Effect of Anular Closure on Disk Height Maintenance and Reoperated Recurrent Herniation Following Lumbar Diskectomy: Two-Year Data

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J Neurol Surg A 2014;00:1–8.

Abstract

Objective To assess the potential benefits of disk reherniation reduction and disk height maintenance in limited diskectomy combined with the implantation of the anular closure device.

Summary and Background Data Postoperative disk height loss is apparent in most patients undergoing lumbar diskectomy for herniated nucleus pulposus. Less favorable patient outcomes are associated with significant loss in disk height that can occur after aggressive disk tissue removal. More conservative disk removals, however, are often burdened by the increased risk of recurrent disk herniation.

Methods Two prospective single-arm studies on patients treated with limited diskectomy and an anular closure device were conducted. Outcome measures included disk height maintenance relative to preoperative values, Oswestry Disability Index, back pain, leg pain, and complications such as reherniations. Patients were evaluated preoperatively and postoperatively at 6 weeks and at 3-, 6-, 12-, and 24-month time points.

Results A total of 75 patients were included in this cohort consisting of 40 men and 35 women with an average age of 40 years. Disk height maintenance within the group overall was 90% at 24 months. Overall, 97% of the treated disks demonstrated disk height maintenance of at least 75% of preoperative levels at 12 months and 92% at 24 months. Disk height maintenance was correlated with less nucleus removal. Patient disability, back pain, and leg pain were significantly improved from preoperative levels at 6 weeks and maintained over the course of study. There was a single symptomatic reherniation requiring surgical intervention within this series.

Conclusions Limited lumbar diskectomy combined with the use of an anular closure device provided very low rates of disk reherniation and exhibited excellent disk height maintenance and sustained disability, leg pain, and back pain improvement within a

Keywords
- anular closure
- diskectomy
- disk height
- reherniation

received
March 17, 2014
accepted after revision
June 26, 2014

DOI http://dx.doi.org/10.1055/s-0034-1393930.
ISSN 2193-6315.

24-month postoperative study period. As with prior diskectomy studies, disk height maintenance was correlated with lower nucleus removal, although recurrence was less than in prior reports of limited diskectomy. Anular closure may allow for achievement of both objectives.

Introduction

Lumbar diskectomy is viewed as the surgical standard for lumbar pain and radicular symptoms associated with herniated disks in the lumbar spine.[1–5] Despite the prevalence of this condition and the volume of procedures conducted, lumbar diskectomy long-term clinical results are inconsistent and unsatisfactory.[6,7] This inconsistency in results may be attributed to the complexity and progression of disk degeneration. Degeneration of the vertebral disk continues and may even be accelerated after diskectomy. In a long-term study of diskectomy patients compared with an asymptomatic nonoperative control group, both the severity and rate of radiographic degeneration was higher in the diskectomy group.[8] Radiographic confirmation of disk degeneration is evident in the form of disk height loss, end-plate changes, facet arthrosis, and anular protrusions.[2,8–11] Radiographic degenerative markers, such as disk height loss, have been associated with postoperative back pain and poor outcomes.[1,9,11–14] However, correlations between disk height and patient outcomes could not be made in some studies.[6,10,13,15]

Loss of disk height is a characteristic marker of degeneration that is readily measurable in all imaging modalities. Disk height loss after diskectomy has been reported in as many as 49 to 100% of patients,[1,6,8,9,13] and postoperative disk height loss exceeding 25 to 33% has been reported in 24 to 64% of diskectomy patients.[1,3,6,8,9,15] A postoperative loss in disk height exceeding 25 to 33% has been associated with low back pain,[1,3,9] poor outcomes,[12] altered biomechanical stresses,[16] and segment instability.[17]

Disk height loss after diskectomy may be partly explained by the loss of nuclear material from both the herniation and the subsequent diskectomy procedure performed. Additional loss of intradiskal material and/or hydration may occur due to the remaining anular defect. Studies have positively correlated disk height loss with the amount of nucleus removed during diskectomy.[15,17,18] Disk height loss can be mitigated by a more limited removal of nucleus pulposus; however, this surgical strategy has been associated with higher rates of reherniation.[3,4,19–21] Surgical outcomes for recurrent herniation are poorer than primary diskectomy.[5,22,23] An ideal surgical option would combine a limited diskectomy, preserving as much nucleus pulposus as possible, while maintaining a low risk for reherniation. Anular closure devices (ACD) have been developed to fulfill this need.

In 2008, an ACD (Barricaid, Intrinsic Therapeutics, Inc., Woburn, Massachusetts, United States) became available in Europe. This device is a flexible woven polyester mesh held in place with a titanium (Ti-6Al-4V) anchor. The mesh is intended to be a mechanical barrier for anular defects created or found during a standard posterior diskectomy (►**Fig. 1**). The primary purpose of this study was prospectively to evaluate the disk height maintenance at time points up to 2 years in patients treated with primary limited lumbar diskectomy, augmented with the Barricaid ACD. Additionally, correlations between disk height maintenance and clinical outcome were assessed, and the influence of demographic or surgical factors on disk height was evaluated.

Materials and Methods

Two separate single-arm, multicenter, prospective clinical studies were conducted using the ACD as an adjunct to primary lumbar diskectomy. Interim clinical outcomes have been reported previously.[24] For study A, Medical Ethics Committee (MEC) approvals were obtained at each study site prior to initiation, and some subsequent changes to the protocol and device were retrospectively reviewed. For study B, MEC approvals were received at each study site before initiation. An independent data safety monitoring board oversaw each study. The first study (study A) was conducted in two medical institutions in Croatia beginning in April 2008. The second study (study B) was conducted at four medical institutions in Germany and the Netherlands beginning in 2009. Ten surgeons performed the diskectomies across the six study sites. The only significant difference between study protocols was the decreased minimum posterior disk height inclusion criterion from 5 mm in study A to 3 mm in study B. The instrumentation and implant surgical technique were

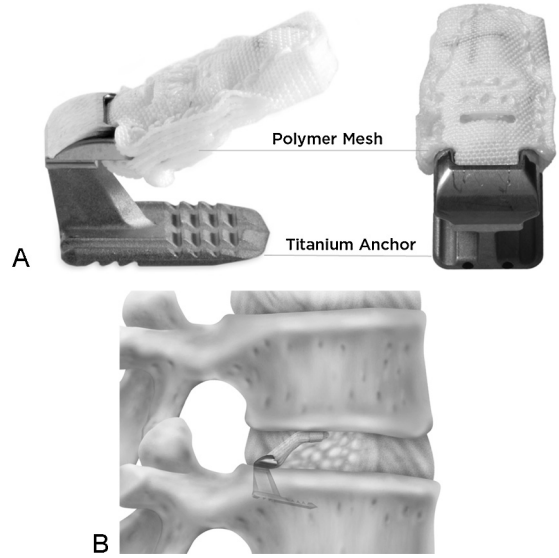

Fig. 1 The Anular Closure Device (ACD). (A) Components. (B) In situ representation.

identical. The implant materials, bone anchor design, and mesh size were the same in both studies. A slight difference in the mesh design was implemented by the manufacturer between the two studies, resulting in two half layers of material being added to the eight-layer assembly to further increase strength. Variance in preoperative variables was assessed to ensure the ability of the two groups to be pooled.

Patient Selection

Patients undergoing primary surgical diskectomy for symptomatic herniated lumbar disks at one or two levels between L1 and S1 with at least 6 weeks of failed conservative treatment prior to surgery were eligible for inclusion. Additional inclusion criteria included (1) visual analog scale (VAS) leg pain of at least 40 of 100; (2) Oswestry Disability Index (ODI) of at least 40 of 100; (3) minimum posterior disk height of 5 mm (study A) or 3 mm (study B) at the index level; (4) patient age between 18 and 75 years; (5) radiographic confirmation of neural compression using computed tomography(CT) and/or magnetic resonance imaging (MRI). Exclusion criteria included (1) spondylolisthesis grade II or higher; (2) back or nonradicular leg pain of unknown etiology; (3) systemic or local active infection; (4) cauda equina syndrome or neurologic bowel/bladder dysfunction; (5) body mass index $>$ 40 or weight $>$ 100 lbs over ideal body weight.

Surgical Technique

Surgeons were instructed to remove only a limited amount of nucleus. The volume of nucleus removed was measured in each case in cubic centimeters, through the displacement of water[15] or dry compression in a syringe. After the limited diskectomy was performed, the height and width of the anular defect was measured using a series of sizing paddles (Intrinsic Therapeutics, Inc., Woburn, Massachusetts, United States). At the time of the study, the implant was available in one size capable of blocking an anular defect up to 10 mm wide and up to 6 mm tall. If the defect was within these parameters, the ACD was delivered into the defect in accordance with the manufacturer's surgical technique and instructions for use. Patients were discharged and given discharge instructions per each hospital's standard regimen following lumbar diskectomy, without any additional bracing or activity restriction.

Radiographic Measures

Multiplanar CT scans with two-dimensional coronal and sagittal reconstructions and/or MRI with both T1- and T2-weighted axial and sagittal images were performed prior to surgery. Lateral radiographs in neutral position were taken preoperatively and postoperatively at 6 weeks, 3, 6, 12, and 24 months. Additional radiographic assessment was used at the discretion of the surgeon if adverse events were suspected. All radiographic data were evaluated by an independent blinded radiologist for device migration and device condition.

Disk height was measured from lateral X-rays in neutral position by (1) identifying the four corners of the disk space (►**Fig. 2**); (2) measuring the anterior and posterior disk heights; and (3) calculating the simple average of the anterior and posterior disk heights. 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. 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 end plate of the inferior vertebra. All measurements were performed using analysis software (QMA, Medical Metrics, Inc., K022585) approved by the Food and Drug Administration.[25] This software optimizes the registration of sequential (e.g., flexion-extension) or longitudinal images so that measurements can be taken from consistent landmarks and has been validated to measure changes in disk height accurate to within 1 mm or better.[26] Reproducibility has also been validated in the lumbar spine.[27] Radiographic success was defined as disk height maintenance of $\geq$ 75% of preoperative disk height. Preoperative disk volume was calculated from CT reconstructions by the sponsor as described by McGirt et al.[15]

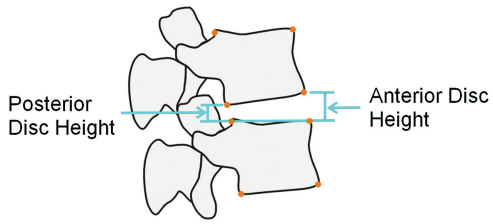

Fig. 2 Disk height was defined as the average of the anterior and posterior disc heights.

Clinical Outcomes

Subjective clinical outcome measures were determined prior to surgery and at 6 weeks, and 3, 6, 12, and 24 months after surgery. At each time point, patients completed an ODI questionnaire[28] and a visual analog scale[29] for back (BVAS) and leg (LVAS) pain. These were each calculated on a 0 to 100 scale with lower scores indicating better outcome. Device related serious adverse events and reoperative recurrence were also reported.

Statistical Analysis

Patient demographics and surgical variables including age, gender, weight, disk height, disk volume, surgical level, defect height, defect width, defect area, disk volume removed, and percentage volume removed were recorded or determined. Descriptive statistics are reported in mean plus or minus standard deviation. Gender impact on disk height maintenance at 12 and 24 months was analyzed using the Student *t* test. The effect of operative level on disk height maintenance at 12 and 24 months was determined using the Kruskal-Wallis one-way analysis of variance by ranks. The relationship between the remaining preoperative variables and 12- and 24-month disk maintenance was determined using regression analysis. Disk height over time was analyzed using unpaired Student *t* tests between individual time points. Clinical

Table 1 Patient[Q3] demographics of Study A and Study B

	Study A	Study B	Combined	*p* value
No. or patients	30	45	75	
Male-to-female ratio	16:14	24:21	40:35	1.000
Age, y	38.3 (9.5)	42.3 (11.4)	40.7 (10.8)	0.1075
BMI	26.8 (2.8)	26.0 (4.9)	26.3 (4.2)	0.3665
Operated level				
L3–L4	0	2	2	
L4–L5	19	22	41	0.447
L5–S1	12	21	33	
Defect size, mm^2	51.0 (8.3)	38.6 (10.9)	44 (12)	0.000
Disc volume removed, cm^3	1.3 (0.84)	1.6 (1.1)	1.5 (1.0)	0.2254
% disc volume removed	16.2 (15.4)	26.2 (18.3)	21.9 (17.7)	0.0138
Preoperative disc height, mm	8.6 (1.7)	8.0 (1.9)	8.3 (1.8)	0.1310
Preoperative BVAS[a]	66.3 (16.6)	57.8 (27.9)	61.3 (24.1)	0.1075
Preoperative LVAS[a]	79.8 (12.8)	81.7 (13.2)	80.9 (13.0)	0.5471
Preoperative ODI[a]	62.7 (13.7)	60.3 (12.7)	61.3 (13.1)	0.4596

Abbreviations: BMI, body mass index; BVAS, visual analog scale for back score; LVAS, visual analog scale for leg score; ODI, Oswestry Disability Index.
[a]Two patients were excluded from the analysis due to intraoperative procedural errors.

outcome measures at preoperative and individual postoperative time points were compared using the Wilcoxon rank-sum test. The Fisher exact test was used to compare success rates between study A and study B at 12 months. Clinical outcome measures at 12 and 24 months were assessed via the Wilcoxon rank-sum test when grouping patients according to disk height maintained ($\geq$ 75% versus $<$ 75% disk height maintenance). All statistical analyses were performed using the Intercooled Stata v.6.0 program (StataCorp, College Station, Texas, United States). Statistical significance was set at a p value < 0.05.

Results

Patient Population

Thirty patients were enrolled in study A between April 2008 and June 2009. Forty-five patients were enrolled in study B between April 2009 and July 2010. Of the 75 patients enrolled, 2 were excluded from study B for intraoperative procedural errors. All patients were implanted at one level, except for one patient in study A who was implanted at two levels. Patient characteristics and defect dimension data measured intraoperatively are summarized in ►**Table 1**. Follow-up at 12 months was 100% in study A and 95% in study B (41 of 43), with an overall 12-month retention of 97%. At 24 months, one patient was lost to follow-up in study A for a 97% rate of retention (29 of 30). In study B, 90% completed their 24-month follow-up (39 of 43) for an overall rate of 93%.

One patient's data was censored after 6 months due to a device removal as described later. Calculations of disk height maintenance require both preoperative and postoperative neutral-lateral X-rays. Due to missing images, accountability for disk height maintenance was 81% (58 of 72 patients or 59 of 73 disks) at 12 months and 86% (62 of 72 patients or 63 of 73 disks) at 24 months.

Reoperative Recurrence and Device-Related Serious Adverse Events

A single symptomatic ipsilateral reherniation requiring surgical intervention occurred in study B. The reoperation occurred $\sim$ 7 months postoperative, and the device was removed with the assistance of a tool provided by the implant manufacturer so that a fusion could be performed, per the surgeon's standard of care after a reherniation. Following careful adhesiolysis and mobilization of the dural sac, a small rim of bone posterior to the anchor was removed; afterward the device could be extracted without much difficulty. No intraoperative complications were noted. Postoperative outcomes from this patient, including disk height maintenance, were excluded from analysis after 6 months. The overall rate of symptomatic recurrent herniation was 1.5% (1 of 68 patients) for all patients who completed a 24-month follow-up visit.

Through 24 months, two device-related serious adverse events for mesh dislocation were reported, one in each study (2.7% or 2 of 73 patients) at 22 and 24 months postoperatively, respectively. A reoperation was performed for each occurrence to remove the mesh and perform a further diskectomy, with full patient recovery. In one case the anchor was left in place; in the other the anchor was also removed; neither patient received additional hardware. A new iteration of the mesh was subsequently designed to mitigate these types of failure.

Radiographic Results

Disk height loss predominantly occurred in the immediate postoperative period. The maintained disk height over time

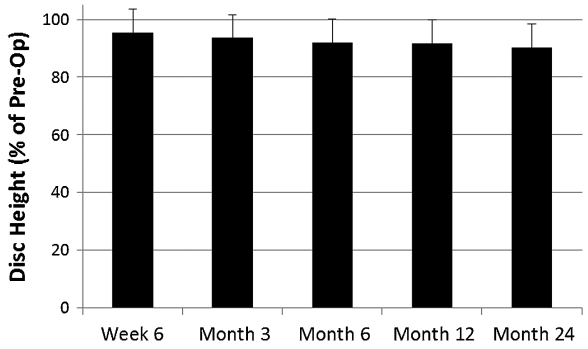

Fig. 3 Disk height maintenance over time (mean plus or minus standard deviation).

can be seen in ►**Fig. 3**. A representative example of the radiographic progression of a L4–L5 disk treated with limited diskectomy and the ACD is given in ►**Fig. 4**. Disk height at 6 weeks was significantly less than the preoperative height with 95.3 ± 8.5% disk height maintained ($p < 0.001$). All other postoperative periods exhibited significantly lower disk heights than the preoperative height; however, further statistically significant loss in disk height was not seen during the study. At 12 and 24 months, the mean disk height was 91.5 ± 8.4% and 90.0 ± 8.4% relative to preoperative heights, respectively. With respect to the success criteria of maintaining at least 75% of the preoperative disk height, 97% of disks (57 of 59) demonstrated radiographic success at 12 months and 92% (58 of 63) at 24 months.

No patient demographics were significantly correlated with disk height loss. The volume of nucleus removed intraoperatively was negatively correlated with the postoperative disk height maintenance at both 12 months ($p < 0.001$) and 24 months ($p = 0.009$). Similarly, a statistically significant negative correlations between the percentage volume removed and disk height maintenance at 12 months ($p < 0.001$) was seen; a trend was observed at 24 months ($p = 0.072$).

Clinical Outcome Results

All clinical outcome measures significantly improved in the immediate postoperative period (►**Figs. 5** and **6**).

Correlations between disk height loss and ODI, LVAS, and BVAS could not be made at either the 12- or 24-month time points. When patients were grouped according to maintained disk height using 75% as the delimiter, worse ODI, LVAS, and BVAS outcomes were seen on average in patients with > 25% disk height loss at 24 months, although these differences did not reach statistical significance ($p > 0.34$). It is important to note that the power of this test may be too low to detect other differences due to the small number of disks exceeding 25% disk height loss: only 3% ($n = 2$) of the followed levels at

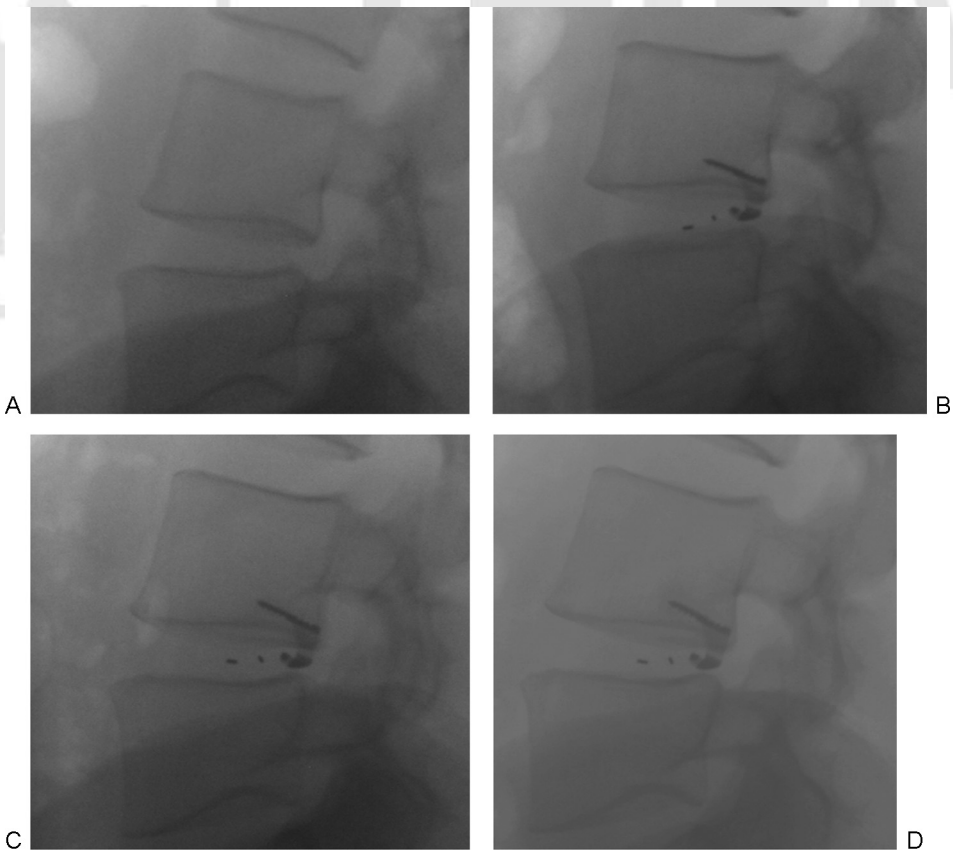

Fig. 4 Representative example of disk height maintenance over the study period. (A) A 36-year-old woman with a L4–L5 herniation preoperatively and at 6 weeks (B), 12 months (C), and 24 months (D) postoperative periods. This patient demonstrated a 1% and 2% loss at 12 and 24 months, respectively.

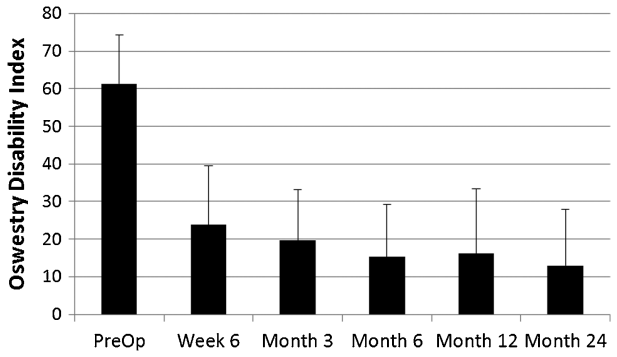

Fig. 5 Oswestry Disability Index score over time (mean plus or minus standard deviation).

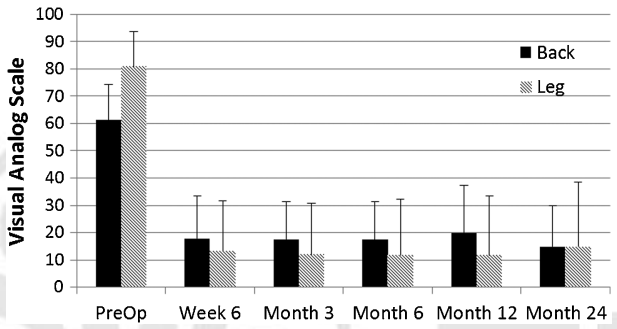

Fig. 6 Visual analog scale for leg and for back scores over time (mean plus or minus standard deviation).

12 months and 8% ($n = 5$) of the followed levels at 24 months had incurred a $\geq$ 25% loss in disk height.

Discussion

Use of an ACD in conjunction with a limited lumbar diskectomy may have had a positive effect in this cohort of patients, with excellent maintenance of postoperative disk height as compared with preoperative disk height. At the 24-month postoperative period, disks had maintained an average of 90% of their preoperative height, only 8% of the studied disks had lost $>$ 25% of their preoperative height, and the maximum extent of disk height lost for a single patient at any time point was 30%. In contrast, McGirt et al found a 26% average height loss at 24 months with 50% of the disks exceeding 25% loss in a prospective cohort study of 108 patients treated with primary lumbar diskectomy.[15] Yorimitsu et al reported a 21% average height loss with losses exceeding 25% in 48% of the standard diskectomy population.[3] Mariconda et al reported moderate to severe disk space narrowing in 90% of diskectomy patients in a long-term study. Of those patients, 64% exhibited disk height loss exceeding 33%.[8] Thus the frequency and severity of disk height loss in the present series was reduced compared with previous reports.

Increased removal of the nucleus, both in the disk volume percentage and overall volume, correlated with greater disk height loss in these cohorts of patients. This association between the amount of disk removed and postoperative disk height loss is in keeping with other reports.[15,17,18] McGirt et al found a 26% disk height loss in a series of patients with an average of 2 ± 1.1 cm^3 nucleus pulposus removed and a mean anular defect of 45.6 mm^2. Of their patients with $<$ 8% loss, the volume of disk removed was 1.5 ± 0.6 cm^3.[15] Mochida et al had $>$ 30% disk height loss in 20% of their patients with $\sim$ 1 g (range: 0.8–1.3 g) of disk removed.[18] In the present study, the average volume of nucleus pulposus removed (1.4 ± 1.1 cm^3) was comparable with other studies with low rates of disk height loss. Although this correlation between nucleus removed and disk height loss was not negated with the use of the anular closure device, the magnitude of disk height loss was diminished. Furthermore, studies have associated a higher risk of recurrent herniation with more limited nucleus removal. The 1% symptomatic reherniation rate at 12 months is low and compares favorably with reported reherniation rates ranging between 2% and 27%,[4,7,15,19–22] and particularly to the average 7 to 9% reported for limited diskectomy.[4,21] The low rate of recurrence in this series may indicate that the anular closure device could enable the disk height maintenance that others have associated with minimal nucleus removal without the added risk of recurrence.

Disk height loss has been associated with further degeneration and poor clinical outcomes in prior reports. In a retrospective study of patients with symptomatic segmental single-level instability after lumbar microdiskectomy, Schaller found that instability was associated with more extensive surgical procedures and disk height loss $>$ 30%. The extent of disk height loss also correlated to grade of radiologic instability and severity of clinical instability signs.[17] If disk height loss after diskectomy is limited to $<$ 25% of the preoperative height, radiographic instability over time may also be reduced or prevented. Mochida et al found that poor clinical outcomes correlated with increased losses in disk height after aggressive surgical procedures.[18] Worse clinical outcomes were also reported by Yorimitsu et al in patients who had lost $>$ 25% of their preoperative disk height.[3]

Studies have shown that most outcome improvement occurs in the first 2 years after surgery.[5,23] If the initial postoperative period is crucial, measures taken to improve early outcome may be foundational for long-term success. Patient disability, leg pain, and back pain within this cohort of patients significantly improved after surgery. In this series, the lack of significant disk height change after the 6-week period indicates sustainable disk height maintenance. The plateau in ODI, BVAS, and LVAS scores over the 24-month period also signifies consistency in clinical outcomes over time. Based on previous reports of preserved functional outcome and patient satisfaction in the 2- to 10-year postoperative period,[5] there is reason to think that these results would continue in longer postoperative periods excluding recurrent herniation or implant failure.

Distinguishing the specific effects of disk height loss is difficult when most of the population exhibits some form of loss. Disk degeneration scales also combine various radiographic features and a large range of height loss within a single score.[1,8] In this series the low threshold of disk height loss may have limited the identifiable connections between

disk height and clinical outcome. Disk height losses > 25% or 33% have been shown to have a significant impact on clinical outcome.[1,3,8,12,17] In this series, 31% disk height loss was the maximum loss reached, and only 4 patients exhibited > 25% loss. If patients in this series were all below the clinically significant level of disk height loss, it may not be surprising that we did not observe significant correlations between disk height and clinical outcome.

We recognize the inherent limitations of this study. The lack of a control group may make it difficult to assess the influence of the ACD on maintaining disk height and positive clinical outcomes, and the participation of 10 different surgeons may have led to variability in outcomes. A prospective controlled trial comparing limited diskectomy with and without the ACD is suggested to derive ACD influence apart from surgeon-specific results. Additionally, the 2-year end point of this study may be insufficient in determining long-term stability; thus long-term evaluation of this technique is recommended.

Conclusion

Excellent radiographic and clinical results were demonstrated in this prospective clinical evaluation of patients treated with an ACD device implanted as an adjunct to primary lumbar diskectomy, followed through a 24-month postoperative period. Within this series of patients, 97% of the treated disks had maintained at least 75% of their preoperative height after 1 year and 92% after 2 years. As with prior diskectomy studies, disk height maintenance was correlated with lower nucleus removal, although in this series recurrent herniation was minimal, which may have been influenced by the ACD. Patient disability, back pain, and leg pain were significantly improved from preoperative levels throughout the course of study. Long-term evaluation of limited diskectomy both with and without the ACD is recommended to clearly delineate the implant's impact on disk height maintenance, recurrent disk herniations, and clinical outcomes over time.

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