Plasma disc decompression compared with fluoroscopy-guided transforaminal epidural steroid injections for symptomatic contained lumbar disc herniation: a prospective, randomized, controlled trial

Clinical article

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Object. Patients with radiculopathy, with or without back pain, often do not respond to conservative care and may be considered for epidural steroid injection therapy or a disc decompression procedure. Plasma disc decompression (PDD) using the Coblation SpineWand device is a percutaneous, minimally invasive interventional procedure. The purpose of this study was to evaluate clinical outcomes with PDD as compared with standard care using fluoroscopy-guided transforaminal epidural steroid injection (TFESI) over the course of 2 years.

Methods. This was a multicenter randomized controlled clinical study. Ninety patients (18–66 years old) who had sciatica (visual analog scale score ≥ 50) associated with a single-level lumbar contained disc herniation were enrolled. In all cases, their condition was refractory to initial conservative care and 1 epidural steroid injection had failed. Participants were randomly assigned to receive either PDD (46 patients) or TFESI (44 patients, up to 2 injections).

Results. The patients in the PDD Group had significantly greater reduction in leg pain scores and significantly improved Oswestry Disability Index and 36-Item Short Form Health Survey (SF-36, physical function, bodily pain, social function, and physical components summary) scores than those in the TFESI Group. During the 2-year follow-up, 25 (56%) of the patients in the PDD Group and 11 (28%) of those in the TFESI Group remained free from having a secondary procedure following the study procedure (log-rank p = 0.02). A significantly higher percentage of patients in the PDD Group showed minimum clinically important change in scores for leg and back pain and SF-36 scores that exceeded literature-based minimum clinically important changes. Procedure-related adverse events, including injection site pain, increased leg or back pain, weakness, and lightheadedness, were observed in 5 patients in the PDD Group (7 events) and 7 in the TFESI Group (14 events).

Conclusions. In study patients who had radicular pain associated with a contained lumbar disc herniation, those patients treated with PDD had significantly reduced pain and better quality of life scores than those treated using repeated TFESI. In addition, significantly more PDD patients than TFESI patients avoided having to undergo a secondary procedure during the 2-year study follow-up. (DOI: 10.3171/2009.10.SPINE09208)

Key Words • contained disc herniation • disc decompression • epidural steroid injection • lumbosacral spine • low-back pain • minimally invasive spine surgery • plasma disc decompression

Abbreviations used in this paper: APLD = automated percutaneous lumbar discectomy; BMI = body mass index; GEE = generalized estimating equations; ITT = intent-to-treat; MCID = minimum clinically important difference; ODI = Oswestry Disability Index; PDD = plasma disc decompression; SF-36 = 36-Item Short Form Health Survey; TFESI = transforaminal epidural steroid injection; VAS = visual analog scale.

LEG and back pain associated with lumbar disc herniation is estimated to affect 10 million people each year in the US. The majority of patients with lumbar disc herniation–related radicular pain and symptoms presenting for medical care respond to conservative therapy. Overall, 60–70% of those affected will
recover within 6 weeks and 80–90% within 12 weeks. A natural history study conducted in the 1970s showed that radiculopathy associated with lumbar disc herniation resolved within 6 months in 90% of cases. Over the last 3 decades, conservative care has been well documented to provide resolution of symptoms, often coinciding with regression of disc tissue impingement as seen using MR imaging. Nevertheless, a significant number of cases do not resolve with conservative care. Epidemiological studies suggest a lifetime prevalence of persistent sciatica in 1.6% of the population, with the highest prevalence, approximately 1 of every 4 people, in persons between the ages of 45 and 64 years.

Neurologically stable patients having persistent radiculopathy with or without back pain are initially managed conservatively with a progressive course of rest and medical therapies, including analgesics and NSAIDs, followed by physical therapy. For those responding poorly to non-operative treatment, including corticosteroid injections, surgical disc decompression or discectomy may be pursued. Surgical discectomy has been performed for more than half a century and remains the gold standard for the treatment of lumbar disc herniation, while the technique—often termed “microdiscectomy”—has become less invasive, it still requires a surgical incision and is associated with residual back pain, neurological, cardiovascular, and infectious complications, and reherniation in 5% of patients or more. In addition, the likelihood of a full recovery after microdiscectomy varies based on the morphology of the disc injury, with the lowest success observed in patients with contained herniation.

Percutaneous disc decompression was developed as a minimally invasive surgical procedure designed to treat neurologically stable patients having evidence of contained disc herniation. Concerns regarding the complications of open surgery and an awareness of the reduced effectiveness of open discectomy in this patient population have stimulated an interest in percutaneous treatment methods. The most commonly applied percutaneous techniques used to date include arthroscopic microdiscectomy, automated percutaneous lumbar discectomy (APLD), and chemonucleolysis with chymopapain. These techniques involve the use of chemical or mechanical destruction to excise (ablate) a portion of the nucleus pulposus but are accompanied by significant practical limitations.

Plasma-mediated ablation using the Coblation Spine-Wand device (ArthroCare Corporation) has been used for several years to perform lumbar disc decompression. In a previously published case series of 53 patients, side effects with PDD were noted to be limited to short-term pain at the needle insertion site. In published clinical case series containing a combined total of over 300 cases, potential adverse effects associated with PDD were limited to a single case of epidermal fibrosis. The PDD devices use radiofrequency energy to excite electrolytes in a conductive medium, such as saline solution, creating a focused plasma. The energized particles in the plasma have sufficient energy to break molecular bonds, exciting or dissolving soft tissue at temperatures typically ranging between 40°C and 70°C. Plasma-forming radiofrequency controller settings are used for dissolving tissue in a defined area. This is in contrast to non–plasma-forming settings, which are used to perform procedures in which tissue shrinkage or coagulation is the goal.

This randomized, controlled trial was designed to test the effectiveness of PDD using plasma-mediated ablation against transforaminal epidural injection, a standard treatment for radicular pain associated with disc herniation. For neurologically stable patients having refractory sciatica with or without back pain due to a contained disc herniation, the standard conservative care regimen generally includes an epidural corticosteroid injection, progressing to a series of multiple injections if pain remains or returns after the first injection. This therapy is optimized using a transforaminal approach conducted under fluoroscopic guidance. The objective of this study was to compare clinical outcomes through a 2-year follow-up in patients who were treated using either PDD or the interventional standard-of-care regimen consisting of a series of fluoroscopy-guided TFESIs.

**Methods**

**Study Design and Detail**

This was a multicenter, prospective, randomized controlled clinical trial. Twelve clinical sites contributed patients to the study. By design, the initial 6-month follow-up period was considered the randomized, controlled portion of the trial, since it was expected that a number of study participants would request additional procedure(s) and it would be difficult to retain these patients in the trial “as treated” through the 2-year follow-up. The data collected between 6 months and 2 years was considered observational.

All eligible patients who agreed to participate in the study provided informed consent. Clinical study sites were granted approval to perform the study by either the institutional review board governing their health care site or the Western Institutional Review Board in Olympia, Washington.

**Study Cohort**

All candidates considered for participation in the study were between 18 and 75 years old, had a BMI less than 40, had a radicular pain score of 50 or greater as measured using a 0- to 100-mm VAS, and had received an epidural corticosteroid injection for the same symptoms between 3 weeks and 6 months previously. Patients may have experienced no response to this injection, temporary relief, or only partial relief and had residual symptoms sufficient to meet the above inclusion criteria. Candidates demonstrated normal neurological function and were required to have imaging evidence of a focal lumbar disc protrusion and disc height of more than 50% of that of the normal adjacent discs. In addition, the level and site of the disc protrusion had to correlate with pattern of pain. Candidates demonstrating evidence of extruded or sequestered disc herniation were not considered for participation.

Exclusion criteria included having sciatica originat-
CONTAINED LUMBAR DISC HERNIATION

TABLE 1: Baseline demographic characteristics, clinical findings, and health measures in 45 patients undergoing PDD and 40 undergoing TFESI*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean age in yrs</td>
<td>46 ± 12</td>
<td>42 ± 11</td>
</tr>
<tr>
<td>female sex</td>
<td>24 (53)</td>
<td>19 (48)</td>
</tr>
<tr>
<td>employment status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>full- or part-time</td>
<td>28 (62)</td>
<td>26 (65)</td>
</tr>
<tr>
<td>unemployed</td>
<td>6 (13)</td>
<td>6 (15)</td>
</tr>
<tr>
<td>homemaker</td>
<td>3 (7)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>other</td>
<td>6 (13)</td>
<td>6 (15)</td>
</tr>
<tr>
<td>unknown</td>
<td>2 (4)</td>
<td>0</td>
</tr>
<tr>
<td>mean BMI in kg/m²</td>
<td>26.9 ± 4.7</td>
<td>27.3 ± 5.1</td>
</tr>
<tr>
<td>median duration of radicular pain in mos (range)</td>
<td>12 (1–192)</td>
<td>24 (2.5–156)</td>
</tr>
<tr>
<td>frequency of medication use</td>
<td>0.42</td>
<td></td>
</tr>
<tr>
<td>none</td>
<td>7 (16)</td>
<td>4 (10)</td>
</tr>
<tr>
<td>1–2 times per week or less</td>
<td>2 (4)</td>
<td>3 (8)</td>
</tr>
<tr>
<td>2 times a week up to once daily</td>
<td>8 (18)</td>
<td>5 (13)</td>
</tr>
<tr>
<td>2 or more times daily</td>
<td>27 (60)</td>
<td>28 (70)</td>
</tr>
<tr>
<td>unknown</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>type of medication use</td>
<td>0.40</td>
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<tr>
<td>over-the-counter</td>
<td>9 (20)</td>
<td>7 (18)</td>
</tr>
<tr>
<td>prescription non-narcotic</td>
<td>7 (16)</td>
<td>7 (18)</td>
</tr>
<tr>
<td>prescription narcotic</td>
<td>21 (47)</td>
<td>22 (55)</td>
</tr>
<tr>
<td>unknown</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>herniation level</td>
<td>0.63</td>
<td></td>
</tr>
<tr>
<td>L2–3</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>L3–4</td>
<td>5 (11)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>L4–5</td>
<td>14 (31)</td>
<td>12 (30)</td>
</tr>
<tr>
<td>L5–S1</td>
<td>25 (56)</td>
<td>26 (65)</td>
</tr>
<tr>
<td>mean leg pain VAS score</td>
<td>72 ± 13</td>
<td>75 ± 14</td>
</tr>
<tr>
<td>mean back pain VAS score</td>
<td>44 ± 24</td>
<td>53 ± 23</td>
</tr>
<tr>
<td>mean ODI score</td>
<td>42 ± 14</td>
<td>43 ± 17</td>
</tr>
<tr>
<td>mean SF-36 scores</td>
<td></td>
<td></td>
</tr>
<tr>
<td>physical functioning</td>
<td>31 ± 9</td>
<td>32 ± 9</td>
</tr>
<tr>
<td>role, physical</td>
<td>29 ± 10</td>
<td>29 ± 10</td>
</tr>
<tr>
<td>bodily pain</td>
<td>31 ± 6</td>
<td>32 ± 6</td>
</tr>
<tr>
<td>general health perceptions</td>
<td>47 ± 10</td>
<td>47 ± 7</td>
</tr>
<tr>
<td>vitality</td>
<td>42 ± 10</td>
<td>43 ± 10</td>
</tr>
<tr>
<td>social function</td>
<td>33 ± 12</td>
<td>35 ± 12</td>
</tr>
</tbody>
</table>

*(Values represent numbers of patients (%) unless otherwise indicated. Means are presented with SDs.† Values in this section represent numbers of patients (%) who showed full strength on muscle testing or normal results on testing of deep tendon reflexes or tactile sensitivity. Values for the left and right sides are presented in order and separated by a comma.*

From more than one disc level, more severe axial (back) pain than radicular (leg) pain, clinical evidence of cauda equina syndrome, progressive neurological deficit, radiological evidence of spondylolisthesis or moderate or severe stenosis at the level to be treated, history of previous spinal surgery at or directly adjacent to the level to be treated, spinal fracture, tumor, or infection. Other exclusion criteria included having suspected or planned pregnancy within the study time frame, having a cardiac pacemaker or automatic defibrillator, having spinal cord stimulator leads in the lumbar area, allergies to contrast media or drugs to be used in the intended procedure, and medical comorbidities that precluded surgical intervention. In addition, ongoing treatment with antipsychotic medication, receiving Workman’s Compensation, or participating in ongoing litigation related to back or leg pain were also criteria for exclusion.
Treatment Assignment

Patients were randomly assigned to receive either fluoroscopy-guided TFESI or PDD. A permuted block design, with 6 patients per block (PDD/TFESI ratio 3:3), was used to allow equal treatment assignments at each site. Sealed envelopes were provided to each study site by the study sponsor for use in random assignment. The envelope labels were sequentially numbered and the envelopes remained sealed until a patient had given informed consent and was enrolled in the study. Patients were assigned to treatment in sequential order immediately upon enrollment into the study. The study participants were scheduled to return to the clinic to undergo either TFESI or PDD, depending on treatment assignment; patients assigned to the TFESI group were scheduled to receive up to 2 injections (if 2 injections were given, they were scheduled 3 weeks apart). One week prior to the second TFESI, patients were contacted and reminded of the appointment. In the event that the subject wished to decline the second TFESI, the second injection was cancelled after approval of the investigator. Patients were not blinded to treatment since one treatment group was to receive only one procedure and the other group up to 2 procedures; informed consent required that each procedure be described to the subject in detail.

Interventions

Transforaminal Epidural Steroid Injection Procedure. The TFESI procedure was performed under fluoroscopic guidance. The location of the TFESI was determined by the treating physician with the goal of delivering corticosteroids to the site of the disc protrusion and nerve irritation. Details of the technique have been previously reported.41,55,59 Medication type and dose were left to the discretion of each clinician.

Plasma Disc Decompression Procedure. The PDD was performed on an outpatient basis using the Coblation DLR or DLG SpineWand surgical device (ArthroCare Corp.). The procedure was conducted under fluoroscopic guidance. After placing the patient in the prone position, a 17-gauge spinal cannula was introduced into the disc using a posterolateral extrapedicular approach. The cannula was positioned at the junction of the annulus and nucleus. The stylet was removed from the cannula and the SpineWand was placed into the spinal cannula and advanced until its tip was approximately 5 mm beyond the tip of the spinal cannula. At this point, the active portion of the SpineWand was situated beyond the inner layer of the annulus and within the nucleus. The proximal channel limit was determined by referring to a circumferential reference mark on the shaft of the device that corresponds with this position. Next, the SpineWand was advanced until it came into contact with the annulus on the opposite side. The depth stop marker on the shaft was advanced to the hub of the cannula to designate the distal channeling limit. The SpineWand was returned to the proximal limit and activated with the controller on a setting of 2 (ablation mode), advanced at a speed of approximately 2 mm per second. The SpineWand was retracted, returning...

**Fig. 1.** Study participant flow. Ninety patients were enrolled and randomly assigned to treatment—46 were assigned to PDD and 44 to TFESI. The ITT group consisted of 85 patients—45 in the PDD Group and 40 in the TFESI Group. * n = 2, myocardial infarction; ‡ n = 1, acute pyelonephritis.
it to its original starting position, and rotated slightly (2 hours on an imaginary clock face or approximately 60°) to make the next channel. This maneuver was repeated to create a total of 6 channels.

**Postprocedure Care**

Patients in both treatment groups were allowed to receive additional conservative therapies, including bed rest, braces, physical therapy, narcotic analgesics, or NSAIDs, at the discretion of the treating investigator.

**Outcomes Instruments**

The primary outcome was pain reduction, assessed using a VAS score. Patients were asked to make a vertical tick mark on the 100-mm horizontal VAS containing word anchors at each extreme, with “no pain” on the left end (0 mm) and “worst pain imaginable” on the right end (100 mm), to show pain intensity “right now.” Patients reported analgesic drug use by frequency, analgesic scale (0 = none, 1 = NSAID, 2 = prescription nonnarcotic, 3 = narcotic), and primary reason for taking the medication (leg pain, back pain, or leg and back pain). Patients also completed an employment status questionnaire in which they reported their current employment situation as currently employed, unemployed, full-time homemaker, or other. If employed, patients provided details regarding the demands of their current job.

Self-reported function and quality of life were assessed using the ODI, the SF-36 questionnaire, and satisfaction with treatment. The ODI is a validated, back-specific 10-item measure of pain and physical function. The SF-36 questionnaire was used to determine quality of life and is a validated, patient-based health status assessment survey designed to assess the impact of a disease on an individual’s general sense of well being. Satisfaction with treatment was assessed by asking the patient to answer the following question: “All things considered (such as your pain level and functionality prior to treatment versus after treatment), how satisfied are you with the results of your treatment for your leg and back pain?”, by selecting the most appropriate response from a 6-item scale, including: 1 = extremely satisfied, 2 = very satisfied, 3 = somewhat satisfied, 4 = somewhat dissatisfied, 5 = very dissatisfied, 6 = extremely dissatisfied.

**Nonresolution Following the Index Procedure**

If a patient had persistent pain and requested further treatment, he or she was allowed to undergo further out-of-protocol treatment as determined appropriate by the principal investigator at each site. Participants were encouraged to continue with the study follow-up schedule until at least the 6-month visit. In cases in which patients requested and received any additional procedure during the 2-year study period, the study procedure was considered to have failed for purposes of statistical analyses.

**Statistical Analysis**

**Sample Size.** The study sample size was estimated to test the null hypothesis, “The mean of postprocedural VAS pain scores will be no different for treatment groups 6 months postprocedure,” against the 2-sided alternative hypothesis. Using a previously reported SD of 25 points on the VAS for pain and setting the Type I error rate at 5%, a sample size of 44 patients in each treatment group provided 80% power to detect a difference in means of 15 points at 6 months posttreatment on the VAS for pain.

**Randomized, Controlled Portion of the Trial Through 6 Months’ Follow-Up**

**General Statistical Methods.** The statistical analyses for all outcomes used all available data for each visit and were performed on an ITT basis. The ITT group included all patients who underwent either the TFESI (control) or the PDD procedure. Inferences about means from continuous data were based on standard parametric statistics except when comparing baseline duration of radicular pain between the PDD and TFESI groups, where the Wilcoxon 2-sample rank test was used because of lack of normality. Comparisons based on nonordered categorical data were evaluated using the chi-square or Fisher exact test and ordered categorical data were examined using the Wilcoxon 2-sample rank test. The SF-36 scores were statistically evaluated by calculating the change from baseline at each time point and then comparing the change from baseline between treatment groups using 2-sample t-tests.

**Longitudinal Analyses.** Generalized Estimating Equations (GEE) models were used to analyze changes in leg and back pain VAS and ODI scores. The GEE method uses all available data from all participants and accounts
for both the within- and between-participant 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. The GEE model included 3 covariates because these variables were found to differ at baseline between treatment groups at \( p \leq 0.15 \): 1) preprocedure back VAS scores; 2) duration of radicular pain; and 3) a variable to characterize data collected by sites enrolling more patients (\( \geq 10 \)) from those enrolling fewer patients (< 10). Preprocedure back VAS scores and duration of radicular pain were included in the model as continuous variables. “Large site” was included as a binary variable.

**Missing Data.** The primary GEE analysis used all available data from all patients, accounting for missing data by using maximum likelihood estimation for longitudinal models under “missing at random” assumptions. A sensitivity analysis was performed to: 1) address the potential effect of intermittent missing data on the outcomes and 2) account for the patients whose data were truncated due to undergoing secondary procedures beyond the procedure as randomly assigned before the 6-month follow-up. Intermittent missing data were imputed by taking the average of the values before and after the missing item on a per participant basis. For the patients who underwent secondary out-of-protocol treatment, the baseline value of the variable of interest was carried forward through 6 months. For all other participants with truncated data, the last recorded value was carried forward.

**Treatment Cohorts Through 2 Years’ Follow-Up.** Minimum clinically important change has recently been suggested as a threshold value that represents clinical effectiveness for individual patients.\(^{17,18,27,36,49,61}\) Outcomes through 2 years were assessed using literature-based values for minimum clinically important change. For this study, the thresholds corresponding to minimum clinically important change consisted of \( \geq 25 \) points for leg pain VAS scores,\(^{36} \geq 13 \) points for back pain VAS scores,\(^{17} \geq 12 \) points for ODI scores,\(^{17}\) and \( \geq 5 \) points for SF-36 scores.\(^{17}\) In cases in which patients received an out-of-protocol procedure, the study protocol was considered to have failed and the patients were included in the statistical analysis as having not achieved a minimum clinically important change. The results for treatment groups were statistically compared using the chi-square test.

The rates and times at which secondary out-of-protocol procedures were used were assessed using a Kaplan-Meier curve and compared between groups using a log-rank test. Cox proportional hazards modeling was used to evaluate potential predictors of the need for a secondary procedure.

**Results**

Ninety patients were consecutively enrolled into the study between February 2005 and March 2007. The study cohort was evenly split by gender and two-thirds of patients were employed full-time (Table 1). Ages ranged from 20 to 66 years for patients in the PDD Group and 18 to 64 years for those in the TFESI Group. All baseline status measures were statistically similar between treatment groups except for duration of leg pain, which was significantly longer in the TFESI Group.

All 90 patients were randomly assigned to undergo either PDD or TFESI (Fig. 1). Five patients did not receive the study treatment after random assignment. Of these 5, 3 did not return for treatment, 1 died, and the last began receiving Workman’s Compensation benefits and thus was ineligible for continued participation in the study as specified by the study eligibility criteria. The ITT group included all patients who received a study.
randomized, controlled portion of the trial through 6 months

Leg pain VAS scores were significantly reduced (p < 0.001) with both study treatments (Fig. 2, Table 3). Back pain VAS scores for patients in the PDD Group were significantly reduced from baseline scores while scores for patients in the TFESI Group were not. Leg pain VAS scores, back pain VAS scores, and ODI scores differed significantly between the PDD Group and TFESI Group, with the PDD Group having significantly better scores through 6 months. For all variables, the raw data (crude) estimates, the imputation approach for the sensitivity GEE analysis, and percent change scores showed similar results to the principal GEE models.

Although longer duration of leg pain at baseline was controlled for statistically in the GEE modeling, the effect of this variable on treatment group results was explored further by plotting change (from baseline) in leg pain VAS scores at 6 months against pretreatment duration of leg pain (Fig. 3). Duration of pain was stratified into 3 categories: “less than 1 year,” “1–3 years,” and “longer than 3 years.” For the PDD Group, the average reduction in pain scores at 6 months for all 3 pain duration categories was approximately 50 points. For the TFESI Group, the average reduction in leg pain score for all strata was con-
sistently less than the PDD Group, ranging from a mean reduction of 12 points to a mean reduction of 38 points. Of the patients who had preprocedure pain duration of “1–3 years,” those in the PDD Group had significantly greater reduction in leg pain than those in the TFESI Group (p = 0.009).

Before undergoing the study treatment, patients in both treatment groups tended to have SF-36 scores lower than population norms (Fig. 4). Several SF-36 component scores—including physical function, bodily pain, social function, and the physical components score—were significantly improved from baseline with both treatments. The PDD Group demonstrated significant improvement for the role physical and role emotional component scores as well. Compared with the TFESI Group, the PDD Group had significantly greater improvement for the components of physical function, bodily pain, social function, and the physical components summary scores.

The number of patients working full or part-time at 6 months after the study procedure was similar for both treatment groups (69–70%). Reduction in use of narcotics, nonnarcotic prescriptions, and over-the-counter analgesics did not differ significantly between treatment groups. A significantly greater percentage of patients in the PDD Group than in the TFESI Group were satisfied with care (PDD and TFESI Groups, respectively: “extremely satisfied,” 38 vs 15%; “very satisfied,” 24 vs 18%; “somewhat satisfied,” 31 vs 26%; “somewhat dissatisfied,” 3 vs 15%; “very dissatisfied,” 3 vs 15%; “extremely dissatisfied,” 0 vs 11%; p = 0.004). The significant difference between treatment groups noted at 6 weeks for the deep tendon reflex neurological examination measures persisted at 6 months.

Treatment Cohorts Through 2 Years

During the 2-year follow-up period, 25 patients in the PDD Group (Kaplan-Meier estimate 52%) and 11 in the TFESI Group (Kaplan-Meier estimate 17%) remained free from having a secondary procedure following the study procedure (Fig. 5). The majority of requests for further intervention occurred at the 6-month follow-up visit. Controlling for duration of leg pain and back pain VAS score at baseline, the Cox proportional hazards model revealed that membership in the TFESI Group and relatively lower baseline SF-36 physical components summary scores were associated with an increased probability of having a secondary treatment (TFESI Group membership: p = 0.025, HR 1.989; baseline SF-36 physical components summary score: p = 0.05, HR −0.957). All patients who requested a secondary procedure were cared for as considered appropriate by the study investigator. For the TFESI and PDD Groups, respectively, secondary procedures that were pursued included additional TFESI (5 and 13 patients), radiofrequency ablation (2 and 2), PDD (20 and 0), microdiscectomy (2 and 4), and lumbar interbody fusion (0 and 1). Of patients in the TFESI Group who were followed up through 2 years as initially treated (that is, those who did not receive an out-of-protocol secondary procedure), 8 had received methylprednisolone acetate, and 3 had received betamethasone (1 patient), methylprednisolone (1), or triamcinolone acetonide (1). Seven of these 11 patients had opted to undergo the second TFESI.

A significantly higher percentage of patients in the PDD Group than patients in the TFESI Group attained minimum clinically important change scores for leg and back pain and SF-36 scores that exceeded literature-based MICD thresholds (Table 4). For almost all comparisons, the percentage of patients in the PDD Group having change scores that met or exceeded the literature-based clinically important change threshold was at least double that of the percentage of patients in the TFESI Group.

Discussion

In this study we sought to directly compare a percutaneous PDD technique using the Coblation SpineWand device to fluoroscopy-guided TFESI as a treatment intervention for patients with symptomatic contained lumbar disc herniations. Both study procedures were associated with significantly reduced leg pain scores and improved ODI and SF-36 scores. However, the PDD Group had significantly greater reduction of leg and back pain scores as well as significantly better ODI and SF-36 scores than
the TFESI Group. Four SF-36 quality of life components, including physical function, bodily pain, social function, and the physical components summary, were also significantly improved with PDD over TFESI. Clinically significant side effects were comparable between procedures and included pain at the injection site, increased radicular pain, increased back pain, and muscle tightness or spasms. The results of this study showed that clinical results were significantly enhanced with PDD compared with TFESI while exposing patients to a similar procedure-related risk profile.

Although patients were randomized to treatment groups, when designing this study, choosing an appropriate control group was a difficult task. The inclusion criteria specifying that all candidates for the study had to have failed to benefit from an epidural steroid injection before being considered for enrollment into the study had the potential to bias the study in favor of PDD. Epidural corticosteroid injection therapy was selected as the control since it is considered an important treatment option for patients who have refractory sciatica with or without back pain. A series of 3 injections is generally recommended before assuming failure. To conform to generally accepted standard care for our control group, a second TFESI was offered since our intention was to provide control patients with optimal care. Hence, subject blinding was sacrificed in favor of providing a clinically acceptable standard of care to the control group. Although lack of blinding might be regarded as a weakness in the study design, a strength of the study design is that results of PDD are contrasted with the results in a group who received optimal care.

Pathophysiology surrounding the genesis of leg and back pain is not clearly defined, although the mechanisms involved are thought to include both mechanical and biochemical mediators. Over half a century ago, Mixter and Barr established that treatment conducted to remove a small amount of herniated disc compressing a nerve root was associated with pain relief. This observation led to the general belief that the functional effectors of sciatica were mechanical in nature, where the physiological characteristics of the affected nerve root render it susceptible to compression. Treatments such as chymopapain, nucleotomy, and discectomy were conceived as methods to alleviate mechanical compression of the nerve root stemming from the herniated disc. Disc decompression is based on the principle that excising a small amount of disc tissue can promote significant relief of pressure, reduce irritation of the adjacent nerve, and therefore ameliorate or eliminate pain. More recently, biochemical effectors have been posited as important mediators in pain pathogenesis. For pain to manifest with nerve root compression, it has been hypothesized that an affected nerve root may be hypersensitive to biochemical mediators found in the disc and disc space. Biochemical mediators recognized to contribute to sensitization of the nerve root include tumor necrosis factor-alpha (TNF-α), interleukin 1-beta (IL-1β), and phospholipase A2 (PLA2), which are important proinflammatory agents associated with radiculopathy.

Fluoroscopically guided injections are used to deliver steroid medication to the area where the nerve root comes into contact with the herniated disc. Corticosteroids are thought to be beneficial for alleviating the regional inflammation driving the patient’s symptoms. Specifically, corticosteroids inhibit the activity of PLA2 and of IL-1β. Nevertheless, the mechanism of action of steroid medication in this application has not been clearly eluci-
dated, and more research in this area is required. Pain reduction reported by the patients in our TFESI Group was consistent with previously reported results describing the effectiveness of TFESI. In 20 patients who had radicular symptoms associated with lumbar disc herniation and in whom conservative care had failed, Schaufele and colleagues reported significantly decreased leg pain scores, as measured using the verbal numerical rating scale (1–10), declining from 5.9 before the injection to 3.2 at a mean of 18 days after the procedure. Our TFESI Group demonstrated a mean reduction of the same relative magnitude, approximately 20 points, as measured using the 100-point VAS, at 6 weeks, and it persisted through 6 months.

The PDD procedure was designed as a method to be used to perform disc decompression percutaneously, similar to APLD and laser-assisted percutaneous discectomy. Chen and colleagues found that creating 2 channels in the disc using the PDD device was associated with dramatically decreased intradiscal pressure. Plasma radiofrequency-based ablation has also been shown to affect the biochemistry of the extracellular environment in intervertebral disc cells. Rhyu et al. found that plasma radiofrequency-based ablation had an acute effect on proinflammatory mediator production in disc cells and concluded that these effects may be a mechanism of pain relief with the treatment. O’Neill and colleagues reported that plasma radiofrequency-based treatment affected levels of inflammatory cytokines such as IL-1β, IL-6, IL-8, and TNF-α in injured porcine intervertebral discs. Discs treated using plasma radiofrequency-based discectomy had decreased IL-1β and increased IL-8 levels compared with untreated discs at 12 weeks after treatment. The authors suggested that the temporal alterations in cytokine production observed in the study were consistent with a positive analgesic effect. These studies suggest that PDD treatment might alleviate pain by positively altering production of inflammatory mediators. Hence, the PDD procedure may affect both neuropathic and nociceptive pain effectors. If PDD does address mechanical as well as biochemical pain mediators, that may explain why patients receiving the PDD treatment had significantly better results than those receiving TFESI.

![Kaplan-Meier curve showing freedom from a secondary procedure through 2 years of follow-up. Significantly more patients in the PDD Group remained free from having a secondary procedure than patients in the TFESI Group (log-rank test, p = 0.02).](image)

<table>
<thead>
<tr>
<th></th>
<th>6M</th>
<th>12M</th>
<th>24M</th>
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</thead>
<tbody>
<tr>
<td><strong>PDD</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At Risk</td>
<td>28</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>K-M Estimate +/- SE</td>
<td>67.7% +/-7.1</td>
<td>57.9% +/-7.8</td>
<td>52.1% +/-7.9</td>
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<tr>
<td><strong>TFESI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At Risk</td>
<td>25</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>K-M estimate +/- SE</td>
<td>75.3% +/-7.2</td>
<td>29.0% +/-7.7</td>
<td>16.6% +/-6.5</td>
</tr>
</tbody>
</table>

Fig. 5. Kaplan-Meier curve showing freedom from a secondary procedure through 2 years of follow-up. Significantly more patients in the PDD Group remained free from having a secondary procedure than patients in the TFESI Group (log-rank test, p = 0.02).
Electrode located more proximally on the same bipolar device. Current flows through an electrically conductive solution, such as saline, or, in this case, intradiscal fluid. A voltage (150–350 V) is introduced across the electrodes on a wand. This electrical field interacts with fluid to excite electrolytes and molecules in the fluid and create a high-density energy field, or plasma. 56–68,84 The plasma field contains energized particles with sufficient energy to break soft tissue molecular bonds, thus producing conditions that are effective in dissolving tissue at relatively low temperatures (40–70°C). The formation of a gas layer is an important process leading to plasma-forming conditions. Gas formation at the electrode is the result of an electrochemical process at the surface of the electrodes. In addition, when the local heating of the saline induced by the electrical field and current density near the energized electrodes exceeds the heat of vaporization of the fluid (for example, water) and the rate at which the heat dissipates due to thermal conduction, localized vaporization can develop. As a very thick vapor layer forms (on the order of 100 µm) and high impedance of the vapor layer as compared with the saline occurs, the electric field across this area, which is localized in thin regions around the electrode(s), increases dramatically (300 V across 100 µm is 30,000 V/cm), ionizing and fragmenting the water molecules in the vapor layer and forming the plasma field. The plasma field is an ionized gas consisting of free electrons, ions, and excited radicals. Though the electrons contained in the plasma field are relatively energetic, the ions and neutral particles in the plasma remain relatively cool, and many of the fragments are chemically reactive. In contact with biological tissue, these plasma particles are sufficiently reactive to disintegrate organic molecular structures within the tissue into elementary molecules. In this manner, the target tissue is effectively dissolved or volatilized at low temperature, inducing minimal or no damage to surrounding healthy tissue. An in vitro study investigated the volume and composition of gases developed during the ablation of bovine myocardium in a saline field using a loop-type device sometimes used for hysteroscopic surgery. 67 Although the tissue type, device, and surgical field used in that study do not correspond precisely to those in the present study, the basic mechanisms of tissue ablation are likely to be similar; the gas evolution is consistent with the model suggesting that tissue ablation occurs via a plasma-induced chemical process. 56

At 6 months, nearly 1 in every 4 patients had requested a secondary out-of-protocol procedure, and by 1 and 2 years, respectively, the numbers had increased to 42% and 44% for the PDD Group and 68% and 73% for the TFESI Group. Clearly, higher success rates with these procedures would be ideal, but these rates may be the best that we can expect for patients with symptoms associated with contained disc herniation treated using a percutaneous procedure. Nonresolution rates in patients with contained disc herniation have been reported following open lumbar surgery. Carragee et al. 3 found that 25% of sciatica patients undergoing lumbar microdiscectomy had recurrent sciatica by 9 months; 6% had another operation. Investigators at the University of Washington reported a 5–10% reoperation rate during the first year following surgical decompression (without fusion) and fusion with or without decompression in patients treated for symptoms due to a herniated disc. 38 It is not clear how many patients in that cohort had recurrent pain but elected not to have a second surgery. Although not limited to patients with contained disc herniation, the SPORT trial 82 observed 45% of conservative care patients elected to have a surgical procedure within a 2-year period to treat new or recurring symptoms, as did 52% of patients undergoing epidural steroid injections in a study by Butterman. 7 Of course, these rates are somewhat dependent on the care regimens that payers make to patients as well as clinical options provided by individual practitioners.

Success rate with discectomy, the usual pathway for patients whose symptoms do not resolve with percutaneous procedures, is lower for patients with contained lumbar disc herniation than for patients with noncontained disc herniation. 3,8,44,24 Carragee et al. 8 examined outcomes in relation to disc herniation type observed during surgery and found that patients whose cases were classified as “no fragment-contained” had the longest duration of postoperative sick leave, the worst postoperative ODI.

<table>
<thead>
<tr>
<th>Threshold &amp; End Point</th>
<th>Group</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>leg pain VAS score change ≥25 points†</td>
<td>PDD</td>
<td>TFESI</td>
</tr>
<tr>
<td>6 mos</td>
<td>36 (50)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>1 yr</td>
<td>33 (42)</td>
<td>10 (20)</td>
</tr>
<tr>
<td>2 yrs</td>
<td>14 (33)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>back pain VAS score change ≥12 points‡</td>
<td>PDD</td>
<td>TFESI</td>
</tr>
<tr>
<td>6 mos</td>
<td>36 (50)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>1 yr</td>
<td>33 (42)</td>
<td>10 (20)</td>
</tr>
<tr>
<td>2 yrs</td>
<td>14 (33)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>ODI score change ≥13 points§</td>
<td>PDD</td>
<td>TFESI</td>
</tr>
<tr>
<td>6 mos</td>
<td>36 (50)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>1 yr</td>
<td>33 (42)</td>
<td>10 (20)</td>
</tr>
<tr>
<td>2 yrs</td>
<td>14 (33)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>SF-36 score change ≥5 points¶</td>
<td>PDD</td>
<td>TFESI</td>
</tr>
<tr>
<td>6 mos</td>
<td>36 (50)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>1 yr</td>
<td>33 (42)</td>
<td>10 (20)</td>
</tr>
<tr>
<td>2 yrs</td>
<td>14 (33)</td>
<td>5 (11)</td>
</tr>
</tbody>
</table>

* Study participants who underwent a secondary procedure were counted as not having achieved the literature-based MCID threshold.
† Data were available for 39 patients in the PDD Group and 39 in the TFESI Group.
‡ Data were available for 39 patients in the PDD Group and 39 in the TFESI Group.
§ Data were available for 44 patients in the PDD Group and 40 in the TFESI Group.
¶ Data were available for 43 patients in the PDD Group and 39 in the TFESI Group.
scores, and the highest rate of recurrent sciatica. Ng and Sell\textsuperscript{44} noted that patients with noncontained herniations had shorter duration of symptoms as well as better functional outcomes upon recovery than those with contained herniations. A prospective 2-year follow-up study of 160 consecutive Swedish patients undergoing primary surgery for a suspected lumbar disc herniation showed that male patients with a ruptured annulus and no preoperative comorbidity were most likely to have a successful outcome; focal disc protrusion was significantly associated with lack of clinical success.\textsuperscript{29} The results of these surgical studies suggest that success with surgery in the subgroup of patients who have a contained disc herniation may have limitations and therefore make percutaneous techniques a reasonable treatment option before considering open surgery.

In the last few years, minimum clinically important change and similar concepts have been suggested as valuable for assessing clinical success after treatments for low-back and radicular pain.\textsuperscript{17,27,36,40,70} Critical threshold values defining clinical benefit have been reported for leg and back pain VAS scores,\textsuperscript{17,27,36,40} ODI score,\textsuperscript{17,27,40} Roland-Morris Disability Questionnaire (RMDQ) score,\textsuperscript{36} and SF-36 score.\textsuperscript{17} In this study, a significant difference between treatment groups was found in the proportion of patients attaining the MCID thresholds as suggested by Kovacs et al.\textsuperscript{36} for leg pain (≥ 25 points), and by Copay et al.\textsuperscript{17} for back pain VAS score, ODI score, and SF-36 scores, where the PDD Group fared significantly better than the TFESI Group. At 1 and 2 years, 44% of the patients in the PDD Group compared with 1 in 5 (20%) of those in the TFESI Group had results exceeding the ≥ 25 point threshold for leg pain VAS scores. Tafazal and Sell\textsuperscript{70} reported 52% of patients achieving a clinically relevant threshold, corresponding to ≥ 50 point reduction (the remaining patients [48%] had ≤ 10 point reduction), after surgical decompression. The percentage of patients showing evidence of a clinically relevant change in SF-36 score after PDD was 33% compared with 48% for the Copay et al.\textsuperscript{17} fusion sample. In contrast, the percentage of patients in this study who attained the suggested MCID value for improved ODI score was slightly less than literature-based values in patients undergoing surgery. Thirty percent of patients in the PDD Group had an improvement in their ODI score of ≥ 10 points compared with between 52% and 86% of patients treated with surgery.\textsuperscript{17,27,70} Part of this difference may be due to the patients in our study having higher functional (for example, baseline ODI) scores than a fusion population might.

Sociodemographic, psychosocial, and emotional factors all affect clinical outcomes in this patient population. Hasenbring et al.\textsuperscript{29} reported that persistent pain at 6 months was best predicted by a combination of psychosocial factors, such as depression and health locus of control, along with the degree of disc displacement. Trief et al.\textsuperscript{71} suggested that the Zung Depression Scale and Modified Somatic Perception Questionnaire (Distress and Risk Assessment Method) could be used effectively to strongly predict poorer outcomes with surgery. McLain and colleagues\textsuperscript{41} reported that past studies have revealed that failed injection therapy is useful for predicting poorer surgical outcome when treating chronic radiculopathy. Some investigators have even suggested that patients who are predicted to have a poor outcome may be better served by continued conservative care and psychological treatment.\textsuperscript{13,32} The Cox proportional hazards model analysis in this study revealed that in addition to assignment to the TFESI Group, relatively lower baseline SF-36 physical components summary scores were associated with an increased probability of having a secondary treatment.

Previous investigators have expressed the opinion that the likelihood of resolving symptoms with conservative care is reduced the longer back pain and symptoms persist.\textsuperscript{5,9,79} In this study, baseline duration of leg pain differed significantly between treatment groups. This variable, as well as baseline back pain and membership in a more largely enrolled site, were statistically controlled in both the GEE statistical modeling and the Cox proportional hazards modeling. Furthermore, a stratified evaluation of the effects of longer duration of leg pain on clinical outcomes was also conducted to control for this variable, and no significant effect was detected. Investigators previously studied the effect of psychological and somatic factors, including duration of pain before treatment, on persistent pain in 111 patients treated for radicular pain.\textsuperscript{29} Persistent pain at 6 months was not found to be significantly associated with duration of pain before treatment. In another study, Kovacs et al.\textsuperscript{36} detected no relationship between duration of pain prior to undergoing conservative care and achieving minimum clinically important reduction in pain after treatment. The results of these studies suggest that clinical outcomes are not significantly associated with longer duration of leg pain in radicular pain patients.

Conclusions

The results of this randomized, controlled clinical study of patients with radicular pain associated with a contained lumbar disc herniation showed that the PDD procedure following a failed TFESI was associated with clinically significant benefits over a repeated course of TFESI, the current standard care. Pain, function, and quality-of-life measures were significantly enhanced for patients in the PDD Group compared with those in the TFESI Group and significantly more patients in the PDD Group remained free from having a secondary procedure during the 2-year follow-up period. Significantly more patients in the PDD Group than patients in the TFESI Group had leg and back pain, ODI, and SF-36 scores exceeding literature-based thresholds for minimum clinical change. Although higher rates of freedom from a secondary procedure would be ideal with either PDD or TFESI, the results with PDD were superior to current interventional standard care.

Appendix I: The SPINE Study Group

Peter C. Gerszten, M.D., University of Pittsburgh Medical Center, Pittsburgh, PA; Matthew Smuck, M.D., Stanford Interventional Spine Center, Stanford University, Redwood City, CA; James P. Rathmell, M.D., Massachusetts General Hospital/Harvard Medical School, and 86% of patients treated with surgery.\textsuperscript{17,27,70} Part of this difference may be due to the patients in our study having higher functional (for example, baseline ODI) scores than a fusion population might.

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Disclosure

Financial support for the conduct of this study was provided by the ArthroCare Corp. In addition, the following authors report being consultants for ArthroCare Corp: Ms. Crabtree, Dr. Bloch, Dr. Gerszten, and Dr. Smuck; Dr. Smuck reports financial support from ArthroCare Corp. for non–study-related clinical or research effort overseen by him.

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Contained lumbar disc herniation


Accepted October 22, 2009.
Please include this information when citing this paper: published online March 5, 2010; DOI: 10.3171/2009.10.SPINE09208.
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