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Efficacy of a New Navigable Percutaneous Disc Decompression Device (L'DISQ) in Patients with Herniated Nucleus Pulposus Related to Radicular Pain

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Abstract

Study Design. An institutional, prospective clinical data analysis.

Objective. To evaluate the safety and efficacy of a new navigable percutaneous disc decompression device (L'DISQ) in patients with lumbar disc herniation with radicular pain.

Methods and Outcome Measures. We performed disc decompressions using L'DISQ on 27 patients with persistent disabling back and leg pain for 1 month or longer (average 6.48 months) due to a herniated lumbar intervertebral disc. Baseline data were prospectively gathered before the index procedure and at 1, 4, 12, and 24 weeks post-procedure. Data included pain intensity (visual analog scale [VAS]), measure of disability (Oswestry Disability Index [ODI] and Rolando–Morris Questionnaire [RM]), health-related quality of life (Bodily Pain Scale of Short Form-36 version 2 [SF-36 BP]), and passive straight leg raising test (SLR).

Results. The VAS fell from 7.08 ± 1.22 to 1.84 ± 0.99 scores at 24 weeks post-procedure. At 24 weeks, the ODI had fallen from 41.88 ± 10.61 to 16.66 ± 8.55% and the RM from 11.52 ± 3.91 to 2.68 ± 1.97 points. The SF-36 BP dropped significant improvement from 32.89 ± 5.83 to 49.57 ± 4.96 scales. In the SLR test, the angular change of 24 weeks showed considerable improvement from 60.20 ± 20.02 to 83.00 ± 14.29 degrees. No major complication occurred, although two cases developed a disc reherniation 1 month post-procedure.

Conclusions. The L'DISQ device is specifically designed to remove herniated disc using a wand that can be navigated into a disc protrusion or extrusion. Following decompression, we measured clinically significant pain improvement and decreased disability for patients with both radicular and axial pain caused by protruded and extruded discs.

Key Words. Percutaneous Decompression; Disc Herniation; Radiofrequency; Low Back Pain

Introduction

Minimally invasive disc decompression procedures have been developed over the last c. 20 years to treat radicular pain caused by disc herniation. Although partial nuclear decompression by various minimally invasive techniques

is generally safe and less invasive than open surgery, studies report inconsistent axial pain relief, and most studies report a lower success rate than open and microdiscectomy for relieving radicular pain [1,2]. One reason for these inconsistent results may be the device design does not easily allow direct decompression of herniated disc material.

Introduced in 1999 and promoted to cause minimal collateral thermal damage [3], Nucleoplasty (ArthroCare Co., Sunnyvale, CA) is representative of nuclear decompression devices that remove nuclear tissue through introducer needles that is typically inserted into a lumbar disc using a posterior lateral approach. Although different devices use various methods to remove nuclear tissue, the Nucleoplasty wand vaporizes nuclear tissue using a bipolar radiofrequency technology applied to a saline conducting medium. The disadvantage of the Nucleoplasty device, and indeed the disadvantage of most other minimally invasive devices and techniques, is the inability to easily reach the herniated nucleus. Direct removal of herniated disc tissue is therefore limited, and removal of disc extrusions is impossible. Instead, nuclear decompression relies on pressure reduction and "implosion" of a disc protrusion to reduce pressure on the traversing or exiting nerve roots. While studies show reduced disc pressure in hydrated discs [4], implosion of nuclear material has not been validated [5].

Funding from the Korean Health Industry Development Institute facilitated the development of a navigable decompression device named L'DISQ (U&I Co., Uijeongbu, Korea). Designed to allow direct access to herniated disc material, the device vaporizes the herniated nucleus using bipolar radiofrequency current similar to Nucleoplasty. (Figure 1) In contrast to the Nucleoplasty device, the L'DISQ wand can be curved by rotating a control wheel and directed into a disc herniation. After inventing this new device, coworkers initiated a clinical feasibility pilot study of L'DISQ treatment. From the pilot study, the technical catheter and treatment protocol were developed.

The purpose of this study is to evaluate the ability, ease, and safety of navigating the L'DISQ wand into a herniated disc and to explore whether percutaneous removal of a herniated disc using L'DISQ might provide comparable outcomes to microscopic discectomy and other small bore percutaneous devices that decompress only the nucleus. Our ultimate goal of this pilot study is to gather data to be used in a feasibility analysis for a future controlled comparative study and not to prove or disprove the ultimate worth of this procedure.

Methods

Patient Recruitment

In a 5-month period after obtaining study approval from the Korean University institutional review board, 91 consecutive patients complaining of low back and leg pain were prospectively recruited for study inclusion. The 91 patients included all the patients seen in a university spinal pain outpatient clinic by the first author or one of his fellows that had persistent disabling axial and radicular pain unresponsive to conservative treatment for a least 1 month. All 91 patients were then further investigated or had recently obtained a lumbar spine X-ray, magnetic resonance image (MRI), and an electromyographic (EMG) study. From the original 91 patients, 28 patients met the inclusion criteria, which included in addition to the disabling axial and radicular pain, and intervertebral disc herniation related to spinal root compression demonstrated on an MRI scan or MRI evidence of disc herniation with EMG evidence of lumbar radiculopathy. Exclusion criteria included a normal MRI and normal EMG finding, prior surgery at the herniated level, symptoms or signs of lumbar canal stenosis, psychological issues raised by the examination or history, tumor, systemic infection or localized infection at the anticipated entry needle sites, traumatic spinal fracture, a history of coagulopathy, unexplained bleeding, other peripheral neuropathies of the lower extremities, and the patient's denial. In particular, 67 patients were excluded for the following reasons: 27 patients were excluded because of normal MRI and EMG findings, 26 patients were excluded because of symptoms and signs of lumbar stenosis that correlated with the MRI findings, five patients were excluded because of prior surgery at the target level, five patients were excluded because of EMG findings of diabetic peripheral polyneuropathy, and one patient was excluded for denying treatment by L'DISQ.

Figure 1 The wand and navigable tip of the L'DISQ is illustrated. The tip of the wand is curved to the desired angle by rotating the control wheel. After placing the tip into the posterior annulus, plasma energy induced by radiofrequency is used to ablate and decompress the disc herniation.

Patient Preparation

Prophylactic intravenous antibiotics were administered 30 minutes before the procedure, and in the surgical suite,

we monitored patients with electrocardiogram, pulse oximetry, and automated blood pressures. The patients were positioned prone on the surgical table and fluoroscopic examination of the spine was performed to confirm segmentation and determine the appropriate level of needle. Sedation was limited to 20 mg of profopol administered as necessary during anesthetization of the skin and subcutaneous fascia onto the superior articular process contralateral to the herniated disc.

Procedure Protocol

We used a standard posterior lateral approach to the disc as previously described [6] but modified the technique to approach the disc further lateral so that the introducer needle would contact the disc margin at a line drawn between the medial border of adjacent pedicles rather than the midline. We also slightly curved the distal end of the introducer needle to facilitate directing the introduced wand medial across the posterior annulus either slightly within or in some cases, outside the posterior disc annulus.

A 25-gauge needle was first inserted into the target disc nucleus and 1 to 2 mL of contrast was injected to outline the disc herniation. Next, we marked the skin 12 to 15 cm from the midline to provide the approximate site of needle entry. The endplates of the target disc space were aligned and the C-arm rotated ipsilateral to position the lateral margin of the ipsilateral superior articular process approximately 3/5 distance across the vertebral body as visualized in the oblique position. This typically required rotating the C-Arm 15 degrees from a zero-degree lateral projection. After anesthetizing the skin and subcutaneous fascia to the superior articular process, we manually curved the 16-gauge introducer needle approximately 15 degrees in the distal, ~1 cm from the distal tip. The introducer needle was directed toward the lateral edge of the superior articular process following the local anesthesia tract and guided by intermittent fluoroscopic “down the beam” projection using a “corkscrew” rotation of the slightly curved distal tip. Once the lateral edge was touched, we directed the needle tip over the process with the curve pointing away from the midline, and then once over the superior articular process, we typically rotated the needle to point toward the midline. Prior to advancing the introducer needle across the midline, the anterioposterior projection was checked. A lateral projection was used to slowly advance the needle across the foramen toward the disc margin. As the needle tip was directed toward the midline, the AP projection was intermittently checked to assure that the needle tip was always lateral of the medial border of the pedicle. Care was taken not to penetrate the neural tissues, and the patient was asked to report any buttock or leg pain. Our ideal technique was to avoid puncturing a normal posterior annulus if we felt that we could safely pass the introducer needle directly into central protrusions or pass the wand posterior to the disc annulus in cases of contralateral disc extrusions (Figure 2).

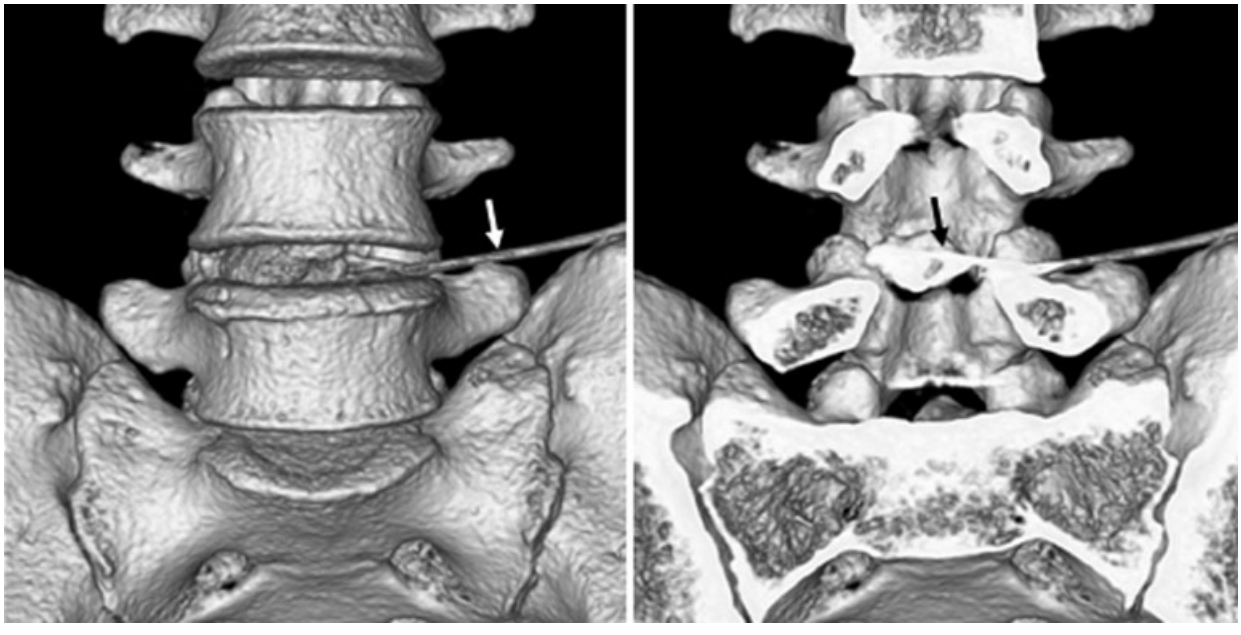

Figure 2 A three-dimension computed tomographic reconstruction image of the pathway of the L’DISQ wand is shown. In this case, the introducer needle (white arrow) was advanced posterior to the annulus into the annular extrusion. The tip of the L’DISQ wand (black arrow) is seen within the extrusion disc. The computed tomography scan was obtained with the patient’s permission to evaluate immediate post procedure changes.

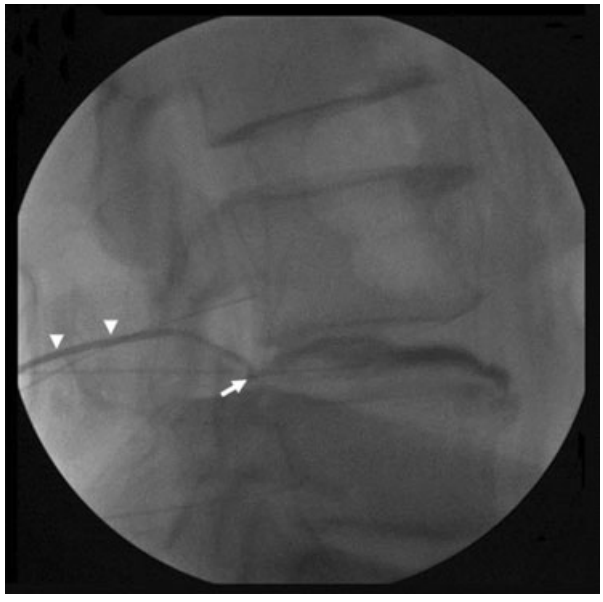

Figure 3 Confirmed by the injection of contrast media, a lateral C-arm fluoroscopic view shows the tip of wand (arrow) within a herniation. The arrowhead indicates the introducer needle.

The advancement of the needle was precisely controlled by rotating the direction of the needle tip bend. Entering the herniation was identified by a sudden loss of resistance. After confirming the introducer needle position with the lateral and AP view, the stylet was removed and through the introducer needle, the wand was advanced to the center of the herniated disc using fluoroscopic monitoring of the AP and lateral views. Before ablation, negative motor nerve stimulation confirmed the needle was not close to the traversing or exiting nerve root. During the ablation, the tip of the wand was continuously rotated and moved back and forth to increase the ablated volume. We also strived to remove disc material within the annular tears with either the same wand position or in some cases, after repositioning of the wand (Figure 3). The entire procedure was monitored, recorded, and evaluated by C-arm fluoroscopy.

Outcome Measures

The baseline values were obtained before the procedure, and patient outcome data were obtained at follow-up visits scheduled at 1, 4, 12, and 24 weeks post-procedure. Gathered data at each follow-up included a visual analog scale (VAS), Oswestry Disability Index (ODI), Rolando–Morris questionnaire (RM), Bodily Pain Scale in Short Form-36 version 2 (SF-36 BP), and degrees of angle in passive straight leg raising test. Paired *t*-tests before and at each follow-up period were used to determine statistical significance. The SF-36 BP scores were compiled with the standard accompanying software. SPSS 12.0KO for windows (SPSS Korea Datasolution Inc., Seoul, Korea) was used to evaluate the variance of outcomes measured at different follow-up intervals.

Results

Patient Characteristics

Twenty-seven of 91 patients included in this study and were treated with lumbar disc decompression using L'DISQ. Patient gender distribution was 19 males (70.4%), eight females, with a mean age of 40.7 ± 15.3 years, ranging from 16 to 68 years. Mean duration of symptoms was 6.5 ± 4.0 months, ranging from 1 to 14 months. Follow-up data were obtained in 25 patients to the sixth month follow-up. Two patients dropped out because they had an open surgical operation before the final 6-month follow-up period. Levels of targeted disc were L3/4 in three cases, L4/5 in 18 cases, and L5/S1 in 6 cases. Among the 27 intervertebral discs, seven discs had disc protrusions and 20 discs had extrusions (Table 1) [7]. Most of the patients' symptoms and physical signs correlated to the MRI findings, and in particular, the MRI showed a protrusion or extrusion contacting or displacing or traversing or exiting nerve root. If the disc protrusion was small and did not directly contact the traversing or exiting root, a positive EMG was required to confirm radiculopathy (Table 2).

Success Rate

A successive outcome for the patient was defined as a reduction of VAS more than 50%. A greater than 50% reduction of the VAS score was measured in 76.0% of patients at 1 week, 84.0% at 1 month, and 88.0% at 3 and 6 months (Figure 4A).

Table 1 Study group patient characteristics (N = 27)

Gender	
Male: female	19: 8 (Male, 70.4%)
Age (year)	
Mean ± SD	40.67 ± 15.26
Range	16 to 68
Duration of symptoms (month)	
Mean ± SD	6.48 ± 3.96
Range	1 to14
Level of targeted disc (cases)	
L3/4	3
L4/5	18
L5/S1	6
Configuration of targeted disc	
Focal protrusion	7
Extrusion	20

SD = standard deviation.

Table 2 Characteristics of patients' radicular pain

Nerve root level	Physical examination	Confirmative study
L5 (N = 20)	Abnormal sensation on lateral leg with or without weakness of great toe dorsiflexor	MRI (N = 14): L5 nerve root compression EMG (N = 4): L5 radiculopathy
S1 (N = 6)	Abnormal sensation on sole with or without weakness of ankle plantar flexor	MRI (N = 2): S1 nerve root compression EMG (N = 4): S1 radiculopathy
L5 and S1 (N = 1)	Abnormal sensation on lateral leg and sole with weakness of great toe dorsiflexor	EMG (N = 1): L5 and S1 radiculopathies

EMG = electromyographic study; MRI = magnetic resonance image study.

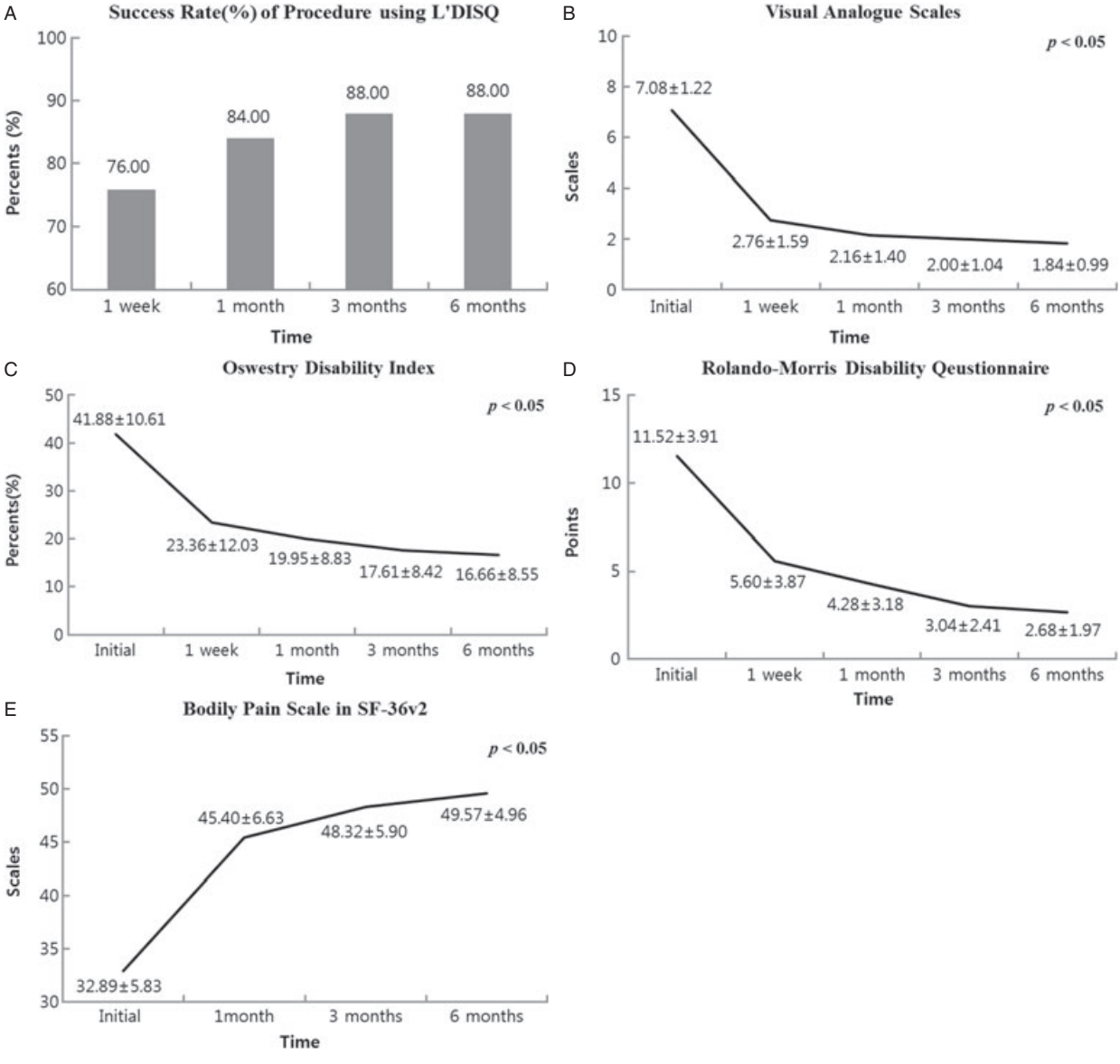

Figure 4 The figure documents statistical improvement ($P < 0.05$) during the period between initial and post-1 week in all outcome measurements. (A) Success rate as defined by a greater than 50% drop in the visual analog scale. (B) The serial visual analog scales. (C) The serial Oswestry Disability Indexes. (D) The serial points of Rolando–Morris Disability Questionnaire. (E) The serial Bodily Pain scales of Short Form-36 version 2.

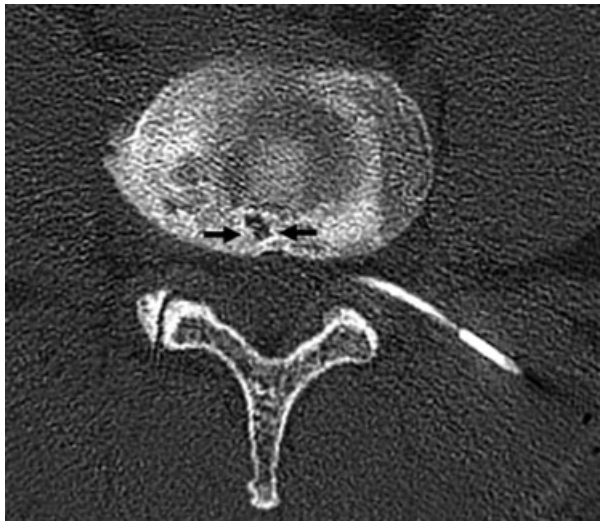

Figure 5 A computed tomographic scan performed just after the procedure illustrates the probable results of radiofrequency ablation as indicated by opacity (arrow) around the treated disc herniation.

Outcome Measures

All of the VAS, ODI, RM points, and SF-36 BP scales showed statistical and meaningful clinical improvement (Figure 4B–E). By the first 4-week follow-up, the major VAS and ODI signs of improvement were present ($P < 0.05$) and were sustained but with little further improvement at 1-month and 6-month follow-up visits. The RM points decreased significantly until the third month ($P < 0.05$) and maintained at the 6-month follow-up visit. The SF-36 BP scales increased steadily for 6 months from a starting average of 32.89 ± 5.83 to 49.57 ± 4.96 ($P < 0.05$) at 6 months. The mean degree of straight leg raising angle averaged 60.20 ± 20.02 preoperatively and improved to 83.00 ± 14.29 at 1-week post-operatively ($P < 0.05$), sustaining the improvement between post-1 week and 6 months. Likewise, the improved angles between preoperative and 1 week postoperative were 22.80 degrees, sustaining the improvement at 6 months.

Post-Imaging Study

In one case, after completing the procedure by C-arm guidance, the morphologic state of the target point was confirmed by computed tomography. The opacity around the target point increased, and thus, this change may be a tissue defect by ablation (Figure 5).

Failure of Treatment and Complications

Within 2 months of the procedure, two patients had a reherniation and elected to undergo open surgical discectomy. Both patients' VAS scores were, however, improved immediately before surgery with scores falling from 8 to 2 and 8 to 5. There were no procedure-related complications including infection, bleeding, or worsening of their preoperative symptoms.

Discussion

We prospectively gathered and analyzed 1- through 6-month follow-up data on 25 consecutive patients post-percutaneous disc decompression for radicular and axial pain using the L'DISQ percutaneous disc decompression device. All of the patients showed statistical and clinically significant improvement in both pain scores and functional status at each follow-up period, with a trend for gradually improvement over 6 months. The average 88% improvement in VAS scores is better than the 75% to 80% improvement reported using other percutaneous interventional decompression devices [8]. In this small series, we had no significant morbidity and more importantly, no patients reported worsening of their symptoms.

Although all patients had disc protrusions, several patients had protrusion of only 1 to 2 mm. In those cases, a positive EMG was consistent with radiculopathy caused by a "leaking" disc or direct irritation caused by a more significant bulge in a weighted position. These patient were offered and accepted a percutaneous disc decompression because of the intensity and persistence of their pain

Percutaneous disc decompression procedures are an alternative treatment to open disc surgery to treat lumbar disc herniation [9]. Various interventional techniques include chemonucleolysis, ozone, automated percutaneous lumbar discectomy, intradiscal laser discectomy, intradiscal electrothermal therapy, and percutaneous nucleoplasty [10–15]. Although the injectable liquids and gasses may reach the herniated nucleus, most devices are designed to decompress the center of the nucleus rather than the herniated disc.

In contrast to most percutaneous nuclectomy devices that use a rigid and uncontrolled tip, L'DISQ has a navigable tip that can be curved to the desired angles by rotation of the control wheel. Direct removal of the herniated tissue by the L'DISQ allows access to larger herniations and extruded fragments that are currently considered a contraindication for most percutaneous devices [16–18]. In addition, compared with open surgical discectomy, percutaneous removal through a relatively small bore introducer cannulae placed directly into the herniation or though the posterior–lateral annulus will theoretically better preserve the integrity of the outer annulus and potentially reduce the 7% to 25% reherniation rate following open discectomy [19].

As the distance between the two electrodes on L'DISQ tip is 2 mm, a nerve root greater than 2 mm from the tip is theoretically safe from electric injury. Indeed, the electric currents should pass to the other electrode instead of the nerve root rather than passing to the nerve root. In addi-

tion, the thin outer annulus membrane is, at best, a poor conductor of electrical current, which should theoretically reduce neural damage due to the bipolar electrical current. Closely monitoring for the occurrence of leg pain should prevent injury due to heat. In addition, the wand tip should obviously be moved if electric stimulation causes lower extremity contraction. In this regard, we noted muscle contraction in two cases, and the wand tip was moved. No patients suffered neural injury, and no patients reported neural irritation symptoms post-procedure.

As this cohort has a small sample size, has a relatively short follow-up, and is the first pilot study using this devise and technique, comparative studies with appropriate sample size are the next step. The initial outcome results are, however, promising, and the procedure appears as safe as other percutaneous techniques with comparative or better short-term outcomes.

Acknowledgment

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