DISCOGENIC PAIN TREATMENT

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COVERAGE RATIONALE

The following thermal intradiscal procedures (TIPs) and percutaneous discectomy using other methods are unproven for the treatment of discogenic pain:
- Intradiscal electrothermal therapy (IDET)
- Intradiscal biacuplasty (IDB)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- Nucleoplasty (percutaneous disc decompression)
- Percutaneous lumbar discectomy (by other method)
- Percutaneous laser disc decompression (PLDD)
- Percutaneous endoscopic discectomy with or without laser (PELD)
- Yeung Endoscopic Spinal Surgery (YESS)
- Percutaneous intradiscal annuloplasty
The evidence is insufficient to demonstrate short or long-term health benefits. Studies are primarily uncontrolled and limited to small sample size. Larger comparative studies are needed to evaluate the safety and effectiveness of these procedures.

**Annulus fibrosis repair (i.e., XClose) following spinal surgery is unproven.** Evidence is limited to a single narrative review. Further studies are needed to establish whether annulus fibrosis repair is beneficial for health outcomes in patients with low back pain following spinal surgery.

**BACKGROUND**

Percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The goals of thermal disc treatments are to remove unwanted tissue such as herniated discs, create a seal to limit expression of matrix components, shrink collagen tissue, and destroy nociceptors.

TIPs are also identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, Accutherm, TransDiscal electrodes)

Examples of electrothermal intradiscal therapies include, (but are not being limited to) the following:

Annuloplasty may be done with any of 3 techniques: intradiscal electrothermal therapy (IDET), intradiscal biacuplasty (IDB), and intradiscal radiofrequency thermocoagulation (IRFT). Percutaneous procedures are performed through stab incisions in the skin using a large bore needle and maybe other devices to expand the opening.

Intradiscal electrothermal therapy (IDET) or intradiscal electrothermal annulorrhaphy (IEA) is a minimally invasive procedure that uses x-ray imaging (fluoroscopy) to insert a disposable flexible catheter (SpineCATH) and a heating element into the spinal disc, directly to the annulus fibrosis, the outer component of the intervertebral discs. IDET destroys the nerve fibers and toughens the disc tissue, sealing any small tears. Degeneration of the intervertebral disc can be the source of severe low back pain. IDET has been proposed as a treatment option for patients with low back pain; symptomatic internal disc disruption that is nonresponsive to conservative medical care. This is an outpatient procedure using local anesthesia and mild sedation so the patient is awake and can provide feedback to the physician during the procedure.

Intradiscal biacuplasty (IDB) (also referred to as biacuplasty) is a modification of IDET that destroys the nerve fibers that generate pain sensations. IDB is a minimally invasive procedure that uses radiofrequency energy to heat the tissue while circulating water is used to cool the tissue that is near the disc. The bilateral approach is intended to facilitate controlled lesioning between the electrodes in the disc. This is an outpatient procedure utilizing either sedative or local anesthesia.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), also known as intradiscal electrothermal annuloplasty (IEA), intradiscal radiofrequency thermomodulation, radiofrequency (RF) annuloplasty, or radiofrequency posterior annuloplasty, is a minimally invasive method similar to IDET. One difference, however, PIRFT uses a radiofrequency probe that is placed into the center of the disc rather than around the annulus. The device is activated for 90 seconds at a temperature of 70 degrees Celsius. PIRFT does not ablate the disc material but instead alters the biomechanics of the disc or destroys nociceptive pain fibers. PIRFT is performed using the Radionics RF Disc Catheter System. The Radionics catheter system is designed for patients with...
chronic discogenic back pain for the coagulation and decompression of disk material to treat symptomatic patients with annular disruption of contained herniated disks. This is an outpatient procedure utilizing either sedative or local anesthesia.

Nucleoplasty, also known as percutaneous disc decompression (PDD) or percutaneous plasma discectomy uses x-ray images (fluoroscopy) for guidance to insert a multifunctional device called a SpineWand™ to reach the disc nucleus. Radiofrequency energy is used to ablate (coablate) nuclear material and create small channels within the disc. This decompresses the disc, reducing the pressure both inside the disc and on nerve roots. Typically patients are awake and able to speak to the physician during the procedure. Nucleoplasty is performed on an outpatient basis with minimal anesthesia requirements.

Percutaneous endoscopic discectomy is performed under local anesthesia since patient cooperation is required during the procedure. The disc space is punctured with a cannula and the tip of the needle is placed into the center of the disc. A second cannula is placed on the opposite lateral side of the disc. Parts of the nucleus pulposus are removed to allow for examination. The remaining disc material is vaporized using a laser.

The Yeung Endoscopic Spinal Surgery (YESS), also known as arthroscopic microdiskectomy or percutaneous endoscopic discectomy (PELD), is a minimally-invasive procedure designed to relieve symptoms caused by herniated discs pressing on nerves. The YESS system uses an endoscopic approach to selectively remove the nucleus pulposus within annular tears. This is an outpatient procedure utilizing either sedative or local anesthesia.

Annulus fibrosis repair systems reinforce or bridge material to form a strong flexible wall between the annulus and nucleus of the herniated region to close the defect and repair the annulus fibrosis of the intervertebral disc.

**CLINICAL EVIDENCE**

Chou et al. (2009) conducted a systematic review assessing the benefits and harms of nonsurgical interventional therapies for low back and radicular pain and found that there are few nonsurgical interventional therapies for low back pain that have been shown to be effective in randomized, placebo-controlled trials.

**Intradiscal Electrothermal Therapy (IDET) and Intradiscal Biacuplasty (IDB)**

Tsau et al. (2010) evaluated ninety-three consecutive patients undergoing IDET at 134 disc levels from October 2004 to January 2007. All patients had discogenic disease with chronic low back pain (LBP), as determined by clinical features, physical examination and imaging studies, and had failed to improve with conservative treatment for at least 6 months. Follow-up period was from 1 week to 3 or more years postoperatively. There were 50 male and 43 female patients, with a mean age of 46.07 years (range, 21-65 years). The results were classified as symptom free (100% improvement), better (≥50% improvement), slightly better (<50% improvement), unchanged and aggravated. Eighty-nine patients were followed up in the first week; of them, 77 (86.52%) patients had improvement (4, symptom free; 45, better; and 28, slightly better). The improvement rate gradually decreased to 80.90% in 1 year; and 73.91%, in 3 years. In conclusion, IDET offers a safe, minimally invasive therapy option for carefully selected patients with chronic discogenic LBP who have not responded to conservative treatment. Although IDET may provide intermediate-term relief of pain, further studies with long-term follow-up are necessary.

Helm et al. (2009) conducted a systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. A total of 67 articles were reviewed of which 36 were either randomized controlled trials (n=2) or observational studies (n=34). The authors conclude that while the evidence is generally weak, IDET offers functionally significant relief in
approximately one-half of appropriately chosen chronic discogenic low back pain patients. There is minimal evidence supporting the use of radiofrequency annuloplasty and IDB.

A systematic review by Urrutia et al. (2007) included six studies with a total of 283 patients. Two open, nonrandomized trials (95 patients) showed positive results for IDET compared with rehabilitation and percutaneous intradiscal radiofrequency therapy (PIRFT). Results from 2 RCTs showed no differences between PIRFT and placebo, and between different PIRFT techniques. Two RCTs compared IDET with placebo. One suggested differences only in pain and in disability, while the best quality RCT showed no differences. The authors concluded that the available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic low back pain.

A meta-analysis by Appleby et al. (2006) was conducted to determine the representative outcomes of intradiscal electrothermal therapy (IDET) for pain relief, reduction of disability, and risk of complications. The outcomes analyzed were the visual analog scale (VAS) assessment of pain, the bodily pain, and physical functioning subscales of the SF-36 health survey, and the Oswestry disability index. From 1998 to March 2005, 62 peer-reviewed articles were identified regarding the IDET procedure. The authors concluded that although variation exists in the reported outcomes among the various studies of the IDET procedure, the pooled results of the published studies provide compelling evidence of the relative efficacy and safety of the IDET procedure. However, the studies that were included in this meta-analysis used subjective evaluation of improvement as key outcome measures.

Freeman, et al. (2005) reported on 57 patients who were randomized to either IDET (n = 38) or sham (n = 19). The objective of the study was to test the safety of IDET compared with sham treatment for low back pain of at least 3 months duration. Study participants were chosen from consecutive patients of 3 spine surgeons if they satisfied eligibility criteria. Randomization occurred after catheter placement via sealed envelope by an independent technician who covertly connected the catheter if the patient was to receive active treatment. All subjects followed a common rehabilitation program. Patient evaluations occurred at 6 weeks and 6 months by an independent investigator. Outcomes measures were recorded at baseline and 6 months and included the VAS, low back pain outcome score (LBOS), Oswestry Disability Index (ODI), SF-36, Zung Depression index, the modified somatic perception questionnaire, sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Success was defined a priori as a composite measure: no neurologic deficit resulting from the procedure, an improvement in the LBOS of 7 or more points, and an improvement in the SF-36 subscales of bodily pain and physical functioning of greater than 1 standard deviation from the mean. Sample size was calculated before the study and using a 2:1 allocation with 80 % power, 75 patients were required. The authors reported that no serious adverse events in either arm of the study occurred, without defining serious adverse events. The authors also reported, “Transient radiculopathy (less than 6 weeks) was reported in 4 study participants who underwent IDET and in 1 study participant who underwent the sham procedure.” The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic low back pain.

Pauza et al. (2004) reported a randomized, placebo-controlled, prospective trial of IDET (3). Of 64 enrolled patients, 37 were treated by IDET and 27 by sham treatment. Patients in both groups showed improvement; however mean improvements in pain, disability and depression were significantly greater in patients treated with IDET. The investigators are the developers of the technology and they have a financial investment in Oratec, the developer of the device, now owned by Smith & Nephew.

A small, double-blind, randomized, controlled trial by Kapural et al. (2005) comparing IDET (n=38) to sham catheter (n=19) found that six months after treatment, neither group had experienced statistically significant improvement from baseline. The investigators concluded that
IDET was safe, but not demonstrably better than placebo. There was no improvement in pain over sham treatment.

A prospective study by Derby et al. (2000) reported results for 32 patients with back pain for longer than 6 months, who underwent IDET. One-year results were reported on outcome measures of 1) pain relief, using a 10-point VAS scale, and 2) a 24-point Roland and Morris (RM) Disability Questionnaire. Mean decrease in VAS scores was 1.84 and in RM score was 4.03. Seventy-eight percent of patients reported that they would undergo the procedure again, with 53.1% of patients believing their condition was better than before the procedure, 34.4% perceiving no change in condition, and 12.5% believing their condition worse. However, the investigators reported that 62.5% of patients had a favorable outcome, 25% no change, and 12.5%, an unfavorable outcome.

A prospective case series by Lutz et al., (2003) reported results for 33 patients with chronic constant lumbar discogenic pain who have not responded to at least 6 months of aggressive nonoperative care, who underwent IDET. Fifteen months results were reported on outcome measures of 1) pain relief, using the Roland and Morris (RM) Disability Questionnaire, 2) visual analog scale (VAS) pain scores for the back and for the lower extremity, and 3) North American Spine Society Patient Satisfaction Index. Relief of pain and improvement in physical function were associated with a mean change in the VAS score of 3.9, a mean change in the lower-extremity VAS score of 3.7, and a mean change in the RMDQ of 7.3. For patient satisfaction, 75.7% reported that they would undergo the same procedure for the same outcome. Complete pain relief was achieved in 24% of the patients, and partial pain relief in 46% of the patients. The authors concluded that IDET offers a safe, minimally invasive treatment option for carefully selected patients with chronic lumbar discogenic pain who have not responded to aggressive nonoperative care. The study is limited by subjective outcomes with greater than one-fourth of the patients reporting no pain relief.

Saal and Saal (2000a) reported the results of 25 consecutive patients with chronic back pain (duration 10 months to 11 years) who were followed at 6 and 12 months post-IDET. The authors reported pre- and post-treatment (minimum, 6 months) means for a 10-point visual analogue pain scale (VAS), sitting tolerance, physical function (SF-36), and bodily pain scale. Statistically significant changes were reported for all four measures. There was a mean reduction in VAS of 3.74, a mean increase of 15 points on the SF-36, and a mean increase of 14 points on the bodily pain scale. Eighteen of 25 patients reported an improvement in sitting tolerance (from 23.6 minutes pretreatment to 47.2 minutes post-treatment). Weaknesses of the study include the small sample size, that the trial was not blinded or randomized, the short follow-up, and reliance on subjective measures of improvement. In addition, the investigators reported that “co-intervention was kept to a minimum, and consisted of noncreative treatments to which they already had been exposed without success before thermal treatment,” but no further description of potentially confounding therapy was provided.

In another study by Saal and Saal (2000b), results of IDET were reported for 62 consecutive patients with chronic low back pain. Again, outcome measures included visual analogue scale (VAS) pain scores, Short Form (SF-36) Health Status Questionnaire Physical Function subscale and SF-36 Bodily Pain subscale scores at baseline and at least one year later. It appears that there is probable overlap in the subjects reported in the series above and in this series of patients, i.e. that the results of the above study are not additional to, but are included in these results. Mean preoperative duration of symptoms was reported as 5 years, and mean follow-up as 16 months. Mean changes in VAS score was 3.0, in SF-36 physical function was 20, and in bodily pain was 17. Twelve (19%) of the patients did not show improvement on any scale. The investigators suggested that while a cohort of patients demonstrated statistically significant and clinically meaningful improvement at one year post-operatively, the results should be validated with “placebo-controlled randomized trials and studies comparing IDET with alternative treatments.” This study’s design and weaknesses were similar to those described in the earlier
Karasek and Bogduk (2004) reported results of a case-controlled study of 53 patients with back pain caused by internal disc disruption. 35 of the patients whose insurance would cover the procedure received IDET, and 17 of the patients who did not have insurance that would cover the procedure were deemed "controls," and received physical therapy, education and counseling. Outcomes evaluated were pain using a 10-point VAS scale, return to work, and use of opioid analgesics. In the control group, at three months, VAS scores were improved in 3, unchanged in 4, and worsened in 9. The remaining measures included reporting of only 15 patients, but the investigators did not explain why 17 three-month VAS scores were reported, but only 15 return-to-work and 16 opioid use scores were obtained. Five patients discontinued opioids, 7 continued to use them, and 4 began use.

In a case series (n=33) by Bryce et al., statistically significant improvement of pain and functional capacity was strongly associated with female gender and age. Males did not retain significant improvement beyond 6 months.

In a study reported by Cohen et al. (2007), nine consecutive patients with discogenic low back pain who obtained excellent pain relief from intradiscal electrothermal therapy were treated with a repeat procedure after the beneficial effects had diminished. Although 4 of 9 patients obtained > or =50% pain relief and were satisfied with the results, both the degree and duration of benefit were less pronounced than after the first procedure. Prospective studies are needed to identify the best candidates for repeat intradiscal electrothermal therapy.

Kapural and Mekhail (2007) reported the treatment of severe axial discogenic pain in a young man using IDB. The investigators reported that there were no intra- and post-operative complications, and significant improvements in patient functional capacity and pain scores were noted. At 6-month follow-up, visual analog scale pain scores decreased from 5 cm to 1 cm, Oswestry disability scores improved from 14 points (28 % or moderate disability) to 6 points (12 % or minimal disability) and SF-36-PF (physical function) score changed from 67 to 82. These findings need to be confirmed by well designed controlled clinical studies.

National Institute for Health and Clinical Excellence (NICE): NICE evaluated percutaneous intradiscal electrothermal therapy for lower back pain in 2009 and concluded that current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent. NICE encourages further research which should describe patient selection, use validated measures of long-term pain relief and quality of life, address the role of the procedure in avoiding major surgery, and measure long-term safety outcomes.

Professional Societies

American Society of Interventional Pain Physicians (ASIPP)
The American Society of Interventional Pain Physicians (ASIPP) has prepared practice guidelines, and found that the evidence for intradiscal electrothermal therapy (IDET) is moderate in managing chronic discogenic low back pain (Boswell, 2007).

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

In a prospective, parallel, randomized and gender stratified, double-blind placebo-controlled study, Kvarstein et al (2009) evaluated the long-term effect and safety aspects of PIRFT with the discTRODE probe. A total of 20 patients with chronic LBP and a positive 1-level pressure-controlled provocation discography were randomized to either intra-annular PIRFT or intra-annular sham treatment. A blinded interim analysis was performed when 20 patients had been followed for 6 months. The 6-month analysis did not reveal any trend towards overall effect or difference between active and sham treatment for the primary endpoint: change in pain intensity (0 tp 10). The inclusion of patients was therefore discontinued. After 12 months, the overall reduction from baseline pain had reached statistical significance, but there was no significant
difference between the groups. The functional outcome measures (ODI, and SF 36 subscales
and the relative change in pain) appeared more promising, but did not reach statistical
significance when compared with sham treatment. Two actively treated and 2 sham-treated
patients reported increased pain levels, and in both groups a higher number was unemployed
after 12 months. The study did not find evidence for a benefit of PIRFT, although it can not rule
out a moderate effect. The authors stated that considering the high number reporting increased
pain in this study, they would not recommend intra-annular thermal therapy with the discTRODE
probe.

Urrutia et al. (2007) conducted a systematic review to evaluate the evidence for the percutaneous
thermocoagulation intradiscal techniques IDET and PIRFT in the treatment of discogenic low
back pain. Six studies with a total of 283 patients were included. Two randomized controlled
trials, including the Barendse trial described above, showed no differences between PIRFT and
placebo and between different PIRFT techniques. The authors stated that, although previous
case reports and nonrandomized trials suggested positive results, results from randomized
clinical trials show that PIRFT is not effective for the treatment of discogenic low back pain.

Barendse et al. (2001) reported on a double-blind trial that randomized 28 patients with chronic
low back pain to undergo PIRFT or a sham procedure. The primary outcome was the percentage
of success at eight week, as measured by changes in pain level, impairment, Oswestry Disability
Scale, and analgesics taken. At the end of the eight weeks, there were two treatment successes
in the sham group compared to one in the treatment group. The authors concluded that PIRFT
was not better than placebo procedure in reducing pain and disability.

Ercelen et al. (2003) conducted a prospective randomized trial evaluating the efficacy of
percutaneous intradiscal radiofrequency thermocoagulation in 39 patients. Patients were
randomly selected and divided into two groups. In the first group, treatment was performed for
120 seconds and in the second group for 360 seconds, both at 80C. Evaluations were performed
before, immediately after treatment, at 1 and 2 weeks, and at 1, 3, and 6 months after the
procedure. There were no statistical differences in pain relief and functional improvement
between two groups. The immediate, 1-week and 2- week, and 1-month visual analogue scale
(VAS) scores were decreased significantly in both groups when comparing them with the
pretreatment scores. However, the final values after 6 months were similar to those measured at
the beginning of the study. The authors concluded that percutaneous intradiscal radiofrequency
thermocoagulation has been suggested and performed to relieve discogenic pain. In the previous
controlled study, no effective pain relief has been obtained. In this study, the authors increased
the duration of radiofrequency thermocoagulation to improve the effectiveness of this method.
However, the authors have not yet found any significant differences between the application of
lesioning at two different times in percutaneous intradiscal radiofrequency thermocoagulation.

Kapural et al. (2005) performed a prospective matched controlled trial of intradiscal thermal
annuloplasty versus intradiscal radiofrequency ablation for treatment of discogenic pain. They
matched 42 patients with 21 having IDET and 21 having radiofrequency annuloplasty. They
reported the IDET group had significantly lower mean pain scores than the radiofrequency
annuloplasty group however; there was improvement noted in both groups. VAS pain scores
decreased from 6.6 + 2.0 before to 4.4 + 2.4 at one year after radiofrequency annuloplasty,
whereas in IDET group the average VAS pain score decreased from 7.4 + 1.9 before IDET to 1.4
+ 1.9 at 1-year follow-up. Similarly, pain disability index scores in the IDET group had a
significantly larger improvement than those for patients who received radiofrequency
annuloplasty.

Finch et al. (2005) studied 31 patients by heating of their annular tears with a flexible
radiofrequency electrode placed across the posterior annulus and compared 15 patients with
conservative management. The visual analog scale decreased significantly after the
radiofrequency treatment and this decrease persisted at 12 months follow-up. The VAS did not
change over 12 months in untreated controlled subjects. The Oswestry Disability Index also decreased in treated patients but not in control group subjects. This study is limited by small sample size.

**National Institute for Health and Clinical Excellence (NICE):** NICE evaluated the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain and concluded that the evidence does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. (NICE, 2004a)

**Professional Societies**


The ASIPP has prepared practice guidelines, and found that the evidence for radiofrequency posterior annuloplasty was limited for short-term improvement, and indeterminate for long-term improvement in managing chronic discogenic low back pain (Boswell, 2007).

**Nucleoplasty**

There are no published RCTs assessing Coblation (ArthroCare Spine, Stockholm, Sweden) technology (Freeman, 2008).

Cohen et al., (2003) conducted a nonrandomized controlled trial that evaluated IDET as an adjunct to nucleoplasty for lumbar disc herniations. A total of 7 patients underwent nucleoplasty alone (nucleoplasty group) and 9 patients underwent nucleoplasty combined with IDET (IDET group). Patients were assigned to the IDET group if they had sitting intolerance, degenerative disc disease on MRI, and concurrent axial discogenic pain during provocative discography. At a mean follow-up of 9 months, mean pain scores had decreased from 6.0 2.0 to 4.8 1.8 in the nucleoplasty group and from 7.2 1.8 to 6.3 1.0 in the IDET Group. Using >= 50% pain relief as the definition of clinical success, only 1 (6%) patient had a successful procedure. Due to the poor results obtained, Cohen et al. (2005) recommended that future clinical trials enroll patients who have herniations < 6 mm, annular integrity confirmed by CT discography, and radicular symptoms confirmed by nerve blocks or neurological studies.

The largest available controlled trial of nucleoplasty was performed by Nardi et al. (2005) who assigned 50 patients to nucleoplasty and 20 patients to conventional therapy with anti-inflammatory medications and physical therapy. Unlike most of the other available studies of nucleoplasty, this trial enrolled patients who had herniated or protruding cervical discs rather than damaged lumbar discs. At 60 days post-treatment, complete resolution of cervical and radicular pain was reported by 40 (80%) patients in the nucleoplasty group and by 4 (20%) patients in the conventional group. MRI findings at 4 months after nucleoplasty appeared to correlate with clinical resolution. In contrast, no spontaneous regression of disc herniation was observed in MRI exams of patients in the conventional group. Nardi et al. reported that clinical improvements were statistically significant in the nucleoplasty group but not in the conventional group; however, these investigators do not appear to have performed an intergroup analysis.

A prospective, non-randomized, longitudinal, cohort study, Gerszten et al. (2006) assessed pain, functioning, and quality of life (QOL) in 67 patients with radicular leg and back pain who underwent Nucleoplasty-based percutaneous disc decompression. Pain relief, functioning, and quality of life (QOL) were evaluated. Patients completed the Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, EuroQol 5D (EQ5D), and a VAS for pain preoperatively, and at 3 and 6 months after surgery. Compared with pre-operative QOL, there was a statistically significant improvement in QOL at 3 months as measured using the SF-36 Physical Component Summary (PCS) scale, the EQ5D and the VAS for pain. Six-month results in 36 patients continued to reflect improvement as measured using the SF-36 PCS and the EQ5D. The authors concluded that Nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36.
EQ5D, and VAS for pain, three generic QOL outcome instruments. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. They noted that further follow-up evaluation is underway to determine the durability of QOL improvement after nucleoplasty.

Sharps and Isaac (2002) conducted a prospective, single site study that evaluated 49 consecutive patients with complaints of back pain with or without leg pain secondary to a contained focal protrusion. Success was defined as a minimum 2-point reduction on a Visual Analog Scale (VAS), patient satisfaction, absence of narcotic use, and return to work if not working secondary to back pain. The pre-procedure and post-procedure VAS differences were 4.28, 4.66, 4.75, and 3.3 at the one-month, 3-month, 6-month, and 12-month intervals respectively. Overall, there was a 79% success rate, with 67% success in the group of patients that had previous surgery and 82% success in the group that had no prior surgical intervention. The study is limited by mixed diagnoses of study participants and subjective outcomes.

The largest available uncontrolled study of nucleoplasty was performed by Alexandre et al. (2005) who assessed outcomes for 1390 patients treated for lumbalgia or lumbosciatica due to disc bulging or partially contained disc herniation. Alexandre et al. reported few details of demographics and no information concerning fraction of patients lost to follow-up. Based on Japanese Orthopedic Association scores, at 1 year of follow-up, improvements were excellent for 56% of patients, good for 25%, scanty for 12%, and none for 7%. No clear trend was observed when outcomes at 15 days, 1 month, 6 months, and 1 year were compared. Findings on MRI and/or CT at 6 months after nucleoplasty showed the elimination of disc bulging in 34% of patients, a reduction in 48%, and no change in 18%. The study is limited by uncontrolled study design.

Marin (2005) reported on 64 patients treated with nucleoplasty for discogenic low back and/or leg pain. Improvements in pain scores were recorded in 76% to 83% of patients at all follow-ups to 12 months. The study is limited by small sample size.

Bhagia et al. (2006) reported the short-term side effects and complications after percutaneous disc decompression utilizing coblation technology (nucleoplasty) in a retrospective study on 53 patients. The authors reported statistically significant reductions in VAS scores for both back and leg pain. The procedure was associated at 24 hours with short-term increased pain at the needle insertion site (76%), new numbness or tingling (26%), increased preprocedure back pain (15%) and new areas of back pain (15%). By 2 weeks no patients had soreness at injection site or new areas of back pain, and only 2 had increased intensity of preprocedure back pain, while new numbness or tingling was present in 15% of patients. The study is limited by retrospective study design, subjective outcomes and new symptoms in 15% of study participants.

The largest improvement in mean VAS score was reported in this follow-up study by Masala et al. (2007) who treated 72 patients affected by lumbar disk herniation were treated with nucleoplasty coblation. Average preprocedural pain level for all patients was 8.2, while the average pain level at 12 months follow-up was 4.1. At the 1 year evaluation, 79% of patients demonstrated a statistically significant improvement in numeric pain scores: 17% (12 patients) were completely satisfied with complete resolution of symptoms, and 62% (43 patients) obtained a good result. a decrease from 8.2 at baseline to 4.1 (4.1 points) at 1-year follow-up. The study is limited by subjective outcomes with only a 50% decrease in pain and no documentation of improvement in functional status.

Mirzai et al. (2007) evaluated outcomes 2 weeks, 6 months, and 1 year after nucleoplasty in 52 consecutive patients with leg pain and MRI evidence of small and medium-sized herniated discs. Thirty-four patients had one and 18 had two discs treated; a total of 70 procedures were performed. Mean VAS reduced from preprocedure 7.5 to 3.1 at postprocedure 6 months and to 2.1 at the latest follow-up. Mean Oswestry index decreased from 42.2 to 24.8 at 6 months and to
20.5 at the latest examination. Analgesic consumption was stopped or reduced in 42 patients (85\%) at 6 months and in 46 patients (94\%) 1 year after the procedure. Overall patient satisfaction was 81\% at 2 weeks, 85\% at 6 months, and 88\% at the latest follow-up. The study is limited by subjective outcomes.

A technology assessment by Hayes, Inc. (2007) evaluated evidence that identified 2 nonrandomized controlled trials and 10 uncontrolled case series on nucleoplasty. Results of these studies provide preliminary evidence that nucleoplasty is a safe and effective treatment for patients who have small herniations or protrusions of spinal discs. However, most of this evidence comes from uncontrolled studies and all of the available studies assessed results of nucleoplasty for less than one year after treatment. Therefore, the efficacy of nucleoplasty relative to other treatments for disc disease has not been established and the durability of improvements after nucleoplasty has not been investigated adequately. Further controlled studies with long-term measurement of pain and physical function are needed to establish the efficacy of disc nucleoplasty.

National Institute for Health and Clinical Excellence (NICE) evaluated percutaneous disc decompression using coblation for lower back pain in 2006 and concluded that there was some evidence of short-term efficacy; however it was insufficient to support the use of this procedure without special arrangements for consent and for audit or research.

Professional Societies
The American Society of Interventional Pain Physicians (ASIPP) has prepared practice guidelines, and found that clinical effectiveness of nucleoplasty is moderate for short-term and limited to long-term relief (Boswell, 2007).

Percutaneous Lumbar Discectomy (PLD)
A systematic review by Hirsch et al. (2009) evaluated the effectiveness of APLD and concluded that APLD is a safe procedure and may provide relief in properly selected patients with contained disc herniation. The authors also stated that the effectiveness of APLD appears to compare favorably with the results of chymopapain injection and open discectomy, however assumptions have not been proven in randomized trials.

A meta-analysis by Gibson et al. (2006) analyzed 27 randomized controlled trials of surgery for lumbar disc prolapse that included 3 trials evaluating the effect of APLD for lumbar herniation. Analysis of the pooled data from these trials indicated there is moderate evidence that APLD results in poorer clinical outcomes than standard discectomy or chymopapain treatment.

Chatterjee et al. (1995) conducted a randomized controlled trial to compare automated percutaneous lumbar discectomy (APLD) with microdiscectomy in 71 patients. In the original study design, the recruitment goal was 160 patients. However, when interim analysis found that results with APLD were inferior to microdiscectomy, further recruitment of subjects to the APLD treatment arm was halted. Of the 31 patients treated with APLD, 9 (29\%) had a successful outcome, while 32/40 (80\%) patients treated with microdiscectomy had a successful outcome. Grevitt et al. (1995) studied the safety and efficacy of APLD in 115 of 137 patients for whom long-term data was available. Excellent to good results were noted in 45\% of this group, although approximately 30\% of the patients who were initially rated as successful had deterioration in symptoms and increased disability from back pain at long-term follow-up.

Kotilainen and Valtonen (1994) reported on 2-year follow-up status of 53 patients treated with manual percutaneous discectomy. Both back and leg pain were relieved or markedly diminished in approximately 80\% of patients, with the effect seen as largely durable for 2 years. Discitis at the operated disc space was noted in 4\% of patients. Mochida et al. (2001) reported the results of a study...
after long-term follow-up of a group of 42 patients treated with percutaneous nucleotomy. Although 71% of the patients reported relief in the immediate postoperative period, this decreased to 55% after 2 years.

Gronemeyer et al. (2003) provided long-term follow-up on 200 patients with nonsequestered lumbar disc herniation who underwent PLDD. These patients were followed for 4 years, primarily through telephone interviews regarding severity of pain, degree of impairment, use of pain medication, and number of back pain-related sick days, in comparison with presurgical levels. At final follow-up, 73% of patients reported either no pain or a substantial reduction in pain, with 15% reporting no change and 8.5% reporting increased pain. Sensorimotor impairment was also either eliminated or improved in 74% of patients. Approximately half of the patients required some type of pain medication; half of these patients were using levels similar to those required prior to surgery, while half had reduced their consumption. Overall, patient satisfaction was high, 74% of patients were satisfied with the outcome of the therapy, and 81.5% of patients said they would undergo another laser discectomy procedure in the event of another disc herniation. The study is limited by subjective outcomes.

Amoretti et al. (2005) reported on the use of DeKompressor probe for the percutaneous discectomy 10 patients chosen at random. Results were satisfactory with a decrease of the initial VAS by more than 70% and a complete elimination of medical therapy in eight patients. The authors state their results should be confirmed by a multicentric large series with the criteria of inclusion or exclusion strictly respected.

Percutaneous Laser Disc Decompression (PLDD)

Tassi (2004) described the results of PLDD in 92 patients as evaluated with the MacNab criteria with a follow-up range of 5 to 12 months. Good to excellent improvement was achieved in 76 (82.8%), poor improvement was achieved in 16 (17.2%) patients. No complications were observed. The study is limited small sample size and lack of long term follow up.

McMillan et al. (2004) evaluated the short-term efficacy of PLDD in 32 consecutive patients using the standardized symptom score on the American Academy of Orthopedic surgery Outcomes Assessment Questionnaire for neurogenic and back pain. Thirty patients had sciatica at baseline. At 3 months, 24 reported improvement in sciatica symptoms. Thirty-two patients had discogenic pain at baseline, 24 reported improvement at 3 months. The study is limited by small sample size and self-reported outcomes.

Ahn et al. (2004) evaluated posterolateral endoscopic laser-assisted disc excisions in 43 patients. Follow-up was 24 to 39 months with a mean of 31 months. According to the MacNab criteria, 81.4% showed excellent or good outcomes. The mean visual analog scale decreased from 8.72 to 2.58. The study is limited by small sample size and subjective outcomes.

Toyone et al. (2004) reported on 40 consecutive patients. Twenty underwent standard discectomy, 20 underwent microendoscopic discectomy. The mean duration of follow-up was 40 months. No difference was found in the two groups for resolution of leg pain or low back pain. Method of assessment of pain was not reported in the abstract.

A prospective study of 41 patients by Haufe and Mork (2004) evaluated complications associated with cervical endoscopic laser discectomy. Complications included vessel compromise in 2 patients due to the guidewire, 1 episode of discitis, 1 episode of hoarseness potentially related to laryngeal nerve damage, and 2 complaints of a clicking sensation in the neck. The authors concluded that there is the potential for life threatening complications from this procedure.

A retrospective study by Lee et al. (2009) compared percutaneous endoscopic laser discectomy (n=25 patients) to open lumbar microdiscectomy (OLM) (n=29 patients) for recurrent disc herniation. Clinical outcomes were assessed using Visual Analogue Scale (VAS) score and
Oswestry Disability Index (ODI). Radiological variables were assessed using plain radiography and/or magnetic resonance imaging. Mean operating time and hospital stay were significantly shorter in laser group (45.8 minutes and 0.9 day, respectively) than open group (73.8 minutes and 3.8 days, respectively). At a mean follow-up duration of 34.2 months, the laser group had better improvements in back and leg pain, and functional improvement than the open group. Disc height did not change after percutaneous endoscopic laser discectomy, but significantly decreased after open lumbar microdiscectomy. The authors concluded that both percutaneous endoscopic laser discectomy and open lumbar microdiscectomy showed favorable outcomes for recurrent disc herniation, but the laser group had advantages in terms of shorter operating time, hospital stay, and disc height preservation. The study is limited by retrospective study design and small number of patients.

Peng et al. (2009) indicated that while percutaneous endoscopic lumbar discectomy (PELD) is a relatively new technique, few studies have reported the clinical outcome of PELD regarding quality of life and return to work. In a retrospective study of 55 subjects, clinical outcomes were reviewed using the North American Spine Score (NASS), Medical Outcomes Study Short Form-36 scores (SF-36), the Visual Analogue Scale (VAS) and return to work. The treatment sites varied as well as the disc status. Thirty nine (70.9%) subjects had L4-L5 discectomy, 12 (21.8%) had L5-S1 discectomy, 2 (3.6%) had L3-L4 and 2 (3.6%) had two levels L4-L5 and L5-S1 performed. There were 44 (80%) disc protrusions, 10 (18.2%) extrusions and 1 (1.8%) sequestrated disc. The mean follow-up period was 3.4 years (range 2.0 – 6.5 years). All who were working preoperatively returned to work. The mean time to return to work was 24.3 days (range 10 – 60 days). Back pain and lower limb symptoms were reduced NASS and VAS, (p less than 0.05) at 6 months and 2 years. There were improvements in Quality of Life (SF-36, p less than 0.05) scores except for general health at 6 months and 2 years post surgery. The recurrence rate was 5% or 3 subjects who subsequently underwent lumbar fusion for persistent back pain. The limitations of this study were that it was retrospective, uncontrolled and limited in size.

The National Institute for Health and Clinical Excellence (NICE) evaluated the safety and efficacy of percutaneous endoscopic lumbar and cervical discectomy in 2009 and found the current evidence inadequate to conclude that this is a safe and effective treatment.

In 2003, the National Institute for Health and Clinical Excellence (NICE) evaluated the safety and efficacy of endoscopic laser foraminoplasty and found the evidence inadequate to support the use of this procedure. Additionally, the NICE guidance stated that further research was needed to evaluate safety and efficacy to reduce uncertainty of this procedure.

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (2000) found that there is insufficient evidence surrounding the use of percutaneous endoscopic laser discectomy to draw any conclusions about the safety or effectiveness of this procedure.

**Annulus Fibrosis Repair**

Evidence is limited to a single narrative review covering a variety of technologies for annulus fibrosis closure, including surgical, regenerative, and alternative strategies. (Bron, 2009)

Anuлекс Technologies, Inc., is sponsoring a randomized, single blind study of annular repair using the Xclose Tissue Repair System. The study start date was March 2007, with an estimated enrollment of 750 patients. The primary outcome measure is a repeat discectomy procedure, and secondary outcomes measures include results on the Oswestry Disability Scale, Visual Analogue Scale, and SF-12 quality-of-life assessment; healthcare utilization, and return-to-work time. The estimated completion date is August 2011. (ECRI, 2009)

There were two 510(k) approvals for the SpineWand device. There are additional approvals for the Controller (radiofrequency electrosurgical generator); these listings are available from the Center for Devices and Radiological Health 510(k):

- PercD SpineWand. Arthrocare Corporation. [decision date 04/16/03]
- PercD SpineWand. Arthrocare Corporation. [decision date 05/31/01]

The ArthroCare System 2000 (K001588) received 510(k) approval on August 17, 2000. It is a bipolar, high-frequency electrosurgical system that has three components: an electrosurgical generator (Controller), disposable, single use Wand, and a reusable cable. The ArthroCare 8000S Coblator Surgery System received a special 510(k) approval on December 6, 2005. The Perc™ received 510(k) approval (K010811) on May 30, 2001 for ablation, coagulation, and decompression of dFSc material to treat symptomatic patients with contained herniated discs.

Three subsequent 510(k) approvals (K020621, K030954, and K053447) were issued for the ArthroCare® Perc-D® SpineWand™ on March 28, 2002, April 16, 2003, and December 27 2005, respectively, noting modifications in dimensional and performance specifications, materials, and labeling for the device. Indications for both approvals for use, technology, principle of operation, packaging, and sterilization parameters of the wands were unchanged from those of the predicate device. The ArthroCare System 2000 received CE marking. Endoscopes, catheters, and needles that can be used for epidural lysis of adhesions are regulated by the FDA as Class II devices and a number of these devices have been approved via the FDA 510(k) process. The Racz Catheter received FDA approval on October 8, 1996 (K954584). The Myelotec Myeloscope received 510(k) approval on September 4, 1996 (K960194).

Other examples include the PercScope, Yeung Endoscopic Spine System, and The Spine Endoscope, discTRODE, Accutherm and TransDiscal electrodes.


There are 3 commercially marketed devices indicated for closure of the annulus fibrosis:


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Effective for services performed on or after September 29, 2008, CMS has determined that Thermal Intradiscal Procedures (TIPs) are not reasonable and necessary for the treatment of low back pain. See the National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPS) 150.11
Local Coverage Determinations (LCDs) for Thermal Intradiscal Therapy do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for Automated Percutaneous Lumbar Discectomy (APLD). Local Coverage Determinations (LCDs) for APLD do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for Percutaneous Laser Disc Decompression (PLDD). Local Coverage Determinations (LCDs) for PLDD do not exist at this time. Medicare recognizes the use of lasers for many medical indications. In the absence of a specific non-coverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered. The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated. Refer to the National Coverage Determinations (NCD) for Laser Procedures (140.5)

Medicare does not have a National Coverage Determination (NCD) for the Xclose tissue repair system. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed September 19, 2011)

**APPLICABLE CODES**

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>22526</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level</td>
</tr>
<tr>
<td>22527</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)</td>
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<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar</td>
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<td>S2348</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar</td>
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REFERENCES


Accessed October 1, 2011


### POLICY HISTORY/REVISION INFORMATION

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<tr>
<td>01/01/2012</td>
<td>• Updated description of services to reflect most current clinical evidence and references</td>
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<tr>
<td></td>
<td>• No change to coverage rationale; clarified existing content:</td>
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| o Replaced language indicating “the listed thermal intradiscal procedures (TIPs) are unproven for the treatment of discogenic pain” with “the listed intradiscal procedures (TIPs) and percutaneous discectomy using other methods are unproven for the treatment of discogenic pain” |
| Updated list of applicable CPT codes to reflect annual code edits (effective 1/1/12): |
| o Revised description for 62287 |
| o Archived previous policy version 2011T0105H |