (LBN) to treat chronic SIJ-mediated LBP in a large European study population. The electronic records of 126 patients with chronic LBP who underwent treatment with cooled RF LBN were identified. Subjects were selected for treatment based on physical examination and positive response (greater than or equal to 50% pain relief) to an intra-articular SIJ block. Cooled RF LBN involved lesioning the L5 dorsal ramus and lateral to the S1, S2, and S3 posterior sacral foraminal apertures. Visual analog scale pain scores, quality of life, medication usage, and satisfaction were collected before the procedure, at 3 to 4 weeks post-procedure (n = 97), and once again between 4 and 20 months post-procedure (n = 105). When stratified by time to final follow-up (4 to 6, 6 to 12, and greater than 12 months, respectively): 86%, 71%, and 48% of subjects experienced greater than or equal to 50% reduction in VAS pain scores, 96%,
93%, and 85% reported their quality of life as much improved or improved, and 100%, 62%, and 67% of opioid users stopped or decreased use of opioids. The authors concluded that the current results showed promising, durable improvements in pain, quality of life, and medication usage in a large European study population, with benefits persisting in some subjects at 20 months after treatment. The main drawbacks of this study were its retrospective nature, lack of a control group, difficulty in contacting certain subjects, missing data for some subjects, as well as variable length of time to final follow-up.

Ho and colleagues (2013) noted that SIJ pain is a common cause of chronic LBP. Different techniques for RF denervation of the SIJ have been used to treat this condition. However, results have been inconsistent because the variable sensory supply to the SIJ is difficult to disrupt completely using conventional RF. Cooled RF is a novel technique that uses internally cooled RF probes to enlarge lesion size, thereby increasing the chance of completely denervating the SIJ. These researchers evaluated the effectiveness of cooled RF denervation using the SInergy™ cooled RF system for SIJ pain. The charts of 20 patients with chronic SIJ pain who had undergone denervation using the SInergy™ cooled RF system were reviewed at 2 years following the procedure. Outcome measures included the Numeric Rating Scale for pain intensity, Patient Global Impression of Change, and Global Perceived Effect for patient satisfaction. Fifteen of 20 patients showed a significant reduction in pain (a decrease of at least 3 points on the Numeric Rating Scale). Mean Numeric Rating Scale for pain decreased from 7.4 ± 1.4 to 3.1 ± 2.5, mean Patient Global Impression of Change was “improved” (1.4 ± 1.5), and Global Perceived Effect was reported to be positive in 16 patients at 2 years following the procedure. The authors concluded that cooled RF denervation showed long-term effectiveness for up to 2 years in the treatment of SIJ pain. Limitations of this study included:

I. small sample size (n = 20),

II. it was a retrospective review with no placebo-control or sham-control group, and

III. no comparison with conventional RF treatment for SIJ pain.

1. small sample size (n = 20),
2. it was a retrospective review with no placebo-control or sham-control group, and
3. no comparison with conventional RF treatment for SIJ pain.
Facet Joint Implantation

Facet joint replacement/implant is a new device/procedure for facet joint degeneration, which may be used in conjunction with a spinal fusion. It is purported as a system for facet joint reconstruction, matching the joint shape and size in order to provide pain relief, normal motion and stability. An example of this device includes, but may not be limited to, the Acadia Facet Replacement System. Please note: the Acadia is not US Food and Drug Administration (FDA) approved; it is currently in an ongoing clinical trial.

Spinal facet (zygapophyseal) joints are diarthroidal joints that provide both sliding articulation and load transmission features. In addition to the intervertebral disc, facet joints help to support axial, torsional and shear loads that act on the spinal column. Thus, facet joints play an important role in maintaining segmental stability of the spinal cord. Pathology of the facet joints may result in back/neck pain as well as segmental instability within the spine. One of the most common treatment for spinal trauma or degenerative diseases/disorders is arthrodesis (spinal fusion) of one or more vertebral segments. However, spinal fusion decreases function by limiting the range of motion (ROM) for patients in flexion, extension, rotation, and lateral bending. It also creates increased stresses that may lead to accelerated degeneration of adjacent non-fused vertebral segments. Furthermore, pseudoarthrosis, as a result of an incomplete or ineffective fusion, may reduce or even eliminate the desired pain relief. Finally, migration of the fusion device may occur.

Researchers have tried to recreate the natural biomechanics of the spine by the use of artificial discs, which provide for articulation between vertebral bodies to recreate the full ROM allowed by the elastic properties of the natural intervertebral disc that directly connects two opposed vertebral bodies. However, artificial discs available to date do not fully address the mechanics of motion of the spinal column.

Facet joint implantation is a new approach to overcome the shortcomings of currently available devices/implants. These implants are employed to replace a bony portion of the facets so as to remove the source of arthritic-, traumatic-, or other disease-mediated pain. In conjunction with artificial disc replacements, facet joint implantation may represent a way to recreating a fully functional motion segment that is compromised due to disease or trauma. This combination can supposedly eliminate all sources of pain, return full function and ROM, and completely restore the natural biomechanics of the spinal column. Moreover, degenerative or traumatized facet joints may be replaced in the absence of disc replacement when the natural intervertebral disc is unaffected by the disease or trauma. Facet implants include a superior implant for placement on a
superior articulating surface and an inferior implant for placement on an inferior articulating surface. These facet implants are positioned within the affected facet joint(s) for distraction, thus increasing the area of the canals and openings through which the spinal cord and nerves must pass, and decreasing pressure on the spinal cord and/or nerve roots. These implants can be inserted via a lateral or posterior approach.

While facet joint implants are designed to provide patients with degenerative or traumatized facet a motion-preserving alternative to spinal fusion, and to restore the natural motion, stability, and balance to the spine, there is currently a lack of evidence regarding their clinical benefits. The North American Spine Society’s guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis (2007), the American College of Occupational and Environmental Medicine’s guideline on low back disorders (2007), and the Work Loss Data Institute’s guideline on low back - lumbar and thoracic (2008) did not mention the use of facet implant/arthroplasty. Furthermore, in a review on the treatment of neck pain by the Bone and Joint Decade 2000-2010 Task Force on neck pain and its associated disorders facet implant/arthroplasty is not mentioned as an option (Carragee et al, 2009).

**Lateral Interbody Fusion**

A proposed minimally invasive approach to spinal fusion uses a laparoscope (endoscope), and purports to decrease injury to surrounding tissues and promote a quicker recovery time. There are several types of these procedures/techniques including, but not limited to, direct lateral interbody fusion (DLIF), extreme lateral interbody fusion (XLIF), and laparoscopic anterior lumbar interbody fusion (LALIF).

The aim of lateral interbody fusion in the lumbar spine is to achieve a spinal fusion procedure via a lateral approach in order to avoid the major muscle groups in the back (posterior approach) or the organs and blood vessels in the abdomen (anterior approach) (NICE, 2009). A probe is inserted under fluoroscopic guidance through the psoas muscle, to lie alongside the affected disc, via a lateral approach.

Nerve monitoring is recommended to avoid damage to motor nerves. However, lower limb dysthesia may occur from damage of sensory nerves (NICE, 2009). In one study, 30% of patients developed post-operative numbness, and in 2/3 of these patients the numbness lasted longer than 1 month (Bergey et al, 2004).

Extreme lateral interbody fusion (XLIF) is a novel surgical technique for anterior lumbar interbody fusion. In XLIF (NuVasive, Inc., San Diego, CA) access to the disc space is
achieved through 2 small incisions from the side of the body instead of through the muscles of the back. The proposed benefits of XLIF include reduced operative time, reduced blood loss, minimal scarring and reduced hospital stay. However, the procedure is technically difficult to perform and vertebral access is limited to those vertebrae of the spine that are available from the side of the body.

Because the extreme lateral lumbar approach is relatively new, long-term data about XLIF is not currently available and the published data "is sparse at best" (Bahtia et al, 2008). In a feasibility study of XLIF for anterior lumbar interbody fusion (n = 13), Ozgur, et al (2006) reported that the technique allowed anterior access to the disc space without an approach surgeon or the complications of an anterior intra-abdominal procedure; however, the authors concluded that longer-term follow-up and data analysis are needed. A paucity of significant long-term data exists in the literature regarding outcomes of XLIF (Bahtia et al, 2009).

Direct lateral interbody fusion (DLIF) uses a similar approach as XLIF. Knight et al (2009) reported on the results of a prospective chart review (n = 98) of complications from DLIF or XLIF compared to a historical cohort of patients who underwent an open posterior approach. The investigators reported that there was no statistically significant difference in the total complication rate between patients treated with lateral interbody fusion techniques (22.4%) and patients treated with an open postero-lateral approach (22.5%). In the lateral interbody fusion group, nerve root damage occurred in 3% (2/58) of patients; both showed residual motor effects at 1-year follow-up.

Eck et al (2007) stated in a review of anterior minimally invasive back procedures that minimally invasive techniques for lumbar spine fusion are often associated with significantly greater incidence of complications and technical difficulty than their associated open approaches. An assessment of lateral interbody fusion techniques, including extreme, extra and direct lateral interbody fusion, by the National Institute for Health and Clinical Excellence (NICE, 2009) concluded that current evidence on the safety and efficacy of lateral interbody fusion in the lumbar spine is inadequate in quantity and quality. The assessment noted that a very limited number of clinical efficacy outcomes were reported.

The North American Spine Society (NASS) Operative Coding Committee (Mitchell, 2006) stated that XLIF should be reported using the same Current Procedural Terminology (CPT) codes as an anterior interbody fusion. In addition, NASS has concluded that lateral interbody fusion (XLIF or DLIF) should not be considered experimental or investigational (Baker, 2010). NASS has stated that, while additional clinical outcomes data would be helpful for any surgical procedure including lateral interbody fusion, these data are not
needed to endorse continued use of these forms of interbody fusion. NASS explained that "if one were to consider [lateral interbody fusion] as experimental or investigational, than one would need to conclude that there is only one correct method of performing an anterior lumbar interbody fusion, that all surgeons access the spine through the exact same tissue planes, and that the disc and vertebral bodies are all accessed in the exact same orientation. Not only is this technically impossible, it is not verifiable" (Baker, 2010).

**Minimally Invasive / Endoscopic Cervical Laminoforaminotomy**

Choi et al (2007) performed a prospective analysis of the first 20 patients operated for cervical radiculopathy by a new modification of trans-corporeal anterior cervical foraminotomy technique. To evaluate early results of a functional disc surgery in which decompression for the cervical radiculopathy is done by drilling a hole in the upper vertebral body and most of the disc tissue is preserved. A total of 20 patients suffering from cervical radiculopathy not responding to conservative treatment were chosen for the new technique. Upper vertebral trans-corporeal foraminotomy was performed with the modified technique in all the patients. All the patients experienced immediate/early relief of symptoms. No complications of vertebral artery injury, Horner's syndrome or recurrent laryngeal nerve palsy were noted. Modified trans-corporeal anterior cervical microforaminotomy is an effective treatment for cervical radiculopathy. It avoids unnecessary violation of the disc space and much of the bony stabilizers of the cervical spine. The authors stated that short-term results of this technique are quite encouraging; longer-term analysis can help in outlining the true benefits of this technique.

Holly et al (2007) described the surgical indications, technique, and preliminary clinical outcomes in a series of patients who underwent the 2-level minimally invasive posterior cervical foraminotomy procedure. This report was composed of 21 consecutive patients with cervical radiculopathy who underwent a minimally invasive 2-level posterior cervical foraminotomy at the authors' institution between 2003 and 2005. Magnetic resonance imaging demonstrated foraminal or postero-lateral pathology at 2 ipsilateral adjacent spinal levels in each patient. Radicular arm pain was the most common presenting symptom, and was encountered in all 21 patients. The mean follow-up for the patients was 23 months (range of 12 to 36). Complete resolution of pre-operative symptoms was achieved in 19 out of 21 patients (90%). Sixteen patients were discharged home the same day of surgery, and the mean estimated blood loss was 35 ml (range of 10 to 100 ml). There were no peri-operative complications. The authors concluded that minimally invasive 2-level posterior cervical foraminotomy can be safely performed on an
outpatient basis with results comparable to that of conventional foraminotomy. This procedure should be considered as a potential alternative to 2-level anterior cervical discectomy and fusion or open foraminotomy in selected patients.

In an editorial on minimally invasive/endoscopic versus "open" posterior cervical laminoforaminotomy, Epstein (2009) stated that there is a need to address the complications of minimally invasive surgery in general, and minimally invasive/endoscopic laminoforaminotomy in particular to make it clear when minimally invasive is not only minimally effective, but also potentially "maximally" harmful.

**Minimally Invasive Transforaminal Lumbar Interbody Fusion (MITLIF)**

Minimally invasive transforaminal lumbar interbody fusion is performed through small incisions using specialized retractors that gradually open an operative corridor through the muscles rather than pulling the muscles aside as with conventional open surgery. Endoscopes are used to visualize the spine and TLIF is performed with specialized instruments through the retractors with less trauma to soft tissues, which may result in reduced operative time and hospitalization. The operation is carried out by means of fluoroscopic guidance.

Although operative time, blood loss and hospitalization were lower for MITLIF compared with more traditional procedures, there was little difference between MITLIF and open TLIF in the single study that compared them, except for lower blood loss and a higher number of complications in the MITLIF group. Overall, due to deficiencies in study design and the relatively small numbers of patients studied, the evidence is insufficient to demonstrate long-term safety and effectiveness of MITLIF, or to determine whether this technique is equivalent to open TLIF or more established surgeries such as anterior-posterior lumbar interbody fusion (APLIF) and posterior lumbar interbody fusion (PLIF). It is also unknown how the various techniques for MITLIF compare with one another.

Isaacs and associates (2005) retrospectively compared 20 patients receiving MITLIF with 24 patients receiving traditional PLIF. All patients had grade I or II spondylolisthesis or mechanical LBP and radiculopathy and had failed conservative therapy. Two interbody grafts were placed with bilateral pedicle screws using Medtronic instrumentation in the MITLIF group. One senior surgeon supervised all MITLIF operations, while 5 surgeons performed the PLIF operations. Mean operative time was 300 mins in MITLIF recipients versus 276 mins in PLIF recipients. For the MITLIF and PLIF groups, respectively, the mean estimated blood loss (EBL) was 226 and 1147 ml (p < 0.001); mean hospital length of stay (HLOS) was 3.4 versus 5.1 days (p < 0.02) and complications occurred in 1 versus
6 patients in these groups, respectively. The retrospective nature of this design limits the ability to draw firm conclusions regarding efficacy.

In a case-series study, Deutsch and Musacchio (2006) prospectively evaluated 20 patients with degenerative disc disease (DDD); all of whom had failed conservative therapy and who received MITLIF with unilateral pedicle screw placement. Mean operative time was 246 mins, mean EBL was 100 ml and mean HLOS was 2.5 days. At follow-up from 6 to 12 months, a good result (greater than 20% decrease in ODI) was observed in 17/20 (85%) patients with no improvement in 3 (15%). Mean ODI decreased from 57% to 25%, VAS score decreased from 8.3 to 1.4 (p < 0.005) and 13/20 (65%) patients displayed some degree of fusion at 6 months. Cerebrospinal fluid (CSF) leaks occurred in 2 patients, and 1 new post-operative radiculopathy was observed, which resulted in further surgery to re-adjust a pedicle screw.

Villavicencio et al (2006) retrospectively compared outcomes in 167 consecutive patients with DDD treated with MITLIF (n = 73), open TLIF (n = 51), or APLIF (n = 43). Patients who underwent MITLIF had fewer previous surgeries (18%) compared with TLIF (39%) or APLIF (49%) recipients. The mean operative time for APLIF was 455 mins, for MITLIF 255 mins, and open TLIF 222 mins. The mean blood loss for APLIF was 550 ml, for minimally invasive TLIF 231 ml, and open TLIF 424 ml. The mean hospitalization time for APLIF was 7.2 days, for MITLIF 3.1 days, and open TLIF 4.1 days. The total rate of complications was 76.7% for APLIF, including 62.8% major and 13.9% minor complications. The MITLIF patients group had the total 30.1% rate of complications, 21.9% of which were minor and 8.2% major complications. There were no major complications in the open TLIF patients group, with 35.3% minor complications. The authors concluded that APLIF is associated with a more than 2 times higher complication rate, significantly increased blood loss, and longer operative and hospitalization times than both percutaneous and open TLIF for lumbar disc degeneration and instability. This study was limited by its retrospective design.

In a retrospective study, Scheufler and co-workers (2007) reported technique, clinical outcomes, and fusion rates of percutaneous transforaminal lumbar interbody fixation (pTLIF). Results were compared with those of mini-open transforaminal lumbar interbody fixation (oTLIF) using a muscle splitting (Wiltse) approach. Percutaneous transforaminal lumbar interbody fixation was performed in 43 patients with single-level and 10 patients with bi- or multi-level lumbar discopathy or degenerative pseudolisthesis resulting in axial back pain and claudication, pseudo-radicular, or radicular symptoms. Post-operative pain was significantly lower after pTLIF after the second post-operative day (p < 0.01). The overall clinical outcome was not different from oTLIF at 8 and 16 months. The authors concluded that pTLIF allows for safe and
Efficient minimally invasive treatment of single and multi-level degenerative lumbar instability with good clinical results. They stated that further prospective studies investigating long-term functional results are needed to evaluate the definitive merits of percutaneous instrumentation of the lumbar spine.

Park and Foley (2008) discussed their retrospective review study results in 40 patients who underwent MITLIF for symptomatic spondylolisthesis utilizing this approach. Thirty cases involved a degenerative spondylolisthesis while the remaining 10 were isthmic. The minimum follow-up was 24 months with a mean of 35 months. The authors concluded that MITLIF for symptomatic spondylolisthesis appears to be an effective surgical option with results that compare favorably to open procedures. However, the findings of this study are limited by study design, small patient numbers and the lack of a control group.

**TruFuse Facet Fusion**

TruFuse facet fusion (miniSURG Corp., Clearwater, FL) is a minimally invasive back procedure that uses specially designed bone dowels made from allograft material (donated cortical bone) that are inserted into the facet joints. The procedure is designed to stop facet joints from moving and is intended to eliminate or reduce back pain caused by facet joint dysfunction. There are no published studies of the effectiveness of the TruFuse product in the peer reviewed published literature. A systematic evidence review of TruFuse by the American Association of Neurological Surgeons (AANS) concluded, "[t]here is insufficient objective information to evaluate the safety and utility of this device or to make recommendations regarding clinical usage".

**Nu-Fix**

Nu-Fix (Nutech Medical, Birmingham, AL) is a cortical screw that is used for facet arthropsis with spine pain, Nu-Fix was cleared by the FDA based upon a 510(k) premarket notification. This allograft interference screw is percutaneous or through stab incision, inserted into the facet joint (cervical, thoracic, or lumbar) to stiffen the joint and promote fusion.

A technical assessment of Nufix prepared by the American Association of Neurological Surgeons (2009) reached the following conclusions about the Nufix: "Nu-Fix is FDA approved as a threaded bone dowel for minimally invasive facet fusion. Marketing has been primarily aimed at non-surgeons in out patient pain clinic settings. There is no published data to assess safety, efficacy, or outcomes. There is no relevant
biomechanical data available to use as a comparison to currently performed spinal fusion procedures. Manufacturer sponsored literature is very limited in number, scope and follow-up. In conclusion there is insufficient objective information to evaluate the safety and utility of this device or to make recommendations regarding clinical usage".

**Epidural Fat Graft during Lumbar Decompression Laminectomy/Discectomy**

Epidural fat grafts have been used to prevent epidural and perineural fibroses. In a case series study, Martin-Ferrer (1989) reported failure of autologous fat grafts to prevent post-operative epidural fibrosis in surgery of the lumbar spine in 3 patients. Hypertrophic epidural scarring occurred in these 3 cases despite the presence of autologous fat grafts. Histopathological examination of the fat removed from 2 patients who were operated on a second time showed a fibrotic infiltration into the fat graft. One randomized study (Mackay et al, 1995) found no reduction in fibrosis with use of epidural fat graft in lumbar laminectomy and discectomy. A non-randomized comparative study (Gorgulu et al, 2004) found no improvement in long-term outcomes with use of epidural fat grafts in lumbar disc surgery. Moreover, there were reports of cauda equina syndrome following hemi-ilaminectomy and discectomy for lumbar disc herniation. Computed tomography-scan revealed the migration of the free fat graft used for preventing peridural scar formation; and removal of the graft resulted in patients' recovery (Urvoy et al, 1990; Imran and Halim, 2005).

**Interlaminar Lumbar Instrumented Fusion (ILIF)**

Interlaminar lumbar instrumented fusion (ILIF) combines direct neural decompression with an allograft inter-spinous spacer to maintain the segmental distraction and a spinous process fixation plate to maintain stability for eventual segmental fusion. Nuvasive, Inc. (San Diego, CA) is conducting a clinical trial to evaluate ILIF in patients with single-level degenerative disc disease (DDD) of the lumbar spine. The estimated completion date is July 2012.

Sharma et al (2011) evaluated the radiographical change in the coronal and sagittal plane alignment of the lumbar spine after the lateral lumbar interbody fusion (LLIF) approach using XLIF cages (Nuvasive, Inc.). Radiographical and clinical outcomes, and complications associated with the approach were also described. A retrospective review of 43 consecutive patients’ pre-operative, immediate post-operative, and 1-year follow-up radiographs was done. All patients had LLIF procedure performed for lumbar DDD, spondylolisthesis, or de novo scoliosis. The radiographical measurements were taken to assess change in the sagittal and coronal plane alignment of the individual instrumented
disc level, overall lumbar spine, and lumbar scoliotic curves. The radiographs were also analyzed for fusion at 1 year, end-plate fracture, and other complications. Patients' hospital and clinic charts were reviewed to identify the complications and patient outcomes. There was a mean correction of 3.7 degrees ($p \leq 0.001$) at each instrumented disc level in coronal plane in 87 instrumented levels. Similarly, there was a mean gain of 2.8 degrees ($p \leq 0.001$) of lordosis at each level. In 25 patients with lumbar scoliosis (greater than 10 degrees), mean scoliosis angle correction was 10.4 degrees ($p = 0.001, 43\%$). There was no significant change in the overall coronal or sagittal plane alignment of the lumbar spine. The most common post-operative complication (25\%) was anterior thigh pain, which was transitory in the majority of cases. End-plate breach was common at the instrumented disc levels; however, it was non-progressive in most of the cases, and did not affect the fusion or alignment at the instrumented levels. The outcome scores were improved significantly at the final follow-up. The authors concluded that the LLIF approach is effective in correcting the coronal plane deformity and in gaining lordosis at individual instrumented levels. They parallelized adjacent end plates to correct the lumbar scoliotic curves. The complications are mostly approach-related and transitory. The authors stated that a larger cohort with long-term follow-up is needed to establish the advantages and shortcomings of the procedure.

### Khan Kinetic Treatment (KKT)

The Khan Kinetic Treatment, manufactured by Datrend Systems Inc (Richmond, British Columbia, Canada), is a medical device for the treatment of spine-related abnormalities causing pain. According to the manufacturer, the KKT uses high-frequency small-amplitude sinusoidal waves to vibrate the vertebrae and repeatedly activate associated neuromuscular structures, which evoke multiple mechanisms of pain relief. In a small, unblinded, randomized trial without placebo control, Desmoulin et al (2007) presented their initial findings on the use of KKT as a chronic neck pain treatment. They reported that, compared with a control group, the treatment group lowered both their self-recorded neck pain scores ($p = 0.012$) as well as pain medication dose ($p = 0.048$), although current functional assessment questionnaires (range of motion, overall activity, and recreation/work activities) did not detect changes ($p = 0.233, 0.311, \text{and} 0.472$, respectively). Limitations of this study included a lack of blinding and lack of placebo control. The authors concluded that although they await randomized, placebo-controlled trials and additional results from ongoing mechanistic studies, initial results show that KKT is potentially an effective treatment for chronic neck pain and may contribute to the reduction of pain relieving. Other published literature on KKT spine treatment consists of a study of the effect of KKT in an animal model (Desmoulin et al, 2010).
The OptiMesh Grafting System

OptiMesh is a conformable, porous, polymeric containment device that is inserted into the evacuated disc space and filled with a mixture of cortico-cancellous allograft with demineralized bone matrix, autograft, and bone marrow aspirate to aid traumatic fracture repair and interbody fusion. Evidence is limited to a single case study that utilized OptiMesh for a compression fracture. Long-term safety and effectiveness have not been established. OptiMesh received 510(k) approval in November, 2003 as a class II device. The device is intended to maintain bone graft material within a vertebral defect. This device is contraindicated for patients with instability and does not provide structural support. The safety and effectiveness of OptiMesh used for fusion of the interbody space has not been established. Further studies are needed to evaluate its safety and effectiveness.

Inamasu et al (2008) reported a patient with a flexion-distraction injury of the L1 vertebra treated with a combination of short-segment posterior fixation and Optimesh (Spineology Inc., St. Paul, MN), a flexible balloon-shaped mesh that is deployed into the fractured vertebra together with allograft. The patient, a 47-year-old man, was admitted after sustaining a motor vehicle accident. Imaging studies showed an L1 compression fracture. The patient had no neurological deficits and was treated conservatively. However, intense back pain persisted and significant kyphosis was noted when he mobilized. Review of the imaging studies strongly suggested disruption of the posterior spinal ligaments. Surgical intervention was performed to address both restoration of the posterior tension band and anterior column height simultaneously. The combined procedure consisted of short-segment posterior fixation from T12 to L2, and placement of OptiMesh filled with allograft into the L1 vertebral body. The anterior column height was restored and spinal alignment was corrected by the procedure, and the patient’s back pain subsided soon after the procedure. The role of minimally invasive procedures for reconstruction of the vertebral column height, including the OptiMesh system, in patients with thoracolumbar compression fracture seems promising. However, the long-term effectiveness of these new techniques is unknown. It also remains to be seen how the delivery of allograft into the fractured vertebra via OptiMesh affects remodeling, and whether the restored vertebral height is maintained.

Radiofrequency / Pulsed Radiofrequency Ablation of Trigger Point Pain

Tamimi et al (2009) noted that clinical reports using pulsed radiofrequency (PRF) have shown promise in the treatment of a variety of focal, neuropathic conditions. To date, scant data exist on the use of PRF to treat myofascial and neuromatous pain. All cases in
which PRF was used to treat myofascial (trigger point) and neuromatous pain within the authors' practice were evaluated retrospectively for technique, efficacy, and complications. Trigger points were defined as localized, extremely tender areas in skeletal muscle that contained palpable, taut bands of muscle. A total of 9 patients were treated over an 18-month period. All patients had longstanding myofascial or neuromatous pain that was refractory to previous medical management, physical therapy, and trigger point injections. Eight out of 9 patients experienced 75 to 100% reduction in their pain following PRF treatment at initial evaluation 4 weeks following treatment. Six out of 9 (67%) patients experienced 6 months to greater than 1 year of pain relief. One patient experienced no better relief in terms of degree of pain reduction or duration of benefit when compared with previous trigger point injections. No complications were noted. The authors concluded that this review suggested that PRF could be a minimally invasive, less neurodestructive treatment modality for these painful conditions and that further systematic evaluation of this treatment approach is warranted.

Lee et al (2011) noted that recently, clinical reports using PRF have shown favorable effects in the treatment of a variety of focal pain areas, even in non-nervous tissues; however, the mechanism of effect underlying this treatment to non-nervous tissue remains unclear. These researchers reported the case of a 67-year old male who presented with pain reliving point in the posterior neck. The patient had pain in the posterior neck for 3 years. The pain subsided with pressure applied to a point in the posterior neck. There were no specific abnormal findings on laboratory testing and radiological examinations. After PRF treatment to the pain-relieving point, he had pain relief that lasted more than 5 months.

**Coflex**

Bae et al (2015) stated that approved treatment modalities for the surgical management of lumbar spinal stenosis encompass a variety of direct and indirect methods of decompression, though all have varying degrees of limitations and morbidity which potentially limit the efficacy and durability of the treatment. The Coflex inter-laminar stabilization (ILS) implant examined under a Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical trial, is shown to have durable outcomes when compared to posterolateral fusion in the setting of post-decompression stabilization for stenotic patients. Other clinical and radiographic parameters, more indicative of durability, were also evaluated. The data collected from these parameters were used to expand the FDA composite clinical success (CCS) endpoint; thus, creating a more stringent Therapeutic Sustainability Endpoint (TSE). The TSE allows more precise
calculation of the durability of ILS when compared to the fusion control group. These investigators performed a retrospective analysis of data generated from a prospective, randomized, level-1 trial that was conducted at 21 US sites. A total of 344 per-protocol subjects were enrolled and randomized to ILS or fusion after decompression for lumbar stenosis with up to grade 1 degenerative spondylolisthesis. Clinical, safety, and radiographic data were collected and analyzed in both groups; 4-year outcomes were assessed, and the TSE was calculated for both cohorts. The clinical and radiographic factors thought to be associated with therapeutic sustainability were added to the CCS endpoints which were used for pre-market approval (PMA). Success rate, comprised of no second intervention and an ODI improvement of greater than or equal to 15 points, was 57.6% of ILS and 46.7% of fusion patients (p = 0.095). Adding lack of fusion in the ILS cohort and successful fusion in the fusion cohort showed a CCS of 42.7% and 33.3%, respectively. Finally, adding adjacent level success to both cohorts and maintenance of foraminal height in the Coflex cohort showed a CCS of 36.6% and 25.6%, respectively. With additional follow-up to 5 years in the U.S. PMA study, these trends are expected to continue to show the superior therapeutic sustainability of ILS compared to posterolateral fusion after decompression for spinal stenosis. The authors concluded that there are clear differences in both therapeutic sustainability and intended clinical effect of ILS compared to posterolateral fusion with pedicle screw fixation after decompression for spinal stenosis. There are CCS differences between Coflex and fusion cohorts noted at 4 years post-op similar to the trends revealed in the 2 year data used for PMA approval. They stated that when therapeutic sustainability outcomes are added to the CCS, ILS is proven to be a sustainable treatment for stabilization of the vertebral motion segment after decompression for lumbar spinal stenosis. This study provided mid-term (4 years) follow-up; long-term follow-up is needed to determine the durability of the Coflex inter-spinous device. The author also noted that the radiographic indicators of long-term therapeutic sustainability utilized in this study were supported by the literature and further validation through extended follow-up will be of benefit.

Musacchio and colleagues (2016) stated that if non-operative treatment for lumbar stenosis fails, surgery may be considered. This traditionally includes decompression often combined with fusion. Desire for less extensive surgery led to developing new techniques and implants, including an interlaminar device designed with the goal of providing segmental stability without fusion, following decompression. These researchers examined 5-year outcomes associated with an interlaminar device. This prospective, randomized, controlled trial was conducted at 21 centers. Patients with moderate-to-severe lumbar stenosis at 1 or 2 contiguous levels and up to Grade I spondylolisthesis were randomized (2:1 ratio) to decompression and interlaminar stabilization (D+ILS; n = 215) using the Coflex Interlaminar Stabilization device or decompression and fusion with pedicle screws (D+PS; n = 107). Clinical evaluations were
made pre-operatively and at 6 weeks and 3, 6, 12, 18, 24, 36, 48, and 60 months post-operatively. Overall, Food and Drug Administration success criteria required that a patient meet 4 criteria:

I. greater than 15 point improvement ODI score;

II. no re-operation, revision, removal, or supplemental fixation;

III. no major device-related complication; and

IV. no epidural steroid injection after surgery.

At 5 years, 50.3% of D+ILS versus 44% of D+PS patients (p > 0.35) met the composite success criteria. Re-operation/revision rates were similar in the 2 groups (16.3% versus 17.8%; p > 0.90). Both groups had statistically significant improvement through 60 months in ODI scores with 80.6% of D+ILS patients and 73.2% of D+PS patients demonstrating greater than 15 point improvement (p > 0.30). VAS, SF-12, and ZCQ scores followed a similar pattern of maintained significant improvement throughout follow-up. On the SF-12 and ZCQ, D+ILS group scores were statistically significantly better during early follow-up compared to D+PS. In the D+ILS group, foraminal height, disc space height, and range of motion at the index level were maintained through 5 years. The authors concluded that both treatment groups achieved and maintained statistically significant improvements on multiple outcome assessments throughout 5-year follow-up. On some clinical measures, there were statistically significant differences during early follow-up favoring D+ILS. At no point were there significant differences favoring D+PS. They stated that results of this 5-year follow-up study demonstrated that decompression and interlaminar stabilization with coiffe is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate-to-
severe stenosis at 1 or 2 lumbar levels. (This appeared to be 1 of the 2 post-approval studies that are required for the continued FDA approval of the Coflex)

This study provided mid-term (5 years) results; long-term safety and effectiveness of the coffle has yet to be established. Another drawback of this study was that it was not blinded during follow-up, which may have introduced a bias. Furthermore, as the authors noted that “There is always difficulty in determining how to address patients who undergo additional surgery or injections after the study surgery, as their outcome measures may then be reflecting the effect of the additional intervention rather that the index procedure. In the current protocol, these patients were classified outcome failures in the composite assessment of success, and excluded from the analyses of individual outcome assessments such as VAS and ZCO”.

Nomura (2016) stated that Auerbach’s group (Davis et al, 2013) proposed a new spinal fusion option using the novel spinal implant Coflex Interlaminar Stabilization (ILS) (Paradigm Spine), which was approved by the Food and Drug Administration, with 2-year results from prospective and randomized study published in Spine in 2013. The Coflex ILS is a U-shaped titanium device implanted in the interlaminar space with the “U” placed within millimeters of the dura after laminectomy. This has superior and inferior wings that are crimped against the spinous process to provide stability. Implantation is done by simply placing the device into the interlaminar space between the superior and inferior spinous processes after bilateral segmental laminectomy. Functionally, the device acts as a third joint and offloads the facet joints, providing neutral stabilization while maintaining normal spinal kinematics. Furthermore, it allows for compression in extension while permitting normal flexion, allowing maintenance of sagittal balance and lordosis as well as rotational and translational motion as opposed to fusion. Additionally, the mechanical offloading of the facets aids in the relief of back pain and maintenance of foraminal height over time. Hence, this implant appears ideal in overcoming time-dependent degenerative changes after laminectomy; however, further long-term safeguard examination is needed .... If the long-term outcome of decompression plus ILS is almost the same as that of decompression alone, the latter would be more favorable because it has no graft-related complication, as described above. Further comparative studies of ILS stabilization to decompression alone, especially performed using a minimally invasive technique, are interesting .... the ILS has applications for various types of degenerative lumbar disorders as it may be sufficient beneficial for long-term outcomes. A further report on the ILS is appreciated.

Pan et al (2016) retrospectively evaluated the radiography change of LSS treated with the implantation of Coflex inter-spinous device. A total of 60 patients (34 men and 26 women) with LSS who underwent the decompression and Coflex device implanted
surgery from January 2010 to December 2013 were followed-up. The mean age of the patients was 59.4 years. There were 33 cases underwent Coflex surgery and 27 cases underwent Topping-off surgery. The Coflex segment ranged from L1/2 to L4/5 (L1-2: 1, L2-3: 5, L3-4: 19, L4-5: 35). The foraminal height (FH), foraminal width (FW) and intervertebral space height (ISH) change of the Coflex segment as well as its adjacent segment were recorded pre-/post-operatively and at last follow-up. Meanwhile, the ODI and VAS were measured in all patient pre-/post-operatively and at last follow-up. The measurement data were recorded as x ± s. And the independent and paired samples t-test was used to conduct the statistical analysis. The FH increased from (19.82 ± 2.38) mm to (22.28 ± 2.95) mm (p < 0.05) post-operatively, and the FH decreased to (19.31 ± 3.32) mm at the last follow up(p > 0.05, compared to the post-operation). The average FW was 11.2 mm, 11.58 mm and 11.12 mm at pre-/post-operation and follow up, which had no significant different change(p > 0.05). The post-operative ISH increased from (7.84 ± 1.56) mm to (10.05 ± 2.39) mm (p < 0.05), and the ISH decreased to (7.91 ± 1.77) mm at the last follow up(p > 0.05, compared to the post-operation). The lumbar lordosis (LL) was 43.13° ± 15.93°, 38.41° ± 10.82° and 43.10° ± 13.21° at pre-/post-operation and follow up, there was no significant difference between pre- and post-operation (p > 0.05). All patients showed statistically significant improvement(p < 0.05) in the clinical outcome assessed in the VAS and ODI at the time of follow up compared to the pre-operation. The ODI score decreased from 65.12 ± 13.56 to 9.89 ± 1.77; the VAS score decreased from 8.02 ± 1.81 to 1.66 ± 0.51. The authors concluded that Coflex device could temporarily improve the FH and ISH after operation. However, it could not maintain the improvement as the follow-up time extended. The surgical decompression is the responsible factor for the good clinical outcome but not the improvement of FH.

Zhang and colleagues (2018) examined the curative effect of dynamic fixation Coflex treatment for patients with degenerative lumbar spinal stenosis. In the present study, a total of 78 patients with degenerative lumbar spinal stenosis were recruited and divided equally into the control group (n = 39)and observation group (n = 39). The control group was treated with traditional decompression fusion and the observation group received dynamic fixation Coflex system. Surgery and hospitalization were shorter in the observation group than in the control group. Intra-operative blood loss and drainage volume after surgery were significantly lower in the observation group compared to the control group. The treatment effective rate for the observation group was significantly higher; VAS, ODI and Japanese Orthopedic Association pain and functional scores as well as post-operative vertebral canal area and adjacent segment quantitative scores improved after surgery in the 2 groups, but the observation group showed greater improvement. The authors concluded that the curative effect of dynamic fixation Coflex
treatment for degenerative lumbar spinal stenosis demonstrated advantages over traditional surgery, including less trauma and bleeding, pain reduction, improved post-operative rehabilitation, and lower incidence of adjacent segment degeneration. Moreover, they stated that dynamic fixation Coflex treatment for patients with degenerative lumbar spinal stenosis featured remarkable effects. It can reduce the influence on adjacent segments and delay degeneration, which improves spine stability. However, the sample size of this study was small (n = 39 for the Coflex group) and the follow-up time was short (12 months), which requires a further study of large sample size and long-term follow-up.

Kleck and Burger (2018) reported the development of bilateral symptomatic facet joint cysts in a 78-year old man who had been treated with decompression and placement of a Coflex device (Paradigm Spine) at L3 to L4 and L4 to L5. Pre-operative imaging clearly demonstrated fluid in the facet joints without cysts. He underwent standard surgical treatment, but developed symptomatic facet joint cysts at 4 months post-operatively. The patient was treated with a revision decompression and replacement of the devices; there were no issues at the 32-month follow-up. The authors concluded that while the Coflex device has possible long-term biomechanical advantages, vigilance with adherence to appropriate decompression surgical technique is necessary.

Dong et al (2018) examined if Coflex implantation following spinal decompression provided better clinical outcomes compared with traditional decompression and fusion for symptomatic lumbar spinal stenosis through mid-term follow-up. A total of 100 patients who were confirmed L4/L5 lumbar spinal stenosis was surveyed from June 2007 to June 2010. They were randomly and equally divided into 2 groups: 50 cases underwent spinal decompression with Coflex implantation, and 50 cases were treated with spinal decompression with fixation and fusion. The operation time, intra-operative blood loss, ambulation time, and hospitalization days, Japanese Orthopedic Association scores, VAS scores, ODI and SF-36 scores were compared between the 2 groups. The ROM and the height loss at adjacent segments (L3/L4 and L5/S1) were measured pre-operative and post-operative, respectively. Adjacent segment degeneration at L3/L4 and L5/S1 was assessed by Pfirrmann classification. Complications were also recorded. The average age was 57.6 ± 5.9 years old in Coflex implantation group and 59.0 ± 6.7 years old in fusion group, respectively. The average follow-up period was 7.12 ± 1.1 year in Coflex implantation group and 7.31 ± 1.6 year in fusion group, respectively. JOA, ODI, VAS and SF-36 scores were improved at the last follow-up in all the 2 groups with significant differences (p < 0.01) compared with those pre-operative, but no statistical differences between the 2 groups (p > 0.05). The intervertebral heights of adjacent segments were decreased at the last follow-up and the ranges of intervertebral motions were increased in both groups. The height loss and the ROM increase of adjacent segments...
segments were greater in fusion group than those in Coflex group with statistical significant difference (p < 0.01). At the last follow-up, adjacent segment disc Pfirrmann grade progressed more obviously in fusion group compared with that in Coflex group, and there was significant difference (p < 0.05) between the 2 groups. The authors concluded that based on the present study, it showed that Coflex implantation and fusion after spinal decompression had the same clinical outcomes and satisfaction in treatment of symptomatic lumbar spinal stenosis after 7 years follow-up. However, Coflex implantation had the advantages of less bleeding loss, less trauma and quick recovery. Compared with fusion surgery, Coflex implantation had also advantages in maintaining intervertebral height and delaying intervertebral disc degeneration of adjacent segments.

Moreover, the authors stated that the main drawbacks of this study were: the number of cases was small (n = 50 in the Coflex-treated group), and the follow-up period was not long enough (mid-term follow-up; approximately 7 years). These researchers stated that further research is needed prior to wide application.

Schmidt and colleagues (2018) noted that surgical decompression is extremely effective in relieving pain and symptoms due to lumbar spinal stenosis (LSS). Decompression with interlaminar stabilization (D+ILS) is as effective as decompression with posterior-lateral fusion for stenosis, as shown in a major US FDA pivotal trial. These researchers reported a multi-center, randomized controlled trial (RCT) in which D+ILS was compared with decompression alone (DA) for treatment of moderate-to-severe LSS. Under approved institutional ethics review, a total of 230 patients (1:1 ratio) randomized to either DA or D+ILS (Coflex, Paradigm Spine) were treated at 7 sites in Germany. Patients had moderate-to-severe LSS at 1 or 2 adjacent segments from L3 to L5. Outcomes were evaluated up to 2 years post-operatively, including ODI scores, the presence of secondary surgery or lumbar injections, neurological status, and the presence of device- or procedure-related severe adverse events (SAEs). The composite clinical success (CCS) was defined as combining all 4 of these outcomes, a success definition validated in a US FDA pivotal trial. Additional secondary endpoints included visual analog scale (VAS) scores, Zürich Claudication Questionnaire (ZCQ) scores, narcotic usage, walking tolerance, and radiographs. The overall follow-up rate was 91% at 2 years. There were no significant differences in patient-reported outcomes at 24 months (p > 0.05). The CCS was superior for the D+ILS arm (p = 0.017). The risk of secondary intervention was 1.75 times higher among patients in the DA group than among those in the D+ILS group (p = 0.055). The DA-arm had 228% more lumbar injections (4.5% for D+ILS versus 14.8% for DA; p = 0.0065) than the D+ILS one. Patients who underwent DA had a numerically higher rate of narcotic use at every time-point post-surgically (16.7% for D+ILS versus 23% for DA at 24 months). Walking Distance Test results were statistically
significantly different from baseline; the D+ILS group had greater than 2 times the improvement of the DA. The patients who underwent D+ILS had greater than 5 times the improvement from baseline compared with only 2 times the improvement from baseline for the DA group. Foraminal height and disc height were largely maintained in patients who underwent D+ILS, whereas patients treated with DA showed a significant decrease at 24 months post-operatively (p < 0.001). The authors concluded that this study showed no significant difference in the individual patient-reported outcomes (e.g., ODI, VAS, ZCQ) between the treatments when viewed in isolation. The CCS (survivorship, ODI success, absence of neurological deterioration or device- or procedure-related SAEs) was statistically superior for ILS. Microsurgical D+ILS increased walking distance, decreased compensatory pain management, and maintained radiographic foraminal height, extending the durability and sustainability of a decompression procedure. While the CCS was statistically superior for ILS, it is unclear whether these findings are also clinically significant. Furthermore, this study provided only short-term follow-up (up to 2 years); long-term follow-up data are needed.

The authors also stated that this study had drawbacks. Despite being a RCT, imperfections in its conduct meant that some patients were lost to follow-up, and there were some missing data. Also, any randomized trial that is industry-sponsored raises the question of bias, even if the bias was unintentional.

Furthermore, UpToDate reviews on “Lumbar spinal stenosis: Treatment and prognosis” (Levin, 2018) and “Subacute and chronic low back pain: Surgical treatment” (Chou, 2018) do not mention “Coflex / dynamic distraction stabilization / interlaminar stabilization” as a therapeutic option.

The CoFlex-F Implant

The Coflex-F implant is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1 to S1) that can be delivered through a minimally invasive approach. The implant is a type of posterior fixation instrumentation intended to rigidly hold vertebrae together while spinal fusion occurs. It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients suffering from DDD, with or without attendant grade I spondylolisthesis. On October 6, 2010, the Coflex-F implant was cleared by the FDA via the 501(k) process for the purpose of achieving stabilization to facilitate fusion in patients treated for DDD (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); with up to grade 1 spondylolisthesis. However, the
Belgian Health Care Knowledge Center (2011) stated that it is unclear what data for the Coflex-F was submitted for FDA clearance.

An UpToDate review on "Lumbar spinal stenosis: Treatment and prognosis" (Levin, 2012) states that "Intraspinous spacer implantation – A potentially less invasive treatment option involves implanting a device between the spinous processes at one or two vertebral levels, relieving compression. This procedure is said to be appropriate for those patients with spinal stenosis without spondylolisthesis who have intermittent claudication symptoms that are exacerbated in extension and relieved in flexion......It is unclear how this newer procedure compares with the standard surgical procedure, decompressive laminectomy, in terms of effectiveness, side effects, recovery time and long-term outcomes. This treatment does not appear to be helpful in patients who have spondylolisthesis".

**Coccygectomy**

Patel et al (2008) stated that coccydynia is a term that refers to pain in the region of the coccyx. Most cases are associated with abnormal mobility of the coccyx which may trigger a chronic inflammatory process leading to degeneration of this structure. In some patients this instability may be detected on dynamic radiographs. Non-surgical management remains the gold standard treatment for coccydynia, consisting of decreased sitting, seat cushioning, coccygeal massage, stretching, manipulation, local injection of steroids or anesthetics, and postural adjustments. Those patients who fail these conservative modalities may potentially benefit from coccygectomy. However, surgical intervention is typically reserved for patients with evidence of advanced coccygeal instability (e.g., subluxation or hypermobility) or spicule formation, as this population appears to exhibit the greatest improvement post-operatively.

Trollegaard et al (2010) reported that between 1993 and 2008, a total of 41 patients underwent total coccygectomy for coccydynia which had failed to respond to 6 months of conservative management. Of these, 40 patients were available for clinical review and 39 completed a questionnaire giving their evaluation of the effect of the operation. Excellent or good results were obtained in 33 of the 41 patients, comprising 18 of the 21 patients with coccydynia due to trauma, 5 of the 8 patients with symptoms following childbirth and 10 of 12 with idiopathic onset. In 8 patients the results were moderate or poor, although none described worse pain after the operation. The only post-operative complication was superficial wound infection, which occurred in 5 patients and which settled fully with antibiotic treatment. One patient required re-operation for excision of the distal cornua of the sacrum. The authors concluded that total coccygectomy offered
satisfactory relief of pain in the majority of patients regardless of the cause of their symptoms.

The Work Loss Data Institute’s clinical practice guideline on “Low back - lumbar & thoracic (acute & chronic)” (2011) recommended the use of coccygectomy. Furthermore, an UpToDate review on “Coccydynia (coccygodynia)” (Fletcher, 2012) suggests that coccygectomy be performed only as a last resort for intractable cases.

**BacFast HD**

According to the manufacturer, BacFast HD (Hyper-Demineralized) is a demineralization technology used to expose the collagen surface. With the use of HD technology and increased collagen surface area, BacFast HD also provides the graft with osteo-inductive properties without compromising the structural integrity of the graft. These characteristics, coupled with an osteo-conductive design through increased surface contact and locking edges to prevent migration, BacFast HD is engineered with a focus on fusion as well as facet stabilization. Benefits of the facet stabilization procedure using BacFast HD are thought to include

1. osteo-inductive surface for enhanced fusion,

2. stabilization of the spine, and

3. reduction of pain, blood loss, and tissue/bone destruction.

**Oxygen-Ozone Therapy (Injection)**

Kallewaard and colleagues (2010) stated that an estimated 40% of chronic lumbosacral spinal pain is attributed to the discus intervertebralis. Degenerative changes following loss of hydration of the nucleus pulposus lead to circumferential or radial tears within the annulus fibrosus. Annular tears within the outer annulus stimulate the ingrowth of blood vessels and accompanying nociceptors into the outer and occasionally inner
annulus. Sensitization of these nociceptors by various inflammatory repair mechanisms may lead to chronic discogenic pain. The current criterion standard for diagnosing discogenic pain is pressure-controlled provocative discography using strict criteria and at least 1 negative control level. The strictness of criteria and the adherence to technical detail will allow an acceptable low false-positive response rate. The most important determinants are the standardization of pressure stimulus by using a validated pressure monitoring device and avoiding overly high dynamic pressures by the slow injection rate of 0.05 mL/s. A positive discogram requires the reproduction of the patient’s typical pain at an intensity of greater than 6/10 at a pressure of less than 15 psi above opening pressure and at a volume less than 3.0 ml. Perhaps the most important and defendable response is the failure to confirm the discus is symptomatic by not meeting this strict criteria. Various interventional treatment strategies for chronic discogenic LBP unresponsive to conservative care include reduction of inflammation, ablation of intradiscal nociceptors, lowering intra-nuclear pressure, removal of herniated nucleus, and radiofrequency ablation of the nociceptors. Unfortunately, most of these strategies do not meet the minimal criteria for a positive treatment advice. In particular, single-needle radiofrequency thermo-coagulation of the discus is not recommended for patients with discogenic pain (2 B¬). Interestingly, a little used procedure, radiofrequency ablation of the ramus communicans, does meet the (2 B+) level for endorsement. The authors concluded that there is currently insufficient proof to recommend intradiscal electrothermal therapy (2 B±) and intradiscal biaucuplasty (0). It is advised that ozone discolysis, nucleoplasty, and targeted disc decompression should only be performed as part of a study protocol; future studies should include more strict inclusion criteria.

In a systematic review and meta-analysis of RCTs, Magalhaes et al (2012) evaluated the therapeutic results of percutaneous injection of ozone for LBP secondary to disc herniation. A comprehensive literature search was conducted using all electronic databases from 1966 through September 2011. The quality of individual articles was assessed based on the modified Cochrane review criteria for randomized trials and criteria from the Agency for Healthcare Research and Quality. The outcome measure was short-term pain relief of at least 6 months or long-term pain relief of more than 6 months. A total of 8 observational studies were included in the systematic review and 4 randomized trials in the meta-analysis. The indicated level of evidence for long-term pain relief was II-3 for ozone therapy applied intradiscally and II-1 for ozone therapy applied paravertebrally. The grading of recommendation was 1C for intradiscal ozone therapy and 1B for paravertebral ozone therapy. The authors concluded that ozone therapy appears to yield positive results and low morbidity rates when applied percutaneously for the treatment of chronic LBP. The main drawbacks of this review were the lack of precise diagnosis and the frequent use of mixed therapeutic agents. The
meta-analysis included mainly active-control trials. No placebo-controlled trial was found.

The Work Loss Data Institute’s clinical guideline on “Low back - lumbar & thoracic (acute & chronic)” (2011) listed oxygen-ozone therapy (injection) as interventions/procedures that are under study and are not specifically recommended.

In a prospectively randomized, single-blind study, Elawamy and co-workers (2018) evaluated the quality of pain alleviation using 2 different doses of intradiscal injections of O₃-O₂ mixture. A total of 60 patients with symptomatizing single lumbar disc herniation (DH) were subjected to O₃-O₂ intradiscal injection and randomly allocated into 1 of 2 groups; group A: received 10 ml, 40 µg/ml of O₃-O₂; and group B: received 10 ml, 30 µg/ml of O₃-O₂. Pain score and functional ability of the patients using the VAS and ODI were evaluated after 1, 6, and 12 months and compared to the basal values. Patient satisfaction and reduction of DH were evaluated after the 6th month. There were no significant differences between the 2 groups regarding the clinical outcome; however both the ODI and VAS evaluations showed highly significant improvement (decreased) (p < 0.01) after injection and during the entire follow-up period. There were highly significant negative correlations between the DH reduction percentage and both the VAS and ODI scores after 6 months in both of the groups. The authors concluded that intradiscal injection of O₃-O₂ mixture was a very valuable maneuver in the reduction of DH size and improvement of pain quality, with either ozone concentrations of 40 µg/ml or 30 µg/ml.

The authors stated that this study was limited by a small sample size (n = 60); it was also an active control trial, which may explain the insignificant difference in between the groups, in addition to being a single-blind trial. Moreover, these researchers noted that they did find that an O₃-O₂ mixture can offer rapid onset and sustained improvement of LBP.

Rahimzadeh and associates (2018) noted that intervertebral disc herniation with the pressure on the surrounding neural structures is one of the most important causes of chronic LBP, which sometimes leads to open surgery. Intradiscal intervention such as laser irradiation or ozone injection have been used to reduce the pressure inside the disc. In this clinical trial, these 2 methods were compared with each other. A total of 40 patients with back pain radiating to lower limb due to lumbar intervertebral disc herniation were selected. These patients were randomly divided into 2 equal groups for percutaneous intradiscal intervention. The Laser Disc Decompression Group (LDG) (n = 20) was exposed to 1,500 J of laser irradiation into the disc center. In the Ozone Injection Group (OZG) patients (n = 20), 6 mL of ozone 30 µg/ml was injected into the
center of the disc. Considering the level of neural root involvement, both groups received 20 mg of triamcinolone injection via transforaminal epidural. Patients were followed-up for 12 months regarding score on VAS and life performance improvement based on ODI and satisfaction level. No difference was found between the 2 groups for ODI variable before intervention, whereas OZG showed better ODI scores in the measured time intervals. In LDG, only a significant difference in terms of ODI score was found between the times of before surgery and the first month. The authors concluded that intradiscal ozone injection could be an effective and cost-effective method for treatment of patients with discogenic back pain.

The authors stated that this study had some drawbacks such as lack of a control group receiving placebo; lack of morphological assessment of disc and surrounding structures; lack of MRI control; small sample size (n = 20 in both groups); and limited time-frame (12 months) for patients’ assessment.

In a systematic review, Costa and colleagues (2018) examined the safety and effectiveness of ozone therapy for LBP in patients with lumbar disc herniation. These researchers carried out a systematic search in PubMed and Scopus, followed by a 3-step selection process. Data was processed by 2 independent reviewers and information was gathered based in pre-defined variables. Only articles performed in humans; original and English written; on treatment with ozone; comparing the result of ozone therapy (experimental group) with another non-ozone intervention (control group); and on patients with lumbar pain and disc hernia, were included. From 439 references retrieved after duplicates removal, inclusion and exclusion criteria were applied, and 7 studies were included in the final revision; 1 article compared treatment with ozone versus placebo, 1 ozone and global postural re-education versus global postural re-education alone, 2 the combination of ozone with steroid versus steroid alone, 2 ozone versus steroid, and 1 ozone versus micro-discectomy. All but the study comparing ozone application with micro-discectomy, showed similar or better results in the experimental group. Only 3 studies evaluated the presence of side effects. In 2 papers no complication was reported, and in the other, a low percentage of adverse effects was observed, not significantly different between the 2 study groups. The authors concluded that only a small number of poor quality studies on ozone effect in LBP and disc herniation were available for inclusion in this review. Nevertheless, these reported an improvement in pain and functional scores with its application. Complications, mostly minor, but potentially serious were under-reported. These researchers stated that additional studies with adequate and consistent methodologies are needed before the role of ozone can be established in the management of LBP.

Minimally Invasive Sacroiliac Joint Fusion
Sacroiliac joint (SIJ) fusion has been suggested as a possible treatment option for individuals with low back pain due to sacroiliac joint dysfunction or syndrome. This procedure may be performed by an open surgical approach or as a minimally invasive procedure in order to place plates and/or screws to develop a bony fusion across the SIJ for stabilization. The iFUSE Implant System consists of small titanium implants placed across the sacroiliac joint to stabilize and fuse it via a minimally invasive (percutaneous) approach with use of fluoroscopy to visualize proper placement of the implants. Other minimally invasive systems for SIJ fusion include the SIJFuse Sacroiliac Joint Fusion Device System, Silex Sacroiliac Joint System and SImmetry Sacroiliac Joint Fusion System.

In a consecutive case-series study, Buchowski et al (2005) described the outcome of sacro-iliac joint (SIJ) arthrodesis for SIJ disorders, with the hypothesis that SI arthrodesis leads to improved post-operative function. The patient population consisted of 20 patients undergoing SIJ arthrodesis between December 1994 and December 2001. Patients undergoing concomitant procedures at the time of SIJ arthrodesis were excluded. The 3 men and 17 women in the study group had an average age of 45.1 years (range of 21.8 to 66.4 years), a mean duration of symptoms of 2.6 years (range of 0.5 to 8.0 years), and a mean follow-up period of 5.8 years (range of 2.0 to 9.0 years). Outcome measures included general health and function, clinical evaluation, and radiographic assessment. For all 20 patients, non-operative treatment had failed, and for all, the diagnosis was confirmed by pain relief with intra-articular SIJ injections under fluoroscopic guidance. Sacroiliac joint arthrodesis (via a modified Smith-Petersen technique) was recommended only when a positive response to the injection was noted, and patients had recurrence of symptoms after the initial positive response. Pre-operative and post-operative general health and function were assessed via the 36-item Short-Form (SF-36) Health Survey and American Academy of Orthopaedic Surgeons (AAOS) Modems Instrument, which were collected prospectively. Medical records and plain radiographs were reviewed retrospectively to determine the clinical and radiographic outcome. Multiple etiologies of sacroiliac symptoms were observed: SIJ dysfunction (13 patients), osteoarthritis (5 patients), and spondyloarthropathy and SIJ instability (1 each). Seventeen patients (85%) had solid fusion. Fifteen patients (75%) completed pre-operative and post-operative SF-36 forms. Significant (p < or = 0.05) improvement occurred in the following categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional, as well as neurogenic and pain indices. Improvement (not statistically significant) was also noted in general and mental health. The authors concluded that for carefully selected patients, SI arthrodesis appears to be a safe, well-tolerated, and successful procedure, leading to significant improvement in functional outcome and a high fusion rate. Limitations of this study were:
I. the 85% fusion rate may be an over-estimation because more precise methods (such as a CT scan) were not used to confirm successful arthrodesis,

II. small number of patients (n = 20), and

III. only 75% of patients were available for follow-up.

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2. small number of patients (n = 20), and
3. only 75% of patients were available for follow-up.

Wise and Dall (2008) compared efficacy and outcomes of a new technique for SI arthrodesis. This study described the radiographic and clinical outcomes of this procedure. A total of 13 consecutive patients underwent minimally invasive SI arthrodesis between February and December 2004 at a single teaching hospital and were prospectively followed. Six patients had bilateral fusions for a total of 19 joints. The average age was 53.1 (range of 45 to 62). Average body mass index was 31.2 (range of 21.9 to 46.9). Mean follow-up was 29.5 months (range of 24 to 35). Diagnosis was confirmed using fluoroscopically guided intra-articular injections of local anesthetic and corticosteroid when their pain was relieved 2 or more hours. Arthrodesis was only performed on patients with positive injections who subsequently had their symptoms recur. Outcome measurements included radiographic assessment for fusion and improvement in VAS for LBP, leg pain, and dyspareunia. Computed tomography scan to evaluate implant placement was performed post-operatively and again at 6 months to assess fusion. The overall fusion rate was 89% (17/19 joints). Significant improvements were seen in final LBP score on a VAS (0 to 10) (average improvement 4.9, p < or = 0.001). Leg pain improved an average of 2.4 (p = 0.013). Dyspareunia improved an average of 2.6 (p = 0.0028). One patient was revised to an open arthrodesis secondary to nonunion and persistent pain. There were no infections or neurovascular complications. The authors concluded that minimally invasive SI arthrodesis via a percutaneous posterior approach is a safe and efficacious procedure, leading to a high fusion rate and significant improvement in LBP, leg pain, and dyspareunia. Limitations of this study were its small sample size and the lack of a control group.
In a consecutive case-series study, Al-Khayer (2008) reported a new percutaneous SIJ arthrodesis technique utilizing a Hollow Modular Anchorage screw. Pre-operative and post-operative Oswestry Disability Index (ODI), VAS for pain, and post-operative subjective patients' satisfaction were assessed for all patients. Minimum 2 years follow-up was documented. A total of 9 patients underwent SIJ arthrodesis with the new technique. The mean ODI value dropped from 59 (range of 34 to 70) pre-operatively to 45 (range of 28 to 60) post-operatively ($p < 0.005$). The mean VAS value dropped from 8.1 (range of 7 to 9) pre-operatively to 4.6 (range of 3 to 7) post-operatively ($p < 0.002$). The mean patients' satisfaction was 6.8 (range of 5 to 8). The authors concluded that the new technique may offer a safe and effective treatment for intractable SIJ pain. Limitations of this study were its small sample size, lack of a control group, and despite the encouraging radiographic findings, the exact fusion status of SIJ arthrodesis cannot be determined by plain radiographs.

Khurana et al (2009) examined the effects of percutaneous fusion of the SIJ with hollow modular anchorage screws. These investigators reviewed 15 consecutive patients, 11 women and 4 men, with a mean age of 48.7 years (37.3 to 62.6), who between July 2004 and August 2007 had undergone percutaneous SI fusion using hollow modular anchorage screws filled with demineralized bone matrix. Each patient was carefully assessed to exclude other conditions and underwent pre-operative CT and MR scans. The diagnosis of symptomatic SI disease was confirmed by an injection of local anesthetic and steroid under image intensifier control. The short form-36 questionnaire and Majeed's scoring system were used for pre- and post-operative functional evaluation. Post-operative radiological evaluation was performed using plain radiographs. Intra-operative blood loss was minimal and there were no post-operative clinical or radiological complications. The mean follow-up was for 17 months (9 to 39). The mean short form-36 scores improved from 37 (23 to 51) to 80 (67 to 92) for physical function and from 53 (34 to 73) to 86 (70 to 98) for general health ($p = 0.037$). The mean Majeed's score improved from 37 (18 to 54) pre-operatively to 79 (63 to 96) post-operatively ($p = 0.014$). There were 13 good to excellent results. The remaining 2 patients improved in short form-36 from a mean of 29 (26 to 35) to 48 (44 to 52). Their persistent pain was probably due to concurrent lumbar pathology. The authors concluded that percutaneous hollow modular anchorage screws are a satisfactory method of achieving SI fusion.

In a retrospective study, Rudolf (2012) evaluated the safety and effectiveness of minimally invasive SIJ fusion using a series of triangular, porous plasma spray coated titanium implants. A total of 50 consecutive patients were treated by a single orthopedic spine surgeon in private practice. Medical charts were reviewed for peri-operative metrics, complications, pain, quality of life and satisfaction with surgery. All patients
were contacted at a 24 months post-op to assess SIJ pain, satisfaction with surgery and work status. An early and sustained statistically significant improvement in pain function was identified at all post-operative time points (ANOVA, p < 0.000). A clinically significant improvement (greater than 2 point change from baseline) was observed in 7 out of 9 domains of daily living. The complication rate was low and more than 80% of patients would have the same surgery again. The authors concluded that minimally invasive SIJ fusion appears to be a safe and effective procedure for the treatment of SIJ disruption or degenerative sacroiliitis. The drawbacks of this study included its retrospective design, small sample size, a single surgeon’s experience, a non-standard outcomes measure, and the lack of a comparator group. Moreover, the author noted that prospective studies are currently underway to further evaluate this technology.

In a retrospective study, Sachs and Capobianco (2012) evaluated the safety and effectiveness of minimally invasive SIJ arthrodesis via an ileo-sacral approach in patients who were refractory to conservative care. These investigators reported on the first 11 consecutive patients treated with a novel minimally invasive SIJ fusion system by a single surgeon. Medical charts were reviewed for peri-operative metrics and baseline pain scores recorded using a 0 to 10 numerical rating scale. Ninety one percent (91%) of patients were female and the average patient age was 65 years (range of 45 to 82). Mean baseline pain score (SD) was 7.9 (+/- 2.2). Mean pain score at the 12 month follow-up interval was 2.3 (+/- 3.1), resulting in an average improvement of 6.2 points from baseline, representing a clinically and statistically significant (p = 0.000) improvement. Patient satisfaction was very high with 100% indicating that they would have the same surgery again for the same result. The authors concluded that the findings of this small case series illustrated the safety and effectiveness of minimally invasive SIJ fusion using a series of triangular porous plasma coated titanium implants in carefully selected patients. Moreover, they stated that larger multi-centered studies are needed.

The Work Loss Data Institute’s clinical guideline on “Low back - lumbar & thoracic (acute & chronic)” (2011) does not mention sacroiliac joint fusion as a therapeutic option. In fact, the Work Loss Data Institute’s clinical guideline on “Hip & pelvis (acute & chronic)” (2011) listed sacroiliac joint fusion as one of the interventions/procedures were considered, but are not recommended. In a systematic review on “The therapeutic effectiveness of sacroiliac joint interventions” (Hansen et al, 2012), sacroiliac joint fusion is not mentioned as a therapeutic option. Furthermore, American College of Occupational and Environmental Medicine’s clinical guideline on “Low back disorders” (ACOEM, 2011) did not recommend sacroiliac joint fusion for any low back pain conditions because of insufficient evidence.
In a retrospective study, Sachs and Capobianco (2013) reported on the safety and effectiveness of MIS SIJ arthrodesis using a series of triangular, porous plasma coated implants in patients who were refractory to conservative care. These investigators reported on the first 40 consecutive patients with 1-year follow-up data that underwent MIS SIJ fusion with the iFUSE Implant System (SI-BONE, Inc., San Jose, CA) by a single surgeon. Medical charts were reviewed for demographics, peri-operative metrics, complications, pain scores, and satisfaction. Mean age was 58 years (range of 30 to 81) and 75% of patients were female. Post-operative complications were minimal and included transient trochanteric bursitis (5%), facet joint pain (20%), and new LBP (2.5%). There were no re-operations at 1 year. Mean pain score improved from 8.7 (1.5 SD) at baseline to 0.9 (1.6) at 12 months, a 7.8-point improvement (p < 0.001). Patient satisfaction was very high. The authors concluded that the results of this case series reveal that MIS SIJ fusion using the iFUSE Implant System is a safe and effective treatment option in carefully selected patients. This was an extension of the 2012 study by these investigators. The findings of this small study are promising. Moreover, the authors stated that “additional prospective controlled trials are underway”.

Miller et al (2013) stated that MIS SIJ arthrodesis was developed to minimize the risk of iatrogenic injury and to improve patient outcomes compared with open surgery. Between April 2009 and January 2013, a total of 5,319 patients were treated with the iFUSE SI Joint Fusion System® for conditions including SIJ disruption and degenerative sacroiliitis. A database was prospectively developed to record all complaints reported to the manufacturer in patients treated with the iFUSE device. Complaints were collected through spontaneous reporting mechanisms in support of ongoing mandatory post-market surveillance efforts. Complaints were reported in 204 (3.8%) patients treated with the iFUSE system. Pain was the most commonly reported clinical complaint (n = 119, 2.2%), with nerve impingement (n = 48, 0.9%) and recurrent SIJ pain (n = 43, 0.8%) most frequently cited. All other clinical complaints were rare (less than or equal to 0.2%). Ninety-six revision surgeries were performed in 94 (1.8%) patients at a median follow-up of 4 (range of 0 to 30) months. Revisions were typically performed in the early post-operative period for treatment of a symptomatic mal-positioned implant (n = 46, 0.9%) or to correct an improperly sized implant in an asymptomatic patient (n = 10, 0.2%). Revisions in the late post-operative period were performed to treat symptom recurrence (n = 34, 0.6%) or for continued pain of undetermined etiology (n = 6, 0.1%). The authors concluded that analysis of a post-market product complaints database demonstrated an overall low-risk of complaints with the iFUSE SIJ Fusion System in patients with degenerative sacroiliitis or SIJ disruption. The authors noted that the initial results are promising; however, clinical effectiveness outcomes were not assessed in this study.
Noting that there is minimal literature published on percutaneous fixation of the sacroiliac joint, Kim, et al. (2014) reported on a retrospective review of 31 patients operated on by a single surgeon. The investigators reported that 27 patients expressed satisfaction, 4 patients did not. Pain relief was noted to be Complete (16 patients), Excellent (5 patients), Good (9 patients), and Fair (1 patients). Four patients had postoperative complications. These were infected hematoma (2), L5 nerve root irritation (1), and L5-S1 discitis (1). One patient required revision. On 6 month postop CT scan, 18/19 patients had radiographic evidence of bone ingrowth and bone into or across the SI joint was evident in 8/19 patients. Lucency was noted around at least one implant in 5/19 patients.

In an editorial regarding “Stabilization of the sacroiliac joint”, Shaffrey and Smith (2013) stated that “There are numerous unanswered questions regarding patient selection for SIJ fusion or stabilization. There are an increasing number of surgical techniques for treating SIJ pathology and it is not clear which method may provide the best outcomes. Without prospective trials with non-conflicted surgeons and standardized selection criteria, the true role for SIJ fusion procedures in the management of chronic lower back pain will remain murky. The consequences of the unsupported enthusiasm for the surgical management of discogenic back pain still negatively impacts the public perception of spinal surgeons. Much more high quality information is needed regarding the surgical management of SIJ pathology before widespread use of this technique should be adopted”.

Whang and colleagues (2015) noted that sacroiliac (SI) joint pain is a prevalent, under-diagnosed cause of lower back pain. SI joint fusion can relieve pain and improve quality of life in patients who have failed non-operative care. To-date, no study has concurrently compared surgical and non-surgical treatments for chronic SI joint dysfunction. These researchers conducted a prospective randomized controlled trial of 148 subjects with SI joint dysfunction due to degenerative sacroilitis or sacroiliac joint disruptions who were assigned to either minimally invasive SI joint fusion with triangular titanium implants (n = 102) or non-surgical management (NSM, n = 46). SI joint pain scores, Oswestry Disability Index (ODI), Short-Form 36 (SF-36) and EuroQol-5D (EQ-5D) were collected at baseline and at 1, 3 and 6 months after treatment commencement. Six-month success rates, defined as the proportion of treated subjects with a 20-mm improvement in SI joint pain in the absence of severe device-related or neurologic SI joint-related adverse events or surgical revision, were compared using Bayesian methods. Subjects (mean age of 51, 70% women) were highly debilitated at baseline (mean SI joint VAS pain score 82, mean ODI score 62). Six-month follow-up was obtained in 97.3%. By 6 months, success rates were 81.4% in the surgical group versus 23.9% in the NSM group (difference of 56.6%, 95% posterior credible interval 41.4 to
70.0%, posterior probability of superiority > 0.999). Clinically important (greater than or equal to 15 point) ODI improvement at 6 months occurred in 75% of surgery subjects versus 27.3% of NSM subjects. At 6 months, quality of life improved more in the surgery group and satisfaction rates were high. The mean number of adverse events in the first 6 months was slightly higher in the surgical group compared to the non-surgical group (1.3 versus 1.0 events per subject, p = 0.1857). The authors concluded that the 6-month follow-up from this level 1 study showed that minimally invasive SI joint fusion using triangular titanium implants was more effective than non-surgical management in relieving pain, improving function and improving quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruptions. This was a study with short-term follow-up (6 months); well-designed studies with long-term follow-up are needed to ascertain the clinical effectiveness of SI fusion.

Soriano-Baron et al (2015) stated that minimally invasive placement of SIJ fusion implants is a potential treatment for SIJ disruptions and degenerative sacroiliitis. Biomechanical studies of screw fixation within the sacrum have shown that placement and trajectory are important in the overall stability of the implant. Although clinical results have been promising, there is the possibility that a more optimal arrangement of implants may exist.

Zaidi et al (2015) stated that the SI joint (SIJ) and surgical intervention for treating SIJ pain or dysfunction has been a topic of much debate in recent years. There has been a resurgence in the implication of this joint as the pain generator for many patients experiencing low-back pain, and new surgical methods are gaining popularity within both the orthopedic and neurosurgical fields. There is no universally accepted gold standard for diagnosing or surgically treating SIJ pain. The authors systematically reviewed studies on SIJ fusion in the neurosurgical and orthopedic literature to investigate whether sufficient evidence exists to support its use. A literature search was performed using MEDLINE, Google Scholar, and OvidSP-Wolters Kluwer Health for all articles regarding SIJ fusion published from 2000 to 2014. Original, peer-reviewed, prospective or retrospective scientific papers with at least 2 patients were included in the study. Exclusion criteria included follow-up shorter than 1-year, non-surgical treatment, inadequate clinical data as determined by 2 independent reviewers, non-English manuscripts, and nonhuman subjects. A total of 16 peer-reviewed journal articles met the inclusion criteria: 5 consecutive case series, 8 retrospective studies, and 3 prospective cohort studies. A total of 430 patients were included, of whom 131 underwent open surgery and 299 underwent minimally invasive surgery (MIS) for SIJ fusion. The mean duration of follow-up was 60 months for open surgery and 21 months for MIS. SIJ degeneration/arthrosis was the most common pathology among patients undergoing surgical intervention (present in 257 patients [59.8%]), followed by SIJ
dysfunction (79 [18.4%]), postpartum instability (31 [7.2%]), post-traumatic (28 [6.5%]), idiopathic (25 [5.8%]), pathological fractures (6 [1.4%]), and HLA-B27+/rheumatoid arthritis (4 [0.9%]). Radiographically confirmed fusion rates were 20% to 90% for open surgery and 13% to 100% for MIS. Rates of excellent satisfaction, determined by pain reduction, function, and quality of life, ranged from 18% to 100% with a mean of 54% in open surgical cases. For MIS patients, excellent outcome, judged by patients' stated satisfaction with the surgery, ranged from 56% to 100% (mean of 84%). The re-operation rate after open surgery ranged from 0% to 65% (mean of 15%). Re-operation rate after MIS ranged from 0% to 17% (mean of 6%). Major complication rates ranged from 5% to 20%, with 1 study that addressed safety reporting a 56% adverse event rate. The authors concluded that surgical intervention for SIJ pain is beneficial in a subset of patients. However, with the difficulty in accurate diagnosis and evidence for the efficacy of SIJ fusion itself lacking, serious consideration of the cause of pain and alternative treatments should be given before performing the operation.

Duhon et al (2016) reported on a prospective uncontrolled industry sponsored study of subjects with SI joint dysfunction who underwent minimally invasive SI joint fusion with triangular titanium implants. One hundred ninety-four patients were enrolled between August 2012 and December 2013 at 26 sites. Of these, 10 withdrew prior to SI joint fusion and data from 12 subjects at a single site were eliminated due to the site's persistent non-compliance with the study protocol, leaving 172 subjects enrolled and treated. Two additional sites were terminated more than 1 year into the study for protocol non-compliance, resulting in 3 additional subjects not having 24-month study follow-up. Subjects underwent structured assessments preoperatively and at 1, 3, 6, 12, 18 and 24 months postoperatively, including SIJ pain ratings (0-100 visual analog scale), Oswestry Disability Index (ODI), Short Form-36 (SF-36), EuroQOL-5D (EQ-5D), and patient satisfaction. Adverse events were collected throughout follow-up. All participating patients underwent a high-resolution pelvic CT scan at 1 year. The primary study endpoint, evaluated at six months after the most recent SI joint fusion, was a binary success/failure composite endpoint. A subject was considered a success if all of the following were met: reduction from baseline VAS SI joint pain by at least 20 points, absence of device-related serious adverse events, absence of neurological worsening related to the sacral spine, and absence of surgical re-intervention (removal, revision, reoperation, or supplemental fixation) for SI joint pain. Of the 172 participants, 167 (97.1%) had 6-month follow-up, 157 (91.3%) had 12-month follow-up and 149 (86.6%) had 24-month follow-up. At month 6, 138 of 172 subjects met the study's success endpoint definition, for an intent-to-treat success rate of 80.2% (95% posterior credible interval 73.8-85.7%). Using available data only, the 12-month success rate was 127/159 (79.9%) and the 24-month success rate was 119/149 (79.9%). SIJ pain decreased from 79.8 at baseline to 30.4 at 12 months and 26.0 at 24 months (p<.0001 for change from
baseline). ODI decreased from 55.2 at baseline to 31.5 at 12 months and 30.9 at 24 months (p<.0001 for change from baseline). The proportion of subjects taking opioids for SIJ or low back pain decreased from 76.2% at baseline to 55.0% at 24 months (p < .0001). At the time of the report, 8 subjects (4.7%) had undergone one or more revision SIJ surgeries. 7 device-related adverse events occurred. CT scan at one year showed a high rate (97%) of bone adherence to at least 2 implants on both the iliac and sacral sides with modest rates of bone growth across the SIJ.

The authors stated that this study had 2 main drawbacks. First, the lack of a concurrent control group undergoing non-surgical treatment. Secondly, a 24-month follow-up rate that was not as high as desired. Furthermore, 13.4% of subjects were lost to follow-up during the study or did not have 24-month visits. Pain and ODI scores in exiting subjects were higher than subjects who continued to participate; however, the impact of missing values on pain and ODI scores were analyzed and found to be minor, and did not affect overall study conclusions.

Polly et al (2016) described short and mid-term results of a randomized controlled trial of minimally invasive SIJ fusion. Subjects with SIJ dysfunction were randomly assigned to minimally invasive SIJ fusion with triangular titanium implants (SIJF, n = 102) or non-surgical management (NSM, n = 46). SIJ pain (measured with a 100-point visual analog scale, VAS), disability (measured with Oswestry Disability Index, ODI) and quality of life scores were collected at baseline and at scheduled visits to 24 months. Diagnosis of SIJ dysfunction was based on a history of pain at or near the SI joint, positive provocative testing on at least 3 of 5 physical examination tests, and at least a 50% decrease in pain after image-guided injection/arthrogram into the SI joint with local anesthetic. Crossover from non-surgical to surgical care was allowed after the 6-month study visit was complete. After the 6-month visit, 39 of 44 (89%) NSM subjects who were still participating crossed over to surgical treatment, and all crossover procedures were SIJF using the study device. The authors stated that subjects who had crossed over were not included in the report because they are continuing to be evaluated. In the SIJF group, 13 subjects withdrew prior to month 24. One site was terminated after 12-month subject visits were complete due to "persistent non-compliance with the study protocol." The primary study endpoint, evaluated at 6 months after the most recent SIJF, was a binary success/failure composite measure. A subject was considered to be a success if all of the following criteria were met: reduction in VAS SIJ pain score by at least 20 points from baseline, absence of device-related serious adverse events, absence of neurological worsening related to the lumbosacral nerve roots, and absence of surgical re-intervention (i.e. removal, revision, reoperation, or supplemental fixation) for SIJ pain. By month 6, 84 of 102 SIJF subjects (82%, 95% posterior credible interval [CI] 74-89%) and 12 of 46 NSM subjects (26%, 14-41%) met the study's primary success endpoint. In the
SIJF group, the mean SIJ pain score improved from 82.3 at baseline to 30.1 at 6 month follow-up, 28.6 at 12 months and 26.7 at 24 months. In the NSM group, mean SIJ pain improved from 82.2 to 70.3 at 6 months (12.2-point improvement). Limitations include lack of blinding and large crossovers after 6 months. In addition, the nonsurgical option described usual care “consistent with existing US practices and directed by each site investigator for each subject” and not an intensive multidisciplinary back pain intervention (Chou, et al., 2009). This was an industry sponsored study; the study sponsor also performed the statistical analysis and participated in the writing.

Also note that there is no gold standard for the diagnosis of sacroiliac joint dysfunction. In the study by Polly, diagnosis of SIJ pain was defined as pain elicited on at least 3 of 5 physical examination provocative tests. Note that the study authors cited a systematic evidence review by Szadek, et al. (2009) to support the diagnostic validity of provocative test criteria for sacroiliac joint pain; however, this systematic evidence review had a number of important flaws, including a lack of consideration of the quality of the studies in synthesizing results (CRD, 2014). The main drawbacks of this study were:

I. the lack of a sham control (i.e., incision and dissection to the ilium, possible drilling, but no implant placement),

II. the study was industry-sponsored,

III. in the SIJ fusion group, these researchers were unable to determine the separate contributions of the surgical procedure itself as opposed to post-operative rehabilitation to pain and disability relief and improvement in quality of life,

IV. short-term follow-up – these investigators reported relatively early (1 year) outcomes, trial follow-up continued to 2 years, and

V. moderate sample size – SIJ fusion (n = 102).

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5. moderate sample size – SIJ fusion (n = 102).

Sturesson et al (2017) reported on the short-term (6 month) results of a randomized study of minimally invasive SIJ fusion (SIJF) versus conservative management (CM) in subjects (n=103) with chronic sacroiliac joint pain. At 6 months, mean LBP improved by 43.3 points in the SIJF group and 5.7 points in the CM group (difference of 38.1 points, p < 0.0001). This study suffers from similar limitations as the study by Polly, et al.

The North American Spine Society (2015) has posted online insurance coverage policy recommendation for sacroiliac joint fusion. The coverage recommendation notes: "Due to the relatively moderate evidence, it is particularly critical that inclusion criteria are scrutinized and patient selection is executed with vigilance. The procedure itself has proven to be relatively safe. There is a valid concern for bias in that the overwhelming majority of the data produced so far has been industry-sponsored and generally composed of case series. However there are some data on five-year outcomes that demonstrate sustained benefit that does not appear to degrade from 1 year to 5 year time-points. The committee will revisit the quality of forthcoming evidence as it is produced in re-evaluations of the indications and coverage of this procedure."

In a retrospective study with long-term (up to 6 years) follow-up, Vanaclocha and colleagues (2018) determined responses to conservative management (CM), SIJ denervation, and SIJF in patients with SIJ pain unresponsive to CM. A total of 137 patients with SIJ pain seen in an out-patient neurosurgery clinic who received either CM (n = 63), sacroiliac denervation (n = 47), or minimally invasive SIJF (n = 27) were included in this analysis. At each routine clinic visit, patients completed pain scores and ODI. Additional data were extracted from medical charts. Patients treated with continued CM had no long-term improvement in pain (mean worsening of 1 point) or disability (mean ODI worsened by 4 to 6 points), increased their use of opioids, and had poor long-term work status; SIJF patients had large improvements in SIJ pain (mean of 6 points), large improvements in disability (mean of 25 points), a decrease in opioid use, and good final work status. Sacroiliac denervation patients had intermediate responses (0 to 1 and 1 to 2 points, respectively). The authors concluded that in patients with SIJ pain unresponsive to CM, SIJF resulted in excellent long-term clinical responses, with
low opioid use and better work status compared to other treatments. This study had several drawbacks:

I. It is not a randomized trial,

II. Patients in the CM group had some demographic and clinical factors that were different from those treated with SI denervation and SIJF groups, and

III. Although some patients have 6-year follow-up, mean follow-up in this study was just under 4 years, and further follow-up is of interest.

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Dengler, et al. (2017) stated that devices to fuse the SIJ are now commercially available, but high-quality evidence supporting their effectiveness is limited. The investigators reported on the 12-month outcomes of a trial (6-months outcomes reported by Sturesson, et al., described above) to evaluate the safety and effectiveness of conservative management (CM) to minimally invasive sacroiliac joint fusion (SIJF) in 103 patients with chronic LBP originating from the SIJ. Patients were randomly assigned to CM (n = 51) or SIJF using triangular titanium implants (n = 52). CM consisted of "optimization of medical therapy" (not further defined), individualized physiotherapy, and information and reassurance. Physical therapy was short term (twice a week for "up to" 8 weeks), and a full quarter of subjects had 15 or fewer physical therapy sessions. The primary outcome was the difference in change in self-rated LBP at 6 months using a 0 - 100 visual analog scale (VAS). Other effectiveness and safety endpoints, including leg pain, disability using Oswestry Disability Index (ODI), quality of life using EQ-5D, and SIJ function using active straight leg raise test (ASLR), were assessed up to 12 months. At 12 months, mean LBP improved by 41.6 VAS points in the SIJF group vs. 14.0 points in the CM group (treatment difference of 27.6 points, P < 0.0001). Mean ODI improved by 25.0 points in the SIJF group vs. 8.7 points in the CM group (P < 0.0001). Mean improvements in leg pain and EQ-5D scores were large after SIJF and superior to those after CM. CM patients were allowed to crossover to SIJF after 6 months. Patients who crossed to surgical treatment had no pre-crossover
improvement in pain and ODI scores; after crossover, improvements were as large as those originally assigned to SIJF. One case of postoperative nerve impingement occurred in the surgical group. Two SIJF patients had recurrent pain attributed to possible device loosening and one had postoperative hematoma. In the CM group, one crossover surgery patient had recurrent pain requiring a revision surgery. Primary limitations of the study was short term nature, with crossovers allowed after 6 months, lack of blinding, and subjective nature of self-assessed outcomes. Almost half (43 percent) of subjects assigned to CM crossed over to surgery by the first followup at 6 months, confounding interpretation of the results. In addition, similar to the study by Polly, et al. described above, the study did not employ best standard of care intensive multidisciplinary back pain intervention to the conservative management group (Chou, et al., 2009). This was an industry sponsored study; the study sponsor also participated in the statistical analysis and writing.

Spain, et al. (2017) retrospectively identified all patients in a surgical practice who underwent SIJ fixation or fusion between 2003 and 2015. Using both chart review and focused contact with individual patients, the authors determined the likelihood of surgical revision. Revision rates were compared using Kaplan-Meier survival analysis. Thirty-eight patients underwent SIJ fixation with screws and 274 patients underwent SIJ fusion using triangular titanium implants. Four-year cumulative revision rates were 30.8% for fixation and 5.7% for fusion. The authors found that SIJ fixation with screws had a much higher revision rate compared to SIJ fusion with triangular titanium implants designed for bone adherence. The study described herein was sponsored by the product manufacturer, who also helped with statistical analysis.

Bornemann et al (2016) noted that SIJ syndrome can cause various symptoms and may also be one reason for persistent low back pain, especially in patients with prior spinal fusions. If conservative treatments fail to improve symptoms, arthrodesis surgery can be considered. Minimally invasive approaches have emerged recently providing a good alternative to conventional methods. A novel triangular implant system (iFuse) can achieve an arthrodesis of the SIJ without the use of additional screws or bone material. These investigators evaluated the short-term safety and effectiveness of the implant system. A total of 24 patients were included in the study and treated with the iFuse system. In addition to demographic data, pain intensity (visual analog scale [VAS]) and functional impairment (Oswestry-disability index [ODI]) were assessed prior to surgery and 1 month, 3 months, 6 months, 12 months and 24 months thereafter. During surgery and the follow-up period all adverse events (AEs) were documented and the correct implant position was controlled via plain radiographs. VAS scores and ODI improved significantly directly after surgery from 84.3 ± 9.2 mm to 40.7 ± 9.2 mm and from 76.8 ± 9.2% to 40.7 ± 9.2% (p < 0.001). The ODI improved further to 31 ± 5.4% after 24 months.
whereas the VAS improved until the 3 months examination and 10 stayed constant between 27.7 mm and 26.5 mm to 27 ± 6.6 mm at 24 months. No AEs, intra-operative complications, implant mal-positioning or loosening could be recorded at any time. The author concluded that the iFuse system is an effective and safe treatment for minimally invasive surgical arthrodesis of the SIJ. Pain and functional impairment can be significantly improved. However, they stated that in addition to this case series, further controlled studies are needed, particularly in terms of a previous spinal fusion history.

National Institute for Health and Clinical Excellence’s guideline on “Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain” (NICE, 2017) provides the following recommendations:

- Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.
- Conservative treatments for SI joint pain include analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, manipulative therapy, intra-articular SI joint corticosteroid injections, periarticular injections, botulinum toxin injections and radiofrequency denervation. Surgical treatment is considered for persistent chronic symptoms that are unresponsive to conservative treatment. Surgical techniques include open SI joint fusion surgery or minimally invasive SI joint fusion using percutaneous implants to stabilize the joint and treat joint pain.

Kancherla and co-workers (2017) determined morbidity, complications, and patient reported outcomes from minimally invasive SIJF. Patients diagnosed by more than 2 physical examination maneuvers and subjective relief from a CT-guided lidocaine-bupivacaine-steroid injection underwent SIJF after failing conservative management (CM) with a combination of oral anti-inflammatory medications, physical therapy, and pelvic belt stabilization. Peri-operative data collected include EBL and operative time, ODI, SF-12, VAS, and functional status were analyzed. All complications were noted. The study cohort of 45 cases (69% women) achieved post-operative survey follow-up at 9.9 and 32.3 months; SF-12 physical component summary statistically improved while all other scores were equivalent. Mean EBL and operative time were 22 ml and 36 minutes, respectively. Initial survey showed that 64% of patients discontinued narcotics (29/45), 71% did not use an assistive device (32/45), and 15.6% did not work due to pain (7/45); 73% of patients stated they would have the surgery again (33/45). For the second survey, 65% of patients discontinued narcotics (26/40), 70% did not use an assistive
device (28/40), and 17.5% did not work due to pain (7/40). A history of thoracolumbar instrumentation (16/45) did not significantly affect outcomes; 3 complications described by screw malposition with neurologic deficit (6.7%) were treated with screw repositioning (1 case) and removal of a single superior implant (2 cases) with time to revision of 2.2 months. All 3 ultimately had resolution of radicular pain. The authors concluded that percutaneous SIJF offered minimal morbidity and acceptable functional outcomes. While women and those with a prior history of lumbar instrumentation may be at increased risk of having SIJ dysfunction requiring surgical intervention, it was not found to affect post-operative functional outcomes when compared to the non-instrumented group. They stated that the findings of this series suggested that a thorough work-up with strict indications was paramount in achieving good functional outcomes with this technique. Ultimately, a significant number of patients may have suboptimal outcomes and this must be taken into consideration when counseling patients regarding operative intervention. The drawbacks of this study included a small sample size and all those associated with a retrospective review. While these researchers did obtain pre-operative VAS scores, they did not have any other pre-operative data for post-operative comparison. Also, 16 patients were excluded from the original 57 patients due to lack of data points, which could suggest selection bias. Lastly, the objective of this study was to demonstrate clinical outcomes based on a less invasive fusion procedure. Unfortunately, these investigators were unable to document any evidence of radiographic fusion bed given the technique of surgery utilized. The on-growth of bone onto the implants did not project nicely in any radiographic platform. The authors assumed on post-operative follow-up imaging that a fusion had taken place if there were no radiographic signs of loosening/loss of fixation (halos around the implants).

Rappoport and colleagues (2017) stated that proper diagnosis and treatment of SIJ pain remains a clinical challenge. Dysfunction of the SIJ can produce pain in the lower back, buttocks, and extremities. Triangular titanium implants for minimally invasive surgical arthrodesis have been available for several years, with reputed high levels of success and patient satisfaction. These investigators reported on a novel hydroxyapatite-coated screw for surgical treatment of SIJ pain. Data were prospectively collected on 32 consecutive patients who underwent minimally invasive SIJ fusion with a novel hydroxyapatite-coated screw. Clinical assessments and radiographs were collected and evaluated at 3, 6, and 12 months post-operatively. Mean (SD) patient age was 55.2 ± 10.7 years, and 62.5% were women. More patients (53.1%) underwent left versus right SIJ treatment, mean operative time was 42.6 ± 20.4 minutes, and estimated blood loss did not exceed 50 ml. Over-night hospital stay was required for 84% of patients, and the remaining patients needed a 2-day stay (16%). Mean pre-operative VAS back and leg pain scores decreased significantly by 12 months post-operatively (p < 0.01). Mechanical
stability was achieved in 93.3% (28/30) of patients, and all patients who were employed pre-operatively returned to work within 3 months; 2 patients who needed revision surgery reported symptom improvement within 3 weeks and did not require subsequent surgery. The authors concluded that positive clinical outcomes were reported 1 year post-operatively after implantation of a novel implant to treat SIJ pain. Moreover, they stated that future clinical studies with larger samples are needed to evaluate long-term patient outcomes.

In a prospective, multi-center RCT, Dengler and associates (2017) compared the safety and effectiveness of CM to minimally invasive SIJF in patients with chronic LBP originating from the SIJ. Subjects were 103 adults in spine clinics with chronic LBP originating from the SIJ. Patients were randomly assigned to CM (n = 51) or SIJF using triangular titanium implants (n = 52); CM consisted of optimization of medical therapy, individualized physiotherapy, and adequate information and reassurance as part of a multi-factorial treatment. The primary outcome was the difference in change in self-rated LBP at 6 months using a 0 to 100 VAS. Other effectiveness and safety end-points, including leg pain, disability using ODI, quality of life (QOL) using EQ-5D, and SIJ function using active straight leg raise test (ASLR), were assessed up to 12 months. At 12 months, mean LBP improved by 41.6 VAS points in the SIJF group versus 14.0 points in the CM group (treatment difference of 27.6 points, p < 0.0001). Mean ODI improved by 25.0 points in the SIJF group versus 8.7 points in the CM group (p < 0.0001). Mean improvements in leg pain and EQ-5D scores were large after SIJF and superior to those after CM; CM patients were allowed to crossover to SIJF after 6 months. Patients who crossed to surgical treatment had no pre-crossover improvement in pain and ODI scores; after crossover, improvements were as large as those originally assigned to SIJF. One case of post-operative nerve impingement occurred in the surgical group; 2 SIJF patients had recurrent pain attributed to possible device loosening and 1 had post-operative hematoma. In the CM group, 1 crossover surgery patient had recurrent pain requiring a revision surgery. The authors concluded that for patients with chronic LBP originating from the SIJ, minimally invasive SIJF with triangular titanium implants was safe and more effective than CM in relieving pain, reducing disability, and improving patient function and QOL. They stated that their findings suggested that minimally invasive SIJF may be a reasonable option for patients with SIJ pain not responsive to non-surgical care. The main drawbacks of this study were

I. the lack of blinding,

II. the subjective nature of self-assessed outcomes, and
III. short-term follow-up (12 months).

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3. short-term follow-up (12 months).

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Cummings and Capobianco (2013) reported outcomes from 18 patients with 12 months of postoperative follow-up following minimally invasive sacroiliac joint fusion. Demographics, complications, and clinical outcomes using VAS for pain, ODI for back function and SF-36 for quality of life (QOL) were collected pre-operatively and at 3, 6 and 12 months post-operatively. Mean age was 64 years and 67% of patients were women. There were no intra-operative complications and 1 explant at 3 months for malposition. All patient-reported outcomes showed both clinically and statistically significant improvement at 12 months (p < 0.001 for each of the following): VAS improved by 6.6 points, ODI scores improved by -37.5 points. One year SF-12 physical and mental component (PCS, MCS) scores approximated population normal scores for both physical and mental functioning. Patient satisfaction with outcomes was high at 95%; 89% said would have the same surgery again. The authors concluded that MIS SI joint fusion using a series of triangular porous TPS coated titanium implants is a safe and effective procedure for patients with SI joint disorders who have failed conservative care.

The authors noted that although the current study sample size was small (n = 18), the results were very encouraging. Favorable outcomes in this cohort underscore the necessity to suspect the SI joint as a pain generator in patients with low back pain especially after lumbar spine surgery. Results for this reported procedure in patients with instrumented fusion are as favorable as in patients with no prior lumbar surgical history. They state that this procedure has the potential to significantly benefit the elderly population, who are not candidates for other conventional techniques due to poor bone quality, delayed healing and reduced mobility.

Duhon et al (2013) reported early results of a multi-center prospective single-arm cohort of patients with SI joint degeneration or disruption who underwent minimally invasive fusion using the iFuse Implant System. The safety cohort included 94 subjects at 23 sites with chronic SI joint pain who met study eligibility criteria and underwent minimally invasive SI joint fusion with the iFuse Implant System between August 2012 and September 2013. Subjects underwent structured assessments preoperatively, immediately post-operatively, and at 1, 3, and 6 months post-operatively, including SI joint and back pain VAS, ODI, SF-36, and EuroQoL-5D (EQ-5D). Patient satisfaction with surgery was assessed at 6 months. The effectiveness cohort included the 32 subjects who have had 6-month follow-up to-date. Mean subject age was 51 years (n = 94, safety cohort) and 66% of patients were women. Subjects were highly debilitated at baseline (mean VAS pain score 78, mean ODI score 54); 3 implants were used in 80% of
patients; 2 patients underwent staged bilateral implants; 23 adverse events (AEs) occurred within 1 month of surgery and 29 additional events occurred between 30 days and latest follow-up; 6 AEs were severe but none were device-related. Complete 6-month post-operative follow-up was available in 26 subjects. In the effectiveness cohort, mean (± standard deviation) SI joint pain improved from a baseline score of 76 (± 16.2) to a 6-month score of 29.3 (± 23.3, an improvement of 49 points, p < 0.0001), mean ODI improved from 55.3 (± 10.7) to 38.9 (± 18.5, an improvement of 15.8 points, p < 0.0001) and SF-36 PCS improved from 30.7 (± 4.3) to 37.0 (± 10.7, an improvement of 6.7 points, p = 0.003); 90% of subjects who were ambulatory at baseline regained full ambulation by month 6; median time to full ambulation was 30 days. Satisfaction with the procedure was high at 85%. The authors concluded that minimally invasive SI joint fusion using the iFuse Implant System was safe; mid-term follow-up indicated a high rate of improvement in pain and function with high rates of patient satisfaction. These researchers stated that study enrollment and follow-up are ongoing.

The authors stated that this study had several drawbacks. First, the study lacked an active control group. However, given that all participating patients had chronic pain (a mean of 5 years of pain and at least 6 months of SI joint pain under the care of a physician) and had failed conservative care, the likelihood of high response rates with continued conservative management was likely to be low. Second, the study used ODI to assess baseline disability due to back pain and post-operative improvement related to pain. While ODI was designed for lower back pain and not SI joint pain, in the absence of validated SI joint instruments, ODI was a reasonable proxy, and improvements observed to date appear clinically significant. The improvements in ODI in this study were similar to those reported after percutaneous SI joint fusion. Similarly, the improvements in SF-36 quality of life scores were similar to those observed in a retrospective case series of patients undergoing percutaneous SI joint fusion using hollow modular anchorage screws plus demineralized bone matrix. Finally, while the procedure was termed arthrodesis and the goal of the procedure was to fuse the SI joint, the rate of SI joint fusion was not known. Radiographic analysis in the current study (based primarily on 1-year CT scan) is in progress and results will be reported elsewhere. These were of interest as the procedure used did not directly decorticate the joint and did not involve placement of bone graft.

Cher and Poly (2016) stated that the SIJ is an important cause of LBP. The degree to which minimally invasive surgical fusion of the SIJ improves health state utility has not been previously documented. Health state utility values were calculated using the EQ-5D and SF-36 at baseline and 6 and 12 months after SIJ fusion surgery in subjects participating in a prospective, multi-center clinical trial (n = 172). Values were compared with individuals who participated in a nationally representative cross-sectional survey
Health utility values in the SIJ cohort were compared with those of the NMHS participants using both weighted linear regression and calculation of “health quantile” (i.e., percentile of health normalized to the NHMS cohort adjusted for age and gender). Baseline health state utility was significantly depressed in SIJ patients compared with normal subjects (SF-6D 0.509 versus 0.789, SF-36 physical component summary 31.7 versus 49.2, SF-36 mental component summary 8.5 versus 53.8, EQ-5D 0.433 versus 0.868; all p < 0.0001 after adjustment for age and gender). In the SIJ cohort, all the measures improved by 6 months post-operatively, and improvements were sustained at 12 months. Baseline health quantile was low (5th percentile) in the SIJ cohort and improved significantly at follow-up. The authors concluded that QOL was markedly impaired in patients with SIJ pain compared with age- and gender-matched cohorts. SIJ fusion in this cohort resulted in a substantial improvement in health state utility, bringing the population back toward the expected levels of overall health. The quantile approach helped to explain the degree to which health was improved compared with age- and gender-matched cohorts. The study from which data analyzed in this report was derived was sponsored by SI-BONE; and DJ Cher is an employee of SI-BONE.

Araghi et al (2017) documented 6-month results of the first 50 patients treated in a prospective, multi-center study of a minimally invasive (MI) sacroiliac joint (SIJ) fusion system. This cohort included 50 patients who had MI SI joint fusion surgery and completed 6 month follow-up. Average age at baseline was 61.5 years, 58% were women, and SIJ-related pain duration was greater than or equal to 2 years in 54.0% of patients; VAS SIJ pain, ODI, QOL and opioid use were assessed pre-operatively and at 6 months. At 6 months, mean VAS pain demonstrated a significant reduction from 76.2 at baseline to 35.1 (54% reduction, p < 0.0001), with 72% of patients attaining the minimal clinically important difference (MCID, greater than or equal to 20 point improvement). Mean ODI improved from 55.5 to 35.3 at 6 months (p < 0.001), with 56% of patients achieving the MCID (greater than or equal to 15 point improvement). Prior to surgery 33/50 (66%) of patients were taking opioids, but by 6 months the number of patients taking opioids had decreased by 55% to 15/50 (30%). Few procedural complications were reported. Two procedure-related events required hospitalization: a revision procedure (2%) for nerve impingement and 1 case of ongoing low back pain (LBP). The authors concluded that analysis of patients treated with MI SIJ fusion using the SImmetry System demonstrated that the procedure can be performed safely and resulted in significant improvements in pain, disability, and opioid use at 6 months. Moreover, they stated that longer term follow-up in this study will determine whether these improvements are durable, as well as the associated radiographic fusion rates.
The authors noted that the greatest limitations with this trial were the sample size (n = 50) and limited follow-up (6 months). The current data represented the first interim analysis of what will be the largest cohort of patients prospectively enrolled in a trial to evaluate both fusion and pain following MI SIJ fusion surgery. An additional 200 patients are planned to be enrolled to provide enough statistical power to determine contributing factors to fusion and pain relief. At present, this interim analysis of 50 patients provided sufficient positive outcome data to validate continuing with the trial protocol through 2 years of follow-up. Another limitation of this trial was a lack of a control group. The comparison of minimally invasive SIJ fixation to non-surgical therapy was previously established in a randomized trial reported by Polly et al. Results from the trial demonstrated that the surgery group had a substantially significant improvement in pain compared to non-surgical therapy group. Greater improvement in disability and QOL was also shown in the surgical group with results lasting through 2 years. In light of the superior results shown with SIJ surgery, the authors felt that there was no clinical equipoise to suggest that additional randomized controlled trials (RCTs) would be acceptable. Instead, the purpose of this trial was to evaluate patient outcomes using the technology of decortication, bone grafting and threaded implants described herein. In this discussion the results were compared to a similar study of another MI SIJ fusion system. While this comparison provided relevant context, it must be acknowledged that differences in methodology, investigational site standards of care, and even changes in public attitudes toward opioid painkillers could impact differences seen in the results of the 2 studies.

Darr et al (2018) reported clinical and functional outcomes of SIJ fusion (SIJF) using triangular titanium implants (TTI) in the treatment of chronic SI joint dysfunction due to degenerative sacroiliitis or SIJ disruption at 3 years post-operatively. A total of 103 subjects with SIJ dysfunction at 12 centers were treated with TTI in 2 prospective clinical trials and enrolled in this long-term follow-up study. Subjects were evaluated in study clinics at study start and again at 3, 4, and 5 years. Mean (SD) pre-operative SIJ pain score was 81.5, and mean pre-operative ODI was 56.3. At 3 years, mean pain SIJ pain score decreased to 26.2 (a 55-point improvement from baseline, p < 0.0001). At 3 years, mean ODI was 28.2 (a 28-point improvement from baseline, p < 0.0001). In all, 82% of subjects were very satisfied with the procedure at 3 years. EuroQol-5D (EQ-5D) time trade-off index improved by 0.30 points (p < 0.0001). No adverse events (AEs) definitely related to the study device or procedure were reported; 1 subject underwent revision surgery at year 3.7. SIJ pain contralateral to the originally treated side occurred in 15 subjects of whom 4 underwent contralateral SIJF. The proportion of subjects who were employed outside the home full- or part-time at 3 years decreased somewhat from baseline (p = 0.1814), and the proportion of subjects who would have the procedure again was lower at 3 years compared to earlier time-points. The authors concluded that
in long-term (3-year) follow-up, minimally invasive trans-iliac SIJF with TTI was associated with improved pain, disability, and QOL with relatively high satisfaction rates.

The authors stated that the primary disadvantage of this study was the lack of long-term data from a concurrent control group receiving only non-surgical treatment. In the INSITE study, most subjects in the non-surgical control group who experienced inadequate pain relief at month 6 crossed-over to surgical care. However, long-term non-surgical follow-up appeared to be associated with very poor outcomes. Another limitation was that several sites in INSITE and SIFI could not participate in the current study due to either low numbers of subjects or lack of clinical trial resources; subjects at participating sites had slightly larger 24-month improvements in SIJ pain and ODI compared to those at non-participating sites. The calculated impact on 3-year scores reported herein was small – approximately 4 points for VAS SIJ pain and 2.4 points for ODI. Another limitation was that the data from this study of triangular implants were not applicable to clinical outcomes from devices with other designs and fusion strategies for SIJF.

Cross et al (2018) noted that SIJ degeneration is a common source of LBP. A recently developed MI SIJ fusion system incorporates decortication, placement of bone graft and fixation with threaded implants (DC/BG/TF). A total of 19 patients who had MI SIJ fusion with DC/BG/TF were enrolled at 3 centers. Fusion was assessed in CT images obtained 12 and 24 months post-operatively by an independent radiographic core laboratory. LBP was assessed using a 0 to 10 numerical pain scale (NPS) pre-operatively and at 12 and 24 months post-operatively. At 12 months, 15/19 patients (79%) had bridging bone across the SIJ, and at 24 months 17/18 patients (94%) available for follow-up had SIJ fusion. Of the patients with bridging bone 88% had fusion within the decorticated area, with solid fusion in 83%. A significant reduction in NPS scores was demonstrated, representing a 73% reduction in average LBP. The authors concluded that the patients in this series demonstrated significant improvement in LBP. Fusion rates at 24 months demonstrated promise for this system, which utilized the established orthopedic principles of DC/BG/TF to achieve arthrodesis. These researchers stated that further study is needed to demonstrate comparative fusion rates for different implant systems and predictive correlation to clinical outcomes.

The authors stated that weaknesses in this study included the small patient sample size (n = 19). Importantly, it was not powered to detect associations between radiographic fusion status and clinical outcomes and instead, the primary outcome assessment was radiographic fusion. The paucity of reported fusion rates versus clinical outcomes demanded further investigation; larger prospective, comparative studies should enable
predictive association of pre-operative variables, fusion status and implant system characteristics to clinical outcomes.

An assessment of sacroiliac joint fusion by the RTI International–University of North Carolina Evidence-based Practice Center for the Washington State Healthcare Authority Health Technology Assessment Program (Kahwati, et al., 2018) reached the following conclusions: "Among patients meeting diagnostic criteria for SI joint pain or dysfunction and who have not responded adequately to conservative care, minimally invasive SI joint fusion surgery with the iFuse Implant System is more effective than conservative management for reducing pain and improving function, and is likely cost-effective. Minimally invasive SI joint fusion surgery with iFuse is also more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay. Serious adverse events from surgery with iFuse are infrequently reported in controlled studies but may be higher in usual practice based on evidence from uncontrolled studies. The incidence of revision surgery is likely no higher than 3.4% at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or that evaluates procedures other than iFuse."

The Washington State Health Technology Assessment Committee reviewed the data on sacroiliac joint fusion for sacroiliac syndrome (2019). The agency medical directors (2019) found that available studies of sacroiliac joint fusion for sacroiliac pain suffer from a number of significant limitations leading to a serious risk of bias.

- Most studies are uncontrolled
- Controlled studies suffer from a number of limitations, including:
  - a lack of sham studies or studies with an independent masked assessment of outcome;
  - a lack of an adequate evidence-based multidisciplinary conservative management comparator; and
  - a lack of a diagnostic gold standard for sacroiliac joint syndrome

- In addition, all available studies are funded by the device manufacturer
- Available studies reported a wide range of adverse events, and failed to employ standardized definitions or a common protocol for safety data assessment

They explained that, inclusion criteria in studies of sacroiliac fusion varied, and were typically a combination of physical exam tests (3 out of 5 tests positive) and reduction of pain (variable degree, often 50% or 80%) with sacroiliac anesthetic injection, with variable requirements for imaging guidance of the injection. They also noted that the
physical exam parameters had poor reliability. Citing van Tilburg, et al. (2017), the Kappa values for pooled parameters of inter-rater reliability for physical exam for sacroiliac joint pain was less than 0.20. They also noted that an analysis using combined data from two trials (1 randomized controlled trial [INSITE] and 1 uncontrolled trial [SIFI], total N = 320) (citing Dengler, et al., 2017; Polly, et al., 2016; Duhon, et al., 2016) found no relationship between the level of immediate response to sacroiliac joint block (average percent decrease in pain after injection from 40% to 100%) and 6- and 12-month pain and disability scores among patients undergoing sacroiliac joint fusion. They explained that, in clinical studies, the “conservative management” comparator was defined at providers’ discretion, not an evidence-based multidisciplinary management program. Regarding safety, they found no common protocols for data assessment or standardized definitions, with a range of reported adverse events for iFuse of 0 to 30%. They concluded that the evidence for efficacy of sacroiliac joint fusion for sacroiliac joint syndrome is based on unblinded, manufacturer-funded trials with a high risk of bias and lack of objective data. The noted that serious adverse events may be under-reported in trials.

In a prospective, multi-center, RCT, Dengler and colleagues (2019) compared the safety and effectiveness of minimally invasive SIJ arthrodesis using triangular titanium implants and conservative management in patients with chronic SIJ pain. This study enrolled adults with chronic SIJ pain assigned to either conservative management or SIJ arthrodesis with triangular titanium implants. The study end-points included self-rated LBP (VAS), back dysfunction (ODI), and QOL; 90% of subjects in both groups completed the study. Between June 6, 2013, and May 15, 2015, a total of 103 subjects were randomly assigned to conservative management (n = 51) or SIJ arthrodesis (n = 52). At 2 years, the mean LBP improved by 45 points (95% CI: 37 to 54 points) after SIJ arthrodesis and 11 points (95% CI: 2 to 20 points) after conservative management, with a mean difference between groups of 34 points (p < 0.0001). The mean ODI improved by 26 points (95% CI: 21 to 32 points) after SIJ arthrodesis and 8 points (95% CI: 2 to 14 points) after conservative management, with a mean difference between groups of 18 points (p < 0.0001). Parallel improvements were observed in QOL. In the SIJ arthrodesis group, the prevalence of opioid use decreased from 56% at baseline to 33% at 2 years (p = 0.009), and no significant change was observed in the conservative management group (47.1% at baseline and 45.7% at 2 years). Subjects in the conservative management group, after cross-over to the surgical procedure, showed improvements in all measures similar to those originally assigned to SIJ arthrodesis. In the first 6 months, the frequency of AEs did not differ between groups (p = 0.664). By 24 months, these researchers observed 39 SAEs after SIJ arthrodesis, including 2 cases of SIJ pain, 1 case of a post-operative gluteal hematoma, and 1 case of post-operative nerve impingement. The analysis of CT imaging at 12 months following SIJ arthrodesis showed
radiolucencies adjacent to 8 implants (4.0% of all implants). The authors concluded that minimally invasive SIJ arthrodesis with triangular titanium implants was safe and effective at 2 years for the treatment of chronic SIJ pain and provided lasting improvements compared with conservative management. They stated that these findings suggested that minimally invasive SIJ arthrodesis may be a reasonable option for patients with SIJ pain not responsive to 6 months of conservative management. This study provided only short-term (2 years) follow-up data.

The authors noted that the main drawback of this study was a lack of subject and outcome assessor blinding, which would have been challenging because implants were radiopaque and preventing subjects from seeing their radiographic studies would have been impossible. The large effect sizes seen strongly argued against a marked contribution from placebo effects. Although this trial followed non-surgical European guidelines for the treatment of SIJ pain with intensive physical therapy provided, it was possible that more intensive conservative management might have provided somewhat better results. An additional drawback was the high cross-over rate after 6 months. Finally, these investigators stated that this trial used SIJ arthrodesis with a single system (triangular titanium implants); whether these findings apply to other SIJ arthrodesis surgical approaches, systems, and devices is not known. Except for smoking status, baseline parameters were distributed evenly across treatment groups. Subjects assigned to SIJ arthrodesis were more likely to be smokers; if smoking reduces the rate of bone-healing, as is commonly accepted, the increased proportion of smokers in the SIJ arthrodesis group would have biased study results against SIJ arthrodesis. Post-randomization interventions or subject behaviors that could have impacted the study’s results were not readily apparent; some subjects in the conservative management group received prolonged physical therapy, which theoretically could have increased its effect. The collection of information to support the calculation of health indices (e.g., Charlson Comorbidity Index) and further opioid history during a 6-month period prior to the study start could also have been helpful. An analysis of predictors of response in the conservative management group is also of interest; however, the sample size was too small to accomplish this goal.

An independent randomized controlled trial of sacroiliac joint fusion for sacroiliac pain is currently ongoing (NCT03507049). This prospective randomized double blinded controlled multicenter trial will examine whether there is a difference in SI joint pain in patients operated with minimally invasive arthrodesis of the SI joint compared to a sham operated control group.

Cryoablation for the Treatment of Lumbar facet Joint Pain
Barlocher and colleagues (2003) carried out a prospective study to examine the efficacy of kryorhizotomy, an alternative procedure for lumbar medial branch neurotomy, in the treatment of lumbar facet syndrome (LFS). A total of 50 patients with chronic LBP, in whom pain was relieved by controlled diagnostic medial branch blocks of the lumbar zygapophyseal (facet) joints, underwent lumbar medial branch kryorhizotomy. Outcome was evaluated using the VAS score and assessment of work capacity. All outcome measures were repeated at 6 weeks, 6 months, and 1 year after surgery. At 1-year follow-up examination, 31 (62%) of 50 patients experienced a good response to lumbar facet kryorhizotomy. Good results with pain relief of 50% or more were obtained in 85% of patients without previous spinal surgery but only in 46% who had undergone previous spinal surgery. This difference was statistically significant. In 5 patients (16%) in whom a good initial benefit was observed but who experienced increased pain within 6 weeks after kryorhizotomy, the beneficial result was regained after an early repeated procedure. There were no side effects. Overall, 19 (38%) of 50 procedures were not considered successful. In 6 of these 19 cases a rigid stabilization of the involved segment provided permanent pain relief. The authors concluded that based on this study, patients with LFS who have not undergone previous spinal surgery benefited significantly from percutaneous lumbar kryorhizotomy. Kryorhizotomy, which has virtually no risk, appeared to be a valuable alternative technique to lumbar medial branch neurotomy.

Staender and associates (2005) prospectively evaluated the therapeutic effect of computerized tomography (CT)-guided kryorhizotomy in the treatment of patients with lumbar facet joint syndrome (LFJS) and examined prognostic factors that predict this effect. Between February 2001 and March 2004, CT-guided kryorhizotomy of facet joints was carried out in 76 patients with LFJS. A diagnosis was established after 3 positive CT-guided medial nerve branch blocks. Outcome was determined by evaluating the results of a standardized questionnaire, including VAS score, use of medication, ability to work, and physical conditions. Measurement was carried out before treatment and repeated post-operatively at 3 days, 3 months, and every 6 months thereafter. On September 2004, all patients underwent clinical re-evaluation. The median follow-up period was 22.5 months (range of 6 to 43 months); the median interval to pain reduction was 6 months (range of 0.1 to 31 months) after the 1st kryorhizotomy. The mean VAS pain score was 6.7 pre-operatively and 2.9, 3.2, and 3.4 at 3 days, 3 months, and 6 months post-operatively, respectively. In 40% of patients pain was reduced for 12 months or longer. In patients in whom there was no prior surgical treatment of the relevant spinal segment, the duration of pain relief was significantly longer than in patients who had previously undergone surgery (p < 0.03); 18 patients underwent a 2nd, 7 a 3rd, and 1 a 4th kryorhizotomy. No patient reported any side effect. The use of CT guidance guaranteed an exact needle-tip position control.
and documentation for repeated procedures. The authors concluded that CT-guided kryorhizotomy was a minimally invasive and repeatable treatment that yielded good long-term results in patients with LFJS.

Birkenmaier et al (2007) stated that facet joint pain is an important aspect of degenerative lumbar spine disease, and radiofrequency medial branch neurotomy remains an established therapy, while cryodenervation has still been poorly examined. This study was undertaken to examine the effects of medial branch cryodenervation in the treatment of lumbar facet joint pain. This was a prospective clinical case series. Patient selection was based on the history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were LBP (VAS), limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain-free or had major improvement of LBP; 13 (28 %) had no or little improvement. Including failures, mean LBP decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months (p < 0.0001). Limitation of the activities of daily living improved parallel to reduced pain. The authors concluded that these findings suggested that medial branch cryodenervation is a safe and effective treatment for lumbar facet joint pain. Moreover, they stated that at the 12 month follow-up period, the failure rate rose to 43 %.

Wolter and co-workers (2011) noted that LFJS is the cause of pain in 15 to 54 % of the patients with LBP. There are few studies of cryotherapy for LFJS, focusing mainly on pain scores rather than further outcome measures. In a retrospective, observational study, these researchers determined the long-term outcome after cryoneurolysis of lumbar facet joints, looking at pain scores, pain-related impairment patient satisfaction, and pain-related anxiety/depression. In a 4-year period, a total of 117 cryoneurolyses were carried out in 91 patients under CT guidance in the prone position. Data from patient charts and questionnaires pre- and post-treatment were evaluated. The mean pain rating decreased from 7.70 pre-treatment to 3.72 post-treatment. In the post-interventional 3 months follow-up, this value rose to 4.22. At follow-up (mean of 1.7 years, range of 6 to 52 months), the mean VAS was 4.99. The pain disability index revealed statistically significant improvements in the following items: familiar and domestic duties, recreation, social activities, profession and vitally indispensable activities (p < 0.05). Hospital anxiety and depression scale (HADS) scores for depression showed a statistically significant decline after therapy, whereas scores for anxiety did not. A subgroup of patients who did not benefit from cryoneurolysis had elevated depression scores. The authors concluded that cryoneurolysis for LFJS could lead to
favorable results with sustained pain relief, amelioration of pain-related disability and reduction of depression scores.

An UpToDate review on “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2013) discusses the use of facet joint injection and medial branch block; but does not mention the use of cryoablation as a therapeutic option.

Minimally Invasive Thoracic Discectomy

Kasliwal and Deutsch (2011) stated that the management of symptomatic thoracic disc herniation (TDH) has evolved tremendously ever since the first laminectomy was performed. The last decade has witnessed the evolution of minimally invasive approaches for TDH most of which have been posterior/postero-lateral. Traditional anterior approaches involve a thoracotomy or more recently, thorascoscopic techniques. The authors described a less invasive anterior retropleural surgical approach to address central thoracic disk herniations that is less extensive than a thoracotomy and allows better anterior access than posterior or postero-lateral approaches. The retropleural approach allows the use of the operative microscope with a tubular retractor in the anterior thoracic spine. A total of 7 patients with central disc herniation who were managed with the minimally invasive lateral retropleural approach from 2007 to 2010 at their institution were included in the study. Surgical technique consisted of a lateral position followed by retro-pleural exposure through tubular retractor system without the need of intra-operative lung collapse. Clinical details including age, sex, clinical presentation, surgical details, complications and outcome at last follow-up were analyzed. Patients age ranged in age from 30 to 70 years (mean of 52 years). The duration of symptoms ranged from 4 days to 3 years. All patients presented with thoracic myleopathy on physical examination. The average length of stay in the hospital was 2.6 days (range of 1 to 4 days). Follow-up was available for all the patients. Myelopathy was assessed by the Nurick scale. On examination, 3 of 7 patients improved by 1 point on the Nurick scale. No patient deteriorated after surgery. There were no complications related to the approach. The authors concluded that a minimally invasive retropleural approach using tubular retractor system for central thoracic disc herniation is feasible and may be a less invasive anterior alternative to a thoracotomy. This was a small feasibility study.

Regev et al (2012) noted that surgical decompression of thoracic disc herniations is technically challenging because retraction of the thecal sac in this area must be avoided. Standard open thoracic discectomy procedures require fairly extensive soft tissue
dissection and vertebral resection to provide safe decompression of the spinal cord. These researchers described their experience using a minimally invasive, transforaminal thoracic discectomy (MITTD) technique for the treatment of thoracic disc herniation. A total of 12 patients undergoing MITTD were evaluated pre-operatively and post-operatively at 1-, 3-, and 6-month intervals with neurologic examination, and were graded using the American Spinal Injury Association (ASIA) impairment scale and a pain visual analog scale (VAS). Thoracic instability and bony fusion were assessed clinically and radiographically with plain radiographs and computed tomography (CT) scans. Surgical time, blood loss, complications, and hospital length of stay were recorded. Twelve patients (7 men and 5 women) underwent MITTD. The median surgical time was 128 (80 to 185) minutes, the median estimated blood loss was 100 (30 to 250) mL, and the median hospital stay was 2 (1 to 4) nights. All discs were successfully removed, and a CT or magnetic resonance imaging confirmed adequate cord decompression in all cases. All patients reported easing of neurologic symptoms and improved walking ability. The median VAS scores improved from 4.5 to 2 for back pain. The ASIA score improved from D to E in the 2 patients who suffered from motor weakness. Pre-operative sensory deficit was reduced in 3 of the 5 patients. Patients who suffered from sexual and urinary disturbances did not report improvement. Serious systemic or local complications and neurologic deterioration were not reported. The authors concluded that the transforaminal approach enabled sufficient access to the midline of the spinal canal without extensive resection of the facet joint or the adjacent pedicle. Because most of the osseous and ligamentous structures were preserved, additional instrumentation was not required to prevent postoperative instability. They stated that these early results suggested that minimally invasive thoracic discectomy by transforaminal microscopic technique is a valuable choice in the management of thoracic disc herniation. These preliminary results need to be validated by well-designed studies.

In a case-series study, Smith et al (2013) presented operative details and clinical follow-up of a series of patients with thoracic disk herniation treated with the minimally invasive technique of thoracic microendoscopic diskectomy (TMED). TMED was performed in 16 consecutive patients (age range of 18 to 79 years old) with 18 thoracic disk herniations. One patient with a calcified herniation in a direct ventral location was not included in this series. Patients were positioned prone, and a tubular retractor system was placed through a muscle dilating approach. The procedure was performed with endoscopic visualization. Outcomes were assessed using modified McNab criteria. There were no complications, and no case required conversion to an open procedure. The mean operative time was 153 minutes per level, and mean blood loss was 69 mL per level. Mean hospital stay was 21 hours. At a mean follow-up of 24 months (median of 22 months), 13 patients (81%) had excellent or good outcomes, 1 patient (6%) had a fair outcome, and 2 patients (13%) had poor outcomes. The 2 patients with poor outcomes
had neurologic diagnoses (multiple sclerosis and multiple systems atrophy) that were ultimately proven to be responsible for their symptoms and deficits. The authors concluded that TMED is a safe and effective minimally invasive postero-lateral approach for the treatment of thoracic disk herniations that lacks the morbidity associated with traditional approaches. The findings of this case-series study need to be validated by well-designed studies.

Furthermore, the Work Loss Data Institute’s clinical practice guideline on “Low back - lumbar & thoracic (acute & chronic)” (2011) did not mention the use of minimally invasive thoracic discectomy as a therapeutic option.

**Dynamic (Intervertebral) Stabilization**

Li and colleagues (2011) explored the value of application of Bioflex dynamic stabilization system in treating multi-segment lumbar degenerative disease. Clinical data of 13 patients with multi-segment lumbar degenerative disease (8 males and 5 females; average age of 65.0 years, range of 51 to 72) were retrospectively analyzed between April 2008 and May 2009. The involved area included L3 to S1 in 7 cases, L2 to S1 in 3 cases, L3 to L5 in 1 cases, L4 to S1 in 2 cases. All patients underwent decompression, dynamic stabilization with Bioflex system, according to the severity of degenerative disc with/without interbody fusion. The clinical effects were evaluated by VAS, ODI. Range of motion and fusion segments were also observed. The mean follow-up period was 19.5 months (range of 12 to 26). The mean operative time was 183.4 mins (range of 90 to 240) and the mean volume of blood loss was 610.2 ml (range of 400 to 1,220 ml). The mean VAS score was 7.8 +/- 1.3 pre-operatively, 2.3 +/- 0.9 post-operatively and 2.1 +/- 0.8 at the last follow-up. The average ODI was (60.50 +/- 4.40)% pre-operatively, (17.80 +/- 2.10)% post-operatively and (16.20 +/- 2.40)% at the last follow-up. The VAS and ODI significant improved in post-operatively (p < 0.05), and there was no statistical difference between post-operative and last follow-up (p > 0.05). ROM of whole lumbar and non-fused segment showed obviously decreased and adjacent segment showed insignificant increased. The fusion rate of interbody fusion level was 95.0% (19/20). The authors concluded that the preliminary clinical results showed the Bioflex system combined with intebody fusion is a safe and effective technique in treating multi-segment lumbar degenerative disease. These preliminary findings need to be validated by well-designed studies.

Zhang and associates (2012) examined the short-term effectiveness of ISOBAR TTL semi-rigid dynamic stabilization system (ISOBAR TTL system) in treatment of lumbar degenerative disease. Between June 2007 and May 2011, a total of 38 cases of lumbar...
degenerative disease were treated, including 24 males and 14 females with an average age of 51.2 years (range of 21 to 67). The disease duration was 8 months to 10 years (mean of 4.7 years). In 38 cases, there were 4 cases of grade I spondylolisthesis, 11 cases of lumbar instability and lumbar disc protrusion, 21 cases of lumbar spinal stenosis and lumbar disc protrusion, and 2 cases of post-operative recurrence of lumbar disc protrusion. There were 22 cases of adjacent segment disc degeneration. All cases underwent posterior decompression and implantation of ISOBAR TTL system. The double-segment-fixed patients underwent interbody fusion. Visual analog scale and Japanese Orthopedic Association scores for LBP were used to evaluate clinical outcomes. The ROM at the semi-rigid dynamic stabilization segment was also measured. The other cases achieved healing of incision by first intention, except 1 case of delayed healing. All the patients were followed-up for 8 to 53 months (mean of 27.8). After operation, ISOBAR TTL system showed reliable fixation, and no loosening, breakage, or kyphosis deformity occurred. No adjacent segment degeneration was observed. The ROM of the fixed segments was 0 to 1 degrees in 3 cases, 1 to 2 degrees in 4 cases, 2 to 3 degrees in 14 cases, 3 to 4 degrees in 15 cases, and greater than 4 degrees in 2 cases. At last follow-up, the VAS score was 1.93 +/- 2.43, and was significantly lower than pre-operative score (8.20 +/- 1.78) (t = 7.761, p = 0.000). Japanese Orthopedic Association score was 23.06 +/- 7.75, and was significantly higher than pre-operative score (4.87 +/- 3.44) (t = 10.045, p = 0.000). According to Stauffer-Coventry evaluation standard, the results were excellent in 32 cases, good in 3 cases, fair in 2 cases, and poor in 1 case, with an excellent and good rate of 92.1%. The authors concluded that good short-term effectiveness can be achieved by surgical intervention with ISOBAR TTL system in treatment of lumbar degenerative disease. The results of this small study need to be validated by well-designed studies.

Li and co-workers (2013) retrospectively evaluated the indications, safety and efficacy of a new dynamic stabilization system (the Isobar TTL Semi-Rigid Rod System, Scient’x, Bretonneux, France) for the treatment of lumbar degenerative disease in 37 consecutive patients (M:F = 16:21, mean age of 40.2 years) with lumbar degenerative disease who underwent surgery between June 2006 and May 2009. One patient was lost to follow-up. Clinical outcomes were evaluated using the ODI and the VAS; ROM and disc height index (DHI) were assessed with radiography. Patients were followed for a mean of 24 months (range of 12 to 36 months). At the 3-month follow-up, there was significant improvement in VAS and ODI (p < 0.05); at long-term follow-up VAS showed additional significant improvement (p < 0.05) and ODI remained stable. At short-term follow-up, DHI was significantly restored (p < 0.05) and ROM declined slightly (but not significantly); however, at long-term follow-up DHI was significantly reduced (p < 0.05) compared to short-term follow-up and ROM was significantly decreased compared to the pre-operative values (p < 0.05). There were new signs of degeneration at adjacent
levels in 14 patients (39%) on long-term follow-up MRI. Revision was required in 3 patients (8%) 24 months after the first operation due to adjacent segment disease. Screw loosening was observed in 4 patients (11%). The authors concluded that the Isobar System after microsurgical decompression for lumbar degenerative disease provided excellent improvement in leg and back pain and patient satisfaction at late follow-up; however, evidence to suggest that Isobar outperforms traditional fusion is lacking. Moreover, they stated that larger studies of longer duration are warranted.

**Total Facet Arthroplasty System**

The Total Facet Arthroplasty System (TFAS; Facet Solutions, Inc., Hopkinton, MA) is a non-fusion spinal implant indicated for treatment of moderate-to-severe spinal stenosis. The TFAS replaces the diseased facets (and lamina, if necessary, to attain adequate decompression) following surgical removal.

Phillips et al (2009) stated that lumbar fusion is traditionally used to restore stability after wide surgical decompression for spinal stenosis. The TFAS is a motion-restoring implant suggested as an alternative to rigid fixation after complete facetectomy. In a biomechanical in-vitro study, these researchers investigated the effect of TFAS on the kinematics of the implanted and adjacent lumbar segments. A total of 9 human lumbar spines (L1 to sacrum) were tested in flexion-extension (+8 to -6Nm), lateral bending (+/-6Nm), and axial rotation (+/-5Nm). Flexion-extension was tested under 400 N follower preload. Specimens were tested intact, after complete L3 laminectomy with L3 to L4 facetectomy, after L3 to L4 pedicle screw fixation, and after L3 to L4 TFAS implantation. Range of motion was assessed in all tested directions. Neutral zone and stiffness in flexion and extension were calculated to assess quality of motion. Complete laminectomy-facetectomy increased L3 to L4 ROM compared with intact in flexion-extension (8.7 +/- 2.0 degrees to 12.2 +/- 3.2 degrees, p < 0.05) lateral bending (9.0 +/- 2.5 degrees to 12.6 +/- 3.2 degrees, p = 0.09), and axial rotation (3.8 +/- 2.7 degrees to 7.8 +/- 4.5 degrees p < 0.05). Pedicle screw fixation decreased ROM compared with intact, resulting in 1.7 +/- 0.5 degrees flexion-extension (p < 0.05), 3.3 +/- 1.4 degrees lateral bending (p < 0.05), and 1.8 +/- 0.6 degrees axial rotation (p = 0.09). The Total Facet Arthroplasty System restored intact ROM (p > 0.05) resulting in 7.9 +/- 2.1 degrees flexion-extension, 10.1 +/- 3.0 degrees lateral bending, and 4.7 +/- 1.6 degrees axial rotation. Fusion significantly increased the normalized ROM at all remaining lumbar segments, whereas TFAS implantation resulted in near-normal distribution of normalized ROM at the implanted and remaining lumbar segments. Flexion and extension stiffness in the high-flexibility zone decreased after facetectomy (p < 0.05) and increased after simulated fusion (p < 0.05). The Total Facet Arthroplasty System...
restored quality of motion parameters (load-displacement curves) to intact \( (p > 0.05) \). The quality of motion parameters for the whole lumbar spine mimicked L3 to L4 segmental results. The authors concluded that TFAS restored ROM and quality of motion at the operated segment to intact values and restored near-normal motion at the adjacent segments.

Sjovold et al (2012) noted that to gain insight into a new technology, a novel TFAS was compared to a rigid posterior fixation system (UCR). The axial and bending loads through the implants and at the bone-implant interfaces were evaluated using an ex-vivo biomechanical study and matched finite element analysis. Kinematic behavior has been reported for TFAS, but implant loads have not. Implant loads are important indicators of an implant's performance and safety. The rigid posterior fixation system is used for comparison due to the extensive information available about these systems. Unconstrained pure moments were applied to 13 L3 to S1 cadaveric spine segments. Specimens were tested intact, following decompression, UCR fixation and TFAS implantation at L4 to L5. UCR fixation was via standard pedicle screws and TFAS implantation was via PMMA-cemented trans-pedicular stems. Three-dimensional 10 Nm moments and a 600 N follower load were applied; L4 to L5 disc pressures and implant loads were measured using a pressure sensor and strain gauges, respectively. A finite element model was used to calculate TFAS bone-implant interface loads. UCR experienced greater implant loads in extension \( (p < 0.004) \) and lateral bending \( (p < 0.02) \). Under flexion, TFAS was subject to greater implant moments \( (p < 0.04) \). At the bone-implant interface, flexion resulted in the smallest TFAS (average = 0.20 Nm) but greatest UCR (1.18 Nm) moment and axial rotation resulted in the greatest TFAS (3.10 Nm) and smallest UCR (0.40 Nm) moments. Disc pressures were similar to intact for TFAS but not for UCR \( (p < 0.04) \). The authors concluded that these findings were most applicable to the immediate post-operative period prior to re-modeling of the bone-implant interface since the UCR and TFAS implants are intended for different service lives (UCR – until fusion, TFAS – indefinitely). The Total Facet Arthroplasty System reproduced intact-like anterior column load-sharing – as measured by disc pressure. The highest bone-implant moment of 3.1 Nm was measured in TFAS and for the same loading condition the UCR interface moment was considerably lower (0.4 Nm). For other loading conditions, the differences between TFAS and UCR were smaller, with the UCR sometimes having larger values and for others the TFAS was larger. The long-term physiological meaning of these findings was unknown and demonstrated the need for a better understanding of the relationship between spinal arthroplasty devices and the host tissue as development of next generation motion-preserving posterior devices that hope to more accurately replicate the natural functions of the native tissue continues.
The TFAS clinical trial is a multi-center, prospective, randomized controlled clinical trial comparing the safety and effectiveness of the TFAS to spinal fusion surgery in the treatment of moderate-to-severe degenerative lumbar spinal stenosis. However, the status of this clinical trial is unknown (last verified February 2009).

The AccuraScope Procedure

The AccuraScope procedure is employed to treat LBP. It entails the use of a thin, flexible catheter that is inserted into the center of the spinal canal. Once inside the spinal canal, the catheter can be maneuvered to multiple levels of the lumbar spine, both sides. Using a high-definition camera and other diagnostic tools, the procedure’s goals are

I. to pin-point all sources of chronic lower spine symptoms and

II. treat them with advanced tools including a laser.

1. to pin-point all sources of chronic lower spine symptoms and
2. treat them with advanced tools including a laser.

This out-patient procedure usually takes less than 45 minutes. However, there is a lack of evidence regarding the effectiveness of the AccuraScope procedure.

Chemical Ablation of Facet Joints

The American Society of Anesthesiologists Task Force on Chronic Pain Management/American Society of Regional Anesthesia and Pain Medicine’s practice guidelines on “Chronic pain management” (2010) stated that “Conventional or other thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain”. Furthermore, an UpToDate review on “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2014) states that “Glucocorticoid injections into the facet joint have not been shown to be effective in the treatment of low back pain. A 2009 American Pain Society guideline recommends against their use. There are limited data regarding the efficacy of facet joint injection with glucocorticoids. Two evidence-based reviews concluded that there is not sufficient evidence to support their use. Similarly, a more recent trial comparing facet joint glucocorticoid injection and systemic glucocorticoids found no difference in
either pain or functional capacity over six months between the groups, although patients receiving facet injections had a decrease in nonsteroidal antiinflammatory drug use. Blocks to the medial branch of the primary dorsal ramus, innervating the facet joints have been used both diagnostically and therapeutically for presumed facet joint pain. However, there are no trials comparing efficacy of medial branch blocks to placebo injections”.

**The Deuk Laser Disc Repair®**

Deuk Laser Disc Repair® is a surgical technique that incorporates 3 distinct procedures including a selective partial discectomy, foraminoplasty, and annular debridement. All of the results of full-length articles in peer-reviewed journals of the Deuk Laser Disc Repair® are from a single investigator group. These studies did not include internal comparison groups of patients undergoing ACDF.

Deukmedjian et al (2012) stated that cervical Deuk Laser Disc Repair® is a novel full-endoscopic, anterior cervical, trans-discal, motion preserving, laser assisted, non-fusion, out-patient surgical procedure to safely treat symptomatic cervical disc diseases including herniation, spondylosis, stenosis, and annular tears. These researchers described a new endoscopic approach to cervical disc disease that allows direct visualization of the posterior longitudinal ligament, posterior vertebral endplates, annulus, neuroforamina, and herniated disc fragments. All patients treated with Deuk Laser Disc Repair® were also candidates for ACDF. A total of 142 consecutive adult patients with symptomatic cervical disc disease underwent Deuk Laser Disc Repair® during a 4-year period. This novel procedure incorporates a full-endoscopic selective partial decompressive discectomy, foraminoplasty, and posterior annular debridement. Post-operative complications and average volume of herniated disc fragments removed were reported. All patients were successfully treated with cervical Deuk Laser Disc Repair®. There were no post-operative complications. Average volume of herniated disc material removed was 0.09 ml. The authors concluded that potential benefits of Deuk Laser Disc Repair® for symptomatic cervical disc disease include lower cost, smaller incision, non-fusion, preservation of segmental motion, out-patient, faster recovery, less post-operative analgesic use, fewer complications, no hardware failure, no pseudoarthrosis, no post-operative dysphagia, and no increased risk of adjacent segment disease as seen with fusion.

Deukmedjian et al (2013) stated that the Deuk Laser Disc Repair® is a new full-endoscopic surgical procedure to repair symptomatic cervical disc disease. In this study, a prospective cohort of 66 consecutive patients underwent cervical Deuk Laser Disc
Repair® for 1 (n = 21) or 2 adjacent (n = 45) symptomatic levels of cervical disc disease and were evaluated post-operatively for resolution of headache, neck pain, arm pain, and radicular symptoms. All patients were candidates for ACDF or arthroplasty. The Mann-Whitney Wilcoxon test was used to calculate p values. All patients (n = 66) had significant improvement in pre-operative symptoms with an average symptom resolution of 94.6%. Fifty percent (n = 33) had 100% resolution of all pre-operative cervicogenic symptoms. Only 4.5% (n = 3) had less than 80% resolution of pre-operative symptoms. Visual analog scale significantly improved from 8.7 pre-operatively to 0.5 post-operatively (p < 0.001) for the cohort. Average operative and recovery times were 57 and 52 minutes, respectively. There were no peri-operative complications. Recurrent disc herniation occurred in 1 patient (1.5%). Average post-operative follow-up was 94 days and no significant intergroup difference in outcomes was observed (p = 0.111) in patients with less than 90 days (n = 52) or greater than 90 days (n = 14, mean 319 days) follow-up. No significant difference in outcomes was observed (p = 0.774) for patients undergoing 1- or 2-level Deuk Laser Disc Repair®. Patients diagnosed with post-operative cervical facet syndrome did significantly worse (p < 0.001). The authors concluded that Deuk Laser Disc Repair® is a safe and effective alternative to ACDF or arthroplasty for the treatment of 1 or 2 adjacent symptomatic cervical disc herniations with an overall success rate of 94.6%.

**Least Invasive Lumbar Decompression Interbody Fusion (LINDIF)**

In a case-series study, Osman (2012) the feasibility of the least invasive lumbar decompression, interbody fusion (LINDIF) and percutaneous pedicle screw implantation, for disorders which are usually treated by open decompression, fusion and pedicle screw implantation. Patients completed VAS forms and Roland-Morris questionnaires pre- and post-operatively. Surgical procedures included arthroscopic decompression of the foramina and the discs; end-plate preparation and implantation of allograft bone chips and BMP-2 on collagen carrier; and percutaneous implantation of pedicle screws. Patients' charts were reviewed for operative notes, hospital stay, medications, and imaging studies. The latest x-ray and CT scan films were reviewed and analyzed. Patients were followed up for the minimum of 6 months. Outcome measures included operating time; intra-operative blood loss; hospital stay; VAS scores for back and leg pain; Roland-Morris Disability Questionnaire; and post-operative imaging studies. A total of 60 patients met the inclusion criteria. The average age is 52.8 years. The duration of illness ranged 2 months to 32 years. All patients had back and leg pain. Follow-up averaged 12 months; OR time was 2:90 hours. Estimated blood loss averaged 57.6 cc. Hospital stay averaged 2.6 days. Pre- and post-operative back pain averaged 7.5 and 2, respectively (p < 0.005). Pre- and post-operative leg pain averaged 7.0 and 1.7, respectively (p < 0.005). A total of 47 imaging studies available at the last visits including x-ray and CT scan,
showed solid fusion in 28 (59.6%) patients, stable fixation in 17 (36.2%), and osteolysis around the pedicle screws in 2 patients (4.2%). All patients had improved motor function and 2 patients complained of residual numbness; 8 (13%) patients complained of residual discomfort on the extension of the lumbar spine; 1 patient (1.6%) had medial penetration of 1 S1 screw with S1 nerve root irritation which required revision; 1 patient with painful loose pedicle screws required hardware removal. Both patients had satisfactory outcome after their 2nd operations. The authors concluded that the LINDIF produced satisfactory results in all demographics. Anesthesia time was consistently short, blood loss was negligible. Hospital stay was brief for most healthy patients irrespective of age. The results of this study demonstrated how drastically the surgery related morbidity, and the economics thereof, can be reduced. They stated that the outcomes relating to patients in the age group of 71 to 90 years are particularly encouraging, given their increasing proportion in the population. The findings of this study need to be validated by well-designed studies.

Microsurgical Lumbar Sequestrectomy for the Treatment of Lumbar Disc Herniation

Ran and colleagues (2015) stated that lumbar disc removal is currently the standard treatment for lumbar disc herniation. No consensus has been achieved whether aggressive disc resection with curettage (discectomy) versus conservative removal of the offending disc fragment alone (sequestrectomy) provides better outcomes. These researchers compared the re-herniation rate and clinical outcomes between discectomy and sequestrectomy by literature review and a meta-analysis. They performed a systematic search of PubMed, Medline, Embase and the Cochrane Library up to June 1, 2014. Outcomes of interest assessing the 2 techniques included demographic and clinical baseline characteristics, peri-operative variables, complications, recurrent herniation rate and post-operative functional outcomes. A total of 12 eligible trials evaluating discectomy versus sequestrectomy were identified including 1 RCT, 5 prospective and 6 retrospective comparative studies. In contrast to discectomy, sequestrectomy was associated with significantly less operative time (p < 0.001), lower VAS for LBP (p < 0.05), less post-operative analgesic usage (p < 0.05) and better patients’ satisfaction (p < 0.05). Recurrent herniation rate, re-operation rate, intra-operative blood loss, hospitalization duration and VAS for sciatica were without significant difference. The authors concluded that according to their pooled data, sequestrectomy entailed equivalent re-herniation rate and complications compared with discectomy, but maintained a lower incidence of recurrent LBP and higher satisfactory rate. They stated that high-quality prospective RCTs are needed to evaluate these 2 procedures.
In a meta-analysis, Huang et al (2015) compared the effects of sequestrectomy and microdiscectomy in the treatment of patients with lumbar herniated discs (LHD). Clinical trials published in PubMed, Embase, and Web of Science were systematically reviewed to compare the effects of sequestrectomy and microdiscectomy for LHD. Outcomes included re-herniation rate, duration of surgery, length of hospital stay, and post-operative VAS scales for leg and back pains. A fixed-effects or random-effects were used to pool the estimates, depending on the heterogeneity among the studies. A total of 5 cohorts and 2 RCTs with a total of 929 patients met the inclusion criteria and were included in this meta-analysis. All patients underwent sequestrectomy or microdiscectomy. Pooled estimates showed that patients treated with sequestrectomy had comparable effects in re-herniation rate ($RR = 1.36$, $95\% CI: 0.81$ to $2.27$; $p = 0.240$), length of hospital stay ($WMD = -0.22$ days, $95\% CI: -0.45$ to $0.01$; $p = 0.060$), and post-operative VAS scales for leg pain ($WMD = 0.53$, $95\% CI: -1.54$ to $2.60$; $p = 0.617$) or back pain ($WMD = 0.18$, $95\% CI: -1.64$ to $2.00$; $p = 0.846$), but had a shorter duration of surgery ($WMD = -6.97$ minutes, $95\% CI: -12.15$ to $-1.78$; $p = 0.008$), when compared with those treated with microdiscectomy. The authors concluded that based on the current evidence, sequestrectomy significantly reduced the operational time, but had similar effects on re-herniation rate, length of hospital stay, and post-operative VAS scales for leg and back pains, when compared with microdiscectomy. They stated that further well-designed RCTs are needed to validate these findings.

In a systematic review, Azarhomayoun et al (2015) compared the effects of sequestrectomy versus conventional microdiscectomy for LDH. These investigators searched Medline and Embase from 1980 to November 2014. They selected RCTs and non-randomized prospective studies of conventional discectomy versus sequestrectomy for adult patients with LDH that evaluated the following primary outcomes: radicular pain or LBP as measured by a VAS, or neurological deficits of the lower extremity. These researchers also evaluated the following secondary outcomes: complications of surgery, re-herniation rate, duration of hospital stay, post-operative analgesic use, and health-related quality-of-life measures. Two authors independently reviewed citations and articles for inclusion. They assessed the risk of bias, synthesized data, and the level evidence using standard methodological procedures as recommended by the Cochrane Back Review Group. These investigators identified 5 studies (746 participants) of sequestrectomy versus microdiscectomy; 1 study was RCT and the other 4 were non-randomized prospective comparisons; all studies were assessed as being at a high-risk of bias. There were no significant differences for leg pain, LBP, functional outcomes, complications, and hospital stay or recurrence rate for 2 years (level of evidence: Low). Sequestrectomy was associated with less analgesic consumption versus discectomy (level of evidence: Very low). The authors concluded that sequestrectomy and standard microdiscectomy were associated with similar effects on pain after surgery, recurrence
rate, functional outcome, and complications; more evidence is needed to determine whether sequestrectomy is associated with less post-operative analgesic consumption (Level of Evidence: 2).

**Intradiscal Steroid Injections**

Nguyen and colleagues (2017) noted that refer for invasive procedure is usually at the bottom of the LBP treatment algorithm. In this study, one invasive procedure – injection of prednisolone acetate 25-mg following discography – produced a short-term reduction in, but not elimination of, pain as compared with no treatment. However, the benefit was gone within 1 year. The process of discography, though, seemed to improve both pain and function in patients whether or not they received an injection. That benefit could be simply due to participation in a research study.

**Cooled Radiofrequency Ablation for Facet Denervation**

McCormick et al (2014) stated that while cooled radiofrequency ablation (C-RFA) appeared to be a promising technology for joint denervation, outcomes of this technique for the treatment of lumbar facet syndrome have not been described. These researchers reported clinical outcomes in a case series of patients treated with C-RFA for lumbar facet syndrome. Consecutive patients aged 18 to 60 years diagnosed with lumbar facet syndrome, confirmed by greater than or equal to 75% symptom relief with at least 1 set of diagnostic medial branch nerve blocks, who underwent C-RFA between January 2007 and December 2013 in an urban academic pain center were included. The respective proportions of participants who reported greater than or equal to 50% improvement in pain and in function were calculated. Change in median NRS score, daily morphine equivalent consumption (DME), and medication quantification scale III (MQS III) score were measured. A total of 12 patients underwent C-RFA; 3 were lost to follow-up. The median and 25% to 75% interquartile range (IQR) for age was 44 years (35, 54). The median duration of follow-up was 34 months, IQR (21, 55). The percentage and 95% confidence interval (CI) of patients who reported greater than or equal to 50% improvement in pain was 33% CI (12%, 64%) and in function was 78%, CI (41%, 96%). There was no significant change in DME or MSQ III score. Approximately 50% of patients sought additional healthcare by long-term follow-up. No complications were reported. The authors concluded that the findings of this is case-series study suggested that C-RFA may improve function and to a lesser degree pain at long-term follow-up. Moreover, they stated that a randomized, controlled trial is needed.
Walega and Roussis (2014) noted that RFA of medial branch nerves is considered a safe and effective treatment for chronic facet joint pain in the cervical, thoracic, and lumbosacral spine. Cooled radiofrequency ablation is gaining popularity over conventional thermal RFA in pain management. However, complications of C-RFA have not been reported in the literature. These investigators presented a first report of 3rd-degree skin burn resulting from C-RFA electrode use for the treatment of facet syndrome. A 61-year old woman (BMI of 21.8 kg/m²) with thoracic facet syndrome underwent C-RFA of the T1 to T4 medial branch nerves. Lesioning at the superior-lateral aspect of the thoracic transverse processes at each level was performed. During lesioning of the T2 MBN on the T3 transverse process, skin blanching 15 mm in diameter was noted around the introducer needle with patient complaints of severe, localized pain. Post-procedurally the skin injury at this level worsened in appearance, with a 20 mm × 4 mm skin defect, which took nearly 5 months to heal. With C-RFA, internally cooled electrodes are capable of creating large volume spherical lesions, a size advantage over conventional RFA. The authors concluded that although C-RFA lesion size may overcome the anatomic variability of target nerve location and potentially improve pain outcomes, added vigilance is needed in thin patients and in anatomic regions of minimal subcutaneous tissue between the lesion target and the dermis. Skin burns at the site of the RF electrode are a potential risk under such conditions.

Furthermore, an UpToDate review on “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2017) suggested not performing radiofrequency denervation for chronic LBP due to available data that are inconsistent and the authors suggested that, compared with placebo, radiofrequency denervation may modestly reduce pain in the short-term; however, there does not appear to be clear long-term benefit. Also, there is no mention of “cooled” RFA for treatment of back pain.

Cheng and colleagues (2013) noted that SI joint pain is a common cause of LBP. Cooled radiofrequency ablation (c-RFA) of the lateral branches was recently introduced with the hypothesis that it creates larger lesions to overcome the anatomic variability of the lateral branches and achieve better outcomes as compared with the traditional RFA (t-RFA). In a comparative study, these researchers examined if c-RFA is superior over t-RFA in providing longer pain relief. Data on 88 patients were retrospectively collected between January 2006 and June 2009. Patients' pain relief was registered as less than 50%, 50% to 80%, or greater than 80% at 1, 3, 6, and 12 months after procedure. The duration of pain relief, defined as the time until the patient reported less than 50% pain relief, served as the primary outcome. Demographic, morphometric, and procedural characteristics were analyzed using standard descriptive statistics and univariable tests. The relationship between RFA technique and duration of pain relief was evaluated using multi-variable Cox regression. Among the 88 patients, 30 received t-RFA and 58 received
c-RFA. These investigators did not find a significant univariable relationship between RFA technique and duration of pain relief either before (p = 0.76, Sun test) or after (p = 0.95, Wald test) adjusting for the potentially confounding variables. Both cooled and traditional RFAs provided greater than 50% pain reduction for 3 to 6 months in majority of the patients. The authors concluded that the findings of this study did not reveal evidence that c-RFA of the lateral branches provided longer relief of SI joint pain as compared with t-RFA.

Patel (2016) reported the long-term outcomes of cooled RF ablation (CRF) lateral branch neurotomy (LBN) as a treatment for SI region pain. Whereas the 1-, 3-, 6-, and 9-month outcomes of this procedure compared to sham treatment were previously reported, this current report shows the 12-month outcomes of CRF/LBN treatment for SI region pain. This study originally included 51 subjects who were randomized 2:1 to receive CRF/LBN treatment or a sham intervention, respectively, for SI region pain. Subjects and assessors were blinded for 3 months. At that time, sham participants were permitted to receive CRF/LBN, designated as "cross-over" study subjects, and followed for 6 additional months. For the purpose of this evaluation, the original CRF/LBN-treated study subjects were followed for a total of 12 months. Study participants were 18 to 88 years of age and had chronic (symptomatic for greater than 6 months) axial back pain. All subjects were qualified for study inclusion following positive responses to dual lateral branch blocks. Lateral branch neurotomy was performed by CRF to ablate the S1 to S3 lateral branches and the L5 dorsal ramus. Pain was measured by a NRS and Short Form 36-bodily pain (SF36-BP) scores. The ODI and Short Form 36-physical functioning (SF36-PF) assessment each served to evaluate subject disability. Treatment successes ("responders") in the originally treated CRF/LBN group at 12 months, and in the cross-over group at 6 months, were also determined. In the original CRF/LBN treatment group, 12-month outcomes compared to baseline were favorable, with a mean 2.7 point drop in the NRS score, a 13.9 decrease in the ODI, and a 15.8 increase in SF-36BP. In the cross-over study group, 6-month outcomes were also favorable, with a mean NRS score decrease of 2.5 points, a reduction in ODI of 8.8, and an increase in SF36-BP of 11.9. The authors concluded that these favorable 12-month results illustrated the durability of effective CRF/LBN-mediated treatment of SI region pain for selected patients. Furthermore, successful CRF/LBN treatments in unblinded cross-over study subjects demonstrated the unlikelihood that such positive outcomes were attributable to a "placebo" effect, and suggested that CRF/LBN is an effective therapeutic option for alleviating pain, and improving physical function and QOL, with few complications.

McCormick et al (2019) stated that no previous study has assessed the outcomes of cooled radiofrequency ablation (C-RFA) of the medial branch nerves (MBN) for the treatment of lumbar facet joint pain nor compared its effectiveness with traditional RFA
(T-RFA). In a blinded, prospective study, these researchers examined 6-month outcomes for pain, function, psychometrics, and medication usage in patients who underwent MBN C-RFA versus T-RFA for lumbar Z-joint pain. Patients with positive diagnostic MBN blocks (greater than 75 % relief) were randomized to MBN C-RFA or T-RFA. The primary outcome was the proportion of “responders” (greater than or equal to 50 % numeric rating scale (NRS) reduction) at 6 months. Secondary outcomes included NRS, Oswestry Disability Index (ODI), and Patient Global Impression of Change. A total of 43 patients were randomized to MBN C-RFA (n = 21) or T-RFA (n = 22). There were no significant differences in demographic variables (p > 0.05). A greater than or equal to 50 % NRS reduction was observed in 52 % (95 % confidence interval [CI]: 31 % to 74 %) and 44 % (95 % CI: 22 % to 69 %) of subjects in the C-RFA and T-RFA groups, respectively (p = 0.75). A greater than or equal to 15-point or greater than or equal to 30 % reduction in ODI score was observed in 62 % (95 % CI: 38 % to 82 %) and 44 % (95 % CI: 22 % to 69 %) of subjects in the C-RFA and T-RFA groups, respectively (p = 0.21). The authors concluded that when using a single diagnostic block paradigm with a threshold of greater than 75 % pain reduction, treatment with both C-RFA and T-RFA resulted in a success rate of approximately 50 % when defined by both improvement in pain and physical function at 6-month follow-up. While the success rate was higher in the C-RFA group, this difference was not statistically significant. Moreover, these researchers stated that future study should use the effect size or success rate demonstrated in this prospective study for power calculation.

The authors stated that this study had several drawbacks. The primary drawback was the relatively small sample size; 5 patients dropped-out after being enrolled by prior to randomization; selection bias was possible but not dissimilar to other studies of procedural interventions in which individuals may elect for additional non-invasive care prior to undergoing intervention. Further, subjects were lost to follow-up; of 43 subjects who underwent treatment intervention, 3 (7 %) did not report outcomes for the full 6-month duration of the study. A drop-out effect could have altered the overall outcome of the study. Analysis by conservative worst-case scenario definitions (treating all subjects lost to follow-up as treatment failures) would adjust the treatment success rate to 50 % (95 % CI: 29 % to 71 %) and 59 % (95 % CI: 9 % to 80 %) for pain reduction and functional improvement, respectively, in the C-RFA group. 20-gauge rather than 16-gauge or 18-gauge RFA electrodes were used for conventional ablations; as such, the success rate in the T-RFA group may be lower than would be expected when using larger gauge electrodes. Furthermore, some providers use bi-polar lead placement, longer lesion duration times, higher lesioning temperatures or longer active tips when employing C-RFA, all of which expanded the size of the lesion and may increase the chance of successful MBN capture. A heterogeneous group of 5 faculty members, assisted by Pain Medicine fellows, performed these procedures; difference in experience

level with the procedural technique may have influenced patient outcomes, although this heterogeneity did improve generalizability of the reported findings. Finally, RFA represents a treatment that is implemented with the goal of long-term treatment; these investigators measured a primary outcome at 6 months, and did not follow subjects beyond this time period, but future study would ideally capture outcomes at a post-RFA time point of at least 1 year. Indeed, it is conceivable that an inter-group difference may have been observed if outcomes had been examined beyond 6 months.

Davis et al (2019) stated that as a follow-up to the 6-month report, these investigators examined the analgesic effect of C-RFA in patients with knee osteoarthritis (OA) 12 months post-intervention and its ability to provide pain relief in patients who experienced unsatisfactory effects of intra-articular steroid injection (IAS); 78 % (52/67) of patients originally treated with C-RFA were examined at 12 months, while at 6 months post-IAS, 82 % (58/71) of those patients crossed-over to C-RFA and examined 6 months later. At 12 months, 65 % of the original C-RFA group had pain reduction greater than or equal to 50 %, and the mean overall drop was 4.3 points (p < 0.0001) on the NRS; 75 % reported “improved” effects. The cross-over group demonstrated improvements in pain and functional capacity (p < 0.0001). No unanticipated adverse events (AEs) occurred. The authors concluded that the findings of this study demonstrated that analgesia following C-RFA for OA knee pain could last for at least 12 months and could rescue patients who continue to experience intolerable discomfort following IAS.

The authors stated that a limitation of this study was the 1-way cross-over option, from IAS to C-RFA, but not vice versa. This paradigm was consistent with the intention of the study to test C-RFA as a rescue intervention for knee OA, rather than long-standing, conservative IAS. The limitations of this portion of the study were that the remaining IAS group sample size was not large enough to carry out statistical test-based comparisons between the originally treated C-RFA patients and the IAS group members at 12 months, outcomes of the originally treated C-RFA group and those of the crossed-over cohort could not be directly compared at 6 months, because the groups were derived from 2 different study populations, and an effect of C-RFA on opioid use could not be detected, perhaps due to alternate patient conditions that also utilized opioids as therapy. Furthermore, the late addition of the amendment to collect X-rays at the final visit limited the ability to capture data on a large portion of the patients enrolled.

**Intradiscal Injection of Platelet-Rich Plasma**

In a preliminary clinical trial, Akeda and colleagues (2017) determined the safety and initial effectiveness of intradiscal injection of autologous platelet-rich plasma (PRP)
releasate in patients with discogenic LBP. Inclusion criteria for this study included chronic LBP without leg pain for more than 3 months; 1 or more lumbar discs (L3/L4 to L5/S1) with evidence of degeneration, as indicated via MRI; and at least 1 symptomatic disc, confirmed using standardized provocative discography. Platelet-rich plasma releasate, isolated from clotted PRP, was injected into the center of the nucleus pulposus. Outcome measures included the use of a VAS and the Roland-Morris Disability Questionnaire (RDQ), as well as X-ray and MRI (T2-quantification). Data were analyzed from 14 patients (8 men and 6 women; mean age of 33.8 years). The average follow-up period was 10 months. Following treatment, no patient experienced AEs or significant narrowing of disc height. The mean pain scores before treatment (VAS, 7.5 ± 1.3; RDQ, 12.6 ± 4.1) were significantly decreased at 1 month, and this was generally sustained throughout the observation period (6 months after treatment: VAS, 3.2 ± 2.4, RDQ: 3.6 ± 4.5 and 12 months: VAS, 2.9 ± 2.8; RDQ, 2.8 ± 3.9; p < 0.01, respectively). The mean T2 values did not significantly change after treatment. The authors demonstrated that intradiscal injection of autologous PRP releasate in patients with LBP was safe, with no AEs observed during follow-up. Moreover, they stated that future prospective, randomized, double-blinded, and placebo-controlled studies are needed to determine the effectiveness of this treatment.

**Ultrasound Guidance for Sacroiliac Joint Injections**

In a prospective, randomized, controlled trial, Soneji et al (2016) compared the accuracy and effectiveness of ultrasound (US) and fluoroscopy (FL) guidance for sacro-iliac joint (SIJ) injections. A total of 40 patients with chronic moderate-to-severe low back pain (LBP) secondary to SIJ arthritis were randomized to receive US- or FL-guided unilateral SIJ injections. Primary outcomes included pain at 1 month measured by numerical rating scale (NRS) scores. Secondary outcomes included NRS scores at 24 hours, 72 hours, 1 week, and 3 months after injection, physical functioning at 1 month after the procedure, procedure time, incidence of intra-articular and peri-articular needle placement, patient discomfort, overall patient satisfaction, and daily opioid consumption. There was no significant difference in NRS pain scores between the 2 groups at 1 month or at any other follow-up points. A significant reduction from baseline mean NRS scores was observed in both groups at 1 month after injection (US 22.7%, p = 0.025; FL 37.3%, p < 0.001). There was no significant difference in procedure-related variables, physical functioning, discomfort, opioid utilization, and patient satisfaction between the 2 groups. The authors concluded that US-guided SIJ injection with fluoroscopic confirmation has similar accuracy and efficacy to fluoroscopy alone for SIJ injections in patients with chronic LBP secondary to SIJ arthritis. This was a small study (n = 40); its main drawback was the lack of a control group (i.e., SIJ injection without imaging guidance).
Perry et al (2016) stated that US-guidance has been proposed as an alternative imaging modality for SIJ injections. Few studies have studied the accuracy of this modality for the procedure. In a controlled laboratory study, these investigators determined the accuracy of US-guided SIJ injections using a cadaveric model. The study was performed in the Skills Laboratory of the American Sports Medicine Institute in St. Vincent’s Hospital, Birmingham, AL. A total of 17 cadaveric SIJs were injected under US-guidance and dissected to determine the accuracy of intra-articular injections. Main outcome measure was the presence of intra-articular spread of a white paint marker in the SIJ after US-guided injection. Of 17 SIJs, 15 (88.2%) were accurately injected intra-articularly. One of the joints with no intra-articular spread was found to be partially frozen at the time of dissection, and the 2nd joint was considered an unsuccessful injection before dissection due to difficulty entering the joint under US-guidance because of marginal osteophytes at the joint line. Of the 15 joints with intra-articular placement, 5 joints (33.3%) showed partial extra-articular spread at the time of initial injection and required re-direction of the needle under US-guidance, and 3 joints (20%) had extra-articular spread that was not seen during US. The authors concluded that US allowed intra-articular injection in 88.2% of joints in this cadaveric study; it did not expose the patient to radiation, as seen with FL-guidance, which is currently the gold standard for this injection. In addition, US may allow visualization of extra-articular spread when caused by extra-articular needle placement, which can allow for re-direction of the needle to achieve intra-articular injection. Level of Evidence = IV.

Furthermore, an UpToDate review on “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2017) states that “The sacroiliac joints are thought to be the source of low back pain in some patients. Effective methods for diagnosing and treating sacroiliac joint pain in patients without spondyloarthropathy remain controversial. Periarticular steroid injection does not require radiographic guidance. One small (n = 24), randomized trial found periarticular sacroiliac joint glucocorticoid injection more effective than local anesthetic injection for pain relief (change in pain of -40 versus -13 mm on a 100 mm visual analogue scale 1 month after injection) in patients with chronic pain in the sacroiliac joint area and at least 1 physical exam finding for sacroiliac pain. These results should be considered preliminary, due to the small sample size and relatively short-term follow-up. There are no randomized trials of intraarticular sacroiliac joint steroid injection in patients without spondyloarthropathy”.

**Posterior Cervical Cages**

Supplemental posterior instrumentation has been widely used to enhance stability and improve fusion rates in higher risk patients undergoing anterior cervical discectomy and
fusion (ACDF) (Voronov, et al., 2016). These typically involve posterior lateral mass or pedicle screw fixation with significant inherent risks and morbidities. More recently, cervical cages placed bilaterally between the facet joints (posterior cervical cages) have been used as a less disruptive alternative for posterior fixation.

Voronov, et al. (2016) compared the stability achieved by both posterior cages and ACDF at a single motion segment and determine the stability achieved with posterior cervical cages used as an adjunct to single- and multilevel ACDF. Seven cadaveric cervical spine (C2-T1) specimens were tested in the following sequence: intact, C5-C6 bilateral posterior cages, C6-C7 plated ACDF with and without posterior cages, and C3-C5 plated ACDF with and without posterior cages. Range of motion in flexion-extension, lateral bending, and axial rotation was measured for each condition under moment loading up to ±1.5 Nm. All fusion constructs significantly reduced the range of motion compared to intact in flexion-extension, lateral bending, and axial rotation (P<0.05). Similar stability was achieved with bilateral posterior cages and plated ACDF at a single level. Posterior cages, when placed as an adjunct to ACDF, further reduced range of motion in both single- and multilevel constructs (P<0.05). The investigators concluded that the biomechanical effectiveness of bilateral posterior cages in limiting cervical segmental motion is comparable to single-level plated ACDF. Furthermore, supplementation of single- and multilevel ACDF with posterior cervical cages provided a significant increase in stability and therefore may be a potential, minimally disruptive option for supplemental fixation for improving ACDF fusion rates.

McCormick, et al. (2016) reported on one-year clinical and radiographic outcomes of 10 patients with single level cervical radiculopathy due to spondylosis and stenosis treated with a minimally disruptive instrumented fusion procedure employing bilateral posterior cervical cages. A retrospective study of 10 patients with one-year follow-up who underwent cervical fusion using bilateral posterior cervical cages placed between the facet joints was conducted at a single center. Neck Disability Index (NDI), Visual Analog Scale (VAS) for neck and arm pain, neurological status, adverse events, x-rays and computed tomography (CT) were collected at baseline and 6-weeks, 3-, 6- and 12-months postoperatively. X-ray and CT were assessed for segmental and overall cervical lordosis, fusion, and device retention. Subject age range was 51 to 78 years with a mean of 68 (6 male, 4 female). Five patients were treated at C5-6, four at C6-7, and one at C4-5. NDI and VAS scores significantly improved immediately after surgery; outcomes were sustained at one year. NDI scores improved from a mean of 35 at baseline to 15 at one year. Mean scores on VAS for neck pain improved from a baseline of 8 to 2.5 at one year. Results were similar for arm pain on VAS; scores improved from 7.5 to 1.5 pre- and post-op, respectively. Evidence of fusion was observed for all subjects on lateral flexion/extension plain film radiographs. Bridging bone on CT was present in 9 subjects;
findings were indeterminate for one subject. No significant change in segmental or overall lordosis was observed. There were no device breakages, device back out, or surgical re-interventions at one year. The authors concluded that one-year results show favorable improvements in pain and function in subjects with single level cervical radiculopathy due to spondylosis and foraminal stenosis treated with minimally disruptive posterior cervical fusion using bilateral cervical cages.

**Transforaminal Endoscopic Discectomy**

Hoogland and colleagues (2008) performed a prospective, cohort evaluation of consecutive patients who underwent endoscopic transforaminal discectomy (ETD) for recurrent lumbar disc herniation, after previous discectomy. These investigators reviewed complications and results of the ETD for recurrent herniated disc with a 2-year follow-up. Between January 1994 and November 2002, 262 patients with primarily radicular problems underwent an ETD for a recurrent herniated disc; 238 of these patients (90.84%) completed 2-year follow-up questionnaire. Initial surgery of 82 patients was performed in-house, 180 external. Average age was 46.4 years. The female/male ratio was 29/71%. At 2-year follow-up, 85.71% of patients rated the result of the surgery as excellent or good; 9.66% reported a fair and 4.62% patients an unsatisfactory result. Average improvement of back pain of 5.71 points and 5.85 points of leg pain on the VAS scale (1 to 10). According to Mac Nab, 30.67% of the patients felt fully regenerated, 50% felt their functional capacity to be slightly restricted, 16.81% felt their functional capacity noticeably restricted, and 2.52% felt unimproved or worse. All patients participated in a 3-month follow-up to establish the peri-operative complications. The overall complication rate was 10/262 (3.8%), including 3 nerve root irritations and 7 early recurrent herniation (less than 3 month). There was no case of infection or discitis. After 3 months and within 2 years, 4 patients have been treated for a recurrent herniated disc in the authors’ own center and 7 patients have been treated elsewhere, resulting in a recurrence rate 11/238 (4.62%). The authors concluded that ETD for recurrent disc herniation appeared to be an effective method with few complications and a high patient satisfaction. The main drawback of this study was its relative short-term follow-up (2 years).

Gibson and associates (2012) described transforaminal endoscopic spinal surgery (TESS) using HD-video technology, that is generally performed as a day case procedure under sedation or light general anesthesia, and collated the evidence comparing the technique to micro-discectomy. The method of TESS was described and an electronic literature search performed to identify papers reporting clinical outcomes. International data were translated where necessary and proceedings' abstracts included. In addition, papers held
by the authors and colleagues in personal libraries were carefully cross-referenced to the obtained database. Analysis of the data supported the use of a transforaminal endoscopic approach to the lumbar intervertebral disc and suggested that outcomes following surgery were at least equivalent to those following micro-discectomy. Significant cost-savings in terms of in-patient stay may be generated. In addition, there was also some evidence supporting endoscopic surgery for relief of foraminal stenosis. The authors concluded that based on current evidence there are good arguments supporting a more wide-spread adoption of transforaminal endoscopic surgery for the treatment of lumbar disc prolapse with or without foraminal stenosis. Moreover, these researchers noted that although still relatively scarce, RCT evidence including their own, suggested that outcomes at least equate and were probably better than those from micro-discectomy in selected patients.

In a retrospective study, Jasper et al (2013a) evaluated the benefit of transforaminal endoscopic discectomy and foraminotomy in geriatric patients with single level and multi-level lumbar disc herniation and lumbar radiculopathy. After Institutional Review Board (IRB) approval, charts from 50 consecutive patients aged 75 and older with complaints of lower back and radicular pain who underwent 1 or more endoscopic procedures between 2007 and 2011 were reviewed. The average pain relief 6 months post-operatively was reported to be 71.8%, good results as defined by MacNab. The average pre-operative VAS score was 9.04, indicated in the questionnaire as severe and constant pain. The average 6 month post-operative VAS score was 2.63, indicated in the questionnaire as mild and intermittent pain. The authors concluded that endoscopic discectomy was a safe and effective alternative to open back surgery. The 6-month follow-up data appeared to indicate that an ultra-minimally invasive approach to the geriatric spine that has a low complication rate, avoided general anesthesia, and was out-patient might be worth studying in a prospective, longer term way. The main drawback of this study was that it was a retrospective study and only offered 6 month follow-up data for geriatric patients undergoing endoscopic spine surgery.

Jasper et al (2013b) noted that transforaminal endoscopic surgery has evolved from an intra-discal procedure to a true foraminal epidural procedure where both a targeted discectomy and foraminal decompression can be performed. These investigators described the success of transforaminal decompression for radiculopathy using pre-operative selective nerve root block as part of a treatment algorithm for single level and multi-level lumbar disc herniation. After IRB approval, charts from 195 patients with complaints of lower back and radicular pain who received 1 or more endoscopic discectomy procedures were reviewed; VAS was applied to each patient pre-operatively and 6 months after the procedure. Patients with multi-level pathologies receiving 1 procedure had an average relief of 69.7% attributed to correct diagnosis of the inflicting
level as opposed to 83.9% improvement in patients with a single level herniation. The authors concluded that patients with single level lumbar herniation receiving 1 endoscopic discectomy had excellent outcomes, but with a good response to a selective nerve root block as a pre-operative adjunct, patients with multi-level disc herniation also had significant benefit from single level endoscopic discectomy. This study had the same limitations and may have had overlapping subjects with their earlier trial (Jasper et al, 2013a).

Jasper et al (2014) stated that transforaminal endoscopic discectomy and foraminotomy is an ultra-minimally invasive outpatient surgical option available to obese patients that does not require general anesthesia and does not necessitate additional retraction due to additional thicker soft tissue. These researchers assessed the benefit of transforaminal endoscopic discectomy and foraminotomy in obese patients with single-level lumbar disc herniation and lumbar radiculopathy. After IRB approval, charts from 82 consecutive patients with BMIs of at least 30 kg/m2 who had undergone single-level endoscopic lumbar discectomies and foraminotomies were retrospectively identified and categorized according to BMI: Class I obesity, BMI 30.0 to 34.9 kg/m2; Class II obesity, BMI 35.0 to 39.9 kg/m2; or Class III obesity, BMI greater than or equal to 40.0 kg/m2. Patients aged 40 and older (average age of 61.8, 40% women) with complaints of lower back and radicular pain who underwent endoscopic procedures between 2007 and 2012 were reviewed. The average pain relief 1 year post-operatively was reported to be 68.4% for Class I, 66.1% for Class II, and 43.5% for Class III. The average pre-operative VAS scores were 8.8 for Class I, 9.2 for Class II, and 9.0 for Class III, all as indicated in the questionnaire as describing severe and constant pain. The average 1 year post-operative VAS scores were 2.6 for Class I, 3.0 for Class II, and 3.2 for Class III, indicated in the questionnaire as mild and intermittent pain. There were no infections or other complications reported and the re-herniation rate for the 1 year was 7.5% in Class I, 12.5% in Class II, and 0% in Class III. The authors concluded that endoscopic discectomy was a safe and effective alternative to open back surgery. The 1-year follow-up data appeared to indicate that an ultra-minimally invasive approach to the obese spine patient that has a low complication rate, avoided general anesthesia, was performed in the lateral position, and was out-patient might be worth studying in a prospective, longer term way. This study had the same limitations and may have had overlapping subjects with their earlier trials (Jasper et al, 2013a; and Jasper et al, 2013b).

Sclafani and co-workers (2015) stated that minimally invasive transforaminal endoscopic procedures can achieve spinal decompression through either direct or indirect techniques. Subtle variations in trajectory of the surgical corridor can dictate access to the pathologic tissue. Two general strategies exist: the intra-discal "inside-out" technique and the extra-discal, intra-canal (IC) technique. The IC technique utilizes a
more lateral transforaminal approach than the intra-discal technique, which allows for a more direct decompression of the spinal canal. These researchers carried out an assessment of IC patient outcome data obtained through analysis of a previously validated MIS Prospective Registry. Post-hoc analysis was performed on the MIS Prospective Registry database containing 1,032 patients. A sub-group of patients treated with the endoscopic IC technique was identified. Patient outcome measures after treatment of symptomatic disk herniation and neuro-foraminal stenosis were evaluated. A total of 86 IC patients were analyzed. Overall, there was significant improvement in employment and walking tolerance as soon as 6 weeks post-op as well as significant 1 year VAS and ODI score improvement. Sub-analysis of IC patients with 2 distinct primary diagnoses was performed. Group IC-1 (disc herniation) showed improvement in Oswestry disability index (ODI) and VAS back and leg outcomes at 1 year post-op. Group IC-2 (foraminal stenosis) showed VAS back and leg score improvement at 1 year post-op but did not demonstrate significant improvement in overall ODI outcome at any time-point. The 1-year re-operation rate was 2% (1/40) for group IC-1 and 28% (5/18) for group IC-2. The authors concluded that the initial results of the MIS Registry IC subgroup showed a significant clinical improvement when the technique was employed to treat patients with lumbar disc herniation. The treatment of foraminal stenosis could lead to improved short-term clinical outcome but was associated with a high re-operation rate at 1 year post-op.

The authors stated that the main limitation of this study was the inconsistent rate of data collection at scheduled follow-up intervals, including the 1-year follow-up period. Although data collection through a prospective registry allowed post-hoc extraction of a large sample size, there was inherently less stringent monitoring of patient data collection than with a RCT. Additionally, this study did not record the duration of symptoms prior to surgical intervention and did not include a non-surgical control group. Nevertheless, this study of endoscopic transforaminal discectomy demonstrated promising results in patients with symptomatic disc herniation.

Gadjradj et al 92016) stated that throughout the last decades, full-endoscopic techniques to treat lumbar disc herniation (LDH) have gained popularity in clinical practice. To-date, however, no Class I evidence on the efficacy of percutaneous transforaminal endoscopic discectomy (PTED) has been published, and studies describing its safety and short- and long-term efficacy are scarce. These investigators evaluated the safety and clinical outcomes in patients undergoing PTED for LDH. Patients who underwent PTED for LDH between January 2009 and December 2012 were prospectively followed. The primary outcomes were the VAS score for leg pain and the score on the Quebec Back Pain Disability Scale (QBPDS). Secondary outcomes were the perceived experience with the local anesthesia used and satisfaction with the results
after 1 year using Likert-type scales. The pre-treatment means were compared with the means obtained 6 and 52 weeks after surgery using paired t-tests. A total of 166 patients underwent surgery for a total of 167 LDHs. The mean duration of surgery (± SD) was 51.0 ± 9.0 mins. The 1-year follow-up rate was 95.2%. The mean reported scores on the VAS and QBPDS were 82.5 ± 17.3 mm and 60.0 ± 18.4 at baseline, respectively. Six weeks after surgery, the scores on the VAS and QBPDS were significantly reduced to 28.8 ± 24.5 mm and 26.7 ± 20.6, respectively (p < 0.001). After 52 weeks of follow-up, the scores were further reduced compared with baseline scores (p < 0.001) to 19.6 ± 23.5 mm on the VAS and 20.2 ± 18.1 on the QBPDS. A total of 4 complications were observed, namely 1 dural tear, 1 deficit of ankle dorsiflexion, and 2 cases of transient paresis in the foot due to the use of local anesthetics. The authors concluded that PTED appeared to be a safe and effective intervention for LDH and had similar clinical outcomes compared to conventional open micro-discectomy. Moreover, they stated that high-quality RCTs are needed to study the efficacy and cost-effectiveness of PTED.

The authors stated that the present study had several limitations. Due to the design, a proper control group is lacking; however, as previously mentioned, the objective of this study was not to emphasize the merits of PTED over other procedures, but to share the short- and long-term results that showed its potential. Moreover, PTED also has a long learning curve due to the concept of a 2D view. Surgeons are exposed to different landmarks, another direction of approach, and a laborious identification of anatomical structures during surgery. Considering the long learning curve of PTED and potential bias, all surgeries were performed by a single neurosurgeon who already had extensive experience in performing the PTED technique.

Pan et al (2016) compared the safety and efficacy of percutaneous transforaminal endoscopic spine system (TESSYS) and traditional fenestration discectomy (FD) in treatment of lumbar disc herniation (LDH). A total of 106 LDH patients were divided into TESSYS group (n = 48) and FD group (n = 58); VAS, ODI, Japanese Orthopedic Association (JOA), and modified MacNab criteria were used for efficacy evaluation. Post-operative responses were compared by enzyme-linked immunosorbent assay (ELISA) based on detection of serum IL-6, CRP, and CPK levels. In the TESSYS group, compared with the FD group, these researchers observed, shorter incision length, less blood loss, shorter hospital stay, lower hospitalization cost, shorter recovery time, lower complication rate (all p < 0.001), and lower VAS scores of lumbago and skelalgia at 3 days and 1, 3, and 6 months post-operatively (all p < 0.05). At 24 and 48 hours post-operatively, CRP level was remarkably higher in the FD group compared to the TESSYS group (p < 0.001). Further, comparison of IL-6 levels at 6, 12, 24, and 48 hours post-operatively revealed significantly higher levels in the FD group than in the FESSYS group (all p < 0.001). The authors concluded that TESSYS had clinical advantages over FD and
entailed less trauma and quicker post-operative recovery, suggesting that TESSYS was well-tolerated by patients and was a better approach than FD in surgical treatment of LDH. This was a relatively small (n = 48 in the TESSY group) study with short-term follow-up (6 months).

The authors stated that this study had several drawbacks. TESSYS was not suitable for patients with lumbar spinal stenosis, lumbar instability, or intervertebral space stenosis. TESSYS was highly effective in a narrow set of patients and, therefore, traditional surgical procedures are still very valuable in the clinic. As lifestyles and physical activities change in society, researchers would need to periodically re-assess their options to effectively treat LDH.

Ren et al (2017) described a percutaneous endoscopic herniotomy technique by using a unilateral approach for lumbar disc herniation with bilateral obvious symptoms. From June 2014 to October 2015, a total of 26 patients who had back as well as bilateral leg pain and/or weakness due to lumbar disc herniation were treated by transforaminal endoscopic lumbar discectomy (TELD), with a unilateral approach. Clinical outcomes were evaluated via a VAS (0 to 10), and functional status was assessed with the ODI (0 to 100%) post-operatively and 3 and 12 months post-operatively. Surgical satisfaction rate was assessed during the final follow-up. The mean VAS for leg pain on the operative side improved from pre-operative 8.39 ± 1.84 to 2.18 ± 1.26 post-operatively, 1.96 ± 0.83 at 3 months post-operatively, and 2.05 ± 1.42 at 1 year post-operatively (p < 0.01). The mean VAS for leg pain on the contralateral was 7.12 ± 1.74 and improved to 1.57 ± 1.66 post-operatively, 1.22 ± 1.58 at 3 months post-operatively, and 1.15 ± 1.35 at 1 year post-operatively (p < 0.01). The mean pre-operative ODI was 83.63 ± 8.49, with 23.58 ± 7.24 at 1 week post-operatively, 19.81 ± 11.26 at 3 months post-operatively, and 17.54 ± 13.40 at 12 months post-operatively (p < 0.01). Good or excellent global results were obtained in 96.2% of patients. The authors concluded that TELD could be effective for lumbar disc herniation causing bilateral symptoms, through 1 working channel.

The authors stated that the limitations of this study included that relatively short follow-up period (12 months) and the size of patient cohort (n = 26).

Gibson et al (2017) stated that transforaminal endoscopic discectomy (TED) minimizes para-spinal muscle damage. These researchers compared clinical outcomes of TED to micro-discectomy (Micro). A total of 143 patients, age 25 to 70 years and less than 115 kg of weight, with single-level lumbar prolapse and radiculopathy, were recruited and randomized – 70 received TED under conscious sedation and 70 Micro under general anesthesia; ODI, VAS of back and leg pain, and Short Form Health Survey indices (SF-36)
were measured pre-operatively and at 3, 12 and 24 months. All outcome measures improved significantly in both groups (p < 0.001). Affected side leg pain was lower in the TED group at 2 years (1.9 ± 2.6 versus 3.5 ± 3.1, p = 0.002). Hospital stay was shorter following TED (0.7 ± 0.7 versus 1.4 ± 1.3 days, p < 0.001); 2 Micro patients and 5 TED patients required revision giving a relative risk of revision for TED of 2.62 (95% CI: 0.49 to 14.0). The authors concluded that functional improvements were maintained at 2 years in both groups with less ongoing sciatica after TED. A greater revision rate after TED was offset by a more rapid recovery.

The authors stated that the drawbacks of this study included the non-blinded nature of the trial. Both surgeon and patient were aware of their treatment and the senior surgeon acknowledged a specific interest in endoscopy that may introduce bias. However, all outcomes were collected independently and were patient-reported. The data were scrutinized by all authors. Different anesthetic techniques were used which may favor shorter length of stay in the TED group. This was pragmatic as it was considered safer to perform TED under conscious sedation. Though length of stay was significantly shorter in the TED group, this was a secondary outcome measure and the study was not powered to detect differences therein. No record was made of any litigation pertaining to any presenting injury. Finally, data were analyzed “as treated” not as “intention-to-treat”. This was considered acceptable as only 1 case crossed-over between treatment arms and this was due to equipment failure not clinical choice; 13 patients (9.3%) were lost to follow-up by 2 years. This was within the 10% allowed by the power calculation and was significantly less than the 20% required by a level 1 trial.

Kim et al (2017) reported the surgical procedure and preliminary clinical results of percutaneous endoscopic stenosis lumbar decompression (PESLD) technique using a uniportal-contralateral approach for bilateral decompression of degenerative spinal stenosis. Electronic medical records of 48 consecutive patients who were treated between January 2016 and August 2016 were reviewed retrospectively. All patient received PESLD through the uniportal-contralateral approach. These investigators analyzed the outcomes using the VAS, Macnab criteria, ODI, and complication rate. There were 48 cases (15 men, and 33 women). Mean age of patients was 62.44 ± 8.68 years. Mean symptom duration was 20.13 ± 16.87 months. Neurogenic intermittent claudication was 550 m on average. Follow-up period was 7.75 ± 2.28 months (range of 5 to 13 months); VAS and ODI decreased significantly (p < 0.001) and decreased by 1.073 and 5.795 odds ratio (OR), respectively, in contralateral foraminotomy cases. Macnab outcome grade was good-to-excellent in 96% of patients. Dural tear occurred in 3 cases (6.25%), and 2 cases (4.17%) required transforaminal lumbar interbody fusion operation after this procedure. The authors concluded that these preliminary findings of this uniportal-contralateral PESLD technique was encouraging (96% demonstrated a
good-to-excellent outcome), and the procedure was safe. Moreover, these researchers stated that long-term follow-up and a more detailed study for more accurate results of this technique is needed.

Cementoplasty

Iannessi et al (2011) noted that the current gold standard treatment of localized painful bone lesion is radiotherapy but this technique has limitations. In a prospective study, these researchers demonstrated that cementoplasty is an efficient alternative for these palliative indications when lesions involve extra-spinal bones. They prospectively followed 20 patients who received a percutaneous cementoplasty on painful lytic bone lesions between May 2008 and May 2010; 17 patients also had difficulty walking in relation to the pain experienced. The clinical indication for treatment was severe pain (greater than or equal to 4 on the numeric scale) due to bone lesion on CT or MRI. All procedures (except 1) were performed under local anesthesia. Feasibility was 100% without immediate complications. The patients experienced a significant and rapid decrease of their pain (4.1 points, p < 000.1) and this effect was sustained over the long-term (7.75 months of follow-up on average); 64% of patients treated on the lower limbs and pelvis improved mobility. The authors concluded that percutaneous cementoplasty may be a safe and effective palliative treatment for localized painful lytic lesion. Combining CT and fluoroscopic guidance appeared to be the safer option because of extra-vertebral localization. Smart fill of the bone and careful selection of patient determined the effectiveness of the procedure. Diffuse painful lesions and long bone diaphysis should not be good indications.

Rollinghoff et al (2013) noted that percutaneous cement augmentation systems have been proven to be an effective treatment for vertebral compression fractures in the last 10 years. A special form available since 2009 is the radiofrequency (RF) kyphoplasty in which the applied energy raises the viscosity of the cement. These investigators examined if a smaller cement amount in radiofrequency kyphoplasty can also restore vertebral body height in osteoporotic vertebral compression fractures. The treatment was minimally invasive using the StabiLiT vertebral augmentation system by DFine. In a retrospective study from 2011 to January 2012, 35 patients underwent RF kyphoplasty for 49 fresh osteoporotic vertebral compression fractures. From the clinical side the parameters, demographics and pain relief using a visual analog scale (VAS: 0 to 100 mm) were collected. For the radiological outcome the vertebral body height (anterior, mean and posterior vertebral body height with kyphosis angle) after surgery and after 3 months was measured and compared to the cement volume. All patients still had permanent pain on the fractured level after conservative treatment. The time from initial
painful fracture to treatment was 3.0 weeks ± 1.3. Average VAS results decreased significantly from 71 ± 9.2 pre-operatively to 35 ± 6.2 post-operatively (p < 0.001) and to 30 ± 5.7 (p < 0.001) after 3 months. With a mean cement volume in the thoracic spine of 2.9 ± 0.7 ml (1.8 to 4.1) and lumbar spine of 3.0 ± 0.7 ml (2.0 to 5.0), there was a significant vertebral body height restoration. Anterior and mean vertebral body heights significantly increased by an average of 2.3 and 3.1 mm, kyphosis angle significantly decreased with an average of 2.1° at 3-month follow-up (p < 0.05). In 2 vertebrae (4.1%) a minimal asymptomatic cement leakage occurred into the upper disc. In 2 patients (5.7%) there were new fractures in the directly adjacent segment that were also successfully treated with radiofrequency kyphoplasty. The authors concluded that with a mean cement volume of 3.0 ml radiofrequency kyphoplasty achieved rapid and short-term improvements of clinical symptoms with a significant restoration of vertebral body height. There was no correlation between restoration of vertebral body height and pain relief. With a cement leakage of 4.1% RF kyphoplasty was a safe and effective minimally invasive percutaneous cement augmentation procedure.

In a retrospective study, Sun et al (2014) examined the effect of treatment with cementoplasty in patients with painful bone metastases in the extra-spinal region. This study was conducted to review 51 consecutive patients who underwent cementoplasty under CT or fluoroscopic guidance, a total of 65 lesions involving the ilium, ischium, pubis, acetabulum, humeral, femur and tibia. In 5 patients with a high risk of impending fracture in long bones based on Mirels' scoring system, an innovative technique using a cement-filled catheter was applied. The clinical effects were evaluated using the VAS pre-operatively and post-operatively. All patients were treated successfully with a satisfying resolution of painful symptoms at 3 months' follow-up. Cement leakage was found in 8 lesions without any symptoms; VAS scores decreased from 8.19 ± 1.1 pre-operatively to 4.94 ± 1.6 at 3 days, 3.41 ± 2.1 at 1 month and 3.02 ± 1.9 at 3 months post-operatively. There was a significant difference between the mean pre-operative baseline score and the mean score at all of the post-operative follow-up points (p < 0.01). The authors concluded that cementoplasty is an effective technique for treating painful bone metastases in extra-spinal regions, which is a valuable, minimally invasive, method that allows reduction of pain and improvement of patients' quality of life.

Kim et al (2014) stated that percutaneous stabilization (PS; percutaneous flexible nailing and intramedullary bone cement injection) was performed at lower extremity long bones in patients with multiple bone metastases with short life expectancy to get mechanical stability and local tumor control. These researchers evaluated the usefulness of PS by clinical status, F-18-FDG PET-CT and bone scintigraphy (BS). Patients comprised 15 patients (total 20 sites) who had undergone PS for the metastatic bone tumors of
lower extremity long bones (femur and tibia). After percutaneous flexible nailing, bone cement was injected (mean amount = 15.5 ± 6.4 ml). Patients' clinical status was evaluated by VAS. Qualitative assessment of PET-CT and BS was categorized by improved, stable and aggravated states of PS lesion. Quantitative assessment of PET-CT was performed by maximum and mean standardized uptake value (SUVmax and SUVmean). Percutaneous stabilization was performed in all of the patients without complication, and showed significant pain improvement of VAS (7.2 ± 0.2 versus 2.8 ± 0.3, p < 0.001); PS lesion showed improved state in 65% (13/20) and stable state in 35% (7/20). However, naive bony metastatic lesion showed mostly aggravated state in 90% (19/20) in the same patients, which was significantly different compared with PS lesion (p < 0.001). In PS lesion, SUVmax (10.1 ± 6.9 versus 7.1 ± 5.2, p = 0.008) and SUVmean (6.2 ± 4.8 versus 4.6 ± 3.7, p = 0.008) showed significantly decreased uptake after PS. The authors concluded that by PS in lower extremity long bones, patients can reduce regional pain, and has the possibility of local tumor control. They stated that PS can be performed for lower extremity bone metastasis in poor general condition to perform conventional intramedullary nailing.

Cazzato et al (2015) noted that percutaneous cementoplasty (PC) is rarely applied to long bone tumors, since cement is not considered to be sufficiently resistant to torsional forces. These investigators reviewed the literature to understand the effects of percutaneous long bone cementoplasty (PLBC) in terms of analgesia, limb function and complications. This study followed the Cochrane’s guidelines for systematic reviews of interventions. Inclusion criteria were

I. prospective/retrospective studies concerning PC;

II. cohort including at least 10 patients;

III. at least 1 patient in the cohort undergoing PLBC;

IV. published in English; and

V. results not published by the same author more than once.
1. prospective/retrospective studies concerning PC;
2. cohort including at least 10 patients;
3. at least 1 patient in the cohort undergoing PLBC;
4. published in English; and
5. results not published by the same author more than once.

A total of 1,598 articles were screened and 13 matched the inclusion criteria covering 196 PLBC patients. Pain improvement was high in 68.2% patients (σ = 0.2) and mild in 27.4% (σ = 0.2). Functional improvement was high in 71.9% patients (σ = 0.1) and mild in 6% (σ = 0.1). Use of PLBC correlated with pain reduction (p < 0.001). Secondary fractures occurred in 16 cases (8%, σ = 2.5); other complications in 2% cases. Percutaneous stabilization (PS) was coupled with PLBC in 17% of cases without any subsequent fracture; PS was not associated with absence of secondary fracture (p = 0.08). The authors concluded that PLBC is safe, offering good pain relief and recovery of impaired limb function. Secondary fractures are uncommon and PS may reduce their occurrence. However, no evidence is currently available to support PS plus PLBC as compared to PLBC alone.

Guarnieri e al (2015) stated that vertebroplasty (VP) is a percutaneous mini-invasive technique developed in the late 1980s as antalgic and stabilizing treatment in patients affected by symptomatic vertebral fracture due to porotic disease, traumatic injury and primary or secondary vertebral spine tumors. The technique consists of a simple metameric injection of an inert cement (poly-methyl-methacrylate, PMMA), through a needle by trans-peduncular, para-peduncular or trans-somatic approach obtaining a vertebral augmentation and stabilization effect associated with pain relief. The technique is simple and fast, and should be performed under fluoroscopy or CT guidance in order to obtain a good result with low complication rate. The authors illustrated the utility of VP, the indications-contraindications criteria, how to technically perform the technique using imaging guidance, and the results and complications of this treatment in patients affected by symptomatic vertebral compression fracture.

Muto et al (2016) stated that vertebral cementoplasty is a well-known mini-invasive treatment to obtain pain relief in patients affected by vertebral porotic fractures, primary or secondary spine lesions and spine trauma through intra-metameric cement injection. Two major categories of treatment are included within the term vertebral cementoplasty: the first is vertebroplasty in which a simple cement injection in the vertebral body is performed; the second is assisted technique in which a device is positioned inside the metamer before the cement injection to restore vertebral height
and allow a better cement distribution, reducing the kyphotic deformity of the spine, trying to obtain an almost normal spine biomechanics. The authors described the most advanced techniques and indications of vertebral cementoplasty, having recently expanded the field of applications to not only patients with porotic fractures, but also spine tumors and trauma.

The National Institute for Health and Care Excellence’s clinical practice guideline on “Percutaneous cementoplasty for palliative treatment of bony malignancies” (2006) stated that “Current evidence on the safety and efficacy of percutaneous cementoplasty for the palliative treatment of bony malignancies is limited, but appears adequate to support the use of this procedure in patients for whom other treatments have failed, provided that the normal arrangements are in place for consent, audit and clinical governance”.

Furthermore, the Scottish Intercollegiate Guidelines Network’s clinical guideline on “Control of pain in adults with cancer” (2008) stated that “Patients with bone pain from pelvic bone metastases proving difficult to control by pharmacological means and reduced mobility should be considered for percutaneous cementoplasty”.

**Intracpet System (Intra-Osseous Basivertebral Nerve Ablation) for the Treatment of Low Back Pain**

Becker and colleagues (2017) noted that lumbar axial back pain arising from degenerative disc disease continues to be a challenging clinical problem whether treated with non-surgical management, local injection, or motion segment stabilization and fusion. These researches determined the efficacy of intra-osseous basi-vertebral nerve (BVN) ablation (Intracept System, Relievant Medsystems, Inc, Redwood City, CA) for the treatment of chronic lumbar back pain. Patients meeting pre-defined inclusion or exclusion criteria were enrolled in a study using RF energy to ablate the BVN within the vertebral bodies adjacent to the diagnosed level. Patients were evaluated at 6 weeks, and 3, 6, and 12 months post-operatively. A total of 17 patients with chronic, greater than 6 months, LBP unresponsive to at least 3 months of conservative care were enrolled; 16 patients were treated successfully following screening using MRI finding of Modic type I or II changes and positive confirmatory discography to determine the affected levels. The treated population consisted of 8 men and 8 women; the mean age was 48 years (34 to 66 years). Self-reported outcome measures were collected prospectively at each follow-up interval. Measures included the ODI, VAS score, and SF-36. Mean baseline ODI of the treated cohort was 52 ± 13, decreasing to a mean of 23 ± 21 at 3 months follow-up (p < 0.001). The statistically significant improvement in ODI
observed at 3 months was maintained through the 12-month follow-up. The mean baseline VAS score decreased from $61 \pm 22$ to $45 \pm 35$ at 3 months follow-up ($p < 0.05$), and the mean baseline physical component summary increased from $34.5 \pm 6.5$ to $41.7 \pm 12.4$ at 3 months follow-up ($p = 0.03$). The authors concluded that ablation of the BVN for the treatment of chronic LBP significantly improved patients' self-reported outcome early in the follow-up period; the improvement persisted throughout the 1-year study period. It should be noted that this was an industry-sponsored study; it was a small ($n = 17$) with a relatively short-term follow-up (12 months).

In a prospective, randomized, double-blind, sham-controlled, multi-center study, Fischgrund and associates (2018) evaluated the safety and efficacy of RFA of the BVN for the treatment of CLBP in a FDA-approved IDE trial. The BVN has been shown to innervate endplate nociceptors which are thought to be a source of CLBP. A total of 225 patients diagnosed with CLBP were randomized to either a sham (78 patients) or treatment (147 patients) intervention. The mean age within the study was 47 years (range of 25 to 69) and the mean baseline ODI was 42. All patients had type I or type II Modic changes of the treated vertebral bodies. Patients were evaluated pre-operatively, and at 2 weeks, 6 weeks and 3, 6 and 12 months post-operatively. The primary end-point was the comparative change in ODI from baseline to 3 months. At 3 months, the average ODI in the treatment-arm decreased 20.5 points, as compared to a 15.2 point decrease in the sham-arm. In the intention-to-treat population, the difference in change in ODI (the prespecified primary endpoint) between subjects assigned to intraosseous basivertebral nerve ablation and subjects assigned to sham treatment was not statically significantly different ($p = 0.109$) ($p = 0.019$, per-protocol population). A responder analysis based on ODI decrease of greater than or equal to 10 points showed that 75.6% of patients in the treatment-arm as compared to 55.3% in the sham-arm exhibited a clinically meaningful improvement at 3 months. The authors concluded that patients treated with RFA of the BVN for CLBP exhibited significantly greater improvement in ODI at 3 months and a higher responder rate than sham-treated controls. They stated that BVN ablation represents a potential minimally invasive treatment for the relief of CLBP. These researchers stated that the ability in the SMART trial to distinguish the active treatment from the sham treatment suggested that ablation of the BVN has therapeutic value, although the overall pain response in a given patient is a complex function of the combined effects of placebo and treatment. However, it is unclear why the 3-month follow-up was chosen as the primary end-point. Could it be that ODI questionnaire between the treatment and sham groups were non-significant at 6- and 12-month post-operatively. The least squares mean (LSM) improvement in VAS in the treatment-arm was 2.97, 3.04, and 2.84 cm at 3, 6, and 12 months, respectively. The LSM improvement in VAS in the sham-arm was 2.36, 2.08, and 2.08 cm at 3, 6, and 12 months, respectively. There were no difference between the 2 groups at 3 months; however, the differences
between the 2 groups attained statistical significance at 6 and 12 months (clinical
significant of these differences was unclear).

Fischgrund et al (2019) reported the 2-year clinical outcomes for chronic low back pain
(CLBP) patients treated with radiofrequency (RF) ablation of the basi-vertebral nerve
(BVN) in a randomized controlled trial that previously reported 1-year follow-up. A total
of 147 patients were treated with RF ablation of the BVN in a randomized controlled trial
designed to demonstrate safety and efficacy as part of a Food and Drug Administration
(FDA)-Investigational Device Exemption (IDE) trial. Evaluations, including patient self-
assessments, physical and neurological examinations, and safety assessments, were
performed at 2 and 6 weeks, and 3, 6, 12, 18, and 24 months post-operatively.
Participants randomized to the sham control arm were allowed to cross-over to RF
ablation at 12 months. Due to a high rate of cross-over, RF ablation treated participants
acted as their own control in a comparison to baseline for the 24-month outcomes.
Clinical improvements in the Oswestry Disability Index (ODI), visual analog scale (VAS),
and the Medical Outcomes Trust Short-Form Health Survey Physical Component
Summary were statistically significant compared to baseline at all follow-up time points
through 2 years. The mean percent improvements in ODI and VAS compared to baseline
at 2 years were 53.7 and 52.9%, respectively. Responder rates for ODI and VAS were also
maintained through 2 years with patients showing clinically meaningful improvements in
both: ODI greater than or equal to 10-point improvement in 76.4% of patients and ODI
greater than or equal to 20-point improvement in 57.5%; VAS greater than or equal to
1.5 cm improvement in 70.2% of patients. The authors concluded that patients treated
with RF ablation of the BVN for CLBP exhibited sustained clinical benefits in ODI and
VAS and maintained high responder rates at 2 years following treatment. They stated
that basi-vertebral nerve ablation appeared to be a durable, minimally invasive
treatment for the relief of CLBP. This was an extension study (2-year follow-up) of their
earlier study that provided 1-year follow-up (Fischgrund et al, 2018).

In a prospective, single-arm, open-label study, Truumees et al (2019) examined the
effectiveness of intraosseous RF ablation of the BVN for the treatment of vertebrogenic-
related CLBP in typical spine practice settings using permissive criteria for study
inclusion (n = 28). Consecutive patients with CLBP of at least 6 months duration and
with Modic Type 1 or 2 vertebral endplate changes between L3 and S1 were treated with
RF ablation of the BVN in up to 4 vertebral bodies. The primary end-point was patient-
reported change in ODI from baseline to 3 months post-procedure. Secondary outcome
measures included change in VAS, SF-36, EQ-5D-5L, and responder rates. Median age
was 45 years; baseline ODI was 48.5; VAS was 6.36; 75% of the study patients reported
LBP symptoms for greater than or equal to 5 years; 25% were actively using opioids; and
61% were previously treated with injections. Mean change in ODI at 3 months post-
treatment was - 30.07 + 14.52 points (p < 0.0001); mean change in VAS was - 3.50 + 2.33 (p < 0.0001); 93% of patients achieved a greater than or equal to 10-point improvement in ODI, and 75% reported greater than or equal to 20-point improvement. The authors concluded that minimally invasive RF ablation of the BVN demonstrated a significant improvement in pain and function in this population of real-world patients with chronic vertebrogenic-related LBP.

The authors stated that potential limitations to generalizability include the use of research coordinators, a medical monitor, and a defined pre-screening process. However, pure effectiveness trials are nearly impossible to perform without some research infra-structure to promote population homogeneity and ensure data quality. Additional potential criticisms may include the relatively small sample (n = 28) and short follow-up (3 months) for the primary end-point. However, durability of the 3-month results up to 24 months has been established previously, and these researchers will continue to collect longer term outcomes as a part of this study.

Khalil et al (2019) noted that current literature suggests that degenerated or damaged vertebral end-plates are a significant cause of CLBP that is not adequately addressed by standard care. Prior 2-year data from the treatment arm of a sham-controlled randomized controlled trial (RCT) showed maintenance of clinical improvements at 2 years following RF ablation of BVN. In a prospective, parallel, open-label RCT conducted at 20 U.S. sites, these researchers compared the effectiveness of intraosseous RF ablation of the BVN to standard care for the treatment of CLBP in a specific subgroup of patients suspected to have vertebrogenic related symptomatology. A total of 140 patients with CLBP of at least 6 months duration, with Modic Type 1 or 2 vertebral end-plate changes between L3 to S1, were randomized 1:1 to undergo either RF ablation of the BVN or continue standard care; ODI was collected at baseline, 3, 6, 9, and 12-months post-procedure. Secondary outcome measures included a 10-point VAS for LBP, ODI and VAS responder rates, SF-36, and EQ-5D-5L. The primary end-point was a between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment. Patients were randomized 1:1 to receive RF ablation or to continue standard care. Self-reported patient outcomes were collected using validated questionnaires at each study visit. An interim analysis to evaluate for superiority was pre-specified and overseen by an independent data management committee (DMC) when a minimum of 60% of patients had completed their 3-month primary end-point visit. The interim analysis showed clear statistical superiority (p < 0.001) for all primary and secondary patient-reported outcome measures in the RF ablation arm compared to the standard care arm. This resulted in a DMC recommendation to halt enrollment in the study and offered early cross-over to the control arm. These results were comprised of the outcomes of the 104 patients included in the intent-to-treat (ITT) analysis of the 3-month primary end-point,
which included 51 patients in the RF ablation arm and 53 patients in the standard care arm. Baseline ODI was 46.1, VAS was 6.67, and mean age was 50 years. The percentage of patients with LBP symptoms greater than or equal to 5 years was 67.3%. Comparing the RF ablation arm to the standard care arm, the mean changes in ODI at 3 months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points (p < 0.001). Mean changes in VAS were -3.46 versus -1.02, respectively, an adjusted difference of 2.44 cm (p < 0.001). In the RF ablation arm, 74.5% of patients achieved a greater than 10-point improvement in ODI, compared with 32.7% in the standard care arm (p < 0.001). The authors concluded that minimally invasive RF ablation of the BVN led to significant improvement of pain and function at 3-months in patients with chronic vertebrogenic related LBP.

The authors stated that limitations of this study included the use of a non-structured standard care control and open label design. In addition, industry funding is a potential source of study bias. This report only provided short-term 3-month outcomes from the planned interim analysis and long-term results from the complete study cohort are underway. Although this study was designed to collect longer-term data from both randomized groups, a review of the study results from the planned interim analysis led to the independent DMC’s recommendation to halt enrollment and offered early cross-over to patients in the standard care group. It was noted that the Informed Consent regulations and the Declaration of Helsinki require that study participants be advised of any new information from the study that may impact their willingness to continue, and the results of the interim analysis would have such an impact, especially on the control group. Ultimately, the DMC determined that it was not ethical to continue the control arm, and that further enrollment into the treatment arm was not needed. As a result, follow-up will be limited in the standard care patients in the final analysis to results collected up to the point of cross-over or study exit. Further follow-up of the treatment arm patients for 5 years is underway as a single arm study, and control subjects that elected to cross-over to treatment are being followed at 3 and 6 months post-procedure. Finally, another important limitation of this study was a lack of generalizability to the broader CLBP population who did not meet the strict clinical and radiographic criteria of this study.

Fischgrund, et al. (2020) reported on the 5-year outcomes of the U.S. treated patients in the active treatment arm of the aforementioned study. Of the 117 US treated patients 100 (85%) were available for review with a mean follow-up of 6.4 years (5.4-7.8 years). Mean ODI score improved from 42.81 to 16.86 at 5-year follow-up, a reduction of 25.95 points (p < 0.001). Mean reduction in VAS pain score was 4.38 points (baseline of 6.74, p < 0.001). In total, 66% of patients reported a > 50% reduction in pain, 47% reported a > 75% reduction in pain, and 34% of patients reported complete pain resolution.
Composite responder rate using thresholds of $\geq 15$-point ODI and $\geq 2$-point VAS for function and pain at 5 years was 75%. The current study is the 5-year follow-up of subjects assigned to intraosseous basivertebral nerve ablation (Fischgrund, et al., 2020). This study, however, does not include a comparison group. Because the study was not able to demonstrate statistically significant differences between the active treatment and control groups during the randomized portion of the study for the prespecified primary endpoint, change in ODI at 3 months, in subjects as randomized, conclusions about the effectiveness of this procedure cannot be reached.

Markman et al (2020) hypothesized that CLBP patients reporting reduced opioid use have superior functional outcomes following RF ablation (RFA) of the BVN. This post-hoc analysis from a sham-controlled trial examined short-acting opioid use from baseline through 1 year. Opioid use was stratified into 3 groups by 2 blinded external reviewers. Two-sample t-tests were used to compare ODI and VAS measurements between those patients who increased or decreased their opioid usage compared to baseline. Actively treated patients with decreased opioid use at 12 months had a mean ODI improvement of $24.9 \pm 16.0$ (n = 27) compared to $7.3 \pm 9.8$ (n = 18) for patients reporting increased opioid use ($p < 0.001$). In the sham-arm, the improvements in ODI were $17.4 \pm 16.1$ (n = 19) and $1.2 \pm 14.3$ (n = 5; $p = 0.053$) for the patients reporting decreased versus increased opioid usage, respectively. Actively treated patients reporting decreased opioid use had a mean improvement in VAS of $3.3 \pm 2.5$ (n = 27) compared to $0.6 \pm 1.8$ (n = 18) for patients reporting increased opioid use ($p < 0.001$). In the sham-arm, the improvements in VAS were $2.5 \pm 2.6$ (n = 19) and $1.4 \pm 1.9$ (n = 5; $p = 0.374$) for patients reporting decreased versus increased opioid usage, respectively. The authors concluded that subjects undergoing BVN ablation who decreased opioid use had greater improvement in ODI and VAS scores compared with those reporting increased opioid usage. There was an association between functional benefit from BVN ablation and reduced opioid use. Moreover, these researchers stated that the findings of this study suggested that the ability to lower or eliminate opioid usage through a minimally invasive surgical procedure may represent an important improvement to the treatment armamentarium for CLBP and warrants further investigation. It should also be noted that this study was funded by Relievant Medsystems; and 3 of the co-authors (Drs. Fischgrund, Rhyne, and Vajkoczy) had a consulting relationship with the study's device manufacturer.

The authors stated that this post-hoc analysis had several drawbacks. Opioid use was monitored using self-reported patient questionnaires, asking about the past week's dosage, which relied on patient recall. Patients receiving long-acting opioid therapy for CLBP were excluded from the protocol, which may account for the relatively low baseline opioid usage in the study population; however, most patients taking opioids for
CLBP are treated with short-acting opioids. This sub-analysis sample size was relatively small, with 77 total patients in the active and sham treatment groups taking opioids at the time of enrollment, which may have limited the ability to detect differences using inferential analyses for some end-point measures. Furthermore, whereas analyses of opioid sparing effects and outcomes followed the pre-specified outcomes and analyses of the trial protocol statistical analysis plan, this sub-analysis was not pre-planned and was executed after database lock and unblinding, potentially introducing bias.

The International Society for the Advancement of Spine Surgery's guideline on “Intraosseous ablation of the basivertebral nerve for the relief of chronic low back pain” (Lorio et al, 2020) stated that intraosseous ablation of the BVN is a new procedure; its limitations included industry funding is a potential source of study bias for the available data reviewed, limited number of studies, short-term follow-up for the majority of studied patients, and unknown effect on the primary degenerative process.

**Intradiscal Injections of Notochordal Cell-Derived Matrix for the Treatment of Intervertebral Disc Disease**

Bach and colleagues (2018) noted that the socioeconomic burden of chronic back pain related to intervertebral disc (IVD) disease is high and current treatments are only symptomatic. Minimally invasive strategies that promote biological IVD repair should address this unmet need. Notochordal cells (NCs) are replaced by chondrocyte-like cells (CLCs) during IVD maturation and degeneration. The regenerative potential of NC-secreted substances on CLCs and mesenchymal stromal cells (MSCs) has already been demonstrated. However, identification of these substances remains elusive. These researchers examined the regenerative NC potential by using healthy porcine NC-derived matrix (NCM) and used the dog as a clinically relevant translational model. NCM increased the glycosaminoglycan and DNA content of human and canine CLC aggregates and facilitated chondrogenic differentiation of canine MSCs in-vitro. Based on these results, NCM, MSCs and NCM+MSCs were injected in mildly (spontaneously) and moderately (induced) degenerated canine IVDs in-vivo and, after 6 months of treatment, were analyzed. NCM injected in moderately (induced) degenerated canine IVDs exerted beneficial effects at the macroscopic and MRI level, induced collagen type II-rich extracellular matrix production, improved the disc height, and ameliorated local inflammation. MSCs exerted no (additive) effects. The authors concluded that NCM induced in-vivo regenerative effects on degenerated canine IVDs. They stated that NCM may, comparable to demineralized bone matrix in bone regeneration, serve as “instructive matrix”, by locally releasing growth factors and facilitating tissue repair. Thus, intradiscal NCM injection could be a promising regenerative treatment for IVD disease, circumventing the cumbersome identification of bioactive NC-secreted
substances. These investigators noted that this was the 1st study that showed that intradiscally injected NCM could potentially be a promising treatment for human and canine IVD disease, by harnessing the NC regenerative and anti-inflammatory potential, and circumventing the challenging identification of bioactive NC-secreted factors. This approach should be feasible in light of the wide clinical application of demineralized bone matrix within the bone regeneration field. They stated that future studies should focus on removal of nucleic acid from NCM, and the mechanism of NCM-mediated regeneration.

**Spinal Fusion for Bertolotti’s Syndrome**

The cause of LBP with Bertolotti’s syndrome (chronic, persistent LBP and radiographically diagnosed transitional lumbar vertebra) remains controversial, and various treatments such as local injection of anesthetic and/or steroid, RF coagulation, surgical resection, and spinal fusion have been reported. Santavirta and colleagues (1993) surgically treated 16 patients with Bertolotti’s syndrome; 8 had posterolateral fusion and another 8 resection of the transitional articulation; 13 patients had in addition to the chronic LBP, suffered from repeated episodes or chronic sciatica. In 6 cases with resection treatment, local injections were administered at the transitional articulation before deciding for resection of the transitional joint; each patient reported transient relief of pain, while this pre-operative test did not correlate with successful outcome of treatment; 6 patients had to be treated with 2nd operations; 10 of the 16 operatively treated patients showed improvement of the LBP, and this result was similar in the group treated with fusion and in that treated with resection; 7 had no LBP at follow-up, and the improvement according to the Oswestry pain scale was similar in the 2 groups, and statistically significant; 11 patients still had persisting episodes of sciatica (versus 13 pre-operatively). The average disability according to the Oswestry total disability scale was 30%, corresponding with moderate outcome, and both operatively treated groups did equally well. At follow-up the 1st disc above the fused segments was found to be degenerated in 7 out of 8 cases, and in the group treated with resection the 1st disc above the transitional vertebra was degenerated in 5 cases.

Li and co-workers (2014) noted that Bertolotti’s syndrome consists of LBP caused by lumbosacral transitional vertebrae (LSTVs) and LSTV-associated biomechanical spinal changes. There is a lack of consensus regarding the cause, clinical significance, and treatment of this condition. These investigators characterized the clinical presentation of patients with Bertolotti’s syndrome and described a minimally invasive surgical treatment for this condition. A total of 7 patients who underwent minimally invasive para-median tubular-based resection of the LSTV for Bertolotti’s syndrome were
identified over the course of 5 years. Diagnosis was based on patient history of chronic LBP, radiographic findings of LSTV, and pain relief on trigger-site injection with steroid and/or anesthetics. Electronic medical records were reviewed to identify demographics, operative data, and outcomes. All patients presented with severe, chronic LBP lasting an average of 8 years that was resistant to non-operative care. At presentation, 6 (86%) of 7 patients experienced radicular pain that was ipsilateral to the LSTV. Radiographic evidence showed a presence of LSTV in all patients on the left (43%), right (29%), or bilaterally (29%). Degenerative disc changes at the L4 to L5 level immediately above the anomalous LSTV were observed in 6 of 7 (86%) patients; these changes were not observed at the level below the LSTV. Following pseudo-joint injection, all patients experienced temporary relief of their symptoms. All patients underwent a minimally invasive, para-median tubular-based approach for resection of the LSTV; 3 (43%) of 7 patients reported complete resolution of LBP, 2 (29%) of 7 patients had reduced LBP, and 2 patients (29%) experienced initial relief but return of LBP at 1 and 4 years post-operatively; 3 (50%) of the 6 patients with radicular pain had complete relief of this symptom. The median follow-up time was 12 months. No intra-operative complication was reported; 2 (29%) of 7 patients developed post-operative complications including 1 with a wound hematoma and another with new L5 radiculopathy that resolved 2 years after surgery. The authors concluded that diagnosis of Bertolotti’s syndrome should be considered with adequate patient history, imaging studies, and diagnostic injections. A minimally invasive surgical approach for resection of the LSTV was presented here for symptomatic treatment of select patients with Bertolotti’s syndrome whose conditions were refractory to conventional therapy and who had pain that could be attributed to the LSTV. Several short-term complications were noted with this procedure, but overall this procedure is effective for treating symptoms related to Bertolotti’s syndrome.

Jancuska and colleagues (2015) stated that LSTV are increasingly recognized as a common anatomical variant associated with altered patterns of degenerative spine changes. These researchers focused on the clinical significance of LSTV, disruptions in normal spine biomechanics, imaging techniques, diagnosis, and treatment. A PubMed search using the specific key words “LSTV”, “lumbosacral transitional vertebrae” and “Bertolotti’s Syndrome” was performed. The resulting group of manuscripts from this search was evaluated. LSTV were associated with alterations in biomechanics and anatomy of spinal and para-spinal structures, which have important implications on surgical approaches and techniques. LSTV were often inaccurately detected and classified on standard antero-posterior (AP) radiographs and MRI. The use of whole-spine images as well as geometric relationships between the sacrum and lumbar vertebra increase accuracy. Uncertainty regarding the cause, clinical significance, and treatment of LSTV persists. Some authors suggested an association between LSTV types II and IV and LBP. Pseudo-articulation between the transverse process and the sacrum
creates a “false joint” susceptible to arthritic changes and osteophyte formation potentially leading to nerve root entrapment. The diagnosis of symptomatic LSTV was considered with appropriate patient history, imaging studies, and diagnostic injections. A positive radionuclide study along with a positive effect from a local injection helped distinguish the transitional vertebra as a significant pain source. Surgical resection is reserved for a subgroup of LSTV patients who fail conservative treatment and whose pain is definitively attributed to the anomalous pseudo-articulation. The authors noted that the literature contains a total of 43 cases of surgical intervention for symptomatic LSTV; 27 patients were treated with resection, 8 underwent fusion, 6 patients were treated for far-out syndrome, and the remaining 2 cases involved surgical intervention for extraforaminal nerve root impingement or pain contralateral to the LSTV. Only Santavirta et al (1993) compared the surgically treated patients to a conservative treatment control group. The results of surgical treatment were only slightly better. The authors of these cases advocated for operative treatment of Bertolotti’s syndrome in very select patients whose refractory pain is definitively attributed to the transitional vertebrae. The authors concluded that given the paucity of evidence, further investigations with larger patient cohorts and longer follow-up are needed to better understand the association between the anomalous transverse process and LBP that occurred with LSTV and to better demonstrate the effectiveness of surgical intervention.

Holm and co-workers (2017) noted that Bertolotti’s syndrome refers to the possible association between the congenital malformation LSTV and LBP. Several treatments have been proposed including steroid injections, resections of the LSTV, laminectomy, and lumbar spinal fusion. These researchers compared the clinical outcomes in previous trials and case reports for these treatments in patients with LBP and LSTV. A PubMed search was conducted. These investigators included English studies of patients diagnosed with LSTV treated with steroid injection, laminectomy, spinal fusion or resection of the transitional articulation. Of 272 articles reviewed, 20 met the inclusion criteria. Their level of evidence were graded I to V and the clinical outcomes were evaluated. Only 1 study had high evidence level (II). The remainders were case series (level IV). Only 5 studies used validated clinical outcome measures. A total of 79 patients were reported: 31 received treatment with steroid injections, 33 were treated with surgical resection of the LSTV, 8 received lumbar spinal fusion, and 7 cases were treated with laminectomy. Surgical management appeared to improve the patient’s symptoms, especially patients diagnosed with “far out syndrome” treated with laminectomy. Clinical outcomes were more heterogenous for patient’s treated with steroid injections. The literature regarding Bertolotti’s syndrome is sparse and generally with low evidence. Non-surgical management (e.g., steroid injections) and surgical intervention could not directly be compared due to lack of standardization in clinical outcome. Generally, surgical management appeared to improve patient’s clinical outcome over time,
whereas steroid injection only improved the patient’s symptoms temporarily. The authors concluded that further studies with larger sample size and higher evidence are needed for the clinical guidance in the treatment of Bertolotti’s syndrome.

**Discseel Procedure (Regenerative Spine Procedure) for the Treatment of Back Pain**

According to Discseel, the Discseel procedure supposedly can repair one’s damaged spinal disc, using an FDA-approved biologic fibrin, allowing patients to avoid risky spinal fusions and discectomies. This is possible because the fibrin is able to repair and seal damaged spinal disc, where spine surgery, including spinal fusions, can’t. During the Discseel procedure, the physician will inject fibrin into the damaged disc, which will seal the disc. The entire procedure is observed through live x-rays.

In a retrospective, observational, pilot study, Kirchner and Anitua (2016) examined the clinical outcome of plasma rich in growth factors (PRGF-Endoret) infiltrations (1 intradiscal, 1 intra-articular facet, and 1 transforaminal epidural injection) under fluoroscopic guidance-control in patients with chronic LBP. A total of 86 patients with a history of chronic LBP and DDD of the lumbar spine who met inclusion and exclusion criteria were recruited between December 2010 and January 2012; 1 intradiscal, 1 intra-articular facet, and 1 transforaminal epidural injection of PRGF-Endoret (fibrin was embedded with a pool of growth factors) under fluoroscopic guidance-control were carried out in 86 patients with chronic LBP in the operating theater setting. Descriptive statistics were performed using absolute and relative frequency distributions for qualitative variables and mean values and standard deviations for quantitative variables. The non-parametric Friedman statistical test was used to determine the possible differences between baseline and different follow-up time-points on pain reduction after treatment. Pain assessment was determined using a VAS at the 1st visit before (baseline) and after the procedure at 1, 3, and 6 months. The pain reduction after the PRGF-Endoret injections showed a statistically significant drop from $8.4 \pm 1.1$ before the treatment to $4 \pm 2.6$, $1.7 \pm 2.3$, and $0.8 \pm 1.7$ at 1, 3, and 6 months after the treatment, respectively, with respect to all the time evaluations ($p < 0.0001$) except for the pain reduction between the 3rd and 6th month whose signification was lower ($p < 0.05$). The analysis of the VAS over time showed that at the end-point of the study (6 months), 91% of patients showed an excellent score, 8.1% showed a moderate improvement, and 1.2% were in the inefficient score. The authors concluded that fluoroscopy-guided infiltrations of intervertebral discs and facet joints with PRGF in patients with chronic LBP resulted in significant pain reduction assessed by VAS. One of the keywords in this study was fibrin matrix.
The authors stated that this study had several drawbacks. The absence of a control (placebo) group in this study was certainly a limitation. There were other weaknesses in this study as to these researchers did not perform a previous diagnostic block for patients’ selection, and thus, their diagnosis and selection of patients relied on a careful clinical examination. Another drawback to this study was the lack of measurement of physical activity levels before and after the treatment. Last but not the least, to limit the bias of a single assessment, the self-reported VAS pain scale should have been associated with other health survey questionnaires, which encompassed pain and functional evaluation. These researchers stated that in the light of several limitations of this trial, a RCT is considered imperative.

Furthermore, UpToDate reviews on “Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment” (Chou, 2019a), “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2019b), and “Subacute and chronic low back pain: Surgical treatment” (Chou, 2019c) do not mention fibrin injection as a therapeutic option.

**Intramuscular Steroid Injection for the Treatment of Neck Pain**

In a meta-analysis, Nouged and colleagues (2019) examined the effectiveness of local anesthetic trigger-point injections in adults with myofascial pain syndrome (MPS) in the head, neck, and shoulder regions compared to dry needling, placebo, and other interventions; RCTs using local anesthetic injections in adults diagnosed with MPS were included, and searches were conducted in the Cochrane Library, Medline via PubMed, Web of Science and Embase. The initial search strategy yielded 324 unduplicated references up to April 1, 2018. A total of 15 RCTs were included, with 884 adult patients diagnosed with MPS. Meta-analysis showed a significant improvement in VAS pain scale of 1.585 units at 1 to 4 weeks in the local anesthetic group compared to the dry needling group \( (p = 0.020) \). However, when only including double-blinded studies, the effect was not statistically significant \( (p = 0.331) \). There was also a significant improvement in pain of 0.767 units with local anesthetic at 2 to 8 weeks compared to placebo \( (p = 0.007) \). No statistically significant differences were found in other secondary outcomes between local anesthetic and all other interventions. The authors concluded that although local anesthetics provided a significant improvement in pain compared to dry needling, evidence was of low quality, and sensitivity analyses including only double-blinded studies provided no statistically significant difference, and that additional studies are needed to confirm these findings.
An UpToDate reviews on “Treatment and prognosis of cervical radiculopathy” (Robinson and Kothari, 2019) does not mention intramuscular steroid injection as a therapeutic option.

Furthermore, an UpToDate review on “Treatment of neck pain” (Isaac, 2019) states that “Routine use of corticosteroid should be discouraged due to its propensity to cause local muscle necrosis”.

**Anterior Lumbar Interbody Fusion (ALIF) for Degenerative Disk Disease / Back Pain**

Rao et al (2015) stated that there is limited information on clinical outcomes after anterior lumbar interbody fusion (ALIF) based on the indications for surgery. In a prospective, clinical study, these researchers compared the clinical and radiological outcomes of ALIF for each surgical indication. This trial included 125 patients who underwent ALIF over a 2-year period. Patients were examined pre-operatively and post-operatively. Outcome measures included the Short Form-12 (SF-12), Oswestry disability index (ODI), visual analog scale (VAS) and patient satisfaction index (PSI). After a mean follow-up of 20 months, the clinical condition of the subjects was significantly better than their pre-operative status across all indications. A total of 108 patients had a PSI score of 1 or 2, indicating a successful clinical outcome in 86%. Patients with degenerative disk disease (DDD) with and without radiculopathy, spondylolisthesis, and scoliosis had the best clinical response to ALIF, with statistically significant improvement in the SF-12, ODI, and VAS. Failed posterior fusion and adjacent segment disease showed statistically significant improvement in all of these clinical outcome scores, although the mean changes in the SF-12 Mental Component Summary, ODI, and VAS (back pain) were lower. The overall radiological fusion rate was 94.4%. Superior radiological outcomes (fusion of greater than 90%) were observed in patients with DDD with and without radiculopathy, spondylolisthesis, and failed posterior fusion, whereas in adjacent segment disease, it was 80%. The authors concluded that ALIF was an effective treatment for DDD with and without radiculopathy and spondylolisthesis. Moreover, these researchers stated that although results were promising for scoliosis, failed posterior fusion, and adjacent segment disease, further studies are needed to establish the effectiveness of ALIF in these conditions.

Mobbs et al (2015) noted that degenerative disc and facet joint disease of the lumbar spine is common in the aging population, and is one of the most frequent causes of disability. Lumbar spondylosis may result in mechanical back pain, radicular and claudicating symptoms, reduced mobility and poor quality of life (QOL). Surgical interbody fusion of degenerative levels is a therapeutic option to stabilize the painful motion segment, and may provide indirect decompression of the neural elements.
restore lordosis and correct deformity. The surgical options for interbody fusion of the lumbar spine include: posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), minimally invasive transforaminal lumbar interbody fusion (MI-TLIF), oblique lumbar interbody fusion/anterior to psoas (OLIF/ATP), lateral lumbar interbody fusion (LLIF) and ALIF. The indications may include: discogenic/facetogenic low back pain (LBP), neurogenic claudication, radiculopathy due to foraminal stenosis, lumbar degenerative spinal deformity including symptomatic spondylolisthesis and degenerative scoliosis. In general, traditional posterior approaches are frequently used with acceptable fusion rates and low complication rates, however they are limited by thecal sac and nerve root retraction, along with iatrogenic injury to the para-spinal musculature and disruption of the posterior tension band. Minimally invasive (MIS) posterior approaches have evolved in an attempt to reduce approach related complications. Anterior approaches avoid the spinal canal, cauda equina and nerve roots, however have issues with approach-related abdominal and vascular complications. Furthermore, lateral and OLIF techniques have potential risks to the lumbar plexus and psoas muscle. These investigators comprehensively reviewed the available literature and evidence for different LIF techniques. They proposed a set of recommendations and guidelines for the indications for interbody fusion options. In addition, these researchers provided a description of each approach, and showed the potential benefits and disadvantages of each technique with reference to indication and spine level performed.

The authors stated that disadvantages of the ALIF technique include approach-related complications such as retrograde ejaculation, visceral and vascular injury. They also noted that there were multiple limitations in this systematic review. Some studies reported ALIF and TLIF combined with posterolateral fusion, thus skewing the potential fusion results and outcomes. Furthermore, studies revealed a heterogeneous patient population, with different levels and pathologies reported that impacted radiological fusion rates and clinical outcomes; thus, the conclusions could not be made regarding the effects of different levels and pathologies on clinical outcomes. These researchers stated that ALIF, TLIF and PLIF remain the more commonly performed techniques for LIF; LLIF has established its place as a robust technique for deformity correction and interbody fusion, with OLIF requiring further studies and data to establish its place. Moreover, these researchers also stated that available data suggested that anterior techniques are superior to posterior in terms of disc height restoration, lumbar lordosis and deformity correction, and that clinical outcomes and fusion rates were similar to those in posterior techniques; however, these data were based on heterogeneous studies with multiple indications and therefore comparison was difficult to make.
Vieli et al (2019) noted that as a possible therapeutic option for chronic lower back pain (CLBP) due to single-level DDD, the efficacy of ALIF has been reviewed various times in the existing literature. However, a scarcity of data exists pertaining to ALIF procedures performed in a short-stay setting using an Enhanced Recovery after Surgery (ERAS) protocol, especially concerning the safety. These investigators examined prospectively collected data to study the safety and efficacy of short-stay ERAS ALIF in treatment of single-level DDD; VAS in both back and leg pain along with the ODI were used to collect measure outcomes. The primary end-point was a minimum clinically important difference (MCID) of greater than or equal to 30% for the ODI at 12 months. A total of 44 patients underwent surgery after failed long-term conservative treatment; MCID was achieved in 78%. Age was the only significant factor in association with MCID (p = 0.03), while gender, Modic changes, results of prognostic tests, prior surgery and smoking status had no significant influence on either MCID or change scores for any outcome measure. One complication in the form of transient new radiculopathy occurred in 1 patient (2.3%). The authors concluded that with overall positive outcomes in terms of both safety and efficacy, an ALIF procedure with subsequent implementation of an ERAS protocol in a short-stay setting could be an option for strictly selected patients with CLBP. Moreover, these researchers stated that further study, possibly with a larger sample size, is needed to validate these findings.

The authors stated that this study was largely limited by the small sample size (n = 44) and partly incomplete data, which resulted in low statistical power. Furthermore, although this was not the focus of this study, the finding pertaining to prognostic factors may be less powerful due to the low sample size, and the one statistically significant finding may have been arrived at by multiple testing. However, all data were derived from a prospective registry. All procedures were conducted in a single-center, which may have led to further bias. The results may not be applicable to all treatment groups since the subjects were already highly selected on the grounds of a positive Pantaloon Cast Test, and hence the analysis regarding patient-reported outcomes only concerned subsets of the general surgical population. In a similar manner, these findings might not be applicable to older adults, since the data-set did not include patients over the age of 62 years.

Shah et al (2019) stated that lumbar spinal stenosis is defined as narrowing of the lumbar spinal canal, which causes compression of the spinal cord and nerves. Spinal stenosis could cause leg pain and potentially back pain that can affect the QOL. Ultimately, surgical decompression is needed to alleviate the symptoms. In this review, these investigators used several important studies to compare lumbar laminectomy alone versus lumbar laminectomy and fusion. They also compared the effectiveness of more novel surgical approaches, stand-alone ALIF, and stand-alone
LLIF. These techniques have their own advantages and disadvantages in which many factors must be taken into account before choosing a surgical approach. Furthermore, the patient's anatomy and pathology, lifestyle, and desires should be analyzed to help determine the ideal surgical strategy. These researchers stated that there have not been many studies regarding stand-alone ALIF surgery for lumbar stenosis; however, since the advances in interbody cages, it has shown very promising results.

**AnchorKnot Tissue Approximation Kit for Lumbar Discectomy**

The AnchorKnot Tissue Approximation Kit (Anchor Orthopedics XT Inc., Burlington, MA) was developed to augment the existing standard of care for herniated disc repair procedures. The AnchorKnot Tissue Approximation Kit may be considered for patients undergoing herniated disc repair procedures if the surgeon identifies that the tissue is amenable to repair. This procedure may not be appropriate for all patients, and not all patients may benefit. However, there is a lack of evidence regarding the clinical effectiveness of the AnchorKnot Tissue Approximation Kit for any indication.

**DiscoGel (Intradiscal Alcohol Injection) for the Treatment of Back and Neck Pain**

de Seze et al (2013) noted that sciatica is a common disease; between 13 % and 40 % of the general population will experience at least 1 episode of sciatica due to spinal disc herniation and nerve root irritation. In some specialist centers, percutaneous intradiscal techniques can be applied as an intermediate measure between conservative treatment and surgery, with a view to avoiding the AEs associated with surgical discectomy. DiscoGel is a percutaneously implanted medical device for the treatment of lumbar sciatica due to a herniated disc. These researchers performed an open, prospective, observational study to examine if the prior use of air disc manometry could limit the risk of nerve root irritation reportedly associated with nucleolysis and administration of DiscoGel, and examine the technique's safety and efficacy. A total of 79 DiscoGel-treated patients were systematically reviewed. A nurse anesthetist examined each patient's pain levels during the procedure itself. The therapist evaluated the patient on inclusion and 8 weeks after the DiscoGel procedure. A 3rd assessment was based on a telephone interview (by an independent assessor) at least 4 months after the procedure. Pain levels immediately after the DiscoGel procedure (1.7 ± 2.0) were markedly lower than before the procedure (5.5 ± 2.3); there were no complications. Two months after DiscoGel administration, the initial pain level had fallen by an average of 74 ± 34 %. The outcome was quite stable over time (mean follow-up of 8 months). At the end of the follow-up period, 60.7 % of the patients were pain-free, 76 % considered the treatment outcome to be good or very good, 74 % had returned to work and 76 % would recommend the treatment to a friend. The authors
concluded that the favorable outcomes associated with the procedure should now be confirmed in a controlled trial.

Sayhan et al (2018) stated that radiopaque gelified ethanol (RGE; DiscoGel, Gelscom SAS, France) is used as a chemo-nucleolysis substance in treating intradiscal herniation, showing good results without complications. It has also been used in cervical disc herniations (CDHs), demonstrating the potential efficacy of this substance. In a cross-sectional, single-center study, these investigators examined the safety and long-term effectiveness of DiscoGel in patients with CDH and chronic neck pain. The trial was carried out from November 2013 to May 2016 on patients visiting Sakarya University Training and Research Hospital's pain clinic. Each patient was evaluated before the procedure (baseline) and at 1, 3, 6, and 12 months after the procedure, using the VAS score for pain, the ODI score to measure degree of disability, and estimate QOL for those with pain; this coincided with scores on the Neuropathic Pain Questionnaire (DN4) for differential diagnoses. A total of 33 patients with CDH underwent the same treatment with DiscoGel between November 2013 and May 2016. Significant pain relief was noted, as opposed to pre-operative pain, at 1, 3, 6, and 12 months after the procedure according to each patient's self-evaluation (p = 0.01). Differences in VAS, ODI, and DN4 scores between 1, 3, 6, and 12 months with the same variables were not statistically significant. There were no complications with the procedure. The authors concluded that RGE was a potential alternative to surgery for patients with pain at the cervical level. However, these researchers stated that that more studies with longer follow-up intervals with RGE are needed for assessment of the technique's efficiency. The drawbacks of this study were that this trial was conducted retrospectively, which led to problems with long-term follow-up data. Furthermore, this study was performed with a small group of patients (n = 33).

Kuhelj e al (2019) stated that percutaneous image-guided intradiscal injection of gelified ethanol was introduced to treat herniated disc disease lately. These researchers examined the clinical efficacy and durability over a 36-months period. A total of 83 patients (47 men, 36 women, mean age of 48.9 years (18 to 79 years) were treated between May 2014 and December 2015 for 16 cervical and 67 lumbar contained CDHs. For pain assessment evaluation, the VAS was used. Physical activity, the use of analgesics, patients' satisfaction with the treatment results and patient's willingness to repeat the treatment were also evaluated. A total of 59 patients responded to questionnaire; 89.8 % had significant reduction in VAS after 1 month (p < 0.001); 76.9 % of patients with cervical symptoms and 93.5 % of patients with lumbar symptoms. In the cervical group, it remained stable, while in the lumbar group, VAS decreased even more during 36 months (p = 0.012), and 1 ingle patient had spinal surgery. Moderate and severe physical disability prior to treatment (96.6 %) was reduced to less than 30 %
after 12 months. The majority of active patients returned to their regular job (71.1%); 78% needed less analgesics. Only 5.1% patients were not satisfied with the treatment and 10.2% would not repeat the treatment if needed. The authors concluded that percutaneous image-guided intradiscal injection of gelified ethanol was safe, effective and durable therapy for chronic contained cervical and lumbar herniations. Due to minimal invasiveness and long-lasting benefits, this kind of treatment should be proposed to designated group of patients as 1st-line therapy.

The author stated that the major drawback of this study was that the number of patients included, especially in cervical group was relatively low. Larger cohort might show different results. More than 1/4 of patients did not respond to questioner, so these researchers were able to follow-up only 59 patients for the designated period. Observational character of the study could also not exclude additional external parameters (such as different techniques for pain reduction including physical activity, exercises, additional or alternative analgesics, acupuncture, etc.) possibly influencing results, especially long-term VAS reduction. These investigators stated that a large, double-blinded, randomized study would be helpful in confirming these findings.

Hashemi et al (2020) noted that LBP secondary to discopathy is a common pain disorder. Multiple minimally invasive therapeutic modalities have been proposed; however, to-date no study has compared percutaneous laser disc decompression (PLDD) with intradiscal injection of DiscoGel. These investigators introduced the 1st study on patient-reported outcomes of DiscoGel versus PLDD for radiculopathy. A total of 72 patients were randomly selected from either a previous strategy of PLDD or DiscoGel, which had been performed in the authors’ center during 2016 to 2017. Subjects were asked about their NRS scores, ODI scores, and progression to secondary treatment. The mean NRS scores in the total cohort before intervention was 8.0, and was reduced to 4.3 in the DiscoGel group and 4.2 in the PLDD group after 12 months, which was statistically significant. The mean ODI score before intervention was 81.25%, which was reduced to 41.14% in the DiscoGel group and 52.86% in the PLDD group after 12 months, which was statistically significant. Between-group comparison of NRS scores after 2 follow-ups were not statistically different (p = 0.62); but the ODI score in DiscoGel was statistically lower (p = 0.001); 6 cases (16.67%) from each group reported undergoing surgery after the follow-up period, which was not statistically different. The authors concluded that both techniques were equivalent in pain reduction but DiscoGel had a greater effect on decreasing disability after 12 months, although the rate of progression to secondary treatments and/or surgery was almost equal in the 2 groups.

This study had several drawbacks. The present analysis was performed in a Persian
context, which limited the generalizability of findings since it may not be representative for other settings. Also, the lack of a comparison population for conservative therapies in the course of symptoms was another limitation for which future multi-central extensive studies with comparison groups are recommended to further document the safety, efficacy, and effectiveness of PLDD and intradiscal injection of DiscoGel in discopathies. These researchers stated that although several cohort studies have been published, to-date no study had been performed comparing PLDD with intradiscal injection of DiscoGel.

In a randomized, double-blind, clinical study, Papadopoulos et al (2020) compared 2 new techniques: intradiscal injection of DiscoGel (group D), and the combination of intradiscal PRF and DiscoGel injection (PRF+D), regarding their efficacy in discogenic LBP treatment. The final sample was randomized into group A (n = 18, D) and group B (n = 18, PRF+D). During the procedure, 4 patients from group B were excluded from the study. Groups A and B were assessed regarding the pain score (VAS; 0 to 10), before the interventional procedures, and 1, 3, 6, and 12 months after. Secondary objectives of the study were to compare the 2 groups regarding the results of the Roland Morris Disability Questionnaire, Lanss score, and QOL score (EQ-5D). There was no significant evidence for an overall difference in pain score between the 2 groups (analysis of variance, F = 3.24, df = 1, p = 0.084), except for the 6th and 12th months, when group B presented a statistically important difference compared with group A (Wilcoxon test). Group B appeared to be more effective, with a statistically significant difference, compared with group A regarding the secondary objectives of the study. The authors concluded that after rigorous and comprehensive assessment by an independent observer, both Discogel alone and Discogel in combination with PRF produced tangible improvements in pain, function, QOL, and consumption of analgesics, which were sustained at 12 months. The drawbacks of this study were its small sample size (n = 18 in group A and n = 14 in group B), and it relatively short-term follow-up (12 months).

**SpineJack System**

Noriega et al (2016) stated that in patients with osteoporotic vertebral compression fractures (OVCFs), both SpineJack (SJ) and balloon kyphoplasty (BKP) led to a rapid and marked improvement in clinical signs. In a prospective, mono-centric, investigator-initiated, pilot study, these investigators compared 2 percutaneous vertebral augmentation procedures (SpineJack and Kyphx Xpander balloon) in the treatment of OVCF. A total of 30 patients were randomized to receive SJ (n = 15) or BKP (n = 15). Analgesic consumption, back pain intensity (VAS and ODI) scores were recorded pre-operatively, at 5 days and 1, 3, 6, and 12 months post-surgery; QOL (EQ-VAS score) was evaluated at 1, 3, 6, and 12 months. Spine X-rays were performed 48 hours prior to
procedure and 5 days, 6, and 12 months post-treatment. SpineJack resulted in a significantly shorter intervention period (23 mins versus 32 mins; p < 0.001), a strong, rapid, and long-lasting decline in pain (94 % versus 82 % at 12 months) and in functional disability (94 % versus 90 % at 12 months), a greater and sustainable mean correction of anterior (12 ± 13 % versus 0 ± 7 % for BKP, p = 0.003) and central height (12 ± 10 % versus 2 ± 6 % for BKP, p = 0.001) at 12 months, and a larger restoration of the vertebral body angle still evident 12 months after implantation (-4.4° ± 5.8° versus 0.2° ± 3.0° for BKP; p = 0.012). The authors concluded that the findings of this pilot study showed that both techniques were safe and efficient for the treatment of OVCF. Radiological results indicated that the SpineJack procedure had a higher potential for vertebral body height restoration and maintenance over time.

Jacobson (2020) presented a case of short-term symptomatic failure with continued vertebral collapse after a T12 kyphoplasty for an acute fracture in a severely osteoporotic elderly patient. The original trajectory of the unilateral balloon and subsequently injected bone cement failed to fill the fracture, allowing further vertebral collapse that resulted in a rapid return of pain. Within 30 days, a titanium intravertebral body implant, SpineJack (Stryker Corp, Kalamazoo, MI), combined with injection of polymethylmethacrylate (PMMA) bone cement, was placed in the collapsed area. This provided both sagittal and coronal partial correction of the collapse, fuller distribution of bone cement throughout the fractured vertebrae, and rapid reduction of pain, which was found to have been maintained at the long-term follow-up. The author reviewed the technical issues causing failure of vertebral augmentation (VA) as well as the advantage of providing a permanent internal scaffolding to ensure stabilization of any fracture, especially where there is a high risk for progressive instability, such as the thoracic-lumbar junction. This was a single-case study; its findings need to be validated by well-designed studies.

Long et al (2020) noted that OVCF is a common cause of pain and disability and is steadily increasing due to the growth of the elderly population. To-date, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are almost universally accepted as appropriate vertebral augmentation procedures for OVCFs. There are many advantages of vertebral augmentation, such as short surgical time, performance under local anesthesia, and rapid pain relief; however, there are certain issues regarding the utilization of these vertebral augmentations, such as loss of vertebral height, cement leakage, and adjacent vertebral refracture. Hence, the treatment for OVCF has changed in recent years. Satisfactory clinical results have been obtained worldwide after application of the OsseoFix System, the SJ System, radiofrequency kyphoplasty (RFK) of the vertebral body, and the Kiva VCF treatment system. The authors stated that considering the short-term follow-up, the results and function of the SJ system need to
be studied in a larger series, and future studies should focus on long-term clinical and radiological outcomes.

Chang et al (2021) stated that VP, KP, SJ, RFK, Kiva system (Kiva), Sky kyphoplasty system (SK), and conservative treatment are widely used in the treatment of OVCFs; however, it is still unclear which approach is the best intervention. These researchers examined the safety and effectiveness of VP, KP, SJ, RFK, Kiva, SK, and CT in the treatment of OVCFs; RCTs and cohort studies comparing VP, KP, SJ, RFK, Kiva, SK, or CT for the treatment of OVCFs were identified on the basis of data-bases including PubMed, the Cochrane Library, Web of Science, and Springer Link. A network meta-analysis was carried out using STATA 15.1. A total of 56 studies with 6,974 patients and 7 interventions were included in this study. The results of the surface under the cumulative probability demonstrated that SK was the best intervention in decreasing VAS scores and recovering middle vertebral height; RFK was the best intervention in improving ODI scores and decreasing incidence of new fractures; SJ was the best intervention to restore kyphosis angle; and Kiva was the best intervention to reduce incidence of bone cement leakage. Cluster analysis showed that SK was the preferable intervention based on the outcomes of VAS, ODI, middle vertebral height, and kyphotic angle, and RFK was the preferable treatment in decreasing the incidence of AEs. In this network meta-analysis, node-splitting analysis and loop inconsistency analysis showed no significant inconsistencies. The authors concluded that SK may be the most effective treatment in relieving pain, improving the QOL, and recovering vertebral body height and kyphotic angle, while RFK may be the safest intervention for OVCFs. However, considering the limitations of this study, more high-quality trials are needed in the future to confirm the current conclusion.

**Tendon Sheath injections for the Treatment of Back Pain**

Cho et al (2019) noted that calcific tendinitis is commonly found in the rotator cuff; however, it is very rare in the long biceps tendon (LBT). Furthermore, calcific tendinitis involving the LBT in the hemiplegic shoulder after a stroke has not been previously reported. These researchers presented the case of a 63-year old man who suffered from a stroke and atypical calcific tendinitis involving the LBT as a rare cause of hemiplegic shoulder pain. The patient had experienced intractable pain in the right hemiplegic shoulder for more than 6 months with a waxing and waning course. Marked tenderness to palpation was present at the biceps tendon adjacent to the bicipital groove. Ultrasound (US) and computed tomography (CT) revealed a long, blade-shaped, circumscribed, cloudy and irregular dense calcific deposit in the LBT site, distal to the bicipital groove. The patient underwent US-guided corticosteroid injection at the posterior intra-articular joint. Symptoms failed to resolve; these investigators injected
an additional corticosteroid into the biceps tendon sheath adjacent to the calcific deposit. This procedure provided satisfactory relief, and follow-up US revealed mild diminution of the calcification through absorption. The authors concluded that this was the 1st report on atypical calcific tendinitis involving the LBT causing hemiplegic shoulder pain following a stroke.

Furthermore, an UpToDate review on “Subacute and chronic low back pain: Nonsurgical interventional treatment” (Chou, 2020) does not mention tendon sheath injection as a therapeutic option.

**Appendix**

**Oswestry Disability Index** opens a dialog
**Numeric Rating Scale (NRS)** opens a dialog

**Provocative tests of the sacroiliac region**

Provocative tests of the sacroiliac region are thought to indicate sacroiliac joint dysfunction when at least 3 different tests reproduce the patient’s typical pain in the SI region, including:

- **Compression test**, also called the approximation test, stresses the SI joint structures, in particular the posterior SI joint ligament, to attempt to replicate the patient’s symptoms.
- **Thigh thrust test** involves the examiner applying downward pressure along the femur with the patient supine. Pain at the ilium or SI joint suggests SI joint dysfunction.
- **Patrick’s sign** is also referred to as the Fabere test. The examiner flexes, abducts, externally rotates, and extends the affected leg so that the ankle of that leg is on top of the opposite knee (a figure of 4 configuration). The affected leg is then slowly lowered toward the examining table. A negative result occurs when the test leg falls at least parallel to the opposite leg. A positive test result occurs when the affected leg remains above the opposite leg and pain arises unilaterally in the active hip.
- **Distraction test**, also known as the gaping test, is positive for pain sacroiliac joint dysfunction or other pelvic abnormalities when downward pressure is applied simultaneously to the iliac crest when the patient is in supine position.
- **Gaenslen’s test** is accomplished with the patient supine. One hip is flexed by pushing the patient’s knee to their chest, while simultaneously extending the opposite hip
joint. This maneuver stresses both sacroiliac joints. Posterior pelvic pain indicates a positive test.

**Noncovered Interspinous Fixation Devices (considered experimental and investigational; not an all-inclusive list)**

- Affix II and Affix II Mini Spinous Process Plating System (NuVasive)
- Aileron Interspinous Fixation System (Life Spine)
- Aspen MIS Fusion System (Biomet)
- Aspen Spinosus Process Fixation System (Lanx)
- Axle (X-Spine)
- BacFuse (Pioneer Surgical)
- Benefix Interspinous Fixation System
- Biomet Aspen fusion system
- BridgePoint (Alphatec)
- CD Horizon Spire Fixation System (Medtronic Sofamor Danek)
- Coflex-F (Paradigm Spine)
- Inspan (Spine Frontier)
- Minuteman Interspinous Interlaminar Fusion Device (Spinal Simplicity)
- PrimaLOK SP (OsteoMed)
- Octave (Life Spine)
- StabiLink MIS Interspinous Fixation Device (Southern Spine)
- SP-Fix Spinous Process Fixation System (Globus Medical)

**Noncovered Interspinous and Interlaminar Distraction Devices (considered experimental and investigational; not an all-inclusive list)**

- Aperius PercLID System (Kyphon/ Medtronic Spine)
- Coflex Interlaminar Technology Implant (Paradigm Spine)
- CoRoent Extensure (Nuvasive)
- DIAM Spinal Stabilization System (Medtronic Sofamor Danek)
- ExtenSure (Nuvasive)
- FLEXUS (Globus Medical)
- Falena Interspinous Decompression Device (Mikai Spine)
- Helifix Interspinous Spacer System (Alphatec Spine)
- In-Space (Synthes)
- NL-Prow Interspinous Spacer (Non-Linear Technologies)
- Stenofix (Synthes)
- Superion ISS Interspinous Spacer System (VertiFlex)
- Wallis System (Abbott Spine/ Zimmer Spine)
- X-STOP Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)
- X-STOP PEEK Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)

**Spine Cages (Not an all-inclusive list) (considered medically necessary when criteria are met)**

- A-CIFT SoloFuse (SpineFrontier)
- ACIS cage (Synthes)
- Acromed Lumbar I/F Cage (Depuy)
- Aero AL (Stryker)
- Aero C (Stryker)
- Aesculap PEEK
- Alamo Spine Cage (Alliance Spine)
- Aleutian Spacer System (K2M)
- ALIF Spine Truss System (4web)
- Alphatec Novel TL Spacer System
- Anatomic PEEK PTC cervical fusion system (Medtronic)
- Ancora spacer (Zimmer)
- AnyPlus PEEK TLIF (GS Medical)
- Apache spacer (Genesys)
- Arch ODL spacer (Synthes)
- Arena-C (SpineFrontier)
- Ascential (Stryker)
- Athlet (Signus)
- Avenue-L (Zimmer Biomet)
- AVS Anchor-L Lumbar Cage System (Stryker)
- AVS AS PEEK (Stryker)
- AVS Navigator (Stryker)
- AVS PL PEEK (Stryker)
- BAK Interbody Fusion System (Zimmer)
- Bengal Corpectomy Cage (Depuy)
- BoneBac Interbody System (Thompson MIS)
- Brantigan (DePuy)
- Brigade (Nuvasive)
- Bullet-Tip PEEK VBR/IBF (RTI Surgical)
- CALIX cage (X-Spine)
- Cambria anterior cervical interbody system (Integra/Theken Spine)
- Capstone PEEK Cage (Medtronic)
- Cascadia TL implant system (K2M)
- Cavetto cage (Neurostructures)
- Cezanne II (Accel Spine)
- Chesapeake Spinal System (K2M)
- Cimplicity (SpineSmith)
- Clariance TLIF cage
- Clydesdale (Medtronic)
- Co Roent XL (Nuvasive)
- Coalition Spacer (Globus)
- Concorde Bullet Spine System (DePuy Synthes)
- Construx Mini PTC Spacer System (Orthofix)
- Continental (Globus)
- Corelink Anterior Cervical Interbody Cage System (Foundation)
- Cornerstone PSR Spinal System (Medtronic)
- CoRoent Interbody Cage (Nuvasive)
- Cougar Cage System (Depuy)
- Coveris (Camber)
- C-Plus IBF (Pioneer Surgical\RTI Surgical)
- Crescent cage (Medtronic)
- Devex TLIF Cage (DePuy)
- Dorado (Spine Frontier)
- Ebi PEEK optima spacer (Biomet)
- Emerald cervical PEEK system (Glasir)
- Eminent Sidewinder DLIF PEEK Cage
- Endoskeleton TCS (Titan Spine)
- Express IBFD (Advanced Vertebral Solutions)
- Foundation Cervical Interbody Device (CoreLink)
- Fuse (Medtronic)
- FuseLox Lumbar Cage (Captiva Spine)
- Harpoon, Hawkeye, Hornet, Shark (ChoiceSpine)
- Honour cage (Nexxt Spine)
- Honour Orb (Nexxt Spine)
- IN:C2 spacer (SpineSmith)
- InFill Lateral Interbody Device (Pinnacle Spine)
- Innovasis Box PEEK IBF System
- Innovasis C-Box PEEK cage
- Interfuse - T (Vertebral Technologies)
- Irix-C (X Spine)
- Juliet TL Lumbar Interbody Fusion Device (Spineart)
- LANX Lateral Cage
- LDR ROI-A Implant System
- Leopard (DuPuy)
- Levo fixed cage (non-expandable) (Alphatec Spine)
- LLC Reveal VBR System (Theken)
- Lucent Magnum (Spinal Elements)
- Lucent TiBond Interbody System (Spinal Elements)
- Luna Interbody Fusion System (Benvenue)
- Magnum + Stand-alone Lumbar Interbody Fusion system (Spinal Elements)
- Maxim Surgical X-Treme interbody fusion system
- MectaLIF transforaminal lumbar interbody fusion device (Genesys)
- Medyssey BN
- NanoLOC (Titan)
- Nanovis cage
- Novel Spinal System (Alphatec Spine)
- OLIF PEEK (Medtronic)
- OLIF 51 (Medtronic)
- Orio-AL, Orio-C, Orio-PL, Orio-TL (SpineCraft)
- Osteofix Pillar (AL, SA, PL, TL)
- OsteoStim (Biomet)
- Pathway AVID (Custom Spine)
- Pillar SA PEEK Spacer (Orthofix)
- Pioneer Interbody Fusion (IBF)/Vertebral Body Replacement System (C-Plus)
- Precision Vault ALIF System (Precision Spine)
- Prevail Interbody Device (Medtronic)
- PRO-LINK Stand-Alone Cervical Spacer System (Life Spine)
- Pulse cervical cage system (DePuy)
- Ravine (K2M)
- Ray Threaded Fusion Cage (Synthes)
- Renovis PEEK ALIF Cage
- ROI-C (LDR)
- Scarlet AC-T Secured Anterior Cervical Cage (SpineArt)
- Silverstone IBF System (Altus Spine)
- Solitaire C Cervical Spacer System (Biomet)
- Spine 360 plate & cage for cervical fusion
- Spine 360 Cervical Interbody Fusion System
- Spine Vu c-POD Intervertebral Body Fusion Device (Integra\Theken)
- Stalif-C (Cervical Cage) (Centinel Spine)
- Stalif Midline and Stalif Midline ABO Screws (Centinel Spine)
- Stingray (Spine 360)
- Surgical Titanium Mesh (Depuy)
- Sustain-O (Globus)
- Syncage (Synthes)
- SYNFIX LR system (Synthes)
- T-Pal (Synthes)
- Timberline Cage (Lanx)
- TiNano (Aurora Spine)
- TiLink-T (Acuity Surgical)
- Titanium PL cage (Stryker)
- Tomcat (Choice Spine)
- Transcontinental (Globus)
- Tryptik CA (Spineart)
- Valeo C (Amedica)
- Valeo II LL (Amedica)
- Vault ALIF system (Precision Spine)
- Velofix (U & I Corporation)
- Vertigraft (Lifenet)
- Vertu TiBond PEEK cage
- Vu POD (Integra\Theken)
- XP L Spinal System (Arcadius)
- Zavation PEEK cage
- Zero-P Zero-Profile Anterior Cervical Interbody Fusion Device (Synthes)
- Zeus A (Amendia)
- Zeus C cervical spacer (Amendia)
- Zeus L (Amendia)
- Zeus T (Amendia)
- Zimmer TM-S cervical fusion device
- Zyston Curved Spacer System (Biomet)
- Zyston Straight Spacer System (Biomet)

**Expandable Spine Cages (considered medically necessary when criteria for expandable cages are met; not an all-inclusive list)**

- Acculif Expandable Cage (Stryker)
- Bengal Stackable (DePuy Synthes)
- Elevate Expandable Cage (Medtronic)
- Globus Altera Expandable Cage
- Globus Caliber Expandable Cage
- Globus Fortify Corpectomy Spacer
- Globus Latis Expandable Cage
- Globus Magnify
- Globus Magnify S
- Globus Rise
- Leva Expandable Cage (Spine Wave, Inc)
- Nuvasive X-Core Expandable Cage
- Omni VBR Expandable cage (Ulrich)
- Per 360 expandable cage (Interventional Spine)
- Staxx XD Expandable Cage (Spine Wave, Inc)
- Ulrich ADDPlus
- Wenzel Spine Varilift Expandable Cage

**Pedicle Screw Systems (considered medically necessary when criteria are met) (not an all-inclusive list)**

- ABC Cervical Plating System (Aesculap)
- Accufit ALIF plate (Precision Spine)
- AcuFx Thinline (Zimmer)
- Aesculap S4
- Alphatec ASPIDA anterior lumbar plating system
- Altus Cervical Spine Plate System
- Anax (U & I Corporation)
- Antegra plate (Synthes)
- Anterior cervical stabilization system (Southern Spine)
- Anterior tension band (ATB) (Synthes)
- Apelo (Atlas Spine)
- Apex Deformity Spine System (SpineCraft)
- Arch ODL Fixation System (Synthes)
- Arsenal (Alphatec Spine)
- Archon Anterior Cervical Plate System (NuVasive)
- Armada Spinal System (NuVasive)
- Aspect Plate and Screws (Pioneer Surgical)
- Assure (Globus)
- Astra Spine System (SpineCraft)
- Athena (Royal Oak Medical)
- Atlantis Translational Plate for Cervical Fusion (Medtronic)
- Aviator Anterior Cervical plating system (Stryker)
- Balboa plate (SeaSpine)
- Binary plates and screws (Genesys spine)
- Biomet MaxAn Cervical Plate System
- Blackbird spinal system (Choice Spine)
- Blueridge Cervical Plate and Screws (K2M)
- Brigade anterior plate system (NuVasive)
- Cabo (SeaSpine)
- Caplox II Spinal System (non-cervical) (Captiva Spine)
- CapSure PS3 Spine System (Spine Wave, Inc)
- Cayman KZ plate (Signus)
- CD Horizon Legacy Spinal System (Medtronic)
- CD Horizon Spine Fixation System (Medtronic)
- Centerpiece plate (Medtronic)
- Cequence anterior cervical plate (Pioneer Surgical)
- CerviFix Cervical Spine Locking Plate (CSLP) (Synthes)
- Click'X pedicle screw system (Synthes)
- Coral Spinal System (Integra\Theken)
- Corelink Tiger pedicle screws
- CREO system (Globus)
- Decade plate (NuVasive)
- Degas plate (Accel Spine)
- Denali Degenerative Spine System (K2M)
- Diamond (Amendia)
- Dio Medical Rex Anterior Cervical Plate System
- DynaTran anterior cervical plate (Stryker)
- Eagle plate (DePuy)
- Ellipse Occipito-Cervical-Thoracic spinal system (Globus)
- EOS spinal system (Korean Bone Bank)
- Erisma - LP (Clariance)
- Everest Pedicle Screw Spinal System (K2M)
- Excella (Innovasis)
- Expedium Verse System (DePuy Synthes)
- Express pedicle screw and rod system (X-Spine)
- Firebird (Orthofix)
- Flamenco (Ulrich)
- Fortress Pedicle Screw System (Spineology)
- Fortex pedicle screw (X-spine)
- Fortibridge plate (Nanovis)
- G surgical plate system T LOC
- Genesis TiLock
- Globus XTEND plate
- Gruve (Life Spine)
- Hallmark plate for cervical fusion (Orthofix)
- Hyper-C (DenGen)
- Iliad spinal thoracolumbar system (Medyssey)
- Illico pedicle screw system (Alphatec)
- Invizia plate (Zimmer)
- Invue plate (SpineFrontier)
- Iris anterior cervical plate (Life Spine)
- Kinetic-SL Dynamic Anterior Cervical Plate System (Life Spine)
- King Cobra Anterior Cervical Plate (Eminent Spine)
- Lanx Pedicle Screw Spinal System
- Leucadia (Phygen LLC)
- Lineum OCT spine system (Biomet)
- Lnk thoraco-lumbar pedicle screw system (Aegis)
- Lotus System (Spinal Elements)
- Malibu (SeaSpine)
- Mambo plate (Ulrich)
- Manta Ray Anterior Cervical Plate System (Theken Spine)
- Mantis (Stryker)
- Medical Mesa System (K2M)
- Medical N Cervical Plate System (Sharp Medical Spine)
- Medyssey Zenius spinal system
- Mercury Spine Element screw and rod system (Spinal Elements)
- MonoPoly Pedicle Screw System (Signus)
- Mosaic System (Spinal Elements)
- Mountaineer OCT Spinal System (DePuy)
- MUST pedicle screw sytem (Medacta)
- Nautilus Thoracolumbar Spinal System (Life Spine)
- NEO SL (Life Spine)
- Newport MIS system (Integra\Thesen)
- Nex-Link rods and screws (Zimmer)
- Ni-lock (Spine Wave, Inc)
- Osteonics Techtonix System (Stryker)
- Optio-C Anterior Cervical Plate (Zimmer)
- Pagoda (Odev)
- Palisade (Spineology)
- Pathfinder NXT Sequoia Pedicle Screw (Zimmer)
- Pedfuse pedicle screw system (SpineFrontier)
- Perpos pedicle screws (i-Spine)
- Phoenix Minimally Invasive Spinal Fixation System (Orthofix)
- Pioneer Posterior Occipito-Cervico-Thoracic (OCT) System
- Polaris 5.5 (Biomet)
- Polyaxial spinal system (Zimmer)
- Precept Spinal System (NuVasive)
- Preference Pedicle Screw System (Amedica)
- Proliant Polyaxial Pedicle Screw System (Exactech)
- Quantum (RTI Surgical)
- Quintex anterior plating system (Aesculap)
- Reflex Hybrid Anterior Cervical Plate System (Stryker)
- Reform (Precision Spine)
- Reliance Screw System (Reliance Medical Systems)
- ReSet (SpineFrontier)
- ReSpond (SpineFrontier)
- ReTurn (SpineFrontier)
- Revere stabilization system (Globus)
- Revolve Pedicle Screw (Globus)
- Rhausler anterior cervical plate system
- Romeo MIS (Spineart)
- Santis Hybrid Pedicle Screw System (Lanterna Medical Technologies)
- Sapphire Anterior Cervical Plate System (Spinal Elements)
- Savannah High Top (Amendia)
- Sintea Plustek's Posterior Lumbar System Pedicle Screws
- Skyline (DePuy)
- Sniper screws (Spine Wave, Inc)
- Snowcap anterior cervical plate (Biomet)
- Solera screws (Medtronic)
- SpheRx DBR H (NuVasive)
- Spider Cervical Plating System
- Spinal USA Simplicity Solo (X-Spine)
- Spine 360 Talon Pedicle screw system
- Spine ST360 (Zimmer)
- Spire Z (Medtronic)
- Starfire (ChoiceSpine)
- Streamline TL (RTI Surgical)
- Struxxure plate (Nexxt Spine)
- SureLOK PC Posterior Cervical System (Precision Spine)
- Swift Anterior Cervical Plate System (DePuy)
- Synapse (Synthes)
- Tempus Cervical Plate system (Neurostructures)
- Timberline Plate (Bioment)
- Trestle Anterior Cervical Plating System (Alphatec)
- Trinica Anterior Cervical Plate (Zimmer)
- TSRH 3DX pedicle screws (Medtronic)
- Typhoon (ChoiceSpine)
- Uniplate 2 (DePuy)
- Valencia Pedicle Screws (Altus)
- Valiant ALIF plate system (Biomet)
- Van Gogh plate (CTL Medical)
- Vectra (Synthes)
- Venus Facet Screw System (Apollo Spine)
- Vertex Reconstruction System (Medtronic)
- Viper Screws (DePuy)
- Virage system (Zimmer)
- Vitality (Zimmer)
- VuePoint OCT System (NuVasive)
- XIA 3 (Stryker)
- XIA 4.5 (Stryker)
- Zavation Pedicle Screw System
- Zavation cervical plate
- Zevo anterior cervical plate system (Medtronic)
- Zodiac Posterior screws (Alphatec)
- Zou plate (Corelink).

**Table: CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coccygectomy:</strong></td>
<td></td>
</tr>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
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<tr>
<td>27080</td>
<td>Coccygectomy, primary</td>
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<tr>
<td>ICD-10 codes covered if selection criteria are met:</td>
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<tr>
<td>M53.3</td>
<td>Sacroccygeal disorders, not elsewhere classified [for individuals with coccygodynia who have tried and failed to respond to 6 months of conservative management]</td>
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<tr>
<td><strong>Facet joint injections [not covered for intradiscal and/or paravertebral oxygen/ozone injection]:</strong></td>
<td></td>
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<tr>
<td>CPT codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>64490</td>
<td>Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level</td>
</tr>
<tr>
<td>64491</td>
<td>second level</td>
</tr>
</tbody>
</table>
### Table: CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+";

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tr>
<td>64492</td>
<td>third and any additional level(s) level</td>
</tr>
<tr>
<td>64493</td>
<td>Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level</td>
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<tr>
<td>64494</td>
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<tr>
<td>64495</td>
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</table>

**CPT codes not covered for indications listed in the CPB:**

<table>
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<th>Code Description</th>
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<tbody>
<tr>
<td>0213T</td>
<td>Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level</td>
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<tr>
<td>+ 0214T</td>
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</tr>
<tr>
<td>+ 0215T</td>
<td>third and any additional level(s)</td>
</tr>
<tr>
<td>0216T</td>
<td>Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level</td>
</tr>
<tr>
<td>+ 0217T</td>
<td>second level</td>
</tr>
<tr>
<td>+ 0218T</td>
<td>third and any additional level(s)</td>
</tr>
</tbody>
</table>

**Other CPT codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>72275</td>
<td>Epidurography, radiological supervision and interpretation</td>
</tr>
<tr>
<td>76942</td>
<td>Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation</td>
</tr>
<tr>
<td>77002</td>
<td>Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)</td>
</tr>
<tr>
<td>77021</td>
<td>Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0702</td>
<td>Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg</td>
</tr>
<tr>
<td>J1020</td>
<td>Injection, methylprednisolone acetate, 20 mg</td>
</tr>
<tr>
<td>J1030</td>
<td>Injection, methylprednisolone acetate, 40 mg</td>
</tr>
<tr>
<td>J1040</td>
<td>Injection, methylprednisolone acetate, 80 mg</td>
</tr>
</tbody>
</table>
Table: CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1094</td>
<td>Injection, dexamethasone acetate, 1 mg</td>
</tr>
<tr>
<td>J1100</td>
<td>Injection, dexamethasone sodium phosphate, 1mg</td>
</tr>
<tr>
<td>J1700</td>
<td>Injection, hydrocortisone acetate, up to 25 mg</td>
</tr>
<tr>
<td>J1710</td>
<td>Injection, hydrocortisone sodium phosphate, up to 50 mg</td>
</tr>
<tr>
<td>J1720</td>
<td>Injection, hydrocortisone sodium succinate, up to 100 mg</td>
</tr>
<tr>
<td>J2650</td>
<td>Injection, prednisolone acetate, up to 1 ml</td>
</tr>
<tr>
<td>J2920</td>
<td>Injection, methylprednisolone sodium succinate, up to 40 mg</td>
</tr>
<tr>
<td>J2930</td>
<td>Injection, methylprednisolone sodium succinate, up to 125 mg</td>
</tr>
<tr>
<td>J3300</td>
<td>Injection, triamcinolone acetonide, preservative free, 1 mg</td>
</tr>
<tr>
<td>J3301</td>
<td>Injection, triamcinolone acetonide, not otherwise specified, 10 mg</td>
</tr>
<tr>
<td>J3302</td>
<td>Injection, triamcinolone diacetate, per 5mg</td>
</tr>
<tr>
<td>J3303</td>
<td>Injection, triamcinolone hexacetonide, per 5mg</td>
</tr>
<tr>
<td>• Q9951, Q9958 - Q9967</td>
<td>High and low osmolar contrast material</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

- M53.0 - M53.1  Cervicocranial - cervicobrachial syndrome
- M53.81 - M53.83 Other specified dorsopathies [cervical region]
- M54.2  Cervicalgia
- M54.6  Pain in thoracic spine
- M54.30 - M54.5  Sciatica and lumbago
- M54.9  Dorsalgia, unspecified [backache]

ICD-10 codes not covered for indications listed in the CPB:

- C41.2  Malignant neoplasm of vertebral column
- C41.4  Malignant neoplasm of pelvic bones, sacrum and coccyx
- C79.51  Secondary malignant neoplasm of bone [vertebral column]
- D16.6  Benign neoplasm of vertebral column
- D16.8  Benign neoplasm of pelvic bones, sacrum and coccyx
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D48.0</td>
<td>Neoplasm of uncertain behavior of bone and articular cartilage [vertebral column]</td>
</tr>
<tr>
<td>D49.2</td>
<td>Neoplasm of unspecified behavior of bone, soft tissue, and skin [vertebral column]</td>
</tr>
<tr>
<td>M46.20 - M46.28</td>
<td>Osteomyelitis of vertebra</td>
</tr>
<tr>
<td>M46.30 - M46.39</td>
<td>Infection of intervertebral disc (pyogenic)</td>
</tr>
<tr>
<td>M80.08xA - M80.08xS</td>
<td>Age-related osteoporosis with current pathological fracture, vertebra(e)</td>
</tr>
<tr>
<td>M80.88xA - M80.88xS</td>
<td>Other osteoporosis with current pathological fracture, vertebra(e)</td>
</tr>
<tr>
<td>M84.38xA - M84.38xS</td>
<td>Stress fracture, other site [vertebrae]</td>
</tr>
<tr>
<td>M84.48xA - M84.48xS</td>
<td>Pathological fracture, other site [vertebrae]</td>
</tr>
<tr>
<td>M84.58xA - M84.58xS</td>
<td>Pathological fracture in neoplastic disease, other specified site [vertebrae]</td>
</tr>
<tr>
<td>M84.68xA - M84.68xS</td>
<td>Pathological fracture in other disease, other site [vertebrae]</td>
</tr>
<tr>
<td>S12.000A - S12.9xxS</td>
<td>Fracture of cervical vertebra and other parts of neck</td>
</tr>
<tr>
<td>S22.000A - S22.089S</td>
<td>Fracture of thoracic vertebra</td>
</tr>
<tr>
<td>S32.000A - S32.059S</td>
<td>Fracture of lumbar vertebra</td>
</tr>
<tr>
<td>S32.10xA - S32.19xS</td>
<td>Fracture of sacrum</td>
</tr>
</tbody>
</table>

**Ganglion Nerve Block:**

CPT codes not covered for indications listed in the CPB:

64450  | Injection, anesthetic agent; other peripheral nerve or branch [coccygeal ganglion (ganglion impar) block]

ICD-10 codes not covered for indications listed in the CPB:

M53.3  | Sacrococcygeal disorders, not elsewhere classified [coccygodynia]

**Trigger point Injections:**

CPT codes covered if selection criteria are met:

20552  | Injection(s); single or multiple trigger point(s), 1 or 2 muscles(s) [no repeats more than every 7 days, up to four sets to diagnose and achieve therapeutic effect, no additional sets if no clinical response, once diagnosed and therapeutic effect achieved, no repeats more than once every two months and beyond 12 months requires clinical review]
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20553</td>
<td>single or multiple trigger point(s), 3 or more muscles(s) [no repeats more than every 7 days, up to four sets to diagnose and achieve therapeutic effect, no additional sets if no clinical response, once diagnosed and therapeutic effect achieved, no repeats more than once every two months and beyond 12 months requires clinical review]</td>
</tr>
<tr>
<td>76942</td>
<td>Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation</td>
</tr>
<tr>
<td>95873</td>
<td>Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95874</td>
<td>Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>20560</td>
<td>Needle insertion(s) without injection(s); 1 or 2 muscle(s)</td>
</tr>
<tr>
<td>20561</td>
<td>3 or more muscles</td>
</tr>
<tr>
<td>77002</td>
<td>Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)</td>
</tr>
<tr>
<td>77021</td>
<td>Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation</td>
</tr>
<tr>
<td>97001 - 97139</td>
<td>Physical medicine and rehabilitation modalities and therapeutic procedures</td>
</tr>
</tbody>
</table>

Other HCPCS codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0200 - E0239</td>
<td>Heat/cold application</td>
</tr>
<tr>
<td>S9117</td>
<td>Back school, per visit</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M54.5</td>
<td>Low back pain</td>
</tr>
<tr>
<td>M79.10 - M79.10</td>
<td>Myalgia</td>
</tr>
</tbody>
</table>

**Sacroiliac joint injections:**

CPT codes covered if selection criteria are met:
### CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27096</td>
<td>Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid [up to two injections to diagnose and achieve therapeutic effect, no repeats more than once every 7 days, no additional injections more once every two months or beyond 12 months]</td>
</tr>
<tr>
<td>64451</td>
<td>Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)</td>
</tr>
</tbody>
</table>

**CPT codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>76942</td>
<td>Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation</td>
</tr>
</tbody>
</table>

**Other CPT codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77003</td>
<td>Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, subarachnoid or sacroiliac joint), including neurolytic agent destruction</td>
</tr>
</tbody>
</table>

**HCPCS codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0260</td>
<td>Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0259</td>
<td>Injection procedure for sacroiliac joint; arthrography</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M54.30 - M54.5</td>
<td>Sciatica and lumbago [more than 3 months duration and part of a comprehensive pain management program, including physical therapy, patient education, psychosocial support, and oral medication where appropriate]</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M43.16</td>
<td>Spondylolisthesis, lumbar region</td>
</tr>
<tr>
<td>M47.896</td>
<td>Other spondylosis, lumbar region [lumbar facet degeneration]</td>
</tr>
<tr>
<td>M48.061 - M48.062</td>
<td>Spinal stenosis, lumbar region</td>
</tr>
<tr>
<td>M51.26</td>
<td>Other intervertebral disc displacement, lumbar region</td>
</tr>
<tr>
<td>M51.36</td>
<td>Other intervertebral disc degeneration, lumbar region</td>
</tr>
<tr>
<td>S32.000A - S32.059S</td>
<td>Fracture of lumbar vertebra</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>62320</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance</td>
</tr>
<tr>
<td>62321</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)</td>
</tr>
<tr>
<td>62322</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance</td>
</tr>
<tr>
<td>62323</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)</td>
</tr>
<tr>
<td>62324</td>
<td>Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance</td>
</tr>
<tr>
<td>62325</td>
<td>Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)</td>
</tr>
<tr>
<td>62326</td>
<td>Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances,</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>62327</td>
<td>interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance</td>
</tr>
<tr>
<td>64479</td>
<td>Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)</td>
</tr>
<tr>
<td>+64480</td>
<td>each additional level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>64483</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level</td>
</tr>
<tr>
<td>+64484</td>
<td>each additional level (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**Other CPT codes related to the CPB:**

- **72275** Epidurography, radiological supervision and interpretation
- **97161-97168** Physical therapy evaluations

**Other HCPCS codes related to the CPB:**

- **J1020** Injection, methylprednisone acetate, 20 mg
- **J1030** Injection, methylprednisone acetate, 40 mg
- **J1040** Injection, methylprednisone acetate, 80 mg

**ICD-10 codes covered if selection criteria are met:**

- **M47.20 - M47.28** Other spondylosis with radiculopathy
- **M50.10 - M50.13** Cervical disc disorder with radiculopathy
- **M51.14 - M51.17** Intervertebral disc disorders with radiculopathy
- **M53.0 - M53.1** Cervicocranial - cervicobrachial syndrome
- **M53.81 - M53.83** Other specified dorsopathies [cervical region]
- **M54.10 - M54.18** Radiculopathy
- **M54.2** Cervicalgia
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M54.30 - M54.5</td>
<td>Sciatica and lumbago</td>
</tr>
<tr>
<td>M54.6</td>
<td>Pain in thoracic spine</td>
</tr>
<tr>
<td>M54.9</td>
<td>Dorsalgia, unspecified</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:
- C41.2: Malignant neoplasm of vertebral column
- C41.4: Malignant neoplasm of pelvic bones, sacrum, and coccyx
- C70.1: Malignant neoplasm of spinal meninges
- C72.0: Malignant neoplasm of spinal cord
- C79.31: Secondary malignant neoplasm of brain
- C79.49: Secondary malignant neoplasm of other parts of nervous system [includes spinal cord]
- C79.51 - C79.52: Secondary malignant neoplasm of bone and bone marrow
- D16.6: Benign neoplasm of vertebral column
- D16.8: Benign neoplasm of pelvic bones, sacrum, and coccyx
- D32.1: Benign neoplasm of spinal meninges
- D33.4: Benign neoplasm of spinal cord
- D42.0 - D42.9: Neoplasm of uncertain behavior of meninges
  - D43.0 - D43.2,
  - D43.4: Neoplasm of uncertain behavior of brain and spinal cord
- D49.7: Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system

**Chymopapain chemonucleolysis:**

CPT codes covered if selection criteria are met:
- **62292**: Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar

Other CPT codes related to the CPB:
- **62302 - 62305**: Myelography via lumbar injection, including radiological supervision and interpretation
- **72125 - 72133**: Computed tomography, spine
### Table: CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72141 - 72158</td>
<td>Magnetic resonance (eg, proton) imaging, spinal canal and contents</td>
</tr>
<tr>
<td>72240 - 72270</td>
<td>Myelography of spine</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M51.06 - M51.07</td>
<td>Intervertebral disc disorders with myelopathy, lumbar/lumbosacral region</td>
</tr>
<tr>
<td>M51.26 - M51.27</td>
<td>Other intervertebral disc displacement, lumbar/lumbosacral regions</td>
</tr>
<tr>
<td>M54.30 - M54.32</td>
<td>Sciatica [due to herniated disc]</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C41.2</td>
<td>Malignant neoplasm of vertebral column</td>
</tr>
<tr>
<td>C41.4</td>
<td>Malignant neoplasm of pelvic bones, sacrum, and coccyx</td>
</tr>
<tr>
<td>C70.1</td>
<td>Malignant neoplasm of spinal meninges</td>
</tr>
<tr>
<td>C72.0</td>
<td>Malignant neoplasm of spinal cord</td>
</tr>
<tr>
<td>C79.31</td>
<td>Secondary malignant neoplasm of brain</td>
</tr>
<tr>
<td>C79.49</td>
<td>Secondary malignant neoplasm of other parts of nervous system [includes spinal cord]</td>
</tr>
<tr>
<td>C79.51 - C79.52</td>
<td>Secondary malignant neoplasm of bone and bone marrow</td>
</tr>
<tr>
<td>D16.6</td>
<td>Benign neoplasm of vertebral column [excludes sacrum and coccyx]</td>
</tr>
<tr>
<td>D16.8</td>
<td>Benign neoplasm of pelvic bones, sacrum, and coccyx</td>
</tr>
<tr>
<td>D32.1</td>
<td>Benign neoplasm of spinal meninges</td>
</tr>
<tr>
<td>D33.4</td>
<td>Benign neoplasm of spinal cord</td>
</tr>
<tr>
<td>D42.0 - D42.9</td>
<td>Neoplasm of uncertain behavior of meninges</td>
</tr>
<tr>
<td>D43.0 - D43.2</td>
<td>Neoplasm of uncertain behavior of brain</td>
</tr>
<tr>
<td>D43.4</td>
<td>Neoplasm of uncertain behavior of spinal cord</td>
</tr>
<tr>
<td>D49.7</td>
<td>Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system</td>
</tr>
<tr>
<td>G00.0 - G99.8</td>
<td>Diseases of the nervous system</td>
</tr>
<tr>
<td>G83.4</td>
<td>Cauda equina syndrome</td>
</tr>
<tr>
<td>M43.06 - M43.08</td>
<td>Spondylolysis, lumbar, lumbosacral, sacral and sacrococcygeal, region</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>M43.10 - M43.19</td>
<td>Spondylolisthesis [acquired]</td>
</tr>
<tr>
<td>M43.27 - M43.28</td>
<td>Disorders of sacrum</td>
</tr>
<tr>
<td>M53.2x7 - M53.2x8</td>
<td>Disorders of sacrum</td>
</tr>
<tr>
<td>M53.87 - M53.88</td>
<td>Disorders of sacrum</td>
</tr>
<tr>
<td>M43.8x9</td>
<td>Other specified deforming dorsopathies, site unspecified</td>
</tr>
<tr>
<td>M48.00 - M48.01</td>
<td>Spinal stenosis, other than cervical</td>
</tr>
<tr>
<td>M48.03 - M48.08</td>
<td>Spinal stenosis, other than cervical</td>
</tr>
<tr>
<td>M48.02</td>
<td>Spinal stenosis, cervical region</td>
</tr>
<tr>
<td>M50.00 - M50.03</td>
<td>Cervical disc disorder with myelopathy</td>
</tr>
<tr>
<td>M50.20 - M50.23</td>
<td>Other cervical disc displacement</td>
</tr>
<tr>
<td>M51.04 - M51.05</td>
<td>Thoracic, thoracolumbar intervertebral disc disorder with myelopathy</td>
</tr>
<tr>
<td>M51.24 - M51.25</td>
<td>Other thoracic, thoracolumbar disc displacement</td>
</tr>
<tr>
<td>M53.2x7 - M53.2x8</td>
<td>Spinal instabilities, lumbosacral, sacral, sacrococcygeal region</td>
</tr>
<tr>
<td>M54.03 - M54.09, M62.830</td>
<td>Other symptoms referable to back</td>
</tr>
<tr>
<td>M54.5</td>
<td>Low back pain [lumbago]</td>
</tr>
<tr>
<td>M54.6</td>
<td>Pain in thoracic spine</td>
</tr>
<tr>
<td>M54.89 - M54.9</td>
<td>Other and unspecified dorsalgia</td>
</tr>
<tr>
<td>M96.1</td>
<td>Postlaminectomy syndrome, not elsewhere classified</td>
</tr>
<tr>
<td>O01.9 - O94</td>
<td>Complications of pregnancy, childbirth, and the puerperium</td>
</tr>
<tr>
<td>Q76.2</td>
<td>Congenital spondylolisthesis</td>
</tr>
<tr>
<td>R29.810 - R29.898</td>
<td>Other symptoms and signs involving the nervous and musculoskeletal systems</td>
</tr>
<tr>
<td>Z34.00 - Z34.93</td>
<td>Encounter for supervision of normal pregnancy</td>
</tr>
</tbody>
</table>

**Percutaneous lumbar discectomy or laser-assisted disc decompression (LADD):**

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels,</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td>lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62267</td>
<td>Percutaneous aspiration within the nucleus pulposus, intervertebral disc, or paravertebral tissue for diagnostic purposes</td>
</tr>
<tr>
<td>62303 - 62305</td>
<td>Myelography via lumbar injection, including radiological supervision and interpretation</td>
</tr>
<tr>
<td>63001 - 63091</td>
<td>Laminectomy, discectomy and related procedures (eg, decompression of spinal cord)</td>
</tr>
<tr>
<td>63185 - 63190</td>
<td>Laminectomy with rhizotomy</td>
</tr>
<tr>
<td>72125 - 72133</td>
<td>Computed tomography, spine</td>
</tr>
<tr>
<td>72141 - 72158</td>
<td>Magnetic resonance (eg, proton) imaging, spinal canal and contents</td>
</tr>
<tr>
<td>72240 - 72270</td>
<td>Myelography of spine</td>
</tr>
<tr>
<td>77002</td>
<td>Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)</td>
</tr>
</tbody>
</table>

HCPCS codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0276</td>
<td>Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial</td>
</tr>
</tbody>
</table>

Other HCPCS codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2614</td>
<td>Probe, percutaneous lumbar discectomy</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M51.06 - M51.07</td>
<td>Intervertebral disc disorder with myelopathy, lumbar/lumbosacral region</td>
</tr>
<tr>
<td>M51.26 - M51.27</td>
<td>Other intervertebral disc displacement, lumbar/lumbosacral regions</td>
</tr>
</tbody>
</table>

Minimally Invasive Lumbar Decompression (MILD):

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0274T</td>
<td>Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image</td>
</tr>
</tbody>
</table>
Table: CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+": Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0275T</td>
<td>lumbar</td>
</tr>
</tbody>
</table>

Radiofrequency facet denervation:

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint [not covered for cooled radiofrequency ablation]</td>
</tr>
<tr>
<td>64634</td>
<td>cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure) [not covered for cooled radiofrequency ablation]</td>
</tr>
<tr>
<td>64635</td>
<td>lumbar or sacral, single facet joint [not covered for cooled radiofrequency ablation]</td>
</tr>
<tr>
<td>64636</td>
<td>lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure) [not covered for cooled radiofrequency ablation]</td>
</tr>
</tbody>
</table>

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64625</td>
<td>Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22548 - 22812</td>
<td>Arthrodesis, vertebra</td>
</tr>
<tr>
<td>62302 - 62305</td>
<td>Myelography via lumbar injection, including radiological supervision and interpretation</td>
</tr>
<tr>
<td>64479 - 64484</td>
<td>Injection, anesthetic agent and/or steroid, transforaminal epidural</td>
</tr>
<tr>
<td>72125 - 72133</td>
<td>Computed tomography, spine</td>
</tr>
<tr>
<td>72141 - 72158</td>
<td>Magnetic resonance (eg, proton) imaging, spinal canal and contents</td>
</tr>
<tr>
<td>72240 - 72270</td>
<td>Myelography of spine</td>
</tr>
<tr>
<td>97001 - 97139</td>
<td>Physical medicine and rehabilitation modalities and therapeutic procedures</td>
</tr>
</tbody>
</table>

Other HCPCS codes related to the CPB:

Proprietary
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L0112 - L0999</td>
<td>Orthotic devices-spinal</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

- M53.0 - M53.1: Cervicocranial - cervicobrachial syndrome
- M53.81 - M53.83: Other specified dorsopathies [cervical region]
- M54.2: Cervicalgia
- M54.30 - M54.5: Sciatica and lumbago
- M54.6: Pain in thoracic spine
- M54.9: Dorsalgia, unspecified [backache]

**ICD-10 codes not covered for indications listed in the CPB:**

- M43.27 - M43.29
- M53.2x7 - M53.2x8
- M53.87 - M53.88

- M50.00 - M51.9: Intervertebral disc disorders
- M50.00 - M50.19: Kyphosis and lordosis [requiring spinal instrumentation]
- M40.00 - M40.57: Arthrodesis status [vertebra]
- M41.00 - M41.9: Idiopathic scoliosis [infantile, juvenile/adolescent, thoracogenic, neuromuscular]
- M41.00 - M43.19: Acquired spondylolisthesis [grades I-IV]
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M96.1</td>
<td>Postlaminectomy syndrome, not elsewhere classified</td>
</tr>
<tr>
<td>Numerous options (7th character must be &quot;K&quot;)</td>
<td>Nonunion of fractures [pseudoarthrosis]</td>
</tr>
<tr>
<td>Q67.5</td>
<td>Congenital deformities of spine</td>
</tr>
<tr>
<td>Q76.2</td>
<td>Congenital spondylolisthesis</td>
</tr>
<tr>
<td>Q76.411 - Q76.419</td>
<td>Congenital kyphosis [not associated with scoliosis]</td>
</tr>
<tr>
<td>Q76.49</td>
<td>Other congenital malformations of spine, not associated with scoliosis</td>
</tr>
<tr>
<td></td>
<td>• S12.000+ - S12.691+</td>
</tr>
<tr>
<td></td>
<td>• S12.9xx+,</td>
</tr>
<tr>
<td></td>
<td>• S22.000+ - S22.089+</td>
</tr>
<tr>
<td></td>
<td>• S32.000+ - S32.2xx+</td>
</tr>
<tr>
<td></td>
<td>Fracture of vertebral column, without mention of spinal cord injury</td>
</tr>
<tr>
<td></td>
<td>• S13.100+ - S13.181+</td>
</tr>
<tr>
<td></td>
<td>• S23.100+ - S23.171+</td>
</tr>
<tr>
<td></td>
<td>• S33.100+ - S33.39x+</td>
</tr>
<tr>
<td></td>
<td>Dislocation of vertebrae</td>
</tr>
<tr>
<td>ICD-10 codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• M50.30 - M50.33</td>
</tr>
<tr>
<td></td>
<td>• M51.34 - M51.37</td>
</tr>
<tr>
<td></td>
<td>Other disc degeneration</td>
</tr>
<tr>
<td>M54.5</td>
<td>Low back pain [lumbago]</td>
</tr>
<tr>
<td>Transforaminal lumbar interbody fusion:</td>
<td></td>
</tr>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>22630</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar</td>
</tr>
<tr>
<td>22632</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>ICD-10 codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>C41.2</td>
<td>Malignant neoplasm of vertebral column, excluding sacrum and coccyx</td>
</tr>
<tr>
<td>C70.1</td>
<td>Malignant neoplasm of spinal meninges</td>
</tr>
<tr>
<td>C79.31 - C79.32</td>
<td>Secondary malignant neoplasm of brain and spinal cord</td>
</tr>
<tr>
<td>C79.49</td>
<td>Secondary malignant neoplasm of other parts of nervous system</td>
</tr>
<tr>
<td>C79.51 - C79.52</td>
<td>Secondary malignant neoplasm of bone and bone marrow</td>
</tr>
<tr>
<td>D32.1</td>
<td>Benign neoplasm of spinal meninges</td>
</tr>
<tr>
<td>D33.4</td>
<td>Benign neoplasm of spinal cord</td>
</tr>
<tr>
<td>D42.0 - D42.9</td>
<td>Neoplasm of uncertain behavior of meninges</td>
</tr>
<tr>
<td>D43.0 - D43.2, D43.4</td>
<td>Neoplasm of uncertain behavior of brain and spinal cord</td>
</tr>
<tr>
<td>D48.0</td>
<td>Neoplasm of uncertain behavior of bone and articular cartilage</td>
</tr>
<tr>
<td>G06.1</td>
<td>Intraspinal abscess and granuloma</td>
</tr>
<tr>
<td>M40.50 - M40.57</td>
<td>Lordosis, unspecified</td>
</tr>
<tr>
<td>M41.00 - M41.35, M41.80 - M41.9</td>
<td>Scoliosis</td>
</tr>
<tr>
<td>M43.00 - M43.19</td>
<td>Spondylolysis and spondylolisthesis</td>
</tr>
<tr>
<td>M46.20</td>
<td>Osteomyelitis of vertebra, site unspecified</td>
</tr>
<tr>
<td>M46.30</td>
<td>Infection of intervertebral disc (pyogenic), site unspecified</td>
</tr>
<tr>
<td>M48.061 - M48.07</td>
<td>Spinal stenosis, lumbar and lumbosacral region</td>
</tr>
<tr>
<td>M48.50x+, M48.58x+, M80.08x+, M84.48x+, M84.58x+, M84.68x+</td>
<td>Pathologic fracture of vertebrae</td>
</tr>
<tr>
<td>M86.18</td>
<td>Other acute osteomyelitis, other site [spinal]</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>M86.28</td>
<td>Subacute osteomyelitis, other site [spinal]</td>
</tr>
<tr>
<td>M86.68</td>
<td>Other chronic osteomyelitis, other site [spinal]</td>
</tr>
<tr>
<td>M96.0</td>
<td>Pseudoarthrosis after fusion or arthrodesis</td>
</tr>
<tr>
<td>M96.5</td>
<td>Postradiation scoliosis</td>
</tr>
<tr>
<td>Numerous options</td>
<td>Nonunion of fracture [Codes not listed due to expanded specificity]</td>
</tr>
<tr>
<td>Q76.2</td>
<td>Congenital spondylolisthesis</td>
</tr>
<tr>
<td>S31.000+</td>
<td>Unspecified open wound of lower back and pelvis without penetration into retroperitoneum</td>
</tr>
<tr>
<td>S32.000+ - S32.059+</td>
<td>Fracture of lumbar vertebra</td>
</tr>
<tr>
<td>S33.100+ - S33.141+</td>
<td>Subluxation and dislocation of lumbar vertebra</td>
</tr>
<tr>
<td>S34.101+ - S34.129+</td>
<td>Other and unspecified injury of lumbar spinal cord</td>
</tr>
<tr>
<td>Z98.1</td>
<td>Arthrodesis status</td>
</tr>
</tbody>
</table>

Intervertebral body fusion devices:

CPT codes covered if selection criteria are met:

22853  Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)

22854  Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)

22859  Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)

Other CPT codes related to the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20936 - 20938</td>
<td>Autograft for spine surgery</td>
</tr>
<tr>
<td>63081 - 63082</td>
<td>Vertebral corpectomy</td>
</tr>
</tbody>
</table>

**HCPCS codes covered if selection criteria are met:**

*Synthetic cervical cages/spacers, Spine Cages, Expandable cages - no specific code (not an all-inclusive list):*

(e.g., BAK Interbody Fusion System, Ray Threaded Fusion Cage, STALIF stand-alone anterior lumbar fusion cage, carbon fiber cage)

**ICD-10 codes covered if selection criteria are met:**

- C41.2: Malignant neoplasm of vertebral column
- C79.51: Secondary malignant neoplasm of bone
- M24.08: Loose body, other site [retropulsed bone fragments]
- M25.78: Osteophyte, vertebrae [of spine causing spinal cord or nerve root compression, confirmed by imaging studies] [see criteria in CPB 743]
- M48.02: Spinal stenosis, cervical region [symptomatic central canal stenosis]
- M50.00 - M50.03: Cervical disc disorders with myelopathy [see criteria in CPB 743]
- M50.20 - M50.23: Other cervical disc displacement [see criteria in CPB 743]
- M51.34 - M51.37: Other thoracic, thoracolumbar and lumbosacral intervertebral disc degeneration [see criteria in CPB 743]
- M54.11 - M54.13: Radiculopathy, cervical region [see criteria in CPB 743]
- M89.78: Major osseous defect, other site
- M96.0: Pseudarthrosis after fusion or arthrodesis
- Q76.2: Congenital spondylolisthesis [see criteria in CPB 743]
- S12.000A - S12.691S: Fracture of cervical vertebra

**Percutaneous polymethylmethacrylate vertebroplasty (PPV) or kyphoplasty:**

CPT codes covered if selection criteria are met:

- 22510 - 22511: Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic or lumbosacral
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22512</td>
<td>each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22513 - 22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic or lumbar</td>
</tr>
<tr>
<td>22515</td>
<td>each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

- **C41.2**  
  Malignant neoplasm of vertebral column
- **C41.4**  
  Malignant neoplasm of pelvic bones, sacrum, and coccyx
- **C70.1**  
  Malignant neoplasm of spinal meninges
- **C72.0**  
  Malignant neoplasm of spinal cord
- **C79.31**  
  Secondary malignant neoplasm of brain
- **C79.49**  
  Secondary malignant neoplasm of other parts of nervous system
- **C79.51 - C79.52**  
  Secondary malignant neoplasm of bone and bone marrow
- **C83.30 - C95.92**  
  Malignant neoplasm of lymphoid, hematopoietic and related tissue
- **D18.09**  
  Hemangioma of other sites [painful and/or aggressive]
- **E88.89**  
  Other specified metabolic disorders [painful vertebral eosinophilic granuloma]
- **M48.30 - M48.38**  
  Traumatic spondylopathy
  - M48.50x+
  - M48.58x+
  - M80.08+,
  - M80.88x+
  - M84.58x+,
  - M84.68x+
  - Pathological fracture of vertebra(e) [painful, debilitating osteoporotic collapse/compression fractures]
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M81.0 - M81.8</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>S12.000+ - S12.691+</td>
<td>Fracture of vertebral column, without mention of spinal cord injury [steroid-induced] [with spinal cord injury, use spinal cord injury codes also]</td>
</tr>
<tr>
<td>S12.9xx+, S22.000+ - S22.089+</td>
<td>Fracture of vertebral column, without mention of spinal cord injury [steroid-induced] [with spinal cord injury, use spinal cord injury codes also]</td>
</tr>
<tr>
<td>S32.000+ - S32.2xx+</td>
<td>Fracture of vertebral column, without mention of spinal cord injury [steroid-induced] [with spinal cord injury, use spinal cord injury codes also]</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M50.20 - M51.9</td>
<td>Intervertebral disc disorders</td>
</tr>
</tbody>
</table>

**Endoscopic Spinal surgery:**

**Other CPT codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62267</td>
<td>Percutaneous aspiration within the nucleus pulposus, intervertebral disc, or paravertebral tissue for diagnostic purposes</td>
</tr>
<tr>
<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)</td>
</tr>
<tr>
<td>77002</td>
<td>Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)</td>
</tr>
</tbody>
</table>

**Vertebral body replacement spacers (e.g., AVS AL PEEK Spacer):**

No specific code

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M43.8X9</td>
<td>Other specified deforming dorsopathies, site unspecified [damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures]</td>
</tr>
<tr>
<td>M48.50x+ - M48.58x+</td>
<td>Collapsed vertebra, not elsewhere classified</td>
</tr>
</tbody>
</table>

**Cementoplasty:**

**CPT codes covered if selection criteria are met:**

**Cementoplasty - no specific code:**

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C41.4</td>
<td>Malignant neoplasm of pelvic bones, sacrum and coccyx</td>
</tr>
</tbody>
</table>

**Experimental and Investigational Interventions for treatment of back pain:**

**Chronic Back Pain:**
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT codes not covered section to the CPB:</td>
<td></td>
</tr>
<tr>
<td>Direct visual rhizotomy, Discseel procedure - no specific code:</td>
<td></td>
</tr>
<tr>
<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
</tr>
<tr>
<td>Other CPT codes related to the CPB:</td>
<td></td>
</tr>
<tr>
<td>96365 - 96368</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis</td>
</tr>
<tr>
<td>HCPCS codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td>C9757</td>
<td>Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar [Barricaid, DART disc annular repair devices, Xclose Tissue Repair System]</td>
</tr>
<tr>
<td>J0702</td>
<td>Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg</td>
</tr>
<tr>
<td>J1020</td>
<td>Injection, methylprednisolone acetate, 20 mg</td>
</tr>
<tr>
<td>J1030</td>
<td>Injection, methylprednisolone acetate, 40 mg</td>
</tr>
<tr>
<td>J1040</td>
<td>Injection, methylprednisolone acetate, 80 mg</td>
</tr>
<tr>
<td>J1094</td>
<td>Injection, dexamethasone acetate, 1 mg</td>
</tr>
<tr>
<td>J1100</td>
<td>Injection, dexamethasone sodium phosphate, 1 mg</td>
</tr>
<tr>
<td>J1700</td>
<td>Injection, hydrocortisone acetate, up to 25 mg</td>
</tr>
<tr>
<td>J1710</td>
<td>Injection, hydrocortisone sodium phosphate, up to 50 mg</td>
</tr>
<tr>
<td>J1720</td>
<td>Injection, hydrocortisone sodium succinate, up to 100 mg</td>
</tr>
<tr>
<td>J2001</td>
<td>Injection, lidocaine HCL for intravenous infusion 10 mg</td>
</tr>
<tr>
<td>J2650</td>
<td>Injection, prednisolone acetate, up to 1 ml</td>
</tr>
<tr>
<td>J2920</td>
<td>Injection, methylprednisolone sodium succinate, up to 40 mg</td>
</tr>
<tr>
<td>J2930</td>
<td>Injection, methylprednisolone sodium succinate, up to 125 mg</td>
</tr>
<tr>
<td>J3300</td>
<td>Injection, triamcinolone acetonide, preservative free, 1 mg</td>
</tr>
<tr>
<td>J3301</td>
<td>Injection, triamcinolone acetonide, not otherwise specified, 10 mg</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>J3302</td>
<td>Injection, triamcinolone diacetate, per 5 mg</td>
</tr>
<tr>
<td>J3303</td>
<td>Injection, triamcinolone hexacetonide, per 5 mg</td>
</tr>
<tr>
<td>J3304</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M54.5</td>
<td>Low back pain</td>
</tr>
<tr>
<td>M54.9</td>
<td>Dorsalgia, unspecified</td>
</tr>
</tbody>
</table>

**Experimental and investigational Interventions for treatment of neck pain:**

**Other CPT codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96365 - 96368</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis</td>
</tr>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0702</td>
<td>Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg</td>
</tr>
<tr>
<td>J1020</td>
<td>Injection, methylprednisolone acetate, 20 mg</td>
</tr>
<tr>
<td>J1030</td>
<td>Injection, methylprednisolone acetate, 40 mg</td>
</tr>
<tr>
<td>J1040</td>
<td>Injection, methylprednisolone acetate, 80 mg</td>
</tr>
<tr>
<td>J1094</td>
<td>Injection, dexamethasone acetate, 1 mg</td>
</tr>
<tr>
<td>J1100</td>
<td>Injection, dexamethasone sodium phosphate, 1 mg</td>
</tr>
<tr>
<td>J1700</td>
<td>Injection, hydrocortisone acetate, up to 25 mg</td>
</tr>
<tr>
<td>J1710</td>
<td>Injection, hydrocortisone sodium phosphate, up to 50 mg</td>
</tr>
<tr>
<td>J1720</td>
<td>Injection, hydrocortisone sodium succinate, up to 100 mg</td>
</tr>
<tr>
<td>J1885</td>
<td>Injection, ketorolac tromethamine per 15 mg</td>
</tr>
<tr>
<td>J2001</td>
<td>Injection, lidocaine hcl for intravenous infusion, 10 mg</td>
</tr>
<tr>
<td>J2650</td>
<td>Injection, prednisolone acetate, up to 1 ml</td>
</tr>
<tr>
<td>J2920</td>
<td>Injection, methylprednisolone sodium succinate, up to 40 mg</td>
</tr>
<tr>
<td>J2930</td>
<td>Injection, methylprednisolone sodium succinate, up to 125 mg</td>
</tr>
<tr>
<td>J3300</td>
<td>Injection, triamcinolone acetonide, preservative free, 1 mg</td>
</tr>
<tr>
<td>J3301</td>
<td>Injection, triamcinolone acetonide, not otherwise specified, 10 mg</td>
</tr>
</tbody>
</table>
Table: CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

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<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3302</td>
<td>Injection, triamcinolone diacetate, per 5 mg</td>
</tr>
<tr>
<td>J3303</td>
<td>Injection, triamcinolone hexacetonide, per 5 mg</td>
</tr>
<tr>
<td>J3304</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
</tr>
<tr>
<td>J3420</td>
<td>Injection, vitamin B-12 cyanocobalamin, up to 1000 mg</td>
</tr>
<tr>
<td>J3475</td>
<td>Injection, magnesium sulfate, per 500 mg</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:

- M54.2: Cervicalgia

Endoscopic transforaminal discectomy:

CPT codes not covered for indications listed in the CPB:

- 62287: Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar [not covered for endoscopic transforaminal discectomy]

Other CPT codes related to the CPB:

- 96365 - 96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug [magnesium, Toradol and vitamin B12 cyanocobalamin] for the treatment of back pain)

HCPCS codes not covered for indications listed in the CPB:

- J1885: Injection, ketorolac tromethamine per 15 mg [Toradol]
- J3420: Injection, vitamin B-12 cyanocobalamin, up to 1000 mg
- J3475: Injection, magnesium sulfate, per 500 mg

ICD-10 codes not covered for indications listed in the CPB:

- M54.5: Low back pain
- M54.9: Dorsalgia, unspecified

Minimally Invasive Thoracic discectomy:

CPT codes not covered for indications listed in the CPB:

- 22532: Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percutaneous cervical diskectomy:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Minimally Invasive Lumbar Decompression (MILD):</strong></td>
<td></td>
</tr>
<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td>0274T</td>
<td>Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic</td>
</tr>
<tr>
<td>0275T</td>
<td>lumbar</td>
</tr>
<tr>
<td>HCPCS codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td>G0276</td>
<td>Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial</td>
</tr>
<tr>
<td><strong>Epiduroscopy:</strong></td>
<td></td>
</tr>
<tr>
<td>Other CPT codes related to the CPB:</td>
<td></td>
</tr>
<tr>
<td>62318</td>
<td>Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; cervical or thoracic</td>
</tr>
<tr>
<td>62319</td>
<td>lumbar, sacral (caudal)</td>
</tr>
<tr>
<td>72275</td>
<td>Epidurography, radiological supervision and interpretation</td>
</tr>
<tr>
<td><strong>Epidural injections of lytic agents:</strong></td>
<td></td>
</tr>
<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td>62280</td>
<td>Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; subarachnoid Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation [not covered for chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints]</td>
</tr>
</tbody>
</table>
### CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62281</td>
<td>epidural, cervical or thoracic [not covered for chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints]</td>
</tr>
<tr>
<td>62282</td>
<td>epidural, lumbar, sacral (caudal) [not covered for chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints]</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72275</td>
<td>Epidurography, radiological supervision and interpretation</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

- J3470 Injection, hyaluronidase, up to 150 units
- J3471 Injection, hyaluronidase, ovine, preservative free, per 1 USP unit (up to 999 USP units)
- J3472 Injection, hyaluronidase, ovine, preservative free, per 1000 USP units
- J3473 Injection, hyaluronidase, recombinant, 1 USP unit

**ICD-10 codes not covered for indications listed in the CPB:**

- G03.0 - G03.9 Meningitis due to other and unspecified causes
- M43.00 - M43.9 Dorsopathies
- M54.10 Radiculopathy, site unspecified
- M79.2 Neuralgia and neuritis, unspecified
  - S12.000S - S12.691S Fracture of vertebral column, sequela
  - S12.9xxS,
  - S22.000S - S22.089S
  - S32.000S - S32.2xxS
  - S39.002+ - S39.003+
  - S39.092+ - S39.093+
  - S39.82x+ - S39.83x+
  - S39/92x+ - S39.93x+
  - S39.002+ - S39.003+
  - S39.82x+ - S39.83x+
  - S39/92x+ - S39.93x+

**Intercept System:**

HCPCS codes not covered for indications listed in the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9752</td>
<td>Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum</td>
</tr>
<tr>
<td>C9753</td>
<td>Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:

- M54.5 Low back pain [chronic]

Intradiscal injections of notochordal cell-derived matrix:

CPT codes not covered for indications listed in the CPB:

- Intradiscal injections of notochordal cell-derived matrix - no specific code:

ICD-10 codes not covered for indications listed in the CPB:

- M50.00 - M50.93 Cervical disc disorders
- M51.04 - M51.9 Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders

Microsurgical anterior foraminotomy:

No specific codes

Other CPT codes related to the CPB:

- 63075 - 63078 Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy

Other HCPCS codes related to the CPB:

- S2350 Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace
- S2351 Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

Sacroiliac fusion:

CPT codes covered if selection criteria are met:

- 27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
**Table: CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".*

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<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>27280</td>
<td>Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed [may be medically necessary for sacroiliac joint infection, tumor involving the sacrum, and sacroiliac pain due to severe traumatic injury where a trial of an external fixator is successful in providing pain relief]</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

*Titanium triangular implants - no specific code:*

**ICD-10 codes covered if selection criteria are met:**

- **C41.4** Malignant neoplasm of pelvic bones, sacrum and coccyx
- **C76.3** Malignant neoplasm of pelvis
- **D16.8** Benign neoplasm of pelvic bones, sacrum and coccyx
- **M01.x8** Direct infection of vertebrae in infectious and parasitic diseases classified elsewhere [sacroiliac joint infection]
- **M02.88** Other reactive arthropathies, vertebrae [sacroiliac joint infection]
- **M46.1** Sacroiliitis, not elsewhere classified [sacroiliac joint syndrome]
- **M53.3** Sacrococcygeal disorders, not elsewhere classified [sacroiliac joint syndrome]
- **M54.17** Radiculopathy, lumbosacral region [due to severe traumatic injury]
- **M54.18** Radiculopathy, sacral and sacrococcygeal region [due to severe traumatic injury]
- **S32.301A - S32.9xxB** Sacroiliac injuries

**ICD-10 codes not covered for indications listed in the CPB:**

- **M11.08** Hydroxyapatite deposition disease, vertebrae [lumbar]
- **M11.18** Familial chondrocalcinosis, vertebrae [lumbar]
- **M11.28** Other chondrocalcinosis, vertebrae [lumbar]
- **M11.88** Other specified crystal arthropathies, vertebrae [lumbar]
- **M43.16** Spondylolisthesis, lumbar region
- **M45.6** Ankylosing spondylitis lumbar region
- **M47.896** Other spondylosis, lumbar region [lumbar facet degeneration]
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M48.061 - M48.062</td>
<td>Spinal stenosis, lumbar region</td>
</tr>
<tr>
<td>M51.26</td>
<td>Other intervertebral disc displacement, lumbar region</td>
</tr>
<tr>
<td>M51.36</td>
<td>Other intervertebral disc degeneration, lumbar region</td>
</tr>
</tbody>
</table>

**Sacroplasty:**

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0200T</td>
<td>Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed</td>
</tr>
<tr>
<td>0201T</td>
<td>Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed</td>
</tr>
</tbody>
</table>

**Racz procedure (epidural adhesiolysis with the Racz catheter):**

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62263</td>
<td>Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62264</td>
<td>1 day</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72275</td>
<td>Epidurography, radiological supervision and interpretation</td>
</tr>
</tbody>
</table>

**Microdiskectomy:**

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22220 - 22226</td>
<td>Osteotomy of spine, including discectomy, anterior approach</td>
</tr>
<tr>
<td>62267</td>
<td>Percutaneous aspiration within the nucleus pulposus, intervertebral disc, or paravertebral tissue for diagnostic purposes</td>
</tr>
<tr>
<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)</td>
</tr>
</tbody>
</table>

+ 69990 | Operating microscope
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77002</td>
<td>Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2614</td>
<td>Probe, percutaneous, lumbar discectomy</td>
</tr>
<tr>
<td>S2350</td>
<td>Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace</td>
</tr>
<tr>
<td>S2351</td>
<td>Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**Microendoscopic discectomy (MED):**

**Other CPT codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22206</td>
<td>Osteotomy of spine, posterior or posterolateral approach, three columns, one vertebral segment (e.g., pedicle/vertebral body subtraction); thoracic</td>
</tr>
<tr>
<td>22207</td>
<td>lumbar</td>
</tr>
<tr>
<td>+ 22208</td>
<td>each additional vertebral segment (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22214</td>
<td>Osteotomy of spine, posterior or posterolateral approach, one vertebral segment; lumbar</td>
</tr>
<tr>
<td>+ 22216</td>
<td>each additional vertebral segment (List separately in addition to primary procedure)</td>
</tr>
<tr>
<td>22224</td>
<td>Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar</td>
</tr>
<tr>
<td>+ 22226</td>
<td>each additional vertebral segment (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>62287</td>
<td>Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy)</td>
</tr>
<tr>
<td>+ 69990</td>
<td>Operating microscope</td>
</tr>
<tr>
<td>77002</td>
<td>Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

Proprietary
Table: CPT Codes / HCPCS Codes / ICD-10 Codes

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<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2614</td>
<td>Probe, percutaneous, lumbar discectomy</td>
</tr>
<tr>
<td>S2350</td>
<td>Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace</td>
</tr>
<tr>
<td>S2351</td>
<td>Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace</td>
</tr>
<tr>
<td></td>
<td>(list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**Intercostal nerve blocks:**

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64420</td>
<td>Injection, anesthetic agent; intercostal nerve single</td>
</tr>
<tr>
<td>64421</td>
<td>intercostal nerves, multiple, regional block</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G54.8</td>
<td>Other nerve root and plexus disorders [intercostal neuritis]</td>
</tr>
</tbody>
</table>

**Inter-spinous distraction (X Stop Device, Coflex interspinous stabilization spinal implant, Extensure bone allograft inter-spinous spacer, Eclipse inter-spinous distraction device, and the TOPS System):**

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
<tr>
<td>22868</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
</tr>
<tr>
<td>22870</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>0202T</td>
<td>Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

- **C1821** Interspinous process distraction device (implantable)

**Piriformis muscle resection:**

No specific codes

**CPT codes not covered for indications listed in the CPB:**

- **27006** Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)
- **64712** Neuroplasty, major peripheral nerve, arm or leg, open; sciatic nerve [not covered for surgery for piriformis syndrome]

**ICD-10 codes not covered for indications listed in the CPB:**

- **G57.00 - G57.03** Lesion of sciatic nerve
- **M25.751 - M25.759** Osteophyte, hip
- **M54.30 - M54.32** Sciatica
- **M70.60 - M70.72** Trochanteric and other bursitis
- **M76.00 - M76.22** Enthesopathies, hip

**Radiofrequency denervation for sacroiliac joint pain:**

**CPT codes not covered for indications listed in the CPB:**

- **27035** Denervation, hip joint, intrapelvic or extrapelvic intrarticular branches of sciatic, femoral, or obturator nerves [not covered when specified as radiofrequency denervation for sacroiliac pain]
- **64625** Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)

**ICD-10 codes not covered for indications listed in the CPB:**

- **G57.00 - G57.03** Lesion of sciatic nerve
- **M25.751 - M25.759** Osteophyte, hip
- **M54.14 - M54.17** Radiculopathy, thoracic or lumbosacral region

Proprietary
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M54.30 - M54.32</td>
<td>Sciatica</td>
</tr>
<tr>
<td>M70.60 - M70.72</td>
<td>Trochanteric and other bursitis</td>
</tr>
<tr>
<td>M72.9</td>
<td>Neuralgia and neuritis, unspecified</td>
</tr>
<tr>
<td>M76.00 - M76.22</td>
<td>Enthesopathies, hip</td>
</tr>
</tbody>
</table>

**Facet joint implantation:**

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0219T</td>
<td>Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical</td>
</tr>
<tr>
<td>0220T</td>
<td>thoracic</td>
</tr>
<tr>
<td>0221T</td>
<td>lumbar</td>
</tr>
<tr>
<td>0222T</td>
<td>each additional vertebral segment (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**Epidural fat grafting:**

Other CPT codes related to the CPB:

15769  Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)

**Endoscopic disc decompression:**

CPT codes not covered for indications listed in the CPB:

62380  Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

**No specific codes:**

AccuraScope procedure, ACIS cage (Synthes), Ancora spacer, Aspen spinous process fixation system, Benefix Interspinous Fixation System, Biomet Aspen fusion system, Brantigan, Brigade anterior plate system, Brigade (Nuvasive), Cambria anterior cervical interbody system, Cavetto cage, Centerpiece plate, Crescent cage, CD HORIZON SPIRE Plate, PrimaLOK SP, and SP-Fix Spinous Process Fixation Plate, Coccygeal ganglion (ganglion impar) blockade for pelvic pain, Degas plate, Deuk Laser Disc Repair, Diamond (Amendia), DiscFX System, Dynamic (intervertebral) stabilization devices BioFlex, CD Horizon Agile Dynamic Stabilization Device, Dynamic stabilization (e.g., Dynesys Spinal System and the Stabilimax NZ Dynamic Spine Stabilization System), Ebi PEEK optima spacer, Ellipse Occipito-Cervical-Thoracic spinal system, Endoscopic laser foraminoplasty, EOS spinal system (Korean Bone Bank), Epidural ozone, Extreme lateral interbody fusion (XLIF), G surgical plate system T loc, Illico pedicle
Table: CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>screw system (Alphatec), IN:C2 spacer, Interlaminar lumbar instrumented fusion (ILIF), Invizia plate, Kinetic-SL Dynamic Anterior Cervical Plate System, LINDIF, OptiMesh grafting system, Oxygen injection, Psoas compartment block, Radiofrequency lesioning of dorsal root ganglia, Radiofrequency lesioning of terminal (peripheral) nerve endings, Radiofrequency/pulsed radiofrequency ablation of trigger points, Stabilink interspinous fixation device, Total Facet Arthroplasty System, TSRH 3DX pedicle screws (Medtronic), Van Gogh plate, Vesselplasty (e.g., Vessel-X), Yeung Endoscopic Spinal Surgery System, Y.E.S.S., Zeus C cervical spacer</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

Facet Joint Injections

4. Canadian Agency for Drugs and Technologies in Health (CADTH). Facet joint injection as diagnostic and therapeutic tools for pain of the cervical and lumbar spine: A review of clinical and cost-effectiveness. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); 2011.

**Trigger Point Injections / Dry Needling**

Sacroiliac Joint Injections


**Epidural Steroid Injections for Relief of Back Pain**


Chymopapain Chemonucleolysis

Percutaneous Lumbar Discectomy


Non-Pulsed Radiofrequency Facet Denervation


**Pedicle Screws for Spinal Fixation**


**Intervertebral Body Fusion Devices (Spine Cages)**


Cervical Spine Cages


26. Ryken TC, Heary RF, Matz PG, et al.; Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and

Epiduroscopy


**Epidural Injections for Lysis of Adhesions**

Endoscopic Transforaminal Percutaneous Discectomy


Percutaneous Polymethylmethacrylate Vertebroplasty and Kyphoplasty

5. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Percutaneous vertebroplasty for vertebral fractures caused by osteoporosis and malignancy, or hemangioma. Technology Assessment Program. Chicago, IL: BCBSA; December 2004;19(13).
6. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Percutaneous vertebroplasty and kyphoplasty for vertebral fractures caused by
osteoporosis or malignancy. TEC Assessment Program. Chicago, IL: BCBSA; September 2008;23(5).
7. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. TEC Assessment Program. Chicago, IL: BCBSA; April 2010; 24(7).


**Sacroplasty**


**Vesselplasty**


**Laser-Assisted Disc Decompression**


Yeung Endoscopic Spinal Surgery (Y.E.S.S.) and Endoscopic Laser Diskectomy

Microdiscectomy


Pulsed Radiofrequency Treatment


Microendoscopic Discectomy


Far Lateral Microendoscopic Diskectomy (FLMED)


Dynamic Stabilization


Inter-Spinous Distraction and Interlaminar Stabilization Procedures


25. Levin K. Lumbar spinal stenosis: Treatment and prognosis. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2012; November 2020.


29. Medical Services Advisory Committee (MSAC). Minimally invasive, lumbar decompression and dynamic stabilisation using an interlaminar device, with no rigid fixation to the vertebral pedicles, of one or two lumbar motion. Public Summary Document. Canberra, ACT: MSAC; 2017.


**Piriformis Muscle Resection**


**Endoscopic Laser Foraminoplasty**


**Xclose Tissue Repair System**


**Barricaid Annular Closure Device**


**Radiofrequency Denervation for Sacroiliac Joint Pain**


Facet Joint Implantation


**Lateral Interbody Fusion**

Minimally Invasive/Endoscopic Cervical Laminoforaminotomy


Minimally Invasive Lumbar Decompression Procedures (including MILD)


Minimally Invasive Transforaminal Lumbar Interbody Fusion (MITLIF)


**TruFuse Facet Fusion**


**Nu-Fix**


**Epidural Fat Graft during Lumbar Decompression Laminectomy/Discectomy**


**Interlaminar Lumbar Instrumented Fusion (ILIF)**


**Khan Kinetic Treatment (KKT)**


**The OptiMesh Grafting System**

2. Radiofrequency/Pulsed Radiofrequency Ablation of Trigger Point Pain

**Coccygectomy**
1. Fletcher RH. Coccydynia (coccygodynia). UpToDate [online serial]. Waltham, MA: UpToDate; reviewed November 2012.

Oxygen-Ozone Therapy (Injection)


Sacroiliac Joint Fusion


Cryoablation for the Treatment of Lumbar Facet Joint Pain

Minimally Invasive Thoracic Discectomy


Total Facet Arthroplasty System


Dynamic (Intervertebral) Stabilization / Bioflex

Least Invasive Lumbar Decompression, Interbody Fusion


The Deuk Laser Disc Repair


Microsurgical Lumbar Sequestrectomy for the Treatment of Lumbar Disc Herniation


Intradiscal Steroid Injections

Cooled Radiofrequency Ablation for Facet Denervation


Intradiscal Injection of Platelet-Rich Plasma


Ultrasound Guidance for Sacroiliac Joint Injections

**Posterior Facet Cages**


**Expandable Cages**


**Coflex**

4. Levin K. Lumbar spinal stenosis: Treatment and prognosis. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed October 2018.

Proprietary

Cementoplasty


Intracept Procedure (Intra-Osseous Basivertebral Nerve Ablation) for the Treatment of Low Back Pain


**Intradiscal Injections of Notochordal Cell-Derived Matrix for the Treatment of Intervertebral Disc Disease**


**Transforaminal Endoscopic Discectomy**


Lumbosacral Fusion for Bertolotti Syndrome


Discseel Procedure (Regenerative Spine Procedure)


2. Chou R. Subacute and chronic low back pain: Nonsurgical interventional treatment. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed September 2019b.

3. Chou R. Subacute and chronic low back pain: Surgical treatment. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed September 2019c.


Intramuscular Steroid Injection for the Treatment of Neck Pain

2. Robinson J, Kothari MJ. Treatment and prognosis of cervical radiculopathy. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed September 2019.


**Anterior Lumbar Interbody Fusion (ALIF)**


**DiscoGel (Intradiscal Alcohol Injection)**


IV. Papadopoulos D, Batistaki C, Kostopanagiotou G. Comparison of the efficacy between intradiscal gelified ethanol (Discogel) injection and intradiscal combination of pulsed radiofrequency and gelified ethanol (Discogel) injection for chronic discogenic low


**SpineJack System**


**Tendon Sheath injections for the Treatment of Back Pain**


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0016 Back Pain -
Invasive Procedures

There are no amendments for Medicaid.

revised 03/19/2021