

# Intradiscal Electrothermal Annuloplasty Therapy: A Case Series Study Leading to New Considerations

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## ABSTRACT

**Objective:** To evaluate outcomes of intradiscal electrothermal annuloplasty (IDEA) therapy in the treatment of chronic discogenic low back pain in consecutive IDEA patients treated at a rural pain management clinic.

**Study Design:** An observational case series study design was applied to consecutive IDEA patients qualifying under the inclusion and exclusion criteria. Patient assessment of pain and disability were performed at baseline and 6 weeks, 3, 6, 12, and 24 months post-IDEA.

**Methods:** Selected patients underwent IDEA for an average of 15 minutes at a temperature of 90°C. Analyses of outcomes included Visual Analog Scale (VAS) assessments of levels of pain, and Roland Morris Disability Questionnaire (RMDQ) assessments of functional capacity at pretreatment, and 6 weeks, 3, 6, 12, and 18 months post-treatment time points.

**Results:** At 6 months post-IDEA treatment, patients (n=51) demonstrated statistically significant improvement ( $P<0.001$ ) as measured by a mean change of over 20 points from the pretreatment score on the RMDQ. At 1 year, post data remained significant in the 33 patients who had achieved this time point. VAS pain data were also statistically significant at 6 months ( $P=0.023$ ). Analysis of patient profiles revealed that statistically significant improvement of pain and functional capacity was strongly associated with female gender and age (range of 18-45 years), and that statistically significant

improvement was not sustained in males beyond the 3-6 month point. These data support the outcomes reported in the few existing observational studies to date. Of 86 patients receiving IDEA therapy, 73 provided RMDQ data at baseline and at 3 months or later and were included in the analyses. Some patients were lost to follow-up at later time points.

**Conclusions:** These data show favorable outcomes after IDEA therapy, and suggest that women may experience more improvement than men, particularly with regard to perceived disability improvements. Data suggest that greater improvement in IDEA outcomes may be achieved by profiling the characteristics of patients who achieve the optimal long-term outcomes following treatment and should be considered during evaluation of patient eligibility for IDEA.

## INTRODUCTION

Low back pain ranks second among causes for office visits. The estimated annual direct cost of health care for treatment of back pain is estimated to range from \$38 to \$200 billion annually. Absenteeism from the workplace, disability, and often dramatic psychosocial ramifications add to the financial and personal toll these patients suffer.<sup>1,2</sup> Discogenic pain comprises about 40% of patients who present with chronic low back pain in the working age group.<sup>3</sup> Despite its high incidence rate, however, the diagnosis and treatment of discogenic back pain remains problematic and controversial.

Discogenic back pain is thought to arise when the annulus of ligamentous tissue around the periphery of the intervertebral disc frays and tears from use or injury. Nerves and blood vessels move into the injury site, triggering pain receptors in the ligament tissue. Discogenic back pain differs from ruptured or herniated disc pain in that it originates in the disc, not from the nerves of other structures. Discogenic pain is confined to the back and does not radiate down the legs.

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Pain related to the lumbar discs usually radiates to the back and buttocks. There is absence of a true radicular nerve pattern.

Few treatment options are available to patients with chronic discogenic low back pain. Intradiscal electrothermal annuloplasty (IDEA) therapy is 1 treatment option. IDEA is a non-surgical intervention involving the percutaneous threading of a flexible catheter into the disc. Under fluoroscopic guidance, it is circumferentially placed across the disrupted annulus fibrosus, across the radial fissure, and/or parallel to any circumferential fissure.<sup>4,5</sup> The catheter is a thermal resistive coil that transduces a radiofrequency signal into thermal energy. Treatment involves heating the tip to 90°-95°C over approximately 10 minutes and maintaining it at that temperature for 4-15 minutes.<sup>6,7</sup> The therapeutic efficacy of IDEA, while not yet definitively determined, is generally considered to be achieved by annealing the fissure through heat-stimulated collagen denaturation and disk nerve ablation.<sup>4,5,8-11</sup>

The procedure was developed in 1997 by Jeffrey and Joel Saal,<sup>12</sup> and results of many case series have now been reported with follow-ups for as long as 2 years.<sup>5,6,12-25</sup> Apart from a single randomized, placebo-controlled trial of IDEA reporting a treatment response rate of 60%, there is a paucity of long-term outcomes from randomized, placebo-controlled clinical trials and mechanistic work with animal models.<sup>7,8,26-28</sup> A few attempts have been made to study the procedure in cadaver spines, with mixed results.<sup>9-11</sup>

In the absence of further randomized controlled studies, observational case reviews can yield potentially useful information on the preselection of patients with specific characteristics that would enhance therapeutic outcomes. We sought specifically to document further the long-term outcomes of IDEA therapy for chronic discogenic low back pain and examine the impact of age or gender on outcomes. We hoped to gain further evidence regarding age- and gender-specific differences in association with IDEA therapy outcomes, as suggested previously in observational outcome studies of IDEA in small numbers of patients.

## METHODS

This study received prior approval from the Marshfield Clinic Research Foundation Institutional Review Board.

### *Setting*

Study subjects were chosen from patients referred to the Interventional Pain Management Clinic of

Marshfield Clinic. Marshfield Clinic is a multispecialty group practice with 41 regional centers serving the largely rural population of central and northern Wisconsin. The pain management program is an interdisciplinary, outpatient-based pain management center with a full spectrum of anesthesiology-based pain management techniques, with psychological and physical rehabilitation support. About 60% of patients referred to the Interventional Pain Management Clinic have chronic back pain.

### *Study Design*

An observational case series study design was applied to a comprehensive sample of all available consecutive patients meeting the inclusion criteria within the study timeframe. Because of the nature of back pain, designs that would propose inter-subject comparisons are not readily feasible because back pain varies widely among individuals in its physical nature, origin, and perception. Thus, attempts at identifying an adequate control for a specific patient becomes problematic. In the present study we utilized the accepted research design of allowing patients to serve as their own control with pain and disability level at baseline (pre-IDEA) serving as the reference point for evaluation of change in level of pain post-IDEA treatment.

### *Inclusion Criteria*

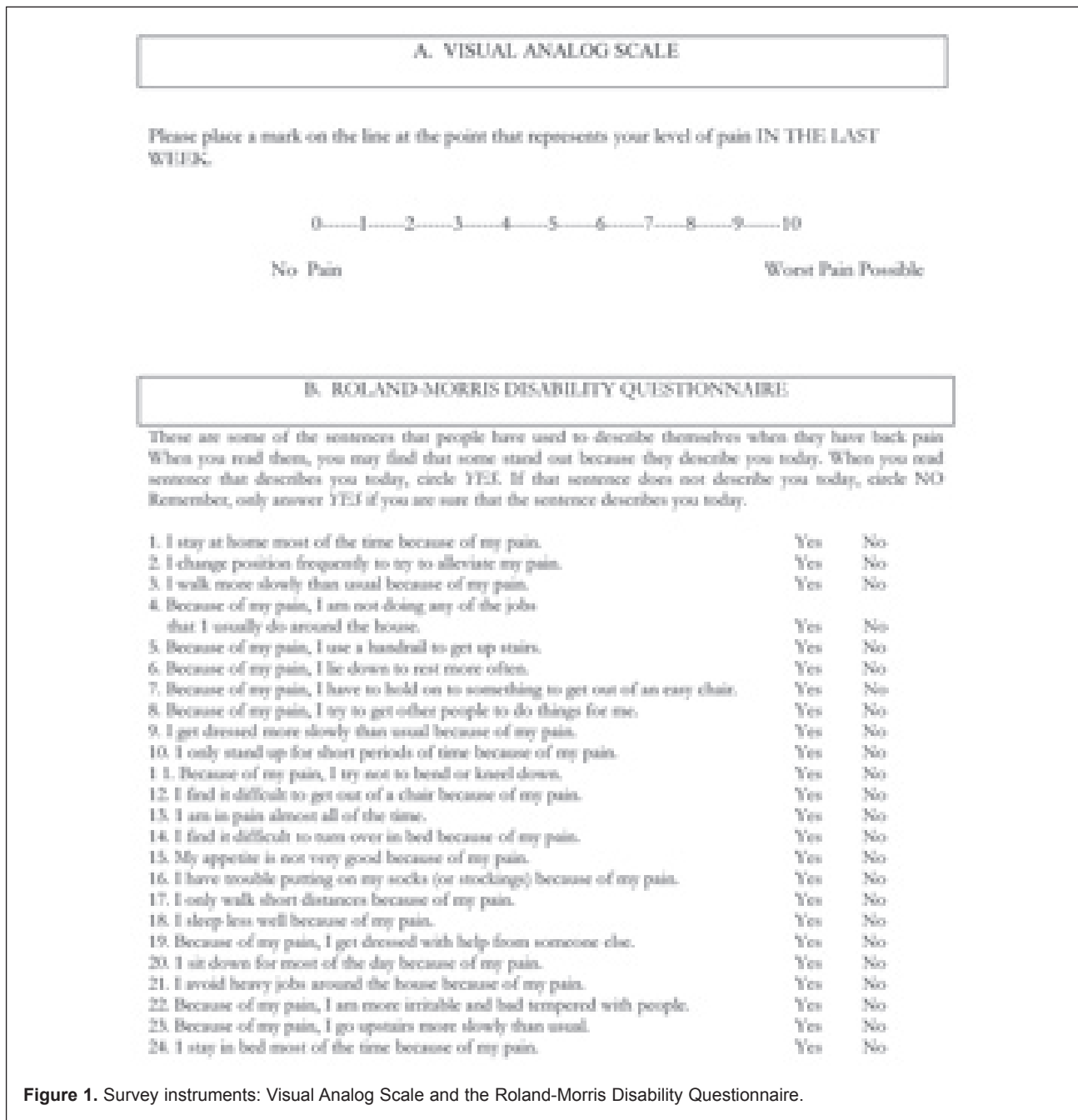
Patients who met the following inclusion criteria were treated with IDEA: (1) chronic low discogenic back pain of a minimum duration of 6 months, (2) no response to conventional treatment, (3) back pain represented >60% of other symptoms, (4) normal score on neurological assessment tools including Zung Depression Scale and Modified Somatic Perception Questionnaire, (5) lack of neurological neuropathy, (6) disk tested positive on provocative discography, (7) discographic computed tomography confirmed presence of post annular tears which were classified as single discrete fissures or annular tears, and (8) age range from 18-50 years.

### *Exclusion Criteria*

Patient exclusion criteria included: (1) presence of inflammatory arthritis, (2) non-spinal conditions mimicking lumbar pain, (3) any amount of spinal instability, (4) medical or metabolic disorders that would preclude patient follow-up or participation, and (5) age <18 years or >80 years.

### *IDEA Procedure*

Following application of local anesthesia, the SpineCath (Oratec Interventions Inc., Menlo Park, CA) catheter



was inserted and advanced antero-laterally to cross the posterior annular wall. A radiofrequency generator (Oratec Interventions, Inc.) converted radiofrequency waves to electrothermal heat upon entering the resistive tip of the catheter. Patients were treated for an average of 15 minutes at a temperature of 90°C.

#### Post-IDEA Physical Therapy

All patients were referred to the same physical therapy treatment regardless of where IDEA treatment was received. Physical therapy was monitored by 1 physical therapist who referred patients to a local physical therapist.

In addition, all patients wore a brace for 6 weeks post-IDEA.

#### Patient Outcomes Assessment

Variables collected included age and gender. At baseline and 6 weeks, 3, 6, 12, and 18 months post-IDEA therapy, patients were assessed for “current day” and “last week” pain using the Visual Analog Scale (VAS) and functional capacity using the Roland Morris Disability Questionnaire (RMDQ) (Figure 1). The RMDQ is a self-administered disability measure in which greater levels of disability are reflected by higher numbers on a 24-point

**Table 1.** Baseline Scores by Gender

	Male				Female			
	N	Median	Minimum	Maximum	N	Median	Minimum	Maximum
Age	31	40.5	25	73	42	37.3	21	55
RMDQ	31	75.0	13	92	42	75.0	0	100
“Current day” pain	28	5.5	1	10	35	7.0	3	10
“Last week” pain	29	7.0	3	10	35	7.1	3	10

RMDQ = Roland Morris Disability Questionnaire

**Table 2.** Change in Pain and Disability Scores from Baseline – All Patients

Time Post-IDEA	N	Mean	SD	Median	Minimum	Maximum	Signed-Ranks P-Value
<b>Roland-Morris Disability Scale Scores</b>							
6 weeks	55	-15.5	28.8	-8.3	-92.0	33.3	<0.001*
3 months	54	-22.4	27.5	-12.5	-92.0	16.7	<0.001*
6 months	57	-20.8	30.4	-12.5	-92.0	29.2	<0.001*
12 months	49	-19.6	31.7	-8.5	-92.0	33.3	<0.001*
18 months	30	-26.7	36.0	-10.4	-92.0	33.3	<0.001*
<b>“Current Day” Visual Analog Pain Scores</b>							
6 weeks	43	-1.0	2.8	-0.6	-7.0	6.0	<0.026*
3 months	40	-1.6	2.5	-1.0	-6.9	2.5	<0.001*
6 months	38	-1.0	2.8	-0.2	-6.0	6.0	<0.064
12 months	32	-1.5	3.1	-1.5	-7.5	3.6	0.023*
18 months	23	-1.5	2.9	-1.0	-8.5	3.6	0.021*
<b>“Last Week” Visual Analog Pain Scores</b>							
6 weeks	43	-2.0	2.7	-2.0	-9.0	2.5	<0.001*
3 months	40	-2.3	2.7	-2.0	-8.3	3.0	<0.001*
6 months	39	-1.1	2.5	-1.0	-7.0	5.0	0.010*
12 months	32	-1.9	3.1	-0.8	-8.0	3.0	0.002*
18 months	23	-2.4	3.2	-2.0	-9.0	3.0	0.001*

\* Significant improvement in functional capacity or reduction in pain from baseline score

IDEA=intradiscal electrothermal annuloplasty; SD=Standard deviation

scale. The RMDQ data are presented on a 0–100 scale, where 0 means none of 24 items applied, and 100 means all 24 items applied (100%). The RMDQ has been shown to yield reliable measurements that are valid for inferring the level of disability and to be sensitive to change over time for groups of patients with low back pain.<sup>29,30</sup>

*Statistical Analysis*

The primary analyses involved assessing changes in the RMDQ and VAS pain scores from baseline to the specified time points post-treatment. The Wilcoxon signed rank statistic was used to test the statistical significance of changes in these measures, with a threshold of significance set at  $P=0.05$  (2-tailed).

**RESULTS**

Eighty-six patients received IDEA therapy. Of these patients, 73 had RMDQ data available at baseline (Table 1)

and at 3 months or later and were included in the analyses. The study revealed statistically significant improvements in ratings on the RMDQ at all times during the 18-month follow-up period at all time points ( $P<0.001$ ) (Table 2). These perceived improvements in functional capacity were reflected in significantly improved “current day” at 6 weeks, 3 months, 12 months, and 18 months compared to baseline ( $P<0.026$ , 0.001, 0.023 and 0.021, respectively). Similarly, statistically significant differences in “last week” VAS pain scores over time compared to baseline were observed at 6 weeks, 3 months, 12 months, and 18 months ( $P<0.001$ , 0.001, 0.002, 0.001, respectively) (Table 2). “Current day” pain score was not statistically significant at the 6-month time point ( $P=0.064$ ), although “last week” pain scores did demonstrate significant improvement ( $P=0.010$ ). No significant differences in perceived disability or pain improvements were found when the data were stratified by age into those <40 years and those >40 (Table 3).

**Table 3.** Change in Disability Scale and Pain Scores from Baseline – By Age

Time Post-IDEA	Age <40 years				Age 40+ years				Wilcoxon P-value
	N	Mean	SD	Median	N	Mean	SD	Median	
<b>Roland-Morris Disability Scale Scores</b>									
6 weeks	33	-14.8	32.3	0.0	22	-16.7	23.3	-12.5	0.266
3 months	30	-22.9	29.5	-14.3	24	-21.7	25.5	-12.3	0.875
6 months	34	-22.9	30.5	-14.6	23	-17.5	30.7	-8.3	0.349
12 months	24	-22.9	33.2	-12.5	25	-16.5	30.4	-8.3	0.516
18 months	16	-32.9	38.5	-31.3	14	-19.6	32.9	-8.3	0.405
<b>“Current Day” Visual Analog Pain Scores</b>									
6 weeks	25	-1.4	2.6	-1.3	18	-0.4	3.0	-0.1	0.337
3 months	21	-2.3	2.7	-2.0	19	-0.9	2.1	-0.5	0.103
6 months	19	-1.3	3.1	-2.0	19	-0.6	2.4	0.0	0.492
12 months	15	-1.4	3.2	-1.0	17	-1.5	3.1	-2.0	0.865
18 months	11	-1.9	3.0	-3.0	12	-1.2	2.9	-1.0	0.478
<b>“Last Week” Visual Analog Pain Scores</b>									
6 weeks	25	-2.1	2.9	-2.0	18	-2.0	2.5	-1.7	0.990
3 months	21	-2.7	3.1	-3.0	19	-1.9	2.0	-2.0	0.385
6 months	20	-1.3	2.7	-1.8	19	-0.9	2.4	-0.7	0.298
12 months	15	-1.6	3.3	-0.7	17	-2.2	3.0	-2.0	0.637
18 months	11	-2.8	3.2	-3.0	12	-2.0	3.3	-1.3	0.388

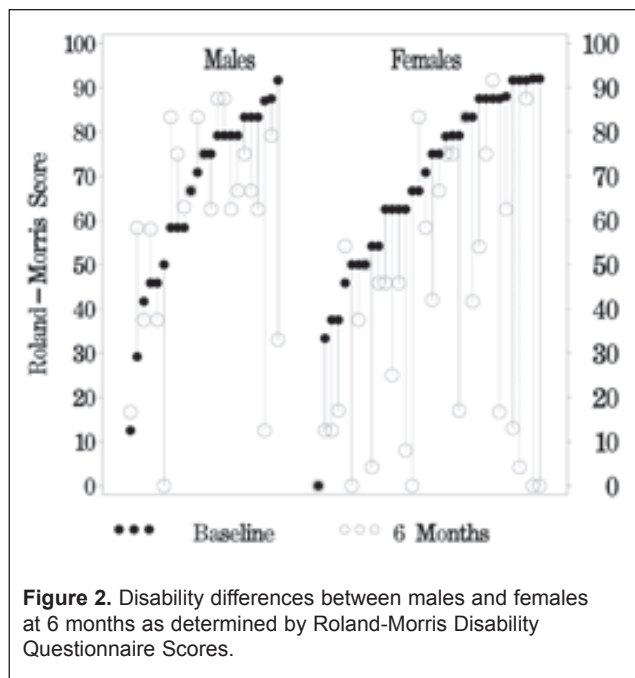
IDEA=intradiscal electrothermal annuloplasty; SD=Standard deviation

**Table 4.** Change in Disability Scale and Pain Scores from Baseline – By Gender

Time Post-IDEA	Male				Female				Wilcoxon P-value
	N	Mean	SD	Median	N	Mean	SD	Median	
<b>Roland-Morris Disability Scale Scores</b>									
6 weeks	25	-8.6	23.7	-4.2	30	-21.3	31.7	-12.5	0.180
3 months	25	-16.0	21.6	-12.5	29	-27.9	31.1	-16.7	0.309
6 months	23	-7.4	25.2	-4.2	34	-29.8	30.6	-20.7	0.004*
12 months	18	-10.1	26.3	-2.3	31	-25.1	33.6	-12.5	0.063
18 months	9	-11.9	28.5	-8.3	21	-33.0	37.7	-29.2	0.135
<b>“Current Day” Visual Analog Pain Scores</b>									
6 weeks	21	-1.0	2.5	-1.3	22	-0.9	3.0	-0.4	0.942
3 months	21	-1.0	2.0	-0.5	19	-2.3	2.9	-1.5	0.122
6 months	17	-0.2	2.1	0.1	21	-1.6	3.1	-1.6	0.069
12 months	12	-1.0	3.1	-0.5	20	-1.7	3.2	-2.0	0.586
18 months	7	-0.7	2.4	-1.0	16	-1.9	3.1	-1.0	0.421
<b>“Last Week” Visual Analog Pain Scores</b>									
6 weeks	21	-2.2	2.6	-2.0	22	-1.9	2.9	-2.0	0.706
3 months	21	-2.0	2.6	-2.3	19	-2.7	2.8	-2.0	0.408
6 months	18	-0.5	2.3	-1.2	21	-1.6	2.7	-1.0	0.176
12 months	12	-1.9	2.5	-1.5	20	-1.9	3.4	-0.6	0.815
18 months	7	-1.5	3.1	-0.6	16	-2.8	3.3	-2.3	0.315

\*Significantly reduced disability in women as compared to men

IDEA=intradiscal electrothermal annuloplasty; SD=Standard deviation



**Figure 2.** Disability differences between males and females at 6 months as determined by Roland-Morris Disability Questionnaire Scores.

When stratified by gender, no statistically significant differences in perceived pain were seen between men and women (Table 4). At 6 months, women reported significantly less disability than men (Figure 2). Differences were not significant at subsequent time points (Table 4), but less data were available at those times.

**DISCUSSION**

Data presented here suggest that IDEA improved outcomes in men and women between the ages of 18 and 80 experiencing chronic low discogenic back pain that had previously proven refractory to conventional treatments. Statistically significant improvement in functional scores from baseline were achieved and sustained over time. After the conclusion of this study, 1 randomized, prospective trial comparing IDEA to sham-operated controls was completed.<sup>28</sup> Authors reported a treatment response rate of 60% with a positive placebo control response of 35%, suggesting that it might be expected that a proportion—but not all—of patients to improve regardless of treatment over time. In the present study, while it is not possible to know what the natural course of pain symptoms would have been without the treatment, the history of long-term chronic pain in these patients and relatively rapid post-treatment improvements in VAS and RMDQ scores that coincided temporally with IDEA treatment were highly suggestive of treatment effectiveness.

Previous studies have reported the same timeframe for improvement post-IDEA as was observed in the

present study with optimum improvement occurring 6 months post-IDEA. The notion that all patients see improvement only after a protracted physical therapy program many months post-IDEA would suggest that a major physical therapy component is required for positive treatment outcome. No study has excluded physical therapy as part of the treatment regimen post-IDEA. A study is currently in progress that looks at IDEA without physical therapy, as part of the post-procedure treatment (Bogduk, personal communication).

Although the major improvement in pain and function level is generally achieved at 6 months post-IDEA, the observation period in the present study was extended to 18 months. As expected, the observed magnitude of change in pain and disability scores beyond 6 months was not significant. However, the 18-month follow-up also demonstrated that the improvements in pain and disability were sustained at the level of the initial response.

While the long-term outcomes of several series of patients have been reported, to date few studies have attempted to stratify the results according to age and gender. In the present study, whereas age had no influence on treatment outcome, women tended to show more improvement in follow-up than men. Although statistically significant only at 6 months, the trend was consistent throughout. Our data support observations of Lui et al<sup>31</sup> who reported a statistically significant decrease in VAS pain scores ( $P < 0.001$ ) in women compared to men during subsequent follow-up following IDEA treatment. In the present study, missing data compromised statistical power. Totta<sup>23</sup> looked specifically at gender effects in IDEA therapy and found no difference in the pain (VAS) or physical function scale of the Short Form-36 Questionnaire (SF-36) outcomes in men versus women. Our data, however, show statistically significant improvement among women on follow-up. Recent reports have demonstrated gender differences in the perception of pain with females having lower tolerance to back pain.<sup>32-42</sup> These data lend further support to the statistically significant gender differences observed in the efficacy of the IDEA procedure in the present study. If there was an equal physical treatment effect at the tissue level between men and women, women may subjectively feel that the reduction in pain level is greater. Alternatively, and more likely, assuming that the physical treatment effect at the treatment level was larger in women than men, the greater perceived elimination of pain might reflect an even greater physical treatment effect (ie, if they felt any residual pain, they would be expected to feel it more). This study cannot

address either of these possibilities directly, but suggests that pain perception and IDEA outcomes warrant further study.

## Limitations

One limitation of this study is that not all patients could be evaluated at all follow-up time points. This not only reduces the statistical power, but might also introduce a bias if patients with less favorable outcomes were less likely to provide data. However, follow-up completion rates were similar for men and women. The lack of good controls is likely to have introduced other unidentified confounders. An additional limitation is that in this type of study design, by selecting patients with a clinical history refractory to conventional treatment, any post-interventional improvement serves as suggestive evidence that the therapy was efficacious. A limitation of this type of study is that a spontaneous resolution of the symptomology unrelated to intervention cannot be ruled out. However, since the improvement observed occurred temporally in the post-IDEA intervention, the likelihood is high that the improvement observed is directly related to IDEA treatment.

## CONCLUSION

IDEA is steadily gaining recognition as a viable treatment option for patients with chronic low discogenic back pain refractory to conventional treatment. Our data lend confirmatory evidence to the conclusion that IDEA therapy may lead to favorable outcomes in such patients, and suggest that women may experience more improvement than men, particularly with regard to perceived disability improvements.

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