

# Post-lumbar discectomy reoperations that are associated with poor clinical and socioeconomic outcomes can be reduced through use of a novel annular closure device: Results from a 2-year randomized controlled trial

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## Abstract

**Introduction:** Lumbar discectomy patients with large annular defects are at a high risk for reherniation and reoperation, which could be mitigated through the use of an annular closure device (ACD). To identify the most effective treatment pathways for this high-risk population, it is critical to understand the clinical outcomes and socioeconomic costs among reoperated patients as well as the utility of ACD for minimizing reoperation risk.

**Methods:** This was a post hoc analysis of a prospective, multicenter, randomized controlled trial (RCT) designed to investigate the safety and efficacy of an ACD. All 550 patients (both ACD treated and control) from the RCT with follow-up data through 2 years were included in this analysis (69 reoperated and 481 non-reoperated). Reoperations were defined as any revision surgery of the index level, regardless of indication. Equivalent U.S. Medicare expenditures for reoperations were estimated through cost multipliers derived from the commercially available PearlDiver database.

**Results:** A significantly greater number of control patients (45/278; 16%) compared to ACD patients (24/272; 9%) underwent a revision surgery at the index level within 2 years of followup ( $p=0.01$ ). At 2 years of follow-up, the reoperated patients had significantly worse Oswestry Disability Index scores and visual analog scale for leg and back pain scores compared to their non-reoperated counterparts ( $p<0.0001$ ). The total estimated direct medical costs for reoperation were US \$952,348 (\$13,802 per reoperated patient), with control patients accounting for the majority of this cost burden (\$565,188; 59%).

**Conclusions:** Post-discectomy reoperation is associated with significantly increased patient morbidity, missed work, and direct treatment costs in a population at high risk for reherniation. Annular closure helped minimize this clinical and socioeconomic burden by reducing the incidence of reoperation by nearly 50% (16% control vs 9% ACD).

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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.

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