Effect of an Annular Closure Device (Barricaid) on Same-Level Recurrent Disk Herniation and Disk Height Loss After Primary Lumbar Discectomy

Two-year Results of a Multicenter Prospective Cohort Study

Scott L. Parker, MD, Gordan Grahovac, MD,† Duje Vukas, MD,‡ Milorad Vilendecic, MD,† Darko Ledic, MD,‡ Matthew J. McGirt, MD,* and Eugene J. Carragee, MD§*

Study Design: A prospective cohort study.

Objective: To evaluate whether an annular closure device could be implanted safely to reduce same-level recurrent disk herniation, or attenuate disk height loss and improve the outcome after lumbar discectomy.

Summary of Background Data: Same-level recurrent disk herniation, disk height loss, and progressive degeneration are common complications and sequelae after lumbar discectomy. Techniques to reduce these consequences may improve outcomes.

Methods: Forty-six consecutive patients undergoing lumbar discectomy for single-level herniated disk at 2 institutions were followed prospectively with clinical and radiographic evaluations at 6 weeks and 3, 6, 12, and 24 months (control cohort). A second consecutive cohort of 30 patients undergoing 31 lumbar discectomies with implantation of an annular closure device was followed similarly. Incidence of recurrent disk herniation, disk height loss, the leg and back pain visual analog scale (VAS), and the Oswestry Disability Index were assessed at each follow-up.

Results: Cohorts were well matched at baseline. By 2 years of follow-up, symptomatic recurrent same-level disk herniation occurred in 3 (6.5%) patients in the control cohort versus 0 (0%) patients in the annular repair cohort ($P = 0.27$). A trend of greater preservation of disk height was observed in the annular repair versus the control cohort 3 months (7.9 vs. 7.27 mm, $P = 0.08$), 6 months (7.81 vs. 7.18 mm, $P = 0.09$), and 12 months (7.63 vs. 6.9 mm, $P = 0.06$) postoperatively. The annular closure cohort reported less leg pain (VAS-LP: 5 vs. 16, $P < 0.01$), back pain (VAS-BP: 13 vs. 22, $P < 0.05$), and disability (Oswestry Disability Index: 16 vs. 22, $P < 0.05$) 1 year postoperatively.

Conclusions: Implantation of a novel annular repair device was associated with greater maintenance of disk height and improved 1-year leg pain, back pain, and low-back disability. Recurrent disk herniation did not occur in any patient after annular repair. Closure of annular defect after lumbar discectomy may help preserve the physiological disk function and prevent long-term disk height loss and associated back and leg pain.

Key Words: annular closure device, Barricaid, disk height discectomy, lumbar, recurrent disk herniation

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Lumbar discectomy is the most common surgical procedure performed in the United States for patients experiencing back and leg pain from herniated lumbar disks.[1,2] Although lumbar discectomy results in an improvement in body pain, physical function, and disability in the vast majority of patients,[2–6] a small proportion of patients will incur same-level recurrent lumbar disk herniation.[7,8] In addition, some patients will develop progressive degeneration and loss of height of the operative disk space.[9–11] Recurrent disk herniation and/or progressive disk space loss often leads to increased pain and disability, which may necessitate repeat surgery.[11–13] Repeat surgery, however, does not always improve symptoms.[11–13]

The reported incidence of same-level recurrent disk herniation after lumbar discectomy varies between 3% and 18% in retrospective studies.[3,7,8,14–16] This wide range is secondary to variations in the follow-up time, management paradigms, annular disruption, and the surgical technique.[3,7,8,14–16] We recently reported the results of a prospective, controlled, multi-institutional cohort study with standardized sequential imaging for 2 years after lumbar discectomy.[17] This study demonstrated a 10% incidence of symptomatic same-level recurrent disk herniation requiring

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From the *Department of Neurosurgery, Vanderbilt University School of Medicine, Nashville, TN; †Department of Neurosurgery, University Hospital Dubrava, Zagreb; ‡Localitet Susak Neurosurgery, Rijeka, Croatia; and §Department of Orthopedics, Stanford University, Stanford, CA.

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Reprints: Scott L. Parker, MD, Department of Neurosurgery, Vanderbilt Medical Center, 1500 21st Ave. South, Suite 1506, Nashville, TN 37212 (e-mail: scott.parker@vanderbilt.edu).

reoperation.[17] Furthermore, there was a mean 30% loss in preoperative disk height by 2 years postoperatively,[17] which was consistent with previous disk height studies.[9–11] More importantly, this study demonstrated that patients requiring revision discectomy reported a worsened disability and quality of life at 2 years, suggesting that recurrent herniation may be associated with both immediate and long-term consequences. These results support the need to develop techniques to prevent recurrent herniation and disk height loss after discectomy.

One potential technique to decrease reherniation and/or disk space loss is annular closure. Annular closure or annular barrier devices allow for closure of the post-discectomy annular defect through which recurrent nucleus pulposus herniation can occur. This device is implanted in the disk space after discectomy and is anchored into one of the adjacent vertebral bodies. Preliminary in vitro biomechanical studies suggest that closure of annular defects with an annular closure device has the potential to restore intradiskal pressures to pre-operative levels.[18] Normal physiological pressures help regulate many key cellular processes within the disk and may therefore promote improved disk health post-discectomy. In addition, annular closure theoretically recreates the contained physiological anatomy of the disk space, may prevent subclinical egress of disk material, and potentially attenuates disk height collapse. The annular closure device utilized in this study (Barricaid; Intrinsic Therapeutics, Woburn, MA) is a CE-marked device and is approved for marketing wherever the CE mark is accepted.

We conducted a prospective, nonrandomized, comparison cohort study with standardized clinical and radiographic evaluation every 3 months for 2 years to determine whether implantation of a novel annular closure device could (1) be placed safely without increasing perioperative complications, (2) reduce same-level recurrent disk herniation or disk height loss after lumbar discectomy, and (3) be associated with improvement in pain and disability by 2 years after lumbar discectomy.

METHODS

Patient Selection

This prospective, controlled, nonrandomized comparative cohort study was conducted at 2 university medical institutions with the primary aim of comparing the 12-month incidence of same-level recurrent disk herniation, disk height loss, and outcome after primary lumbar discectomy between patients receiving implantation of an annular closure device versus those not receiving implantation. Secondary endpoints included perioperative morbidity and postoperative improvement in pain and disability. Patients undergoing surgical discectomy for a single-level, herniated lumbar disk resulting in radiculopathy between January 2003 and May 2006 were eligible for inclusion in the control cohort. This cohort of control patients was a subset of a previously published 5-institution study evaluating the effect of annular defect size and disk volume removal on recurrent herniation.[17] These consecutive patients underwent discectomy without any form of annular closure. Patients undergoing surgical discectomy between May 2008 and May 2009 at the same 2 institutions were eligible for inclusion in the annular closure cohort. These consecutive patients received implantation of the annular closure device (Barricaid; Intrinsic Therapeutics) at the completion of discectomy. Surgeons, institutions, follow-up, and all patient care were standardized across both cohorts. The implant study was prospectively approved by the local site Ethics Committees. Changes were made to the implant design and protocol, which were submitted for Ethics review after implementation. All patients provided informed consent. The Barricaid cohort was monitored by an independent data safety monitoring board (DSMB).

To be included in either cohort, a patient had to have (1) failed at least 6 weeks of conservative therapy or had a neurological deficit, (2) a preoperative magnetic resonance imaging (MRI) study confirming a disk herniation localizing to radicular symptoms, (3) leg pain graded on the visual analog scale (VAS) as higher than 40/100, (4) dysfunction graded on the Oswestry Disability Index (ODI) as greater than 40/100, and (5) an age of 18–70 years.

For all included patients, surgery was offered if a patient had failed 6 weeks of nonoperative treatment, had intolerable sciatica, or had severe neurological deficit including motor loss or symptoms or signs of cauda equina. The only surgery offered to the surgical candidates was a unilateral posterior lumbar discectomy. All patients were evaluated and operated upon by the same 3 surgeons, regardless of the cohort.

Patients were excluded if they (1) had a history of back operation, (2) had foraminal or extraforaminal disk herniation, (3) had an extraspinal cause of sciatica, (4) had an active medical or workman's compensation lawsuit, (5) had any preexisting spinal pathology, or (6) were unwilling or unable to participate in follow-up procedures. Patients with notable nonintervertebral disk abnormalities, such as spondylolysis, spondylolisthesis, inflammatory arthritis, or metabolic bone disease, were also excluded.

The Surgical Technique

Posterior lumbar discectomy was performed in all cases. All patients received prophylactic antibiotics at incision. In some patients, discectomy could be performed through the interlaminar space alone. A small unilateral laminotomy was performed in the remaining patients. Medial facetectomy was performed rarely and only if the medial facet was clearly impinging on the nerve root after discectomy. The surgical technique was identical for the annular closure and the control cohorts and was performed by the same 3 surgeons.

The Barricaid annular prosthesis is a device designed to close defects in the annulus after discectomy and is implanted immediately after the discectomy before

closure. This device has a titanium anchor that is placed into one of the adjacent vertebral bodies using tamp and mallet (Fig. 1A); the mesh polymer expands across the entirety of the posterior intervertebral space in the region of the annular defect, overlying the residual physiological nucleus pulposus. Two platinum-iridium markers within the polymer mesh allows visualization on plain films (Fig. 2).

Radiographic Measures

All patients underwent computerized tomography of the lumbar spine preoperatively and 12 and 24 months after surgery. Patients also underwent MRI of the lumbar spine without contrast preoperatively and 12 and 24 months after surgery. Patients experiencing symptoms indicative of recurrent disk herniation during a standardized clinical follow-up between discharge and 24 months after surgery underwent MRI and computerized tomography of the lumbar spine at the time of symptom onset to be assessed for same-level reherniation. X-rays, taken at each follow-up visit, were assessed for device migration, dislodgement, and integrity.

The disk height was assessed preoperatively, 6 weeks and 3, 6, 12, and 12 months after surgery by x-ray evaluation (Medical Metrics Inc., Houston, TX). These measurements were made by an independent radiologist not involved in clinical care. Preoperative and postoperative disk heights were compared between cohorts at each time point. The disk height was measured from neutral lateral x-rays by (1) identifying the 4 corners of the disk space, (2) measuring the anterior and the posterior disk heights, and (3) calculating the simple average of the anterior and the posterior disk heights. The anterior disk height was defined as the distance between the anterior-inferior corner of the superior vertebra and the corresponding corner of the inferior vertebra. The posterior disk height was defined as the distance between the posterior-inferior corner of the superior vertebra and the corresponding corner of the inferior vertebra. These distances were measured perpendicular to the superior endplate of the inferior vertebra. All measurements were performed using an FDA-approved analysis software (QMA, Medical Metrics Inc., K022585).[19] This software optimizes the registration of sequential (eg, flexion-extension) or longitudinal images so that measurements can be taken from consistent landmarks and has been validated to measure changes in the disk height accurate to within 1 mm or better.[20] The reproducibility has also been validated in the lumbar spine.[21]

Two-year Outcome Measures

All patients were followed for 24 months after discectomy. Clinical outcomes were determined by independent evaluation preoperatively, 6 weeks, and 3, 6, 12, and 24 months after surgery. At each follow-up time point, quantitative measurements of pain and disability were assessed by two patient assessed questionnaires: the Oswestry Back Pain Disability Questionnaire[22] and the visual analog scale[23] for low back pain (VAS-BP) and leg pain (VAS-LP).[23] Patients were classified as having symptomatic recurrent disk herniation when same-level recurrent disk herniation was present on MRI and was localized to the patient's recurrent symptoms.

Any complications occurring during placement of the annular closure device, such as durotomy, nerve root injury, inability to implant, or the need to remove the device, were recorded. Any episodes of postoperative leg or back pain accruing within 24 months after surgery

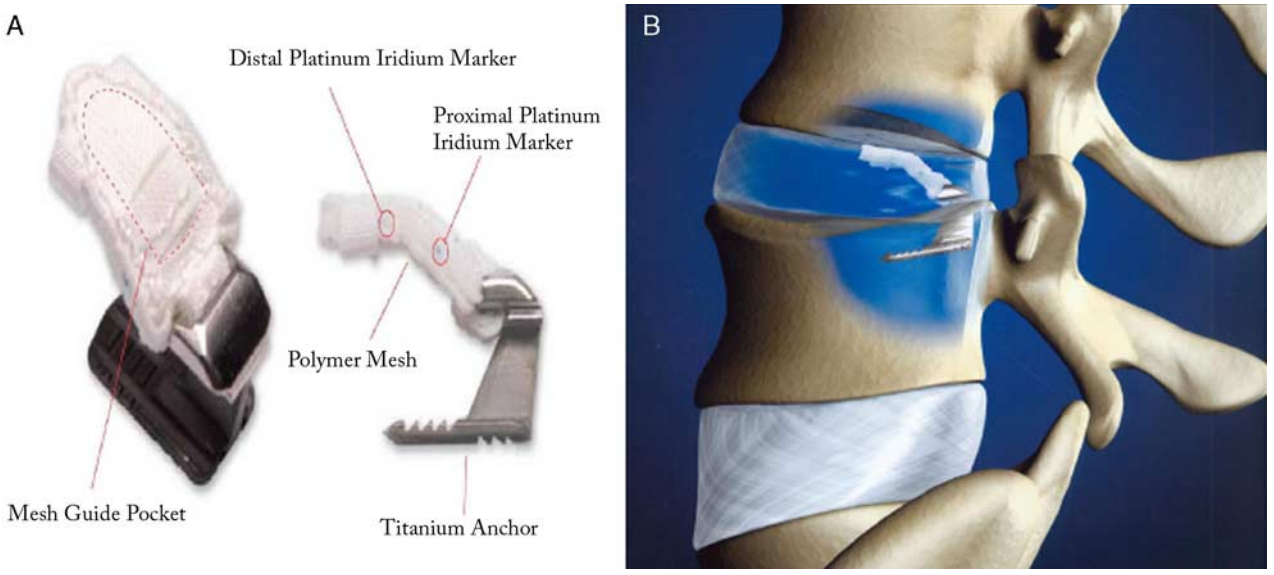

FIGURE 1. An illustration depicting (A) the Barricaid device and (B) the device implanted. This device has a titanium anchor that is placed into the lower vertebral body using tamp and mallet. The mesh polymer expands across the entirety of the intervertebral space, overlying the residual physiological nucleus pulposus. Two platinum-iridium markers within the polymer mesh allow visualization on plain films. full color online

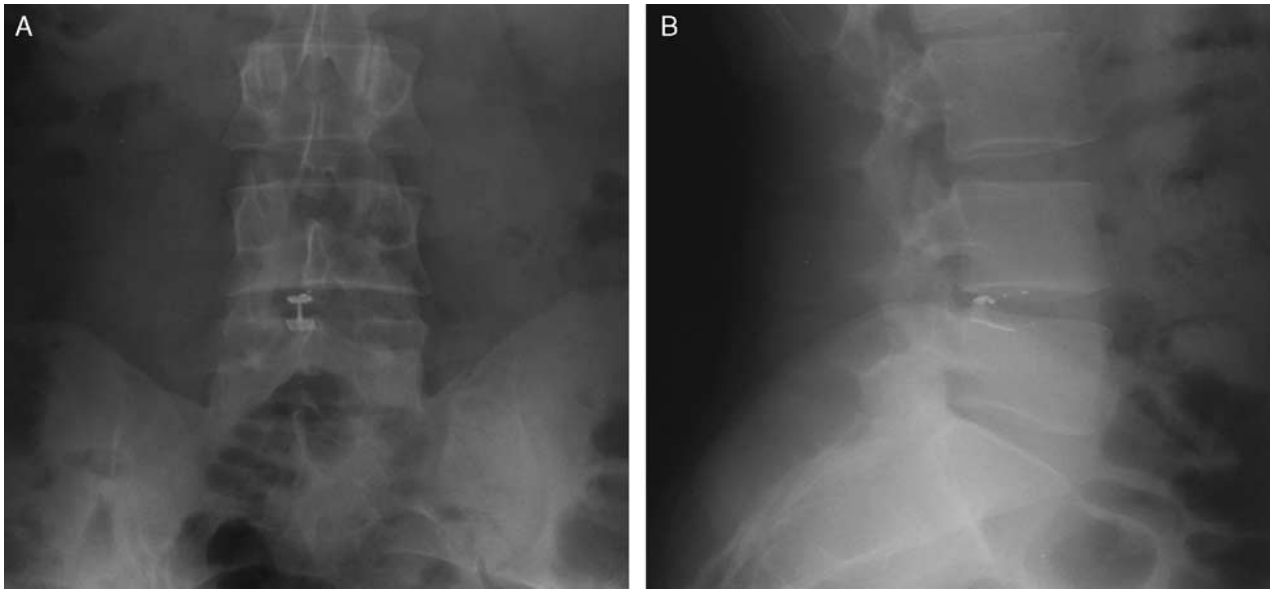

FIGURE 2. Anterior-posterior (A) and lateral (B) x-ray radiographs of the lumbar spine, demonstrating Barricaid implantation.

found to be associated with device placement or migration were also recorded.

Statistical Analysis

Primary endpoints of this study were symptomatic, same-level, recurrent disk herniation and same-level disk height loss. Incidence of recurrent herniation and the percent disk height loss were compared between the Barricaid and the control cohorts by a Fisher exact test or χ^2 and Student t tests with a 2-tailed analysis, respectively (Statview 5.0, SAS, 1998). Postoperative VAS-LP, VAS-BP, and ODI (mean ± SD) were the secondary endpoints compared between cohorts.

RESULTS

Patient Population

Forty-six patients were enrolled in the control cohort and 30 patients were enrolled in the annular closure cohort. One patient in the annular closure cohort underwent a 2-level discectomy for concurrent herniated disks and received annular closure at both levels. Annular closure versus control cohorts were similar with respect to the mean ± SD age (38 ± 9 vs. 41 ± 9 y), the weight (83 ± 9 vs. 81 ± 12 kg), the preoperative disk height (8.6 ± 1.7 vs. 8.3 ± 1.3 mm), and the preoperative low-back disability (ODI: 63 ± 14 vs. 57 ± 13). Preoperative VAS-BP (66 ± 17 vs. 50 ± 23) and VAS-LP (80 ± 13 vs. 69 ± 17) were greater in the annular closure cohort ($P < 0.01$). Levels of disk herniation were similar between cohorts (Table 1).

In the annular closure cohort, there was no device-related morbidity such as durotomy or nerve root injury during implantation, inability to place the device, or postoperative device migration. A durotomy occurred in 1 patient in the Barricaid cohort during disk fragment removal and was not related to placement of the annular closure device. One patient in the control cohort also experienced a durotomy. One patient underwent disk debridement and wound incision and drainage for suspected discitis 56 days after the primary surgery. The annular closure device was left in place. Clinical and serological indicators of discitis resolved with intravenous antibiotic therapy. Otherwise, there was no perioperative morbidity in the control cohort.

Recurrent Disk Herniation

All patients in both cohorts were followed for 24 months for recurrent disk herniation. Recurrent same-level disk herniation occurred in 3 (6.5%) patients in the control cohort; of these, 2 (66%) elected for revision discectomy, and 1 (33%) elected for conservative therapy alone, despite persistent back pain and leg pain at 1 and 2 years. No patients in the annular closure cohort experienced symptomatic recurrent disk herniation. This difference (0% vs. 6.5%) in symptomatic recurrent disk herniation in the annular closure cohort did not reach statistical significance for this sample size ($P = 0.27$, Fisher exact test).

Loss of Disk Height

Disk height measurement was obtained at the 12-month follow-up in all annular repair patients and in 33 (72%) patients in the control group. The two-year disk height measurement was available in 29 (96%) of the annular repair and 25 (54%) of the control cohort patients. The mean disk height was similar between cohorts at baseline before discectomy (8.6 ± 1.7 vs. 8.3 ± 1.3 mm). A trend of greater preservation of disk height was observed in the annular repair cohort 3 months (7.9 ± 1.6 vs. 7.27 ± 1.2 mm, $P = 0.08$), 6 months (7.81 ± 1.6 vs. 7.18 ± 1.1 mm, $P = 0.09$), and 12 months

TABLE 1. A Summary of Patient Characteristics in the Barricaid and the Control Discectomy Cohorts

Variables	Barricaid (n = 30)	Control (n = 46)	*P*
Age (y)	38 ± 9	41 ± 9	NS
Weight (kg)	83 ± 9	81 ± 12	NS
L3–L4	0 (0%)	2 (4%)	NS
L4–L5	19 (64%)	24 (48%)	NS
L5–S1	12 (36%)	20 (40%)	NS
PreOp Disk Height (mm)	8.6 ± 1.7	8.3 ± 1.3	NS
PreOp VAS-BP	66 ± 17	50 ± 23	< 0.01
PreOp VAS-LP	80 ± 13	69 ± 17	< 0.01
PreOp ODI	63 ± 14	57 ± 13	NS

The surgical technique, institutional care, the surgeon, and postoperative follow-up were standardized between these sequential cohorts. Barricaid patients had a greater mean back and leg pain at presentation. Age, weight, the level of disk herniation, the preoperative disk height, and the preoperative low-back disability (ODI) were similar between cohorts.

NS indicates not significant; ODI, Oswestry Disability Index; PreOp, preoperative; VAS-BP, back pain visual analog scale; VAS-LP, leg pain visual analog scale.

after surgery (7.63 ± 1.5 vs. 6.9 ± 1.1 mm, $P = 0.054$) (Fig. 3).

Pain and Disability

In the annular closure cohort, all (100%) patients completed their patient-reported outcome assessment 1 year after surgery, and 29 (96%) patients, 2 years after surgery. A significant ($P < 0.01$) improvement in all outcome measures was observed at 6 weeks and 3, 6, 12, and 24 months after surgery [the mean 12-month improvement from baseline: VAS-BP (53 ± 21), VAS-LP (75 ± 13), and ODI (47 ± 18); (Fig. 4)]. In the control cohort, 38 (83%) patients completed their patient-reported outcome assessment 1 year after surgery. Only 23 (50%) patients in the control group completed outcome questionnaires 2 years after surgery. A significant ($P < 0.01$) improvement in all outcome measures was also observed at 6 weeks and 3, 6, 12, and 24 months after discectomy alone [the mean 12-month improvement from baseline: VAS-BP (31 ± 25), VAS-LP (53 ± 27), and ODI (35 ± 19)].

Despite presenting with more severe back and leg pain preoperatively, the annular closure cohort reported less leg pain (VAS-LP: 5 ± 8 vs. 16 ± 18, $P < 0.01$), back pain (VAS-BP: 13 ± 16 vs. 22 ± 22, $P < 0.05$), and disability (ODI: 16 ± 12 vs. 22 ± 14, $P < 0.05$) 1 year after surgery (Fig. 4). The extent of 1-year improvement (the change score) was significantly greater in the annular repair versus the control cohort (VAS-LP: 75 ± 12 vs. 52 ± 27, $P < 0.001$; VAS-BP: 53 ± 22 vs. 31 ± 25, $P < 0.001$; ODI: 47 ± 17 vs. 35 ± 19, $P < 0.005$). The mean VAS-LP (9 ± 20 vs. 18 ± 18, $P < 0.05$), VAS-BP (10 ± 19 vs. 21 ± 22, $P < 0.05$), and ODI (11 ± 10 vs. 21 ± 17, $P < 0.05$) scores remained significantly lower in the annular repair versus the control cohorts 2 years after surgery (Fig. 4).

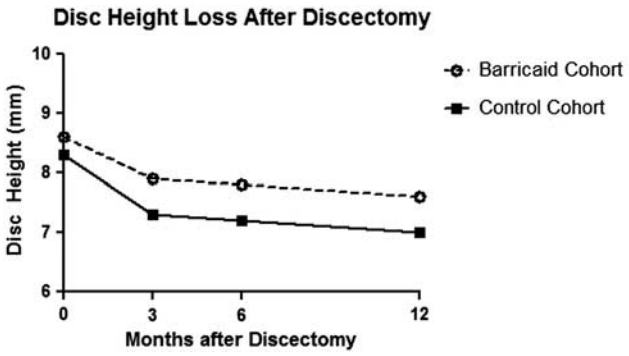

FIGURE 3. Percentage disk height loss at the operative disk level in patients undergoing standard lumbar discectomy (control cohort) versus lumbar discectomy with implantation of Barricaid annular repair device (Barricaid cohort). Disk height loss was attenuated in the annular closure cohort.

DISCUSSION

In this prospective comparison cohort study, we evaluated the safety and performance of a novel annular closure device in reducing the incidence of same-level recurrent disk herniation, disk height loss, and long-term leg/back pain and disability after lumbar discectomy. There was no device-related morbidity associated with Barricaid implantation including durotomy, nerve root injury, and/or postoperative device migration. Patients receiving annular closure experienced a trend toward less disk height loss by 2 years. While underpowered to observe a moderate effect using a statistical significance α of 0.5, the annular closure was associated with a decrease in the incidence of recurrent disk herniation from 6.5% to 0%. Back pain and disability improved in all patients regardless of the use of annular closure. These results suggest that this novel annular closure device may be associated with limited risks in the setting of lumbar discectomy, while apparently attenuating disk degeneration and collapse after discectomy. The results also suggest that the preservation of disk height and annular competence may decrease post discectomy back pain and disability.

Lumbar discectomy is the most common surgical procedure performed for herniated disk causing back and/or leg pain.[1,2] Many studies have found that this procedure is more effective at improving patient symptoms, disability, and quality of life than other common spine procedures including cervical laminectomy and lumbar fusion.[24–26] Although the majority of patients will experience significant clinical improvement after lumbar

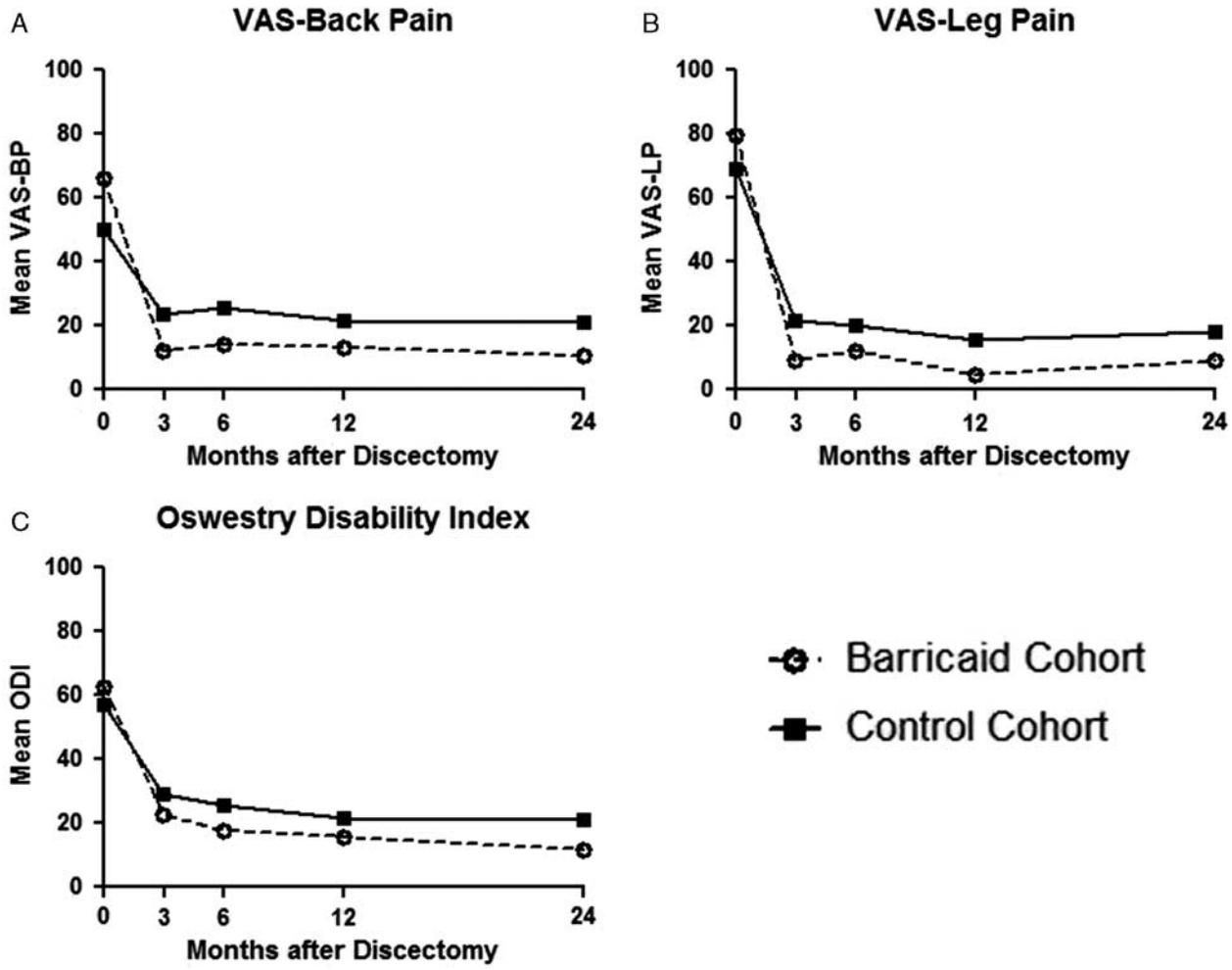

FIGURE 4. Mean ± SD of the (A) back pain visual analog scale (VAS-BP) score, (B) leg pain (VAS-LP) score, and (C) Oswestry Disability Index (ODI) in the Barricaid versus the control cohort. By 6 weeks after primary discectomy, a significant improvement in back pain, leg pain, and low-back disability was observed and maintained over the 24-month follow-up period in both cohorts. Despite greater pain and disability at baseline, the mean VAS-BP, VAS-LP, and ODI were significantly ($P < 0.05$) less in the annular repair versus the control cohort at all follow-up time points.

laminectomy, up to 20% of patients may not experience sustained clinical improvement with long-term follow-up.[2–6] This lack of clinical improvement has been attributed to a variety of factors including disk reherniation, disk height loss, and degeneration.[3,7,8,14–16]

The development of recurrent disk herniation, disk height loss, and degeneration is a well-known consequence of lumbar discectomy.[7,9–11,27] The reported incidence of recurrent disk herniation ranges from 3% to 18% in retrospective studies.[3,7,8,14–16] The average reported disk height loss after discectomy has been reported to be 25%.[9–11] Increasing disk height loss is associated with back pain, increased disability, and worsened quality of life.[28,29] We recently reported a rate of recurrent disk herniation of 10% and a mean 30% loss in the preoperative disk height in a 2-year prospective cohort study.[17] Reherniation occurred most frequently in a bimodal distribution, with the majority of patients experiencing reherniation within 4 months postoperatively and the remaining patients after 11 months.[17] A subset of patients who experience reherniation develop back and/or leg symptoms poorly responsive to conservative and surgical therapy.[11–13,30,31] Hence, surgical treatments aimed at decreasing the incidence of disk reherniation and/or height loss may allow for improved outcomes after lumbar discectomy.

The Barricaid annular closure device was designed to block the annular defect effectively. This device is implanted in the disk space after discectomy, and is anchored into one of the adjacent vertebral bodies. It serves to decrease recurrent herniation by blocking potential disk protrusion/extrusion through the open annular defect. The mechanism by which disk height is preserved is less clear. The prevention of egress of disk material through the annular defect over time may help preserve the disk volume and hydration, indirectly maintaining the physiology of the disk space and preserving the disk height. The improved long-term leg and back pain scores

reported by patients receiving annular closure were of note. This phenomenon occurred despite greater pain scores preoperatively in the annular closure cohort. It is well reported that an increased disk height results in greater foraminal height and area, leading to improved radicular pain symptoms.[29,32] Furthermore, postdiscectomy disk degeneration and height loss can be associated with significant mechanical back pain. Through this mechanism, it is likely that Barricaid effect on disk height preservation indirectly contributed to the improved leg and back pain observed 2 years after surgery, translating into less low-back disability after lumbar discectomy. These results suggest that this novel annular closure device can be used safely in the setting of lumbar discectomy and provides favorable outcomes to discectomy alone, while attenuating postdiscectomy disk height loss.

CONCLUSIONS

Implantation of a novel annular repair device was performed without clear device-related morbidity and was associated with greater maintenance of disk height and improved 1-year leg pain, back pain, and low-back disability. Recurrent disk herniation did not occur in any patients after annular repair. Closure of the annular defect after lumbar discectomy may help preserve some aspects of the physiological disk function and prevent long-term disk height loss and associated back and leg pain.

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