Acta Neurochirurgica
https://doi.org/10.1007/s00701-020-04651-9

CASE REPORT - SPINE - OTHER

Annular closure device breakage due to recurrent lumbar disc herniation: a case report

Benedikt W. Burkhardt[1,2] · Joachim M. Oertel[1]

Received: 9 September 2020 / Accepted: 12 November 2020

Abstract
Detailed surgical management, magnetic resonance imaging (MRI), and computer tomography (CT) images of a broken annular closure device (ACD) have not been reported yet. In this case, a 28-year-old male presented with a new onset of radiculopathy three years after lumbar discectomy and placement of an ACD. The CT-myelography and MRI revealed a recurrent disc herniation (RDH) and dislocation of a broken ACD. ACD removal was performed and confirmed breakage due to RDH with scarring around the RDH and displaced ACD. Implant-associated complications and management should be reported in detail in order to enhance knowledge on device-related complications.

Keywords Annuloplasty · Annular closure device · Barricaid · Breakage · Complication · Recurrent disc herniation

Background

Microsurgical lumbar discectomy (MLD) is a standardized procedure for the treatment of sciatica caused by lumbar disc herniation (LDH). Long-term follow-up studies have demonstrated that MLD offers a high rate of clinical success [4, 5]. However, several drawbacks following MLD have been reported such as a rate of recurrent disc herniation (RDH), which varies between 5 and 15%, loss of disc height, and progressive degeneration of the facet joints [7, 13]. Reoperation for RDH is challenging since it is associated with higher rate of complication, and lower rate of clinical success than primary MLD procedures [1, 8]. The risk of reoperation for RDH is higher in patients with larger annular defect width [15]. An annular closure device (ACD) has been developed to reduce the risk of RDH [12]. The ACD consists of a flexible polymer occlusion component, which closes the annular defect. This flexible component attaches to a titanium alloy bone anchor, which is driven into the adjacent vertebral body to secure the correct poisoning of the ACD. A multicenter randomized trial was conducted to determine the effectiveness of additional placement of a ACD to lower the risk of RDH and reoperation in patients with large annular defects following MLD. According to a meta-analysis performed by Miller et al., the risk of reoperation for RDH following implantation of an ACD is 7.7% within two years of follow-up and therefore 48% lower compared to 14.5% following conventional MLD [14]. However, literature body of detailed descriptions of device-related complications and reoperation is small. In this case report, the authors describe a ACD-related complication which occurred three years postoperatively and resulted in revision surgery in detail.

This article is part of the Topical Collection on *Spine - Other*

✉ Benedikt W. Burkhardt
benedikt.burkhardt@gmail.com

[1] Department of Neurosurgery, Saarland University Medical Center and Saarland University Faculty of Medicine, Homburg, Saar, Germany

[2] Klinik für Neurochirurgie, Universitätsklinikum des Saarlandes und Medizinische Fakultät der Universität des Saarlandes, Kirrbergerstrasse 100 Gebäude 90.5, 66421 Homburg, Saar, Germany

Published online: 21 November 2020

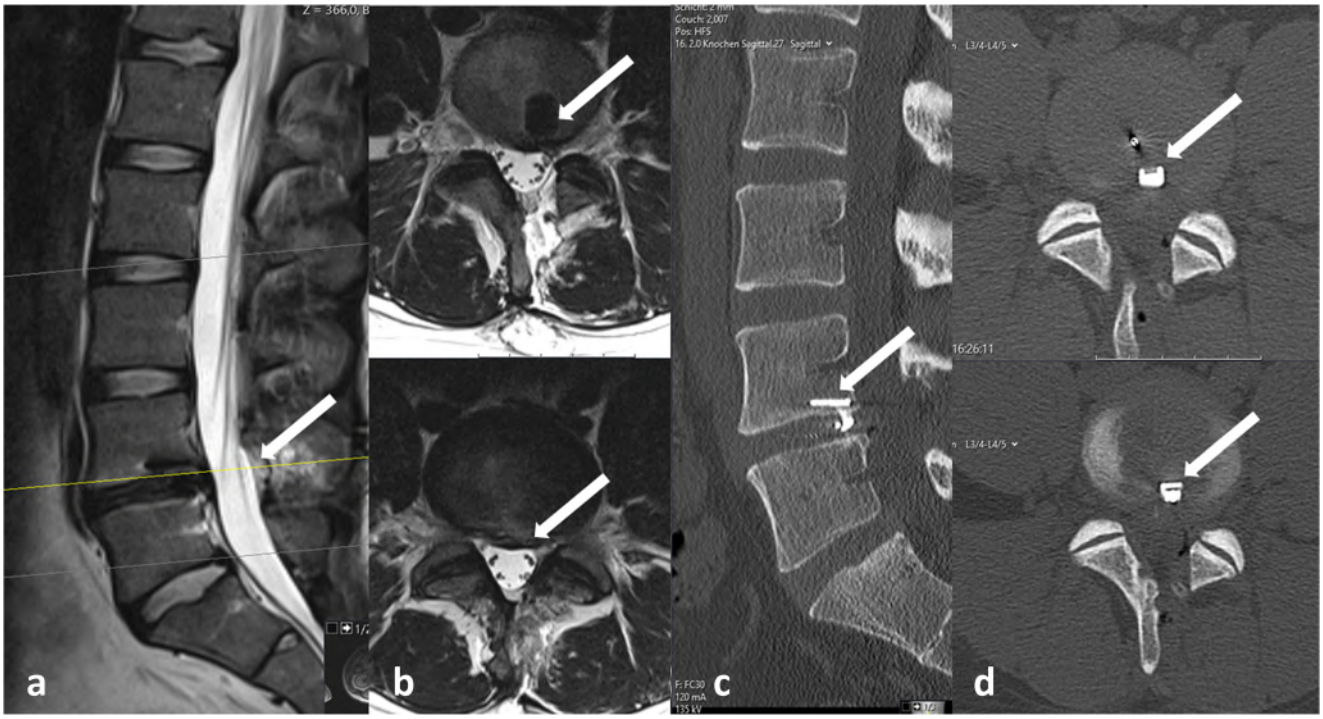

Fig. 1 Postoperative MRI and CT scan. **a** Sagittal MRI image of the L4/5 disc space showing the decompressed spinal canal (white arrow). **b** Axial MRI image showing the anchor of the ACD (arrow, upper image) and the decompressed spinal canal (lower image). **c** Sagittal CT image showing the regular position of the ACD anchor (arrow) within the vertebral body. **d** Axial image showing the position of the anchor of the ACD

Case presentation

A 28-year-old male patient underwent MLD with implantation of a 10-mm ACD (Barricaid Intrinsic Therapeutics, Inc., Woburn, MA, USA) for treatment of a left-sided LDH. Postoperative MRI and computer tomography (CT) scan showed a complete resection of the LDH as well as a regular positioning of the ACD (Fig. 1). Six months after surgery, the patient reported to be pain free and had a complete neurological recovery. A radiograph showed regular positioning on the device (Fig. 2).

Three years after the procedure, the patient presented again and reported new back pain which worsened continuously over the past two years. Also a new onset of intensive left-sided leg pain did not respond to conservative therapy. A MRI scan showed a recurrent left-sided disc herniation and migration of the ACD towards the spinal canal with consecutive nerve root compression (Fig. 3).

A post-myelogram CT scan was performed for better understanding of the relationship between the ACD and nerval structures, which revealed no loosening of the titanium alloyed anchor and no erosion of the vertebral body endplates but did reveal a breakage of the titanium arm that connects the anchor to the polymer mesh occlusion component (Fig. 3).

During revision surgery, massive scarring, particularly around the mesh occlusion component, was observed. Therefore, microsurgical neurolysis of the thecal sac and exiting nerve root was performed starting with the resection of remnant ligamentum flavum to expose healthy dura. Decompression was then continued from cranial to caudal with undercutting of the base of the spinous process to achieve circumferential exposure of the scar tissue and the broken part of the ACD. Decompression was sufficient once the scar and dura could be mobilized of the broken part of the ACD. A big RDH which was firmly attached to the polymer occlusion component by very adhesive scar tissue was identified before the arm of the device including the polymer component was safely removed in one piece (Fig. 4). The inspection of the ACD confirmed that the mesh occlusion component was intact besides the massive scarring around it and that only the arm of the ACD was broken. The anchor of the device was left in place since it was firmly fixed into vertebral body and did not appear to compress the spinal canal (Fig. 4).

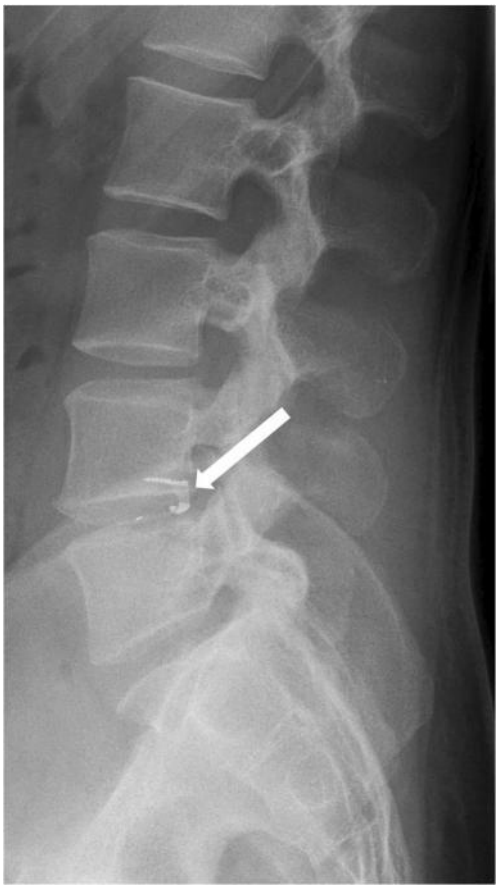

Fig. 2 Follow-up radiograph. ACD (arrow) is in regular position without signs of loosening or migration

The patient was discharged on the third day after surgery. At 3 months' follow-up examination, the patient reported to be free of leg and back pain, and no motor and sensory deficit was noted.

Discussion

In the past decade, a multitude of studies have been performed to evaluate the effectiveness of ACD. In general, all among those studies had the intention to compare the clinical outcome, the reoperation rate, and radiographical outcome of patients treated with MLD and additional placement of an ACD to patients who underwent MLD alone.

Independently it has been reported that placement of an ACD reduced the risk for a procedure related adverse event and risk for reoperation due to RLH within a period of 90 days after surgery. Therefore, ACD is considered to be highly cost-effective compared to MLD alone [2, 10, 18].

With respect to clinical outcome, a multicenter randomized trial has demonstrated no significant difference for leg and back pain severity as well as Oswestry disability index (ODI) scores for patients who underwent MLD compared to MLD and additional ACD implantation within 24 months of follow-up [19]. At three and four years of follow-up, the improvement tended to be greater in patients treated with additional ACD for leg pain and ODI [11, 16]. In addition, it has been reported that disc height was significantly higher in patients treated with additional ACD placement within 12 and 24 months of follow-up. Even though the actual difference was just about 1 mm [6, 17].

The rate for revision surgery for RLH following ACD placement has been reported to vary from 0 to 6.7% within 12 months, and 0 to 5% within 24 months of follow-up. After three and four years of follow-up, a smaller incidence for symptomatic reherniation and reoperation has been reported for patients treated with ACD compared to MLD [9, 16].

Despite the observed clinical benefit of MLD with ACD, some disadvantages of ACDs include longer operative times and the potential risk of serious device-related complication. A closer look on the existing literature reveals that the data on this issue is not addressed in detail. Implantation of the ACD was not possible in about 2% of patients, and one instance of nerve root injury has been reported [20]. Van den Brink et al. reported a 7.1% rate of device-related serious adverse events with 12 months, even though this has not been described in detail. This rate remained stable until 24 months' follow-up and increased to 10.7% at three-year follow-up [9, 19]. The rate for serious adverse events due to device deficiency has been reported to vary from 0 to 4.4% [3, 17, 19]. Unfortunately, radiographic images or intraoperative findings on device-related complications are missing in all among those studies. Device deficiency included mesh migration or detachment or whole ACD migration. Also, one case of anchor fracture has been reported, which the authors believe must be very similar to the presented case. Interestingly, in only one-third of those patients who underwent reoperation, a RDH was identified which leads to the impression that ACD failure might also occur without mechanical force (i.e., due to RDH). The largest detailed series of type and sequence of reoperations has been analyzed by Klassen et al. Fifty-one reoperations, mainly for reherniation and low back pain, were performed in 44 patients treated with ACD. In 25 among those patients, removal or partial removal has been performed. It

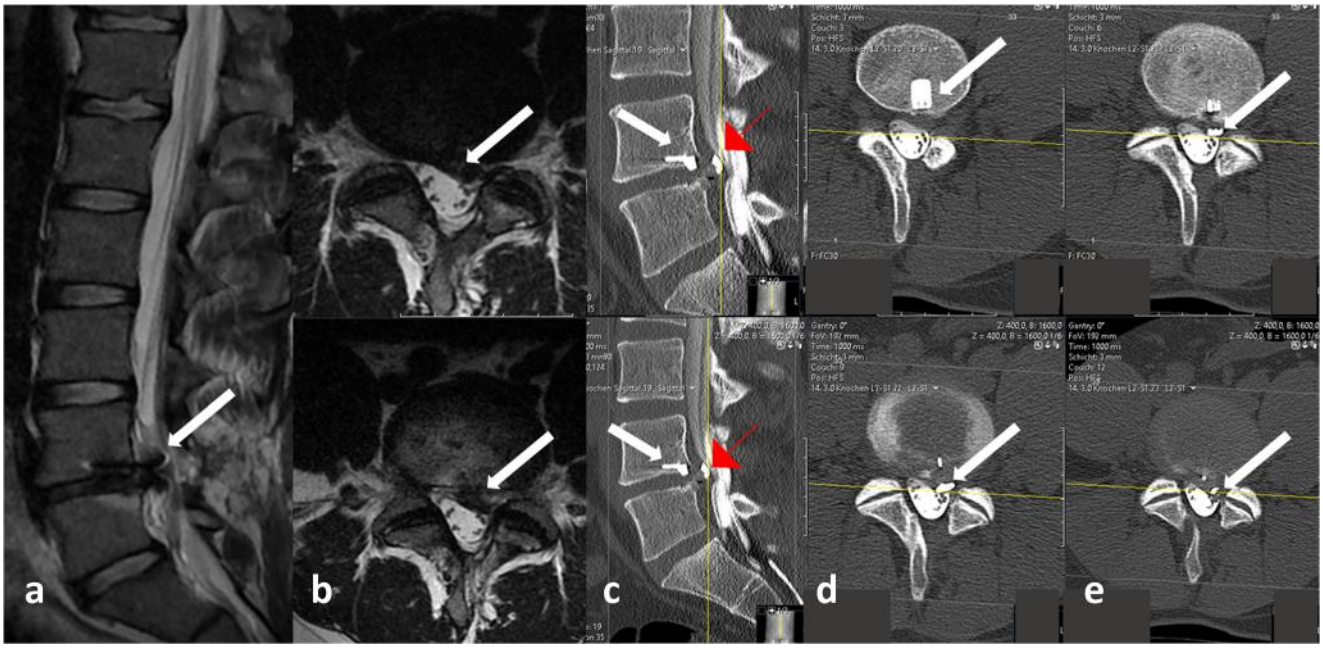

Fig. 3 MRI and post-myelogram CT scan prior to revision surgery (3 years after initial surgery). **a** Sagittal image of a L4-5 cranial displacement of the ACD into the spinal canal with compression (white arrow). **b** Axial image of the left-sided recurrent disc herniation and displaced ACD with compression of the thecal sac. **c** Sagittal CT image of ACD anchor which is in regular position (white arrow) and broken arm of the ACD (red arrow head). **d**, **e** Axial image of the compressed L5 nerve root, showing the recurrent disc herniation and displaced mesh and broken ACD arm (white arrow)

remains unclear why parts of the device or entire device had been removed in almost 10% of patients. In the authors' opinion, two causes might lead to device-related revision procedure. This might be either due to spontaneous failure of the implant or because of the force of a large RLH. According to the surgical report of the initial procedure, no intraoperative complication was noted and the postoperative course was uneventful. The occurrence and intensity of postoperative scarring is following lumbar spine surgery is variable between patients. Therefore, it is not possible for the authors to come with a sound conclusion. Also we do not know if breakage occurred at once or stepwise, which could explain the massive scarring. It would be interesting to see a detailed analysis of a series of cases who underwent revision procedure for implant failure. Patients in whom the ACD has been implanted improperly should be excluded. In the authors' opinion, it is important to present a detailed account of implant-associated complication to the spinal community for several reasons. ACD failures ought to be reported to better inform surgeons about risk factors for failure, management of this complication, and expectations during revision surgery.

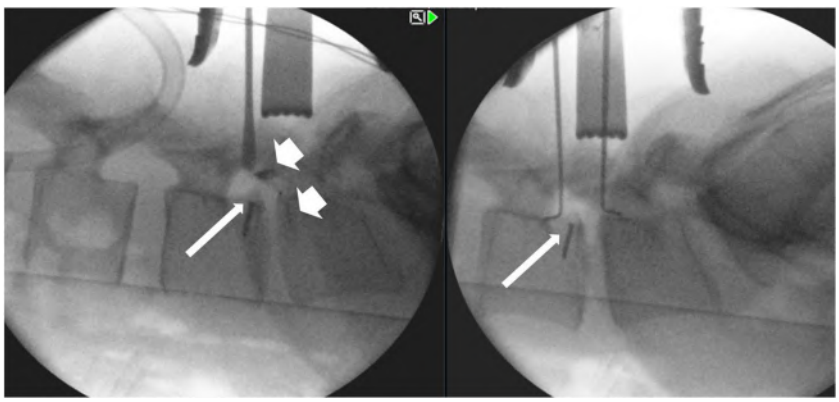

Fig. 4 Intraoperative fluoroscopy. ACD anchor is in regular position (arrow) and the arm and mesh are displaced into the spinal canal (arrow head)

Compliance with ethical standards

The patient has consented to the submission of the case report for submission to the journal.

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Abdu RW, Abdu WA, Pearson AM, Zhao W, Lurie JD, Weinstein JN (2017) Reoperation for recurrent intervertebral disc herniation in the spine patient outcomes research trial: analysis of rate, risk factors, and outcome. Spine 42:1106–1114. https://doi.org/10.1097/BRS.0000000000002088
2. Ament J, Thaci B, Yang Z, Kulubya E, Hsu W, Bouma G, Kim KD (2019) Cost-effectiveness of a bone-anchored annular closure device versus conventional lumbar discectomy in treating lumbar disc herniations. Spine 44:5–16. https://doi.org/10.1097/BRS.0000000000002746
3. Ardeshiri A, Miller LE, Thome C (2019) Two-year real-world results of lumbar discectomy with bone-anchored annular closure in patients at high risk of reherniation. Eur Spine J 28:2572–2578. https://doi.org/10.1007/s00586-019-06036-8
4. Burkhardt BW, Grimm M, Schwerdtfeger K, Oertel JM (2019) The microsurgical treatment of lumbar disc herniation: a report of 158 patients with a mean follow-up of more than 32 years. Spine 44:1426–1434. https://doi.org/10.1097/BRS.0000000000003113
5. Caspar W, Campbell B, Barbier DD, Kretschmmer R, Gotfried Y (1991) The Caspar microsurgical discectomy and comparison with a conventional standard lumbar disc procedure. Neurosurgery 28:78–86 discussion 86-77
6. Cho PG, Shin DA, Park SH, Ji GY (2019) Efficacy of a novel annular closure device after lumbar discectomy in korean patients: a 24-month follow-up of a randomized controlled trial. J Korean Neurosurg Soc 62:691–699. https://doi.org/10.3340/jkns.2019.0071
7. Dunlop RB, Adams MA, Hutton WC (1984) Disc space narrowing and the lumbar facet joints. J Bone Joint Surg (Br) 66:706–710
8. Fritzell P, Knutsson B, Sanden B, Stromqvist B, Hagg O (2015) Recurrent versus primary lumbar disc herniation surgery: patient-reported outcomes in the Swedish Spine Register Swespine. Clin Orthop Relat Res 473:1978–1984. https://doi.org/10.1007/s11999-014-3596-8
9. Kienzler JC, Klassen PD, Miller LE, Assaker R, Heidecke V, Frohlich S, Thome C, Annular Closure RCTSG (2019) Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation. Acta Neurochir 161:1389–1396. https://doi.org/10.1007/s00701-019-03948-8
10. Klassen PD, Bernstein DT, Kohler HP, Arts MP, Weiner B, Miller LE, Thome C (2017) Bone-anchored annular closure following lumbar discectomy reduces risk of complications and reoperations within 90 days of discharge. J Pain Res 10:2047–2055. https://doi.org/10.2147/JPR.S144500
11. Klassen PD, Lesage G, Miller LE, Hes R, Wolfs JFC, Eustacchio S, Vajkoczy P (2019) Reoperation after primary lumbar discectomy with or without implantation of a bone-anchored annular closure device: surgical strategies and clinical outcomes. World Neurosurg 130:e926–e932. https://doi.org/10.1016/j.wneu.2019.07.038
12. Lequin MB, Barth M, Thome C, Bouma GJ (2012) Primary limited lumbar discectomy with an annulus closure device: one-year clinical and radiographic results from a prospective, multi-center study. Korean J Spine 9:340–347. https://doi.org/10.14245/kjs.2012.9.4.340
13. McGirt MJ, Ambrossi GL, Datoo G, Sciubba DM, Witham TF, Wolinsky JP, Gokaslan ZL, Bydon A (2009) Recurrent disc herniation and long-term back pain after primary lumbar discectomy: review of outcomes reported for limited versus aggressive disc removal. Neurosurgery 64:338–344; discussion 344-335. https://doi.org/10.1227/01.NEU.0000337574.58662.E2
14. Miller LE, Allen RT, Duhon B, Radcliff KE (2020) Expert review with meta-analysis of randomized and nonrandomized controlled studies of Barricaid annular closure in patients at high risk for lumbar disc reherniation. Expert Rev Med Devices:1-9. https://doi.org/10.1080/17434440.2020.1745061
15. Miller LE, McGirt MJ, Garfin SR, Bono CM (2018) Association of annular defect width after lumbar discectomy with risk of symptom recurrence and reoperation: systematic review and meta-analysis of comparative studies. Spine 43:E308–E315. https://doi.org/10.1097/BRS.0000000000002501
16. Nanda D, Arts MP, Miller LE, Kohler HP, Perrin JM, Fluh C, Vajkoczy P (2019) Annular closure device lowers reoperation risk 4 years after lumbar discectomy. Med Devices (Auckl) 12:327–335. https://doi.org/10.2147/MDER.S220151
17. Parker SL, Grahovac G, Vukas D, Vilendecic M, Ledic D, McGirt MJ, Carragee EJ (2016) 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. Clin Spine Surg 29:454–460. https://doi.org/10.1097/BSD.0b013e3182956ec5
18. Thaci B, McGirt MJ, Ammerman JM, Thome C, Kim KD, Ament JD (2019) Reduction of direct costs in high-risk lumbar discectomy patients during the 90-day post-operative period through annular closure. Clinicoecon Outcomes Res 11:191–197. https://doi.org/10.2147/CEOR.S193603
19. Thome C, Klassen PD, Bouma GJ, Kursumovic A, Fandino J, Barth M, Arts M, van den Brink W, Bostelmann R, Hegewald A, Heidecke V, Vajkoczy P, Frohlich S, Wolfs J, Assaker R, Van de Kelft E, Kohler HP, Jadik S, Eustacchio S, Hes R, Martens F, Annular Closure RCTSG (2018) Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. Spine J 18:2278–2287. https://doi.org/10.1016/j.spinee.2018.05.003
20. van den Brink W, Fluh C, Miller LE, Klassen PD, Bostelmann R (2019) Lumbar disc reherniation prevention with a bone-anchored annular closure device: 1-year results of a randomized trial. Medicine (Baltimore) 98:e17760. https://doi.org/10.1097/MD.0000000000017760