**Systematic Review** 

# Percutaneous Lumbar Laser Disc Decompression: A Systematic Review of Current Evidence

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Free full manuscript: www.painphysicianjournal.com **Background:** Since the descriptions by Mixter and Barr of open surgical treatment for rupture of the intervertebral disc in 1934, open surgical procedures have become a common practice. Disc herniations have been reported as being contained and non-contained. The results of open surgical discectomy for contained disc herniation have been poor. Consequently, several alternative techniques have been developed which are minimally invasive including percutaneous laser disc decompression.

Study Design: A systematic review of the literature.

**Objective:** The objective of this systematic review is to evaluate the clinical effectiveness of percutaneous laser discectomy in managing radicular pain secondary to contained disc herniation.

**Methods:** A comprehensive evaluation of the literature relating to mechanical disc decompression was performed. The literature was evaluated according to Cochrane review criteria for randomized controlled trials (RCTs), and Agency for Healthcare Research and Quality (AHRQ) criteria was utilized for observational studies.

A literature search was conducted by using only the English language literature through PubMed, EMBASE, the Cochrane library, systematic reviews, and cross references from reviews and systematic reviews.

The level of evidence was classified as Level I, II, or III with 3 subcategories in Level II based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF).

**Outcome Measures:** Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, opioid intake, and return to work.

Short-term effectiveness was defined as one year or less, whereas, long-term effectiveness was defined as greater than one year.

**Results:** Based on USPSTF criteria the indicated level of evidence for percutaneous lumbar laser discectomy (PLLD) is II-2 for short- and long-term relief.

**Limitations:** Even though laser discectomy has been in utilization for a number of years and numerous procedures have been performed there continues to be a paucity of literature of randomized clinical trials.

**Conclusion:** This systematic review illustrates Level II-2 evidence for percutaneous laser disc decompression which is equivalent to automated percutaneous lumbar disc decompression.

**Key words:** Intervertebral disc disease, chronic low back pain, disc herniation, disc protrusion, radiculitis, contained disc herniation, mechanical disc decompression, percutaneous lumbar laser discectomy, laser assisted spinal endoscopy

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ixter and Barr (1) reported an open surgical treatment for rupture of the intervertebral disc in 1934. Since then numerous surgeries have been performed (2-5). Disc displacement may occur in many forms with disc prolapse, protrusion, or herniation with nerve root irritation, accounting for less than 5% of all low back problems (5). Disc herniation has been reported as contained and non-contained. The main objective of surgical treatment of a disc prolapse, protrusion, or extrusion is the relief of nerve root compression by removing the herniated nuclear material. Despite the prevalence of open discectomy, in many ways surgical treatment of lower lumbar disease has never been put to rigorous scientific study. Carragee et al (6) studied clinical outcomes after lumbar discectomy for sciatica and found a number of noteworthy results. These investigators demonstrated that patients in the no fragment-contained group did very poorly with 38% having recurrent or persistent sciatica, and the standard outcomes scores were less improved compared with those in other groups. In contrast, patients in the fragment-fissure group, who had disc fragments and small anular defects, had the best overall outcomes and the lowest rates of reherniation (1%) and reoperation (1%). Further, patients in the fragment-contained group had a 10% rate of reherniation and a 5% rate of reoperation and patients in the fragment-defect group with extruded fragments and massive posterior anular loss had a 27% rate of reherniation and 21% rate of reoperation. Similar to Carragee et al, Dewing et al (7) showed that patients with sequestered or extruded lumbar disc herniations had significantly better outcomes than did those contained herniations. Thus, it is crucial not only that patients are selected appropriately, but also that the technique is properly chosen. Consequently, several alternative techniques have been developed which are minimally invasive. Percutaneous laser disc decompression (PLDD) is one of the so-called "minimally invasive" treatment modalities for contained lumbar disc herniation (8).

The treatment is performed percutaneously, so morbidity is expected to be lower and the convalescence period is postulated to be shorter than for conventional surgery. However, considerable skepticism exists about this technology. Opponents usually dismiss PLDD as being an experimental treatment with unproven efficacy, whereas those advocating for the use of PLDD present contrary evidence with regards to its effectiveness (8). The paucity of literature on the subject without randomized controlled trials (RCTs) is a major source of skepticism. Schenk et al (8) in review of the literature on percutaneous lumbar laser disc decompression concluded that all trials were case series, with a relatively low strength of evidence. They concluded that despite the fact that PLDD has been around for almost 20 years, scientific proof of its efficacy still remains relatively poor, though the potential medical and economic benefits of PLDD are too high to justify discarding it as experimental or ineffective on the sole basis of insufficient scientific proof.

Gibson and Waddell (5) in the Cochrane Collaboration review presented the results from 40 RCTs and 2 quasi-randomized controlled trials (QRCTs) of surgical interventions for lumbar disc prolapse. This review indicated that the place for other forms of discectomy other than traditional open discectomy is unresolved. Trials of percutaneous discectomy and laser discectomy suggest that clinical outcomes following treatment are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged. Gibson and Waddell (5) concluded that discectomy provides faster relief from the acute attack of sciatica, although any positive or negative effects on the long-term natural history of the underlying disc disease are unclear.

In a technology assessment report (9), no randomized published studies of PLDD were identified for the analysis. However, the majority of the observational studies evaluating percutaneous laser discectomy showed positive evidence. Boswell et al (10) in evidence-based guidelines of spinal interventional techniques showed that evidence was moderate for shortterm and limited for long-term relief for automated and laser discectomy.

Due to the fact that the treatment principle of PLDD is based on the concept of the invertebral disc being a closed hydraulic system, only contained herniations can be expected to respond to reduction of intradiscal pressure (8). Consequently, the presence of disc extrusion or sequestered herniation are considered to be exclusion criteria for PLDD. Further, patients with narrowed intervertebral disc space or obstructive vertebral abnormalities, and severe neurologic symptoms, such as cauda equina syndrome, severe paresis, or other conditions that require acute surgical intervention are not generally considered candidates for PLDD.

This systematic review was undertaken to evaluate the current evidence of percutaneous mechanical disc decompression with lumbar laser discectomy. Due to the experience of previous systematic reviews (5,9) with lack of randomized trials, this systematic review also focused on observational studies to improve the generalizability and applicability in clinical practice (11-15).

# METHODS

### Literature Search

Databases reviewed were PubMed, EMBASE, the Cochrane Library, and the Database of Reviews of Effectiveness (DARE). Bibliographies of reviewed papers were also examined. In addition, authors known to be active in the field were contacted. The time frame covered was 1966 to January 2009.

Inclusion criteria were:

- 1. Lumbar disc related pain of at least 3 months duration.
- 2. Treatment with percutaneous laser disc decompression.
- 3. Minimum of 12-month follow-up.
- 4. At least 50 patients included in observational studies.

Search terms included intervertebral disc, degenerative disc disease, disc herniation, disc protrusion, disc extrusion, disc prolapse, disc displacement, radiculitis, percutaneous laser discectomy, percutaneous laser disc decompression, and laser nuclear decompression.

Only articles in English or with English abstracts, systematic reviews, RCTs, and observational studies were reviewed by 2 reviewers. Discrepancies in ratings were resolved by adjudication by a third reviewer. If there was a conflict of interest with the reviewed manuscripts such as authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence.

#### **Methodologic Quality Assessment**

Table 1. Quality of evidence developed by USPSTF.

The method of quality assessment was a function of the type of study. For RCTs, the Cochrane review

criteria were used (16). Assessment of study quality for observational studies was done according to the Agency for Healthcare Research and Quality (AHRQ) criteria (17). Both the RCTs and observational forms provide a maximum of 100 points; only studies with scores of over 50 points were included. Consensusbased weighted scoring developed by the guidelines committee of the American Society of Interventional Pain Physicians (ASIPP) was utilized. The same scoring system has been used in multiple previous evaluations (18-34).

## **Outcome Measures**

Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, and return to work.

A decrease of either 2 points or 30% of pain scores provides a useful benchmark of clinical importance to assess effectiveness (35,36). Similarly, a 10% improvement in functioning outcomes provides an accepted benchmark of clinically useful benefit (37). However, in interventional pain management settings, a significant improvement has been defined as 50% or more relief, while significant improvement in disability has been defined as a 40% or more decrease in disability scores in multiple publications (13-15,38-44).

Significant pain relief ( $\geq$  50%) of short-term ( $\leq$  12 months) and long-term (> 12 months) was the primary outcome measure. Secondary outcomes included functional or psychological improvement, improvement in work status, and complications.

# Analysis of Evidence

Level of evidence was determined based on the United States Preventive Services Task Force (USPSTF) criteria using 5 levels of evidence, ranging from Level I to III with 3 subcategories in Level II, as illustrated in Table 1 (45).

I:	Evidence obtained from at least one properly randomized controlled trial
II-1:	Evidence obtained from well-designed controlled trials without randomization
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
II-3:	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III:	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees

Adapted from the U.S. Preventive Services Task Force (USPSTF) (45).

# Recommendations

Recommendations for effectiveness were made according to Guyatt et al's criteria (46) (Table 2).

## RESULTS

The results of the literature search for percutaneous laser disc decompression are illustrated in Fig. 1. A total of 33 articles (47-79) were located in the literature search. There were no RCTs.

## **Methodologic Quality Assessment**

There were no randomized trials identified for analysis. However, multiple observational studies were identified describing mechanical disc decompression with percutaneous laser disc decompression.

Multiple studies (47-49,51,54,56,60,66,68-70,72-79) as shown in Table 3 were excluded for various reasons as described. Overall 14 observational studies met the inclusion criteria for methodologic quality assessment (17). Methodologic quality scores are described in Table 4, ranging from 30 to 80. Of these, 10 studies scored 50 or above (52,53,57,58,61,62,64,65,67,71 ), meeting the percutaneous laser disc decompression methodologic quality assessment criteria for evidence synthesis.

## **Study Characteristics**

Table 5 illustrates the results of percutaneous disc decompression with laser-assisted disc removal. All the studies showed positive results. Results varied from satisfactory improvement in 56% of the patients to 87% of the patients. In the 10 reports included in the evidence synthesis, 2,447 patients were studied with positive outcome in 1,774 patients or 72%.

Knight and Goswami (64) sought to determine the outcome of laser disc decompression in the man-

Grade of Recommendation/ Description	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A/strong recommenda- tion, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observa- tional studies	Strong recommendation, can apply to most patients in most circum- stances without reservation
1B/strong recommenda- tion, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (incon- sistent results, methodological flaws, indi- rect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circum- stances without reservation
1C/strong recommenda- tion, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evi- dence becomes available
2A/weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observa- tional studies	Weak recommendation, best action may differ depending on circum- stances or patients' or societal values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (incon- sistent results, methodological flaws, indi- rect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circum- stances or patients' or societal values
2C/weak recommendation, low-quality or very low- quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Table 2. Grading recommendations.

Adapted from Guyatt G et al. Grading strength of recommendations and quality of evidence in clinical guidelines. Report from an American College of Chest Physicians task force. *Chest* 2006; 129:174-181 (46).



Study	Reason for Exclusion
Gevargez et al (47)	< 50 patients (26 patients)
Ohnmeiss et al (48)	< 50 patients (41 patients)
Davis (49)	< 50 patients (40 patients)
Steiner et al (51)	Short-term follow-up with < 50 patients (7 patients)
Schatz & Talalla (54)	Short-term follow-up with < 50 patients (14 patients)
Simons et al (56)	Short-term follow-up with < 50 patients
Agarwal (60)	< 50 patients (36 patients)
Tassi (66)	Preliminary report of Tassi (72)
Lee et al (68)	Endoscopic diskectomy < 50 patients
Tonami et al (69)	Short-term follow-up
McMillan et al (70)	Short-term follow-up with < 50 patients
Tonami et al (72)	Complication – osteogenesis of vertebral body
Plancarte & Calvillo (73)	Complication – CRPS Type II
Quigley et al (74)	Basic science in-vitro study
Savitz et al (75)	Endoscopic surgery
Yonezawa et al (76)	Basic science study
Tașdemiroğlu et al (77)	Spondylodiscitis - review of reports of complications
Choy (78)	Review of device and procedure
Casper et al (79)	Description of evolution

Table 3. Reasons for exclusion of observational studies.

agement of painful degenerative disc disease with or without associated disc prolapse. Nonendoscopic PLDD was performed under x-ray control via the posterolateral approach in 576 patients. All patients with chronic back pain who had reproduced pain during discography of a nature, pattern, and distribution similar to what they experienced normally were included in the study. Magnetic resonance which confirmed stenosis and sequestrated discs, and patients with acute neurological findings were excluded from the study. Laser disc decompression was done using the KTP532 wavelength. The functional outcome was assessed prospectively using the Oswestry Disability Index. Clinical benefit was considered significant in those patients with a percentage change in the index of  $\geq$  or = 50% at review 3–9 years (mean, 5.33 years) following surgery. A total of 52% of patients demonstrated a sustained significant clinical benefit, with an additional 21% in whom functional improvement was noted. Cohort integrity was 67%. They concluded that long-term benefit of the laser disc decompression for disc protrusion suggests a mechanism other than principally mechanical as a cause of chronic back and sciatic pain. It may suggest that efficacy occurs by reduction in the intradiscal production of irritative products and by an effect upon discal and annular neoneuralization. The sustained nature of the benefit after long-term preoperative symptoms (mean 4.7 years) rules out any placebo effect. They recommended that selection should be restricted to patients without significant lateral recess stenosis, retrolisthesis, or olisthesis of  $\geq$  3 mm, significant dorsal or foraminal osteophytosis, extrusion, or sequestration.

Knight and Goswami (64) provided 3-year followup. Cohort integrity was 67%, even then, it is significant. The report stated that a total of 56% of these patients achieved more than 50% of the preoperative rehabilitative objectives, on the patient target achievement scores these were considered to be successes and another 12% were satisfied with the targets achieved. The emphasis on patient selection cannot be underscored. The authors also cautioned that an ideal candidate with predominat sciatic pain of anatomic dermatomal distribution, without significant spondylosis or facet osteoarthritis and ample bony canal, is relatively rare to find in most back pain referral centers (80,81). The authors also described that there are further complicating factors such as comorbid depression, issues related to compensation. All in all it appears that the long-term follow-up of patients with lumbar disc dis-

CRITERION	Weighted Score (points)	Casper et al (61)	Siebert et al (59)	Senel et al (63)	Knight & Goswami (64)	Bosacco et al (52)	Choy (53)	Zhao et al (67)
1. Study Question	2	2	2	2	2	2	2	2
Clearly focused and appropriate question					2			
2. Study Population	8	5	4	4	5	5	5	5
Description of study population	5	5	4	4	5	5	5	5
Sample size justification	3	_	-	_	_	-	-	-
3. Comparability of Subjects	22	11	5	6	11	14	11	17
Specific inclusion/exclusion criteria for all groups	5	5	3	3	5	5	5	5
Criteria applied equally to all groups	3	3	2	3	3	3	3	3
• Comparability of groups at baseline with regard to disease status and prognostic factors	3	_	-	-	-	3	-	3
• Study groups comparable to non-participants with regard to confounding factors	3	3	-	-	-	-	3	3
• Use of concurrent controls	5	-	-	-	-	-	-	-
• Comparability of follow-up among groups at each assessment	3	-	-	-	3	3	-	3
4. Exposure or Intervention	11	8	7	7	8	8	8	11
Clear definition of exposure	5	5	4	4	5	5	5	5
Measurement method standard, valid and reliable	3	3	3	3	3	3	3	3
• Exposure measured equally in all study groups	3	-	-	-	-	-	_	3
5. Outcome measures	20	15	7	6	15	13	13	20
Primary/secondary outcomes clearly defined	5	5	2	3	5	5	5	5
Outcomes assessed blind to exposure or intervention	5	5	-	-	-	-	-	5
• Method of outcome assessment standard, valid and reliable	5	-	-	-	5	3	3	5
Length of follow-up adequate for question	5	5	5	3	5	5	5	5
6. Statistical Analysis	19	13	0	0	10	0	0	8
Statistical tests appropriate	5	5	-	-	5	-	_	5
Multiple comparisons taken into consideration	3	3	-	-	3	-	-	3
Modeling and multivariate techniques appropriate	2	-	-	_	2	-	-	-
Power calculation provided	2	-	-	-	-	-	-	-
Assessment of confounding	5	5	-	-	-	-	_	-
Dose-response assessment if appropriate	2	-	-	-	-	-		-
7. Results	8	8	5	4	8	6	6	7
• Measure of effect for outcomes and appropriate measure of precision	5	5	2	2	5	3	3	4
Adequacy of follow-up for each study group	3	3	3	2	3	3	3	3
8. Discussion	5	5	3	3	5	5	5	5
• Conclusions supported by results with possible biases and limitations taken into consideration					5			
9. Funding or Sponsorship	5	5	5	5	5	5	5	5
Type and sources of support for study					5			
TOTAL SCORE=	100	72	38	37	69	58	55	80

 $Table \ 4. \ Methodological \ assessment \ of \ observational \ studies \ evaluating \ the \ effectiveness \ of \ laser \ disc \ decompression.$ 

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CRITERION	Weighted Score (points)	Tassi (71)	Grönemeyer et al (65)	Nerubay et al (57)	Gangi et al (50)	Ascher (58)	Botsford (62)	Liebler (55)
1. Study Question	2	2	2	2	2	2	2	2
Clearly focused and appropriate question								
2. Study Population	8	5	5	5	5	5	5	4
Description of study population	5	5	5	5	5	5	5	4
Sample size justification	3	-	-	_	-	_	-	_
3. Comparability of Subjects	22	15	11	11	6	8	14	3
Specific inclusion/exclusion criteria for all groups	5	5	5	5	3	5	5	3
Criteria applied equally to all groups	3	3	3	3	-	-	3	-
Comparability of groups at baseline with regard to disease status and prognostic factors	3	1	-	-	_	_	-	-
Study groups comparable to non-partici- pants with regard to confounding factors	3	3	3	3	3	3	3	-
Use of concurrent controls	5	-	-	-	-	_	-	-
• Comparability of follow-up among groups at each assessment	3	3	-	_	_	-	3	-
4. Exposure or Intervention	11	11	11	8	6	11	11	7
Clear definition of exposure	5	5	5	5	4	5	5	4
Measurement method standard, valid and reliable	3	3	3	3	2	3	3	3
• Exposure measured equally in all study groups	3	3	3	-	-	3	3	-
5. Outcome measures	20	11	15	13	9	10	13	3
Primary/secondary outcomes clearly defined	5	3	5	5	2	3	4	2
• Outcomes assessed blind to exposure or intervention	5	-	-	_	-	-	-	-
• Method of outcome assessment standard, valid and reliable	5	3	5	3	2	2	4	-
• Length of follow-up adequate for question	5	5	5	5	5	5	5	1
6. Statistical Analysis	19	0	13	0	0	0	0	0
Statistical tests appropriate	5	-	5	-	-	-	-	-
Multiple comparisons taken into consideration	3	_	3	-	-	-	-	-
Modeling and multivariate techniques appropriate	2	-	-	_	-	-	-	-
Power calculation provided	2	-	-	_	_	_	_	-
Assessment of confounding	5	-	5	-	-	-	-	-
Dose-response assessment if appropriate	2	_	_	_	_	_	-	-
7. Results	8	7	8	6	6	4	8	3
Measure of effect for outcomes and appro- priate measure of precision	5	4	5	3	3	2	5	2
Adequacy of follow-up for each study group	3	3	3	3	3	2	3	1
8. Discussion	5	5	5	5	3	5	5	3
Conclusions supported by results with possible biases and limitations taken into consideration								
9. Funding or Sponsorship	5	5	5	5	5	5	5	5
• Type and sources of support for study								
TOTAL SCORE=	100	61	75	55	42	50	63	30

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Adapted and modified from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (17).

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief	Results
Knight & Goswami (64)	О	69	576	56%	Р
Bosacco et al (52)	0	58	63	66%	Р
Choy (53)	0	55	518	75%	Р
Zhao et al (67)	0	80	139	82%	Р
Tassi (71)	О	61	419	84%	Р
Grönemeyer et al (65)	0	75	200	73%	Р
Nerubay et al (57)	0	55	50	74%	Р
Ascher (58)	0	50	90	74%	Р
Botsford (62)	0	63	292	75%	Р
Casper et al (61)	0	72	100	87%	Р

O = observational; P = positive; N/A = not applicable.

ease with contained disc herniation and laser disc ablation, based on this study, provides an initially gratifying result, but the results deteriorate over a period of time. Based on the results of this study the majority of the deterioration occurred in the first and second year. They also reported that results were less gratifying in patients who had previous open surgical intervention. They postulated that with the laser disc ablation they failed to adequately address secondary inflammatory processes in the disc. They reported progressive clinical deterioration secondary to further reduction in disc height in 17% of the patients who were subsequently treated with endoscopic laser foraminoplasty with success. They also reported 4 patients developing aseptic discitis with increased pain and muscular spasm. Additional disc prolapse occurred at the same level in 2% of the patients.

Bosacco et al (52) sought to evaluate laser disc decompression with the KTP 532 laser, used in conjunction with a percutaneous technique, in contained, small to moderately sized lumbar disc herniation. Sixty-three patients who had a contained herniated nucleus pulposus (HNP) and underwent PLDD were prospectively studied. Sixty-one were available for follow-up. Access to the disc space was attained with an 18-gauge probe, followed by dilating cannulas guided with an image intensifier. Discography was not performed. The power was set at 10 W, and laser pulses were delivered for 0.2 seconds, with an interval of 0.5 seconds. A total of 1250 J was delivered to the disc space. The average follow-up was 31.75 months

(range 20 to 45 months). Overall, 44 patients (72%) achieved relief of radicular pain and 33 patients (54%) achieved relief of low back pain. Thirty-six of 61 patients (59%) returned to work by postoperative week 4. Fourteen patients failed treatment, experiencing persistent symptoms (with scores on the Andrews and Lavyne rating scale of  $\leq$ 3). In this study group, optimal results were obtained when symptoms were treated within one-year of presentation. Results from a historical control group are provided for comparison. These authors (52) provided functional results with laser discectomy as well as open discectomy. Based on the results, 85% of the patients with open discectomy showed good to excellent pain relief, whereas 66% of patients with laser discectomy showed good to excellent results. They reported only one minor complication involving a single patient who had acute urinary retention and reflex ileus, requiring admission to the hospital for a period of 5 days, 1 week after the laser discectomy procedure. They were not quite sure if this was due to the procedure or the narcotic medication, however, there were no complications involving infection, hematoma, neurologic injury, myelitis, or great vessel disease. In this study, they were able to compare results of laser discectomy with results of open lumbosacral discectomy. However, open surgical results were superior. All other factors have not been evaluated. Based on the results of 1992 and 1993 reports, the hospital costs for percutaneous laser discectomy were \$3,720 compared to \$10,600 for open discectomy. Further, if they excluded the compensation patients, the success rate would have increased to 76%. In previously reported data from the same institution the open surgical treatment of lumbar disc disease in a group of city workers' compensation patients resulted in a dismal 80% rate of permanent disability (82). Further, at the time of publication of Bosacco et al's (52) manuscript, it was a common observation among spinal surgeons that success rates in workers' compensation cases do not keep pace with those in non-compensation circumstances (83-85).

Choy et al (53) conducted a non-randomized, nonblinded study in male and female patients with symptomatic, image-documented intervertebral herniated discs in a 12-year period using PLDD as the only treatment modality. The author's own series consists of 752 intervertebral discs in 518 patients over a period of 12 years. The overall success rate ranged from 75% to 89% with a complication rate of less than 1%. They concluded that PLDD has proven to be safe and effective. It is minimally invasive, is performed in an outpatient setting, requires no general anesthesia, results in no scarring or spinal instability, reduces rehabilitation time, is repeatable, and does not preclude open surgery should that become necessary.

Zhao et al (67) evaluated 173 patients with lumbar disc herniations by PLDD. In a non-randomized concurrent controlled trial, 173 patients (101 males and 72 females aged from 18 to 75 years) received PLDD from July 1998 to August 2002 and were followed up for over one year. They divided 173 patients into 2 groups: good indication group (Group A, n = 139) and poor indication group (Group B, n = 34). In addition, Group B was further divided into extrusion group (Group B1 8 patients), lumbar canal stenosis group (Group B2 15 patients), and other conditions group (Group B3 11 patients). Outcome measurements included VAS and modified Macnab criteria, with a primary objective of the degree of pain relief and function. In Group A, excellent results were seen in 63 cases, good in 51 cases, fair in 20 cases, and poor in 5 cases, with 82% excellent and good rates. The excellent and good rate in Group B was 55.9%. There was a significant difference between Group A and Group B ( $\chi 2 = 10.38$ , P < 0.05). They concluded that PLDD is a convenient, safe, and reliable procedure in treating lumbar disc herniation because of its high success rate, satisfactory results, and fewer complications, and proper selection of indications helps improve the curative effects of lumbar disc herniation.

Zhao et al (67) utilized independent evaluation; but more importantly, they isolated the patients with appropriate indications and without appropriate indications. Consequently, the results were that the excellent and good rate was only 56% for poor indication good, whereas it was 82% for the good indication group. Further, the excellent and good rate in other conditions was only 36%. Consequently, appropriately selecting patients can improve the effect of curing prolapse of lumbar intervertebral disc. Further, they indicated that herniation is possible when lumbar disc projection is greater than 0.6 mm, because it may not be differentiated well on MRI, resulting in poor outcomes. In this study the results were similar for patients based on the size of the lumbar disc herniation, but no definite conclusions can be reached because of the small number of cases. They recommended an MRI examination before operation for careful imaging observation to correctly differentiate extrusion from herniation, and fragmented or free nucleus pulposus, because the latter are not indications for percutaneous laser discectomy.

Tassi (71) analyzed the neurosurgical results of 500 patients treated with microdiscectomies and 500 patients treated with PLDD. Patients with herniated discs were treated by microdiscectomy (n = 500) according to the Caspar technique, and patients with discogenic pain were treated with PLDD (n = 500) according to the Choy technique. The inclusion and exclusion criteria were the same for both groups of patients. Age, gender distribution, multiple levels involved, and associated pathologies were not statistically different. The results were evaluated for both groups with the MacNab criteria. The follow-up period was 2 years (+/-1 year). In the microdiscectomy group, 85.6% of patients (n = 428) had a good or excellent outcome; in the PLDD group, 83.8% of patients (n = 419) had a good or excellent outcome. Complications occurred in 2.2% (n = 11) of the microdiscectomy group and in 0% of the PLDD group. They concluded that the analysis of results for the 2 groups supports the conclusion that PLDD is a safe, minimally invasive, and strong alternative treatment to microdiscectomy in patients affected by herniated discs.

Grönemeyer et al (65) sought to describe the longterm effect in 200 patients treated with image-guided PLDD for herniated lumbar disks. The follow-up was over a period of 4 +/- 1.3 years. Treatments were carried out under CT/fluoroscopic guidance with local anesthesia on an outpatient basis with an Nd:YAG laser of 1064 nm. At follow-up, back pain was eliminated or reduced in 73% of the patients. Regarding sensorimotor impairment, PLDD had a positive effect on 74% of the patients. In the majority of patients, the number of sick days and consumption of pain medication was reduced. In one patient, diskitis occurred as a complication of PLDD. They concluded that image-guided PLDD is an effective and secure method to treat contained herniated lumbar disks.

Nerubay et al (57) reported data from a prospective study of 50 patients with low back and radicular pain caused by an L4-L5 protruded disc treated by percutaneous laser nucleolysis with a carbon dioxide laser. The follow-up ranged from 2 to 5 years, and all the patients were evaluated clinically and by imaging with CT scans and MRI before and after the procedure. According to the MacNab criteria, 74% of the patients had excellent or good results and 26% had fair or poor results. They concluded that the laser disc decompression opens up new options in the treatment of discogenic pain, but in their opinion was still an experimental procedure.

Casper et al (61) reported results of a clinical trial of laser disc decompression with a 2-year follow-up. They selected 100 patients based on strict criteria including failure to respond to conservative management. However, all the patients did not undergo fluoroscopically directed epidural injections. Patients with lateral recess or central stenosis, sequestered discs, or predominately scar tissue from a previous discectomy were not considered candidates for laser discectomy. They performed laser discectomy under fluoroscopy with Holmium: YAG laser. An independent interviewer via direct telephone communication carried out evaluations at one week, 3 months, 6 months, one year, and 2 years. The ratings were based on McNab criteria. At 2 years, a success rate of 86.9% was achieved. Further, for patients requiring an additional laser discectomy procedure results at 6-month follow-up yielded a success rate of 80%. Nineteen patients out of the 100 within the study were recommended for open laminectomy by a neurosurgeon or orthopedic surgeon. The recommendations were made independent from the authors, and prior to consideration of laser discectomy, patients subsequently elected to undergo laser discectomy. Of these patients, 84% responded with a successful result. In this study the results were similar at one- and 2-year follow-up without any deterioration in the relief. The findings of this study suggested that laser discectomy provides a safe and efficacious method of treatment for patients with non-sequestered, herniated nucleus pulposus previously unresponsive to conservative treatment. Further, this study showed that the numbers of discs treated were not an independent predictor of outcomes, i.e, there were similar results in patients with single level disc herniation as well as multiple level herniations. The results also showed that previous surgery did not impede the results with 88% of patients showing a successful outcome.

## **Complications and Side Effects**

Complications of percutaneous discectomy laser can be divided into intraoperative and postoperative categories (86-89). Ohnmeiss et al (48) in a series of 164 laser discectomies, reported the tip of the instrument bent in one case, 12 patients complained of postoperative dermatomal dysesthesia, which resolved in 5 cases, and 2 patients had signs of reflex sympathetic dystrophy. Mayer et al (86) in a retrospective analysis of 658 cases treated at 9 different centers observed 1.1% intraoperative complications and 1.5% postoperative complications. They reported for radicular deficits in 4 patients (0.5%), L5 nerve root injury in 3 cases, vascular injuries in 2 cases, sigmoid artery injury in one patient, anomalous iliolumbar artery injury in one patient, and transverse process injury in one patient. In a report of 10 cases, complications were present in 1.5% of the total number of cases, which were reported to have spondylodiscitis (87). In another report, after PLDD a patient developed a subacute cauda equina syndrome (88).

The most frequently described complication of PLDD is spondylodiscitis both aseptic and septic (50,51,53,54,58,59,64). The reported frequency of discitis varies from 0% (48,52,57,60) to 1.2% (50). Aseptic discitis is the result of heat damage to either the disc or the adjacent vertebral endplates (89). Septic discitis also can occur. A special complication occurs with a CO2 laser for PLDD with delivering the laser beam through a metal cannula, 4 cases of thermal nerve root damage occurred due to heating of this cannula, presenting a total complication frequency of 8% (57). Epidural fibrosis also has been reported following percutaneous disc decompression with coblation technology (90).

#### **Level of Evidence**

The indicated level of evidence based on USPSTF criteria (45) is II-2 for short- and long-term relief.

#### Recommendations

The recommendation based on Guyatt et al's (46) criteria is 1C/strong recommendation.

# Discussion

This systematic review evaluated the role of lumbar disc decompression with automated percutaneous laser discectomy. The present evaluation indicates evidence of II-2 for short- and long-term relief with percutaneous laser discectomy with 1C/strong recommendation.

In percutaneous laser disc discectomy, or PLDD, laser energy is used to reduce pressure by vaporizing a small volume of the nucleus pulposus, which reduces the pressure between the nucleus pulposus and the peridiscal tissue causing retraction of the herniation away from the nerve root. The systematic review by Gibson and Waddell (5) concluded that clinical outcomes following laser discectomy are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is important. The evidence for laser discectomy comes from multiple observational studies (52,53,57,58,61,62,64,65,67,71). Overall, a number of patients were evaluated with relief variable from 56% to 87% with an average relief of 72% followed for one-year and the sample size of at least 50 patients.

Even though, conclusive evidence is lacking, randomized trials do not exist, and procedures are labeled as experimental (5), intradiscal therapies and percutaneous mechanical disc decompression techniques continue to increase (91-95). At present, it is believed the potential medical and economic benefits of PLDD are too high to justify discarding it as experimental or ineffective on the sole basis of insufficient scientific proof (8). Well-designed research of sufficient scientific strength, comparing PLDD to both conventional and minimally invasive surgery and conservative management of lumbar disc herniation, is needed to determine whether PLDD deserves a prominent place in the treatment arsenal for lumbar disc herniation. Based on the present evidence it appears that PLDD is equivalent to automated percutaneous lumbar discectomy (32) and superior to coblation and Dekompressor technology (33,34).

The idea of using laser in the treatment of lumbar disc herniations arose in the early 1980s (8). After a series of in vitro experiments, Choy and colleagues performed the first PLDD on a human patient in February 1986 (96). The U.S. Food and Drug Administration approved PLDD in 1991. By 2002, over 35,000 PLDDs had been performed worldwide (97). The treatment principle of PLDD is based on the concept of the intervertebral disc being a closed hydraulic

system. This system consists of the nucleus pulposus, containing a large amount of water, surrounded by the inelastic annulus fibrosis. An increase in water content of the nucleus pulposus leads to a disproportionate increase of intradiscal pressure. In vitro experiments have shown that an increase of intradiscal volume of only 1.0 mL causes the intradiscal pressure to rise by as much 312 kPa or 2340 mmHg (96). On the other hand, a decrease of intradiscal volume causes a disproportionately large decrease intradiscal pressure. A reduction of intradiscal pressure causes the herniated disc material to recede toward the center of the disc, thus leading to reduction of nerve root compression and relief of radicular pain. In PLDD, this mechanism is exploited by application of laser energy to evaporate water in the nucleus pulposus. The evaporation of water and the increase in temperature causes protein denaturation and subsequent renaturation, causing a structural change of nucleus pulposus, limiting its capability to attract water and therefore leading to a permanent reduction of intradiscal pressure by as much as 57% (96).

Ten clinical studies (52,53,57,58,61,62,64,65,67 ,71) were included in this systematic review, representing a total of 2447 patients. Studies were only included if they met inclusion criteria. Schenk et al (8) included 16 clinical studies representing a total of 1,579 patients. However, since it was a narrative review, the criteria were different. They included studies only if they provided enough information on techniques used in procedure (laser type, parameters used, etc.) and no additional techniques such as endoscopy were used. In this systematic review we also excluded if endoscopy was used except with LASE. Schenk et al (8) also included only trials when they addressed the outcome of PLDD. In the present systematic review and the review by Schenk et al (8) the basic technique of PLDD appears to be the same for all trials. However, in the different studies, while basic principles remain the same, it appears there is a considerable degree of variation in the way PLDD is performed. Differences can be found in the choice of laser type and laser parameters used. While most studies used fluoroscopy some also used additional CT imaging or even MR imaging.

The inclusion and exclusion criteria used within the different studies showed similarities. The presence of radiologically confirmed herniated disc with corresponding disc with corresponding radicular symptoms was required in all studies for a patient to qualify for inclusion. Further, patients with severe neurological symptoms were excluded (50,55,56,60,61,64,67). The majority of the studies considered disc extrusion or sequestered herniation as exclusion criteria and required contained herniations to qualify for the procedure.

Schenk et al (8) reported success rates in the larger studies varying from 75% (with 95% CI of 69% to 81%) (58) to 87% (with 95% CI of 80% to 94%) (61). Because of insufficient improvement of symptoms or recurrent herniation, 4.4% (61) to 25% (58) of patients received additional surgical treatment. In most cases, surgery revealed the presence of free fragments in the spinal canal.

# CONCLUSION

This systematic review indicated Level II-2 evidence for percutaneous lumbar laser disc decompression with 1C/strong recommendation. Thus, laser disc decompression may provide appropriate relief in properly selected patients with contained disc herniations.

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