

## Nucleoplasty – General Overview

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### Abstract

The management of disc protrusion is multidisciplinary. In the midway between conservative treatment and open surgery are minimal invasive procedures.

Nucleoplasty is a new treatment of discogenic leg pain using bipolar radiofrequency device for vaporising a small volume of nucleus pulposus. Percutaneous removal of nuclear tissue is thought to lower nuclear pressure, thereby reducing nerve root tension and allowing retraction of the protrusion.

Causes of discogenic pain are discussed. Indications of the procedure and surgical technique and the literature results are presented.

**Keywords:** coblation, disc protrusion, discogenic pain, nucleoplasty.

### Introduction

The chronic low back pain is the most frequent illness in modern societies, having serious financial and social consequences. Disc sciatalgia affects almost 10.106 persons every year, with an estimated cost of over 20x10<sup>9</sup> \$ (Carey and col. 1995).

The traditional treatment of low back pain, which appears frequently in association with leg pain includes: bed rest, immobilizing the spinal column, physiotherapy and the prescription of opioid medicines or NSAIDs. Although this is the routine treatment, it may not be

the optimal solution: patients could develop intolerance towards opioids, the NSAIDs have secondary, potentially dangerous effects, and physiotherapy may be ineffective.

When the symptoms don't respond to traditional treatment, other, more aggressive therapies must be taken into consideration, including the percutaneous disc decompression, minimally invasive.

The surgical HLD treatment by standard, open discectomy is indicated for patients with big, uncontained herniations and/or for patients with disc sequestration.

Carragee and col. (2001) reported that for patients with contained HD that measure less than 6 mm in  $\Phi$  AP, the post discectomy success rate was of only 24% as compared to 98% for patients with HD greater than 9 mm  $\Phi$  AP.

The general tendency in spinal surgery was reductionist and minimalist in order to reduce the patient's trauma and in order to create alternatives to the open surgical procedures.

In the last decades there have been imagined and applied several disc pain minimally invasive techniques for discogenic pain among which:

1975 - Hijikata – percutaneous discectomy

1984 – Onik - automated percutaneous disc decompression

1986 – Choy/Ascher – laser

percutaneous disc decompression

2000 – Saal – IDET: intradiscal electrothermal annuloplasty

2000 – ArthroCare - nucleoplasty/coblation

The minimally invasive intradiscal percutaneous techniques aim at clearing off the discal material which is supposed to produce lumbago and/or radiculopathy.

Percutaneous discal decompression is based on the principle of producing a small drop in volume in a closed hydraulic space as the intact disc is (including the contained disc hernia), which produces a pressure drop and reduces or eliminates thus pain. By reducing intradiscal pressure, the disc synthesises a smaller quantity of inflammatory mediators, reduces its volume and initiates the healing process. All percutaneous discectomy techniques have in common the main purpose of clearing off a portion of the nucleus pulposus by laser energy or thermal ablation.

### Causes of discogenic pain

Small protrusions produce at the same time axial pain (lumbago) and radicular pain, as a consequence of raised pressure on the external annulus that contains nervous terminations and of neural inflammation.

Discogenic pain is caused partially by inflammatory chemical substances like: matrix metalloproteinases, the prostaglandin PGE<sub>2</sub>, interleukins, TNF, pH changes and by an influx of inflammatory cells given by chemical signals that appear in the degenerated disk. The anatomic structure in which these substances are produced must be cleared away as thoroughly as possible.

The minimal change of the offending disc geometrical anatomy may be sufficient in the treatment of HD and the more

elaborated treatments (fusion, artificial disk) may no longer be necessary.

David Choy, in 1997 reports the case of an acrobatic pilot with a sciatic LDH, whose pain became more acute when he was redressing from a dive with a force of 6G. The pilot observed that the pain was ameliorated immediately when he went up to 3000 m and executed a looping, producing a force of -3G.

In the first situation, the centrifugal force raises the body weight by 6X gravitation. In the second, when the plane flies making a downwards curve, the body weight is 3 times diminished. This demonstrates that discogenic pain is due to a mechanical/pressure mechanism rather than to a chemical mechanism. Nerve edema can be induced by pressure of only 50mmHg for 2 minutes. Compression of the nerve root could in fact by disc protrusion contribute to low back pain. (Takahashi et al. 1999)

Nucleoplasty alters the expression of inflammatory cytokines in the degenerated disks, leading to the dropping of IL-1 and the rising of IL-8. Because IL-8 has an anabolic effect, nucleoplasty can initiate a repair response in the disc.

### Nucleoplasty

Nucleoplasty was introduced in clinic in July 2000.

Nucleoplasty is a new procedure, minimally invasive, that uses radiofrequency energy in order to clear away material from the nucleus pulposus and to create channels tubes in the disc.

Nucleoplasty uses the technique of controlled ablation in order to ablate and coagulate the soft tissue, combining both accesses to clear off a part of the disc. During coblation, the energy of RF (radio-

frequency) converts the fluid in the nucleus pulposus into a layer of ionized steam, called 'plasma'. These full particles (excited ions) disintegrate the connections between disc molecules, and the disc interior is transformed into hydrogen and oxygen. These gases are eliminated through the cannula introduced percutaneously in the disc. During ablation the nucleus temperature reaches 45-55o C and during thermal coagulation the temperature rises to 70 o C. Thus, the soft tissue dissolves itself and the healthy nearby tissue is kept integrally. By creating a series of channels in the disc the pressure exercised y the contained disc hernias on the nervous root is reduced.

Nucleoplasty is a simple procedure, that doesn't involve complications.

**Table 1 Inclusion/exclusion criteria for percutaneous disc nucleoplasty**

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• sciatalgy <math>\geq</math> lombalgy</li> <li>• contained disc protrusion (MRI)</li> <li>• failure of traditional therapy for 6 weeks</li> <li>• the disk height <math>\geq</math> 75% as compared with the adjacent ones</li> <li>• contained HD with <math>\Phi</math> AP <math>\leq</math> 6mm</li> </ul>	<ul style="list-style-type: none"> <li>• complete annular fracture</li> <li>• excluded or sequestred disc</li> <li>• fracture, tumour or spinal infection at the suspected level</li> <li>• the disk height <math>&lt;</math> 25% as compared to adjacent levels (discal collapse)</li> <li>• severe canal stenosis</li> <li>• signifiant scoliosis</li> <li>• segmentary instability</li> <li>• psychiatric disorders</li> <li>• coagulopathies</li> <li>• more than 2 simptomatic levels</li> </ul>

**Nucleoplasty action mechanism**

By nuclear tissue ablation, using thermal energy, we obtain a decrease of intranuclear pressure, the tension exercised by the protruded nuclear material on the nervous root drops, this one having the possibility to come back in the interior of the disc.

The back pain and the leg pain are explained through several mechanisms: the theory referring to the pressure exercised on the nervous root is one of these mechanisms.

Chen and Le showed that by creating 6 channels in the intervertebral disk nucleus on a dead body, the intradiscal pressure dropped by 100% at young dead persons.

On the other hand, in degenerated disks, the fall was insignificant.

Carragee and col (2003) obtained better results by removing through open surgery less nuclear material. Although the rate of recurrent herniations was greater in this group, the surgical result measured by the degree of satisfaction, pain and function was superior.

The more discal material is ablated, the more the height of the disk diminishes, a "bulge" appears and the stress on the discal annulus grows.

The nuclear tissue is ablated using bipolar radiofrequency energy with high voltage (100-300V) and with a frequency of 120KHz.

This current creates a plasmatic field thick of approximately 75 $\mu$ m, composed of very ionised particles that have sufficient energy to break the organic molecular connections in the disk nucleus tissue and to vaporize thus this tissue.

The coblation produces the normothermal molecular dissociation.

The water content of the nucleus pulposus varies between 50-89%, being

dependant on age and dropping with age.

Through nucleoplasty one reduces at a minimum level the volume of the nucleus pulposus and the intradiscal pressure. The reducing of pressure creates a pressure gradient that leads to the migration of the portion of nucleus that is herniated and to its removal from the nervous root that it constricts. This approach is based on the principle according to which in a closed, intact hydraulic space, the water being impossible to compress, a small change of volume will lead to a disproportionately big pressure change.

### **The implosion theory**

Another purpose of the central nuclear decompression is to create spaces inside the disk in which the protruded/herniated fragment can recede reducing the pressure on the nervous root and the annulus. There are few evidences to maintain this theory.

### **The chemical theory:**

In a discal cells culture, coblation led to the augmentation of inflammatory mediators in the normal cells of the annulus and nucleus, but in the abnormal nuclear cells, it led to a fall of inflammatory mediators.

### **Surgical technique**

#### *The anesthesia*

The nucleoplasty can be made under local anesthesia. The patient remains awake and thus he can tell the doctor when he feels a pain caused by the nerve irritation. The disadvantage of such type of anesthesia is that the patient doesn't maintain the correct position on the surgical table.

For avoiding this drawback, local anesthesia is supplemented with i.v sedation

using propofol.

General anesthesia is not indicated because inadverted lesion of the nerve root is not evident. Antibiotics are given i.v, preoperative and 12 hours postoperative, using cephasilyn 1gr/dose.

### **Positioning**

The patient is placed in lateral decubitus position on the healthy side with his knees and his thighs bent. The head rests on a pillow.

In the access of the disk L5-S1, in order to facilitate the approach, a pillow is placed under the basin in order to generate a scoliosis.

The surgical table must be fluoroscopically compatible and to allow easy access for the C-Arm in order to get AP and lateral images.

On the skin is marked the iliac crest, the regarded discal space at the level of the posterior median line (Figure 1).

The C-Arm is tilted towards the head or the legs till it's obtained a fluoroscopically clear image of the discal space with the end-plates perfectly parallel.

The level of interest and the angle of access of the cannula in the disc are verified fluoroscopically.

### **Surgical steps**

The skin puncture is done at a distance of 8-11 cm from the median line, with a needle of 17 gauge that is introduced under fluoroscopic control at the junction between the annulus and nucleus, on the symptomatic side.

A radiofrequency electrode calted Spine Wand is introduced then on this needle, overrunning the needle end by 5 mm.



**Figure 1** Skin markers



**Figure 2** The catheter is introduced percutaneously into the discal space



**Figure 3** Intraoperative fluoroscopic image which shows the catheter position into the L5-S1 disc space

**Table 2 Complications**

Open	Nucleoplasty
<ul style="list-style-type: none"> <li>▪ the damaging of the recurrent laryngeous nerve ( 11%)</li> <li>▪ the damaging of the vertebral artery (0.3 %)</li> <li>▪ the damaging of the cervical roots</li> <li>▪ the dysphagia (50%)</li> </ul>	<ul style="list-style-type: none"> <li>▪ pain in the place of the pin prick (76%)</li> <li>▪ paresthesias (26%)</li> <li>▪ the growing pain intensity (15%)</li> <li>▪ discitis (1.3%)</li> <li>▪ the damaging of the nervous structures (1%)</li> <li>▪ the intradiscal break of the electrode (0.5%)</li> </ul>

On the proximal side of the caterer, the starting point has a circumferential marker. The caterer advances from the starting point to the junction between the anterior part of the annulus and the nucleus and a new marker (stop marker) is made on the caterer in order not to overrun this final position (Figure 2 & 3).

The discal decompression process includes the caterer's progression into the ablative sequence, with a speed of 0.5 cm/sec then its retraction in the coagulation sequence with the same speed.

By repeated ablation and coagulation several channels are created, with  $\Phi=1\text{mm}$  in the clock positions 2, 4, 6, 8, 10 and 12. At the end, the needle and the caterer are extracted and the puncture place is sterilely bandaged. At the end of the procedure an epidural injection with Depo-Medrol is done. The intervention takes 15 minutes.

The patient is discharged after 2 hours. He can resume his activities in 2-3 days. For 14 days he must continue a treatment with NSAIDs: Arcoxia.

**Complications**

The complications of nucleoplasty, in comparison with standard disc herniation procedure are presented in Table 2.

Bhagia et al (2006) reported the short term side effects and complications after nucleoplasty in 49 patients.

The most common side effects at 24 hours post-procedure was soreness at the needle insertion side (76%), new numbness (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 was present in 15% of patients. Two patients (4%) had increased intensity of pre-procedure back pain. The authors concluded that nucleoplasty produced statistically significant reductions in visual analog scale (VAS) score, for back pain and leg pain.

The classical operation is accompanied by many types of complications, some of which may be permanent. The dysphagia and the paralysis of the recurrent laryngeous nerve are the most frequent.

The nucleoplasty's complications are less important and can be remitted with anti-inflammatory medication.

The advantages of this method are: percutaneous access, local anesthesia and intravenous sedation, reduced operating time (10-15 minutes), avoiding (avoidance) epidural scarring risk. The procedure can be repeated at the same level or at adjacent levels. And NP doesn't contraindicate the open surgery if the results obtained are satisfactory.

## Results

The discal nucleoplasty is a relatively new technique and that is why literature contains few references to this subject.

In 2005, Marin published a retrospective study where he shows that he got 80% ameliorations of the VAS score at 6 and 12

months.

Singh and col 2002 analyzed the results obtained by using nucleoplasty at 67 of his patients with LDH.

One year after, 80% of the patients demonstrated a statistically significant amelioration of the numeric scores of pain.

In another study published in 2004, he got a pain amelioration greater than 50% after 1 year, in 80% of the 49 patients treated.

Gerszten et al (2006) in a prospective, nonrandomised cohort study, using nucleoplasty-based percutaneous disc decompression, in patients with symptomatic contained disc herniations, concluded that nucleoplasty is safe and improves QOL.

Yakovlev et al (2007) assessed 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. Reported pain and medication was improved at 1,3,6 and 12 months following nucleoplasty. These were no complications associated with the procedure and continued improvements were observed over time.

Mirzai, in 2007, demonstrated a medium reduction of the VAS score from 7,5 to 2,1 6 months after operating 52 patients.

Favourable results were also obtained in the case of cervical nucleoplasty (Li, 2008; Birnbaum, 2009).

The results reported up to the present day show that nucleoplasty is associated with a significant decrease of pain and an amelioration of life quality.

After nucleoplasty, the chronic back pain is reduced with about 50%.

Nucleoplasty is indicated especially in the treatment of leg pain.

## Conclusions

Nucleoplasty: is attractive because it's simple, relatively safe procedure and destroys a minimum of discal tissue. The disc height is generally maintained. The discal collapse is reduced slowly, allowing the body to adapt.

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