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ORIGINAL RESEARCH

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Effectiveness of Dryshield system *vs.* cotton roll isolation on sealant's retention, placement time, and children's acceptance in a dental school setting

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Abstract

Background: Effective isolation from moisture is a crucial component in the application of pit and fissure sealants (PFS) in children. The Dryshield system is a recent dental isolation technology. This study conducted a randomized clinical trial to assess pits and fissure sealants' (PFS) retention, patients' acceptance, and placement time needed during PFS application using two isolation techniques—Dryshield system (DS) and cotton roll isolation (CRI)—within a dental school environment. **Methods**: The trial involved participants aged 7 to 12 years, each with at least one caries-free permanent first molar (PFM) in each quadrant, who attended a university dental clinic and met the eligibility criteria. Participants were randomly divided to receive sealants using either DS or CRI methods, with their placement time recorded. An interview-based questionnaire was used to evaluate patients' acceptance. PFS retention was assessed at 6, 12 and 18 months. **Results**: About 153 PFM were sealed (DS = 81, CRI = 72). The average placement times (in seconds) were 2.37 $\pm$ 0.7 for the DS group and 2.21 $\pm$ 0.6 for the CRI group. Most sealants (66.6%) remained completely retained after 18 months. However, no significant difference was detected between the groups. Participants' acceptance was similar between the groups across the assessed parameters. Both the Dryshield and CRI techniques were well accepted by pediatric participants. The placement time and sealant retention rates were comparable when senior dental students applied either technique. **Conclusions**: The Dryshield® system can be considered an effective option, comparable to cotton roll isolation, for applying pit and fissure sealants in pediatric patients. **The PROSPERO Registration**: The study was registered with ClinicalTrials.gov as NCT05749991.

Keywords

Fissure sealants; Isolation; Dryshield; Molars; Clinical trial; Retention

1. Introduction

Dental caries is among the most widespread chronic and complex disorders affecting individuals [1–3]. In children, dental caries is more prevalent in the pits and fissures of permanent molars [4–6]. Preventing dental caries in children is essential to preserve permanent dentition [7]. Dental sealants are one of the successful materials for preventing occlusal dental caries [7]. Pit and fissure sealant (PFS) is advised for primary and permanent dentitions in patients at risk of developing or progressing dental caries [7, 8]. When correctly applied, dental PFS achieves three major goals: preventing dental caries formation, delaying the initial phase of caries progression, and inhibiting the spread of cariogenic bacteria [7, 9].

To ensure effectiveness, PFS must be applied under appropriate conditions [10]. The capacity to manipulate the wet conditions in the mouth and around the specific teeth undergoing treatment is known as moisture control [11]. Rubber dam isolation (RDI) and cotton roll isolation (CRI) are two common techniques for moisture control during the sealant application [12, 13]. Effective moisture isolation is essential for the proper placement of sealants [12]. The American Dental Association recommends using RDI to apply fissure sealants [4], although pediatric dentists most frequently employ CRI [14]. Children's resistance to RDI is frequently encountered as a challenge [15, 16]. RDI requires local anesthesia, while CRI does not. Also, RDI use is delayed until the tooth is sufficiently erupted to permit dam placement. On the other hand, placing cotton rolls inside the mouth to use them as an isolation method during sealant placement has been reported to elicit gag reflex, induce taste discomfort, and necessitate repeated replacement of the wet cotton rolls [17]. Also, CRI is deemed time-consuming when both the upper and lower teeth are planned for PFS [17].

A recent dental isolation technology, Dryshield System (DS), was unveiled [18]. DS is similar to the Isolite System (IS); nevertheless, DS is autoclavable without illumination.

DS is designed to isolate two quadrants at the same time. A mouthpiece of latex-free silicone in different sizes connects to the isolation system. The DS mouthpieces' key features include soft tissue retraction, continuous suctioning, and bite blocking [17, 18]. A limited number of clinical trials have compared sealant retention, placement time, and children's acceptance of IS with those of CRI or RDI [17, 19–23]. To the best of our knowledge, there is a dearth of studies examining PFS retention, chair time and patients' acceptance using DS isolation compared to other isolation types. Only one published study has been found that evaluated patients' satisfaction and acceptance between DS and RDI [24]. Therefore, this study aimed to evaluate the retention rate of pit and fissure sealant in pediatric patients using a Dryshiled system compared with cotton roll isolation in a dental school setting. Also, PFS placement time and children's acceptance between the two isolation systems were investigated.

2. Material and methods

This randomized clinical trial was approved by the Kuwait University Health Sciences Institutional Ethical Committee (VDR/EC/3344). It was carried out at the Kuwait University Dental Clinics, Kuwait. It started in June 2018 and was intended to be for two years follow-up. Due to the coronavirus outbreak, the trial was concluded in February 2020. This study adhered to the Consolidated Standards of Reporting Trials (CONSORT) recommendations (Fig. 1). The study was registered with ClinicalTrials.gov as NCT05749991.

2.1 Eligibility criteria

The inclusion criteria were as follows: (1) healthy patients with no medical conditions; (2) ages ranging from seven to twelve years old; (3) at least one fully erupted first permanent molar free from caries; (4) molar tooth with normal anatomy; (5) molar tooth with an International Caries Detection and Assessment System (ICDAS) score of 0–2; (6) no previous sealants or restorations on the molar under investigation; (7) cooperative patients; and (8) consent from the legal guardian for participation in the study.

The exclusion criteria were as follows: (1) history of chronic disease; (2) inability to attend follow-up visits; (3) partially erupted molars; (4) permanent molar with enamel defect or abnormal anatomy; (5) uncooperative behavior—Frankl Behaviour Rating Scale of 1 or 2; (6) Allergies to latex; (7) Severe gag reflex.

2.2 Sample size

For power analysis for a repeated-measures experiment in G*Power software (version 3.1.9.7, Heinrich Heine University Dusseldorf, Dusseldorf, NRW, Germany), an Analysis of Variance (ANOVA) was performed to compare the statistical significance of the mean retention rate using the two techniques (CRI and DS) to provide fissure sealants. An alpha of 0.05, a power of 0.80 (80%), and a medium effect size ($f = 0.30$) were used to calculate the required minimum sample size of 50 teeth in each group [25]. With a 10% expected attrition rate, n = 5 was added, resulting in a sample size of 55 teeth.

2.3 Screening of participants and randomization

A single experienced pediatric dentist (AA) screened each participant to determine eligibility for the study. Oral examination was conducted in the University clinic settings, by trained senior dental students, under headlamp light using dental mirrors and blunt probes to examine permanent first molars (PFMs). Two bitewing radiographs were taken as part of initial documentation and clinic admission. The PFMs were checked for the absence of dental caries or anomalies. Informed consent and assent were obtained from the parents/legal guardians and their children before the study commenced.

Randomization was done using R 2.11.1 software (R Foundation for Statistical Computing, Murray Hill, NJ, USA) to generate random numbers. Simple random allocation was used to ensure equal randomization for each isolation system. Each participant was provided with an envelope containing a printed participant number. Each number specified the isolation technique type and the application sequence assigned to that participant. Only one isolation technique was used for each participant.

2.4 Intervention

Each participant in the study received the sealant application in the university clinics from their primary care provider, a senior dental student (7th-year graduating student). The participants handed the envelope to the primary care provider to identify the isolation system and its technique. Ten senior students were involved in the study and were trained by an experienced pediatric mentor (AA). All PFS applications were performed under the close supervision of a single experienced pediatric mentor (AA). All clinical procedures were carried out using a strict aseptic sterile technique consistent with standard practice in the university dental clinic.

All PFMs were cleaned with non-fluoridated pumice paste using a low-speed handpiece and a prophylaxis polishing brush before isolation. The teeth were thoroughly rinsed and dried with a dental air spray. Finally, if any debris was present, a blunt instrument was used to check for it, and re-cleaning was performed as necessary.

2.5 CRI procedure

The operator used and secured a medium-sized #2 cotton roll (Cotton Roll, ASA Dental, Italy). For maxillary isolation, cotton rolls were positioned on the cheek side of the teeth in the buccal fold. For mandibular isolation, cotton rolls were placed in the mucobuccal fold and the lingual side of the arch of the mandible. Cotton rolls were replaced after each acid etch rinsing. A dental assistant handled a high-volume suction.

2.6 DS procedure

A pediatric mouthpiece (Dryshield Systems®, Marlborough, MA, USA) was selected. Petroleum jelly was applied to the participant's lips. Instructions were given to participants to keep their mouths open. The mouthpiece was placed in the participant's mouth, while the cheek shield component was folded forward toward the tongue retractor. The bite

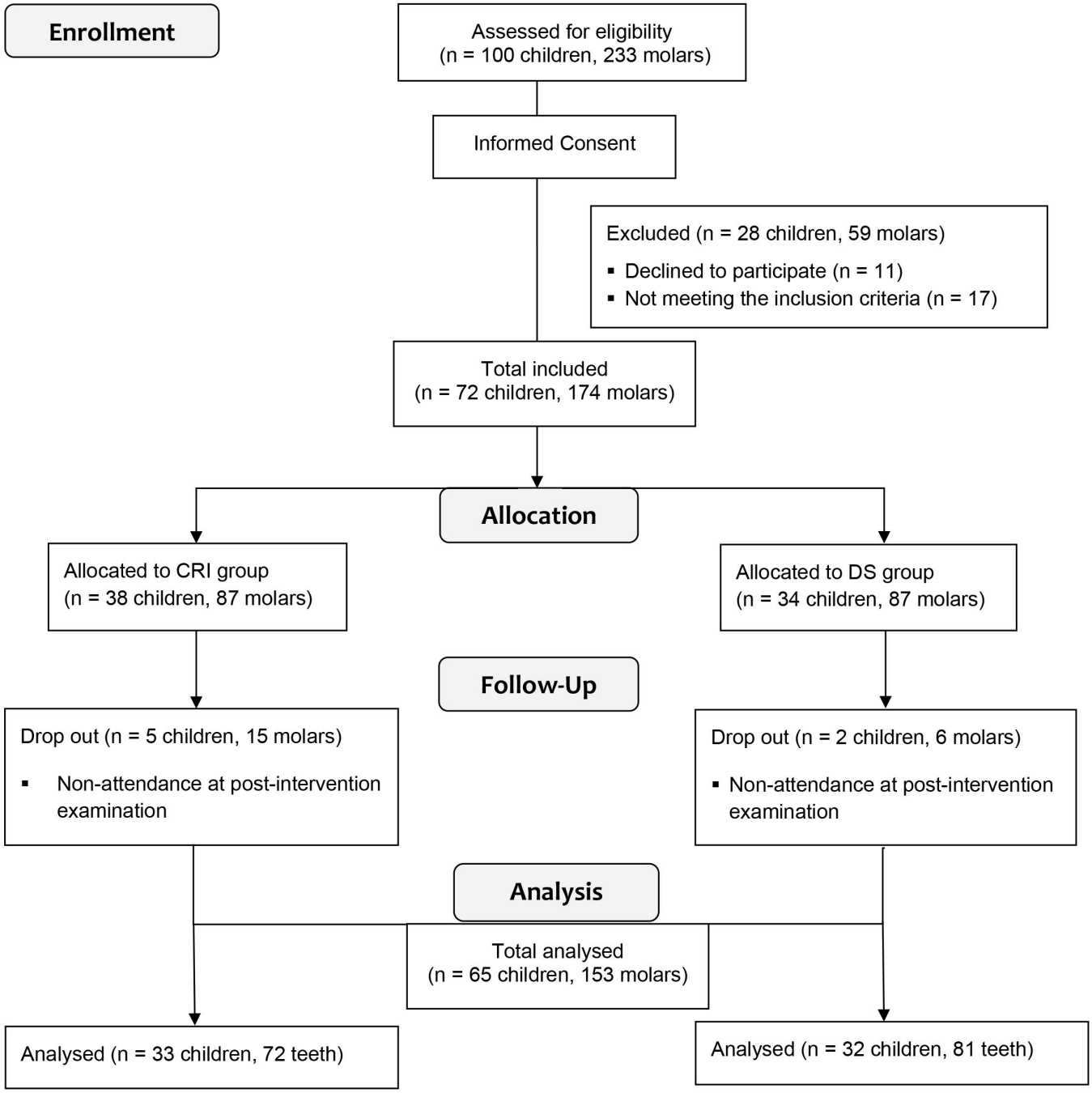

FIGURE 1. Flow diagram of study participants. DS: Dryshield system; CRI: Cotton Roll Isolation.

block component of the system was positioned on the occlusal surface. Then, the participant was instructed to bite down. Every procedure was done according to the manufacturer's guidelines.

2.7 PFS procedure

Following the application of the isolation technique, each tooth was etched for 30 seconds with a 37% phosphoric acid dental etching gel (Ultra-Etch, Ultradent, Utah, USA) [26]. The etched tooth was thoroughly rinsed and dried for 15 seconds. After drying, the tooth was examined to ensure that the enamel was properly etched and had a frosty white appearance [27]. Resin-based pit and fissure sealant (3M ESPE, St. Paul, MN, USA) was applied to the tooth surfaces, ensuring it covered the pits and fissures. The material was placed approximately halfway-up the inclined plane of the cusp ridge. The sealant was a light-cure and low viscosity sealant with a unique patented white color. The occlusal and palatal fissures of the maxillary molars, as well as the occlusal and buccal fissures of the mandibular molars, were sealed. Any air bubbles present were removed using a sharp explorer or a micro brush. According to the sealant manufacturer, the sealant was cured for 20 seconds. Finally, the occlusion was checked, and any necessary adjustments were made with finishing burs. For each participant, all PFS placements were handled by a single operator with the help of a dental assistant.

2.8 Follow-up clinical evaluation

Clinical evaluation of patients at 6, 12 and 18 months of sealant placement, was conducted by a study supervisor acting as a blinded outcome assessor (QA). Follow-up clinical exams were performed using a mouth mirror and a dental probe in a dental chair. The criteria for evaluation were based on Simonsen's criteria [24], which include the following:

- Completely retained—If some peripheral fissures were uncovered following sealant wear, but no ledges were visible.
- Partially retained—If, due to wear or material loss, part of a previously sealed pit/fissure was exposed.
- Missing—No sealant detected.

If the sealant was completely intact during the follow-up, it was considered a "Success". If the sealant was partially retained or missing, it was considered a "failure" and was resealed.

2.9 Placement time measurement

An assigned assistant measured the time in seconds, using a stopwatch for each isolation technique. The timing started with the placement of the first cotton roll for CRI and the insertion of DS. For each isolation method, the time measurement concluded when the isolation part was entirely removed from the mouth.

2.10 Interview-based questionnaire

Following the completion of each PFS, a six-item interview-based questionnaire developed from a previous study [19] was used to evaluate the participant's acceptance of the isolation technique employed. The questionnaire was administered verbally at the end of the visit by an assigned dental assistant. Each participant was shown the isolation technique used; questions were repeated if needed. Each patient was given sufficient time to respond to encourage an accurate response for each question.

2.11 Statistical analysis

Data entry was completed in an Excel spreadsheet and analyzed using Statistical Package for the Social Science version 25.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean ± standard deviation (SD) and analyzed using either an independent *t*-test or a Mann-Whitney test based on normality. Frequencies and percentages were used to describe dichotomous data, which were compared using the Chi-Square test or Fisher's exact test. Repeated measures ANOVA assessed the time required to place sealants among the groups. Pearson's correlation coefficient examined the link between age and time taken for the procedure. The sealant placement duration, by arch, gender and tooth type, was analyzed by independent *t*-tests. Differences in technique acceptance for each question were evaluated using a one-sample chi-square test. Finally, a mixed-effects logistic regression model, accounting for individual-level clustering, was employed to investigate the findings. The level of significance for all tests was set at $p < 0.05$.

3. Results

A total of 100 children were invited to participate, of which 17 did not meet the inclusion criteria, and eleven refused to participate (Fig. 1). The sample originally comprised 72 children. Only 65 children (38 male, 27 female) completed the trial with follow-up exams. Seven children did not attend the post-intervention examination. All participants were between seven and eleven years old (Table 1). Thirty-two children received DS isolation, and thirty-three received CRI. A total of 153 teeth were fissure-sealed (DS = 81, CRI = 72), of which the majority were left maxillary first molars. No significant difference was detected in tooth or jaw type among the isolation groups ($p > 0.05$). The mean age of the participants was eight, with no significant difference in age among the groups ($p = 0.493$). More males were isolated using DS (68.8%); however, the difference was insignificant ($p = 0.097$).

3.1 PFS retention with follow-up time period

Table 2 demonstrates the comparative analysis of PFS retention with the follow-up time period between the two isolation groups. The majority of sealants were fully retained after 6 (79%), 12 (71.9%) and 18 (66.6%) months of sealant placement. CRI groups have slightly more retained PFS than the DS group at all follow-up periods (Table 2). However, the two groups had no statistically significant difference ($p > 0.5$). Both groups showed a statistically significant difference in retention rates between 6–12 and 6–18 months of analysis ($p < 0.001$).

3.2 Mixed-effects logistic regression

Table 3 illustrates the effectiveness of the two isolation techniques. Teeth isolated using the DS method had 1.63 times the odds of achieving complete retention at 6 months compared to those isolated using the CRI method (odds ratio (OR) = 1.63, 95% confidence interval (CI): 0.73–3.64) and 1 time the odds of having complete retention at 12 and 18 months when compared to CRI-isolated teeth (OR = 1.04, 95% CI: 0.51–2.13; OR = 1.02, 95% CI: 0.51–2.01). However, no significant difference was detected.

3.3 Placement time measurement

The overall time for sealant placement using each isolation technique was compared (Table 1). There was no significant difference in the time of sealant placement among the groups ($p = 0.139$). When the time for isolation was compared between the arches, the placement of sealants in teeth isolated with both systems took longer in the maxilla than in the mandible. However, this finding was insignificant between the study groups ($p = 0.262$). A negative correlation was seen for both types of isolation and age (DS = −0.072, CRI = −0.124). The placement time decreased as the children's age increased. Although this association was stronger in the CRI group compared to the DS group, no statistical significance was documented (DS, $p = 0.299$; CRI, 0.523).

TABLE 1. General characteristics of the study population (n = 65, competed the study).

Variable	Dryshield Isolation N = 32 child (%) 81 teeth	Cotton Roll Isolation N = 33 child (%) 72 teeth	*p* value
Age, mean (SD)	8.06 (1.35)	8.38 (1.44)	0.493
Gender			
Male	22 (68.8)	16 (48.5)	0.097
Female	10 (31.2)	17 (51.5)	
Number of teeth sealed, mean (SD)	2.44 (1.23)	2.15 (1.12)	0.362
Sealant time (seconds), mean (SD)			
All teeth	2.37 (0.71)	2.21 (0.68)	0.139
Maxilla	2.45 (0.64)	2.23 (0.76)	0.339
Mandible	2.30 (0.76)	2.18 (0.69)	0.754

$p < 0.05$ = Significant. SD: standard deviation.

TABLE 2. Comparison of pit and fissure sealant retention among the isolation groups at 6, 12 and 18 months.

Duration	Dryshield Isolation N = 81, (%)				Cotton Roll Isolation N = 72, (%)				Between groups *p* value
	Fully Retained	Partially Retained	Missing	Resealed	Fully Retained	Partially Retained	Missing	Resealed	
6 mon	61 (75.3)	16 (19.8)	4 (4.9)	- 20 (24.7)	60 (83.3)	8 (11.1)	4 (5.6)	- 12 (16.6)	0.341
12 mon	58 (71.6)	3 (3.7)	-	23 (28.3)	52 (72.2)	8 (11.1)	-	20 (27.7)	0.122
18 mon	54 (66.6)	4 (4.9)	-	27 (33.3)	48 (66.6)	4 (5.6)	-	24 (33.3)	0.980
Within groups		*p* value					*p* value		
6–12 mon		<0.001*					<0.001*		
6–18 mon		<0.001*					<0.001*		

**p < 0.05 = Significant. mon: month.*

TABLE 3. Mixed-effect logistic regression model.

Timepoint	Comparison	OR	95% CI	*p*-value
6-mon	DS *vs.* CRI	1.63	0.737–3.647	0.226
12-mon	DS *vs.* CRI	1.04	0.51–2.13	0.940
18-mon	DS *vs.* CRI	1.02	0.51–2.01	0.967

mon: month; DS: Dryshield system; CRI: cotton roll isolation; OR: odds ratio; CI: confidence interval.

3.4 Participants' acceptance

The participants were asked about specific acceptance parameters related to each type of isolation, and their responses were documented (Table 4, Fig. 1). The majority of participants (75%) reported that both isolation systems were comfortable during their use. Although 45% of the CRI group stated that the isolation uncomfortably stretched their mouth compared to those of the DS group (34%), the result was not significant ($p = 0.362$). On the other hand, around half of the DS group described that they tasted the material compared to a third of the CRI group. When asked about the feeling of gagging during the application, most participants in both groups (81%) positively agreed. Overall, there were no statistically significant differences in the participants' responses between both groups.

TABLE 4. Responses of participants' preference parameters among the isolation groups.

Preference Parameters	Dryshield Isolation N = 32, (%)	Cotton Roll Isolation N = 33, (%)	*p* values
Was the used system of isolation for this procedure noisy?			
Yes	8 (25.0)	6 (18.2)	0.504
No	24 (75.0)	27 (81.8)	
Was the used system of isolation uncomfortably stretching your mouth, cheeks and lips?			
Yes	11 (34.4)	15 (45.5)	0.362
No	21 (65.6)	18 (54.5)	
Would you regard the used system as comfortable?			
Yes	24 (75.0)	26 (78.8)	0.717
No	8 (25.0)	7 (21.2)	
If we did the procedure again, would you prefer the same system?			
Yes	21 (65.6)	24 (72.7)	0.535
No	11 (34.4)	9 (27.3)	
Did the used system for isolation make you feel as if you needed to gag?			
Yes	26 (81.3)	27 (81.8)	0.953
No	6 (18.7)	6 (18.2)	
Did you taste any of the materials used?			
Yes	18 (56.2)	11 (33.4)	0.102
No	14 (43.8)	22 (66.6)	

$p < 0.05$ = Significant.

4. Discussion

The Dryshield system is a recently developed dental isolation system, similar to the Isolite System, used to control moisture during PFS application. Yet, no published study has evaluated the retention rate, patients' acceptance, and placement time of PFS application using the DS isolation compared to other isolations. This randomized clinical study aimed to detect the difference in the parameters mentioned above using the DS system compared to cotton roll isolation.

According to the National Institute of Health, the sealant retention rate after one year was 85%, then it was reduced to 50% after five years [7]. The rate of sealant retention decreases gradually with time, and most sealants exhibit 5 to 10% annual failure rate [7]. In our study, the overall sealant retention was about 72% after one year and 66.6% after 18 months. No significant difference was detected in the PFS retention rate between the two isolation groups. Inadequate isolation during the treatment process could explain the loss of sealant retention. This issue might arise from an improperly fitted isolation device, a child's cooperation, or contamination with saliva or gingival crevicular fluid during PFS placement [8, 10]. The operator's skill can also determine the treatment's success [28]. All operators in our study were senior dental students. Previous research on the retention rates of fissure sealants using two isolation techniques, IS versus CRI [22, 23] and RDI versus CRI [12, 19, 21], also found that there were no significant differences in the retention rates. Our results are consistent with previous findings, indicating that all isolation techniques do not impact sealant retention if appropriately used on patients.

The results of our study showed that the average placement time was similar using the DS or CRI technique, regardless of the arch type or participant's age. Collette *et al.* [19] and Alhareky *et al.* [20] reported that the placement of sealants took significantly longer with CRI than IS. On the contrary, Mattar *et al.* [22] demonstrated that IS took longer to apply PFS than CRI. The variation in recording the starting point could be a main factor. In this study, the DS insertion was considered the beginning of the time recording, consistent with Collette's starting time for recording. However, Alhareky's beginning time was considered when adapting the IS mouthpiece on the system, including any adjustments needed.

In terms of participants' acceptance, the results showed that DS was noisier than CRI, though statistically insignificant. This result agrees with the previous studies [19–22] and could be attributed to DS's continuous suctioning property. Both DS and CRI were found to be less painful and more comfortable for participants. Regarding participants' satisfaction, almost equal numbers of children preferred to use the same isolation system (DS or CRI) for the PFS application. These findings are consistent with findings by Bagher *et al.* [24] and Collette *et al.* [19]. On the other hand, Mattar *et al.* [21] showed that most of their participants preferred CRI significantly over IS.

There are some limitations in our study. All our study participants were cooperative. The effect of behavior on the isolation acceptance was not considered. Therefore, further studies on isolation systems, including children with various behaviors, are recommended. Also, this study included only two isolation techniques: DS and CRI. Additional research

is advocated to explore the impact of DS and other isolation techniques, *e.g.*, RDI, on sealant retention over more extended and more consistent periods. Additionally, our study planned to follow each sealant at 6-, 12-, 18- and 24-months post-placement. However, college dental clinics were closed during the COVID-19 pandemic lockdown. Due to the fact that the baseline data of sealant placement varied among participants, a constant follow-up visit was unachievable. Also, some participants could not be followed due to unreachable phone numbers or traveling abroad. Missing follow-up data might impact the generalizability of the results, especially if those to follow-up have different outcomes. Including a larger and more diverse sample size can buffer the impact of some lost follow-ups on the overall study.

5. Conclusions

In conclusion, our findings revealed that the type of isolation had no effect on PFS retention, placement time, and patients' acceptance. Also, PFS retention was not influenced by the dental arch, type of tooth, or the follow-up duration for sealant placement. The Dryshield® system could be a valid alternative to CRI during sealant placement in pediatric patients.

AVAILABILITY OF DATA AND MATERIALS

Raw data have been stored securely at Kuwait University Dental School. Data are available upon request to the corresponding author.

AUTHOR CONTRIBUTIONS

ANA, DA—conceptualization. ANA, SM and DA—methodology. ANA, SM and QA—data collection. ANA—data analysis; writing–original draft preparation. DA—quality assurance. ANA, DA and QA—writing–review and editing. All authors have read and agreed to the published version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethics committee of the Health Science Centre, Kuwait University, Kuwait, approved the study protocol (VDR/EC/3344). Guidelines documented in the Helsinki-2013 Declaration of experiments on humans were adopted for this study. Informed consent was obtained from the participants and their legal guardians. Before signing the consent form, all participants were informed that they could withdraw from this study at any time without any consequences; they were also encouraged to ask questions.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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