Acta Orthop. Belg., 2022, **88**, 491-504

ORIGINAL STUDY

doi.org/ 10.52628/88.3.10248

Is annular repair technique useful for reducing reherniation and reoperation after limited discectomy?

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The annular defect because of the primary lumbar disc herniation (LDH) or surgical procedure is considered a primary reason for recurrent herniation and eventually reoperation. Efforts to close the defect with annular repair devices have been attempted several times, but the results were controversial. The present aims to detect whether the annular repair techniques were useful for reducing the re-herniation and re-operation rate. The Pubmed, Cochrane library, and Embase databases were searched to retrieve relevant studies published before January 1, 2021. Continuous variables were compared by calculating the standard difference of the means (SDM), whereas categorical dichotomous variables were assessed using relative risks (RRs). A random-effects model was used if the heterogeneity statistic was significant; otherwise, a fixed-effects model was used. A total of 10 researches were suitable for the meta-analysis, including four different repair techniques and 1907 participates. Compared with the control group, there was no statistical difference with the ODI, VAS-leg, and VAS-back scales for patients treated with the annular repair. However, using an annular repair device was associated with a significant reduction in the re-herniation (p=0.004) and re-operation (0.004) rates. There was no difference between the groups with perioperative complications. However, much more device-related long-term complications happened in the annual repair group (p=0.031) though it still

Competing interests: The authors declare that they have no conflict of interest. Funding: The study was funded by the Youth project of National Natural Science Foundation of China (81601919) and Changzhou Science and Technology Bureau Project (CZ20200037). Acknowledgements: Thanks for anyone helpful but not able to list in the manuscript, such as Haibo Li, Luming Nong, et al. Haibo Li and Luming Nong has been listed as authors in the previous preprint version (https://www.researchsquare.com/article/rs-32052/v1). However, because of the big revision of the present paper and the two authors did not contribute anything during the revision, these two authors were removed from the author list.

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decreased the overall re-operation rate significantly (p=0.006).Our results demonstrated that using an annular repair device was safe and beneficial for reducing re-herniation and re-operation rates.

Keywords : annular repair; LDH; annular closure device; recurrent disc herniation; Barricaid; Anulex; Xclose.

INTRODUCTION

Lumbar disc herniation (LDH) is one of the most common spine disorders, with over 266 million patients worldwide diagnosed per year *(1)*. Surgical discectomy, especially open discectomy, is considered the standard treatment with favourable outcomes. Initially, a radical discectomy of both the disc material and the cartilaginous endplates was recommended as the standard procedure. Though excellent outcomes after discectomy were reported, the postoperative segmental instability and low back pain with the incidence rate of 11% to 15% could not be ignored *(2)*. Nowadays, a "limited" discectomy, even microendoscopic discectomy, which excises only fragments with minimal invasive exposure, was widely used to minimize the influence of segmental stability *(3)*. However, the reoperation incidence persists at 13% to 25% after the limited discectomy procedure, mainly due to the symptomatic recurrent disc herniation presenting as the primary contributor *(4-6)*. The annular defect because of the primary LDH or discectomy, especially for large and massive defect (≥ 6 mm), is considered the main reason for recurrent disc herniation *(7-9)*. Thus, many surgeons advance the hypothesis if annular repair after discectomy will benefit the patients from recurrent disc herniation.

Several prosthesis/techniques have been developed for annular repair to minimize the morbidity of re-herniation till now, including annular closure device (ACD) – Barricaid ™ (Intrinsic Therapeutics, Inc., Woburn, MA, USA) technique, Anulex-Xclose (Anulex Technologies, Minnetonka, MN) technique, sutures and PushLock technique *(10-13)*, and "jetting suture" technique *(14)*. However, controversy result continues about the outcomes during follow-up *(10,12,15-19)*. The present study aims to figure out whether the annular repair technique is useful for reducing recurrent LDH after limited discectomy.

MATERIALS AND METHODS

The Pubmed, Cochrane library, and Embase databases were searched independently by two investigators (Q.Z and JL.T) to retrieve relevant studies published before January 1, 2021. The search criteria "annular repair or annulus fibrosus repair or annular closure or annular reinforcement or annular reconstruction or Xclose or ACD or Barricaid or Jetting Suture" were used in text word searches. The "related articles" function was used to broaden the search. The reference lists of the selected articles were also manually examined to find relevant studies that were not discovered during the database searches.

We selected any studies that reported outcomes after the operation of annular repair. All titles, abstracts and full papers of potentially relevant studies were assessed for eligibility. Articles were excluded if no matched outcomes were reported or were laboratory studies. When several reports from the same study were published, only the most recent or informative one was included. The language was restricted to only English.

The data extraction of all variables and outcomes of interest were performed independently by two readers (Q.Z and JL.T). Disagreements were resolved through discussion and consensus. The methodological quality was assessed by the Quality Index, consisting of 27 items distributed between five sub-scales *(20)*. Matched outcomes were checked throughout the papers. The VAS scale (leg and back), ODI scale, re-herniation rate, and re-operation rate were the matched outcome and were extracted from all the studies included. Besides, we extracted data on clinical design, country of study, number of participants, and mean follow-up. If articles reported insufficient data, we contacted corresponding authors for additional information.

The statistical analysis was performed using meta-analysis software called ''Comprehensive Meta-Analysis''. Continuous variables were compared by calculating the standard difference of the means (SDM), whereas categorical dichotomous

variables were assessed using relative risks (RRs). All the results were presented as forest plots. A P value of 0.05 was statically significant, and a 95% confidence interval was given for each effect size. Heterogeneity is expressed as I2. This value ranges from 0% (complete consistency) to 100% (complete inconsistency). A random-effects model was used if the Q or I2 statistic was significant; otherwise, a fixed-effects model was used. Egger's test was performed to access the publication bias of studies included in this meta-analysis.

RESULTS

The initial literature search retrieved 9230 relevant articles. After a careful screen of the titles,9071 articles were excluded for not investigating the topic of interest. After reviewing the abstracts, 105 more articles were excluded (73 animal/cell studies, 30 cadaver studies, and 25 reviews), leaving 31 studies for further full publication review. One study was excluded because it only reported the protocol of an RCT *(12)*. Another four studies were excluded because the articles did not report any useful outcomes. Therefore, a total of 26 papers matched the selection criteria, but only 10 papers were suitable for the meta-analysis, as lots of papers were reporting the outcomes of the same study (Fig.1).

A total of 1907 participates (1203 treated and 704 control) were enrolled in the study. The key characteristics of the included studies are summarized in Table I. Seven of the included studies were prospective cohort studies (3 RCTs), and the remaining three were retrospective. Seven of the studies were from European or American, two from Korea, and the remaining from China. Seven of the studies utilized an annular closure device called Barricaid, and the remaining three studies used suture-based techniques, including the Xclose technique, sutures and PushLock technique, and jetting suture technique. Most studies followed the patients for at least two years, and only one reported the outcomes at the mean of 15 months. Table II listed the studies' basic characteristics, including population number, gender, age, BMI, and operating level.

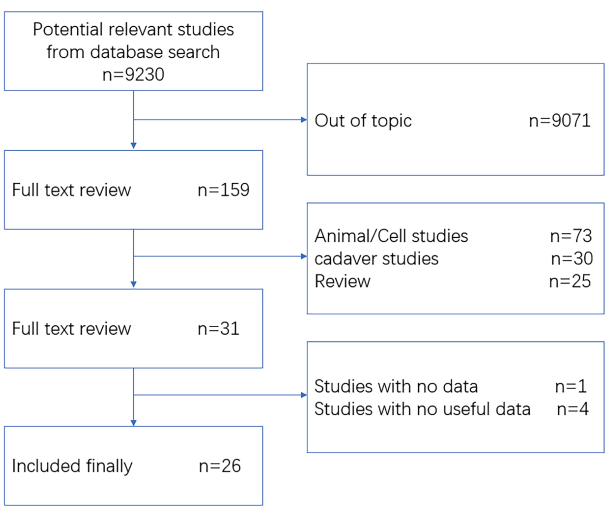


Fig. 1. – Search strategy flow diagram.

Among the included studies, only the VAS scale of leg and back, the ODI scale, the symptomatic re-herniation rate, and the re-operation rate were matched. Table III listed the extracted matched outcomes. On review of the data extraction, there was 100% agreement between the two reviewers. According to the checklist for measuring study quality, all the studies were considered medium/high-quality methodology. Thus, the methodological bias of this study was deemed to be low.

Compared with the control group, the ODI scales of the annular repair group demonstrated no statistical difference (p=0.945, Fig. 2). Similar results were found for the VAS-leg and VAS-back scales (p=0.82 and p=0.847, Fig .3 and Fig. 4, respectively).

For the comparison of the radiological and symptomatic re-herniation, a significant decrease was found in the annular repair group (treated v.s. control, 4.9% v.s. 14.6%, p=0.004, Fig. 5). Similarly, the treated group demonstrated a significantly lower re-operation rate than the control group (4.7% vs 14.3%, p=0.004, Fig. 6), when only taking the re-herniation related re-operation into consideration.

The adverse problems, especially annular repair related complications, were also analyzed, including peri-operation complications and device-related long term complications. There is no doubt that the surgical time and blood loss are much more in the annular repair group because of the additional annular repair procedures. For peri-operation complications, all annular repair techniques seem

Table I. – The key characteristics of the included studies

Study	Characteristics	Time of the cases included	inclusion	Surgical Technique	Repair Method	follow-up
1	A multi-center RCT (NCT01283438) in 21 centers of six European countries	2010.12-2014.12	one-level disc herniation	single-level limited discectomy	ACD (Barricaid)	2 years
2	A retrospective case series with minimally invasive discectomy technique in Belgium	2011.03-2017.12	unilateral, single level lumbar disc herniation	limited tubular minimally-invasive lumbar microdiscectomy	ACD (Barricaid)	2 years
3	Multicenter prospective non-randomized controlled cohort study in Croatia	2008.05-2009.05	patients with single-level herniated lumbar disc	discectomy	ACD (Barricaid)	2 years
4	A multi-center prospective cohort study (NCT01534065) in Germany and Netherland	2009.04-2010.07	Posterior or posterolateral disc herniations at one or two levels between	Posterior limited lumbar discectomy	ACD (Barricaid)	2 years
5	A retrospective case series study based on "real-world" population in Germany	2009.07-2015.11	posterior or posterolateral symptomatic disc herniations of a single level	limited lumbar discectomy	ACD (Barricaid)	mean 15 months
6	A single-blind RCT with Xclose technique (NCT00760799) in USA	2007.03-2011.11	symptomatic herniated nucleus pulposus of 1- and 2-level cases	discectomy	Xclose Tissue Repair System.	2 years
7	A retrospective case series based on conventional Implant technique in Korea	2007.01-2008.01	LDH of a single level	discectomy	No. 2 fiberwire sutures and PushLock implants	three years
8	A prospective single-cohort observational study with "jetting suture" technique in China	2012.09-2013.07	one-level lumbar disc herniation	microendoscopic discectomy	"jetting suture" technique	mean 26.7 months
9	A prospective, single-center study based on patients at high risk of reherniation in Germany	2015.05-2016.11	Lumbar disc herniation of a single level with large annular defects and a disc height of at least 5 mm	limited lumbar discectomy	ACD (Barricaid)	2 years
10	A prospective randomized controlled trial in Korea	NA	one-level lumbar disc herniation	limited discectomy	ACD (Barricaid)	2 years

safe enough as only a few complications (mainly dural tear and perioperative infections) were reported, with no statistically significant difference found (Table IV). However, there were much more device-related long term complications such as device failure, loosing, migration, and epidural infection in the annular repair group, especially for the cases with ACD (Barricaid) technique (p=0.031, Table III). However, though much more device-related complications happened, the overall re-operation rate is still much lower in the annular repair group (7.9% v.s. 16.2%, p=0.006, Fig.7).

The annular repair technique is always recommended for LDH patients with large annulus

Table II. – The basic characteristics of the studies (population number, gender, age, BMI, and operating level) - 1/2

Study	Population	Gender (Male/ Female)		Age (mean)	BMI (mean)	Operate level		
	Control/ Treated	Control	Treated	Control/ Treated	Control/ Treated	□	Control	Treated
1	278/272	171/107	156/116	44/43	26/26	L2/3	1	2
						L3/4	5	8
						L4/5	101	123
						L5/S1	171	139
2	NA/60	NA	25/35	NA/42	NA/24.1	L4/5	□	23
						L5/S1	□	37
3	72/30	49/23	16/14	40.6/38.3	NA/26.8	L3/4	□	0
						L4/5	24	19
						L5/S1	20	12
	46/NA	□	□	41/NA	□	L3/4	2	□
						L4/5	24	□
						L5/S1	20	□
4	29/45	14/15	24/21	40.1/42.3	26.3/26	L3/4	0	2
						L4/5	10	22
						L5/S1	19	21
5	NA/44 (Trail)	NA	25/19	NA/46.7	□	L2/3	□	1
						L3/4	□	1
						L4/5	□	25
						L5/6	□	0
						L5/S1	□	17
	NA/120 (Non-Trail)	NA	66/54	NA/45.6	□	L2/3	□	0
						L3/4	□	4
						L4/5	□	69
						L5/6	□	1
						L5/S1	□	45
6	249/478	140/149	284/194	41.9/42.4	29.1/28.6	L2/3 or L3/4	19	29
						L4/5	98	193
						L5/6 or L6/ S1	1	2
						L5/S1	146	273
						2 levels	15/249	19

Table II. – The basic characteristics of the studies
(population number, gender, age, BMI, and operating level) - 2/2

7	NA/19	NA	8/11	NA/34.7	□	L3/4	□	2
						L4/5		11
						L5/S1		6
8	NA/30	NA	12/18	NA/36.6		L4/5		19
						L5/S1		11
9	NA/75	NA	31/44	NA/45	NA/28	L3/4		8
						L4/5		37
						L5/6		1
						L5/S1		29
10	30/30	20/10	25/5	42.63/41.37	24.43/24.41	L3/4	3	5
						L4/5	24	16
						L5/S1	3	9

fibrosus defect, so subgroup analysis according to the defect size was performed. For patients with large annulus fibrosus defect, namely, high-risk patients, only the repair technique based on ACD device was employed. The analysis demonstrated a disc re-herniation rate (radiology and symptomatic) of 4.4%, a re-herniation induced reoperation rate of 4.3%, and an overall re-operation rate of 7.4% (Table V).

No publication bias was found among the studies.

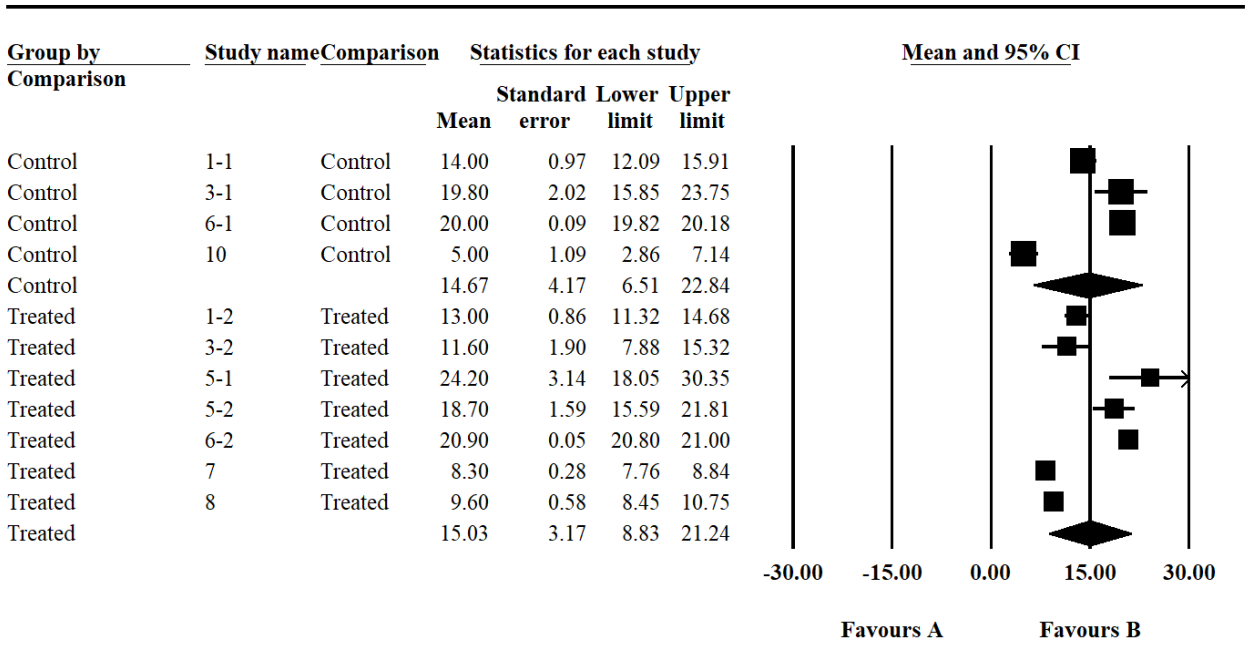


Fig. 2. – Difference of the ODI scale: the forest plots present the mean ODI score of each study with a random effect model. Each square represents the individual study's mean score with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 4; Treated, n = 7. Mean control, 14.67; Treated, 15.03; Significance: P = 0.945.

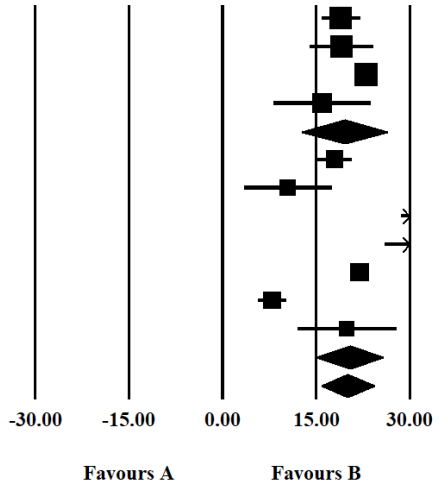
Table III. – The extracted data of matched outcomes

Study	Groups (population number)	□24 months post-operative (mean ± SD or mean (95% CI))			Disc re-herniation (radiological and symptomatic)□	Disc repair related long term complications	Re-operation □number of cases because of re-herniation of the same disc□
		VAS-leg	VAS-back	ODI			
1	control □283□	14 ± 21	19 ± 24	14 ± 15	40		54 (40)
	treated □267□	12 ± 21	18 ± 23	13 ± 14	14	Device failure (4)	27 (14)
2	treated □60□	□	□	□	3		3 (2)
3	control (46)	□	□	□	3		2 (2)
	treated (30)	8.9 ± 20.1	10.5 ± 19.5	11.6 ± 10.4	0	Epidural infection (1)	0 (0)
□	control (72)	21.2 ± 23.1	19.1 ± 21.9	19.8 ± 17.1	5		5 (5)
4	control (29)	□	□	□	5		5 (5)
	treated (45)	□	□	□	1	Mesh dislocation (1)	1 (1)
5	treated-trail (44)	28.2 ± 29.9	38.4 ± 32.7	24.2 ± 20.8	3	Mesh migrations and/or separations (5)	3 (3)
	treated-non-trail (120)	27.6 ± 27.6	30.5 ± 24.8	18.7 ± 17.4	3	Mesh migrations and/or separations (10)	11 (3)
6	control (249)	1.7 (95% CI: 1.3-2.1)	2.3 (95% CI: 1.9-2.7)	20.0 (95% CI: 17.1-22.9)	50	NA	50 (50)
	treated (478)	1.5 (95% CI: 1.2-1.7)	2.2 (95% CI: 2.0-2.5)	20.9 (95% CI: 18.6-23.3)	69	NA	69(69)
7	treated (19)	0.8 ± 0.5	0.8 ± 0.5	8.3 ± 1.2	0	0	0
8	treated (30)			9.6 ± 3.2	0	0	0
9	treated (75)	0.6	1.3	7	1	Epidural infection (1) Device dislocation (1)	3 (1)
10	control (21)	1.2 ± 1.8	1.6 ± 1.8	5 ± 5	6	0	6 (6)
	treated (20)	1.6 ± 2.0	2 ± 1.8	10 ± 11	1	0	1 (1)

DISCUSSION

The present study demonstrated the use of an annular repair device was associated with a significant reduction in the re-herniation and re-operation rates compared to patients without annular repair. But no such difference was found in the functional outcomes, including ODI and VAS scores. There was no difference between the groups with the perioperative complications, but much more device-related long

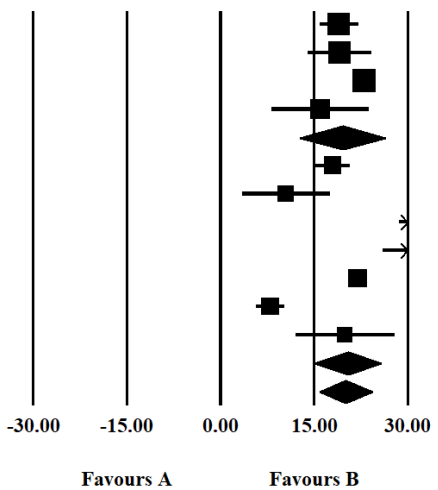
Group by Comparison	Study name	Comparison	Statistics for each study			
			Mean	Standard error	Lower limit	Upper limit
Control	1-1	Control	19.000	1.556	15.951	22.049
Control	3-1	Control	19.100	2.581	14.041	24.159
Control	6-1	Control	23.000	0.129	22.747	23.253
Control	10-1	Control	16.000	3.928	8.301	23.699
Control			19.528	3.490	12.687	26.369
Treated	1-2	Treated	18.000	1.408	15.241	20.759
Treated	3-2	Treated	10.500	3.560	3.522	17.478
Treated	5-1	Treated	38.400	4.930	28.738	48.062
Treated	5-2	Treated	30.500	2.264	26.063	34.937
Treated	6-2	Treated	22.000	0.058	21.886	22.114
Treated	7	Treated	8.000	1.147	5.752	10.248
Treated	10-2	Treated	20.000	4.025	12.111	27.889
Treated			20.380	2.693	15.100	25.659
Overall			20.062	2.132	15.882	24.241



Meta Analysis

Fig. 3. – Difference of the VAS-leg scale: the forest plots present the mean VAS-leg score of each study with a random effect model. Each square represents the individual study's mean score with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 4; Treated, n = 7. Mean control, 16.233; Treated, 15.570; Significance: P =0.82.

Group by Comparison	Study name	Comparison	Statistics for each study			
			Mean	Standard error	Lower limit	Upper limit
Control	1-1	Control	19.000	1.556	15.951	22.049
Control	3-1	Control	19.100	2.581	14.041	24.159
Control	6-1	Control	23.000	0.129	22.747	23.253
Control	10-1	Control	16.000	3.928	8.301	23.699
Control			19.528	3.490	12.687	26.369
Treated	1-2	Treated	18.000	1.408	15.241	20.759
Treated	3-2	Treated	10.500	3.560	3.522	17.478
Treated	5-1	Treated	38.400	4.930	28.738	48.062
Treated	5-2	Treated	30.500	2.264	26.063	34.937
Treated	6-2	Treated	22.000	0.058	21.886	22.114
Treated	7	Treated	8.000	1.147	5.752	10.248
Treated	10-2	Treated	20.000	4.025	12.111	27.889
Treated			20.380	2.693	15.100	25.659
Overall			20.062	2.132	15.882	24.241



Meta Analysis

Fig. 4. – Difference of the VAS-back scale: the forest plots present the mean VAS-back score of each study with a random effect model. Each square represents the individual study's mean score with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 4; Treated, n = 7. Mean control, 19.528; Treated, 20.380; Significance: P = 0.847.

Table IV. – The extracted data of complications

Study	Groups (population number)	Annular repair procedure related short time complications		
		dural tear	nerve root injuries	perioperative infections
1	control (283)	0	NA	6
	treated (267)	1	NA	0
3	control (46)	1	0	0
	treated (30)	1	0	1
4	treated (45)	0	0	0
5	treated-trail (44)	NA	NA	0
	treated-non-trail (120)	NA	NA	4
6	control (249)	4	NA	1
	treated (478)	1	NA	2
7	treated (19)	0	0	0
8	treated (30)	0	0	0
9	treated (75)	1	0	0
Over all	control (mean rate)	0.014	0	0.014
	treated (mean rate)	0.009	NA	0.013
	p	0.516	NA	0.909

Table V. – The extracted data of re-herniation and re-operation rates of high risk patients

Study	Groups (population number)	Re-herniation	Re-operation (number of cases because of re-herniation of the same disc)
1	treated (267)	14	27 (14)
2	treated (60)	3	3 (2)
3&4	treated (65)	1	1 (1)
5	treated-trail (44)	3	3 (3)
	treated-non-trail (120)	3	11 (3)
9	treated (75)	1	3 (1)
Overall rate		4.4%	7.4% (4.3%)

term complications happened in the annual repair group though it still decreased the overall re-operation rate significantly.

Though the minimally invasive surgery "limited" discectomy is more and more widely used worldwide to maintain segmental stability after surgery, concerns regarding re-herniation rates due to the small volume of nuclear material removed have not gone away. Some authors think that the remaining large volume of nuclear material and the annular defect because of the primary herniation or surgery incision are the main reason contributing to post-discectomy re-herniation and, ultimately, reoperation *(13,14)*. In 2006, Carragee et al. reported an 18% re-herniation rate after limited discectomy, compared to 9% after aggressive procedures *(21)*. Some studies also reported a much higher incidence of symptomatic recurrent LDH to about 18%-27.3% in patients with large annular defects (> 6 mm) *(22,24)*. Thus, attempts to reduce the recurrent herniation have been tried repeatedly, and annular repair may be an answer. First reported by Yasargil in 1977 *(25)* and subsequently by others *(26,27)*, the annular repair is considered a valuable method to close the defect and subsequently prevent recurrent herniation.

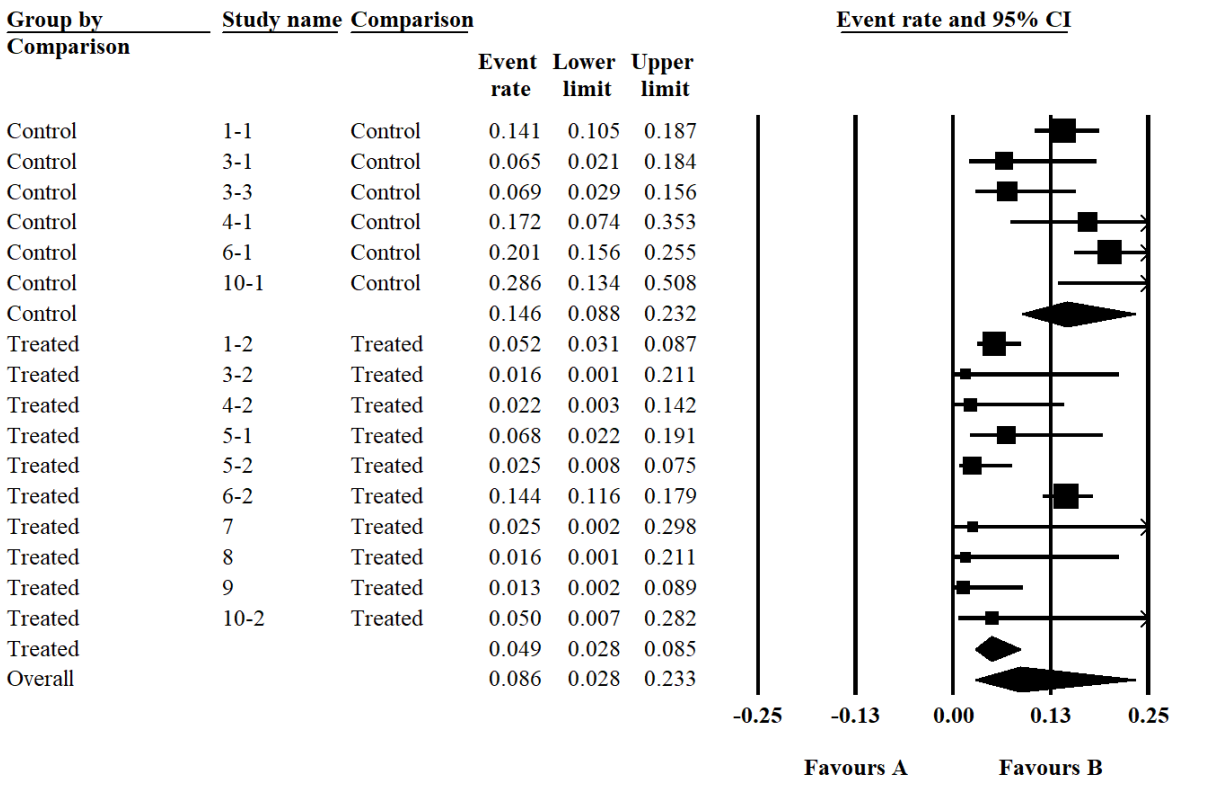


Fig. 5. – Difference of the re-herniation rate: the forest plots present the mean re-herniation rate of each study. Each square represents the individual study's mean rate with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 6; Treated, n = 10. Mean control, 14.6%; Treated, 4.9%; Significance: P = 0.004.

Till now, two kinds of techniques have been developed, the suture-based technique and the annular closure device (Barricaid) technique. The suture-based device includes three different techniques: the Xclose technique, sutures and PushLock technique, and jetting suture technique *(10,14,17)*. The similarity among the three techniques is the use of suture wire to close the annular defect, which is relatively less invasive but also limits the application in large defect or poor annular quality cases, and the biomechanical strength is doubtful *(28)*. The Xclose technique research reported no statistical difference for the rate of re-herniation surgery between patients with an annular repair or not. But there was a significant decrease in predominant leg pain, the non-symptomatic re-herniation risk for patients receiving annular closure *(10)*. For another two techniques, favourable outcomes were also reported as functional assessments improved significantly, and no cases of re-herniation or any annular repair related complications happened. However, neither of the two researches enrolled a control group, so the conclusion was not strong enough *(14,17)*. The subgroup meta-analysis of the suture-based techniques was not available; high evidence level researches are needed to figure out whether these techniques are useful or not.

Barricaid is one of the devices designed for annular closure. It is implanted in the disc space following discectomy and is anchored into one of the adjacent vertebral bodies, which can restore intradiscal pressures to preoperative levels *(29)*. The implantation of it has been associated with greater disc height maintenance and improved one-year leg pain, back pain, low back disability, and most importantly, decreased incidence of recurrent disc herniation *(12,30)*. However, there

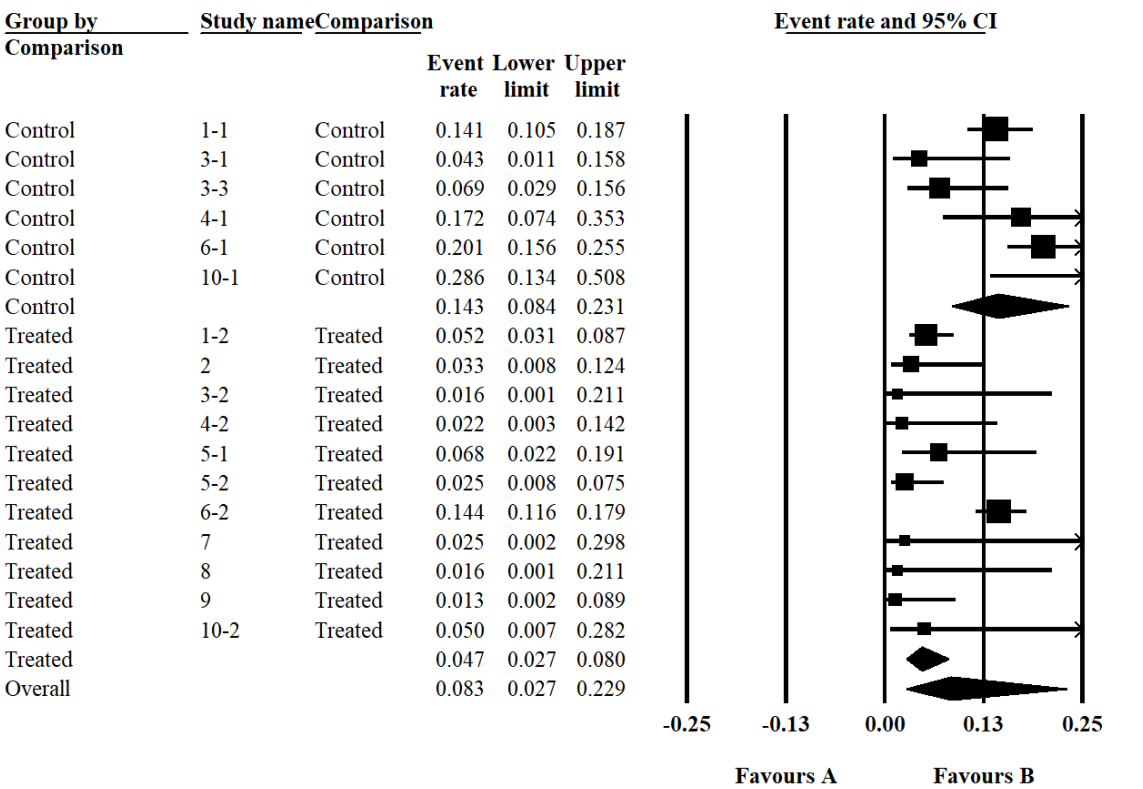


Fig. 6. – Difference of the re-herniation related re-operation rate: the forest plots present the mean re-operation rate of each study. Each square represents the individual study's mean rate with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 6; Treated, n = 11. Mean control, 14.3%; Treated, 4.7%; Significance: P = 0.004.

is also a lot of worries about the Barricaid device, especially for the complex implanting procedures, which means a longer surgery time and more invasive procedures and the device implanting related short and long term complications *(31)*. The present study demonstrated a symptomatic disc re-herniation rate of 4.4%, a re-herniation induced reoperation rate of 4.3%, and an overall re-operation rate of 7.4% with the use of ACD device in large annular defect patients, which is much lower than those reported re-herniation rates (12%-27%) *(23,32,33)* and re-operation rate (12%-20%) in patients treated with discectomy only *(32,34)*. Moreover, the procedure safety was not a major concern as there was no statistically significant difference for the perioperative complications, and though more long-term device-related complications, there was no statistically significant difference for the overall re-operation rate. Token together, the present meta-analysis demonstrated that the use of an annular repair device was associated with a significant reduction in the re-herniation and re-operation rates compared to patients without repair. There are several limitations with the present study. First, the heterogeneity among the studies included. Four different annular repair techniques and two diverse population were employed, and most importantly, the medical-related differences. For example, the patient inclusion criteria, the definition of re-herniation and the re-operation criteria differed from each other, and the discectomy procedure and functional evaluation standard. The recovery procedures also differed from each other, which might affect the post-operation rehabilitation. Second, the follow-up time points were various among the studies, and no long-time follow-

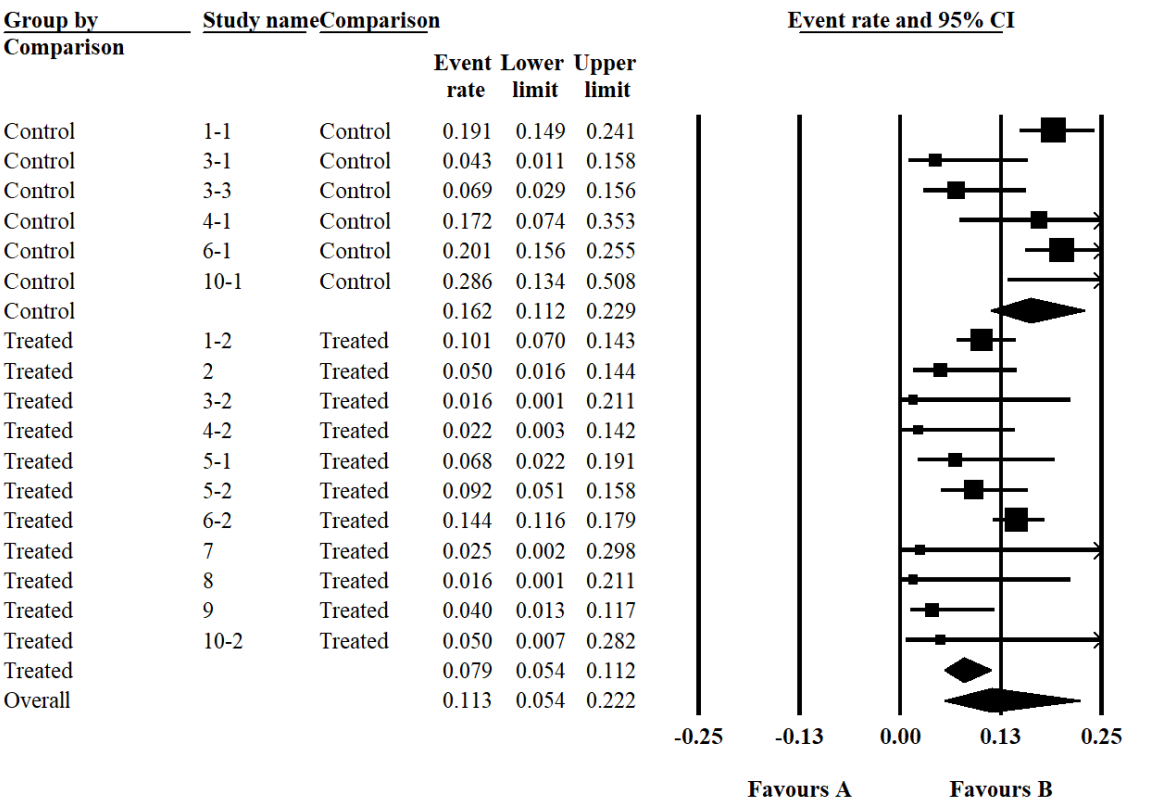


Fig. 7. – Difference of the overall re-operation rate: the forest plots present the mean re-operation rate of each study. Each square represents the individual study's mean rate with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 6; Treated, n = 11. Mean control, 16.2%; Treated, 7.9%; Significance: P = 0.006.

up was available. Third, no short-term functional outcomes were analyzed, considering the more tissue damage due to the complex procedures for annular repair. Finally, though all the researches included reported no potential conflict of interest, the industry and surgeon bias could not be ignored. It's not sure whether the surgeons were less likely to perform a reoperation or even report the negative results if they had already used a closure device.

CONCLUSION

Our results demonstrated that using an annular repair device was safe and beneficial for reducing re-herniation and re-operation rates.

Abbreviations: lumbar disc herniation (LDH); standard difference of the means (SDM); relative risks (RRs); annular closure device (ACD); annular tissue repair system (AR).

REFERENCES

1. **Ravindra VM, Senglaub SS, Rattani A, Dewan MC, Hartl R, Bisson E, *et al.*** Degenerative Lumbar Spine Disease: Estimating Global Incidence and Worldwide Volume. *Global Spine J.* 2018;8(8):784-94.
2. **Hanley EN, Jr., Shapiro DE.** The development of low-back pain after excision of a lumbar disc. *J Bone Joint Surg Am* Vol. 1989;71(5):719-21.
3. **Spengler DM.** Lumbar discectomy. Results with limited disc excision and selective foraminotomy. *Spine.* 1982;7(6):604-7.
4. **Kim CH, Chung CK, Park CS, Choi B, Kim MJ, Park BJ.** Reoperation rate after surgery for lumbar herniated

intervertebral disc disease: nationwide cohort study. *Spine.* 2013;38(7):581-90.

5. **Leven D, Passias PG, Errico TJ, Lafage V, Bianco K, Lee A, *et al.*** Risk Factors for Reoperation in Patients Treated Surgically for Intervertebral Disc Herniation: A Subanalysis of Eight-Year SPORT Data. *J Bone Joint Surg Am* Vol. 2015;97(16):1316-25.
6. **Chen JX, Li YH, Wen J, Li Z, Yu BS, Huang YC.** Annular Defects Impair the Mechanical Stability of the Intervertebral Disc. *Global Spine J*. 2021:21925682211006061.
7. **Ammerman J, Watters WC, Inzana JA, Carragee G, Groff MW.** Closing the Treatment Gap for Lumbar Disc Herniation Patients with Large Annular Defects: A Systematic Review of Techniques and Outcomes in this High-risk Population. *Cureus.* 2019;11(5):e4613.
8. **Kursumovic A, Rath S.** Performance of an Annular Closure Device in a 'Real-World', Heterogeneous, At-Risk, Lumbar Discectomy Population. *Cureus.* 2017;9(11):e1824.
9. **Martin BI, Mirza SK, Spina N, Spiker WR, Lawrence B, Brodke DS.** Trends in Lumbar Fusion Procedure Rates and Associated Hospital Costs for Degenerative Spinal Diseases in the United States, 2004 to 2015. *Spine.* 2019;44(5):369-76.
10. **Bailey A, Araghi A, Blumenthal S, Huffmon GV.** Anular Repair Clinical Study G. Prospective, multicenter, randomized, controlled study of anular repair in lumbar discectomy: two-year follow-up. *Spine*. 2013;38(14):1161-9.
11. **Hahn BS, Ji GY, Moon B, Shin DA, Ha Y, Kim KN, *et al.*** Use of Annular Closure Device (Barricaid(R)) for Preventing Lumbar Disc Reherniation: One-Year Results of Three Cases. Korean *J Neurotrauma.* 2014;10(2):119-22.
12. **Parker SL, Grahovac G, Vukas D, Vilendecic M, Ledic D, McGirt MJ, *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):454-60.
13. **Trummer M, Eustacchio S, Barth M, Klassen PD, Stein S.** Protecting facet joints post-lumbar discectomy: Barricaid annular closure device reduces risk of facet degeneration. *Clin Neurol Neurosurg.* 2013;115(8):1440-5.
14. **Qi L, Li M, Si H, Wang L, Jiang Y, Zhang S, *et al.*** The clinical application of "jetting suture" technique in annular repair under microendoscopic discectomy: A prospective single-cohort observational study. *Medicine.* 2016;95(31):e4503.
15. **Martens F, Lesage G, Muir JM, Stieber JR.** Implantation of a bone-anchored annular closure device in conjunction with tubular minimally invasive discectomy for lumbar disc herniation: a retrospective study. *BMC Musculoskelet Disord*. 2018;19(1):269.
16. **Klassen PD, Hsu WK, Martens F, Inzana JA, van den Brink WA, Groff MW, *et al.*** Post-lumbar discectomy reoperations that are associated with poor clinical and socioeconomic outcomes can be reduced through use of a novel annular closure device: results from a 2-year randomized controlled trial. *CEOR.* 2018;10:349-57.
17. **Suh BG, Uh JH, Park SH, Lee GW.** Repair using conventional implant for ruptured annulus fibrosus after lumbar discectomy: surgical technique and case series. *Asian Spine J*. 2015;9(1):14-21.
18. **Li J, Yuan X, Li F, Wang F, Li Y, Wang E, *et al.*** A novel full endoscopic annular repair technique combined with autologous conditioned plasma intradiscal injection: a new safe serial therapeutic model for the treatment of lumbar disc herniation. *Ann Palliat Med.* 2021;10(1):292-301.
19. **Yang JJ, Lin YY, Chao KH, Wang JL.** Gelatin-Poly (gamma-Glutamic Acid) Hydrogel as a Potential Adhesive for Repair of Intervertebral Disc Annulus Fibrosus: Evaluation of Cytocompatibility and Degradability. *Spine.* 2021;46(4):E243-E9.
20. **Downs SH, Black N.** The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Public Health*. 1998;52(6):377-84.
21. **Carragee EJ, Spinnickie AO, Alamin TF, Paragioudakis S.** A prospective controlled study of limited versus subtotal posterior discectomy: short-term outcomes in patients with herniated lumbar intervertebral discs and large posterior anular defect. *Spine*. 2006;31(6):653-7.
22. **Kim KT, Lee DH, Cho DC, Sung JK, Kim YB.** Preoperative Risk Factors for Recurrent Lumbar Disk Herniation in L5-S1. *J Spinal Disord Tech.* 2015;28(10):E571-7.
23. **Carragee EJ, Han MY, Suen PW, Kim D.** Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and anular competence. *J Bone Joint Surg Am* Vol. 2003;85(1):102-8.
24. **Martens F, Vajkoczy P, Jadik S, Hegewald A, Stieber J, Hes R.** Patients at the Highest Risk for Reherniation Following Lumbar Discectomy in a Multicenter Randomized Controlled Trial. *JB & JS open access.* 2018;3(2):e0037.
25. **Dauch WA.** Infection of the intervertebral space following conventional and microsurgical operation on the herniated lumbar intervertebral disc. A controlled clinical trial. *Acta Neurochir* (Wien). 1986;82(1-2):43-9.
26. **Tomkins-Lane C, Melloh M, Lurie J, Smuck M, Battie MC, Freeman B, *et al.*** ISSLS Prize Winner: Consensus on the Clinical Diagnosis of Lumbar Spinal Stenosis: Results of an International Delphi Study. *Spine.* 2016;41(15):1239-46.
27. **Kursumovic A, Rath SA.** Effectiveness of an annular closure device in a "real-world" population: stratification of registry data using screening criteria from a randomized controlled trial. *Medical devices.* 2018;11:193-200.
28. **Long RG, Torre OM, Hom WW, Assael DJ, Iatridis JC.** Design Requirements for Annulus Fibrosus Repair: Review of Forces, Displacements, and Material Properties of the Intervertebral Disk and a Summary of Candidate Hydrogels for Repair. *J Biomech Eng.* 2016;138(2):021007.

29. **Bostelmann R, Steiger HJ, Cornelius JF.** Effect of Annular Defects on Intradiscal Pressures in the Lumbar Spine: An in Vitro Biomechanical Study of Diskectomy and Annular Repair. *J Neurol Surg A Cent Eur Neurosurg.* 2016;78(01):46-52.
30. **Ledic D, Vukas D, Grahovac G, Barth M, Bouma GJ, Vilendecic M.** Effect of anular closure on disk height maintenance and reoperated recurrent herniation following lumbar diskectomy: two-year data. *J Neurol Surg A Cent Eur Neurosurg.* 2015;76(3):211-8.
31. **Choy WJ, Phan K, Diwan AD, Ong CS, Mobbs RJ.** Annular closure device for disc herniation: meta-analysis of clinical outcome and complications. *BMC Musculoskelet Disord.* 2018;19(1):290.
32. **Heindel P, Tuchman A, Hsieh PC, Pham MH, D'Oro A, Patel NN, *et al.*** Reoperation Rates After Single-level Lumbar Discectomy. *Spine*. 2017;42(8):E496-E501.
33. **McGirt MJ, Eustacchio S, Varga P, Vilendecic M, Trummer M, Gorensek M, *et al.*** A prospective cohort study of close interval computed tomography and magnetic resonance imaging after primary lumbar discectomy: factors associated with recurrent disc herniation and disc height loss. *Spine.* 2009;34(19):2044-51.
34. **Martin BI, Mirza SK, Flum DR, Wickizer TM, Heagerty PJ, Lenkoski AF, *et al.*** Repeat surgery after lumbar decompression for herniated disc: the quality implications of hospital and surgeon variation. *Spine J.* 2012;12(2):89-97.