

Percutaneous Discectomy

Department of Labor and Industries
Office of the Medical Director

February 24, 2004

Percutaneous Discectomy

Table of Contents

<u>Topic</u>	<u>Page</u>
Introduction	1
Manual Percutaneous Lumbar Discectomy (MPLD)	2
Randomized Trials	2
Case Series	5
Automated Percutaneous Lumbar Discectomy (APLD)	9
Predictive Factors	9
Randomized Trials	9
Case Series	16
Adverse Events and Complications	21
Cost Study	21
Percutaneous Laser Discectomy	22
Case Series	22
Costs and Payer Systems	30
Nucleoplasty	31
Case Series	32
Coding and Insurers	34
Conclusion	36
References	37

Percutaneous Discectomy

Introduction

A herniated intervertebral lumbar disc results from a protrusion of the nucleus pulposus. A ruptured annulus fibrosis causes an extruded disc while an intact but stretched annulus fibrosis results in a contained disc prolapse. This may compress one or more nerve roots causing pain along the sciatic nerve. (Boult 2000)

Percutaneous discectomy is a class of minimally invasive surgical procedures that treat contained, herniated discs. One theory for improvement from percutaneous discectomy suggests that removal of disc material reduces the intradiscal pressure so that the herniated segment can fall back into place. Another proposed mechanism is that removing disc material may prevent release of chemical mediators that directly injure the nerve root. (Delamarter 1995)

Specific procedures within the class include manual percutaneous lumbar discectomy, automated percutaneous lumbar discectomy (APLD), laser discectomy, and nucleoplasty. Manual discectomy removes disc material with forceps whereas APLD removes disc material with a suction cutting probe. Laser discectomy uses laser energy transformed into heat to vaporize disc tissue. Finally, Nucleoplasty uses radiofrequency energy to break molecular bonds within tissue, creating small channels in the disc.

Percutaneous discectomy is generally indicated for patients with contained disc herniations or prolapse resulting in radicular pain equal to or greater than back pain. Patients should have attempted conservative treatment. MRI, CT, CT myelogram, or discography may confirm disc pathology.

General contraindications for percutaneous discectomy are free disc fragment, bone spur impingement on the nerve root, previous surgery with scar tissue nerve entrapment, spondylolisthesis, and bony spinal stenosis. (Caspar 1995) (Choy 1998)

Advocates of percutaneous approach cite a shorter stay in the hospital, decreased epidural scar formation, avoidance of general anesthesia, preservation of spinal stability, and decreased cost as advantages. (Delamarter 1995)

This review includes prospective studies with more than 20 subjects and published in English after 1993.

Manual Percutaneous Lumbar Discectomy

Published Studies

I. Randomized Trials

- a. Hermantin compared arthroscopic posterolateral discectomy to open discectomy and laminotomy with regard to low back pain and radicular symptoms, objective physical findings, duration of disability, and medication use. (Hermantin 1999)

Arthroscopic discectomy was performed with an oval 5 by 8 mm cannula that fit within the boundaries of the triangular working zone between the traversing and exiting nerve roots. The herniated disc fragments are pulled back into the intervertebral disc space and then are withdrawn. While the arthroscopic discectomy was outpatient, the laminotomy/discectomy required one night hospital stay.

Patients were considered to have satisfactory outcomes if they were rated as excellent or good.

- Excellent - radicular symptoms ceased, negative tension sign, return to normal activities, patient expressed satisfaction
- Good - excellent results, but with residual back pain and modified occupation

Follow-up occurred at 2 weeks, 3 months, 6 months, 1 year, and 2 years.

Study Population: The study randomized 60 patients (mean age 39.5 years) to open laminotomy and discectomy or video-assisted arthroscopic microdiscectomy.

	Number of patients	
	open laminotomy and discectomy	video-assisted arthroscopic microdiscectomy
L2-L3		1
L3-L4	1	6
L4-L5	23	19
L5-S1	6	4
Reflex abnormalities	9	12
Sensory deficit	28	26
Motor weakness	26	24

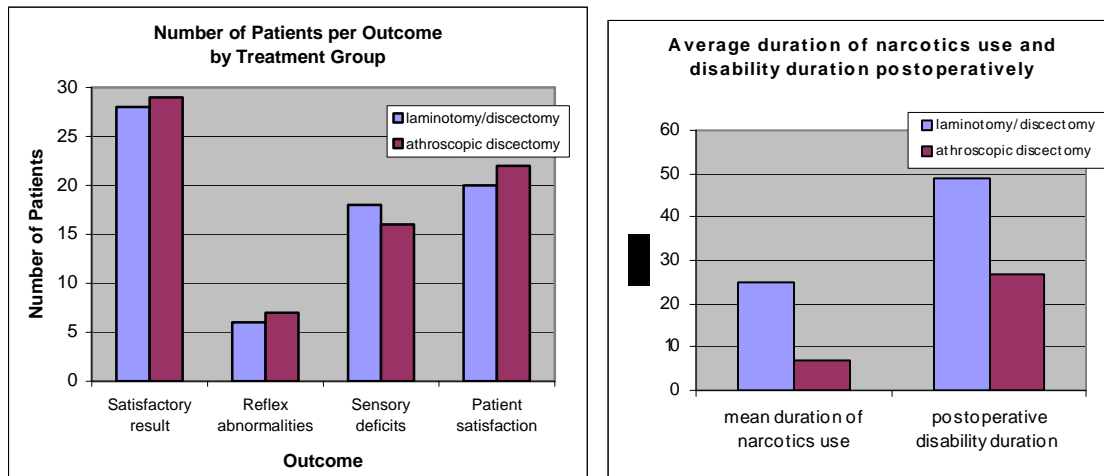
The study included patients with more pain in the lower extremities than in the back that failed 14 weeks of nonoperative measures. They had a single disc herniation that did not exceed one-half of the diameter of the spinal canal. There was an absence of ventral or lateral osseous or ligamentous stenosis. Patient had positive tension signs and had no previous operation on the low back.

Manual Percutaneous Lumbar Discectomy (MPLD)

The study excluded patients due to central or lateral stenosis, severe degenerative narrowing of the disc space, global bulging of the intervertebral disc associated with central or lateral stenosis, sequestered herniation that had migrated, large central or extraligamentous herniation between L5-S1, or litigation or workers' compensation claim.

Results: The mean duration of follow-up was 31 months for the open discectomy group and 32 months for the arthroscopic discectomy group.

Mean postoperative pain score was 1.9 points for the open discectomy group and 1.2 for the arthroscopic group.



At latest follow-up, 6 open discectomy patients reported occasional use of codeine derivatives for control of LBP or lower extremity pain. One patient experienced procedure failure.

One arthroscopic discectomy patient required additional surgery.

Conclusion: Although the number of patients who had a satisfactory outcome was similar in the two groups, the rate of postoperative morbidity was lower in the patients who had the minimally invasive surgery.

- b. Mayer compared 40 patients randomly assigned to one of 2 groups of 20 patients treated with percutaneous discectomy (PLD) or by microdiscectomy (micro). (Mayer 1993)

Patient symptoms were transformed into a 10-point scoring system modified from the Suezawa and Schreiber system. Patients were followed for two years.

Manual Percutaneous Lumbar Discectomy (MPLD)

Study Population:

Patient Demographic		
	PLD	Micro
Number of patients	20	20
Average age	39.8 years	42.7 years
Average duration of symptoms	6.9 months	7.3 months
Average preoperative disability	10.4 weeks	10.4 weeks
Preoperative sensory disturbances	13 patients	16 patients
L4-L5	18	19
L3-L4	1	1
L3-L4, L2-L3	1	0
Time of procedure	40.7 minutes	58.2 minutes
Amount of disc material removed	4.3 g	12.8 g

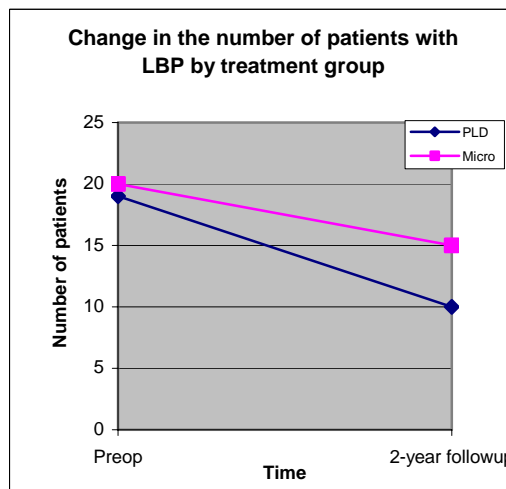
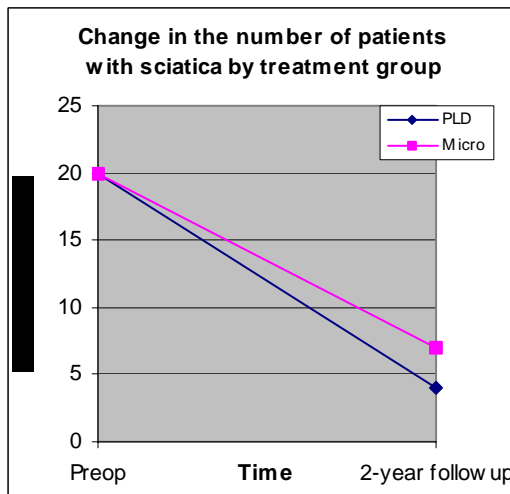
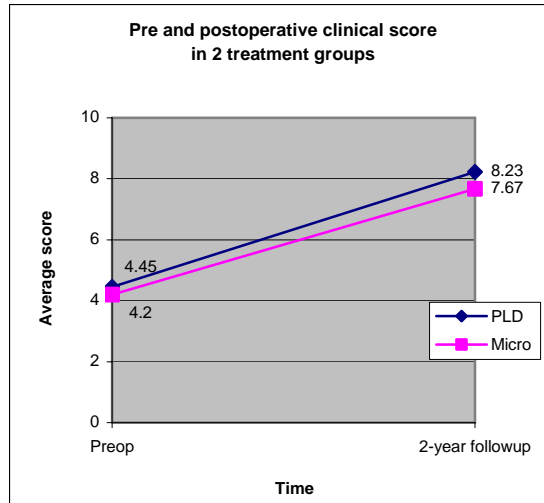
The study included patients with discogenic nerve root compression. Patients showed radicular symptoms such as straight-leg raising test, sciatica, sensory disturbances, mild motor weakness, and reflex differences. MRI, CT, discography, post-discography CT, or myelography showed a contained herniation or small, noncontained herniation. A small, noncontained herniation was defined as extrusion of nucleus pulposus under the posterior longitudinal ligament and occupying not more than one-third of the sagittal diameter of the spinal canal.

Patients were excluded due to severe motor deficits, conus or cauda equina syndrome, progressing neurological symptoms, segmental instability, previous surgery, psychogenic aggravation, workers' compensation, large noncontained herniation, sequestered disc, stenosis, or spondylolisthesis.

Results: All 20 PLD patients were satisfied with their procedures compared to 17 satisfied microdiscectomy patients.

Outcomes by Treatment Group		
	PLD	Micro
Excellent	11 patients	7 patients
Good	3 patients	6 patients
Moderate	3 patients	4 patients
Bad	--	3 patients
Mean duration of postop disability	7.7 weeks	22.9 weeks
Return to work	19 patients	13 patients

Manual Percutaneous Lumbar Discectomy (MPLD)



Conclusion: The authors conclude that the clinical results are comparable. The results of the study justify percutaneous discectomy as a surgical alternative for patients with “contained” or slight subligamentous lumbar disc herniations.

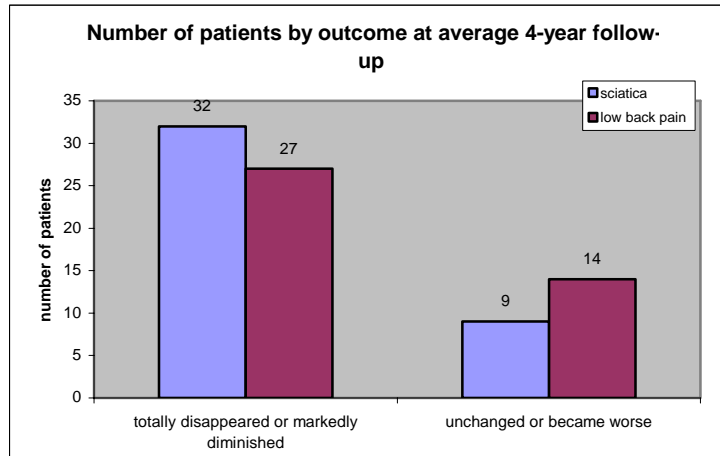
II. Case Series

- a. Kotilainen evaluated 41 patients, which represented 91% of the original study population. The patients’ mean age was 49 years. 17 patients (55%) were employed in light work and 14 patients (45%) in heavy work. (Kotilainen 1998)

Patients were evaluated with a 100mm VAS and examined for the presence of segmental instability of the lumbar spine using 3 criteria: instability catch, painful catch, and apprehension. The mean postoperative follow-up time was 5 years.

Manual Percutaneous Lumbar Discectomy (MPLD)

Results: The mean VAS decreased from 83 to 36.

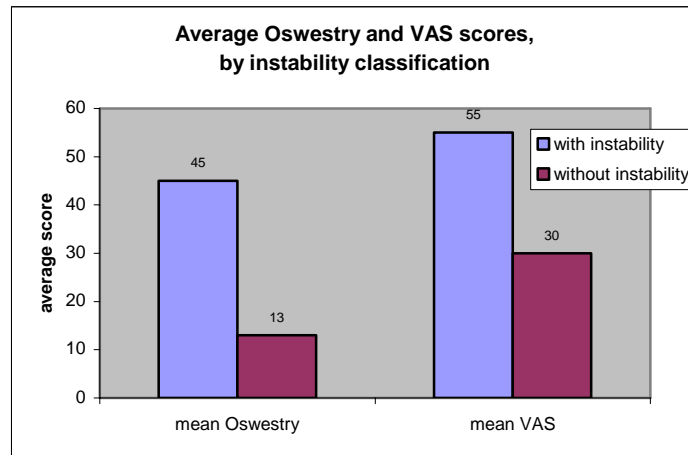


Various signs and symptoms of segmental instability were detected in 10 (24%) patients. Five of these patients did not show instability preoperatively.

	Number of patients	Percent of patients
Instability Catch	8	20%
Painful Catch	6	15%
Apprehension	9	22%

Of the 29 patients who were working at follow-up, 13 patients managed their work well. 2 patients were on sick leave due to back pain. 5 patients were retired because of the back and 5 patients retired due to other reasons.

Postoperative outcome was evaluated separately for patients with and without segmental instability. Patients with instability suffered more often from low back pain and sciatica than did those without instability.



Manual Percutaneous Lumbar Discectomy (MPLD)

During the follow-up period, 6 (15%) patients required reoperation. Recurrent disc herniation was detected in 3 (7%) patients. Mean duration between the original operation and reoperation was 2.5 years.

Conclusion: Nucleotomy is an effective and safe alternative to open disc surgery in the treatment of patients with a small prolapse or a small protrusion who have not responded to conservative treatment. The subgroup of patients with segmental instability experienced inferior outcomes.

- b. Lin evaluated 35 cases (mean age 35.5 years) with fourth or fifth lumbar or first sacral radiculopathy unresponsive to 6 weeks of unsuccessful therapy. Image studies showed a herniated nucleus pulposus. Patients were excluded due to moderate or severe spinal stenosis, lateral recess stenosis, degenerative facet disease, far lateral herniation, free fragment, or previous lumbar spinal surgery. (Lin 1994)

The study used the following grading system to monitor outcomes. The average follow-up was 9.3 months.

Grading system

	Activity level	Pain	Analgesic use	Work Status
1 points	Severely limited	Continuous	Continuous	Unemployed
2 points	Use of cane or assistance	Frequent	Frequent	Modified
3 points	Minimally limited	Occasional	Occasional	Original
4 points	Full activity	None	None	

The treatment was considered successful if:

Original score	Functional score
<10	>10 and increase > 3
>=10	Increase >3

Failure was defined as requiring an additional procedure or patient dissatisfaction.

The mean duration of symptoms was 15.6 months and the average time out of work before the operation was 3.2 months. The procedure removed 4 to 7 g of disc material.

Results:

Number (%) of Patients with Successful Outcome by Disc Level and Follow-up

Level	2 month	6 month
L3-L4	1/1 (100%)	1/1 (100%)
L4-L5	25/30 (83%)	22/29 (76%)
L5-S1	3/4 (75%)	3/4 (75%)
Total	29/35 (83%)	26/34 (76%)

One case of discitis developed.

Manual Percutaneous Lumbar Discectomy (MPLD)

Conclusion: The authors state that the study provides an objective means of selecting cases and evaluating surgical results, which makes the use of the procedure predictable.

- c. Mochida observed 107 patients and analyzed data from 85 patients (average age 26.3 years) with unilateral involvement of the lower extremity induced by one level compression to the spinal nerve root. The patients attempted conservative therapy for more than 6 months. The study excluded patients if CT after discography and MRI showed perforation of the posterior longitudinal ligament or stenosis. (Mochida 1993)

Patients were monitored for a minimum of 2 years with the Japanese Orthopaedic Association (JOA) score for low back pain. Scores higher than 12 points were considered successful.

	LBP	Leg Pain and/or Tingling	Gait	Straight leg raising test	Sensory disturbance	Motor disturbance
0 pts	Frequent or continuous severe		Unable to walk farther than 100 m because of pain, tingling, or muscle weakness	Less than 30 degrees	Marked	
1 pts	Frequent mild or occasional severe		Unable to walk farther than 500 m because of pain, tingling, or muscle weakness	30 to 70 degrees	Slight	
2 pts	Occasional mild		Walk farther than 500 m although it results in pain, tingling, or muscle weakness	Normal	Normal	
3 pts	None		Normal			

Results: At average 2.4-year follow-up, 54 subjects (64%) had successful results. Of the 31 unsuccessful patients, 22 were retreated with open surgery.

Subgroup analysis showed that 5 of 7 patients older than 40 had unsuccessful results. Of the 78 patients younger than 40, 26 had unsuccessful results. Grade 3 on manual muscle testing in the innervated muscles also showed less successful outcomes.

Conclusion: The researchers recommend excluding patients older than 40 because of degenerative change of the bone structure, which is likely to compress the spinal nerve root.

Automated percutaneous lumbar discectomy (APLD)

In 1985, Automated Percutaneous Lumbar Discectomy (APLD) was developed. APLD is performed with a pneumatically driven, suction-cutting probe in a cannula with 2.8 mm outer diameter. The automated probe or rongeur is passed anterolateral to the actual herniation and comes to rest in the center of the disc. Most of the disc removal occurs 1 cm anterior to the herniation. APLD generally removes 2 to 3 g of disc material to reduce intradiscal pressure and decompress the nerve root compression. (Delamarter 1995) (Revel 1993) (Sakou 1993)

Predictive Factors

Delamarter reviewed the MRI studies of 30 patients (mean age 34 years) before and after APLD to identify features that might predict outcome. Preoperative studies were reviewed retrospectively and average follow-up was 14 months. The study defined success nearly complete pain resolution, no pain medication, and return to work without restrictions.

Imaging studies 4 to 6 weeks after the operation for 14 successful patients did not show any changes in disc morphology. Studies at mean 8 months showed that 3 patients had a reduction of the size of the herniated segment. However, Delamarter found no association between preoperative size or location of the herniated disc and a successful clinical outcome. They conclude that it is difficult to predict the clinical outcome of a percutaneous discectomy. (Delamarter 1995)

Dullerud conducted a retrospective review of 142 patients to assess predictive clinical factors. The study used broader inclusion criteria allowing patients with predominant LBP, bulging disks with diffuse posterior extension of the disk margin beyond the adjacent vertebral endplates, or concomitant spinal stenosis.

Patients with normal or slightly narrowed disc space experienced better results compared to patients with a larger degree of disc space narrowing. Results were also better at the 5th disc level than at the 4th disc level. (Dullerud 1995)

Published Studies

I. Randomized trials of APLD and chemonucleolysis

- a. Revel randomized patients with sciatica caused by a disc herniation to undergo either APLD or chemonucleolysis (CN). (Revel 1993)

The study measured outcomes with a 100 mm VAS to measure sciatica and LBP, a straight leg test, the Schober test, neurologic status, self-assessment, disc height, and herniation size.

Automated Percutaneous Lumbar Discectomy (APLD)

The principal outcome was overall assessment of the patient 6 months after treatment. Nil and moderate results, withdrawal because of surgery, or loss to follow-up were considered failures.

Follow-up occurred at the day of discharge, 1 month, 3 months, and 6 months.

Revel calculated that 80 patients in each treatment group would permit observation of a 20% difference in outcome.

Study Population: The study included and excluded patients based on the following criteria.

Inclusion	Exclusion
<ul style="list-style-type: none"> • Unresponsive to conservative medical therapy (average 20 weeks) • CT scan, MRI, or myelography demonstrated herniation at only one level • Chief symptom of sciatica caused by herniation 	<ul style="list-style-type: none"> • Prior lumbar surgery or chymopapain injection • Severe neurologic problems • Lateral recess or central spinal stenosis • Disc migration of more than 5 mm away from vertebral endplates • Large herniation, calcified herniation, vacuum disc, or disc height less than 5 mm

Of the 164 eligible patients initially randomized, 19 subjects were excluded just before the procedure and 5 treated patients were excluded after first follow-up. The reduced number did not affect statistical power.

The trial included 72 CN (mean age 40 years) and 69 APLD (mean age 37 years) subjects. 43% of CN and 26% of APLD were considered sedentary subjects, and the disc appeared degenerated more often in the CN group (92%) than in the APLD group (76%).

15% of CN and 20% of APLD subjects received workers' compensation.

The study considered the 32 patients who withdrew during trial as therapeutic failures.

	CN	APLD
open laminectomy	5	23
technical failure	0	2
lost to follow-up	2	0

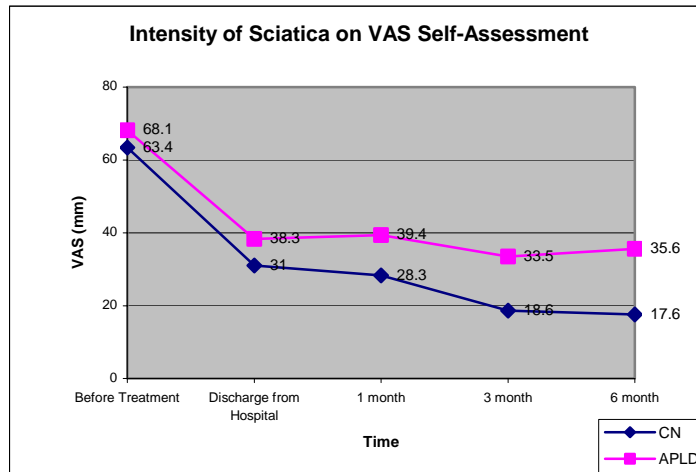
Results:

	CN	APLD
6 months	44/72 (61%)	30/69 (44%)
1 year	48/58 (83%)	25/41 (61%)

Automated Percutaneous Lumbar Discectomy (APLD)

Overall assessment of success rate at 6 months

	CN	APLD
Physician opinion	77%	83%
Patient opinion	69%	68%



Among the 52 CN and 41 APLD subjects employed at study entry, the duration of absence from work was 107 days in the CN group and 93 days in the APLD group.

Percent of patients who returned to normal activity

	CN	APLD
Housework	72%	75%
Spare time activities	50%	46%

The main side effect that 30 CN and 7 APLD patients experienced was back-muscle spasms requiring analgesic drugs.

Conclusion: Trial results suggest that further controlled studies should be carried out before APLD can be considered a useful intervention.

- b. Krugluger conducted a study comparing APLD with chemonucleolysis (CN). The study initially selected 29 patients with symptomatic disc lesion confirmed by discography. (Krugluger 2000)

Epidural leakage of contrast material excluded 7 patients resulting in the randomization of the remaining 22 subjects to either CN or APLD.

Clinical and radiological data were recorded at 6 weeks, 12 months, and 2 years. The study placed emphasis on neurological symptoms and on the Oswestry score.

Automated Percutaneous Lumbar Discectomy (APLD)

Study Population:

Patient Demographics		
	CN	APLD
Number of patients	12 patients	10 patients
Average age	37 years	42 years
Lasegue's sign and sensory abnormalities	10 patients	8 patients
Weakness in a myotome related muscle	6 patients	5 patients
Abnormal reflexes	3 patients	1 patients
Duration of Back Pain	3 years	3 years
Duration of Leg pain	5 months	11 months
Herniation at L4-L5	4 patients	5 patients
Herniation at L5-S1	8 patients	5 patients

Results: At 6 weeks, both groups showed significant improvement in neurological deficits and Oswestry score. However, the differences between groups were not statistically significant. Follow-up at 12 months did not reveal further improvement in either group.

Two CN patients reported mild back pain and leg pain reappearing after 6 months. One patient developed nerve root symptoms after 3 months necessitating open discectomy.

Equipment failure caused one APLD patient to undergo an open operation. Another APLD patient required microdiscectomy 4 weeks after the initial procedure due to nerve root pain. Five APLD subjects experienced recurring back and leg pain that produced significant deterioration when compared both to earlier assessments and to the CN group.

The average time away from work for the CN group was 6 weeks.

Conclusion: Any further percutaneous techniques that are developed will have to give results that are superior to those produced either by chemonucleolysis or by microdiscectomy.

II. Randomized trials of APLD and microdiscectomy

- a. Chatterjee compared APLD to microdiscectomy in the treatment of contained lumbar disc herniation in a randomized study with blind assessment. (Chatterjee 1995)

Microdiscectomy was performed by standard technique with the removal of the herniated portion of the disc and all loose intradiscal material. APLD was performed with a 2 mm nonflexible automated suction nucleotome. Disc aspiration was continued until no more nuclear material could be obtained. The

Automated Percutaneous Lumbar Discectomy (APLD)

study offered microdiscectomy to patients who failed APLD and whose herniations were unchanged.

The clinician and a masked observer assessed all patients with the MacNab criteria at 3 weeks, 2 months, and 6 months.

The study intended to recruit 160 patients in order to achieve adequate power. However, inferior results in one group during the trial halted patient recruitment.

Study Population: The study included 71 patients who experienced radicular pain as their dominant symptom. They attempted conservative therapy for at least 6 weeks. MRI showed a contained disc herniation at a single level. Disc height was less than 30% of the sagittal canal size.

The study excluded patients with dominant symptoms of LBP, disc extrusion, sequestriations, subarticular or foraminal stenosis, or multiple levels of herniation.

Patient Demographics

	APLD	Microdiscectomy
L4-L5	12 patients	17 patients
L5-S1	19 patients	23 patients
Duration of LBP	18 months	33 months
Duration of radicular pain	13 weeks	20 weeks
Age	38.9 years	41.3 years

Results: Outcomes between groups was statistically significant.

Comparison of Outcome by Number and Percent of Patients

	Microdiscectomy	APLD alone	APLD → Micro	APLD alone and APLD → Micro
Excellent or Good	32/40 (80%)	9/31 (29%)	13/20 (65%)	22/31 (71%)

The mean length of hospital stay for the microdiscectomy group was 3.5 days and 5.3 days for microdiscectomy after APLD.

Three of the microdiscectomy patients failed to return to work or to their previous level of activity within 3 months.

Conclusion: APLD is ineffective as a method of treatment for small, contained lumbar disc herniation. If APLD is more effective in patients with a short history of radicular pain and a possibly less degenerated disc, then it is essential that further carefully controlled and randomized studies are performed to evaluate the efficacy of APLD as compared to more prolonged nonsurgical therapy.

Automated Percutaneous Lumbar Discectomy (APLD)

- b. Haines conducted a randomized study that had the primary objective of comparing APLD to conventional discectomy (CD) as a firstline treatment for herniated lumbar discs. (Haines 2002a) (Haines 2002b)

Randomization occurred through a permuted block design.

The study measured outcomes with physical signs related to the severity of LBP and sciatica, the Modified Roland Scale for disability assessment, and the SF-36 for general health status.

Four measures (average pain severity, use of pain medications, work activity and leisure activity) were combined in a matrix to produce an overall clinical outcome. The primary endpoint was the patient's outcome rating 12 months after surgery:

- Excellent – return to full time pre-morbid work, no limitation in leisure activity, essentially no back or leg pain and no regular analgesics use
- Good – some restriction in work and leisure activity, occasional non-narcotic analgesic use, average pain score no higher than 3 on a 7 point scale

Success was defined as an excellent or good rating. Unsuccessful outcomes were defined as a fair or poor rating or a second surgical procedure on the same disc within 12 months of the initial operation.

Follow-up occurred at 1 week, 2 months, 6 months, and 12 months.

The study intended to recruit 330 patients with an expectation that 30 would be lost-to-follow-up. This would detect a difference of 15% at a significance level $P < .05$.

Study population: 34 patients were randomized to percutaneous discectomy (n=21) or CD (n=13). Of the 21 percutaneous subjects, 15 patients received APLD with the Nucleotome. 9 patients (5 APLD, 4 CD) were lost to follow-up.

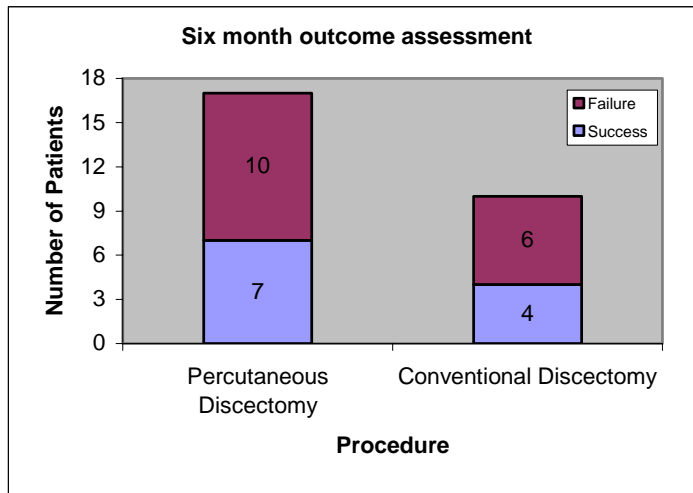
6-month follow-up was obtained on 27 patients, and 12-month follow-up was obtained for 19 patients. One patient randomized to CD actually received a percutaneous discectomy, but is analyzed as randomized.

The study included patients with unilateral leg pain or paresthesia with no history of lumbar spinal surgery. At least 2 of the following conditions were present: dermatomal sensory loss, myotomal weakness, reflex loss, positive straight leg raising, or femoral stretch test.

The study excluded patients due to moderate or advanced lumbar spondylosis, spondylolisthesis, lateral recess stenosis, herniated disc fragment occupying more than 30% of the AP diameter of the spinal canal, herniated disc fragment migrating more than 1 mm above or below the disc space, calcified disc herniation, lateral disc herniation, or posterior disc space height less than 3 mm.

Automated Percutaneous Lumbar Discectomy (APLD)

Results: Success rate of the two procedures was identical (APD 41%, CD 40%).



Outcome evaluation of SF-36 subscores and Modified Roland

	Preoperative	Postoperative
SF-36 subscores		
Physical functioning (mean)		
APD	36.0	74.7
CD	37.2	73.0
General Health		
APD	70.2	75.7
CD	66.5	70.0
Modified Roland		
APD	16.9	6.1
CD	17.3	6.5

Conclusion: The study did not have power to identify clinically important differences because of insufficient patient enrollment. As a result, the trial could not reach a definitive conclusion about the efficacy of standard and percutaneous discectomy.

Haines also states, “It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation...If evidence should guide the treatment recommendations of physicians and surgeons to their patients, if evidence should guide the allocation of limited health care resources, if science has a role in evaluating surgical innovation, then the advocates of percutaneous discectomy should provide that evidence before asking their patients to undergo or pay for such procedures.”

Automated Percutaneous Lumbar Discectomy (APLD)

III. Case Series Studies

- a. Teng evaluated 1525 patients (mean age 48.2 years) with lumbar disc herniation or back pain that failed conservative therapy for 2 months. 950 patients had disc protrusion, and 357 patients had sequestration. 48 cases had calcification of disc or longitudinal ligament and 22 had previous surgical discectomy. (Teng 1997)

Patients were excluded due to previous chymopapain injection, progressive neurologic deficit or cauda equina syndrome, spinal stenosis, lateral recess stenosis, severe degenerative facet disease, or spondylolysis.

Results were judged as excellent, good, or poor. Excellent was defined as symptom free with no restriction in daily activities. Good was defined as greatly improved and return to work. Poor was defined as no improvement, worsening, or surgical discectomy or chemonucleolysis during the follow-up period.

Of the 1525 patients, 1474 patients were followed for at least 1 year. Mean follow-up after APLD was 18.3 months.

The average time between onset of symptoms to the procedure was 15.2 months.

Results: Excellent and good results were obtained in 56% and 26% of patients.

Number (%) of Patients with Excellent and Good Outcomes	
	Excellent and Good
L3-L4	82 (88%)
L3-L4, L4-L5	91 (88%)
L4-L5	372 (82%)
L5-S1	349 (83%)
L4-L5, L5-S1	235 (79%)
Extrusion/sequestration	258 (72%)
Bulging/protrusion	819 (86%)
Back and leg pain	1031 (80%)
Symptoms more than 2 years	516 (79%)
Age older than 60 years	1055 (84%)

Nine patients (0.06%) in this study developed discitis after APLD.

Conclusion: APLD with Teng's instrument has excellent results. Indications may include back pain alone. A straight needle can be used at L5-S1 in most patients, with proper positioning.

- b. Bernd observed 238 patients with disc protrusion or extrusion who failed 6 weeks of conservative therapy. The study also included patients without Lasegue's sign and without pathological preoperative neurological findings, such as sensory or motor deficits. (Bernd 1997)

Automated Percutaneous Lumbar Discectomy (APLD)

The study excluded patients due to isolated back pain, facet syndrome, degenerative disc disease, sacroiliac pathology, sequestered discs, or spinal stenosis.

182 patients (78.4%) of median age 41 years were suitable for evaluation at mean follow-up of 2.5 years. Patients were evaluated based on MacNab criteria, pain relief, patient satisfaction, activity, return to work and compensation claims.

Results: 52% of patients were satisfied with the outcome of the procedure. In 60%, pain decreased after APLD, and 15% reported being free of pain. Those without sensory deficit reported satisfaction (60%) more often compared to those with sensory deficit (43%).

The mean duration of inability to work was 8 weeks. Patients claiming compensation (n=7) were unable to work for a mean of 20 weeks.

Complications consisted of 2 cases of discitis. The risk for reoperation was 25%.

The only significant factor for a positive outcome with respect to improvement in condition and pain relief was age less than 41 years. A positive Lasegue's sign and an age of more than 41 years were risk factors for reoperation.

Conclusion: As the best results are achieved in younger, active patients with little neurological dysfunction, the authors state that APLD should play only a minor role in the treatment of lumbar pain related to disc herniation.

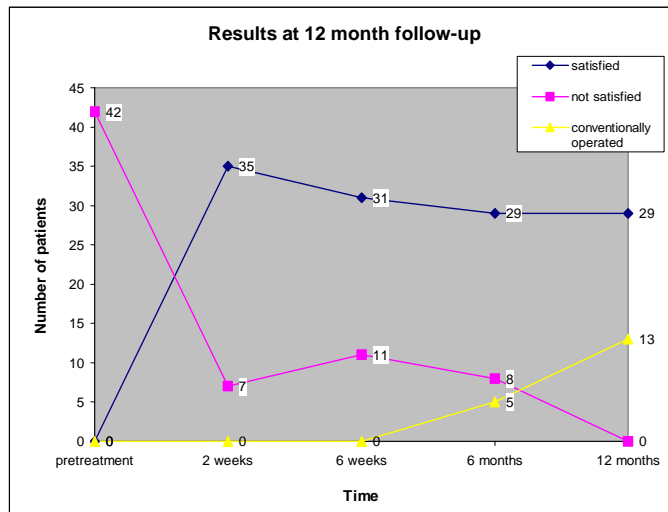
- c. Sortland observed for 1 year 45 patients (average age 35 years) from the Norwegian workers' compensation system. Patients experienced paresis, sensory alteration, or reflex alteration that did not respond to at least 6 weeks of conservative therapy. CT showed disc hernia protrusion less than 50% of the thecal sac and no sign of a free fragment. They did not have stenosis in the lateral recesses or in the spinal canal or spondylosis in the actual disc space. (Sortland 1996)

Cutting and suction were carried out until no more disc material could be obtained. Mean total procedure time was 85 minutes, and the weight of removed disc material ranged from 0.4 g to 7.7 g.

Follow-up occurred at 2 weeks, 6 weeks, 6 months, and 1 year.

Results: 42 patients treated with success had a history of back pain and sciatica with an average duration of 10 months. At one-year follow-up, 69% of the patients were satisfied. Of the 29 patients treated at the L4-L5 disc level, 9 later had conventional surgery. Of the 13 treated in L5-S1, 4 were later operated conventionally.

Automated Percutaneous Lumbar Discectomy (APLD)



Satisfied patients required an average of 11 weeks of sick leave. Unsatisfied patients were on sick leave until they underwent conventional operations.

No complications occurred.

Conclusion: Based on the strict criteria, 45 patients with small and medium sized disc hernias were chosen for percutaneous discectomy. Of the 42 patients who achieved technical success, 29 (69%) patients were successful at the 1-year follow-up.

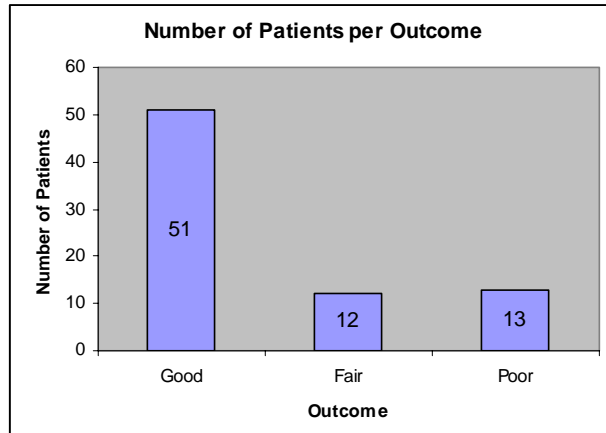
- d. Negri assessed 76 patients (mean age 45 years) who underwent percutaneous nucleotomy at L4-L5 (n=63), L3-L4 (n=12), L5-S1 (n=9), and L2-L3 (n=3). In 11 cases a two level approach was required for a total of 87 discs. All patients were followed for at least 12 months and up to 4 year. Patients attempted 6 weeks of rest or pharmacological treatment. (Negri 1996)

CT or MRI showed protrusion bulging in 36 cases, protrusion towards expulsion in 31 cases, expulsion in 7 cases, and sequester in 2 cases.

Clinical success was defined as a good rating with regression or considerable decrease in nerve root pain. Fair described some lumbar pain and moderate peripheral signs.

Results: Protrusion-bulging patients experienced no failures compared to patients with protrusion-expulsion who had a 34% failure rate. Expulsed patients had a 35% failure rate, and migrated patients a 100% failure rate.

Automated Percutaneous Lumbar Discectomy (APLD)

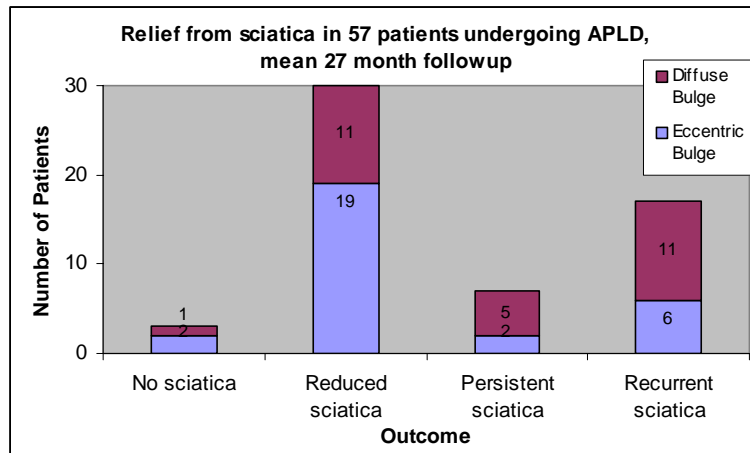


9 of 13 patients who did not obtain any improvement as a result of APLD underwent laminectomy. 2 other patients with less accentuated symptoms received peridural injections with a steroid base. The remaining 2 patients received vertebral traction and infiltrations of the interapophysary joints.

Conclusion: The best results were obtained in young, protrusion-bulging patients with acute symptoms and clinical signs corresponding to the nerve root involved.

- e. Shapiro examined 57 patients (mean age 45 years) with unilateral sciatica as their primary complaint. CT scan or MRI showed lumbar discs with either diffuse bulging or eccentric bulging. All patients had at least 6 weeks of conservative therapy prior to undergoing APLD at L3-L4 (n=4), L4-L5 (n=49), or L5-S1 (n=4). The overall amount of disc aspirate was 3.5 g. (Shapiro 1995)

Results: At 2 weeks, 50 (88%) patients had reduced sciatica, and all 47 with reduced sciatica who were employed preoperatively returned to work. At 2 months, 40 of 57 patients had reduced sciatica. Of the 10 recurrences of sciatica at 2 months, 7 subjects underwent lumbar microdiscectomy. At 2.5 years, sciatica recurred at a 34% rate.



Automated Percutaneous Lumbar Discectomy (APLD)

Patients with eccentrically bulging discs compared to diffusely bulging discs had a significantly better chance of reduced sciatica.

Conclusion: APLD is safe and in selected patients can reduce sciatica, but only completely eliminated sciatica in 5% of patients with a follow-up of 2.5 years.

- f. Grevitt examined 137 patients (mean age 33 years) with MRI confirmed disc protrusion. Patients had predominant leg symptoms, radicular pain distribution, restricted straight leg raise, and positive sign of nerve root tension. They also failed conservative treatment. (Grevitt 1995)

The study excluded patients with facet arthrosis, neurogenic claudication, and radiographs showing more than 50% loss of disc height. Patients with workers' compensation were also excluded.

The study includes in the final analysis 115 patients available at mean 55 months follow-up.

Results: 76% of patients were in full or part-time employment at last follow-up. If patients with a fair or poor outcome and those who had a further operation were considered as failures, the overall success rate was 45% (52/115).

There was a progressive deterioration in the health profile, and the mean transformed scores for the variables of mental health, energy/vitality and health perception were significantly lower than those of the general population.

- g. Fiume examined 200 patients (mean age 44 years) complaining of lumbo-sacral radicular pain due to herniated discs. The procedure was conducted at disc level L4-L5 (n=133), L5-S1 (n=45), and L3-L4 (n=22). 6 patients were treated at 2 levels. The study excluded patients due to spinal stenosis, lateral recess syndrome, disc calcification, severe neurological conditions, or recurrences at previously treated level. (Fiume 1994)

The study divided patients into two groups depending on severity of symptoms:

- Group A moderate root pain: 116 patients with radicular pain unresponsive to PT or analgesics for 2 or more months. They did not experience work impediment
- Group B severe root pain: 84 patients with pain for 2 or more months that impeded working ability

Excellent was defined as complete functional recovery and return to work. Good was defined as mild pain with return to work.

Operations lasted 21 minutes on average and removed a mean of 2.3 g of disc material.

Automated Percutaneous Lumbar Discectomy (APLD)

Results: 76% of cases experienced good to excellent results.

	Group A	Group B
Number of patients	116 patients	84 patients
Excellent or Good Results	98 patients (85%)	53 patients (64%)
Recurrences	2.5%	15%
Days to Pain Relief and Return to Work	13 days	24 days

The nucleotome was positioned correctly in only 34% of L5-S1 cases.

Conclusion: APLD has a high success rate and low morbidity rate in patients that are submitted for conservative care.

Adverse Events and Complications

Gill presented a case report of a 24 year-old male who underwent APLD at L5-S1 for relief of LBP. He developed new onset acute right lumbar radicular syndrome. MRI showed far lateral extraforaminal disc herniation at L5-S1 with compression of the right nerve. This corresponded to the nucleotomy site of the probe. (Gill 1994)

Dullerud's retrospective review of 243 patients treated at 271 disc levels showed 7 technical failures (2.6%). Of these, 6 failures were at the 5th disc level using a 2.5 mm nucleotome. Two patients developed clinical and radiological changes consistent with discitis. 9% of the patients reported mild spasm in the extensor muscles, and 25% of patients reported a mild to moderate sensation of instability. One patient developed functional paresis of the lower limbs one month after treatment. (Dullerud 1997)

Cost Study

Stevenson conducted a prospective cost evaluation including socioeconomic data comparing APLD to microdiscectomy.

Total and Average Cost for Each Patient Group: £s 1992 Pay and Prices

Treatment Group	Number of Patients	Total Cost (£)	Average Cost (£)
APLD only	11	8272	752
Microdiscectomy only	39	58,734	1506
APLD + Microdiscectomy	20	63,540	3177
Repeat Microdiscectomy	1	3931	3931

Average cost of treatment and follow-up surgery was £2317 per APLD patient compared to £1567 per microdiscectomy patient. The average cost per APLD successful outcome was £3264 compared to £1958 per microdiscectomy successful outcome.

Percutaneous Laser Discectomy (PLD)

Percutaneous Laser Discectomy

Percutaneous Laser Discectomy (PLD) is an alternative to the standard open discectomy treatment. PLD, first introduced by Choy in 1984, uses laser energy to reduce pressure by vaporizing a small volume of the nucleus pulposus. Laser energy transmitted in the form of light is transformed into heat. The thermal energy raises the tissue temperature to boiling and vaporization occurs. It is hypothesized that the change in pressure between the nucleus pulposus and the peridiscal tissue causes retraction of the herniation away from the nerve root. (Caspar 1995) (Bosacco 1996) (Choy 1998)

Lasers have different characteristics, energy requirements, and rates of application. Medical lasers consist of four basic components: the laser medium, an energy source, a feedback mechanism like a series of mirrors, and an output coupler. Lasers and wavelengths used in the intervertebral disc are (Caspar 1995):

- KTP (potassium-titanyl-phosphate) at 532 nm
- Nd:YAG at 1.064 and 1.44 μm
- CO₂ at 10.6 μm
- holmiumYAG at 2.1 μm

Published Studies

I. Case Series Study with Historical Comparison Group

- a. Bosacco evaluated the KTP 532 laser for its use in contained, small to moderately sized disc herniation. The laser system was set at 10 W, and laser pulses were delivered for 0.2 seconds. A total of 1250 J was delivered to the disc space. (Bosacco 1996)

Outcomes were assessed with the following criteria:

	Pain	Return to function	Postoperative stay	Return to work interval
0	No relief	Disabled	3 days	6 weeks
1	Partial relief, medication	Function level unchanged	Less than 3 days	Less than 6 weeks
2	Partial relief, no medication	Increased, but not premorbid function		
3	Pain free	Return to premorbid function		

Study Population: Of the 63 patients who underwent PLD, 61 patients (mean age 48 years) were available at average 31.75-month follow-up.

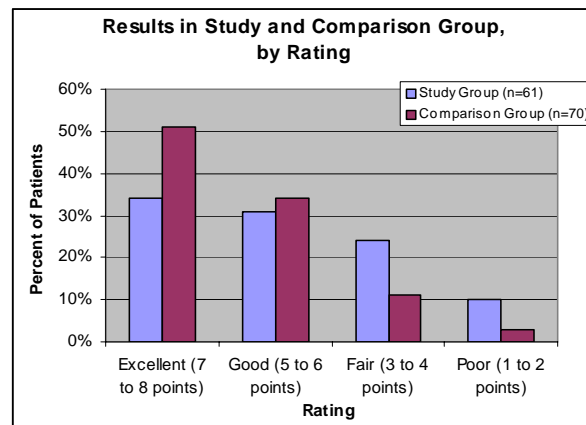
The study also included a retrospective comparison group of 70 patients who were treated with open discectomy (mean age 45 years).

Percutaneous Laser Discectomy (PLD)

Inclusion criteria were single nerve root signs and symptoms, positive straight leg raising test, and disease at only L4-L5. MRI findings showed a focal, asymmetric annular protrusion into the spinal canal that did not occupy more than 25% of the canal.

Subjects were excluded due to previous surgery, spinal stenosis, disease at more than one level, or extruded or sequestered disc fragments.

Results: 17 patients had complete pain relief, and 40 patients had partial relief.



One patient developed acute urinary retention with reflex ileus.

A previous report showed that the open surgical treatment of lumbar disc disease in workers' compensation patients resulted in an 80% rate of permanent disability. If compensation patients were excluded from this study, the success rate would have been 76%.

Conclusion: PLDD is a safe and successful alternative for the treatment of patients with a small to moderately sized herniated nucleus pulposus. Satisfactory relief of radicular pain is to be expected.

II. Prospective Case Series Study without Comparison Group

- a. Gronemeyer investigated whether PLD with the Nd:YAG laser reduced pain, sensorimotor impairment, and medication consumption. (Gronemeyer 2003)

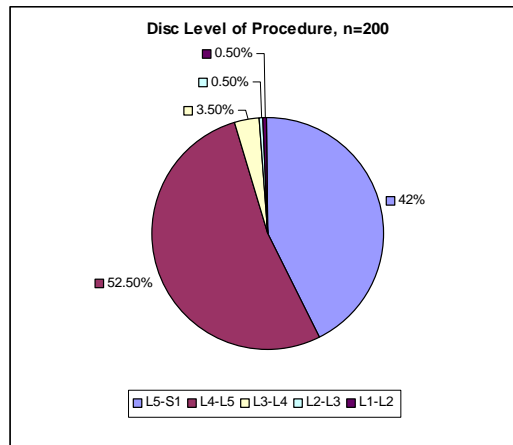
Using CT/fluoroscopy guidance, a cannula helped with placement of a 400-nm laser fiber. The laser procedure involved 1-second pulses of 10 W until an overall energy of 1100 to 1200 J was reached.

Percutaneous Laser Discectomy (PLD)

Study Outcomes

Pain Scale	Sensorimotor Impairment	Pain Medication	Sick Days
None Clear reduction Mild reduction No reduction		Reduced Unchanged Increased	Decreased Remained the same Increased

Study Population: The study included 200 patients (mean age 46 years). 165 patients had neurological deficits in addition to pain, and 171 patients reported use of pain medication.

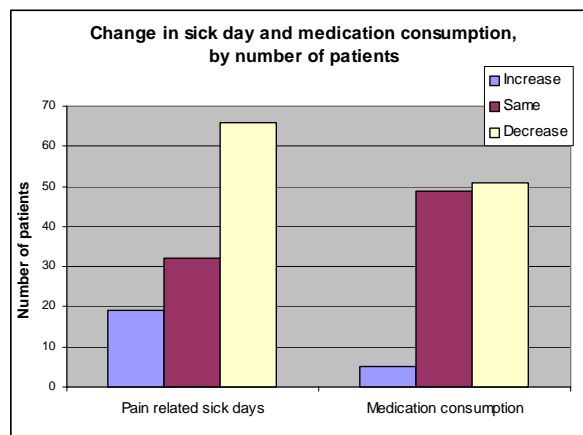
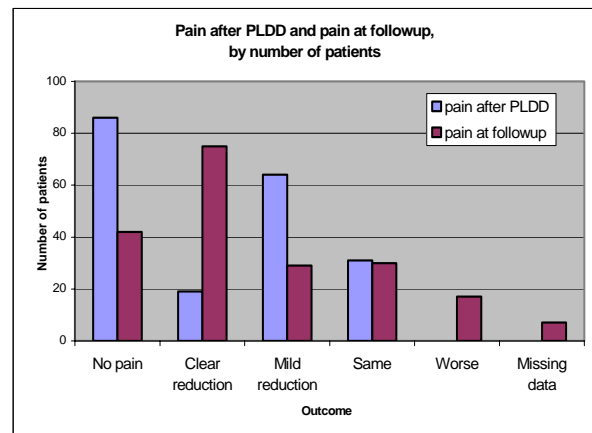
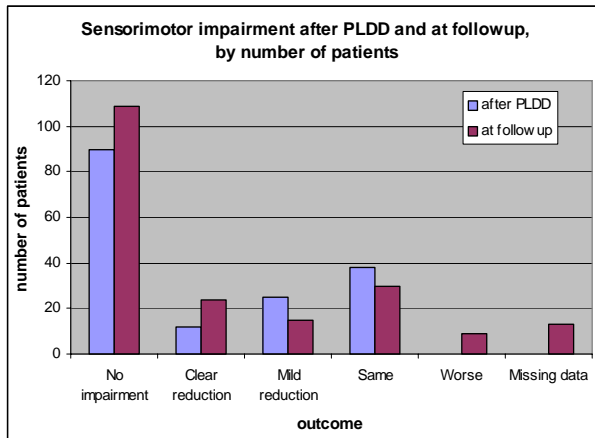


Patients experienced radicular pain with or without neurological signs. CT or MRI confirmed the contained disk herniation. All patients failed at least 6 weeks of conservative therapy.

The study excluded patients with nondiscogenic root compression, narrow spinal canal or intervertebral space, dislocated sequester, tumor, spondylolisthesis, pseudospondylolisthesis, a mass prolapse with decompression of the dural sac and the cauda equina, or facet syndrome.

Results: Immediately after PLD, 86 patients were pain free. 83 patients experienced a reduction in pain that lasted an average of 3.1 years. At 4-year follow-up, 148 patients reported that they were satisfied with outcomes.

Percutaneous Laser Discectomy (PLD)



One patient developed discitis.

Conclusion: The researchers suggest that the Nd:YAG laser is a safe and effective method to treat symptomatic contained intervertebral disk herniations

- b. Tonami studied whether immediate postoperative MRI could show early tissue changes after PLD with the Ho:YAG laser system. The study also correlated MRI findings with clinical outcomes. (Tonami 1997)

The laser power was set at 1 to 1.6 J per pulse repeating at 10 to 12 J per second. The procedure was terminated when total energy reached 20 kJ.

Patients underwent MRI 24 hours after PLD. Surface measurement related the size of the herniated mass to that of the spinal canal. Signal intensity of the herniated disc was also related to that of the adjacent vertebral body.

The study assessed clinical outcomes with the Japanese Orthopaedic Association (JOA) scale (29 points). Success was defined as a recovery rate of over 25%.

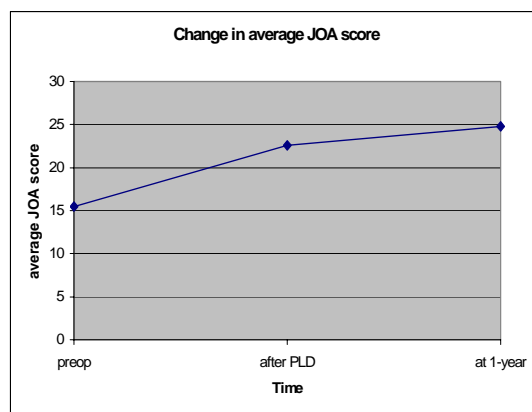
Percutaneous Laser Discectomy (PLD)

Study Population: PLD was performed on 29 discs in 26 patients (mean age 35 years).

Inclusion criteria were radicular leg pain with or without LBP; motor, sensory, or reflex deficits; contained disc herniation; and 3 months of conservative treatment.

Subjects were excluded due to non-contained or sequestered herniations or previous disc surgery.

Results: The average recovery rate after treatment was 53.1% and 64.6% at 1 year. Three patients with recovery rates below 25% underwent additional surgeries.



Although most patients improved clinically after PLD, no patient showed an obvious change in disc herniation size. Researchers did not detect correlations between herniation size and recovery rate or between signal changes within the disc and the recovery rate.

MRI showed soft tissue changes along the laser tract caused by PLD in 5 patients.

Conclusion: Although postoperative MRI showed early tissue changes from laser exposure, the study did not prove whether MRI could predict clinical outcome after PLD.

- c. Nerubay conducted a study using a CO₂ laser on 50 patients. Laser energy was delivered in four 30-second periods interrupted by a 30-second pause. The system delivered 8 watts during a 2-minute period. (Nerubay 1997)

The study assessed outcome with the MacNab criteria:

- Excellent - no pain and no activity restriction.
- Good - occasional back or leg pain, pain that interferes with ability to do normal work or enjoy leisure time.
- Fair - improved functional capacity, but handicapped by intermittent pain that curtails or modifies work or leisure activities.
- Poor- no improvement or insufficient improvement to increase activities.

Percutaneous Laser Discectomy (PLD)

Follow-up occurred at 1 week, 1 month, 3 months, and 6 months, and every 6 months thereafter. The average follow-up was 2 years and 8 months.

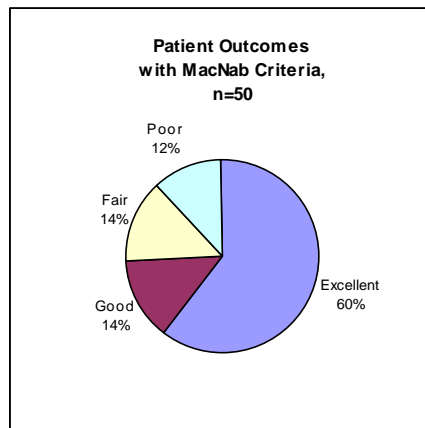
An independent neuroradiologist examined CT and MRI findings.

Study Population: The 50 patients had a mean age of 34 years and mean duration of pain of 33 months. 22 (44%) subjects reported sensory disturbance, and 16 (32%) subjects reported motor disturbance.

The study included patients with LBP and radicular pain that did not respond to conservative treatment for 3 months. Radiographs, CT, or MRI showed a L4-L5 disc lesion.

The study excluded patients due to spinal stenosis, spondylolisthesis, degenerative disc disease, previous back surgery, or huge protruded or extruded disc.

Results:



Change in the size of the herniated nucleus pulposus

	Number (%) of patients
No change	29 (58%)
Slight decrease	14 (28%)
Marked decrease	7 (14%)

In 6 patients, changes in the end plates suggested thermal damage. No correlation was found between clinical outcome and CT and MRI changes.

Four patients had signs of root irritation probably caused by thermal damage to the root.

Conclusion: The use of lasers is still an experimental procedure. More research is needed, and endoscopic control will be necessary to obtain better results.

Percutaneous Laser Discectomy (PLD)

- d. Liebler conducted a study with different lasers delivering 1200 to 1500 J of energy. If heat expanded the disc and caused discomfort, the surgeon paused until the heat dissipated. (Liebler 1995)

The study used the MacNab criteria to assess outcomes and averaged the scores by disc level. Follow-up occurred at 24 hours, 6 weeks, 3 months, 6 months, and 1 year. At Week 3 or 4, patients began a back strengthening program.

Study Population:

Patient Demographics

	2-Year Follow-up	1-Year Follow-up
Number of patients	23	36
Type of laser	KTP laser	Nd:YAG
Duration of pain	43.8 months	13.8 months
Age	43 years	47.3 years
Weight	153.2 pounds	155.8 pounds

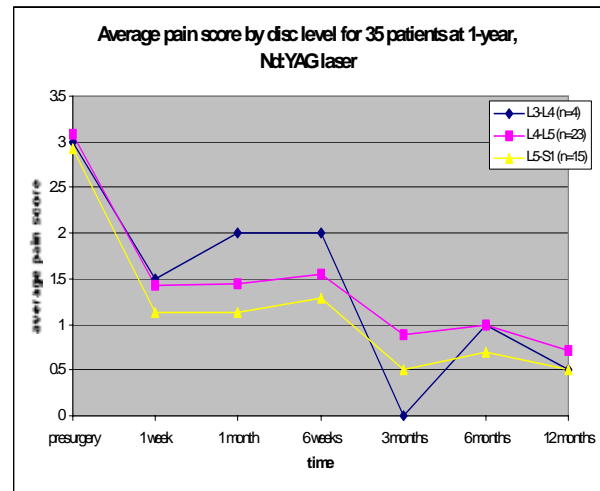
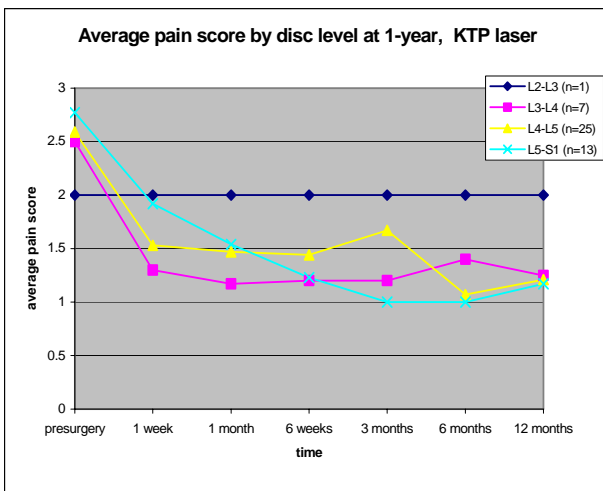
The study included patients with a history of lumbar, leg, or lumbosacral leg pain with positive neurologic findings. They had not had previous surgery or chemonucleolysis. CT scan, myelogram or MRI showed a bulging contained disc. Patients attempted at least 6 weeks of conservative therapy.

Patients were excluded due to stenosis or facet syndrome, spondylolisthesis, advanced disc degeneration, workers' compensation or disability litigation, or cauda equina syndrome.

Results:

Results at one year by laser type

	KTP laser	Nd:YAG laser
Good	75%	70%
Fair	15%	16%
Poor	10%	14%



Percutaneous Laser Discectomy (PLD)

- e. Simons used a 1064 nm Nd-YAG laser to apply 10 W pulses of 1-second duration followed by a 5-second pause. The average delivered energy equaled 1171 J/disc. (Simons 1994)

The study used the following criteria to assess the effect of the laser.

- Very good - no neurological deficit, free of pain, return to work
- Good - minor complaints, no medication needed to return to work
- Satisfactory - more complaints under strain, return to part-time work, medication needed
- Failure - major complaints or microdiscectomy needed, no return to work

On average, first follow-up occurred at 184 days.

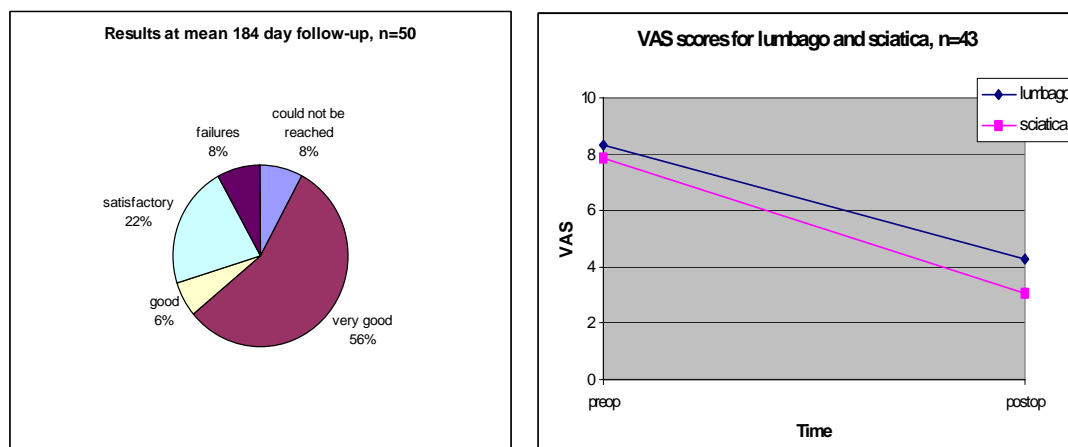
Study Population: PLD was conducted in 50 patients on 55 lumbar discs (20 L5-S1, 31 L4-L5, 4 L3-L4)

The study included patients with nerve root compression who did not respond to more than 3 months of conservative therapy. MRI verified the lumbar disc protrusion.

Patients were excluded due to pareses greater than grade 4 out of 5 and severe bony compression.

Results: 43 patients experienced satisfactory, good, or very good results. Pareses in these 43 patients were reduced to 20% of preoperative findings and the Lasegue sign was reduced by half.

After surgery, 26 of 35 patients returned to the same job or worked in modified settings. 3 were studying for another job, and 6 could not return to work because of complaints.



Conclusion: Laser denaturation reduces lumbar nerve root compression. The results showed a low complication rate.

Percutaneous Laser Discectomy (PLD)

Costs

One surgeon reported in 1996 that the average hospital cost for PLDD was \$3720. This was 35% of the average hospital cost for open discectomy, \$10,600. Total operating time assumes a 3-hour procedure for open and 1 hour for PLDD. (Bosacco 1996)

Other Payer System Reviews

In 2000, a review for Australia classified PLD as level 2 stating “The safety and/or efficacy of the procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. It is recommended that further research be conducted to establish safety and/or efficacy.” The review recommended randomized controlled trials to test PLD against placebo, chemonucleolysis, or open discectomy. (Boult 2000)

Nucleoplasty

Nucleoplasty

Nucleoplasty is a percutaneous procedure intended to treat discogenic back pain through decompression. Nucleoplasty uses the Perc-D Spine Wand, a 1 mm diameter bipolar probe that decompresses the disc nucleus with energy and heat. This Coblation technology generates a low temperature plasma field for controlled ablation.

The wand tip generates a plasma field, which is a millimicron thick field of energized particles that can break organic molecular bonds in disc material. This creates a channel through the annulus. On probe withdrawal, the coagulation mode is used. The thermal effect results in denaturization and shrinkage of the collagen thereby widening and thermally treating the channel. Thus, nucleoplasty combines coagulation and tissue ablation (patented Coblation technology) to form channels in the nucleus and decompress the herniated disc.

The technology is designed so that most of the energy applied is used to ablate, with minimal amounts dissipating as heat into tissue. The by-products of this non-heat driven process are elementary molecules and low-molecular weight inert gases, which are removed from the disc via the needle. (Sharps 2002) (Welch 2002) (ArthroCare 2003) (Chen 2003)

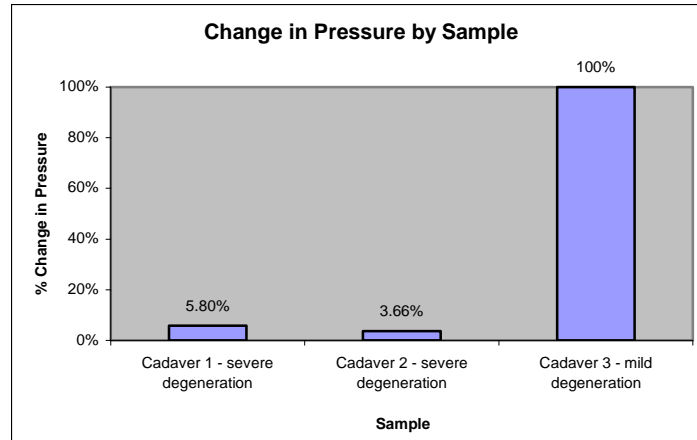
Food and Drug Administration (FDA) Approval

The FDA granted 510(k) approval to ArthroCare in 2001 for the marketing of the Perc-D Spine Wand. The wand is approved for “ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.” It is classified under Electrosurgical Cutting and Coagulation Device and Accessories. (FDA 2001)

Effect of Disc Degeneration on Outcomes

Chen analyzed the influence of disc degeneration on intradiscal pressure change after nucleoplasty in 3 cadaver spines. Intradiscal pressure was markedly reduced in the younger, healthy disc. In the elderly cadavers, the small intradiscal pressure reduction (less than 2 psi) had little clinical impact on overall disc pressure. (Chen 2003)

Nucleoplasty



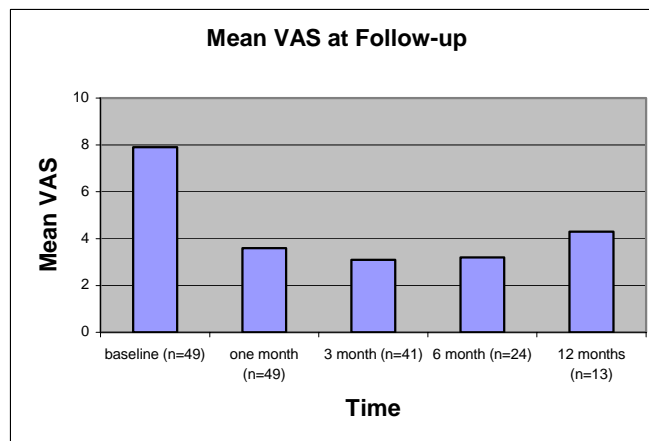
This study demonstrated that nucleoplasty's pressure-reducing effects are dependent on the degree of spine degeneration. Although disc material has been removed, the dehydrated fibrotic nature of the degenerated discs prevents decompression that reduces intradiscal pressure. The treatment is ineffective for severely degenerated discs.

Case Series

a. Sharps evaluated 49 patients (mean age 38 years) who had back pain with or without radicular pain. The study excluded patients due to sequestered herniation, contained herniation larger than 1/3 the sagittal diameter of the spinal canal, or stenosis. (Sharps 2002)

The study evaluated a pain VAS at 1 month, 3 months, 6 months, and 1 year. Success was defined as a 2 point reduction on the VAS, patient satisfaction, no use of narcotics, and return to work.

Results:



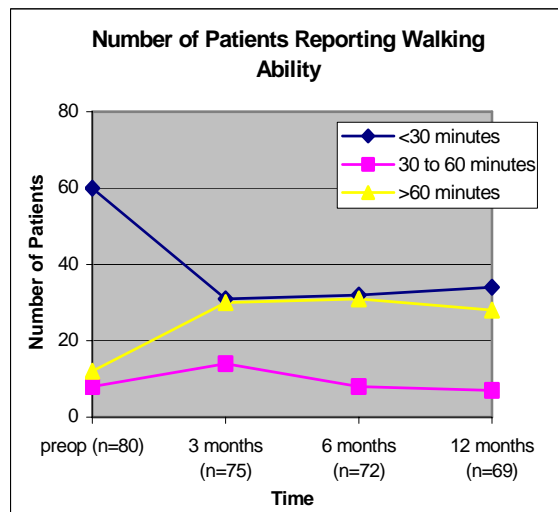
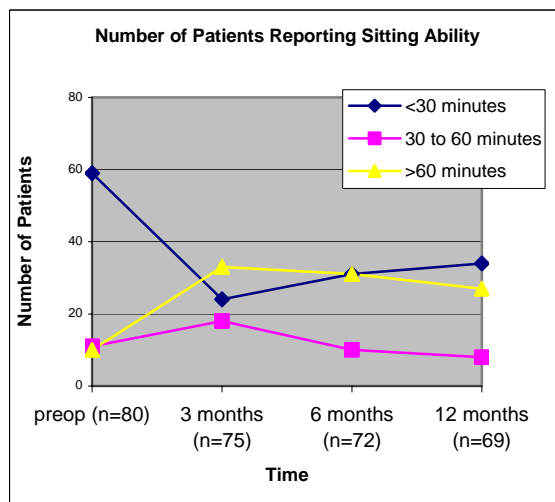
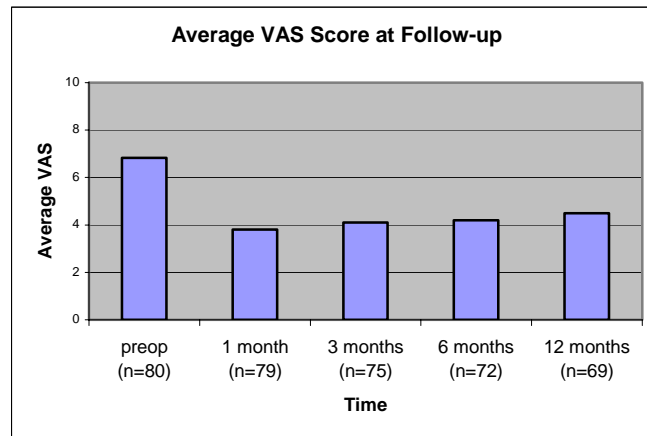
Conclusion: Prospective randomized studies with long-term outcomes would delineate for whom the procedure is helpful.

Nucleoplasty

b. Singh evaluated 80 patients (average age 44.8 years) who had LBP and/or leg pain for 3 or more months that failed conservative therapy. Patients were excluded due to secondary gain issues, heavy opioid usage, sequestration, large contained herniation occupying more than one-third of the spinal canal, or stenosis due to osteophytosis.

The study assessed patients at 1, 3, 6, and 12 months with a pain VAS and functional improvement. 69 patients were analyzed at 12 months.

Results: At 12 month follow-up, 52 of 69 subjects (75%) reported a decrease in pain score.



Ten patients previously unemployed due to back pain returned to work.

No complications were reported.

Conclusion: The authors concluded that the study demonstrated a statistically significant improvement in pain and function at 12 months.

Coding and Insurers

The applicable code for these series of procedures is 62287, “Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy).”

Percutaneous Lumbar Discectomy

BlueCross BlueShield of Massachusetts (2000) and Humana (2000) do not cover Percutaneous Lumbar Discectomy.

BlueCross BlueShield of North Carolina (2003) covers Percutaneous Lumbar Discectomy, a procedure where the herniated disc is scraped, suctioned or lasered until pressure on the irritated nerve is relieved. Percutaneous Lumbar Discectomy is eligible for coverage when:

- Diagnostic imaging shows an uncomplicated herniated lumbar disc with no evidence of a detached fragment or disc separated from the vertebral column.
- Acute unilateral leg pain is localized to a single area, indicating a single spinal nerve affected OR acute and intractable back pain is consistent with disc herniation without fragmentation or separation of the disc from the vertebrae.
- Neurologic signs or symptoms are consistent with disc herniation without fragmentation or separation of the disc from the vertebrae, i.e., sensory abnormalities, altered reflexes, a positive straight-leg raising test, or weakness.
- MRI, CT or myelography show herniation of a single lumbar disc (L1 -L2 through L5 - S1) that is consistent with the signs and symptoms of disc herniation without fragmentation or separation of the disc from the vertebrae.
- Conservative therapy has failed to relieve pain and other signs and symptoms, thereby making the patient a candidate for surgery

Percutaneous Lumbar Discectomy is not medically necessary for BCBS NC patients with physical or diagnostic imaging evidence of disease other than an uncomplicated herniation of a single lumbar disc. Complications include evidence of a fragment or disc separated from the vertebrae and the clinical indications below:

- Progressive neurologic dysfunction
- Impairment of the bowel or bladder function
- Evidence of vertebral disease such as spinal stenosis (narrowing or stricture of the spinal canal) or spondylolisthesis (disc is slipped forward in relation to adjacent vertebra).

Percutaneous Laser Discectomy

The Regence Group (2003) does not cover percutaneous laser discectomy because it is considered investigational.

Coding and Insurers

In 2003, the National Institute for Clinical Excellence of the United Kingdom chose to provide laser discectomy. Physicians are instructed to discuss the safety and efficacy uncertainties with their patients. Patients must provide consent, and physicians must monitor outcomes. (NICE 2003)

Nucleoplasty

The following insurers do not cover nucleoplasty because it is considered investigational.

- Aetna (2003)
- BlueCross BlueShield of Alabama (2003)
- BlueCross of California (2003)
- Medicare of Kansas, Nebraska, and Northwest Missouri (2003)
- The Regence Group (2003)

Conclusion

Percutaneous discectomy procedures are minimally invasive surgeries that act as alternatives to conventional discectomy. Many studies have been conducted on the array of percutaneous discectomy procedures. The quality of the studies ranged from randomized trials to case series studies. Most of the studies were small, case series studies without comparison groups. As a result, these studies did not conclusively show treatment efficacy.

Two randomized trials of manual percutaneous discectomy have indicated that the percutaneous groups experienced shorter disability duration. The first randomized trial comparing arthroscopic to open discectomy showed comparable clinical results between treatment groups at mean 31 months. The second study comparing percutaneous to microdiscectomy also showed comparable clinical results at 2-year follow-up. While the results were promising, these two trials do not show that manual percutaneous discectomy is more efficacious than the gold standard conventional discectomy.

APLD has also been compared to alternative treatments. In one trial against chemonucleolysis, chemonucleolysis patients experienced better outcomes at both 6 months and 1 year. A second study showed comparable results between chemonucleolysis and APLD patients. When APLD was compared to microdiscectomy, researchers halted study recruitment due to poor outcomes experienced by the APLD group. A small study examining APLD against conventional discectomy showed comparable results between the two groups, but the study did not have adequate power to detect significant findings. Although the studies were all small trials, they generally found that chemonucleolysis and microdiscectomy resulted in better patient outcomes.

No randomized trials have been conducted to study the efficacy of either percutaneous laser discectomy or nucleoplasty. One study of laser discectomy included a historical comparison group of patients who underwent open discectomy. The authors note that the comparison group generally showed stronger results, but the laser group would have had a higher success rate if compensation patients had been excluded from the study. Because only case series studies have been conducted to examine the efficacy of these two procedures, they are considered investigational.

References

References

- Aetna. "Nucleoplasty." *Clinical Policy Bulletins*. 2003 May 13; Available at <http://www.aetna.com/cpb/data/CPBA0602.html>. Last accessed on February 19, 2004.
- ArthroCare Spine. "System 2000 Controller." 2003; Available at <http://www.nucleoplasty.com/dphy/dphy.aspx?s=0502>. Last accessed on February 19, 2004.
- Bernd, L, et al. "No indications for percutaneous lumbar discectomy?" *International Orthopaedics*. 1997; 21: 164-168.
- BlueCross BlueShield of Alabama. "Nucleoplasty-Coblation." 2003 January; Available at http://www.bcbsal.com/providers/final_lmrp/090.pdf. Last accessed on February 19, 2004.
- BlueCross of California. "Percutaneous Disc Decompression Using Radiofrequency Energy (Disc Nucleoplasty)." *Medical Policy*. 2003 October 3; Available at http://medpolicy.bluecrossca.com/policies/surgery/disc_nucleoplasty.html. Last accessed on February 19, 2004.
- BlueCross BlueShield of Massachusetts. "Percutaneous Lumbar Discectomy, Percutaneous Vertebroplasty, Intradiscal Electrothermal Therapy, and Chemonucleolysis for spinal discs." 2000 December; Available at http://www.bcbsma.com/common/en_US/hresource/fs099.jsp. Last accessed on February 19, 2004.
- BlueCross BlueShield of North Carolina. "Herniated Lumbar Disc Treatment, Percutaneous." *Corporate Medical Policy*. 2003 September; Available at http://www.bcbsnc.com/services/medical-policy/pdf/herniated_lumbar_disc_treatment_percutaneous.pdf. Last accessed on February 19, 2004.
- Bosacco, SJ, et al. "Functional Results of Percutaneous Laser Discectomy." *American Journal of Orthopedics*. 1996; 825-828.
- Boult, M, et al. *Systematic review of percutaneous endoscopic laser discectomy: Update & Re-appraisal* ASERNIP-S Report No. 5. Adelaide, South Australia: ASERNIP-S, February 2000.
- Caspar, GD, et al. "Percutaneous Laser Disc Decompression with Holmium:YAG laser." *Journal of Clinical Laser Medicine & Surgery*. 1995; 13(3): 195-203.
- Chatterjee, S, et al. "Report of a Controlled Clinical Trial Comparing Automated

References

- Percutaneous Lumbar Discectomy and Microdiscectomy in the Treatment of Contained Lumbar Disc Herniation." *Spine*. 1995; 20(6): 734-738.
- Chen, YC, et al. "Intradiscal Pressure Study of Percutaneous Disc Decompression with Nucleoplasty in Human Cadavers." *Spine*. 2003; 28(7): 661-665.
- Choy, DSJ. "Percutaneous Laser Disc Decompression (PLDD): Twelve Years' Experience with 752 Procedures in 518 Patients." *Journal of Clinical Laser Medicine and Surgery*. 1998; 16(6): 325-331.
- Delamarter, RB, et al. "Percutaneous Lumbar Discectomy." *Journal of Bone and Joint Surgery*. 1995; 578-584.
- Dullerud, R, et al. "Clinical Results After Percutaneous Automated Lumbar Nucleotomy." *Acta Radiologica*. 1995; 36:418-424.
- Dullerud, R, et al. "Side effects and complications of automated percutaneous lumbar nucleotomy." *Neuroradiology*. 1997; 39: 282-285.
- Fiume, D, et al. "Automated percutaneous discectomy in herniated lumbar discs treatment: experience after the first 200 cases." *Journal of Neurosurgical Sciences*. 1994; 38(4): 235-237.
- Food and Drug Administration (FDA). "Perc-D SpineWand." *510(k) Summary of Safety and Effectiveness*. 2001; Available at <http://www.fda.gov/cdrh/pdf/k010811.pdf>. Last accessed on February 19, 2004.
- Gill, K. "New-Onset Sciatica After Automated Percutaneous Discectomy." *Spine*. 1994; 19(4): 466-467.
- Grevitt, MP, et al. "Automated Percutaneous Lumbar Discectomy." *Journal of Bone and Joint Surgery*. 1995; 77(B): 626-629.
- Gronemeyer, DHW, et al. "Image-Guided Percutaneous Laser Disk Decompression for Herniated Lumbar Disks: a 4-Year Follow-up in 200 Patients." *Journal of Clinical Laser Medicine & Surgery*. 2003; 21(3): 131-138.
- Haines, SJ, et al. "Discectomy strategies for lumbar disc herniation: results of the LAPDOG trial." *Journal of Clinical Neuroscience*. 2002a; 9(4): 411-417.
- Haines, SJ, et al. "Discectomy strategies for lumbar disc herniation: study design and implications for clinical research." *Journal of Clinical Neuroscience*. 2002b; 9(4): 440-445.
- Hermantin, FU, et al. "A Prospective, Randomized Study Comparing the Results of

References

- Open Discectomy with Those of Video-Assisted Arthroscopic Microdiscectomy.” *Journal of Bone and Joint Surgery*. 1999; 81A(7): 958-965.
- Humana. “Discectomy, Percutaneous (Laparoscopic) Lumbar.” 2000 January.
- Kambin, P, et al. “Arthroscopic Discectomy of the Lumbar Spine.” *Clinical Orthopaedics and Related Research*. 1997; 337: 49-57.
- Kotilainen, E, et al. “Long-Term Outcome of Patients who Underwent Percutaneous Nucleotomy for Lumbar Disc Herniation: Results after a Mean Follow-up of 5 Years.” *Acta Neurochir (Wien)*. 1998; 140:108-113.
- Krugluger, J, et al. “Chemonucleolysis and automated percutaneous discectomy – a prospective randomized comparison.” *International Orthopaedics*. 2000; 24: 167-169.
- Liebler, WA. "Percutaneous Laser Discectomy." *Clin Orthop*. 1995; 310: 58-66.
- Lin, SM, et al. “Percutaneous Lumbar Discectomy: Indications and Surgical Results in 35 Consecutive Cases.” *J Formos Med Assoc*. 1994; 93(8): 702-708.
- Mayer, HM, et al. “Percutaneous endoscopic discectomy: surgical technique and preliminary results compared to microsurgical discectomy.” *J Neurosurg*. 1993; 78: 216-225.
- Mochida, J et al. “Percutaneous Nucleotomy in Lumbar Disc Herniation.” *Spine*. 1993; 18(14): 2063-2068.
- Murti, Saty. “Percutaneous Intradiscal Treatments for Low Back Pain.” Available at http://www.kansasmedicare.com/part_B/med_review/articles/2003/022403PercIntTreatLowBack.htm. Last accessed February 23, 2004.
- National Institute for Clinical Excellence (NICE). “Laser lumbar discectomy: Understanding NICE guidance – information for people considering the procedure, and for the public.” 2003; Available at <http://www.nice.org.uk/pdf/ip/IPG027publicinfoenglish.pdf>. Last accessed on February 23, 2004.
- Negri, V, et al. "Percutaneous nucleotomy according to Onik: indications and results in 76 cases." *Chir Organi Mov*. 1996 Jan - Mar; 81(1): 49-54.
- Nerubay, J, et al. "Percutaneous carbon dioxide laser nucleolysis with 2 to 5 year follow-up." *Clinical Orthopaedics and Related Research*. 1997; 337: 45-48.
- The Regence Group. “Decompression of Intervertebral Discs Using Laser (Laser

References

- Discectomy) or Radiofrequency Energy (Disc Nucleoplasty™)." *Medical Policy*. 2003 December; Available at <http://www.regence.com/trgmedpol/surgery/sur131.html>. Last accessed on February 19, 2004.
- Revel, M, et al. "Automated Percutaneous Lumbar Discectomy Versus Chemonucleolysis in the Treatment of Sciatica." *Spine*. 1993; 18(1): 1-7.
- Sakou, T, et al. "Percutaneous Discectomy in Athletes." *Spine*. 1993; 18(15): 2218-2221.
- Shapiro, S. "Long-term follow up of 57 patients undergoing automated percutaneous discectomy." *J Neurosurg*. 1995; 83: 31-33.
- Sharps, LS, et al. "Percutaneous Disc Decompression Using Nucleoplasty." *Pain Physician*. 2002; 5(2): 121-126.
- Simons, P, et al. "Percutaneous nucleus pulposus denaturation in treatment of lumbar disc protrusions - a prospective study of neurosurgical patients." *European Spine Journal*. 1994; 3(4): 219-221.
- Singh, V, et al. "Evaluation of Percutaneous Disc Decompression Using Coblation in Chronic Back Pain With or Without Leg Pain." *Pain Physician*. 2003; 6:273-280.
- Sortland, O, et al. "Percutaneous Lumbar Discectomy: Technique and Clinical Result." *Acta Radiologica*. 1996; 37: 85-90.
- Stevenson, RC, et al. "An Economic Evaluation of a Clinical Trial to Compare Automated Percutaneous Lumbar Discectomy with Microdiscectomy in the Treatment of Contained Lumbar Disc Herniation." *Spine*. 1995; 20(6): 739-742.
- Teng, GJ, et al. "Automated Percutaneous Lumbar Discectomy: a Prospective Multi-institutional Study." *Journal of Vascular and Interventional Radiology*. 1997; 8(3): 457-463.
- Tonami, H, et al. "Percutaneous Laser Discectomy: MR Findings within the First 24 Hours after Treatment and Their Relationship to Clinical Outcome." *Clin Radiology*. 1997; 52(12): 938-944.
- Welch, WC, et al. "Alternative strategies for lumbar discectomy: intradiscal electrothermy and nucleoplasty." *Neurosurg Focus*. 2002; 13(2): 1-6.