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A technology update of current minimally-invasive treatment options of lumbar discogenic pathology and internal disc disruption.

Editor's note: this article is a follow-up to Dr. Pinzon's article 'Treating Lumbar Back Pain' in the March/April 2001 issue of Practical Pain Management¹ and updates the diagnostic and therapeutic intradiscal procedures currently available for spinal pain practitioners.

iscogenic-referred pain is now recognized in multiple retrospective and prevalence studies as the single most common etiology of chronic lower back pain ($\sim 40\%$ of lower back pain generators).²⁻¹¹ The application of lumbar discography in diagnosing internal disc disruption (IDD) has provided the spine specialist with crucial information in order to consider various nonsurgical as well as surgical treatment options. For an intervertebral disc to cause pain there needs to be an established innnervation pattern and mechanisms by which nociception can be precipitated. The pathophysiology of discogenic pain involves both *biochemical* (internal disc disruption: proteolytic/enzymatic denaturation of nuclear proteoglycans, decreased nuclear hydrophilicity) and *biomechanical* factors (annular disc disruption: chemical and mechanical sensitization, secondary inflammation). Painful degenerative discs have demonstrated biophysiological changes in the matrix including reduced total glycosaminogylcans, reduced water content, increased matrix metalloproteinases, increased vascularity, and deeper penetration of nociceptive fibers from the outer annulus. The nucleus pulposus contains inflammatory and nociceptive chemical mediators, and even the extent of annular wall tearing has been well correlated with concordant discogenic pain during diagnostic discographic stimulation.

Discogenic lumbar pain may present in a number of overlapping fashions: axial pain, axial pain with somatic-referred extremity pain, axial pain with radicular-referred pain, and axial pain with concurrent axial joint pain. Discogenic lumbar pain management options are available with more treatment opportunities than what were available 10-20 years ago. Over the last few years, these intradiscal therapeutic options have presented with such a flurry of newer technologies and techniques that, at times, they have outpaced the importance of reproducible, clinical outcome studies to verify their technical success and validity. Many pain management specialists are left with empirical and anecdotal experiences from personal and other colleague's accounts. With this important thought in mind, I will mention a few of the more popular, common, and novel intradiscal lumbar therapeutic techniques available for lumbar spine pain management practitioners.

Intradiscal Electrothermal Annuloplasty

Intradiscal electrothermal annuloplasty (IDET[™] or IDEA) using the SpineCATH® Intradiscal Catheter (created and trademarked in 1997 by ORATEC Interventions, Inc. and currently owned and operated by Smith & Nephew, Inc.) is a novel addition to the interventional physician's armamentarium of treatments for patients with chronic, contained discogenic low back pain and concordant IDD and who have failed a program of aggressive, non-operative therapy.¹²⁻²⁴ IDET provides a new outpatient treatment option for patients who are not recommended for, or who do not elect, other more invasive treatments, such as lumbar disc surgery (ie. discectomy or fusion). The SpineCATH intradiscal catheter has been approved by the Federal Drug Administration (FDA) for use in treating symptomatic patients with annular disruption of contained, lumbar herniated discs.12 This new technology has been developed to safely treat intervertebral discs in a minimally invasive manner and still provide physicians with a definitive approach to addressing internal disc disruption. The intradiscal catheter delivers controlled thermal energy directly to the annular wall and disc nucleus via a resistive heating coil in order to create temperature-controlled coagulation and shrinkage of intradiscal collagenous tissue. The SpineCATH system was specifically developed to thermocoagulate annular tissue, thermally modulate intradiscal collagen tissue, cauterize granulation tissue, and to minimally reduce intranuclear volume in small, contained disc herniations. The steerable catheter (which has undergone slight modifications in design since it's inception) allows for precise intradiscal navigation for percutaneous spinal intervention. Performed under light sedation, the catheter is inserted through a 17-gauge introducer trochar needle and is easily positioned with fluoroscopic guidance. Since this procedure is significantly less invasive than operative disc surgery; the result is a percutaneous outpatient procedure that is no more invasive than a lumbar discogram. The initial success rate for the procedure, depending on patient selection, has been noted to be around 50-75%.14-24 A recent ongoing, randomized, double-blind, placebo-controlled 6month outcome trial evaluating the efficacy of IDET for the treatment of chronic discogenic low back pain by Dr. Kevin Pauza and colleagues has verified the validity of statistically significant reduction in pain levels and physical limitations in treated vs. control subjects.24 This valuable ongoing study is something to be emu-

lated by the other intradiscal pain management techniques in order to continue to verify the continual, reproducible successes of these newer technologies for the benefit of both insurance companies and patients alike.

The disc itself is a virtually avascular structure which allows heat to be held in the tissue with relatively little fluctuation during treatment. Adjacent structures are protected from thermal injury by the vascular circulation outside the disc which quickly dissipates any heat conducted beyond the disc. Temperature and power control give the IDET catheter the optimal ability to deliver focused energy at the point of contact. Heat is transferred by conduction from the catheter to the

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adjacent disc tissue. Temperature sensors deliver feedback to the generator which adjusts power levels as necessary to reach and maintain set target catheter temperatures. Optimum treatment temperatures are followed as previously documented in temperature mapping experiments done in the cadaveric and in vivo validation studies.12,14-16 These mapping studies indicated that optimal temperature levels for achieving collagen modulation (80-90° C) and for neurolysis of nociceptor destruction in the inner/outer annular wall (45-60° C) are achieved while maintaining low epidural temperature levels (maximum 40° C) and avoiding damage to myelinated nerves. These validation studies also documented an average total disc volume reduction, due to morphologic changes in the outer disc surface was 12.7% (range: 10-16.7%); and it was estimated that in the area of treated tissue alone (tissue reaching at least 60° C), there was an approximate 40% decrease in disc tissue volume, with type 1 collagen contraction.¹²⁻¹⁶

The indications noted for the IDET annuloplasty procedure include axial, lower back pain and mild referral leg pain due to symptomatic (painful) internally disrupted disc with annular fissures (documented through discography) and symptomatic (painful) contained disc herniation without significant radicular symptoms.^{12,14-19,24} Other potential IDET candidates include: 1) patients with discogenic pain after a previous discectomy; 2) disc space volume >50%; 3) some multi-level degenerative disc disease involvement; and 4) discogenic pain above or below a previous fusion. The procedure is contraindicated in patients with the following: 1) severe radicular symptoms due to frankly herniated discs or sequestered discs on MRI; 2) compressive pathology due to significant spinal stenosis; 3) segmental instability; and 4) severely collapsed discs (>50%). The recommended post-procedure recovery program involves a trial of physical therapy and lumbar bracing with improvements generally observed between 4 to 12 weeks.

A recent development based upon the previous IDEA/IDET technology, is the Electrothermal Decompression Catheter (presented in 2002, from Smith & Nephew, Inc.)²⁵ Similar to the IDEA/IDET, this device utilizes thermal energy for focal decompression of contained lumbar herniated discs, based upon a patented, clinically and scientifically validated thermal technology and is appropriate for symptomatic patients who have failed to respond to conservative treatments. The decompression catheter is designed to provide a high degree of steerability to reach the disc tissue and to gauge the intradiscal temperatures. The heat is slowly increased to a target temperature and is kept at that temperature for a few minutes. It differs slightly from the IDEA/IDET in that the goal is intradiscal decompressive effects for bulging or contained herniated discs that primarily cause radicular leg and, to lesser extent, axial lower back pain. No known significant studies have yet to be published although research is ongoing. Documented studies will be welcome for this newer "spin-off" of the former electrothermal technology.

Percutaneous Lumbar Discectomy-Nucleoplasty Method

Percutaneous decompression of contained herniated discs, or partial removal of the nucleus, is a well-established technology with over 500,000 procedures performed during the past 20 years.²⁶⁻²⁹ The therapeutic mechanism of the procedure is to relieve intradiscal pressure which, in turn, reduces pressure exerted by the disc on nerve roots and thereby providing relief from discogenic-referred pain in many cases.

Traditional percutaneous disc decompression techniques (chemonucleolysis, automated percutaneous lumbar discectomy, and percutaneous laser discectomy) have been used successfully and are clinically proven in several research trials to be an efficacious method for treating lumbar radicular pain, although they have their technical drawbacks.26-29 Percutaneous discectomy using DISC Nucleoplasty[™], a minimally-invasive procedure utilizing a patented Coblation® technology for the ablation and coagulation of intradiscal soft tissue, combines elements of previous approaches for partial decompression of nucleus pulposus.30-33 DISC Nucleoplasty builds upon the benefits of these previous approaches by providing a more controlled, efficient, and practical method of nuclear tissue removal, while retaining the underlying proven rationale.

DISC Nucleoplasty, from ArthroCare Corp. in Sunnyvale, CA, utilizes a multifunctional bipolar radiofrequency device which generates a "cold-energy" plasmaenhanced process, in which radiofrequency energy is applied to a conductive medium (saline) to generate a preciselyfocused, low-temperature ionic plasma field around the electrode at the tip of the Perc-DLE SpineWand ("Coblation").30-33 The plasma of highly-ionized particles has enough energy to break the molecular bonds within tissue at low temperatures (~40-70° C). A series of six channels are created in the disc by ablating, or removing tissue, and then thermally treating the channels, in effect removing approximately 1-2cc of nuclear tissue, or roughly 10-15% of the nucleus pulposus. This highly-focused, controlled ablation technique allows an effective percutaneous disc decompression with minimal

risk of thermal injury to surrounding tissue. The procedure is performed in an outpatient setting with fluoroscopic guidance while the patient is under local or conscious sedation.

Worldwide to date, over 12,000 patients with lower back pain and/or leg-referred pain have been treated using DISC Nucleoplasty, with no significant reported adverse complications. Clinical study results up to one to two years following the procedure have shown that pain, as well as use of narcotics, is substantially reduced and patients have reported high overall satisfaction of 89%.31-33 Reported success rates for the procedure are as high as 80% with 57% reduction in VAS Pain Scores.34 Further prospective, controlled, randomized studies are underway to precisely demonstrate the benefits, limitations, and clinical outcomes of this new technology.

Percutaneous Decompression — LASE Method

Percutaneous Laser Disc Decompression (PLDD) procedure has been around for over a decade in one form or another using different laser types, technology, and methodology.^{1,35-40} The LASE method of PLDD (developed by Clarus Medical, Minneapolis, MN) is a relatively new intradiscal technique (within 10 years), with an endoscopically-visualized fiberoptic scope and utilizing the Holmium YAG laser.^{35,37,40}The technique is designed to reduce the bulging/herniated nucleus enough to reduce the pressure it is placing on the surrounding nerve root. A miniature endoscope with a laser fiber is inserted into the disc, leaving an incision through the skin which is less than 0.25 inch. The LASE endoscope allows the physician to view the bulging nucleus tissue and remove it with the laser fiber. In clinical theory, by removing the bulging nuclear disc tissue, the pressure on the nerve root is reduced or eliminated along with the resultant referred pain.

To date, about 20,000 LASE procedures have been performed world-wide with about 75% of those performed in the US.^{35,36,40} Multiple studies have shown that around 80% of properly selected patients with contained herniated discs and having lower back and leg pain, may benefit from this procedure.^{1,35,37,40} The essence of the procedure is that it is an outpatient, decompressive discectomy without the risks of routine invasive surgery. The LASE methodology involves copious irrigation (30 ml/min) with nearly 1 liter involved in a procedure. Although the LASE was initially designed with irrigation in order to keep the disc cool (temperature gradient between inflow/outflow is about 1 degree Celsius) and provide a clear viewing field for endoscopy, the lavage also removes potentially toxic nuclear material disintegrated by the laser pulses. A further benefit of irrigation is that the Ho:YAG laser has a very shallow penetration in water (less than 0.5mm) and so is very precise in it's application.

The procedural recovery time is approximately 1-2 weeks. This procedure is less indicated in primarily axial back pain of discogenic etiology, lumbar stenosis due to degenerative conditions, or failed back surgery syndrome with perineural scar tissue. The complication and risks are similar to those noted for other intradiscal therapeutic/diagnostic procedures, such as IDET and lumbar discography procedures.^{1.3-6,8,9,12, 35-40}

Percutaneous Lumbar Discectomy-Dekompressor Method

As discussed in the two previous intradiscal, percutaneous lumbar discectomy techniques; discectomy of the intervertebral disc nucleus pulposus for relief of lower back pain and radicular pain is the most commonly performed neurosurgical procedure achieving success rates in excess of 90%, with open surgical discectomy for over 50 years.^{35-40,51-53} Percutaneous lumbar discectomy (PLD), which has been performed successfully for over 25 years with both purely mechanical and laserbased instrumentation in an outpatient clinical setting, was developed to reduce technical complications associated with open disc surgery. Benefits resulting from the use of PLD have been reported to include: good to excellent success rates, reduced procedural trauma, lower outpatient treatment costs, rapid post-surgical rehabilitation progress, and lower morbidity. Less invasive methods for discectomy and disc pressure reduction will play an important role in the future treatment of patients suffering from disc herniations. The Dekompressor® 1.5mm percutaneous lumbar discectomy probe is a new instrument that has been developed to perform percutaneous lumbar discectomy.51 This newer intradiscal decompressive device utilizes a highly efficient method for aspiration and removal of intervertebral disc nucleus pulposus

through a small 1.5mm probe channel allowing percutaneous discectomy entirely under fluoroscopic guidance. The patented probe tip utilizes an Archimede's pump principle to efficiently remove nucleus pulposus tissue from bulging or herniated discs. This results in pressure reduction in the disc and area surrounding the painful nerve root, resulting in pain relief. Further clinical research studies are needed to validate this technique.

Percutaneous Radiofrequency Annular Neurolysis-DiscTRODE Annuloplasty

Percutaneous Radiofrequency (RF) Annular Neurolysis or Denervation developed in the 1980's primarily by M.E. Sluijter, proposed a method to denervate the intervertebral disc through thermocoagulation and reported a series of patients who had obtained relief of their chronic low back pain with annular denervation.41-47 It was proposed as a treatment for internal disc disruption (IDD) and painful disc degeneration (PDD). Annular denervation uses the technology of percutaneous radiofrequency (RF) neurolysis, which is primarily used to treat spasticity, malignant pain, trigeminal neuralgia, and zygapophyseal joint nerve pain. Dr. Sluijter theorizes that intradiscal placement of a RF probe will globally increase disc temperature and produce neurolysis of the nociceptive fibers found in the outer annulus. Critics argue that the lesion generated by the RF probe (which technically covers only a 6mm radius from the probe tip) will not reach the annular fibers and that previous studies have noted elliptical or spheroid denervation areas secondary to induced tissue temperature elevation and not from any direct heating effects of the probe itself.48-50 Therefore the area of coagulation is dependent on temperature, probe size, and probe orientation.48-50,54-56

Based on this previous data and clinical results, Radionics developed disc-TRODE[™], an annuloplasty device that is a relatively new addition to percutaneous intradiscal therapies currently available.⁵⁴⁻⁵⁶ Radiofrequency (RF) annuloplasty is a minimally-invasive procedure for treatment of discogenic, axial lower back pain.⁵⁴⁻⁵⁶ By using RF energy to directly excite and heat the intradiscal annular tissue to temperatures that have been demonstrated to be sufficient for neural tissue ablation — yet insufficient for collagen modulation - the Radionics disc-TRODE[™] is able to achieve more consistent annular heating over a wider range of temperatures with greater safety.54-56 In skilled hands, discTRODE[™] is a promising addition to percutaneous intradiscal therapies and offers the clinical potential for greater flexibility and consistency in intradiscal annular heating. Similar to the IDET, Nucleoplasty, and PLDD procedures; the RF annular denervation procedures need further prospective clinical studies and consistent clinical results, but seems safe for the treatment of IDD and PDD refractory to conservative care. The indications, risks, and complications are similar to other intradiscal procedures

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and lumbar discography procedures.^{1,3-6,8,9,12,35-40,54-56} The risk of infection, hemorrhage, and neurologic insult is obviously considered to be significantly less than compared with any open, invasive surgical intradiscal procedure.

Conclusion

Pain is the most complex problem modern medicine faces today, and is considered one of the "last frontiers" in clinical medical practice. It is the primary complaint prompting medical consultation. Compartmentalization of pain problems into physiological, physical, and psychosocial categories may be useful diagnostically, but must be synergistically joined to achieve therapeutic success. The interventional pain specialist (often the PM&R musculoskeletal/spine specialist, anesthesiologist, orthopedist, or neurosurgeon) is a valuable and often most crucial member of the pain management team. Injury and tissue-specific therapeutic exercise programs must form the basis of physical rehabilitation and functional restoration protocols. The program can combine a core of sedentary exercises coupled with the injury-specific exercises. Importantly, the protocol must expand to encompass psychotherapeutic intervention in chronic pain conditions. Neuromuscular reconditioning must be included to ensure a function-specific, task-oriented program. Essentially and most importantly, the program must be geared to enhance and foster functional recovery of the affected patient.

Injectional pain management techniques play a major role in the rehabilitation of disorders of the musculoskeletal system. Various minimally-invasive procedures and techniques have been used over the years, and are being developed for the interventional management of spinal-related pain. From the 1980's through this new millineum, more novel spinal injection techniques have been developed, and traditional injection techniques have been refined concurrent with the technological advances in imaging modalities and a clearer understanding of the biopathomechanics and the biophysiochemistry of pain. The role of the interventional spinal specialist in this assurgency of injection techniques for the diagnosis and management of spinal-based pain syndromes, peripheral joint dysfunction, and soft-tissue abnormalities has become more prominent. Many of the painful states seen by the interventional pain specialist can be greatly assisted by using a rehabilitation program that may include injection techniques. Some of these interventional procedures are relatively simple and common to perform, whereas others can be technically challenging and should be done only by a spine specialist with adequate experience and knowledge to perform these procedures accurately and in a timely fashion. It is important to emphasize that the use of fluoroscopy to aid in proper needle placement is now the standard and should be the norm. Fluoroscopic direction of needle placement increases the accuracy and efficacy of several types of selective

spinal procedures. Interventional spinal specialists should remain rooted in the emphasis of functional assessment and physical medical management. Indeed, it is this concept, intrinsic and unique to the physical medicine and rehabilitation specialist, that centrally places him in an ideal position to be a leader in injectional pain management. Furthermore, the use of appropriate selective injection techniques, combined with a comprehensive, personal rehabilitation plan, is theoretically more beneficial than isolated spinal injectional treatment strategies.

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