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Protecting facet joints post-lumbar discectomy: Barricaid annular closure device reduces risk of facet degeneration

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ABSTRACT

Lumbar discectomy is an effective treatment for lumbar disc herniation (LDH). Although the majority of patients experience successful outcomes, a significant fraction will experience a recurrence of their back pain due to facet joint degeneration. Facet joint degeneration after discectomy may be the result of excessive nuclear removal, disc space narrowing, and annular injury. This study investigated whether implantation with the Barricaid annular closure device (ACD) during discectomy reduced the rate of facet degeneration. Inclusion criteria were primary lumbar disc herniation failing conservative treatment, Visual Analog Scale (VAS) Leg ≥ 40/100, Oswestry Disability Index (ODI) ≥ 40/100 and defects that were ≤60 mm^2 (Barricaid arm only), and patient age 18–75. CT interpretations were collected preoperatively and 12 months post-discectomy. Patients implanted with Barricaid had significantly reduced rates and grades of facet degeneration than patients without Barricaid. Reinforcing the annulus fibrosus with Barricaid during lumbar discectomy may slow the progression of facet joint degeneration.

1. Introduction

Lumbar discectomy, a procedure performed more than 300,000 times per year in the U.S., is a highly effective treatment for lumbar disc herniation (LDH) [1]. Although the majority of patients experience successful pain reduction and quality of life improvements from lumbar discectomy, a substantial fraction will have unsatisfactory outcomes due to residual back pain and reherniation [1,2]. Ten year follow-up studies have elucidated a progressive worsening of clinical outcome, causing discectomy results to mirror nonsurgical results after ten years [3]. In fact, as many as 30% of open lumbar discectomies end poorly, with 18% requiring reinterventions which may cost $42,554 per patient [1,2,4]. The recurrence of radicular and/or back pain after primary discectomy has multiple etiologies such as epidural fibrosis, true disc reherniation, local arachnoiditis, and facet joint arthritis [2,5]. Even though the majority of residual back pain can be attributed to reherniation and epidural fibrosis, facet joint pathology can be equally as disabling and is the cause of back pain in as many as 16% of post-discectomy patients with residual pain [6,7].

The lumbar facet joints are highly innervated paired synovial joints that connect the vertebral arches of adjacent vertebrae [8,9]. These joints experience substantial forces and serve to shield the lower lumbar disks from shear loads. During standing, normal healthy facets absorb approximately 16% of the compressive load in the spine, while arthritic facets may experience as much as 47% of the load [10].

Facetogenic pain, often at its highest intensity in the morning, is "pseudoradicular" in nature and is often referred to the groin, hip, and buttocks [11,15,16]. Facet joint pain can often be unresponsive to conservative treatment and may require invasive procedures like intraarticular corticosteroid injections [17].

LDH, and the discectomy used to treat it, has been shown to significantly alter the biochemical milieu of the spinal motion segment [9–11,18–20]. More specifically, lumbar disc herniation, degeneration, and discectomy have been shown to cause significant disc space narrowing leading to overloading of facet joints [18]. In fact, 89% of lumbar discectomy patients demonstrate loss of disc height and facet joint arthritis on MRI and CT [21]. Discectomies that aggressively remove nuclear material in order to

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reduce reherniation risk, are more likely to cause disc space loss, endplate degeneration, facet joint disease, and residual back pain [3,22,23]. Herniations with large annular defects and discectomies that leave compromised annuli have been associated with higher rates of residual pain, facet joint arthrosis, and poorer outcomes [23–25]. The biomechanical consequences of these changes may lead to adjacent segment disease affecting the entire spine [28,29].

Annular closure devices (ACDs) reduce the risk of reherniation, especially in those patients with large annular defects [26,27]. In addition to reducing reherniation, ACDs prevent the need for excessive nuclear material removal during discectomy by reinforcing the compromised annulus [26,27]. Theoretically, by salvaging more nucleus, ACDs may lead to restored disc space heights and reduced rates of facet joint degeneration. ACDs may ultimately help to preserve the entire spine by preventing excessive degeneration of the herniated level and any potential adjacent segment degeneration. In this study we sought to investigate the differences in facet joint degeneration between discectomy patients with and without implantation of an ACD. Specifically the objectives were to:

(1) Compare the distributions of facet grades pre-operatively and post-operatively in each group of patients, and between the operative and non-operative sides.
(2) Compare the rates of facet degeneration in each group of patients after one year.
(3) Investigate any correlations between demographic, surgical, or radiographic factors and facet degeneration or facet grade.
(4) Investigate any correlations between facet degeneration or facet grade with clinical outcomes.

2. Clinical materials and methods

2.1. Patient selection

Three separate prospective, multi-center, single-arm studies were performed in Europe. Ethics committee approval was obtained at each site. A total of 75 Barricaid patients were enrolled in two of the studies, and 137 Discectomy-ONLY patients were enrolled in the third study. The Barricaid was not available clinically at the time of the Discectomy-ONLY study. Patients had a confirmed primary lumbar disc herniation with at least six weeks of failed conservative treatment prior to surgery. Other inclusion criteria consisted of Visual Analog Scale (VAS) IPSI-lateral leg pain of at least 40 out of 100 and patient age between 18 and 75 years. Exclusion criteria included spondylolisthesis Grade II or higher; prior surgery at the index level; bone density t-scores less than -2.0 for subjects requiring a DEXA; clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology; and scoliosis of greater than ten degrees.

The inclusion and exclusion criteria of the two groups (Discectomy-ONLY and Discectomy-BARRICAID) were largely similar except that the Discectomy-ONLY arm had no preoperative ODI requirement or maximum defect size. The later Discectomy-BARRICAID patients required ODI ≥ 40 and defects that were $\leq 60\,mm^2$ (6 mm tall by 10 mm wide) preoperatively.

2.2. Annular closure endoprosthesis

The Barricaid annular closure endoprosthesis consists of a woven polyester (PET) mesh attached to a titanium bone anchor. The mesh is intended to occlude the annular defect through which the surgeon accesses the disc (typically the defect through which they herniation occurred) and is fixed in position by the bone anchor that is implanted into either of the adjacent vertebral bodies of the disc (see Fig. 1). The device is implanted after the discectomy procedure has been performed, just prior to wound closure.

2.3. Image assessments

CT was performed pre-operatively and at 12 months postoperatively. A single independent radiologist (SS) utilized axial CT and a four-point scale to grade facet joint osteoarthritis. Images were viewed using OsiriX, an Apple-based DICOM viewer. Bilateral facets for L3–4, L4–5, or L5–S1 were evaluated for each patient. The degree of abnormality was scored on a four-point scale in which 0 indicated normal; 1 indicated mild degenerative disease (narrowing of the facet joint); 2 indicated moderate degenerative disease (narrowing plus sclerosis or hypertrophy); and 3 indicated severe degenerative disease (narrowing, sclerosis, osteophytes) [12]. Additionally, postsurgical changes and the presence of spondylolysis were noted. The radiologist was blinded to operative status (i.e., pre-operative or post-operative) and subject status (i.e., implanted or not implanted), but the device was not removed from the follow-up CT images, so the radiologist could likely identify implanted patients post-operatively. Facet degeneration was defined as a worsening of facet-joint grade in at least one of the facets of the index-level at 12 months.

An independent radiographic lab (Medical Metrics, Houston, TX, USA) utilized radiographs to measure disc height and range of motion both preoperatively and postoperatively. The analysis was conducted using US FDA 510k software (QMA®, K022585). The lab also looked prospectively for device migration, subsidence and fracture.

2.4. Assessment of outcomes

ODI, VAS-Back, and VAS-Ipsilateral-Leg were collected preoperatively and at 12 months post-operatively.

2.5. Statistical analysis

Unpaired t-tests assuming unequal variance (numerical variables) and Fisher's Exact tests (categorical variables) were used to compare patient characteristics. Fisher's Exact tests were used to compare distribution of facet grades and rates of facet degeneration (Objectives 1 and 2).

To investigate if any patient characteristics (age, BMI, gender, operative level, volume of nucleus removed, anular defect size) or radiographic measures (disc height and angular range of motion) were significant predictors of facet degeneration risk (Objective 3), univariate logistic regressions were used. Correlations of those same variables with facet grade (Objective 3) were investigated through the use of Kruskal–Wallis analyses (numerical variables) or Fisher's Exact tests (categorical variables).

Correlations with clinical outcomes were investigated using Wilcoxon Rank-sum tests (Objective 4). Specifically, pain and function were compared between patients who exhibited facet degeneration and those who had not.

All analyses were performed using Intercooled Stata 6.0 (Stata Corporation, College Station, TX, USA).

3. Results

3.1. Patient characteristics

Paired preoperative and 12-month follow-up CT Scans were available for 94 Discectomy-ONLY patients and 63 Discectomy-BARRICAID patients. Patient characteristics, defect dimension, clinical outcome scores, and discectomy data were measured intraoperatively and are summarized in Table 1. Note that one Barricaid

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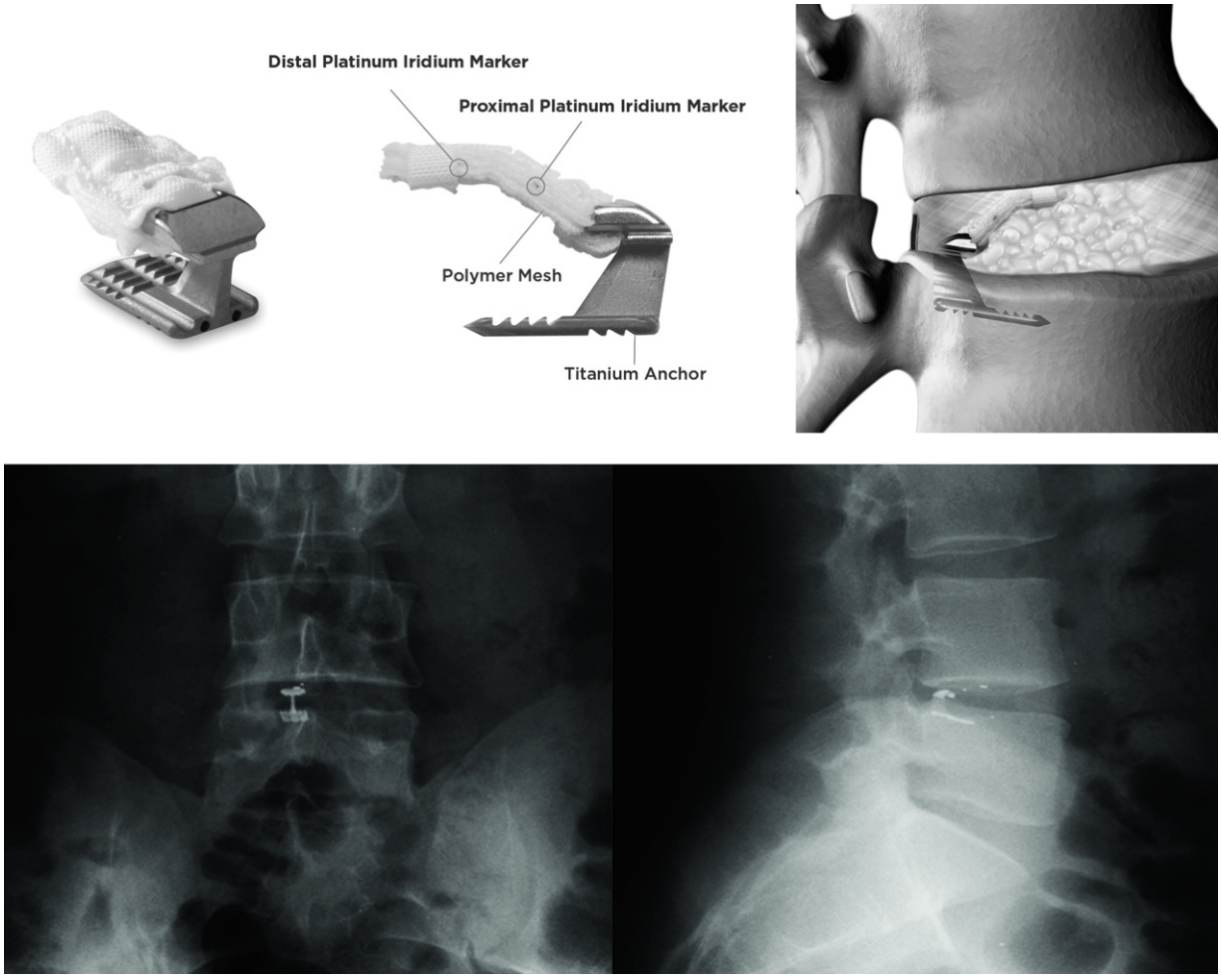

Fig. 1. Barricaid device (upper left), representation of implanted position (upper right) and typical post-operative lateral and AP X-rays (below).

patient was implanted in two levels, yielding 64 Barricaid levels that were implanted.

We were able to use all available data to detect trends between facet degeneration (or grade) and demographic and/or surgical parameters. When directly comparing the rates of facet degeneration between Discectomy-ONLY and Discectomy-BARRICAID patients, two analyses are presented: one for all patients in each of the two groups, and one for only those patients in each of the two groups who met the matched inclusion criteria (i.e., pre-operative ODI $\geq$ 40 and defect size $\leq$ 60 mm^2).

3.2. Facet grade (Objective 1)

Of the 188 facets (94 patients) in the control group (Discectomy-ONLY), 35% were grade 0, 59% were grade I, 6% were grade II, and 0% were grade III preoperatively. At 12 months post-discectomy

Table 1
Patient characteristics (SD in parentheses).

	Barricaid	*n*	Control	*n*	*p*-Value
Total *n*	63		94		n/a
Age	40.5 (10.6)	63	40.5 (10.5)	94	0.9992
BMI	25.9 (3.6)	63	26.6 (4.9)	91	0.3592
M:F	1.1	63	1.7	94	0.247
Level of discectomy					
L3/4	2		3		
L4/5	34	64	45	94	0.867
L5/S1	28		45		
Pre-op disc height	8.3 (1.9)	60	8.3 (1.4)	66	0.9921
Defect size (mm^2)	44.2 (11.6)	64	48.7 (16.0)	74	0.0656
Nucleus removed	1.5 (1.0)	64	2.2 (1.2)	91	0.0006
Preop ODI	61.2 (13.2)	63	47.7 (17.0)	93	<0.0001
Preop VAS Leg	80.4 (13.1)	63	59.9 (26.7)	94	<0.0001
Preop VAS Back	61.2 (24.5)	63	43.6 (25.9)	94	<0.0001
% with leg and ODI $\geq$ 40	98%	63	61%	94	<0.001
% with defect $\leq$ 60	98%	64	64%	94	<0.001
% both criteria	97%	63	37%	94	<0.001

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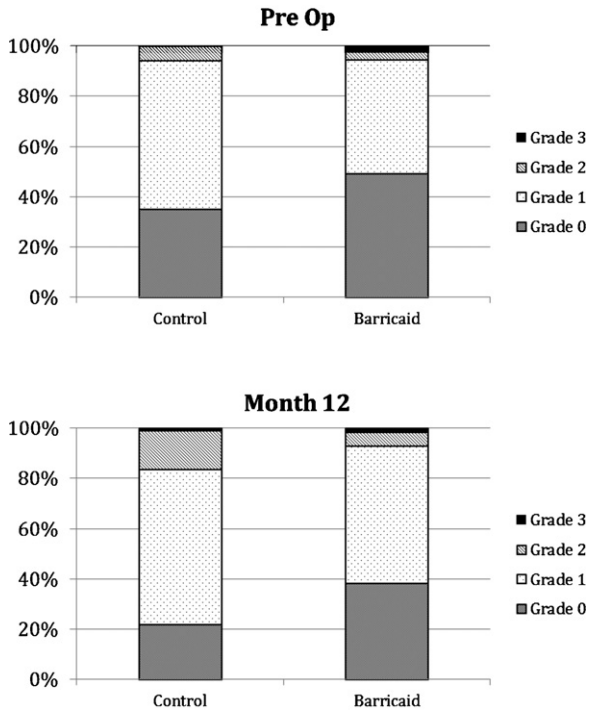

Fig. 2. Facet grade pre-operatively and at 12 months.

22% were grade 0, 62% were grade I, 15% were grade II, and 1% were grade III. Of the 128 facet (63 patients) in the treatment group (Discectomy-BARRICAID), 49% were grade 0, 45% were grade I, 3% were grade II, and 2% were grade III preoperatively. At 12 months, 38% were grade 0, 55% were grade I, 5% were grade II, and 2% were grade III. When grouping grades 0 and I vs. grades II and III, there was no difference in the pre-operative distribution of Discectomy-ONLY and Discectomy-BARRICAID ($p = 1.000$). At 12 months the Discectomy-ONLY group had a significantly higher grade of Facet degeneration than the Discectomy-BARRICAID group ($p = 0.015$) (see Fig. 2).

The conditions of the operative side were not significantly different from the non-operative side pre-operatively ($p = 0.539$) and at 12 months ($p = 0.919$) for all patients. This was also true when looking at the Discectomy-ONLY ($p = 0.7$ pre-op; $p = 0.955$ at 12 months) and Discectomy-BARRICAID ($p = 0.66$ pre-op; $p = 0.561$ at 12 months) groups individually.

3.3. Facet degeneration (Objective 2)

Of the 94 patients in the control group (Discectomy-ONLY) 40 patients (43%) exhibited facet degeneration at 12 months. Of the 64 patients in the treatment group (Discectomy-BARRICAID) 15 patients (23%) exhibited facet degeneration at 12 months. The difference between the two groups was statistically significant ($p = 0.017$).

More specifically, the progression of facet degeneration in Discectomy-ONLY patients was: 25/94 (26.6%) progressed to mild (grade 1), 14/94 (15%) to moderate (grade 2), and 1/94 (1%) to severe (grade 3). The progression of facet degeneration in Discectomy-BARRICAID patients was: 12/64 (19%) progressed to mild (grade 1), 3/64 (5%) to moderate (grade 2), and none to severe degenerative disease (grade 3). No patient exhibited a change of more than one grade.

When the patient populations of the two groups were restricted to the same, more restrictive ODI and defect size requirements of the Barricaid study, the rate of degeneration was: 51% (18/35) in Discectomy-ONLY patients and 24% (15/62) in Discectomy-BARRICAID patients ($p = 0.008$). Using these same restrictions, the progression of facet degeneration in Discectomy-ONLY patients was: 11/35 (31%) progressed to mild (grade 1), 7/35 (20%) to moderate (grade 2), and none progressed to severe degenerative disease (grade 3). The progression of facet degeneration in Discectomy-BARRICAID patients was: 12/62 (19%) progressed to mild (grade 1), and 3/62 (5%) progressed to moderate (grade 2), and none progressed to severe degenerative disease (grade 3) (see Fig. 3).

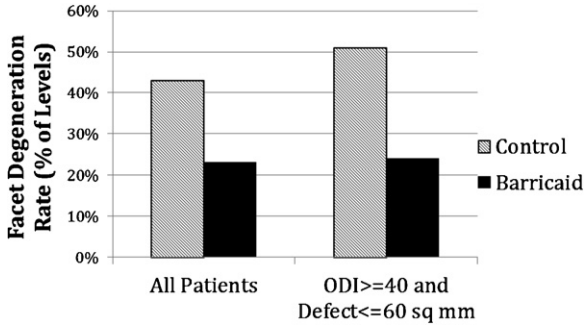

Fig. 3. Facet degeneration rate with and without inclusion criteria.

3.4. Demographic, surgical, and radiographic correlations (Objective 3)

3.4.1. Facet grade at 12 months

The results of these statistical analyses are summarized in (Table 2). In all patients, worse facet grades were significantly correlated with advancing age ($p = 0.0001$), and there was a trend toward worse facet grades and more limited ranges of motion ($p = 0.0982$). Age was not significantly different between the two groups (Table 1). Unpaired *t*-tests were performed to compare range of motion between the two groups. Pre-operatively, Discectomy-ONLY and Discectomy-BARRICAID patients exhibited similar angular ranges of motion ($p = 0.6162$). At 12 months, however, the Discectomy-BARRICAID patients exhibited a greater range of motion ($p = 0.0092$).

3.4.2. Facet degeneration risk

The results of these statistical analyses are summarized in (Table 3). Using all patients in univariate logistic regressions, a lower probability for facet degeneration was significantly correlated with smaller annular defects ($p = 0.041$) and discs implanted with the Barricaid ($p = 0.014$). There was a trend toward decreased facet degeneration for discs with less nuclear material removed during discectomy ($p = 0.079$) and discs with larger preoperative disc heights ($p = 0.080$).

Table 2
Correlation of patient characteristics and facet grade at 12 months. *p*-Values < 0.05 indicate parameters which were significantly correlated with the facet grade. Facet grade for each level was defined as the worse of the two facets.

Parameter	*p*-Value
Age	0.0001
BMI	0.2514
Gender	0.244
Level	0.108
Nucleus	0.5517
Defect size	0.4884
Preoperative disc height	0.8502
Disc height maintenance 12 m	0.2492
Preoperative angular range of motion	0.7262
Angular range of motion 12 m	0.0982

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Table 3
Correlation of patient characteristics with facet degeneration risk at 12 months. *p*-Values < 0.05 indicate parameters which were significantly correlated with facet degeneration risk.

Parameter	*p*-Value
Age	0.141
BMI	0.262
Gender	0.253
Level	0.366
Nucleus	0.079
Defect size	0.041
Preoperative disc height	0.080
Disc height maintenance 12 m	0.539
Preoperative angular range of motion	0.410
Angular range of motion 12 m	0.527
Barricaid implant	0.014

3.5. Clinical outcomes (Objective 4)

At 12 months of follow-up, there were no statistically significant differences in any of the clinical outcome scores (ODI, VAS-Back, VAS-Ipsilateral-Leg) between patients who exhibited facet degeneration and those who had not (see Table 4). This was true whether looking at all patients combined or at the Discectomy-BARRICAID and Discectomy-ONLY groups separately.

3.6. Device-related complications

No cases of implant migration, subsidence, disassembly or fracture were reported by the sites or observed by the independent lab.

4. Discussion

The facet joints and discs of the lumbar spine have an intimate and complex relationship that when disrupted, either through annular injury, disc herniation, or lumbar discectomy, can cause significant facet joint degeneration [4,6,12–14,21]. Van Goethem et al. showed facet joint enhancement on MRI in 53% of patients six months post-disectomy, with 43% of patients showing bilateral facet enhancement [5]. Mariconda et al. showed a significant increase in facet joint rim narrowing, sclerosis, osteophytes, and other arthritic changes on CT and MRI in patients after lumbar discectomy. These investigators concluded that lumbar discectomy could act as a traumatic event that accelerates and worsens the natural degenerative process of the spinal motion segment [21].

Facet degeneration is a significant cause of residual back pain, disability, and poor outcomes in lumbar discectomy patients. Manchikanti et al. showed in his 100 patient-study that residual back pain after lumbar discectomy was attributed to facet joint pathology in 32% of patients [4]. In another study, Manchikanti et al. showed that of 243 patients having residual back pain, 123 met the criteria for facet pain [6]. Parker et al. showed that 23% of patients had moderate back pain after lumbar discectomy that required conservative therapy and 9% had severe back pain that required fusion surgery. When radiographically evaluated all of these patients showed significant signs of disc degeneration such as disc space narrowing [1]. Finally, Steib et al. showed that 8.4% of patients after discectomy met the criteria for postoperative facet joint syndrome (PFJS) [7].

Table 4
Wilcoxon Rank-sum results comparing clinical outcomes at 12 months between those with and without facet degeneration. Each entry represents the *p*-Value from the statistical test. Analyses were performed on the combined patient population and on each individual group.

	All patients	Discectomy only patients	Barricaid patients
ODI	0.8354	0.8875	0.6914
VAS Leg	0.9365	0.4599	0.0989
VAS Back	0.9789	0.8718	0.7579

Although the gold standard for diagnosing facetogenic pain are local anesthetic blocks, numerous studies have proven certain imaging tests like CT to be invaluable [6]. Kalichman et al. found CT to be superior to standard radiography in its ability to improve delineation of the facet joint by capturing the joint in the axial plane, along with its high ability to contrast between bone and soft tissue [11]. Moreover, CT allows for precise visualization of pathognomonic sequelae of arthritis within the facet joint such as joint space narrowing, osteophyte formation, and bone sclerosis [12–14]. Pathria et al. found limitations in conventional radiography such as its insensitivity to degenerative alterations affecting the apophyseal articulations and recommended CT as the imaging study of choice when diagnosing facet joint pathology [12].

In this cohort of 157 patients, those discectomy patients implanted with the Barricaid ACD at the time of surgery had a significantly lower grade of facet degeneration as seen on CT than those that were not implanted with this device. In addition, discectomy patients with smaller annular defects, less nucleus removal, and greater pre-operative disc height were associated with a lower rate of facet degeneration. Most importantly, we were able to show that those patients implanted with the Barricaid had a significantly reduced rate of facet degeneration than the patients without the device.

Our results suggesting that reinforcing annular defects during discectomy protects the facet joints from degeneration are widely supported in the literature. Moore et al. showed that injury to the annulus was predictive of advanced arthritic changes in neighboring facet joints [25]. Carragee et al. showed that patients with disc herniations having massive posterior annular loss had more residual back pain, worse outcomes, and higher reoperation rates than patients with disc herniations having an intact annulus [24]. Finally, McGirt et al. showed that disc herniations with larger annular defects were associated with increased disc height loss after discectomy. The recommendation by the investigators was that annular repair may be indicated in those patients having large annular defects at the time of surgery [23].

Patients implanted with the Barricaid ACD during lumbar discectomy were also shown to have better ROM than patients that had a discectomy without the Barricaid. In addition, our results suggest that patients without the Barricaid lose significantly more ROM after surgery compared to patients implanted with the Barricaid. The pathophysiological mechanism may be that the facet joints of patients without the Barricaid exhibit more arthritic sequelae after discectomy like osteophytes, hypertrophic bone, sclerosis, and inflammation that impede ROM. A similar mechanism of erosive changes over time might also explain our findings of a strong association between advancing age and facet grade.

None of the results obtained from our analysis suggests that facet degeneration negatively impacts clinical outcome scores at 12 months after follow-up. This is not surprising since radiographic evidence of pathology oftentimes precedes symptomatology. For example, in Mariconda et al. patients were followed for at least 21 years and arthritic changes on MRI/CT were associated with back pain during the last 12 months in 97% of patients [21]. In Parker et al., discectomy patients were investigated on average 37.3 months after their operation, and 23% had residual back pain that correlated with degenerative changes on imaging [1]. Fritsch et al., followed lumbar surgery patients for a mean of 11.5 years and attributed facet joint arthritis as one of the causes for residual back pain, poor outcomes, and reoperation in a large fraction of postoperative patients [2].

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5. Limitations of the study

Although the results from our investigation suggest that implantation with the Barricaid ACD during lumbar discectomy may protect or slow the progression of facet joint degeneration, there are some shortcomings inherent in the study design that require mentioning. First, the sole radiologist in this study was not blinded to the treatment and control groups at follow-up since the Barricaid ACD is visible on CT. In the future, a follow-up study utilizing the interpretations of numerous radiologists to corroborate CT interpretations, and more complete blinding, might be warranted. Our results failed to show statistically significant correlations in any of the three clinical outcome scores, possibly due to our patients being followed for only 12 months. A longer follow-up study that specifically investigates clinical benefit as evidenced by improvements in clinical outcome scores (ODI, VAS-BACK, VAS-IPSI LEG) would certainly be warranted. The final limitation worth mentioning is that our two study groups were not subjected to the same preoperative inclusion criteria (pre-operative ODI and defect size). However, when the two arms were regrouped using the same restrictions, identical findings were obtained. Nevertheless, study of the Barricaid against discectomy alone in a randomized setting would provide a much higher level of evidence one way or the other. Such a study is ongoing.

6. Conclusion

Lumbar discectomy is an extremely successful surgical intervention for LDH patients failing conservative therapy. Although most patients report significant pain reduction, a substantial fraction will experience debilitating residual pain that originates from the lumbar facet joints. The pathophysiological mechanism tying lumbar discectomy to facet joint degeneration and residual back pain has been well established and relates to the tendency of discectomy to reduce disc space height and alter the biomechanical equilibrium within the spinal motion segment. These biomechanical changes alter the amount of shear forces experienced by facet joints, and over time significant inflammatory responses are elicited that lead to classic arthritic changes. Of particular importance is that these pathologic changes appear not to be localized to the level of discectomy, but are instead distributed throughout most of the lumbar spine. Therefore, our findings, similar to those published by Mariconda et al., suggest that lumbar discectomy may lead to a "hot spot" at the level of discectomy which can evoke a systemic degenerative process [21].

ACDs may be able to maintain disc space height and reduce facet degeneration by minimizing the amount of nuclear material that is removed during discectomy. Our findings support this theory and suggest that implantation with the Barricaid during discectomy has significant benefits in disc space maintenance and facet degeneration risk. The fact that none of the clinical outcome scores demonstrated statistically significant benefits from Barricaid implantation emphasizes the need for longer follow-up studies in the future.

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