Disc Repair Technologies

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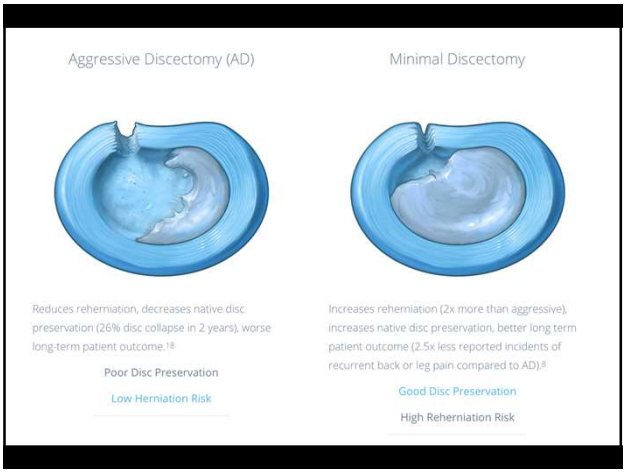
TEXAS SPINECARE™ CENTER

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



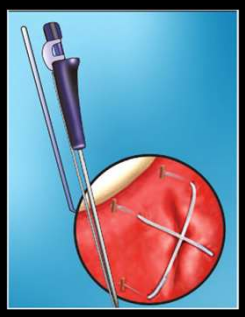
Is There Any Literature?

- 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

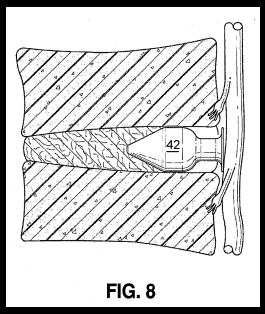


FIG. 8

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