Medical Policy Manual Surgery, Policy No. 131

Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty)

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Ablation of the nucleus pulposus using laser energy (laser discectomy) and radiofrequency energy (coblation or nucleoplasty) is being evaluated as a technique for decompression of the intervertebral disc.

MEDICAL POLICY CRITERIA

Note: This policy does *not* address intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), or percutaneous and endoscopic discectomy which are considered in separate medical policies (see Cross References below).

I. Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered **investigational** for all indications, including but not limited to disc decompression and treatment of associated pain.

II. Chemonucleolysis as an adjunct to percutaneous disc decompression procedures including, but not limited to disc nucleoplasty, is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation, Surgery, Policy No. 118
2. Automated Percutaneous and Endoscopic Discectomy, Surgery, Policy No. 145
3. Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176

BACKGROUND

Patients considered candidates for laser discectomy or disc nucleoplasty include those with bulging discs and sciatica.

LASER DISCECTOMY

A variety of different lasers have been investigated for laser discectomy, including YAG, KTP, holmium, argon and carbon dioxide lasers. Regardless of the type of laser, the procedure involves vaporization (also referred to as ablation or coagulation) of disc tissue using laser energy delivered via a needle or catheter inserted into the disc nucleus under fluoroscopic guidance. Due to differences in absorption, the energy requirements and the rate of application differ among the lasers. Additionally, 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.

DISC NUCLEOPLASTY

The disc nucleoplasty procedure uses bipolar radiofrequency energy directed into the disc to ablate disc tissue in a process commonly 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.

CHEMONUCLEOLYSIS AS AN ADJUNCT TO DISC NUCLEOPLASTY

After FDA approval in 1982, chemonucleolysis was used for a number of years in the United States as a stand-alone procedure to ablate or dissolve disc material. In this procedure, chymopapain, a protein-dissolving enzyme derived from papaya, is injected into a ruptured or bulging disc. However, it largely fell out of favor following disclosure of neurological sequelae and other complications. More recently, chemonucleolysis has been proposed to pre-treat a disc prior to percutaneous disc decompression procedures including disc nucleoplasty.

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 SpineWands™ 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. Smith & Nephew acquired ArthroCare in 2014.

EVIDENCE SUMMARY

The most clinically relevant outcomes of treatments of back pain are improvements in pain and/or function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of back pain. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to compare ablative disc decompression with open surgical disc decompression, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of the ablative techniques outweigh any risks and provide a significant advantage over conventional open techniques.

The focus of the following literature review is on systematic reviews (SRs), RCTs, prospective comparative trials, and clinical practice guidelines.

LASER DISCECTOMY

Although laser discectomy has been practiced for over a decade, and there is fairly extensive literature describing different techniques using different types of lasers, most of the evidence in the published literature is from case series, retrospective reviews, and a number of review articles.

SYSTEMATIC REVIEWS

In a 2007 update of a 2003 Cochrane review[1] of surgery for lumbar disc prolapse, Gibson and Waddell noted the generally poor methodological quality of the available studies.[2] Only three small RCTs of laser discectomy were found. The authors concluded that these data did not provide conclusive evidence of its efficacy, and that clinical outcomes following laser discectomy "are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged."

Goupille (2007) 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".[3] They cited the lack of consensus regarding technique, that methodology and conclusions of published studies are questionable, and absence of a controlled study.

Singh (2013) published an update to a 2009[4] SR that rated the current evidence for percutaneous lumbar laser disc decompression for short- and long-term relief of pain as "limited" or poor when rated according to U.S.[5] Preventive Services Task Force (USPSTF) criteria. There were 17 observational studies and no RCTs. Due to the lack of RCTs, meta-analysis could not be conducted. There was a lack of standardization of both selection and outcome criteria. In addition, the authors noted that the lack of a control group in observational studies limited the conclusions that could be made on efficacy.

RANDOMIZED CONTROLLED TRIALS

No RCTs were identified that were published after the SRs above.

NONRANDOMIZED COMPARATIVE STUDIES

No nonrandomized comparative studies were published after the SRs above.

ADVERSE EFFECTS

Few adverse effects have been reported. Choy reported complications in 10 of 1275 patients who had 2400 procedures over an 18 year period.[6] The only complication was infections discitis which was cured with antibiotics in all 10 patients. Other adverse effects have included instrument failures, nerve damage, reflex sympathetic dystrophy (RSD), sigmoid artery injury, anomalous iliolumbar artery injury, spondylodiscitis, and cauda equina syndrome.[7] Reoperation with conventional surgical disc decompression following laser decompression was reported in up to 40% of cases.[8, 9]

RADIOFREQUENCY COBLATION (DISC NUCLEOPLASTY)

SYSTEMATIC REVIEWS

Manchikanti (2013) published a SR that identified one RCT, rated as moderate in quality, and 14 observational studies on nucleoplasty that included at least 50 subjects and had at least one-year follow-up.[10] The available evidence was ranked as "limited to fair" when rated according to USPSTF criteria.

Chou (2009) 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 SR identified no RCTs, and there was insufficient evidence from small case series to evaluate efficacy.

RANDOMIZED CONTROLLED TRIALS

De Rooij (2020) compared the effects of percutaneous cervical nucleoplasty and anterior cervical discectomy in 48 patients with cervical radicular pain due to a single-level contained soft-disc herniation.[12] The primary outcome measure was arm pain intensity as measured by a visual analog scale. Overall, a statistically significant interaction between the groups on arm pain intensity and the secondary outcome of SF-36 item pain, in favor of anterior cervical discectomy, was noted at three months. There was also a trend for more improvement of arm pain in favor of anterior cervical discectomy at 12 months, with no statistical interactions on the secondary outcomes observed. Of note, the trial was discontinued before reaching the required sample size as enrollment into the trial was low.

NONRANDOMIZED COMPARATIVE STUDIES

Chen (2022) conducted an open-label, case-control, single-center study in individuals with cervical herniated intervertebral disc and cervical radiculopathy treated with nucleoplasty (n=71) compared to conventional treatment (n=21).[13] The nucleoplasty group demonstrated significantly greater changes from baseline in pain scores measured by the visual analog scale at one month post-operation (p<.001), three months post-operation (p<.001), and six months post-operation (p<.01) compared to conventional therapy. At one month post-operation, the nucleoplasty group also exhibited improved Oswestry Disability Index scores (p<.05) and Neck Disability Index scores (p<.05) compared to conventional therapy, but there was no difference between groups at six months follow-up. These results are limited by the small sample size, lack of randomization, and loss to follow-up of some participants at the six month point.Adverse Effects

Adverse effects and reoperation rates have not been consistently reported in the available published literature.

One study was found in which Cuellar reported accelerated degeneration after failed nucleoplasty.[14] 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. 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, four (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 one 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 occurred after nucleoplasties that were considered to be successful. Additional study of this potential adverse effect of nucleoplasty is needed.

One case of transient epidural fibrosis three months post nucleoplasty has also been reported.[15]

CHEMONUCLEOLYSIS AS PRE-TREATMENT FOR PERCUTANEOUS DISCECTOMY

No clinical trials were found in which chemonucleolysis was combined with laser discectomy or nucleoplasty procedures.

PRACTICE GUIDELINE SUMMARY

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS (ASIPP)

In 2013 a task force of the ASIPP updated guidelines for interventional techniques in the management of chronic spinal pain.[16] The guidelines reported limited evidence for percutaneous laser disc decompression and fair evidence for nucleoplasty, as described in the 2013 SRs by Singh and Manchikanti summarized above.

- For percutaneous laser discectomy, the guidelines reported Level II-2 evidence for short-term and long-term relief of pain, citing the review by Singe[4] which is summarized above.[7] Level II-2 evidence was defined as evidence from at least one properly designed small diagnostic accuracy study. The recommendation for use of percutaneous lumbar laser discectomy was graded as 1C, defined as a strong recommendation from low-quality or very low-quality evidence from observational studies or case series. The 1C definition further states that this recommendation "may change when higher quality evidence becomes available." The authors noted that "these guidelines do not represent a "standard of care."
- For radiofrequency disc nucleoplasty in managing predominantly lower extremity pain attributable to contained disc herniation a grade 2B weak recommendation was given based on Level II-3 evidence (i.e., "multiple time series with or without the intervention"). No recommendation for nucleoplasty was given regarding managing axial low back pain because no related evidence was found.

AMERICAN PAIN SOCIETY (APS)

A 2009 APS clinical practice guideline found insufficient evidence to evaluate alternative surgical methods, including laser- or endoscopic-assisted techniques, various percutaneous techniques, coblation nucleoplasty, or the Disc Decompressor compared with standard open discectomy and microdiscectomy.[17]

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

The National Institute for Health and Care Excellence 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.[18]

The 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.[19]

SUMMARY

There is not enough research to show that laser discectomy or radiofrequency coblation (disc nucleoplasty) improve health outcomes for people with any indication, including but not limited to people needing disc decompression and treatment of associated pain. In addition, there is not enough research to show that chemonucleolysis as an adjunct to percutaneous disc decompression procedures, including, but not limited to disc nucleoplasty improves health outcomes. Therefore, laser discectomy and radiofrequency disc nucleoplasty for disc decompression, with or without chemonucleolysis, are considered investigational.

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CODES

NOTE: CPT code 62287 specifically describes a percutaneous aspiration or decompression procedure of the lumbar spine. This code does not distinguish between a laser decompression procedure (addressed in this policy) and an aspiration procedure (addressed in separate medical policies). Also, note that this code is specifically limited to the lumbar region.

Codes	Number	Description
CPT	62287	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 discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
	62292	Injection procedure for chemonucleolysis including discography, intervertebral disc, single or multiple levels, lumbar
HCPCS	S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

Date of Origin: *December 2003*