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ORIGINAL ARTICLE

Two-year real-world results of lumbar discectomy with bone-anchored annular closure in patients at high risk of reherniation

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Abstract

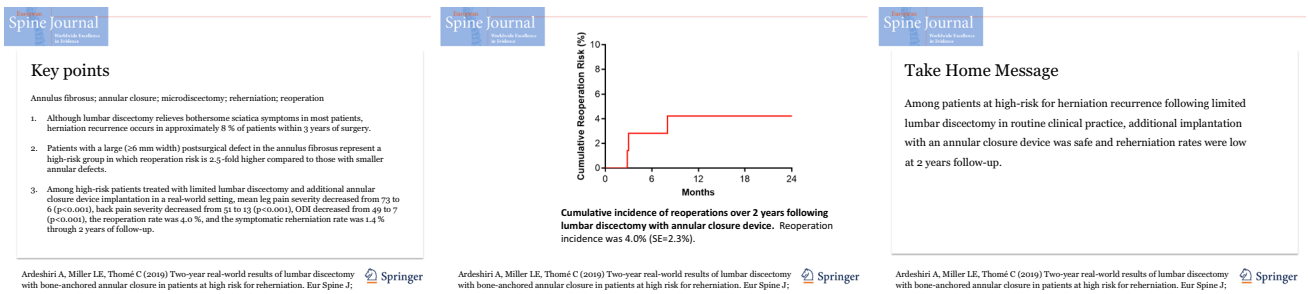
Purpose To determine the safety and effectiveness of limited lumbar discectomy with additional implantation of an annular closure device (ACD) among patients at high risk of herniation recurrence treated in routine clinical practice.

Methods This was a prospective, single-center study of lumbar discectomy for sciatica caused by intervertebral disc herniation with adjunctive ACD implantation to reduce herniation recurrence risk among high-risk patients with large annular defects. Patients returned for follow-up visits at 6 weeks, 12 weeks, 26 weeks, 1 year, and 2 years. Main outcomes included reoperation, herniation recurrence, back pain severity, leg pain severity, and Oswestry Disability Index (ODI). The minimum important difference was defined as ≥ 20 mm decrease relative to baseline for leg pain severity, ≥ 20 mm decrease for back pain severity, and ≥ 15-point decrease for ODI.

Results Among 75 high-risk patients (mean age 45 years, 59% female), the cumulative event incidence through 2 years was 4.0% for reoperation and 1.4% for herniation recurrence. Mean leg pain severity decreased from 73 to 6 ($p < 0.001$), back pain severity decreased from 51 to 13 ($p < 0.001$), and ODI decreased from 49 to 7 ($p < 0.001$). The percentage of patients achieving the minimum important difference was 91% for leg pain, 65% for back pain, and 94% for ODI.

Conclusion In patients at high risk of herniation recurrence following limited lumbar discectomy in routine clinical practice, additional implantation of an ACD was safe and reherniation recurrence rates were low at 2-year follow-up, which is favorably compared to reported rates in high-risk patients.

Graphic abstract



Keywords Annulus fibrosus · Annular closure · Microdiscectomy · Reherniation · Reoperation

Introduction

Sciatica affects between 1 and 5% of the population annually, with lumbar disc herniation responsible for most cases [1] Sciatica eventually resolves regardless of treatment in most patients, but approximately 20% of affected individuals report persistent symptoms despite conservative

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management [2, 3]. In these patients, lumbar discectomy offers faster and more durable pain relief compared to continued nonsurgical management [4, 5]. Although lumbar discectomy relieves bothersome sciatica symptoms in most patients, herniation recurrence occurs in approximately 8% of patients within 3 years of surgery [6]. Patients with a large (≥ 6 mm width) postsurgical defect in the annulus fibrosus represent a high-risk group in which reoperation risk is 2.5-fold higher compared to those with smaller annular defects [6]. A bone-anchored device intended for annular defect closure was developed to prevent reherniation in this high-risk patient subset. In a randomized trial of 554 patients, limited lumbar discectomy with additional annular closure device (ACD) implantation significantly reduced the risk of herniation recurrence and reoperation through 2-year follow-up compared to lumbar discectomy only [7]. Since this randomized trial utilized stringent eligibility criteria and follow-up requirements, additional research is warranted to better characterize the performance of the ACD in real-world settings. The purpose of this study was to determine the safety and effectiveness of limited lumbar discectomy with ACD among high-risk patients treated in routine clinical practice.

Materials and methods

Study design and ethics

This was a prospective, single-center study of limited lumbar discectomy for sciatica caused by intervertebral disc herniation with additional ACD implantation to reduce herniation recurrence risk among high-risk patients with large annular defects. All study procedures were conducted in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. Written informed consent was obtained from all participants included in the study.

Patients

Consecutive patients were prospectively assessed for study eligibility at the section for Spine Surgery, Klinikum Itzehoe, Germany. Eligible patients were adults (≥ 18 years) with symptomatic, magnetic resonance imaging (MRI)-confirmed lumbar disc herniation at a single level with a disc height of at least 5 mm. Patients with significant osteoporosis, active infection, malignancy, or significant spondylolisthesis (> 25% slip) were excluded from participation, but patients with previous disc surgery could be enrolled. Eligible patients were then scheduled for surgery, during which the final eligibility criterion regarding annular defect size was assessed. Key preoperative evaluations included patient demographics and medical history, physical and neurological examination, back pain and leg pain severity (each measured on a 100 mm visual analog scale), and functional disability measured on the Oswestry Disability Index (ODI).

Surgery

All operations were performed under standard microsurgical conditions. After limited lumbar discectomy [8], selective incision of the posterior longitudinal ligament was

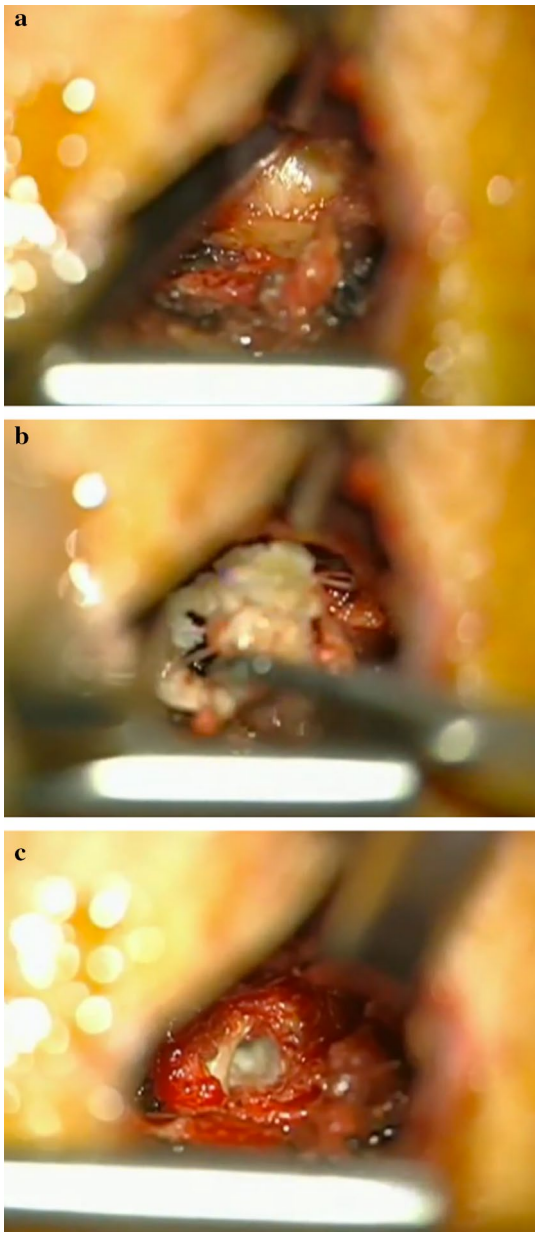


Fig. 1 Major procedural steps for annular defect identification including: **a** exposure of subligamental disc hernia (center of image), **b** removal of sequester (center of image), and **c** exposure of annular defect (center of image)

performed to inspect the annular defect (Fig. 1). If an annular defect was observed, the defect height and width were measured with sizing instruments (Intrinsic Therapeutics, Inc., Woburn, MA, United States). If the defect height was between 4 and 6 mm, and the width was at least 6 mm, the patients additionally received a bone-anchored ACD (Intrinsic Therapeutics, Inc.); otherwise, the discectomy procedure was completed and patients were discontinued from the study. In patients with large annular defects, a sizing trial was performed under fluoroscopic control to establish the correct position and angle of the ACD. Next, the ACD was implanted under fluoroscopic guidance by impacting the anchor into the vertebral body while the mesh was placed in the annular defect to prevent expulsion of disc material into the extradiscal space. After fluoroscopic confirmation of correct device placement, the surgical site was inspected and standard wound closure was performed.

Follow-up and outcomes

After hospital discharge, patients returned for follow-up visits at 6 weeks, 12 weeks, 26 weeks, 1 year, and 2 years. At each visit, patient-reported outcomes, neurological status, clinical signs of herniation recurrence, and complications were recorded. Patient-reported outcomes included back pain severity, leg pain severity, and ODI. Herniation recurrence was suspected if pain severity increased or functional/neurological status declined relative to the previous visit. In such patients, MRI and X-ray were performed to confirm or exclude the diagnosis. Herniation recurrence was defined as clinical and radiographic evidence of reherniation at the level of the original herniation, regardless of side. MRI and X-ray were also performed in patients with suspected wound complications. The minimum important difference (MID) was defined as ≥ 20 mm decrease relative to baseline for leg pain severity [9], ≥ 20 mm decrease relative to baseline for back pain severity [9], and ≥ 15-point decrease relative to baseline for ODI [10].

Statistical analysis

By assuming a 6% herniation recurrence rate and 20% attrition through 2 years, a sample size of 75 patients provided a 95% upper confidence limit of 15%, which is less than the reherniation rates reported with limited lumbar discectomy without ACD among patients with large postsurgical annular defects [6]. Baseline patient characteristics were reported using the mean and standard deviation for normally distributed continuous outcomes, median and interquartile range for non-normally distributed continuous data, and count and frequency for categorical data. Mixed-model analysis of variance was used to analyze longitudinal changes in patient-reported outcomes. Kaplan–Meier methods were used to estimate the cumulative incidence and standard error (SE) of herniation recurrence and reoperation. Data were analyzed using SAS version 9.4 (SAS Institute, Cary, NC, United States). All statistical tests were two-sided, and p values of less than 0.05 indicated statistical significance.

Results

Between May 2015 and November 2016, 75 patients were treated with limited lumbar discectomy and additional ACD implantation at a single center. Baseline patient characteristics and procedural details are reported in Table 1. Mean patient age was 45 years, 59% were female, and typical clinical presentation was characterized by severe sciatica (mean

Table 1 Patient characteristics and intraoperative findings

Characteristic	Value[a]
Age (years)	45 ± 13
Female sex	44 (59)
Body mass index (kg/m^2)	28 ± 6
Smoking history	48 (64)
Disc height (mm)	6.2 ± 1.4
Annular defect height (mm)	4.5 ± 0.6
Annular defect width (mm)	10.1 ± 1.6
Annular defect area (mm^2)	46 ± 11
Back pain	51 ± 34
Leg pain	73 ± 24
Oswestry Disability Index	49 ± 17
Symptom duration (months)	4 (2, 9)[b]
Previous nonsurgical treatment	73 (97)
Previous lumbar surgery/intervention	15 (21)
Previous surgery at level of herniation	7 (9)
Operative level	
L3/L4	8 (11)
L4/L5	37 (49)
L5/L6	1 (1)
L5/S1	29 (39)
Operative side	
Left	45 (60)
Right	30 (40)
Volume of removed nucleus (ml)	0.9 (0.5, 1.3)[b]
Annular closure device width (mm)	
8	4 (5)
10	16 (21)
12	55 (73)
Surgery time (min)	47 ± 16
Hospital stay (days)	3 (3, 4)[b]

[a]Values are mean ± standard deviation or count (percentage) unless reported otherwise

[b]Values are median (interquartile range)

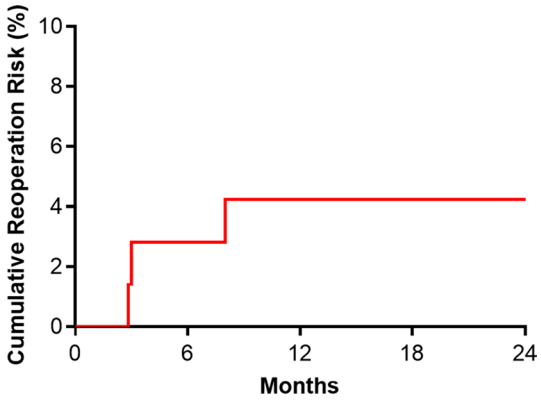


Fig. 2 Cumulative incidence of reoperations over 2 years following lumbar discectomy with annular closure device. Reoperation incidence was 4.0% (SE = 2.3%)

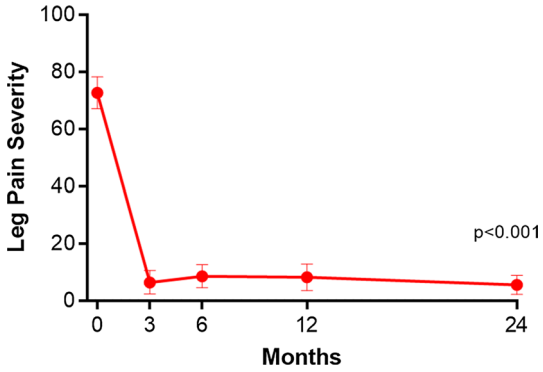


Fig. 3 Change in leg pain severity over 2 years following lumbar discectomy with annular closure device. Plotted values are mean and 95% confidence interval derived from mixed-model analysis of variance

leg pain 73) of 4 months median duration. All enrolled patients had large annular defects (mean defect area 46 mm^2) after lumbar discectomy. The most common operative levels were L4/L5 (49%) or L5/S1 (39%).

In one patient, detachment of the applicator from the implant required more force than normal and resulted in a dural tear. The dural tear was glued, and there were no postoperative complications. In one patient, the ACD was improperly implanted at the posterior border of the vertebral body instead of 2 mm ventral to the vertebral body as recommended by the manufacturer. There were no nerve root injuries or perioperative infections. Median hospital stay following surgery was 3 days, which is standard for lumbar discectomy in Germany.

Patient compliance with follow-up visits was 91% at 3 months, 92% at 6 months, 96% at 1 year, and 90% at 2 years. Three patients underwent a reoperation during follow-up, which included herniation recurrence (same level on the same side) involving resequestrectomy and ACD removal at 6 months, irrigation and drainage of an epidural infection at 2-month follow-up and subsequent lumbar fusion at 5-month follow-up, and device dislocation requiring ACD removal at 8 months. Over 2-year follow-up, the cumulative event incidence was 4.0% for reoperation (Fig. 2) and 1.4% for herniation recurrence. No other clinical or radiographic complications were observed during follow-up.

Statistically significant improvements were observed among all patient-reported outcomes through 2 years. Comparing values reported at baseline and 2 years, mean leg pain severity decreased from 73 to 6 ($p < 0.001$) (Fig. 3), back pain severity decreased from 51 to 13 ($p < 0.001$) (Fig. 4), and ODI decreased from 49 to 7 ($p < 0.001$) (Fig. 5). At the 2-year follow-up visit, the percentage of patients achieving the MID was 91% for leg pain, 65% for back pain, and 94% for ODI. In a post hoc analysis, previous surgery at the level of the herniation was the only variable that influenced all

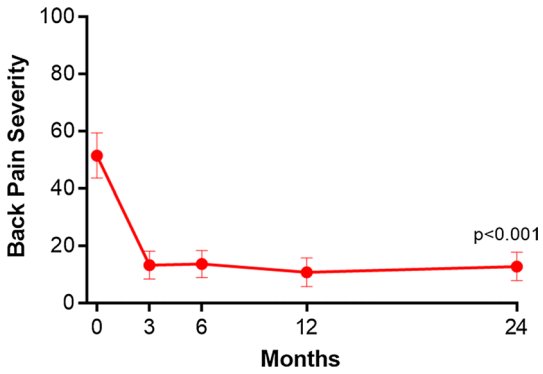


Fig. 4 Change in back pain severity over 2 years following lumbar discectomy with annular closure device. Plotted values are mean and 95% confidence interval derived from mixed-model analysis of variance

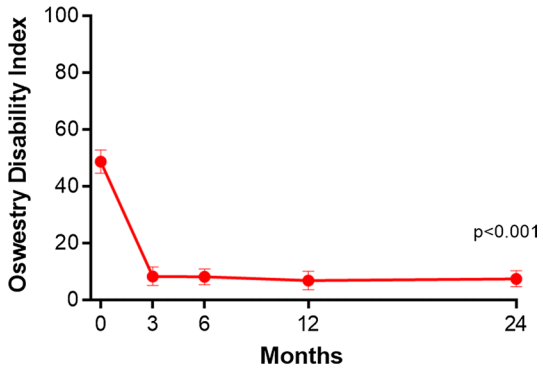


Fig. 5 Change in Oswestry Disability Index over 2 years following lumbar discectomy with annular closure device. Plotted values are mean and 95% confidence interval derived from mixed-model analysis of variance

patient-reported outcomes. The magnitude of improvement over 2 years was statistically greater for all outcomes among patients with no surgical history at the level of herniation versus those with prior surgery (Table 2).

Discussion

Among patients at high risk of herniation recurrence following limited lumbar discectomy in routine clinical practice, additional implantation with an ACD was safe and reherniation rates were low at 2-year follow-up, which is favorably compared to rates reported with limited lumbar discectomy in high-risk patients.

Meta-analysis findings reveal that 21% of patients with large annular defects after limited lumbar discectomy will reherniate within 3 years [6]. In comparison, we noted a recurrence rate of 1.4% at 2-year follow-up with additional ACD implantation in the current study. The presented real-world results also appear favorable relative to data derived from a large randomized trial in which rates of symptomatic reherniation through 2 years were 12% with ACD and 25% with limited lumbar discectomy only [7]. Among 154 high-risk patients treated with ACD in routine clinical practice, Kursumovic and colleagues [11] reported a 3.2% recurrence rate over 15-month follow-up. These authors also reported no differences in outcomes among patients who met the eligibility criteria of an ongoing randomized trial of ACD versus those who did not meet those criteria [12]. It may be speculated that the real-world results demonstrate even lower recurrence rates than the randomized trial due to the vast experience of the involved centers and due to the use of wider, thus "oversized," implants. In the presented series, most patients received a 12 mm device, which may have avoided reherniations compared to the ACD used in the randomized trial with 8 and 10 mm device sizes. These results collectively lend support for the conclusion that additional implantation with an ACD following limited lumbar discectomy not only reduces recurrence risk in a clinical trial setting, but also appears to provide at least comparable benefits in real-world clinical practice settings.

The mechanism of action of the ACD evaluated in this study is physical occlusion of a large annulus fibrosus defect following limited lumbar discectomy whereby the occlusion component of the defect blocks nuclear material from exiting the disc space. This is an important distinction in light of the previous failures of alternative annular defect closure methods such as sutures or fibrin glue [13–16]. A schematic of the device with representative postoperative images of the device is provided in Fig. 6. Prevention of herniation recurrence is potentially cost saving since reoperation is required in nearly 80% of cases to adequately resolve radicular symptoms [17]. Reoperations are expensive and technically demanding; therefore, treatments that reduce the risk of reoperation may contribute to lowering healthcare costs. Indeed, additional implantation of the ACD evaluated in this trial has previously been shown to improve quality of life at lower cost versus limited discectomy only over 2 years [18]. Obviously, the implant itself comes at an additional cost and there is an implant-associated complication rate. With a single device failure requiring reoperation in our study (1.3%) and comparable results in the randomized trial, the extra risk is low and appears acceptable in view of the significant reduction in reherniations provided that clinical utility is maintained in longer term follow-up.

There were several limitations of this study. First, study data were derived from a single center with extensive experience with ACD implantation. Although it is plausible that different results may be observed among centers with less procedural experience, the fact that comparable outcomes were observed in a large multicenter randomized trial with the ACD suggests that this limitation may not substantially impact study conclusions. Second, this study did not include a control group and, therefore, comparisons of these results to other studies should be interpreted cautiously. While it appears that differences in postoperative restrictions may not influence patient outcomes [19], differences in patient characteristics, surgeon experience, and follow-up intensity are potential confounders that may complicate study-to-study comparisons. Third, because this was a pragmatic study, follow-up imaging was only performed for suspected herniation recurrence or wound complication. Therefore, radiographic assessments of possible vertebral endplate changes, disc height changes, or device complications were not available.

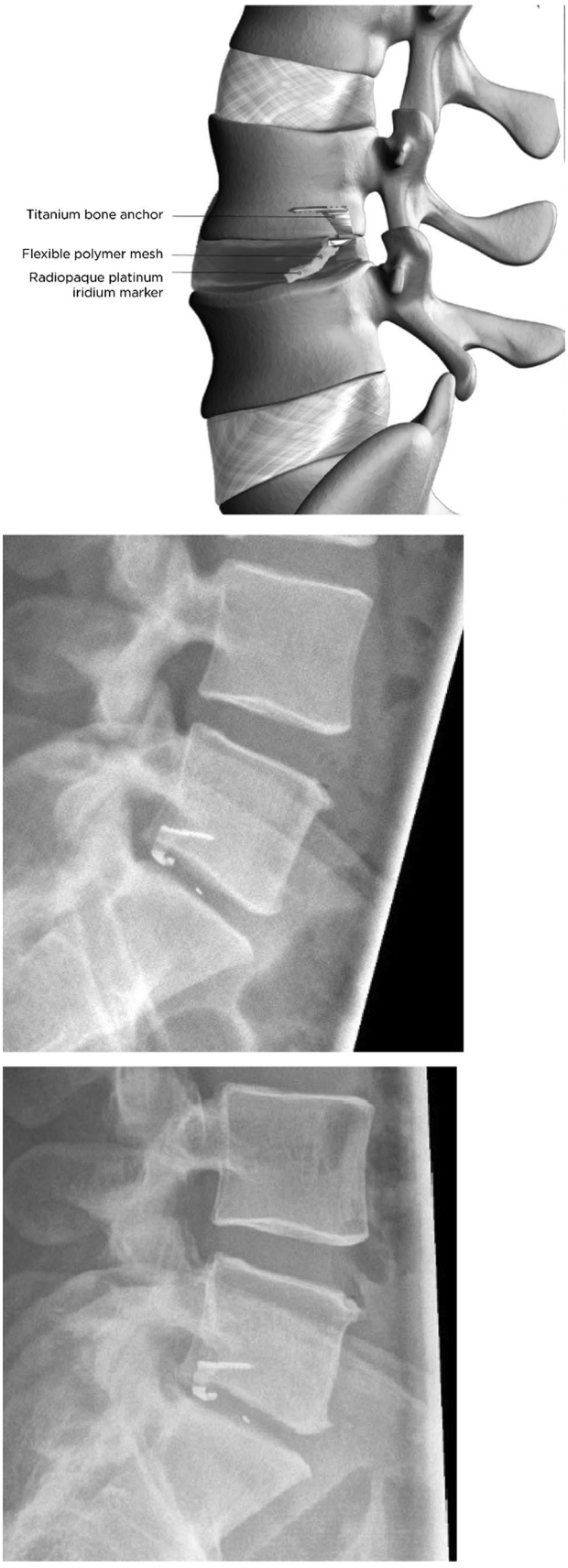
Table 2 Influence of surgical history on patient-reported outcomes

Characteristic	Previous surgery at level of herniation[a]		*p* value[b]
	Yes	No	
Leg pain			
Pre-treatment	46 ± 30	75 ± 23	
2 years	14 ± 17*	5 ± 13**	0.025
Back pain			
Pre-treatment	50 ± 42	52 ± 33	
2 years	38 ± 24	10 ± 18**	< 0.001
Oswestry Disability Index			
Pre-treatment	50 ± 12	48 ± 18	
2 years	31 ± 12*	5 ± 9**	< 0.001

Values are mean ± standard deviation

[a]Statistically significant changes from pre-treatment to 2 years are indicated by $*p < 0.05$ or $**p < 0.001$

[b]*p* value compares values at 2 years with the pre-treatment value used as a covariate in patients with versus without previous surgery at the level of the herniation



◂**Fig. 6** Schematic of bone-anchored annular closure device (top). Radiograph demonstrating imaging appearance of bone-anchored annular closure device implanted at L5/S1 early in the postoperative course (middle) and at 2-year follow-up (bottom)

Fourth, since eligible patients had large annular defects following lumbar discectomy, these results are not applicable to the approximately 70% of lumbar discectomy patients with small postsurgical defects [6]. Finally, 2 years of follow-up is a relatively short duration in a patient population typically presenting in the fifth decade of life. Nevertheless, most reherniations occur early after microdiscectomy and follow-up rates were high at ≥ 90%. Patients in the current study will be followed for 3 years to determine the durability of effect with ACD and to assess the risk of late-onset safety- or device-related complications.

Conclusions

Among patients at high risk of herniation recurrence following limited lumbar discectomy in routine clinical practice, additional implantation with an ACD was safe and reherniation rates were low at 2-year follow-up, which is favorably compared to rates reported with limited lumbar discectomy in high-risk patients.

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Compliance with ethical standards

Conflict of interest AA, LM, and CT disclose consultancy with Intrinsic Therapeutics. The authors maintain full control of study data and agree to allow the journal to review the data upon request.

Research involving human participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments.

Informed consent Informed consent was obtained from all individual participants included in the study.

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