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ORIGINAL RESEARCH

Annular closure device lowers reoperation risk 4 years after lumbar discectomy

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Objective: To determine whether implanting an annular closure device (ACD) following a lumbar discectomy procedure in patients with large defects in the annulus fibrosus lowers the risk of reoperation after 4 years.

Methods: In a multicenter randomized trial, patients with large annular defects following single-level lumbar discectomy were intraoperatively randomized to additionally receive an ACD or no treatment (Controls). Clinical and imaging follow-up were performed at routine intervals over 4 years of follow-up. Main outcomes included reoperations at the treated lumbar level, leg pain scores on a visual analog scale, Oswestry Disability Index (ODI), and Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36 questionnaire.

Results: Among 550 patients (ACD 272, Control 278), the risk of reoperation over 4 years was 14.4% with ACD and 21.1% with Controls (P=0.03). The reduction in reoperation risk with ACD was not significantly influenced by patient age (P=0.51), sex (P=0.34), body mass index (P=0.21), smoking status (P=0.85), level of herniation (P=0.26), leg pain severity at baseline (P=0.90), or ODI at baseline (P=0.54). All patient-reported outcomes improved in each group from baseline to 4 years (all P<0.001). The percentage of patients who achieved the minimal clinically important difference without a reoperation was proportionally higher in the ACD group compared to Controls for leg pain (P=0.07), ODI (P=0.10), PCS (P=0.02), and MCS (P=0.06).

Conclusion: The addition of a bone-anchored ACD following lumbar discectomy in patients with large post-surgical annular defects reduces the risk of reoperation and provides better long-term pain and disability relief over 4 years compared to lumbar discectomy only.

Keywords: annular closure device, annulus fibrosus, disc herniation, lumbar discectomy, randomized controlled trial, reoperation, sciatica

Introduction

Herniation of a lumbar intervertebral disc resulting in radiating buttock and leg pain is common in middle-aged adults.[1] In most cases, sciatica symptoms arising from lumbar disc herniation resolve without specific treatment.[2,3] However, approximately 1 in 5 affected individuals report persistent bothersome symptoms that are refractory to non-surgical treatments.[2,3] Although continuation of conservative care may be considered in these chronic cases, accumulating evidence demonstrates that lumbar discectomy provides more rapid and longer lasting symptom relief.[4,5] Lumbar discectomy as described by Spengler[6] involves surgical removal of the herniated disc material in the extradiscal space. This limited disc excision procedure alleviates radicular symptoms by decompression of nerve roots and reductions in herniation-induced local inflammation.[7] Although lumbar discectomy is highly effective in relieving radicular symptoms in most patients,[8] symptom recurrence is a challenging complication that requires a

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reoperation in most cases to adequately manage symptoms.[9,10] Reoperations are technically demanding, more expensive,[10] and less effective[11,12] than primary procedures. Consequently, determination of factors that increase reoperation risk and identification of therapies that reduce this risk is of clinical and economic importance to patients, surgeons, hospitals, and health care payers.

A major risk factor for reoperation is a post-discectomy defect in the annulus fibrosus of sufficient size to allow reherniation of the intervertebral disc contents. In a meta-analysis by Miller and colleagues,[13] the risk of reoperation in patients with a large (≥6 mm width) post-discectomy annular defect was more than double that of patients with smaller defects. In order to lower the risk of symptom recurrence and reoperation among these high-risk patients, an implantable bone-anchored device was developed to provide durable occlusion of the annular defect. A 554-patient multicenter randomized trial confirmed that lumbar discectomy followed by annular closure device (ACD) implantation lowered the risk of reoperation through 3 years compared to lumbar discectomy only in patients with large annular defects.[14] Demonstration of treatment durability over longer term follow-up is crucial in this relatively young patient population and, given the recent marketing approval of this device in the United States, dissemination of current trial results will facilitate shared decision making between patients and surgeons. Thus, we report the 4-year outcomes from this randomized trial in high-risk patients who underwent lumbar discectomy with or without ACD implantation for treatment of symptomatic intervertebral disc herniation.

Methods

Trial design

This multicenter randomized trial was conducted to determine whether additional treatment with a bone-anchored ACD would lower the risk of lumbar disc reherniation and reoperation in patients with large postsurgical annular defects following lumbar discectomy. Patients with large annular defects were specifically targeted for this trial given their well-known high risk of reherniation after lumbar discectomy.[13] The trial was conducted in accordance with the Declaration of Helsinki, ethics committees at each participating site (listed in Table S1) approved the study protocol, and patients provided written informed consent prior to participation. The trial was prospectively registered at ClinicalTrials.gov (NCT 01283438). The trial design[15] and 3-year results[14] have previously been reported.

Participants

A complete listing of inclusion and exclusion criteria was previously published.[16] Preoperative imaging included magnetic resonance imaging, low-dose computed tomography at the index level, and anteroposterior/lateral and flexion/extension X-rays. Eligible patients presented with a single-level lumbar disc herniation identified on preoperative imaging that was associated with persistent leg pain (≥40 on a 0–100 visual analog scale) despite at least 6 weeks of conservative treatment and with a positive physical examination diagnostic test. Additional important eligibility criteria were a score ≥40 on the Oswestry Disability Index and disc height ≥5 mm. Patients with osteoporosis of the lumbar spine, previous surgery at the level of the herniation, spondylolisthesis with >25% slip, or active infection were not eligible for the trial.

Surgical procedure

Patients who met all preoperative eligibility criteria were treated with lumbar discectomy as described by Spengler[6] and were evaluated for a final intraoperative inclusion criterion before enrollment in the trial. At completion of the lumbar discectomy procedure, surgeons used a sizing tool to measure the height and width of the defect in the annulus fibrosus. Patients with a large defect (4–6 mm height and 6–10 mm width) were enrolled in the trial and randomly allocated 1:1 to receive discectomy only (Controls) or to additionally receive a bone-anchored ACD (Barricaid, Intrinsic Therapeutics, Woburn, MA, United States) at completion of the lumbar discectomy. Patients with an annular defect outside of this size range were excluded from further participation in the trial.

In patients assigned to the ACD group, a bone-anchored ACD was implanted as a stand-alone procedure following the lumbar discectomy. A sizing trial under fluoroscopic control was first performed to determine access trajectory and device placement. The ACD was then implanted under fluoroscopic guidance by placing the occlusion component in the annular defect and securing the anchor into an adjacent vertebral body. After correct device placement was confirmed under fluoroscopic guidance, the surgical site was inspected and standard wound closure was performed.

Follow-up and outcomes

Clinical follow-up occurred at 6 weeks, 3 months, 6 months, and annually thereafter for 4 years; patients will continue in follow-up for 5 years. Low-dose CT, MRI, and

flexion-extension X-rays were performed annually. Reoperations were defined as any repeat procedure at the index level including discectomy, supplemental fixation, fusion, or device explant. Clinical outcomes included leg pain severity on a 0 to 100 visual analog scale, Oswestry Disability Index (ODI), SF-36 Physical Component Summary (PCS) score, and SF-36 Mental Component Summary (MCS) score. The minimal clinically important difference (MCID) for each patient-reported outcome was defined as a ≥20-point decrease from baseline for leg pain,[17] ≥15-point decrease from baseline for ODI,[18] ≥5.7-point increase from baseline for PCS,[19] and ≥6.3-point increase from baseline for MCS.[19]

Statistical analysis

Treatment group comparisons were performed with Student's *t*-test for continuous data or Fisher's exact test for categorical data. The risk of reoperation was analyzed with Kaplan–Meier methods and the log-rank test. Treatment-by-subgroup interactions were tested using a Cox proportional hazards model containing the main effects of treatment (ACD or Control), subgroup, and treatment-by-subgroup interaction. Longitudinal patient-reported outcomes were analyzed with mixed-model analysis of variance and adjusted for the confounding effects of reoperations.[20] Statistical significance was set at $P<0.05$ and hypothesis testing was two-sided. Statistical analyses were performed using SAS v9.4 (SAS Institute, Cary, NC, United States).

Results

Between 2010 and 2014, 554 patients with large post-discectomy defects in the annulus fibrosus were enrolled in the trial, including 276 who were randomized to additional treatment with an ACD and 278 who received no additional treatment (Controls). The analysis excluded 4 patients in whom ACD implantation was not attempted due to anatomic constraints, resulting in a sample size of 550 patients (272 ACD, 278 Controls). Baseline patient characteristics were well-matched between treatment groups. Comparing the ACD group to Controls, mean age was 43±11 versus 44±10 years, 57% versus 62% were male, and body mass index was 26±4 kg/m^2 in each group. Intervertebral disc herniation was identified at L4-L5 or L5-S1 in 97% of the cases. Mean leg pain on the visual analog scale was 81±15 in each group despite at least 6 weeks of conservative management. The ACD was successfully implanted in 267 (98.2%) patients; the occlusion component of the device was malpositioned in 4 patients and a nerve root injury occurred in 1 patient.

Compliance with clinical and imaging follow-up was 76% in the ACD group and 72% in the Control group over 4 years (Figure 1). Through 4 years, there were 49 reoperations in 37 ACD patients (0.18 per patient) and 77 reoperations in 55 Control patients (0.28 per patient). At 1 year, the risk of reoperation was 6.7% in the ACD group and 12.9% in Controls. This early benefit of ACD was maintained over 4 years of follow-up with reoperation rates of 14.4% with ACD and 21.1% with Controls (Figure 2). The corresponding hazard ratio (HR) was 0.63 (95% CI: 0.42, 0.96; $P=0.03$), which indicates a 37% reduction in the risk of reoperation with ACD over 4 years. The reduction in reoperation risk with ACD was not significantly influenced by patient age ($P=0.51$), sex ($P=0.34$), body mass index ($P=0.21$), smoking status ($P=0.85$), level of herniation ($P=0.26$), leg pain severity at baseline ($P=0.90$), or ODI at baseline ($P=0.54$) (Figure 3). Risk factors for reoperation in each treatment group are reported in Table 1. In a multivariate Cox proportional hazards model, female sex (HR =2.38; $P<0.01$), and smoking (HR =2.24; $P<0.01$) were independently associated with a higher reoperation risk in the Control group. No patient characteristic influenced the risk of reoperation in the ACD group.

The primary indications for reoperation in each group were reherniation and lumbar/extremity pain or dysfunction. Although the risk of reoperation was lower in the ACD group, the distribution of reoperation techniques was comparable between the groups. Discectomy with or without a fusion procedure was the most common reoperation type in each group. The ACD was removed partially or entirely in 23 reoperations, 5 of which involved device removal with no additional surgeries. None of the reoperations in the ACD or Control group were attributable to morphologic changes in the vertebral endplates. After a review of all operative notes from patients treated with the ACD who underwent reoperation, no report indicated that the presence of the device interfered with surgical planning or altered the operative technique.

All patient-reported outcomes (leg pain, ODI, PCS, and MCS) significantly improved in each group from baseline to 4 years (all $P<0.001$). The magnitude of improvement from baseline tended to be greater in the ACD group versus Controls for leg pain severity (−56 vs −49, $P=0.04$; Figure 4), ODI (−38 vs −34, $P=0.04$; Figure 5), PCS (16.4 vs 14.5, $P=0.11$; Figure 6), and

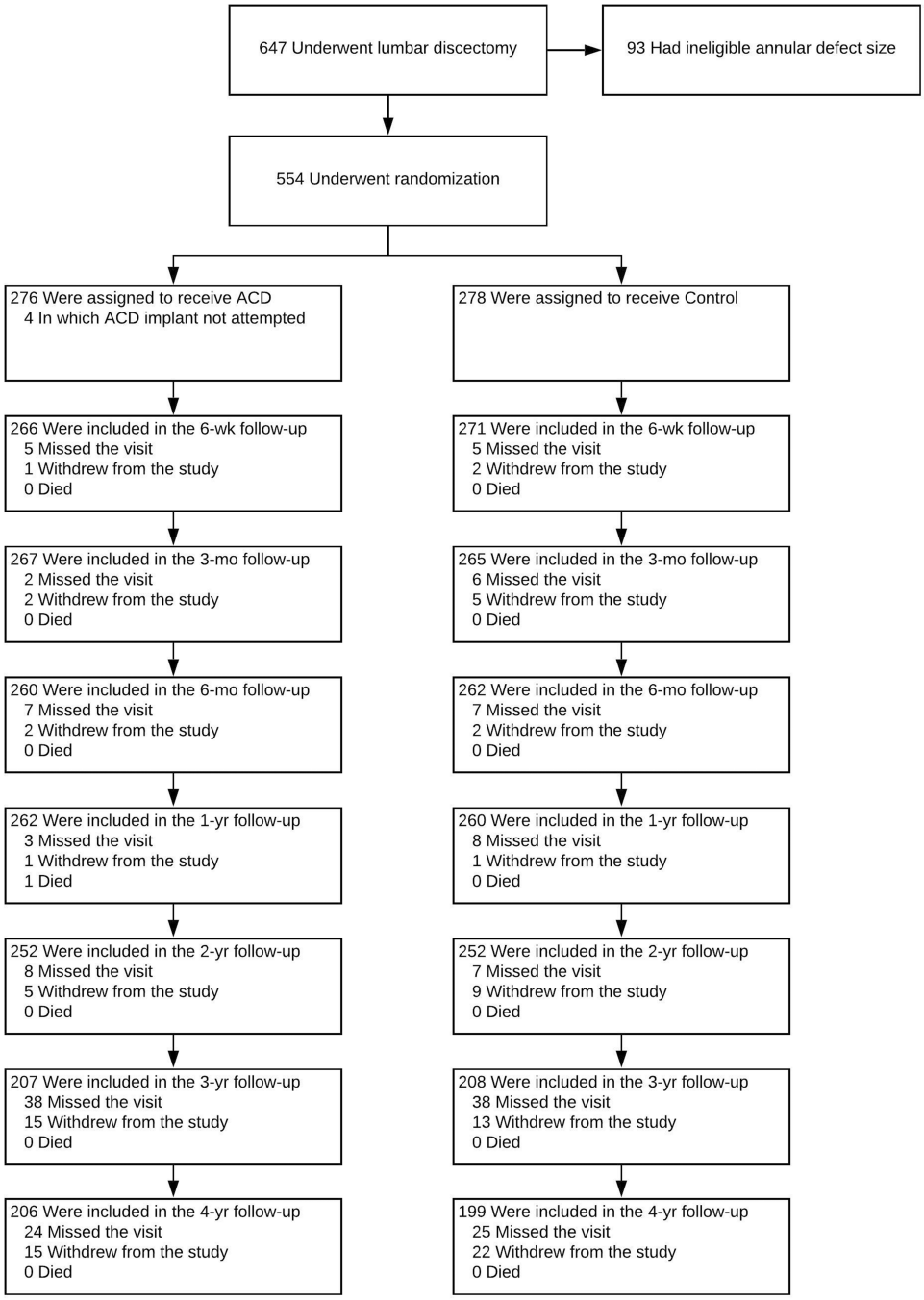

Figure 1 Enrollment and randomization of patients.
Notes: Among 554 randomized patients, 276 were allocated to ACD and 278 to Control. Owing to 4 patients in whom ACD implant was not attempted, the modified intent-to-treat population consisted of 272 patients with attempted ACD implant and 278 patients assigned to Control. Compliance with clinical follow-up at 4 years was 76% with ACD and 72% with Controls.
Abbreviation: ACD, annular closure device.

MCS (10.4 vs 6.2, P=0.02; Figure 7). At 4 years, the percentage of patients who achieved the MCID without a reoperation was proportionally higher in the ACD group compared to Controls for leg pain (P=0.07), ODI (P=0.10), PCS (P=0.02), and MCS (P=0.06) (Figure 8).

Discussion

Patients with a large post-discectomy defect in the annulus fibrosus have a high risk for reoperation.[13] In the current trial, this risk was 21.1% over 4 years of follow-up, which was reduced to 14.4% in patients who received an ACD.

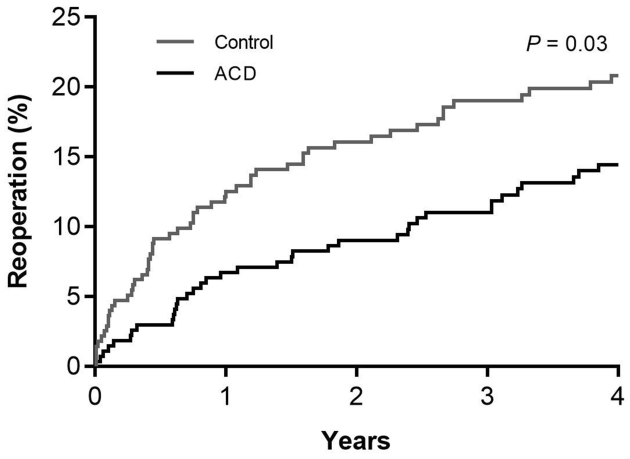

Figure 2 Cumulative risk of reoperation over 4 years of follow-up.
Notes: Risk of reoperation was 14.4% (standard error 2.2%) with ACD and 21.1% (standard error 2.5%) with Controls. Log-rank *P*-value =0.03.
Abbreviation: ACD, annular closure device.

Interestingly, most reoperations occurred early in follow-up with reoperation rates of 6.7% with ACD and 12.0% with Controls at 1 year. Thereafter, the reoperation rate declined considerably to approximately 2.5% annually in each group. Thus, it appears that in patients with large postsurgical annular defects, the excess risk of reoperation is mainly confined to the first postoperative year, after which reoperation rates approximate that of the general lumbar discectomy population.[21] Our results demonstrated the ability of an ACD to significantly reduce the risk of reoperation in the first year and to maintain this benefit through 4 years of follow-up.

Both treatment groups reported statistically significant and clinically meaningful improvements in leg pain and ODI over 4 years, with results slightly favoring patients treated with an ACD. Similarly, health-related quality of life considerably improved on the PCS and MCS in both groups, with slightly greater improvements noted for the ACD group relative to Controls. A striking observation in this study was the deleterious impact of lumbar disc herniation on preoperative physical function. At baseline, the

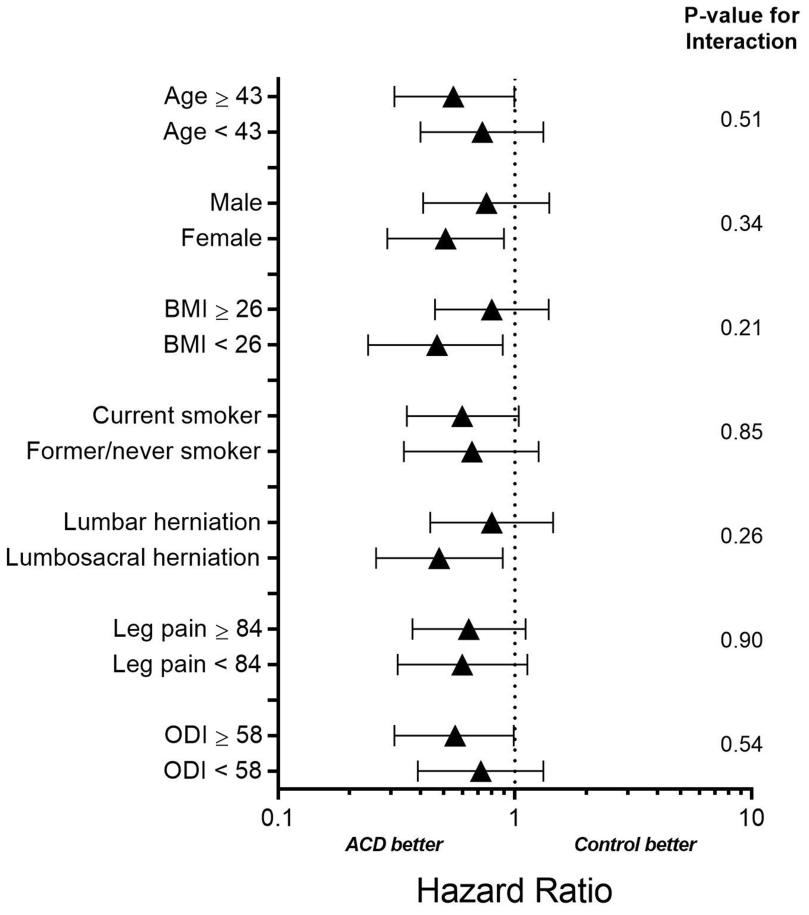

Figure 3 Hazard ratio for reoperation by baseline patient characteristics.
Notes: Plotted values are hazard ratio and 95% confidence interval. Hazard ratio <1 indicates lower risk with ACD; >1 indicates higher risk with ACD. Continuous variables are categorized by the median value.
Abbreviations: ACD, annular closure device; BMI, body mass index; ODI, Oswestry Disability Index.

Table 1 Predictors of reoperation through 4 years by treatment group

Characteristic	Unit	ACD		Control	
		HR (95% CI)	*P*	HR (95% CI)	*P*
Univariate					
Current smoker	Yes vs no	1.86 (0.95, 3.67)	0.07	2.13 (1.21, 3.72)	<0.01
Sex	Female vs male	1.42 (0.73, 2.77)	0.30	2.09 (1.18, 3.69)	0.01
ODI	Per 10-mm increase	1.02 (0.73, 1.41)	0.91	0.86 (0.67, 1.10)	0.22
Leg pain	Per 10-mm increase	1.01 (0.79, 1.29)	0.94	1.14 (0.92, 1.42)	0.23
Age	Per 10-yr decrease	1.24 (0.92, 1.68)	0.16	0.89 (0.66, 1.19)	0.42
Index level	L5-S1 vs lumbar	1.62 (0.82, 3.20)	0.17	0.88 (0.50, 1.56)	0.67
BMI	Per 5-kg/m^2 increase	1.18 (0.81, 1.73)	0.40	1.03 (0.73, 1.39)	0.95
Multivariate					
Sex	Female vs male	—	—	2.38 (1.39, 4.06)	<0.01
Current smoker	Yes vs no	—	—	2.24 (1.30, 3.85)	<0.01

Note: Results derived from Cox proportional hazards model.
Abbreviations: ACD indicates annular closure device; BMI, body mass index; CI, confidence interval; HR, hazard ratio; ODI, Oswestry Disability Index.

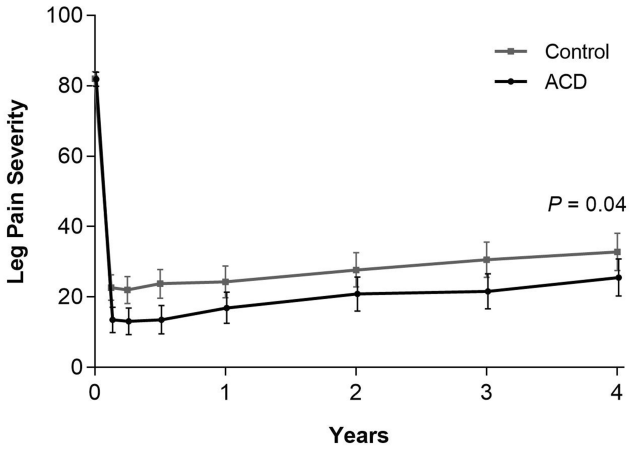

Figure 4 Change in leg pain severity over 4 years of follow-up.
Note: Plotted values are mean and 95% confidence interval.
Abbreviation: ACD, annular closure device.

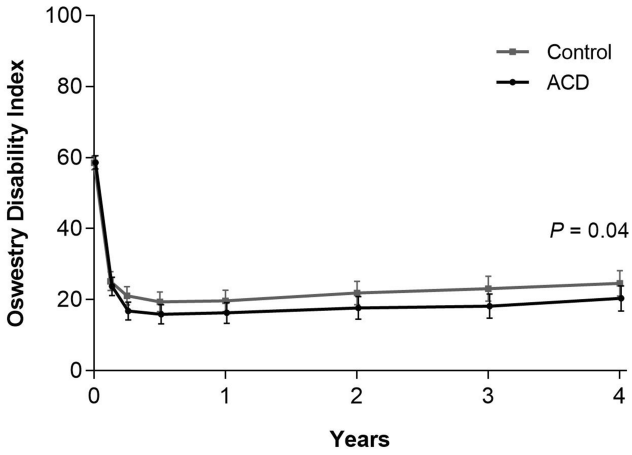

Figure 5 Change in Oswestry Disability Index over 4 years of follow-up.
Notes: Plotted values are mean and 95% confidence interval.
Abbreviation: ACD, annular closure device.

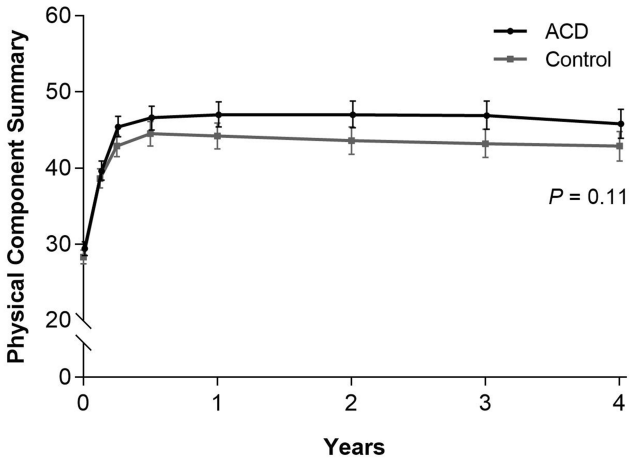

Figure 6 Change in Physical Component Summary score from SF-36 questionnaire over 4 years of follow-up.
Note: Plotted values are mean and 95% confidence interval.
Abbreviations: ACD, annular closure device; SF-36, 36-Item Short Form Health Survey.

mean PCS scores in each group were in the 10th percentile of population-based norms.[22] Following lumbar discectomy, PCS scores peaked at 6 months and were maintained at this level for 4 years such that postoperative PCS values corresponded to the 41st and 34th percentiles in the general population with ACD and Control, respectively. Although cost-utility data were not a focus of this paper, the combination of lower reoperation rates and better improvements in health-related quality of life identified in the current study with the ACD suggest the potential for cost savings with routine ACD use in high-risk patients, a conclusion that has been corroborated by others.[23,24]

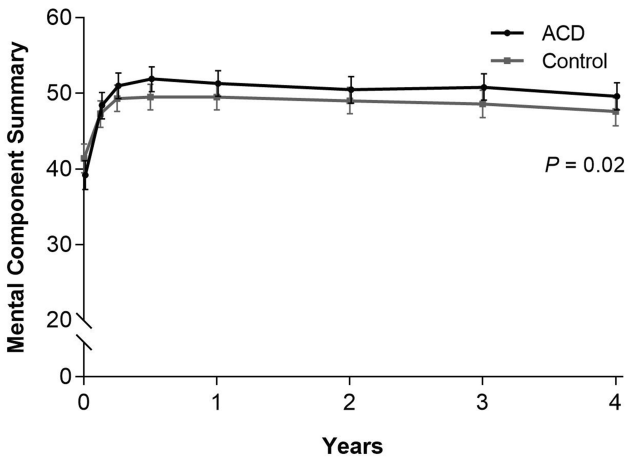

Figure 7 Change in Mental Component Summary score from SF-36 questionnaire over 4 years of follow-up.
Note: Plotted values are mean and 95% confidence interval.
Abbreviations: ACD, annular closure device; SF-36, 36-Item Short Form Health Survey.

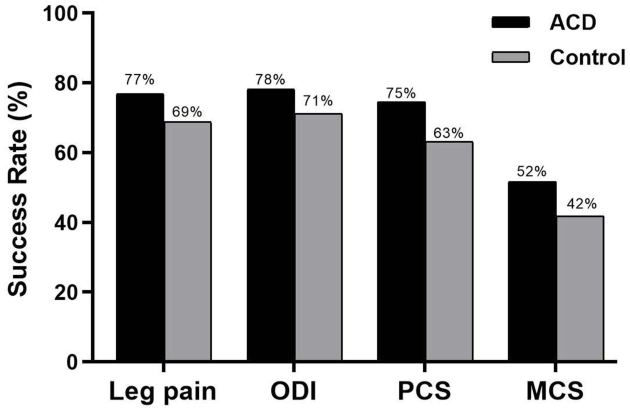

Figure 8 Percentage of patients achieving the minimal clinically important difference in patient-reported outcomes over 4 years of follow-up.
Notes: Minimal clinically important difference defined as reoperation-free improvement from baseline of at least 20 points for leg pain, 15 points for ODI, 5.7 points for PCS, and 6.3 points for MCS (all reported on 0–100 scale).
Abbreviations: ACD, annular closure device; MCS, Mental Component Score; ODI, Oswestry Disability Index; PCS, Physical Component Score.

In the Control group composed of patients with large annular defects, the risk of reoperation was 21.1% at 4 years, which is double the 10.5% reoperation rate reported through 4 years in the SPORT trial.[25] This finding parallels that of a meta-analysis that reported a large annular defect more than doubled the risk of reoperation.[13] The reoperation rate in patients treated with lumbar discectomy only in the current trial was comparable to rates reported in previous studies of patients with large annular defects.[26,27] Additionally, female sex and current smoking status were identified as independent risk factors for reoperation in the Control group. While the deleterious influence of smoking on post-discectomy reoperation rates has been reported by others,[28] the association of female sex on reoperation risk is less clear as most studies report no independent association of sex.[12,25,28,29] In this study, the risk of reoperation in females with large post-surgical annular defects was 30.3% through 4 years, and this risk was significantly lower (17.4%) among females treated with an ACD. Additional research to understand the mechanisms of sex differences in lumbar disc surgery is crucial for optimal treatment outcomes.

The conclusions of this trial were strengthened by the randomized trial design, large sample size, and the longest follow-up duration of any study in patients with large post-discectomy annular defects. There are also several limitations of this trial. First, the results presented here are applicable only to patients with large post-discectomy annular defects, who account for approximately 30% of all lumbar discectomy cases.[13] Implantation of an ACD in patients with small annular defects cannot be justified clinically given the inherently low risk of symptom recurrence in these individuals. Additional patient characteristics that are crucial to achieving positive results include adequate disc height and non-osteoporotic bone mineral density of the lumbar spine. Second, the decision to reoperate involved shared decision making between the patient and surgeon and, therefore, there is potential for bias in the reported reoperation rates. Finally, 5-year follow-up in this study is ongoing and these long-term outcomes are anxiously awaited to provide final comparative efficacy, safety, and cost-utility results of bone-anchored ACD implantation.

Conclusion

The addition of a bone-anchored ACD to lumbar discectomy in patients with large post-surgical annular defects reduces the risk of reoperation and provides for better long-term pain and disability relief over 4 years compared to lumbar discectomy only.

Abbreviations

ACD, annular closure device; HR, hazard ratio; MCID, minimal clinically important difference; MCS, Mental Component Summary; ODI, Oswestry Disability Index; PCS, Physical Component Summary.

Data sharing statement

All authors have agreed to the submission and publication of this manuscript. The authors confirm that requests for

data underlying the findings described in this manuscript may be made to the corresponding author starting 1 year following publication of this article.

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There were no contributors to the article other than the authors. No writing assistance regarding this study was received.

Author contributions

All authors contributed to conception and design, LM contributed to data analysis, DN, MA, HK, JP, CF, and PV contributed to data interpretation, and all authors contributed to drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

Mark P Arts reports consultancy with Intrinsic Therapeutics; personal fees from Zimmer-Biomet, EIT, and Silony, outside the submitted work; and receipt of royalties from EIT. Larry Miller reports consultancy with Intrinsic Therapeutics. The authors report no other conflicts of interest in this work.

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