

Disc Repair Technologies

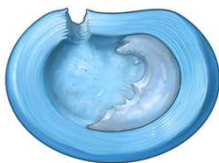
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Why do we care?

- Generally good results from discectomy
 - Success rates between 80 and 98%
- Reherniation rates can be as high as 15% in the early postoperative period
 - 27% require a repeat surgery within 10 years
- One study showed 25% reherniation rate at 2 years with 50% of those symptomatic

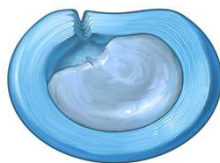
Aggressive Discectomy (AD)



Reduces reherniation, decreases native disc preservation (26% disc collapse in 2 years), worse long-term patient outcome.¹⁸

Poor Disc Preservation
Low Herniation Risk

Minimal Discectomy



Increases reherniation (2x more than aggressive), increases native disc preservation, better long term patient outcome (2.5x less reported incidents of recurrent back or leg pain compared to AD).⁸

Good Disc Preservation
High Reherniation Risk

Is There Any Literature?

Spine
RANDOMIZED TRIAL

SPINE Volume 36, Number 14, pp 1111-1119
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Prospective, Multicenter, Randomized, Controlled Study of Anular Repair in Lumbar Discectomy

Two-Year Follow-up

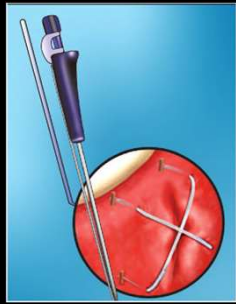
Alexander Bailey, MD,* Ali Araghi, DO,† Scott Blumenthal, MD,‡ George V. Huffmon, MD,§ and the Anular Repair Clinical Study Group

- Prospective, single blind, randomized controlled trial
- 2:1 patient randomization
 - 478 with repair (22 attempted but not implanted)
 - 250 without repair
- 55.7% lost to follow up by 1 year
- 40% overall reduction in reherniation (p=.131)
 - 50% in high volume surgeons (p=.049)

What are our options?

Anulex Xclose

- Statistically significant reduction in revision surgery at 3- and 6-month time points
- Received 510K for "soft tissue repair system"
- Post-market study for annulus repair caused warning letter from FDA for IDE
- All marketing pulled



Magellan DART

- Disc Annular Repair Technology System
- Received European CE Mark in 2009
- No FDA marketing clearance to date

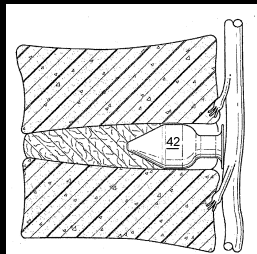


FIG. 8

Barricaid

- Polymeric mesh that anchors to the endplate
- 7 year study with 554 patients that had 50.8% no reherniation rate vs 30.1% in control at 24 months
- 93.1% adverse events vs 78% in control
 - 88% had endplate lesions
- FDA voted 5-8 against recommending approval for use in December 2017



Anchor AnchorKnot

[VIDEO](#)

Anchor AnchorKnot

- "Indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure"
- First procedure performed in February 2017 at Texas Back Institute
- No current studies, relying on studies from Anulex Xclose at this time

