Anthem

Medical Policy

Subject: Annulus Closure After Discectomy
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Description/Scope

This document addresses annulus closure devices proposed for use in annular repair following a discectomy procedure.

Position Statement

Investigational and Not Medically Necessary:

Annulus closure using devices for annular repair is considered **investigational and not medically necessary.**

Rationale

The intervertebral disc is composed of two distinct structures: the nucleus pulposus and surrounding annulus fibrosus. Treatment of a herniated disc may involve removal (discectomy) of the herniated nucleus pulposus material through an annular incision (annulotomy), or in some cases, repair of an annular defect responsible for the herniation. The annulus fibrosus has a limited healing capacity after an annulotomy and reherniation may result in a poor clinical outcome. A variety of surgical techniques designed to preserve, repair, or reinforce the annulus fibrosus following annulotomy are under study. The following devices are proposed for use in annulus closure after a discectomy to reduce the risk of reherniation.

Xclose® Tissue Repair System

The Xclose Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) received U.S. Food and Drug Administration (FDA) 510(k) clearance on August 7, 2006. The FDA labeled indications state the system is used for soft tissue approximation in general and orthopedic surgery procedures. The Xclose Tissue Repair System (modified sutures with anchors) was subsequently proposed for re-approximation of the annulus fibrosus after a lumbar discectomy procedure. As of late 2022, it appears that the Xclose device is no longer available on the market in the U.S.

Inclose™ Surgical Mesh System

The Inclose Surgical Mesh System (Anulex Technologies, Inc., Minnetonka, MN) received FDA 510(k) clearance on August 18, 2005, and is proposed as an alternative procedure for annular repair following discectomy to re-approximate the compromised tissue of the annulus fibrosus. Similar to the Xclose device, this product is no longer available in the U.S.

Barricaid® Annular Closure Device (ACD)

The Barricaid ACD (Intrinsic Therapeutics, Inc., Woburn, MA) was granted FDA premarket approval on February 8, 2019, and 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 (U.S. Food and Drug Administration, 2019).

Implanted between the annulus and the nucleus, the Barricaid ACD forms a strong, yet flexible wall that creates a mechanical barrier that closes the annular defect.

Trummer and colleagues (2013) compared the results of three prospective, multicenter, single-arm European studies that compared rates of facet joint degeneration between individuals who had lumbar discectomy implantation of the Barricaid ACD (discectomy-Barricaid group) with rates of joint degeneration for individuals who had discectomy without Barricaid ACD implantation (discectomy-only group). Two studies enrolled a total of 75 participants into the discectomy-Barricaid group. A third study included 137 discectomy-only participants, The Barricaid ACD was not clinically available at the time of the discectomy-only study. Prior to surgery, participants in all three studies had confirmed primary lumbar disc herniation, had failed at least 6 weeks of conservative treatment, and had VAS ipsilateral-leg pain of at least 40 out of 100. Participants in the discectomy-only study did not have a required Oswestry Disability Index (ODI) assessment or a maximum defect size. Computed tomography (CT) was performed preoperatively and 12-months postoperatively. Only 94 discectomy-only participants (69% of the original cohort) and 63 discectomy-Barricaid participants (84/%) received the 12 month postoperative CT. One independent radiologist compared preoperative and 12-month postoperative computed tomography (CT) scan images. for 94 of the original 137 discectomy-only group members and for 63 of the original 75 discectomy-Barricaid participants. Preoperatively, the discectomy-Barricaid group had a higher percentage of participants with grade 0 facet degeneration compared to the discectomy alone group; however, the combined percentage of those with grade 0 or grade I were similar between the two groups (p=1.000). At 12 months postoperative, progression of facet degeneration was observed in 43% of the evaluated discectomy-only group compared to 23% of the evaluated discectomy-Barricaid group (p=0.017). No participant experienced facet degeneration progression of more than 1 grade. Univariate logistic regression analysis performed for all participants suggested a lower probability for facet degeneration was significantly correlated with smaller annular defects (p=0.041) and discs implanted with the Barricaid (p=0.014). A trend was noted toward decreased facet degeneration for discs with less nuclear material removed during discectomy (p=0.079) and discs with larger preoperative disc heights (p=0.080). The results, however, failed to show statistically significant correlations in any of the three patient-centered outcome scores (ODI, VAS-Back and VAS-ipsilateral-leg pain scores). Limitations of this study include dissimilar entry criteria for the intervention and control arms, lack of randomization, the presence of more advanced baseline facet degeneration in the control group, significant attrition, lack of observer blinding (the Barricaid ACD is visible on CT), absence of observed differences for patient-centered outcomes, and short-term follow-up of 12 months.

Parker and colleagues (2013) prospectively evaluated the 12-month incidence of same-level recurrent disc herniation, disc height loss, and cost outcomes in a nonrandomized study of 46 European individuals undergoing lumbar discectomy for a single-level herniated disc compared to a second consecutive cohort of 30 individuals undergoing 31 lumbar discectomy procedure with implantation of the Barricaid ACD. Additional post hoc analysis modeled on direct Medicare costs and indirect costs of work-day losses was performed to predict cost savings between the procedures associated with surgical treatment of same-level, recurrent lumbar disc herniation. The authors reported a reduction in recurrent disc herniation from 6.5 % to 0% was associated with the annular closure device within the 12-month follow-up period. Limitations of this study include lack of randomization, the post hoc nature of the analysis, and lack of reporting on patient-centered clinical outcomes such as measurements of back pain severity, and lack of statistical power to observe significant differences.

Barth (2016) reported the results of a retrospective post-hoc reanalysis of data from previously reported controlled but not randomized trials involving 95 subjects with lumbar disc herniation undergoing limited discectomy with implantation of the Barricaid ACD. Although the aggregated demographic data were similar for the two groups, clinical characteristics for cases and controls were not matched. Complete 18-month data were available for 42 (93.3%) members of the ACD group and for 29 (72.5%) control group members. Significantly less MRI-confirmed reherniation occurred in the ACD group (2 vs. 14, p<0.001). One annular tear was reported in the control group whereas none were observed in the ACD group(p<0.001). The rate of acquiring new vertebral endplate changes (VEPC) was significantly higher in the ACD group (22 [52.4%]in the ACD group vs. 3 [10.3%] in the control group; p<0.001). The authors reported 5 new lesions in the endplate opposite to the titanium implant, 3 in the adjacent endplate, and 5 at both the opposite and adjacent endplates. One subject in the ACD group experienced a reherniation (2.2%) compared to 5 (12.5%) in the control group (p=0.095). Following data safety review, the single ACD group reherniation was determined to be due to the implant being implanted too far anteriorly, allowing nuclear extrusion. Reoperation was reported in 4 ACD subjects and 5 control individuals, with no significant differences in the reoperation rate (p=0.729). The authors concluded that ACD implantation was associated with a significantly lower reherniation rate, but a significantly higher rate of endplate erosions. Limitations of this study include its retrospective nature, the lack of matching between cases and controls, the fact that no significant patient-centered outcome differences were found, and the lack of reporting for the extent of reherniations. Prospective study will be needed to confirm the observed results.

Parker and colleagues (2016) reported an industry-sponsored, prospective, controlled, nonrandomized comparative study to evaluate the incidence of same-level disk herniation and disk height loss after primary discectomy between individuals receiving implantation of an annular device versus those not receiving implantation. The intervention group included 30 consecutive individuals who received implantation of an annular closure device after lumbar discectomy. The control group was comprised of 46 individuals selected as a subset from a previously-published study that evaluated rates of recurrent disc herniation in relation to the volume of disc removed in a primary discectomy. One individual in the annular closure group underwent a disk debridement and wound incision and drainage for suspected discitis 56 days after the primary surgery. The annular closure device was left in place and clinical and serological indicators were resolved. At the 24-month follow-up, recurrent same level disk herniation occurred in 3 (6.5%) individuals in the control group and none in the annular closure device group. At the 12-month follow-up, the disk height measurement was obtained from all of the annular closure group and 72% (n=33) in the control group. At the 24-month follow-up, the measurement was available in 96% (n=29) of the annular device group and in 54% (n=25) of the control group. The authors noted a trend toward greater preservation of disk space observed in the annular closure group 12 months after surgery (7.63 ± 1.5 vs. 6.9 ± 1.1 mm, $p = 0.054$). The authors concluded that the annular closure after lumbar discectomy may prevent long-term disk height loss and associated back and leg pain.

In 2017, Kuršumović and Rath published a retrospective analysis to assess the Barricaid ACD in 171 subjects undergoing discectomy for lumbar disc herniation. Study participants were assessed preoperatively, 3 months postoperatively, and 12 months postoperatively with ODI and VAS scores, plain radiographs, and functional imaging (MRI or CT at preoperative visit and 12 month visit). The authors found symptomatic reherniation in 6 subjects (3.5%), partially or completely detached mesh from the titanium anchor in 12 subjects (8.8%), and all subjects improved in ODI and VAS scores by the 12-month follow-up (ODI: 15.8 ± 16.9; VAS Leg: 23.3 ± 27.1; VAS Back: 26.9 ± 24.8). Study limitations include retrospective design, lack of comparator group, minimal exclusion criteria, and short follow-up.

A randomized, controlled trial reported by Thomé and colleagues in 2018 evaluated whether use of a bone-anchored ACD reduces reherniation and the need for reoperation while improving treatment success of the discectomy. Intrinsic Therapeutics financially supported the study, but statistical analysis and radiographic assessments were conducted independent from this support. The study enrolled 554 individuals from 21 European institutions. All participants had a single-level disc herniation with lumbar radiculopathy and ODI and VAS scores each reported to be at least 40/100. Candidates for ACD placement needed to have an annular defect between 4 and 6 mm tall and 6 to 10 mm wide. Eligible participants were randomized to receive discectomy plus an ACD (ACD group n=276) or discectomy alone (control group n=278). Participants were followed at 6 weeks, 3 months, 6 months, 1 year, and 2 years. Diagnostic imaging (CT or MRI, flexion-extension x-rays) was performed at the 1- and 2-year visits. Patient-centered measures included ODI, VAS, and SF-36 scoring. The primary outcomes included lack of reherniation at 2 years and a composite measure including ODI; VAS; measures of disc height, device condition, and neurologic status; and freedom from index-level reherniation, reoperation, and adverse events. The clinical characteristics of the ACD and control groups were well matched at baseline. There was approximately 9% attrition at the 2-year follow up (24 of 276 ACD group members and 26 of 278 control group members lost to follow up). At the 2-year visit, reherniation was identified in 50% of the ACD group members and 70% of the control group members (mean difference 95% confidence interval [CI]: −12% to −28%, P<.001). Symptomatic reherniation was observed in 25% of control group members and in 12% of the ACD group members (p<0.001). This rate of symptomatic reherniation was noted to be significantly higher than the 7-18% rate typically seen after discectomy. That finding was attributed to the enrollment of individuals with larger than usual annulus defects. There was no significant between-group difference at the 2-year follow up for neurologic function, leg or back pain, ODI, or SF-36 scores. Index level reoperation to address recurrent herniation was performed for 5% of the ACD group (14 procedures in 14 individuals) compared to 13% of the control group members (42 procedures in 37 individuals). Procedure-related serious adverse events were more common in the control group (17% for controls vs. 7% for ACD; p=0.001). This difference reflected the higher rate of reherniation for the control group. Serious device-related adverse events were observed in 8 (2.9%) of the 276 participants who received an ACD. There was no significant difference in all-cause serious adverse events (30% for controls vs. 25% for ACD; p=0.15). This study has several strengths including a multi-center randomized controlled design, large sample sizes, relatively low attrition, and independent assessment of diagnostic imaging. Lack of blinding of the participants and providers may have affected decisions to reoperate. The study did not find significant differences in patient-centered outcomes including pain, ODI, VAS, or SF-36 scores.

Cho and colleagues (2019) conducted a prospective single-center randomized controlled study to evaluate the efficacy of annular closure devices in improving outcomes following lumbar discectomy compared to conventional discectomy. The study included a total of 60 Korean individuals with sciatica unresponsive to at least 6 weeks of conservative treatment. The authors noted that Asians tend to have smaller vertebrae and different bone cortex densities compared to non-Asians. Individuals were assigned to the annular closure device group (ACD: n=30) or the conventional lumbar discectomy group (CLD; n=30). The average volume of disc material removed was significantly lower in the ACD group (0.5±0.3 vs. 0.9± 0.6 mL; p=0.009). Preoperative disc height for the ACD group compared to the CLD group was 13.3 ± 1.2 mm versus 12.9 ± 1.7 mm, $p = 0.297$. At 12 months, the disc height decreased for both

groups (12.0 ± 1.3 mm versus 10.8 ± 1.2 mm, $p = 0.007$). At 24 months, no significant between-group difference was noted in VAS leg pain scores (ACD: 16 ± 20; CLD: 12 ± 18, $p = 0.55$), VAS back pain scores (ACD: 20 ± 18; CLD: 16 ± 18); SF-12 physical scores (ACD 26 ± 5; CLD: 27 ± 4); or SF-12 mental scores (ACD: 30 ± 5; CLD: 31 ± 5). At 24 months, the Oswestry Disability Index (ODI) trended higher for the ADC group than for the CLD group (ACD: 10 ± 11; CLD: 5 ± 5; p=0.08). Higher ODI scores indicate greater disability. The study did not identify any complications. Re-herniation was reported in 1 individual in the annular closure device group and 6 individuals in the conventional lumbar discectomy group. The study was limited by a small initial sample size and significant attrition. The authors report that "70% or fewer patients were actually followed up" 2 years after their procedure and do not provide the actual number of participants for whom 2-year data were available.

Five-year follow-up data was published by Thomé in 2021. This study included data from 207 ADC group subjects and 197 control group subjects, which was 75% and 70.8% of the original study population in each group, respectively. The risks of symptomatic reherniation were 18.8% in the ACD group and 31.6% in the control group (p<0.001). In the 5 years following the studied procedure, reoperation was performed for 16.0% in the ADC group and 22.6% of those in the control group (p=0.03). Device-specific reoperation was performed for 5.2% of the ADC group members. Device-related adverse events, including migration of the mesh or device and detachment or subsidence of the mesh, was observed to have occurred in 12.0% of the ACD group members. Both the ACD group and the control group had significant improvements in leg pain severity, ODI, and SF-36 measures of physical and mental health. There were no significant between-group differences for these patient-centered measures. Serious adverse events were less frequent in the device group (12.0% vs. 20.5%; p=0.008). The authors attributed this to the lower risk of lumbar disc reherniation. The incidence of any adverse event was not significantly different between the groups (85.4% vs. 82.0%; p=0.30). VEPCs were more commonly reported in the device group (20.2% vs. 1.4%; p<0.001), although no association was observed between VEPCs and clinical outcomes including leg pain severity, ODI score, and health-related quality of life. In addition to potential confounding due to the lack of blinding noted above, this 5-year report is further limited by significant attrition.

One-year and 4-year results of the above-mentioned study were published in 2019 by van den Brink and Nanda, respectively. Several post-hoc analyses have also been published (Klassen 2017, Kienzler, 2019, 2021b; Kuršumović, 2018, 2020; van den Brink, 2018). Overall, the results of these papers indicate no between-group differences in pain, disability, or quality of life. However, significant risks were identified related to implantation failures and device-related adverse events. Longer term data are needed to understand the implications of the high rate of VEPC. The strength of the reported findings is reduced by methodologic weaknesses including lack of blinding, use of intention-to-treat methodology with no per-protocol analysis, post-hoc analyses, and significant attrition.

The results of a prospective, single-center study of adjunctive ACD implantation to reduce herniation recurrence risk among high-risk individuals with large annular defects were released in 2019 by Ardeshiri. All participants had undergone lumbar discectomy for sciatica caused by intervertebral disc herniation. Participants (n=75) were evaluated at 6 weeks, 12 weeks, 26 weeks, 1 year, and 2 years after their initial procedure for reoperation, herniation recurrence, back pain or leg pain severity (each measured on a 100 mm visual analog scale), and ODI. Individual follow-up compliance was 91% (n=68) at 3 months, 92% (n=69) at 6 months, 96% (n=72) at 1 year, and 90% (n=67) at 2 years. Compliance was not reported for the 6-week follow-up. The evaluators reported outcomes cumulatively through 2 years. Results showed the event incidence was 4.0% for reoperation and 1.4% for herniation recurrence with mean leg pain severity decreasing from 73 to 6 (p<0.001), back pain severity decreasing from 51 to 13 (p<0.001), and ODI decreasing from 49 to 7 (p<0.001). Adverse events included 1 individual with a dural tear and another individual with the ACD improperly implanted. Limitations to this study included the absence of a control group, lack of individual outcome reporting (only cumulative results were reported), single-center study design, and lack of radiographic assessments of possible vertebral endplate changes, disc height changes, and device complications.

Miller and colleagues (2020) published an industry-sponsored systematic review and meta-analysis evaluating the effectiveness of the Barricaid ACD device when used in addition to a limited lumbar discectomy procedure. The review identified 50 published papers of the Barricaid device since 2012, which included two randomized trials and two non-randomized controlled studies. These 4 studies included 801 individuals of whom 381 were treated with lumbar discectomy and the Barricaid device and 420 were treated with lumbar discectomy only. The review included 481 males and 320 females. The mean age in the studies ranged from 40 to 44 years and body mass index (BMI) ranged from 24 to 26 kg/m^2. The follow-up duration was 2 years in three studies and 4 years in one study. Among the four studies, the risk of symptomatic reherniation over 2 years of follow-up was 55% lower with the ACD device (9.3% vs. 20.3%, risk ratio = 0.45, p < 0.001). Each study reported a risk ratio of less than 1 indicating more favorable outcomes with ACD use. No heterogeneity was observed (I2=0%). The risk of reoperation was 48% lower with the ACD device (7.7% vs. 14.5%, risk ratio=0.52, p=0.003) and no heterogeneity was observed (I2=0%). This meta-analysis did not report on the effects of ACD use on pain, neurological function, or quality of life.

Keinzler (2021c) published a case series study involving 72 individuals, 29 of whom were participants in the RCT reported above (Thomé, 2018) and an additional 43 non-RCT subjects treated with the Barricaid device by the same investigator. The mean follow-up duration was 14.7 months. VEPC were found in 71 (99%), with change volumes significantly larger in the lower endplate (median of 230 mm^3) compared to the upper endplate (median of 105 mm^3; p=0.006). ACD anchor localization was the only factor predictive of VEPC in multivariate regression analysis (p=0.038). A subsequent univariate regression analysis showed anchor localization in the superior endplate had a significant effect on lower VEPC (p=0.025). In this study, 46 (64%) of the ACDs were implanted in the superior endplate with the polymer mesh component linked to the lower endplate of the adjacent vertebra. At the conclusion of the study, 65 subjects (90%) had their ACD still in place. Removal was required in 7 (10%) subjects, with 4 having the whole implant removed and in 3 only the polymer mesh was removed. Reherniation occurred in 17 (24%) subjects as detected on MRI, with 10 (13.8%) symptomatic and 7 (10%) asymptomatic. Reoperation occurred in 13 (18.1%) subjects, with 6 (8.3%) in symptomatic subjects. Device failure, defined as dislocation of the whole device >2 mm (n=5, 6.9%), device anchor-head breakage (n=1, 1.3%), or posterior dislocation of the mesh into spinal canal (n=13, 18%), occurred in 19 (26.4%) subjects. Additionally, mesh subsidence into the endplate was documented in 15 (20.8%) subjects. Overall, 7 subjects (9.7%) underwent reoperation due to device failure. Unintended durotomy during reoperation occurred in 31% of cases. Overall clinical outcomes were reported to be good, with significant improvements in mean ODI (57.27 to 17.58; p<0.001), low back pain VAS (63.53 to 19.80; p<0.001), left leg pain VAS (45.66 to 11.46; p<0.001), and right leg pain VAS (42.97 to 10.79; p<0.001). Lower VEPC showed significant correlation with postoperative ODI at the last follow-up only (p=0.01) and the authors noted that VEPC "do not seem to affect postoperative clinical outcome in a significant manner". The high rates of both device failure and unintended durotomy warrant further investigation.

Kurzbuch and colleagues (2022) conducted a nonrandomized historical cohort study analyzing 53 consecutive individuals admitted for a single level microdiscectomy. The aim of this study was to determine the percentage eligible for annular closure device and to evaluate the incidence of recurrent disc herniation at 12-months. Individuals included in the study either had the discectomy alone (n = 41, group 1) or discectomy plus annular closure device (n = 12, group 2). The annular closure device used in this study was Barricaid®. Reherniation at the index level in group 1 occurred in 6 individuals (6/14, 14.6%) and 1 recurrence of disc herniation occurred in group 2 (1/12, 8.3%). The authors concluded that one out of five individuals with lumbar disc herniation and high risk for reoccurrence is suitable for insertion of an annular closure device. Study limitations include lack of randomization, small sample size, and a short-term follow-up of 12 months.

Data addressing the clinical utility of the Barricaid device is from methodologically weak trials, many of a retrospective or post-hoc nature, and none with blinded evaluators. A large number of publications are from a single trial, reporting on different measures at different time points. While most studies report reductions in reoperation and reherniation rates, there have been a concerning number of reports of significant VEPC with unknown long-term consequences. Only one study has reported on the findings of the implantation procedure, with a concerning number of failures, second attempts and aborted attempts. Additionally, several serious adverse events have been reported, including unintended durotomy and neve root amputation. Further study is needed to fully understand the benefits and risks of the Barricade device.

Disc Annular Repair Technology (DART) System

The DART System (Magellan Spine Technologies, Inc., Irvine, CA) is a polyetheretherketone (PEEK) implant that provides closure of the annulus following a standard lumbar microdiscectomy procedure. When implanted, the DART was placed near the central axis of rotation along the posterior edge of the vertebral body. The device was aligned with the vertebral body load column and secured in place at the apophyseal ring. There are no studies published in the peer-reviewed medical literature that evaluate the efficacy and safety of the DART system.

In April 2009, the DART System received CE Mark approval for marketing in Europe. To date, the DART System has not received FDA 510K clearance for marketing in the United States. As of late 2022, it appears that the DART System is unavailable on the market in the U.S.

The Discseel® procedure

The Discseel Procedure (Discseel® Technologies, Tyler, Texas) involves the simultaneous injection of prothrombin and fibrinogen into a tear in the annulus, resulting in the formation of fibrin in the disc. The fibrin has been proposed to seal and repair the tear. This is an off-label use of fibrin, which is an FDA-approved biologic product with many other applications.

At this time there are no published, peer-reviewed studies addressing the safety or clinical utility of this product.

Other Considerations

Ambrossi and colleagues (2009) examined the incidence of complications after primary discectomy. In 156 consecutive individuals undergoing primary single-level lumbar discectomy, the incidence of symptomatic same-level recurrent disc herniation responding to either conservative therapy or requiring revision discectomy was assessed. Twelve months after surgery, 141 individuals were available for follow-up; of this group, 124 (88%) were symptom free or had minimal symptoms not affecting their daily activity. A total of 17 individuals (12%) developed symptomatic same-level recurrent disc herniation confirmed by imaging at 8 months (median) after primary discectomy. Of this group, 11 (7%) individuals required revision surgery and 6 (3.9%) individuals responded to conservative therapy alone. The authors advocated the development of surgical techniques to prevent recurrent lumbar disc herniation.

Sherman and colleagues (2010) performed a claims-based analysis of individuals having discectomies. Using International Classification of Diseases (ICD) and Current Procedural Terminology (CPT) codes, they identified 497 individuals having discectomies within a 6-month period. A total of 137 (28%) individuals had subsequent insurance claims within 18 months after surgery for additional related treatment. Individuals were studied whose claims included codes for a second operation (n=52, 11%) and those not having a second surgery, but requiring medical or nonsurgical management (n=85, 17%). Of the group requiring a second surgery, 80% had a repeat discectomy and 20% had a spinal fusion. Procedure-related complications within 40 days of surgery were evident in 15% of the group. The authors concluded that development of surgical technologies that improve outcomes of discectomy can positively impact the quality of life.

It has been proposed that improved annular closure procedures may reduce disc reherniation and the need for fusion by the use of devices designed specifically for annulus fibrosus closure. In a review publication, Bron and colleagues (2008) observed that lumbar discectomy is an effective therapy for neurological decompression due to herniated disc. However, there are high recurrence rates of reherniation and persisting post-operative low back pain. The authors noted that suturing techniques for annulus closure have been studied; however, these techniques are directed to containment of the nucleus pulposus and do not compensate the loss of annulus material or reverse the biomechanical changes that have occurred in the damaged annulus fibrosus. The authors propose that development of techniques that deal with the damaged annulus fibrosus, such as tissue engineering and annulus repair are needed in order to prevent re-herniation.

In 2018, Choy and colleagues published a meta-analysis comparing devices intended to help reduce recurrent lumbar disc herniation. Two randomized, prospective studies and two non-randomized prospective studies met the inclusion criteria. In the 4 studies, there were a total of 811 subjects that underwent discectomy with an annular closure device or with annular repair (ACD/AR), and 645 subjects that underwent discectomy only. Results showed 24 symptomatic reherniations in the ACD/AR group and 51 symptomatic reherniations in the control group (OR, 0.34; 95% confidence interval [CI], 0.20, 0.56; I^2 =0%; p<0.0001). While this study showed a significant reduction in symptomatic disc reherniations, there are several limitations. Only four studies met search criteria, which limited the data, and the included studies had small sample sizes with no long-term follow-up. Larger studies with long-term evaluations of clinical utility are needed.

Wang and colleagues (2023) completed a meta-analysis comparing the clinical outcomes of discectomy and various annular repair techniques to explore their clinical value. Their analysis includes the results of studies discussed above published by Cho, Barth, Kurzbach, Parker, and Thome and addressed four methods of annular repair: The Barricaid Annular Closure Device; the Xclose system (Xclose is no longer available); annular fibrosis suturing; and various fillers and caulking agents such as platelet-rich plasma and amniotic membrane patching. The authors noted a general lack of high-quality randomized controlled studies for any of these techniques. The pooled results for the included studies showed a high degree of heterogeneity whose source could not be identified. Although they note that the study published by Thome et al. may have had a significant impact on the combined results, the authors concluded that lumbar discectomy combined with ACD can effectively reduce the postoperative recurrence and reoperation rates in patients with LDH. The Thome study was the only one of the studies including ACD devices that showed a reduction in recurrence and readmission rates.

Background/Overview

The vertebral disc is composed of two parts: the nucleus pulposus and the annulus fibrosus. The nucleus pulposus is a gelatinous substance at the center of the disc and distributes hydraulic pressure in all directions within the disc under compressive loads. The nucleus pulposus consists of chondrocytes, collagen fibrils, and proteoglycan aggregates.

The annulus fibrosus encircles the nucleus pulposus and is made up of tough, fibrous layers. Both structures fit together like two concentric cylinders. The nucleus pulposus bears the axial load of the body and acts as pivot point for movement. The annulus fibrosus acts as a barricade to contain the nucleus pulposus and its hydraulic pressure so it maintains its load bearing and pivot

functions.

Definitions

Annulus: The outer fibrous ring of an intervertebral disc; also referred to as annulus fibrosus.

Chondrocyte: A cell that forms cartilage which is the tough, elastic, fibrous connective tissue found in various parts of the body, such as the joints, outer ear, and larynx.

Collagen fibrils: A threadlike fiber or filament that is a constituent of a cell or larger structure.

Herniated disc: A rupture of fibrocartilagenous material (annulus fibrosus) that surrounds the intervertebral disc. This rupture involves the release of the disc's center, the nucleus pulposus, into the spinal column.

Nucleus pulposus: The jelly-like substance in the center of a spinal disc.

Proteoglycan: A type glycoprotein of high molecular weight found in the extracellular matrix of connective tissue.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

	No specific code for annulus closure after annulotomy; not separately reportable

ICD-10 Procedure

	For the following procedures when specified as closure using an annular repair device:
0RU30JZ-0RU34JZ	Supplement cervical vertebral disc with synthetic substitute [by approach; includes codes 0RU30JZ, 0RU33JZ, 0RU34JZ]
0RU50JZ-0RU54JZ	Supplement cervicothoracic vertebral disc with synthetic substitute [by approach; includes codes 0RU50JZ, 0RU53JZ, 0RU54JZ]
0RU90JZ-0RU94JZ	Supplement thoracic vertebral disc with synthetic substitute [by approach; includes codes 0RU90JZ, 0RU93JZ, 0RU94JZ]
0RUB0JZ-0RUB4JZ	Supplement thoracolumbar vertebral disc with synthetic substitute [by approach; includes codes 0RUB0JZ, 0RUB3JZ, 0RUB4JZ]
0SU20JZ-0SU24JZ	Supplement lumbar vertebral disc with synthetic substitute [by approach; includes codes 0SU20JZ, 0SU23JZ, 0SU24JZ]
0SU40JZ-0SU44JZ	Supplement lumbosacral disc with synthetic substitute [by approach; includes codes 0SU40JZ, 0SU43JZ, 0SU44JZ]

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Ambrossi GL, McGirt MJ, Sciubba DM, et al. Recurrent lumbar disc herniation after single-level lumbar discectomy: incidence and health care cost analysis. Neurosurgery. 2009; 65(3):574-578.
2. Ardeshiri A, Miller LE, Synowitz M, et al. Surgical experience and complications in 50 patients treated with an annular closure device following lumbar discectomy. Orthop Surg. 2019; 11(3):431-437.
3. Ardeshiri A, Miller LE, Thomé C. Two-year real-world results of lumbar discectomy with bone-anchored annular closure in patients at high risk of reherniation. Eur Spine J. 2019; 28(11):2572-2578.
4. Arts MP, Kuršumović A, Miller LE, et al. Comparison of treatments for lumbar disc herniation: systematic review with network meta-analyses. Medicine (Baltimore). 2019; 98(7):e14410.
5. Barth M, Fontana J, Thomé C, et al. Occurrence of discal and non-discal changes after sequestrectomy alone versus sequestrectomy and implantation of an anulus closure device. J Clin Neurosci. 2016; 34:288-293.
6. Bouma GJ, Ardeshiri A, Miller LE, et al. Clinical Performance of a bone-anchored annular closure device in older adults. Clin Interv Aging. 2019; 14: 1085-1094.
7. Bron JL, Helder MN, Meisel HJ, et al. Repair, regenerative and supportive therapies of the annulus fibrosus: achievements and challenges. Eur Spine J. 2009; 18(3):301-313.
8. Cho PG, Shin DA, Park SH, Ji GY. 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. 2019; 62(6):691-699.
9. 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(1):290.
10. Kienzler JC, Fandino J, Van de Kelft E, et al. Risk factor for early reherniation after lumbar discectomy with or without annular closure: results of a multicenter randomized controlled study. Acta Neurochir (Wien). 2021a; 163(1): 259-268.
11. Kienzler JC, Fandino J, Van de Kelft E, et al.; Barricaid® Annular Closure RCT Study Group. Risk factors for early reherniation after lumbar discectomy with or without annular closure: results of a multicenter randomized controlled study. Acta Neurochir (Wien). 2021c; 163(1):259-268.
12. Kienzler JC, Heidecke V, Assaker R, et al. Intraoperative findings, complications, and short-term results after lumbar microdiscectomy with or without implantation of annular closure device. Acta Neurochir (Wien). 2021b; 163(2):545-559.
13. Kienzler JC, Klassen PD, Miller LE, et al.; Annular Closure RCT Study Group. Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation. Acta Neurochir (Wien). 2019; 161(7):1389-1396.
14. Klassen PD, Bernstein DT, Köhler HP, et al. Bone-anchored annular closure following lumbar discectomy reduces risk of complications and reoperations within 90 days of discharge. J Pain Res. 2017; 10:2047-2055.

15. Klassen PD, Lesage G, Miller LE, et al. Reoperation after primary lumbar discectomy with or without implantation of a bone-anchored annular closure device: surgical strategies and clinical outcomes. World Neurosurg. 2019; 130:e926-e932.
16. Kuršumović A and Rath S. Performance of an annular closure device in a 'real-world', heterogeneous, at-risk, lumbar discectomy population. Cureus. 2017; 9(11):e1824.
17. Kuršumović A, Bouma GJ, Miller LE, 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. J Pain Res. 2020; 13:669-675.
18. Kuršumović A, Kienzler JC, Bouma GJ, et al.; Annular Closure RCT study group. Morphology and clinical relevance of vertebral endplate changes following limited lumbar discectomy with or without bone-anchored annular closure. Spine (Phila Pa 1976). 2018; 43(20):1386-1394.
19. Kurzbuch AR, Tuleasca C, Fournier JY. Lumbar discectomy with annulus fibrosus closure: a retrospective series of 53 consecutive patients. Neurochirurgie. 2022; 68(4):393-397a.
20. Miller LE, Allen RT, Duhon B, et al. 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. 2020; 17(5): 461-469.
21. Nanda D, Arts MP, Miller LE, et al. Annular closure device lowers reoperation risk 4 years after lumbar discectomy. Med Devices (Auckl). 2019; 12:327-335.
22. Nunley P, Strenge KB, Huntsman K, et al. Lumbar discectomy with Barricaid device implantation in patients at high risk of reherniation: initial results from a postmarket study. Cureus. 2021; 13(12):e20274.
23. Nunley P, Strenge KB, Huntsman K, et al. Lumbar discectomy with bone-anchored annular closure device in patients with large annular defects: one-year results. Cureus. 2023; 15(6):e40195.
24. Parker SL, Grahovac G, Vukas D, et al. Cost savings associated with prevention of recurrent lumbar disc herniation with a novel annular closure device: a multicenter prospective cohort study. J Neurol Surg A Cent Eur Neurosurg. 2013; 74(5):285-289.
25. Parker SL, Grahovac G, Vukas D, et al. 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. 2016; 29(10):454-460.
26. Sherman J, Cauthen J, Schoenberg D, et al. Economic impact of improving outcomes of lumbar discectomy. Spine J. 2010; 10(2):108-116.
27. Strenge KB, DiPaola CP, Miller LE, et al. Multicenter study of lumbar discectomy with Barricaid annular closure device for prevention of lumbar disc reherniation in US patients: a historically controlled post-market study protocol. Medicine (Baltimore). 2019; 98(35):e16953.
28. 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(12):2278-2287.
29. Thomé C, Kuršumovic A, Klassen PD, et al.; Annular Closure RCT Study Group. Effectiveness of an annular closure device to prevent recurrent lumbar disc herniation: a secondary analysis with 5 years of follow-up. JAMA Netw Open. 2021; 4(12):e2136809.
30. Trummer M, Eustacchio S, Barth M, et al. Protecting facet joints post-lumbar discectomy: Barricaid annular closure device reduces risk of facet degeneration. Clin Neurol Neurosurg. 2013; 115(8):1440-1445.
31. van den Brink W, Flüh C, Miller LE, et al. Lumbar disc reherniation prevention with a bone-anchored annular closure device: 1-year results of a randomized trial. Medicine (Baltimore). 2019; 98(44):e17760.
32. Wang Y, He X, Chen S, et al. Annulus fibrosus repair for lumbar disc herniation: a meta-analysis of clinical outcomes from controlled studies. Global Spine J. 2023; 17:21925682231169963.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Intrinsic Therapeutics. Study of lumbar discectomy with annular closure. NLM Identifier: NCT03986580. Last updated January 11, 2022. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03986580. Accessed on September 27, 2023.
2. North American Spine Society(NASS). Evidence-based clinical guidelines for multidisciplinary spine care. Diagnosis and treatment of low back pain. Available at: https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Clinical-Guidelines. Accessed on September 27, 2023.
3. North American Spine Society(NASS). Spine definitions. Available at: https://www.spine.org/KnowYourBack/Resources/Definitions. Accessed on September 27, 2023.
4. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Xclose Tissue Repair System, Model SRS. Summary of Safety and Effectiveness. No. K062307. Rockville, MD: FDA. September 1, 2006. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=k062307. Accessed on September 27, 2023.
5. U.S. Food and Drug Administration Premarket Approval (PMA) Database. Barricaid Anular Closure Device (ACD) Summary of Safety and Effectiveness. No. P160050. Rockville, MD: FDA. February 8, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160050B.pdf. Accessed on September 27, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	11/10/2022	MPTAC review. Updated Rationale, Reference, and Index sections.
Reviewed	11/11/2021	MPTAC review. Updated Rationale and Reference sections.
Reviewed	11/05/2020	MPTAC review. Updated Rationale and References sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale, References, and Index sections.
Reviewed	11/08/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated References section.
Reviewed	02/02/2017	MPTAC review. Updated References section.
Reviewed	02/04/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.

Reviewed	02/05/2015	MPTAC review. Format changes throughout document sections.
Reviewed	02/13/2014	MPTAC review. Updated Rationale, References, and Index sections.
	07/23/2013	Updated Rationale and Reference sections with peer-reviewed published literature addressing the Xclose Tissue Repair System and Barricaid devices.
Reviewed	02/14/2013	MPTAC review. Clarified the Description. Updated the Rationale, Definitions, References, and Index.
New	02/16/2012	MPTAC review. Initial document development.

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