



# Nucleoplasty® Clinical Summary



# Executive Summary

Nucleoplasty/Percutaneous Disc Decompression (PDD) is a minimally invasive surgical approach for painful disc protrusions and contained herniations in the lumbar and cervical regions. The procedure can be performed on an outpatient basis and is based on the Coblation technology for controlled tissue removal. Nucleoplasty is a clinically evidence based and well documented procedure which has resulted in over 40 publications in peer reviewed papers. The clinical data available today demonstrates and validates the benefits of Coblation and the Nucleoplasty procedure. Reduction of intradiscal pressure, positive biochemical changes in vitro as well as in vivo, and significant improvements in a number of clinical standardized outcome measures have been recognized as results of Nucleoplasty. The procedure also allows for rapid patient recovery.

This minimally invasive technique presents benefits including:

- Short procedure times
- Fast postoperative recovery
- Few complications

The patented Nucleoplasty technology has been used to perform over 180,000 procedures worldwide since the year 2000.

## Nucleoplasty Clinical Summary

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# 1. Randomized Controlled Trials

## PLASMA DISC DECOMPRESSION (PDD) COMPARED WITH FLUOROSCOPY-GUIDED TRANSFORAMINAL EPIDURAL STEROID INJECTIONS (TFSEI) FOR SYMPTOMATIC CONTAINED LUMBAR DISC HERNIATION: A PROSPECTIVE, RANDOMIZED, CONTROLLED TRIAL

Peter C. Gerszten M.D. et al

*J Neurosurg Spine* 12:357-371, 2010

### Study Description

Prospective randomized clinical trial, n=90, comparing PDD (n=46) with TFSEI (n=44) treatment in patient with radicular pain (VAS >50). The symptoms should have been unresolved 3 weeks to 6 months after an epidural corticosteroid injection. Only patients with one single lumbar disc (L2-L3 to L5-S1) with a disc height more than 50% were included. The objective was to measure clinical outcome up to 2 years.

### Results

- The PDD group had significantly greater reduction in leg pain score compared to the TFSEI group during the 2 year follow up

- Improved scores for the PDD group compared to the TFSEI group for:
  - Oswestry Disability Index (ODI)
  - SF-36 Short Form Health Survey
  - Physical, social function and bodily pain
- The 2 year follow up shows 25 patients (56%) in the PDD group and 11 (28%) in the TFSEI group remained free from having undergone a secondary procedure

### Conclusions

This RCT study demonstrated that patients with radicular pain associated with a contained lumbar disc herniation treated with PDD had significantly reduced pain and better quality of life than those treated using repeated TFSEI. In addition, significantly more PDD patients than TFSEI patients avoided having to undergo a secondary procedure during the 2 year follow up period.

## PLASMA DISC DECOMPRESSION FOR CONTAINED CERVICAL DISC HERNIATION: A RANDOMIZED, CONTROLLED TRIAL

Alessandro Cesaroni, Pier Vittorio Nardi

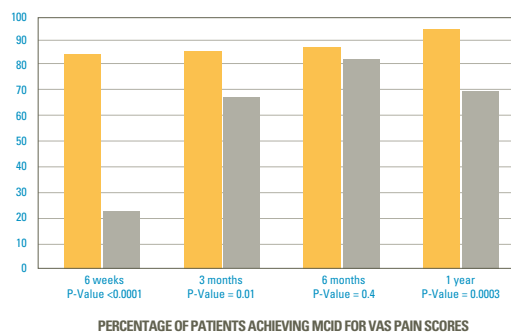
*Eur Spine J*, published online: 10<sup>th</sup> November 2009

### Study Description

Prospective randomized controlled clinical study, n=115 comparing Plasma Disc Decompression (PDD, n=62) with Conservative Care (CC, n=52) in patients with arm/neck pain (VAS >50), and unresolved symptoms over 30 days. Only patients with one single contained symptomatic focal disc protrusion between C3 and T1 that failed to respond to or refused epidural steroid injections were included.

### Results

- VAS pain scores were significantly (P<0.0001) reduced at all follow up times vs baseline
- NDI scores revealed significant improvement vs baseline for PDD compared to CC at the 6 weeks (P<0.0001) and 1 year (P = 0.005) follow ups
- At 1 year, the PDD subjects showed statistically significant improvement vs. baseline in SF-36 quality of life scores compared to CC



Percentage of patients achieving minimal clinical important difference for VAS pain scores. At all time points, 80% or more PDD patients achieved  $\geq 25$  reduction in VAS; the difference in percentage of patients achieving MCID for pain VAS scores was statistically significant between treatment groups at 6 weeks, 3 months, and 1 year

### Conclusions

This RCT study concluded that PDD offered improved pain relief as well as superior immediate and long-term gains in functional ability and quality of life when compared to conservative care. PDD is a minimally invasive treatment option for symptomatic contained disc herniation that provides an excellent medium for both results and safety.

## 2. Additional Clinical Publications

### Lumbar Nucleoplasty

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#### PERCUTANEOUS NUCLEOPLASTY FOR DISCORADICULAR CONFLICT

A. Alexandre, L. Coro, A. Azuelos and M. Pellone.

*Acta Neurochir (2005) [Suppl] 92: 83-86.*

#### Study Description

Study aiming to highlight procedure safety and clinical outcomes at one year follow-up. This retrospective case series included 1390 patients with lumbosciatalgic pain caused by disc pathology. Follow-up at 15 days, 1 month, 6 months and 1 year.

#### Results

- Bulging reduced or eliminated in over 80% of the cases

#### Conclusions

This large case series demonstrated significant reduction or elimination of disc bulging following Nucleoplasty treatment. The technique is minimally invasive and does not prevent patients from physical therapy or activity after the procedure.

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#### THE RESULTS OF NUCLEOPLASTY IN PATIENTS WITH LUMBAR HERNIATED DISC: A PROSPECTIVE CLINICAL STUDY OF 52 CONSECUTIVE PATIENTS

H. Mirzai, I. Tekin, O. Yaman and A. Bursali.

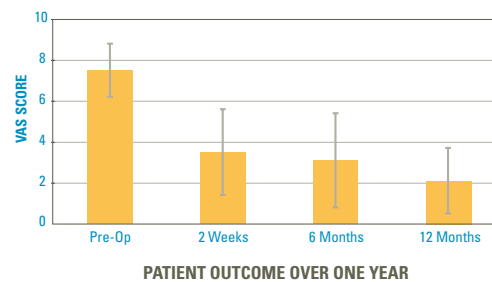
*The Spine Journal (2007) 7: 88-93.*

#### Study Description

Prospective clinical study evaluating the efficacy of Nucleoplasty treatment in 52 consecutive patients with lumbar disc herniations. Patients included suffered from leg pain caused by radicular encroachment and had radicular pain resistant to previous therapy and medical treatment for at least 3 months. Discography was performed to evaluate annular integrity prior to Nucleoplasty.

#### Results

- Mean VAS reduced from 7.15 to 2.1 at 1 year
- Mean Oswestry decreased from 42.2 to 20.5 at 1 year
- Significant reduction in analgesics use



#### Conclusions

Nucleoplasty is an effective method in patients with radiculopathy. Outcomes are excellent in carefully selected patients with leg pain caused by radicular encroachment. The Nucleoplasty method is recommended for patients with small (<6 mm) contained disc herniations with disc height of >50% and annular integrity.

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## NUCLEOPLASTY IN THE TREATMENT OF LUMBAR DISKOGENIC BACK PAIN: ONE YEAR FOLLOW-UP

S. Masala, F. Massari, S. Fabiano, A. Ursone, R. Fiori, F. Pastore and G. Simonetti.

*Cardiovasc Intervent Radiol* (2007) 3: 426-32.

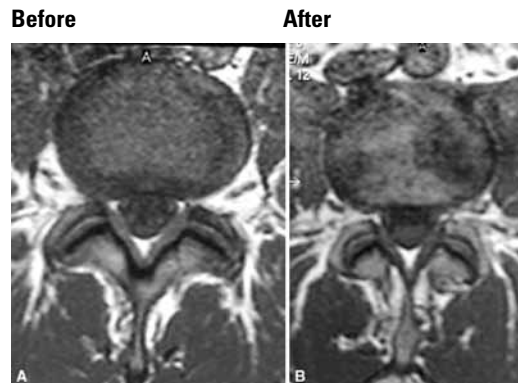
### Study Description

Clinical study including 72 patients with discal protrusion or contained herniation undergoing Nucleoplasty after lack of response to 6 wks conservative therapy. All patients were evaluated clinically, with radiography and with MRI to confirm lumbalgic and/or sciatalgic pain in absence of major neurological deficit.

### Results

- No significant complications or pain post-operatively
- 79% of patients had significant improvement in VAS scores at 1 year

- 79% good results or complete resolution of symptoms at 1 year
- Reduction in lesion in almost 80 % of the cases



MRI illustrating the reduction in diskal lesion at 1 year.

### Conclusions

Nucleoplasty proved to be an effective and safe treatment with an overall success rate of 79%. It is a minimally invasive procedure recommended for treatment of patients with symptomatic contained disc herniation with discogenic axial back and/or leg pain.

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## Cervical Nucleoplasty

### PERCUTANEOUS CERVICAL NUCLEOPLASTY USING COBLATION TECHNOLOGY. CLINICAL RESULTS IN FIFTY CONSECUTIVE CASES

P.V. Nardi, D. Cabezas, and A. Cesaroni.

*Acta Neurochir* (2005) [Suppl] 92:73-78.

### Study Description

Randomized Controlled Trial comparing conservative care (medical and physical therapy) with Nucleoplasty. 50 consecutive patients with contained herniated disc or focal protrusion treated with Nucleoplasty included. Control group of 20 patients treated with conservative care.

### Results

- Nucleoplasty group showed complete resolution of symptoms in 80% of the patients compared to in 20 % for conservative care group

### Conclusions

Cervical Nucleoplasty gives clear and positive results in cases of contained herniated cervical disc/focal protrusion compared to conservative care. Continued use of this technique in patients selected using the appropriate selection criteria is encouraged.

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**PLASMA RADIO-FREQUENCY–BASED DISK-ECTOMY FOR TREATMENT OF CERVICAL HERNIATED NUCLEUS PULPOSUS: FEASIBILITY, SAFETY, AND PRELIMINARY CLINICAL RESULTS**

G. Bonaldi, F. Baruzzi, A. Facchinetti, P. Fachinetti and S. Lunghi.

*Am J. Neuroradiol.*, (2006) 27: 2104-2111.

**Study Description**

Study assessing feasibility, safety and preliminary clinical results of Nucleoplasty in 55 patients with radicular pain, treated over a 29 month period.

**Results**

- Good or excellent results in 80% of patients at 2 months and in 85 % of patients at 6 months
- All cases could be performed under local anaesthesia on an outpatient basis
- Few complications occurred, all of reversible nature

**Conclusions**

Nucleoplasty appears to be a minimally invasive, low risk approach which is easy to perform and associated with minimal discomfort to the patient.

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### 3. Health Economics

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**QUALITY OF LIFE ASSESSMENT IN PATIENTS UNDERGOING NUCLEOPLASTY BASED PERCUTANEOUS DISCECTOMY**

P. C. Gerszten, W. C. Welch and J. T. King Jr.

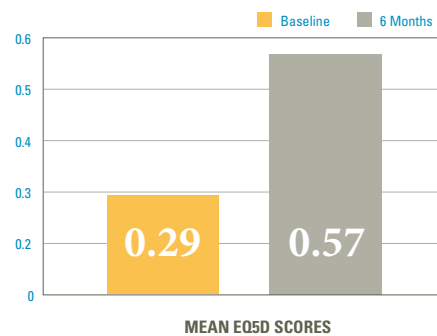
*Journal of Neurosurgery: Spine* (2006). 4: 36-42.

**Study Description**

Study aiming to evaluate pain, function and quality of life in patients with radicular leg and back pain undergoing lumbar Nucleoplasty. Prospective non-randomized longitudinal cohort study on 67 patients with 3 and 6 month follow-ups.

**Results**

- No infections or nerve root injuries
- Mean EQ-5D significantly improved from 0.29 to 0.57 and SF-36 PCS from 33 to 41 at 6 months
- Significant improvement in QOL at 3 months and continued at 6 months



**Conclusions**

Nucleoplasty is a safe and effective method, significantly improving QOL measured by EQ5D as well as SF-36. The Nucleoplasty technique is a complication-free minimally invasive surgical treatment to be used in patients with contained herniated discs.

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## 4. Basic Science

### Temperature

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#### **DISC TEMPERATURE MEASUREMENTS DURING NUCLEOPLASTY AND IDET PROCEDURES**

D. Yetkinler, W. H. Nau, L. Brandt and C. Diederich.  
*European Spine Journal* (2002) 11:417.

#### **Study Description**

Series of experiments using animal tissue as well as human cadaveric lumbar spine models to assess temperature in and around intervertebral disc tissue during the Nucleoplasty procedure.

#### **Results**

- Intradiscal temperatures of 60-65°C in cadaveric spine

- Average temperature increase in cadaveric nucleus and superior endplate of 6.0 and 1.8°C respectively
- Max temperature change at tip 19.7°C
- 0.5°C change at radial distance of 4 mm

#### **Conclusions**

This study confirms that Nucleoplasty is a low temperature technique with a high margin of safety which assures the avoidance of traumatization to adjacent tissue.

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### Histology

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#### **HISTOLOGICAL FINDINGS OF DISC, ENDPLATE AND NEURAL ELEMENTS AFTER COBLATION® OF NUCLEUS PULPOSIS: AN EXPERIMENTAL NUCLEOPLASTY STUDY**

Y. Chen, S. Lee, Y. Saenz, and N. Lehman.  
*The Spine Journal* (2003) 3: 466-470.

#### **Study Description**

Histological study of intervertebral discs and adjacent neural tissues following Coblation in pig cadavers.

#### **Results**

- No evidence of mechanical or thermal damage to surrounding tissue
- Clear evidence of Coblation channels
- Normal neural elements of spinal cord, nerve root and end plates

#### **Conclusions**

Coblation enables precise volumetric removal of target disc tissue without damage to adjacent tissues.

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## Pressure

### INTRADISCAL PRESSURE STUDY OF PERCUTANEOUS DISC DECOMPRESSION WITH NUCLEOPLASTY IN HUMAN CADAVERS

Y. Chen, S. Lee and D. Chen.

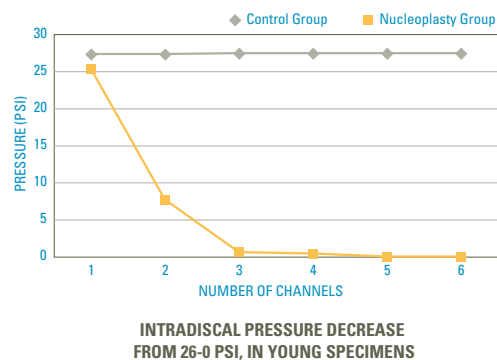
*SPINE*, (2003) 28: 661-665.

#### Study Description

Study aiming to evaluate intradiscal pressure after Nucleoplasty in human cadavers with different degrees of disc degeneration, and to analyze the influence of degeneration on the intradiscal pressure change.

#### Results

- Markedly reduced intradiscal pressure in young healthy disc cadavers
- Less pressure reduction in older degenerative discs



#### Conclusions

The study demonstrates a significant reduction of pressure in healthy non-degenerative discs after just two channels. It also highlights the importance of applying appropriate patient selection criteria for this treatment.

## Biochemistry

### PERCUTANEOUS PLASMA DECOMPRESSION ALTERS CYTOKINE EXPRESSION IN INJURED PORCINE INTERVERTEBRAL DISCS

C. O'Neill, J. Liu, E. Leibenberg, S. Hu, V. Deviren, B. Tay, C. Chin and J. Lotz.

*The Spine Journal* (2004) 4: 115-118.

#### Study Description

Study aiming to investigate biochemical changes in the degenerative disc following Nucleoplasty using an adult porcine model.

#### Results

- Increase of IL-8 and decrease in IL-1 in discs treated with Nucleoplasty
- No difference in morphological and biomechanical parameters between treated and non treated discs

#### Conclusions

Nucleoplasty induces significant biochemical changes in the degenerative disc. The alterations in cytokine expression are consistent with a mechanism of pain relief. These results suggest that Nucleoplasty may be capable of initiating a repair response in the disc.

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**THE SHORT-TERM EFFECTS OF ELECTROSURGICAL ABLATION ON PROINFLAMMATORY MEDIATOR PRODUCTION BY INTERVERTEBRAL DISC CELLS IN TISSUE CULTURE**

K.W. Rhyu, A. J. Walsh, C. O'Neill, D.S. Bradford and J. Lotz.

*The Spine Journal (2007) 7: 451-8.*

**Study Description**

Study aiming to determine biochemical effects of Nucleoplasty in vitro.

**Results**

- Coblation resulted in significantly higher levels of IL-8 at 3 and 6 days, Hsp70 at 3 days and NO at 6 days in normal nucleus cells

- For degenerated nucleus cells IL-6, IL-8 and TNF- $\alpha$  were significantly decreased at 3 and 6 days

**Conclusions**

Nucleoplasty has a direct effect on proinflammatory mediator production by disc cells, which may initiate a regenerative response in the disc. This may also be one explanation to the pain relief observed clinically.

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## 5. Safety

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**SIDE EFFECTS AND COMPLICATIONS AFTER PERCUTANEOUS DISC DECOMPRESSION USING COBLATION TECHNOLOGY**

S. M. Bhagia, C. W. Slipman, M. Nirschl, Z. Isaac, O. El-Abd, L. S. Sharps and C. Garvin.

*Am. J. Phys. Med. Rehabil (2006) 85:6-13.*

**Study Description**

Prospective clinical study including 53 patients with contained disc herniation, discogenic axial back or leg pain, and lack of response to 6 wks rehabilitation management. The study aim is to report side effects and complications of Nucleoplasty. Follow up by independent reviewer at 24 hrs, 72 hrs, 1 wk and 2 wks regarding 17 possible symptom complications.

**Results**

- Most common side effect tat 24 hrs post procedure was soreness at needle insertion site, 76%
- New numbness and tingling, 26%
- Increased intensity of pre-procedure back pain, 15%
- New areas of back pain, 15%
- Statistically significant reductions in VAS for back pain and leg pain ( $P < 0.05$ )

**Conclusions**

The results show that minimal side effects and complications are involved with Nucleoplasty. At 2 wks, no patients had soreness at the needle insertion site or new areas of back pain.



[www.Nucleoplasty.com](http://www.Nucleoplasty.com)



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