Clinical Policy Bulletin:  
Back Pain - Invasive Procedures  

Revised April 2014  

Number: 0016  

Policy  

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 (intraarticular and medial branch blocks) are considered medically necessary in the diagnosis of facet pain in persons with chronic back or neck pain (pain lasting more than 3 months despite appropriate conservative treatment).  

Facet joint injections (intraarticular and medial branch blocks) 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.  

A set of facet joint injections (intraarticular or medial branch blocks) means up to 6 such injections per sitting, and this can be repeated once at the same levels and side to establish the diagnosis. 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 therapies such as bed rest, exercises, heating or cooling modalities, massage, and pharmacotherapies such as non-steroidal anti-inflammatory drugs, 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.

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.

III. Sacroiliac joint injections are considered medically necessary to relieve pain associated with lower lumbosacral disturbances in members who meet both of the following criteria:

A. Member has back pain for more than 3 months; and

B. The injections are not used 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.

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 sacroiliac injections are considered medically necessary to diagnose the patient's pain and achieve a therapeutic effect. It is not considered medically necessary to repeat these injections more frequently than once every 7 days. If the member experiences no symptom relief or functional improvement after 2 sacroiliac joint injections, additional sacroiliac joint injections are not considered medically necessary. Once the diagnosis is established, it is rarely medically necessary to repeat sacroiliac injections more frequently than once every 2 months. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity.

IV. 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:
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 2 or more weeks of conservative measures (e.g., rest, systemic analgesics and/or physical therapy); and

C. Epidural injections beyond the first set of 3 injections are provided as part of a comprehensive pain management program, which includes physical therapy, patient education, psychosocial support, and oral medications, where appropriate.

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.

Repeat epidural injections beyond the first set of 3 injections are considered medically necessary when provided as part of a comprehensive pain management program, which includes physical therapy, patient education, psychosocial support, and oral medications, where appropriate. Repeat epidural injections more frequently than every 7 days are not considered medically necessary. Up to 3 epidural injections are considered medically necessary to diagnose a member's pain and achieve a therapeutic effect; if the member experiences no pain relief after three epidural injections, additional epidural injections are not considered medically necessary. Once a therapeutic effect is achieved, it is rarely medically necessary to repeat epidural injections more frequently than once every 2 months. In selected cases where more definitive therapies (e.g., surgery) can not be tolerated or provided, additional epidural injections may be considered medically necessary. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity.

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

See also CPB 0722 - Selective Nerve Root Blocks

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 leg pain worse than low back pain; and

B. Member has radicular symptoms reproduced by sciatic stretch tests; and

C. Member has only a single level herniated disc with nerve root impingement at clinically suspected level demonstrated by MRI, CT, or myelography; and

D. Member has objective neurologic deficit (e.g., diminished deep tendon reflex, motor weakness, or hypalgesia in dermatomal distribution); and

E. Pain not relieved by at least 6 weeks of conservative therapy.

Chymopapain chemonucleolysis is considered experimental and investigational for all other indications, including the following because its effectiveness for these indications has not been established:
A. Acute LBP alone
B. Cauda equina syndrome
C. For herniated thoracic or cervical discs
D. Multiple back operations (failed back surgery syndrome)
E. Neurologic disease (e.g., multiple sclerosis)
F. Pregnancy
G. Profound or rapidly progressive neurologic deficit
H. Sequestered disc fragment
I. Severe spinal stenosis
J. Severe spondylolisthesis
K. Spinal cord tumor
L. Spinal instability
M. 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 management; 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:

A. Member has experienced severe pain limiting activities of daily living for at least 6 months; and
B. Member has had no prior spinal fusion surgery; and
C. Neuroradiologic studies are negative or fail to confirm disc herniation; and
D. Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; and
E. Member has tried and failed 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
F. Trial of facet joint injections has been successful in relieving the pain.
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.

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:

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

A. Decompressive laminectomy for spinal stenosis without evidence of instability  
B. Degenerative disc disease  
C. Failed lumbar surgery without documentation of instability pattern or pseudoarthrosis  
D. First time intervertebral disc herniation  
E. Isolated low back pain without spinal instability or neurologic deficits  
F. Single level discectomy

IX. Intervertebral body fusion devices (spine cages) (see appendix e.g., BAK Interbody Fusion System, carbon fiber cage, Ray Threaded Fusion Cage, STALIF stand-alone anterior lumbar fusion cage) are considered medically necessary for use with 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. Spine cages for cervical fusion are considered medically necessary for members who meet criteria in CPB 0743 Spinal Surgery: Laminectomy and Fusion with any of the following indications for use of a cage:

A. Multilevel (three vertebral bodies) 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 percent compression fracture of vertebrae, or
3. retropulsed bone fragments, or
4. central canal stenosis with myelopathy.

B. Multilevel (three vertebral bodies) fusion for pseudarthrosis in person with prior fusion; or
C. Jehovah's Witness with poor bone stock (e.g., due to osteoporosis, osteogenesis imperfecta, ESRD, diabetes, long-term steroid use, immunosuppression after transplant, or parathyroid deficiency). 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 all other indications because their effectiveness for indications other than those listed above has not been established.

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:

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

AND all of the following criteria have been met:

I.
A. Other causes of pain such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging; and
B. Severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g., acetaminophen, non-steroidal anti-inflammatory drugs [NSAIDS], narcotic analgesics, braces, physical therapy, etc.); and
C. The affected vertebra has not been extensively destroyed and is at least one-third of its original height.

II. 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.

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

IV. 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)).

Experimental and Investigational Interventions

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

- Annulus repair devices (Xclose Tissue Repair System, Barricaid, Disc Annular Repair Technology (DART) System)
- BacFast HD for isolated facet fusion;
- Coccygeal ganglion (ganglion impar) block for coccydynia, pelvic pain, and all other indications;
- Cryoablation (cryoanesthesia, cryodenervation, cryoneurolysis, or cryosurgery) for the treatment of lumbar facet joint pain;
- Devices for annular repair (e.g., Inclose Surgical Mesh System);
- Endoscopic disc decompression, ablation, or annular modulation using the DiscFX System;
- Endoscopic laser foramoplasty, endoscopic foramotomy, laminotomy, and rhizotomy (endoscopic radiofrequency ablation);
- Endoscopic transfemoral 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;
- Intercostal nerve blocks for intercostal neuritis;
- Interlaminar lumbar instrumented fusion (ILIF);
- Interspinous and interlaminar distraction devices (see Appendix);
- Interspinous fixation devices (CD HORIZON SPIRE Plate, PrimaLOK SP, and SP-Fix Spinous Process Fixation Plate) for spinal stenosis or other indications (see Appendix)
- Intradiscal, paravertebral, or epidural oxygen or ozone injections;
- Intradiscal steroid injections;
Intravenous administration of corticosteroids, lidocaine, magnesium, Toradol or vitamin B12 (cyanocobalamin) as a treatment for back pain;
Khan kinetic treatment (KKT);
Laser facet denervation;
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;
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 (MILTIF; same as MAST fusion) for lumbar disc degeneration and instability or other indications;
OptiMesh grafting system;
Percutaneous cervical discectomy;
Percutaneous endoscopic discectomy with or without laser (PELD) (also known as arthroscopic microdiscectomy or Yeung Endoscopic Spinal Surgery System [Y.E.S.S.]);
Piriformis muscle resection and other surgery for piriformis syndrome; 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;
Sacroiliac fusion or pinning for the treatment of LBP due to sacroiliac joint syndrome; Note: Sacroiliac fusion 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;
Sacroiliac joint fusion (e.g., by means of the iFuse System and the SImetry Sacroiliac Joint Fusion System);
Sacroplasty for osteoporotic sacral insufficiency fractures and other indications;
Total Facet Arthroplasty System (TFAS) for the treatment of spinal stenosis;
Vesselplasty (e.g., Vessel-X).

See also CPB 0602 - Thermal Intradiscal Procedure.

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 injection 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. 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 are injections of local anesthetic medication, saline, and/or steroids into trigger points. 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 triggers 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).

**Lumbar Laminectomy with or without Fusion**
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.

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. Thirty-three studies with 2267 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. (2011) reached similar conclusions. The author reported 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. The majority of studies document 95%-100% fusion rates when iliac crest autograft is utilized to perform single level ACDF (X-ray or CT confirmed at 6-12 postoperative months). The author found no clinically

http://qawww.aetna.com/cpb/medical/data/1_99/0016_draft.html
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 found 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.

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.

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

A facet block is an injection of local anesthetic and/or steroids into or near the facet joint of the spine. Degenerative changes in the posterior lumbar 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 demonstrate 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 (Lilus 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, FJJs [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 FJJs have not been proven to be superior to local anesthetic FJJs 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".

Radiofrequency Facet Denervation
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.

Facet Chemodenervation/Chemical Facet Neurolysis and Laser Facet Denervation

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.

There is a lack of published evidence of laser facet denervation for lumbar facet pain.

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 though 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).

**Vertebroplasty**

Percutaneous polymethylmethacrylate vertebroplasty (PPV) is a therapeutic, interventional radiologic procedure, which consists of the injection of a bone cement (usually methyl methacrylate) into a cervical, thoracic or lumbar vertebral body lesion for the relief of pain and the strengthening of bone. 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. 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.

The BlueCross BlueShield Association Technology Evaluation Center, the Washington State Health Technology Assessment Program, and the California Technology Assessment Forum are conducting reassessments of the vertebroplasty procedure.

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 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.

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.

The BlueCross BlueShield Association Technology Evaluation Center and the Washington State Health Technology Assessment Program are conducting assessments of kyphoplasty.

Sacroplasty

Sacroplasty is a variation of the vertebroplasty technique, and involves the injection of polymethylmethacrylate cement into sacral insufficiency fractures for stabilization. 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 Interventional 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".

Racz Catheter

The Racz catheter is a small caliber, flexible catheter that is introduced into the sacral hiatus and into the lumbo-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 Racz catheter treatment. The study was unblinded and utilized a biased control group, as control group subjects were patients who refused Racz 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 Racz treatment procedure".

**Epidural Lysis of Adhesions**

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.

Sacroiliac Fusion

Sacroiliac fusion involves bony fusion of the sacroiliac joint 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".

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 diskectomy or endoscopic laser percutaneous diskectomy (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))
Yeung Endoscopic Spinal Surgery (YESS) (also known as arthroscopic microdiscectomy or percutaneous endoscopic discectomy (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 microdiscectomy 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 microdiscectomy 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 microdiscectomy has been limited to review articles and reports of retrospective case series. There are no published prospective, RCTs of arthroscopic microdiscectomy, 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 microdiscectomy does not meet Aetna's criteria.

Minimally Invasive Lumbar Decompression Procedures

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 discectomy, 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.

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 overnight 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.

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 (ii) efficacy parameters were not collected in this safety survey. 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.

**Laser Diskectomy**

Laser disectomy, or laser-assisted disc decompression (LADD), involves the use of a laser to vaporize a small portion of the nucleus pulposus in order to decompress a herniated disc. In laser disectomy, the surgeon places a laser through a delivery device that has been directed under radiographic control to the disc, and removes the disc material using the laser. It uses many of the same techniques used in automated percutaneous disectomy. 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. 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 disectomy 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 disectomy conducted for the National Institute of Clinical Excellence (NICE, 2003) concluded that current evidence on the safety and efficacy of laser lumbar disectomy 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 disectomy is "unknown".

**Microdisectomy**

Microdisectomy refers to removal of protruding disc material, using an operating microscope to guide surgery. Dent (2001) recently assessed the evidence supporting the use of microdisectomy for prolapsed intervertebral disc, and found no evidence of differences in clinical outcomes between microdisectomy and standard open disectomy. A Cochrane review found evidence that microdisectomy takes longer to perform than standard open disectomy (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 microdisectomy has not been shown to be more effective than standard disectomy.
**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 Disectomy (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).

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.

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.

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 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 disc index L5 to S1 was significantly decreased in Group B by 13 % (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 radiological 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 Stablimax NZ Dynamic Spinal Stabilization System is an investigational device that is being evaluated for the treatment of patients with symptomatic spinal stenosis. The Stablimax 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 Stablimax 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 Stablimax 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 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. 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). 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
Spondylosis 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 spinal 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 is pending publication evaluating 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 in this group of subjects are 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. 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.

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 section 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 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 disectomy issued by the National Institute for Health and Clinical Excellence (NICE, 2003) stated that "Current evidence on the safety and efficacy of laser lumbar disectomy 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 microdisectomy 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 disectomy stated that "Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar disectomy. 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 disectomy and laser disectomy. The reviewers found four trials on automated percutaneous disectomy that met their inclusion criteria: 2 trials that compared automated percutaneous disectomy with chymopapain (Revel, 1993; Kruglger, 2000) and 2 that compared automated percutaneous disectomy with microdisectomy (Chatterjee, 1995; Haines, 2002). The reviewers reported that the results from these 4 trials suggested that automated percutaneous disectomy produced inferior results to either more established procedure. The reviewers found 2 trials that met their inclusion criteria on laser disectomy: 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 disectomy (Steffen and Wittenberg, 1997) and reported that the study results favored chemonucleolysis. The reviewers concluded that while microdisectomy gives broadly comparable results to open disectomy, 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 disectomy 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, intradisc[al] 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 (Boul 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**

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.

**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 SnergyTM cooled RF system for SIJ pain. The charts of 20 patients with chronic SIJ pain who had undergone denervation using the SnergyTM 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.

Facet Joint Implantation

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**

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
psosas muscle, to lie alongside the affected disc, via a lateral approach.

Nerve monitoring is recommended to avoid damage to motor nerves. However, lower
limb dysesthesia 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 posterolateral 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 Transformaminal Lumbar Interbody Fusion (MITLIF)**

Minimally invasive transformaminal 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 arthrosis with spine pain, Nu-Fix was cleared by the FDA based upon a 510(k) premarket notification. This allograft interference screw is percutaneously 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-laminectomy 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. (Available at: http://clinicaltrials.gov/ct2/show/NCT01019057.)

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 XLIIF 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 ≤ 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 ≤ 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, 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 (Spinoneology 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 relieving 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.

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 coccyectomy 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 coccyectomy. Furthermore, an UpToDate review on “Coccydynia (coccygodynia)” (Fletcher, 2012) suggests that coccyectomy 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 (i) osteo-inductive surface for enhanced fusion, (ii) stabilization of the spine, and (iii) 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 biacaplasty (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.

Sacroiliac Joint Fusion

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 spondyloarthopathy 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.

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 < or = 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 < or = 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 systemic 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, 2007) 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.

Cryoaablation for the Treatment of Lumbar facet Joint Pain

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 %.

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, thorascopic 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, transformaminal 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 transformaminal 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 transformaminal 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 discectomy (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 posterolateral 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 interbody 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, Scientx, 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 loosenings 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).


Appendix

Table 1: Noncovered Interspinous Fixation Devices (not an all-inclusive list)

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

Table 2: Noncovered Interspinous and Interlaminar Distraction Devices (not an all-inclusive list)

- Aperius PercLID System (Kyphon/ Medtronic Spine)
- Cofflex 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/Medronic Spine)
X-STOP PEEK Interspinous Process Decompression (IPD) System (Kyphon/Medronic Spine)

Spine Cages (Not an all-inclusive list) (covered when criteria are met)

Aesculap PEEK (brand name Synthes)

Synthes Aesculap PEEK
Alamo Spine Cages
Alphatec Novel TL Spacer System
Atlantis translational plate fixation
BAK Interbody Fusion System
Biomet OsteoStim
CALIX cage (X-Spine)
ChoiceSpine
Harpoon, Hawkeye, Hornet, Shark
CORNERSTONE® PSR Spinal System (Medronic)
CoRoent Interbody Cage (Nuvasive)
Depuy Acromed Lumbar I/F Cage
Depuy Bengal Corpectomy cage
Genesys MectaLIF transforaminal lumbar interbody fusion device
Globus Caliber Globus
Sustain-O Globus
Coalition Spacer Integra
Vu POD
K2 Ravine
K2M Aleutian Spacer Systems
K2M Chesapeake Spinal System
LANX Lateral Cage
LDR ROI-A Implant System
Medtronic Capstone
Nanovis cage
NEXXT spine intervertebral cage
Nuvasive Brigade
Osteofix Pillar (AL, SA, PL, TL)
Pinnacle
InFill Lateral Interbody Device
PRO-LINK Stand-Alone Cervical Spacer System (Life Spine, Inc.)
Ray Threaded Fusion Cage
Renovis PEEK ALIF Cage Signus
cage Caymankz plate Spinal
Elements Lucent Magnum
Spine 360 plate & cage for cervical fusion
Spine 360 Cervical Interbody Fusion System
Stalif-C (Cervical Cage)
Stalif Midline and Stalif Midline ABO Screws
Stryker AVS Anchor-L Lumbar Cage System
Stryker AVS AS PEEK
Synthes SYNFIX LR system
Synthes Zero-P (zero-Profile anterior cervical interbody fusion device)
Synthes T-Pal
Theken LLC Reveal VBR System
Theken Spine Vu c-POD Intervertebral Body Fusion Device
XP L Spinal System (Arcadius™)
Zimmer TM-S cervical fusion device

Noncovered Spine Cages (not an all-inclusive list)

Globus Latis
Wenzel Spine Varilift

CPT Codes / ICD-9 Codes / HCPCS Codes

Coccygectomy:

CPT codes covered if selection criteria are met:

27080

ICD-9 codes covered if selection criteria are met:

724.79 Disorders of coccyx[for individuals with coccygodynia who have tried and failed to respond to 6 months of conservative management]

Facet joint injections [not covered for intradiscal and/or paravertebral oxygen/ozone injection]:

CPT codes covered if selection criteria are met:

64479
+ 64480
64483
+ 64484
64490
64491
64492
64493
64494
64495
0213T
+ 0214T
+ 0215T
0216T
+ 0217T
+ 0128T

Other CPT codes related to the CPB:
72275
76942
77002
77021

ICD-9 codes covered if selection criteria are met:
723.1 Cervicalgia [covered for the diagnosis of facet pain with chronic back or neck pain lasting more than 3 months despite appropriate conservative treatment - not for therapy]
723.2 Cervicocranial syndrome [covered for the diagnosis of facet pain with chronic back or neck pain lasting more than 3 months despite appropriate conservative treatment - not for therapy]
723.8 Other syndromes affecting cervical region [covered for the diagnosis of facet pain with chronic back or neck pain lasting more than 3 months despite appropriate conservative treatment - not for therapy]
724.2 Lumbago [covered for the diagnosis of facet pain with chronic back or neck pain lasting more than 3 months despite appropriate conservative treatment - not for therapy]
724.3 Sciatica [covered for the diagnosis of facet pain with chronic back or neck pain lasting more than 3 months despite appropriate conservative treatment - not for therapy]
724.5 Backache, unspecified [covered for the diagnosis of facet pain with chronic back or neck pain lasting more than 3 months despite appropriate conservative treatment - not for therapy]

Ganglion Nerve Block:

CPT codes not covered for indications listed in the CPB:
64450

ICD-9 codes not covered for indications listed in the CPB:
724.79 Disorders of coccyx [coccydynia]


**Trigger point Injections:**

CPT codes covered if selection criteria are met:

20552

20553

Other CPT codes related to the CPB:

76942

77002

77021

97001 - 97139

Other HCPCS codes related to the CPB:

E0200 - E0239  Heat/cold application

S9117  Back school, per visit

**ICD-9 codes covered if selection criteria are met:**

723.1  Cervicalgia

723.2  Cervicocranial syndrome

723.8  Other syndromes affecting cervical region

724.1  Pain in thoracic spine

724.2  Lumbago

724.3  Sciatica

724.5  Backache, unspecified

729.1  Myalgia and myositis, unspecified

Other ICD-9 codes related to the CPB:

V58.64  Long term (current) use of non-steroidal anti-inflammatories (NSAID)

**Sacroiliac joint injections:**

CPT codes covered if selection criteria are met:

27096

Other CPT codes related to the CPB:

77003
HCPCS codes covered if selection criteria are met:

G0260 Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

Other HCPCS codes related to the CPB:

G0259 Injection procedure for sacroiliac joint; arthrography

ICD-9 codes covered if selection criteria are met:

724.2 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]

724.3 Sciatica [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]

Epidural injections of corticosteroid preparations:

CPT codes covered if selection criteria are met:

62310
62311
62318
62319

Other CPT codes related to the CPB:

72275
97001 - 97139

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-9 codes covered if selection criteria are met:

723.1 Cervicalgia
723.2 Cervicocranial syndrome
723.8 Other syndromes affecting cervical region
724.1 Pain in thoracic spine
724.2 Lumbago
724.3 Sciatica
724.5 Backache, unspecified

**ICD-9 codes not covered for indications listed in the CPB:**

170.2 Malignant neoplasm of vertebral column, excluding sacrum and coccyx
170.6 Malignant neoplasm of pelvic bones, sacrum, and coccyx
192.2 Malignant neoplasm of spinal cord
192.3 Malignant neoplasm of spinal meninges
198.3 Secondary malignant neoplasm of brain and spinal cord
198.4 Secondary malignant neoplasm of other parts of nervous system
198.5 Secondary malignant neoplasm of bone and bone marrow
213.2 Benign neoplasm of vertebral column, excluding sacrum and coccyx
213.6 Benign neoplasm of pelvic bones, sacrum, and coccyx
225.3 Benign neoplasm of spinal cord
225.4 Benign neoplasm of spinal meninges
237.5 Neoplasm of uncertain behavior of brain and spinal cord
237.6 Neoplasm of uncertain behavior of meninges
239.7 Neoplasm of unspecified nature of endocrine glands and other parts of nervous system

**Chymopapain chemonucleolysis:**

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

62292

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

72125 - 72133
72141 - 72158
72240 - 72270

**ICD-9 codes covered if selection criteria are met:**

722.10 Displacement of lumbar intervertebral disc without myelopathy
### ICD-9 codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>170.2</td>
<td>Malignant neoplasm of vertebral column, excluding sacrum and coccyx</td>
</tr>
<tr>
<td>170.6</td>
<td>Malignant neoplasm of pelvic bones, sacrum, and coccyx</td>
</tr>
<tr>
<td>192.2</td>
<td>Malignant neoplasm of spinal cord</td>
</tr>
<tr>
<td>192.3</td>
<td>Malignant neoplasm of spinal meninges</td>
</tr>
<tr>
<td>198.3</td>
<td>Secondary malignant neoplasm of brain and spinal cord</td>
</tr>
<tr>
<td>198.4</td>
<td>Secondary malignant neoplasm of other parts of nervous system</td>
</tr>
<tr>
<td>198.5</td>
<td>Secondary malignant neoplasm of bone and bone marrow</td>
</tr>
<tr>
<td>213.2</td>
<td>Benign neoplasm of vertebral column, excluding sacrum and coccyx</td>
</tr>
<tr>
<td>213.6</td>
<td>Benign neoplasm of pelvic bones, sacrum, and coccyx</td>
</tr>
<tr>
<td>225.3</td>
<td>Benign neoplasm of spinal cord</td>
</tr>
<tr>
<td>225.4</td>
<td>Benign neoplasm of spinal meninges</td>
</tr>
<tr>
<td>237.5</td>
<td>Neoplasm of uncertain behavior of brain and spinal cord</td>
</tr>
<tr>
<td>237.6</td>
<td>Neoplasm of uncertain behavior of meninges</td>
</tr>
<tr>
<td>239.7</td>
<td>Neoplasm of unspecified nature of endocrine glands and other parts of nervous system</td>
</tr>
<tr>
<td>320 - 359.9</td>
<td>Diseases of the nervous system</td>
</tr>
<tr>
<td>344.60 - 344.61</td>
<td>Cauda equina syndrome</td>
</tr>
<tr>
<td>630 - 677</td>
<td>Complications of pregnancy, childbirth, and the puerperium</td>
</tr>
<tr>
<td>722.0</td>
<td>Displacement of cervical intervertebral disc without myelopathy</td>
</tr>
<tr>
<td>722.11</td>
<td>Displacement of thoracic intervertebral disc without myelopathy</td>
</tr>
<tr>
<td>722.71</td>
<td>Intervertebral disc disorder with myelopathy, cervical region</td>
</tr>
<tr>
<td>722.72</td>
<td>Intervertebral disc disorder with myelopathy, thoracic region</td>
</tr>
<tr>
<td>722.80 - 722.83</td>
<td>Postlaminectomy syndrome</td>
</tr>
<tr>
<td>723.0</td>
<td>Spinal stenosis of cervical region</td>
</tr>
</tbody>
</table>
724.00 - Spinal stenosis, other than cervical
724.09

724.1 Pain in thoracic spine
724.2 Lumbago
724.5 Backache, unspecified
724.6 Disorders of sacrum
724.8 Other symptoms referable to back
724.9 Other unspecified back disorders
738.4 Acquired spondylolisthesis
756.11 Spondylysis, lumbosacral region
756.12 Spondylolisthesis
781.0 - 781.99 Symptoms involving nervous and musculoskeletal systems
V22.0 - V23.9 Supervision of pregnancy

Other ICD-9 codes related to the CPB:

728.87 Muscle weakness (generalized)
729.2 Neuralgia, neuritis, and radiculitis, unspecified
729.5 Pain in limb
782.0 Disturbance of skin sensation

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

CPT codes covered if selection criteria are met:

62287

CPT codes not covered for indications listed in the CPB:

0274T
0275T

Other CPT codes related to the CPB:

62267
63001 - 63091
63185 - 63190
72125 - 72133
72141 - 72158
72240 - 72270
77002

Other HCPCS codes related to the CPB:
C2614  Probe, percutaneous lumbar discectomy

ICD-9 codes covered if selection criteria are met:
722.10  Displacement of lumbar intervertebral disc without myelopathy
722.73  Intervertebral disc disorder with myelopathy, lumbar region

Radiofrequency facet denervation:

CPT codes covered if selection criteria are met:
64633
64634
64635
64636

Other CPT codes related to the CPB:
22548 - 22812
64479 - 64484
72125 - 72133
72141 - 72158
72240 - 72270
97001 - 97139

Other HCPCS codes related to the CPB:
L0112 - L0999  Orthotic devices-spinal

ICD-9 codes covered if selection criteria are met:
723.1  Cervicalgia
723.2  Cervicocranial syndrome
723.8  Other syndromes affecting cervical region
724.1  Pain in thoracic spine
724.2  Lumbago
724.3  Sciatica
724.5  Backache, unspecified

**ICD-9 codes not covered for indications listed in the CPB:**

722.0 - 722.93  Intervertebral disc disorders
724.6  Disorders of sacrum

**Other ICD-9 codes related to the CPB:**

V58.64  Long term (current) use of non-steroidal anti-inflammatories (NSAID)

**Pedicle screws for spinal fixation:**

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

22840 - 22847

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

22548 - 22812
63001 - 63091

**ICD-9 codes covered if selection criteria are met:**

722.80  Postlaminectomy syndrome
722.83

733.82  Nonunion of fracture [pseudoarthrosis]
737.0 - 737.9  Curvature of spine [requiring spinal instrumentation]
738.4  Acquired spondylolisthesis [grades I-IV]
754.2  Certain congenital musculoskeletal deformities of spine
756.11  Spondylolysis lumbosacral region [grades I-IV]
756.12  Spondylolisthesis [grades I-IV]
756.19  Other anomalies of spine
805.00 - 805.7  Fracture of vertebral column without mention of spinal cord injury
839.00 - 839.59  Dislocation of vertebra

**ICD-9 codes not covered for indications listed in the CPB:**

722.4 - 722.73  Degeneration of intervertebral disc
724.2  Lumbago
Other ICD-9 codes related to the CPB:

V45.4 Arthrodesis status [status post fusion]

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

CPT codes covered if selection criteria are met:

+22851

Other CPT codes related to the CPB:

20936 - 20938

ICD-9 codes covered if selection criteria are met:

722.51 Degeneration of thoracic or thoracolumbar intervertebral disc [see criteria in CPB 743]

722.52 Degeneration of lumbar or lumbosacral intervertebral disc [see criteria in CPB 743]

756.11 Spondylolysis, lumbosacral region [see criteria in CPB 743]

756.12 Spondylolisthesis [see criteria in CPB 743]

*Percutaneous polymethylmethacrylate vertebroplasty (PPV) or kyphoplasty:*

CPT codes covered if selection criteria are met:

22520

22521

+ 22522

22523

22524

+ 22525

Other CPT codes related to the CPB:

72291

72292

HCPCS codes covered if selection criteria are met:

S2360 Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical
each additional cervical vertebral body (list separately in addition to code for primary procedure)

**ICD-9 codes covered if selection criteria are met:**

170.2 Malignant neoplasm of vertebral column, excluding sacrum and coccyx
170.6 Malignant neoplasm of pelvic bones, sacrum, and coccyx
192.2 Malignant neoplasm of spinal cord
192.3 Malignant neoplasm of spinal meninges
198.3 Secondary malignant neoplasm of brain and spinal cord
198.4 Secondary malignant neoplasm of other parts of nervous system
198.5 Secondary malignant neoplasm of bone and bone marrow
200.00 - 208.92 Malignant neoplasm of lymphatic and hematopoietic tissue
228.09 Hemangioma of other sites [painful and/or aggressive]
277.89 Other specified disorders of metabolism [painful vertebral eosinophilic granuloma]
721.7 Traumatic spondylopathy
733.00 - 733.09 Osteoporosis
733.13 Pathologic fracture of vertebrae [painful, debilitating osteoporotic collapse/compression fractures]
805.00 - 805.7 Fracture of vertebral column without mention of spinal cord injury [steroid-induced]
806.00 - 806.79 Fracture of vertebral column with spinal cord injury [steroid-induced]

**ICD-9 codes not covered for indications listed in the CPB:**

722.0 - 722.93 Intervertebral disc disorders

**Other ICD-9 codes related to the CPB:**

723.1 Cervicalgia
723.2 Cervicocranial syndrome
723.8 Other syndromes affecting cervical region
724.1 Pain in thoracic spine
Back Pain

724.2  Lumbago
724.3  Sciatica
724.5  Backache, unspecified
E932.0  Adverse effect of adrenal cortical steroids
V58.65  Long term (current) use of steroids

**Endoscopic Spinal surgery:**

No specific code

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

62267
62287
77002

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

No specific code

**ICD-9 codes covered if selection criteria are met:**

724.9  Other unspecified back disorders [damaged or unstable vertebral]
733.13  Pathologic fracture of vertebrae [collapsed vertebral body resected or excised during total and partial vertebrectomy procedures]

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

**Chronic Back Pain:**

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

96365 - 96368

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

J2001  Injection, lidocaine HCL for intravenous infusion 10 mg

**ICD-9 codes not covered for indications listed in the CPB:**

724.2  Lumbago
724.5  Unspecified backache

**Endoscopic transforaminal diskectomy:**

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

62287
Other CPT codes related to the CPB:

96365 - 96366

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-9 codes not covered for indications listed in the CPB:

724.2 Lumbago
724.5 Unspecified backache

Minimally Invasive Thoracic diskectomy:

CPT codes not covered for indications listed in the CPB:

22532

Percutaneous cervical diskectomy:

Minimally Invasive Lumbar Decompression (MILD):

CPT codes not covered for indications listed in the CPB:

0274T
0275T

Epiduroscopy:

Other CPT codes related to the CPB:

62318
62319
72275

Epidural injections of lytic agents:

CPT codes not covered for indications listed in the CPB:

62280
62281
62282

Other CPT codes related to the CPB:

72275
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-9 codes not covered for indications listed in the CPB:

322.0 - 322.9  Meningitis of unspecified cause
720.0 - 724.9  Dorsopathies
729.2  Neuralgia, neuritis, and radiculitis, unspecified
905.1  Late effect of fracture of spine and trunk without mention of spinal cord lesion
907.3  Late effect of injury to nerve root(s), spinal plexus(es), and other nerves of trunk
959.19  Other injury of other sites of trunk

Microsurgical anterior foraminotomy:

Other CPT codes related to the CPB:

63075 - 63078

Other HCPCS codes related to the CPB:

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

Sacroiliac fusion:

CPT codes not covered for indications listed in the CPB:

0334T
27280

Sacroplasty:

CPT codes not covered for indications listed in the CPB:
0200T
0201T

_Racz procedure (epidural adhesiolysis with the Racz catheter):_

CPT codes not covered for indications listed in the CPB:
62263
62264

Other CPT codes related to the CPB:
72275

_Microdisectomy:_

Other CPT codes related to the CPB:
22220 - 22226
62267
62287
+ 69990
77002

Other HCPCS codes related to the CPB:
C2614       Probe, percutaneous, lumbar discectomy
S2350       Discetomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; lumbar, single interspace
S2351       Discetomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

_Microendoscopic disectomy (MED):_

Other CPT codes related to the CPB:
22206
22207
+ 22208
22214
+ 22216
22224
+ 22226
62287
+ 69990
77002

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

C2614  Probe, percutaneous, lumbar discectomy
S2350  Discetomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; lumbar, single interspace
S2351  Discetomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; lumbar, each additional interspace (list separately in addition to code for primary procedure)

**Intercostal nerve blocks:**

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

64420
64421

**ICD-9 codes not covered for indications listed in the CPB:**

353.8  Other nerve root and plexus disorders [intercostal neuritis]

**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:**

0171T
+ 0172T
0202T

**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
64712
ICD-9 codes not covered for indications listed in the CPB:

355.0 Lesion of sciatic nerve
724.3 Sciatica
726.5 Enthesopathy of hip region

Radiofrequency denervation for sacroiliac joint pain:

CPT codes not covered for indications listed in the CPB:

27035
64635
+ 64636

ICD-9 codes not covered for indications listed in the CPB:

355.0 Lesion of sciatic nerve
724.3 Sciatica
724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified
726.5 Enthesopathy of hip region

Facet joint implantation:

CPT codes not covered for indications listed in the CPB:

0219T
0220T
0221T
0222T

Epidural fat grafting:

Other CPT codes related to the CPB:

20926

No specific codes:

Aspen spinous process fixation system, Barriacaid and DART disc annular repair devices, CD HORIZON SPIRE Plate, PrimaLOK SP, and SP-Fix Spinous Process Fixation Plate, Coccygeal ganglion (ganglion impar) blockade for pelvic pain, 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), Endoscopic laser foraminalplasty, Extreme lateral interbody fusion (XLIF), Interlaminar lumbar instrumented fusion (iILIF), OptiMesh grafting system, Psoas compartment block,
Radiofrequency lesioning of dorsal root ganglia, Radiofrequency lesioning of terminal (peripheral) nerve endings, Radiofrequency/pulsed radiofrequency ablation of trigger points, Total Facet Arthroplasty System, Vesselplasty (e.g., Vessel-X), Yeung Endoscopic Spinal Surgery System, Y.E.S.S., Xclose Tissue Repair System

The above policy is based on the following references:

Facet Joint Injections


24. 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


Sacral iliac 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

6. Schnee CL, Freese A, Ansell LV. Outcome analysis of adults with
spondylolisthesis treated with posterolateral fusion and transpedicular screw
fixation on lumbar/lumbosacral autogenous bone graft fusion in adult patients
improve correction in the lumbar spine of patients with idiopathic scoliosis.
9. Ricciardi JE, Pfleuger PC, Isaza JE. Transpedicular fixation for the treatment of
10. Schwab FJ, Nazarian DG, Mahmoud F. Effects of spinal instrumentation on fusion
11. Yuan HA, Garfin SR, Dickman CA. A historical cohort study of pedicle screw
-2299S.
12. Zdeblick T. A prospective, randomized study of lumbar fusion -- preliminary
of the lumbar spine: Operative technique and outcome in 104 cases. J
14. West JL, Bradford DS, Ogilvie JW. Results of spinal arthrodesis with pedicle
15. Cope R, Henstorf JE, Gaines RW. A new interpeduncular screw fixation system:
Biomechanics, radiologic appearances and complications of the Steffee spine
technique using the variable screw placement spinal fixation system. State of the
17. Vaccaro AR, Garfin SR. Internal fixation (pedicle screw fixation) for fusions of the
18. Rhee JM, Bridwell KH, Won DS, et al. Sagittal plane analysis of adolescent
idiopathic scoliosis: The effect of anterior versus posterior instrumentation.
19. Washington State Department of Labor and Industries. Guidelines for lumbar
fusion (arthrodesis). Olympia, WA: Washington State Department of Labor and

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

Should backache be treated with spinal fusion? The case for spinal fusions is
2. Hacker RJ, Follett KA. Comparison of interbody fusion approaches for disabling
4. U.S. Food and Drug Administration (FDA). BAK interbody fusion with
instrumentation. Summary of Safety and Effectiveness Data. PMA


Cervical Spine Cages


**Epiduroscopy**


Epidural Injections for Lysis of Adhesions


**Endoscopic Transforaminal Percutaneous Discetomy**


**Percutaneous Polymethylmethacrylate Vertebroplasty and Kyphoplasty**


33. Kallmes DF. If one vertebroplasty is good, two must be better. Spine. 2008;33(6):579-580.

34. 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).


37. Rousing R, Andersen MO, Jespersen SM, et al. Percutaneous vertebroplasty compared to conservative treatment in patients with painful acute or subacute


46. 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


http://qawww.aetna.com/cpb/medical/data/1_99/0016_draft.html

11/26/2014
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:


33. Levin K. Lumbar spinal stenosis: Treatment and prognosis. Last reviewed February 2012. UpToDate Inc. Waltham, MA.


Piriformis Muscle Resection


Endoscopic Laser Foraminoplasty


5. Takeno K, Kobayashi S, Yonezawa T, et al. Salvage operation for persistent low back pain and sciatica induced by percutaneous laser disc decompression performed at outside institution: Correlation of magnetic resonance imaging and

**Xclose Tissue Repair System**


**Radiofrequency Denervation for Sacroiliac Joint Pain**


**Facet Joint Implantation**


Lateral Interbody Fusion


Minimally Invasive/Endoscopic Cervical Laminoforaminotomy


Minimally Invasive Lumbar Decompression (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


Radiofrequency/Pulsed Radiofrequency Ablation of Trigger Point Pain


Coccygectomy


Oxygen-Ozone Therapy (Injection)


Sacroiliac Joint Fusion


Cryoablation for the Treatment of Lumbar Facet Joint Pain:

2. Chou R. Subacute and chronic low back pain: Nonsurgical interventional treatment. Last reviewed September 2013. UpToDate Inc., Waltham, MA.

Minimally Invasive Thoracic Discectomy:


Total Facet Arthroplasty System:


Dynamic (intervertebral) stabilization/Bioflex:
