Should Annular Closure Devices Be Utilized to Reduce the Risk of Recurrent Lumbar Disk Herniation?

Timothy P. Murphy, MD, Nicholas M. Panarello, MD, Michael D. Baird, MD, Melvin D. Helgeson, MD, and Scott C. Wagner, MD

YES

Timothy P. Murphy, MD and Michael D. Baird, MD

Recurrent disk herniation (RDH) following microdiscectomy for lumbar disk herniation is a well-documented phenomenon and radiographic evidence of RDH occurs at rates up to 23.1% at 2 years following surgery among all patients.[1] Symptomatic RDH necessitating reoperation occurs at rates of about 10% at 2 years, is associated with worse patient outcomes and significant health care costs, and the risk increases with annular defects as they grow in size.[1–3] One option to reduce the risk of RDH is to perform an annular closure, potentially decreasing the need for reoperation and minimizing the burden on patients and the health care system.

Annular closures are performed using an implantable device designed to reduce the incidence of RDH. There is currently 1 device in particular that is Food and Drug Administration-approved for this procedure with robust literature supporting its efficacy.[4] Multiple studies, including randomized trials[5,6] have demonstrated clinically significant lower rates of symptomatic reherniation and reoperation following microdiscectomy with the use of an annular closure device in patients at high risk for reherniation.

Although the incidence of symptomatic RDH varies, one prospective observational study reported RDH in 27.3% of patients with disk herniations associated with large/massive annular defect (6 mm or greater defect).[7] In a randomized clinical trial of 554 microdiscectomy patients with large annular defects, the rate of symptomatic RDH among those who did not undergo closure was found to be 25.3%.[5] A significant decrease was found in the group undergoing annular closure, as only 12% of those patients experienced symptomatic RDH at 2-year follow-up.[5] In subsequent analysis of the same group at 3-year follow-up, this significant difference in symptomatic RDH was maintained (14.8% in annular closure device group vs. 29.5% in control group).[6] A higher reoperation rate was also observed in the control group (11% vs. 19.3%) at 3 years. No increase in adverse events was observed the annular closure device group. Serious adverse events were in fact more frequent in the control group, mostly attributable to the incidence of reherniation requiring reoperation.[5,6]

Similarly, larger meta-analysis studies demonstrate encouraging outcomes for patients undergoing lumbar discectomy who are treated with an annular closure device. A significant reduction in symptomatic RDH was observed in patients treated with an annular closure device/annular repair compared with the discectomy only (2.9% vs. 7.9%). Similar improvements were seen in Oswestry Disability Index and visual analogue scale pain scores, suggesting that annular repair does not compromise subjective clinical outcomes. Importantly, no significant difference in postoperative complications was seen in patients treated with annular closure. However, the studies included in this analysis are limited by their relatively short follow-up, between 3 and 24 months. Nonetheless, this meta-analysis of 811 lumbar discectomies treated with an annular closure device/annular repair suggests that these devices reduce symptomatic RDH without an increase in postoperative complications at early follow-up.[8]

Use of an annular closure device in patients identified as high risk for reherniation following discectomy may represent a unique opportunity for meaningful improvement in clinical outcomes and decreased burden on the health care system with costly reoperations. Patients with annular defects wider than 6 mm or with a defect size $> 54\ mm^2$ are known to have higher rates of reherniation than patients with smaller defect sizes.[3,7] Aggressive debridement of the nucleus pulposus has been advocated for these patients to reduce the risk of reherniation, although this must be balanced with the increased risk of back pain associated with this technique.[9] Annular closure following microdiscectomy may allow for more limited debridements, without increasing the symptomatic RDH rate in

From the Department of Orthopaedic Surgery, Walter Reed National Military Medical Center, Bethesda, MD.

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Reprints: Timothy P. Murphy, MD, Department of Orthopaedic Surgery, Walter Reed National Military Medical Center, 4494 North Palmer Road, Building 19, 2nd Floor, Bethesda, MD 20889 (e-mail: tim.p.murphy14@gmail.com).

this high-risk group. A prospective study of 75 patients, the majority of whom had sizeable annular defects (defined as width >6 mm), demonstrated a low rate of symptomatic RDH at 2 years. The rate of symptomatic reherniation was only 1.5% in patients with an annular defect >6 mm.[10] This rate differs substantially from previously reported rates in patient that did not undergo annular closure.[1,5,7] In patients at high risk for reherniation, a limited discectomy with the use of an annular closure device may afford the opportunity to decrease the rate of reherniation while also eliminating the need for aggressive discectomy that can lead to higher rates of back pain.[10]

Reoperation following microdiscectomy represents a serious issue for patients and the health care system as a whole. However, the utilization of annular closure is a proven technique that provides a deterrent to symptomatic RDH. Although longer term studies would be beneficial, the current data suggest that their use represents a viable low-risk strategy to significantly decreasing the likelihood of symptomatic RDH and thereby increasing patient outcomes while simultaneously lowering the risk of reoperation.

NO

Nicholas M. Panarello, MD

Recurrent lumbar disk herniation following lumbar discectomy represents one of the most common postoperative complications, with radiographic evidence of reherniation occurring in up to 23.1% of patients at 2 years following surgery.[1] Recurrent lumbar disk herniation is defined as reherniation of the nucleus pulposus at the operative intervertebral level, after a pain-free interval of at least 6 months.[11] To date, multiple patient-specific risk factors and biomechanical parameters have been described as potential contributors to the risk of reherniation. Large annular tears, >6 mm in diameter, have been identified as one such risk factor.[7] Given that an annular tear may remain unsealed following lumbar discectomy, repair of the annular defect with an annular closure device has been purposed as a possible solution. However, there is limited longitudinal data supporting their use.

At this time, clinical evidence exists for 2 unique annular repair techniques: closure of the annular defect utilizing a soft tissue repair kit and implantation of a bone-anchored annular closure device. Research on this topic is largely relegated to large annular tears, which only comprise ~30% of patients.[12] Bailey et al[13] performed a randomized controlled trial to investigate outcomes following repair of the annulus fibrosus with a suture repair system after lumbar discectomy. In a population of 750 patients randomized in a 2:1 ratio to annular repair or lumbar discectomy without annular repair, the authors found there was no significant difference in recurrent lumbar disk herniation reoperations over a 2-year period. Clinical outcomes, such as back pain, leg pain, physical function, and disability were comparable between the 2 groups. Interestingly, the mean size of the annular defects repaired in this study was only 4.75 mm.[13]

In the case of bone-anchored annular closure devices, several prospective studies have been published supporting their use, citing lower symptomatic recurrent lumbar disk herniation and reoperation rates. In one such study, Thomé et al[5] concluded annular closure with a bone-anchored device lowers the risk of recurrence and reoperation. However, these results do not indicate that the use of annular closure devices represents a panacea. The authors elected not to utilize the annular closure device in 4 patients due to the proximity of the nerve root. When utilized, the device was unsuccessful in 5 patients either because the mesh did not enter the disk (4) or because of nerve root injury during attempted implantation (1). In addition, the authors reported a significantly longer operative time and blood loss within the annular closure group.[5]

Complications involving the use of annular closure devices also remain a clinical concern. A recent case report highlighted an unusual presentation of a young patient with new-onset radiculopathy 5 years status after lumbar discectomy and annuloplasty: imaging and subsequent reoperation revealed loosening of the annular closure device, secondary to *Propionibacterium acnes* infection.[14] As per the FDA Safety and Effectiveness data, this particular device had 34 (12.7%) deficiencies, including 5 anchor migrations and 29 occlusions of the component; 1 deep infection was reported.[15]

Recurrent lumbar disk herniation following lumbar discectomy represents a relatively common complication that portends a poor outcome, even with revision surgery. Although annular closure devices represent a promising innovation, further independent research is required to determine their longitudinal safety and efficacy.

REFERENCES

1. Lebow RL, Adogwa O, Parker SL, et al. Asymptomatic same-site recurrent disc herniation after lumbar discectomy. *Spine*. 2010;36:2147–2151.
2. McGirt MJ, Eustacchio S, Varga P, et al. A prospective cohort study of close interval computed tomography and magnetic resonance imaging after primary lumbar discectomy. *Spine*. 2009;34:2044–2051.
3. Ambrossi GL, McGirt MJ, Sciubba DM, et al. Recurrent lumbar disc herniation after single-level discectomy: incidence and health care cost analysis. *Neurosurgery*. 2009;65:574–578.
4. Barricaid. A proven solution for herniated disc patients [Barricaid Web site]. 2020. Available at: https://www.barricaid.com/. Accessed September 15, 2020.
5. Thomé C, Klassen PD, Bouma GJ, et al. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. *Spine J*. 2018;18:2278–2287.
6. Kienzler JC, Klassen PD, Miller LE, et al. Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation. *Acta Neurochir*. 2019;161:1389–1396.
7. Carragee EJ, Han MY, Suen PW, et al. Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and annular competence. *J Bone Joint Surg Am*. 2003;85-A:102–108.
8. Choy WJ, Phan K, Diwan AD, et al. Annular closure device for disc herniation: meta-analysis of clinical outcome and complications. *BMC Musculoskelet Disord*. 2018;19:290.
9. Watters WC III, McGirt MJ. An evidence-based review of the literature on the consequences of conservative versus aggressive discectomy for the treatment of primary disc herniation with radiculopathy. *Spine J*. 2009;9:240–257.

10. Bouma GJ, Barth M, Ledic D, et al. The high-risk discectomy patient: prevention of reherniation in patients with large anular defects using an anular closure device. *Eur Spine J*. 2013;22:1030–1036.
11. Swartz KR, Trost GR. Recurrent lumbar disc herniation. *Neurosurg Focus*. 2003;15:E10.
12. Miller LE, McGirt MJ, Garfin SR, et al. Association of annular defect width after lumbar discectomy with risk of symptom recurrence and reoperation: systematic review and meta-analysis of comparative studies. *Spine*. 2018;43:E308–E315.
13. Bailey A, Araghi A, Blumenthal S, et al. Prospective, multicenter, randomized, controlled study of anular repair in lumbar discectomy: two-year follow-up. *Spine*. 2013;38:1161–1169.
14. Lange N, Meyer B, Shiban E. Symptomatic annulus-repair-device loosening due to a low-grade infection. *Acta Neurochir (Wien)*. 2018;160:199–203.
15. US Food and Drug Administration. FDA Summary of Safety and Effectiveness Data (SSED). Barricaid® Anular Closure Device (ACD) PMA P160050. 2019.