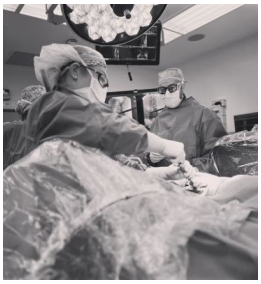
Ace in the Hole: the role of a bone anchored annular closure device

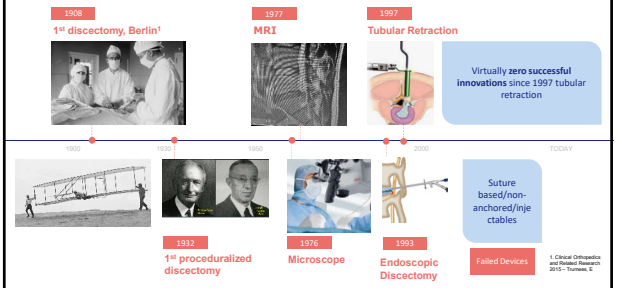
Betsy Grunch, MD

Betsy Grunch, MD, FAANS, FACS, FCNS

- The Longstreet Clinic, Gainesville GA
  - (2013-present)
- University of Georgia, BS Biology (2002)
- Medical College of Georgia, MD (2007)
- Duke University, Neurosurgery Resident (2007-2013)
- Duke University, Synthes Spine Fellowship (2011-2012)
- Board certified, American Board of Neurological Surgery, 2015

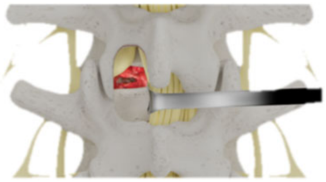


Discectomy – The Forgotten Procedure



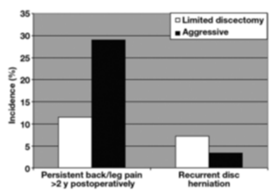
Clinical Need

Large Defects = High Risk of Recurrence/ Reoperation



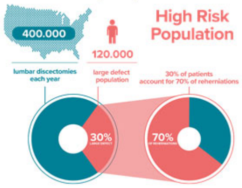
Preserving Disc Material is the Best Thing You Can Do For the Disc

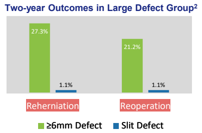
- **Less back pain**:
  - Removing more nucleus substantially increases the risk of low back pain[1,2,3] (see figure from McGirt et al)
- **Less disc height loss**:
  - Removing more nucleus is associated with disc height loss[4] (p=0.01)
- **Less facet degeneration**:
  - Removing more nucleus has been associated with facet degeneration[5] (p<0.08), which in turn is associated with chronic low back pain[6]



1. McGirt et al,. Neurosurg. 2009
2. Watters W, McGirt M. Spine J. 2009.
3. Ran et al. PLoS ONE 2015.
4. McGirt et al. Spine 2009.
5. Trummer et al. ClinNeurolNeurosurg 2013.
6. Manchikanti et al. Pain Physician 2001.

- ~1/3 of discectomy patients have big holes
  - This minority of patients account for 70% of **all** reherniations[1]





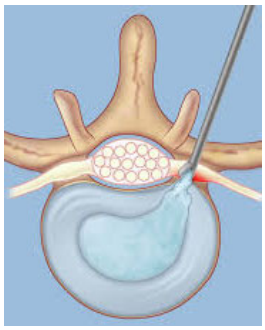
[1]Miller et al. Spine 2018
[2]Carragee et al. JBJS 2003.

Outline

- History of Annular closure
  - Clinical need
  - Failed technologies
- Barricaid Bone-Anchored Annular Closure RCT
- Barricaid: clinical and reimbursement skepticism

Goals for Lumbar Discectomy

- Treat sciatica
- Prevent disc reherniation
- Reduce back pain
- Maintain disc height
- Avoid acceleration of degenerative process



Discectomy Outcomes

Viewed as successful:

- Clear indication
- Minimally invasive surgery
- Quick patient recovery
- Many single center studies show 90%+ good results[1]

→ **But are the results really that good?**

- Population based studies are less positive

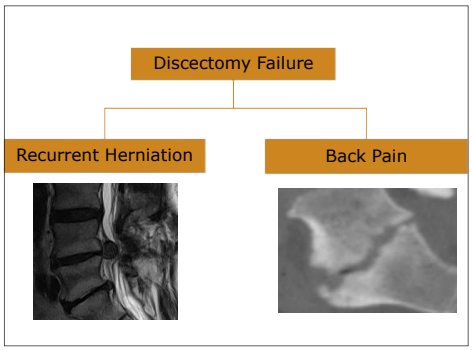
[1]Microlumbar discectomy: Williams Spine 1986

Discectomy Outcomes

- Swedish Spine Registry[1]
  - **2796** discectomy patients
  - **Only 76% patient satisfaction at 1 Yr**
- Washington State Study[2]
  - **3938** discectomy patients
  - **15% reop rate at 5 Yrs**
- Finnish Study[3]
  - **25'359** discectomy patients
  - **18.9% reop rate at 9 Yrs**

[1]The Swedish Spine Register: Strömqvist et al; Eur Spine J 2009
[2]Repeat Surgery Following herniated disc: Martin et al; Spine 2012
[3]Reoperations after lumbar disc surgery: Keskimäki et al; Spine 2000

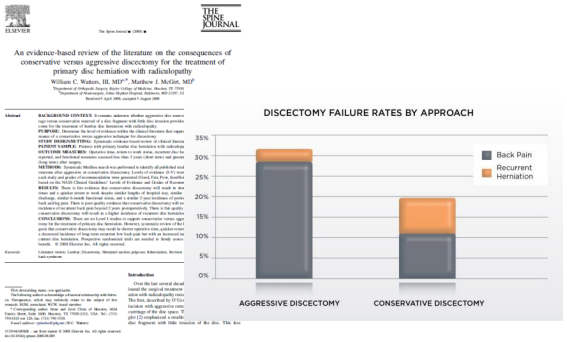
Why do Patients fail?



Recurrent Herniation

- Literature rate of 3 – 18%
- Greater risk in large annular defects
- Aggressive nucleus removal reduces risk, but increases back pain and segmental collapse
- Disc collapse leads to back pain and Modic changes

Literature: Watters and McGirt, Spine Journal 2009

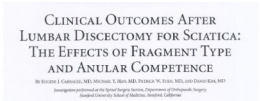


An evidence-based review of the literature on the consequences of conservative versus aggressive discectomy for the treatment of primary disc herniation with radiculopathy

William C. Watters, III, MD[a,*], Matthew J. McGirt, MD[b]

DISCECTOMY FAILURE RATES BY APPROACH

Literature: Carragee et al, JBJS 2003

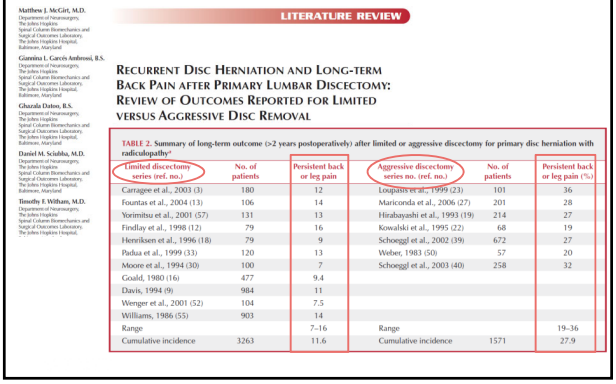


CLINICAL OUTCOMES AFTER LUMBAR DISCECTOMY FOR SCIATICA: THE EFFECTS OF FRAGMENT TYPE AND ANULAR COMPETENCE

TABLE III. Postoperative Patient Characteristic and Outcome Assessments According to Fragment Type and Anular Defect

	All Patients	Fragment-Fissure Group	Fragment-Defect Group	Fragment-Contained Group	No Fragment-Contained Group
No. of patients	180	89	33	42	16
Duration of postoperative sick leave* † *(wk)*	1.2 (0-8)	1.2 (0-8)	1.3 (0-4)	1.0 (0-4)	1.7 (0-4)
Postoperative Oswestry score * *(points)*	12.7 (0-69)	11.6 (0-28)	16.4§ (2-48)	9.2 (0-19)	20.1# (0-69)
Standard score * *(points)*	8.5 (2.8-10)	9.0§ (4.1-10)	8.0 (3.9-10)	8.8 (6.0-10)	6.0# (2.8-9.5)
Rate of recurrent/persistent sciatica †	11.7% (21)	1.1% (1)	27.3% (9)	11.9% (5)	37.5% (6)
Rate of documented rehernation †	8.9% (16)	1.1%§ (1)	27.3%§ (9)	9.5% (4)	12.5% (2)
Rate of reoperation †	6.1% (11)	1.1% (1)	21.2%# (7)	4.8% (2)	6.3% (1)

Literature: McGirt et al, Journal of Neurosurgery 2009



LITERATURE REVIEW

RECURRENT DISC HERNIATION AND LONG-TERM BACK PAIN AFTER PRIMARY LUMBAR DISCECTOMY: REVIEW OF OUTCOMES REPORTED FOR LIMITED VERSUS AGGRESSIVE DISC REMOVAL

TABLE 2. Summary of long-term outcome (>2 years postoperatively) after limited or aggressive discectomy for primary disc herniation with radiculopathy*

Limited discectomy series (ref. no.)	No. of patients	Persistent back or leg pain	Aggressive discectomy series no. (ref. no.)	No. of patients	Persistent back or leg pain (%)
Carragee et al., 2003 (3)	180	12	Loupasis et al., 1999 (23)	101	36
Fountas et al., 2004 (13)	106	14	Mariconda et al., 2006 (27)	201	28
Yorimitsu et al., 2001 (57)	131	13	Hirabayashi et al., 1993 (19)	214	27
Findlay et al., 1998 (12)	79	16	Kowalski et al., 1995 (22)	68	19
Henriksen et al., 1996 (18)	79	9	Schoeggl et al., 2002 (39)	672	27
Padua et al., 1999 (33)	120	13	Weber, 1983 (50)	57	20
Moore et al., 1994 (30)	100	7	Schoeggl et al., 2003 (40)	258	32
Gould, 1980 (16)	477	9.4			
Davis, 1994 (9)	984	11			
Wenger et al., 2001 (52)	104	7.5			
Williams, 1986 (55)	903	14			
Range		7–16	Range		19–36
Cumulative incidence	3263	11.6	Cumulative incidence	1571	27.9

Literature: McGirt et al, Spine 2009

A Prospective Cohort Study of Close Interval Computed Tomography and Magnetic Resonance Imaging After Primary Lumbar Discectomy

Factors Associated With Recurrent Disc Herniation and Disc Height Loss

Matthew J. McGirt, MD,* Sandro Eustacchio, MD,† Peter Varga, MD,‡ Milorad Vilendecic, MD,§ Martin Trummer, MD,† Miro Gorensek, MD,¶ Darko Ledic, MD,‖ and Eugene J. Carragee, MD**

Table 2. Comparison of Patient Age and Weight, Preoperative Disc Volume, Preoperative Disc Height, Volume of Disc Removed, Proportion of Disc Removed, and Anular Defect Size Between Patients in the Top Quartile (>33%) *Versus* Bottom Quartile (<8%) of 2-Year Disc Height Loss After Discectomy

Variable	>33% Disc Height Loss	<8% Disc Height Loss	*P* (*t* test)	Regression Analysis Regression Coefficient, *P*
Age (yr)	40 ± 8	42 ± 7	0.22	−0.004, *P* = 0.11
Weight (kg)	81 ± 15	79 ± 11	0.67	0.003, *P* = 0.09
Preoperative disc volume (cm^3)	8.2 ± 3.1	8.1 ± 2.3	0.91	0.007, *P* = 0.36
Preoperative disc height (mm)	6.2 ± 1.8	6.7 ± 1.2	0.65	0.006, *P* = 0.66
Volume of disc removed (cm^3)	2.4 ± 1.4	1.5 ± 0.6	0.01	0.041, *P* = 0.02
Proportion of disc removed (%)	29 ± 14	22 ± 12	0.09	0.194, *P* = 0.17
Anular defect size (mm^2)	33 ± 20	36 ± 12	0.62	0.001, *P* = 0.93

Literature: Thomé et al, Journal Neurosurgery Spine 2005

- Clinical outcome after sequestrectomy better than after microdiscectomy
- **Recurrent disc herniation** rate (≤ 18 mths):
  - **discectomy 5%**
  - **sequestrectomy 10%**

J Neurosurg Spine 2:271–278, 2005

Outcome after lumbar sequestrectomy compared with microdiscectomy: a prospective randomized study

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Departments of Neurosurgery and Neuroradiology, University Hospital Mannheim, Germany

Object. Microdiscectomy currently constitutes the standard treatment for herniated lumbar discs. Although limiting surgery to excision of fragments has occasionally been suggested, prospective data are lacking. Therefore, the objective of this study was to compare early outcome and recurrence rates after sequestrectomy and microdiscectomy.

Methods. Eighty-four consecutive patients 60 years of age or younger who harbored free, subligamentary, or transanular herniated lumbar discs refractory to conservative treatment were randomized to one of two treatment groups. Intraoperative parameters and findings were documented as well as pre- and postoperative symptoms such as pain, Patient Satisfaction Index (PSI), Prolo Scale score, and Short Form (SF)–36 subscale results. Follow up of at least 12 months was available in 73 patients (87%).

Preoperative intergroup symptoms did not differ significantly. Surgery was significantly shorter in the sequestrectomy-treated group. Overall, low-back pain and sciatica were drastically reduced in both groups and most sensorimo-

Annular Repair: Challenges

- Extremely high pressures (> 2.3MPa)[1]
- Extreme loads (4kN)[1]
- High degree of motion
- Generalized annular degeneration
- Poor healing[2]

1) In vivo measurements of pressures in the intervertebral disc, Wilke Spine 1999
2) Effect of anular repair on the healing strength of intervertebral disc Ahlgren Spine 2000

Annular Repair: Challenges

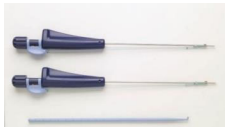
- Suture and glue failed to prevent reherniation
- No actual standard for prevention of disc rehernation
- The implantation of non-cell-based materials to prevent the recurrent disc herniation: Eur Spine J 2007 Wang et al.:
- Four materials, i.e., gelfoam, platinum coil, bone cement and tissue glue, were delivered into the discs via percutaneous spinal needle. They found that the disc injury could not recover after 2 months of healing, and the disc implantation affected the degree of disc integrity

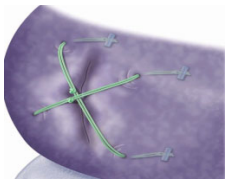
Annular closure device: Anulex Technologies 2006 - 2009

- Spinal disc annulus reconstruction method and spinal disc annulus stent
- **Inclose Surgical Mesh System**™ - a mesh braided implant used to provide a barrier and scaffold for soft tissue repair. Inserted into the hole (defect) and expanded thereby "plugging" the hole.

Annular closure device: Anulex Technologies 2009 - 2014

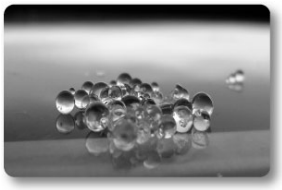
- **Xclose Tissue Repair System™** - a method of soft tissue re-approximation of the anulus fibrosus after a lumbar discectomy procedure. Used to repair the defect at the time of the initial procedure.
- Sutures placed to re-approximate the anular tissue and seal the defect. Due to perceived off-label promotion, they received a warning letter in February, 2011 from the FDA that has substantially disrupted their operations - sold IP and closed in 2014.





Annular closure device: Orthonics

- Orthonics's technology has the ability to direct differentiation and promote **growth of bone and cartilage cells**. The Company visualizes this technology as an *annular repair to prevent recurrent disc herniation*. The technology utilizes the signalizing mechanism of micro-textured **hydrogel to cause cell differentiation and ingrowth of cartilage tissue** to restore function of intact annulus.



Annular closure device: Warsaw Orthopedic

Warsaw Orthopedic, Inc. – a subsidiary of Medtronic, Inc.
Invention/Patent: systems and methods for repairing anulus defects.

Systems include scaffolds, attachment members and anchors.
Scaffold - acts a plug to substantially fill the anulus defect.
The Anchors - secured to the vertebral bodies on each side of the disc space

Annular closure device: Warsaw Orthopedic

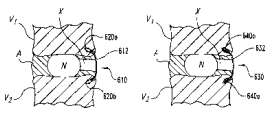


Fig. 28

Fig. 29

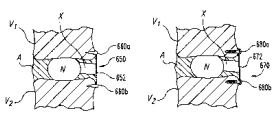


Fig. 30

Fig. 31

Annular closure device: Warsaw Orthopedic

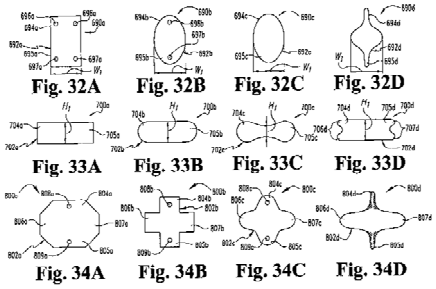


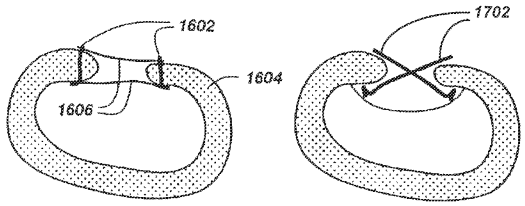
Fig. 32A Fig. 32B Fig. 32C Fig. 32D

Fig. 33A Fig. 33B Fig. 33C Fig. 33D

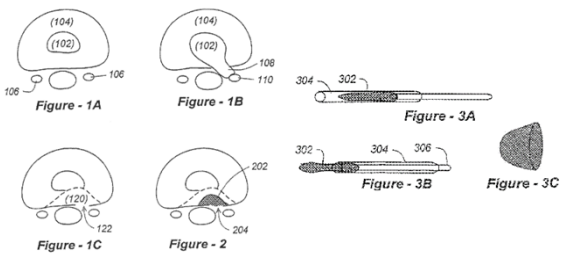
Fig. 34A Fig. 34B Fig. 34C Fig. 34D

Annular closure device: Anova Corporation

Methods and apparatus for treating disc herniation and preventing the extrusion of interbody bone graft



Annular closure device: Anova Corporation



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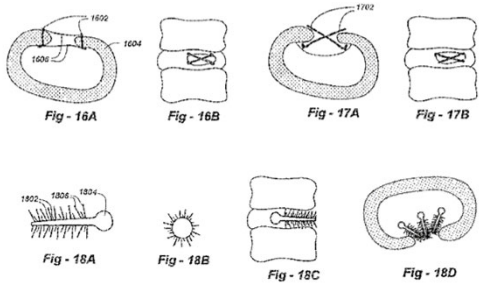

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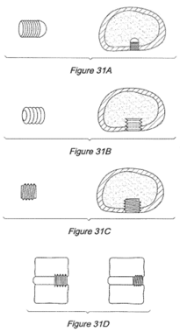


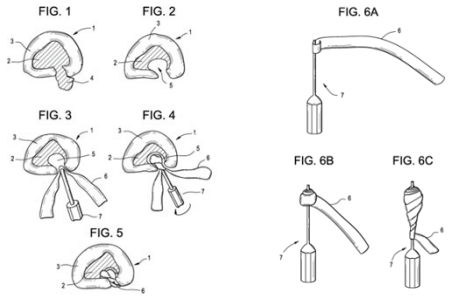
- Animal studies research only
- Never marketed their product
- Company closed

Annular closure device: Depuy Acromed

- Insertion repair material; plugging; porous, biocompatible strip
- SIS – **Small Intestinal Submucosa** – problems with inflammation
- Never used in the disc – only animal studies
- Company backed away

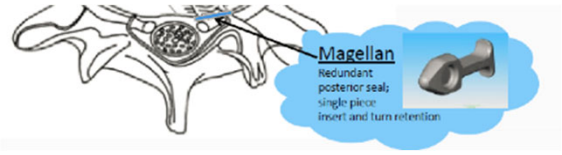
Annular closure device: Depuy Acromed

Insertion repair material; plugging; porous, biocompatible strip

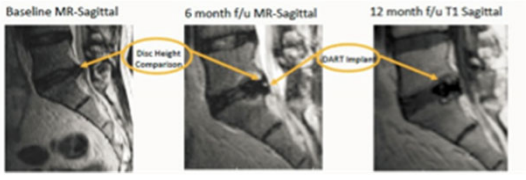


Magellan Spine Corporation

- The DART (Disc Annular Repair Technology) was a solid-state PEEK-Optima "bullet" with a redundant posterior seal.



Magellan Spine Corporation

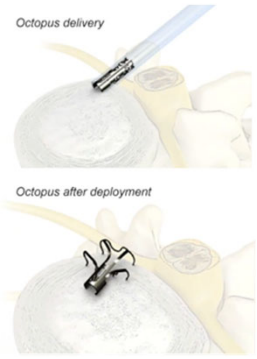


3 month CT Sagittal

The company had an issued patent, several patent applications and performed a first-in-man study with 20 patients and results of 2+ years. The company's assets were liquidated in June 2012.

Newvert

- The Octopus is a deformable nitinol frame that expands in situ upon delivery. It appears that stability is to be gained from interdigitation of nitinol legs into the surrounding anulus.
- After 2012 that included four press releases describing the formation, successful cadaver testing in Prof. Wilke's lab, and a market survey, the company has been quiet for the past 14 months.



Future: Euro-DISC

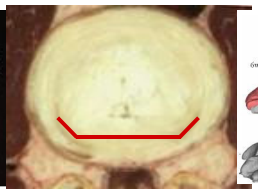
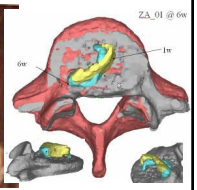
- Clinical experience in **cell-based therapeutics:** disc chondrocyte transplantation.
  - A treatment for degenerated or damaged intervertebral disc.
- Chondrocytes that have been removed from damaged cartilaginous tissues maintain a **capacity to proliferate**, produce and secrete matrix components and respond to physical stimuli such as dynamic loading.

Annular closure device Future: Euro-DISC

- In 2002 a prospective, controlled, randomised, multi-center study, EuroDISC, showed a **clinically significant reduction of low back pain and this was shown by all pain score systems (VAS, Owestry).**
- Decreases in **disc height** over time were only found in the control group, and of potential significance, intervertebral discs in **adjacent segments appeared to retain hydration** when compared to those adjacent to levels that had undergone discectomy without cell intervention.

Annular closure device: Barricaid

- Design History from failure to success
- Early designs failed due to migration (non-fixation to bone)

2003 2005 2008

Annular closure device: Barricaid

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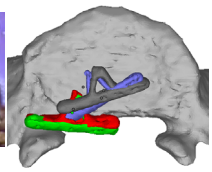
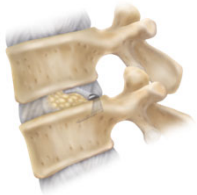
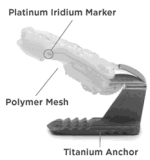


2003 2005 2008

Annular closure device: Barricaid

- Design History from failure to success
- 3rd generation "bone-anchored" concept introduced in 2008 through clinical trials

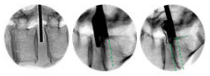


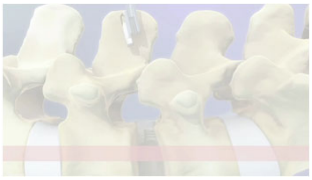
2003 2005 2008

Barricaid Procedure Overview

Following a discectomy with clear access to the defect…



Under Image Guidance



Barricaid RCT Background

- Long term results have shown that aggressive nucleus removal results in increased back pain in the long term[1]
- Limited nucleus removal leads to more frequent reherniation (2-18%), particularly in patients with large annular defects[2,3,4]
- Implantation of an annular closure device may allow for the advantages of limited nucleus removal without increased reherniation risk as well as the potential degeneration associated with aggressive nucleus removal

1 Watters, et al. An Evidence-Based Review of the literature on the consequences of conservative versus agressive discectomy for the treatment of primary disc herniation with radiculopathy. Spine 2009, Mar;9(3) 240-57
2 McGirt, et al. Recurrent Disc Herniation And Long-Term Back Pain After Primary Lumbar Discectomy:Review of Outcomes reported for limited versus aggressive Disc removal. Neurosurgery 2009 Feb 64(2) 338-44
3 Carragee, et al. A prospective controlled Study of limited versus subtotal posterior discectomy: Short-Term Outcomes in patients with herniated lumbar intervertebral discs and large posterior anular defect. Spine 2006 March 15;31(6) 653-7
4 Thome, et al. Outcome after lumbar sequestrctomy compared with microdiscectomy: a prospective randomized study. J Neurosurgery Spine 2:271-278

Barricaid RCT: Methods

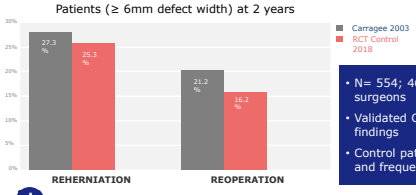
- Multicenter, randomized, controlled, superiority study
- Randomization intraoperatively 1:1 Barricaid : Discectomy
- **Inclusion criteria:** six weeks conservative care, no prior surgery at the index level, minimum Oswestry (40/100) and minimum vas leg pain (40/100)
- Reoperations and adverse events tracked prospectively, patients are evaluated clinically and radiographically at 6 weeks; 3 and 6 months; and annually until 24 months

Barricaid RCT: Results

- 21 clinical sites
- 554 patients enrolled (2010-2014)
- 3 year data used for PMA FDA approval 2018
- 5 year data published in 2022 JAMA

RCT : Validated Reherniation Rates of Large Defects

Patients (≥ 6mm defect width) at 2 years



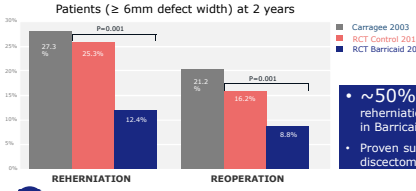
- N= 554; 46 operating surgeons
- Validated Carragee's 2003 findings
- Control patients failed early and frequently

1 in 4 Patients in Control Group has Recurrence within 2 years

Thomé C, Klaesen PD, Bouma GJ, et al. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. Spine J. 2018;Dec;18(12):2278-2287.
Carragee, et al. Clinical Outcomes After Lumbar Discectomy for Sciatica: The Effects of Fragment Type and Anular Competence J Bone Joint Surg Am. (2003) Jan;85-A(1):102-8.

RCT: Barricaid Reduced Reoperations by ~50%

Patients (≥ 6mm defect width) at 2 years



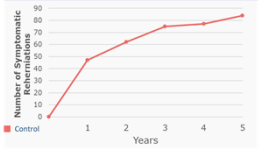
- ~50% Reduction in reherniation and reoperation in Barricaid patients
- Proven superior over discectomy only

1 in 4 Patients in Control Group has Recurrence within 2 years

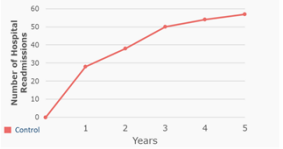
Thomé C, Klaesen PD, Bouma GJ, et al. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. Spine J. 2018;Dec;18(12):2278-2287.
Carragee, et al. Clinical Outcomes After Lumbar Discectomy for Sciatica: The Effects of Fragment Type and Anular Competence J Bone Joint Surg Am. (2003) Jan;85-A(1):102-8.

RCT: Results

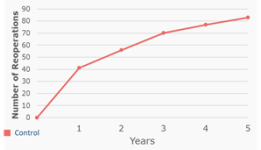
Symptomatic Reherniation



Hospital Readmissions



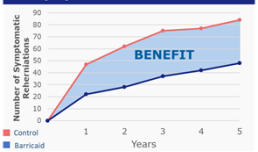
Reoperations



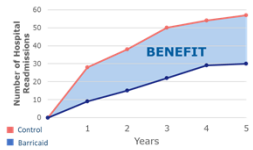
RCT Results through 5 years

23

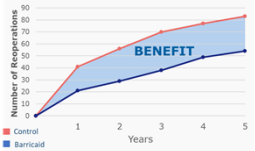
Symptomatic Reherniation



Hospital Readmissions



Reoperations



Study Results

- Barricaid reduces incidence by ~50% @1yr
- Immediate benefit margin sustained over time
- Barricaid superior through 5 years (log-rank test, p<0.05)

Adapted from JAMA Netw Open. 2021

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Annular Closure: Two Types of Surgeon Skeptics

Clinical Skeptic

Economic Skeptic

Clinical Surgeon Skeptic Summary

- I don't have reherniations
- Previous technology failed
- Reherniations are not a big deal
- Are there Published Superiority Studies? RCT?

"I Don't Have Reherniations"

Large Annular Defects Cause Discectomy Failures: Foundational Stanford Study

Carragee[1] foundational study (N=187 patients):

≥6mm Defect Group experiences significantly higher reherniations and reoperations

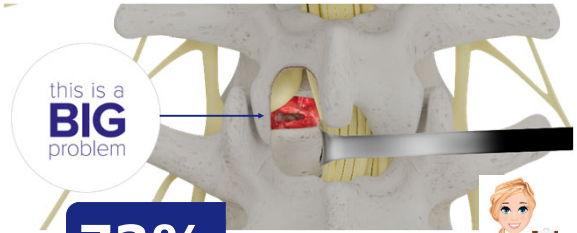
Defects ≥6mm Drive Discectomy Failures		
	Small Defect	≥6mm Defect
Rate of reherniation	1.1%	**27.3%**
Rate of reoperation	1.1%	**21.2%**

CLINICAL OUTCOMES AFTER LUMBAR DISCECTOMY FOR SCIATICA: THE EFFECTS OF FRAGMENT TYPE AND ANULAR COMPETENCE

Published in 2003 –
16 years before Barricaid received FDA approval

1. J Bone Joint Surg Am. 2003 – Carragee, et al

"I Don't Have Reherniations"



73% **of all reoperations come from these large defects[2]**

2. J Bone Joint Surg Am. 2003 – Carragee, et al

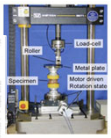
51

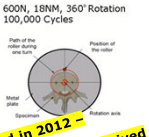
"Previous Technology Failed"

Barricaid's Bone Anchored Approach Solve Biomechanical Issues

Wilke[3] benchtop study:

- Cadaver discs with annular defects herniate within a few cycles
- Must resist (>330psi[4])
- Barricaid survived to 100k cycles with no herniation or device issues





Published in 2012 –

7 years before Barricaid received FDA approval

3. Spine. 2012 – Wilke, et al
4. Spine 1999, Wilke, Hans

"Previous technology failed"

Barricaid is **Only** Annular Repair Technology to Statistically Improve Outcomes

- Evaluation of the safety and efficacy of Barricaid vs. several annular defect repair techniques
- ***Only Barricaid is effective in preventing reherniation and reducing reoperations (p<0.0001)***
- Other annular defect repair technologies proven ineffective
- Barricaid is the only device to show true efficacy of annular repair

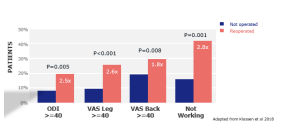
Wang[5] Level 1A Meta-analysis of 2,161 study patients

5. Global Spine Journal 2024. Wang, et al

"Reherniations Are Not a Big Deal"

53%[6] of Reoperations for Reherniations Are Fusions (meta-analysis of 1405 patients)

Reoperations after discectomy are also associated with:
- Increased patient pain and dysfunction
- More missed work



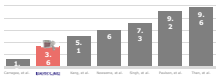
6. J.clineuro 2018 – Kerezoudis
7. ClinicalEconomics and Outcomes Research. 2018 – Klassen, et al

Barricaid Patients Return to Work in Half the Time

Faster return to work

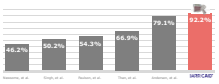
- **3.6 weeks Ave Return To Work**
  - Mean literature: 6.4 weeks
  - **~50% faster**

Mean Return To Work (Weeks)



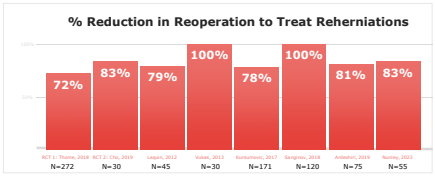
- **92.2% Back at work 90 days**
  - Mean literature: 59.3%
  - **~30.4% improvement**

3 Month Return To Work Success



"Are There Published Superiority Studies? RCT?

Barricaid Demonstrates Improved Success Rate in ~800 Patients



Weighted

81% Reduction in reoperations for reherniations[8]

8. Some studies outside FDA indications. Values at Minimum 1 year Post-op. Minimum study size of 20 Barricaid patients.

Barricaid Clinical Evidence: 70+ Studies

Clinical Need	Biomechanical Solution	Safe	Effective	Durability and Ease of Adoption	Reimbursement
Carragee 2003 • **27%** reherniation rate in patients with large defects (≥6mm width) • ...vs just 1% in small defects	**Wilke 1999** • Lumbar disc pressure is up to 334 psi (10x your car-tire!) • Picking up 45 lbs with poor posture/technique	**Lequin 2012** • Single arm, 12 months • 45 subjects • 2.4% reherniation rate • No device complications	**Thomé 2018** • 2 year Level 1 RCT • Superiority study • 554 subj., 46 surgeons • Reherniation: 12% vs 25% • Reoperation: 9% vs 16% all cause reoperation rate	**Thomé 2021** • 5 year RCT • Maintenance of benefits	**Facility C-Code:** • **C9757** – Facility code assigned by CMS • Medicare national ave show consistent reimb increases over past 4yrs
McGirt 2009 • Aggressive disc removal = 2.5x greater long-term back and leg pain • Conservative disc removal = 2x greater reherniation rate	**Wilke 2012** • Cadaver discs with holes in the annulus herniate in few cycles • Barricaid survived 100k cycles with no herniation/device issues	**Vukas 2013** • Single-arm, 2 years • 30 subjects • 0% reherniation rate • No device complications	**Sanginov 2018** • Single-arm • 120 subjects • 1.7% reherniation rate	**Kursumovic 2017** • 6 year real-world evidence • Single-arm, 171 subjects • 3.5% reherniation rate	**Surgeon Codes** • **63030** discectomy **and** • **22899** unlisted code as recommended by ISASS
Miller 2018 • Meta-analysis: 7 relevant papers on 1650+ patients • Discs with large defects have a 2.5x risk of reherniation and a 2.3x risk of reoperation	**Bostelmann 2015** • Cadaver discs with large holes in the annulus have reduced pressure (relative to intact) • Barricaid restores pressure to the intact state on average	**Cho 2019** • 2 year RCT • 30 Barricaid/30 Control • 5% vs 28.6% reherniation rate • No device complications	**Ardeshiri 2019** • Single-arm • 2 years • 75 subjects • 1.4% reherniation rate	**Wang 2023** • Level 1A meta-analysis • 2,161 study patients • Barricaid was only annular repair technology to statistically improve outcomes	**Claims Reviews** • 1000+ Claim Reviews • Practice and Facility Support

Klassen 2018
• Reoperations after discectomy are associated with:
  • Increased patient pain and dysfunction
  • More missed work
			Nunley 2023
			• Single-arm study
			• 1 year
			• 55 subjects, 12 sites
			• 3.6% reherniation rate
			• 5.5% reop rate
				Klassen 2019
				• 554 Patient RCT
				• Reoperation choices, complications, and outcomes not impacted by Barricaid
					Cigna Positive Coverage Policy
					• Barricaid specific
					• Confirms medical necessity
					• Mimics FDA labeling
					• Evidence supports safety and efficacy

*Some studies outside FDA indications

BARRICAID

"Are There Real World Studies?"

Real-World Experience with a Bone-Anchored Closure Device: Preventing Reherniation and Reoperation After Lumbar Discectomy in a High-Risk Patient Population

Betsy Grunch, MD; Jason Zook, MD; Michael Musacchio, MD; Pierce Nunley, MD; Marcus Stone, PhD; K. Brandon Strenge, MD

- Methods:
  - Patient populations:
    - Single-arm, retrospective
      - 121 levels, 118 subjects
      - 7 sites, IRB approval
      - 3 month follow-up

    Compared to 3 month data from two studies:

    - Level 1 RCT Superiority Trial (Klassen, et al.)
      - 554 subjects enrolled
      - 1:1 Randomization (272 control : 262 Barricaid)
      - (Final FDA Approval through PMA process 2020)
  - Single-arm, prospective post-approval study (Nunley, et al.)
    - 55 subjects enrolled

Results:

- 118 subjects enrolled (121 levels)
  - Source data verification complete for all data
  - Mean age: 45±16 years
  - 58% male
  - Mean BMI 31±5)
  - 3-month rate of symptomatic reherniation was 4.1% (5/121)
    - Four of these reherniations were reoperated with the fifth being treated conservatively. Overall, six reoperations were being performed at 5 levels (4.1%, 5/121).
  - No devices were explanted, and no device migrations or fractures have been observed

Results: 3 Month Reoperation and Reherniation

	US RWE (n=121)	Nunley, et al. Post-market Single-arm (n=55)	Klassen, et. al RCT Barricaid (n=262)	Klassen, et al. RCT Control (n=272)
Reoperation	4.1%	1.8%	2.7%	5.5%
Reherniation	4.1%	3.6%	2.7%	8.5%

Experience to Date: Case Study

- Starting implanting in August 2020
  - 119 patients identified pre-operatively
  - 54 patients to surgery with possibility to use Barricaid
  - 33 patients implanted

Results: Reimbursement

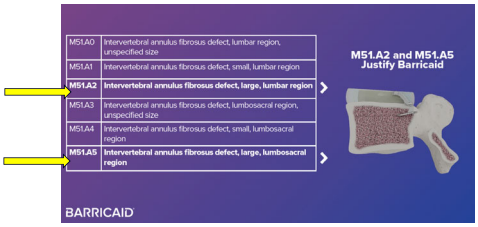
- Under protocol, reimbursement data was collected for the additional work associated with implantation of the bone-anchored annular closure device
  - The average total facility reimbursement for the procedure was $11,628.73.
  - The average surgeon reimbursement (for unlisted CPT 22899) was $810.85 (reported separately and in addition to lumbar discectomy codes)

Economic Surgeon Skeptics?

- Is this a product looking for a procedure?
- Will my facility be reimbursed?
- Will I be reimbursed?
- Prove reimbursement to me; I don't believe what the company says.

"Is This a Product Looking for a Procedure?"

New CMS Codes Include "Large" and "Small" Defects: Medical Necessity



" Will My Facility Be Reimbursed?"

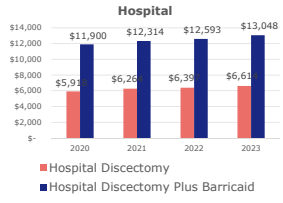
- Facility C-code assigned by CMS[9]
  - C9757 Facility C-code

HCPCS	Description
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar

9. CMS.gov

Facility Reimbursement Medicare National Averages*

Consistent reimbursement increases over past 4 years



*2023 C9757 Medicare National Average payment rates, unadjusted for wage. "National Average Payment" is the amount Medicare determines to be the maximum allowance for any Medicare covered procedure. Actual payment will vary based on the maximum allowance less any applicable deductibles, co-insurance etc. CMS CY 2022 OPPS Final Rule, CMS-1753-FC, Addendum B.

Summary Report from Claim Reviews

1,100+ Claim Reviews*

- Average C9757 Facility Payment:
  - HOSP: $ 12,452
  - ASC: $ 9,137

*Data on file Q2 2024

"Will I Be Reimbursed? Is There a CPT code?"

- Physician (recommended by ISASS[10])
  - 63030 discectomy plus
  - 22899 procedure code
- Prior Authorization success:
  - ~80% approval rate (through Intrinsic's Patient Journey Team)
    - Intrinsic internal Prior-authorization and Patient Journey teams
    - Patient First Program
      - Intrinsic program for reimbursement risk mitigation

10. CPT 22899 identified by ISASS (2020) as appropriate Barricaid procedure code for physician services. Physicians should consult with their local payor to determine the appropriate codes to bill for costs associated with annular repair and the work of implanting Barricaid

Summary Report from Claim Reviews

1,100+ Claim Reviews*

- Average C9757 Facility Payment:
  - HOSP: $ 12,452
  - ASC: $ 9,137
- Average Surgeon Payment**:
  - 63030 primary discectomy: (standard payment)
  - 22899 miscellaneous code: $818**

*Data on file Q2 2024
**Excludes Medicare and Workers Comp
This information is provided for informational purposes only and is not a guarantee of payment or any level of payment.
It is the provider's responsibility to ensure the use of correct codes.

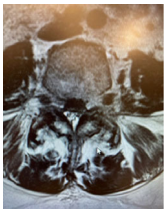
Data Should Satisfy Both Types of Surgeon Skeptics

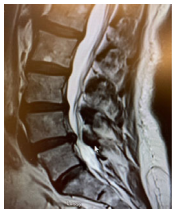
Clinical Skeptic

Economic Skeptic

Pre-operative Imaging

- 73-year-old female
- Primary surgery
- L45 left





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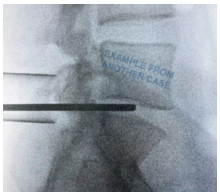
Evaluating Annular Defect

- Defect 4h x 6w → 8mm implant
- Confirmed full-thickness defect
  - Barrier needs clear path to nucleus



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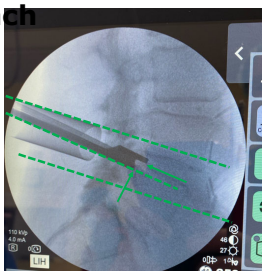
Access and Approach

- Tube placement allows access to either endplate
- Alignment Trial shows eventual delivery tool position:
  - In the defect
  - On the endplate
  - Against the vertebral body
- Note appropriate angle: Anchor will be fully embedded within L5 – not angled up at the endplate



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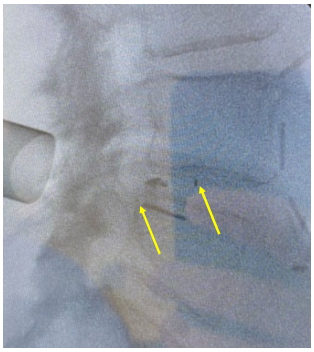
Final Position

- Pt-Ir marker within barrier shows position against opposing endplate
- Confirmed counter-sink of anchor into L5



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To close I want to share the stories of two nurses that I work closely with and that also became my patients

Thank You

Product (Barricaid): This presentation does not contain all risk information about the Barricaid device. 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/instructions).

The Barricaid is indicated for: 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.