NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of
Laser lumbar discectomy

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

Discectomy can be replaced by discotomy (or diskotomy), disc decompression, nucleotomy and nucleolysis
The word percutaneous and automated may also be included in the title
In certain circumstances the word endoscopic may also be used to indicate *in situ* visualisation.

Title combinations include:

- Percutaneous laser lumbar discectomy
- Percutaneous laser nucleotomy
- Percutaneous laser nucleolysis
- Percutaneous laser disc decompression
- Percutaneous endoscopic laser discectomy
- Automated laser discectomy
- Laser-assisted disc decompression (except where assisted refers to the additional use of arthroscopic instrumentation)

Choy[12] uses the name 'percutaneous laser nucleolysis' instead of 'percutaneous laser disc decompression', because "what is being accomplished is not discectomy; only 0.7 – 1.0mm of disc material is vaporized".

Specialty society

British Orthopaedic Association

Executive summary

Laser lumbar discectomy is one of several minimally invasive disc procedures used for treating non-sequestered herniated lumbar discs. A search of the literature located 30 studies, of which 5 were selected for this review. A list of excluded studies is provided. The

selected studies used a variety of methods to establish the success of the procedure, varying from freedom from pain, patient satisfaction, clinical measurements (straight leg raise etc), or no subsequent surgery. There was no mortality and morbidity rates were below 5% (excluding transient postoperative dysesthesia).

A brief appraisal of all the available literature suggests that surgical failures are frequently due to the presence of free fragments, which suggests that selection criteria for patients should be carefully considered. In addition, most articles on laser discectomy were published around 1995 to 1996. Very little of additional use has been published since this time.

Indication(s)

Low back pain is a common and expensive cause of chronic disability. While most people recover within 8 to 10 weeks, those who do not recover, account for most of the health care and social costs for spinal disorders. About 1% undergo surgery, yet surgical and other interventions "account for up to 30% of health care costs for spinal disorders, the scientific evidence for most of these procedures is unclear." [20]

Herniated (or prolapsed) lumbar discs are a common cause of backache and sciatica. The herniation is a result of a protrusion of the nucleus pulposus through the tear in the surrounding annulus fibrosus. The annulus fibrosus may rupture completely resulting in an extruded disc or may remain intact but stretched resulting in a contained disc prolapse. This may then compress one or more nerve roots, resulting in pain, numbness or weakness in the leg.

Surgery is considered when there is nerve compression or persistent symptoms that are unresponsive to conservative treatment. Clinical indications can include unilateral radicular symptoms with leg and back pain, positive straight leg raise test, other signs of root dysfunction, and failure to improve after a certain amount (more than 6 weeks) of conservative treatment. Laser lumbar discectomy can be performed when the prolapse is contained.

Summary of procedure

Laser lumbar discectomy works by vapourising part of a prolapsed disc and can be performed where the prolapse is contained. It forms part of a medley of minimally invasive surgical techniques, as well as open repair procedures such as open lumbar discectomy or laminectomy.

A probe is inserted into the disc through a small incision in the patient's back. The needle is inserted through the annulus and into the nucleus pulposus. Laser energy is delivered through the probe and used to vapourise part of the nucleus pulposus. Several types of laser are available, each with differences in absorption, energy requirements, and rate of application. The procedure is performed under local and/or neuroleptic anaesthetic, and using radiographic imaging.

The major proposed advantages of laser lumbar discectomy relate to its minimal invasiveness, with procedures being performed as day surgery cases under local anaesthesia. Detractors have reported high rates of subsequent open surgery.

Literature review
A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on laser discectomy in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports.

Studies were selected where a laser was the only intended method of repair. Articles described as laser-assisted repair were excluded if arthroscopic instrumentation had also been used. Studies using cadavers were also excluded. Tabulated studies are given in the reference list with reasons for inclusion stated. Studies for which data were not tabulated are listed in the annex following the reference list.

List of studies found
Total number of studies found: 29

- Randomised controlled trials 2
- Systematic reviews 2
- Non-randomised comparative studies (English) 2
- Non-randomised comparative studies (German) 1
- Case series 20
- Case reports 2

RCTs in progress
Two studies of laser lumbar discectomy were located in the National Research Register database. Attempts were made to obtain further information, but both contact people were on leave.

- A randomised prospective study comparing laser disc decompression & steroid injection in alleviating radicular pain secondary to prolapsed lumbar pain. 1/10/95 – 1/10/97, Prospective randomised patient blind parallel group study, 70 patients.

- Effectiveness of laser discectomy on lumbar disc protrusion. 1/4/97 – 31/12/99 (no further description)

Summary of key efficacy and safety findings
See following tables.

Abbreviations:

APD	automated percutaneous discectomy
APLD	automated percutaneous lumbar discectomy
CN	chemonucleolysis
KTP	potassium-titanyl-phosphate
LD	laser discectomy
MRI	magnetic resonance imaging
Nd:YAG	neodymium:yttrium-aluminium-garnet
RSD	reflex sympathetic dystrophy
SLR	straight leg raise

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised controlled trials			
Livesey 1999[1], UK 13 KTP laser discectomy, 16 epidural steroid injections; no date specified. *Follow up:* 1 – 26 weeks. *Selection criteria:* contained disc prolapse, moderate pain, positive tension signs, otherwise normal neurology and disc narrowed by not more than 50% on X-ray	Both groups improved based on a variety of outcome measures (modified MacNab, angle of straight leg raise and Oswestry low back pain disability score). No significant difference detected in improvement between 2 groups.	Not mentioned	*Potential for bias:* no description of method of randomisation. "Patients blindly assessed before and after surgery". Uncertain if patients and assessors were blinded. Brevity of abstract leaves many questions unanswered. *Outcome measures:* MacNab is well validated, but status of modified MacNab is unknown. Status of Oswestry scoring system is not stated. *Comments:* Results from conference abstract. Hospital discontinued laser procedure based on cost following this trial.

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Non-randomised comparative studies			
Bosacco *et al.* 1996[2], US 63 patients treated prospectively with KTP laser (LD); 1992-3. Functional results (not complications) compared with 70 (historical) patients with herniated nucleus pulposus treated with open laminectomy/discectomy (dates of these not stated). *Follow up:* 61 patients scored from telephone questionnaire and chart review. 20- 45 months (mean 31.75) *Selection criteria:* single nerve root signs (L4 and L5) and symptoms, positive straight leg raising test and MRI evidence to support clinical findings. No previous surgery, stenosis, sig. disease, evidence of extruded or sequestered disc.	<table><tr><th></th><th>LD</th><th>Historical control</th></tr><tr><td>Excellent</td><td>21/63 (34%)</td><td>36/70 (51%)</td></tr><tr><td>Good</td><td>19/63 (31%)</td><td>24/70 (34%)</td></tr><tr><td>Fair</td><td>15/63 (24%)</td><td>8/70 (11%)</td></tr><tr><td>Poor</td><td>6/63 (10%)</td><td>2/70 (3%)</td></tr></table> *LD group:* 17/61 (28%) had complete relief of pain. 40/61 (66%) had partial relief of pain. 44/61 (72%) of patients had excellent or good relief of radicular pain and 33/61 (54%) relief of back pain. 76% of patients not involved in compensation cases had good or excellent results. 36/61 (59%) returned to work by postop. week 4. 14/61 (23%) experienced persistent symptoms. 62/63 (98%) length of stay < 24 hours. (no equivalent measures given for historical control group)	1 LD patient (1.6%) required readmission for acute urinary retention and reflex ileus	*Potential for bias:* prospective study with historical control group. 2 patients lost to follow-up. *Outcome measures:* Andrews and Lavyne rating scale (reference and details of scale given – validation uncertain).

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Black 1995[3], US 19 APD, 12 KTP laser, 50 Nd:YAG laser; before Sep 1993. *Follow up:* 9 – 58 months *Selection criteria:* herniated, contained lumbar disc with low back pain, radicular pain and failure to respond to conservative treatment for 10-12 weeks.	APD and KTP laser allocation abandoned early due to a 5/19 (26%) and 3/12 (25%) failure rate. 4/50 (8%) failure rate for Nd:YAG discectomy. Subsequent follow-up case series study of Nd:YAG (1993-1995) showed 1/55 (1.8%) failure rate at 15 months.	2/50 (4%) Nd:YAG patients experienced aseptic discitis.	*Potential for bias:* Concurrent comparison. No blinding. No description of method of allocation of patients. *Outcome measures:* Success was defined as freedom from radicular pain, normal functioning, and medically cleared to return to employment.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Appraisal/Comments</th></tr>
<tr><td colspan="4">Case series</td></tr>
<tr><td>Knight and Goswami 2002[4], UK

687 levels in 576 consecutive patients treated with KTP laser; 1992-97

Follow-up: minimum 3 years (100% for 1st year, decreasing to 67%).

Selection criteria: patients with chronic back pain unresponsive to conservative management, disc bulge, contained disc, radial tears of disc, painful discs proven by spinal probing and discography, stenotic symptoms.

<u>Exclusions:</u> stenosis, sequestration, cauda equina, tumors, acute trauma.</td><td>
<table>
<tr><th>Year</th><th>Result</th><th>Back n=348</th><th>Buttock n=292</th><th>Leg n=310</th></tr>
<tr><td>1</td><td>G</td><td>210 (60%)</td><td>165 (56%)</td><td>184 (59%)</td></tr>
<tr><td></td><td>S</td><td>72 (21%)</td><td>52 (18%)</td><td>58 (19%)</td></tr>
<tr><td></td><td>P</td><td>55 (16%)</td><td>67 (23%)</td><td>59 (19%)</td></tr>
<tr><td></td><td>W</td><td>11 (3%)</td><td>8 (3%)</td><td>9 (3%)</td></tr>
<tr><td>2</td><td>G</td><td>192 (55%)</td><td>145 (50%)</td><td>173 (56%)</td></tr>
<tr><td></td><td>S</td><td>82 (24%)</td><td>65 (22%)</td><td>63 (20%)</td></tr>
<tr><td></td><td>P</td><td>60 (17%)</td><td>71 (24%)</td><td>65 (21%)</td></tr>
<tr><td></td><td>W</td><td>14 (4%)</td><td>11 (4%)</td><td>9 (3%)</td></tr>
<tr><td>3</td><td>G</td><td>181 (52%)</td><td>140 (48%)</td><td>158 (51%)</td></tr>
<tr><td></td><td>S</td><td>86 (25%)</td><td>68 (23%)</td><td>67 (22%)</td></tr>
<tr><td></td><td>P</td><td>71 (20%)</td><td>73 (25%)</td><td>75 (24%)</td></tr>
<tr><td></td><td>W</td><td>10 (3%)</td><td>11 (4%)</td><td>10 (3%)</td></tr>
</table>
G=good/excellent; S=satisfactory; P=poor; W=worse

Further disc prolapse at same level in 2% of patients. 17% of patients required endoscopic laser foraminoplasty for foraminal and lateral recess decompression.</td><td>4 patients (1%) had aseptic discitis with increased pain and muscular spasm.</td><td>Potential for bias: originally consecutive selection of patients, but substantial losses to follow-up.

Outcome measures and their validity: Oswestry Disability Index, Visual Analogue Pain Index, Patient Target Achievement Score and Patient Satisfaction Scores (validation uncertain). Took >50 on Oswestry as excellent and > 20 as satisfactory response.

Comments: patients with demonstrated tears were included. 23% of patients had previous open disc decompression and fusions.</td></tr>
</table>

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Case series			
Ohnmeiss *et al.* 1994[5], US Follow up on 164/204 patients extracted from records for KTP laser disc decompression; before 1994 *Follow-up:* min 1 year, by mail. *Selection criteria:* Group 1 (met all selection criteria) ie leg pain, physical exam finding (motor, sensory, reflex deficit and/or SLR); discographic confirmation of contained disc herniation; no stenosis or spondylolisthesis. Group 2(did not meet selection criteria) ie no deficits identified by physical exam, presence of stenosis or spondylolisthesis, extruded disc fragment or leakage of discographic contrast from disc (discography performed), multiple prior lumbar surgeries. Group 3 (could not be assigned to either of first 2 groups) ie discography not performed, incomplete physical exam recorded. Group 4 - role of discography: additional subgroup of patients meeting all criteria of group 1 but either discography was not performed (n=38) or extravasation of contrast was noted (n=7).	41 patients met all selection criteria (group 1); of these 29/41 (71%) had a "successful result" 42 patients did not meet all selection criteria (group 2); of these 12/42 (29%) had a "successful result", significantly less than group meeting selection criteria (P<0.005;binomial comparison of groups 1 and 2). Remaining 81 patients could not be assigned to either group (group 3), 45 (56%) had a "successful result". Significantly better than among patients in group 2 (P<0.025; binomial comparison) Patients in group 1 had significantly greater success than those in group 3 (0.05<P<0.06). Of 164 patients, 39 (23.8%) had second procedures due to no improvement or worsening of symptoms Success rate better in those meeting selection criteria. Role of discography (group 4): 20/45 (44.4%) had successful outcome. Significantly less than for patients meeting all criteria but including the discogram (70.7% vs 44.4%, P<0.035).	Out of 164 patients: 1 confirmed (0.6%), 1 possible case (0.6%) of reflex sympathetic dystrophy (RSD) 12 cases (7.3%) of postoperative dysesthesia, 5 resolved. During instrument insertion in 3 patients (1.8%), instrument came in contact with nerve, and in another the instrument tip bent. In 5 patients (3%) procedure was stopped periodically due to heat build up. Among reoperated group: 1 RSD (0.6%), 4 (2.4%) postop dysesthesias, 1 (0.6%) post-op. neurological deficit, 2 (1.2%) stenosis, 1 (0.6%) far lateral disc herniation, 3 (1.8%) recurrent disc herniation, 3 (1.8%) extruded disc fragments.	*Potential for bias:* Follow up only available for the 204 patients extracted from records. *Outcome measures and their validity:* Successful outcome defined as "no subsequent lumbar surgery, patient felt that LD had helped, and if patient was working before symptom onset, was able to work at time of follow up (not validated) *Other comments:* Aim of study was to put patients into groups according to whether they met specific selection criteria for procedure, and to review this against the success of procedure.

Specialist advisor's opinion / advisors' opinions

Specialist Advice was sought from the British Orthopaedic Association

One Specialist Advisor described this procedure as definitely novel and performed in very few specialist centres. Damage to nerve roots, vertebral endplates and neighbouring structures, and disc space infection were listed as potential complications. The same Advisor thought that most spinal surgeons believe the procedure is ineffective and mentions one (unnamed) UK trial that showed poor efficacy. The equipment is described as expensive and requires x-ray imaging and/or percutaneous arthroscopy.

Issues for consideration by IPAC

Choy introduced the procedure Nd:YAG laser discectomy in 1986 and has been its main and most influential proponent. He has published many papers, but these were excluded from this report on the basis of that they contribute little to the evaluation of safety and efficacy.

A brief appraisal of all the available literature suggests that surgical failures are frequently due to the presence of free fragments, which suggests that selection criteria for patients should be carefully considered. In addition, most articles on laser discectomy were published around 1995 to 1996. Very little of additional use has been published since this time.

References

1. Livesey JPS. Laser discectomy versus lumbar epidural steroid injection: a randomised comparative study of two treatments for sciatica [Abstract]. Journal of Bone & Joint Surgery - British Volume 2000;82 Suppl 1, pp.74.

    - *Only RCT available in English. Although information taken from conference abstract and minimal data, results were of pragmatic use to hospital.*

2. Bosacco SJ, Bosacco DN, Berman AT, Cordover A, Levenberg RJ, Stellabotte J. Functional results of percutaneous laser discectomy. *Am J Orthop* 1996;25(12):825-8.

    - *Historically controlled study. Useful pain information.*

3. Black WA, Jr. A neurosurgical perspective on PLDD. [Review]. *Journal of Clinical Laser Medicine & Surgery* 1995;13(3):167-71.

    - *Concurrent comparison. Mixture of laser types.*

4. Knight M, Goswami A. Lumbar percutaneous KTP532 wavelength laser disc decompression and disc ablation in the management of discogenic pain. *Journal of Clinical Laser Medicine & Surgery* 2002;20(1):9-13.

    - *Recent case series, clear efficacy data.*

5. Ohnmeiss DD, Guyer RD, Hochschuler SH. Laser disc decompression. The importance of proper patient selection. *Spine* 1994;19(18):2054-8.

- *Aim of case series was to review success against selection criteria. Good safety information included.*

ANNEX: Studies that met the inclusion criteria but which were not tabulated.

Botsford JA. Radiological considerations: patient selection for percutaneous laser disc decompression. Journal of Clinical Laser Medicine & Surgery. 1994;12(5):255-9

Boult M, Fraser RD, Jones N, Osti O, Dohrmann P, Donnelly P et al. Percutaneous endoscopic laser discectomy. Australian & New Zealand Journal of Surgery. 2000;70(7):475-9.

Casper GD, Hartman VL, Mullins LL. Results of a clinical trial of the holmium:YAG laser in disc decompression utilizing a side-firing fiber: a two-year follow-up. Lasers in Surgery & Medicine. 1996;19(1):90-6.

Casper GD, Mullins LL, Hartman VL. Laser-assisted disc decompression: a clinical trial of the holmium:YAG laser with side-firing fiber. Journal of Clinical Laser Medicine & Surgery. 1995;13(1):27-32.

Choy DS. Response of extruded intervertebral herniated discs to percutaneous laser disc decompression. Journal of Clinical Laser Medicine & Surgery. 2001;19(1):15-20.

Choy DS. Percutaneous laser disc decompression (PLDD): twelve years' experience with 752 procedures in 518 patients. Journal of Clinical Laser Medicine & Surgery. 1998;16(6):325-31.

Choy DS. Percutaneous laser disc decompression (PLDD): 352 cases with an 8 1/2-year follow-up. Journal of Clinical Laser Medicine & Surgery. 1995;13(1):17-21.

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Farrar MJ, Walker A, Cowling P. Possible salmonella osteomyelitis of spine following laser disc decompression.

Gangi A, Dietemann JL, Ide C, Brunner P, Klinkert A, Warter JM. Percutaneous laser disk decompression under CT and fluoroscopic guidance: indications, technique, and clinical experience. Radiographics. 1996;16(1):89-96.

Gevargez A, Groenemeyer DW, Czerwinski F. CT-guided percutaneous laser disc decompression with Ceralas D, a diode laser with 980-nm wavelength and 200-microm fiber optics. European Radiology. 2000;10(8):1239-41.

Gibson JN, Grant IC, Waddell G. Surgery for lumbar disc prolapse. [update of Cochrane Database Syst Rev. 2000;(2):CD001350 ; 10796433.]. Cochrane Database of Systematic Reviews. 2000(3):CD001350.

Lee SH, Lee SJ, Park KH, Lee IM, Sung KH, Kim JS et al. [Comparison of percutaneous manual and endoscopic laser diskectomy with chemonucleolysis and automated nucleotomy]. [German]. Orthopade. 1996;25(1):49-55.

Liebler WA. Percutaneous laser disc nucleotomy. Clin Orthop. 1995(310):58-66.

Mayer HM, Brock M. Percutaneous endoscopic lumbar discectomy (PELD). Neurosurgical Review. 1993;16(2):115-20.

Nerubay J, Caspi I, Levinkopf M. Percutaneous carbon dioxide laser nucleolysis with 2- to 5- year followup. Clinical orthopaedics and related research. 1997; 337:45-48

Plancarte R, Calvillo O. Complex regional pain syndrom type 2 (causalgia) after automated laser discectomy: a case report. Spine. 1997;22(4);459-461

Schatz SW, Talalla A. Preliminary experience with percutaneous laser disc decompression in the treatment of sciatica. Canadian Journal of Surgery. 1995;38(5):432-6.

Simons P, Lensker E, von Wild K. Percutaneous nucleus pulposus denaturation in treatment of lumbar disc protrusions--a prospective study of 50 neurosurgical patients. European Spine Journal. 1994;3(4):219-21.

Tonami H, Kuginuki M, Kuginuki Y, Matoba M, Yokota H, Higashi K et al. MR imaging of subchondral osteonecrosis of the vertebral body after percutaneous laser diskectomy. AJR Am J Roentgenol. 1999;173(5):1383-6.

Tonami H, Yokota H, Nakagawa T, Higashi K, Okimura T, Yamamoto I et al. Percutaneous laser discectomy: MR findings within the first 24 hours after treatment and their relationship to clinical outcome. Clinical Radiology. 1997;52(12):938-44.