

# Lumbar disc reherniation prevention with a bone-anchored annular closure device: 1-year results of a randomized trial

Medicine 2019; 98(44):e17760. Doi: 10.1097/MD.00000000000017760

<http://doi.org/10.1097/MD.00000000000017760>.

W van den Brink, C Flüh, LE Miller, PD Klassen, R Bostelmann

## Abstract

**Background:** The risk of recurrent herniation after lumbar discectomy is highest during the first postoperative year. The purpose of this study was to determine whether implantation of a bone-anchored annular closure device (ACD) following limited lumbar discectomy reduced the risk of recurrent herniation and complications during the first year of follow-up compared to limited lumbar discectomy alone (Controls) and whether this risk was influenced by patient characteristics.

**Methods:** In this randomized multicenter trial, patients with symptomatic lumbar disc herniation and with a large annular defect following limited lumbar discectomy were randomized to bone-anchored ACD or Control groups. The risks of symptomatic reherniation, reoperation, and device- or procedure-related serious adverse events were reported over 1 year of follow-up.

**Results:** Among 554 patients (ACD 276; Control 278), 94% returned for 1-year follow-up. Bone-anchored ACD resulted in lower risks of symptomatic reherniation (8.4% vs. 17.3%,  $P=.002$ ) and reoperation (6.7% vs. 12.9%,  $P=.015$ ) versus Controls. Device- or procedure-related serious adverse events through 1 year were reported in 7.1% of ACD patients and 13.9% of Controls ( $P=.009$ ). No baseline patient characteristic significantly influenced these risks.

**Conclusions:** Among patients with large annular defects following limited lumbar discectomy, additional implantation with a bone-anchored ACD lowered the risk of symptomatic reherniation and reoperation over 1 year follow-up. Device- or procedure-related serious adverse events occurred less frequently in the ACD group. These conclusions were not influenced by patient characteristics.

This article contains off-label use information. Please use medical discretion when reviewing this article.

**Barricaid is approved for the following indications for use:**

Reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

**Financial disclosure:**

One or more authors have received financial compensation from Intrinsic Therapeutics. Full financial disclosures can be found in the respective manuscript.

**WARNING:** This product has labeling limitations. See package insert for additional warnings, precautions and possible adverse effects.

**CAUTION:** USA law restricts this device to sale by or on the order of physician. All medical devices have associated risks. Please refer to the package insert and other labeling for a complete list of indications, contraindications, precautions and warnings ([www.barricaid.com/us-en/instructions](http://www.barricaid.com/us-en/instructions)). For further information on Barricaid, contact your Intrinsic representative.