

Annulo-Nucleoplasty Using Disc-Fx in the Management of Degenerative Lumbar Disc Pathology: How Long Can the Effect Last?

Global Spine Journal
2018, Vol. 8(4) 365-373
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DOI: 10.1177/2192568217726525
journals.sagepub.com/home/gsj


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Abstract

Study Design: Prospective analysis.

Objectives: To evaluate 2-year clinical outcomes in patients undergoing Disc-FX for the management of low back pain (LBP) due to degenerate disc (DD) or contained lumbar disc herniation (CLDH). To study salient factors that can potentially influence the clinical outcomes.

Methods: We analyzed the prospectively collected data of 51 patients who underwent Disc-FX procedure for DD or CLDH, nonresponsive to 6 months of nonoperative treatment. Clinical outcome measures collected were visual analogue scale (VAS), Oswestry Disability Index (ODI), and MacNab scores. These preoperative values were compared with respective values at immediate, 6 months, 1 year, and 2 years postoperation. Minimum clinically important difference values for these outcomes in accordance with previously published data was used to evaluate the effectiveness of Disc-FX intervention.

Results: Of 51 patients, 84% had DD and 16% had CLDH. Significant improvement ($P < .01$) in VAS and ODI scores was observed at all assessment periods compared to the respective preoperative values. Based on the MacNab scores, there was significant increase ($P < .01$) in the proportion of patients with excellent/good MacNab outcomes at each time point after the procedure; 78% achieving excellent/good outcomes at 2-year follow-up. Ease of access to the disc space was significantly influencing VAS, ODI, and MacNab scores at 1-year and 2-year follow-ups. VAS and MacNab scores were negatively influenced by high body mass index and smoking status at 6 and 12 months postoperation.

Conclusions: Our data suggests that Disc-FX may be helpful in selected patients with symptomatic degenerative disc disease providing favorable outcomes lasting up to 2 years or more. The results were more favorable in patients with easier access to disc space.

Keywords

degenerative disc, contained lumbar disc herniation, degenerative disc disease, radiofrequency, annulonucleoplasty

Introduction

Low back pain (LBP) due to degenerative disc disease is a global health problem, which has been estimated to be 28% to 40% of all types of LBP.^{1,2} It can cause significant disability leading to difficulty in daily activities and work.³ Pain can present as a spectrum ranging from mild and manageable pain to severe and disabling pain. Two common subtypes of degenerative disc disease are degenerate disc (DD) or contained lumbar disc herniation (CLDH). Patients with DD will have

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predominantly back pain with no leg pain, while in patients with CLDH, the symptoms will be predominant back pain and moderate leg pain. The management of degenerative disc disease usually ranges from physical therapy, simple analgesia, and lifestyle modification to more complex interventions such as surgery. This has been presented as a step ladder pattern by Kumar et al in the recent past.⁴

Treatment options to bridge the gap between less invasive modalities such as injections and more extensive procedures such as spinal fusion surgeries are few and evolving. One such technique is annulo-nucleoplasty using the Disc-FX system (Elliquence, LLC, Baldwin, NY). The concept of this technique is similar to nucleoplasty—both using radiofrequency. Although there is a considerable information on nucleoplasty in the management of back pain and/or leg pain from disc pathology,^{4,5} studies on Disc-FX annulo-nucleoplasty in the management of lumbar disc pathology are limited.

We have previously reported good short-term results using the Disc-FX procedure in patients with DD or CLDH causing LBP who have failed nonoperative management.⁶ Short-term results of the Disc-FX procedure have been reported in a few studies, but the long-term clinical outcomes remain unknown. We aimed to evaluate the 2-year clinical outcomes in patients who underwent Disc-FX for the management of LBP due to DD or CLDH. We also studied a number of salient factors that can potentially influence the improvement in clinical outcomes.

Materials and Methods

We analyzed prospectively collected data of patients with LBP who underwent a Disc-FX procedure for lumbar DD or CLDH at a tertiary referral center between September 2010 and December 2014. Ethics approval was obtained from the institutional review board. All included patients had failed a trial of at least 6 months of nonoperative treatment, which included physiotherapy, acupuncture or chiropractic treatment. The inclusion and exclusion criteria of this study are detailed in Table 1.

All patients had back pain with or without leg pain. They were divided into 2 groups—DD or CLDH—based on the T2W magnetic resonance imaging (MRI) of the lumbar spine. DD will have low signal on T2W images and, in addition, exhibit loss of disc height. CLDH will also exhibit low signal on T2W images and herniation of nucleus pulposus into annulus fibrosus without any extrusion or sequestration. CLDH may present as a focal annular bulge with thinning of the annulus fibrosus and protrusion of the nucleus pulposus up to the annular rim, or as a diffuse annular bulge with no thinning of the annulus and no nuclear material protrusion.

All patients included underwent provocative discography before the Disc-FX treatment. The outcome of discography was recorded as concordant pain provocation and description of disc morphology as described by Adam's classification.⁷ Discography was performed for all the degenerate levels that could be suspected as a potential source of pain and responsible for

Table 1. Inclusion and Exclusion Criteria.

| Inclusion Criteria | Exclusion Criteria |
|--|---|
| <ul style="list-style-type: none"> Age between 18 and 60 years Axial back pain due to degenerate disc (DD) or back pain with leg symptoms due to contained lumbar disc herniation (CLDH) Symptoms unresponsive to at least 6 months of conservative management Preoperative visual analogue scale (VAS) score ≥ 5 Magnetic resonance imaging (MRI) revealing degenerate/symptomatic discs at not more than 3 levels Disc level to be intervened falls within Pfirrmann's grade 2-4 | <ul style="list-style-type: none"> Back pain due to lumbosacral strain or facet arthritis Workmen compensation patients A clear history or MRI pointing toward acute disc prolapse/sequestered disc Previous lumbar spine surgery and revision surgery for Disc-FX Spondylolisthesis/instability Infection/malignant spinal conditions Cauda equina syndrome |

Table 2. Demographics and Clinical Data of the Patients.

| Characteristics | Number of Patients (%) |
|--------------------------------------|------------------------|
| Gender | |
| Male | 38 (75) |
| Female | 13 (25) |
| Age | |
| <41 years | 22 (43) |
| ≥ 41 years | 29 (57) |
| BMI | |
| 18-25 | 22 (43) |
| 25.1-30 | 19 (37) |
| >30 | 10 (20) |
| Smoking | |
| Yes | 44 (67) |
| No | 22 (33) |
| Subtype of degenerative disc disease | |
| CLDH | 8 (16) |
| DD | 43 (84) |
| Provocative discography | |
| Positive | 47 (71) |
| Negative | 19 (29) |
| Ease of access for L4-L5 and L5-S1 | |
| Easy | 44 (77) |
| Difficult | 13 (23) |
| Spinal level operated | |
| L2-L3 | 1 (2) |
| L3-L4 | 8 (12) |
| L4-L5 | 27 (41) |
| L5-S1 | 30 (45) |

Abbreviations: BMI, body mass index; CLDH, contained lumbar disc herniation; DD, degenerate disc.

Table 3. VAS, ODI, and MacNab Outcomes Assessment at Different Time Points.

| | VAS | | ODI | | Excellent/Good MacNab Outcomes | |
|-------------------------|---------------|----------------------|---------------|----------------------|--------------------------------|----------------------|
| | Mean (SD) | P Value ^a | Mean (SD) | P Value ^a | Number (%) | P Value ^b |
| Preoperative | 66.94 (9.28) | | 47.80 (17.92) | | 5 (10) | |
| Immediate postoperative | 37.45 (17.33) | <.01 | 33.13 (15.76) | <.01 | 20 (39) | <.01 |
| 6 Months postoperative | 40.68 (21.79) | <.01 | 31.99 (20.79) | <.01 | 25 (49) | <.01 |
| 1 Year postoperative | 36.94 (19.18) | <.01 | 26.53 (16.79) | <.01 | 29 (57) | <.01 |
| 2 Years postoperative | 28.50 (17.58) | <.01 | 19.63 (14.14) | <.01 | 40 (78) | <.01 |

Abbreviations: VAS, visual analogue scale; ODI, Oswestry Disability Index.

^aP value from *t* test.

^bP value from proportion test.

the patient's symptoms. If the patient had 2-level DD, the treated disc was the one that was discography positive (ie, concordant pain). If the patient had a single-level disc disease and discography was concordant, the disc was definitely treated. However, if the discography was discordant, the DD was treated despite the discography outcome as our preoperative investigation had ruled out other anatomic sites to be the pain source. The potential cause of a patient's symptoms could also be identified based on pain source worked out through the history and clinical presentation matching with the disc level under question. The other method used to detect the potential cause of patients' symptoms was to document progressive degeneration of the doubtful level on serial MRI studies whenever feasible. After the decision for treating the appropriate disc with Disc-FX was taken, annulonucleoplasty was performed in the operating room under managed anaesthesia care, which was under deep sedation (Figure 1).

Clinical outcome measures collected were visual analogue scale (VAS), Oswestry Disability Index (ODI), and MacNab criteria scores before operation, immediately after operation, 6 months, 1 year, and 2 years postoperation. Disc-FX was considered as a failure if patients required a second surgical procedure for their symptoms within the 2-year follow-up period.

Statistical Analysis

Statistical analysis was performed using STATA statistical software. Categorical variables are presented as numbers and percentages. Continuous variables are presented as mean \pm SD or as median and range depending on the distribution of the demographic and clinical data. The preoperative VAS and ODI scores were compared with respective values at immediate, 6 months, 1 year, and 2 years postoperation using paired *t* test. Proportion test was used to compare the proportion of patients with excellent/good MacNab outcomes between the preoperative and postoperative follow-ups at the same stages.

The differences between preoperative and postoperative VAS and ODI scores were calculated to detect a minimum clinically important difference (MCID). MCID values of 12 points for VAS and 12.8 points for ODI were used in accordance with previously published data⁸ to evaluate the effectiveness of Disc-FX intervention on improvement in pain and functional outcomes. As for MacNab functional scores, the

proportion of patients with at least one grade improvement in MacNab scores at immediate postoperation, 6-month, 1-year, and 2-year follow-ups were assessed against baseline preoperation values.

Univariate analysis was performed to evaluate the influence of demographic data (age, gender, body mass index [BMI], and smoking status) and clinical parameters (disc level, ease of access, subtype of degenerative disc disease, and response to discography) on improvement in pain and functional outcomes. Ease of access was classified as difficult if it required more than one attempt to insert the Disc-FX probe in the right position for the disc being treated; otherwise, it was classed as easy. Subtype of degenerative disc disease was divided into DD or CLDH.

Results

During our study period, 54 patients underwent Disc-FX intervention. Of the 54 patients, 24 were the same patients whose 1-year outcomes were presented in a previous publication.⁶ Three patients had a re-intervention within 6 months of the index procedure; the first patient had a concomitant L5 lysis defect and a degenerate L5-S1 disc who was offered L5 lysis repair to address his continuing back pain after a failed L5-S1 Disc-FX procedure; the other 2 patients had DDs L4-L5 and L5-S1, respectively, which were Pfirrmann's grade 3 on presentation, who after having successful Disc-FX procedures presented as disc prolapse at the operated levels at 3 and 6 months, respectively. Both the patients required discectomy to address the symptoms from prolapsed intervertebral disc. Hence, these patients were excluded from the study as the secondary procedures would prevent them from having an outcome assessment for Disc-FX at 6 months, 1 year, and 2 years, leaving 51 patients in the final analysis. All patients had a minimum period of 2 years of follow-up.

The mean age was 41 years (20-63) with a gender distribution of 13 females (25%) and 38 males (75%). The demographic and clinical data of the patients are presented in Table 2. In our study cohort, 84% of patients had DD and 16% had CLDH. Of 51 patients, 36 had a single-level procedure and 15 had a 2-level procedure. Out of the total of 66 levels treated, 1 was at L2-L3, 8 were at L3-L4, 27 were at L4-L5, and 30 were at L5-S1. The placement of the Disc-FX probe was difficult in 23% cases (13/57 levels). Difficulty was

Table 4. Patients With MCID in VAS, ODI, and MacNab Outcomes at Different Time Points After Surgery^a.

| | VAS | ODI | MacNab Outcomes |
|-------------------------|---------|---------|-----------------|
| Immediate postoperative | 40 (78) | 24 (47) | 31 (61) |
| 6 Months postoperative | 34 (67) | 29 (57) | 31 (61) |
| 1 Year postoperative | 39 (76) | 37 (73) | 39 (76) |
| 2 Years postoperative | 45 (88) | 40 (78) | 42 (82) |

Abbreviations: MCID, minimum clinically important difference; VAS, visual analogue scale; ODI, Oswestry Disability Index.

^aThe values are the number of patients with percentages in parentheses.

most commonly encountered for L5-S1 disc space (8/30 levels) due to high iliac crest and less commonly for L4-L5 (5/27 levels). No difficulty was encountered for L3-L4 and L2-L3.

All procedures were carried out uneventfully with no intraoperative complications. The commonest adverse event in the postoperative period was slight increase in radicular pain (16/54 patients; 30%) arising from the traversing nerve root of the treated disc. This may be due to direct effect of radiofrequency on the nerve root. These symptoms resolved within 2 days to 2 weeks. Most of them required anti-inflammatory drugs and pregabalin/gabapentin to relieve the symptoms. Back pain,

however, improved in all patients. One patient developed infective discitis secondary to methicillin-susceptible *Staphylococcus aureus*, which was detected at 35 days postprocedure and treated with intravenous antibiotics. Hence, deep infection rate for this procedure was 1/54 (1.8%).

Mean VAS and ODI values at the preoperative and postoperative visits are shown in Table 3. The VAS scores demonstrated significant improvement ($P < .01$) at immediate, 6-month, 1-year, and 2-year postoperative follow-up visits compared to the preoperative values. Similar findings were observed for the mean ODI scores with significant differences ($P < .01$) at all assessment periods as compared to the preoperative value, indicating functional improvement following the Disc-FX procedure. Based on the MacNab scores, excellent outcomes were achieved in 26 patients (51%), good in 14 patients (27%), fair in 9 patients (18%) and poor in 2 patients (4%) at 2-year follow-up. The percentage of patients with good or excellent MacNab outcomes is also presented in Table 3. There were significant increase ($P < .01$) in the proportion of patients with excellent/good MacNab outcomes at each time point after the procedure as compared to the preoperative value.

Table 4 demonstrates the patients with MCID in VAS, ODI, and MacNab outcomes between preoperative and postoperative

Table 5. Univariate Analysis for the Association Between Demographic, Clinical Parameters, and VAS.

| | Immediate Postoperative | P Value | 6 Months Postoperative | P value | 1 Year Postoperative | P Value | 2 Years Postoperative | P Value |
|-----------------------|-------------------------|---------|------------------------|------------|----------------------|----------------|-----------------------|------------|
| Gender | | | | | | | | |
| Male | 29 (76) | .71 | 25 (66) | .89 | 28 (74) | .71 | 35 (92) | .16 |
| Female | 11 (85) | | 9 (69) | | 11 (85) | | 10 (77) | |
| Age | | | | | | | | |
| <41 years | 19 (86) | .31 | 18 (82) | .07 | 16 (73) | .74 | 21 (95) | .22 |
| ≥41 years | 21 (72) | | 16 (55) | | 23 (79) | | 24 (83) | |
| Spinal level operated | | | | | | | | |
| L2-L3 | 1 (100) | .84 | 1 (100) | .39 | 1 (100) | .85 | 1 (100) | .71 |
| L3-L4 | 7 (88) | | 4 (50) | | 6 (75) | | 8 (100) | |
| L4-L5 | 19 (70) | | 14 (52) | | 18 (67) | | 24 (89) | |
| L5-S1 | 22 (73) | | 21 (70) | | 23 (77) | | 25 (83) | |
| Pathology | | | | | | | | |
| PID | 7 (88) | .66 | 5 (63) | .91 | 7 (88) | .66 | 8 (100) | .57 |
| DDD | 33 (77) | | 29 (67) | | 32 (74) | | 37 (86) | |
| Approach | | | | | | | | |
| Easy | 34 (80) | .38 | 30 (71) | .14 | 37 (88) | <.01 | 40 (95) | .01 |
| Difficult | 6 (66) | | 4 (44) | | 2 (22) | | 5 (55) | |
| BMI | | | | | | | | |
| 18-25 | 16 (73) | .33 | 14 (64) | .04 | 17 (77) | .05 | 20 (91) | .17 |
| 25.1-30 | 17 (89) | | 16 (84) | | 17 (89) | | 18 (95) | |
| >30 | 7 (70) | | 4 (40) | | 5 (50) | | 7 (70) | |
| Smoking | | | | | | | | |
| Yes | 30 (68) | .14 | 24 (55) | .18 | 31 (70) | .77 | 41 (93) | .10 |
| No | 19 (86) | | 16 (73) | | 17 (77) | | 17 (77) | |
| Discography | | | | | | | | |
| Positive | 36 (77) | .54 | 31 (66) | .17 | 36 (77) | .36 | 42 (89) | .68 |
| Negative | 13 (68) | | 9 (47) | | 12 (63) | | 16 (84) | |

Abbreviations: VAS, visual analogue scale; BMI, body mass index; PID, prolapsed intervertebral disc; DDD, degenerative disc disease.

^aThe values presented are the number of patients with percentages in parentheses. All outcome values showing significant change (ie, $P < .05$) have been highlighted in bold.

Table 6. Univariate Analysis for the Association Between Demographic, Clinical Parameters, and ODI^a.

| | Immediate Postoperative | P Value | 6 Months Postoperative | P Value | 1 Year Postoperative | P Value | 2 Years Postoperative | P Value |
|-----------------------|-------------------------|---------|------------------------|------------|----------------------|----------------|-----------------------|------------|
| Gender | | | | | | | | |
| Male | 15 (39) | .11 | 18 (47) | .02 | 26 (68) | .47 | 29 (76) | .71 |
| Female | 9 (69) | | 11 (85) | | 11 (85) | | 11 (84) | |
| Age | | | | | | | | |
| <41 years | 7 (312) | .08 | 12 (55) | .78 | 14 (64) | .34 | 15 (68) | .17 |
| ≥41 years | 17 (58) | | 17 (59) | | 23 (79) | | 25 (86) | |
| Spinal level operated | | | | | | | | |
| L2-L3 | 0 | .85 | 1 (100) | .23 | 1 (100) | .44 | 1 (100) | .71 |
| L3-L4 | 4 (50) | | 2 (25) | | 5 (63) | | 6 (75) | |
| L4-L5 | 11 (41) | | 14 (52) | | 17(63) | | 20 (74) | |
| L5-S1 | 15 (50) | | 18 (60) | | 24 (80) | | 25 (83) | |
| Pathology | | | | | | | | |
| PID | 5 (63) | .45 | 4 (50) | .71 | 7 (88) | .41 | 7 (88) | .66 |
| DDD | 19 (44) | | 25 (58) | | 30 (68) | | 33 (77) | |
| Approach | | | | | | | | |
| Easy | 22 (52) | .14 | 26 (61) | .15 | 34 (80) | <.01 | 36 (85) | .01 |
| Difficult | 2 (22) | | 3 (33) | | 3 (33) | | 4 (44) | |
| BMI | | | | | | | | |
| 18-25 | 11 (50) | .87 | 12 (55) | .35 | 14 (64) | .33 | 16 (73) | .33 |
| 25.1-30 | 8 (42) | | 13 (68) | | 16 (84) | | 17 (89) | |
| >30 | 5 (50) | | 4 (40) | | 7 (70) | | 7 (70) | |
| Smoking | | | | | | | | |
| Yes | 18 (41) | .31 | 23 (52) | .92 | 30 (68) | .56 | 35 (80) | .95 |
| No | 12 (55) | | 12 (55) | | 17 (77) | | 17 (77) | |
| Discography | | | | | | | | |
| Positive | 21 (45) | .95 | 29 (62) | .03 | 35 (74) | .38 | 36 (77) | .74 |
| Negative | 9 (47) | | 6 (32) | | 12 (63) | | 16 (84) | |

Abbreviations: ODI, Oswestry Disability Index; BMI, body mass index; PID, prolapsed intervertebral disc; DDD, degenerative disc disease.

^aThe values presented are the number of patients with percentages in parentheses. All outcome values showing significant change (ie, $P < .05$) have been highlighted in bold.

follow-ups. Univariate analyses of the potential factors influencing the MCID in clinical outcomes are presented in Table 5, 6, and 7. Univariate analysis revealed that the ease of access to the disc space was significantly influencing the MCID in VAS, ODI, and MacNab scores at 1-year and 2-year follow-ups. VAS and MacNab scores were negatively influenced by high BMI and smoking status at 6 and 12 months postoperation.

Discussion

The management philosophy for pain relief in degenerative disc disease was described as a step ladder approach by us in the recent past.⁴ Step 3 involves percutaneous intradiscal disc preserving procedures using physical energies like heat, ozone, laser, or radiofrequency. Radiofrequency treatment modalities rely mainly on indirect decompression due to thermal effect on the disc resulting in shrinkage and reduction in intradiscal pressure. The Disc-FX system is a percutaneous minimally invasive procedure that uses higher radiofrequency of 1.7 MHz through the Elliquence Surgi-Max generator with 2 different modulations—Bipolar Turbo and Bipolar Hemo modes^{6,9,10}—resulting in nucleus ablation and annular modification, respectively. The use of radiofrequency offers the advantages of reduced heat and minimal tissue alteration.^{9,10} This

radiofrequency is applied using a steerable probe (Trigger-Flex, Elliquence), which permits posterolateral entry into the disc space targeting the posterior and posterolateral annulus fibrosus. The procedure decompresses the nerve through disc shrinkage and modulation of nucleus while annuloplasty denervates the nerve fibers of the annulus and favors healing of annular tear. In addition, the Disc-FX procedure also allows manual debulking of the disc.

Our previous evaluation of clinical outcomes after the Disc-FX procedure showed promising results at 6-month and 1-year follow-ups.⁶ The present study included a total of 54 patients of which 24 were the same patients whose 1-year outcomes were presented in a previous publication⁶; hence, there were 30 additional patients to the previous cohort. In line with the previous study, the present study showed that there were significant improvements in VAS, ODI, and MacNab outcomes immediately postoperation through to 2-year follow-ups, indicating durable benefits. Based on the MacNab scores, excellent or good outcomes were achieved in 78% of the patients. Low back pain secondary to degenerative disc disease is, in fact, a difficult clinical problem, especially when the patients have failed nonoperative management. Often, they are subjected to invasive and expensive intervention such as major fusion surgery. We believe that Disc-FX or any other radiofrequency

Table 7. Univariate Analysis for the Association Between Demographic, Clinical Parameters, and MacNab Outcomes^a.

| | Immediate Postoperative | P Value | 6 Months Postoperative | P Value | 1=Year Postoperative | P Value | 2 Years Postoperative | P Value |
|-----------------------|-------------------------|---------|------------------------|------------|----------------------|----------------|-----------------------|----------------|
| Gender | | | | | | | | |
| Male | 23 (61) | .92 | 23 (61) | .92 | 28 (74) | .71 | 31 (82) | .97 |
| Female | 8 (62) | | 8 (62) | | 11 (84) | | 11 (85) | |
| Age | | | | | | | | |
| <41 years | 12 (55) | .56 | 16 (73) | .15 | 17 (77) | .97 | 18 (82) | .98 |
| ≥41 years | 19 (66) | | 15 (52) | | 22 (76) | | 24 (83) | |
| Spinal level operated | | | | | | | | |
| L2-L3 | — | .18 | 1 (100) | .44 | 1 (100) | .54 | 1 (100) | .74 |
| L3-L4 | 7 (88) | | 6 (75) | | 7 (88) | | 7 (88) | |
| L4-L5 | 14 (52) | | 13 (48) | | 17 (63) | | 20 (74) | |
| L5-S1 | 17 (57) | | 18 (60) | | 23 (77) | | 25 (83) | |
| Pathology | | | | | | | | |
| PID | 5 (63) | .97 | 7 (88) | .12 | 8 (100) | .17 | 8 (100) | .32 |
| DDD | 26 (60) | | 24 (55) | | 31 (72) | | 34 (79) | |
| Approach | | | | | | | | |
| Easy | 27 (64) | .28 | 28 (66) | .12 | 36 (85) | <.01 | 39 (92) | <.01 |
| Difficult | 4 (44) | | 3 (33) | | 3 (33) | | 3 (33) | |
| BMI | | | | | | | | |
| 18-25 | 12 (55) | .45 | 11 (50) | .28 | 16 (73) | .63 | 18 (82) | .96 |
| 25.1-30 | 11 (58) | | 14 (74) | | 16 (84) | | 16 (84) | |
| >30 | 8 (80) | | 6 (60) | | 7 (70) | | 8 (80) | |
| Smoking | | | | | | | | |
| Yes | 24 (55) | .60 | 21 (47) | .03 | 30 (68) | .38 | 35 (80) | .92 |
| No | 14 (63) | | 17 (77) | | 18 (82) | | 18 (82) | |
| Discography | | | | | | | | |
| Positive | 28 (60) | .78 | 28 (60) | .78 | 34 (72) | .97 | 39 (83) | .49 |
| Negative | 10 (53) | | 10 (53) | | 14 (73) | | 14 (73) | |

Abbreviations: BMI, body mass index; PID, prolapsed intervertebral disc; DDD, degenerative disc disease.

^aThe values presented are the number of patients with percentages in parentheses. All outcome values showing significant change (ie, $P < .05$) have been highlighted in bold.

intervention provides us with a relatively low-cost and low-risk option for these patients. As such, a 78% good and excellent outcome, in our opinion, is acceptable. In addition, the majority of patients achieved MCID in each of the 3 clinical outcome indicators at each time point after the procedure and the results were sustained throughout the 2-year period. These patients with degenerative disc disease who were included in our study belonged to categories 3 and 4 of the lumbar disc herniation classification by Carragee et al.¹¹ These are the groups where poor outcomes were observed after discectomy. We, therefore, suggest that these patients should get a trial of radiofrequency treatment to alleviate the symptoms.

Our findings were in accordance with other similar studies evaluating the efficacy of Disc-FX in treatment of LBP due to lumbar degenerative disc disease. Recently, Park et al¹² studied 43 patients with lumbar disc herniation and reported that the percentage of patients who experienced pain relief was 55.8% at 1 month and 56.1% at 6 months postprocedure. There was significant improvement in pain regardless of the type of disc herniation or presence of an annular tear. The authors concluded that the Disc-FX procedure is a reasonable treatment option for carefully selected patients with lower back and radicular pain of discogenic origin.

Hellinger¹⁰ conducted a prospective study of 58 patients undergoing the Disc-FX procedure for lumbar pain syndromes secondary to contained disc extrusions and protrusions and reported that there was a significant improvement in back and leg pain, from preoperative mean VAS of 8.5 to 2 postoperatively, 3.5 at 6 weeks, and 3.3 at 6 months. Excellent/good MacNab scores were observed in 90% of the patients after the procedure, and the results were sustained at similar follow-ups. The same author has followed-up the similar cohort for a period of 4 years and reported the long-term outcomes.¹³ He showed that compared to pretreatment assessments, VAS for back pain improved from 8.6 to 2.3, and VAS for leg pain improved from 7.8 to 2.3 at 4-year follow-up. As per SF-12, at 4 years, the majority of patients (83%) reported “satisfied to very satisfied” with their quality of life. The author concluded that in carefully selected patients with sustained contained disc herniations who have failed conservative treatments, manual decompression combined with radiofrequency-assisted decompression and annulus modulation are very likely to have good outcomes up to 4 years posttreatment. Hellinger and colleagues⁹ from various parts of the world reviewed the preliminary results of various ongoing studies worldwide and reported that the Disc-FX system is a tool as valuable as other minimally invasive

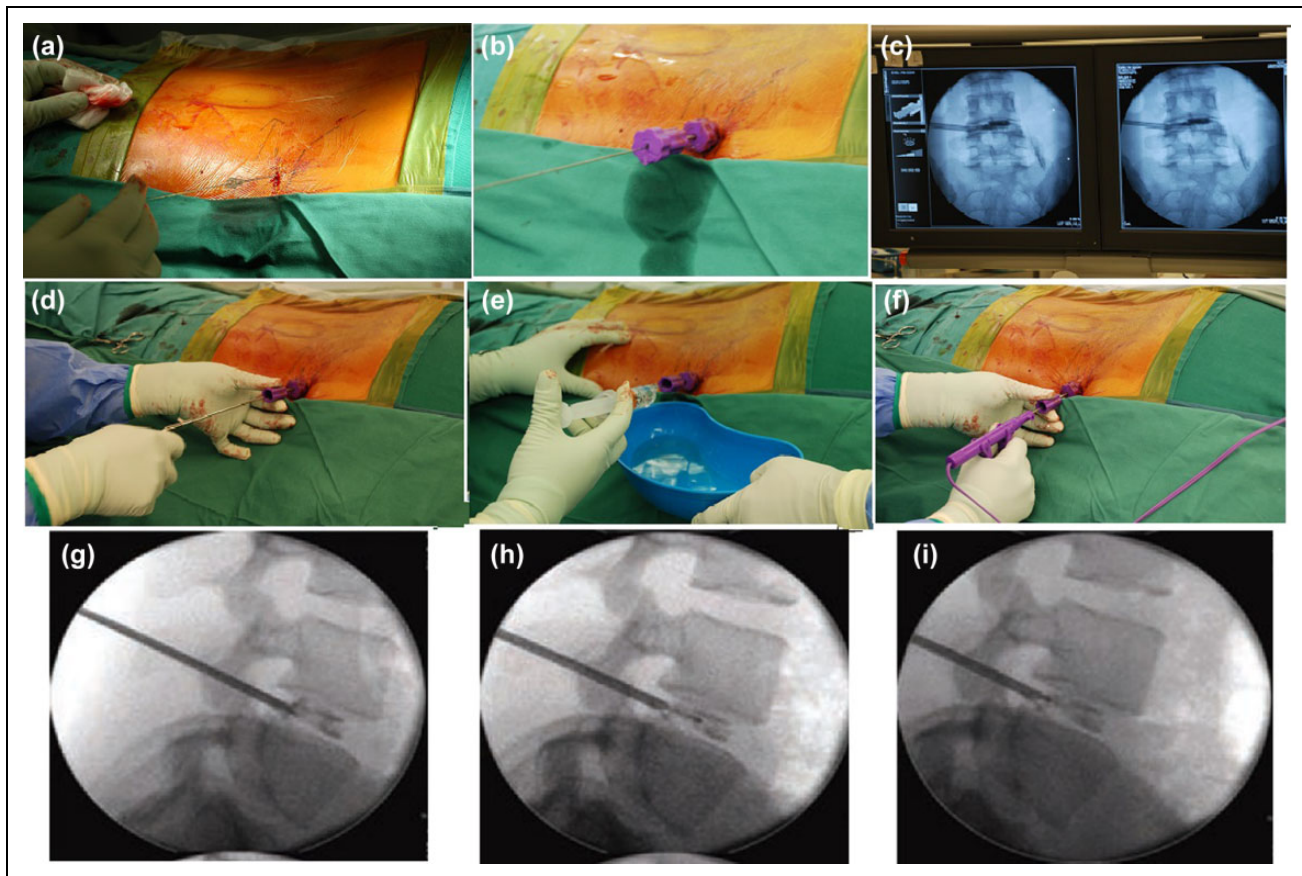


Figure 1. Procedural steps for Disc-FX: (a) Skin incision; (b) Cannula in place; (c) Image Intensifier appearance of cannula placement; (d) Manual discectomy through cannula; (e) Washout; (f) Radiofrequency probe insertion; (g, h, i) Image Intensifier lateral view showing probe in place (from left to right).

procedures in avoiding open surgery, allowing faster rehabilitation and return to work, thereby reducing the cost of treatment.

We found that our results were comparable to several recently published studies on nucleoplasty, which is a more established percutaneous radiofrequency modality in the treatment of degenerative disc disease.¹⁴⁻¹⁸ The most recent study on cone beam computed tomography and its associated image guidance technology for the treatment of lumbar disc herniation (LDH) in 25 patients was reported by Ierardi et al.¹⁵ They found that technical success was 100% with VAS pain score decreasing significantly from 7.6 to 3.9 at 1 week, 2.8 at 1 month, 2.1 at 3 months, and 1.6 at 6 months postoperatively.

Cincu et al recently evaluated a decade of follow-up of patients who underwent coblation nucleoplasty treatment for protruded lumbar intervertebral disc.¹⁶ They found that VAS was 4 and ODI was 7.2 at 24-month follow-up, and analgesic consumption was reduced or stopped in 90% of the cases after 1 year. Ten patients continued to be asymptomatic after 114 months postintervention. However, in another study,¹⁷ the authors found that there was a significant decline in patient satisfaction over time indicating that the effect of percutaneous nucleoplasty is not long-lasting. Significant differences in

preoperative VAS and ODI scores compared to 1 week and 3 years postoperative were observed, but not between the 3- and 5-year postoperative scores. The outcomes of nucleoplasty were also evaluated against open surgery in noninferiority randomized clinical trial of 200 patients with single LDH.¹⁸ The authors stated that while nucleoplasty is as effective as open discectomy in the treatment of LDH, it is also less invasive with higher patient compliance. The Disc-FX procedure is yet to be evaluated through a randomized trial.

In our study, we also studied some salient factors and their influence on the clinical outcomes. We found that patients with CLDH had slightly better improvement in clinical outcomes as compared to DD; however, this correlation was not significant. This may be due to nuclear modulation, disc shrinkage, and reduction in intradiscal pressure contributing to the pain-relieving mechanisms in the contained disc. This finding was also established in a study¹⁹ where the patients with concurrent disc herniation who underwent percutaneous endoscopic lumbar discectomy and thermal annuloplasty showed a better outcome than those with only disc degeneration. The concurrent disc herniation in their study is analogous to CLDH in our study. They concluded that CLDH, which has central disc bulge, was the most significant predictor influencing the outcome.

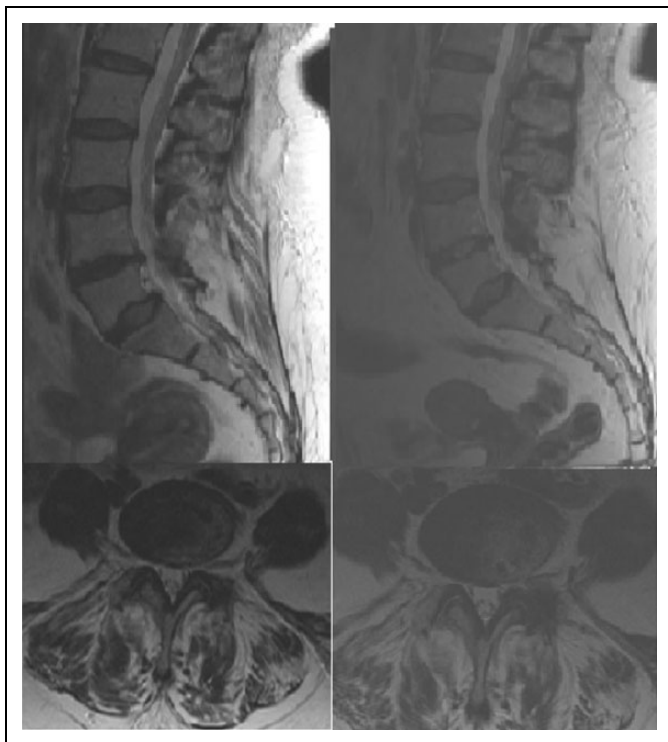


Figure 2. Sagittal T2 MRIs showing improved hydration of L4-L5 disc between preoperative and 2 years post-Disc-Fx procedure (top); Axial T2 MRIs showing improved hydration of L4-L5 disc between corresponding time points (bottom).

Ease of access to the disc space had significant influence on VAS, ODI, and MacNab scores at 1-year and 2-year follow-ups. Difficulty in accessing the disc at both L4-5 and L5-S1 predicts poorer outcomes for Disc-FX in treating symptoms from degenerative disc diseases. Difficult access may result in multiple attempts to insert the probe, resulting in increased damage to the annulus. Difficult access will also make it difficult for steerable probe to reach the posterior surface of annulus. Both these factors may contribute to significantly poorer outcomes. Concordant pain on discography is known to correlate with good outcome after surgical intervention.²⁰ There was a trend toward correlation between improvement in ODI and concordant pain on discography; however, significant correlation was only found in 6-month follow-up. Discography as an outcome predictor for nucleoplasty has been recently reported,¹ where discography results improved the success rate of nucleoplasty for the treatment of degenerative LBP primarily because it would indicate the probable pain source to be addressed.

We found that BMI had significant influence on pain improvement; patients with BMI < 30 had significantly better improvement in VAS at 6 months and 1 year. We conjecture that obese patients can make patient positioning difficult, with difficult approach for probe placement, causing increased episodes of annular injury leading to worse outcomes. In addition, obese patients also have challenge for adequate visualization using intraoperative fluoroscopy. These patients may have a sedentary lifestyle with poor paraspinal muscle strength

leading to early progressive degeneration even after successful annulo-nucleoplasty. Contradictory finding was shown in another study,¹⁹ where they observed that BMI was not associated with the outcomes.

Regarding smoking status, nonsmokers tended to have better improvement in all outcomes than smokers though significant correlation was only found in MacNab scores at 6-month follow-up. In cigarette smokers, degenerate disc neovascularization increases proteolytic enzymes causing rapid disc degeneration and weakening of supporting ligaments, leading to instability.²¹ Disc-FX leads to reduction in neovascularization due to nuclear modulation but cannot address the pain caused by microinstability. Anecdotally, we have observed that in one of the symptomatic cases of degenerate disc at L4-L5 level treated using Disc-FX, showed improvement in disc hydration, as a result, the Pfirrmann's 3 degenerate disc converted to Pfirrmann's 2 at 2-years follow-up (Figure 2).

In our study, no adverse events were recorded during the intraoperative period. However, we observed that one third of the patients had slight increase in leg pain at immediate postoperative period, which responded well to anti-inflammatory treatment. The majority of these patients had improvement in pain within 48 hours. Back pain, however, improved in all patients, which was documented as VAS improvement at the immediate postoperative period. In another study on Disc-FX, the authors reported that 3 respondents (6.4%) had recurrence at 4 years; however, no complications were noted.¹³ As against the radiofrequency procedure, other procedures like CO₂ laser has a higher complication rate of 8%,²² while laser discectomy has an overall complication rate of 2.6%.²³

Limitations

Ours is an analysis of prospectively collected data; however, a randomized study would be desirable for comparing the outcomes with other gold standard interventions, that is, structured physiotherapy rehabilitation program or microdiscectomy or even placebo.²⁴

Conclusions

Our study shows that the improvements in pain and functional outcomes demonstrated at 1 year were still maintained at 2 years with a low rate of reoperation. If these midterm results are sustained on a further follow-up, this procedure may serve to further delay surgical fusion as a treatment option for this group of patients. Our data suggests that this technique may be helpful in successfully treating selected patients with degenerative disc disease but prospective data with a randomized design would be desirable.

Acknowledgment

The authors thank Dr Ravish Shammi Patel for helping with figures and illustrations.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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