Designed to prevent reherniation

Publication Synopsis of Relevant Clinical Data
Introduction

The Barricaid® Annular Closure Device (ACD) 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 publication synopsis of relevant clinical data as it pertains to the clinical need for annular closure treatment, as well as to the safety and effectiveness of the Barricaid implant.

As such this synopsis will guide you through the Clinical Need, Patient Population, Device Safety and Effectiveness, Health Economics, as well as reporting on ‘real-world’ results that have been collected from registry databases.

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 articles.

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.
Clinical Need and Well-Defined Patient Population

SPINE (2018) Volume 43, Number 5, pp E308–E315

Association Of Annular Defect Width After Lumbar Discectomy With Risk Of Symptom Recurrence And Reoperation

LE Miller, et al.

• “Classification typically involves comparing annular defect width to a number-1 Penfield probe (6 mm) after completion of the discectomy. Defects that are wider than the probe are classified as large defects.”

• 7 comparative studies involving 1,653 lumbar discectomy patients showed 30% of patients having large annular defects (≥6mm width) versus 70% having small annular defects.

• The median patient age was 45 years, and median follow-up period was 2.9 years.

• Odds Ratio: 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.

• “We have shown that patients with large annular defects after lumbar discectomy have higher risk for symptomatic recurrence and reoperation compared to those with small annular defects.”


Patients At The Highest Risk For Reherniation Following Lumbar Discectomy In A Multicenter Randomized Controlled Trial

F Martens, P Vajkoczy, S Jadik, A Hegewald, J Stieber, R Hes

• “Only patients presenting with a large anular defect (6 to 10 mm wide by 4 to 6 mm long) were included in the study (n = 278).”

• “At 2 years, the incidence of symptomatic recurrent lumbar disc herniation was 25.3% (64 of 253), with the herniation occurring at a mean of 264 days (range: 2 to 787 days) after the index procedure.”

• Among those large defect patients, females <50 years of age had the highest risk (up to ~10 times higher) of recurrent disc herniation.

• “The outcomes of the present study provide the most substantial evidence to date in confirming previous reports of a high risk of reherniation among patients with large anular defects.”

Level 1 Data From a Multicenter RCT

Device Safety and Effectiveness

The Spine Journal (2018) p DOI: 10.1016/j.spinee.2018.05.003

Annular Closure In Lumbar Microdiscectomy For Prevention Of Reherniation: A Randomized Clinical Trial


• “The frequency of symptomatic reherniation was lower with ACD (12% vs. 25%, P<.001)”
• “The frequency of index level reoperations specifically to address an observed recurrent herniation was 5% with ACD (14 procedures in 14 subjects) and 13% in controls (42 procedures in 37 subjects) (P<.001).”

• “In the as-treated population, the frequency of serious adverse events adjudicated by the DSMB as related to either the implant or procedure was 7% in the ACD group and 17% in the control group (P=.001)”

Medicine: November 2019 - Volume 98 - Issue 44 - p e17760
Lumbar disc reherniation prevention with a bone-anchored annular closure device
W van den Brink, C Flüh, LE Miller, PD Klassen, R Bostelmann

• Among patients with large annular defects following limited lumbar discectomy, additional implantation with a bone-anchored ACD lowered the risk of symptomatic reherniation (8.4% vs 17.3%, P=0.002) and reoperation (6.7% vs. 12.9%, P=0.015) over 1-year follow-up.

• Device- or procedure-related serious adverse events occurred less frequently in the ACD group (7.1% vs 13.9%, P=0.009).

• “These conclusions were not influenced by patient characteristics.”

Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation
JC Kienzler, PD Klassen, LE Miller, R Assaker, V Heidecke, S Fröhlich, C Thomé, Annular Closure RCT Study Group

• Outcomes at 3 years favored ACD for symptomatic reherniation (14.8% vs 29.5%; P<0.001), reoperation (11.0% vs 19.3%; P=0.007), leg pain (21 vs 30; P<0.01), back pain (23 vs 30; P=0.01), ODI (18 vs 23; P=0.02), PCS (47 vs 44; P<0.01) and MCS (52 vs 49; P<0.01).

• “The addition of a bone-anchored ACD in patients with large annular defects following lumbar discectomy reduces the risk of reherniation and reoperation, and has a similar safety profile over 3-year follow-up compared with limited discectomy alone.”

World Neurosurgery (2019): E1-E7
Reoperation after primary lumbar discectomy with or without implantation of a bone-anchored annular closure device: surgical strategies and clinical outcomes
PD Klassen, G LeSage, LE Miller, R Hes, J Wolfs, S Eustacchio, P Vajkoczy

• “Among 550 patients, reoperation risk at 3 years was lower with ACD vs discectomy alone (11.0% vs 19.3%).”

• “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.”

Radiographic Observation of Endplate Change
Morphology And Clinical Relevance Of Vertebral Endplate Changes Following Limited Lumbar Discectomy With Or Without Bone-Anchored Annular Closure
A Kursumovic, J Kienzler, G Bouma, R Bostelmann, M Heggeness, C Thomé, L Miller, M Barth, on behalf of the Annular Closure RCT Study Group
• “Vertebral Endplate Changes (VEPC) are disruptions in endplate integrity that may be characterized as Schmorl’s nodes...”
• “VEPC were preoperatively identified in 18% of patients in the ACD group and in 15% of Controls.”
• “At 2 years, VEPC frequency increased to 85% with ACD and 33% in Controls.”
• “Device- or procedure-related serious adverse event (8% vs. 17%, P = 0.001) and secondary surgical intervention (5% vs. 13%, P < 0.001) favored the ACD group over Controls.”
• “Despite the higher frequency and greater volume of VEPC in the ACD group, main outcomes at 2 years favored the ACD group over Controls including symptomatic reherniation at index level (11% vs. 24%, P < 0.001), secondary surgical intervention (5% vs. 13%, P < 0.001), and device or procedure-related SAE (8% vs. 17%, P = 0.001).”

Health Economics


Bone-Anchored Annular Closure Following Lumbar Discectomy Reduces Risk Of Complications And Reoperations Within 90 Days Of Discharge
PD Klassen, D Bernstein, H Köhler, M Arts, B Weiner, LE Miller, C Thomé

• “...adjunctive placement of an ACD reduces the risk for perioperative complications occurring through 90 days following hospital discharge.”
• “The cumulative probability of a device- or procedure-related Serious Adverse Events (SAE) through 90 days following hospital discharge was 4.5% with ACD and 10.2% with control (p=0.02).”
• “...The most common of these SAEs was herniation at the index level, reported in six (2.2%) ACD patients and 19 (6.8%) control patients (p=0.01).”
• “The risk of reoperation at the index level over this period was also lower with ACD (1.9% vs 5.4%, p=0.03).”
• “In the control group, 18 index-level reoperations were performed in 15 patients... In the ACD group, six index-level reoperations were performed in five patients...”

ClinicoEconomics & Outcomes Research (2018): 10 349-357

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
PD Klassen, W Hsu, F Martens, J Inzana, W van den Brink, M Groff, C Thomé

• “Annular closure helped minimize this clinical and socioeconomic burden by reducing the incidence of reoperation by nearly 50% (16% control vs 9% ACD).”
• “At 2 years of follow-up, the rate of reoperated vs nonreoperated patients who did not achieve clinically significant improvement was 2.9 times higher based on ODI (46% vs 16%).”
• “…3.6 times higher based on VAS leg (25% vs 7%)”
• “…1.4 times higher based on VAS back scores (49% vs 35%).”
• “The greater morbidity among the reoperated patients implied greater indirect costs due to 2.5 times more missed work and 37 times more inpatient hospital days.”
Cost-Effectiveness Of A Bone-Anchored Annular Closure Device Versus Conventional Lumbar Discectomy In Treating Lumbar Disc Herniations
J Ament, B Thaci, Z Yang, E Kulubya, W Hsu, G Bouma, K Kim

- “From a societal perspective, the ICER became negative - a rare scenario in healthcare economics referred to as dominance, which means that superior quality of life was attained at less cost.”
- “And, when costs are considered from an exclusively private insurer’s perspective, the ACD strategy dominated in all scenarios.”

Real-world Data From Additional Patient Populations

Performance Of An Annular Closure Device In A ‘Real-World’, Heterogeneous, At-Risk, Lumbar Discectomy Population
A Kursumovic, S Rath

- “This was a retrospective analysis of 171 patients who underwent limited lumbar discectomy with an ACD for LDH.”
- “A total of six symptomatic reherniations (3.5%) were observed. Of those, five reherniations occurred within the first two months after implantation, with the remaining event occurring at nine months.”
- “There were four recurrences identified on the ipsilateral side and treated by surgical intervention, yielding a reoperative recurrence rate of 2.3%.”
- “...both the rates observed in Bouma, et al. and the current study are substantially lower compared to those reported by both Kim and Carragee, et al., who in the same large annular defect demographic, reported recurrence rates of 18.0% and 27.3%, respectively, without the use of an ACD.”

Effectiveness Of An Annular Closure Device In A ‘Real-World’ Population: Stratification Of Registry Data Using Screening Criteria From A Randomized Controlled Trial
A Kursumovic, S Rath

- Evaluate ACD in “real-world” patients who would meet the inclusion criteria of an ongoing RCT compared with patients who would be excluded from the RCT.
- “Stratification of this “real-world” series on the basis of RCT screening criteria did not result in significant between-group differences.”
- These findings corroborate the robust safety and effectiveness of the ACD beyond the strictly defined patient population included in the RCT of this device.

Outcomes Of Surgical Treatment Of Lumbar Disk Herniation Using An Annular Closure Device
AJ Sanginov, AV Krutko, ES Baykov, AA Lutsik

- Study involved 120 patients with LDH operated on by limited discectomy and annular closure using the
Barricaid device. Average age of patient was 37.6 years and the mean follow-up period was 18.9 months.

- “No intraoperative complications were observed in our case series.”
- “Disc reherniation at the operated level was observed in 1.7% of patients. Postoperative complications occurred in 3 (2.5%) patients. Reoperation rate was 4.2%.”
- “The use of Barricaid annular closure device in 120 patients with lumbar disc herniation and high risk of recurrent herniation showed good clinical and radiographic outcomes.”

Two-year real-world results of lumbar discectomy with bone-anchored annular closure in patients at high risk of reherniation
A Ardeshiri, LE Miller, C Thomé

- “Among 75 high-risk patients (mean age 45 years), the cumulative event incidence through 2 years was 4.0% for reoperation and 1.4% for herniation recurrence.”
- “In patients at high risk of herniation recurrence following limited lumbar discectomy in routine clinical practice, additional implantation of an ACD was safe and reherniation recurrence rates were low at 2-year follow-up, which is favorably compared to reported rates in high-risk patients.”

Minimally Invasive

BMC Musculoskeletal Disorders (2018) 19:269
Implantation of a bone-anchored annular closure device in conjunction with tubular minimally invasive discectomy for lumbar disc herniation: a retrospective study
F Martens, G Lesage, J Muir, J Stieber

- “Our study demonstrated the viability of an annular closure device as an adjunct to minimally-invasive tubular lumbar discectomy in patients with large (~5 mm) annular defects.”
- “Our study demonstrated the excellent safety record associated with this device in this minimally-invasive setting, with no adverse events in 60 procedures, reflecting the overall safety of the procedure in general.”
- “The mean operative time was 29 min (range: 16–50) from incision to wound closure.”
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