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ORIGINAL RESEARCH

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Clinical evaluation of hydrophilic and hydrophobic resin-based sealants in uncooperative children: a randomized controlled clinical trial

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Abstract

This clinical trial aimed to evaluate and compare the retention and cariostatic effects of hydrophilic and hydrophobic resin-based sealants (RBSs) for sealing pits and fissures in the permanent molars of uncooperative children. A split-mouth and double-blind randomized clinical trial (RCT) was conducted among 6- to 9-year-old uncooperative children. One hundred and four sound mandibular and maxillary first permanent molars were randomly allocated to be sealed with group I (UltraSeal XT® hydro™) or group II (Helioseal-F) in 34 uncooperative children. Clinical evaluation was performed by two investigators using the Color, Coverage and Caries system to assess sealant retention and cariostatic effect at 3-, 6- and 12-month intervals. Data analysis was performed using Friedman's and Mann-Whitney U tests. The final analysis included 31 children with 49 pairs of teeth. No significant differences were observed between the retention and cariostatic effects of hydrophilic and hydrophobic RBSs at the 3-, 6- and 12-month intervals ($p = 0.23$, $p = 0.638$, and $p = 0.706$, respectively) ($p = 0.175$, $p = 0.065$, and $p = 0.171$, respectively). After 12 months of follow-up, the hydrophilic RBSs showed an outcome equivalent to that of conventional hydrophobic RBSs in terms of retention and cariostatic effects. Therefore, hydrophilic RBSs could be considered as the sealing material of choice when isolation is difficult, particularly in uncooperative children.

Keywords

Hydrophilic; Hydrophobic; Sealant; Retention; Children

1. Introduction

Caries is a chronic disease prevalent among children and adolescents [1]. Although the overall caries rates decreased, occlusal surface caries did not decline at the same rate as smooth surface caries [2]. The difficulty in cleaning pits and fissures makes them more susceptible to caries than smooth surfaces, because they are not fully protected by fluoride administration [3]. Fissure sealants have proven to be effective protective measures, acting as a barrier that insulates bacteria from nutrition by attaching them to teeth through micromechanical bonding [4].

Dental sealants can be classified into different types, with resin-based sealants (RBSs) being the most commonly used and are known for their higher retention rates than other sealants [5]. However, hydrophobic RBSs, which are widely available, have lower retention rates in the presence of moisture [6]. Additionally, hydrophobic RBSs have been reported to hinder the maturation of pits and fissures in the saliva of newly-erupted molars [7]. To address these limitations, recent advancements have led to the development of hydrophilic RBSs that are moisture tolerant and penetrate deep into pits and fissures without the need for absolute dryness [8]. These sealants exhibit improved mechanical properties and contain a higher amount of fillers as well as bioactive properties that facilitate ion transfer to the enamel while maintaining their physical properties [9, 10].

Cooperation of children during dental treatment is crucial to ensure the delivery of high-quality care [11]. A 2016 study highlighted the significant influence of child behavior on sealant retention, with poor cooperation during sealant placement identified as a risk factor for sealant loss, irrespective of the presence of a bonding agent [12]. Poor behavior can manifest as treatment refusal, crying, fearfulness or a negative attitude affecting cooperation [13]. Therefore, exploring whether fissure sealing is beneficial in preventing caries in children who struggle to cooperate during dental procedures is crucial. Understanding the potential impact of child behavior on the success of fissure sealants and evaluating the effectiveness of this preventive approach in such circumstances can guide the development of tailored strategies and interventions for optimal oral health outcomes in these children.

Previous studies have compared hydrophilic and conventional hydrophobic RBSs, yielding controversial results [14–23]. Five studies did not find any significant

differences between the two types [14–18], whereas three reported a higher success rate for hydrophilic RBSs [19–21]. Two studies reported lower retention rates for hydrophilic RBSs [22, 23]. Given the controversy surrounding previous research and the lack of sufficient evidence regarding the retention of hydrophilic RBSs, evaluating the caries prevention potential of both hydrophilic and hydrophobic RBSs in challenging moisture control situations is necessary, particularly in uncooperative children [20]. Therefore, this study aimed to assess and compare the retention and cariostatic effects of hydrophilic and hydrophobic RBSs on the sealing pits and fissures of permanent molars in uncooperative children. The null hypothesis of this study was that there is no difference in retention and cariostatic effects between hydrophilic and hydrophobic RBSs.

2. Materials and methods

2.1 Study design

This was a double-blind, randomized, controlled clinical trial with a split-mouth design. The study was conducted between November 2020 and March 2022. Randomization was performed to assign the teeth in a 1:1 ratio to one of the two groups. The reporting of the study followed the consolidated standards of the Reporting trials (CONSORT) guidelines [24].

2.2 Participant settings and eligibility criteria

This study was conducted at Pediatric Dental clinics in King Abdulaziz University, Jeddah, Saudi Arabia, over a period of 12 months. Thirty-four children were randomly selected from a list of patients aged 6 to 9 years using a systematic sampling method. All parents who agreed to enroll their children in the study ensured that their children met the inclusion criteria and signed an informed written consent form.

2.2.1 The inclusion criteria

1. Healthy children aged 6–9 years, irrespective of their sex, race and social or economic status.

2. Children with bilateral erupted maxillary and/or mandibular first permanent molars with deep fissures scored 0 on the International Caries Detection and Assessment System (ICDAS) II [25].

3. Uncooperative children with “definitely negative” or “negative” behavioral ratings according to the Frankl behavior classification scale [13].

4. Informed consent to participate in the study was obtained from a parent or guardian.

2.2.2 The exclusion criteria

1. Children with cavitated, hypoplastic, defective, missed or restored contralateral teeth, or with any developmental defect.

2. Children with poor oral habits have occlusion or physical, mental or systemic disorders.

3. Children with a history of allergy to resin or latex.

2.3 Sample size

The sample size was calculated based on a study by Khatri *et al.* [19], (2015). The sample size was determined to be 64 teeth based on an alpha error of 0.05, with sample power of 80%, and the observed difference in retention in both groups was 20% after 1 year follow-up. To account for losses during the 1-year follow-up, 104 teeth were selected.

2.4 Grouping

The bilateral mandibular and/or maxillary first molars were randomly assigned into two groups:

—Group I (Study Group) included 52 mandibular and maxillary first permanent molars sealed using hydrophilic RBSs (UltraSeal XT® hydro™ sealant, Ultradent Products, USA).

—Group II (control group) included 52 mandibular and maxillary permanent first molars sealed with hydrophobic RBSs (Helioseal-F Sealant, Ivoclar-Vivadent, NY, USA).

2.5 Randomization

Block randomization was used to ensure a balanced distribution of treatment materials on both sides. All block numbers, along with the corresponding treatment sequence according to the randomization table, were inserted into sealed opaque envelopes. The list was kept with a professional assisting dental staff member to conceal allocation from the operator.

2.6 Clinical procedures

The children and parents were given instructions following the American Academy of Pediatric Dentistry (AAPD) guidelines. These instructions covered oral hygiene, systemic and topical fluoride application, dietary recommendations, and the importance of regular dental check-ups. The recruited children were scheduled for one visit for sealant application to their bilateral first permanent molars. They were then referred to their dentists to follow-up on their treatment plans.

Prior to sealant application, the primary investigator reviewed the medical history of the child along with sex, age, nationality and contact information, and this was recorded on a “patient information form”. During this visit, each tooth was randomly assigned to one of two groups using the block randomization technique. The opaque envelope was chosen by the child and opened by the operator for allocation during the visit. The patients were not informed about the group allocation. All sealant application procedures were performed by a trained pediatric dentist. The sealant materials, along with their composition and manufacturer information, as well as the etchant used in this study, are described in (Table 1). Child behavior was controlled using different non-pharmacological basic behavior management techniques. Additional prophylaxis was administered before sealant application. The occlusal surface was then washed and dried using an air-water spray.

In both groups, (Group I: UltraSeal XT® hydro™ sealant and Group II: Helioseal-F) the sealants were applied according to the manufacturers’ recommendations. Tooth isolation was achieved using a saliva ejector and cotton roll. The teeth in both groups were then dried using an air-water spray. After etching, Group I was etched for 30 seconds using 35% phos-

TABLE 1. Characteristics of resin based sealants used in the study.

Brand Name	Type	Composition	Lot number	Company
UltraSeal XT® hydro™	Hydrophilic	53% filled, TEGDMA, DUDMA, Aluminum oxide, Methacrylic acid, Titanium dioxide, Sodium monofluorophosphate	BL5RP	Ultradent Products, USA
Helioseal-F	Hydrophobic	40% filled, BisGMA, TEGDMA, UDMA, Fluorosilicate glass, Silicon dioxide, Titanium dioxide, Stabilizers, Catalysts	Y23936	Ivoclar-Vivadent, Germany

TEGDMA: triethylene glycol dimethacrylate; DUDMA: diurethane dimethacrylate; Bis-GMA: bisphenol A glycidyl dimethacrylate; UDMA: urethane dimethacrylate.

phoric acid etchant (BGMHK, Ultradent Products, Inc., South Jordan, USA), whereas group II was etched using 37% phosphoric acid etchant (Y29559, Total Etch, Ivoclar Vivadent, Schaan, Liechtenstein). Rinsing was performed in both groups similarly, using water for approximately 15 seconds before excess moisture was drained from the occlusal surface with cotton pellets. As a result, the tooth remained slightly shiny, moist or glossy in Group I, whereas Group II had a dull chalky-white appearance. A disposable tip attached to a syringe was used to apply the sealants. In Group II, the sealant was allowed to flow for 15 seconds before curing. Using the same light-curing device (Elipar™, Curing Light 2500, 3M EPSE, St. Paul, MN, USA), all sealants in both groups were cured for 20 seconds. Finally, all sealant surfaces were rinsed with water for 30 seconds, and occlusion was checked for any adjustment of occlusal prematurity.

2.7 Follow-up

Follow-up visits were conducted for the clinical assessment of all children at 3, 6 and 12 months of age. Two calibrated, blinded evaluators (the primary investigator and another pediatric dentist) performed a clinical assessment of the applied sealants at each follow-up visit. Sealant retention and caries were scored using Color, Coverage and Caries system for assessment of sealant [26]. Retention coverage was defined as follows—A: sealant present on all of the fissure systems; B: sealant present on >50% of fissure pattern with some missing; C: sealant present on <50% of fissure pattern; D: sealant absent. Caries coding was defined as follows: 0, surface is sound, no caries; 1, initial enamel caries subdivided into 1W (white spot lesion) and 1B (brown spot lesion); 2, enamel caries; 3P, caries extending into dentin with a cavity <0.5 mm, 3L: caries extending into dentin with a cavity >0.5 mm; and 4, caries with probable pulpal involvement.

2.8 Blinding

The two sealants were not visually different. The evaluators were blinded to the group allocation of each tooth as assessed during the follow-up assessments. Furthermore, the participants were blinded to the treatment materials by wrapping the etchant and sealant tubes in opaque white paper.

2.9 Reliability and calibration

For the clinical examination and follow-up evaluation, intra- and inter-examiner calibrations were performed between the two examiners, the primary investigator, and another pediatric dentist. Prior to conducting the clinical examination of the included study sample, the primary investigator was trained and calibrated for the clinical examination of the 10 children who were not included in the main study. The patients were re-examined after 20 days by the same investigator and scheduled for sealant application. All examination forms of the two readings were compared statistically using the kappa test to measure intra-examiner reliability. For the follow-up visits, the primary investigator and other pediatric dentists were trained and calibrated to perform clinical assessments on the same group of patients. Sealed molars were assessed twice over a 2-week interval. All datasets were compared statistically using the kappa test to measure the intra- and inter-evaluator reliability for clinical assessment. The intra- and inter-examiner reliabilities for retention and caries were high, with kappa values of 0.98 and 0.92, respectively.

2.10 Statistical analysis

Data were collected, tabulated, and analyzed using the Statistical Package for the Social Sciences software (IBM, SPSS Statistics, version 25, Armonk, NY, USA). The level of significance was set at α = 0.05, and the confidence interval for this analysis was 95%. Descriptive statistics such as means, frequencies and percentages were used to describe the

sample and data distribution. Within-group comparisons of retention and caries after 3, 6 and 12 months were performed using Friedman's test with repeated measures. Intergroup comparisons of retention and caries were assessed using the Mann-Whitney U test after 3, 6 and 12 months. To determine the correlation between the retention scores and caries development, a contingency coefficient test was performed. The strength of the correlation was rated as follows: $r = 1$, perfect; $r = 0.7–0.9$, strong $r = 0.4–0.6$, moderate $r = 0.1–0.3$ weak; and $r = 0$, indicating no correlation [27].

3. Results

3.1 Baseline characteristics of the sample

Out of 192 patients, only 34 patients were included in this RCT (19 (57.7%) males and 15 (42.3%) females) with an age range of 6–9.92 and a mean age of 7.459 ± 1.139 years. A total of 158 patients were excluded, 151 patients did not meet the inclusion criteria, and seven patients refused to participate. Child behavior ranged from negative to definitely negative, with predominance of negative behavior (76.5%) over the definitely negative behavior (23.5%). The CONSORT flow diagram of the study is shown in Fig. 1. The total number of teeth included was 104 teeth (52 teeth per group) as follows: 52 teeth received UltraSeal XT® hydro™ sealant (Group I) and the other 52 teeth received Helioseal-F Sealant (Group II). Regarding the distribution of sealants among mandibular and maxillary first permanent molars, 62 sealants were applied to the mandibular arch (59.6%), whereas 42 sealants were applied to the maxillary arch (40.4%). Following sealant application and before starting the 3-month follow-up period, three patients dropped out. Two patients discontinued treatment, and one patient left the country; thus, the two groups were equally affected. Finally, the analysis was performed on 31 patients with 49 pairs of teeth after 3, 6 and 12 months.

3.2 Comparison of retention scores among study groups at different follow-up periods

Table 2 presents comparisons of retention among the two groups at different follow-up periods. Regarding the retention within each sealant group, retention was observed to progressively decrease in the teeth of group I and group II after 3, 6 and 12 months, with no statistically significant difference between the two groups ($p = 0.23$, $p = 0.638$ and $p = 0.706$, respectively). Fig. 2 demonstrates clinical intraoral photographs from baseline to 12-months follow-up showing retention scores of Groups I and II.

3.3 Comparison of retention scores by child behavior at different follow-up periods

Table 3 presents the comparisons of retention by child behavior between the two groups at different follow-up periods. The results demonstrated that the retention of sealants decreased progressively after the 3-, 6- and 12-months follow-up in children with both negative and definitely negative behaviors, with the lowest amount of retention after 12 months. In comparing the retention of sealants between children with both behaviors, no statistically significant difference was observed ($p = 0.295$) at the 3-month follow-up period. However, a significant statistical difference was noted in the retention of sealants at the 6- and 12-month intervals when comparing children with negative and definitely negative behaviors ($p = 0.006$, $p < 0.001$, respectively). In children with definitely negative behavior, a higher percentage of teeth exhibited a total loss of sealants.

3.4 Comparison of caries scores among study groups at different follow-up periods

Table 4 presents the comparisons of caries among the two groups at different follow-up periods. Regarding the caries within each sealant group, initial caries gradually increased in the teeth of group I and group II after 3, 6 and 12 months. On the other hand, no statistically significant difference was observed in the caries scores between the two groups during all follow-up periods at 3-, 6- and 12- month intervals ($p = 1$, $p = 0.648$, and $p = 0448$, respectively). Fig. 2 demonstrates clinical intraoral photographs from baseline to 12-months follow-up showing caries scores of groups I and II.

3.5 Comparison of caries scores by child behavior at different follow-up periods

Table 5 presents comparisons of caries by child behavior at different follow-up periods. The results showed that when comparing caries scores between children with negative behavior and those with definitely negative behavior, no statistically significant differences were observed in all the follow-up periods ($p = 1$, $p = 0.486$, and $p = 0.331$). In addition, caries has increased gradually after 6- and 12-month follow-up in children with negative and definitely negative behaviors with the highest percentages of caries at the 12-month follow-up interval.

3.6 Correlation of retention scores and caries development at different follow-up periods

At the 3-month follow-up, no correlation was observed between the retention scores and the development of caries, as an incidence of caries was absent during this time. However, a significant moderate-to-weak correlation was observed between the retention scores and caries development after 6 and 12 months ($r = 0.433$, $p < 0.001$ and $r = 0.365$, $p < 0.001$, respectively).

4. Discussion

The current study was a split-mouth, double-blind RCT aimed at assessing the retention and cariostatic effects of hydrophilic versus hydrophobic RBSs. The results showed no significant difference in retention and cariostatic effects between the hydrophilic and hydrophobic RBSs after 3-, 6- and 12-months follow-up in uncooperative children. Based on these findings, we accepted the null hypothesis.

In this study, a split-mouth design was used; thus, the two sealants could be compared in the same patient at the

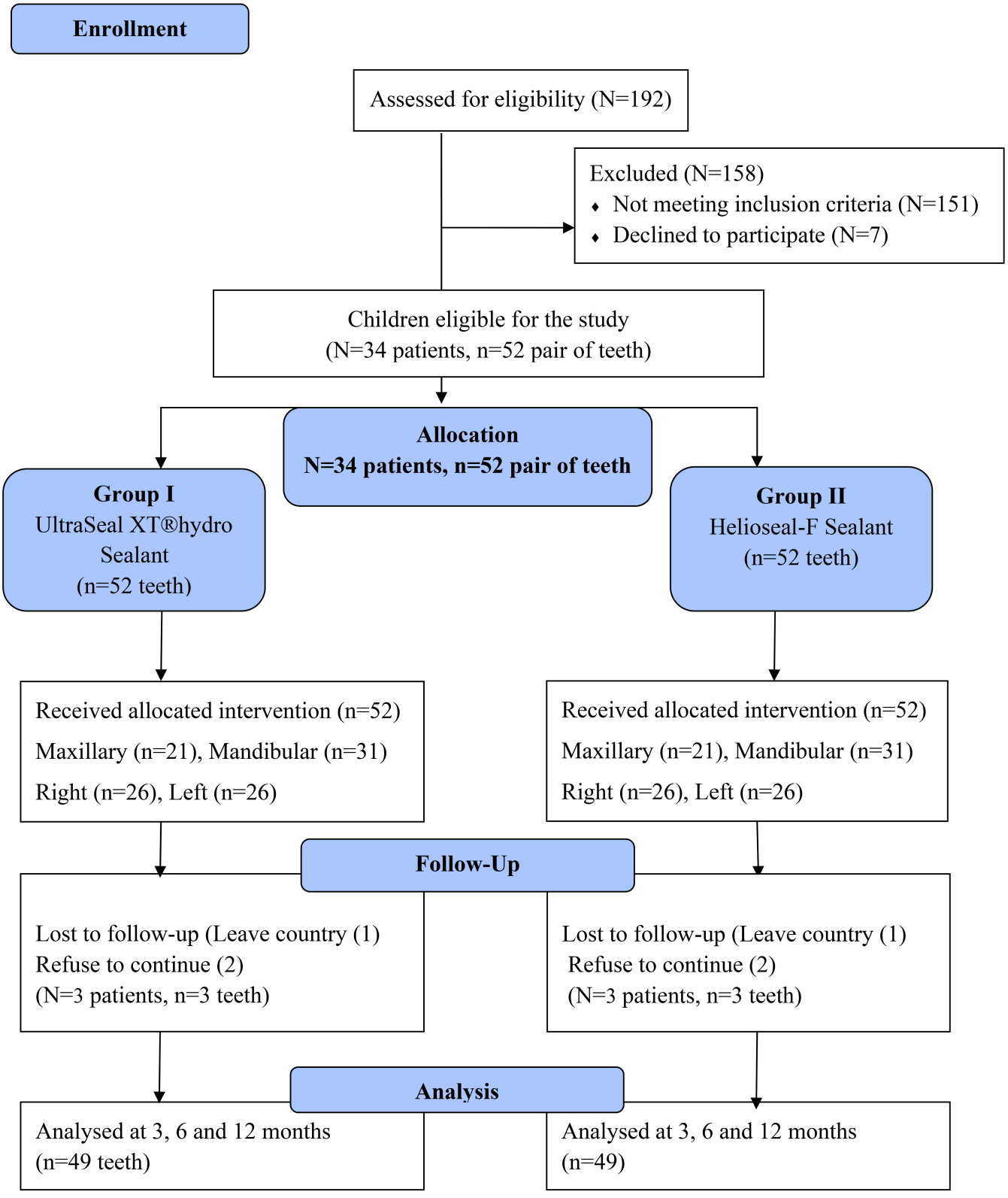

FIGURE 1. Study flow diagram up to 12-months follow-up.

same time in a comparable oral environment to standardize diet, oral hygiene, behaviors, masticatory forces and patient habits. All these factors may significantly affect the rate of caries and amount of sealant retention [28]. A randomized complete block design was used to assign the two groups equally to the right and left sides in the form of randomized blocks. This was done to eliminate selection bias, establish a balance between many confounding factors that may have been unknown to the investigator, ensure that the study groups were not systematically different from each other, and prevent any previous knowledge about group assignment [29].

To the best of our knowledge, no previous studies have as-

TABLE 2. Comparison of retention scores among study group after 3, 6 and 12 months follow-up.

Groups	Scores	Follow-up periods (Months)			*p*-value†
		3 n (%)	6 n (%)	12 n (%)	
Group I					
	A	29 (59.2)	9 (18.4)	2 (4.1)	<0.001*
	B	14 (28.6)	32 (65.3)	27 (55.1)	
	C	5 (10.2)	5 (10.2)	12 (24.5)	
	D	1 (2.0)	3 (6.1)	8 (16.3)	
Group II					
	A	21 (42.9)	7 (14.3)	2 (4.1)	<0.001*
	B	24 (49.0)	33 (67.3)	24 (49.0)	
	C	3 (6.1)	7 (14.3)	16 (32.7)	
	D	1(2.0)	2 (4.1)	7 (14.3)	
p-value∝		0.230	0.638	0.706	

n: Number of teeth.
Group I: UltraSeal XT® hydro™ sealant, Group II: Helioseal-F Sealant.
A: Sealant present on all of the fissure system; B: Sealant present on >50% of fissure pattern but some missing; C: Sealant present on <50% of fissure pattern; D: No sealant present.
*†: Friedman test; ∝: Mann-Whitney U test; *: Statistically Significant p < 0.05.*

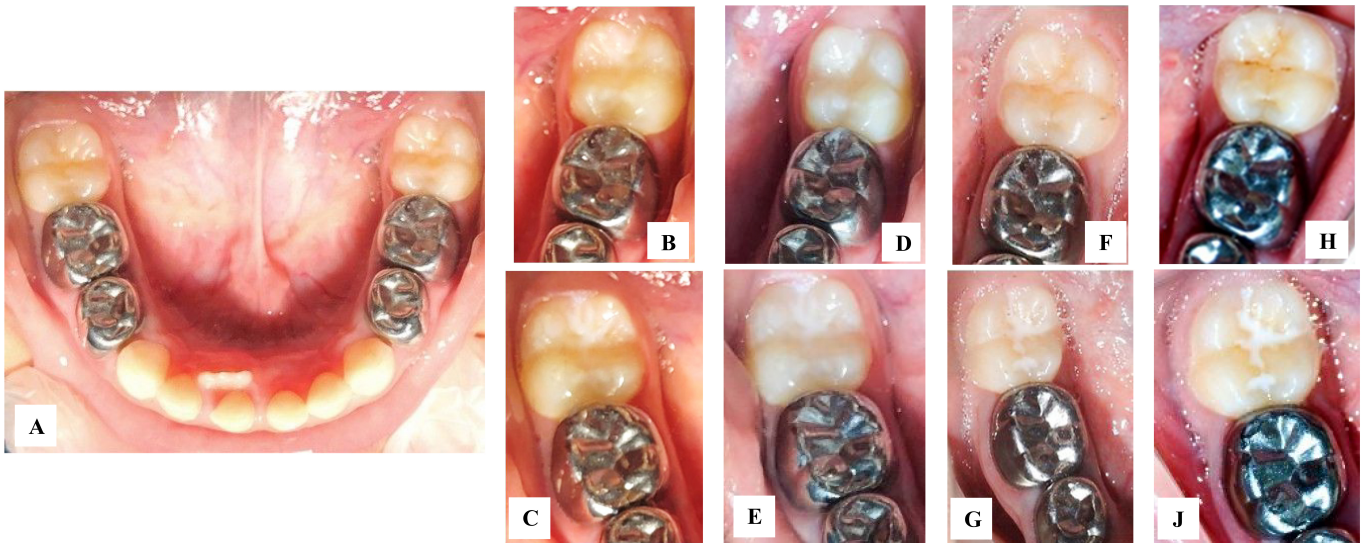

FIGURE 2. Intraoral photographs showing retention and caries scores from baseline up to 12-months follow-up. Retention and caries scores for teeth #36 (hydrophobic sealant) and #46 (hydrophilic sealant). A: sound fissures at baseline in teeth #36 and #46. B,C: sealants at baseline in teeth #36 and #46. D: sealant present on >50% of fissure pattern (score B) with no caries (score 0) #36; E: sealant present on all fissure pattern (score A) with no caries (score 0) #46—at the three months follow-up. F: sealant present on <50% of fissure pattern (score C) with initial enamel caries (score1) #36; G: sealant presaent on all fissure pattern (score A) with no caries (score 0) #46—at the six-months follow-up. H: no sealant present (score D) with enamel caries (score 2) #36; J: sealant present on >50% of fissure pattern (score B) with no caries (score 0) #46—at the twelve months follow-up.

sessed the effectiveness of hydrophilic RBSs in uncooperative children. Therefore, uncooperative children were included in this study. Children were selected based on the Frankl behavior scale as it is a widely accepted tool for research owing to its functionality, ability to categorize behaviors, and reliability [30]. The age of the included children from six to nine was chosen because the first permanent molars typically erupt between the ages of 6 and 7 years, and the occlusal surface of these teeth is considered to be the tooth surface most vulnerable to carious occurrence [31]. A partial isolation method was used in this study for sealant application by utilizing high- and small-volume suctions with cotton rolls because partial isolation has shown similar efficacy to the rubber dam isolation method in the retention of sealants [32].

TABLE 3. Comparison of retention scores among negative and definitely negative behavior after 3, 6 and 12 months follow-up.

Behavior	Scores	Follow-up periods (Months)			*p*-value†
		3 n (%)	6 n (%)	12 n (%)	
Negative behavior					
	A	38 (52.8)	15 (20.8)	4 (5.6)	<0.001*
	B	29 (40.3)	48 (66.7)	43 (59.7)	
	C	5 (6.9)	8 (11.1)	18 (25.0)	
	D	0 (0)	1 (1.4)	7 (9.7)	
Definitely negative behavior					
	A	12 (46.2)	1 (3.8)	0 (0)	<0.001*
	B	9 (34.6)	17 (65.4)	8 (30.8)	
	C	3 (11.5)	4 (15.4)	10 (38.5)	
	D	2 (7.7)	4 (15.4)	8 (30.8)	
p-value∝		0.295	0.006*	<0.001*	

n: Number of teeth.
A: Sealant present on all of the fissure system; B: Sealant present on >50% of fissure pattern but some missing; C: Sealant present on <50% of fissure pattern; D: No sealant present.
†*: Friedman test;* ∝*: Mann-Whitney U test; *: Statistically Significant p < 0.05.*

TABLE 4. Comparison of caries scores among study groups after 3, 6 and 12 months follow up.

Groups	Scores	Follow-up periods (Months)			*p*-value†
		3 n (%)	6 n (%)	12 n (%)	
Group I					
	0	49 (100)	47 (95.9)	40 (81.6)	<0.001*
	1	0	2 (4.1)	5 (10.2)	
	2	0	0 (0)	4 (8.2)	
Group II					
	0	49 (100)	46 (93.9)	37 (75.5)	<0.001*
	1	0	3 (6.1)	6 (12.2)	
	2	0	0 (0)	6 (12.2)	
p-value∝		1.000	0.648	0.448	

n: Number of teeth.
Group I: UltraSeal XT® hydro™ sealant, Group II: Helioseal-F Sealant.
0: Surface sound, no caries; 1: Initial enamel caries; 2: Enamel caries.
†*: Friedman test;* ∝*: Mann-Whitney U test; *: Statistically Significant p < 0.05.*

UltraSeal XT (Hydro) was selected for the experimental group in this trial because of the lack of adequate evidence addressing its clinical effect in uncooperative children. It has a dual function: it is hydrophilic, making it moisture-friendly, and hydrophobic, which makes it durable. The high filler content, which constitutes 53%, in addition to the thixotropic properties, results in high bonding strength to the enamel, which leads to reduction in microleakage and increased retention [33]. Helioseal-F sealant material was used as a control in this trial because of its long record of success in the literature. Helioseal-F is a tooth-colored pit and fissure sealant that contains fillers of fluorosilicate glass (40%) and Bis-GMA matrix. Fluorosilicates have the advantage of releasing fluorides. In addition, this type of sealant was found to have high homogeneity and stability owing to the presence of fillers [34].

Our results showed that the difference in sealant retention within each group over 12 months was statistically significant. This can be explained by the progressive loss of sealants over time due to the gradual degradation of the material, which has been reported in many studies [5, 35, 36]. Moreover, when comparing the retention of hydrophilic sealant to hydrophobic sealant, we found no significant differences during all the follow-up periods which is similar to studies conducted by

TABLE 5. Comparison of caries scores among negative and definitely negative behavior after 3, 6 and 12 months follow-up.

Behavior	Scores	Follow-up periods (Months)			*p*-value†
		3 n (%)	6 n (%)	12 n (%)	
Negative behavior					
	0	72 (100)	69 (95.8)	55 (76.4)	
	1	0 (0)	3 (4.2)	8 (11.1)	<0.001*
	2	0 (0)	0 (0)	9 (12.5)	
Definitely negative behavior					
	0	26 (100)	24 (92.3)	22 (84.6)	
	1	0 (0)	2 (7.7)	3 (11.5)	0.037*
	2	0 (0)	0 (0)	1 (3.8)	
p-value∝		1.000	0.486	0.331	

n: Number of teeth.
0: Surface sound, no caries; 1: Initial enamel caries; 2: Enamel caries.
†*: Friedman test;* ∝*: Mann-Whitney U test; *: Statistically Significant* $p < 0.05$.

Bhat *et al.* [17], (2013), Askarizadeh *et al.* [16], (2017), and Priyadharshini *et al.* [37], (2021) and a recent systematic review [8].

In contrast, a study conducted by Schlueter *et al.* [22] (2012) showed that this difference was significant, favoring hydrophobic sealants. This could be a result of the varied etching times, as the hydrophobic sealant required a longer etching time (40 seconds) than the hydrophilic sealant (20 seconds). Additionally, Prabakar *et al.* [21], (2018) found a significant difference in retention between hydrophilic and hydrophobic RBSs, favoring the hydrophilic sealant after a follow-up duration of only 3 months. Using different types of etching or bonding strategies can explain previous inconsistencies in the outcomes. Furthermore, Khatri *et al.* [19], (2015) showed that hydrophilic sealant was significantly able to achieve complete retention in 72% of cases versus 50% in the hydrophobic RBSs after 12 months of follow-up period. This was not in line with our findings and could be due to different types of hydrophilic RBSs used in the two studies where their study utilized Embrace-Wetbond sealant and our study used UltraSeal XT® hydro™ sealant which has higher fillers and mechanical properties than Embrace-Wetbond sealant.

Although no significant differences were observed between the two sealants in the current study, the retention of the hydrophilic sealant was higher than that of the hydrophobic sealant. This agrees with the results of Bhatia *et al.* [14], (2012) and Baheti *et al.* [15], (2020). Deep penetration with a higher number of resin tags caused by the thixotropic behavior of hydrophilic sealants can explain this [10].

Significantly lower retention was observed among children with definitely negative behaviors than among those with negative behaviors. This may be due to several behavioral factors. Those with negative behaviors have lower levels of cooperation and shorter attention spans [38], which might contribute to lower retention. In addition, high levels of stress and anxiety during dental visits can increase saliva flow [39], which negatively affects sealant retention. The findings of this study are consistent with those of McCafferty and O'Connell (2016) [12]. They discovered that the more intact the sealants recorded at 12 months, the higher the participant behavior score on the Frankl Behavior Rating Scale. Our study results are in agreement with those of McCafferty and O'Connell (2016). They found that after the 1-year period, the lowest amount of intact sealant (25%) was observed in children with negative behavior. This finding aligns with the analysis conducted by Feigal *et al.* [40] (2000), which highlights patient behavior and compliance as significant factors in sealant retention studies.

The results showed that both hydrophilic and hydrophobic sealants completely prevented the occurrence of caries in the first 3 months of the trial, which is consistent with the findings of Prabakar *et al.* [21], (2018). However, caries occurrence increased over time within each group at 6 and 12 months, which may be attributed to the progressive loss of sealant retention and disintegration over time [35].

A comparison between both sealants in caries occurrence revealed no significant difference after 12 months of follow-up, which was similar to the findings of Bhat *et al.* [17], (2013), Askarizadeh *et al.* [16], (2017), and Alharthy *et al.* [8], (2022). This finding could be linked to similar retention rates of the two types, which could affect caries prevention.

Although our results were not significant, caries occurrence in the hydrophilic group was slightly lower at the 6- and 12-month follow-ups. This finding was in line with study by Khatri *et al.* [19], (2015) and Ratnaditya *et al.* [20], (2015). This may be due to the improved ability of hydrophilic sealants to penetrate deep inside the fissures, thereby reducing leakage and caries in these areas.

The findings of Schlueter *et al.* [22] (2013) contradicted our results. They observed that caries had occurred only in the hydrophilic sealant group, but with a low percentage (4%). Similarly, Mohanraj *et al.* [23], (2019) found that caries appeared only after 9 months of follow-up and was higher in the hydrophilic sealant group, which is not consis-

tent with our results. Different evaluation criteria (cavitation and/or opacity at fissures and Modified Simonsen's criteria) for detecting caries were used by Schlueter *et al.* [22] (2013) and Mohanraj *et al.* [23] (2019), which could explain the current disagreement regarding caries outcomes. Furthermore, Priyadharshini *et al.* [37], (2021) in their 6-month follow-up study did not record any incidence of caries, which disagreed with our results. This might be because the inclusion criteria for recruiting first permanent molars in the two studies were different; in Priyadharshini *et al.* [37], (2021) molars with an ICDAS II score of 0 or 1 were included, whereas in the current study, only molars with a score of 0 were included, and any tooth with initial enamel caries with a score of 1 was counted as having caries during follow-up visits.

In terms of the relationship between retention scores and caries development, we observed no correlation at the 3-month follow-up, likely because no instances of caries were detected during this timeframe. This finding aligns with that of a previous study conducted by Prabakar *et al.* [21] in 2018, which also reported similar results at the 3-month mark. This lack of correlation could be attributed to the relatively short duration between sealant loss and caries development. However, our study revealed a statistically significant correlation between the retention scores and caries development at 6 and 12 months. During this extended period, caries occurrence increased, which could be attributed to the gradual loss of sealant retention and disintegration over time [35]. These findings suggest that the loss of coverage in susceptible pits or fissures immediately increases the risk of caries in exposed areas [40].

This study was conducted based on the latest version of CONSORT to ensure optimal adherence to the research quality used in decision-making. The use of sealants that can tolerate moisture offers a remarkable advantage, especially for the management of uncooperative children. To the best of our knowledge, this RCT was the first randomized controlled trial to evaluate hydrophilic sealants against hydrophobic sealants in uncooperative children. In addition, the split-mouth design used in this study allowed for the evaluation of both sealants under the same circumstances. The advantage of this method is that it controls for all confounding factors that may lead to bias in the outcomes. Finally, a double-blind protocol and calibration of the operator and evaluators were performed to ensure the optimal consistency and accuracy of the evaluation, thereby increasing the reliability and validity of the results.

However, a limitation of this study is the 1-year follow-up period, as this time frame is considered relatively short for assessing caries development and progression. The reason for this short follow-up period was that it took longer than usual to recruit all patients due to the difficult timing and nature of restrictions imposed on dental practice during the COVID-19 pandemic. The study was also conducted on a defined population that visited university dental clinics; thus, further studies are needed to explore the generalizability of the findings. Furthermore, this study did not include any cooperative children; only uncooperative children were included. Although it was not known whether compliance would affect sealant outcomes, the primary goal was to investigate the effectiveness of the two sealants and not to address the influence of behavior on the retention of sealants. However, further studies are needed to confirm the findings of the present study on a larger scale, including all behavioral categories. Lastly, additional research should be conducted to investigate other variables that were not addressed in this study, such as the influence of decayed missing filled teeth (dmft) or oral hygiene status on the effectiveness and success of fissure sealants.

5. Conclusions

Based on the results of this study, we conclude that there is no significant difference in retention and caries occurrence between hydrophilic and hydrophobic RBSs. Furthermore, children with negative behavior had better retention rates for both groups of sealants than children with definitely negative behavior.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

HA, HE, and AA—conceptualized and designed the research study. HA and HE—performed the research. AN, NA and KB—analyzed and interpreted the data. HA, HE, NA. AA, AN and KB—wrote the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia (approval number: 29-04-2020) on 29 April 2020. This study was registered in the Clinical Trial Registry before and after ethical approval was obtained (NCT04560985). All parents who agreed to enroll their children in the study ensured that their children met the inclusion criteria and signed an informed written consent form.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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