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Nucleoplasty: one-year follow-up

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ABSTRACT

Nucleoplasty, the most advanced form of percutaneous discectomy developed to date, has important advantages as compared to other surgical methods: minimal tissue trauma, faster recovery time, local anesthetic, short duration and a painful rehabilitation period. Since the method is newly adopted in Romania, the aim of our study is to centralize the benefits and the side effects of the method in order to spread it on the national level.

Material and methods: *A 12-month prospective, nonrandomized, human clinical study was started in the Neurology Department of the Emergency University Hospital, Bucharest, covering one year time interval (December 2006 – December 2007). The study included 60 patients presenting lumbar pathology at more than one level.*

The used method was the Dekompressor, a highly efficient method for removal of intervertebral disc nucleus pulposus under fluoroscopic control. Periprocedural the patients received antibiotics treatment.

Results: *Up to date there were no procedure related complications. 89% of patients reported improvement of the simptomatology with almost 60% the first 6 months postprocedural while 92% of patients were satisfied with results for 12 months, reporting the reduction of the analgesic intake. In 4% of cases no benefit was reported. The follow-up of the patients is still on-going.*

Conclusion: *The results of our study confirm that nucleoplasty provides the therapeutic benefits of earlier percutaneous disc decompression techniques without many side effects. Clinical results are very promising when the inclusion criteria are strictly respected and therefore we encourage the patients to expect rapid and sustained pain reduction after the procedure.*

Key words: percutaneous discectomy, nucleoplasty, lumbar pathology, decompression

INTRODUCTION

Historically, open surgery has been used to treat **sciatica**, by removing part of the interver tebral disc to provide "decom pression" and relieve the pressure of the disc on adjacent nerve roots (1). The use of percutaneous procedures to decompress intervertebral discs dates back to the 1960's. Early procedures showed conclusively that percutaneous disc decompression relieves pain for appropriate patients. Early procedures had limitations and therefore over the years a

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variety of more advanced techniques have been developed. Minimally-invasive methods have been made available, whereby the entire decompression is performed percutaneously through a needle (2,3).

The most advanced form of percutaneous **discectomy** developed to date is DISC Nucleoplasty. Introduced in 2000, DISC Nucleoplasty represents a minimally invasive method of disc decompression using a unique plasma technology called Coblation® to remove tissue from the center of the disc. ❑

AIM

A number of multi-center randomized controlled trials are currently underway comparing Nucleoplasty to a variety of other treatment options. Since the method is newly adopted in Romania the aim of our study was to centralize the benefits as well as the side effects of the method in order to disseminate it on the national level. ❑

MATERIAL AND METHODS

A 12-month prospective, nonrandomized, human clinical study was started in the Neurology Department of the Emergency University Hospital, Bucharest, covering one year time interval (December 2006 – December 2007). The study included 60 patients with age ranged of 35 to 62 years, 40% men and 60% women, presenting lumbar spine degenerative pathology at more than one level, according to the inclusion criteria mentioned bellow. Prior to percutaneous decompression, informed consent was obtained with full disclosure. *Inclusion criteria* (4)

Patients who can benefit from percutaneous disc decompression are those with pain arising from a contained **herniated disc** – that is a bulging disc where there is no rupture in the outer wall.

1. Radicular pain associated with contained disc herniation less than or equal to 6 mm
2. Clinical history and physical exam findings consistent with radiographic findings of disc herniation < 6 mm (5)
3. Duration of radicular pain greater than 6 months
4. Failure of conservative therapy including: physical therapy, therapeutic epidural injections (Dexamethasone), oral analgesics and oral or intravenous anti-inflammatory medications
5. Good to excellent short-term (<2 weeks) response to fluoroscopically guided transforaminal injection of local anesthetic and corticosteroid at symptomatic level(s)
6. Confirmatory selective segmental spinal nerve block with 0.5 1.5 cc of anesthetic providing > 80% relief of radicular pain lasting at least the duration of local anesthetic
7. Preservation of disc height (less than 50% loss)

Exclusion criteria (4)

1. Patients with no previous conservative therapy for at least 6 weeks
2. Significant and progressive neurological deficits, reflex change, patients with bladder/bowel functional loss (6,7)
3. Patients with disc extrusion, presence of a disc fragment or with disc height less than 50% of normal
4. More than two symptomatic disc levels
5. Previous open surgery at proposed treatment level
6. Spinal fracture or tumor
7. Extruded disc
8. Complete annular disruption (8)
9. Moderate to severe spinal stenosis
10. Severe degenerative disc disease
11. Bone deformities
12. Significant coexisting medical or psychological condition.

The current and newer techniques promise to further clarify multidermatomal unilateral and bilateral cross-innervation presentations. The used method was the Dekompressor, a highly efficient method for removal of intervertebral disc nucleus pulposus through the smallest available channel under fluoroscopic control. Thus, once the root(s)/level(s) were symptomatically confirmed, the Dekompressor® PLD probe was applied to extract the specific contained herniated nucleus pulposus in question.

Benefits of Nucleoplasty (9)

The method presents few advantages such as:

1. minimal tissue trauma
2. it is performed using x-ray guidance
3. short duration (less than 15 minutes) (10)
4. use of local anesthetic drugs

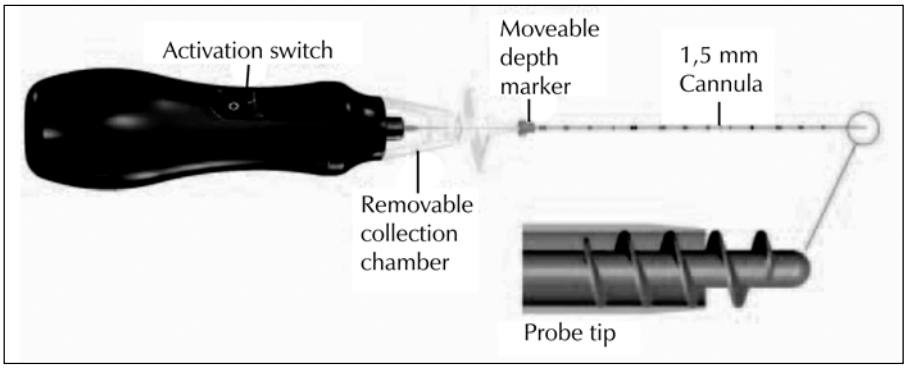

FIGURE 1. Dekompressor® 1.5-mm (17-gauge) Percutaneous Lumbar Discectomy probe: component parts and posterolateral, extrapedicular cannula disc positioning

5. painless and rapid rehabilitation period
6. elimination of complications that may result from open surgery
7. quick symptom relief within two weeks for most patients

During the procedure, the DISC Nucleoplasty SpineWand is introduced through a needle and placed into the center of the disc where a series of channels are created to remove tissue from the nucleus. Tissue removal from the nucleus acts to decompress the disc and relieve the pressure exerted by the disc on the nearby nerve root. As pressure is relieved, pain is reduced, consistent with the clinical results of earlier percutaneous **discectomy** procedures (11,12). Cannulation was technically specific for the herniation location (posterolateral vs. posterolateralcentral) (13).

The procedure is performed by specialists including pain management, neurologist, physiatrist, interventional radiologist and surgeons using x-ray guidance to accurately place the needle in the disc. ❑

RESULTS AND DISCUSSION

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 regards 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 posttreatment.

In the literature there are mentioned few complications of the procedure (14):

1. Stolke (15) reported a complication rate of 13% with:
   - one death
   - three nerve root injuries
   - 1% discitis rate
2. Ramirez and Thisted (16,17) reviewed 28.000 discectomy procedures with:
   - 1 in 64 patients having a major complication
   - 1 in 335 having a neurological complication
   - 1 in 500 having a cardiovascular complication
   - 1 in 1700 dying from the procedure
3. Bhagia et all showed in 2006, for the 53 patients enrolled, as the most common side effects at 24 hrs postprocedure soreness at the needle insertion site (76%), new numbness and tingling (26%), increased intensity of preprocedure back pain (15%), and new areas of back pain (15%). (18)

In the current case series, percutaneous discectomy with Dekompressor® resulted

in significant improvement in functionality, pain scores (VAS) and patient satisfaction in carefully selected patients with radicular pain at 1 year as confirmed by Carey et all in 2000 (19). Furthermore, these results were achieved with small volumes of disc removal (mean 1.25 cc) objectively in all patients within an average of 3 minutes. Follow-up MRI at 1 year has demonstrated as well sustained postoperative reductions in treated contained herniations without accelerated disc degeneration, auger fragmentation or tissue injury (20,21).

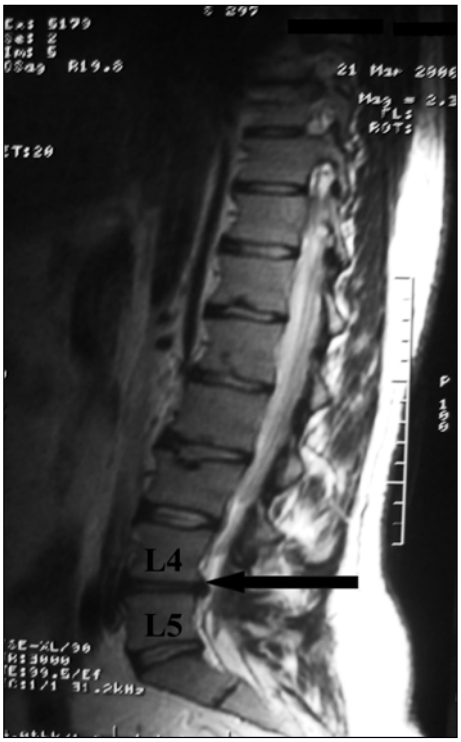

FIGURE 2. L4 – L5 disc herniation

Despite the mentoned complications, during the present study, up to date there were no procedure related complications reported. 89% of patients reported improvement of the simptomatology with almost 60% the first 6 months post procedure and 92% of patients were satisfied with results of 12 months post procedure reporting the reduction of the analgesic intake. In 4% of cases there was no benefit of the method.

This report is a follow-up to the initial 12-month study. Discogenic leg pain was purposefully correlated between clinical exam, imaging study and response to the local anesthetic phase dermatomaly of low-volume selective nerve root blockade. No previously operated disc level was included. Finally, all patients were given ample time to fail more conservative medical management (at least 6 months of rest, physical therapy, medication use and lack of sustained response to epidural and/or selective root block corticosteroid). ❑

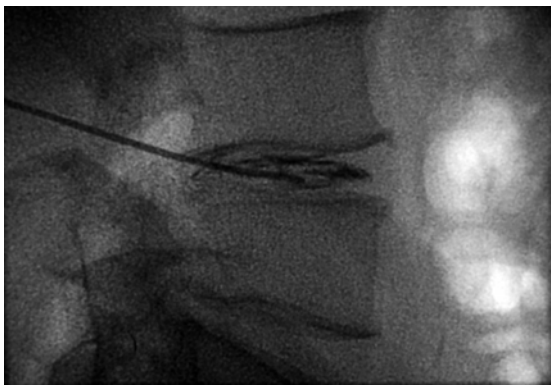

FIGURE 3. a – Plain film of the spine shows localization of the disc under flouroscopy. The Nucleoplasty device has been placed into the disc for partial ablation to decrease pressure on the spinal nerves.

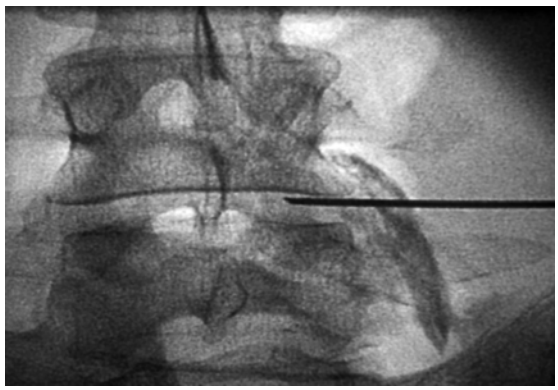

FIGURE 3. b – Plain film of the spine shows localization of the disc under flouroscopy. The Nucleoplasty device has been placed into the disc for partial ablation to decrease pressure on the spinal nerves.

CONCLUSION

Nucleoplasty provides the therapeutic benefits of earlier percutaneous disc decompression techniques without many side effects. The study obtained safe and effective disc removal and pain relief with the Dekompressor® PLD probe at 1 year.

The preliminary cohort obtained safe and efficacious disc removal when inclusion criteria were strictly respected and therefore the percutaneous disc decompression/discectomy can be successfully integrated into a long-term conservative treatment program for chronic discogenic leg pain but longer follow-up is necessary.

Randomized, controlled studies are required to further evaluate its long-term efficacy. ❑

REFERENCES

1. **Lipetz JS** – Pathophysiology of inflammatory, degenerative, and compressive radiculopathies. *Phys Med Rehabil Clin N Am* 2002; 13:439-449
2. **Carey TS, Garrett J, Jackman A, et al** – The outcomes and costs of care for acute low back pain among patients seen by primary care practitioners, chiropractors, and orthopedic surgeons. The North Carolina Back Pain Project. *N Engl J Med* 1995; 333:913-917
3. **Adams MA, Freeman BJ, Morrison HP, et al** – Mechanical initiation of intervertebral disc degeneration. *Spine* 2000; 25:1625-1636
4. **Alò KM, Wright RE, Sutcliffe J, et al** – Percutaneous lumbar discectomy: clinical response in an initial cohort of 50 consecutive patients with chronic radicular pain. *Pain Pract* 2004; 4:19-29
5. **Friedman WA** – Percutaneous discectomy: an alternative to chemonucleolysis? *Neurosurgery* 1983; 13(5):542-547
6. **Alò K** – Interventional Algorithm for Back and Leg Pain: A Clinicians Guide to Success. 6th International Neuromodulation Society World Congress/6th annual meeting of the Spanish Society of Pain live interactive cadaver course. Madrid, Spain; June 24, 2003; and Healthstream Percutaneous Discectomy hands on cadaver course. St.Louis, MO. March 15, 2003; section 4
7. **Southern EP, Fye MA, Panjabi MM, et al** – Disc degeneration: a human cadaveric study correlating magnetic resonance imaging and quantitative discomanometry. *Spine* 2000; 25:2171-2175
8. **Alò K, Wright R, Fu ZJ** – *Open Human Torso Laboratory Dissection with Annular and Nuclear Lumbar Disc Analysis Pre and Post Dekompressor®.* Denver, CO: University of Colorado Health Sciences Center College of Medicine, Department of Anatomy; January 19/20, 2003
9. **Wright R** – *Preclinical Laboratory Analysis of Dekompressor® Percutaneous Decompression in Sheep and Human Cadaver Discs: Internal Data.* Fort Collins, CO: Colorado State University; May 2000
10. **Alò K, Wright R** – First Human Dekompression: Case Report of 2-Year Follow-up. Poster and oral presentation at theEuropean Society of Regional Anesthesia meeting Spanish chapter, Oviedo, Spain; October 2, 2003
11. **Alò KM, Wright RE, Sutcliffe J, et al** – Percutaneous lumbar discectomy: clinical response in an initial cohort of 50 consecutive patients with chronic radicular pain. *Pain Pract* 2004; 4:19-29
12. **Friedman WA** – Percutaneous discectomy: an alternative to chemonucleolysis? *Neurosurgery* 1983; 13(5):542-547
13. **Prescher A** – Anatomy and pathology of the aging spine. *Eur J Radiol* 1998; 27:181-195
14. **Coppes MH, Marani E, Thomeer RT, et al** – Innervation of the painful lumbar discs. *Spine* 1997; 22:2342-2350
15. **Takahashi K, Shima I, Porter RW** – Nerve root pressure in lumbar disc herniation. *Spine* 1999; 24:2003-2006
16. **Caragee EJ, Hahn M, Suen P, et al** – Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and annular competence. *J Bone Joint Surg* 2003; 85-A:102-108
17. **Stolke D, Sollmann WP, Seifert V** – Intra- and postoperative complications in lumbar disc surgery. *Spine* 1989; 14:5659
18. **Ramirez LF, Thisted R** – Using a national health care data base to determine surgical complications in community hospitals: lumbar discectomy as an example. *Neurosurgery* 1989; 25:218-225
19. **Ramirez LF, Thisted R** – Complications and demographic characteristics of patients undergoing lumbar discectomy in community hospitals. *Neurosurgery* 1989; 25:226-230, discussion 230-231
20. **Bhagia S, Slipman CW, Nirschl M, et al** – Side effects and complications after percutaneous dis decompression using coblation technology. *American Journal of Physical Medicine & Rehabilitation.* 2006; 85(1):6-13
21. **Carey T, Garrett J, Jackman A** – Beyond a good prognosis: examination of an inception cohort of patients with chronic low back pain. *Spine* 2000; 25:115-120
22. **Smith SE, Darden BV, Rhyne AL, et al** – Outcome of unoperated discogram-positive low back pain. *Spine*1995; 20:1997-2000
23. **Van Tulder MW, Koes BW, Bouter LM** – Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions. *Spine* 1997; 22:2128-2156