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Original Contribution

Percutaneous Disc Decompression Using Coblation (Nucleoplasty™) in the Treatment of Chronic Discogenic Pain

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Clinical outcome data was analyzed for 67 patients with contained disc herniation who underwent percutaneous disc decompression procedure using Coblation® technology, also referred to as Nucleoplasty after failing to respond to conservative management. Patients presented with clinical symptoms of discogenic low back pain and/or leg pain and were not considered candidates for open surgery. Follow-up data was collected up to 12 months.

Patient gender distribution was 70% female, 30% male, with a mean age of 44 years. The onset of the pain was predominantly of nontraumatic origin with an average duration of pain of 5.4 years ranging from 4 months to 29 years with history of previous surgical intervention in 13% of the patients. At 1 year, 80% of the patients demonstrated statistically significant improvement in numeric pain scores. Average pre-procedure pain level for all patients was reported as 6.8 while average pain level was 4.1 at the 12-month follow-up period. Statistically significant improvement was observed in 62%, 59%, and 60% of patients in sitting, standing, and walking ability at 12 months, respectively.

The results of this analysis indicated that PDD using Coblation technology, also referred to as Nucleoplasty, is an effective procedure for patients presenting with discogenic back and/or leg pain who have failed conservative therapies and are not considered candidates for open surgical interventions.

Keywords: Percutaneous disc decompression, nucleotomy, contained disc herniation, Coblation, Nucleoplasty, radiofrequency

Chronic low back pain is the most common ailment in modern industrial societies. It ranks first among musculoskeletal disorders, resulting in serious financial and social consequences (1-5). Because of its highly specialized role and relatively susceptible nature, the intervertebral disc is the focal point of pathology for most low back pain, including sciatica, though the mechanism and pathway of pain generation and conduction has not been elucidated (6). Kuslich et al. (7) identified intervertebral discs as capable of generating pain in the low back, along with facet joints, nerve root dura, ligaments, fascia, and muscles. Many investigators have estimated that, in a substantial percent of patients with chronic low back pain, the lumbar disc is the principle pain generator (8, 9). While the uncertainty continues as to whether discogenic pain is mediated via a chemical, mechanical, neural, or combination of the above mechanisms, primary discogenic pain has been reported in 39% of chronic low back pain patients by Schwarzer et al. (8) and 26% of the patients by Manchikanti et al. (9). Pain arising from the posterior annulus of the intervertebral disc can present as buttock, hip, groin, and lower limb pain without direct involvement of the nerve root (10).

It is a commonly held belief that compressive forces applied to the intervertebral disc play a role in causing disc degeneration resulting in discogenic pain. The nature of the association between mechanical force and disc degeneration remains obscure, however it is evident that mechanical, physical, chemical and pharmacological factors must maintain a precarious equilibrium for proper regulation of cellular activity and tissue morphology (11). Hydrostatic pressure plays a very important role in the regulation of nutrient supply to the disc (12). Studies conducted on intervertebral discs indicate that the disc functions optimally within a specific intradiscal pressure range, with a hypothesized average of 0.33 MPa (13,14). Hans-Joachim et al. (15) reported the range of an adult, 70kg, 45 year-old male at L4-L5 as 0.1MPa to 2.3MPa. Variation outside of an individual's normal range may reduce the number of viable cells within the disc and will directly affect collagen and proteoglycan synthesis, contributing to disc degeneration (12, 16-18).

Treatment of discogenic low back pain by reduction of intradiscal pressure involves removal of part of the nucleus

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via surgical or minimally invasive methods. Surgical treatment of intervertebral disc herniation such as open discectomy, microdiscectomy, and laminectomy are often targeted for patients with uncontained or large herniations, and/or sequestered discs. Patients presenting with small contained herniated discs who have not responded to conservative non-invasive treatment, are often not considered as surgical candidates. A recent study conducted by Carragee et al. (19) indicated that patients with contained disc herniation, measuring less than 6 mm anterior-posterior (AP) measurement had a success rate of only 24% after discectomy compared to a success rate of 98% for patients with disc herniation measuring more than 9 mm. In the past, patients with small, contained disc herniations have had limited options for relief of back pain. However, over the last three decades, minimally invasive percutaneous techniques using an intradiscal approach have evolved as a viable option. The various modalities utilized have ranged from intradiscal injection of chymopapain for nucleolysis, percutaneous manual nucleotomy with the nucleotome, and thermal vaporization with laser. These percutaneous disc decompression methods decrease intradiscal pressure by virtue of volumetric reduction of the nucleus pulposus using a minimally invasive approach (20).

The efficacy of disc decompression has been verified through 40 years of disc decompression techniques. Chemonucleolysis using chymopapain became available in 1964 and has demonstrated long-term success rates between 66% and 88% (21-25). Though it has become commercially unavailable in the U.S., chymopapain is still widely used outside of the U.S. Manual percutaneous discectomy, automated percutaneous lumbar discectomy, and percutaneous endoscopic lumbar discectomy have all demonstrated successful treatment of back pain, with results varying from 50% to 100% (26-29).

In 1984, Case et al. (30) proposed pressure reduction using laser energy introduced through a needle to remove a small volume of nucleus pulposus. Success rates for the various lasers used range between 63% and 89%, with pain relief lasting over 12 years (20,31,32).

Percutaneous disc decompression, regardless of technique, has been based on the principle that a small reduction of volume in a closed hydraulic space, like an intact disc, results in a disproportionately large fall of pressure. Case et al. have justified this theory in two separate in vitro studies, showing that a large rise in pressure will regularly result from a small increase in volume and that, therefore, the opposite is also true, confirming the biochemical basis for the benefits obtained from interventions designed for disc decompression (30,33).

Percutaneous disc decompression (PDD) using Coblation technology, introduced in July of 2000, implements this principle of volumetric reduction to achieve disc decompression. Approximately 8000 patients have undergone the Nucleoplasty procedure. Coblation technology is an alternative to traditional electrosurgical techniques and laser for use during soft tissue surgery. The advantages of Coblation technology over electrosurgical techniques include a significant reduction of heat generated collateral damage to surrounding tissue, replacing the thermally damaging vaporization and pyrolysis of standard electrosurgery with molecular disintegration via a low temparature ablative process (34).

When Coblation technology was extended as a treatment option for patients with discogenic axial back and/or leg pain, it had already been successfully utilized for soft tissue removal in over 1 million surgeries in various medical fields, including arthroscopic orthopedic surgery and neurosurgery (34-36). Coblation or "controlled ablation," is a voltage-mediated process consisting of two modes, tissue ablation and coagulation. Temperatures in both modes are between 40° to 70° C. During ablation, a plasma field is generated between the electrode and tissue from isotonic saline solution. As a result of the voltage gradient across this plasma layer, charged particles are accelerated towards the tissue, breaking molecular bonds in the plasma of the disc nucleus into element molecules and low molecular weight gases. These byproduct gases, i.e., oxygen, nitrogen, hydrogen, carbon dioxide, etc., exit the disc through the introducer needle. A zone of thermal coagulation of approximately 1 mm radius is created during coagulation when the wand is moved 0.5 cm per second, inducing shrinkage of collagen (34). The final result of this process is six channels created in disc, with approximately 1 cc of tissue volume removed.

The safety and efficacy of the PDD procedure using Coblation technology has been carefully analyzed in three separate studies by Chen et al. They concluded that a safe volumetric removal of the nucleus is achieved and that no disruption or necrosis of the surrounding vital structures, nucleus, annulus, endplate, spinal cord, or nerve root occurs (37), that no change in temperature is detected at 5 mm away from the tip of the wand (38), and that after two channels are created within the disc, intradiscal pressure decreases dramatically (39).

Sharps and Isaac (40) reported an overall success rate of 79%, with 67% success in the group of patients that had previous surgery and 82% success in the group that had no prior surgical intervention at 12 months. They concluded that PDD using Coblation technology is a promising and efficacious minimally invasive procedure for the treatment of symptoms associated with contained herniated discs.

METHODS

From October 2000 to December 2001, sixty-seven patients who met inclusion criteria, underwent percutaneous disc decompression (PDD) with Coblation technology in this outcome analysis. Inclusion criteria were as follows: contained disc herniation with presence of discogenic axial back pain and/or leg pain for greater than three months, absence of neurologic deficit, lack of response to conservative management and fluoroscopically directed injection therapies, and positive provocative discography with elicitation of concordant pain and at least one negative control disc. Exclusion criteria for this outcome analysis were: litigation, heavy opioid usage, and uncontrolled psychological disorders. Patients presenting with disc herniation with sequestration, large contained herniation occupying one-third or more of the spinal canal, non-qualifying results on provocative discography, evidence of infection or spinal instability, and marked spinal stenosis due to extensive osteophytosis are not considered candidates for this procedure.

PDD using Coblation technology was performed on an outpatient basis under local anesthesia and monitored anesthesia care in an operating room using sterile technique. The same physician performed all procedures in a prone or semi-oblique position using a uniportal approach under fluoroscopic guidance, entering the disc from the side of predominant pain. A 17-gauge six-inch long Crawford type spinal access cannula was introduced into the disc using a posterolateral extrapedicular approach. The access cannula was positioned at the junction of the annulus and nucleus (Fig. 1). Under fluoroscopy in the anterior-posterior projection, this was regarded at a site just medial to the medial border of the pedicles above and below the disc space. The Perc-DLE tissue ablation and coagulation spinal wand (ArthroCare, Inc. - Sunnyvale, CA) was placed into the access cannula and was advanced until the tip of the wand was approximately 5 mm beyond the tip of the cannula, assuring that the active portion of the wand was beyond the inner layer of the annulus and was placed in the nucleus (Fig. 2). A circumferential reference mark on the shaft of the spine wand was placed adjacent to the needle hub at the entry site, marking the proximal channel limit. The wand was advanced until it came into contact with the annulus on the opposite side (Fig. 3). The depth stop marker on shaft of the Perc-DLE spine wand was advanced close to the needle hub to designate the distal channeling limit. The process of decompression involved advancing the wand, in ablation mode, at a speed of 0.5 cm/sec and, similarly, retraction of the wand was performed in coagulation mode at a speed of 0.5 cm/sec. A total of six channels were created at the twelve, two, four, six, eight, and ten o'clock positions.

Postoperatively, patients were permitted to perform limited walking, standing, and sitting as needed during activities of daily living. No lifting of over 10 pounds, bending, or

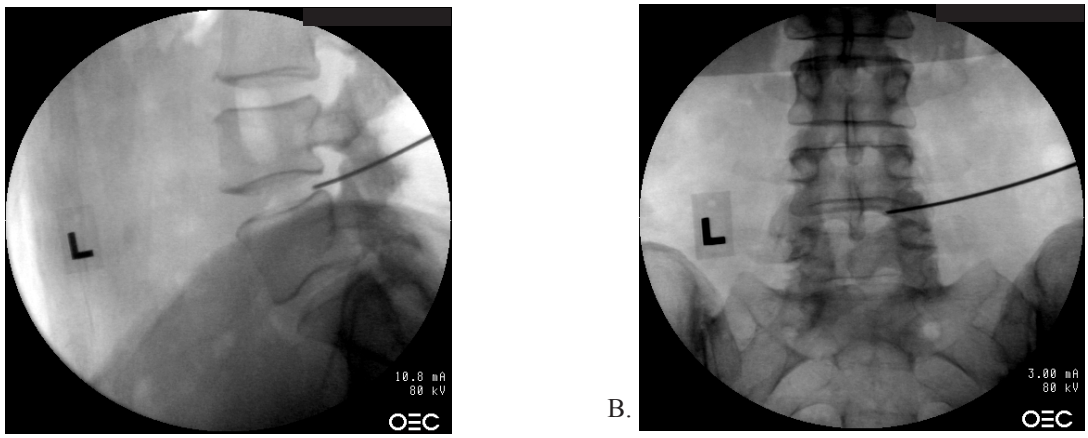

Fig 1. Position of the cannula entering through the annulus. A-Lateral View, B-AP View.

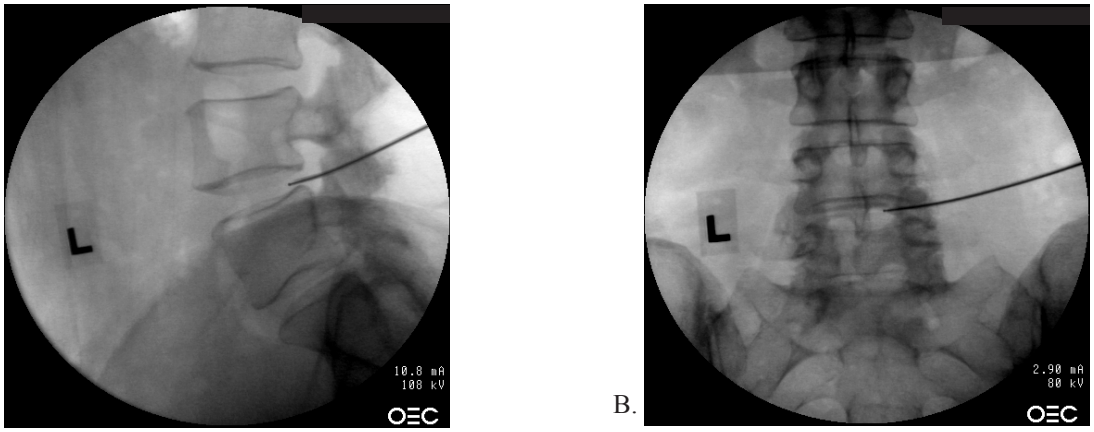

Fig 2. Proximal position of the wand protruding from the cannula. A-Lateral View, B-AP View.

stooping was permitted for 2 weeks following percutaneous disc decompression. Patients were returned to sedentary or light work after two weeks and were provided with home exercise instructions by a qualified physical therapist.

Data was collected at 1, 3, 6 and 12 months. The outcome measures used were the patient's report of pain intensity using a numeric scale of 0 to 10 (with 0 being no pain and 10 being the most severe pain), percent of pain relief, and improvement in functional status determined on the basis of ability to sit, stand, and walk.

Data were recorded on a Microsoft® Excel work sheet; the SPSS Version 9.0 statistical package was used to generate frequency tables, the Student's *t*-test with a two-tailed paired comparison was used to compare the means between visits and to compare success based on demographic variables. Statistical analyses were performed independently by a non-clinical research assistant and an outside party to ensure objectivity. Results were considered statistically significant if the *p*-value was equal to or less than 0.05 for continuous variables. For percentage outcomes and non-parametric values, 95% confidence intervals and Wilcoxon sign test were used to show statistical significance, respectively.

RESULTS

Demographics

Demographics of the 67 patients included in the study are illustrated in Table 1. Patient gender distribution was 70% female, 30% male, with a mean age of 44 ± 10.6 years,

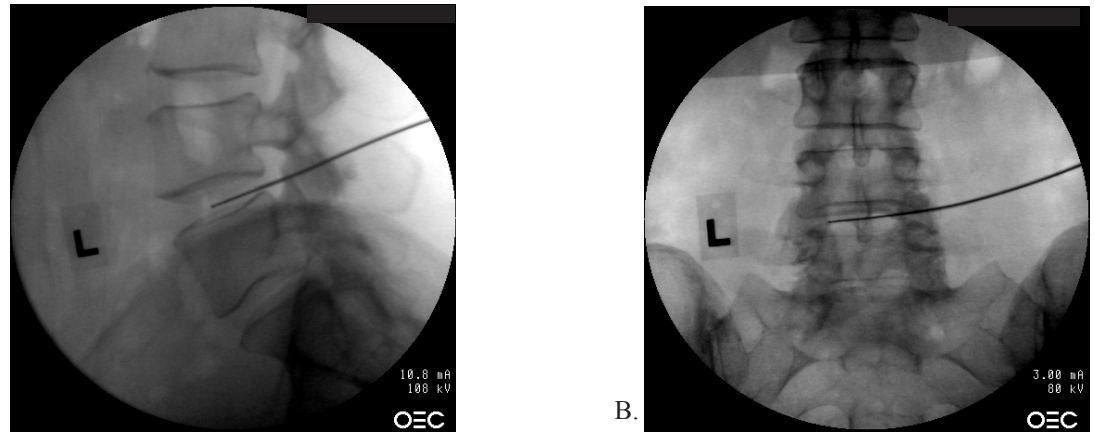

Fig 3. Distal position of the wand with the tip in contact with the opposite side of the annulus. A-Lateral View, B-AP View.

Table 1. *Demographic characteristics*

Gender	Male	30% (20)
	Female	70% (47)
Age (Years)	Mean ± SD	44 ± 10.6
	Range	15 - 62
Onset of Pain	Traumatic	13% (9)
	Non-traumatic	87% (58)
Duration of Pain (Years)	Mean ± SD	5.4 ± 5.6
	Range	0.5 - 29
Height (Inches)	Mean ± SD	67 ± 4
Weight (lbs.)	Mean ± SD	181 ± 34
Smoking Habits	Nonsmoking	60% (40)
	Smoking	40% (27)
Level(s) of Decompression	Single level	81% (54)
	Multi-level	19% (13)
Distribution of Primary Pain	Mostly Back	70% (47)
	Mostly Leg	10.5% (7)
	Equal Back and Leg	10.5% (7)
	Other*	9% (6)
Previous Surgical Intervention		13% (9)

*Primary pain present in groin or buttocks.

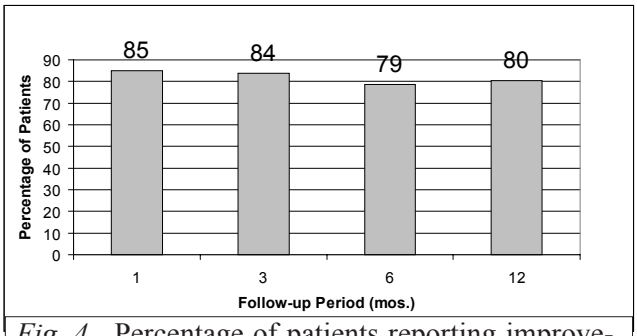

Fig. 4. Percentage of patients reporting improvement in numeric pain scores post-percutaneous disc decompression (PDD)

ranging from 14 to 62 years. A non-traumatic onset of pain was reported by 87% of patients. The average duration of pain was 5.4 ±5.6 years, ranging from 4 months to 29 years. A history of previous surgical intervention was indicated by 13% of the patients, while 39% of the patients reported smoking. Pre-operatively, primary back pain was reported by 70% of the patients, while 10.5% reported primary leg pain, 10.5% reported equal levels of back and leg pain, and 9% reported primary pain in the groin or buttocks. The majority of patients, 63%, reported regular full-time or part-time employment.

Follow-up Characteristics

Of the 67 patients, 66, 62, 61, and 41 were available for follow-up at 1, 3, 6, and 12 months respectively. Four patients were excluded from the follow-ups at 6 and 12 months because they had suffered re-injury, while one patient was lost after the 2-week follow-up and another after her 2-month follow-up due to relocation. Twenty patients had not yet reached their 12-months visit.

Overall, 85%, 84%, 79%, and 80% of the patients indicated improvement in their numeric pain scores at 1, 3, 6, and 12 months as compared to their baseline results

Table 2. *Numeric pain score results reported by patients post-percutaneous disc decompression (PDD)*

	Percentage of patients reporting improvement in numeric pain scores (%)		**Average numeric pain score for all patients**	
Follow-up	Percentage	95% Confidence Interval (Low, High)	Average ± SD	*p* values
Baseline (N=67)	NA	NA	6.80 ± 1.10	NA
1 month (N=66)	85	76%, 94%	3.56 ± 2.15	<0.001
3 month (N=62)	84	69%, 89%	3.85 ± 2.47	<0.001
6 month (N=61)	79	69%, 89%	4.23 ± 2.59	<0.001
12 month (N=41)	80	68%, 92%	4.10 ± 2.52	<0.001

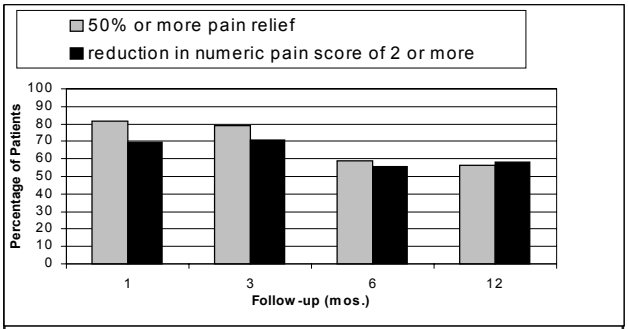

Fig. 5. Percentage of patients reporting 50% or more pain relief and a numeric pain score reduction of 2 or more post-percutaneous disc decompression (PDD)

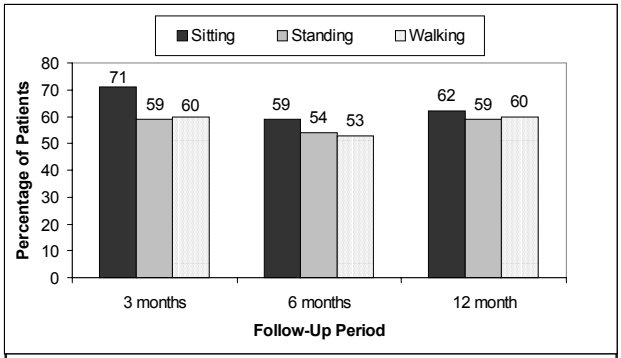

Fig. 6. Percentage of patients reporting improvement in sitting, standing, and walking ability post-PDD

(Fig. 4). It was observed that improvement in numeric pain scores were similar at all follow-up periods, ranging from 79% to 85%. Average pre-procedure pain level for all patients was reported as 6.80 ± 1.10 while average pain levels post- procedure were 3.56 ± 2.15, 3.85 ± 2.47, 4.23 ± 2.59, and 4.10 ± 2.52 at 1, 3, 6, and 12-month follow-up periods, respectively.

The success of the procedure was further evaluated by analyzing patients reporting 50% or more pain relief, and patients reporting a 2-point or greater reduction in their numeric pain scores (Fig. 5). The average percentages of patients reporting greater than 50 percent pain relief were 82%, 79%, 59%, and 56% at 1, 3, 6, and 12 months, respectively. The percentages of patients reporting reduction in numeric pain scores of 2-points or more were 70%, 71%, 56% and 59% at 1, 3, 6, and 12 months, respectively.

Functional abilities were evaluated based on patient's reported assessment of sitting, standing, and walking in the following categories: less than 15 min., 15 to 30 min., 31 to 45 min., 45 min. to 1 hour, 1 to 2 hours, and greater than 2 hours. Improvements were observed in ability to sit, stand, and walk at all follow-up periods as shown in Tables 3-5. For example, a 3-fold increase was observed in patients reported ability to sit, stand, and walk for more than 2 hours at one-year follow-up as compared to baseline values. All of these differences were found to be statistically significant ($p<0.05$).

Overall, when one or more levels of functional improvement were assessed, 71%, 59%, and 60% of patients indicated improvement in sitting, standing, and

Table 3. *Percentage of patients reporting sitting ability prior to and after PDD*

	Percentage of Patients (Number of Patients)			
Time	Pre-PDD (N=66)	3 month (N=61)	6 month (N=59*)	12 month (N=40*)
<15 min	50% (33)	18% (11)	34% (20)	35% (14)
15-30 min	26% (17)	10% (6)	10% (6)	15% (6)
31-45 min	6% (4)	21% (13)	7% (4)	7% (3)
45 min -1 hr	4% (3)	5% (3)	7% (4)	3% (1)
1-2hr	3% (2)	20% (12)	5% (3)	5% (2)
>2 hr	11% (7)	26% (16)	37% (22)	35% (14)
Significance of Improvement from Pre-Op	N/A	<0.0001	<0.0001	0.008

* 2 patients at 6 months and 1 patient at 12 months did not evaluate their functional ability

Table 4. *Percentage of patients reporting standing ability prior to and after PDD*

	Percentage of Patients (Number of Patients)			
Time	Pre-PDD (N=66)	3 month (N=61)	6 month (N=59*)	12 month (N=40*)
<15 min	54% (36)	26% (16)	36% (21)	37% (15)
15-30 min	26% (17)	17% (10)	15% (9)	10% (4)
31-45 min	3% (2)	18% (11)	8% (5)	10% (4)
45 min -1 hr	3% (2)	3% (2)	3% (2)	5% (2)
1-2hr	3% (2)	8% (5)	14% (8)	5% (2)
>2 hr	11% (7)	28% (17)	24% (14)	33% (13)
Significance of Improvement from Pre-Op	N/A	<0.0001	<0.0008	0.03

* 2 patients at 6 months and 1 patient at 12 months did not evaluate their functional ability

walking ability at 3 months, respectively (Fig. 6). At 6 months, 59%, 54%, and 53% of the patients indicated improvement in sitting, standing, and walking ability. At 12 months, 62% of the patients indicated sitting improvement, 59% indicated standing improvement, and 60% indicated walking improvement.

Table 6 illustrates the correlation coefficient between pain relief and functional improvement based on sitting, standing, and walking ability. Significant correlation was observed at 1 month, 3 months, 6 months, and 12 months between pain relief and functional improvement.

There were no complications associated with the PDD procedure using Coblation technology during the procedure or post-operatively. Specifically, there were no cases of infection or neurologic deficit reported.

DISCUSSION

The long-standing theory that, "80-90% of attacks of low-back pain recover in about six weeks, irrespective of the type of treatment" (41), has been challenged by Croft et al. (42). After analyzing Waddell's methodology, Croft et al. reported that Waddell's study was based on the percentage of patients who had not returned to their primary care physician after an initial visit for acute low back pain. In a separate study based on the percentage of low-back pain sufferers who were pain and disability free after 3 months, Croft et al. concluded that only a minority of patients with low-back pain recover.

Table 5. *Percentage of patients reporting walking ability prior to and after PDD*

	Percentage of Patients (Number of Patients)			
Time	Pre-PDD (N=66)	3 month (N=61)	6 month (N=59*)	12 month (N=40*)
<15 min	50% (33)	23% (14)	32% (19)	35% (14)
15-30 min	24% (16)	15% (9)	14% (8)	5% (2)
31-45 min	4% (3)	15% (9)	7% (4)	10% (4)
45 min -1 hr	5% (3)	4% (3)	5% (3)	2% (1)
1-2hr	3% (2)	10% (6)	10% (6)	10% (4)
>2 hr	14% (9)	33% (20)	32% (19)	38% (15)
Significance of Improvement from Pre-Op	N/A	<0.0001	0.0001	0.006

* 2 patients at 6 months and 1 patient at 12 months did not evaluate their functional ability

Table 6. *Correlation coefficient between pain relief and functional improvement*

	Total	*p*-value
1-month	0.525*	<0.01
3-months	0.473*	<0.01
6-months	0.644*	<0.01
1-year	0.519*	<0.01

* Indicates significant difference

Treatment of back pain by primary care providers typically involves prescription of opioids, expensive non-steroidal anti-inflammatory drugs (NSAIDs), or physical therapy. Though these are common treatments, they may not be the optimal solution. Opioids may be addictive and patients are likely to build drug tolerances. NSAIDs have potentially dangerous side-effects, and physical therapy may be ineffective (43,44). Though the benefits of NSAID use for short-term acute low back pain have been demonstrated, the risks and benefits must be closely examined when NSAIDs are used in chronic long-term conditions (45, 46). More than 30 million people worldwide consume NSAIDs on a daily basis and approximately 25% of all reported adverse drug reactions are attributed to their use (47,48). Approximately 107,000 patients are hospitalized for NSAID related GI complications. Each year at least 16,500 NSAID related deaths occur among arthritis patients alone (49). These studies provide compelling evidence that chronic use of NSAIDs is not without complications. Moreover, many patients suffering with discogenic pain become refractory to medical management after some time. Minimally invasive techniques addressing the discogenic pain should therefore be made available to these patients.

This analysis demonstrates an encouraging outcome following PDD using Coblation technology (Nucleoplasty), a minimally- invasive technique for patients with contained disc herniation presenting with discogenic low back pain and/or leg pain. Overall, at 12 months, 80% of the patients indicated improvement in pain relief, 59% reported a numeric pain score reduction of 2 or more points, and 56% reported improvement of 50% or more pain relief. Functional improvement was observed in 62%, 59%, and 60% of the patients for sitting, standing, and walking abilities, respectively. A significant correlation was also established between pain relief and functional improvement.

While other minimally invasive procedures, such as laser assisted disc decompression, demonstrate complication rates of 1-2%, including discitis, transient temporary parasthesias, and lesion of the endplate (20,31,50), no complications were observed during or after the PDD procedure using Coblation technology.

Although this outcome analysis may receive criticism that it is neither randomized to a placebo-controlled group nor double-blinded, the data is nevertheless compelling. Moreover, several reports indicate that the results of observational studies do not differ significantly from the results of randomized, controlled trials (51,52).

Future studies using this technology should address issues pertaining to the amount of volumetric reduction of the disc for optimal disc decompression, the comparison of a biportal versus uniportal approach, as well as the optimal duration for both the tissue ablation and coagulation phases of the procedure. Additional studies are also warranted to compare various minimally invasive techniques in order to establish a standard for the primary mode of therapy, as well as the efficacy of combining various treatment modalities such as Nucleoplasty and annuloplasty (53,54) in selective cases.

CONCLUSION

Our data indicates that PDD using Coblation (Nucleoplasty) technology is a promising treatment option for patients with contained disc herniation, presenting with discogenic axial back pain and/or leg pain who have failed conservative therapies and are not considered candidates for open surgery.

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