## Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

### Medical Policy

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<td>Surgery</td>
<td>12/2013</td>
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**Issue**

12/2013

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**Description**

Laser energy (laser discectomy) and radiofrequency coblation (nucleoplasty) are being evaluated for decompression of the intervertebral disc. For laser discectomy under fluoroscopic guidance, a needle or catheter is inserted into the disc nucleus, and a laser beam is directed through it to vaporize tissue. For DISC nucleoplasty™, bipolar radiofrequency energy is directed into the disc to ablate tissue.

**Background**

A variety of minimally invasive techniques have been investigated over the years as treatment of low back pain related to disc disease. Techniques can be broadly divided into techniques that are designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus. The former category includes chymopapain injection, automated percutaneous lumbar discectomy, laser discectomy, and most recently, disc decompression using radiofrequency energy, referred to as a DISC nucleoplasty™.

Techniques that alter the biomechanics of the disc (disc annulus) include intradiscal electrothermal annuloplasty (i.e., the percutaneous intradiscal electrothermal annuloplasty [IDET] procedure) or percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). It should be noted that 3 of these procedures use radiofrequency energy—disc nucleoplasty, IDET, and PIRFT—but apply the energy in distinctly different ways such that the procedures are unique.

Patients considered candidates for DISC nucleoplasty™ or laser discectomy include patients with bulging discs and sciatica. In contrast, the presence of a herniated disc is typically...
considered a contraindication for the IDET or PIRFT procedure. The IDET and PIRFT procedures, chymopapain injection, and automated percutaneous lumbar discectomy are considered in separate policies. Laser discectomy and DISC nucleoplasty™ are the subjects of this policy.

A variety of different lasers have been investigated for laser discectomy, including YAG, KTP, holmium, argon, and carbon dioxide lasers. Due to differences in absorption, the energy requirements and the rate of application differ among the lasers. In addition, it is unknown how much disc material must be removed to achieve decompression. Therefore, protocols vary according to the length of treatment, but typically the laser is activated for brief periods only.

The Disc nucleoplasty™ procedure uses bipolar radiofrequency energy in a process referred to as coblation technology. The technique consists of small, multiple electrodes that emit a fraction of the energy required by traditional radiofrequency energy systems. The result is that a portion of nucleus tissue is ablated, not with heat but with a low-temperature plasma field of ionized particles. These particles have sufficient energy to break organic molecular bonds within tissue, creating small channels in the disc. The proposed advantage of this coblation technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal therapy damage to surrounding tissue.

Regulatory Status

A number of laser devices have received U.S. Food and Drug Administration (FDA) 510(k) clearance for incision, excision, resection, ablation, vaporization, and coagulation of tissue. Intended uses described in FDA summaries include a wide variety of procedures, including percutaneous discectomy. Trimedyne, Inc. received 510(k) clearance in 2002 for the Trimedyne Holmium Laser System Ho1mium:Yttrium Aluminum Garnet (Ho1mium:YAG), Lisa Laser Products for Revolix Duo Laser System in 2007, and Quanta System LITHO Laser System in 2009. All were cleared, based on equivalence with predicate devices for percutaneous laser disc decompression/discectomy, including foraminoplasty, percutaneous cervical disc decompression/discectomy, and percutaneous thoracic disc decompression/discectomy. The summary for the Trimedyne system states that indications for cervical and thoracic decompression/discectomy include uncomplicated ruptured or herniated discs, sensory changes, imaging consistent with findings, and symptoms unresponsive to 12 weeks of conservative treatment. Indications for treatment of cervical discs also include positive nerve conduction studies.

Arthrocare’s Perc-D SpineWand received 510(k) clearance in 2001 based on equivalence to predicate devices. It is used in conjunction with the Arthrocare Coblation System 2000 for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

Policy

Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered investigational as techniques of disc decompression and treatment of associated pain.
Policy Guidelines

CPT code 62287 describes any method of decompression of intervertebral disc; therefore, based on this code alone, it might not be possible to distinguish among automated percutaneous discectomy, laser discectomy, or DISC nucleoplasty™.

CPT code 77002 (fluoroscopic guidance for needle placement) may be used to describe the radiologic guidance.

A specific HCPCS S code is available for the radiofrequency procedure – S2348 - Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar.

Rationale

Randomized, controlled trials (RCTs) are considered particularly important when assessing treatment of low back pain. RCTs are necessary to minimize the impact of demographic and clinical factors that can confound outcomes, to control for the expected placebo effect and other non-specific effects of enrollment in a trial, and also to control for the variable natural history of low back pain, which may resolve with conservative treatment alone. The currently available literature primarily consists of uncontrolled case series.

Laser Discectomy

Laser discectomy has been practiced for more than 20 years, and a fairly extensive literature describes different techniques using different types of lasers. In 2003, Gibson and colleagues published a Cochrane review of surgery for lumbar disc prolapse, which included a review of laser discectomy. (1) The review aimed to determine the relative treatment effectiveness of laser discectomy compared to either no treatment, discectomy, or automated percutaneous discectomy. The review also included chemonucleolysis and open surgical discectomy. In their overall review of all surgeries, 27 randomized controlled clinical trials were identified, but none addressed laser discectomy. This review concluded that unless or until better scientific evidence is available, laser discectomy should be regarded as a research technique.

The 2007 updated Cochrane review of surgical interventions for lumbar disc prolapse included 2 comparative studies reported in U.S. Congress proceedings and abstracts. (2) One study, comparing 2 types of lasers, did not report comparative outcome results, and the other, which compared laser discectomy with chemonucleolysis, reported limited results favoring chemonucleolysis. (3, 4) The authors concluded that clinical outcomes following automated discectomy and laser discectomy “are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged.”

In a 2007 paper, Goupille et al. reviewed the literature on laser disc decompression and concluded that “although the concept of laser disc nucleotomy is appealing, this treatment
cannot be considered validated for disc herniation-associated radiculopathy resistant to medical treatment.” (5) They cite the lack of consensus regarding technique, the questionable methodology and conclusions of published studies, and the absence of a controlled study in their discussion.

Singh et al. reported in 2009 that, based on a systematic review of current evidence, there is Level II-2 evidence for percutaneous laser disc decompression for short- and long-term relief of pain “which is equivalent to automated percutaneous lumbar disc decompression.” (6) Evidence was rated according to U.S. Preventive Services Task Force (USPSTF) criteria; Level II-2 describes studies from well-designed cohort or case-control analytic studies, preferably from more than one center or research group. (BCBSA considers the evidence on automated percutaneous lumbar disc decompression to be insufficient.)

A retrospective review reported outcomes from 500 patients with discogenic pain and herniated discs treated with microdiscectomy (1997–2001 by 6 surgeons) and 500 patients treated with percutaneous laser disc decompression (2002–2004 by a single surgeon). (7) Patients with sequestered discs were excluded. This retrospective review found that the hospital stay (6 vs. 2 days), overall recovery time (60 vs. 35 days), and repeat procedure rates (7% vs. 3% - all respectively) were lower in the laser group; these were not compared statistically. The percentage of patients with overall good/excellent outcomes (MacNab criteria) was found to be similar in the 2 groups (85.7% vs. 83.8%, respectively) at the 2-year assessment; quantitative outcome measures were not reported.

Other than the comparative studies mentioned above, the evidence for laser discectomy is limited to case series. In 2004, Choy described the largest series of 1,275 patients treated with 2,400 procedures (including cervical, thoracic, and lumbar discs) over a period of 18 1/2 years, reporting an overall success rate, according to the MacNab criteria (measuring pain and function) of 89%. (8) “The complication rate (only infectious discitis) was 0.4%; all 10 patients with complications were cured with appropriate antibiotics. The recurrence rate was 5% and usually due to reinjury.” Menchetti and colleagues reported a retrospective review of 900 patients treated with laser discectomy for herniated nucleus pulposus in 2011. (9) The success rate according to MacNab criteria at a mean of 5 years (range, 2-6 years) was 68%. Visual analog scores (VAS) for pain decreased from 8.5 preoperatively to 2.3 at 3-year follow-up and 3.4 at 5-year follow-up. There was a correlation between fair/poor results and subannular extrusion; 40% of these cases were treated with microsurgery after 1-3 months.

In 2009, an article describing the design for an RCT was published by investigators in the Netherlands. (10) No results from this trial have been identified.

Disc Nucleoplasty

Disc nucleoplasty™ is a relatively new technology, and at the time this policy was created, the literature consisted of case series with no controlled trials. In 2009, Chou et al. published a review of the evidence for nonsurgical interventions for low back pain for an American Pain Society guideline. (11) The authors noted that one lower quality systematic review identified no RCTs, and there was insufficient evidence from small case series to evaluate efficacy. Key studies and controlled studies published after this systematic review are described below.

Bokov and colleagues reported a non-randomized cohort study comparing nucleoplasty and microsurgery in 2010. (12) Inclusion criteria were evidence of nerve root compression, pain resistant to conservative treatment including selective nerve root blocks during at least 1 month.
with VAS equal to or greater than 40/100 and disability equal to or greater than 40% on the Oswestry Disability Index (ODI). Only patients with mild motor and sensory deficits were included in the study. Patients undergoing nucleoplasty received pretreatment questionnaires and testing and were divided into those with a disc protrusion (<5 mm; n=24; 6-9 mm, n=22) or a disc extrusion (n=27). The patients with disc extrusion chose nucleoplasty despite a total annulus disruption. Patients were examined at 1, 3, 6, 12, and 18 months with VAS for pain and ODI. A satisfactory result was defined as a 50% decrease in VAS and a 40% decrease in ODI, and the rates of satisfactory and unsatisfactory responses were compared between nucleoplasty and microdiscectomy (n=65). There were no significant differences in outcomes for patients with a disc protrusion equal to or less than 5 mm versus 6-9 mm, and these groups were combined. For all patients with a disc protrusion treated with nucleoplasty, satisfactory results were obtained in 36 (78%, 95% confidence interval [CI]: 66-90%). For the microdiscectomy group, a satisfactory result was observed in 61 patients (94%, 95% CI: 85-98%). For patients with a disc extrusion, nucleoplasty had a significantly higher rate of unsatisfactory results; clinically significant improvements were observed in 12 cases (44%), and 9 patients (33%) with disc extrusion treated with nucleoplasty subsequently underwent microdiscectomy for exacerbation of pain. These results support the conclusion that nucleoplasty is not as effective as microdiscectomy for disc extrusion. Prospective controlled trials are needed to evaluate efficacy and time for recovery in patients with disc protrusion.

In 2009, Birnbaum reported a series of 26 patients with cervical disc herniation (29 discs) treated with disc nucleoplasty who had 2 years of follow-up. (13) He compared their outcomes with a group of 30 patients who received conservative treatment. It does not appear that patients were randomly assigned to either treatment group but that the control patients were randomly chosen. Conservatively treated patients received perineural injections with bupivacaine and prednisolone acetate during the first week of treatment. Baseline VASs were 8.4 in the control group and 8.8 in the nucleoplasty group. At 1 week, scores were 7.3 and 3.4, respectively, and at 24 months, 5.1 and 2.3, respectively. No other outcome data were provided.

A prospective study from 2007 assessed outcomes in 52 consecutive patients treated with radiofrequency nucleoplasty of lumbar discs. (14) Included in the study were patients younger than 60 years of age with radicular pain that was resistant to at least 3 months of conservative treatment, combined with magnetic resonance imaging (MRI) evidence of small and medium-sized herniated discs (less than 6 mm) that correlated with the patient’s symptoms. Patients with a disc height of less than 50% of adjacent discs, severe degenerated or fractured disc material, or evidence of extruded disc herniation were excluded. Independent assessment at 2 weeks, 6 months, and 1 year (94% follow-up) found a decrease in VAS pain scores from 7.5 to 2.1, a change from 42 to 21 on the ODI, and a reduction or complete stopping of use of analgesics in 94% of patients.

Cuellar et al. reported accelerated degeneration after failed nucleoplasty in 2010. (15) Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by MRI to determine the source of their symptoms. The total number of procedures performed could not be determined. VAS for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6 to 52) after nucleoplasty, no change was observed between the baseline and postoperative MRI for increased signal hydration, disc space height improvement, or shrinkage of the preoperative disc bulge. Of 17 cervical levels treated in 12 patients, 5 (42% of patients) appeared to show progressive degeneration at treated levels. Of 17 lumbar procedures in 16 patients, 4 (15% of patients) showed progressive degeneration. Overall, a total of 26% of the patients in this series showed progressive degeneration at the treated level less than 1 year after nucleoplasty. The
proportion of discs showing progressive degeneration out of the total nucleoplasty procedures performed cannot be determined from this study. It is also unknown whether any morphologic changes occur after nucleoplasties that were considered to be successful. Additional study of this potential adverse effect of nucleoplasty is needed.

**Ongoing Clinical Trials**

A search of the online site www.clinicaltrials.gov in June 2012 identified an industry-sponsored randomized controlled trial of nucleoplasty compared to conservative care (NCT00940810). The study has an estimated enrollment of 46 patients with completion expected November 2011.

An industry-sponsored sham-controlled randomized trial on nucleoplasty is listed as completed as of March 2008 (NCT00124774). No publications from this trial have been identified.

**Summary**

While numerous case series and uncontrolled studies report improvements in pain and functioning following laser discectomy and nucleoplasty, the lack of well-designed and conducted controlled trials limits interpretation of reported data. Questions remain about the safety and efficacy of these treatments. Reconsideration of the policy position awaits randomized trials with adequate follow-up (at least 1 year) that control for selection bias, the placebo effect, and variability in the natural history of low back pain. These procedures are considered investigational.

**Practice Guidelines and Position Statements**

The National Institute for Clinical Excellence (NICE) published guidance on laser lumbar discectomy in 2009, stating that current evidence “is inadequate in quantity and quality”, that this procedure should only be used with special arrangements for clinical governance, consent, and audit or research, and that patients should understand the uncertainty about the safety and efficacy of the procedure. (16) Guidance on percutaneous disc decompression using coblation for lower back pain was published in 2006 stating that there is some evidence of short-term efficacy; however “this is not sufficient to support the use of this procedure without special arrangements for consent and audit or research." (17)

A 2009 American Pain Society Clinical Practice Guideline on nonsurgical interventions for low back pain states that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including coblation. (11, 18)

Practice Guidelines published in 2009 by the American Society of Interventional Pain Physicians report U.S. Preventive Services Task Force (USPSTF) Level II-2 evidence of short-term and long-term relief of pain for percutaneous laser discectomy, citing the review by Singh et al. (6) and make a strong recommendation. (19) The guidelines report Level II-3 evidence for disc nucleoplasty in managing predominantly lower extremity pain due to contained disc herniation and state that there is no evidence available for axial low back pain. The guidelines make a weak recommendation for radiofrequency disc nucleoplasty in managing radicular pain due to contained disc herniation. No recommendation for nucleoplasty is given regarding managing axial low back pain.

**Medicare National Coverage**

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The Centers for Medicare and Medicaid Services (CMS) has determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression (PDD) or coblation, are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered. (20)

CMS has not published a national coverage decision regarding laser discectomy; however, it states the following in its decision on laser procedures: “Medicare recognizes the use of lasers for many medical indications. (21) Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage 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.”

References:


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