

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

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## Research article

**Keywords:** annular repair, LDH, Annular closure device, Recurrent disc herniation, Barricaid, Anulex, Xclose

**Posted Date:** June 8th, 2020

**DOI:** <https://doi.org/10.21203/rs.3.rs-32052/v1>

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# Abstract

## Background

The annular defect because of the primary lumbar disc herniation (LDH) or surgical procedure is considered as a main 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 after limited discectomy for LDH patients.

## Methods

The Pubmed, Cochrane library, and Embase databases were searched to retrieve relevant studies published before January 1, 2020. 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.

## Results

A total of 10 researches were suitable for the meta-analysis, including four different repair techniques and a total of 1907 participates (1203 treated and 704 control). In comparison with the control group, there was no statistical difference with the ODI, VAS-leg, and VAS-back scales for patients treated with annular repair. However, the use of 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 the perioperative complications, but much more device related long term complications happened in the annual repair group ( $p=0.031$ ) though it still decreased the overall re-operation rate significantly ( $p=0.006$ ).

## Conclusion

Our results demonstrated that the use of an annular repair device was safe and useful for reducing re-herniation and re-operation rates.

# Introduction

Lumbar disc herniation (LDH) is one of the most common happened spine disorders, with over 266 million patients all over the world diagnosed per year [1]. Surgical discectomy, especially open discectomy, is considered the standard treatment with favorable outcomes. Initially, a radical discectomy including both the disc material and the cartilaginous endplates were recommended for the standard procedure. Though great outcomes about the primary LDH 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 that excising only fragments with minimal

invasive exposure was more and more widely used to minimize the influence to the segmental stability [3]. However, the incidence of reoperation persists at 13% to 25% after the limited discectomy procedure, mainly due to the symptomatic recurrent disc herniation presenting as the primary contributor [4,5]. The annular defect because of the primary LDH or discectomy, especially for cases with large and massive defect ( $\geq 6$  mm), is considered as the main reason for recurrent disc herniation [6-8]. Thus, lots of 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 implantation of an annular closure device (ACD) – Barricaid™ (Intrinsic Therapeutics, Inc., Woburn, MA, USA), using an annular tissue repair system (AR) – Anulex-Xclose (Anulex Technologies, Minnetonka, MN), utilizing No. 2 fiberwire sutures and PushLock implants [9-12], and “jetting suture” technique [13]. However, controversy results were reported about the outcomes during follow-up [14,15,11,9,16]. The present study aims to figure out whether the annular repair technique is useful for reducing recurrent LDH after limited discectomy.

## Methods

The Pubmed, Cochrane library, and Embase databases were searched independently by 2 investigators (Q.Z and J.L.T) to retrieve relevant studies published before January 1, 2020. 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. Papers were excluded if no matched outcomes were reported or were laboratory studies. When several reports from the same study were published, only the most recently or informative one was included. The language was restricted to only English.

Data extraction:

The data extraction of all variables and outcomes of interest were performed independently by 2 readers (Q.Z and J.L.T). Disagreements were resolved through discussion and consensus. The methodological quality of the included studies was assessed by the Quality Index, which consisted of 27 items distributed between five sub-scales [17]. 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.

## Statistical analysis:

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 I<sup>2</sup>. This value ranges from 0% (complete consistency) to 100% (complete inconsistency). A random-effects model was used if the Q or I<sup>2</sup> 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

### Literature Search

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 participants (1203 treated and 704 control) were enrolled in the study. The key characteristics of the included studies are summarized in Table 1. 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 utilized suture-based techniques including Xclose technique, No. 2 fiberwire sutures and PushLock implant technique, and jetting suture technique. Most studies followed the patients for at least 2 years and only one reported the outcomes at the mean of 15 months. Table 2 listed the basic characteristics of the studies, including population number, gender, age, BMI, and operating level.

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 3 listed the extracted matched outcomes. On review of the data extraction, there was 100% agreement between the 2 reviewers. According to the checklist for measuring study quality, all the studies were considered as medium/high quality of methodology. Thus, the methodological bias of this study was considered low.

### Main Analysis

In comparison 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 compared with the control group (4.7% vs. 14.3%,  $p=0.004$ , Fig.6), when only take 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. As the additional annular repair procedures, there is no doubt that the surgical time and blood loss are much more in annular repair group. For peri-operation complications, all annular repair techniques seem safe enough as only a few complications (mainly dural tear and perioperative infections) were reported, with no statistically significant difference found (Table 4). However, there were much more device related long term complications such as device failure, loosening, migration, and epidural infection happened in annular repair group, especially for the cases with ACD (Barricaid) technique ( $p=0.031$ , Table 3). 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 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 5).

#### Publication bias

No publication bias was found among the studies.

## 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. 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 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 all over the world to maintain the segmental stability after surgery, concerns regarding re-herniation rates due to the small volume of nuclear material removed has not gone away. It is thought by some authors 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 [18]. 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) [19-21]. Thus, attempts to reduce the recurrent herniation have been tried again and again, and annular repair may be an answer. First reported by Yasargil in 1977[22] and subsequently by others [23,24], the annular repair is considered as a valuable method to close the defect and subsequently prevent recurrent herniation.

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, No. 2 fiberwire sutures and PushLock implants technique, and jetting suture technique [9,16,13]. 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 [25]. The Xclose technique research reported no statistical difference for the rate of re-herniation surgery between patients with annular repair or not. But there was a significant decrease in predominant leg pain, non-symptomatic re-herniation risk for patients receiving annular closure [9]. For another two techniques, favorable 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 [13,16]. 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 is considered able to restore intradiscal pressures to preoperative levels [26]. The implantation of it has been associated with greater maintenance of disc height and improved one-year leg pain, back pain, low back disability, and most importantly, decreased incidence of recurrent disc herniation [11,27]. However, there 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, as well as the device implanting related short and long term complications [28]. 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%) [29,20,30] and re-operation rate (12%-20%) in patients treated with discectomy only [31,29]. 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. Taken 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. There are several limitations with the present study, first, the heterogeneity among the studies included. Four different

annular repair techniques and two different 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, as well as 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 different among the studies, and no long-time follow-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 the use of an annular repair device was safe and useful 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).

## Declarations

§ Ethics approval and consent to participate: Not applicable.

§ Consent for publication: Not applicable.

§ Availability of data and material: We state that all data generated during the present study are included in this article.

§ 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).

§ Authors' contributions: Q.Z and GM.G performed the study design. Q.Z and JL.T participated in the literature search and data extraction. Q.Z and JL.T were in charge of quality assessment and statistical analysis. YQ.J, HB.L, GM.G and LM.N was responsible for the literature review. All authors read and approved the final manuscript.

§ Acknowledgements: Thanks for anyone helpful but not able to list in the manuscript.

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## Tables

Table 1. 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

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

Study	Population	Gender (Male/ Female)		Age (mean)	BMI (mean)	operate level			
		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	
	46/NA			41/NA		L3/4	2		
						L4/5	24		
4	29/45	14/15	24/21	40.1/42.3	26.3/26	L5/S1	20	12	
						L3/4	0	2	
						L4/5	10	22	
5	NA/44 (Trail)	NA	25/19	NA/46.7		L5/S1	19	21	
						L3/4			
						L4/5			
						L5/6			
	NA/120 (Non-Trail)	NA	66/54	NA/45.6			L5/S1		1
							L3/4		1
							L4/5		25
							L5/6		0
6	249/478	140/149	284/194	41.9/42.4	29.1/28.6	L2/3 or L3/4		17	
						L4/5		19	
						L5/6 or L6/S1		25	
						L5/S1	1	0	
						2 levels	146	19	
7	NA/19	NA	8/11	NA/34.7		L5/S1	15/249	19	
						L3/4		2	
						L4/5		11	
8	NA/30	NA	12/18	NA/36.6		L5/S1		6	
						L4/5		19	
9	NA/75	NA	31/44	NA/45	NA/28	L5/S1		11	
						L3/4		8	
						L4/5		37	
						L5/6		1	
10	30/30	20/10	25/5	42.63/41.37	24.43/24.41	L5/S1		29	
						L3/4	3	5	
						L4/5	24	16	
						L5/S1	3	9	

Table 3. 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)

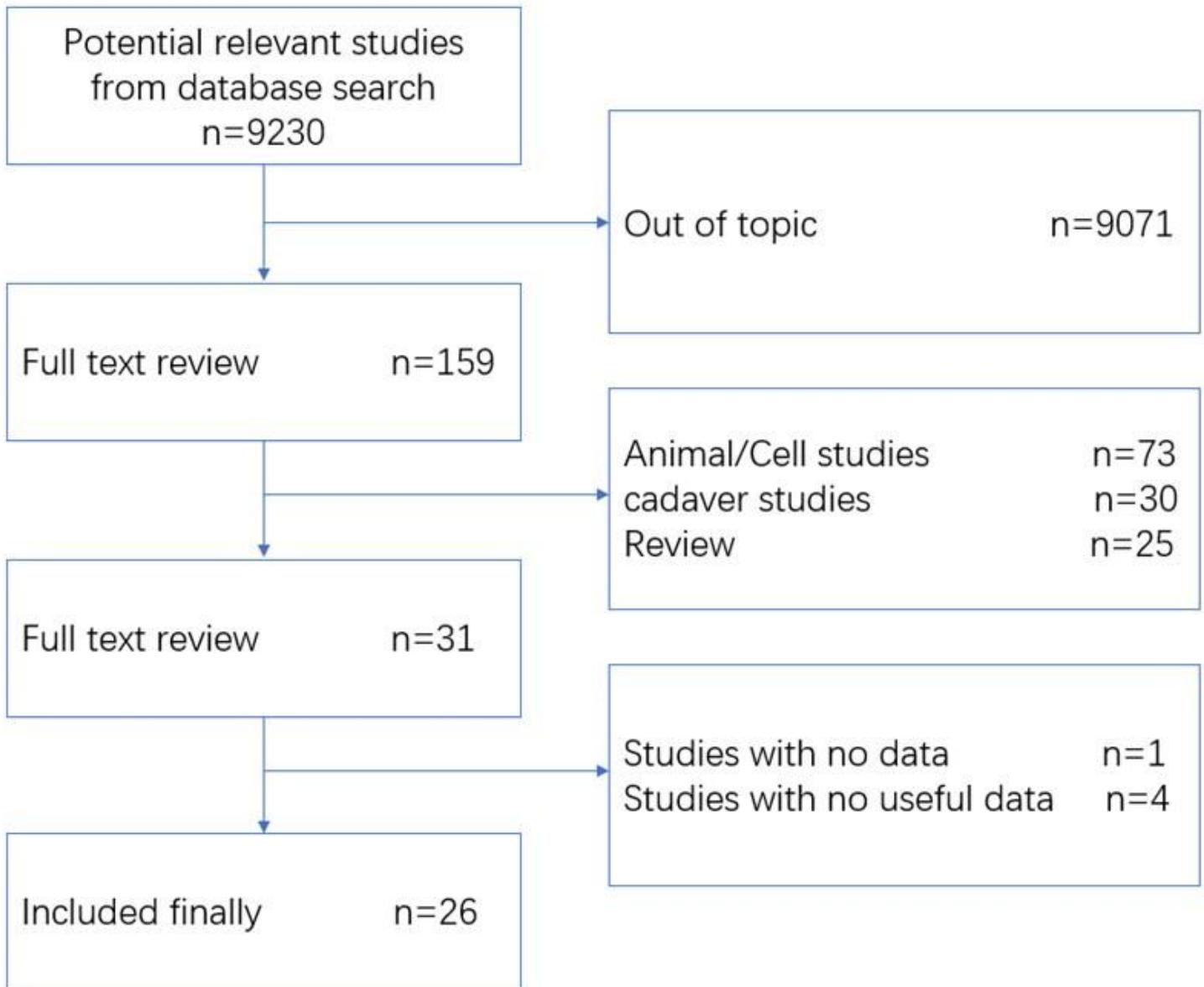
Table 4. The extracted data of complications

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 5. The extracted data of re-herniation and re-operation rates of high risk patients.

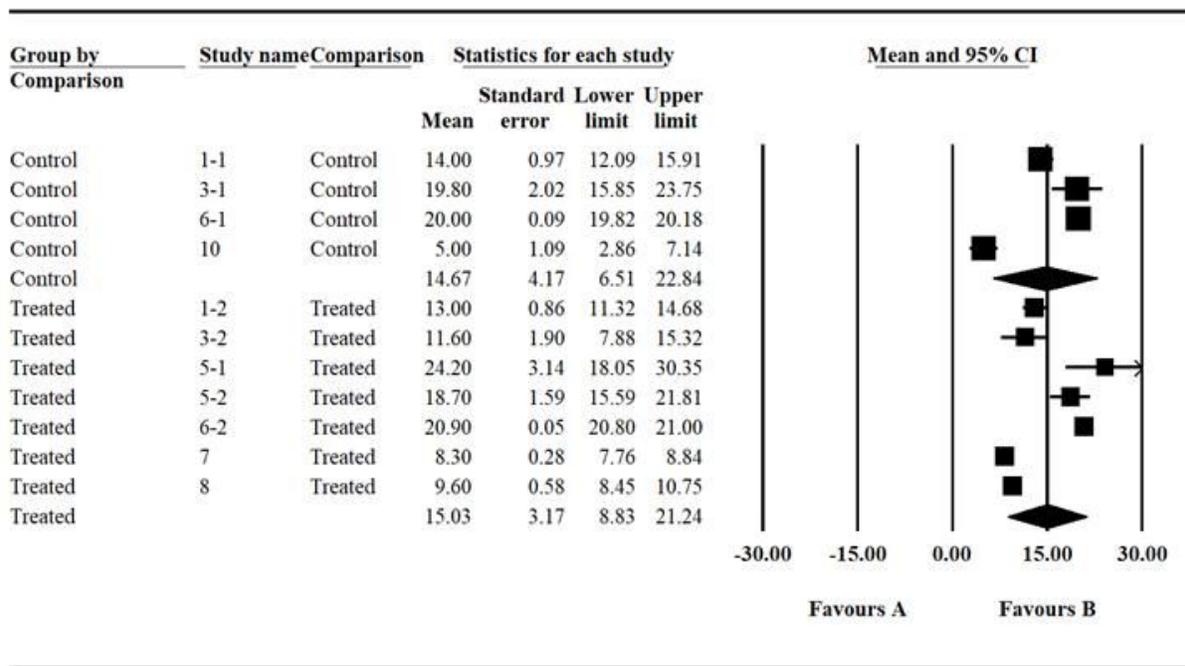
Study	Groups (population number)	Re-herniation	Re-operation (number of cases because of re-herniation of the same disc)
1	treated [267]	14	27 (14)
2	treated [60]	3	3 (2)
3&4	treated (65)	1	1 (1)
5	treated-trail (44)	3	3 (3)
	treated-non-trail (120)	3	11 (3)
9	treated (75)	1	3 (1)
Overall rate		4.4%	7.4%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

## Figures



**Figure 1**

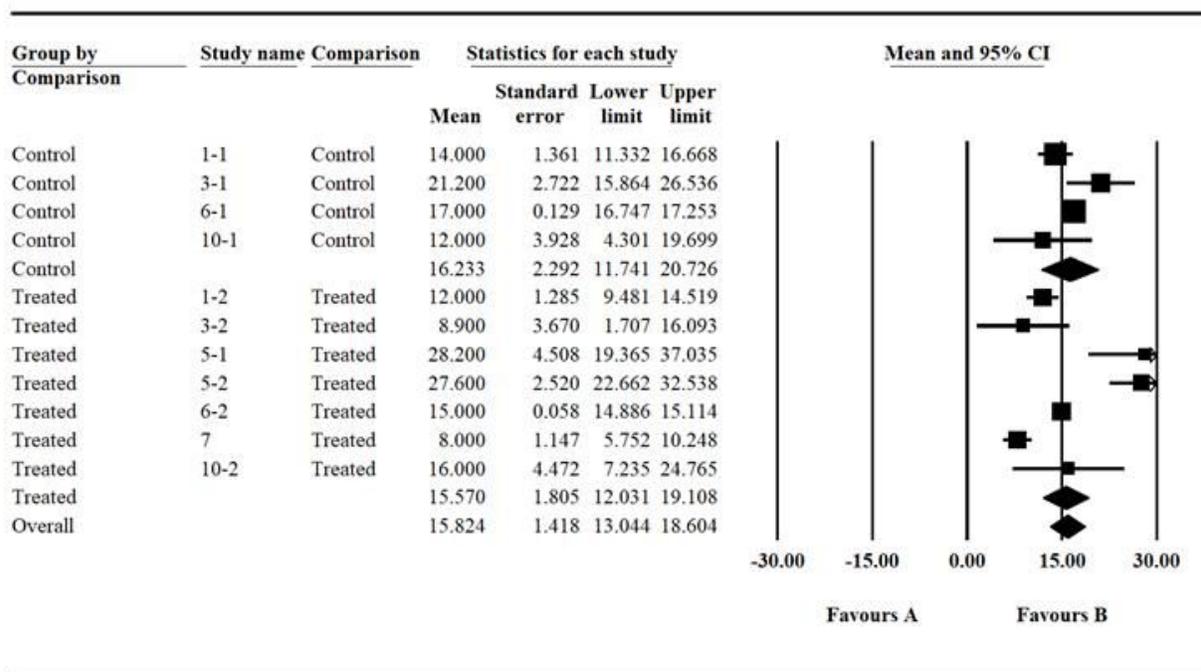
Search strategy flow diagram



Meta Analysis

Figure 2

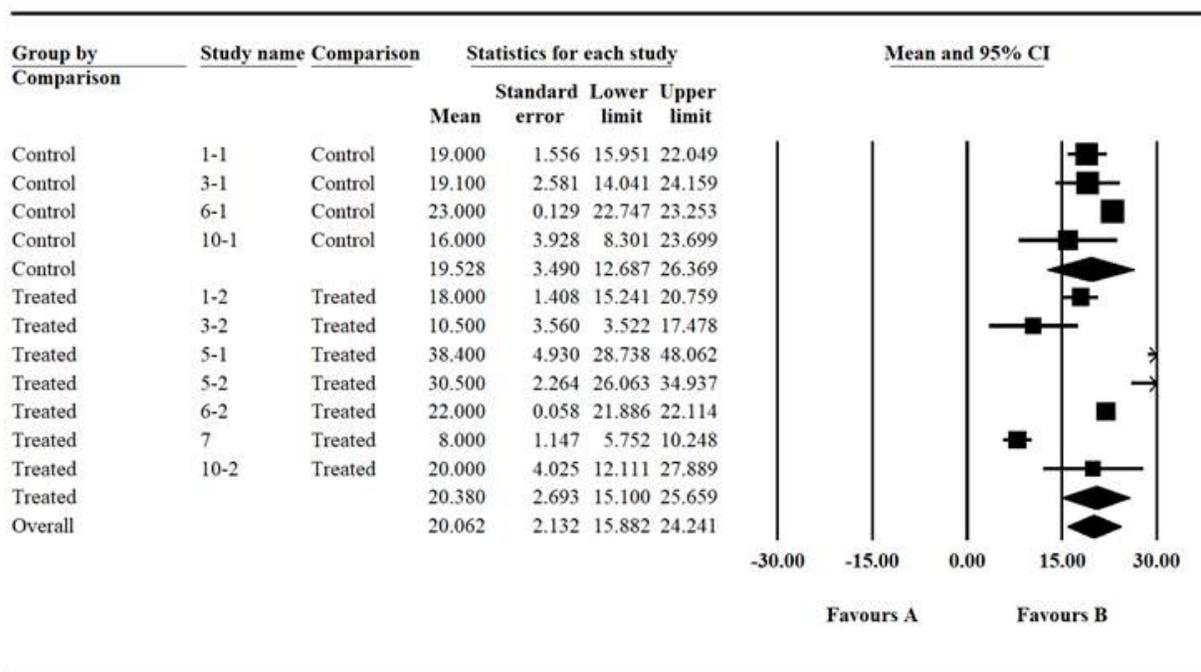
Difference of the ODI scale: the forest plots present the mean ODI score of each study with a random effect model. Each square represents the individual study's mean score with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 4; Treated, n = 7. Mean control, 14.67;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



**Meta Analysis**

**Figure 3**

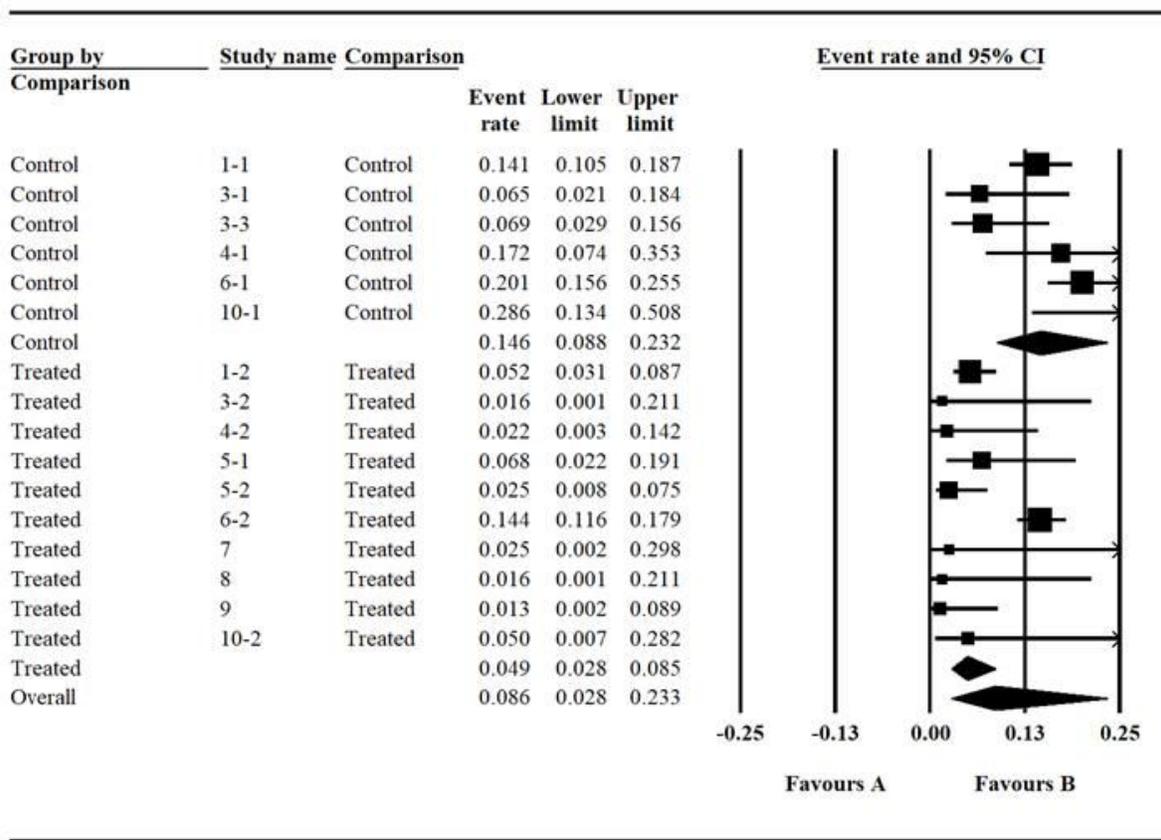
Difference of the VAS-leg scale: the forest plots present the mean VAS-leg score of each study with a random effect model. Each square represents the individual study's mean score with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 4; Treated, n = 7. Mean control,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



Meta Analysis

Figure 4

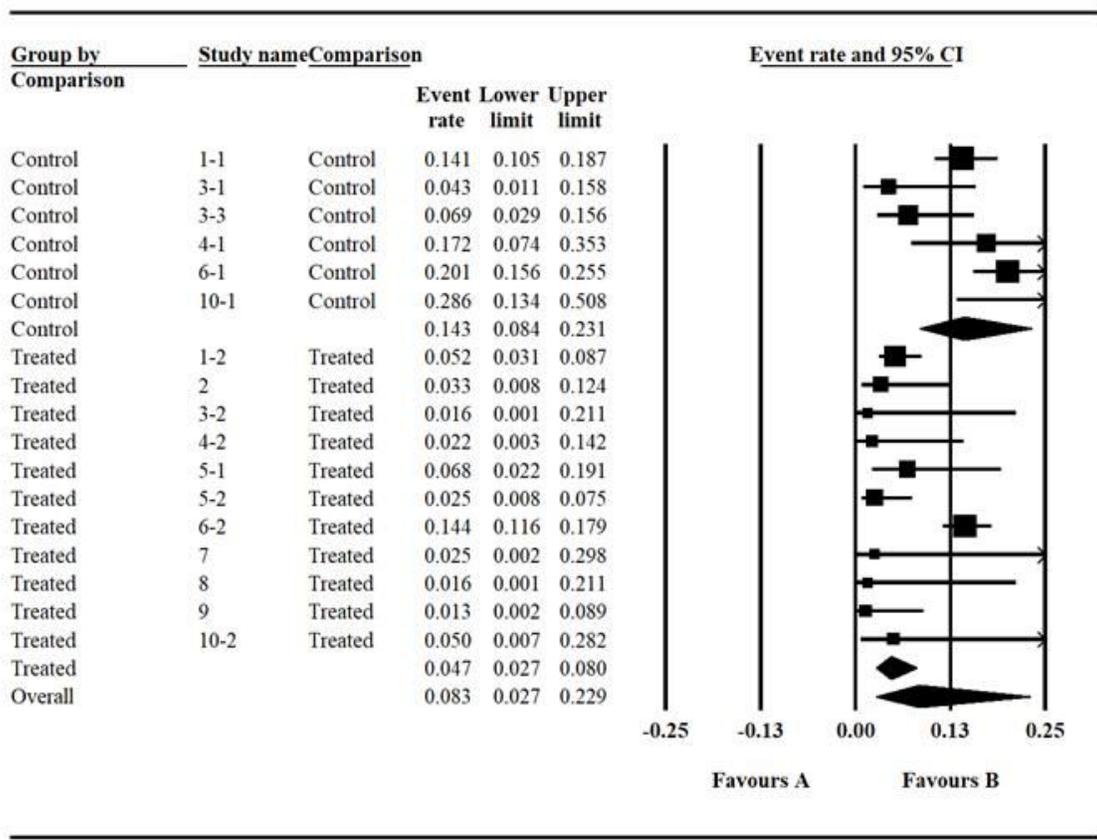
Difference of the VAS-back scale: the forest plots present the mean VAS-back score of each study with a random effect model. Each square represents the individual study's mean score with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 4; Treated, n = 7. Mean control,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



Meta Analysis

Figure 5

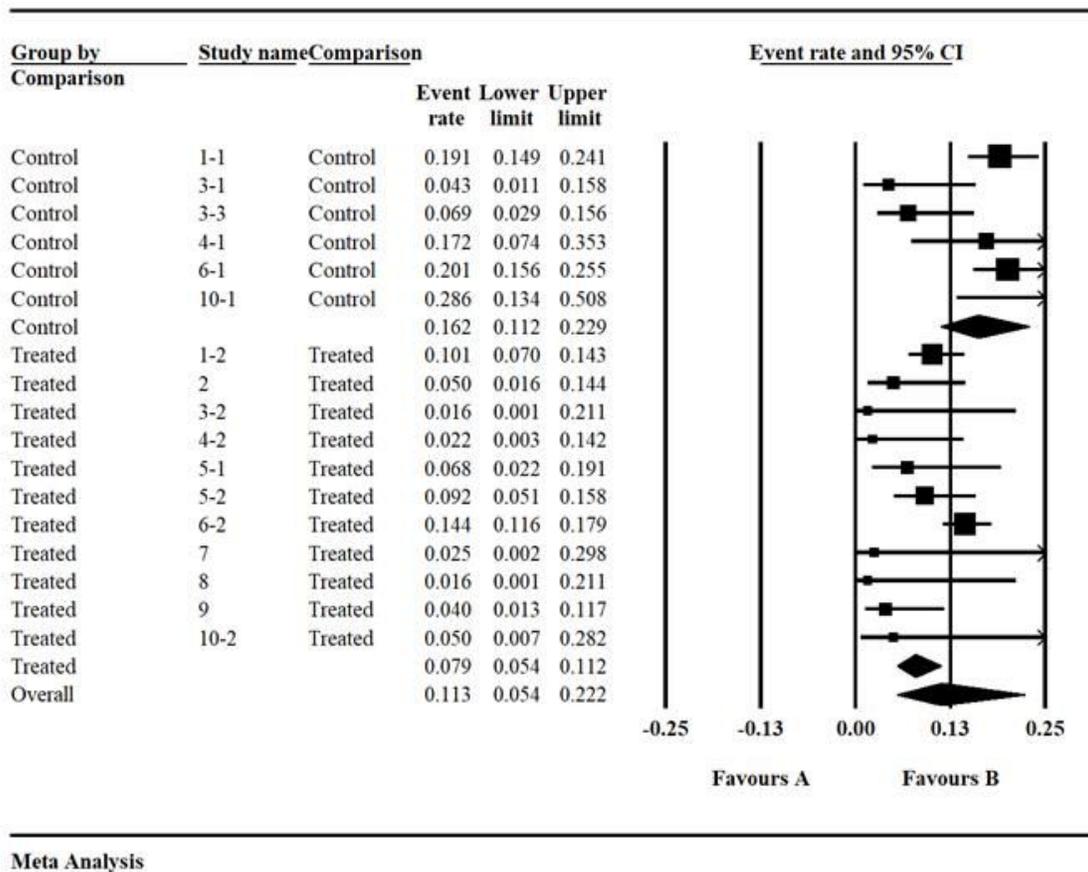
Difference of the re-herniation rate: the forest plots present the mean re-herniation rate of each study. Each square represents the individual study's mean rate with a 95 % CI indicated by the horizontal lines. Number of included studies: Control, n = 6; Treated, n = 10. Mean control, 14.6%; Treated,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



Meta Analysis

Figure 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.



**Figure 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.