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ORIGINAL ARTICLE

Plasma disc decompression for contained cervical disc herniation: a randomized, controlled trial

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Abstract Prospective case series studies have shown that plasma disc decompression (PDD) using the COBLATION SpineWand device (ArthroCare Corporation, Austin, TX) is effective for decompressing the disc nucleus in symptomatic contained cervical disc herniations. This prospective, randomized controlled clinical trial was conducted to evaluate the clinical outcomes of percutaneous PDD as compared to conservative care (CC) through 1 year. Patients ($n = 115$) had neck/arm pain $\geq$50 on the visual analog scale (VAS) pain scale and had failed at least 30 days of failed CC. Patients were randomly assigned to receive either PDD ($n = 62$) or CC ($n = 58$). Clinical outcome was determined by VAS pain score, neck disability index (NDI) score, and SF-36 health survey, collected at 6 weeks, 3 months, 6 months, and 1 year. The PDD group had significantly lower VAS pain scores at all follow-up time points (PDD vs. CC: 6 weeks, -46.87 ± 2.71 vs. -15.26 ± 1.97; 3 months, -53.16 ± 2.74 vs. -30.45 ± 2.59; 6 months, -56.22 ± 2.63 vs. -40.26 ± 2.56; 1 year, -65.73 ± 2.24 vs. -36.45 ± 2.86; GEE, $P < 0.0001$). PDD patients also had significant NDI score improvement over baseline when compared to CC patients at the 6 weeks (PDD vs. CC: -9.15 ± 1.06 vs. -4.61 ± 0.53, $P < 0.0001$) and 1 year (PDD vs. CC: -16.70 ± 0.29 vs. -12.40 ± 1.26, $P = 0.005$) follow-ups. PDD patients showed statistically significant improvement over baseline in SF-36 physical component summary scores when compared to CC patients at 6 weeks and 1 year (PDD vs. CC: $8.86 + 8.04$ vs. 4.24 ± 3.79, $P = 0.0004$; 17.64 ± 10.37 vs. 10.50 ± 10.6, $P = 0.0003$, respectively). In patients who had neck/arm pain due to a contained cervical disc herniation, PDD was associated with significantly better clinical outcomes than a CC regimen. At 1 year, CC patients appeared to suffer a "relapse, showing signs of decline in most measurements, whereas PDD patients showed continued stable improvement.

Keywords Contained disc herniation · Cervical spine · Disc decompression · PDD · Conservative care

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Introduction

Cervical disc herniation is a common cause of localized neck and radicular pain. Bulging annulus or nuclear material can impinge on a nearby exiting nerve root, compressing it as it enters the neuroforamen and causing pain and potential neurological deficit. In neurologically stable patients, conservative pain management is pursued through a course of rest, analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), and physical therapy. However, conservative care (CC) has limited success in resolving radiculopathy, with persistent pain and disability in as many as two-thirds of patients [14, 27]. When CC fails, more invasive treatments such as epidural steroid injections and surgical procedures become appropriate.

Plasma disc decompression (PDD) has been used with promising results for a number of years in the lumbar region [19, 31, 35, 48, 51, 65], but has been practiced and studied less frequently in the cervical spine [37, 50]. Bonaldi et al. [3] performed a prospective case study utilizing PDD to treat 55 patients with cervical disc herniations and symptoms of neck and arm pain; 85% of these patients had a good to excellent clinical outcome by 6 months post-procedure. More recently, Li et al. [28]

performed cervical PDD on 126 consecutive patients with similar results: a good to excellent clinical outcome of 83.73% by 1-year post-procedure. These early results suggest that cervical PDD may be an appropriate method to resolve pain symptoms in these patients before attempting open surgery, which can be accompanied by severe complications [2, 15, 16, 43, 56].

PDD alleviates nerve root compression by removing a portion of the nucleus pulposus of the herniated disc, as is done in other percutaneous discectomies [30, 34, 41]. This causes "disc decompression", reducing intradiscal pressure, and theoretically redistributing and alleviating the internal forces which cause irritation of the neighboring nerve root [1, 8, 39, 48, 53]. This is posited to down-regulate local inflammatory mediators, reduce disc size, and initiate the healing process, all contributing to a reduction in discogenic pain [13].

The procedure uses the COBLATION SpineWand device (ArthroCare Corporation, Austin, TX) to surgically ablate tissue using a thin plasma field comprised of highly ionized particles. COBLATION ("controlled ablation") devices are widely used in an array of medical applications, including otolaryngology, arthroscopy, laparoscopy, urology, and gynecology. Chen et al. [7] studied the effect of PDD on surrounding structures, and concluded that volumetric removal of nucleus tissue could be obtained without necrosis or disruption of non-targeted nucleus, annulus, endplate, spinal cord, or nerve root.

This was the first prospective, clinical study conducted to evaluate clinical outcomes of percutaneous PDD to CC in a randomized, controlled fashion. The objective of the study was to evaluate clinical outcomes through 1 year in patients with cervical or arm pain associated with a single contained symptomatic cervical disc protrusion, who were treated with either PDD or continued CC.

Clinical materials and methods

This was a prospective, controlled clinical study conducted to determine whether subjects undergoing PDD demonstrated improved clinical outcomes or a more rapid abatement of symptoms than patients receiving a regimen of CC. It was hypothesized that after 3 months, subjects undergoing PDD would demonstrate a significant reduction in neck/arm pain visual analog scale (VAS) scores as well as an improvement in functional status, as measured using the Neck Disability Index Questionnaire, and quality of life (SF-36 scores) when compared to patients undergoing CC. All eligible patients who agreed to participate in the study provided informed consent. The study was approved by the Review Board of the Ospedale Policlinico Casilino in Rome, Italy. All patients signed informed consent.

Study cohort

Patients seeking medical treatment for symptoms consistent with a cervical disc contained herniation who satisfied the initial eligibility criteria were approached to participate in the study. All candidates considered for participation in the study were between 18 and 75 years old, and had unresolved symptoms after at least 30 days of failed CC. Patients had a neck/arm pain VAS score of >50 on a scale of 0–100. Additionally, patients were required to have imaging evidence of a single contained symptomatic focal disc protrusion between C3 and T1 which did not compromise more than one-third of the AP diameter of the spinal canal, minimal corroborative myotomal deficit, a positive diagnostic nerve root block, and failed to respond to or refused epidural steroid injection.

Exclusion criteria included evidence of an extruded or sequestered disc herniation, history of anterior fusion in the cervical level to be treated, spinal fracture, tumor, or infection, a central cord lesion in the cervical spine, progressive neurological deficit, focal protrusion exceeding one-third of the spinal canal, hyperostosis causing concurrent foraminal stenosis at the symptomatic level, myotomal deficit with motor strength less than 4/5, disc height reduction of $\geq$50% (which indicated total degeneration and treatment via fusion), and carotid stenosis or significant plaque-like carotid disease. Additional exclusion criteria included a planned or suspected pregnancy within the study timeframe, a cardiac pacemaker, automatic defibrillator, or any peripheral stimulator leads within the neck area, a known allergy to contrast media or drugs to be used in the procedure, psychological instability or undergoing anti-psychotic therapy, or involvement in litigation related to arm and neck pain.

Treatment assignment

Subjects were randomly assigned to receive either PDD or conservative care (CC). In order to randomize, sealed envelopes were labeled with consecutive numbers and remained sealed until a given subject was to be assigned treatment. Immediately upon study enrollment, subjects were assigned treatment by opening the envelopes in sequential order. Study participants were then scheduled to return to the clinic for PDD or to continue a CC regimen within 7 days after assignment. Subjects were not blinded to treatment.

Interventions

Conservative treatment

Subjects in the conservative care (CC) group received an array of CC therapies, depending on the patient's condition

and preference. These included transcutaneous electrical nerve stimulation (TENS), progressive neck mobilization (both active and passive) accompanied by a gradual reduction in collar usage, postural rehabilitation of the Mezieres technique, as well as analgesics and/or NSAIDs. All procedures were performed on an outpatient basis; subjects returned to the investigator's clinic for all necessary follow-up visits.

Plasma disc decompression

PDD was performed using the COBLATION Perc-DC SpineWand® surgical device (ArthroCare Corporation). This bipolar radiofrequency-based device generates an electric field between two electrodes. The resultant electrical field excites the electrolytes and molecules in the surrounding fluid to create a field of high-density energy, or plasma. This plasma field contains energized particles of sufficient energy to break the molecular bonds in soft tissue, effectively dissolving targeted tissue at relatively low temperatures (40–70°C).

The creation of a gas layer is key to plasma formation. Gas forms at the electrodes due to local electrochemical processes on the electrode surface. Additionally, when joule heating induced by the current density near the energized electrodes exceeds the surrounding fluid's heat of vaporization and the rate of heat dissipation due to thermal conduction, localized vaporization can lead to the formation of a relatively thick vapor layer ($\sim$100 μm). The high impedance of the vapor layer when compared to the surrounding fluid causes the electrical field across this area (which is localized in thin regions near the electrodes) to increase dramatically: 300 V across 100 μm is effectively 30,000 V/cm. This fragments the water molecules in the vapor layer, ionizing them and generating the plasma field.

The PDD procedure was performed under intravenous sedation (Fentanyl and Propofol) with a facial mask (oxygen 40%, air 60%, sevorane MAC 0.81%). The patient was placed in a supine position with head slightly hyper extended. The intervertebral space was detected under a fluoroscopic view. The surgeon held the sternocleidomastoideus muscle laterally and the trachea medially. The introducer cannula (19-gauge, 7.6 cm) was then inserted medially to the SCM and vessels through an anterior lateral approach, and stopped when the annulus/nucleus junction was reached. The tip of the cannula stylet was aimed for the center of the nucleus in both the coronal and sagittal planes. AP and lateral X-ray monitoring views confirmed the precise positioning of the cannula within the annulus.

The stylet was withdrawn from the introducer cannula and replaced with the SpineWand. The wand was advanced until its tip extended approximately 5 mm beyond the tip of the cannula, in order to ensure that the active portion of the wand was deployed in the center or posterior third of the nucleus pulposus. A short initial coagulation (<0.5 s) was performed upon wand insertion to ensure correct placement; if stimulation or movement was detected, the wand was repositioned. As the wand was drawn back out through the disc, three ablation cycles of 5–10 s each were performed, rotating the wand tip 180° each time to form three consecutive pockets within the disc.

Patients were immediately mobilized following the procedure. They were discharged 24 h after surgery; antibiotic prophylaxis with a common cephalosporin was given in all cases. They were assigned additional conservative therapies (such as progressive active/passive neck mobilization, postural rehabilitation with Mezieres technique, and analgesics and/or NSAIDs) following standard protocol. No collars were applied post-op.

Outcomes instruments

Clinical status was assessed when subjects returned for follow-up assessment at 6 weeks, as well as 3, 6, and 12 months. Clinic visits included a physical examination and completion of study questionnaires. Subjects reported neck/arm pain on the VAS for pain. They were asked to make a vertical tick mark on a 100-mm horizontal scale, where 0 mm represented no pain and 100 mm represented the greatest conceivable pain. The neck disability index (NDI) was administered to patients as well during follow-up. A modified form of the Oswestry low back pain index, the NDI is a 10-item scaled questionnaire designed to determine how neck injury impairs the ability to perform everyday activities [59]. Patients also filled out the SF-36 questionnaire, which is a validated, subject-based health status survey employed to assess the influence of a disease state on an individual's sense of well being and quality of life [60–62].

Statistical analysis

Sample size estimation

The study sample size was estimated to test the null hypothesis, "The mean post-procedural pain scores will be no different for treatment groups 3 months post procedure", against the two-sided alternative hypothesis. Estimating a common standard deviation of 25 points on the VAS scale for pain, and setting the type I error rate at 5%, a sample size of at least 44 subjects in each treatment group had 80% power to detect a difference in means of 15 points on the VAS. The sample size was increased by 30% (115 patients) to accommodate possible subject dropout.

Inferences about means from continuous data were based on standard parametric statistics. Comparisons based

on non-ordered categorical data were evaluated using the Chi-square or Fisher's exact test and ordered categorical data were examined using Wilcoxon's two-sample rank test. Generalized estimating equations (GEEs) models were used to analyze changes in the pain VAS and NDI scores over the 12-month assessment period. The GEE method uses all available data from all patients and accounts for both the within and between subject sources of variation in the repeated measures over time. An identity link was used with an exchangeable correlation structure. Indicator variables for each follow-up visit and the interaction between follow-up visit and treatment group were included in the model. Missing data was addressed in these GEE models by using maximum likelihood estimation for longitudinal models under "missing at random" assumptions.

An increased emphasis has recently been placed on evaluating clinical outcomes by their meaningfulness and relevance to individual subjects. The minimum clinically important difference (MCID) has been used as a threshold value to determine clinical success [11, 12, 49]. This study utilized as MCID thresholds a VAS pain score improvement of $\geq$25 points and an NDI score improvement of $\geq$3.5 points. The NDI MCID value was derived from a study by Pool et al. [40]. All treated subjects were accounted for during analysis when determining the proportion of subjects achieving MCID at any given post-procedure time point. Missing data points were imputed by carrying forward the last available data point.

Results

One hundred twenty subjects were enrolled in the study between April 2005 and December 2006. Sixty-two subjects were assigned to undergo PDD and 58 were assigned to CC. Five subjects in the CC group did not undergo treatment after random assignment, as they had an insufficient VAS score ($\leq$50) to meet the subject selection criteria. As a result, the data analysis included 115 subjects: 62 in the PDD group and 53 in the CC group.

The study cohort consisted of 42% males and 58% females; subjects ranged from 23 to 65 years of age. Both groups were comparable in basic demographics, VAS pain and NDI scores (Table 1). SF-36 scores were not significantly different between both groups with the exception of scores for general health perceptions, vitality, and social function, which were significantly lower in the CC group.

No significant clinical events beyond local anesthetic-related side effects were observed in this study. At the 6-month follow-up, two study subjects, a PDD patient and a CC patient underwent microdiscectomy with fusion.

The VAS pain scores were significantly ($P < 0.0001$) reduced from baseline for PDD patients as compared to CC (CC) patients at all follow-up time points (Table 2). The GEE model for NDI scores revealed significant improvement over the baseline in PDD patients when compared to CC patients at both the 6 weeks ($P < 0.0001$) and 1 year ($P = 0.005$) follow-ups. The 3- and 6-month follow-up scores did not differ significantly between the two groups. At 1 year, the PDD subjects showed statistically significant improvement over the baseline in SF-36 quality of life scores when compared to their CC counterparts in physical functioning, role physical, bodily pain, and physical components summary.

The percentage of PDD patients achieving the MCID for VAS pain score steadily increased throughout the 1 year follow-up, reaching 95%, while the percentage of CC patients achieving MCID dropped between 6 months and

Table 1 Patient demographics, preoperative (baseline) pain, and functional measures

Measure	PDD ($n = 62$)	Conservative care ($n = 53$)	P value
Age, mean (SD)	45.03 (10.72)	47.43 (11.49)	0.249
Women (%)	39 (62.9)	28 (52.8)	0.275
VAS pain score, mean (SD)	73.47 (13.29)	74.91 (11.87)	0.5
NDI score, mean (SD)	62.5 (17.6)	66.7 (22.3)	0.266
SF-36 score, mean (SD)			
Physical functioning	36.46 (10.70)	35.04 (9.98)	0.5
Role physical	32.56 (10.30)	33.17 (10.67)	0.8
Bodily pain	32.61 (7.85)	33.96 (9.11)	0.4
General health perceptions	37.97 (10.39)	33.64 (10.72)	0.03
Vitality	44.59 (9.33)	40.30 (8.31)	0.009
Social function	38.38 (11.49)	33.72 (12.36)	0.03
Role emotional	35.19 (14.64)	32.89 (13.55)	0.4
Mental health	36.06 (13.29)	36.61 (11.67)	0.8
Physical components summary	35.46 (8.96)	34.66 (8.75)	0.6
Mental components summary	39.55 (13.83)	36.74 (11.9)	0.2

Table 2 Treatment effects for primary and secondary outcomes

	6 weeks			3 months			6 months			1 year		
	PDD ($n = 62$)	CC[1] ($n = 58$)	Treatment effect (P value)	PDD ($n = 62$)	CC ($n = 58$)	Treatment effect (P value)	PDD ($n = 61$)	CC ($n = 57$)	Treatment effect (P value)	PDD ($n = 61$)	CC ($n = 57$)	Treatment effect (P value)
VAS pain score, mean [SE][a]	−46.87 [2.71]	−15.26 [1.97]	−38.16 **(< 0.0001)**	−53.16 [2.74]	−30.45 [2.59]	−22.71 **(< 0.0001)**	−56.22 [2.63]	−40.26 [2.56]	−15.96 **(< 0.0001)**	−65.73 [2.24]	−36.45 [2.86]	−29.28 **(<0.0001)**
NDI, mean [SE][a]	−9.15 [1.06]	−4.61 [0.53]	−4.54 **(< 0.0001)**	−11.75 [1.08]	−9.27 [0.8]	−2.48 (0.1)	−13.36 [1.12]	−12.86 [0.8]	−0.51 (0.7)	−16.7 [0.29]	−12.40 [1.26]	−4.30 **(0.005)**
SF-36 score, mean [SD]												
Physical function	6.38 [9.09]	4.35 [4.17]	2.027 (0.12)	10.08 [10.12]	8.6 [7.19]	1.49 (0.35)	12.25 [11.77]	11.83 [7.96]	0.42 (0.82)	15.15 [11.42]	9.78 [11.12]	11.28 **(0.01)**
Role physical	8.93 [9.98]	3.76 [4.82]	5.17 **(0.0004)**	12.36 [11.63]	7.05 [7.11]	5.31 **(0.003)**	15.56 [12.42]	12.46 [8.05]	3.11 (0.10)	18.11 [11.43]	10.31 [10.48]	7.8 **(0.0002)**
Bodily pain	12.64 [11.53]	6.01 [5.19]	6.63 **(< 0.0001)**	16.91 [12.03]	11.19 [8.12]	5.71 **(0.0027)**	17.23 [14.31]	15.04 [8.92]	2.19 (0.31)	22.52 [10.7]	12.52 [12.5]	10.0 **(<0.0001)**
General health	7.18 [10.27]	4.2 [4.8]	2.98 **(0.04)**	7.57 [11.6]	8.75 [8.97]	−1.172 (0.54)	9.55 [14.42]	10.86 [7.65]	−1.31 (0.53)	12.86 [14.57]	9.95 [10.9]	2.9 (0.22)
Vitality	3.88 [8.03]	4.09 [6.46]	−0.214 (0.87)	6.4 [8.99]	8.67 [7.4]	−2.271 (0.135)	7.4 [10.69]	11.36 [7.01]	−3.96 **(0.018)**	10.08 [10.41]	12.05 [8.82]	−1.97 (0.27)
PCS	8.86 [9.04]	4.24 [3.79]	4.62 **(0.004)**	12.28 [10.47]	8.72 [5.99]	3.55 **(0.0237)**	14.04 [11.62]	12.39 [6.60]	1.65 (0.337)	17.64 [10.37]	10.50 [10.59]	7.14 **(0.0003)**
Social function	5.72 [10.43]	4.98 [5.34]	0.73 (0.63)	7.83 [11.79]	10.06 [8.47]	−2.23 (0.234)	9.41 [13.97]	14.95 [9.34]	−5.54 **(0.012)**	12.96 [13.7]	12.44 [13.19]	−0.53 (0.83)
Role emotional	6.65 [10.11]	4.69 [6.7]	1.95 (0.21)	9.22 [12.62]	7.91 [8.61]	1.31 (0.51)	11.85 [15.62]	13.34 [9.33]	−1.49 (0.52)	14.47 [17.84]	9.82 [11.78]	4.65 (0.096)
Mental health	7.13 [11.23]	4.81 [7.08]	2.32 (0.18)	8.86 [11.75]	8.11 [9.06]	0.749 (0.696)	10.63 [15.21]	9.71 [8.86]	0.92 (0.68)	13.20 [13.97]	9.49 [10.57]	3.72 (0.105)
MCS	4.89 [9.73]	4.56 [6.65]	0.33 (0.83)	6.31 [11.72]	8.04 [8.13]	−1.74 (0.345)	8.02 [13.95]	11.31 [7.83]	−3.29 (0.1112)	10.44 [15.02]	10.15 [10.25]	0.29 (0.903)

CC conservative care

[a] Based on estimates from the GEE model

Statistically relevant values are given in bold

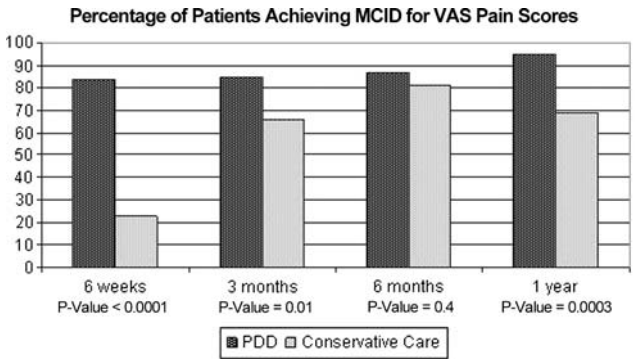

Fig. 1 Percentage of patients achieving minimal clinical important difference for VAS pain scores. At all time points, 80% or more PDD patients achieved had $\geq$25 reduction in VAS pain scores; the difference in percentage of patients achieving MCID for pain VAS scores was statistically significant between treatment groups at 6 weeks, 3 months, and 1 year

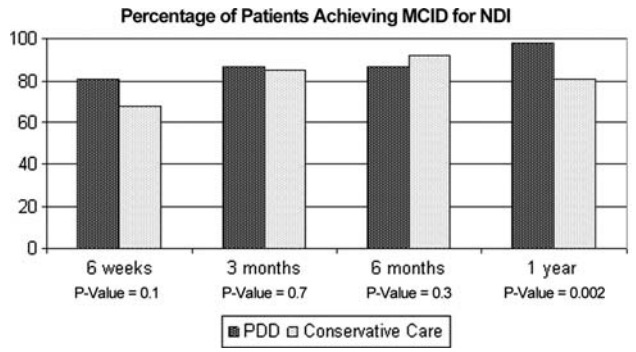

Fig. 2 Percentage of patients achieving minimal clinical important difference for NDI scores. The difference in percentage of patients achieving MCID for NDI scores was statistically significant between treatment groups at 1 year

1 year, from 81 to 69% (Fig. 1). A statistically significantly higher percentage of PDD patients achieved the VAS MCID compared to those in the CC group at 6 weeks ($P < 0.0001$), 3 months ($P = 0.01$), and 1 year ($P = 0.0003$) (Fig. 1).

There was a steady increase in the percentage of PDD patients achieving the NDI MCID throughout the 1 year follow-up, reaching 98.36% (Fig. 2). However, there was a sharp decline in the percentage of CC patients achieving the NDI MCID between the 6-month and 1-year follow-ups: 92 and 81%, respectively. A statistically significantly higher percentage of PDD patients achieved the NDI MCID compared to those in the CC group at 1 year ($P = 0.002$).

Discussion

Spontaneous resolution of herniated disc symptoms after conservative treatment is a well-characterized phenomenon in the lumbar spine [4, 6, 23, 32, 45, 46, 54, 55, 63]. However, the unique pathology of contained cervical disc herniations may make these cases less responsive to CC. Cervical disc herniations undergo spontaneous regression far less often than their lumbar counterparts [24]. Potential reasons for this may be differences in the odds of a sequestration-type lesion or in the composition of the herniated discs themselves [36]. In a retrospective study by Mochida et al. [36] in which MR imaging was performed over a mean interval of 42 weeks, cervical disc herniation regression and symptom resolution occurred in only 15 of 38 (40%) patients. Regression does not generally occur in focal protrusions. A protrusion-type herniation accounted for only 1 of Mochida et al.'s [36] 15 regressions; the others were classified as migrations. Matsumoto et al. [33] found that diffuse herniations were far more likely to regress spontaneously than focal herniations (78% compared to 37%). During a case study, Kobayashi et al. [24] characterized all prior cervical disc herniation regressions as extruded-type. Saal et al. [47] used rigorous physical rehabilitation to treat 24 patients with cervical disc herniations and radiculopathy; 20 patients achieved a good or excellent outcome, of whom 19 had extruded discs.

Contained disc herniations, in which the annulus remains intact, are problematic because they often do not incite the natural immune and vascular responses that prompt the regression of the herniation. Annular tears allow infiltration of nuclear material into the epidural space, where it expands and engorges due to the hydrophilic properties of its proteoglycans [5]. These proteoglycan chains undergo autolysis and lose their hydrophilic potential, leading to dehydration of the herniated disc and natural shrinkage and regression [5]. Additionally, exposed nuclear material is treated as a foreign body and undergoes phagocytosis by macrophages [5] as well as neovascularization [20]. A CT study by Maigne et al. [29] which showed regression of cervical disc herniations with radiculopathy through conservative therapy found that the largest herniations were the ones with the greatest propensity to reduce in size. This was presumed to be secondary to annular rupture and entry of nuclear material into the epidural space [29]. Bush et al. [5] concluded that the lone cervical herniation which did not regress in their MR study was formed largely of annular rather than nuclear material, as in a contained type.

It is unlikely that cervical disc herniations will spontaneously resolve if they show no improvement during the acute phase [36]. Open surgery has been indicated if severe radicular pain persists for more than 6 weeks [22, 38], in order to avoid progressive disc degeneration and further destabilization of the region. Maigne et al. [29] were able to obtain a follow-up CT scan from 21 of their cervical disc herniation patients, between 1 and 30 months after

conservative treatment, and found decreased intervertebral space with cervical arthritis in 5 (24%). Early surgical interventions can allay these problems. We favor a proactive approach using PDD as an early response treatment, as it is minimally invasive technique. Thus, we chose a minimum of 1 month of failed conservative treatment before considering PDD treatment for candidate patients.

Though anterior cervical discectomy with fusion (ACDF) has become the surgical gold standard for herniated cervical discs [57] since the procedure's introduction in the 1950s [10, 52], it carries a procedure morbidity rate as high as 19.3% [17], and the potential for severe complications [2, 15, 16, 43, 56]. Though fusionless ACD is performed, it is generally avoided due to the risk of disc space collapse, resulting in cervical kyphosis and leading to post-operative neck pain, and the potential to compromise the neural foramen, leading to post-operative radicular pain [21]. The potential downsides of ACD (both with and without fusion) have generated interest in minimally invasive percutaneous alternatives for treating cervical disc herniations, such as PDD. We experienced no complications when treating patients with cervical PDD. In a series of 126 patients treated with cervical PDD, Li et al. [28] had no complications and no recurrent cases, save an incident where the tip of the SpineWand broke in the disc space and remained there with no clinical consequence. A similar complication was encountered by Bonaldi et al. [3] when performing cervical PDD on their first patient in a 55-patient series, and their patient remained asymptomatic and had excellent clinical results through 29 months of follow-up. The only other complication described by Bonaldi et al. [3] was a single case of postoperative infectious discitis. Thus, cervical PDD seems to have a very low complication rate when compared to open surgery, and seems a favorable course of action to resolve pain symptoms in candidate patients.

All of our patients had failed at least 30 days of CC before enrollment in the study, and reported the chronic persistence of significant radicular and neck pain. Though pain as measured by VAS was significantly reduced in both the CC and PDD patients, the PDD group displayed statistically significantly greater pain reduction at all follow-up time points. In their patient series, Li et al. [28] similarly reported statistically significant VAS pain reduction ($P < 0.01$) after PDD when compared to preoperative values through all time points (2 weeks, 1, 3, 6, and 12 months). In our study, by just 6 weeks post-procedure, 84% of PDD patients had achieved a clinically important (MCID) reduction in radicular and neck pain; at no time points did an equivalent proportion of CC patients achieve a MCID reduction in their pain. This rapid drop in neck and arm pain shortly after surgery translates into a quick recovery time and expedites a safe return to work and the activities of daily life.

Furthermore, PDD patients showed continuous improvement throughout the year, as more patients achieved the MCID and the mean improvement over baseline continued to increase. CC patients peaked at 6 months, beginning to show decline in their neck pain reduction by 1 year. This is highlighted by the fact that the number of CC subjects with MCID reductions in pain dropped from 43 (81%) to 36 (69%) out of 53 patients between the 6 months and 1 year marks. A similar result was found in the Bodily Pain scores of the SF-36 quality of life form, where PDD patients showed statistically significantly greater improvement over baseline when compared to CC patients at the 6 weeks, 3 months, and 1 year follow-ups.

The large reduction in VAS pain scores achieved with PDD appears to be at least comparable to that obtained with alternate surgical treatments. Ruetten et al. [44] treated a series of 175 patients with lateral cervical disc herniations with either full-endoscopic posterior cervical foraminotomy (FPCF) or anterior cervical decompression and fusion (ACDF). By 3 months post-treatment, mean VAS scores for arm pain reduced from 81 to 10 in the ACDF group and from 84 to 11 in the FPCF group [44]. After 2 years of followup, patients still had similarly reduced pain scores [44]. Many other studies utilized a similar VAS scoring system which ranged from 0 to 10 instead of 0 to 100. Zöega et al. [67] also treated 46 cervical disc herniation patients with neck pain and arm radiculopathy with anterior cervical discectomy and fusion: patients were stabilized with an anterior graft and randomized to either fixation with a CSLP plate, or no internal fixation. In patients with treatment on one level with a CSLP plate, median arm pain VAS increased from 4.0 preoperatively to 4.5 at 2 years postoperatively, while median neck pain VAS increased from 5.4 to 5.8 in the same time frame. For patients treated on one level without internal fixation, median arm pain VAS lowered from 6.3 preoperatively to 5.9 at the 2 year followup, while median neck pain VAS similarly lowered from 6.3 to 5.6 [67]. In their treatment of 36 patients with a single level disc herniation with radiculopathy, Frédéric et al. [18] obtained excellent pain reduction by following anterior cervical discectomy with implantation of either an empty carbon fiber composite fiber cage (CFCFC) or an iliac crest autograft. Those implanted with an autograft had reduced neck pain VAS from 7.2 to 2.5 by the 1 year follow-up, and radicular pain VAS from 7.8 to 1.4, while those implanted with the CFCFC had reduced their neck pain VAS from 6.4 to 2.0 and their radicular pain VAS from 8.4 to 1.5 [18].

Percutaneous laser disc decompression has also been used to treat cervical disc herniations with positive results; Lee et al. [25] obtained a mean VAS pain reduction from a preoperative score of 7.9 to 2.6 at the final follow-up (mean

71 months). These authors also treated 45 patients (47 levels) with contained cervical disc herniations via percutaneous endoscopic cervical annuloplasty [26]. Favorable outcomes, based upon Macnab criteria, were achieved in 84.5% of those patients [26].

Conservative treatment VAS scores have not been well documented for cervical disc herniations, but one study assessing spa and physical therapy efficacy for treating various chronic ailments included 29 cervical disc herniation patients [9]. Pre-treatment VAS pain score was 6.6 ± 3.7, improving to 2.4 ± 1.5 just prior to discharge (treatment length was unspecified) [9]. Whether this pain improvement was longlasting or short-term is unknown.

Functional ability was also significantly improved by the PDD procedure as measured by the neck disability index (NDI). The NDI is a modification of the lumbar-oriented Oswestry disability index that has been validated as an accurate measure of functional status in neck injury paradigms [59, 64]. A greater measure of PDD patients achieved Pool et al.'s watermark of the MCID for the NDI [40] than CC patients at all follow-ups except the 6 month mark. As was seen in the VAS pain scores, growing numbers of PDD patients continued to reach the minimal clinically important difference over the longterm (6 months: 87%, 1 year: 98%), whereas CC patients peaked at 6 months (92%), and there was a general decline in functional ability in the patient population by 1 year (81%). Van der Haven et al. [58] utilized the NDI in assessing patient functionality after anterior cervical interbody fusion for both disc herniation and spondylosis and found significant ($P < 0.001$) improvement in mean NDI scores, from a preoperative score of 60.4% (SD 24.1) to 43.8% (SD = 28.4) at patients' most recent follow-up.

PDD allows the resolution of patient symptoms with similar or superior clinical outcomes to competitive surgical procedures. This is a major advantage in such a minimally invasive procedure, preserving neck mobility and offering a stable alternative which avoids ACDF's accompanying risks of graft dislodgement, pseudoarthritis, graft site morbidity, as well as plate/implant complications [42]. Conservative treatment of cervical radiculopathy is generally regarded as a short-term measure with no lasting effect [66]. This seems to be supported by our study, which indicates a decline in clinically important pain reduction and functional ability in a significant percentage of CC patients between the 6 month and 1 year marks. Additionally, the majority of CC patients required several months to show clinically important improvements in their VAS pain scores—PDD offers a superior method to expedite recovery and get patients back to daily life more quickly. This argues for a proactive approach to treating patients with contained cervical disc herniations. PDD is a method to offer immediate, significant, and long-lasting pain relief and recovery of patient functional ability.

Conclusion

Conservative treatment and the "wait-and-see" approach are often favored for the cervical spine because of the region's sensitive nature. However, in our experience this is not in the best interests of the patient, if a contained cervical disc herniation is diagnosed. We have found PDD to offer improved pain relief as well as superior immediate and longterm gains in functional ability and quality of life when compared to conservative therapies. PDD is a minimally invasive treatment option for symptomatic contained disc herniation that provides an excellent medium for both results and safety.

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