

# EVIDENCE FOR PERCUTANEOUS PLASMA DISC DECOMPRESSION



SPINEWAND

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## Clinical Guidance

1. NICE – National Institute for Health and Care Excellence. *Percutaneous coblation of the intervertebral disc for low back pain and sciatica - Interventional procedures guidance*. Published: 27 January 2016. Guidance ipg543. ISBN: 978-1-4731-1632-0 <https://www.nice.org.uk/guidance/ipg543/resources/percutaneous-coblation-of-the-intervertebral-disc-for-low-back-pain-and-sciatica-pdf-1899871925113285>

## Clinical Evidence, Meta Analyses, and Systematic Literature Reviews

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## Scientific Evidence

71. Stalder KR, Woloszko J, Brown IG. *Plasma characteristics of repetitively-pulsed electrical discharges in saline solutions used for surgical procedures*. IEEE Transactions on Plasma Science, July 2002 30(3): 1376-1383. DOI: 10.1109/TPS.2002.801612 [https://www.researchgate.net/publication/3165337\\_Plasma\\_characteristics\\_of\\_repetitively-pulsed\\_electrical\\_discharges\\_in\\_saline\\_solutions\\_used\\_for\\_surgical\\_procedures](https://www.researchgate.net/publication/3165337_Plasma_characteristics_of_repetitively-pulsed_electrical_discharges_in_saline_solutions_used_for_surgical_procedures)
72. Stalder KR, McMillen DF and Woloszko J. *Electrosurgical plasmas*. J Phys D: Appl Phys, 38 (2005) 1728-1738. <https://iopscience.iop.org/article/10.1088/0022-3727/38/11/014>







# ABSTRACTS

# ABSTRACTS

## Clinical Guidance

1. NICE – National Institute for Health and Care Excellence. *Percutaneous coblation of the intervertebral disc for low back pain and sciatica - Interventional procedures guidance*. Published: 27 January 2016, Guidance ipg543. ISBN: 978-1-4731-1632-0 <https://www.nice.org.uk/guidance/ipg543/resources/percuteaneous-coblation-of-the-intervertebral-disc-for-low-back-pain-and-sciatica-pdf-1899871925113285>

### Summary

Percutaneous coblation of the intervertebral disc for low back pain and sciatica is safe enough and works well enough for use in the NHS.

Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

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## Clinical Evidence, Meta Analyses, and Systematic Literature Reviews

2. Eichen PM, Achilles N, König V, Mösges R, Hellmich M, Himpe B, Kirchner R. *Nucleoplasty, a Minimally Invasive Procedure for Disc Decompression: A Systematic Review and Meta-analysis of Published Clinical Studies*. *Pain Physician*, 2014; 17: E149-E173. ISSN 2150-1149. PMID: 24658486 <https://pubmed.ncbi.nlm.nih.gov/24658486/>

### Abstract

**Background:** Nucleoplasty, based on Coblation® technology, is a minimally invasive procedure used to decompress herniated discs. Reviews to date – exclusively systematic reviews – recommend nucleoplasty for treating chronic back pain, although with the restriction of limited to fair evidence. We therefore aimed to summarize and interpret our calculated results, where possible comprehensively and quantitatively, using statistical methods in the context of a meta-analysis supplementing a systematic review. In the process, the central question was to statistically determine whether, and to what extent, nucleoplasty can positively affect pain relief and functional mobility as well as lower the complication rate.

**Objective:** Newly published studies made it possible to conduct a meta-analysis of the visual analog scale (VAS), a measuring instrument used to determine pain intensity, and the Oswestry Disability Index (ODI), a scale that reflects the degree of impairment in percent. In addition to having clearly sound evidence for analyzing VAS/NPS data, the present, newly compiled meta-analysis was able to summarize VAS and ODI data quantitatively and to calculate a total complication rate for the first time. It was thereby possible to make a first comparison between nucleoplasty and conservative therapy (including epidural steroid injection).

**Study design:** This meta-analysis examined all study data published in clinical trials involving the nucleoplasty procedure for plasma disc decompression.

**Methods:** A systematic search using the terms nucleoplasty and/or plasma disc decompression was conducted for literature listed in MEDLINE. Twenty-seven eligible studies (22 prospective trials and 5 retrospective trials) were included, and pooled analyses as well as various subgroup analyses (differentiation between cervical and lumbar disc herniations, comparisons with alternative treatments such as epidural steroid injection) were performed based on their data.

**Results:** Pain decreased from a baseline VAS value of 7.27 to 2.12 (postop/first day), 2.50 (one week), 2.70 (2 weeks), 3.23 (one month), 2.66 (6 weeks), 2.84 (3 months), 3.06 (6 months), 3.03 (12 months), 1.54 (18 months), and 3.69 (24 months) after nucleoplasty. The ODI value (baseline: 58.95) dropped to 28.60 (one week), 29.00 (2 weeks), 23.21 (one month), 30.00 (6 weeks), 18.30 (3 months), 22.54 (6 months), 24.43 (12 months), 12.82 (18 months), and 36.98 (24 months). Compared to baseline, significant pain reduction and improvement in functional mobility after nucleoplasty were observed at every time point. Nucleoplasty showed a total complication rate of 1.5%, with the individual rates being 0.8% for cervical and 1.8% for lumbar nucleoplasty. Nucleoplasty was superior to conservative therapy at every time point and for all 3 included parameters, at some measurement time points even significantly.

**Conclusions:** Nucleoplasty reduces pain in the long term and improves patients' functional mobility. It is an effective, low-complication, minimally invasive procedure used to treat disc herniations.

3. **Gerszten PC, Smuck M, Rathmell JP, Simopoulos TT, Bhagia SM, Mocek CK, Crabtree T, Bloch DA, SPINE Study Group. Plasma disc decompression compared with fluoroscopy-guided transforaminal epidural steroid injections for symptomatic contained lumbar disc herniation: a prospective, randomized, controlled trial. Journal of Neurosurgery, Volume 12: Issue 4 (Apr 2010). DOI: 10.3171/2009.10.SPINE09208. PMID: 20201654 <https://pubmed.ncbi.nlm.nih.gov/20201654/>**

## Abstract

**Object:** Patients with radiculopathy, with or without back pain, often do not respond to conservative care and may be considered for epidural steroid injection therapy or a disc decompression procedure. Plasma disc decompression (PDD) using the Coblation SpineWand device is a percutaneous, minimally invasive interventional procedure. The purpose of this study was to evaluate clinical outcomes with PDD as compared with standard care using fluoroscopy-guided transforaminal epidural steroid injection (TFESI) over the course of 2 years.

**Methods:** This was a multicenter randomized controlled clinical study. Ninety patients (18-66 years old) who had sciatica (visual analog scale score  $\geq$  50) associated with a single-level lumbar contained disc herniation were enrolled. In all cases, their condition was refractory to initial conservative care and 1 epidural steroid injection had failed. Participants were randomly assigned to receive either PDD (46 patients) or TFESI (44 patients, up to 2 injections).

**Results:** The patients in the PDD Group had significantly greater reduction in leg pain scores and significantly improved Oswestry Disability Index and 36-Item Short Form Health Survey ([SF-36], physical function, bodily pain, social function, and physical components summary) scores than those in the TFESI Group. During the 2-year follow-up, 25 (56%) of the patients in the PDD Group and 11 (28%) of those in the TFESI Group remained free from having a secondary procedure following the study procedure (log-rank  $p = 0.02$ ). A significantly higher percentage of patients in the PDD Group showed minimum clinically important change in scores for leg and back pain and SF-36 scores that exceeded literature-based minimum clinically important changes. Procedure-related adverse events, including injection site pain, increased leg or back pain, weakness, and lightheadedness, were observed in 5 patients in the PDD Group (7 events) and 7 in the TFESI Group (14 events).

**Conclusions:** In study patients who had radicular pain associated with a contained lumbar disc herniation, those patients treated with PDD had significantly reduced pain and better quality of life scores than those treated using repeated TFESI. In addition, significantly more PDD patients than TFESI patients avoided having to undergo a secondary procedure during the 2-year study follow-up.

# ABSTRACTS

4. **Cesaroni A, Nardi PV. Plasma disc decompression for contained cervical disc herniation: a randomized, controlled trial. *European Spine Journal* (2010), 19: 477–486. DOI: 10.1007/s00586-009-1189-0. PMCID: PMC2899766. PMID: 19902277 <https://pubmed.ncbi.nlm.nih.gov/19902277/>**

## Abstract

Prospective case series studies have shown that plasma disc decompression (PDD) using the COBLATION SpineWand device (ArthroCare Corporation, Austin, TX) is effective for decompressing the disc nucleus in symptomatic contained cervical disc herniations. This prospective, randomized controlled clinical trial was conducted to evaluate the clinical outcomes of percutaneous PDD as compared to conservative care (CC) through 1 year. Patients (n = 115) had neck/arm pain >50 on the visual analog scale (VAS) pain scale and had failed at least 30 days of failed CC. Patients were randomly assigned to receive either PDD (n = 62) or CC (n = 58). Clinical outcome was determined by VAS pain score, neck disability index (NDI) score, and SF-36 health survey, collected at 6 weeks, 3 months, 6 months, and 1 year. The PDD group had significantly lower VAS pain scores at all follow-up time points (PDD vs. CC: 6 weeks, -46.87 +/- 2.71 vs. -15.26 +/- 1.97; 3 months, -53.16 +/- 2.74 vs. -30.45 +/- 2.59; 6 months, -56.22 +/- 2.63 vs. -40.26 +/- 2.56; 1 year, -65.73 +/- 2.24 vs. -36.45 +/- 2.86; GEE, P < 0.0001). PDD patients also had significant NDI score improvement over baseline when compared to CC patients at the 6 weeks (PDD vs. CC: -9.15 +/- 1.06 vs. -4.61 +/- 0.53, P < 0.0001) and 1 year (PDD vs. CC: -16.70 +/- 0.29 vs. -12.40 +/- 1.26, P = 0.005) follow-ups. PDD patients showed statistically significant improvement over baseline in SF-36 physical component summary scores when compared to CC patients at 6 weeks and 1 year (PDD vs. CC: 8.86 + 8.04 vs. 4.24 +/- 3.79, P = 0.0004; 17.64 +/- 10.37 vs. 10.50 +/- 10.6, P = 0.0003, respectively). In patients who had neck/arm pain due to a contained cervical disc herniation, PDD was associated with significantly better clinical outcomes than a CC regimen. At 1 year, CC patients appeared to suffer a “relapse, showing signs of decline in most measurements, whereas PDD patients showed continued stable improvement”.

5. **Nardi PV, Cabezas D, Cesaroni A. Percutaneous cervical nucleoplasty using coblation technology. *Clinical results in fifty consecutive cases. Acta Neurochir* (2005) [Suppl], 92: 73–78. DOI: 10.1007/3-211-27458-8\_16. PMID: 15830972 <https://pubmed.ncbi.nlm.nih.gov/15830972/>**

## Abstract

Conventional open cervical discectomy, with or without bony fusion, in common neurosurgical knowledge is considered the standard treatment for cervical disc herniation. Percutaneous procedures are minimally invasive and offer decreased morbidity, require no bone graft and promise shorter recuperation time. Nevertheless, candidates for a percutaneous procedure as inclusion criteria must complain of symptoms related to contained herniated disc or focal protrusion. It does not substitute conventional open procedures required for extruded discs. We used the coblation technology for nucleoplasty of the cervical intervertebral discs.

Early and long-term effects and/or complications observed with this procedure have not been reported yet. Fifty consecutive patients presenting with contained herniated cervical disc or focal protrusion causing compression of the cervical roots or cervical pain underwent a nucleoplasty procedure on the pathological disc. A randomized control group of twenty patients was treated conservatively with medical and physical therapy in the same period and completed the identical follow-up form. In the nucleoplasty group results were complete resolution of symptoms in 80% of cases, only 10% referred some residual cervical or radicular pain and are still under follow-up with a wait-and-see prospective. Patients who did not have a clinical resolution were treated with alternative traditional methods (10%). Despite the relative low cases number and the limited follow-up the encouraging results induce us to utilize this technique in well-selected cases.

6. **Stronks D, Huygen F, Groeneweg G, Aukes H, Harhangi B, de Rooij J. *The Effect of Percutaneous Nucleoplasty vs Anterior Discectomy in Patients with Cervical Radicular Pain due to a Single-Level Contained Soft-Disc Herniation: A Randomized Controlled Trial.* Pain Physician, 2020 Nov; 23(6): 553-564. PMID: 33185372 <https://pubmed.ncbi.nlm.nih.gov/33185372/>**

## **Abstract**

**Background:** Cervical radicular pain (CRP) is a common problem in the adult population. When conservative treatment fails and the severe pain persists, surgical treatment is considered. However, surgery is associated with some serious risks. To reduce these risks, new minimally invasive techniques have been developed, such as percutaneous nucleoplasty. Several studies have shown that percutaneous nucleoplasty is a safe and effective technique for the treatment of CRP, but until now no randomized controlled trials have been conducted that compare percutaneous cervical nucleoplasty (PCN) to anterior cervical discectomy (ACD) in patients with a single-level contained soft-disc herniation.

**Objectives:** To compare the effects of PCN and ACD in a group of patients with CRP caused by a single-level contained soft-disc herniation.

**Study design:** A randomized, controlled, multi-center trial.

**Setting:** Medical University Center and local hospitals.

**Methods:** Forty-eight patients with CRP as a result of a single-level contained soft-disc herniation were randomized to one of the following 2 treatments: PCN or ACD. The primary outcome measure was arm pain intensity, measured with a Visual Analog Scale (VAS). Secondary outcomes were arm pain intensity during heavy effort, neck pain, global perceived effect, Neck Disability Index (NDI), and the patients' general health (Short Form Generated Health Survey [SF-36]). All parameters were measured at baseline (T0), 3 months after intervention (T2), and one year after intervention (T3). One week after the intervention (T1), an intermediate assessment of arm pain, arm pain during heavy effort, neck pain, satisfaction, and improvement were performed.

**Results:** At 3 months, the intention to treat analyses revealed a statistically significant interaction between the groups on the primary outcome, arm pain intensity, and on the secondary outcome of the SF-36 item pain, in favor of the ACD group. On the other secondary outcomes, no statistically significant differences were found between the groups over time. At 12 months, there was a trend for more improvement of arm pain in favor of the ACD group and no statistical interactions were found on the secondary outcomes.

**Limitations:** Firstly, the inclusion by the participating hospitals was limited. Secondly, the trial was ended before reaching the required sample size. Thirdly, at baseline, after the inclusion by the neurosurgeon, 13 patients scored less than 50.0 mm on the VAS. Fourthly, the withdrawal of the physiotherapy (PT) group and finally, the patients and interventionists could not be blinded for the treatment.

**Conclusions:** At 3 months, the ACD group performed significantly better on arm pain reduction than the PCN group in patients with CRP as a result of a single-level contained soft-disc hernia. However, the clinical relevancy of this treatment effect can be debated. For all parameters, after one year, no significant differences between the groups were found. When it comes to the longer-term effectiveness, we conclude that PCN can be a good alternative for ACD.

# ABSTRACTS

7. **Nikoobakht M, Yekanineajd MS, Pakpour AH, Gerszten PC, Kasch R. Plasma disc decompression compared to physiotherapy for symptomatic contained lumbar disc herniation: A prospective randomized controlled trial. Neurologia i Neurochirurgia Polska, Volume 50, Issue 1, January–February 2016, Pages 24-30. DOI: 10.1016/j.pjnns.2015.11.001. PMID: 26851686 <https://pubmed.ncbi.nlm.nih.gov/26851686/>**

## Abstract

**Introduction:** To evaluate clinical outcomes with PDD as compared with patients who underwent to standard physiotherapy intervention.

**Material and methods:** One-hundred-seventy-seven randomly assigned patients with primarily radicular pain associated with a single-level lumbar contained disc herniation were enrolled. Participants received either PDD (89 patients) or conservative physiotherapy care (88 patients).

**Results:** Patients in the PDD group had significantly greater reduction in leg pain scores and significantly improved VAS ( $p < 0.001$ ), Oswestry Disability Index ( $p < 0.05$ ), and 36-Item Short Form, than those in the physiotherapy group at 12 months. On subset analysis, patients achieved even better outcomes after PDD who: were younger, had a shorter period of radiculopathy, of male gender, and lower BMI. Patients with subacute pain reported better outcomes than those with chronic pain in the PDD group.

**Conclusions:** Patient selection for PDD over physiotherapy favored younger patients who presented with a shorter period of pain symptoms and who had a more favorable body habitus.

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8. **Chitragran R, Sompob P, Tassanawipas W. Result of Percutaneous Disc Decompression Using Nucleoplasty in Thailand: A Randomized Controlled Trial. J Med Assoc Thai, 2012 Oct; 95 Suppl 10: S198-205. PMID: 23451463 <https://pubmed.ncbi.nlm.nih.gov/23451463/>**

## Abstract

**Background:** Chronic low back pain is a major social, economic and healthcare issue in the Thailand. Percutaneous techniques are rapidly replacing traditional open surgery in operations requiring discectomy, decompression and fusion. The percutaneous access to the disc was first used in the 1950s to biopsy the disc with needles. Percutaneous access to the disc using endoscopic techniques was developed in the 1970s. Nucleoplasty has emerged as one of the minimally invasive techniques for treatment of low back pain and lower extremity pain due to contained herniated discs which utilizes coblation technology for ablating and coagulating the nucleus for a partial disc removal.

**Objective:** Evaluate the effectiveness of Nucleoplasty on pain in activity and improvement in MRI in patients with radicular or axial low back pain secondary to contained herniated discs.

**Design:** Prospective, Randomized, Control Trial.

**Material and method:** Sixty-four patients were randomized in two groups equally. Thirty-two patients had undergone Nucleoplasty and another thirty-two patients had undergone conservative treatment. Patients were evaluated at 1, 3, 6 and 12 months postoperatively and were asked to quantify their pain using a visual analog scale ranging from 0 to 10. Data were compared between baselines and at 1, 3, 6 and 12 months post-treatment. Pre-nucleoplasty MRI and Post-nucleoplasty 3 months were compared to evaluate the decrease of bulging disc.

**Results:** Reported pain and medication use were significantly decreased and functional status was improved at 1, 3, 6 and 12 months following Nucleoplasty (p-values < or = 0. 001 for all outcome measures at all time periods) and also the bulging disc was significantly decreased 3 months following nucleoplasty.

**Conclusion:** Nucleoplasty appears to be safe and effective in Thailand. Is an effective procedure for patients presenting with discogenic back and/or radicular pain that have failed conservative therapies and are not considered candidates for open surgical interventions. A result of this analysis indicated that PDD using Coblation technology, also referred to as nucleoplasty, is an effective procedure for patients presenting with discogenic back and/or leg pain who have failed conservative therapies and are not considered candidates for open surgical interventions.

9. **Manchikanti L, Falco FJE, Benyamin RM, Caraway DL, Deer TR, Singh V, Hameed H, Hirsch JA. An update of the systematic assessment of mechanical lumbar disc decompression with nucleoplasty. Pain Physician, 2013 Apr; 16(2 Suppl): SE25-54. PMID: 23615886 <https://pubmed.ncbi.nlm.nih.gov/23615886/>**

## Abstract

**Background:** Lumbar disc prolapse, protrusion, and extrusion account for less than 5% of all low back problems, but are the most common causes of nerve root pain and surgical interventions. The primary rationale for any form of surgery for disc prolapse is to relieve nerve root irritation or compression due to herniated disc material. The primary modality of treatment continues to be either open or microdiscectomy, although several alternative techniques are also utilized, including nucleoplasty, automated percutaneous discectomy and laser discectomy. There is a paucity of evidence for all decompression techniques, specifically alternative techniques including nucleoplasty.

**Study design:** A systematic review of the literature of mechanical lumbar disc decompression with nucleoplasty.

**Objective:** To determine the effectiveness and update the effectiveness of mechanical lumbar disc decompression with nucleoplasty.

**Methods:** The available literature on mechanical lumbar disc decompression with nucleoplasty was reviewed. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria as utilized for interventional techniques for randomized trials and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies. The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF) . Data sources included relevant literature identified through searches of PubMed and EMBASE from 1966 to September 2012, and manual searches of the bibliographies of known primary and review articles.

**Outcome measures:** Pain relief and functional improvement were the primary outcome measures. Other outcome measures were improvement of psychological status, reduction in 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:** For this systematic review, 37 studies were considered for inclusion. Of these, there was one randomized trial and 14 observational studies meeting inclusion criteria for methodological quality assessment. Based on USPSTF criteria, the level of evidence for nucleoplasty is limited to fair in managing radicular pain due to contained disc herniation.

**Limitations:** A paucity of literature with randomized trials.

**Conclusions:** This systematic review illustrates limited to fair evidence for nucleoplasty in managing radicular pain due to contained disc herniation.



# ABSTRACTS

10. Wullems JA, Halim W, van der Weegen W, Lim T, Aukes HA, Vissers KC, Gültuna I, Chua NHL. *The Long-term Efficacy and Safety of Percutaneous Cervical Nucleoplasty in Patients with a Contained Herniated Disk*. *Pain Pract*, 2013 Jun; 13(5): 364-71. Epub 2012 Oct 31. DOI: 10.1111/papr.12003. PMID: 23113964 <https://pubmed.ncbi.nlm.nih.gov/23113964/>

## Abstract

**Background:** Percutaneous cervical nucleoplasty (PCN) is a safe and effective treatment in symptomatic patients with contained cervical herniated disks. It provides simple and efficient disk decompression, using a controlled and highly localized ablation, but evidence regarding long-term efficacy is limited. We conducted a retrospective study to investigate the long-term efficacy and safety of PCN, and the influence of ideal selection settings.

**Methods:** A total of 27 patients treated with PCN fulfilling ideal selection criteria (Group A) were studied and compared to 42 patients not meeting these criteria (Group B). Outcomes were assessed using the Visual Analogue Scale (VAS) and a four-level Likert item for perceived pain and satisfaction, the Neck Disability Index (NDI), and the Short Form 36 (SF-36). Additional relevant outcomes were retrieved from medical records.

**Results:** The postoperative mean VAS pain for Group A was 29.9 (SD  $\pm$  32.6) at a mean follow-up of 24 months (range: 2-45). Only 10% of these patients reported mild transient adverse events. There was a trend, but no difference between both groups in pain scores; however, treatment satisfaction was higher for Group A ( $74.1 \pm 27.2$ - $55.5 \pm 31.4$ ,  $P = 0.02$ ). Group A also reported better physical functioning based on the Physical Component Summary ( $43.6 \pm 10.6$ - $37.3 \pm 12.0$ ,  $P = 0.03$ ) and showed a larger proportion of patients no longer using any medication postoperatively (63-26%,  $P = 0.01$ ).

**Conclusion:** These results show long-term effectiveness and safety of PCN in patients with a one-level contained cervical herniated disk, and the reliance of selecting patients meeting ideal criteria for successful PCN.

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11. Gerges FJ, Lipsitz SR, Nedeljkovic SS. *A systematic review on the effectiveness of the Nucleoplasty procedure for discogenic pain*. *Pain Physician*, Mar-Apr 2010;13(2):117-32. PMID: 20309378 <https://pubmed.ncbi.nlm.nih.gov/20309378/>

## Abstract

**Background:** Nucleoplasty is a minimally invasive procedure for treating pain caused by symptomatic disc herniation that is refractory to conservative therapy. Observational studies have reported differing outcomes for this procedure and thus its effectiveness is yet to be determined.

**Study design:** A systematic review of the efficacy of the nucleoplasty procedure.

**Objectives:** To assess the clinical efficacy of the nucleoplasty procedure for treating back pain from symptomatic, contained disc herniation and to evaluate the methodological quality of the included studies.

**Methods:** The relevant literature for nucleoplasty was identified through a search of the following databases: Pubmed, Ovid Medline, and the Cochrane library, and by a review of the bibliographies of the included studies.

A review of the literature of the effectiveness of the nucleoplasty procedure for managing discogenic pain was performed according to the criteria for observational studies using a 'Quality Index' scale to determine the methodological quality of the literature. The level of evidence was classified as Level I, II, or III based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF) for therapeutic interventions. Recommendations were based on the criteria developed by Guyatt et al.

**Outcome measures:** The main outcome measures evaluated were the percentage of pain relief based on visual analogue scale (VAS) or numeric rating scale (NRS), percentage of patients with more than 50% reduction in pain, percentage of patients meeting one or more success criteria after nucleoplasty, and improvement in patient function. Secondary measures noted were reports of complications and the Quality Index scores of each study that was evaluated.

**Results:** The quality of evidence for improvement in pain or function after a nucleoplasty procedure is Level II-3. The recommendation is 1C/strong for the nucleoplasty procedure based on the quality of evidence available. The median Quality Index score was 16 (range 12-19), indicating adequate methodological quality of the available literature. None of the studies reported major complications related to nucleoplasty.

**Conclusions:** Observational studies suggest that nucleoplasty is a potentially effective minimally invasive treatment for patients with symptomatic disc herniations who are refractory to conservative therapy. The recommendation is a level 1C, strongly supporting the therapeutic efficacy of this procedure. However, prospective randomized controlled trials with higher quality of evidence are necessary to confirm efficacy and risks, and to determine ideal patient selection for this procedure.

12. **Wullems JA, Halim W, van der Weegen W. Current evidence of percutaneous nucleoplasty for the cervical herniated disk: a systematic review. Pain Pract, 2014 Jul; 14(6): 559-69. Epub 2013 Oct 17. DOI: 10.1111/papr.12122. PMID: 24131742 <https://pubmed.ncbi.nlm.nih.gov/24131742/>**

## Abstract

**Background:** Although percutaneous cervical nucleoplasty (PCN) has been shown to be both safe and effective, its application is still debated. PCN applied in disk herniation has not been systematically reviewed before, resulting in a limited insight into its effectiveness and safety, and the quality of available evidence. Therefore, we systematically reviewed the evidence on the efficacy and safety of PCN in patients with a (contained) herniated disk.

**Methods:** MEDLINE, EMBASE, and the Cochrane Library (Central Register of Controlled Trials) were searched for randomized controlled trials (RCTs) and nonrandomized studies using the following keywords: 'Nucleoplasty', 'Cervical', 'Hernia', 'Herniation', 'Prolapse', 'Protrusion', 'Intervertebral disk', and 'Percutaneous disk decompression'. First, all articles were appraised for methodological quality, and then, RCTs were graded for the level of evidence according a best-evidence synthesis, because a meta-analysis was not possible. Finally, the RCTs' applicability and clinical relevance also was assessed.

**Results:** Of 75 identified abstracts, 10 full-text articles were included (3 RCTs and 7 nonrandomized studies). These studies represented a total of 1021 patients: 823 patients ( $\geq$  892 disks) were treated by PCN. All studies showed low methodological quality, except for two. The level of evidence of the RCTs was graded as moderate, with low to moderate applicability and clinical relevance.

**Conclusion:** All included studies showed PCN to be an effective and safe procedure in the treatment of (contained) herniated disks at short-, mid-, and long-term follow-up. However, the level of evidence is moderate and shows only low to moderate applicability and clinical relevance.

# ABSTRACTS

13. Alexandre A, Coro L, Azuelos A, Pellone M. *Percutaneous nucleoplasty for discoradicular conflict. Acta Neurochir Suppl, 2005; 92: 83-6. DOI: 10.1007/3-211-27458-8\_18. PMID: 15830974 <https://pubmed.ncbi.nlm.nih.gov/15830974/>*

## Abstract

Minimally invasive techniques for the treatment of degenerative pathology of the spine have come to be preferred by surgeons since the destructive effect on bony structures is eliminated and scar formation is dramatically reduced. A critical review of the pathogenetic mechanisms for low back pain and sciatalgia has recently yielded that mechanical compression is one but non-essential component of the matter. The importance of chemical irritative processes is stressed. Coblation nucleoplasty is one of these minimally invasive techniques. It provokes ablation of the nucleus of the disk by a controlled thermal effect produced by radiofrequency. By this procedure one to two ml of tissue are colliguated in a few minutes. From February 2001 to May 2003 we treated 1390 patients for of lumbosciatalgic pain caused by disc pathology. The alteration consisted of disc bulging or contained disc herniation. Exclusion criteria as provided by the protocol of the multicentric study conceived by Conor O'Neill have been respected. This technique has been conceived in order to obtain progressive results in cases of contained disc herniation which has scanty natural tendency to shrinkage, as demonstrated by several studies on the natural history of evolution of this pathology. Contained disc herniation is a pathology most difficult to manage by conservative procedures, physiotherapy and drugs, but we all agree that open surgery should be avoided. By this minimally invasive procedure the patient will not be compelled to abandon physiotherapy and his normal daily activities for more than a few days.

14. Gelalis I, Gkiatas I, Spiliotis A, Papadopoulos D, Pakos E, Vekris M, Korompilias A. *Current Concepts in Intradiscal Percutaneous Minimally Invasive Procedures for Chronic Low Back Pain. Asian J Neurosurg, Jul-Sep 2019; 14(3): 657-669. PMCID: PMC6703031. DOI: 10.4103/ajns.AJNS\_119\_17. PMID: 31497082 <https://pubmed.ncbi.nlm.nih.gov/31497082/>*

## Abstract

**Study design:** A systemic review of thermal annular procedures (TAPs) and percutaneous disk decompression procedures (PDDPs) for the treatment of discogenic chronic low back pain (CLBP) was conducted.

**Objective:** The objective of this review is to evaluate and to compare the effectiveness of TAPs and PDDPs in treating discogenic CLBP and to assess the frequency of complications associated with those procedures.

**Materials and methods:** English-language journal articles were identified through computerized searches of the PubMed database and bibliographies of identified articles and review papers. Articles were selected for inclusion if percutaneous minimally invasive procedures were the treatment options for patients with CLBP and if follow-up outcome data included evaluations of back pain severity, functional improvement, and/or incidence of complications. For this review, 27 studies were included.

**Results:** Intradiscal electrothermal therapy (IDET) procedure in properly selected patients may eliminate or delay the need for surgical intervention for an extended period, whereas few adverse effects have been reported. In contrast to IDET, there is far less literature on the effectiveness of radiofrequency annuloplasty and intradiscal biacuplasty procedures. Nucleoplasty is a potentially effective treatment option for patients with contained disc herniation, while the procedure is well tolerated. Increased success rates have been found for percutaneous laser disc decompression and automated percutaneous lumbar discectomy in strictly selected patients.

**Conclusions:** These procedures can be effective and may obviate the need for surgery completely. Further prospective randomized sham-controlled trials with higher quality of evidence are necessary to confirm the efficacy of these procedures.

15. Wu S, Li X, Lin C, Zeng W, Ma C. *CT-guided nucleoplasty with radiofrequency energy for the treatment of lumbar disk herniation*. *J Spinal Disord Tech*, 2015 Feb; 28(1): E9-16. DOI: 10.1097/BSD.000000000000132. PMID: 25023711 <https://pubmed.ncbi.nlm.nih.gov/25023711/>

## Abstract

**Study design:** A clinical randomized controlled trial.

**Objective:** This study sought to compare the clinical effectiveness of CT-guided nucleoplasty, CT-guided nucleoplasty combined with nerve root injection, and CT-guided transforaminal lumbar epidural injections in treating patients with contained lumbar disk herniation and leg pain, which are caused by radicular encroachment.

**Summary of background data:** Lumbar disk herniation is the most common cause of nerve root pain. The conservative treatment is proved to be effective for the majority of these patients, and the remaining patients are not ideal surgical candidates. Studies have found that minimally invasive percutaneous disk procedures may be preferable to open surgery in certain clinical situations. However, nucleoplasty in treating contained lumbar disk herniation and leg pain caused by radicular encroachment is still a controversy.

**Design:** A total of 97 patients with leg pain and MRI evidence of small-sized or medium-sized herniated disks correlating with the symptoms participated in the study. The patients were randomly allocated into 3 groups: the CT-guided nucleoplasty group (N=33), the CT-guided nucleoplasty with nerve root injection group (N=35), and CT-guided transforaminal lumbar epidural injections group (N=29). Numeric Rating Scale (NRS) pain score and Oswestry Disability Index (ODI) values were applied at pre-treatment and 1 week, 1 month, 3 months, and 12 months at post-treatment.

**Results:** There were statistically significant decreases ( $P=0.000$ ) in the NRS and ODI scores for all posttreatment time points when compared with the pre-treatment values in all the 3 groups. The average NRS and ODI results for the transforaminal lumbar epidural injections group were significantly higher than those for the other 2 groups at 3 and 12 months post-treatment ( $P<0.05$ ). The combination of nucleoplasty with nerve root injection produced a significantly greater reduction in the NRS and ODI scores when compared with nucleoplasty at 1 week ( $P=0.000$  for NRS and  $P=0.004$  for ODI) and 1 month ( $P=0.000$  for NRS and  $P=0.007$  for ODI) after the treatment.

**Conclusions:** The results of this study suggest that CT-guided nucleoplasty with radiofrequency energy is a relative effective and safe technique for treating leg pain caused by radicular encroachment. Furthermore, nucleoplasty combined with nerve root injection had achieved a significant greater improvement in pain management and functional level in short term (within 1 month) after treatment than nucleoplasty alone.

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## Abstract

**Background:** Nucleoplasty appears a successful minimally-invasive treatment for symptomatic contained disc herniation (protrusion). The purpose of this prospective study was to assess the effectiveness of nucleoplasty for alleviating pain and dysfunction in our patients.

**Method:** All patients who presented with established low back and/or leg pain of at least 3 months' duration were clinically followed for 1 year following the nucleoplasty procedure. Self-reported grading of pain using the Visual Analogue Scale (VAS) and the Roland Morris Disability Questionnaire (RMDQ), and subjective global rating of overall satisfaction were recorded and analysed.

# ABSTRACTS

**Results:** Eighty-three patients, aged between 20 and 65 years who were treated with nucleoplasty were included in the study. No complications were noted. At the 12-month-follow-up, the median VAS and RMDQ scores were significantly reduced in the patients who were considered successful (VAS by 6-7 points, RMDQ by 8 points) compared to the patients who were considered failed showing much less reduction. (P = 0.000 in both cases; Mann-Whitney U test.) There was no significant difference in the baseline VAS and RMDQ scores in the two groups. Patients who were considered to have failed the procedure tended to be older. Multi-level disc decompression did not appear to be a risk factor for failure.

**Conclusions:** This disc decompression procedure was a safe and effective treatment option for carefully selected patients affected by low back and leg pain due to contained disc herniation.

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## Abstract

**Background:** Cervical disc nucleoplasty is a significant and clinically demonstrated innovation in percutaneous disc decompression in case of non-herniated disc protrusions or prolapse. It allows a percutaneous decompression via a 19-gauge needle under utilization of the Coblation technique and under C-arm control. Until now the patients suffering of a cervicobrachialgia in cause of a disc prolapse had only the therapeutical solution between conservative treatment and monosegmental spondylodesis or disc prosthesis of the mentioned motion segment.

**Methods:** We wanted to demonstrate a new and practicable anatomical pathway for reaching the cervical disc prolapse comparable to the technique for discography of the cervical spine. The introducer needle is advanced into the disc under fluoroscopic guidance using a standard anterior-lateral approach. The controller delivers radiofrequency energy to quickly ablate tissue at temperatures between 50 degrees and 60 degrees C. The decompression will be done in ablation mode by rotating the device through 180 degrees for 5 s in the posterior, medial and ventral third of the cervical disc. After failed conservative treatment over an average time period of 3 months we treated 26 patients with a contained herniated prolapse or protrusion with radicular arm pain by percutaneous decompression under utilization of the Coblation technique with a controlled energy plasma-mediated field. A randomized control group of 30 patients was treated alone conservatively with medical and physical therapy in the same period.

**Results:** The average preoperative VAS was 8.8. With a follow-up time of 2-years we found an average pain reduction with the visual pain score (VAS) of 2.3 who had a further check-up. The VAS was checked 24 h, 1 week, 3, 6, 12 and 24 months postoperatively. No complications with this method were seen. Comparable to the surgically treated group the conservative patients have had a VAS of 8.4. Under using conservative treatment with physical therapy, physiotherapy, analgetics and perineural injections we have had a diminution of the VAS to 5.1 after 2 years.

**Conclusion:** The percutaneous decompression of the cervical disc protrusion with the Perc DC-Spine Wand by using the Coblation mode is a quick and safe procedure. Furthermore, one may state a persistent pain relief in the follow-up time up to 2 years after the percutaneous decompression of the disc.

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## Abstract

**Background:** Intervertebral disc herniation is a major cause of low back pain. Several treatment methods are available for lumbar disc herniation including Chemonucleolysis, open surgery, nucleoplasty, laser disc decompression, and intradiscal electrothermal therapy. The high prevalence of lumbar disc herniation necessitates a minimally invasive yet effective treatment method. In this study, we compared the outcomes of open surgery and nucleoplasty method in patients with single lumbar disc herniation.

**Materials and methods:** This study was a noninferiority randomized clinical trial conducted in one of the University Hospitals of Isfahan Medical University, The Alzahra Hospital. About 200 patients with the diagnosis of lumbar disc herniation were recruited and were assigned to either the treatment or control groups using block randomization. One group received open surgery and the other group received nucleoplasty as the method of treatment. Patients were revisited at 14 days, 1, 2, 3 months, and 1-year after surgery and were assessed for the following variables: Lower back pain, lower limb pain, common complications of surgery (e.g. discitis, infection and hematoma) and recurrence of herniation.

**Results:** The mean (standard deviation) severity of low back pain was reduced from 6.92 (2.5) to 3.43 (2.3) in the nucleoplasty group ( $P = 0.04$ ) and from 7.5 (2.2) to 3.04 (1.61) in the discectomy group ( $P = 0.73$ ). Between group difference was not statistically significant ( $P = 0.44$ ), however, time and treatment interaction was significant ( $P = 0.001$ ). The level of radicular pain evaluated 1 year after treatment was reduced from 8.1 (1.2) to 2.9 (1.2) ( $P = 0.004$ ) and from 7.89 (2.1) to 3.6 (2.5) ( $P = 0.04$ ) in the discectomy and the nucleoplasty groups respectively, significant interaction between time and treatment options was observed ( $P < 0.001$ ) while there was no significant difference between two treatment groups ( $P = 0.82$ ).

**Conclusion:** Our results show that while nucleoplasty is as effective as open discectomy in the treatment of lumbar disc herniation, it is also less invasive with higher patient compliance. Taking factors such as decreased cost and duration of the surgery, as well as faster recovery in patients into account, we suggest considering nucleoplasty as an effective method of treatment in patients with single-level disc herniation.

# ABSTRACTS

19. Luleci N, Dere K, Akbas M, Abdulkarimov V, Luleci E. *Effectiveness comparison of nucleoplasty and automatic percutaneous lumbar discectomy procedures in pain and disability scores for herniated lumbar discs. Turkiye Klinikleri J Med Sci, 2010; 30(1): 201-6. DOI: 10.5336/medsci.2008-9523 <https://www.turkiyeklinikleri.com/article/en-effectiveness-comparison-of-nucleoplasty-and-automatic-percutaneous-lumbar-discectomy-procedures-in-pain-and-disability-scores-for-herniated-lumbar-discs-57254.html>*

## Abstract

**Objective:** Percutaneous decompression approach is associated with potential complications, limitations and poor outcome. Nucleotomy is used for suction of disc material. Nucleoplasty (NP) procedure utilizes coblation technology which allows for decompression of the disc using radiofrequency energy. The aim of study is to evaluate the effectiveness of NP versus automatic percutaneous lumbar discectomy (APLD) in pain and disability scores for decompression of contained herniated discs.

**Material and Methods:** A prospective, randomized study was conducted on 189 consecutive patients with complaints of low back pain with or without leg pain secondary to a contained lumbar herniated disc. Patients were ASA I-II physical status, and aged between 19-55 years. There were 96 patients in Group NP (67 females, 29 males), and 93 patients in Group APLD (66 females, 29 males). Control examinations were performed at 1st, 6th, 12th and 18th months and pain scores and Oswestry Disability Questionnaires (ODQ) were evaluated during controls.

**Results:** The pre-procedure and post-procedure visual analog scale (VAS) scores in group APLD and NP were 6.95, 2.44 and 7.14, 2.51 respectively. The VAS scores decreased in two groups and the difference between pre-procedure and post-procedure VAS scores were statistically significant ( $p < 0.05$ ). The reduction in VAS score continued in control examinations. The pre-procedure and post-procedure ODQ scores in group APLD and NP were 41.79, 22.81 and 41.48, 22.82 respectively. These differences between pre-procedure and post-procedure scores were also statistically significant ( $p < 0.05$ ). The reduction in ODQ scores continued in control examinations. In the APLD group, there was a statistically significant prolongation in time of procedure. No complications were observed in both groups.

**Conclusion:** The results of this study demonstrated a statistically significant improvement in VAS and Oswestry index scores at 1st, 6th, 12th and 18th months in both techniques. Because NP is a short and effective technique, NP should be the first choice for the treatment of symptoms associated with contained lumbar herniated discs.

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## Abstract

**Background:** Nucleoplasty is a minimally invasive intervention used to perform disc decompression in cases of nerve root compression caused by disc herniation. It is important to find rational guidelines for choosing between nucleoplasty and microsurgery.

**Objective:** To analyze factors that may impact the results of nucleoplasty, and to validate the rational guidelines between minimally invasive treatment and open surgery.

**Study design:** Prospective, non-randomized, cohort study with a minimal follow-up period of 18 months.



**Methods:** Patients were given a neurological examination, visual analogue scale and Oswestry disability questionnaire, obligatory MRI, optional RCT, and discography, only before nucleoplasty. Patients have been divided into the following groups: Group 1 – patients with a disc protrusion treated with nucleoplasty (n = 46), which has been divided into Subgroup 1A, those with a disc protrusion size ≤ 5 mm (n = 24), and Subgroup 1B, those with a disc protrusion size 6-9 mm (n = 22); Group 2 – patients with a disc extrusion treated with nucleoplasty (n = 27); Group 3 – patients with a disc extrusion or sequester treated with microdiscectomy (n = 65).

**Outcome measures:** Clinically significant outcomes were a 50% relief of pain intensity and a 40% decrease of Oswestry Disability Index (ODI).

**Results:** A decrease of pain intensity and disability was found in all groups of patients,  $P < 0.0001$ ; SP (statistical power) = 99-100%. Subgroups 1A and 1B showed no clinically significant differences in outcome,  $P = 0.99$ ; SP = 5.3. Clinically significant results: Group 1 – 78%; 95% CI (confidence interval) [66; 90%], Group 2 – 44%; 95% CI [25; 65%], Group 3 – 93%; 95% CI [85; 98%]. Total annulus disruption increases the rate of unsatisfactory results of nucleoplasty, OR (odds ratio) = 4.5; 95% CI [1.57; 12.87] (logistic regression model,  $P = 0.0034$ ). Nucleoplasty performed in cases of uncontained disc herniation (disc extrusion) have a significantly higher rate of unsatisfactory results versus microdiscectomy, OR = 19.06; 95% CI [2.29; 68.73] (logistic regression model,  $P < 0.0001$ ).

**Limitations:** This study was limited by the small number of patients in each group.

**Conclusion:** The size of the disc protrusion does not significantly affect the outcome of nucleoplasty. The rational guideline for choosing between the 2 types of surgery is the integrity of the annulus.

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## Abstract

**Background:** Over the last several decades there has been a general trend toward reduction and minimalization in surgical treatment of chronic back pain, since open surgery brings complications in small and contained disc herniations instead of achieving expected success. Attention has been focused on percutaneous nucleoplasty due to the limited success of other minimally invasive methods, as well due to their associated complications. However, there have been few studies in the English literature with a follow-up period of more than 1 year.

**Material / methods:** Patients with chronic disc herniations having more significant radicular leg pain, who did not respond to non-invasive treatment methods and for whom open surgery was not an option were selected for percutaneous nucleoplasty application. Upon intervention, patients were prospectively questioned by an independent physician regarding pain, physical improvement, and operation satisfaction at 1, 6, 12 and 24 months. Pain was evaluated with VAS, and physical improvement was evaluated based on the Oswestry Disability Index.

**Results:** Mean VAS that was  $8.7 \pm 1.1$  before the procedure was determined to be  $3.4 \pm 1.9$  at 24 months follow-up. At the latest follow-up, 87.5% of the patients reported a 30% or higher decrease in their pain. While Oswestry scores were  $76.1 \pm 10.2$  in the beginning, they went down to  $33.9 \pm 14.9$  at the end of 2 years. The percent of those stating 'good' and 'excellent' satisfaction was 66% (23 persons) on the last follow-up.

**Conclusions:** While it is once more shown that nucleoplasty is a safe method, it is also shown that its effectiveness continues at the end of 2 years.

# ABSTRACTS

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## Abstract

**Object:** Nucleoplasty is a minimally invasive surgical procedure for disc decompression developed to treat patients with symptomatic contained herniated discs. Nucleoplasty uses nonheat-driven radiofrequency energy to ablate and coagulate the disc nucleus via a percutaneous 'discography' trajectory under fluoroscopic guidance. In this study the authors evaluated pain, functioning, and quality of life (QOL) in patients with radicular leg and back pain who underwent nucleoplasty-based percutaneous disc decompression.

**Methods:** The study was designed as a prospective nonrandomized longitudinal cohort study in an academic medical center. Sixty-seven patients (mean age 41 years) with primarily radicular pain due to a contained disc herniation underwent nucleoplasty-based decompression in an outpatient setting. Patients completed the Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, EuroQol 5D (EQ5D), and a visual analog scale (VAS) for pain preoperatively, and at 3 and 6 months after surgery. Postoperative QOL differences were assessed using the Wilcoxon signed-rank test. A surgical probe, the Perc-DLE SpineWand, was placed percutaneously into the disc after application of a local anesthetic or induction of general anesthesia to remove part of the disc (that is, a percutaneous discectomy). Nucleoplasty-treated levels were L2-3 (one case), L3-4 (five cases), L4-5 (44 cases), and L5-S1 (40 cases); there were 22 multiple treatment levels and 42 bilateral treatments. There were no infections or nerve root injuries associated with the procedure. Compared with preoperative QOL, there was a statistically significant improvement in QOL at 3 months as measured using the SF-36 Physical Component Summary (PCS) scale (mean score improvement 4.4 [p = 0.014]), the EQ5D (mean score improvement 0.22 [p = 0.001]), and the VAS for pain (mean score improvement 0.13 [p = 0.021]). Six-month results in 36 patients continued to reflect improvement as measured using the SF-36 PCS (mean score improvement 7.6 [p = 0.002]) and the EQ5D (mean score improvement 0.27 [p = 0.001]).

**Conclusions:** Nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36, EQ5D, and VAS for pain, three generic QOL outcome instruments. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. Further follow-up evaluation is underway to determine the durability of QOL improvement after nucleoplasty.

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## Abstract

Percutaneous disc decompression procedures have been performed in the past. Various percutaneous techniques such as percutaneous discectomy, laser discectomy, and nucleoplasty have been successful. Our prospective study was directly to evaluate the results of percutaneous cervical nucleoplasty (PCN) surgery for cervical disc herniation, and illustrate the effectiveness of PCN in symptomatic patients who had cervical herniated discs. From July of 2002 to June of 2005, 126 consecutive patients with contained cervical disc herniations have presented at the authors' clinic and treated by PCN. The patients' gender distribution for PCN was 65 male, 61 female. The age of patients ranged from 34 to 66 years (mean 51.9 +/- 10.2 years).

The levels of involvement were 21 cases at C3-4, 30 cases at C4-5, 40 cases at C5-6, and 35 cases at C6-7. The clinical outcomes, pain reduction and the segment stability were all recorded during this study. A clinical outcome was quantified by the Macnab standard and using VAS. The angular displacement (AD)  $\geq 11$  degrees or horizontal displacement (HD)  $\geq 3$  mm was considered to be radiographically unstable. In the results of this study, puncture of the needle into the disc space was accurately performed under X-ray guidance in all cases. There was one case where the Perc-D Spine Wand had broken in the disc space during the procedure. The partial Perc-D Spine Wand, which had broken in the disc space could not be removed by the percutaneous cervical discectomy and thus remained there. There were no recurrent cases or complications in our series. Macnab standard results were excellent in 62 cases, good in 41 cases and fair in 23 cases. The rate of excellent and good was 83.73%. The VAS scores demonstrated statistically significant improvement in PCN at the 2-week, 1, 3, 6, and 12-month follow-up visits when compared to preoperational values ( $P < 0.01$ ). There were no cases of instability following the PCN procedure. There was no significant difference in stability either preoperatively or postoperatively ( $P > 0.05$ ). Our findings confirm that PCN for the treatment of cervical disc herniation results in a good outcome without any tampering of the stability of the cervical spine. Hence, PCN as a procedure is safe, minimally invasive, less traumatic, requiring less time with an excellent clinical outcome. PCN should be performed for those patients who fail conservative medical management including medication, physical therapy, behavioral management, psychotherapy, and who are unwilling to undergo a more invasive technique such as spinal surgery.

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## Abstract

**Background:** Nucleoplasty is a minimally invasive percutaneous intradiscal coblation therapy option in patients with chronic discogenic low back pain. The purpose of this prospective study was to assess the effectiveness of nucleoplasty in our patients up to 1 year after treatment.

**Method:** All patients included in this study suffered from established back pain and/or radiating pain in the lower extremities. Age, gender, weight, body mass index (BMI) and smoking status were recorded and the clinical status of the patient documented using a visual analogue pain scale (VAS). Additionally, patients were asked to provide details regarding analgesic consumption, disability and ability to work. Nucleoplasty was carried out under fluoroscopic and CT-guidance. All treated patients were reviewed at 6 and 12 months.

**Findings:** Between April 2005 and December 2006, 96 patients underwent nucleoplasty in our department. The 69 patients reported here were followed-up to 12 months while data for eight others is available only up to 6 months. Seven patients were lost to follow-up, while eleven were excluded due to a secondary disc sequestration, either at the treated segment or elsewhere. The mean age of the 27 females (39%) and 42 males in this study was 42 years (range 18-74). The mean duration of symptoms was 30.5 months (range 1-120). Forty-two percent of patients were smokers and the mean BMI was 26.3 (17.4-42.4). 73% of treated patients experienced an improvement of more than 50% in their symptoms in the early post-operative VAS score. This was reduced to 61% at 6 months post-operatively and 58% after 1 year. A statistically significant reduction in analgesic consumption, disability and occupational incapacitation resulted from treatment with nucleoplasty.

**Conclusions:** Nucleoplasty is an effective therapy for chronic, discogenic back pain which results in significant reductions in levels of disability and incapacity for work as well as decreased analgesic consumption.

# ABSTRACTS

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## Abstract

**Introduction:** Coblation nucleoplasty is a minimally invasive method, at middle way between conservative and open surgical treatment of patients with degenerative disc disease and lumbar disc protrusion. Authors compare the outcome of patients treated through the two methods.

**Material and results:** Two groups of 80 patients each were treated through open discectomy and nucleoplasty. Patients with radicular symptoms caused by disc protrusions, having antero-posterior diameter of herniated disc less 6 mm, resistant to conservative treatment, were operated using nucleoplasty. When antero-posterior diameter of the disc herniation was > 6 mm, classical discectomy method was applied. Classical surgeries (discectomies) were performed by the senior author (D.A.), while the nucleoplasty procedures all three authors equally participated. In the first group improvement of radicular pain was immediate. At 1 year after the procedure only one-third of the patients returned to work. In the group treated through nucleoplasty improvement of pain was slow but gradual. After 1 postoperative year the VAS score of patients treated through the two methods were very close. At 3 days post nucleoplasty all patients returned to work. In this group there were not intraoperative or post-operative complications. One patient was afterwards operated through open discectomy.

**Conclusion:** Coblation nucleoplasty is a safe and efficient method to treat patients with lumbar disc protrusion.

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## Abstract

**Background:** Cervical neck pain is often caused by cervical disk pathology and may cause severe symptoms and disability. Surgeons and patients are increasingly aware of postsurgery-related complications. This simulated the clinical usage of minimally invasive treatments such as percutaneous nucleoplasty (PCN) and pulsed radio frequency (PRF). However, scientific evidence on both treatments is limited.

**Objective:** Our objective was to evaluate the efficacy of PCN compared to PRF in patients with contained cervical disk herniation.

**Methods:** A prospective randomized clinical trial was conducted including 34 patients with radicular pain due to a single contained cervical disk herniation who were treated with either PCN or PRF. Demographic data were collected, and the Medical Outcomes Study 12-Item Short Form (SF-12) Health Survey, visual analog scale (VAS), and the Neck Disability Index (NDI) were completed 1, 2, and 3 months after treatment. Treatment satisfaction and complications were recorded.

**Results:** In the PCN group (n = 17, mean age 52.4 years, 10 female / 7 male), patients were treated at C5 to C6 (8 cases) or C6 to C7 (9 cases). In the PRF group (n = 17, mean age 49.5 years, 8 female / 9 male), patients were treated at C3 to C4 (1 case), C5 to C6 (10 cases), or C6 to C7 (6 cases). At 3 months, mean pain VAS improved significantly from baseline in the PCN group (mean improvement: 43.4 points) and in the PRF group (34.0 points). However, improvement in 1 group was not superior compared to the other group (P = 0.48). No serious complications were reported.

**Conclusion:** Within 3 months, both PCN and PRF show significant pain improvement in patients with contained cervical disk herniation, but none is superior to the other. Both treatment options appear to be effective and safe in regular clinical practice.

**Keywords:** cervicobrachial neuralgia; evidence-based medicine; nerve pain; pain clinics; pulsed radiofrequency.

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### Abstract

The objective of this study was to evaluate the effectiveness of Nucleoplasty for decompression of contained herniated discs, in a prospective, single site study that evaluated 49 consecutive patients with complaints of back with or without leg pain secondary to a contained focal protrusion. Access to the disc was obtained via the posterolateral discography approach, with a 17-gauge introducer needle inserted through the annulus and into the nucleus. The introducer remained in place within the outer annulus during the entire procedure, providing access for the SpineWand into the nucleus. The procedure was performed on an outpatient basis. One-month, three-month, six-month and twelve-month outcomes were assessed by the treating physician and support staff. Success was defined as a minimum 2-point reduction on a Visual Analog Scale (VAS), patient satisfaction, absence of narcotic use, and return to work if not working secondary to back pain. The pre-procedure and post-procedure VAS differences were 4.28 (p<0.001), 4.66 (p<0.001), 4.75 (p<0.001), and 3.3 (p=0.002) at the one-month, three-month, six-month, and twelve-month intervals respectively. Overall, there was a 79% success rate, with 67% success in the group of patients that had previous surgery and 82% success in the group that had no prior surgical intervention. Results indicate that Nucleoplasty may be a promising and efficacious minimally invasive procedure for the treatment of symptoms associated with contained herniated discs. Randomized, controlled studies with subgroup analysis are required to further delineate the role for this procedure.

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### Abstract

The intervertebral disc is the focal point of pathology for most low back pain. Contained disc herniation is a common cause of low back pain and, when unresponsive to conservative measures, is often treatable by disc decompression. To evaluate the safety and efficacy of percutaneous disc decompression using Coblation (Nucleoplasty) in the treatment of back and/or leg pain associated with contained disc herniation, a prospective, nonrandomized cohort analysis was conducted in an interventional pain management practice. Patients were followed for 12 months post procedure. Eighty patients who presented with discogenic low back pain with or without radicular pain associated with contained disc herniation underwent percutaneous disc decompression using Coblation technology (Nucleoplasty) after failing at least 3 months of conservative and injection therapies. Overall, 75% of patients indicated a decrease in their numeric pain scores at 12 months with a statistically significant reduction in numeric pain scores of 2.43 +/- 2.47 (p<0.0001) compared to baseline. A total of 54% of patients indicated pain relief of 50% or more at 12 months. Additionally, significant improvement was reported by 54%, 44%, and 49% of patients in sitting, standing and walking abilities, respectively, at 12 months. There were no instances of complications. These results indicate that disc decompression using Coblation (Nucleoplasty) is a safe and efficacious procedure for reducing discogenic low back pain with or without leg pain.

# ABSTRACTS

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## Abstract

**Study design:** A prospective study of all patients with either mechanical back pain or radicular back pain who underwent nucleoplasty and were followed up prospectively.

**Objective:** To investigate the effectiveness of nucleoplasty procedure in terms of pain and quality of life using the visual analog scale and Oswestry disability questionnaires.

**Summary of background data:** Nucleoplasty is a method of increasing popularity in the past few years. It has a role when dealing with pain of spinal origin either radicular or both radicular and mechanical after conservative treatment has failed and before open procedure.

**Methods:** Eighty-seven patients with a minimal follow-up of 1 year were prospectively followed after they underwent nucleoplasty procedure for either radicular or a combination of radicular and mechanical low back pain. All patients underwent physical examination and completion of visual analog scale score and Oswestry Disability questionnaires after 1, 3, 6, and 12 months. Thirty-nine of them were followed after 2 years.

**Results:** After 1 month, 66 patients (76%) were satisfied with the results. After 3 months, 60 patients (69%) had significant pain relief, whereas in 27 cases (31%) there was no improvement. After 6 months of follow-up, 57 patients (66%) had pain relief and in 30 cases (34%) there was no effect. At 12 months of follow-up, 55 patients (65%) showed good results and 30 patients (35%) had no effect. In the case of the 39 patients who were followed for 24 months, 23 patients (59%) had significant pain relief. A statistically significant reduction in the Oswestry index was also noted for the series in all intervals. Minor complication occurred in 23 patients (26%) who had transient discomfort and burning pain at the insertion site of the nucleoplasty wire.

**Conclusions:** We concluded that the nucleoplasty technique is a safe and effective procedure for radicular or combined radicular and mechanical low back pain and should be used in selected cases before open surgery after conservative treatment has failed.

30. Masala S, Massari F, Fabiano S, Ursone A, Fiori R, Pastore F, Simonetti G. *Nucleoplasty in the treatment of lumbar diskogenic back pain: one year follow-up. Cardiovasc Intervent Radiol, May-Jun 2007; 30(3): 426-32. DOI: 10.1007/s00270-006-0223-4. DOI: 10.1007/s00270-006-0223-4. PMID: 17278033 <https://pubmed.ncbi.nlm.nih.gov/17278033/>*

## Abstract

**Purpose:** The spine is an important source of pain and disability, affecting two thirds of adults at some time in their lives. Treatment in these patients is mainly conservative medical management, based on medication, physical therapy, behavioral management, and psychotherapy, surgery being limited to elective cases with neurologic deficits. This study was carried out to evaluate the efficacy of percutaneous nucleoplasty in patients affected by painful diskal protrusions and contained herniations.



**Methods:** From February 2004 to October 2005, 72 patients (48 men, 24 women; mean age 48 years) affected by lumbar disk herniation were treated with nucleoplasty coblation. All patients were evaluated clinically and with radiography and MRI in order to confirm the presence of lumbalgic and/or sciatalgic pain, in the absence of major neurologic deficit and with lack of response after 6 weeks of conservative management.

**Results:** Average preprocedural pain level for all patients was 8.2 (on a visual analog scale of 1 to 10), while the average pain level at 12 months follow-up was 4.1. At the 1 year evaluation, 79% of patients demonstrated a statistically significant improvement in numeric pain scores ( $p < 0.01$ ): 17% (12 patients) were completely satisfied with complete resolution of symptoms, and 62% (43 patients) obtained a good result.

**Conclusion:** Our data indicate that nucleoplasty coblation is a promising treatment option for patients with symptomatic disk protrusion and herniation who present with lumbalgic and/or sciatalgic pain, have failed conservative therapies, and are not considered candidates for open surgery.

31. Mirzai H, Tekin I, Yaman O, Bursali A. *The results of nucleoplasty in patients with lumbar herniated disc: a prospective clinical study of 52 consecutive patients.* *Spine J*, Jan-Feb 2007; 7(1): 88-92; discussion 92-3. DOI: 10.1016/j.spinee.2006.02.033. Epub 2006 Nov 20. PMID: 17197339 <https://pubmed.ncbi.nlm.nih.gov/17197339/>

## Abstract

**Background context:** Nucleoplasty is a minimally invasive, percutaneous procedure that uses radiofrequency energy to ablate nuclear material and create small channels within the disc.

**Purpose:** To evaluate the efficacy of nucleoplasty technique in patients with leg pain caused by radicular encroachment.

**Study design / setting:** A prospective clinical study of subjects with lumbar disc herniation, and radicular pain resistant to previous medical treatment and physiotherapy for a period of at least 3 months.

**Patient sample:** Fifty-two consecutive patients with leg pain and magnetic resonance imaging evidence of small and medium-sized herniated discs correlating with the patient's symptoms (contained disc herniation <6 mm, with a disc height  $\geq 50\%$  in comparison to normal adjacent discs) were included.

**Outcome measures:** Visual analogue scale (VAS) was administered and Oswestry disability questionnaires were filled out at pre-procedure and post-procedure 2 weeks, 6 months, and 1 year. Reduction of analgesic treatment and the patients' satisfaction were also recorded.

**Methods:** All procedures were performed under local anesthesia and fluoroscopic guidance on an outpatient basis. Patients underwent discography to evaluate annular integrity just before nucleoplasty. Channels were created in the nucleus by advancing the radiofrequency probe (ablating) and withdrawing it (coagulation). In all patients six channels were created.

**Results:** Thirty-four patients had one and 18 had two discs treated; a total of 70 procedures were performed. Mean age of patients was 44.8 $\pm$ 8.6 years. The mean follow-up period was 12.1 $\pm$ 1.6 months. Mean VAS reduced from pre-procedure 7.5 to 3.1 at post-procedure 6 months and to 2.1 at the latest follow-up. Mean Oswestry index decreased from 42.2 to 24.8 at 6 months and to 20.5 at the latest examination. Analgesic consumption was stopped or reduced in 42 patients (85%) at 6 months and in 46 patients (94%) 1 year after the procedure. Overall patient satisfaction was 81% at 2 weeks, 85% at 6 months, and 88% at the latest follow-up. There were no complications related to the procedures.

**Conclusions:** Our results encourage us to use nucleoplasty in carefully selected patients with leg pain caused by radicular encroachment. We recommend applying this minimally invasive technique only in those patients with small (<6 mm) contained disc herniations, with a disc height of  $\geq 50\%$  and with annular integrity.



# ABSTRACTS

32. Kallás JL, Godoy BL, Andraus CF, de Carvalho FG, Andraus MEC. *Nucleoplasty as a therapeutic option for lumbar disc degeneration related pain: a retrospective study of 396 cases*. *Arq Neuropsiquiatr*, 2013 Jan; **71(1)**: 46-50. DOI: 10.1590/s0004-282x2012005000013. Epub 2012 Dec 18. PMID: 23249972 <https://pubmed.ncbi.nlm.nih.gov/23249972/>

## Abstract

**Objectives:** To make a retrospective analysis and evaluate a clinical response to the control of disc degeneration related pain of 396 patients submitted to percutaneous lumbar nucleoplasty; and to make a record of visual analogical scale (VAS) up to a three-year follow-up after the surgical procedure.

**Methods:** Analysis of VAS score in 396 patients with lumbar disc degeneration related pain, according to anamnesis, clinical examination and magnetic resonance imaging (MRI), without improvement of previous clinical treatment, submitted to percutaneous nucleoplasty.

**Results:** A total of 26% of the patients presented 100% remission of pain or paresthesia, of whom 75% showed at least 50% of pain improvement. The median VAS pain improvement was about 67%.

**Conclusions:** The median VAS improvement in inferior disc levels was higher than four points. The VAS showed improvement of the pain and paresthesia up to a three-year follow up after the surgical procedure.

33. Singh V, Piryani C, Liao K. *Role of percutaneous disc decompression using coblation in managing chronic discogenic low back pain: a prospective, observational study*. *Pain Physician*, 2004 Oct; **7(4)**: 419-25. PMID: 16858482 <https://pubmed.ncbi.nlm.nih.gov/16858482/>

## Abstract

**Background:** Percutaneous disc decompression using Coblation (Nucleoplasty™) implements the principle of volumetric reduction to achieve disc decompression and reduce intradiscal pressure. Previous analyses have shown that Nucleoplasty achieves reduction in volume and intradiscal pressure with minimal damage to surrounding tissue in the treated disc.

**Objective:** To determine effectiveness of Nucleoplasty in patients with discogenic back pain.

**Study design:** A prospective, non-randomized, observational study.

**Methods:** Forty-seven patients presenting with predominant back pain undergoing treatment with the Nucleoplasty procedure using Coblation technology were included in this analysis. Patients were followed at 1 month, 3 months, 6 months, and 12 months after the procedure. A numeric pain scale of 0 to 10, percent pain relief, and improvement in functional status as determined on the basis of their ability to sit, stand, and walk.

**Results:** The proportion of patients who reported 50% or more pain relief was 80%, 74%, 63% and 53% at the 1, 3, 6 and 12 months follow-up time periods, respectively. Functional improvements were reported by 46% of patients for sitting ability, 41% for standing ability, and 49% for walking ability at 12 months. There were no complications observed due to the Nucleoplasty procedure.

**Conclusion:** Nucleoplasty for disc decompression is one of the least-invasive techniques in the minimally invasive category, thus far exhibiting a very low incidence of complications. Although no long-term data are available, these preliminary results indicate that the Nucleoplasty procedure is a safe and moderately effective procedure for reducing pain in patients presenting with predominant discogenic low back pain associated with contained disc herniation.

34. Li S, Chen R, Chen Y, Mo G, Zhang L, Xie P, Wang Q, Liu B, Dong J, Rong L. *Therapeutic Effects and Safety of Percutaneous Disc Decompression with Coblation Nucleoplasty in Cervical Vertigo: A Retrospective Outcome Study with 74 Consecutive Patients and Minimum 1-Year Follow-Up.* *Pain Physician*, 2019 May; 22(3): E205-E214. PMID: 31151343 <https://pubmed.ncbi.nlm.nih.gov/31151343/>

## Abstract

**Background:** Surgical treatment of cervical vertigo has been rarely reported. This is the first retrospective study to evaluate the clinical outcomes of percutaneous disc decompression with coblation nucleoplasty (PDCN) for treatment of cervical vertigo.

**Objectives:** To assess the clinical outcomes of patients with cervical vertigo who failed to improve with conservative care and who were subsequently treated with PDCN.

**Study design:** This study used a retrospective design.

**Setting:** The research was conducted within an interventional vertigo management and spine practice.

**Methods:** Seventy-four consecutive patients with cervical vertigo underwent PDCN and were followed for at least one year. Outcome measures included the dizziness intensity Visual Analog Scale (VAS), dizziness frequency, the Dizziness Handicap Inventory (DHI), and neck pain intensity. Clinical efficacy was assessed by rating scale and the modified MacNab evaluation criteria. Surgical complications during the operation and follow-up were also recorded.

**Results:** The vertigo VAS score, frequency of dizziness, DHI, and neck pain intensity were all decreased significantly from evaluation before surgery to one week after surgery and to the last follow-up, giving a mean effective rate of 94.6% one week after surgery and 90.6% at the last follow-up. Good to excellent results were attained in 85.1% of these patients one week after PDCN and in 75.7% of the sufferers at the last follow-up ( $P < 0.001$ ). There were 5 patients with transient adverse effects (6.25%) reported within the first month after surgery; they all recovered after conservative treatment. No neurological complications were found and no patient went on to spinal fusion surgery thereafter.

**Limitations:** The rate of follow-up was 70% and a placebo effect cannot be excluded. There is no gold standard for the diagnosis and treatment of cervical vertigo so far.

**Conclusion:** The clinical outcomes of PDCN for cervical vertigo were satisfactory in both the early and late postoperative period. PDCN is an effective, low-complication, minimally invasive procedure used to treat cervical vertigo. Further prospective randomized controlled trials are essential to verify this conclusion.

# ABSTRACTS

35. Bonaldi G, Baruzzi F, Facchinetti A, Fachinetti P, Lunghi S. *Plasma Radio-Frequency-Based Diskectomy for Treatment of Cervical Herniated Nucleus Pulposus: Feasibility, Safety, and Preliminary Clinical Results*. *AJNR Am J Neuroradiol*, Nov-Dec 2006; 27(10): 2104-11. PMID: 17110676 <https://pubmed.ncbi.nlm.nih.gov/17110676/>

## Abstract

**Background and purpose:** Several techniques, including chymopapain, mechanical aspiration, laser-based disk decompression, and endoscopic keyhole surgery, have been proposed as minimally invasive alternatives to fusion for treating cervical disk herniation, though none has gained wide acceptance. The purpose of this study was to assess feasibility, safety, and preliminary clinical results of percutaneous plasma-mediated radio-frequency-based diskectomy for cervical disk herniation.

**Methods:** Patients (N = 55) with cervical soft disk protrusion were treated over a 29-month period. They had radicular pain; 3 patients also had moderate myelopathy. The procedure was performed with the Perc-DC SpineWand by using an anterior approach. Most cases were conducted with local anesthetic on an outpatient basis. Clinical outcomes were graded by using the Macnab criteria.

**Results:** At 2 months, outcomes were good or excellent in 44/55 (80%) patients; the success rate was similar at 6 months, when 44 (85%) patients (n = 52/55) had good or excellent results. One clinically relevant complication (infectious diskitis) occurred within the first month post-procedure and was successfully treated. One technical complication (*in situ* rupture of the device tip) was observed; however, the patient remained asymptomatic during the 2-year follow-up. The 3 patients with clinical myelopathy experienced regression of cord compression symptoms; MR imaging in 2 patients showed morphologic evidence of reduction of cord compression.

**Conclusions:** Plasma radio-frequency-based diskectomy in the cervical spine appears to be a minimally invasive low-risk approach, which is easy to perform, associated with only minimal discomfort to the patient, and effective in the short term.

36. Kumar NS, Shah SM, Tan BWL, Juned S, Yao K. *Discogenic axial back pain: is there a role for nucleoplasty?* *Asian Spine J*, 2013 Dec; 7(4): 314-21. Epub 2013 Nov 28. DOI:10.4184/asj.2013.7.4.314. PMID: 24353849 <https://pubmed.ncbi.nlm.nih.gov/24353849/>

## Abstract

**Study design:** A prospective observational study.

**Purpose:** To evaluate the role of nucleoplasty in the management of discogenic axial back pain; to determine the influence of concordant pain during provocative discography, annular tear and loss of disc height on the outcome of nucleoplasty.

**Overview of literature:** The role of nucleoplasty in the management of radicular leg pain due to disc herniation is known. However, the data regarding its role in the management of discogenic axial back pain is scarce.

**Methods:** A prospective evaluation of 30 patients with discogenic axial back pain undergoing nucleoplasty was performed. Pain, functional disability and quality of life were assessed using the 100 mm visual analogue scale (VAS), Oswestry Disability Index (ODI) and Short Form-36 (SF-36), respectively.

**Results:** The mean reduction in VAS was 31.03 and 29.03; mean reduction in ODI was 24.53 and 20.60; and mean increment in SF-36 was 13.58 and 12.30, at 6 months and at 12 months, respectively. The differences were statistically significant ( $p < 0.05$ ). Concordant pain during provocative discography, annular tear and loss of disc height did not affect a clinically significant improvement in any of the three outcomes ( $p = 0.882, 0.213, \text{ and } 0.170$ ; respectively).

**Conclusions:** Nucleoplasty produced statistically significant improvements in pain, functional disability and quality of life in patients with discogenic low back pain at 6 months and at 12 months. Concordant pain during provocative discography, annular tear and loss of disc height did not influence any of the outcomes after nucleoplasty in patients with discogenic axial back pain.

37. Yan D, Li J, Zhu H, Zhang Z, Duan L. *Percutaneous cervical nucleoplasty and percutaneous cervical discectomy treatments of the contained cervical disc herniation. Arch Orthop Trauma Surg, 2010 Nov; 130(11): 1371-6. Epub 2010 Jan 8. DOI: 10.1007/s00402-009-1041-3. PMID: 20058017 <https://pubmed.ncbi.nlm.nih.gov/20058017/>*

## Abstract

**Background:** There were no studies in literature to compare the clinical outcomes of percutaneous nucleoplasty (PCN) and percutaneous cervical discectomy (PCD) in contained cervical disc herniation.

**Methods:** A retrospective of patients with symptomatic contained cervical disc herniated were operated on with PCN and PCD from June 2003 to July 2005. Two-hundred and four patients initially fulfilled the study criteria, and 28 patients were lost in follow-up. The patients were categorized into different groups depending on the procedure by PCN (81 cases) or PCD (95 cases).

**Results:** The clinical outcomes, pain reduction, and segment stability were recorded during this study. Puncture of the needle into the disc space was accurately performed under C-arm fluoroscopy guidance in all cases and no intraoperative deaths were reported in our study. At the end, 176 cases had follow-up and 28 cases were lost, and the follow-up rate was 88.0% (81/92) in the PCN group and 84.8% (95/112) in the PCD group. The follow-up time ranged from 16 to 48 months (average 29 months), and on an average of  $28.86 \pm 4.52$  months on PCN and  $8.42 \pm 3.21$  months on PCD ( $t = -0.24, P = 0.81, >0.05$ ). The operation time averages of PCN and PCD are  $4.67 \pm 1.16$  and  $11.95 \pm 1.80$ , respectively ( $P < 0.01$ ). The pain index improved from  $7.12 \pm 1.13$  to  $2.74 \pm 0.89$  ( $t = 27.03, P = 0.0000, <0.001$ ) in PCN patients and from  $7.18 \pm 1.09$  to  $2.71 \pm 0.91$  ( $t = 29.57, P = 0.0000, <0.001$ ) in PCD patients. Clinical results of PCN were excellent in 31 cases, good 32 cases, fair 13 cases, and poor 5 cases; for PCD, the results were 33, 42, 12, and 7 cases, respectively, and 1 in discitis. Good and excellent was 78.4% (77.8% in PCN and 79.5% in PCD,  $P > 0.05$ ). There was one case of PCN that had the partial Perc-D SpineWand broken in the disc space, cannot be moved by the percutaneous cervical discectomy, and remained there itself. One of the cases had discitis in this study after PCD. Patient presented with neck pain and associated radicular pain and numbness in the left upper-limb after 8 days of PCD. There were no instable cases after procedures of PCN and PCD. There was no significant difference in stability of pre-operative and post-operative between PCN and PCD ( $P > 0.05$ ).

**Conclusions:** PCN and PCD treatments of contained cervical disc herniation show good outcomes and there was no difference in the stability of cervical spine. PCN and PCD are safe, minimally invasive, and no differences were observed between the methods in clinical outcome.

# ABSTRACTS

38. Ren D-J, Liu X-M, Du S-Y, Sun T-S, Zhang Z-C, Li F. *Percutaneous Nucleoplasty Using Coblation Technique for the Treatment of Chronic Nonspecific Low Back Pain: 5-year Follow-up Results*. *Chin Med J (Engl)*, 2015 Jul 20; 128(14): 1893-7. DOI: 10.4103/0366-6999.160518. PMCID: PMC4717925. PMID: 26168829 <https://pubmed.ncbi.nlm.nih.gov/26168829/>

## Abstract

**Background:** This study evaluated the efficacy of percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific low back pain (LBP), after 5 years of follow-up.

**Methods:** From September 2004 to November 2006, 172 patients underwent percutaneous nucleoplasty for chronic LBP in our department. Forty-one of these patients were followed up for a mean period of 67 months. Nucleoplasty was performed at L3/4 in 1 patient; L4/5 in 25 patients; L5/S1 in 2 patients; L3/4 and L4/5 in 2 patients; L4/5 and L5/S1 in 7 patients; and L3/4, L4/5, and L5/S1 in 4 patients. Patients were assessed pre-operatively and at 1 week, 1 year, 3 years, and 5 years post-operatively. Pain was graded using a 10-cm Visual Analogue Scale (VAS) and the percentage reduction in pain score was calculated at each post-operative time point. The Oswestry Disability Index (ODI) was used to assess disability-related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria.

**Results:** There were significant differences among the pre-operative, 1-week post-operative, and 3-year post-operative VAS and ODI scores, but not between the 3- and 5-year post-operative scores. There were no significant differences in age, sex, or pre-operative symptoms between patients with effective and ineffective treatment, but there were significant differences in the number of levels treated, Pfirrmann grade of intervertebral disc degeneration, and provocative discography findings between these two groups. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up.

**Conclusions:** Although previously published short- and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, our long-term follow-up results show a significant decline in patient satisfaction over time. Percutaneous nucleoplasty is a safe and simple technique, with therapeutic effectiveness for the treatment of chronic LBP in selected patients. The technique is minimally invasive and can be used as part of a stepwise treatment plan for chronic LBP.

39. P Pandolfi M, Galli F, Borelli A, Gurgitano M, Liguori A, Carrafello G. *Percutaneous cervical coblation as therapeutic technique in the treatment of algo-dysfunctional pain of discal herniation*. *Radiol Med*, 2021 Jun; 126(6): 860-868. Epub 2021 Feb 23. DOI: 10.1007/s11547-021-01336-w. PMCID: PMC8154794. PMID: 33620665 <https://pubmed.ncbi.nlm.nih.gov/33620665/>

## Abstract

**Objective:** To confirm the validity of coblation nucleoplasty in reduction of cervical discogenic nature.

**Study design:** In a monocentric prospective clinical observational study recruiting 20 patients, treated with percutaneous coblation for cervical discogenic pain in 16 months in our hospital, we have clinically evaluated 18 patients. The pain was scored with the Visual Analogic Scale (VAS) in a pre-procedural questionnaire, 3/4 monthly follow-up from treatment and, finally, in a long-term follow-up 2 years after procedure.

**Results:** The mean pre-procedural VAS score was  $7.9 \pm 1.6$  (95%-Confidence Interval 7.198-8.634), while the mean post-procedural score after 3-4 months has been  $2.5 \pm 3.1$  (95%-Confidence Interval 1.089-3.965) and  $2.5 \pm 2.5$  (95%-Confidence Interval 1.367-3.687) after 2 years. Among 18 patients, in the shortly post-treatment follow-up, nine had a complete pain relief, four had a > 50% VAS reduction, two had a < 50% VAS reduction, three did not have any variation of VAS; after 2 years, six patients had a total pain resolution, eight had a > 50% VAS reduction, two had a < 50% VAS reduction, two did not have any benefit. No peri- and post-procedural complication has been observed.

**Conclusions:** In a spite of a little sample, our results showed coblation as a valid therapeutic option to reduce cervical discogenic pain in medicine-refractory patients, as an alternative or a previous choice before a more invasive surgical treatment.

40. **Ebrahim KS, Shehaby A AI, Wardany M AI, Darwish A, Awad M. Percutaneous image guided lumbar disc nucleoplasty: a minimal invasive technique for lumbar disc decompression. Pan Arab J Neurosurgery, 2010; 14 (2): 51-55. P-ISSN: 1319-6995 <https://vlibrary.emro.who.int/imemr/percutaneous-image-guided-lumbar-disc-nucleoplasty-a-minimal-invasive-technique-for-lumbar-disc-decompression-2/>**

### Abstract

Nucleoplasty is a minimally invasive, percutaneous procedure that uses radiofrequency energy to ablate nuclear material and create small channels within the disc. To evaluate the efficacy of nucleoplasty technique in patients with leg pain caused by radicular encroachment. This study was performed on 29 patients [23 males and 6 females] with lumbar disc prolapse causing unilateral sciatica with or without lower back pain for duration more than 3 months with no response to conservative treatment [in the form of medications, bed rest, and physiotherapy] in the period from November 2006 to November 2008. The Perc-D Spine Wand with 1 mm diameter and bipolar tip was used for coblation and the coagulation on the disc utilizing both radiofrequency coblation technology and thermal technology using a radiofrequency Arthrocare™ generator system 2000 [Arthrocare Corporation™], Sunnyvale, CA] to generate coblation and coagulation energy. The mean visual analogue score [VAS] for the treated patients preoperative was 8.3 and there was significant reduction in VAS in follow-up visits with the mean VAS = 3.4, 3.2, 2.5, 3.1, 3.5 at 1 week, 1 month, 3 months, 6 months, and 1 year duration respectively. All patients were satisfied with the procedure and the degree of pain relieved at all follow-up visits. Percutaneous image guided lumbar disc decompression using nucleoplasty technique seems to be an effective, safe, simple and minimal invasive procedure for relief for sciatica due to lumbar disc prolapse in well selected cases. Nonetheless a longer follow-up period and a larger number of patients is needed to assess the long-term efficacy of this procedure.

41. **Reddy A S, Loh S, Cutts J, Rachlin J, Hirsch J A. New approach to the management of acute disc herniation. Pain Physician, 2005 Oct; 8(4): 385-90. PMID: 16850062 <https://pubmed.ncbi.nlm.nih.gov/16850062/>**

### Abstract

**Background:** Over 500,000 percutaneous disc decompression procedures have been performed in the past 20 years. Various percutaneous techniques include chemonucleolysis, percutaneous lumbar discectomy, and laser discectomy which have reported success rates in the 70% to 75% range. This retrospective evaluation of 49 patients who underwent nucleoplasty procedures for treatment of herniated discs, evaluates the effectiveness of nucleoplasty in the reduction of pain, improvement of functional activity, and reduction of pain medication.

**Objective:** To illustrate the effectiveness of nucleoplasty in reducing low back pain in symptomatic patients with contained herniated discs.

**Study design:** A retrospective, non-randomized study.

# ABSTRACTS

**Methods:** Forty-nine patients with either axial or radicular low back pain who had undergone the nucleoplasty procedure were included in this analysis. Patients were categorized in one of three different groups depending on time elapsed since the procedure was performed: less than 6 months, between 6 months and 1 year, and greater than 1 year. Pain reduction, work impairment, leisure impairment, medication use and patient satisfaction were all recorded during this study. Pain was quantified using a numeric pain scale from 0 to 10. Work and leisure impairment were measured on a scale of 1 to 5, with 1 signifying no impairment and 5 signifying extreme impairment. Medication use and patient satisfaction were also measured on a scale of 1 to 5.

**Results:** Significant pain relief, functional improvement, and a decrease in medication use were achieved following nucleoplasty. There were no complications associated with the procedure.

**Conclusion:** Nucleoplasty should be used in those patients who fail conservative medical management including medication, physical therapy, behavioral management, psychotherapy, and who are unwilling to undergo a more invasive technique such as spinal surgery.

42. Bhagia SM, Slipman CW, Nirschl M, Isaac Z, El-Abd O, Sharps LS, Garvin C. *Side effects and complications after percutaneous disc decompression using coblation technology. Am J Phys Med Rehabil, 2006 Jan; 85(1): 6-13. DOI: 10.1097/01.phm.0000184153.98344.a4. PMID: 16357543 <https://pubmed.ncbi.nlm.nih.gov/16357543/>*

## Abstract

**Objective:** To report the short-term side effects and complications after percutaneous disc decompression utilizing coblation technology.

**Design:** Following institutional review board approval, consecutive patients who were to undergo percutaneous disc decompression using coblation technology (nucleoplasty) were prospectively enrolled. Patients were questioned preoperatively, postoperatively, and 24 hrs, 72 hrs, 1 wk, and 2 wks post-procedure by an independent reviewer regarding 17 possible symptom complications, which included bowel or bladder symptoms, muscle spasm, new pain, numbness/tingling or weakness, fevers / chills, rash / pruritus, headaches, nausea / vomiting, bleeding, and needle insertion site soreness. Statistical analysis was performed using Wilcoxon's signed-rank test.

**Results:** A total of 53 patients enrolled, of whom four patients dropped out. Two patients had increased symptoms and opted for surgery. Two patients could not be contacted. The most common side effects at 24 hrs post-procedure was soreness at the needle insertion site (76%), new numbness and tingling (26%), increased intensity of pre-procedure back pain (15%), and new areas of back pain (15%). At 2 weeks, no patient had soreness at the needle insertion site or new areas of back pain; however, new numbness and tingling was present in 15% of patients. Two patients (4%) had increased intensity of pre-procedure back pain. There were statistically significant reductions in visual analog scale score for back pain and leg pain ( $P < 0.05$ ).

**Conclusions:** Based on this preliminary data, nucleoplasty seems to be associated with short-term increased pain at the needle insertion site and increased pre-procedure back pain and tingling numbness but without other side effects.



43. Zhu H, Zhou X-Z, Cheng M-H, Shen Y-X, Dong QR. *The efficacy of coblation nucleoplasty for protrusion of lumbar intervertebral disc at a two-year follow-up*. *Int Orthop*, 2011 Nov; 35(11): 1677-82. Epub 2011 Jan 15. DOI: 10.1007/s00264-010-1196-0. PMCID: PMC3193964. PMID: 21240606 <https://pubmed.ncbi.nlm.nih.gov/21240606/>

### Abstract

**Purpose:** The purpose of this study was to evaluate longer-term efficacy over a two-year follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc.

**Methods:** Forty-two cases of protruded lumbar intervertebral disc treated by coblation nucleoplasty followed-up for two years were analysed. Relief of low back pain, leg pain and numbness after the operation were assessed by visual analogue pain scale (VAS). Function of lower limb and daily living of patients were evaluated by the Oswestry Disability Index (ODI).

**Results:** Operations were performed successfully in all cases. Three patients had recurrence within a week of the procedure. Evaluation of the 42 patients demonstrated significant improvement rate of VAS: defined as 66.2% in back pain, 68.1% in leg pain, and 85.7% in numbness at one-week after the operation; 53.2%, 58.4%, 81.0% at one-year; and 45.5%, 50.7%, 75.0% at two-year follow-up. One week after the operation, obvious amelioration occurred in all the patients, but the tendency decreased. Before operation, the mean value of ODI was  $68.2 \pm 10.9\%$ . The value at one week was  $28.6 \pm 8.2\%$ ; one-year at  $35.8 \pm 6.5\%$ ; and two-years at  $39.4 \pm 5.8\%$ .

**Conclusion:** Coblation nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as two-year follow-up, but longer-term benefit still needs verification.

44. Adakli B, Turhan KSC, Asik I. *The comparison of the efficacy of radiofrequency nucleoplasty and targeted disc decompression in lumbar radiculopathy*. *Bosn J Basic Med Sci*, 2015 Apr 25; 15(2): 57-61. DOI: 10.17305/bjbm.2015.427. PMCID: PMC4469937. PMID: 26042514 <https://pubmed.ncbi.nlm.nih.gov/26042514/>

### Abstract

Chronic low back pain is a common clinical condition causing medical, socioeconomic, and treatment difficulties. In our study, we aimed to compare early and long-term efficacy of lumbar radiofrequency thermocoagulation (RFTC) nucleoplasty and targeted disc decompression (TDD) in patients with lumbar radiculopathy in whom previous conventional therapy had failed. The medical records of 37 patients undergoing TDD and 36 patients undergoing lumbar RFTC nucleoplasty were retrospectively examined and assigned to the Group D and Group N, respectively. In all patients Visual Analogue Scale (VAS) and Functional Rating Index (FRI) were recorded before treatment and after one, six and twelve months after the procedure. The North American Spine Society Satisfaction Scale (NASSSS) was also recorded twelve months after the therapeutic procedure. Statistically significant post-procedural improvement in VAS and FRI was evident in both groups. VAS scores after one, six, and twelve months were slightly higher in Group N, compared to Group D. The overall procedure-related patient satisfaction ratio was 67.5% in the Group D, compared to 75% in the Group N. Regardless of the different mechanism of action, both methods are effective therapies for lumbar radiculopathy, with TDD showing long-term lower pain scores.

# ABSTRACTS

45. **Nikolopoulos P, Maniatis P, Giannila AP, Kelekis AD, Papailiou J, Triantopoulou C. Percutaneous disc decompression using nucleoplasty in patients with discogenic low back pain. ECR 2012 / C-2358. DOI: 10.1594/ecr2012/C-2358. DOI link: <https://dx.doi.org/10.1594/ecr2012/C-2358> <https://epos.myesr.org/poster/esr/ecr2012/C-2358>**

## Abstract

**Purpose:** Open spine surgery for cases of symptomatic disc herniation producing persistent back and leg pain that is intractable to conservative therapy, may be followed by significant morbidity. Furthermore, poor results have been reported for contained disc herniations with open surgical interventions. Percutaneous treatments (table 1) in the therapy of discogenic low back pain and sciatica are used to reduce the intradiscal pressure in the nucleus thus reducing the irritation of the nerve root and the pain receptors in the annulus and the peridiscal space. Recently, coblation nucleoplasty has been added in the therapeutic options for patients with chronic low back pain. The purpose of this study is to report our initial experience and to assess the efficacy of nucleoplasty in treating patients with contained disc protrusion / herniation.

**Methods and Materials:** Thirteen patients (9 men and 4 women) with low back and leg pain underwent nucleoplasty in our department during the last 18 months, after failure of conservative therapy for at least 6 weeks. All patients had MRI proven small to medium size disc protrusion / herniation with preserved disk height of at least 50%. The coblation bipolar device (SpineWand, Arthrocare, USA) was introduced in the nucleus pulposus through a 17 Gauge Trocar (Crawford, 6", Arthrocare), positioned parallel to and at midway between the two end plates under fluoroscopic control. Radiofrequency driven molecular dissociation and removal of nuclear material at relatively low temperatures (typically 40°C to 70°C) was used to create six channels at the two, four, six, eight, ten and twelve o'clock positions, to ensure adequate decompression of the disc space, by slightly rotating the coblation electrode. Provocative discography was performed in 4 patients prior to the percutaneous disc decompression. Selective Neural Root Block was performed in all patients immediately after nucleoplasty with 1.0 ml of betamethasone sodium phosphate and betamethasone acetate (Celestone Chronodose) and 1.0 ml of Bupivacaine 0.5%. The visual analogue pain scale (VAS) was used to document the pain perception of patients before and up to 12 months following coblation. Follow up MRI to assess size disc protrusion / herniation was performed at 3 months.

**Results:** Nucleoplasty was performed successfully in all cases, on an outpatient basis. All patients were monitored post-procedurally for 12 hours and then discharged with instructions not to perform lifting, bending or stooping. One week after the procedure, patients were permitted to return to light work while nonsteroidal anti-inflammatory drugs and muscle relaxants were prescribed. There were no complications associated with the procedure during follow-up period except from two patients reporting soreness at the needle insertion site, which resolved within 10 days. Significant amelioration of symptoms was seen in all patients in the immediate post-procedural period. Before the procedure, the mean value of VAS was  $8,2 \pm 0,2$  in low back and leg pain while the 6-month value was  $2,90 \pm 0,2$  and the 12-month value was  $3,38 \pm 0,2$ . The improvement rates of VAS were 64.6% and 58.7% in 6 and 12 months respectively. Follow up MRI post procedurally revealed radiologic findings in correlation to the symptomatic improvement in all patients.

**Conclusion:** Percutaneous nucleoplasty is a minimally invasive disc ablative technique with satisfactory clinical outcomes and low rate of complications for the treatment of discogenic low back pain and sciatica in a selected patient cohort. The small volumetric reduction of the nucleus pulposus after the application of radiofrequency energy results in a disproportionate decrease in pressure, hence relieving some of the chemical and mechanical factors causing pain.

46. Cincu R, Lorente FdA, Gomez J, Eiras J, Agrawal A. *One-decade follow-up after nucleoplasty in the management of degenerative disc disease causing low back pain and radiculopathy*. *Asian J Neurosurg*, Jan-Mar 2015; 10(1): 21-5. DOI: 10.4103/1793-5482.151504. PMCID: PMC4352623. PMID: 25767571 <https://pubmed.ncbi.nlm.nih.gov/25767571/>

## Abstract

**Objectives:** Nucleoplasty is a minimally invasive procedure that is developed to treat patients with symptomatic, but contained, disc herniations or bulging discs. The purpose of this study was to evaluate a decade follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc.

**Methods:** In this retrospective study a total of 50 patients who underwent intradiscal coblation therapy for symptomatic, but contained, lumbar degenerative disc disease were included. Relief of low back pain, leg pain and numbness after the operation were assessed by visual analog pain scale (VAS). Function of lower limb and daily living of patients were evaluated by the Oswestry disability index (ODI) and subjective global rating of overall satisfaction was recorded and analyzed.

**Results:** There were 27 male and 23 female with mean follow-up of 115 months (range 105-130 months) with a mean age of 52 years (range 26-74 years). Analgesic consumption was reduced or stopped in 90% of these cases after 1 year. At 24 months follow-up VAS was four points and ODI was 7.2. In three patients, we repeated the cool ablation after 36 months, at L3-4 level in two cases. Ten patients continue to be asymptomatic after 114 months of intervention. There were no complications with the procedure including nerve root injury, discitis or allergic reactions.

**Conclusions:** Nucleoplasty may provide intermittent relief in contained disc herniation without significant complications and minimal morbidity. In accordance with the literature the evidence for intradiscal coblation therapy is moderate in managing chronic discogenic low back pain; nucleoplasty appears to be safe and effective.

47. Li C, Qi Y, Liu G, Yin X, Jin Y, Jiang Z, Li P, Kang X, Ye C. *Long-Term Clinical Outcomes of Percutaneous Cervical Nucleoplasty for Cervical Degenerative Diseases with Neck Pain and Cervical Vertigo*. *World Neurosurg*, 2020 Jan; 133: e205-e210. Epub 2019 Sep 5. DOI:10.1016/j.wneu.2019.08.210. PMID: 31493606. <https://pubmed.ncbi.nlm.nih.gov/31493606/>

## Abstract

**Background:** Good short- and mid-term clinical efficacy of percutaneous cervical nucleoplasty (PCN) for cervical degenerative diseases (CDD) with neck pain has been reported. However, few studies have assessed its long-term influence in patients with both neck pain and cervical vertigo. This study aimed to evaluate the curative efficacy of PCN for CDD with neck pain and cervical vertigo with minimum of 6 years of follow-up.

**Methods:** Inpatients who underwent PCN for CDD with neck pain and cervical vertigo between April 2010 and March 2013 were enrolled. Clinical outcomes were assessed using the Cervical Vertigo Evaluation Scale (CVES); greater CVES scores reflected less impairment. Additional open surgeries were recorded.

**Results:** Among 40 patients, 100% completed the 1-year short-term and 3-year mid-term follow-up (FU); 85% completed the 6-year long-term FU. Clinical effective rates were 67.5%, 67.5%, and 52.94% at short-, mid-, and long-term FU, respectively. CVES scores were greater than the preoperative CVES scores at all FU timepoints ( $P < 0.01$ ). However, the CVES score was lower at the final FU than at the 3-year FU ( $P < 0.05$ ). The neck pain score significantly decreased over time and was lower than the cervical vertigo score at the final FU ( $P > 0.05$ ). Reoperation rates were 1/40 (2.50%) and 3/34 (8.82%) at mid- and long-term FU, respectively.

**Conclusions:** PCN in patients with CDD neck pain and cervical vertigo showed satisfactory clinical efficacy at short- and mid-term FU, and it was fair at long-term FU. Thus, PCN could be a complementary operation for CDD.

# ABSTRACTS

48. Karabekir HS, Atar E, Yildizhan A, Yazici AC, Yonguc ND, Mas NG. *Morphometrical and Clinical Analysis of Cervical Nucleoplasty Cases Using Coblation Technique*. *Spine Research*, ISSN 2471-8173, 2017, Vol. 3 No. 1:7. DOI: 10.21767/2471-8173.100021 <https://spine.imedpub.com/morphometrical-and-clinical-analysis-of-cervical-nucleoplasty-cases-using-coblation-technique.pdf>

## Abstract

**Background:** Nucleoplasty is a minimally invasive procedure for managing chronic discogenic cervical pain. We aimed to evaluate the outcomes of nucleoplasty treatment on chronic cervical discogenic pain, intervertebral disc volumetry so as to examine the success of the surgery.

**Methods:** Records of patients who underwent nucleoplasty from two different university hospitals in Turkey were assessed. Records between 2005 and 2014 years of thirty-six cases, who had no recovery from medical and physical treatment and treated with nucleoplasty at single or double levels investigated retrospectively. All assessments included visual analog scale (VAS) evaluation before the surgery and at 6, 12, 24 and 36 months after the surgery. Intervertebral disc volumes between 4th and 5th cervical vertebrae and also between 5th and 6th were measured on axial magnetic resonance images slices using a stereological method, before and after the treatment.

**Results:** VAS results displayed pain improvement at 6, 12, 24 and 36 months after the surgery when compared with that of before the surgery ( $p < 0.05$ ). After the nucleoplasty treatment, the mean intervertebral disc volumes between 4th and 5th, and also between 5th and 6th cervical vertebrae, revealed significant decrease when compared with that of pre-operative assessment ( $p < 0.05$ ). The present study does not compare the results of different techniques used in the disc protrusion management.

**Conclusions:** Good classified patients may have good prognosis with nucleoplasty. The method is minimally invasive, provides a safer surgical experience and has protective effects on intervertebral disc biomechanics.

49. Halim W, Wullems JA, Lim T, Aukes HA, van der Weegen A, Vissers KC, Gültuna I, Chua NHL. *The long-term efficacy and safety of percutaneous cervical nucleoplasty in patients with a contained herniated disk*. *Pain Pract*, 2013 Jun; 13(5): 364-71. Epub 2012 Oct 31. DOI:10.1111/papr.12003. PMID: 23113964 <https://pubmed.ncbi.nlm.nih.gov/23113964/>

## Abstract

**Background:** Percutaneous cervical nucleoplasty (PCN) is a safe and effective treatment in symptomatic patients with contained cervical herniated disks. It provides simple and efficient disk decompression, using a controlled and highly localized ablation, but evidence regarding long-term efficacy is limited. We conducted a retrospective study to investigate the long-term efficacy and safety of PCN, and the influence of ideal selection settings.

**Methods:** A total of 27 patients treated with PCN fulfilling ideal selection criteria (Group A) were studied and compared to 42 patients not meeting these criteria (Group B). Outcomes were assessed using the Visual Analogue Scale (VAS) and a four-level Likert item for perceived pain and satisfaction, the Neck Disability Index (NDI), and the Short Form 36 (SF-36). Additional relevant outcomes were retrieved from medical records.

**Results:** The postoperative mean VAS pain for Group A was 29.9 (SD  $\pm$  32.6) at a mean follow-up of 24 months (range: 2-45). Only 10% of these patients reported mild transient adverse events. There was a trend, but no difference between both groups in pain scores; however, treatment satisfaction was higher for Group A ( $74.1 \pm 27.2$ - $55.5 \pm 31.4$ ,  $P = 0.02$ ). Group A also reported better physical functioning based on the Physical Component Summary ( $43.6 \pm 10.6$ - $37.3 \pm 12.0$ ,  $P = 0.03$ ) and showed a larger proportion of patients no longer using any medication postoperatively (63-26%,  $P = 0.01$ ).

**Conclusion:** These results show long-term effectiveness and safety of PCN in patients with a one-level contained cervical herniated disk, and the reliance of selecting patients meeting ideal criteria for successful PCN.

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50. **Azzazi A, AlMekawi S, Zein M. Lumbar disc nucleoplasty using coblation technology: clinical outcome. J Neurointerv Surg, 2011 Sep; 3(3): 288-92. Epub 2010 Dec 8. DOI: 10.1136/jnis.2010.002402. PMID: 21990844 <https://pubmed.ncbi.nlm.nih.gov/21990844/>**

## Abstract

**Background and purpose:** Although the standard treatment for lumbar disc herniation is lumbar microdiscectomy, nucleoplasty offers a new technique with encouraging results in well selected cases. Nucleoplasty is a minimally invasive technique that manages intradiscal herniation through energy-based removal of part of the nucleus pulposus. The purpose of this study was to assess the safety and clinical outcome of the nucleoplasty procedure in well selected cases.

**Methods:** Coblation technology was used in 50 patients, who had radicular leg pain due to contained disc herniation or focal protrusion, from 2005 to 2008. Clinical outcome was assessed by the Visual Analog Scale and Oswestry Disability Index Questionnaire. Reduction in analgesic treatment was also recorded. The procedure was performed under local anesthesia.

**Results:** The mean Visual Analog Scale score decreased from 8.2 to 1.3 at the 1 year evaluation ( $p=0.001$ ). The Oswestry Disability Index Questionnaire decreased from 62.2 to 9.6 at the 1 year follow-up ( $p=0.001$ ). Analgesic consumption was reduced or stopped in 90% of cases after 1 year. There was complete resolution of symptoms in 40 patients after 1 year. There were four patients who underwent conventional microdiscectomy. Five cases had postoperative discitis which cleared clinically and radiologically within 2 months without sequelae in four of them. One patient had to undergo operative instrumental fusion at the affected level.

**Conclusion:** Nucleoplasty does not require general anesthesia, offers less morbidity and shortens recovery time. Contained herniated disc or focal protrusion are the most important inclusion criteria. Hence this technique is a promising tool in well selected cases.

51. **Yakovlev A, Tamimi MA, Liang H, Eristavi M. Outcomes of percutaneous disc decompression utilizing nucleoplasty for the treatment of chronic discogenic pain. Pain Physician, 2007 Mar; 10(2): 319-28. PMID: 17387355 <https://pubmed.ncbi.nlm.nih.gov/17387355/>**

## Abstract

**Background:** Percutaneous disc decompression utilizing Nucleoplasty has emerged as one of the minimally invasive techniques for treatment of low back pain and lower extremity pain due to contained herniated discs. Only 1 study to date has examined its effect on functional activity and pain medication use; however, results were not analyzed over time, and recall bias was a limitation.

**Objective:** Evaluation of the effect of Nucleoplasty on pain and opioid use in improving functional activity in patients with radicular or axial low back pain secondary to contained herniated discs.

# ABSTRACTS

**Design:** Retrospective, non-randomized case series.

**Methods:** Twenty-two patients who had undergone Nucleoplasty were included in the analysis. Patients were evaluated at 1, 3, 6, and 12 months postoperatively, and were asked to quantify their pain using a visual analog scale ranging from 0 to 10. Patients were also surveyed in regard to their pain medication use, and functional status was quantified by a physical therapist who also used patient reports of ability to perform activities of daily living to assess status. Data were compared between baseline and at 1, 3, 6, and 12 months post-treatment.

**Results:** Reported pain and medication use were significantly decreased and functional status was improved at 1, 3, 6, and 12 months following Nucleoplasty (P values  $\leq 0.0010$  for all outcome measures at all time periods). There were no complications associated with the procedure and we found continued improvements over time.

**Conclusion:** Nucleoplasty appears to be safe and effective. Randomized, controlled studies are required to further evaluate its long-term efficacy.

52. Sim S E, Ko E S, Kim D K, Kim H K, Kim Y C, Shin H Y. *The results of cervical nucleoplasty in patients with cervical disc disorder: a retrospective clinical study of 22 patients.* Korean J Pain, 2011 Mar; 24(1): 36-43. DOI: 10.3344/kjp.2011.24.1.36. Epub 2011 Feb 25. PMID: 21390177 <https://pubmed.ncbi.nlm.nih.gov/21390177/>

## Abstract

**Background:** Nucleoplasty is a minimally invasive spinal surgery using a Coblation® technique that creates small voids within the disc. The purpose of this study was to evaluate the efficacy of cervical nucleoplasty in patients with cervical disc disorder.

**Methods:** Between March 2008 and December 2009, 22 patients with cervical disc disorders were treated with cervical nucleoplasty after failed conservative treatment. All procedures were performed under local anesthesia, and fluoroscopic guidance and voids were created in the disc with the Perc™ DC Spine Wand™. Clinical outcomes were evaluated by the Modified Macnab criteria and VAS score at pre-procedure, post-procedure 1 month, and 6 months.

**Results:** Six patients had one, eight patients had two and eight patients had three discs treated; a total of 46 procedures was performed. Mean VAS reduced from 9.3 at pre-procedure to 3.7 at post-procedure 1 month and to 3.4 at post-procedure 6 months. There was no significant complication related to the procedure within the first month. Outcomes were good or excellent in 17/22 (77.3%) cases. Post-procedure magnetic resonance imaging was acquired in two patients after two months showing morphologic evidence of volume reduction of protruded disc material in one patient but not in the other.

**Conclusions:** Percutaneous decompression with a nucleoplasty using a Coblation® technique in the treatment of cervical disc disorder is a safe, minimally-invasive and less uncomfortable procedure, with an excellent short-term clinical outcome.



53. Liliang P-C, Lu K, Liang C-L, Chen Y-W, Tsai Y-D, Tu Y-K. *Nucleoplasty for treating lumbar disk degenerative low back pain: an outcome prediction analysis*. *J Pain Res*, 2016 Oct 31; 9: 893-898. eCollection 2016. DOI: 10.2147/JPR.S116533. PMID: 27826211 <https://pubmed.ncbi.nlm.nih.gov/27826211/>

## Abstract

**Purpose:** Nucleoplasty is a minimally invasive technique that is considered efficacious in alleviating lumbar disk degenerative low back pain (LBP). The efficacy of nucleoplasty and identified variables that can predict pain relief for nucleoplasty was reported.

**Patients and methods:** Between December 2013 and November 2015, 47 nucleoplasty procedures on 47 lumbar disks in 31 consecutive patients were performed. The outcome was evaluated using a visual analog scale (VAS) score. Improvements of  $\geq 50\%$  in VAS scores were considered substantial pain relief. The variables associated with pain relief after nucleoplasty included: 1) age; 2) sex; 3) body mass index; 4) hyperintensity zone at the rear of the disk; 5) hypointensity of the disk; 6) modic changes of the end plates; 7) spinal instability pain; and 8) discography results.

**Results:** Twenty-one patients (67.7%) experienced substantial pain relief. The most common side effects following nucleoplasty were soreness at the needle puncture site (64.5%), numbness in the lower leg (12.9%), and increased intensity of back pain (9.7%). All side effects were transient. Multivariate analysis revealed that the discography results were the most critical predictor for substantial pain relief of nucleoplasty ( $P=0.03$ ). The sensitivity and specificity of discography were 92.8% and 62.5%, respectively.

**Conclusion:** Discography results could improve the success rate of nucleoplasty in the treatment of disk degenerative LBP.

54. Marín FZ. *CAM versus nucleoplasty*. *Acta Neurochir Suppl*, 2005; 92: 111-4. DOI: 10.1007/3-211-27458-8\_24. PMID: 15830980 <https://pubmed.ncbi.nlm.nih.gov/15830980/>

## Abstract

In recent years the general trend in spinal surgery has been reduction and minimalization. In general, all these have shown a moderate or good clinical result but they have been associated with serious sequelae. Plasma-mediated electrosurgery, widely used in other medical fields, has demonstrated to be well suited for this new indication. To perform the Nucleoplasty (Coblation) and the CAM (Coblation-Assisted Microdiscectomy), the Perc-DLE SpineWand connected to a System 2000 generator (ArthroCare Corp., Sunnyvale, CA) was used. The device functions via plasma-mediated electrosurgery (Coblation) and differs from traditional electrosurgery. From a small sample, 64 operated patients with contained disc herniation were analysed and classified into those who underwent percutaneous disc decompression (PDD) using coblation technology and patients who underwent CAM. All patients who presented with PDD were considered candidates for open surgery but all of them opted for the new technique. There was no contraindication. They had discogenic low back pain and/or leg pain and the procedure was performed on an outpatient basis. Follow-up data was of 1 to 12 months. Patients' gender distribution for PDD was 65% (41.6) male, 35% (22.4) female with a mean age of 43 years. The average duration of pain before nucleoplasty was of 18 months and none of them had previous lumbar surgery. At 6 to 12 months, 80% of the patients demonstrated an improvement in pain scores (75% very good, 5% good, 15% improved but not good, and 5% no effect). None of the patients was worse. Results indicate that Nucleoplasty may be an efficacious minimally invasive technique for the treatment of symptoms associated with contained herniated disc. However, randomized controlled studies are required to know with more precision the role of this procedure. CAM procedure (13 cases) is an excellent method in cases of root compression that needs liberation or in spine stenosis.



# ABSTRACTS

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## Abstract

**Aim:** To compare clinical success and patient satisfaction of percutaneous cervical nucleoplasty (PCN) and percutaneous cervical discectomy (PCD) in contained cervical disc herniation treatment.

**Materials and methods:** We retrospectively identified 50 consecutive patients in our institution: 24 underwent the PCD treatment and 26 patients were treated by the PCN procedure. All patients complained of radicular pain with or without neck pain; diagnosis of contained cervical disc herniation was obtained by MRI; all patients had received conservative therapy which did not result in symptom improvement. Exclusion from our series consisted of patients who had undergone previous surgery at the indicated level, or those with myelopathy, or those in whom more than a sole herniation was treated in the same session. Overall procedure time, fluoroscopy time, radiation dose and complications were recorded. The MacNab scale score was used to assess clinical success in terms of pain relief at 2- and 6-month follow-up. After 4-6 months, a cervical MRI was obtained in 24 patients.

**Results:** Neither major nor minor complications were reported. Regarding patient satisfaction, overall median modified MacNab score was excellent both at 2 and 6 months after treatment. No significant statistical difference was found in mean modified MacNab score at 2 and 6 months among patients grouped by treatment choice ( $p = 0.319$  and  $0.847$ , respectively); radiation dose was inferior in PCN group than in PCD, with no significant statistical difference.

**Conclusion:** PCD and PCN were found to be safe and effective in terms of pain relief in contained cervical herniation treatment.

56. Lee DW, Loh ESY, Kueh CC, Poi JH, Francis T, Koh KC, Wazir NN, Singh H. *Radiofrequency-induced intradiscal nucleoplasty chronic low back pain secondary to lumbar disc herniation*. *Malays Orthop J*, 2013 Jul; 7(2): 18-20. DOI: 10.5704/MOJ.1307.009. PMCID: PMC4341032. PMID: 25722820 <https://pubmed.ncbi.nlm.nih.gov/25722820/>

## Abstract

We set out to assess the efficacy of radiofrequency-induced intradiscal nucleoplasty in reducing pain in symptomatic patients with MRI-defined lumbar disc herniation and their satisfaction with the procedure. We compared the patients' pain intensity and severity of disability scores before and after undergoing the procedure in a retrospective questionnaire. These patients reported statistically significant reduction of pain intensity and disability level after the procedure. We conclude that radiofrequency induced intradiscal nucleoplasty is an acceptable alternative minimally invasive procedure in relieving the symptoms of patients with lumbar disc herniation.

57. Agarwal A, Shamschery C, Ambesh SP, Jain A. *Evaluation of nucleoplasty in patients of low back pain with radiculopathy: A preliminary report*. *Anaesth, Pain & Intensive Care*, Vol 19(3), Jul-Sep 2015. <https://www.apicareonline.com/index.php/APIC/article/view/817/1165>

## Abstract

**Introduction:** Low back pain (LBP) has a point prevalence of  $11.9 \pm 2\%$  worldwide. Nucleoplasty is a minimally invasive procedure, combining disc removal and thermal coagulation using radiofrequency waves in the nucleus pulposus. The purpose of this preliminary study was to evaluate the efficacy of nucleoplasty in patients with low back pain and radiculopathy, and to have comparative evaluation of the disc appearance on MRI pre- and post-procedure.

**Methodology:** We enrolled 20 patients, suffering with low back pain along with radiculopathy undergoing nucleoplasty from June 2010 to June 2012. Inclusion criteria were: patients of either sex, age 18-60 years, one or two level herniated disc (contained), failed conservative therapy for six weeks. Exclusion criteria were loss of >50% disc height and severe disc degeneration. Post-nucleoplasty patients were called for follow-up at 3, 6 and 12 months. Repeat MRI was done after 3 months of nucleoplasty to look for changes in the intervertebral disc. Pain was assessed using the visual analogue scale (VAS) and patient's satisfaction was evaluated by Macnab's outcome assessment. Statistical analysis was done with Friedman ANOVA using the package SPSS 21.0 (SPSS Inc., Chicago, IL). A p-value of  $< 0.05$  was considered significant.

**Result:** There were 4 drop-outs and thus we present results of 16 patients only. In 13 patients single-disc decompression was done, whereas in the remaining 3 patients it was done at two levels. Post-procedure MRI was evaluated in 8 patients. Following nucleoplasty 81% of patients experienced pain relief and improvement in patient satisfaction. MRI performed 3 months after the procedure revealed appreciable reduction in the disc bulge in 3 out of 8 (37.5%) patients.

**Conclusion:** Nucleoplasty appears to be a safe and favorable day care minimally invasive procedure in selected patients. Large randomized, controlled studies are required to correlate MRI findings to clinical outcomes.

**Key words:** Pain; low back pain; low Back Pain, recurrent; failed back surgery syndrome; neurologic manifestations; radiculopathy; neuralgia; lumbar vertebra; decompression; treatment outcome.

**Citation:** Agarwal A, Shamschery C, Ambesh SP, Jain A. *Evaluation of nucleoplasty in patients of low back pain with radiculopathy: A preliminary report*. *Anaesth Pain & intensive Care*, 2015; 19(3): 287-291.

This study was presented as a poster in the ISSPCON conference at Nagpur (India), in February 2013. *Care*, 2015; 19(3): 292-296.

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No abstract available.

# ABSTRACTS

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## Abstract

**Background and aim:** The therapy for low back pain boasts different approaches; one of these is nucleoplasty. We wanted to assess the effectiveness of nucleoplasty by both clinical response and MR imaging evaluation, including even extrusions larger than one-third of the spinal canal.

**Methods:** Fifty-seven patients were treated with nucleoplasty in our hospital, 11 of these patients accepted both clinical and MRI evaluation after six months from treatment. The clinical evaluation was performed with Visual Analogue Scale (VAS) of pain, scored before and after the procedure. MRI evaluation consisted of analysing some imaging parameters of disc protrusions before and after the treatment.

**Results:** In 10 out of 11 (91%) patients, VAS was reduced and only 1 out of 11 (9%) had the same pain after procedure. The mean of decrease of VAS score was 64%. In our population 8/11 (72%) patients had a herniation larger than 1/3 of the sagittal diameter of spinal canal and 100% of them had an improvement with a mean VAS reduction value of 75%. With MRI evaluation, the mean percentage of expulsion before and after treatment was respectively 40% and 34%. The expulsion decreased in 7/13 discs, remained equal in 4/13, and increased in 2/13 discs. Among the 9 larger protrusions, 3 didn't change, 6 reduced with a decrease mean value of 13%. Other MRI parameters didn't change significantly.

**Conclusions:** Our preliminary experience supports the success of coblation on pain relief, aiming to show progressively that this treatment is suitable even in case of great extrusions, which are generally treated only with surgical approach. It's not clear the usefulness of MRI control yet, even if in most of cases we could have found a certain reduction of expulsion degree.

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## Abstract

**Background and objectives:** Symptomatic ASD after lumbar spinal fusion surgery occurs most commonly in the cranial segment. The surgery for ASD contains anterior lumbar interbody fusion, posterior lumbar interbody fusion, decompression alone (laminotomy) and so on. But coblation nucleoplasty for ASD has not been reported previously. In this study, a case of coblation nucleoplasty after posterolateral fusion surgery at L4-L5 for adjacent segment degeneration (ASD) was reported and the clinical results were examined.

**Material and method:** A 32-year-old male patient who had discectomy and fusion on the L4-L5 level seven years ago complained of chronic back pain for four months with numbness on his right leg for a month. X-ray revealed mild lumbar instability on L3-L4 segment. Magnetic resonance imaging confirmed a right-sided L3-L4 herniated disc compressing the L4 nerve root. He underwent L3-L4 coblation nucleoplasty. The visual analog scale (VAS) was adopted to assess the relief of back pain, leg pain and numbness.

**Results:** The operation was performed successfully and the symptoms were relieved significantly at the follow-up of more than twenty-four months.

**Conclusion:** Although coblation nucleoplasty is not a regular therapy for ASD, the excellent outcome of this case suggests that this technique might be an option before a complicated revision surgery.

61. **Smuck M, Benny B, Han A, Levin J. Epidural fibrosis following percutaneous disc decompression with coblation technology. Pain Physician, 2007 Sep; 10(5): 691-6. PMID: 17876367 <https://pubmed.ncbi.nlm.nih.gov/17876367/>**

### Abstract

**Background:** Complications reported from percutaneous disc decompression (PDD) include discitis, anaphylaxis (with chemonucleolysis), instability, increased back pain, and reherniation. To the best of our knowledge, there is no report of epidural fibrosis occurring with any of the many types of PDD.

**Objective:** To document a case of epidural fibrosis following PDD with coblation technology (Nucleoplasty), a previously unreported complication of this procedure.

**Design:** Case report.

**Methods:** Details are presented on a 46-year-old man's history, diagnostic test results, treatments, and progression of his symptoms.

**Results:** Following PDD with coblation technology at L5-S1, the patient noticed improvement in his left lower extremity radicular symptoms and low back pain. He continued to improve over the following week to near complete relief. He resumed his normal activities. Three months post treatment, he experienced a recurrence of his radicular pain with a diminished left Achilles reflex. A subsequent MRI showed improvement of the previous left paracentral protrusion at L5-S1 along with a new contrast enhancing soft tissue mass. This mass, consistent with epidural fibrosis, was located in the left antero-lateral spinal canal and encased the left S1 nerve root. On the patient's next follow-up visit, he reported spontaneous resolution in his symptoms. He had stopped all pain medications and returned to his usual activities.

**Conclusion:** This case is the first reported occurrence of epidural fibrosis following percutaneous lumbar disc decompression.

62. **Buy X, Gangi A. Percutaneous treatment of intervertebral disc herniation. Semin Intervent Radiol, 2010 Jun; 27(2): 148-59. DOI: 10.1055/s-0030-1253513. PMCID: PMC3036519. PMID: 21629404. <https://pubmed.ncbi.nlm.nih.gov/21629404/>**

### Abstract

Interventional radiology plays a major role in the management of symptomatic intervertebral disc herniations. In the absence of significant pain relief with conservative treatment including oral pain killers and anti-inflammatory drugs, selective image-guided periradicular infiltrations are generally indicated. The precise control of needle positioning allows optimal distribution of steroids along the painful nerve root. After 6 weeks of failure of conservative treatment including periradicular infiltration, treatment aiming to decompress or remove the herniation is considered. Conventional open surgery offers suboptimal results and is associated with significant morbidity. To achieve minimally invasive discal decompression, different percutaneous techniques have been developed. Their principle is to remove a small volume of nucleus, which results in an important reduction of intradiscal pressure and subsequently reduction of pressure inside the disc herniation. However, only contained disc herniations determined by computed tomography or magnetic resonance are indicated for these techniques. Thermal techniques such as radiofrequency or laser nucleotomy seem to be more effective than purely mechanical nucleotomy; indeed, they achieve discal decompression but also thermal destruction of intradiscal nociceptors, which may play a major role in the physiopathology of discal pain. The techniques of image-guided spinal periradicular infiltration and percutaneous nucleotomy with laser and radiofrequency are presented with emphasis on their best indications.

# ABSTRACTS

63. Jung YS, Choi SP, Sim S-E. *Cervical nucleoplasty as an effective treatment method of cervical degenerative disc disease*. *Korean J Anesthesiol*, 2013 Dec; 65(6 Suppl): S53-5. DOI: 10.4097/kjae.2013.65.6S.S53. PMID: 24478872 <https://pubmed.ncbi.nlm.nih.gov/24478872/>

No abstract available.

## Preclinical Evidence

64. Chen YC, Lee SH, Chen D. *Intradiscal pressure study of percutaneous disc decompression with nucleoplasty in human cadavers*. *Spine (Phila Pa 1976)*, 2003 Apr 1; 28(7): 661-5. DOI: 10.1097/01.BRS.0000051920.45671.88. PMID: 12671352. <https://pubmed.ncbi.nlm.nih.gov/12671352/>

### Abstract

**Study design:** Intradiscal pressure was measured after percutaneous disc decompression by nucleoplasty in human cadavers with different degrees of disc degeneration.

**Objectives:** To assess intradiscal pressure change after disc decompression, and to analyze the influence of degeneration on the intradiscal pressure change.

**Summary of background data:** Partial removal of the nucleus has been shown to decompress herniated discs, relieving pressure on nerve roots and, in some cases, offering relief from disc pain. Nucleoplasty, a new minimally invasive procedure using patented Coblation technology, combines coagulation and ablation for partial removal of the nucleus. Coblated channels remove the tissue volume and may decrease the disc pressure.

**Methods:** Three fresh human cadaver spinal specimens (T8-L5; age, 54-84 years; mean age, 70.7 years) were used in this investigation. The intradiscal pressure was measured at three points: before treatment, after each channel was created, and after treatment using a 25-gauge 6-inch needle connected to a Merit Medical Systems Intellisystem Inflation Monitor. The needles were calibrated initially to approximately 30 pounds per square inch. For the control, the change in disc pressure was recorded by the same procedure without using Coblation energy. To evaluate the effectiveness of nucleoplasty, disc pressure changes were compared between treatment with and without Coblation energy.

**Results:** Intradiscal pressure was markedly reduced in the younger, healthy disc cadaver. In the older, degenerative disc cadavers, the change in intradiscal pressure after nucleoplasty was very small. There was an inverse correlation between the degree of disc degeneration and the change in intradiscal pressure.

**Conclusions:** Pressure reduction through nucleoplasty is highly dependent on the degree of spine degeneration. Nucleoplasty markedly reduced intradiscal pressure in nondegenerative discs, but had a negligible effect on highly degenerative discs.

65. Kasch R, Mensel B, Schmidt F, Ruetten S, Barz T, Froehlich S, Seipel R, Merk HR, Kayser R. *Disc volume reduction with percutaneous nucleoplasty in an animal model.* PLoS One, 2012; 7(11): e50211. DOI: 10.1371/journal.pone.0050211. Epub 2012 Nov 27. PMID: 23209677 <https://pubmed.ncbi.nlm.nih.gov/23209677/>

## Abstract

**Study design:** We assessed volume following nucleoplasty disc decompression in lower lumbar spines from cadaveric pigs using 7.1Tesla magnetic resonance imaging (MRI).

**Purpose:** To investigate coblation-induced volume reductions as a possible mechanism underlying nucleoplasty.

**Methods:** We assessed volume following nucleoplastic disc decompression in pig spines using 7.1-Tesla MRI. Volumetry was performed in lumbar discs of 21 postmortem pigs. A preoperative image data set was obtained, volume was determined, and either disc decompression or placebo therapy was performed in a randomized manner. Group 1 (nucleoplasty group) was treated according to the usual nucleoplasty protocol with coblation current applied to 6 channels for 10 seconds each in an application field of 360°; in group 2 (placebo group) the same procedure was performed but without coblation current. After the procedure, a second data set was generated and volumes calculated and matched with the preoperative measurements in a blinded manner. To analyze the effectiveness of nucleoplasty, volumes between treatment and placebo groups were compared.

**Results:** The average preoperative nucleus volume was 0.994 ml (SD: 0.298 ml). In the nucleoplasty group (n = 21) volume was reduced by an average of 0.087 ml (SD: 0.110 ml) or 7.14%. In the placebo group (n = 21) volume was increased by an average of 0.075 ml (SD: 0.075 ml) or 8.94%. The average nucleoplasty-induced volume reduction was 0.162 ml (SD: 0.124 ml) or 16.08%. Volume reduction in lumbar discs was significant in favor of the nucleoplasty group ( $p < 0.0001$ ).

**Conclusions:** Our study demonstrates that nucleoplasty has a volume-reducing effect on the lumbar nucleus pulposus in an animal model. Furthermore, we show the volume reduction to be a coblation effect of nucleoplasty in porcine discs.

66. Ren D, Zhang Z, Sun T, Li F. *Effect of percutaneous nucleoplasty with coblation on phospholipase A2 activity in the intervertebral disks of an animal model of intervertebral disk degeneration: a randomized controlled trial.* J Orthop Surg Res, 2015 Mar 25; 10:38. DOI: 10.1186/s13018-015-0175-y. PMID: 25879590 <https://pubmed.ncbi.nlm.nih.gov/25879590/>

## Abstract

**Background:** This randomized controlled trial was carried out to (1) evaluate the effect of nucleoplasty with coblation on the PLA2 activity in the degenerative intervertebral disks of an animal model and (2) explore the possible therapeutic mechanism of coblation in addition to the current theory, which focuses on decreasing the intradiskal pressure in the treatment of intervertebral disk degeneration.

**Methods:** Thirty-six animal models of intervertebral disk degeneration were successfully established and then randomly divided into two groups: the coblation group (n = 18) and coblation control group (n = 18). Nucleoplasty using coblation was performed in the coblation group. L4-5 and L5-6 intervertebral disk samples were harvested and analyzed for PLA2 activity in different groups at different time points.

**Results:** The PLA2 activity in the coblation control group was significantly higher than that in the control group ( $194.86 \pm 11.80$  and  $80.68 \pm 5.56$ , respectively;  $P < 0.01$ ). There was a significant decrease in the PLA2 activity 1 week after coblation than at the real time after coblation ( $154.39 \pm 7.99$  and  $184.98 \pm 9.43$ , respectively;  $P < 0.001$ ). The PLA2 activity at 1 month after coblation remained at a lower level than those at 1 week and at the real time after coblation ( $142.63 \pm 10.72$ ,  $154.39 \pm 7.99$ , and  $184.98 \pm 9.43$ , respectively), but there was no significant decrease in the PLA2 activity between 1 week and 1 month after coblation.

# ABSTRACTS

**Conclusions:** Coblation appeared to effectively degrade the PLA2 activity in the degenerative intervertebral disks of this animal model. This represents a potential mechanism for the clinical use of coblation in the treatment of low back pain.

67. Kuelling FA, Foley KT, Liu JJ, Liebenberg E, Sin AH, Matsukawa A, Lotz JC. *The anabolic effect of plasma-mediated ablation on the intervertebral disc: stimulation of proteoglycan and interleukin-8 production.* *Spine J*, 2014 Oct 1; 14(10): 2479-87. Epub 2014 Apr 18. PMID: 24747799. DOI:10.1016/j.spinee.2014.04.010. <https://pubmed.ncbi.nlm.nih.gov/24747799/>

## Abstract

**Background context:** Plasma-mediated radiofrequency-based ablation (coblation) is an electrosurgical technique currently used for tissue removal in a wide range of surgical applications, including lumbar microdiscectomy. *In vitro* and *in vivo* studies have shown the technique to alter the expression of inflammatory cytokines in the disc, increasing the levels of interleukin-8 (IL-8), which may promote maturation and remodeling of the disc matrix.

**Purpose:** To better understand the effect of coblation treatment, this study characterizes the temporal and spatial pattern of healing after stab injury to the rabbit intervertebral disc, with and without plasma-mediated radiofrequency treatment.

**Patient sample:** A total of 23 New Zealand white rabbits.

**Study design:** Annular and nuclear stab injuries.

**Outcome measures:** Sandwich enzyme-linked immunosorbent assay evaluated the concentrations of cytokines tumor necrosis factor- $\alpha$ , IL-1 $\beta$ , and IL-8. Histopathologic evaluations were performed on whole discs and end plates. Tissue sections were stained with Safranin-O to evaluate nucleus pulposus and annulus fibrosus proteoglycan content and with Alcian blue for extracellular proteoglycan content. Intradiscal leakage pressure was evaluated by injecting methylene blue dye into the nucleus.

**Methods:** Animals underwent annular and nuclear stab injuries on three consecutive lumbar discs (L2-L3 to L4-L5). The three levels were randomly assigned into one of the three groups for treatment with a plasma-mediated radiofrequency ablation device (TOPAZ; ArthroCare Corp., Austin, TX, USA): active treatment of the nucleus only (SN); active treatment of both nucleus and annulus (SNA); sham treatment. Unstabbed / untreated discs from L5-L6 (n=5) served as normal controls. Animals were euthanized at 4, 8, and 28 days post-surgery.

**Results:** Tumor necrosis factor- $\alpha$  was detected in sham discs at 4 and 8 days, but not in coblation groups (SN or SNA); IL-1 $\beta$  was below detection in all three treatment groups. Interleukin-8 levels increased in all treatment groups at 4 and 8 days compared with normal control, peaking at 4th day for sham and SN groups and 8th day ( $p>.3$ ) for the SNA group (a 2.5-fold increase). Pressure measurements revealed higher leakage in the SN group, but no statistically significant differences. Histopathology showed higher proteoglycan production by 28 days in the SNA and SN groups compared with sham. All three treatment groups showed ruptured annular fibers from the stab injury, but maintained the overall architecture. Remnants of notochordal tissue within the nucleus were evident in all treatment groups at 4 and 8 days, but were only found in sham group by 28 days. At this time, unlike the normal or sham controls, the nucleus of SN and SNA discs had fibrocartilaginous tissue with chondrocyte-like cells. Significant differences in the disc architecture grade were only noted when comparing normal controls with other groups by 28 days ( $p<.001$ ).



**Conclusions:** Plasma-mediated radiofrequency ablation appears to have an anabolic effect on disc cells, stimulating proteoglycan and IL-8 production and maintaining annulus architecture. Coblation treatment appears to reduce cellular response to proinflammatory stimuli and restore overall disc architecture that may prove beneficial in a number of degenerative disc paradigms. Further studies are encouraged to investigate the therapeutic effect of the technique.

68. **Chen YC, Lee S-H, Saenz Y, Lehman NL. *Histologic findings of disc, end plate and neural elements after coblation of nucleus pulposus: an experimental nucleoplasty study.* Spine J, Nov-Dec 2003; 3(6): 466-70. DOI: 10.1016/s1529-9430(03)00143-8 PMID: 14609691 <https://pubmed.ncbi.nlm.nih.gov/14609691/>**

## **Abstract**

**Background context:** Partial removal of the nucleus has been shown to decompress herniated discs, relieving pressure on nerve roots and, in some cases, offering relief from disc pain. The nucleoplasty technique builds on earlier surgical approaches that helped validate the strategy of intranuclear tissue removal. Nucleoplasty, a new minimally invasive procedure using patented coblation technology, combines coagulation and ablation for partial removal of the nucleus pulposus to decompress the disc.

**Purpose:** To determine if histologic changes of the intervertebral discs and surrounding tissues occur after nucleoplasty.

**Study design:** A light microscopic study of intervertebral disc and adjacent neural tissues after disc decompression by nucleoplasty in pig cadavers.

**Methods:** Light microscopy was used to examine disc and neural tissues in two pig cadaveric specimens (T12 to sacrum). Nucleoplasty was performed by 1) advancing a radiofrequency wand to a predetermined depth in the disc (ablation), and 2) withdrawing the wand to the starting point (coagulation). Discs and adjacent tissues were removed from treated and nontreated segments, and examined under light microscopy.

**Results:** Histologic examination revealed no evidence of direct mechanical or thermal damage to the surrounding tissues. There was clear evidence of coblation channels with clean coagulation borders of the nucleus pulposus. Normal histologic findings of the annulus and end plate, with normal neural elements of the spinal cord and nerve roots at the level of the procedure, were observed.

**Conclusions:** The histologic findings of this study suggest that the nucleoplasty achieves volumetric removal of target disc tissue without overt thermal or structural damage to the adjacent tissues. Further studies in live animals will be needed to assess the effects of nucleoplasty on the annulus, end plate and neural tissues under physiologic conditions, including assessment of cell viability.

# ABSTRACTS

69. Lee MS, Cooper G, Lutz GE, Doty SB. *Histologic characterization of coblation nucleoplasty performed on sheep intervertebral discs*. *Pain Physician*, 2003 Oct; 6(4): 439-42. PMID: 16871295 <https://pubmed.ncbi.nlm.nih.gov/16871295/>

## Abstract

**Objective:** To characterize the histologic effects of coblation nucleoplasty on sheep intervertebral discs.

**Design:** In vitro histologic study.

**Methods:** Five sheep lumbar discs treated with nucleoplasty and two control discs were evaluated. Specimens were received frozen and thawed to room temperature. A segment consisting of the intervertebral disc and vertebral body above and below the disc was dissected. Using a posterolateral approach, a Perc-DLE SpineWand attached to a standard radiofrequency power generator was bluntly advanced to the annulonuclear junction of each disc. The SpineWand was advanced initially in cauterization mode 8mm into the disc and withdrawn in coagulation mode. The SpineWand was reinserted 8mm into the disc and secured in place. The specimens were fixed in 10% buffered formalin for 1-2 weeks. They were then decalcified in 10% ethylenediaminetetraacetic acid (EDTA) and embedded in paraffin. Specimens were subsequently stained with H & E, Alcian Blue, and Trichrome stain. They were examined under light microscopy and polarized light.

**Results:** There were no gross changes in disc appearance. In the experimental disc, the fenestration created by the procedure left a 1mm diameter hollow channel through which tissue was cauterized leaving little visible debris or residual material. In the area immediately surrounding the channel, the fibrocartilage cells and the collagen matrix arrangement remained intact and resembled the control untreated disc tissue. There was no loss or re-distribution of proteoglycans, no alterations in collagen orientation, nor any indication of damage to the matrix surrounding the probe channel.

**Conclusion:** Radiofrequency nucleoplasty creates a hollow channel leaving surrounding soft tissue intact in the immediate post-procedure period. *In vivo* studies will be necessary to delineate the longitudinal histologic effects of radiofrequency nucleoplasty on discs.

70. O'Neill C, Liu J, Leibenberg E, Hu S, Deviren V, Tay B, Chin C, Lotz J. *Percutaneous plasma decompression alters cytokine expression in injured porcine intervertebral discs*. *Spine J*, Jan-Feb 2004; 4(1): 88-98. DOI: 10.1016/s1529-9430(03)00423-6. PMID: 14749197 <https://pubmed.ncbi.nlm.nih.gov/14749197/>

## Abstract

**Background context:** Discectomy is a surgical technique commonly used to treat bulging or herniated discs causing nerve root compression. Clinical data suggest discectomy may also help patients with contained discs and no clear neural compromise. However, the mechanisms of clinical efficacy are uncertain, and consequently bases for treatment optimization are limited.

**Purpose:** To determine the effect of percutaneous plasma decompression on the histologic, morphologic, biochemical and biomechanical features of degenerating intervertebral discs.

**Study design:** An adult porcine model of disc degeneration was used to establish a degenerative baseline against which to evaluate discectomy efficacy.

**Outcome measures:** Cytokines interleukin (IL)-1, IL-6, IL-8, and tumor necrosis factor (TNF)-alpha were measured from tissue samples using enzyme-linked immunosorbent assay. Histology and morphology images were rated for degenerative findings (of cells and matrix) in both the nucleus and annulus. Proteoglycan content was determined, and intact specimen stiffness and flexibility were measured biomechanically. Magnetic resonance images were collected for biomechanical specimens.

**Methods:** Using a retroperitoneal surgical approach, stab incisions were made in four or five lumbar discs per spine in 12 minipigs. Animals were allocated into one of three groups: 6-week recovery, 12-week recovery and percutaneous plasma decompression using an electrosurgical device at 6 weeks with recovery for 6 additional weeks. Four additional animals served as controls.

**Results:** Discs treated with discectomy had a significant increase in IL-8 and a decrease in IL-1 as compared with the 12-week, nontreated discs. There were no significant differences in morphologic and biomechanical parameters or proteoglycan content between treated discs and time-matched, nontreated discs.

**Conclusions:** Our results demonstrate that percutaneous plasma discectomy alters the expression of inflammatory cytokines in degenerated discs, leading to a decrease in IL-1 and an increase in IL-8. Whereas both IL-1 and IL-8 have hyperalgesic properties, IL-1 is likely to be a more important pathophysiologic factor in painful disc disorders than IL-8. Therefore, the alteration in cytokine expression that we observed is consistent with this effect as a mechanism of pain relief after discectomy. In addition, given that IL-1 is catabolic in injured tissue and IL-8 is anabolic, our results suggest that a percutaneous plasma discectomy may be capable of initiating a repair response in the disc.

# ABSTRACTS

## Scientific Evidence

71. Stalder KR, Woloszko J, Brown IG. *Plasma characteristics of repetitively-pulsed electrical discharges in saline solutions used for surgical procedures*. *IEEE Transactions on Plasma Science*, July 2002, 30(3): 1376–1383. DOI:10.1109/TPS.2002.801612 [https://www.researchgate.net/publication/3165337\\_Plasma\\_characteristics\\_of\\_repetitively-pulsed\\_electrical\\_discharges\\_in\\_saline\\_solutions\\_used\\_for\\_surgical\\_procedures](https://www.researchgate.net/publication/3165337_Plasma_characteristics_of_repetitively-pulsed_electrical_discharges_in_saline_solutions_used_for_surgical_procedures)

### Abstract

Characteristics of plasmas formed by repetitively-pulsed electrical discharges in sodium chloride and barium chloride saline solutions are reported. Spectroscopic observations in conjunction with an analysis of the voltage and current behavior of the discharge lead to a model in which the liquid is vaporized and ionized to form a plasma containing excited water fragments H\* and OH\* as well as ions and neutrals from the salt. For typical conditions under which plasma is formed, the plasma density is estimated to be of order  $10^{12}$  cm<sup>3</sup> and the electron temperature about 4 eV.

72. Stalder KR, McMillen DF and Woloszko J. *Electrosurgical plasmas*. *J Phys D: Appl Phys*, 2005, 38: 1728–1738. <https://iopscience.iop.org/article/10.1088/0022-3727/38/11/014>

### Abstract

Electrosurgical medical devices based on repetitively pulsed nonequilibrium micron-scale to millimetre-scale plasma discharges in saline solutions are described. The formation of vapour layers (bubbles) around active electrodes appears to be a common feature at moderate (<300Vrms) voltages, and dissociation, excitation and ionization of the vapour in these bubbles produces chemical conditions that are thought to be the source of beneficial tissue removal and treatment. Experimental data are discussed, as are the results of modelling efforts of the plasma chemistry. Hydroxyl radicals, hydrogen atoms and other species are observed spectroscopically and their interactions with collagen, a common component of tissue encountered in surgical situations, are considered. Several pathways by which hydroxyl radicals interacting with collagen can lead to tissue removal are discussed.



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