



# Comparison of the Success Rate of Filled and Unfilled Resin-Based Fissure Sealants: A Systematic Review and Meta-Analysis

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## ABSTRACT

**Objectives:** Incorporation of fillers might improve the physical properties of sealants. This systematic review and meta-analysis evaluated the retention and caries development rate of filled and unfilled fissure sealants.

**Materials and Methods:** This study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. The PubMed, Scopus, Embase, Cochrane Database of Systematic Reviews, and ISI Web of Knowledge were searched until October 24, 2019. The risk of bias (ROB) was assessed for the included studies based on the Cochrane collaboration common scheme for bias, and the meta-analysis was performed through a random effects model.

**Results:** The search resulted in 6,336 unrepeated relevant studies. After the title, abstract and full-text screening, 19 studies with 26 comparing groups were finally included in this systematic review and meta-analysis. According to the included studies, both retention rate and caries development in filled and unfilled resin-based sealants did not significantly differ within 2 years of follow-up.

**Conclusion:** Since there was no significant difference in the retention rate and caries development between filled and unfilled sealants, it seems that the final decision should be made uniquely for each patient according to the type of fissure, patient's age, habits, etc.

**Keywords:** Pit and Fissure Sealants; Composite Resins; Meta-Analysis as Topic

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## INTRODUCTION

Pit and fissure sealant therapy is one of the most favorable techniques used in preventive dentistry [1]. A large number of clinical reports are available, indicating that pit and fissure sealants can successfully decrease dental caries [2]. A physical barrier over susceptible pits and fissures might prevent the caries process [3]. Sealant products are available in a variety of forms, viscosities, colors, and filler contents [4]. In addition, their physical characteristics, flowability, and wear

resistance depend on their filler content. Retention is an essential factor that affects the longevity of sealants [5,6]. Theoretically, unfilled sealants can penetrate deeper into the fissures due to their low viscosity so that they might exhibit better retention [7]. Occlusal adjustments are not required when unfilled sealants are applied because unfilled sealants undergo rapid wear because of the lack of fillers. Therefore, it might be considered an advantage because they save time and cost. However, it has been reported that filler

content is necessary to achieve a low shrinkage rate and a high wear resistance [7], giving rise to better longevity. This systematic review and meta-analysis aimed to evaluate the retention and caries susceptibility of filled and unfilled fissure sealants.

**MATERIALS AND METHODS**

*Eligibility criteria, information sources, and search strategy:*

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines were used to design this systematic review and meta-analysis. The PICOS (participants, intervention, comparison, outcomes, and study analysis) were defined (Table 1) and studies were reviewed.

**Table 1.** Search strategy using PICOS analysis

	<b>Definition</b>	<b>Main Search Terms for PUBMED*</b>
<b>Participants</b>	All teeth with fissure sealant preventative treatment	("Pit and Fissure Sealants"[Mesh]) OR (Fissure Sealant) OR (Fissure Sealants) OR (Fissure Seal)
<b>Intervention</b>	Filled fissure sealant material	Search results manually screened to include all studies with both filled and unfilled fissure sealant materials.
<b>Comparisons</b>	Unfilled fissure sealant material	
<b>Outcomes</b>	Not applicable	----
<b>Study design</b>	All included	Search results manually screened to include randomized controlled clinical trials.

\*controlled vocabulary and free text terms

A search was conducted in PubMed, Scopus, Embase, Cochrane Database of Systematic Reviews (via Wiley Online Library), and ISI Web of Knowledge (all databases, including the Web of Science Core Collection, BIOSIS previews, Current Contents Connect, Data

Citation Index, KCI Korean Journal Database, Russian Science Citation Index, SciELO Citation Index, Zoological Record) up to October 24, 2019, to identify studies for inclusion in the current systematic review. The databases above are frequently used in dentistry and other medical fields to develop search strategies. No language or date limits were applied during the search. The authors were contacted for clarification or any extra data, if necessary. For possible inclusion of studies from the gray literature and supplementary search, the cited references of the selected articles were also searched.

*Inclusion and exclusion criteria:*

The randomized or quasi-randomized clinical studies with at least six months of follow-up, which evaluated retention rate with or without caries development and reported the sample size and success rate of each group accurately, were included in this systematic review. Studies that reported P-values were included in the meta-analysis.

*Data selection:*

Two blinded observers, a postgraduate student of pediatric dentistry (EB) and a dental biomaterials PhD candidate (KSH), reviewed the articles independently and selected the relevant articles based on the inclusion criteria. When any disagreement arose, they resolved it by discussion and reached a consensus; if necessary, a third observer (ASS) made the final decision.

*Data extraction:*

The following information was extracted from the articles: Author and year of study, country, tooth sample, type of isolation, follow-up duration, type of material, sample size, outcome (the incidence of caries, complete retention rate, or both), P-values, and the effect of treatment (whether filled or unfilled sealants were better or no difference). Unclear or missing data were requested from the relevant corresponding authors via e-mail; if they did not reply, a second e-mail was sent. All the selected articles were imported into an EndNote Library (EndNote X9, Clarivate Analytics, Philadelphia, PA, USA); the duplicate studies were eliminated.

The risk of bias (ROB) in the included studies was assessed by two different observers (EB and KS) and based on the Cochrane collaboration common scheme for bias [8], which includes random sequence generation, allocation concealment, blinding of the participants and personnel, blinding of the outcome assessment, incomplete outcome data, selective reporting, and so forth. According to the parameters stated above, the articles were classified into three categories: (1) unclear risk, (2) low risk, and (3) high ROB.

#### *Assessment of publication bias:*

Based on the Cochrane Handbook for Systematic Reviews, the publication bias for both the retention rate and caries development was evaluated by using funnel plots and testing the asymmetry with the Egger regression for at least 10 studies in the meta-analysis.

#### *Statistical analysis:*

Comprehensive Meta-Analysis, version 2 (Biostat, NJ, USA) was applied for the statistical analyses. The odds ratios (ORs) at 95% confidence interval (CI) were calculated with the random effects models. The Cochran Q test was used for the assessment of heterogeneity at a significance level of  $P=0.05$ . Furthermore, the  $I^2$  and  $Tau^2$  indices were used to quantify heterogeneity [9]. As a simple rule, the level of heterogeneity may be concluded based on  $I^2$  as follows:

0% to 40%: might not be important;

30% to 60%: may represent moderate heterogeneity;

50% to 90%: may represent substantial heterogeneity;

75% to 100%: considerable heterogeneity [10].

#### *Assessment of outcomes:*

The primary outcome of the meta-analysis consisted of the determination of the retention rate of the use of fissure sealants with and without fillers, with the secondary outcome consisting of the determination of the caries development rate in teeth with a fissure sealant.

## RESULTS

### *Search and selection:*

The PRISMA flow diagram of our search strategy is shown in Figure 1. Initially, 15,778 articles were retrieved by searching the PubMed, Embase, Scopus, Cochrane, and Web of Science databases. After removing the duplicates, there were 6,336 articles up to October 24, 2019. After assessment of the title, abstract and full-text, 19 studies met our inclusion criteria. We obtained the full texts and appraised them in detail. Five studies [11-15] had more than one group comparing filled and unfilled sealants that were included in the meta-analysis. Figure 2 provides detailed information about the included studies.

### *Characteristics of the included studies:*

Due to inadequate data on type and amount of fillers in the studies conducted before 1990, we decided to limit our search to papers published from 1990 to 2019. Although the main materials used were hydrophobic and hydrophilic resin-based sealants, flowable composites, and derivatives of glass ionomers, we picked resin-based sealants with or without filler regardless of other characteristics such as their hydrophilicity. The sealants were classified as filled or unfilled according to the manufacturers' brochures.

Nine of 19 studies evaluated both retention rate and caries development while others only assessed the retention rate. Teeth were also isolated, whether by cotton rolls or rubber dam in all these studies. The number of patients in each group in the studies varied from 30 to 200 and the follow-up duration ranged from 1 month to 48 months. However, as described in the inclusion criteria, we omitted the results of less than 6-month follow-ups. In the included studies, the detection bias was low in seven studies because the assessors were blind when evaluating the outcomes [7,15,16,18,21, 24,26]. We could not specify detection bias for 12 studies and assumed the detection bias for these studies to be unclear [11,12,27,28, 13,14,17,19,20,22,23,25].

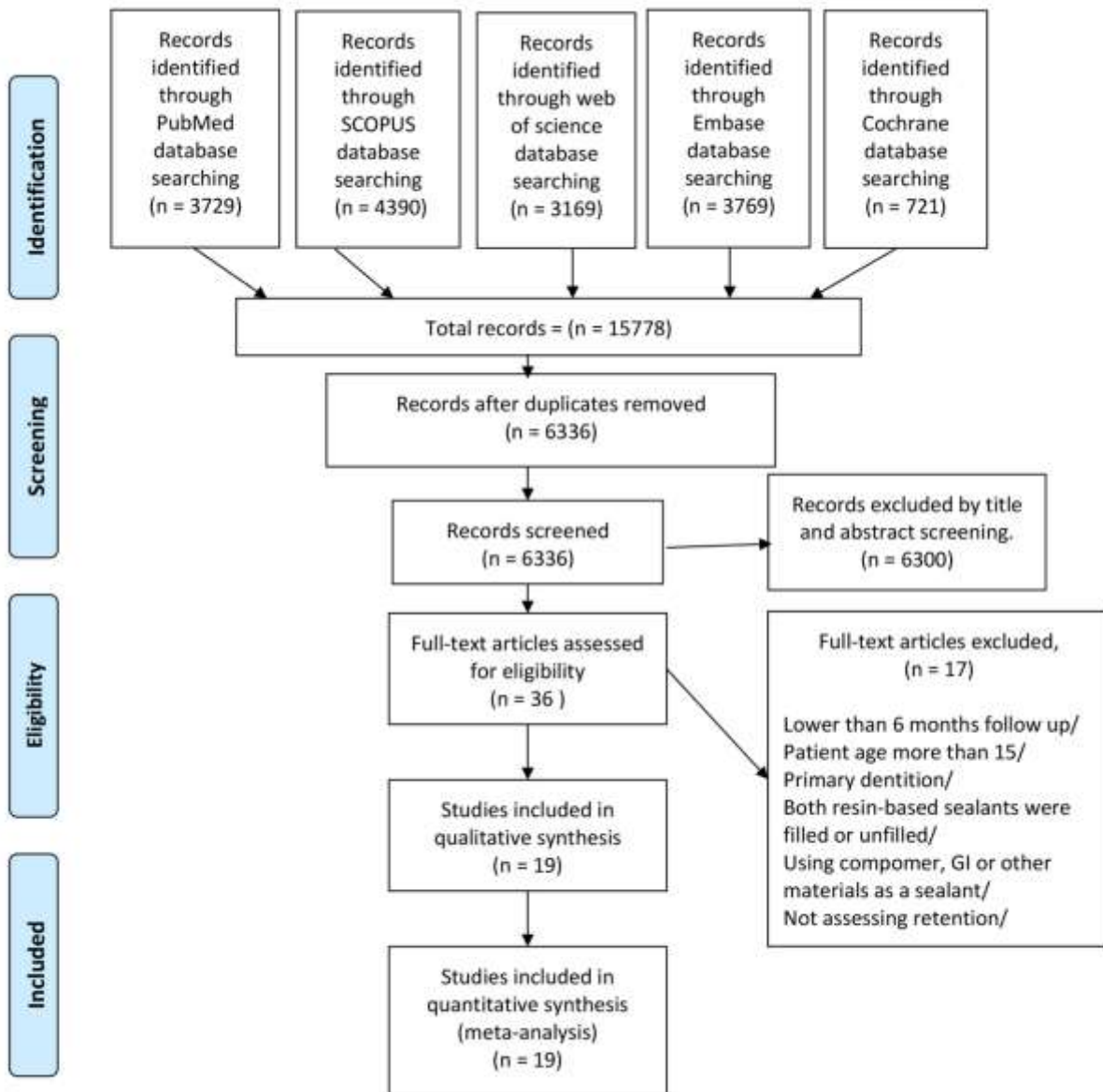


Fig. 1. PRISMA flow diagram of literature search and selection procedure

**Fig. 2.** Detailed information on studies included in the systematic review

N	Author/ Country	Perma- nent Teeth	Isolation	F/U	UG=TN <sup>2</sup>	ET <sup>3</sup>	CRU/T (%) <sup>4</sup>	CDU <sup>5</sup>	FG=TN <sup>6</sup>	ET	CRF <sup>7</sup>	CDF <sup>8</sup>	RP <sup>9</sup>	CP <sup>10</sup>	Effect		
1	Hassan et al (2019)/ Saudi Arabia [11]	1st molars dam	Rubber dam	3		40	34/40(85)	---		40	32/40 (80)	-	---	---			
				6	ClinPro (3M)= 40	40	33/40 (82.5)	---	Delton FS+ (Dentsply)= 40	40	26/40 (65)	-	>0.05	---	IS <sup>11</sup> retention in unfilled group		
				9		40	29/40 (72.5)	---		40	22/40 (55)	-	---	---	---		
				12		40	25/40 (62.5)	---		40	17/40 (42.5)	-	---	---	---	---	
				3		40	34/40(85)	---		40	30/40 (75)	-	---	---	---	---	
				6	Clinpro (3M)= 40	40	33/40 (82.5)	---	Helioseal F (Ivoclar)= 40	40	28/40 (70)	-	---	>0.05	---	---	IS retention in unfilled group
				9		40	29/40 (72.5)	---		40	25/40 (62.5)	-	---	---	---	---	
				12		40	25/40 (62.5)	---		40	20/40 (50)	-	---	---	---	---	
				1		200	189/200 (94.5)	0/200 (0)		200	180/200 (90)	0/200 (0)	0.092	---	---	---	
				3		200	160/200 (80)	0/200 (0)		200	160/200 (80)	0/200 (0)	1.000	---	---	---	S <sup>12</sup> lower retention in 9, and 12 months follow ups in unfilled group
				6		200	138/200 (69)	0/200 (0)	Embrace WetBond (Pulpdent)= 200	200	129/200(64.5)	0/200 (0)	0.339	---	---	---	
				9		200	40/200 (20)	10/200 (5)		200	49/200(25.5)	34/200 (17)	<0.001	---	---	---	
2	Mohanraj et al. (2019)/ India [18]	Molars	Rubber dam	12		200	16/200 (8)	18/200 (9)		200	26/200 (13)	55/200 (27.5)	<0.001	---	---		
				1		44	36/44 (81.8)	0/44 (0)		44	38/44 (86.4)	0/44 (0)	0.184	---	---	Higher retention and lower CD <sup>13</sup> in filled group	
				3		43	28/43 (65.1)	0/43 (0)	Seal It (SPIDENT)= 44	43	31/43 (72.1)	0/43 (0)	0.866	---	---		
				6		41	15/41 (36.6)	2/41 (4.9)		41	21/41 (51.2)	0/41 (0)	0.207	0.152	---		
				3		41	15/41 (36.6)	2/41 (4.9)		41	21/41 (51.2)	0/41 (0)	0.207	0.152	---		
				6		41	15/41 (36.6)	2/41 (4.9)		41	21/41 (51.2)	0/41 (0)	0.207	0.152	---		
3	Elkwatehi & Bukhari (2019)/ Egypt [24]	Molars	Cotton roll	1	ICON	44	36/44 (81.8)	0/44 (0)		44	38/44 (86.4)	0/44 (0)	0.184	---	---	Higher retention and lower CD <sup>13</sup> in filled group	
				3		43	28/43 (65.1)	0/43 (0)	Seal It (SPIDENT)= 44	43	31/43 (72.1)	0/43 (0)	0.866	---	---		
				6		41	15/41 (36.6)	2/41 (4.9)		41	21/41 (51.2)	0/41 (0)	0.207	0.152	---		
				3		41	15/41 (36.6)	2/41 (4.9)		41	21/41 (51.2)	0/41 (0)	0.207	0.152	---		
				6		41	15/41 (36.6)	2/41 (4.9)		41	21/41 (51.2)	0/41 (0)	0.207	0.152	---		

1 Follow up month  
2 Unfilled Group=Total Number of Teeth  
3 Evaluated Teeth Number  
4 Complete Retention Unfilled/Total (%)  
5 Caries Development Unfilled/Total (%)  
6 Filled Group=Total Number of Teeth  
7 Complete Retention Filled/Total (%)  
8 Caries Development Filled/Total (%)  
9 Retention P-Value  
10 Caries Development P-Value  
11 Insignificantly  
12 Significantly  
13 caries development

Fig.2. Detailed information on studies included in the systematic review

Author/ N Country	Permanent Teeth	Isolation	F/U <sup>1</sup>	UG=TN <sup>2</sup>	ET <sup>3</sup>	CRU/T (%) <sup>4</sup>	CDU <sup>5</sup>	FG=TN <sup>6</sup>	ET	CRF <sup>7</sup>	CDR <sup>8</sup>	RP <sup>9</sup>	CP <sup>10</sup>	Effect			
Unal & Oztas (2015)/Turkey [17]	Mandibular 1 <sup>st</sup> molars	Cotton roll	12		41	4/41 (9.8)	3/41 (7.3)		41	16/41 (39)	0/41 (0)	0.001	0.211				
			18		41	0/41 (0)	10/41 (24.4)		41	3/41 (7.3)	1/41 (2.4)	0.041	0.013				
			24		41	0/41 (0)	20/41 (48.8)		41	0/41 (0)	3/41 (7.3)	0.040	<0.001				
			1		20	20/20 (100)	-		20	20/20 (100)	---	>0.05	---				
			3		19	18/19 (94.7)	-		20	20/20 (100)	---	>0.05	---				
			6		19	18/19 (94.7)	-	Aegis (Bosworth) =0	20	20/20 (100)	---	>0.05	---				
			9		19	17/19 (89.5)	-		20	20/20 (100)	---	>0.05	---				
			12		19	17/19 (89.5)	-		20	19/20 (95)	---	>0.05	---				
			5 Reddy et al. (2015)/India [7]	1st molars	Cotton roll	2		112	93/112 (83.04)	-		112	87/112 (77.68)	---	0.3096	---	
						4		112	93/112 (83.04)	-		112	85/112 (75.89)	---	0.1828	---	
						6		112	90/112 (80.36)	-	Helioseal F (Ivoclar)= 112	112	80/112 (71.43)	---	0.1182	---	
						8		112	83/112 (74.11)	-		112	71/112 (63.39)	---	0.0835	---	
10		112				78/112 (69.64)	-		112	64/112 (57.14)	---	0.0482	---				
12		112				72/112 (64.29)	-		112	60/112 (53.57)	---	0.103	---				

1 Follow up month

2 Unfilled Group=Total Number of Teeth

3 Evaluated Teeth Number

4 Complete Retention Unfilled/Total (%)

5 Caries Development Unfilled/Total (%)

6 Filled Group=Total Number of Teeth

7 Complete Retention Filled/Total (%)

8 Caries Development Filled/Total (%)

9 Retention P-Value

10 Caries Development P-Value

11 Insignificantly

12 Significantly

13 caries development



Fig. 2. Detailed information on studies included in the systematic review

N	Author/ Country	Permanent Teeth	Isolation	F/U <sup>1</sup>	UG=TN <sup>2</sup>	ET <sup>3</sup>	CRU/T (%) <sup>4</sup>	CDU <sup>5</sup>	FG=TN <sup>6</sup>	ET	CRF <sup>7</sup>	CDP <sup>8</sup>	RP <sup>9</sup>	CP <sup>10</sup>	Effect
6	Kobayashi et al. (2015)/ Brazil [25]	1st molars	Cotton roll	6	Helioseal clear (Ivoclar)=74	65	54/65 (83.1)	-	Helioseal F (Ivoclar)=79	69	53/69 (76.8)	---	0.5402	---	Higher retention in unfilled group & significant at 12 and 24 months follow-ups
12				12	Helioseal clear (Ivoclar)=74	58	45/58 (77.6)	-		65	36/65 (55.4)	---	0.0345	---	
18				18	Helioseal clear (Ivoclar)=74	61	40/61 (65.6)	-		67	36/67 (53.7)	---	0.1918	---	
24				24		47	31/47 (66.0)	-		52	18/52 (34.6)	---	0.0076	---	
3				3		32	21/32 (66)	2/32 (6.3)		32	26/32 (81)	1/32 (3.1)	0.19	0.56	
6	Khatri et al. (2015)/ India [16]	Mandibular 1 <sup>st</sup> molars	Cotton roll	6	Helioseal (Ivoclar)=32	32	20/32 (63)	4/32 (12.5)	Embrace WetBond (Pulpdent)=32	32	25/32 (78)	2/32 (6.3)	0.29	0.41	IS retention & lower CD in filled group
12				12		32	16/32 (50)	5/32 (15.6)		32	23/32 (70)	2/32 (6.3)	0.03	0.48	
8	Schlueter et al. (2013)/ Germany [26]	Maxillary & mandibular molars	Cotton roll	12	Helioseal (Ivoclar)=55	55	51/55 (93)	0/55 (0)	Embrace WetBond (Pulpdent)=55	55	15/55 (27)	4/55 (7.3)	<0.001	P>0.001	S higher retention in unfilled group. IS lower CD in unfilled group.

<sup>1</sup> Follow up month

<sup>2</sup> Unfilled Group=Total Number of Teeth

<sup>3</sup> Evaluated Teeth Number

<sup>4</sup> Complete Retention Unfilled/ Total (%)

<sup>5</sup> Caries Development Unfilled/Total (%)

<sup>6</sup> Filled Group=Total Number of Teeth

<sup>7</sup> Complete Retention Filled/Total (%)

<sup>8</sup> Caries Development Filled/Total (%)

<sup>9</sup> Retention P-Value

<sup>10</sup> Caries Development P-Value

<sup>11</sup> Insignificantly

<sup>12</sup> Significantly

<sup>13</sup> caries development

Fig. 2. Detailed information on studies included in the systematic review

N	Author/ Country	Permanent Teeth	Isolation	F/U <sup>1</sup>	UG=IN <sup>2</sup>	ET <sup>3</sup>	CRU/T (%) <sup>4</sup>	CDU <sup>5</sup>	FG=IN <sup>6</sup>	ET	CRF <sup>7</sup>	CDP <sup>8</sup>	RP <sup>9</sup>	CP <sup>10</sup>	Effect	
9	Kumar (2013)/India [12]	1 <sup>st</sup> molars	Rubber dam	6	Rubber dam	40	30/40 (75)	---	Delton FS+ (Dentsply)=40	40	25/40 (62.5)	---	---	---	IS retention in unfilled group	
				12		38	25/38 (65.8)	---		38	16/38 (42.1)	---	---	---		
				6	Clinpro (3M)=40	40	30/40 (75)	---	(Helioseal F Ivoclar)=40	40	21/40 (52.5)	---	---	---	---	Higher retention in unfilled group at the 12-month follow up
				12		38	25/38 (65.8)	---		38	11/38 (28.9)	---	<0.005	---	---	
10	Bhat et al. (2013)/India [13]	1 <sup>st</sup> molars	Cotton roll	6	Clinpro (3M)=80	80	72/80 (90)	0/80 (0)	Delton FS+ (Dentsply)=80	80	72/80 (90)	0/80 (0)	0.106	---	IS retention in filled group. No differences in CD	
				12		76	62/76 (81.6)	2/76 (2.6)		76	62/76 (81.6)	2/76 (2.6)	0.134	---		
				6	Clinpro (3M)=80	80	73/80 (91.3)	0/80 (0)	Embrace WetBond (Pulpdent)=80	80	73/80 (91.3)	0/80 (0)	0.069	---	---	IS retention in filled group. No differences in CD
				12		76	61/76 (80.3)	2/76 (2.6)		76	61/76 (80.3)	2/76 (2.6)	0.206	---	---	
11	Mathur et al. (2012)/India [19]	1 <sup>st</sup> molars	Rubber dam	6	Teethmate F1 (Kurarey)= 40	40	28/40 (70)	0/40 (0)	Ultraséal XT plus (Ultradent)=40	40	40/40 (100)	0/40 (0)	< 0.05	p>0.05	Higher retention in filled group. IS CD in unfilled group	
				12		40	21/40 (52.5)	0/40 (0)		40	39/40 (97.5)	1/40 (2.5)	< 0.05	p>0.05		

<sup>1</sup> Follow up month

<sup>2</sup> Unfilled Group= Total Number of Teeth /

<sup>3</sup> Evaluated Teeth Number

<sup>4</sup> Complete Retention Unfilled/ Total (%)

<sup>5</sup> Caries Development Unfilled/Total (%)

<sup>6</sup> Filled Group= Total Number of Teeth

<sup>7</sup> Complete Retention Filled/Total (%)

<sup>8</sup> Caries Development Filled/Total (%)

<sup>9</sup> Retention P-Value

<sup>10</sup> Caries Development P-Value

<sup>11</sup> Insignificantly

<sup>12</sup> Significantly

<sup>13</sup> caries development



Fig. 2. Detailed information on studies included in the systematic review

N	Author/ Country	Perma- nent Teeth	Isolation	F/U 1	UG=TN <sup>2</sup>	ET <sup>3</sup>	CRU/T (%) <sup>4</sup>	CDU <sup>5</sup>	FG=TN <sup>6</sup>	ET	CRF <sup>7</sup>	CDF <sup>8</sup>	RP <sup>9</sup>	CP <sup>10</sup>	Effect
				6		61	47/61 (77)	0/61 (0)		60	56/60 (93.3)	0/61 (0)	<0.0001		
	Kargul et al. (2009)/ Turkey [20]	1 <sup>st</sup> molars	Cotton roll	12	Helioseal Clear Chroma	61	19/61 (31.1)	7/61 (11.5)	Delton FS+ (Dentsply)=60	60	30/60 (50)	3/61 (4.9)	<0.0001		Higher retention in filled group. IS CD in filled group
12				24	(Ivoclar)=61	53	10/53 (18.8)	7/53 (13.2)		54	25/54 (46.2)	5/54 (9.3)	<0.0001		
				36		46	5/46 (10.8)	9/46 (19.6)		46	14/46 (30.4)	6/46 (13)	<0.05		
				12		54	41/54 (75.9)	2/54 (3.7)		54	44/54 (81.5)	0/54 (0)		---	
13	Dukic et al. (2007)/ Croatia [14]	1st & 2nd molars	Cotton roll	12	Helioseal Clear Chroma	54	41/54 (75.9)	2/54 (3.7)	Fissurit FX (VOCO)=54	54	45/54 (83.3)	2/54 (3.7)	>0.05		IS retention in filled group
				12	(Ivoclar)=54	55	42/55 (76.4)	1/55 (1.8)		54	44/54 (81.5)	0/54 (0)		---	
				12		55	41/54 (75.9)	1/55 (1.8)		54	45/54 (83.3)	2/54 (3.7)		---	
14	Baca et al. (2007)/ Spain [15]	1st molars	Cotton roll	12	Delton (Dentsply)=37	37	33/37 (89.2)	---	Delton Plus (Dentsply)=37	37	32/37 (86.5)	---	---	---	IS
				12	Concise (3M)=37	37	29/37 (78.4)	---		37	32/37 (86.5)	---	---	---	
15	Lygidakis and Oulis (1999)/ Greece [21]	1st molars	Cotton roll	48	Delton (Dentsply)=162	162	144/162 (89)	---	Flourosshield (Dentsply)= 162	162	124/162 (77)	14/162 (8.6)	0.01	0.35	Higher retention in unfilled group. IS CD in filled group

1 Follow up month  
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13 caries development

Fig. 2. Detailed information on studies included in the systematic review

N	Author/ Country	Perma- nent Teeth	Isolation	F/U <sup>1</sup>	UG=TN <sup>2</sup>	ET <sup>3</sup>	CRU/T (%) <sup>4</sup>	CDU <sup>5</sup>	FG=TN <sup>6</sup>	ET	CRF <sup>7</sup>	CDI <sup>8</sup>	RP <sup>9</sup>	CP <sup>10</sup>	Effect
16	Morphis & Toumba (1998)/UK [27]	1 <sup>st</sup> & 2 <sup>nd</sup> molars	Cotton roll	3		31	25/31 (80.64)	---		32	26/32 (81.25)	-	-	-	-
				6	Delto (Dentsply)= 35	30	23/30 (76.66)	---	Delton.Plus (Dentsply)= 34	31	23/31 (74.19)	-	>005	-	IS
				12		30	21/30 (70)	---		31	21/31 (67.74)	-	-	-	-
17	Koch et al. (1997)/ Germany [28]	Mandi- bular 1 <sup>st</sup> molars	Rubber dam	12	Delton (Dentsply)= 33	31	30/31 (96.77)	---	Helioseal F (Ivoclar)= 33	31	28/31 (90.32)	-	-	-	IS retention in unfilled group
				6		105	105/105 (100)	---		109	109/10 9 (100)	-	-	-	-
				12	Delton (Dentsply)= 105	105	105/105 (100)	---	Flouroschild (Dentsply)= 109	109	109/10 9 (100)	-	-	-	IS retention in unfilled group
18	Do Rego et al. (1996)/ Brazil [22]	Pre- molar & molars	Rubber dam	18		105	103/105 (98.1)	---		109	104/109 (95.4)	-	-	-	-
				24		102	98/102 (96.1)	---		104	99/104 (95.2)	-	-	-	-
				6	Concise (3M)=213	146	132/146 (90.4)	---		173	149/17 3 (86.1)	-	-	-	-
19	Boksmann et al. (1993)/ Canada [23]	Molars, pre- molars, & lateral incisors	Rubber dam	12		152	129/152 (84.9)	---	Prismashield= 189	147	120/14 7 (81.6)	-	-	-	IS retention in unfilled group
				24		105	85/105 (81)	---		116	89/116 (76.7)	-	-	-	-
				6		105	85/105 (81)	---		116	89/116 (76.7)	-	-	-	-

<sup>1</sup> Follow up month

<sup>2</sup> Unfilled Group=Total Number of Teeth

<sup>3</sup> Evaluated Teeth Number

<sup>4</sup> Complete Retention Unfilled/ Total (%)

<sup>5</sup> Caries Development Unfilled/Total (%)

<sup>6</sup> Filled Group=Total Number of Teeth

<sup>7</sup> Complete Retention Filled/Total (%)

<sup>8</sup> Caries Development Filled/Total (%)

<sup>9</sup> Retention P-Value

<sup>10</sup> Caries Development P-Value

<sup>11</sup> Insignificantly

<sup>12</sup> Significantly

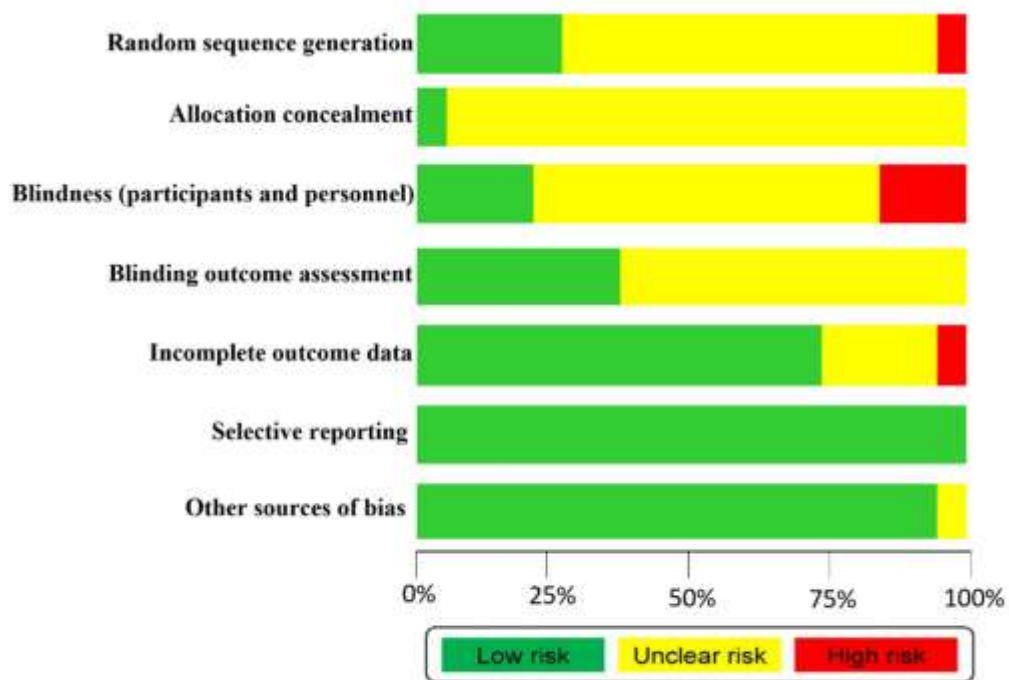
<sup>13</sup> caries development

	Random sequence generation	Allocation concealment	Blindness (participants and	Blinding outcome assessment	Incomplete outcome data	Selective reporting	Other sources of bias
Hassan and Mohammed (2019) [11]	?	?	?	?	?	+	+
Mohanraj et al. (2019) [18]	?	?	?	+	?	+	+
Elkatehy and Bukhari (2019) [24]	+	?	?	+	-	+	+
Unal and Oztas (2015) [17]	?	?	?	?	?	+	+
Reddy et al. (2015) [7]	?	?	?	+	+	+	+
Kobayashi et al. (2015) [25]	+	?	-	?	?	+	+
Khatri et al. (2015) [16]	-	?	+	+	+	+	+
Schlueter et al. (2013) [26]	+	?	-	+	+	+	+
Kumaran (2013) [12]	?	?	+	?	+	+	+
Bhat et al. (2013) [13]	?	?	-	?	+	+	+
Mathur et al. (2012) [19]	?	?	?	?	+	+	+
Kargul et al. (2009) [20]	?	?	?	?	+	+	+

Figure continued on next page

Dukic et al. (2007) [14]	?	?	?	?	+	+	+
Baca et al. (2007) [15]	?	?	?	+	+	+	?
Lygidakis and Oulis (1999) [21]	?	?	?	+	+	+	+
Morphis and Toumba (1998) [27]	+	+	+	?	+	+	+
Koch et al. (1997) [28]	+	?	+	?	+	+	+
Do Rego et al. (1996) [22]	?	?	?	?	+	+	+
Boksman et al. (1993) [23]	?	?	?	?	+	+	+

### A: ROB Summary



### B: ROB Graph

**Fig. 3.** Quality assessment of included studies using risk of bias (ROB) assessment A: ROB summary and B: ROB graph. +: low; -: high; ?: unclear

In evaluation of the attrition bias, the investigators in one study did not explain the reasons for missing outcome data, thus, the risk of this bias was high [24]. Four studies had an unclear ROB since the number of samples was not disclosed [11,17,18,25]. All other studies had a low ROB because they had no missing data, or the investigators explained the reasons for the dropouts [7,12,23,26-28,13-16,19-22]. All of the included studies had a low ROB as the researchers stated all of the predetermined objectives of the study. In the assessment of other biases, we found one study with an unclear ROB, which did not represent the exact inclusion and exclusion criteria [15]. We could not find any problem in the remaining studies; thus, we ranked them as “low risk” in term of “other biases”.

#### *Meta-analysis:*

Twenty-six groups comparing filled and unfilled fissure sealant materials were included in the meta-analysis. As shown in Figure 4, in comparison of retention rate, within 6 months, 12 months, and more than 12 months of follow-up, the OR was 1.010 (P=0.958, CI: 0.704-1.447), 1.042 (P=0.839, CI: 0.700-1.551) and 1.429 (P=0.332, CI: 0.695 - 2.939), respectively. Also, in comparison of caries development, the OR in 6,12 and more than 12 months of follow-up was 2.48 (P=0.227, CI= 0.567-10.843), 0.995 (P=0.991, CI: 0.441-2.224), and 2.764 (P=0.099, CI: 0.825-9.262), respectively. These outcomes recommended that there were no significant differences among the retention rates and caries development rates in filled and unfilled resin-based fissure sealants in different follow-up durations. We assessed the publication bias for both retention rate and caries development by drawing funnel plots and analyzing the presence of asymmetry by the Egger regression method (for meta-analysis with more than 10 studies). Based on the results of the publication bias assessment, it seemed that there was no or little evidence of bias in this issue.

#### *ROB across studies:*

The publication bias funnel plots for the meta-analysis with more than 10 studies are shown in Figure 5. Through visual analysis of funnel plots and also looking at the Egger’s regression test results, it seems that there was no or low evidence of publication bias across the studies.

## DISCUSSION

The results of this meta-analysis revealed that there were no significant differences among the retention rates and also caries development of filled and unfilled sealants.

We preferred to widen our search strategy to include all studies comparing at least two fissure sealants. Then, we manually searched through them to find studies with filled and unfilled sealants even without stating it directly in the article. We observed that before the 1990, pit and fissure sealants were not as diverse as they are today. Also, there were not enough reliable data on the amount or type of fillers. Thus, we decided to only include studies from 1990 to 2019 which assessed both filled and unfilled sealants regardless of other characteristics such as hydrophilicity, color, brand, etc. We classified sealants as filled or unfilled according to the manufacturers’ brochures. We included only randomized or quasi-randomized clinical trials to enhance the quality of this systematic review and meta-analysis. To assess the publication bias, we drew funnel plots and analyzed them by the Egger regression test.

In total, 67-90% of caries in recently erupted molars in children between 5-17 years occur in the pits and fissures [7]. This high incidence rate is mainly due to bacterial retention and food residues [3]. Considering the complex morphology or lack of a salivary path to these fissures, the progression of caries is correlated with the occlusal surface morphology [2]. The sealants can form a mechanical barrier that blocks the penetration of microorganisms and food debris [16].



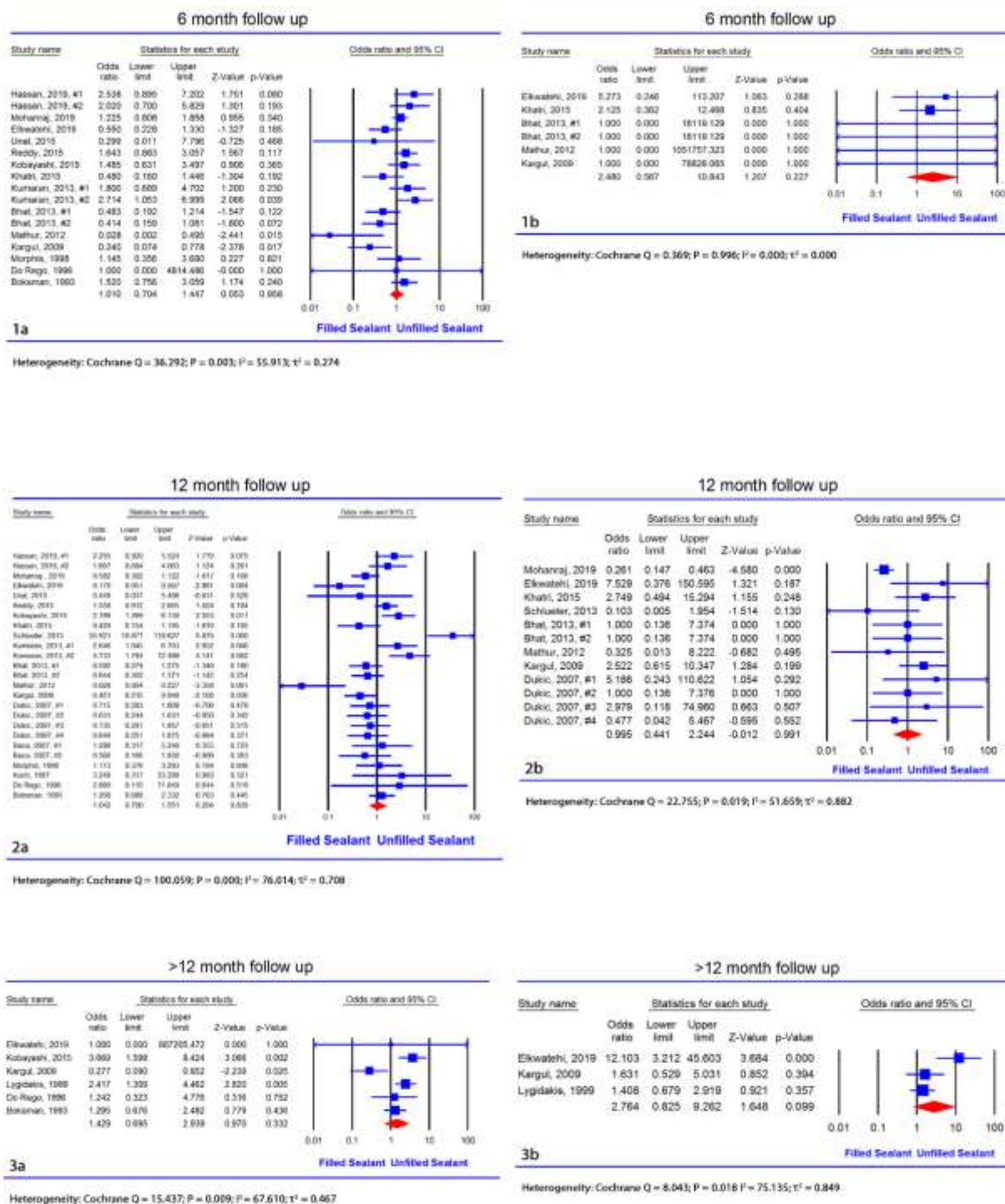


Fig. 4. Forest plots of the retention rate and caries development of filled and unfilled resin-based fissure sealants at different follow-up durations. 1a,2a,3a: retention rate, 1b,2b,3b: caries development

Thus, the sealant's capability to remain on the tooth surface or in other words, the retention rate, plays a crucial role in the success of pit and fissure sealants [17].

On the other hand, inhibition of caries development is the final goal of fissure sealants; thus, we assessed the caries development as our secondary outcome. Numerous types of pits and fissure sealants are accessible in the market, such as filled and unfilled, hydrophobic and

hydrophilic, colored and transparent, and sealants with or without fluoride ion release [29]. The variety of materials has complicated an appropriate selection; thus, the question, "which type of sealant may be better as a sealing material?" remains [30].

This systematic review aimed to evaluate the retention rate and caries development of filled and unfilled sealants at different follow-up durations. Theoretically, it is assumed that unfilled sealants have higher penetration depth in fissures and micro-porosities of etched enamel due to their lower viscosity. As a result, an unfilled sealant could be more prone to fully fill a deep fissure than a filled material and may have a better retention rate than flowable composites or even filled sealants [7]. Also, due to their lower filler content, unfilled sealants do not require much occlusal adjustment, which is a routine step in sealant application procedure that may increase the cost and waste time, but is negligible [33]. From another point of view, an unfilled sealant is more prone to abrasion which may jeopardize the longevity of sealants [4]. In the beginning, fillers were added to pit and fissure sealants to improve their mechanical properties and wear strength [34]. Filled sealants may have caries prevention effect due to filler incorporation, especially calcium-fluoride releasing fillers which remain and act as a calcium or fluoride reservoir [35]. As fissure sealants are a combination of resin matrix and fillers, by adding more fillers, the ratio of organic matrix to inorganic filler changes and pit and fissure sealants' behavior (mechanical and physical properties) may also vary, which may alter the prognosis of these restorations [36,37].

The existing variety in the composition of resin

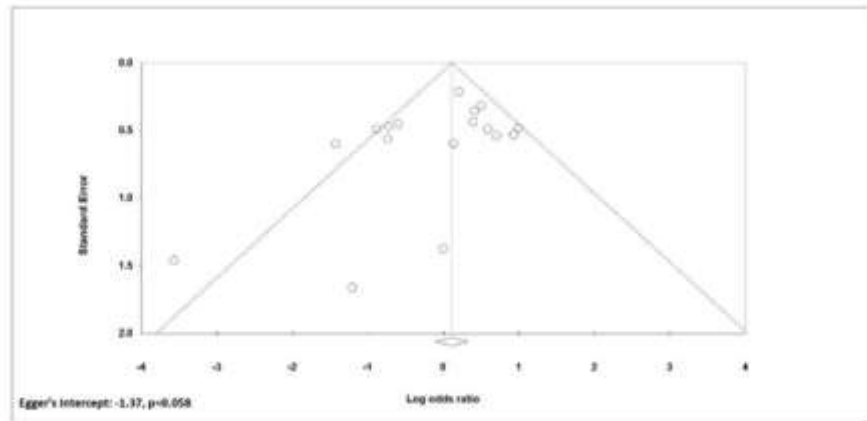
matrix and fillers can also alter the properties of sealants [38]. However, the filled sealants may have lower penetration depth and may not penetrate into deep fissures [15]. Also, as the ion release is assumed to be the result of filler dissolution, filled sealants may degrade more than unfilled sealants over time [39].

Therefore, pit and fissure sealants have very different rheological and mechanical properties and hence various clinical characteristics. It should be noted that some features may be more important in a specific case [36]. Thus, both filled and unfilled sealants have their specific utilization, and material selection according to the specific application may be the most critical point.

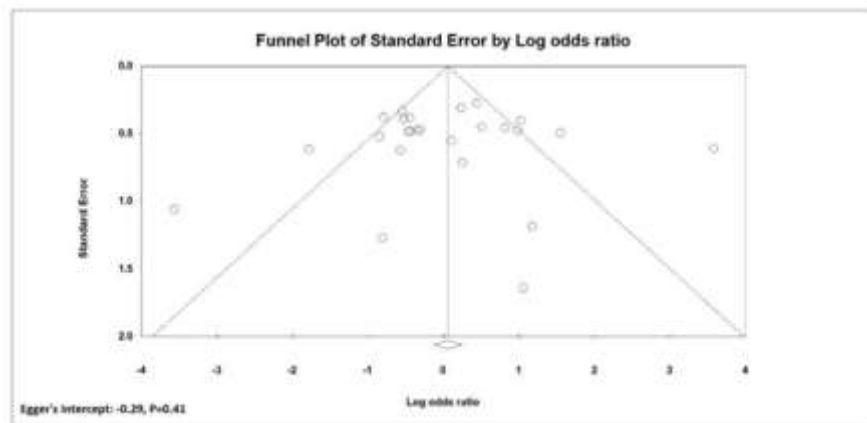
Resin-based fissure sealants are one of the most durable materials, making them the dentists' choice [40]. Some studies believe that adding fillers to resin-based pit and fissure sealants does not have a significant effect on clinical outcome, and both filled and unfilled sealants have comparable retention rates [7,41,42]. However, others may not agree [25,43-45]. The insignificant difference observed in this study highlights the specific case selection. The morphology of pit and fissure is a decisive determinant of the sealant's penetration; thus, in the narrow fissures with lower penetration rate (such as inverted Y-type, IK-type, and I-type) unfilled sealants with a lower viscosity may be a better choice [31,46], but in cases with traumatic occlusion or patients with parafunctional habits, filled sealants with higher wear resistance may be retained longer [7].

Some additional factors, such as tooth preparation, proper bonding, and moisture control may also alter the clinical properties of sealants. The hydrophilicity of some pit and fissure sealants can also influence the retention rate and caries development [18]. Filler characteristics such as size, mode of dispersion, solubility, and surface treatment may also affect the clinical features [36]. Furthermore, with the introduction of nano-fillers, the filler industry is evolving, which may be one of the reasons for the differences in the results obtained in recent studies compared with older ones.

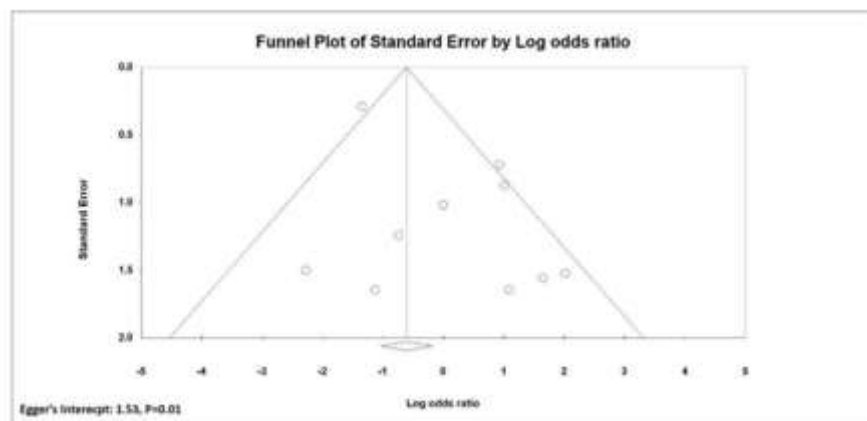




A1 – Funnel Plot of Standard Error by Log Odds Ratio (Retention Rate, 6 Months Follow-Up)



A2 – Funnel Plot of Standard Error by Log Odds Ratio (Retention Rate, 12 Months Follow-Up)



B – Funnel Plot of Standard Error by Log Odds Ratio (Caries Development, 12 Months Follow-Up)

**Fig. 5.** Funnel plots of standard error according to the log odds ratio. A1, A2: retention rate, B: caries development

**CONCLUSION**

The retention rate and caries development did not differ significantly in filled and unfilled sealants in over 12 months of follow-up.

**CONFLICT OF INTEREST STATEMENT**

None declared.

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