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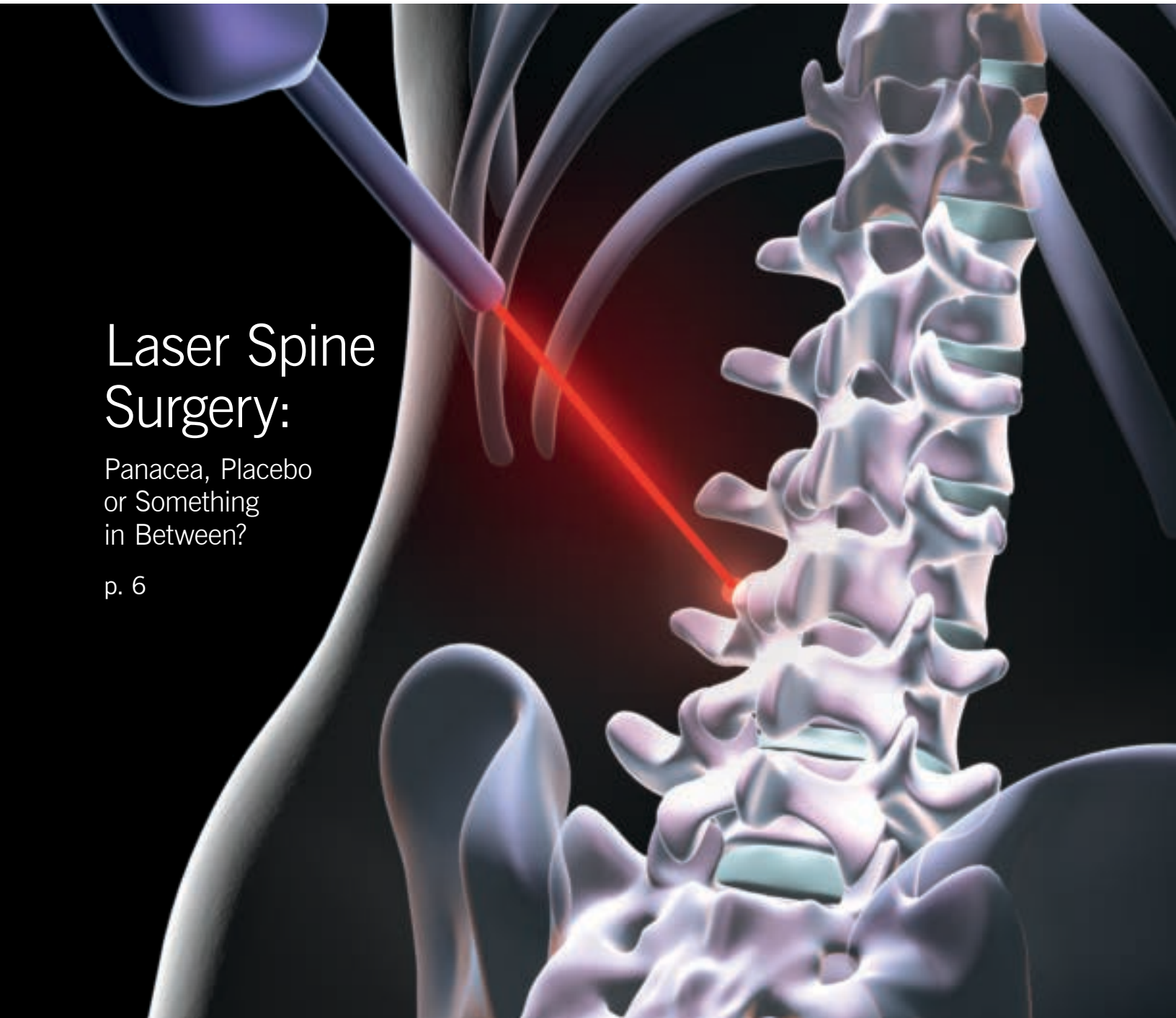
2015

Spinal Column

CENTER FOR SPINE HEALTH



Laser Spine Surgery:

Panacea, Placebo or Something in Between?

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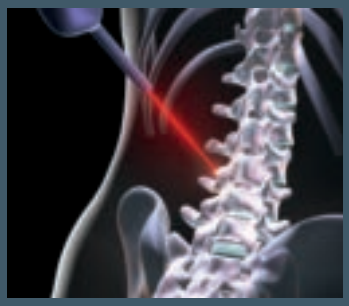

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The Center for Spine Health is part of the multidisciplinary Cleveland Clinic Neurological Institute, which is dedicated to the diagnosis and treatment of common and complex neurological disorders of adult and pediatric patients. Its more than 300 specialists combine expertise and compassion to achieve measurably superior results. By promoting innovative research and care models, the Neurological Institute accelerates development and application of new treatments and technologies to patient care. The Neurological Institute is one of 27 institutes at Cleveland Clinic, a nonprofit academic medical center ranked among the nation's top hospitals (*U.S. News & World Report*), where more than 3,200 physicians in 120 specialties collaborate to give every patient the best outcome and experience.

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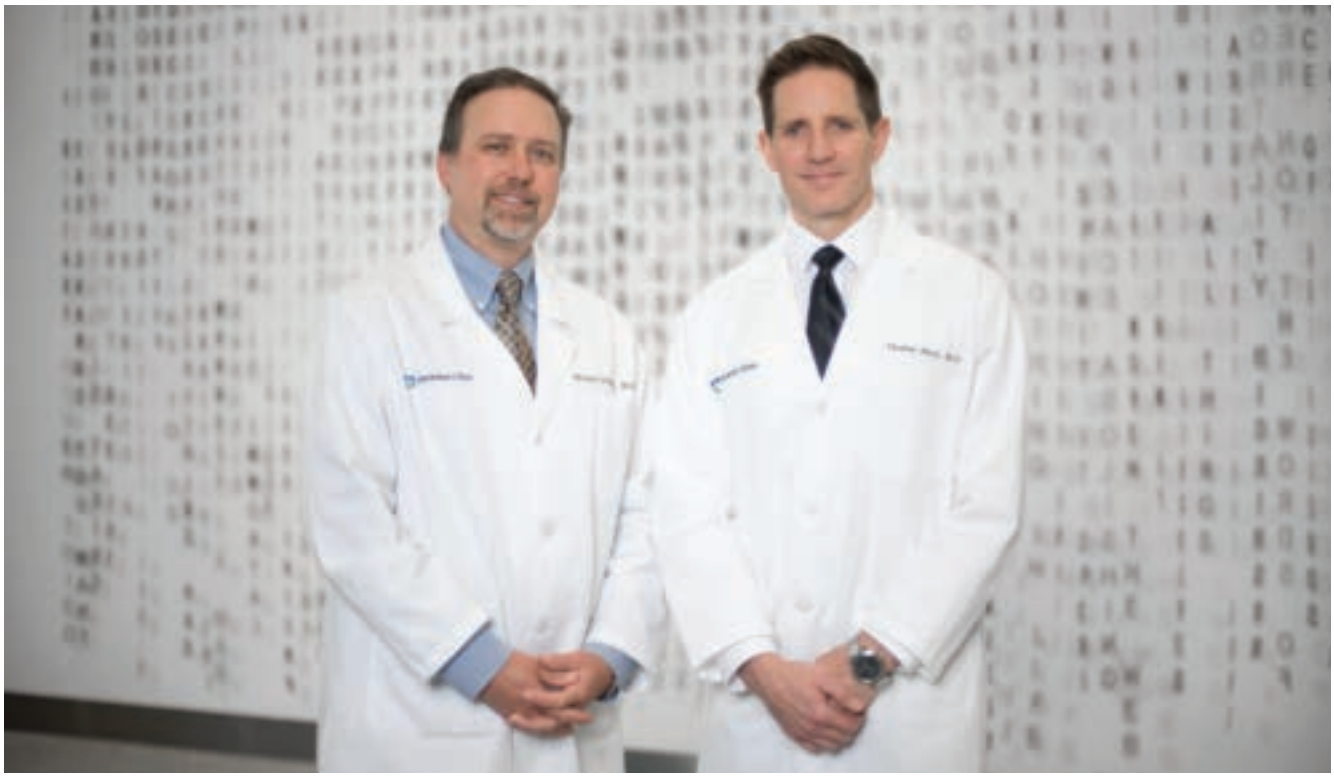

Michael P. Steinmetz, MD (left), and Thomas E. Mroz, MD (right)

Dear Colleagues,

Many of our patients are searching for minimally or less-invasive surgery. The thought of having an operation through a small incision and leaving the hospital on the same day is appealing.

Techniques to accomplish such goals have been developed during the past 20 years and are now routinely utilized in spine care. Despite the availability of the latest technology and the significant marketing employed to promote it, many patients or their conditions are not appropriate for this type of surgery. It remains the job of a diligent spine team to accurately diagnose a patient's condition and offer the most appropriate treatment to alleviate his or her symptoms. When minimally invasive procedures are appropriate, they should be utilized.

This issue of *Spinal Column* is dedicated to minimally invasive spine surgery. The goal of this edition is to discuss the various options available, and to further review the evidence that may or may not support their use.

Marketing of the latest and "sexiest" procedures, technologies and techniques often influences surgeons and patients alike. The articles in these pages will lend support to those approaches that are grounded in solid evidence, and will point out areas that deserve further exploration.

Thomas E. Mroz, MD

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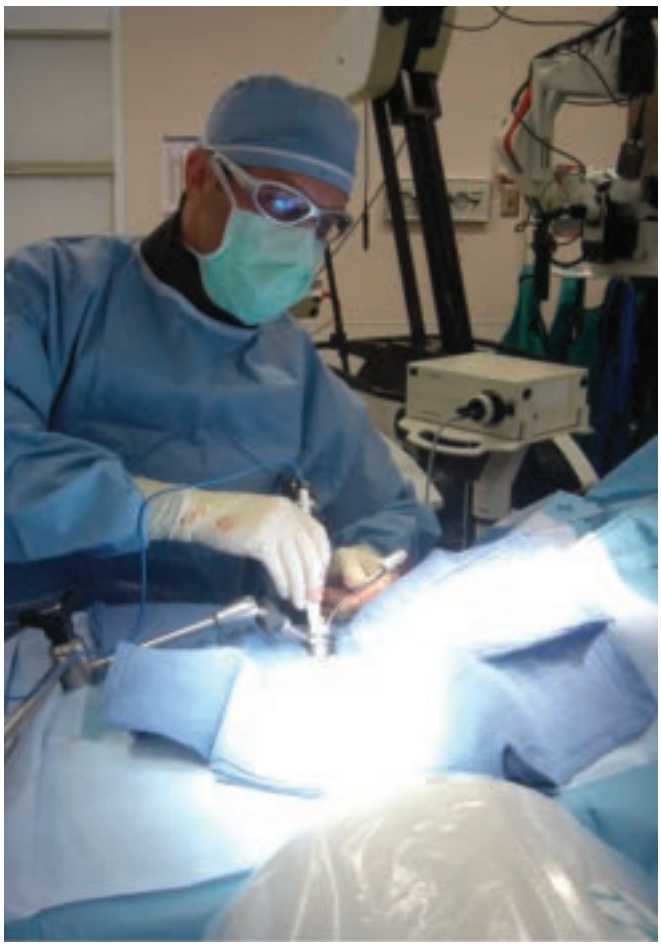
Minimally Invasive Spine Surgery: Does the Evidence Support Its Use?

By Michael P. Steinmetz, MD

A large majority of patients who visit a spine surgeon are seeking a minimally invasive surgery (MIS) option. This approach to treating common spine disease has gained traction with patients due in large part to print and television advertising. One such consumer ad features attractive models, one of whom is sporting a small Band-Aid on her back with the caption: "Guess which one of these people had spine surgery today?"



The surgeon begins working through the minimally invasive retractor in order to remove a herniated disk in the lumbar spine.

In general, many types of surgeries have become minimally invasive. For example, most abdominal procedures have been replaced by outpatient laparoscopic options, including robot-assisted surgery. These same techniques have made their way into spine surgery — yet it remains unclear how effective they are or could be.

Defining Minimally Invasive Spine Surgery

MIS of the spine must first be defined; if not, essentially any operation performed through a small incision would be classified as minimally invasive. Technically speaking, in the spine, MIS involves making a small incision and a corridor through the muscle. This corridor is created by minimally dilating the muscle fibers en route to the spine.

This is in contrast to conventional surgery, which involves "stripping" the muscle from its attachment to the bone. The latter may be associated with more blood loss and certainly greater trauma to the bone.

With this definition in place, the only true difference between MIS and conventional surgery is the approach.

The most commonly performed minimally invasive spine surgeries include lumbar microdiskectomy, laminectomy and transforaminal lumbar interbody fusion (TLIF). In the cervical spine, minimally invasive foraminotomy is also done frequently.

Potential for Improved Perioperative Outcomes

Spine surgeons have been employing a minimally invasive approach to surgery since the 1980s. Unfortunately, we are only now collecting enough data to analyze the effectiveness of MIS for the spine.

It appears, albeit with early and low-quality evidence, that the vast majority of minimally invasive spine surgeries result in improved perioperative outcomes — specifically less blood loss, less pain immediately following the procedure and shorter hospital stays. However, long-term outcomes have not shown any advantages for MIS of the spine.

Proponents of MIS tout the differences in perioperative outcomes as clear advantages, while opponents claim that the differences are not practical in "real life" and that analysis of long-term outcome data is necessary before we draw conclusions.

Studies have clearly shown that patients after MIS surgery have less pain and lose less blood during surgery. However, less pain may be 10 out of 100 on a pain scale versus 15. The difference between the numbers may be significant; however, these same patients' pain may be practically the same.

Short-term advantages aside, research today has moved toward understanding the cost-effectiveness of minimally invasive spine surgery. If long-term benefits are not shown, then the early or perioperative benefits must decrease the cost of the entire healthcare episode. The evidence is extremely limited. Some early studies clearly have demonstrated cost-effectiveness, while others have not.

Mounting Evidence of Benefits, but More Research Is Needed

Surgery as a whole is becoming more and more minimally invasive. Spine is no different. There are clear advantages and disadvantages to MIS of the spine. Minimally invasive spine surgery costs more, often takes longer to perform and exposes the patient to greater amounts of radiation due to more extensive intraoperative imaging. On the other hand, the incision is smaller, and the patient loses less blood, may have less pain and spends fewer days in the hospital.

MIS is appropriate for specific patients with specific pathologies, since one size never fits all. The decision to perform MIS or not largely rests in the pathology or the reason surgery is to be performed.

Evidence continues to mount demonstrating perioperative benefits of MIS over conventional spine surgery. We eagerly await the results of further outcome and cost-effectiveness studies. ■

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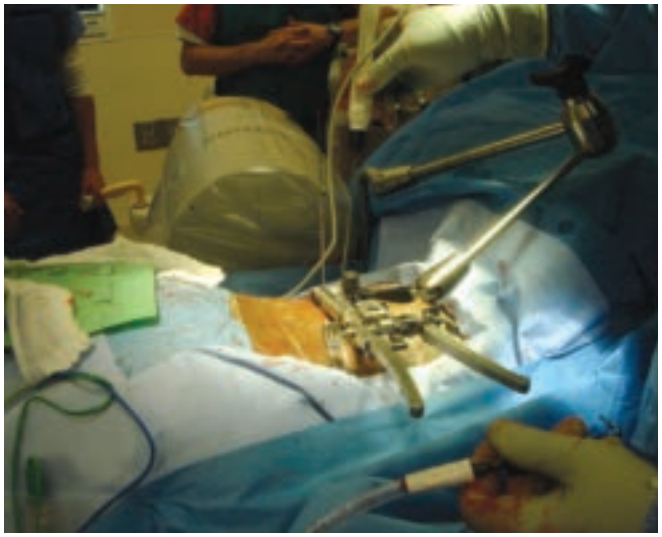

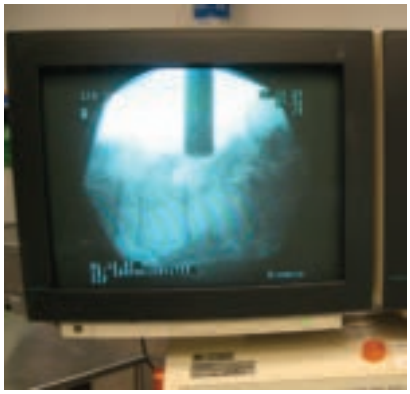

Above: After placing a retractor through the skin, the surgeon begins working through a 2.5 cm incision toward an eventual lumbar fusion with screws and rods.

Left: Intraoperative fluoroscopic image. A minimally invasive tubular retractor has been placed through the skin in the lumbar spine.

KEY POINTS

Minimally invasive techniques have made their way into spine surgery, yet it remains unclear how effective they are or could be.

The vast majority of minimally invasive spine surgeries appear to result in improved perioperative outcomes.

More studies are needed to evaluate long-term outcomes and cost-effectiveness.

Laser Spine Surgery: Panacea, Placebo or Something in Between?

After 30 years in use, this approach is receiving much attention in lay and medical communities

By Ryan Brennan, MD, and Thomas E. Mroz, MD

In recent years, patients have been inundated by advertising and social media campaigns that make laser spine surgery sound like a real-life, science fiction-inspired cure-all. As a result, increasing numbers of patients are expressing interest in this alternative to standard surgical treatments of spinal conditions. The heavy marketing push that positions this surgical technique as a panacea has some spine surgeons tamping down the claims.

What patients — and even some physicians and surgeons — might not know is that this technique has been utilized for nearly 30 years and is an effective approach in selected patients.

Background and Applications

Peter Ascher and Daniel Choy became the pioneers of laser spine therapy in 1986, performing the first percutaneous laser disk decompression (PLDD) procedure at the Neurosurgical Department, University of Graz, in Austria.[1]

The first and still most common application of laser spine therapy is for the treatment of lumbar herniated nucleus pulposus (HNP).

Today, advances in technology, the development of new lasers and equipment, and improved imaging have allowed for the expansion of laser spine interventions to include the cervical, thoracic and lumbar spine.

Applications include percutaneous laser disk decompression of the cervical, thoracic and lumbar spine; laser-assisted posterior cervical foraminotomies and diskectomy for lateral and foraminal cervical disk herniation; laser-assisted anterior cervical corpectomy for cervical myelopathy patients with multilevel ossification of the posterior longitudinal ligament; and laser ablation of spinal growths such as tumors and vascular lesions.

Patient selection criteria for laser spine surgery is similar to that for conventional open surgery: ages 18 to 70, sciatica or cervical radiculopathy due to lumbar or cervical disk herniation for which conservative measures have failed and disk herniation of less than one-third the diameter of the central canal, without concomitant lateral recess stenosis or sequestration.

The use of laser therapy has spread worldwide.

Differing Theories About How PLDD Works

Choy has theorized that the use of PLDD centers on the principle that the disk, surrounded by a fibrous annular ring, represents an enclosed hydrologic space and that laser ablation of even a small amount of intradiskal material can lead to a reduction in the intradiskal pressure that is significantly disproportionate to the reduced volume.[2,3] As a result, a newly created vacuum within the disk pulls the bulging or herniated disk fragment back into this space, thereby relieving the pressure on the neural elements.[2] This theory, however, is not proven — and many doubt that this actually occurs.

Others have suggested that the drop in intradiskal pressure is a placebo byproduct of placing the needle into the disk and not due to the laser ablation itself. However, intradiskal pressure measurements have confirmed that the disk pressure remains stable when the needle is placed and is reduced only after the laser ablation is completed.[4]

Achieving Optimal Outcomes

To obtain optimal outcomes using the percutaneous approach to laser therapy, proper placement of the needle tip just interior to the annulus is key, with the needle parallel to the disk space and centered between the endplates of the levels above and below the

KEY POINTS

- Not every patient nor every spine problem can be treated with laser spine surgery.
- Laser spine surgery potentially offers shorter hospitalization, faster return to work and outcomes equivalent to standard open surgery for certain problems in selected patients.
- Patient selection criteria for laser spine surgery is similar to that for conventional open surgery.

affected disk. An optical fiber is then introduced into the intervertebral disk, allowing administration of laser thermal energy.[3]

Advantages of PLDD include outpatient care, shorter hospitalizations and earlier return to work.

Clinical Research to Date

To date, most clinical studies of this technology are level 2B data (i.e., individual cohort studies, including low-level randomized controlled trials with < 80 percent follow-up), as defined by the National Institutes of Health's levels of evidence scale.

In the laser spine therapy literature, successful outcomes are measured primarily through the assessment of post-procedure pain and disability levels using standard measures such as the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI) and the MacNab criteria, which ranks the patient's pain and any impact on activity from excellent to poor. In the longest follow-up periods to date (17 years), successful outcomes reported in the literature range from 44 to 92 percent (typically 70 to 89 percent) of cases.[1] When laser spine surgery is successful, time from surgery to return to work can be one week or less.[1]

Although rare severe complications have been reported with laser spine surgery, the overall complication rates (0.3 to 1 percent per year) remain lower than those for conventional spine surgery (about 2 percent per year), and these severe complications appear to be aberrations rather than a reflection of the norm.[1] The most common complication appears to be diskitis associated with the percutaneous needle placement, though in reported cases this was mild to moderate in severity and treated successfully with IV antibiotic therapy.

In a 17-year follow-up report, Choy described how this procedure, due to low production of scar tissue, may also confer advantages in revision surgery over open techniques. He also reported that PLDD was not associated with a single nerve or cord injury. Choy suggested that the sustained results demonstrated in this long-term follow-up study clearly rule out the placebo effect that many conventional spine surgeons have asserted occurs in these cases.

Potential Socioeconomic Impact

With conventional open spine surgery, patients typically return to work after six weeks. With laser therapies such as PLDD, some studies report return to work in as few as five days. The faster return-to-work time and lower reported overall complication rate of this minimally invasive surgical technique in theory carries a significant socioeconomic impact, though this is not yet validated.

A literature search did not reveal any prospective, randomized, directly comparative studies to evaluate the socioeconomic impact of conventional open versus laser spine surgery. Further evaluation is needed to determine the true comparative cost-benefit ratio of open versus laser spine surgery.

Looking Forward

A review of the literature suggests that when patients are appropriately selected for laser spine procedures, there is a low infection rate, few complications and outcomes comparable to those achieved with conventional surgical options.

Further prospective, randomized, controlled trials are needed to validate outcome parameters and rule out potential investigator bias in early literature. If outcomes are validated, the potential socioeconomic and clinical impact of wider adoption of this technique could be significant. ■

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Radiofrequency Ablation for Low Back Pain: An Option That Lies Between Injections and Surgery

By Russell DeMicco, DO

A major advantage of large multispecialty spine care practices such as Cleveland Clinic's Center for Spine Health is the broad scope of treatment options that are available to treat low back pain.

The treatment continuum includes:

- Education and observation (i.e., "the tincture of time")
- Physical therapy with home exercises
- Medications
- Injections and other nonsurgical interventional treatments, such as radiofrequency ablation
- Nontraditional/integrative medicine approaches (e.g., acupuncture, pain psychology, manipulation)
- Surgery

Conservative Treatments for Low Back Pain

Patients hoping to have a low back pain problem "fixed" often seek the advice of specialists, including spine surgeons. Whereas the most successful spine surgeries are done to relieve limb pain, the majority of patients with axial low back pain can be treated with nonsurgical measures. Maintenance of a healthy weight, smoking cessation and aerobic conditioning are stressed for spine health and for general well-being.

For subacute to chronic low back pain, an adequate trial of movement-based physical therapy and an independent home program are paramount. Medications and injections are used for pain beyond what can be controlled with exercise, or to allow enough pain relief for active participation in therapy and home programs. Injections may be diagnostic or therapeutic in nature.

KEY POINTS

The majority of patients with axial low back pain can be treated with nonsurgical measures.

Over the past decade, radiofrequency ablation (RFA) has been shown to be an effective nonsurgical option for patients with persistent low back pain.

The pain relief from RFA is longer-lasting (six to 12 months) than what injections provide.

Radiofrequency Ablation: Longer-Lasting Pain Relief

Radiofrequency ablation (RFA) lies in the midrange of the treatment continuum for persistent low back pain.

Over the past decade, RFA has gained traction as an effective treatment for low back pain. Heat generated by radiofrequency electrical pulses is delivered through needles placed in the patient's body to ablate, in a controlled fashion, the nerves that are conducting the pain.

RFA is considered a longer-lasting treatment than injections. Nerves will regenerate, but relief following RFA should average from about six to 12 months.

Patient Selection for RFA

Prior to RFA, the clinician uses anesthetic injections to diagnose which zygapophysial joints are generating pain in the spine. The standard of care requires that image-guided techniques be used for these procedures — most commonly fluoroscopy.

Patients are considered suitable candidates for RFA when they experience "adequate improvement" in painful symptoms for the expected amount of time following two separate anesthetic injections. Adequate improvement may be defined as more than 50 percent or more than 70 percent, depending on the patient's geographic area and/or insurance coverage. These injections are diagnostic and only a temporary measure.

Comprehensive Care for Better Outcomes

At the Center for Spine Health, we strive to use the most clinically effective methods and foster collaborative relationships within the spine continuum of care and across all medical disciplines. Using treatments such as RFA and/or injections as part of a comprehensive spine care path, rather than as isolated treatments, leads to better patient outcomes and satisfaction. ■

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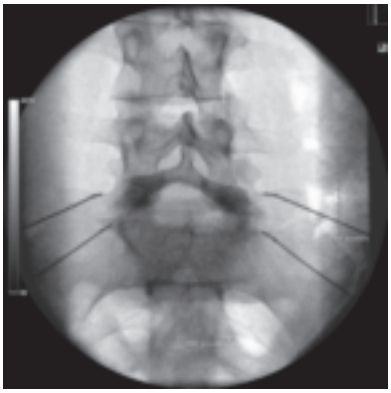
RFA CASE EXAMPLES

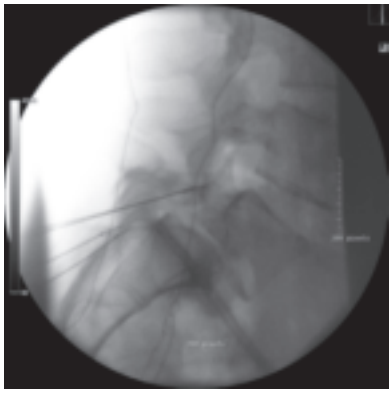
The following cases and images illustrate the successful use of RFA in two patients:

Patient A is a competitive power lifter in her 20s with low back pain who was evaluated for and determined to be a candidate for fusion surgery. Her pain ranged from 4 to 8 on a scale of 1 to 10. She reported that her symptoms often worsened with extended lifting, bending and twisting.

Rather than opting for surgery, the patient decided to try diagnostic anesthetic injections. She underwent bilateral L4 medial branch and L5 dorsal rami injections on two separate occasions. The treatments resulted in excellent relief of her pain. Subsequently, she underwent bilateral L4 medial branch and L5 dorsal rami RFA *(images below)*. The patient has done quite well and reports that she is able to work out regularly and compete as a power lifter.



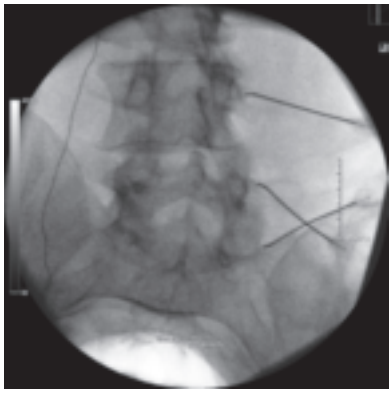
AP fluoroscopic view with RFA needles in place for bilateral L4 medial branch and L5 dorsal rami RFA procedure.



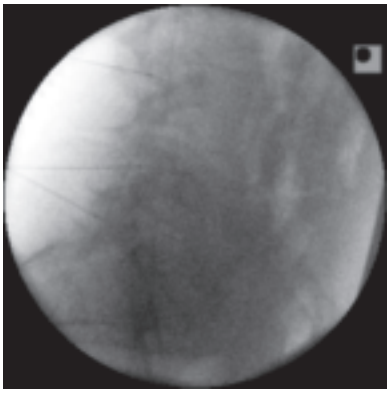
Lateral fluoroscopic view with RFA needles in place for bilateral L4 medial branch and L5 dorsal rami RFA procedure.

Patient B had been seen by multiple specialties for his back pain, including rheumatology, neurology and spine surgery. He was not deemed a surgical candidate. He experienced relief of his buttock pain, but not low back pain, with prior sacroiliac joint injections. Previously, the patient also underwent diagnostic bilateral L3 and L4 medial branch and L5 dorsal rami injections on two separate occasions, with excellent pain relief.

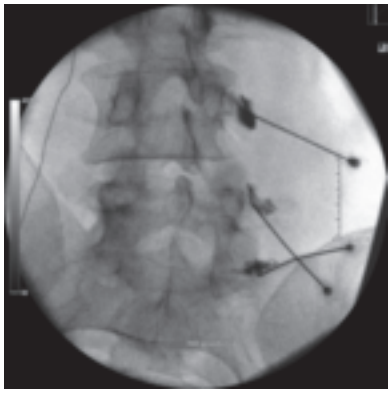
The patient underwent right L3 and L4 medial branch and L5 dorsal rami RFA *(images below)*. He has experienced relief of his right-sided pain and is planning to undergo a procedure on the left side in the near future.



AP fluoroscopic view with RFA needles in place for right L3 and L4 medial branch and L5 dorsal ramus RFA procedure.



Lateral fluoroscopic view with RFA needles in place for right L3 and L4 medial branch and L5 dorsal ramus RFA procedure.



AP fluoroscopic view after contrast administration to confirm position of RFA needles for right L3 and L4 medial branch and L5 dorsal ramus RFA procedure.

Lateral Lumbar Interbody Fusion: A New and Useful Tool for the Spine Surgeon

By R. Douglas Orr, MD

One of the more interesting and useful developments in spine surgery technologies over the past decade has been the emergence of minimal access lateral lumbar interbody fusion (LLIF). Commonly known by the trademarked names XLIF™ and DLIF™ among others, this technology allows surgeons to perform anterior interbody fusions through small incisions (2-4 cm) using a tubular retractor.

An online search of the term XLIF yields more than 150,000 hits, demonstrating a great deal of interest in the technology, presumably by both medical professionals and patients. Minimal access LLIF, which uses a muscle-sparing approach, has been shown to decrease hospital stays and shorten recovery times compared with LLIF performed as an open procedure.[1] Although LLIF was originally developed for degenerative pathology, the indications for minimal access LLIF have increased, and it has become an important tool in lumbar spine deformity surgery.[2]

Rewards and Potential Risks

LLIF technology allows placement of large interbody implants and can be used to restore alignment of the spine in both the frontal and sagittal planes.[2] In most studies, LLIF has demonstrated high fusion rates[2,3] and relatively low complication rates.

As with many new technologies, there was initially a lot of enthusiasm for this approach and very rapid growth in its usage. However, as the technology became more widespread, increased problems were reported, leading to some pullback. Foremost among these issues was the incidence of transient nerve palsies. This is particularly true in surgery done at the L4/5 level, where rates of up to 30 percent have been reported.[4]

The access corridor for this approach is made through the bulk of the psoas muscle. The nerves of the lumbosacral plexus exit the spine at the foramen and then penetrate and traverse the psoas muscle to coalesce into the nerve of the plexus anterior to the psoas. As a result, the procedure is performed using stimulated EMG monitoring in an attempt to avoid injury to the nerves.

Due to a variety of anatomic constraints and variations, the L3 nerve root is at particular risk when operating at the L4/5 level. Consequently, this author no longer uses this technique at the L4/5 level, and instead employs the anterior lumbar interbody fusion (ALIF) approach. Many others still use minimal access LLIF at the L4/5 level.

A Very Useful Tool, but Not a Panacea

Many of its proponents seem to regard LLIF as the solution to most spine problems. A more reasoned viewpoint would be that LLIF has a role in the treatment of many pathologies and can be a very useful tool — but as part of a much larger toolbox. It has both advantages and disadvantages compared with other techniques.

No single technique is the answer to every problem. When a surgeon recommends a particular form of treatment, patients should be encouraged by their referring physician to ask why that technique is preferred over other available options. ■

KEY POINTS

- The minimal access lateral lumbar interbody fusion (LLIF) technique allows surgeons to perform anterior interbody fusions through small incisions using a tubular retractor.
- Due to a variety of anatomic constraints and variations, the L3 nerve root is at particular risk for transient nerve palsies when employing minimal access LLIF at the L4/5 level. Because of this, other techniques should be considered for L4/5.
- With both advantages and disadvantages compared with other techniques, minimal access LLIF remains a useful tool for the surgical treatment of spine pathology.

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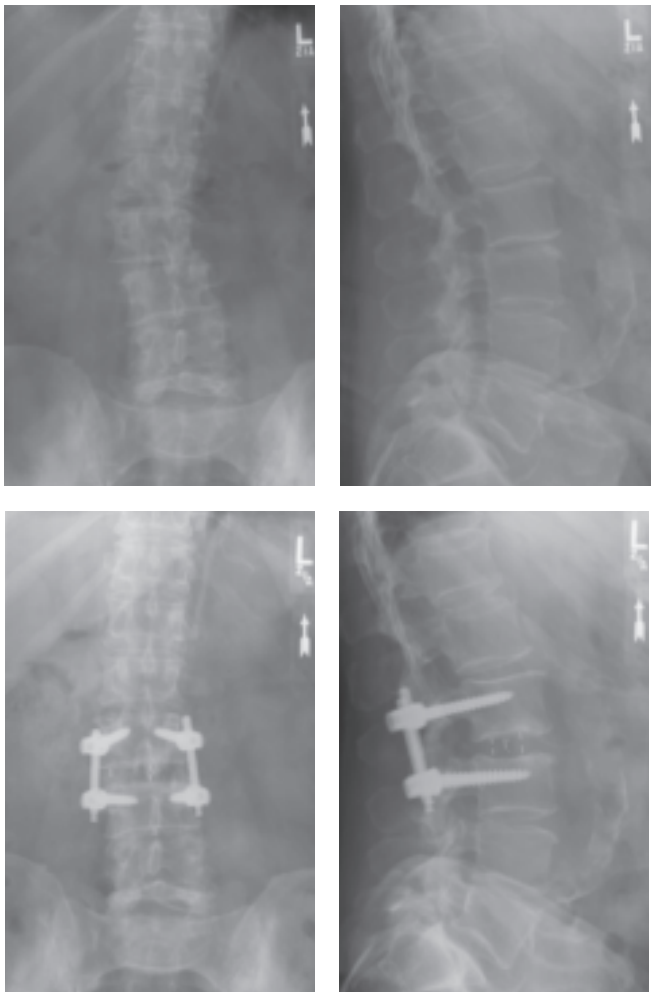
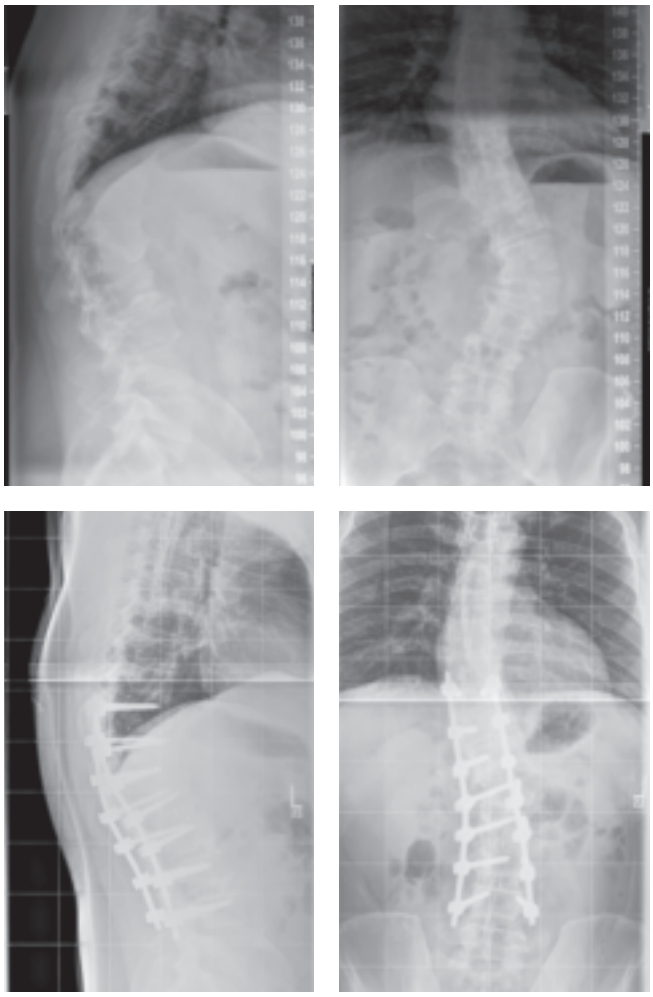
LLIF CASE EXAMPLES

The following images illustrate LLIF used in two patients:



Patient A is a 78-year-old male who had debilitating left leg pain treated with LLIF and percutaneous instrumentation, with complete resolution of pain. Top two images are preoperative AP and lateral X-rays showing rotatory subluxation of L2-3. Bottom two images are three-month postoperative X-rays showing restoration of alignment.



Patient B is a 38-year-old male with a history of back pain due to thoracolumbar kyphoscoliosis. Intraoperative X-rays show the extent of correction that can be achieved using LLIF technique through a single 2 cm incision. The second posterior stage was performed the same day. Bottom two images are from two years postsurgery — three months after the patient received his second-degree black belt in taekwondo.

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Image-Guided Spine Surgery and Its Impact on Modern Minimally Invasive Spine Surgery

By Todd B. Francis, MD, PhD

The modality of image guidance as applied to spine surgery has been growing exponentially in the past several years. Prior to the development of neuronavigation in spine surgery, most spine procedures required large exposures, potentially increased blood loss, increased postoperative pain and high doses of radiation by way of intraoperative fluoroscopy.

Minimally invasive approaches to the spine, combined with image-guided neuronavigation, provide the spine surgeon a valuable tool to approach common problems while potentially limiting complications.

In this review, we will discuss the current state of image-guided spine surgery and how it has impacted the field of minimally invasive spine surgery (MIS). We will discuss in particular two MIS modalities that show a great deal of promise:

1. Percutaneous navigated pedicle screw instrumentation
2. Navigated direct lateral interbody fusion

Development of Modern Image-Guided Systems

Image-guided systems were primarily developed for use in cranial neurosurgery. These systems were first adapted for spine surgery applications in the 1990s. Foley and Glossop et al described their laboratory evaluations of neuronavigational systems for pedicle screw placement. These early systems used a preoperative spinal CT scan correlated to operator-selected fixed spinal points in real time (for example, transverse processes and spinous processes). Nolte et al described the use of a dynamic reference frame attached to the vertebral body of the level to be instrumented, obviating the need to specify bony landmarks intraoperatively. This early research formed the basis for most of the modern image guidance techniques used today.

With the advent of intraoperative CT imaging, surgeons are now able to acquire spinal CT images in the operating room and immediately upload these onto a neuronavigational unit, eliminating the need to obtain a preoperative CT scan. Intraoperative LED-based or reflective tools are used to plan trajectories in space, and the neuronavigational unit can correlate the position of the tool to the uploaded CT scan by way of the reference frame. The technology provides highly accurate intraoperative information, including screw trajectories. This makes it possible to place screws into the pedicles of even a severely deformed spine with a high degree of accuracy that is simply not achievable using traditional freehand techniques.

Advantages of Percutaneous Navigated Pedicle Screw Instrumentation

Percutaneous navigated pedicle screw instrumentation has revolutionized the treatment of many spinal fractures and degenerative conditions. With the arrival of more advanced neuronavigational systems, it is possible to place a pedicle screw at any level in the thoracolumbar spine through a 1-inch skin incision, without any intraoperative radiation exposure to OR staff and without the use of a guidewire.

This technique is very powerful in two specific applications: fixation of a lumbar fracture (e.g., a burst fracture) and posterior instrumentation after anterior interbody fusion. In both cases, pedicle screws need to be placed with minimal to no bone work required (i.e., no laminectomy or posterior fusion). Percutaneous neuronavigation allows the surgeon to avoid having to go through a large midline incision, which involves stripping muscle off several levels of the spine and increasing blood loss, operative time and postoperative pain *(Figures 1 and 2)*.

KEY POINTS

- Image-guided neuronavigation has taken a pivotal role in minimally invasive surgery of the spine.
- Image guidance has allowed surgeons to place instrumentation with a higher level of accuracy compared with traditional techniques. It also decreases levels of intraoperative radiation exposure and results in decreased blood loss and shorter hospital stays and operative times.
- Neuronavigation and minimally invasive surgery are not intended to replace traditional techniques, but they should be an important part of a spine surgeon's repertoire.

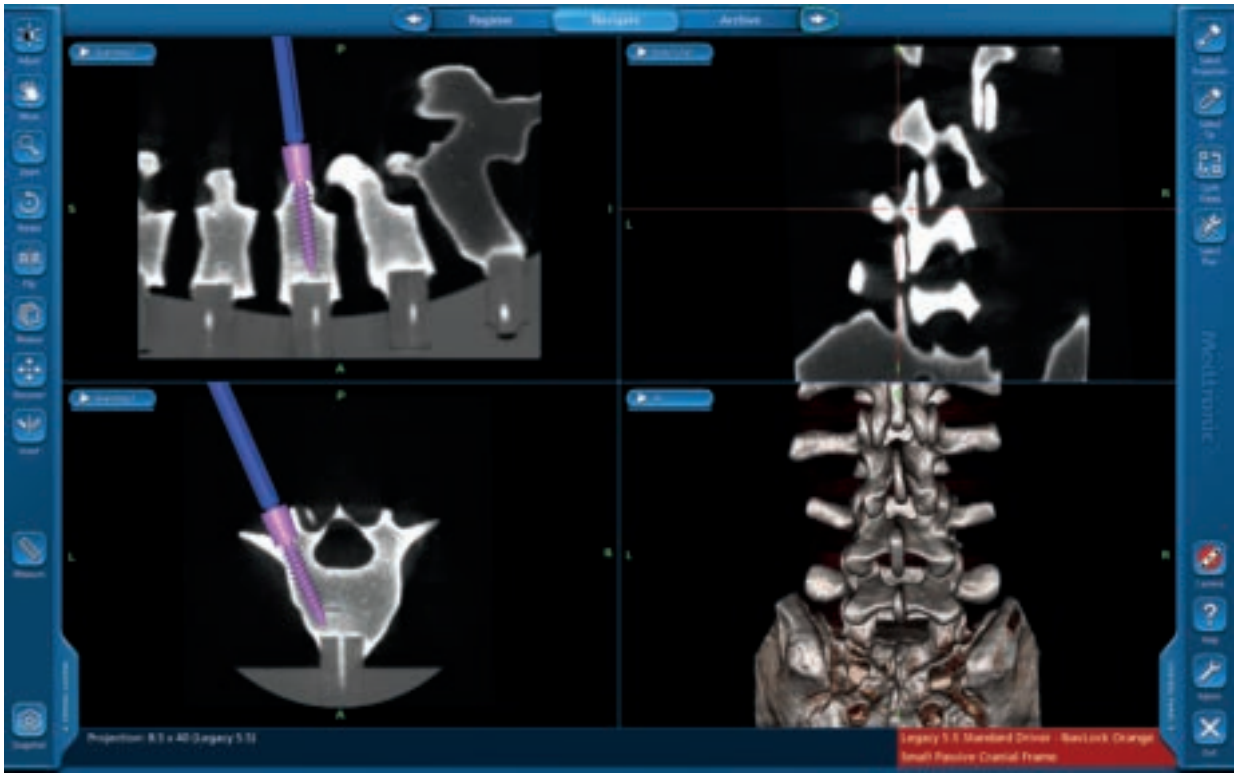


Figure 1: Intraoperative neuronavigational images on workstation demonstrating in near real time the planned pedicle screw trajectory in the sagittal plane (top left) and the axial plane (bottom left) correlated to real-time images of the pedicle screw in three dimensions. The surgeon is able to cannulate the pedicle with a tap and save the trajectory of the tap. Head-on view of instrumentation as it passes through the pedicle (top right). Global image of where the instrumentation is relative to reconstructed 3-D CT view of the spine (bottom right).

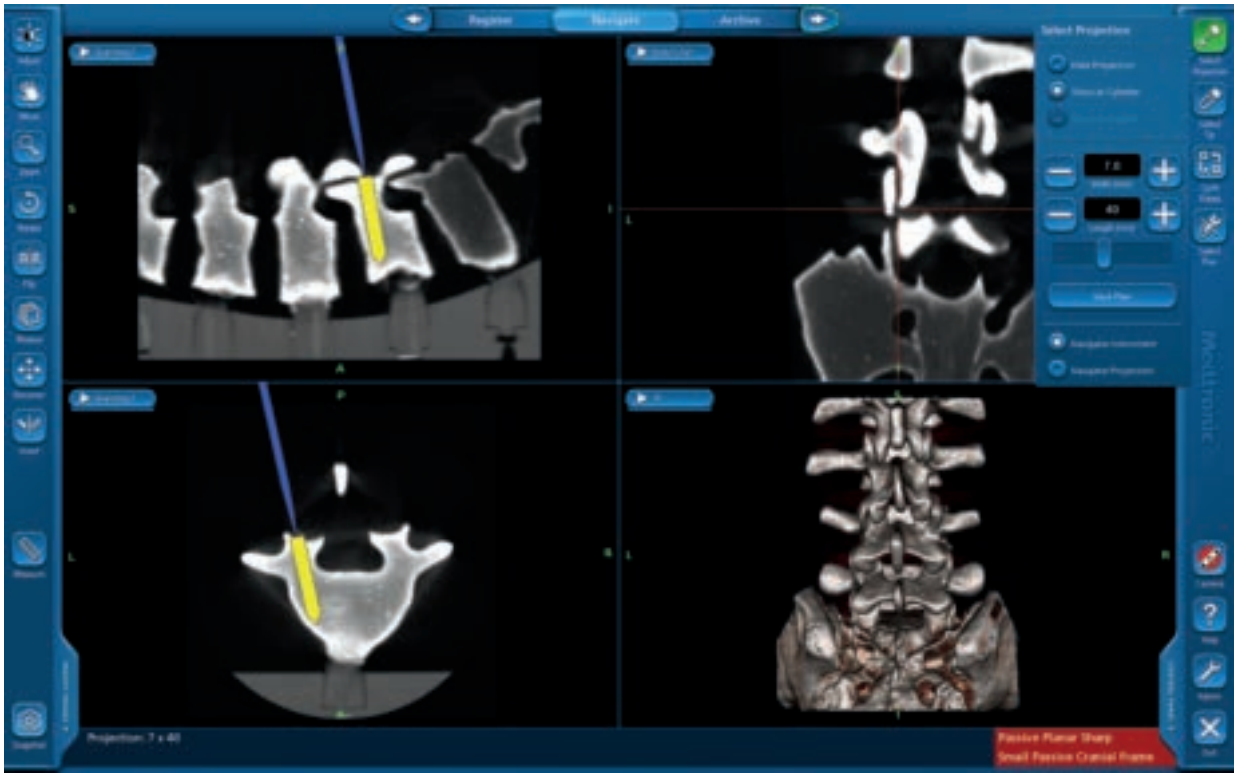
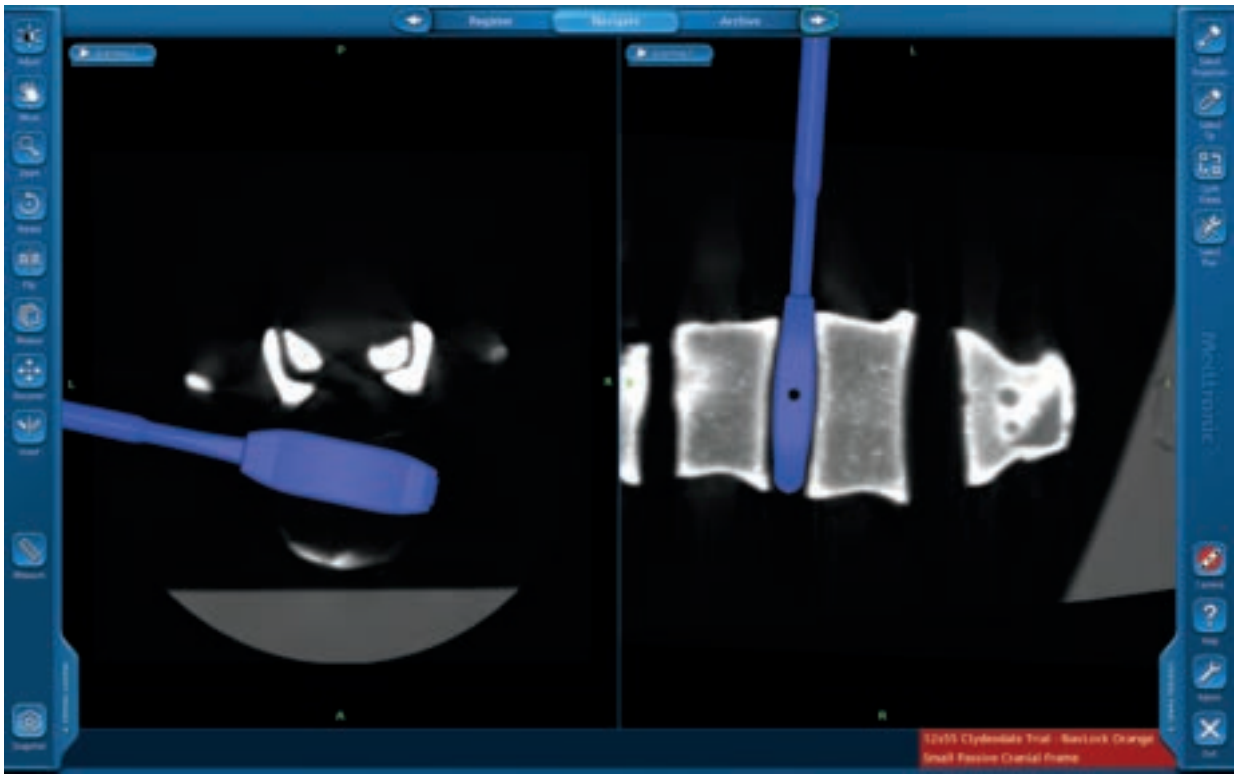


Figure 2: Intraoperative neuronavigational images on workstation demonstrating in near real time transpedicular pedicle screw placement in the sagittal plane (top left) and axial plane (bottom left). Head-on view of instrumentation as it passes through the pedicle (top right) as well as global image of instrumentation relative to reconstructed 3-D CT image (bottom right).



(Images courtesy of Medtronic, Inc.)

Figure 3: Navigated lateral transpsoas approach for lumbar interbody fusion. The navigational system renders a 3-D image of the spine and the implants. The working tools are visible in real time as are the grafts as they are placed in the axial plane (left image) and the coronal plane (right image). The surgeon is able to use the system to accurately identify the targeted lumbar disk, remove it safely and place the implant — all without the use of intraoperative fluoroscopy.

A major limiting factor in traditional (fluoroscopic) intraoperative imaging is its two dimensionality. Intraoperative neuronavigation allows the surgeon to visualize the spine in three dimensions in near real time.

Another major drawback of traditional intraoperative fluoroscopy is the radiation dose to the patient and operating room staff. Radiation exposure to the surgical team during a straightforward lumbar pedicle screw instrumentation using traditional fluoroscopy can be almost 10 times higher than that given during a navigated case. Total cumulative radiation dose to the patient is also higher in traditional fluoroscopy.

Advancements in Navigated Direct Lateral Interbody Fusion

The lateral transpsoas approach is a very powerful tool in the treatment of multilevel lumbar spondylosis and degenerative scoliosis. Through an MIS approach utilizing a relatively small flank incision (potentially 3-4 inches long), it is possible to place large interbody grafts at potentially five lumbar levels (T12/L1, L1/2, L2/3, L3/4, L4/5) when anatomy is favorable.

Prior to the advent of navigational techniques, this procedure required biplane intraoperative fluoroscopy, which exposed both the patient and the surgical team to large intraoperative radiation doses. In addition, the patient's positioning and the bulkiness of the C-arm unit were hard to work around.

Neuronavigation now provides near real-time images of both the working tools of the approach and the graft itself, allowing for a three-dimensional image of the interspace in question without the use of intraoperative fluoroscopy *(Figure 3)*.

The neuronavigational system has reduced the surgical time for this procedure so much that we are now able to complete large

Minimally invasive approaches to the spine, combined with image-guided neuronavigation, provide the spine surgeon a valuable tool to approach common problems while potentially limiting complications … MIS is an important tool for the surgeon to have in his/her arsenal because it allows alternative, potentially safer approaches to surgical problems in properly selected patients. However, MIS is not intended to be a replacement for traditional open techniques, which still hold a central place in the spine surgeon's repertoire.

multilevel interbody fusion cases with posterior instrumentation in one operation. Previously, interbody fusion almost always needed to be staged, with a second operation for the posterior portion of the procedure.

Cleveland Clinic helped pioneer this surgical technique, and we are now one of the national leaders in this surgical approach in terms of volume and applications.

Adding Power to Minimally Invasive Techniques

Neuronavigational techniques have added significant power to MIS techniques in modern spine surgery. In properly selected patients, we can now place pedicle screws and interbody grafts through much smaller incisions with less blood loss, lower operative time, reduced postoperative pain and decreased length of stay. In addition, neuronavigation allows the surgeon to increase accuracy in pedicle screw placement when compared with more traditional freehand techniques.

MIS is an important tool for the surgeon to have in his/her arsenal because it allows alternative, potentially safer approaches to surgical problems in properly selected patients. However, MIS is not intended to be a replacement for traditional open techniques, which still hold a central place in the spine surgeon's repertoire. Advances in neuronavigation are helping MIS quickly become commonplace in modern spine surgery. ■

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Cervical Disk Replacement: A Glimpse into the Future of Spine Surgery

By Jeremy Amps, MD

Degenerative arthritis of the spine is a common ailment. It is a frequent cause of pain and missed work, with the most advanced cases presenting with neurological deficits. Nowhere is this condition more salient than in the cervical spine, where compression of the spinal cord can lead to paralysis. Available treatments are good at relieving symptoms, but none address the underlying problem of degenerative disk disease.

As with so many illnesses, treatments for degenerative spinal disease have improved incrementally over time. However, there has been no revolution in recent years that has fundamentally changed the way most doctors approach the disease. Such a treatment would not only provide relief of symptoms, but would also slow or even reverse the course of the degenerative process. Cervical artificial disk replacement, also known as arthroplasty, has shown promise over the past decade as an encouraging step in this direction.

Degenerative Disk Disease: A Progressive Malady

The practice of medicine is best when it restores the body to its natural state.

At its core, degenerative spinal disease is a progressive loss of the structure and function of the intervertebral disk and other soft tissue components of the spine. The disks lose their height and elasticity, reducing the spine's mobility and accelerating arthritic changes such as osteophyte formation.

The body cannot heal damaged spinal disks because they have no blood supply.

Severe degenerative disk problems can lead to frank disk herniation and osteophytosis. These structures can compress the spinal nerves and even the spinal cord, leading to pain and sometimes neurological deficits. When present, such deficits can progress and fail to respond to intervention. Continued loss of disk height may result in kyphosis, which further stresses the spine and accelerates the degenerative process.

Conservative treatments, including nonsteroidal medications, physical therapy and epidural steroid injections, all are effective at relieving symptoms. Unfortunately, they do little to stop the underlying deterioration.

Fusion: The Gold Standard

A significant fraction of patients with cervical disk problems fail to improve with conservative, nonoperative treatment. For those patients who require surgery, the operation most commonly recommended is anterior cervical diskectomy and fusion. This technique involves removing the cervical disk and osteophytes and placement of a bone graft and metal plate to replace the disk, which ultimately results in biological fusion. Compression of neural elements is relieved, and the arthritic process is arrested between the operated vertebrae once fusion occurs. The success rate of this operation in terms of symptomatic pain relief is among the highest in spine surgery.

While fusion represents success, it is also the procedure's primary drawback. Once vertebrae are fused, there is no mobility between them and neck stiffness increases. As these patients age, the symptoms of arthritis only worsen. Some will develop degenera-

KEY POINTS

- Cervical disk disease is common, with significant morbidity. Conservative treatments may provide symptomatic relief, but they do little to stop the underlying degenerative disease.
- Although many patients initially respond to nonoperative treatment, a large group will require surgery. For those patients, the operation most commonly recommended is anterior cervical diskectomy and fusion. The success rate of this operation in terms of symptomatic pain relief is among the highest in spine surgery. However, once vertebrae are fused, there is no mobility between them and neck stiffness increases.
- Innovations such as facet joint replacement in conjunction with better disks, have the potential to create a sea change in which spine surgery is viewed as restorative instead of restrictive.

tive disks between other vertebrae that will then require additional surgery. If more fusions are performed, neck stiffness increases even more. And fusion is irreversible.

Disk Replacement Surgery May Slow Degeneration

The elegance of successfully replacing a poorly functioning part with a better functioning one cannot be overstated. Cervical disk replacement or arthroplasty has been available in the United States for a decade as an accepted alternative to fusion and has been performed by Cleveland Clinic surgeons for nearly as long.

The approach to the spine is identical, including decompression of nerves and the spinal cord. As the illustration at right shows, the difference comes at the end of the surgery. Instead of placing a bone graft and immobilizing metal plate, the surgeon inserts the artificial disk into the space where the biological disk has been removed. The artificial disk is then secured to the native bone with screws. This concludes the procedure, the incision is closed and the patient is sent to recovery.

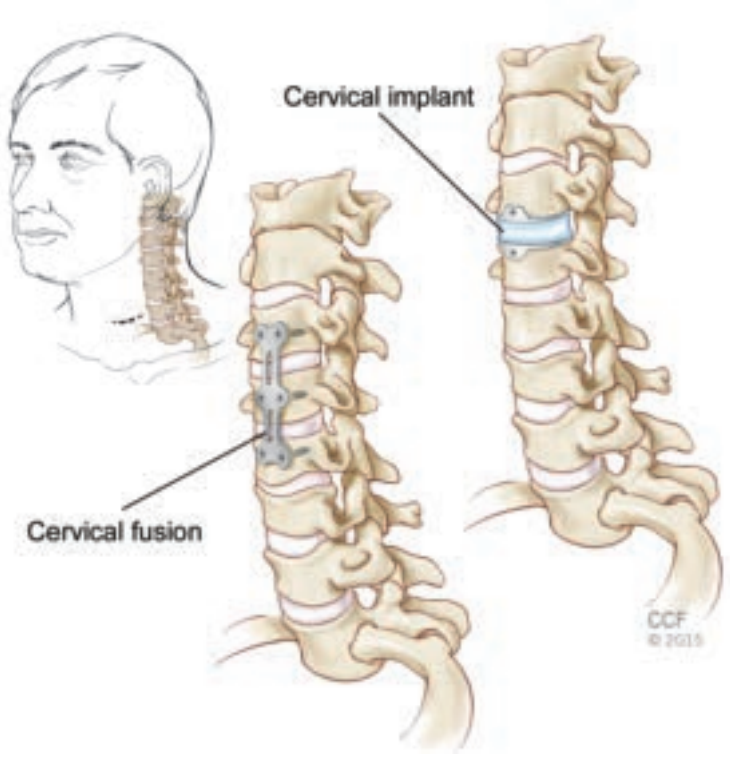
Patients typically spend one night in the hospital, similar to traditional fusion. Follow-up is provided in the weeks and months following surgery, with the patient completing physical therapy as needed and typically returning to normal activity within six weeks.

The artificial disk is mobile and preserves the patient's ability to move his or her neck. In some cases, neck movement is actually improved. Over time, this creation of a more normal neck physiology may slow the degenerative process.

Improves Neck and Arm Pain

Available studies going back seven years show that cervical disk replacement improves neck pain, arm pain and neurological deficits at least as well as fusion.[1]

Cervical arthroplasty is a relatively new technology. It is likely to improve, and at a more rapid pace than the established technique of cervical fusion. New implants will improve on existing models, providing greater benefits to patients. In the future, disk replacements might be plastic, hybrid plastic/metal or even biological.



Paradigm Shift

The move from fusion to disk replacement represents a potential paradigm shift. Arthritic hip joints were once fused, but are now replaced with functional joints that provide patients with an improved quality of life.

At present, cervical arthroplasty is performed far less frequently than fusion — but it is by no means a fad. Early adopters have pioneered arthroplasty and proved its success. In the future, it is likely we will view spine surgery as restorative instead of restrictive. Innovations such as facet joint replacement in conjunction with better disks will undoubtedly further slow spinal degeneration and bring an improved quality of life to those afflicted.

Paradigm shifts require the new model and process to provide a clear improvement over the standard. Cervical arthroplasty certainly satisfies this requirement. ■

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Early Use of a Novel Magnetic Spinal Growing Rod for Early-Onset Scoliosis

Observations and a case study of one of the first U.S. recipients

By Ryan C. Goodwin, MD

Early-onset scoliosis remains one of the most therapeutically challenging entities encountered by the pediatric spine deformity surgeon. Children with severe deformities are often treated with some sort of early nonfusion intervention in an attempt to control the deformity until the chest cage grows large enough to accommodate the child's growing lungs into adulthood.

The Burdens of Traditional Growing Rods

When intervention is required, it often consists of a growing rod construct designed to serve as an internal brace and support the corrected spine without fusion. Unfortunately, these static devices require repeat surgical lengthening roughly every six months to accommodate the child's growing spine from the time of implantation until definitive fusion is accomplished once the chest cage has matured sufficiently — typically at age 10 to 12. This creates a huge burden of morbidity and cost.

Enter the Magnetic Growing Rod

Fortunately, a less burdensome alternative emerged with the 2014 FDA approval of a novel spine implant called the MAGEC® (Magnetic Expansion Control) spinal growing rod, which allows the growing rod construct to be lengthened nonsurgically in the office. Use of a magnetic actuator applied to the patient's skin allows painless lengthening of the construct at the frequency and magnitude desired by the surgeon.

This technology has the ability to significantly reduce the number of revision operations children with severe early-onset scoliosis require to treat their deformities. Its use is illustrated in the accompanying case study of a boy with infantile idiopathic scoliosis. He was the index case for placement of the magnetic growing rod at Cleveland Clinic and among the first U.S. recipients of the device following its FDA approval.

Dr. Goodwin at a follow-up visit with the recipient of the first magnetic growing rod at Cleveland Clinic. The photo shows marking of the patient's back to guide placement of the device's magnetic actuator on the skin to enable painless lengthening of the rod in the office.

KEY POINTS

- Children with severe early-onset scoliosis are typically treated with static devices that require repeat surgical lengthening to accommodate the growing spine.
- FDA recently approved an innovative magnetic spinal growing rod implant that can be lengthened nonsurgically and painlessly in the office.
- The device has the potential to avoid substantial morbidity while achieving cost savings by significantly reducing the number of lengthening surgeries.

The Promise of Reduced Suffering, Lower Costs

This device appears to be a safe alternative to traditional growing rod constructs and has the potential to avoid substantial morbidity and achieve considerable overall cost savings by significantly reducing the number of lengthening surgeries. Future studies on its more widespread use should shed light on the full impact this technology will have in this challenging patient population. ■

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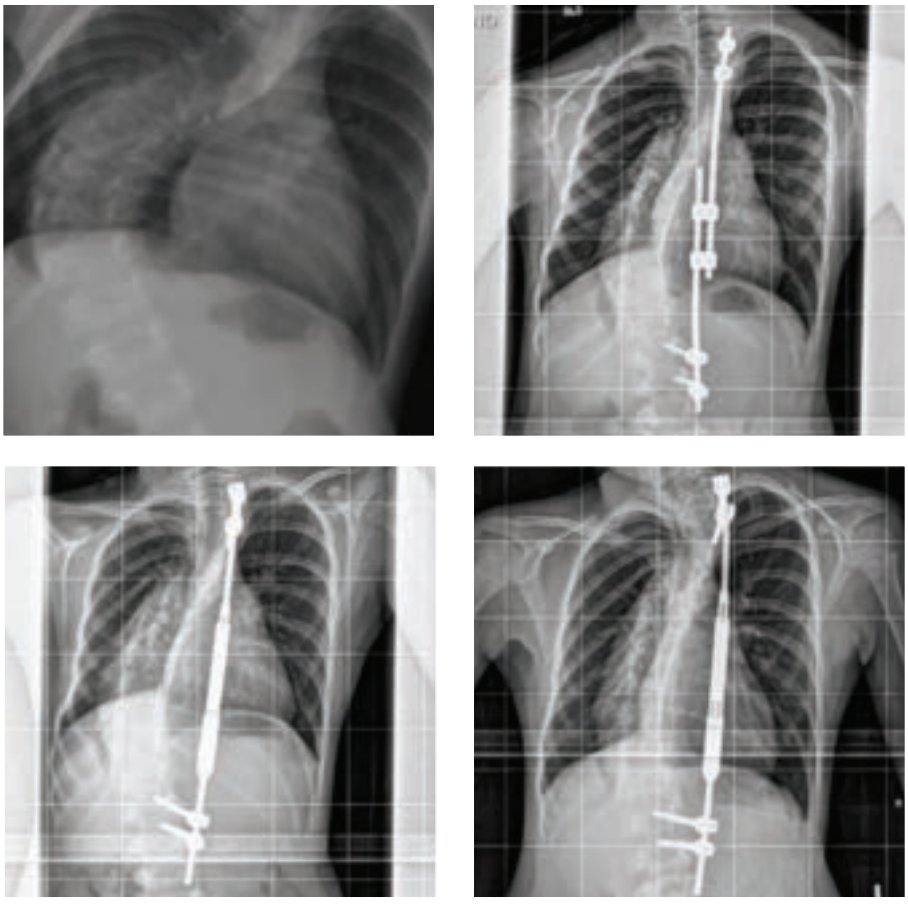
CASE STUDY: The Magnetic Growing Rod in Action

The radiographs below (all posteroanterior views) are from the boy with infantile idiopathic scoliosis who received the first MAGEC magnetic spinal growing rod at Cleveland Clinic.

The patient initially had a traditional growing rod placed at age 2 for a spinal deformity of greater than 90 degrees. He later developed an infection after one of several traditional rod-lengthening surgeries. Removal of all implants was required to eradicate the infection. When the patient was reinstrumented, the MAGEC device was used. He was 5 years old when it was placed in autumn 2014.

The patient has undergone four lengthenings of the device since then, all performed noninvasively in the office using the device's magnetic actuator. The correction has been maintained thus far, and the boy has reported no pain or neurologic complaints during or after the lengthenings.

The Patient's Radiographic Profile over Time



Top left. Image showing the patient's severe early-onset scoliosis at age 2, prior to surgical intervention. Bracing and casting had failed to control the deformity.

Top right. Two years after placement of traditional growing rod instrumentation, prior to infection and the rod's removal.

Bottom left. Following placement of the magnetic growing rod in autumn 2014.

Bottom right. After lengthening of the magnetic growing rod in the office. Note the expansion of the rod's central barrel.

The Perils and Pitfalls of Particulate Steroid Injections: Best Practices to Mitigate Catastrophic Risk

By Russell DeMicco, DO, and Garett Helber, DO

There is ongoing debate over using a particulate versus a nonparticulate corticosteroid for epidural steroid injections (ESIs) as a treatment for radicular pain caused by disk herniation and/or spinal stenosis.

ESIs are known to be associated with both minor and major complications, from severe neurological deficits caused by spinal cord infarct and stroke to minor side effects, including neurogenic/vagal reaction, postdural puncture headache (PDH) and pain exacerbation. Although severe neurological deficits caused by ESIs are rare, the disability associated with them could be catastrophic.

These risks exist even when ESIs are performed by experienced proceduralists.

Given this background, both the proceduralist and the referring physician should fully understand how potential complications might occur in order to recommend the optimal treatment plan for each patient.

Background and Mechanism of Injury

Along the cervical, thoracic and lumbar regions of the spine, corticosteroid administration can be achieved either via the interlaminar or transforaminal route (*see figure on following page*).

Cervical transforaminal epidural steroid injections (CTESI) can be both diagnostic and therapeutic. The diagnostic utility of cervical interlaminar epidural injections (CESI) compared with CTESI is questionable. For this reason, CESI is often used as a therapeutic modality for those with radicular pain, although both procedures incur risk of spinal cord injury complications.

KEY POINTS

- The risk of complications associated with epidural steroid injections (ESIs) exists even when the injections are performed by experienced proceduralists.
- Nonparticulate steroids should be used for all cervical ESIs in conjunction with digital subtraction angiography, if available, or real-time fluoroscopy.
- Proper training and experience should be given high priority in the credentialing process.

Injury may occur either from direct trauma (injection to the spinal cord or spinal nerves) or indirect trauma (vascular blockade from a particulate steroid or vasospasm from a nonparticulate stimulus). Direct trauma is due to intracord injection, hematoma or increased pressure from the injectate. Injury can occur instantaneously if the proceduralist does not recognize abnormal contrast flow patterns under fluoroscopy.

The Risk of Particulate Steroid Injection

Injury from particulate steroid injection has proved to be the main etiology of spinal cord injury. Animal studies, as well as case reports in humans, have hypothesized that particulate steroids are more likely to lead to spinal cord complications than nonparticulate steroids, due to blocked arterial blood supply to the spinal cord.

Anatomical studies have shown that the vertebral artery and the ascending cervical and deep cervical arteries are proximate during cervical transforaminal injections. Betamethasone has the smallest particles, triamcinolone's are intermediate and methylprednisolone's are the largest. With dexamethasone, particulation is not evident, and therefore it is classified as a nonparticulate steroid.

Procedural Risks

It is possible to cannulate the arteries unintentionally, which can cause dissection, perforation or even something as minute as embolization of an intimal flap. All of these scenarios can result in catastrophic events similar to those that may occur from a particulate stimulus.

Given these potential risks, the realistic goal is to reduce complications, even though 100 percent prevention is, without a doubt, utopian.

Reducing the Risk of Catastrophic Events

The U.S. Food and Drug Administration's Safe Use Initiative (SUI) convened in 2009 to facilitate collaboration with pain societies. Scientists and clinicians collaborated to set evidence-based clinical guidelines to mitigate catastrophic events associated with ESIs.

The group unanimously agreed on steroid use, making the following comments and recommendations:

1. ESIs are rarely associated with neurovascular complications.
2. Transforaminal injections are associated with catastrophic neurovascular complications, and particulate steroids appear to be inordinately represented in case reports involving CESI.
3. The nonparticulate steroid dexamethasone is recommended for initial use in lumbar transforaminal epidural steroid injection (LTESI). If pain outcomes are not successful with dexamethasone, the use of particulate steroids for succeeding injections is left to the discretion of the proceduralist.

There is no clear consensus regarding the use of real-time fluoroscopy and/or digital subtraction angiography. Our institution's clinical experience has shown that real-time fluoroscopy (when digital subtraction angiography is not available) is capable of preventing neurovascular complications. This is based on the premise that the proceduralist has adequate training in identifying correct needle positioning and contrast flow patterns.

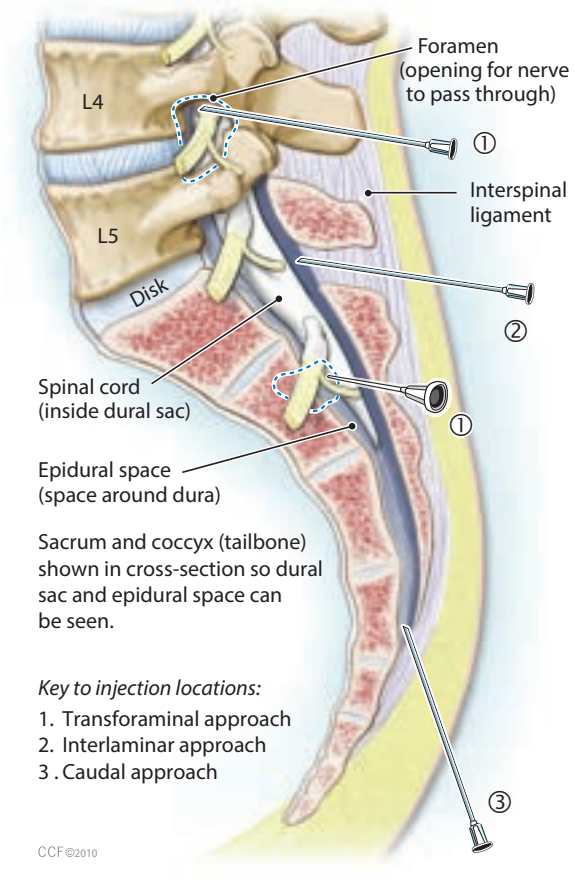
Based on our institutional experience, other recommendations include:

1. Contrast flow may not be perfect, especially in cases of severe foraminal stenosis. Therefore, do not expect a good medial or transforaminal flow — but do expect a neurogram pattern.
2. If a vascular pattern is seen, wisdom dictates canceling the procedure.
3. It is prudent to remember that these procedures are elective, and that potential benefits should absolutely outweigh risks.
4. If complications occur, manage them appropriately.

Take-Home Points

As we move more and more toward evidence-based therapies, it is strongly recommended that a nonparticulate steroid be used for all cervical transforaminal ESIs. If available, digital subtraction angiography should be utilized — or at minimum, real-time fluoroscopy — when performing cervical through lumbosacral injections.

Proper training and experience should be given high priority in the credentialing process, especially for cervical spine injections. Only by following these best practices can we realistically mitigate the risk of these catastrophic injuries. ■



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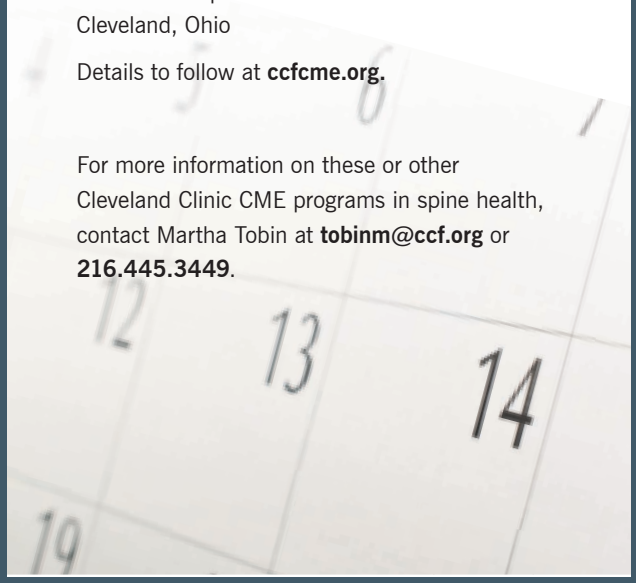

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