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ORIGINAL ARTICLE

Retrospective evaluation of patients treated with intradiscal discectomy + RFTC using the Disc-Fx method in lumbar discopathy

Lomber diskopatide Disc-Fx yöntemiyle intradiskal diskektomi + RFTC uygulanan hastaların retrospektif olarak değerlendirilmesi

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Summary

Objectives: Low back pain is an important public health problem that impairs quality of life and causes limitations in both social and working life. It is attempted to be treated with conservative or surgical procedures. However, how wise is it to plan surgery with a high complication rate when conservative treatment fails to respond?

Methods: In this study, it was planned to investigate the effectiveness of the Disc-Fx procedure, which is one of the minimally invasive techniques for low back pain. Patients who underwent the Disc-Fx procedure were included. After consent was obtained, questions were asked before and after the procedure. The data of the patients were obtained by telephone and hospital database. Data of 40 patients older than 18 years of age were collected and analyzed retrospectively according to the established protocol. Then, the data were subjected to statistical calculation and the results were obtained.

Results: Similar to the literature, there was a significant difference between preoperative and postoperative 1st, 6th, and 12th months of VAS, ODI, and MacNab values. In fact, a significant difference was found between the VAS, ODI, and MacNab values in each postoperative period compared to the preoperative period. In addition, factors that may be important in the etiology of low back pain were also evaluated.

Conclusion: The Disc-Fx procedure is thought to be a promising procedure for carefully selected patients due to its low complication rates. It has been concluded that more precise results can be obtained as a result of randomized controlled studies with a larger number of patients and longer follow-up of patients.

Keywords: Disc-Fx procedure; low back pain; MacNab; ODI; radiculopathy; VAS.

Özet

Amaç: Alt bel ağrısı, hayat kalitesini bozan, hem sosyal hem de çalışma hayatında kısıtlılığa neden olan önemli bir halk sağlığı sorunudur. Özellikle gelişmiş ve gelişmekte olan toplumlarda sıklığı giderek artmaktadır ve konservatif ya da cerrahi prosedürlerle tedavi edilmeye çalışılır. Fakat konservatif tedaviye yanıt alınamadığında, yüksek komplikasyon oranlı cerrahi planlamak ne kadar akıllıcadır? Günümüzde, cerrahi kadar etkin ve daha az komplikasyonlu minimal invazif prosedürler bu nedenle yaygınlaşmaktadır.

Gereç ve Yöntem: Bu çalışmada, alt bel ağrısı nedenli minimal invazif tekniklerden biri olan Disc-Fx prosedürünün etkinliğinin araştırılması planlandı. Bu nedenle, çalışmamıza Disc-Fx prosedürü uygulanan hastalar dâhil edildi. Bu prosedür uygulanan hasta ve hasta yakınları telefonla arandı. Hasta ve hasta yakınlarına bilgi verildi ve onam alındıktan sonra işlem öncesi ve işlem sonrasına yönelik sorular soruldu. Hastaların verileri telefonla ve hastane veritabanından elde edildi. 18 yaşından büyük 40 hastanın bilgileri toplanıp, oluşturulan protokole göre retrospektif olarak incelendi. Daha sonra veriler istatistiksel hesaplamaya tabi tutularak sonuçlar elde edildi.

Bulgular: Elde ettiğimiz veriler ışığında; literatüre benzer şekilde, preoperatif VAS, ODI ve MacNab skorlarının postoperatif 1., 6. ve 12. ayların sonundaki değerleri arasında anlamlı fark tespit edildi. Hatta preoperatif döneme göre postoperatif her bir dönemdeki VAS, ODI ve MacNab değerleri arasında anlamlı fark tespit edildi. Ayrıca çalışmamızda alt bel ağrısı etiyolojisinde önemli olabilecek faktörler de değerlendirildi.

Sonuç: Sonuç olarak, Disc-Fx prosedürünün düşük komplikasyon oranları, hasta sonuçları ve analjezik ihtiyacında azalma oluşturması sebebiyle özenle seçilen hastalar için umut vaat eden bir prosedür olduğu düşünülmektedir. Daha fazla hasta sayısı ile daha uzun süre hasta takibi yapılan randomize kontrollü çalışmaların yapılması sonucu daha net sonuçlar elde edilebileceği kanısına varılmıştır.

Anahtar sözcükler: Alt bel ağrısı; Disc-Fx prosedürü; MacNab; ODI; radikülopati; VAS.

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Introduction

Low back pain associated with degenerative disc disease is a global public health problem that is estimated to account for 28–40% of all low back pain types.[1,2] It can cause significant disability and place limitations on working life and daily activities.[3]

The associated pain can range from that which can be resolved with mild and conservative treatment to severe and limiting pain. Two common subtypes of degenerative disc disease are degenerated disc (DD) and lumbar disc herniation (LDH).[4]

While patients with DD have more low back pain without leg pain, the symptoms are predominantly low back pain and moderate leg pain in patients with LDH. Lumbar radicular low back pain can usually be attributed to lumbar disc herniation, spinal stenosis, and degenerative spondylolisthesis. When a lumbar disc herniation occurs, lumbar radicular pain presents as pain radiating from the back to the leg, usually in a dermatomal pattern corresponding to a compressed nerve root. Patients may experience a strong inflammatory reaction to herniated nucleus pulposus and may feel pain from the pinched nerve root due to compression, making epidural corticosteroid injection a reasonable treatment option.[5,6] Studies have reported that 55–84% of patients experience short-to-moderate pain relief with epidural injection.[7,8] The management approaches to degenerative disc disease range from physical therapy, simple analgesia, and lifestyle modifications to more complex treatments such as surgery. When pain does not respond to less invasive simple treatment options such as epidural steroid injections, other treatment modalities may be considered.[9]

To bridge the broad gap between minimally invasive methods such as injections and more extensive procedures such as spinal fusion surgeries, new approaches are being developed day by day.[4] Minimally invasive disc decompression procedures have been developed for the treatment of the radicular pain caused by lumbar disc herniation.[10,11] The main advantages of minimally invasive techniques for the treatment of degenerative pathologies are better preservation of the spine structure, less tissue destruction, and lower risk.[9] One such technique is anulonucleoplasty using the Disc-FX system (Elliquence, LLC, Baldwin, NY), which, similar to nucleoplasty, makes use of radiofrequency. Although previous studies have provided important information about nucleoplasty for the treatment of low back pain and/or leg pain caused by disc pathology,[12,13] studies of anulonucleoplasty procedures using the Disc-FX method are limited.[4] In previous studies, good short-term results have been reported using the Disc-FX procedure in patients with low back pain due to DD or LDH who did not respond to conservative treatment.[14] Short-term results of the Disc-FX procedure have been reported in several studies, while data on the long-term clinical outcomes are lacking.

In the present study, the postoperative 1-year clinical results of patients who underwent intradiscal discectomy+RFTC (radiofrequency thermocoagulation) using the Disc-FX method for the treatment of low back pain due to DD or LDH between 01.01.2015 and 01.01.2020 were evaluated retrospectively. The study also made a retrospective investigation of the effect on patient outcomes and complications through an evaluation of a number of remarkable factors that could potentially lead to an improvement in clinical outcomes.

Material and Methods

Our study complies with the Declaration of Helsinki, which is in the ethics committee regulation. With the approval of Ankara University Human Research Ethics Committee dated 27.01.2021, patients who underwent intradiscal discectomy+RFTC (radiofrequency thermocoagulation) with the Disc-FX method for the treatment of low back pain due to DD or LDH between 01.01.2015 and 01.01.2020 were evaluated for their 1-year clinical results postoperatively and retrospectively.

In our study protocol, patients were repeatedly asked about their VAS, ODI, and MacNab values at each time period. VAS is a Visual Analogue Scale that measures pain intensity, and the VAS value consists of a 10 cm line with two endpoints representing 0 (no pain) and 10 (pain as bad as possible). The ODI is the Oswestry Disability Index, a patient-completed questionnaire that provides a subjective percentage score regarding the level of function (disability) in activities of daily living for people rehabilitated for low back pain. The MacNab value is a scale used as an indicator of success in pain relief after the procedure.

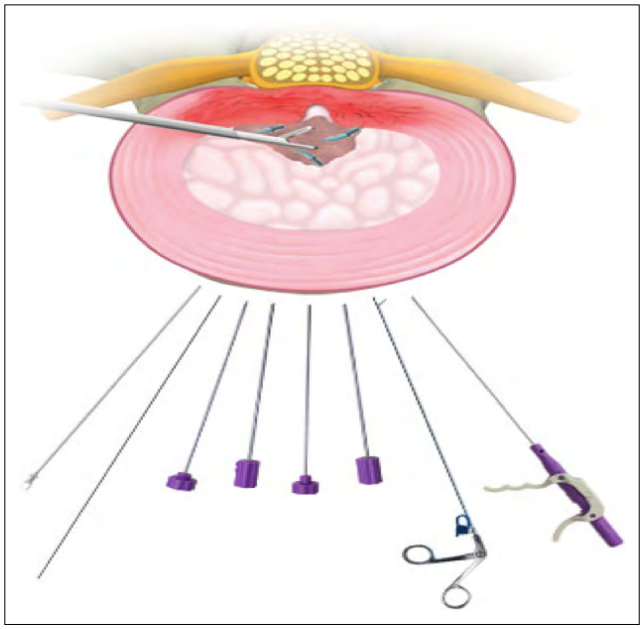

Figure 1. Disc-Fx system.[15]

In addition, age, gender, comorbidities, procedure level, whether or not they would recommend the procedure to anyone else, and smoking and analgesic use history were evaluated.

Disc-FX Procedure and Technique

The Elliquence Disc-FX system allows safe, fast, and efficient discectomy and is considered a safe, simple, and minimally invasive approach for patients with lumbar disc herniation. It is less invasive than traditional discectomy procedures, and since only minimal anulotomy is performed, the risk of re-hernia is reduced. Multifunctional therapeutic options are available, including debulking (volume reduction process), ablation, and modulation. The procedure permits the manual excision of the herniated nucleus through a 3.0 mm portal, and ablation and denervation through the use of Trigger-Flex®.[15]

The Disc-FX system procedure is not difficult to implement but requires experience, knowledge of neuroanatomy, and training in its use. The procedure is performed under mild sedoanalgesia and local anesthesia. Unless there are complications, patients are discharged on the same day. The Disc-FX system is shown in Figure 1.

Complications

Many complications can be seen, from inadequate analgesia, infection, and nerve damage to paralysis. The most common complication in studies is radicular pain, which may be due to the direct effect of radiofrequency on the nerve root, although this mostly improves with drug treatment.[4] The complication rate is much lower than with open surgeries,[14] although the lack of studies and the number of samples prevent an accurate assessment.

Patient Characteristics

Patients who underwent a Disc-Fx procedure between January 2015 and June 2019 were included in the study. The patients who underwent the procedure and their families were called by phone and informed about the study, and after consent was obtained, they were asked questions before and after the procedure. The study made use of the data obtained by telephone and garnered from the hospital database. The patients and their relatives were asked about the changes in their disease status at the beginning of the operation (before the application of sedoanalgesia) and in the postoperative periods at the 1st, 6th, and 12th months, according to the questions in the protocol.

For the Disc-Fx procedure to be considered suitable for the patient, they must meet certain criteria, including: disease suitable for treatment, failed conservative treatment, and absence of any psychological disorders.[16] In addition, important parameters were that the patient had not previously undergone any open surgery in the area where the procedure would be performed and that the VAS value before the procedure was ≥5.[17] The table that meets the inclusion and exclusion criteria is listed below as Table 1.

Statistical Analysis

SPSS (Version 11.5, Chicago, SPSS Inc.) was used for the statistical analysis of the data. Mean±standard deviation and median (minimum–maximum) were used as descriptors for quantitative variables, and the number of patients (percentage) for qualitative variables. A Mann-Whitney U test was used to determine any difference between the categories of the qualitative variable and two categories in terms of quantitative variables, since the assumptions of normal distribution were not met. McNemar's test was used to examine the relationship between two qualitative dependent variables. The presence of a statistically significant difference between quantitative repeated measurements was checked with

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Patients with a VAS ≥5 at admission, 2. Over 18 years of age 3. Not history of back surgery, 4. Having low back and/or radicular pain for at least 6 months prior to admission or having temporarily benefited from previous medical treatments. 5. Intradiscal Discectomy +RFTC procedure with Disc-Fx Method has been applied in our pain clinic 6. Patients with lower back pain with radicular symptom of lumbar degenerative disc disease or lumbar disc herniation 7. Patients without more than one level of disc pathology in magnetic resonance imaging(patients with monodiscopathy) 8. Pfirrmann grade 2–4 of the disc to be intervened	1. Patients who decline treatment 2. Patients with a VAS value below 5 3. Presence of coagulation disorders 4. Presence of infection at the procedure site 5. Patients with lumbosacral tension or facet joint arthritis 6. Patients with acute disc prolapse or sequestration identified by MRI or clinical evaluation 7. Those who have undergone lumbar surgery 8. Paraplegic patients 9. Pregnant 10. Patients with severe spinal stenosis (spinal diameter <7 mm) at the lumbosacral level to be treated 11. Patients under 18 years of age 12. Those with spinal malignancies 13. Those with cauda equina syndrome 14. Those with spondylolisthesis

VAS: Visual Analog Scale; RFTC: Radiofrequency thermocoagulation; MRI: Magnetic resonance imaging.

an ANOVA test in Repeated Measurements. A Friedman test was used to determine whether there was a statistically significant difference between ordinal repeated measurements. The statistical significance level was set at $p<0.05$.

Results

There were 47 patients on the list of patients considered appropriate for the study. Of these, the final sample included 40 patients after one declined to take part in the study and six were unreachable by phone, so 40 patients were included in our study. The mean age of the 40 patients included in our study was 42.93±13.12, the mean BMI (Body Mass Index) was 29.34±5.98, and 37.5% were female and 62.5% were male. Comorbidities included diabetes in 11 (27.5%), hypertension in eight (20.0%), obesity in seven (17.5%), rheumatic disease in two (5.0%), and other diseases in 10 (25.0%) patients. In addition, 52.5% of the participants had never smoked, 20.0% had quit, and 17.5% were active smokers. The number of patients using nonsteroidal anti-inflammatory drugs in the preoperative period was 35 (87.5%), and the number of people using gabapentin-pregabalin was five (12.5%). The number of people using nonsteroidal anti-inflammatory drugs and gabapentin-pregabalin in the postoperative period was 25 (62.5%) and eight (20.0%), respectively (Table 2).

Only two (5.0%) patients underwent Disc-FX again in the postoperative 1-year period, while five (12.5%) patients underwent open spine surgery in the same region and in the same period. The process level of 2.5% of the patients was L1–L2; L2–L3 in 12.5%; L3–L4 in 22.5%; L4–L5 in 35.0%; and L5–S1 in 27.5%. Based on their experience, 60.0% of the patients reported that they would recommend the procedure, while 40.0% said they would not (Table 2).

Table 3 presents the findings of an analysis of any differences in nonsteroidal anti-inflammatory drug use in the preoperative and postoperative periods, revealing a significant difference ($p=0.002$). 28.6% of those who used nonsteroidal anti-inflammatory drugs in the preoperative period stopped using the drug in the postoperative period.

Table 4 presents an analysis of the difference in gabapentin use in the preoperative and postoperative periods, revealing no significant difference ($p=0.375$). While 20.0% of those who used gabapentin in the preoperative period stopped using the drug in the postoperative period, 11.4% of those who did not use the drug in the preoperative period started using it.

Table 5 presents the analysis of the difference between the baseline, 1st month, 6th month, and 12th

Table 2. Identifiers

Variables	
Age	
Mean±standard deviation	42.93±13.12
Median (min–max)	40.50 (26.00–74.00)
BMI	
Mean±standard deviation	29.34±5.98
Median (min–max)	28.50 (19.00–45.70)
Gender, n (%)	
Female	15 (37.5)
Male	25 (62.5)
Diabetes, n (%)	
No	29 (72.5)
Yes	11 (27.5)
Hypertension, n (%)	
No	32 (80.0)
Yes	8 (20.0)
Obesity, n (%)	
No	33 (82.5)
Yes	7 (17.5)
Rheumatic disease, n (%)	
No	38 (95.0)
Yes	2 (5.0)
Other diseases, n (%)	
No	30 (75.0)
Yes	10 (25.0)
Smoking, n (%)	
Never	21 (52.5)
Quit	8 (20.0)
Active smoker	11 (27.5)
Preoperative NSAID use, n (%)	
No	5 (12.5)
Yes	35 (87.5)
Preoperative gabapentin-pregabalin use, n (%)	
No	35 (87.5)
Yes	5 (12.5)
Postoperative NSAID use, n (%)	
No	15 (37.5)
Yes	25 (62.5)
Postoperative gabapentin-pregabalin use, n (%)	
No	32 (80.0)
Yes	8 (20.0)
Undergoing disc-fx procedure again in the postoperative 1 year period, n (%)	
No	38 (95.0)
Yes	2 (5.0)
Undergoing open surgery in the postoperative 1-year period, n (%)	
No	35 (87.5)
Yes	5 (12.5)
Treated spine level, n (%)	
L1-L2	1 (2.5)
L2-L3	5 (12.5)
L3-L4	9 (22.5)
L4-L5	14 (35.0)
L5-S1	11 (27.5)
Recommendation, n (%)	
Would not recommend	16 (40.0)
Would recommend	24 (60.0)

Min: Minimum; Max: Maximum; BMI: Body mass index; NSAID: Nonsteroidal anti-inflammatory drug.

Table 3. Results of baseline-postoperative changes for nonsteroidal anti-inflammatory drug (NSAID) use

	Preoperative NSAID use				p
	No		Yes		
	n	%	n	%	
Postoperative NSAID use					0.002[a]
No	5	100.0	10	28.6	
Yes	0	0.0	25	71.4	

NSAID: Nonsteroidal anti-inflammatory drug; a: Mc-Nemar's Test.

Table 4. Results of baseline-postoperative changes for gabapentin use

	Preoperative gabapentin use				p
	No		Yes		
	n	%	n	%	
Postoperative gabapentin use					0.375[a]
No	31	88.6	1	20.0	
Yes	4	11.4	4	80.0	

a: Mc-Nemar's Test.

Table 5. Results of changes over time for VAS

VAS	Mean±SD	Med. (Min–Max)	p
Beginning	8.13±1.24	8.00 (6.00–10.00)	<0.001[a]
1st month	5.18±2.17	5.50 (1.00–9.00)	
6th month	4.80±2.27	5.00 (1.00–9.00)	
12th month	4.70±2.24	4.00 (1.00–9.00)	

VAS: Visual Analog Scale; SD: Standard deviation; Med: Median; Min: Minimum; Max: Maximum; a: Analysis of Variance Test in repeated measurements (repeated measures ANOVA).

Table 6. Results of changes over time for ODI

ODI	Mean±SD	Med. (Min–Max)	p
Beginning	81.83±9.48	85.00 (60.00–95.00)	<0.001[a]
1st month	52.65±20.19	55.00 (10.00–90.00)	
6th month	47.23±21.68	45.00 (10.00–90.00)	
12th month	45.90±21.77	42.50 (10.00–90.00)	

ODI: Oswestry disability index; SD: Standard deviation; Med: Median; Min: Minimum; Max: Maximum; a: Analysis of variance test in repeated measurements (repeated measures ANOVA).

month VAS measurements, revealing a statistically significant difference between the four VAS measurements (p<0.001). In an analysis of the binary times to identify the sources of meaning, in the baseline-1st month; baseline-6th month; baseline-12th month; 1st month-6th month; and 1st month-12th month periods, the differences were found to be statistically significant (p<0.001, p<0.001, p<0.001, p=0.027, and p=0.007, respectively). The time-dependent changes in VAS are presented in Figure 2.

Table 6 presents the results of an analysis of the difference between the ODI measurements at baseline and at the 1st, 6th, and 12th months. A statistically significant difference was found between the four ODI measurements (p<0.001). An analysis of the binary times that create the meaning in the baseline-1st month, baseline-6th month, baseline-12th month, 1st month-6th month, 1st month-12th month, and 6th month-12th month periods, the differences were statistically significant (p<0.001, p<0.001, p<0.001, p<0.001, p<0.001, and p=0.040, respectively). The time-dependent changes for ODI are presented in Figure 3.

Table 7 presents the results of an analysis of any difference between the measurements of MacNab at baseline, 1st month, 6th month, and 12th months. A statistically significant difference was found between the four MacNab measurements (p<0.001). When we look at the binary times that create the

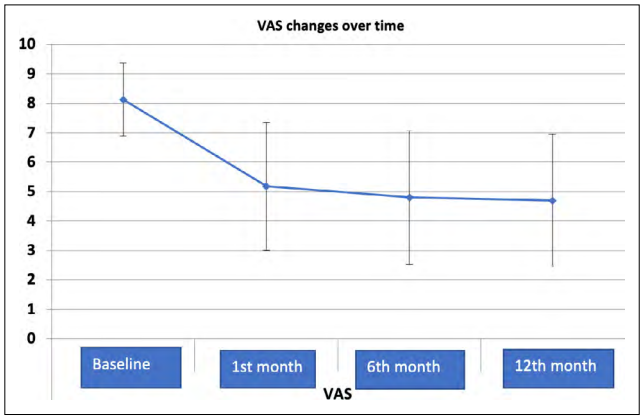

Figure 2. Time-dependent changes for VAS.

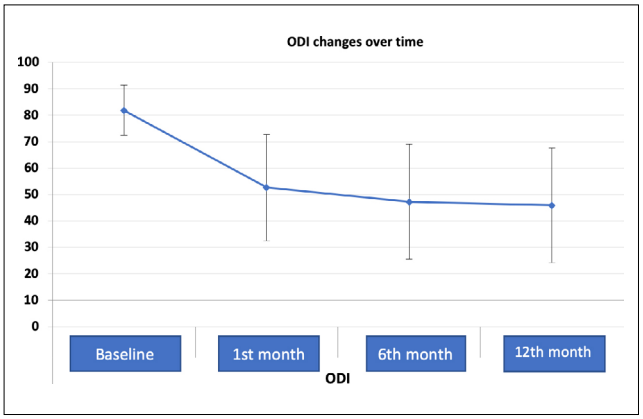

Figure 3. Time dependent changes for ODI.

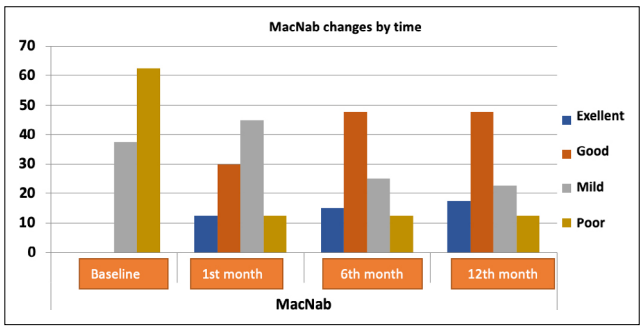

Figure 4. The time-dependent changes for MacNab.

meaning, in the baseline-1st month, baseline-6th month, and baseline-12th month periods, the differences were found to be statistically significant. The time-dependent changes for MacNab are presented in Figure 4.

There were no significant differences between the patients with and without diabetes in terms of changes in the VAS and ODI pain scores (p=0.939 and p=0.915, respectively) (Table 8).

No significant difference in changes in VAS and ODI pain scores was noted between patients with BMI <30 and ≥30 (p=0.413 and p=0.654, respectively) (Table 9).

Table 7. Results of changes over time for MacNab

MacNab	n	%	p
Outset			
Fair	15	37.5	
Poor	25	62.5	
1st month			
Excellent	5	12.5	
Good	12	30.0	
Fair	18	45.0	
Poor	5	12.5	
6th month			<0.001[a]
Excellent	6	15.0	
Good	19	47.5	
Fair	10	25.0	
Poor	5	12.5	
12th month			
Excellent	7	17.5	
Good	19	47.5	
Fair	9	22.5	
Poor	5	12.5	

a: Friedman Test.

Discussion

Lumbar disc disease, as one of the leading causes of low back pain, is a difficult clinical problem to cope with, especially when the patient fails to respond to conservative treatment. Generally, patients must undergo such invasive and expensive treatments as major fusion surgery.[4] Peul et al.[17] evaluated the cost-effectiveness of early surgery as an extremely expensive method from the economic perspective of healthcare services. The high rate of complications (8%) and the pathophysiological changes that occur as a result of trauma caused by surgery are important factors when evaluating the effectiveness of surgical treatment.[18] European guidelines do not recommend fusion surgery unless 2 years of conservative treatment and minimally invasive procedures have failed.[19] Today, interest in minimally invasive procedures is increasing due to the short-term indication of drugs, as well as the increasing complication and variable success rates of surgery.[19] New pain treatments and methods are being researched to fill the gap between surgical procedures and conservative treatment options for the treatment of chronic low back pain.

Table 8. Differences in VAS and ODI scores in diabetes patients between baseline and 12th month

Variables	Diabetes				
	No		Yes		
	Mean±SD	Med. (Min–Max)	Mean±SD	Med. (Min–Max)	p
VAS between baseline and 12th month	3.45±2.32	4.00 (-1.00–8.00)	3.36±3.01	3.00 (-3.00–8.00)	0.939[a]
ODI between baseline and 12th month	36.62±21.24	45.00 (-10.00–75.00)	34.09±29.22	40.00 (-25.00–75.00)	0.915[a]

VAS: Visual Analog Scale; ODI: Oswestry Disability Index; SD: Standard deviation; Med: Median; Min: Minimum; Max: Maximum; a: Mann-Whitney U Test.

Table 9. Differences in VAS and ODI scores in patients between baseline and 12th month for BMI

Variables	BMI				
	<30		≥30		
	Mean±SD	Med. (Min–Max)	Mean±SD	Med. (Min–Max)	p
VAS between baseline and 12th month	3.16±2.27	4.00 (-1.00–6.00)	3.87±2.85	4.00 (-3.00–8.00)	0.413[a]
ODI between baseline and 12th month	34.08±22.11	45.00 (-10.00–65.00)	39.00±25.72	40.00 (-25.00–75.00)	0.654[a]

BMI: Body Mass Index; VAS: Visual Analog Scale; ODI: Oswestry Disability Index; SD: Standard deviation; Med: Median; Min: Minimum; Max: Maximum; a: Mann-Whitney U Test.

The answer to the question of whether other treatment options exist that can be offered to patients before considering surgical options such as discectomy, disc arthroplasty, or spinal fusion remains unclear in cases of chronic low back pain that have failed to respond to treatment with both conservative methods and interventional pain procedures.[20] There is general consensus, however, that minimally invasive interventional procedures such as radiofrequency denervation are effective in patients with mechanical low back pain.[21] An analysis of systematic reviews and clinical guidelines prepared with a multidisciplinary approach for the treatment of patients with chronic low back pain reveals a wealth of poor or moderate quality evidence supporting the efficacy of radiofrequency denervation in clinical practice.[21] Kumar et al.[4] state that Disc-FX or any radiofrequency therapy may be considered as a relatively low-cost and lower-risk option for such patients.

Damaged posterior annulus fibrosus and free nerve endings in the annulus are the focus of discogenic pain.[22] In nucleo-annuloplasty procedures using the Disc-FX® system, granulation tissue is removed with forceps, and annular tears are ablated or cauterized with the steerable Trigger-Flex® probe.[22] The current theories related to discogenic low back pain suggest that neurogenesis at the posterior aspect of the intervertebral disc may be the cause of the pain, with a potential pressure effect on the nerve roots.[23] Based on this theory, thermal or radiofrequency ablation procedures targeting nerve fibers have been suggested as a pain reduction approach.[23] Under radiofrequency waves and thermal energy, intra-disc collagen fibers are reduced and intra-disc pressure decreases,[4,23] thus reducing pain and symptoms triggered by nerve pressure at the posterior edge of the disc.[23] Saal et al.[6] in 1999 adopted an intradiscal electrothermal therapy approach in which a heating coil was applied to the annular region aimed at the thermocoagulation of the pain nociceptors and fibers. One advantage of the Disc-FX procedure is that the orientation of the heating probe is bipolar,[23] which allows thermal energy to be focused on the target area.[23] This mechanism is especially important considering the proximity of the disc to the nerves, and thanks to its flexible tip, the surgeon can work in a wider area while accessing the posterior annulus.[23]

Literature contains a number of studies investigating the clinical effectiveness of the Disc-Fx

procedure as a new treatment option that allows manual discectomy and nuclear ablation in addition to radiofrequency treatment. Park et al.[9] examined 43 patients with lumbar disc herniation and reported that 55.8% of the patients experienced pain reduction in the 1st month and 56.1% in the 6th month following the procedure. In the study by Hellinger et al.,[24] the Disc-Fx procedure was applied to 58 patients with radiculopathy due to LDH, who were followed up prospectively for 4 years. In the patients whose mean VAS score was 8.4 prior to the treatment, the mean VAS value had decreased to 2.3 at the end of 4 years. Similarly, while the mean VAS value for leg pain was 7.8 at baseline, the mean VAS value had decreased to 2.3 4 years later. Furthermore, 83% of the respondents reported being "satisfied" or "very satisfied" with their quality of life.[24] In a retrospective study by Cincu et al.[25] including 10-year follow-up of patients, 50 patients who underwent coblation nucleoplasty for LDH were followed up, and at the end of the 24th month, the mean VAS value was 4 and the ODI was 7.2. The study also determined that the need for analgesics had decreased by 90% at the end of 1 year in the sample.[25] In an evaluation of the results from long-term follow-up, the authors stated that percutaneous nucleoplasty could be considered an effective and safe treatment option.[25] In the present study, the number of patients who stated that their functional capacity was excellent or good according to the MacNab scores before the procedure was zero (0%), while this number increased to 26 (65%) at the end of the 12th month. When the VAS, ODI, and MacNab scores of the patients in the preoperative period were compared with those at the 1st, 6th, and 12th postoperative months, the Disc-Fx procedure was found to be an effective option in pain management. In carefully selected patients with LDH who have failed conservative treatments, manual decompression with radiofrequency-assisted decompression and annulus modulation is likely to have good results up to 4 years after the treatment.[24] It should be noted, however, that since the follow-up period in our study was only one year, we can only comment on the short- and medium-term results. For longer-term results, studies involving larger numbers of patients and longer follow-up periods are needed.

Kim et al.,[26] in a meta-analysis, compared patients who underwent open microdiscectomy for LDH with those who underwent percutaneous endoscopic discectomy, and found that the patient population who underwent percutaneous endoscopic discectomy achieved better VAS and ODI scores, and shorter hospital stays, while no significant difference was noted in the MacNab score, recurrence rate, or reoperation or complication rates.[26] The authors stated that as it was not a randomized controlled trial, no checks were made of whether the patients had undergone previous surgeries or other minimally invasive procedures.[26] They concluded that although percutaneous endoscopic lumbar discectomy produced better results than open lumbar microdiscectomy in some patient groups, open lumbar microdiscectomy still provided good clinical results, and stated, therefore, that a randomized controlled study with a large sample size would be required to compare the two in the future.[26] In a meta-analysis conducted by Ruan et al.,[27] it was observed that patients in the percutaneous lumbar endoscopic discectomy group had shorter operation times and hospital stays than those in the open lumbar microdiscectomy group, although it has been reported that neither surgical approach for the treatment of LDH is superior in terms of functional outcome, complication, and reoperation rates.[27] Hellinger et al.[28] made an evaluation of the preliminary results of ongoing studies and reported the Disc-Fx system to be as valuable as other minimally invasive procedures in the avoidance of open surgery, allowing faster rehabilitation and return to work, thus reducing the cost of treatment. In the study by Abrishamkar et al.[29] comparing the results of nucleoplasty and open surgery, the authors reported nucleoplasty to be as effective as open discectomy for the treatment of LDH, but as a less invasive method with greater patient compliance. In our study, only two patients (5.0%) underwent Disc-Fx again in the postoperative 1-year period, while the number of patients who underwent open spine surgery from the same region was 5 (12.5%). The patients required repeat Disc-Fx procedures or surgery due to the development of postoperative dysesthesia, inability to remove part of the pathological disc, LDH recurrence, or, more rarely, dural rupture.

Obesity and overweight are risk factors in the etiology of low back pain. In a meta-analysis by Shiri et al.,[30] overweight and obesity were found to increase the risk of low back pain. The authors also found that overweight and obesity increased the need for care for low back pain and chronic low back pain. In their study, Kumar et al.[4] reported significantly greater improvement in VAS at 6 months and 1 year in patients with BMI<30, while a high BMI had a negative effect on the pain scores. In a study by Ahn et al.,[31] no significant effect of BMI on discogenic low back pain was reported. In the present study, no significant difference was found between patients with BMI<30 and ≥30 in terms of changes in the VAS and ODI pain scores in the preoperative period and at the end of the 12th month. This may be due to the fact that obese patients were recruited after the team's experience with the procedure had increased, access to the intradiscal area was easier, the quality of fluoroscopy was high, and the patients applied lifestyle changes in the postoperative period.

In the study by Lima Florencio et al.[32] involving 2,095 patients with diabetes mellitus (DM) and 2,095 patients without DM, the incidence of chronic lower back pain was 34.8% in the DM group and 29% in the non-DM patient group, and this difference was found to be significant. It was further observed that both the DM and female groups recorded more pain medication use, worse health status, and more chronic pain, and that diabetes may pose a greater risk for chronic lower back pain.[32] DM was the most common comorbid disease in our patient group, with a rate of 27.5%, although no significant difference was noted between patients with and without diabetes in terms of changes in VAS and ODI pain scores in the preoperative period and at the 12th month. The reason for this may be that the blood sugar regulation of diabetic patients was good in our patient group, and the mean age of our patient population was 42.93, comprising mostly young and middle-aged patients.

The results of the first year of our study reveal that the improvement in pain and functional capacity was accompanied by a low rate of reoperation. We can say that the Disc-Fx procedure can be considered an appropriate treatment option in selected patient groups based on the outcome of randomized controlled studies conducted over longer periods of time, and can help postpone open surgery and avoid the associated risks.

In our study, no intraoperative side effects developed, although spondylodiscitis developed in one patient in the postoperative period. Studies have reported incidences of intervertebral infection after spine surgery in 0.1–0.4% of cases, most of which are caused by bacterial infections.[33] In the study by Gu et al.,[34] an infection rate of 0.47% was recorded in 209 patients who underwent percutaneous endoscopic discectomy for LDH. In the present study, spondylodiscitis developed in 2.5% of the sample, although the result was not significant since our patient population was smaller than that of other studies. The symptoms of the patient who developed spondylodiscitis regressed with antibiotic treatment, and he stated that, in general, the Disc-Fx procedure had reduced his pain, that he was satisfied with the procedure, and that he would recommend it to his relatives after the necessary precautions. In general, the infection rate in the Disc-FX procedure is very low, and the condition is easier to treat once it develops, as no foreign objects, such as spinal cord stimulators, are inserted. Another patient was given a transforaminal injection (TFI) due to increased pain in the first 48 hours postoperatively, and after the relief of his pain after TFI, the patient stated that he would generally recommend the Disc-Fx procedure to his relatives. Some 60% of the patients in our sample reported that they would recommend the operation, while 40% would not. In a study conducted by Kumar et al.[14] involving 24 patients, 81.82% reported that they would recommend the Disc-Fx procedure to their relatives. We believe that the 60% positive feedback in our study should be considered. The satisfaction rates recorded both in the present study and in Kumar et al.[12] were high, but different, which may be attributed to the larger sample size in the present study, the different patient expectations, and the sociocultural differences between the patient groups. In a prospective Disc-Fx study conducted by Hellinger et al.,[24] patient satisfaction was found to be good based on the 4-year results. In another study, it was found that patient satisfaction decreased as time passed after percutaneous nucleoplasty.[35]

In another study of the Disc-FX system, the authors reported that three participants (6.4%) suffered an LDH relapse within 4 years, although no complications were recorded.[36] Compared to the radiofrequency procedure, the complication rates of CO2 laser and laser discectomy were found to be 8.22% and 2.6%, respectively.[37,38] For this reason, we believe that the Disc-Fx procedure, as a minimally invasive procedure that makes use of a radiofrequency ablation technique, should be considered promising for carefully selected patients due to its low complication rates, the above-mentioned patient outcomes, and the reduced need for analgesics. Clearer results may be obtained from randomized controlled studies with a larger number of patients and longer patient follow-up.

Conclusion

Low back pain is a common and significant symptom in hospital admissions and is a serious cause of disability that is generally treated with conservative or interventional procedures. As a result of the inappropriate and excessive use of both diagnosis and treatment options, it has become a public health and social cost problem. Degenerative disc and lumbar disc disease, as significant causes of low back pain, become a difficult clinical problem to cope with, especially when patients fail to respond to conservative treatment. Before the development of recent techniques, patients who failed to respond to conservative treatment were treated with surgery. The minimally invasive techniques developed today, however, are as effective as surgery, but with lower complication rates. Literature contains studies investigating the clinical effectiveness of the Disc-Fx procedure as a new treatment approach that allows manual discectomy and nuclear ablation in addition to the radiofrequency technique. In our study, the VAS, ODI, and MacNab scores of the patients in the preoperative period being treated with the Disc-Fx procedure were compared with scores at the 1st, 6th, and 12th months postoperatively, and a significant difference was found. A number of factors that could affect the results were also evaluated. In conclusion, we believe that the Disc-Fx procedure should be considered for carefully selected patients due to its low complication rates, patient outcomes, and reduced need for analgesics. It may be possible to garner clearer results through randomized controlled studies involving larger numbers of patients, and to ensure longer patient follow-up.

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