

Predictors of Treatment Success Following Limited Discectomy With Annular Closure for Lumbar Disc Herniation

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ABSTRACT

Background: Previous studies have demonstrated bone-anchored annular closure to significantly reduce reherniation and reoperation rates after lumbar discectomy in patients with large annular defects. It is important to identify the prognostic factors that may be associated with successful treatment. This study aimed to identify predictors of treatment success in patients with lumbar disc herniation treated with limited microdiscectomy supplemented by a bone-anchored annular closure device (ACD).

Methods: This study was a retrospective analysis of 133 consecutive patients with lumbar disc herniation treated with the ACD. Treatment success was defined as $\geq 24\%$ improvement in visual analog scale (VAS) for back pain, $\geq 39\%$ improvement in VAS leg pain, and $\geq 33\%$ in the Oswestry Disability Index (ODI), with the raw ODI score ≤ 48 . Success was calculated at 3, 6, and 12 months after surgery. Potentially predictive outcomes included patient characteristics, operative data, and imaging outcomes, such as disc, facet, and end plate morphology. Logistic regression was used to determine the significant predictive factors for treatment success.

Results: After 3, 6, and 12 months, 97 of 131 (74%), 104 of 129 (81%), and 112 of 126 (89%) patients, respectively, achieved the success criteria. At 3 months follow-up, a higher proportion of younger (17–40 years) versus older (41–65 years) patients met the success criteria ($P = .025$). On the basis of logistic regression, the following factors were significantly associated with treatment success at 1 or more of the follow-up time points: sex (male), lower body mass index, higher baseline pain and ODI scores, lower grade preoperative disc degeneration, and the absence of a postoperative complication. The rates of index-level recurrent herniation and reoperation were 1.5% and 3.0%, respectively.

Conclusions: This real-world evidence supports a promising benefit-risk profile for augmenting limited microdiscectomy with a bone-anchored ACD and provides some insights into the patient populations that may have a greater chance of realizing significant improvements in pain and function.

Level of Evidence: 2 (Cohort study).

Lumbar Spine

Keywords: lumbar disc herniation, limited discectomy, annular closure device, large annular defect, treatment success

INTRODUCTION

Microdiscectomy is among the most common methods for surgical treatment of lumbar disc herniation, with success rates between 80% and 90%.^{1–3} Despite these high rates of success, several investigators have reported reherniation and recurrent low back and/or leg pain in 15% to 25% of patients.^{4,5} In a systematic review of 90 studies with more than 21 000 patients, Parker et al⁶ observed a prevalence of approximately 14% for persistent short-term (6–24 months) or long-term (>24 months) leg or back pain. Persistence or recurrence of symptoms can result from disc reherniation, degeneration of the operated segment, or the loss of

disc height and stenosis.^{7–11} Reherniation remains a significant problem, with the frequency after microdiscectomy ranging from 5% to 27%.^{1,9,12–15}

Due to nucleus pulposus removal, subtotal microdiscectomy may be an effective means of reducing reherniation risk. However, this technique can lead to the deterioration of disc height, accelerated degeneration, reduced resistance to axial loads, transfer of axial load to the facet joints, and the recurrence of leg and back pain.¹⁶ Subtotal discectomy is usually accompanied by disc curettage. Asymmetric, excessive curettage of the disc cavity can cause a hernia from the contralateral side and the development of aseptic discitis in the

postoperative period.¹⁷ To avoid the collapse of the intervertebral disc and the associated adverse outcomes, limited discectomy or sequestrectomy is often performed; however, limited discectomy may be associated with a higher rate of recurrent disc herniation.^{9,13} An important factor affecting the risk of recurrent herniation is the size of the defect in the annular ring. Carragee et al¹³ observed recurrent herniation in 27% of patients with an annular defect of at least 6 mm, compared with only 1% reherniation among smaller defects. A recent meta-analysis demonstrated that the risk of symptom recurrence and reoperation was 2.5 and 2.3 times higher, respectively, in patients with large annular defects after microdiscectomy.¹⁸

One strategy to avoid postoperative disc reherniation while preserving the native disc and improving overall results is annular closure. A bone-anchored annular closure device (ACD) that occludes the annular defect has successfully limited the rate of reherniation and revision surgery in several clinical studies, including a 550-patient, multicenter, randomized controlled trial (RCT).^{4,19–22} Despite this success, some ACD-treated patients still experienced recurring symptoms and required reoperation. To better understand the factors that may affect treatment success with this ACD, this study examined the rate and predictors of successful treatment outcomes, on the basis of pain and disability scores, in a consecutive cohort of patients.

MATERIAL AND METHODS

Patient Population

This study was a retrospective analysis of all consecutive patients who underwent limited discectomy and implantation of the Barricaid ACD (Intrinsic Therapeutics, Inc, Woburn, MA) in neurosurgery department No. 2 of Research Institute of Traumatology and Orthopaedics (NRITO) n.a.Ya.L.Tsivyan between 2012 and 2016. The study included 133 patients and was approved by the local ethics committee.

Outcome Assessments

Patients were evaluated at baseline and at 3, 6, and 12 months postdiscectomy. Patient-reported outcomes included leg and back pain on the visual analog scale (VAS) and Oswestry Disability Index (ODI). The primary outcome of this study was a composite definition of treatment success that was

based on the thresholds for pain and disability scores reported by Werner et al.²³ To be considered a treatment success at each follow-up time point, a patient needed to experience $\geq 24\%$ improvement in VAS back pain, $\geq 39\%$ improvement in VAS leg pain, and $\geq 33\%$ in ODI with a raw ODI score ≤ 48 at follow-up.²³ In cases where data on at least 1 of the 3 measures were absent, the patient was excluded from the analysis.

Secondary measures used as potential predictors of treatment success included patient demographic, surgical, and radiological characteristics, occurrence of reherniation or other complications, degree of disc degeneration (Pfirrmann scale),²⁴ degree of facet joint degeneration and sclerosis (Grogan scale),²⁵ and vertebral end plate disruptions (osseous erosion, resorption and Modic changes).

Imaging

Outcomes were evaluated using lumbosacral spine x-ray with flexion-extension, multisite computed tomography (CT) and magnetic resonance imaging (MRI). Radiographs were used to determine disc height, lumbar lordosis angle, and range of motion (ROM). The multisite CT was used to assess the status of the implant, the state of osseous tissue around the implant, the structure of the intervertebral disc, and the state of end plates and facet joints. Postoperative MRI was used to detect the presence of intervertebral disc protrusions and/or hernias, to determine the degenerative stage of the intervertebral disc and facet joints, and to assess the potential presence of end plate disruptions and spinal stenosis. Facet degeneration and sclerosis were evaluated according to the Grogan classification system,²⁵ whereas disc degeneration was graded on the basis of the Pfirrmann scale.²⁴

Statistical Analysis

Descriptive statistics were calculated for each outcome measure. Study groups were compared via the Fisher exact test, Mann-Whitney test, and analysis of variance. Potential predictors of treatment success, which included the patient characteristics, operative data, and imaging outcomes (listed in Tables 1 and 2), were evaluated through logistic regression analysis (see Appendix). All analyses were performed at each follow-up time point, and statistical comparisons were considered significant at $P < .05$. Statistical analysis was performed using IBM SPSS version 21 (IBM Corp, Armonk, NY).

Table 1. Summary of patient and operative characteristics.

Characteristic	Value
Age, mean ± SD	38.3 ± 10.7
BMI, mean ± SD	26.7 ± 4.8
Sex, M:F	73:60
Smoker, %	50.4
Operative level, %	
L3-L4	6.8
L4-L5	45.8
L5-S1	47.4
Duration of operation, mean ± SD, min	58 ± 16.6
Area of annular defect, mean ± SD, mm ²	47.6 ± 6.4
Fraction of disc removed, mean ± SD, %	13.1 ± 6.1
Total disc volume, mean ± SD, cm ³	12 ± 3.6
Type of hernia, %	
Protrusion	49.6
Extrusion	22.6
Sequestration	27.8

RESULTS

Study Population

A total of 133 patients were eligible for inclusion in this study based on implantation of the ACD. Follow-up data were available for 126 patients (94.7%) at 12 months. The average annular defect size was 47.6 ± 6.4 mm². The lumbar disc hernia was characterized as a protrusion in 49.6% of cases, an extrusion in 22.6% of cases, and a sequestration in 27.8% of cases (Table 1). At the 3-, 6-, and 12-month follow-up time points, treatment success was achieved by 97 of 131 (74%), 104 of 129 (81%), and 112 of 126 (89%) patients, respectively. Overall, there was a significant decrease in back pain, leg pain, and ODI scores from baseline through 12 months follow-up ($P < .001$; Figure 1).

At 3 months postprocedure, patients who met the success criteria had higher baseline back pain scores (4.8 ± 1.7 vs 3.2 ± 1.6, $P < .001$), higher baseline leg pain scores (6.7 ± 1.6 vs 5.8 ± 1.7, $P = .007$), higher baseline ODI scores (60.1 ± 13.7 vs

Table 2. Summary of imaging outcome measures at baseline and 12-month follow-up.

Outcome Measure	Value		P Value
	Baseline	12-mo Follow-Up	
Modic changes, %			<.001 ^a
No changes	83	69	
I	11	16	
II	6	14	
III	1	1	
Pfirmann, %			<.001 ^a
I	1	1	
II	14	8	
III	76	80	
IV	9	11	
Facet degeneration (Grogan), %			<.001 ^a
I	23	16	
II	52	51	
III	24	32	
IV	1	2	
Facet sclerosis (Grogan), %			.004 ^a
I	47	44	
II	45	43	
III	8	13	
Superior end plate resorption, %	11	25	<.001 ^b
Inferior end plate resorption, %	5	13	.002 ^b
Lumbar lordosis, mean ± SD, °	42.17 ± 13.89	50.83 ± 8.87	<.001 ^c
Range of motion, mean ± SD, °	4.59 ± 2.56	5.56 ± 2.54	<.001 ^c
Retrolisthesis, %	22	24	.250 ^c
Disc height index, mean ± SD	0.28 ± 0.05	0.24 ± 0.05	<.001 ^c
VAS back, mean ± SD	4.39 ± 1.78	1.15 ± 1.39	<.001 ^c
VAS leg, mean ± SD	6.45 ± 1.66	0.28 ± 0.77	<.001 ^c
ODI, mean ± SD	58.13 ± 13.57	8.77 ± 9.38	<.001 ^c

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

^aWilcoxon signed rank test.

^bMcNemar test.

^cPaired samples *t* test.

52.8 ± 12.1, $P = .007$), a shorter duration of surgery (56.1 ± 15.6 vs 63.7 ± 18.8 min, $P = .023$), and a lower fraction of disc removed (12.4% ± 5.5% vs 15.3% ± 7.1%, $P = .016$) compared with those who did not meet the success

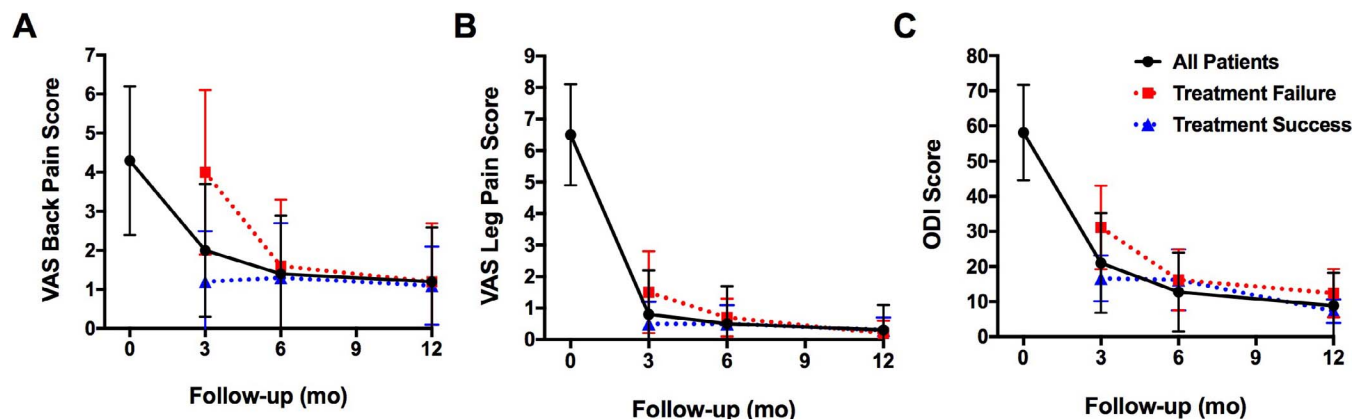


Figure. Summary of back pain, leg pain, and ODI scores through 12 months follow-up.

Table 3. Significantly different characteristics between failed and successful patients.

	Treatment Failure	Treatment Success	P Value
At 3 mo follow-up			
Duration of operation, min			.023
Mean \pm SD	63.7 \pm 18.8	56.1 \pm 15.6	
Range	30–120	30–100	
Baseline VAS (back) score			<.001
Mean \pm SD	3.2 \pm 1.6	4.8 \pm 1.7	
Range	1–7	1–9	
Baseline VAS (leg) score			.007
Mean \pm SD	5.8 \pm 1.7	6.7 \pm 1.6	
Range	3–10	3–10	
Baseline ODI score			.007
Mean \pm SD	52.8 \pm 12.1	60.1 \pm 13.7	
Range	30–80	36–92	
ROM after 3 mo, °			.035
Mean \pm SD	4.3 \pm 2.1	5.4 \pm 2.5	
Range	0–10	0–11	
Fraction of disc removed, %			.016
Mean \pm SD	15.3 \pm 7.1	12.4 \pm 5.5	
Range	4.2–35.0	0.2–31.0	
Baseline facet degeneration, %			.020
I	12	27	
II	50	53	
III	38	20	
IV	0	1	
At 6 mo follow-up			
Baseline VAS (back) score			.001
Mean \pm SD	3.3 \pm 2.0	4.7 \pm 1.7	
Range	1–7	1–9	
Baseline facet degeneration, %			.034
I	12	26	
II	48	52	
III	36	22	
IV	4	0	
Facet degeneration (6 mo), %			.009
I	4	24	
II	52	51	
III	40	23	
IV	4	1	
At 12 mo follow-up			
Baseline VAS (back) score			.001
Mean \pm SD	2.9 \pm 1.7	4.6 \pm 1.7	
Range	1–5	1–9	
Baseline lumbar lordosis, °			.013
Mean \pm SD	50.9 \pm 15.7	41.2 \pm 13.3	
Range	20–75	4–70	
Disc volume, cm ³			.034
Mean \pm SD	10.1 \pm 2.4	12.3 \pm 3.7	
Range	6.2–13.5	5.8–25.3	
Retrolisthesis, %			.015
Presence	50	19	

Abbreviations: ODI, Oswestry Disability Index; ROM, range of motion; VAS, visual analog scale.

criteria (Table 3). At 6 months, only baseline back pain scores were significantly different between the successful and unsuccessful patients, with higher baseline scores among the successful cohort (3.3 \pm 2.0 vs 4.7 \pm 1.7; $P = .001$). At 12 months, patients meeting the success criteria had higher baseline back pain scores (4.6 \pm 1.7 vs 2.9 \pm 1.7, $P = .001$), lower baseline lumbar lordosis (41.2° \pm 13.3° vs 50.9° \pm 15.7°, $P = .013$), and a larger disc volume (12.3 \pm 3.7 vs 10.1 \pm 2.4 cm³, $P = .034$).

Age was only a significant factor at the 3-month follow-up, with a significantly higher proportion of younger patients (aged 17–40 years) meeting the success criteria compared with older patients ($P = .025$; Table 4).

Imaging Assessments

There were significantly greater proportions of patients with grade III facet joint degeneration observed at baseline or follow-up among patients who did not meet the treatment success criteria at 3 months ($P = .020$) and 6 months follow-up ($P = .034$). At 12 months follow-up, retrolisthesis was observed less often among patients meeting the treatment success criteria (19% vs 50%; $P = .015$; Table 3). There were no significant differences among any other imaging measurements, including Modic changes and vertebral end plate disruptions ($P > .05$).

Predictors of Treatment Success

On the basis of logistic regression, the following factors were statistically significant predictors of treatment success at 1 or more of the follow-up time points: sex (male), lower body mass index (BMI), higher baseline back pain and ODI scores, Pfirrmann disc degeneration grades I to II at baseline, and the absence of a postoperative complication. Modic changes and vertebral end plate disruptions were not associated with treatment outcomes (Table 5).

Recurrent Herniations, Complications, and Reoperations

Through 12 months follow-up, the rate of recurrent herniation was 1.5% (2/133 patients). The secondary index-level disc herniation occurred on the contralateral side after 1 month in 1 patient and 6 months in the other patient. Microdiscectomy was performed to remove these contralateral herniations. No ipsilateral reherniations were observed.

Two patients (1.5%), 1 after 3 months and 1 after 6 months, had persistent low back pain. Focal bone resorption around the implant and segmental instability was observed at the surgical level. These 2 patients underwent removal of the ACD and 360° fusion without further complications.

Six additional patients (4.5%) had persistent low back pain. No recurrent disc herniation was detected and the positioning of the implant was

Table 4. Rate of treatment success as a factor of patient age.

Time Point	Group	Age Group, No. (%)		Total	P Value
		17–40	41–65		
After 3 mo	Fail	14 (41)	20 (59)	34	.025 ^a
	Success	63 (65)	34 (35)	97	
After 6 mo	Fail	15 (60)	10 (40)	25	1.0
	Success	61 (59)	43 (41)	104	
After 12 mo	Fail	8 (57)	6 (43)	14	1.0
	Success	66 (59)	46 (41)	112	

^aA higher proportion of younger patients met the success criteria compared with older patients.

correct. The pain symptoms were attributed to spondylarthrosis, which was treated with radiofrequency denervation of the facet joints. All 10 of these patients were included in the Treatment Failure group.

DISCUSSION

This study evaluated the rate of successful symptom mitigation and predictive characteristics associated with microdiscectomy augmented by a bone-anchored ACD for lumbar disc herniation at 3, 6, and 12 months postprocedure. Treatment success was based on alleviation of leg and back pain as well as improvement in disability scores according to the thresholds established by Werner et al.²³ In that study, Werner et al observed that an improvement in ODI less than 33% was the most accurate individual measure of treatment failure. This study used a more conservative composite success metric that required patients to meet the success criteria for improvements in back and leg pain in addition to ODI scores.

Many studies have examined potential risk factors for failed microdiscectomy, with a variety of definitions for failure. Most commonly, studies examine risk factors for recurrent herniation or reoperation,^{8,26–29} which are associated with symptom recurrence and worse clinical outcomes.^{28,30–32} However, different prognostic factors may be associated with treatment failures that are defined according to patient-reported outcomes compared with those that are predictive of recurrent herniation or reoperation. Studies focusing on improvements in patient-reported outcomes have found that shorter preoperative duration of leg pain,^{33,34} shorter time on sick leave,³⁵ higher preoperative ODI scores,^{35,36} higher preoperative leg pain,^{35,37} higher preoperative back pain,³⁵ and lower preoperative EuroQol-5 Dimensions scores³⁷ were significantly associated with better clinical improvements. In this study of microdiscectomy augmented by a

bone-anchored ACD, the significant factors associated with successful improvement in pain and disability at 12 months follow-up were a higher preoperative back pain score, lower baseline lumbar lordosis, and the absence of a complication. Avoiding complications, such as reherniation or reoperation, is consistent with literature demonstrating that worse clinical outcomes are associated with reoperation following discectomy, with or without a bone-anchored ACD.^{28,30–32} A higher back pain score at baseline was the only metric consistently significant across the 3- through 12-month follow-ups. Indeed, Werner et al²³ noted that improvement in back pain was a highly accurate determinant of treatment success. These findings are consistent with other studies that have observed higher preoperative pain or disability scores to be associated with better outcomes.^{35–37}

A higher BMI and smoking are commonly identified risk factors, among others, for recurrent herniation.^{29,38–43} This study observed that a lower BMI was significantly associated with treatment success at early follow-up of 3 months, but was not significant at 6 or 12 months. In addition, smoking did not significantly affect the result of surgery, although the proportion of smokers tended to be greater in the treatment failure group. Because patients experiencing a recurrent herniation and those experiencing persistent pain and/or disability are not identical populations, it is reasonable that different factors would predict treatment outcomes. Furthermore, the use of the bone-anchored ACD in this study may also shift the importance of prognostic factors compared with discectomy alone.

The bone-anchored ACD used in this study has been the subject of many other clinical studies and reports, including a RCT of 550 patients with large annular defects.^{22,44} That study observed a significant reduction in symptomatic reherniation, from 25% in the control group (discectomy alone) to 12% in the ACD group after 2 years. Furthermore,

Table 5. Significant predictive factors from logistic regression analysis.

Index	Coefficient	Chance Ratio	P Value	% Correctly Predicted Index
3 mo				
Sex (male)	1.739	5.690	.001	78.6
BMI	-0.122	0.885	.018	
Baseline back pain score	0.655	1.926	<.001	
Baseline ODI score	0.059	1.061	.006	
6 mo				
Baseline disc degeneration (Pfirrmann)	-1.121	0.326	.043	89.7
Baseline back pain score	0.490	1.632	.001	
12 mo				
Baseline back pain score	0.717	2.049	.001	89.7
Baseline lumbar lordosis	-0.060	0.942	.022	
Complication	-2.635	0.072	.025	

the reoperation rate for reherniations was reduced by more than 60%.²² Real-world evidence from a prospective registry reiterated the effectiveness of the bone-anchored ACD, with low symptomatic reherniation rates (3.5%) in a population that was more diverse than the RCT population.^{19,45} Similarly, in this study, the rate of reherniation was only 1.5% and the rate of reoperation was 3.0%. The average annular defect size of $47.6 \pm 6.4 \text{ mm}^2$ in this study matches well with the reherniation group reported by McGirt et al¹⁵ compared with the average defect size in the nonreherniation group ($46 \pm 20 \text{ mm}^2$ vs $32 \pm 16 \text{ mm}^2$, respectively).

In the RCT study, vertebral end plate disruptions observed on computed tomography were reported for both the control and ACD groups before the primary discectomy surgery and with a greater incidence at 2 years follow-up.⁴⁶ Although the incidence was significantly greater in the ACD group, these end plate disruptions did not significantly affect the clinical outcomes. The current study also did not observe any association between treatment success with the bone-anchored ACD and vertebral end plate disruptions. In fact, the majority of patients with this type of radiographic finding met the treatment success criteria in this study. This is consistent with other evidence on microdiscectomy from the literature, which indicates that Modic changes at the end plates do not adversely affect the clinical results.^{47,48}

CONCLUSIONS

This retrospective registry analysis observed high success rates approaching 90% at 12 months follow-up for microdiscectomy augmented with a bone-anchored ACD to alleviate pain and disability in lumbar disc herniation patients. The rate of reherniation and reoperation were only 1.5% and

3.0%, respectively. The significant factors that were associated with success of the surgery were sex (male), lower BMI, higher preoperative pain and disability scores, less preoperative disc degeneration, and the absence of postoperative complications, such as reherniation. This real-world evidence further supports a promising benefit-risk profile for augmenting limited microdiscectomy with a bone-anchored ACD and provides some insights into the patient populations that may have a greater chance of realizing significant improvements in pain and function.

ACKNOWLEDGMENTS

We would like to thank Telos Partners, LLC for their assistance in technical writing and editing of the manuscript.

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Appendix. Equations of logistic regression.

The equations of logistic regression were built for each time point (3, 6, 12 months) as follows:

$$p = \frac{1}{1 + e^{-z}}$$

$$z = b_0 + b_1 \cdot X_1 + \dots + b_n \cdot X_n$$

where p is the probability of treatment success, X_1, \dots, X_n are the predictors, b_1, \dots, b_n are the corresponding coefficients of predictors, and b_0 is a constant.

Correlation coefficients reflect the relative impact of the independent variable on the chance of success of the procedure (dependent variable).

Disclosures and COI: Technical editing services were provided by Telos Partners, LLC, under funding from Intrinsic Therapeutics. The authors declare no potential conflicts of interest.

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Published 29 February 2020

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