Nucleoplasty

1) Introduction, Procedure background

Disc decompression has been shown to treat symptomatic patients with contained herniated disks. The long term outcome, the complications and suboptimal results which may accompany open disk surgery have led to the early development of other minimal invasive treatment techniques that would avoid a surgical approach through the spinal canal and an extensive disk ablation. A variety of percutaneous disk decompression techniques have been used to decompress disks, including chemical, mechanical, and thermal (radiofrequency and laser) methods. While the basic mechanism of percutaneous disk decompression has been well understood, each of the methods has suffered from limitations. The percutaneous radiofrequency disk decompression (PRDD) or nucleoplasty is a significant innovation in percutaneous disk decompression. It combines tissue removal with thermal treatment, enabling simple and efficient disk decompression to be performed with minimal invasion and trauma. The radiofrequency disk decompression or nucleoplasty procedure has been used to treat 25 patients in our institution.

2) Principle

Principle of nucleoplasty

The advantage of this percutaneous technique is to reduce volume and pressure of the pathological disk without damage to other spinal structures. All minimally invasive techniques like nucleoplasty are based on the reduction of volume of the pathological disk. The aim of nucleoplasty is to vaporize and coagulate a small portion of the nucleus. The ablation of a relatively small volume of the nucleus results in an important reduction of intradiscal pressure thus inducing reduction of disk herniation. Percutaneous disk decompression or nucleoplasty using the Perc-DLE™ SpineWand™ utilizes Coblation® technology for ablating and coagulating soft tissue, combining both approaches for partial disc removal. Coblation® technology removes tissue by using a low-energy bipolar radiofrequency (RF) wave to create an ionic plasma field from sodium atoms within the nucleus. This low-temperature plasma field removes tissue from the treatment area via a molecular dissociation process that converts the tissue into gases which exit the treatment site. Unlike other radiofrequency systems that are temperature-driven, it does not rely on heat energy to remove tissue, so thermal damage and tissue necrosis is avoided. On withdrawal of the SpineWand™, the channels are thermally treated, producing a zone of thermal coagulation.

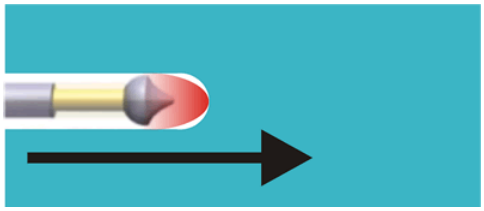


Fig. 1: Coblation® – Removal of tissue as SpineWand™ is advanced.

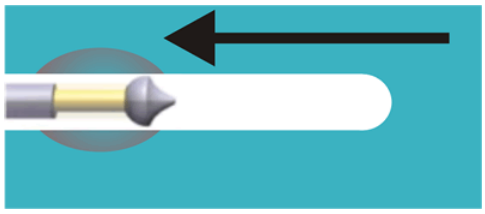


Fig. 2: Coagulation – Thermal treatment of tissue as SpineWand™ is withdrawn.

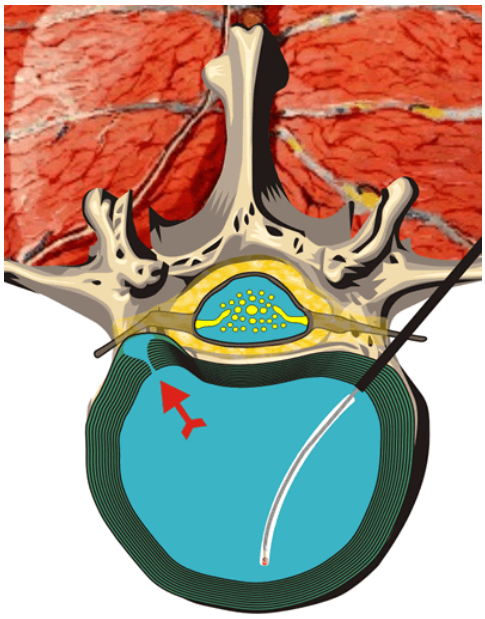


Fig. 3: Principle of nucleoplasty. While monitoring the patient, the SpineWand™ is advanced into the disc under fluoroscopy control. As the SpineWand™ is advanced, the Coblation® plasma mode is activated, so that tissue along the path of the device is removed. Tissue is turned into gas which exits the disc via the introducer cannula.

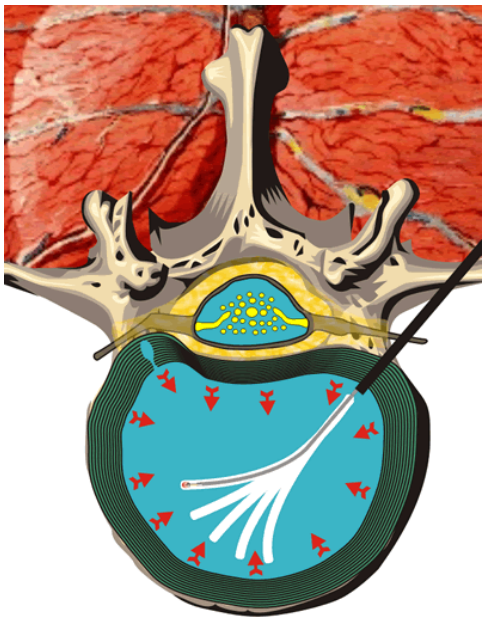


Fig. 4: Principle of nucleoplasty. After the first channel is created, the SpineWand™ is rotated clockwise. As the SpineWand™ device is curved each rotation changes its direction and creates a new channel inside the nucleus. Approximately 6 to 12 channels are created in total, depending on the desired amount of tissue reduction. All minimally invasive techniques like nucleoplasty are based on the reduction of volume of the pathological disk.

3) Advantages

Advantages of nucleoplasty

The nucleoplasty is very similar to PLDD with the same advantages. This minimally invasive technique avoids the drawbacks of classical surgery and has overcome some of the limitations of previous and currently existing percutaneous disc decompression (including laser) techniques:

No Thermal injury to the disk - high temperature (>100 deg. C) tissue removal systems (including laser) remove tissue by exploding molecules with extreme temperatures, but with the result that remaining tissue can be severely burned or charred. This is particularly of concern in the disk where there are no blood vessels to allow necrotic tissue to be resorbed into the body. Disk Nucleoplasty does not rely on heat for tissue removal, and does not introduce excessive heat to cause such tissue damage in the disk.

- no significant soft tissue injury
- no risk of fibrosis
- three to five minutes procedure time once the needle in position.
- no extensive hospitalization, outpatient basis

- performed under local anesthesia
- minimal recovery time of 6 weeks or less
- no scars

The only notable differences with PLDD (laser) are: shorter intervention, simplicity of the technique.

4) Indications & Contraindications

Indications:

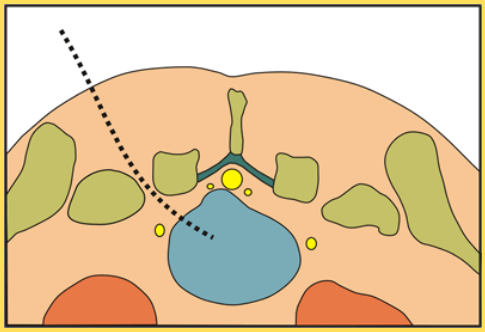
Percutaneous disk decompression has been shown to treat symptomatic patients with contained herniated disks. The ideal patients for percutaneous nucleoplasty or radiofrequency disk decompression (PRDD) are patients with:

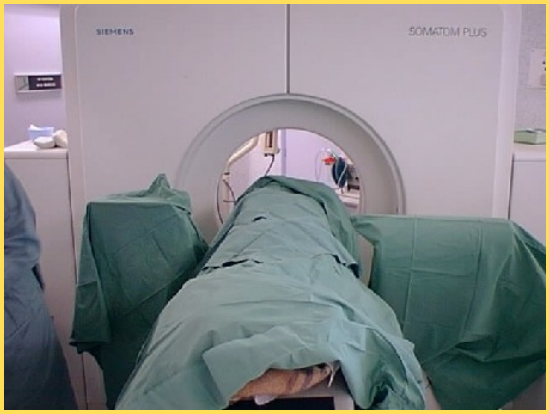
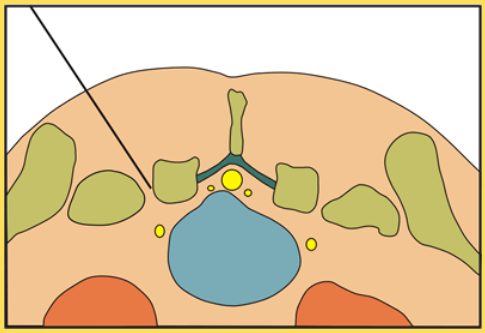
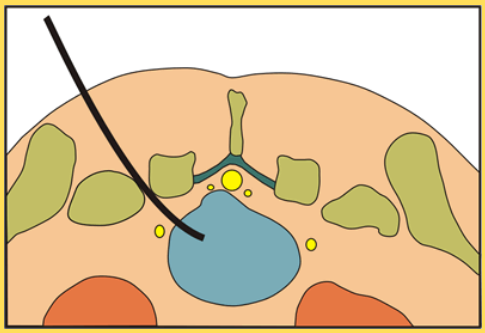
- contained focal disk herniations determined by CT scan or MR imaging with positive and consistent neurologic findings (leg pain of greater intensity than back pain, positive straight-leg-raising test, decreased sensation, normal motor response and tendon reflex) or Discography positive for concordant pain
- and with failure of 6 to 8 weeks of conservative therapy

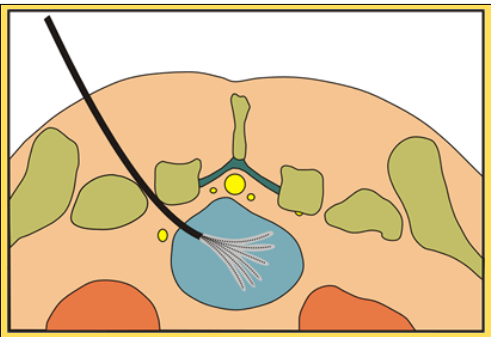
Contraindications: exclusion criteria include

- Significant narrowing of disk space: disk Height < 50%
- Evidence of severe disk degeneration
- Spinal fracture or tumor
- Spinal stenosis, spondylolisthesis
- Hemorrhagic diathesis
- Previous surgery at the same level, significant psychological disorders
- Local infection of cutaneous or subcutaneous or muscular layers.

5) Nucleoplasty: procedure description

1		Placement

2		Material
3		Dual guidance
4		Local anesthesia
5		Disk puncture

6		Disk ablation
7		Follow-up

6) Nucleoplasty: technique

Placement

see percutaneous laser disk decompression, discography

The patient is placed in a prone position on the CT table. In order to open up the posterior aspect of the disk space, rolls are positioned under the abdomen to place the lumbar spine in a semiflexed position.

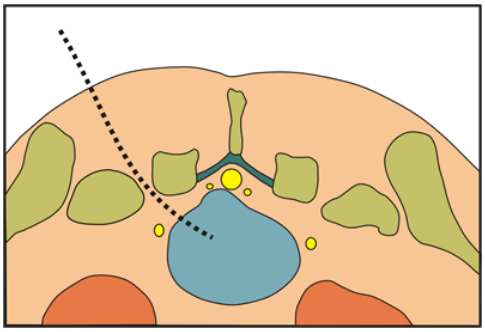


Fig 1: nucleoplasty CT pathway.

Materials

The material for nucleoplasty of ArthroCare™ consists in a needle, a bipolar radiofrequency probe, the SpineWand™, and a radiofrequency generator.

- The needle is a 17-gauge special needle which can be curved if necessary, sometimes especially at level L5-L1 a curved needle is useful. Once in appropriate

position in the disk the stylet is removed and the SpineWand™ radiofrequency probe is placed through it in a coaxial fashion.

- The radiofrequency bipolar probe is the ArthroCare™ SpineWand™ that uses Coblation® to remove tissue and to create small channels within the disk. The design of the Perc-DLE device is bi-polar, which allows for the effect of the Coblation® plasma field to be fully contained to the tip of the device. This provides for highly targeted tissue removal, without injury to surrounding tissue. To achieve coagulation, the device uses a higher energy bipolar radiofrequency mode, designed to generate heat in the surrounding tissue.
- The ArthroCare™ Perc-DLE™ radiofrequency generator.

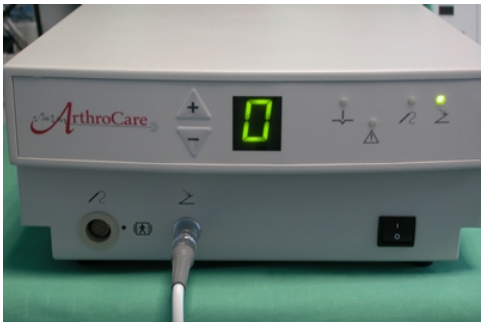


Fig. 1: the ArthroCare™ Perc-DLE™ radiofrequency generator.

Guidance

See discography, and disk biopsy

Nucleoplasty is performed under dual guidance with a combination of CT and fluoroscopy. Two mobile fluoroscopy monitors are placed in front of the physician along with a CT monitor. At any time the operator can switch from CT to fluoroscopy and vice versa. Once the entry point is determined by CT, a lateral fluoroscopy view is obtained at the desired disk level. In this way, the operator can visualize the pathway and the correct angulation of the needle. In most of the cases the angulation is oblique in the three planes, especially at L5-S1 level.

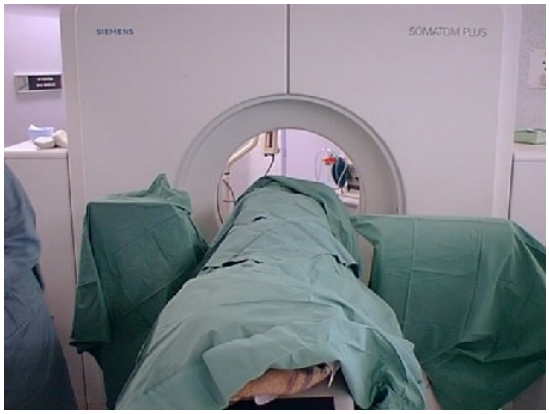


Fig. 1: the patient is placed in prone position. dual guidance CT + fluoroscopy.

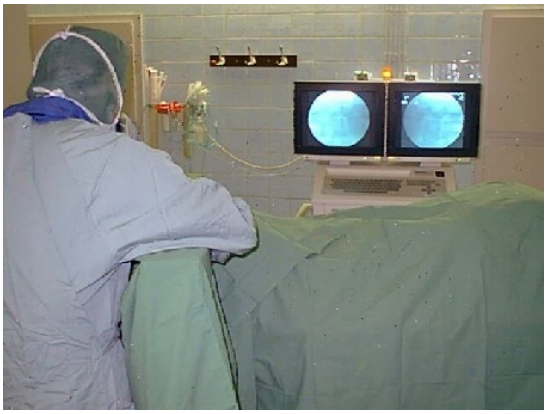


Fig. 2: dual-guidance fluoroscopy.

Local anesthesia

See discography, Percutaneous laser disk decompression

The skin subcutaneous layer, lumbar muscles and the articular process are infiltrated with anesthetic (1% lidocaine) with a 22-gauge needle 9 cm long.

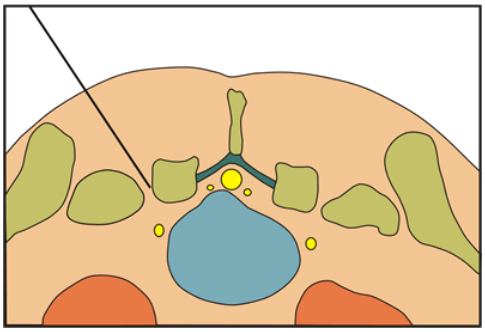


Fig. 1: local anesthesia.

Disk puncture

- Through a skin incision, the 17-gauge needle is inserted under lateral fluoroscopy control using a standard extra-pedicular posterior-lateral approach.
- The tip of the 17-gauge needle must reach the posterior part of the nucleus pulposus. The tip of the needle is placed at the nuclear/annular junction, so that when the device is introduced through the needle, the active tip may pass directly into the nucleus.
- Tissue removal creates channels through the nucleus to the opposite (anterior) side of the disc, where a depth-stopper prevents ablation into the annulus. Prior to

activation of the device, fluoroscocopic and CT confirmation of the placement of the device and the extent of the channel is advisable.

- Patient must be monitored for pain during the whole intervention and the needle has to be repositioned if radicular pain occurs. In order to confirm contained disk herniation, or if any doubt persists, a discography can be performed just before nucleoplasty.

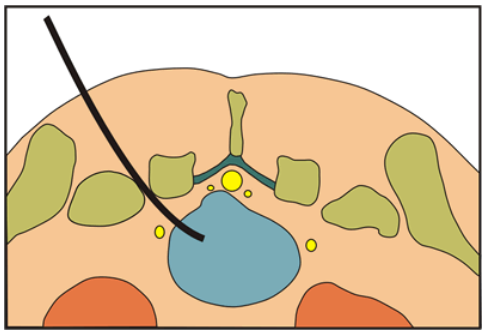


Fig. 1: 17-gauge curve needle placement.

Disk ablation

Radiofrequency Disk Ablation

- While monitoring the patient, the SpineWand™ is advanced into the disc under continuous fluoroscopy control. As the SpineWand™ is advanced; the Coblation® plasma mode is activated, so that tissue along the path of the device is removed.
- After stopping at a pre-determined depth (prior to reaching the anterior annulus), the SpineWand™ is slowly withdrawn, in coagulation mode, to the starting position. During withdrawal, radiofrequency heating at the tip of the device causes the adjacent tissue to coagulate, with the result that the ablation channel is thermally treated. Sufficient thermal energy is generated to denature nerve fibers adjacent to the channel within the nucleus pulposus.
- After the first channel is created, the SpineWand™ is rotated clockwise. As the SpineWand™ device is curved each rotation changes its direction and creates a new channel inside the nucleus. Approximately six to twelve channels are created in total, depending on the desired amount of tissue reduction.

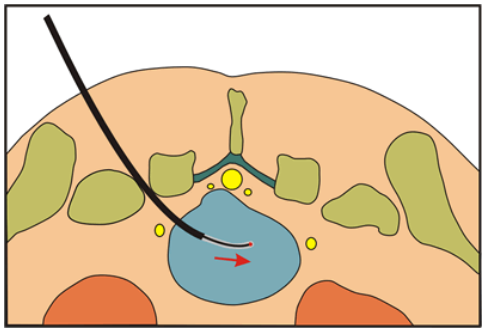


Fig 1: while monitoring the patient, the SpineWand™ is advanced into the disc under continuous fluoroscopy control. As the SpineWand™ is advanced, the Coblation® plasma mode is activated, so that tissue along the path of the device is removed. Tissue is turned into gas which exits the disc via the introducer cannula.

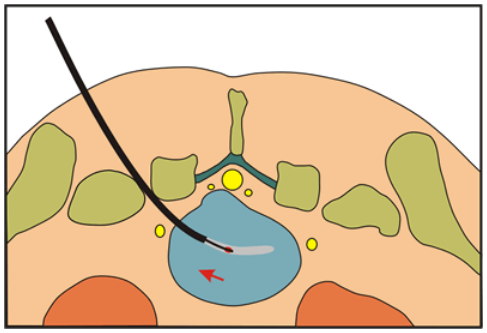


Fig. 2: coagulation – Thermal treatment of tissue as SpineWand™ is withdrawn.

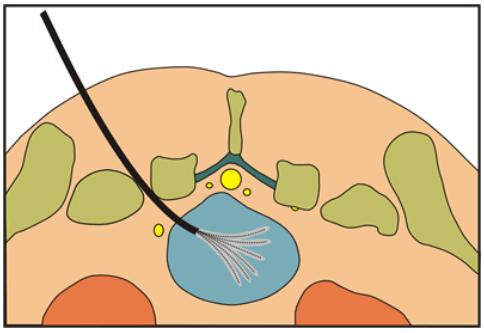


Fig 3: after the first channel is created, the SpineWand™ is rotated clockwise. As the SpineWand™ device is curved each rotation changes its direction and creates a new channel inside the nucleus. Approximately six to twelve channels are created in total, depending on the desired amount of tissue reduction.

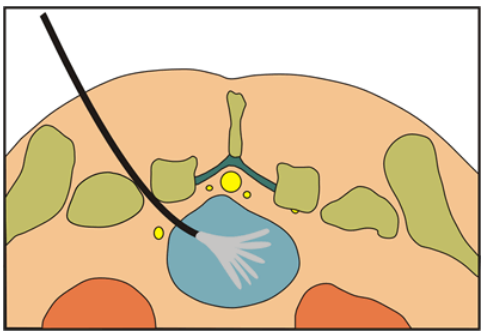


Fig. 4: end of the procedure.

Follow-up

For 2 weeks after the intervention, some positions that could induce hyperkyphosis as well as athletic activities should be restricted. Resolution of sciatica is usually obtained within one to two weeks. The two most critical elements to successful PRDD are proper patient selection and correct needle placement.

7) Results

From 2002 to 2003, 25 patients with herniated lumbar disk and sciatica were treated by nucleoplasty on an out-patient basis in our department. We report the result of 16 patients with enough follow-up in this exhibit. There were 9 male and 7 female patients. The oldest was 51 years and the youngest was 31 years old. Mean age was 45 years. The longest follow-up was 1 year, the average follow-up 6 months. MacNab criteria were used to grade the response to treatment. The overall success rate was 81 % according to MacNab's criteria with 50 % of GOOD and 31 % of FAIR.

These data provide encouraging information substantiating the validity of nucleoplasty for contained lumbar disk herniation. This study is still running, the number of cases must be increased and further comparative studies are necessary to confirm these first data.

Nucleotomy may be more valuable as PLDD as there is no risk of thermal diskitis and the procedure is sensibly shorter. However, the price of the needle electrode is sensibly higher then an optical fiber.

A recent peer-reviewed article (Sharps L, Isaacs Z. Percutaneous disk decompression using nucleoplasty. Pain Physician. 2002;5:121-126) found that percutaneous disk nucleoplasty successfully treated 79% of patients, based on up to a year of follow-up evaluation, and had a success rate of 82% when patients with prior surgery were excluded. These early success rates are comparable to, or slightly better than, those of previous percutaneous approaches. The procedure also seems to lack many of the drawbacks that limited the acceptance of older procedures.

GOOD	Resumed preoperative function. Occasional backache or leg pain. No dependency-inducing medications. Appropriate activity. No objective signs of nerve root damage
FAIR	May be nonproductive if unchanged from preoperative status. Intermittent episodes of mild lumbar radicular pain or low back pain. No dependency-inducing medications. Appropriate activity. No objective signs of nerve root damage

POOR	Subjective: no productivity, continued pain behavior, medication abuse, inactive, compensation litigation focus. Objective: signs of continuing radiculopathy

Fig. 1: MacNab criteria.

Location	Cases
L5-S1	8
L4-L5	8
L3-L4	0

Fig. 2: location of disk herniations : 16 Cases.

8) Cases

Case 1: nucleoplasty at two levels L4-L5 and L5-S1 for disk herniation.

Play movie of the case (avi 720*576 hi res divx-mepg4 movie)

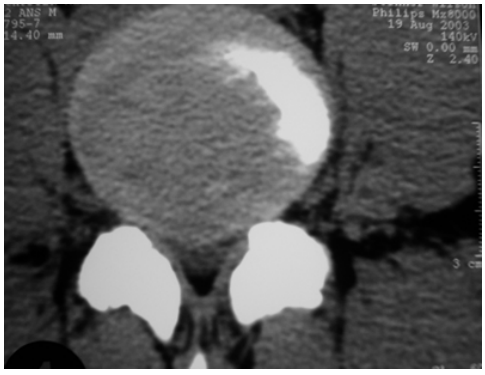


Fig. 1: CT image. L4-L5 midline small-sized subligamentous disk herniation.

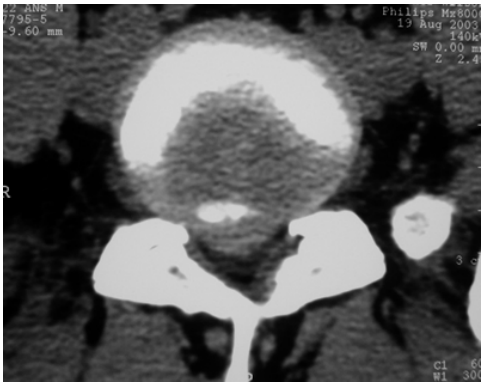


Fig. 2: CT image. L5-S1 midline medium-sized subligamentous disk herniation.

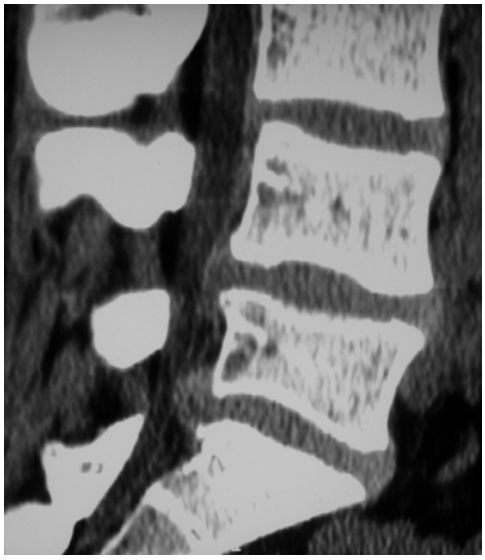


Fig. 3: CT image of same midline disk herniations al level L4-L5 and L5-S1.

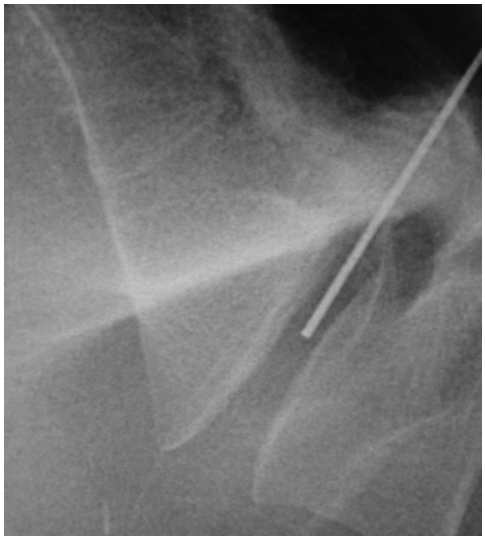


Fig. 4: L5-S1 disk puncture under fluoroscopy control.

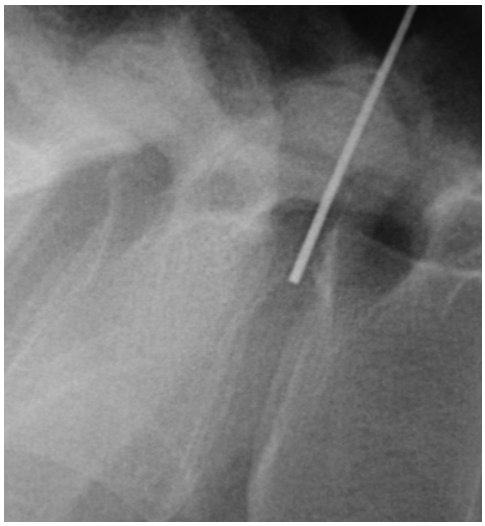


Fig. 5: L4-L5 disk puncture under fluoroscopy control.

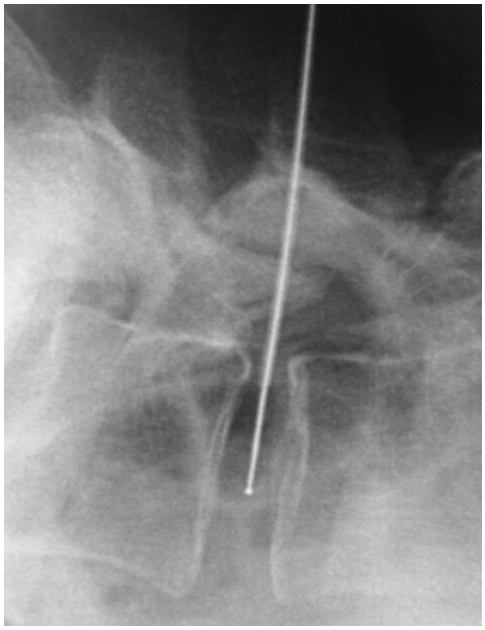


Fig. 6: Level L4-L5, radiofrequency disk ablation, electrode (Spinewand) in position.

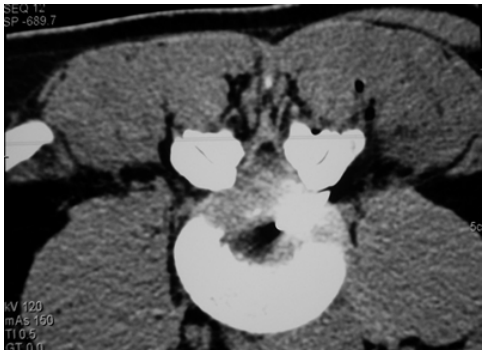


Fig. 7: L4-L5 disk puncture, CT control.

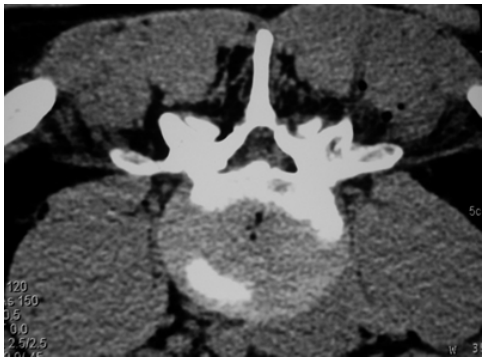


Fig. 8: Level L4-L5, Nucleoplasty, CT control. Gas filling the disk.