Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial

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Abstract

Background Context: Patients with large annular defects after lumbar discectomy for disc herniation are at high risk of symptomatic recurrence and reoperation.

Purpose: The present study aimed to determine whether a bone-anchored annular closure device, in addition to lumbar microdiscectomy, resulted in lower reherniation and reoperation rates plus increased overall success compared with lumbar microdiscectomy alone.

Design: This is a multicenter, randomized superiority study.

Patient Sample: Patients with symptoms of lumbar disc herniation for at least 6 weeks with a large annular defect (6-10 mm width) after lumbar microdiscectomy were included in the study.

Outcome Measures: The co-primary end points determined a priori were recurrent herniation and a composite end point consisting of patient-reported, radiographic, and clinical outcomes. Study success required superiority of annular closure on both end points at 2-year follow-up.

Methods: Patients received lumbar microdiscectomy with additional bone-anchored annular closure device (n=276 participants) or lumbar microdiscectomy only (control; n=278 participants). This research was supported by Intrinsic Therapeutics. Two authors received study-specific support morethan $10,000 per year, 8 authors received study-specific support less than $10,000 per year, and 11 authors received no study-specific support.

Results: Among 554 randomized participants, 550 (annular closure device: n=272; control: n=278) were included in the modified intent-to-treat efficacy analysis and 550 (annular closure device: n=267; control: n=283) were included in the as-treated safety analysis. Both co-primary end points of the study were met, with recurrent herniation (50% vs. 70%, P<.001) and composite end point success (27% vs. 18%, P=.02) favoring annular closure device. The frequency of symptomatic reherniation was lower with annular closure device (12% vs. 25%, P<.001). There were 29 reoperations in 24 patients in the annular closure device group and 61 reoperations in 45 control patients. The frequency of reoperations to address recurrent herniation was 5% with annular closure device and 13% in controls (P=.001). End plate changes were more prevalent in the annular closure device group (84% vs. 30%, P<.001). Scores for back pain, leg pain, Oswestry Disability Index, and health-related quality of life at regular visits were comparable between groups over 2-year follow-up.

Conclusions: In patients at high risk of herniation recurrence after lumbar microdiscectomy, annular closure with a bone-anchored implant lowers the risk of symptomatic recurrence and reoperation. Additional study to determine outcomes beyond 2 years with a bone-anchored annular closure device is warranted.

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