Designed to prevent reherniation

Publication Synopsis

Barricaid® Evidence-Based Value Proposition in 5 Steps

1. Clinical need
2. Patient population
3. Preventing disability
4. Annular Closure treatment
5. Burns no bridges

BARRICAID®
ANNULAR CLOSURE

Introduction

The Barricaid® Annular Closure Device is an implantable device designed to prevent reherniation following limited discectomy in patients with large annular defects, who are at the highest probability of recurrent herniation if treated with just a lumbar discectomy without annular closure.

This document was developed to provide the reader with a synopsis of relevant published clinical data as it pertains to the clinical need for annular closure treatment, the patient population and prevalence, as well as to the safety and effectiveness of the Barricaid implant.

This document is not intended to be an exhaustive listing of all relevant publications, but rather an attempt to provide the reader with a condensed yet comprehensive overview of relevant published literature.

For a complete literature overview, see MLT64 Published Evidence Overview.

INDICATIONS

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 anular 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.

Please refer to the package insert and other labeling for a complete list of indications, contraindications, precautions and warnings (www.barricaid.com/instructions).

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Clinical Need

ELSEVIER

The Spine Journal ■ (2012) ■

THE SPINE JOURNAL

Clinical Study

Repeat surgery after lumbar decompression for herniated disc: the quality implications of hospital and surgeon variation

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Abstract

BACKGROUND CONTEXT: Repeat lumbar spine surgery is generally an undesirable outcome. Variation in repeat surgery rates may be because of patient characteristics, disease severity, or hospital- and surgeon-related factors. However, little is known about population-level variation in reoperation rates.

PURPOSE: To examine hospital- and surgeon-level variation in reoperation rates after lumbar herniated disc surgery and to relate these to published benchmarks.

STUDY DESIGN/SETTING: Retrospective analysis of a discharge registry including all nonfederal hospitals in Washington State.

METHODS: We identified adults who underwent an initial inpatient lumbar decompression for herniated disc from 1997 to 2007. We then performed generalized linear mixed-effect logistic regressions, controlling for patient characteristics and comorbidity, to examine the variation in reoperation rates within 90 days, 1 year, and 4 years.

RESULTS: Our cohort included 29,529 patients with a mean age of 47.5 years, 61% privately insured, and 15% having any comorbidity. The age-, sex-, insurance-, and comorbidity-adjusted mean rate of reoperation among hospitals was 1.9% at 90 days (95% confidence interval [CI], 1.2–3.1), with a range from 1.1% to 3.4%; 6.4% at 1 year (95% CI, 3.9–10.6), with a range from 2.8% to 12.5%; and 13.8% at 4 years (95% CI, 8.8–19.8), with a range from 8.1% to 24.5%. The adjusted mean reoperation rates of surgeons were 1.9% at 90 days (95% CI, 1.4–2.4) with a range from 1.2% to 4.6%, 6.1% at 1 year (95% CI, 4.8–7.7) with a range from 4.3% to 10.5%, and 13.2% at 4 years (95% CI, 11.3–15.5) with a range from 10.0% to 19.3%. Multilevel random-effect models suggested that variation across surgeons was greater than that of hospitals and that this effect increased with long-term outcomes.

CONCLUSIONS: Even after adjusting for patient demographics and comorbidity, we observed a large variation in reoperation rates across hospitals and surgeons after lumbar discectomy, a relatively simple spinal procedure. These findings suggest uncertainty about indications for repeat

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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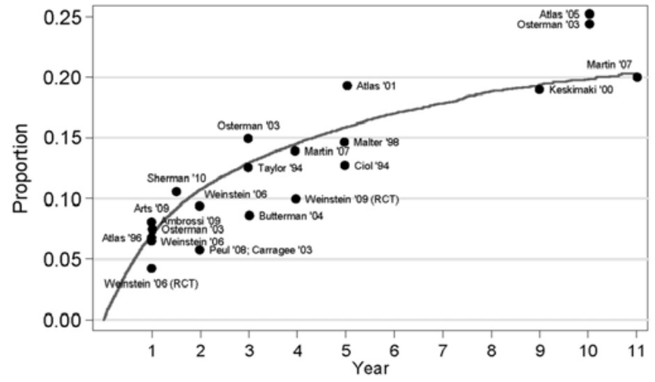
doi:10.1016/j.spinee.2011.11.010

Lumbar discectomy outcomes are great in 80% of the patients

Study Highlight



Source: CHARS 1997-2007
Based on Kaplan Meier hazard estimates

Fig. 1 Eleven-year cumulative incidence of reoperation after decompresson surgery for herniated disc in Washington State (solid line). The figure is annotated with point estimates for reoperation rates from other studies on decompression surgery (clinical and administrative). CHARS, Comprehensive Hospital Abstract Reporting System; RCT, randomized control trial.

Study Summary

- 10 year Washington State registry: 29,529 patients mean age 47.5 years
- 13.8% of patients have at least 1 reoperation at 4 years after discectomy
- 25.7% of reoperations involve a fusion surgery
- Large variation in reoperation rates across hospitals and surgeons after lumbar discectomy for a relatively simple procedure

KEY TAKEAWAYS

- Population based studies show
  - significantly lower patient satisfaction: 75% at one year [2]
  - high reoperation: ~20% reoperation at 10 years
- Female gender, comorbidity, and workers compensation were associated with higher risk for reoperation.[3]

Literature References

1. Martin et al, Repeat Surgery After Lumbar Decompression for herniated disc: the quaity implications of hospital and surgeon variation. Spine J. 2012 Feb;12(2):89-97. doi: 10.1016/j.spinee.2011.11.010. Epub 2011 Dec 21.
2. Stromqvist et al, One-Year Report From The Swedish National Spine Registry, Acta Orthopaedica (suppl 319) 2005; 76
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2
Patient Population

Spine

SPINE Volume 43, Number 5, pp E308–E315

LITERATURE REVIEW

OPEN

Association of Annular Defect Width After Lumbar Discectomy With Risk of Symptom Recurrence and Reoperation

Systematic Review and Meta-analysis of Comparative Studies

Larry E. Miller, PhD,* Matthew J. McGirt, MD,† Steven R. Garfin, MD,‡ and Christopher M. Bono, MD§

Study Design. Systematic review and meta-analysis of comparative studies.
Objective. To characterize the association of annular defect width after lumbar discectomy with the risk of symptom recurrence and reoperation.
Summary of Background Data. Large annular defect width after lumbar discectomy has been reported to increase risk of symptom recurrence. However, this association has not been evaluated in a systematic manner.
Methods. A systematic literature search of MEDLINE and EMBASE was performed to identify comparative studies of large *versus* small annular defects following lumbar discectomy that reported symptom recurrence or reoperation rates. Main outcomes were reported with pooled odds ratios (OR) and 95% confidence intervals (CIs). Sensitivity analyses were performed to assess the robustness of the meta-analysis findings.
Results. After screening 696 records, we included data from 7 comparative studies involving 1653 lumbar discectomy patients, of whom 499 (30%) had large annular defects and 1154 (70%) had small annular defects. Methodological quality of studies was good overall. The median follow-up period was 2.9 years. The risk of symptom recurrence (OR = 2.5, 95% CI = 1.3–4.5, $P = 0.004$) and reoperation (OR = 2.3, 95% CI = 1.5–3.7, $P < 0.001$) was higher in patients with large *versus* small annular defects. Publication bias was not evident. The associations between annular defect width and risk of symptom recurrence and reoperation remained statistically significant in all sensitivity analyses.
Conclusion. Annular defect width after lumbar discectomy is an under-reported modifier of patient outcome. Risk for symptom recurrence and reoperation is higher in patients with large *versus* small annular defects following lumbar discectomy.
Key words: annulus, comparative studies, disc herniation, discectomy, fragment type, lumbar, meta-analysis, microdiscectomy, reherniation, systematic review.
Level of Evidence: 2
Spine 2018;43:E308–E315

Lumbar discectomy is performed on nearly 500,000 patients per year in the United States.[1] While this procedure is successful in most patients, symptom recurrence related to reherniation is reported in 7% to 18% of patients.[2–4] Recurrent symptomatic herniation is associated with poor clinical outcome and often requires a technically demanding reoperation.[5] Commonly reported risk factors for recurrence include disc degeneration,[6] age,[7] sex,[6] and body mass index.[8] However, the influence of surgery-related factors on recurrence risk is unclear. Carragee *et al*[9] identified postsurgical annular defect size as a risk factor for symptom recurrence. In this study, patients with large *versus* small annular defects had higher rates of symptom recurrence and reoperation. However, the association of postsurgical annular defect width with symptom recurrence risk has not been evaluated in a systematic manner. The purpose of this systematic review and meta-analysis was to characterize the association of annular defect width after lumbar discectomy with the risk of symptom recurrence and reoperation.

MATERIALS AND METHODS

Study Selection

This study was performed according to the guidelines specified in the Preferred Reporting Items for Systematic Reviews

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Acknowledgment date: September 14, 2017. First revision date: October 19, 2017. Acceptance date: November 3, 2017.

The manuscript submitted does not contain information about medical device(s)/drug(s).

Intrinsic Therapeutics, Inc. (Woburn, MA, USA) funds were received in support of this work.

Relevant financial activities outside the submitted work: board membership, consultancy, grants, expert testimony.

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DOI: 10.1097/BRS.0000000000002501

30% of patients have large annular defects and account for 70% of all reoperations

Study Highlight

Risk in patients with large vs. small annular defects

	Odds Ratio (OR)	95% Confidence Interval (CI)	P-value
Symptom Recurrence	2.5	1.3 - 4.5	p=0.004
Reoperation	2.3	1.5 - 3.7	p<0.001

Study Summary

- Defects that are at least as wide as than a number-1 Penfield probe (6mm) are classified as large defects.
- 7 comparative studies involving 1,653 lumbar discectomy patients showed 30% of patients having large annular defects.
- The risk of reoperation was 2.3x greater in patients with large versus small annular defects.

KEY TAKEAWAYS

- Discectomy patients with large annular defects have the highest failure rate by recurrence (27%) and reoperation (21%) – while small defects have the lowest failure rate (1.1%).[5]
- Multicenter RCT provides level 1 evidence and confirms large defects being a prognostic biomarker of risk recurrence of 25% at 2 years.[6]

Literature References

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3

Preventing Disability

ClinicoEconomics and Outcomes Research

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ORIGINAL RESEARCH

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

This article was published in the following Dove Press journal:
ClinicoEconomics and Outcomes Research

Peter Douglas Klassen[1]
Wellington K Hsu[2]
Frederic Martens[3]
Jason A Inzana[4]
Wimar A van den Brink[5]
Michael W Groff[6]
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[1]Department of Neurosurgery, St. Bonifatius Hospital, Lingen, Germany; [2]Department of Orthopaedic Surgery, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA; [3]Department of Neurosurgery, OLV Ziekenhuis, Aalst, Belgium; [4]Telos Partners LLC, Denver, CO, USA; [5]Neurochirurgisch Centrum Zwolle, Zwolle, the Netherlands; [6]Neurosurgical Spine Service, Brigham and Women's Hospital, Boston, MA, USA; [7]Department of Neurosurgery, Innsbruck Medical University, Innsbruck, Austria

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 follow-up (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%).

Conclusion: 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).

Keywords: lumbar discectomy, annular closure device, patient-reported outcomes, direct costs, reherniation, reoperation

Introduction

Lumbar discectomy is a highly effective procedure to address back and leg pain associated with intervertebral disc herniation and is one of the most common spinal procedures globally. In the USA alone, the procedure is performed on nearly 500,000 patients per year.[1] Retrospective studies have reported lumbar discectomy

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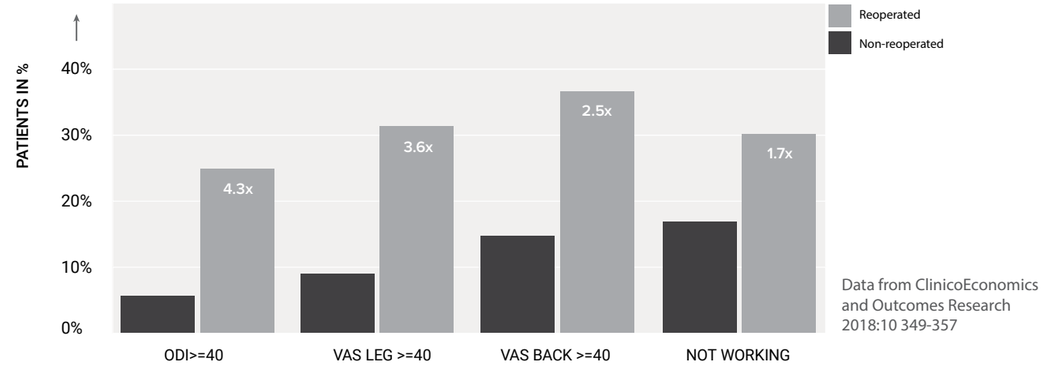
Discectomy reoperations are inferior to primary with 3 times the disability

Study Highlight



Data from ClinicoEconomics and Outcomes Research 2018:10 349-357

Study Summary

- At 2 years of follow-up, the rate of reoperated vs non-reoperated patients who did not achieve clinically significant improvement was 2.9 times higher based on ODI and 3.6 times higher based on VAS leg.
- Greater morbidity among the reoperated patients implied greater indirect cost: 2.5x more missed work & 37x more inpatient hospital days.
- These results are devastating from a patient and societal perspective.

KEY TAKEAWAYS

- Current level 1 evidence demonstrates that, in appropriately selected patient populations, implantation of a bone-anchored annular closure device (ACD) reduces the risk of symptom recurrence and revision surgery compared to discectomy alone (ISASS Guideline).[8]
- Reoperations have greater disability and higher use of opioids.[3, 9]
- Revision patients at higher risk of reherniation and subsequent reoperation.[9]

Literature References

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8. Lorio et al, ISASS Spine Surgery Policy 2019 – Surgeocal Treatment of Lumbar Disc Hernaition with Radiculopathy, Intl J Spine Surgery Vol 14, No 1, 2020 pp 1-17
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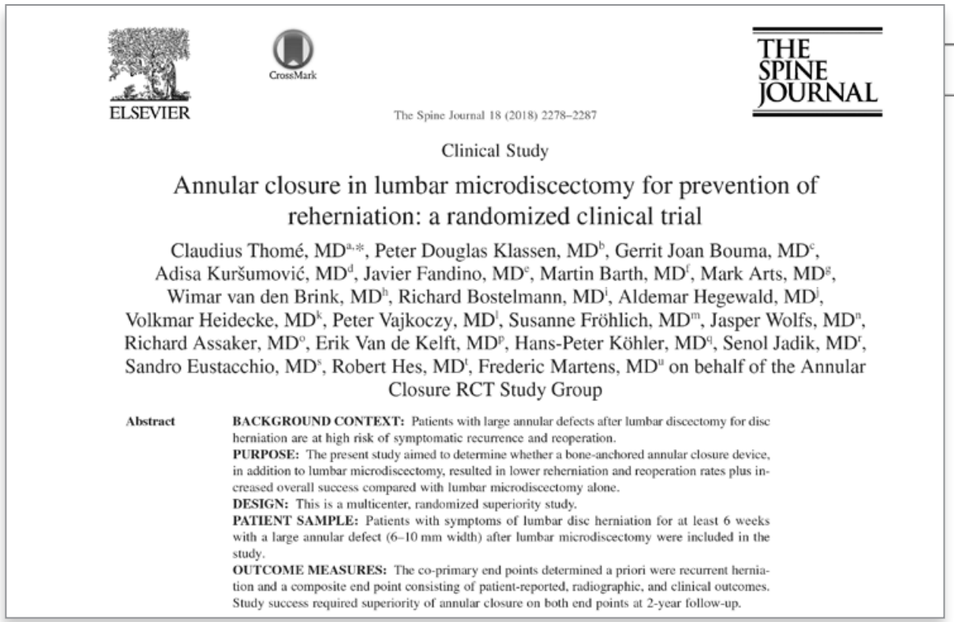
4

Annular Closure Treatment



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THE SPINE JOURNAL

The Spine Journal 18 (2018) 2278–2287

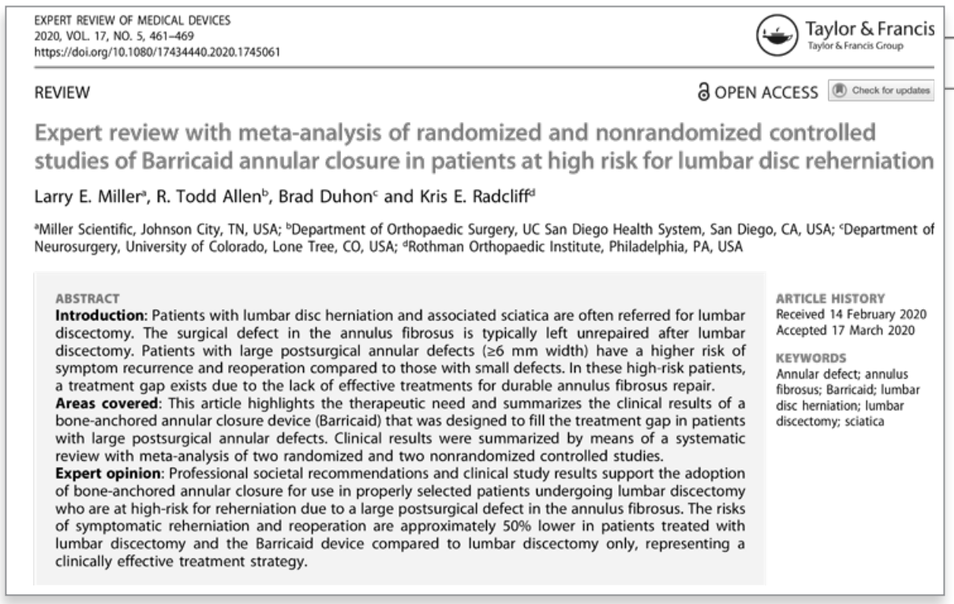
Clinical Study

Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial

Claudius Thomé, MD[a,*], Peter Douglas Klassen, MD[b], Gerrit Joan Bouma, MD[c], Adisa Kuršumović, MD[d], Javier Fandino, MD[e], Martin Barth, MD[f], Mark Arts, MD[g], Wimar van den Brink, MD[h], Richard Bostelmann, MD[i], Aldemar Hegewald, MD[j], Volkmar Heidecke, MD[k], Peter Vajkoczy, MD[l], Susanne Fröhlich, MD[m], Jasper Wolfs, MD[n], Richard Assaker, MD[o], Erik Van de Kelft, MD[p], Hans-Peter Köhler, MD[q], Senol Jadik, MD[r], Sandro Eustacchio, MD[s], Robert Hes, MD[t], Frederic Martens, MD[u] on behalf of the Annular Closure RCT Study Group

Abstract

BACKGROUND CONTEXT: Patients with large annular defects after lumbar discectomy for disc herniation are at high risk of symptomatic recurrence and reoperation.
PURPOSE: The present study aimed to determine whether a bone-anchored annular closure device, in addition to lumbar microdiscectomy, resulted in lower reherniation and reoperation rates plus increased overall success compared with lumbar microdiscectomy alone.
DESIGN: This is a multicenter, randomized superiority study.
PATIENT SAMPLE: Patients with symptoms of lumbar disc herniation for at least 6 weeks with a large annular defect (6–10 mm width) after lumbar microdiscectomy were included in the study.
OUTCOME MEASURES: The co-primary end points determined a priori were recurrent herniation and a composite end point consisting of patient-reported, radiographic, and clinical outcomes. Study success required superiority of annular closure on both end points at 2-year follow-up.



EXPERT REVIEW OF MEDICAL DEVICES
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Taylor & Francis
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REVIEW

OPEN ACCESS Check for updates

Expert review with meta-analysis of randomized and nonrandomized controlled studies of Barricaid annular closure in patients at high risk for lumbar disc reherniation

Larry E. Miller[a], R. Todd Allen[b], Brad Duhon[c] and Kris E. Radcliff[d]

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ABSTRACT

Introduction: Patients with lumbar disc herniation and associated sciatica are often referred for lumbar discectomy. The surgical defect in the annulus fibrosus is typically left unrepaired after lumbar discectomy. Patients with large postsurgical annular defects (≥6 mm width) have a higher risk of symptom recurrence and reoperation compared to those with small defects. In these high-risk patients, a treatment gap exists due to the lack of effective treatments for durable annulus fibrosus repair.
Areas covered: This article highlights the therapeutic need and summarizes the clinical results of a bone-anchored annular closure device (Barricaid) that was designed to fill the treatment gap in patients with large postsurgical annular defects. Clinical results were summarized by means of a systematic review with meta-analysis of two randomized and two nonrandomized controlled studies.
Expert opinion: Professional societal recommendations and clinical study results support the adoption of bone-anchored annular closure for use in properly selected patients undergoing lumbar discectomy who are at high-risk for reherniation due to a large postsurgical defect in the annulus fibrosus. The risks of symptomatic reherniation and reoperation are approximately 50% lower in patients treated with lumbar discectomy and the Barricaid device compared to lumbar discectomy only, representing a clinically effective treatment strategy.

ARTICLE HISTORY
Received 14 February 2020
Accepted 17 March 2020

KEYWORDS
Annular defect; annulus fibrosus; Barricaid; lumbar disc herniation; lumbar discectomy; sciatica

Barricaid cuts reherniation & reoperation rates by 50-60% in patients with large defects

Study Highlight

Symptomatic reherniation

p=0.0001 Log rank test

Reoperation for reherniation

p=0.0015 Log rank test

Study Summary

- Level 1B Randomized Controlled Trial involving 554 patients with large annular defects demonstrates Barricaid to be superior to limited discectomy alone starting at 90 days through 2 years and beyond
- The risk of symptomatic reherniation was 52% lower with Barricaid (12% vs. 25%, p<0.001)
- The risk of reoperation for reherniation was 62% lower with Barricaid (5% vs. 13%, p=0.001)

Study Summary

- Level IA paper: clinical study results (50+ publications involving 801 studied patients) further supported by several real-world prospective case series with symptomatic reherniation rates ranging from 1.4% to 3.2% at 2 years.[11]
- ISASS professional societal recommendation supporting the adoption of bone-anchored annular closure for use in properly selected patients[12]

KEY TAKEAWAYS

- PMA approval of Barricaid by FDA led to professional society (ISASS) review of the evidence supporting use of Barricaid in well-indicated patients.
- Long term Outcomes are durable – follow up through 4 years[13]

Literature References

10. Thome et al, Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial., Spine J. 2018 Dec;18(12):2278-2287
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5

Burns No Bridges

ORIGINAL ARTICLE

Reoperation After Primary Lumbar Discectomy with or without Implantation of a Bone-Anchored Annular Closure Device: Surgical Strategies and Clinical Outcomes

Peter D. Klassen[1], Geoffrey Lesage[2], Larry E. Miller[3], Robert Hes[4], Jasper F.C. Wolfs[5], Sandro Eustacchio[6], Peter Vajkoczy[7]

OBJECTIVE: To determine whether presence of a bone-anchored annular closure device (ACD) impacts reoperation strategies and subsequent outcomes.

METHODS: Patients with large annular defects after single-level limited lumbar discectomy were randomly allocated to receive an ACD or discectomy alone (controls) and were followed for at least 3 years.

RESULTS: Among 550 patients, reoperation risk was lower with ACD (11.0% vs. 19.3%). The types of reoperations and operative time were similar in each group, and the ACD did not interfere with surgical planning or operative technique. Fusion success was 87% with ACD versus 85% for controls. Perioperative complications occurred in 22% and 19% of reoperations, respectively. Leg pain and back function were improved with ACD versus controls after fusion procedures, and no group differences were observed after non-fusion reoperations.

CONCLUSIONS: In patients undergoing post-discectomy reoperation, patients with an ACD were treated with similar operative techniques, were not exposed to additional surgical risks, and reported comparable clinical outcomes versus those without an ACD.

INTRODUCTION

Lumbar discectomy provides relief from sciatica in most patients[1,2] and is one of the most commonly performed spine surgeries.[3] However, approximately 10% of surgical patients require a repeat operation within 4 years mainly because of inadequate symptom relief or symptom recurrence.[4,5] One of the strongest risk factors for symptom recurrence after lumbar discectomy is a postoperative defect of at least 6 mm width in the annulus fibrosus.[6,7] A large annular defect may allow pressurized nuclear material to enter the extradiscal space and reproduce radicular symptoms caused by local inflammatory reactions and/or mechanical nerve root compression. In a meta-analysis comparing patients with large (≥6 mm width) versus small (<6 mm width) annular defects, large defects were associated with more than a 2-fold increase in symptom recurrence and reoperation risk over approximately 3 years follow-up.[6] Reoperations for lumbar herniation are more costly[8] and less effective[4,9] than primary procedures. This has prompted development of technologies intended to repair large postoperative defects to lower recurrence rates in this high-risk patient population.[10] In a randomized trial of 554 patients with large postoperative annular defects, a bone-anchored annular closure device (ACD) implanted at discectomy completion significantly lowered the risk of recurrence and reoperation over 2 years of follow-up[11] and was shown to be highly cost-effective[12] versus discectomy alone. Among patients treated with an ACD who require a reoperation, the impact of an ACD on procedural complexity and subsequent clinical outcomes is unclear. In this post hoc analysis from a randomized trial, our objective was to

Key words
- Annulus fibrosus
- Discectomy
- Fusion
- Revision
- Sciatica

Abbreviations and Acronyms
ACD: Annular closure device
ODI: Oswestry Disability Index

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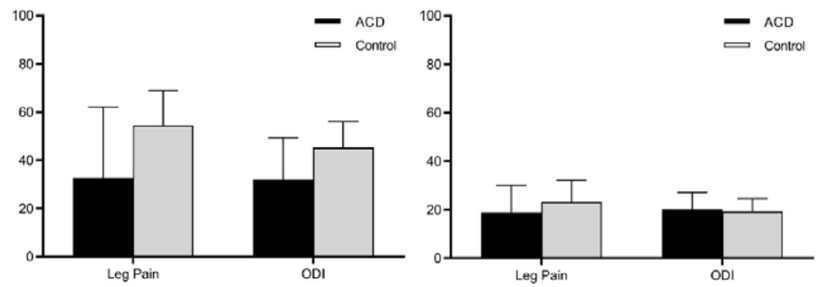
*Available online: **www.sciencedirect.com***

1878-8750/$ - see front matter

Barricaid does not compromise or complicate revision options

Study Highlight



Patient- reported outcomes after fusion

Patient- reported outcomes after non-fusion

Study Summary

- Among 550 patients, reoperation risk was significantly lower with Barricaid compared to discectomy alone
- The types of reoperations and operative time were similar in each group, and Barricaid did not interfere with surgical planning or operative technique
- Perioperative complications equivalent in both groups (22% vs 19%)
- Fusion success equivalent in both groups (87% vs 85%)

KEY TAKEAWAYS

- In patients undergoing post-discectomy reoperation, patients with a Barricaid reported comparable clinical outcomes versus those without.[14]
- Vertebral endplate changes did not present an additional risk factor for patients implanted with Barricaid.[15]
- Reoperated Barricaid patients fare no worse than reoperated discectomy patients.

Literature References

14. Klassen et al, Reoperation After Primary Lumbar Discectomy with or without Implantation of a Bone-Anchored Annular Closure Device: Surgical Strategies and Clinical Outcomes. World Neurosurgery Volume 130, October 2019, Pages e926-e932

15. Kursumovic et al, Clinical implications of vertebral endplate disruptions after lumbar discectomy: 3-year results from a randomized trial of a bone-anchored annular closure device, Journal of Pain Research 2020:13 1-7

Notes [redacted]

The Evidence-Based Annular Closure Treatment

1. Lumbar discectomy outcomes are great in 80% of the patients
2. 30% of patients have large annular defects and account for 70% of all reoperations
3. Discectomy reoperations are inferior to primary with 3 times the disability
4. Barricaid cuts reherniation & reoperation rates by 50-60% in patients with large defects
5. Barricaid does not compromise or complicate revision options

Barricaid has been used to improve outcomes in 7500+ patients over more than 10 years.

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