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

Description

Laser energy (laser discectomy) and radiofrequency (RF) 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 RF energy is directed into the disc to ablate tissue. These minimally invasive procedures are being evaluated for the treatment of discogenic back pain.

Background

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease. Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A variety of minimally invasive techniques have been investigated as treatment of low back pain related to disc disease. Techniques can be broadly divided into those 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 (RF) energy, referred to as a disc nucleoplasty.

Techniques that alter the biomechanics of the disc (disc annulus) include a variety of intradiscal electrothermal procedures that are discussed in evidence review 7.01.72.

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 by the length of treatment, but typically the laser is activated for brief periods only.
RF coblation uses bipolar low-frequency energy in an electrical conductive fluid (e.g., saline) to generate a high-density plasma field around the energy source. This creates a low-temperature field of ionizing particles that break organic bonds within the target tissue. Coblation technology is used in a variety of surgical procedures, particularly related to otolaryngology. The disc nucleoplasty procedure is accomplished with a probe mounted with a RF coblation source. The proposed advantage of coblation is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue.

The ArthroCare SpineWand used coblation technology (ArthroCare, Austin, TX). ArthroCare was acquired by Smith & Nephew in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website.

**Regulatory Status**

A number of laser devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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 Holmium:Yttrium, Aluminum Garnet (Holmium:YAG), in 2007 RevoLix Duo™ Laser System, and in 2009 Quanta System LITHO Laser System. 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. FDA product code: GEX.

In 2001, the Perc-D SpineWand™ (ArthroCare) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent 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. Smith & Nephew acquired ArthroCare in 2014. FDA product code: GEI.

**Related Policies**

7.01.18 Automated Percutaneous Discectomy
7.01.72 Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty
Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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

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 nonspecific effects of enrollment in a trial, and to control for the variable natural history of low back pain, which may resolve with conservative treatment alone. The optimal comparators, therefore, are conservative therapy with a sham control, epidural steroid injection, or conventional discectomy.

Laser Discectomy

Laser discectomy has a fairly extensive literature describing different techniques using different lasers.

Systematic Reviews

In 2013, Singh et al updated their systematic review of current evidence on percutaneous laser disc decompression.\(^1\)\(^2\) They selected 17 observational studies. Due to the lack of RCTs, meta-analysis could not be conducted, and evidence was considered limited, when rated according to U.S. Preventive Services Task Force criteria. A 2007 Cochrane review of surgical interventions for lumbar disc prolapse included 2 comparative studies on laser discectomy that were reported in as proceedings and abstracts.\(^3\) Reviewers 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.”

Observational Studies

Tassi et al (2006) compared 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).\(^4\) Patients with sequestered discs were excluded. This retrospective review found that the hospital stay (6 days vs 2 days), overall recovery time (60 days vs 35 days), and repeat procedure rates (7% vs 3%), all respectively, were lower in the laser group than in the microdiscectomy group. No statistical comparisons were provided. The percentage of patients with overall good/excellent outcomes (MacNab criteria) was found to be similar in both groups (85.7% vs 83.8%, respectively) at the 2-year assessment; quantitative outcome measures were not reported.
Other than the comparative studies previously mentioned, the evidence for laser discectomy is limited to case series. The largest series, published by Choy (2004), included 1275 patients treated with 2400 procedures (including cervical, thoracic, lumbar discs) over 18.5 years, with an overall success rate using the MacNab criteria (measuring pain and function) of 89%. Menchetti et al (2011) retrospectively reviewed 900 patients treated with laser discectomy for herniated nucleus pulposus. The success rate using MacNab criteria at a mean of 5 years (range, 2-6 years) was 68%. Visual analog scale (VAS) scores for pain decreased from 8.5 preoperatively to 2.3 at 3-year follow-up but increased to 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 to 3 months.

**Section Summary: Laser Discectomy**

Evidence on decompression of the intervertebral disc using laser energy consists of observational studies. Given the variable natural history of back pain and the possibility of placebo effects with this treatment, observational studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes.

**DISC NUCLEOPLASTY WITH RADIOFREQUENCY COBLATION**

**Systematic Reviews**

A 2013 systematic review by Manchikanti et al identified 1 RCT (described below) and 14 observational studies on disc nucleoplasty (radiofrequency coblation) that met inclusion criteria; they concluded that the evidence was limited to fair.

**Randomized Controlled Trials**

Included in the systematic review was a 2010, industry-sponsored RCT, an unblinded multicenter comparison of coblation nucleoplasty and 2 epidural steroid injections. The 85 patients included in the study had a focal disc protrusion and had failed conservative therapy. All patients had previously also had an epidural steroid injection at 3 weeks to 6 months with no relief, temporary relief, or partial relief of pain. At the 6-month follow-up, the mean improvement in VAS scores for leg pain, back pain, Oswestry Disability Index (ODI) scores, and 36-Item Short-Form Health Survey (SF-36) subscores were significantly greater in the nucleoplasty group. A greater percentage of patients in the nucleoplasty group also had a minimum clinically important change for leg pain, back pain, ODI, and SF-36 scores. The proportion of patients in each group with unresolved symptoms requiring a secondary procedure during the first 6 month of the study did not differ between groups (27% for nucleoplasty vs 20% for epidural steroid). At 1-year follow-up, secondary procedure rates increased to 42% of the nucleoplasty group and to 68% of the steroid group. By the 2-year follow-up, 44% of the nucleoplasty group and 73% of patients in the steroid group had secondary procedures, including 20 patients who had crossed over from steroid treatment to nucleoplasty.

A 2012 unblinded RCT from Asia compared nucleoplasty with conservative treatment in 64 patients. VAS at 15 days after treatment was reduced by 4 points from a baseline (9 to 5). The nucleoplasty group was reported to have a reduction in pain and medication use compared with conservatively treated controls at 1, 3, 6, and 12 months posttreatment, although the data were not presented in this...
Comparison of magnetic resonance images at baseline and after treatment showed a decrease in disc bulging from 5.09 mm to 1.81 mm at 3 months after nucleoplasty.

Controlled Cohort Studies

Bokov et al reported a nonrandomized cohort study comparing nucleoplasty with microdiscectomy in 2010. Patients undergoing nucleoplasty were grouped into those with a disc protrusion (n=46) or a disc extrusion (n=27). Patients were rated at 1, 3, 6, 12, and 18 months for pain VAS and ODI scores. A satisfactory result was defined as a 50% decrease in VAS score and a 40% decrease in ODI score. For patients with a disc protrusion treated with nucleoplasty, satisfactory results were obtained in 36 (78%). For patients with a disc protrusion treated with microdiscectomy, a satisfactory result was observed in 61 (94%) patients. For patients with a disc extrusion, nucleoplasty had a significantly higher rate of unsatisfactory results; clinically significant improvements were observed in 12 (44%) cases, and 9 (33%) patients with disc extrusion treated with nucleoplasty subsequently underwent microdiscectomy for exacerbation of pain.

In 2009, Birnbaum compared outcomes from a series of 26 patients with cervical disc herniation treated with disc nucleoplasty to a group of 30 patients who received conservative treatment with bupivacaine and prednisolone acetate. Baseline VAS score was 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 outcomes data were provided.

Other

Cuellar et al (2010) reported accelerated degeneration after failed nucleoplasty. Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by magnetic resonance imaging (MRI) to determine the source of their symptoms. VAS score for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6-52 weeks) after nucleoplasty, no change was observed between baseline and postoperative MRI results 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%) patients appeared to show progressive degeneration at treated levels. Of 17 lumbar procedures in 16 patients, 4 (15%) patients showed progressive degeneration. Overall, 26% of the patients in this series showed progressive degeneration at the treatment level less than 1 year after nucleoplasty. The proportion of discs showing progressive degeneration of the total nucleoplasty procedures performed cannot be determined from this study. It is also unknown whether any morphologic changes occurring after nucleoplasties were considered successful. Additional study of this potential adverse effect of nucleoplasty is needed.

Section Summary: Disc Nucleoplasty With Radiofrequency Coblation

Two unblinded RCTs have assessed nucleoplasty. One was from Asia and compared nucleoplasty with conservative therapy. The other RCT was an industry-sponsored comparison of coblation nucleoplasty to epidural steroid injections in a group of patients who had already failed the control intervention. At 6-month follow-up, scores for pain and functional status were superior for the nucleoplasty group, but a similar percentage of patients in the 2 groups had unresolved symptoms and received a secondary procedure. In the observational phase of the study (2-year follow-up), a higher percentage of patients (50%) in the control group crossed over to nucleoplasty. The manner in which alternative interventions
were offered in the observational phase is uncertain. Overall, interpretation of these study results is limited. Results from a cohort study support the conclusion that nucleoplasty is not as effective as microdiscectomy for disc extrusion. Prospective controlled trials of nucleoplasty versus microdiscectomy are needed to evaluate efficacy and time to recovery in patients with disc protrusion. Notably, 1 case series reported accelerated degeneration after nucleoplasty. Adequate follow-up with MRI is needed to determine if nucleoplasty accelerates disc degeneration.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (NICE) guidance on laser lumbar discectomy for the treatment of sciatica was updated in December 2016. The guidance states that current evidence “is inadequate in quantity and quality” and that this procedure should only be used in the context of research.13

NICE’s guidance on percutaneous disc decompression using coblation for lower back pain and sciatica was also updated in 2016. It states: “Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent, and audit.” The guidance also notes that the patient should be informed of the range of treatment options available.14

**American Pain Society**

A 2009 American Pain Society clinical practice guideline on nonsurgical interventions for low back pain has stated 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.15,16

**American Society of Interventional Pain Physicians**

Practice guidelines on lumbar disc compression and chronic spinal pain were published in 2009 and updated in 2013, respectively, by the American Society of Interventional Pain Physicians.17,18 The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.2,7

**U.S. Preventative Task Service Recommendations**

Not applicable

**SUMMARY OF EVIDENCE**

For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack
of well-designed and conducted controlled trials limits interpretation of reported data. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have discogenic back pain or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 2 RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in 1 trial, and inadequate data reporting in the second. The available evidence is insufficient to permit conclusions concerning the effect of these procedures on health outcomes due to multiple confounding factors that may bias results. High-quality randomized trials with adequate follow-up (at least 1 year), which control for selection bias, the placebo effect, and variability in the natural history of low back pain, are needed. The evidence is insufficient to determine the effect of the technology on health outcomes.

Medicare National Coverage

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. 19

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. 20 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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<td>Update Policy</td>
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March 2017  Update Policy  Policy updated with literature review through November 7, 2016; Rationale revised and some references removed. Policy statement unchanged.

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 17, 2017 and is effective April 15, 2017.

Signature on file
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