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ORIGINAL RESEARCH

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Etch-and-rinse versus self-etching sealants for preventing occlusal carious lesions in erupting permanent molars: a randomized controlled trial

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Abstract

Background: This triple-blind, randomized controlled trial evaluated and compared the effectiveness of resin-based sealants (RS) and giomer-based sealants (GS) in preventing dental caries in erupting permanent molars in children. **Methods**: Erupting permanent molars in children (aged 5–14 years) with non-cavitated carious lesions (International Caries Detection and Assessment System scores 1–2) were enrolled and randomly assigned to receive either GS or RS. Clinical assessments were performed at 3, 6, and 12 months. The primary outcome was sealant retention. The secondary outcomes included the incidence of caries and sealant quality (anatomical form, marginal adaptation, superficial texture, and marginal discoloration). **Results**: Among a total of 88 erupting permanent molars in 88 children (aged 6.93–12.11 years) included in the analysis, the RS group demonstrated significantly higher total retention compared with the GS group at both 6 (90.7% (39/43) *vs.* 59.1% (26/44); $p = 0.002$) and 12 (61.9% (26/42) *vs.* 17.1% (7/41); $p < 0.001$) months. Regarding caries, no new lesions were detected in the RS group throughout the study period. In the GS group, new caries were identified in 2.3% (1/44) of teeth at 6 months and 4.9% (2/41) at 12 months. As only two caries events were observed overall, this study was underpowered to detect between-group differences in caries incidence. However, a weak, significant positive correlation was observed between sealant loss and caries development at 12 months ($r = 0.221$, $p = 0.045$). **Conclusions**: While both the RS and GS were associated with a low incidence of caries over 12 months, the RS demonstrated significantly superior retention and overall clinical quality. These findings highlight the clinical trade-off between the enhanced durability of RS and the potential for a simplified application with GS. Further long-term studies are warranted to fully evaluate these differences. **Clinical Trial Registration**: ClinicalTrials.gov Identifier: NCT05969756.

Keywords

Early carious lesions; Fit and fissure sealants; Erupting permanent molars; Pediatric dentistry

1. Introduction

Dental caries remains one of the most prevalent chronic diseases worldwide [1], with the occlusal surfaces of newly erupted permanent molars particularly susceptible during the early post-eruptive years [2]. This susceptibility is largely due to immature enamel and the complex morphology of pits and fissures, which promote plaque accumulation and hinder effective oral hygiene [2]. Despite advances in preventive care, caries incidence in these teeth remains high, highlighting the need for timely and effective interventions [3].

Sealants are well established as a highly effective method for preventing occlusal caries, particularly when applied during the eruption period [4]. Among available materials, resin-based sealants (RS) are widely recognized for their strong mechanical retention and long-term clinical success [4]; however, their application requires a multi-step procedure and strict moisture control, which can be challenging in pediatric patients or in partially erupted teeth where isolation is often suboptimal [5]. These limitations have spurred interest in alternative sealant materials that are easier to apply while maintaining preventive efficacy.

Giomer-based sealants (GS) have emerged as a promising alternative, which combine surface pre-reacted glass-ionomer (S-PRG) fillers with a resin matrix [6]. This hybrid technology is designed to integrate the durability of resins with the therapeutic properties of glass ionomer materials [7]. The results of *in vitro* studies suggest that GS may offer additional benefits,

including fluoride release, antibacterial properties, and enamel remineralization potential [7]. Furthermore, GS exhibits self-etching properties, simplifying clinical application by eliminating the need for separate etching and rinsing steps to reduce chair time, an important consideration when treating pediatric patients [8].

Despite these promising features, clinical evidence comparing GS with conventional RS remains limited, particularly in the context of caries prevention in newly erupted molars. Compared to RS, GS has been less extensively studied in randomized controlled trials (RCTs), which are considered high-level evidence [9]. Therefore, the present RCT was designed to address this gap by evaluating and directly comparing the clinical effectiveness of GS and RS in newly erupted permanent molars. By focusing on children during this high-risk eruption phase, this study aimed to provide practical insights into the effectiveness of these two materials and contribute to evidence-based recommendations for preventive care in pediatric dentistry.

2. Materials and methods

The research protocol was reviewed and approved by the Institutional Review Board of Hue University of Medicine and Pharmacy (H2023/012). The protocol was also registered on ClinicalTrials.gov under the reference NCT05969756.

2.1 Study design

This was a triple-blind, RCT with a two-arm parallel design. Randomization was performed to assign teeth in a 1:1 ratio to one of the two groups. The Consolidated Standards of Reporting Trials (CONSORT) statement was used to design and report the findings of this RCT.

2.2 Participant settings and eligibility criteria

This study was conducted at the dental clinics of Hue University Hospital and Phu Vang Hospital in Hue, Vietnam, from July 2023 to October 2024. Systematic sampling was used to randomly select 88 children from a list of patients aged 5–14 years. All parents who agreed to enroll their children in the study ensured that their children met the inclusion criteria and provided written informed consent.

2.2.1 Inclusion criteria

Children were eligible for inclusion if they were healthy and cooperative, between 5 and 14 years of age, regardless of sex, race, or socioeconomic status. Eligible participants also presented with early carious lesions on the occlusal surface of a permanent molar (first or second) with International Caries Detection and Assessment System (ICDAS) scores of 1 or 2 [10, 11]. In addition, included molars were at eruption stage 2 (fully erupted occlusal surface with less than half of the crown exposed) or 3 (fully erupted occlusal surface with more than half of the crown exposed) [12, 13]. Finally, signed informed consent was obtained from a parent or guardian.

2.2.2 Exclusion criteria

Children were excluded if parents reported any history of allergy or if the child was unable to return for recall visits. Teeth were also excluded if the occlusal surface was completely covered by gingival tissue or if they presented with hypoplastic defects, restorations, or existing sealants.

2.3 Sample size

The unit of analysis for this study was the individual tooth. To ensure the independence of observations, one qualifying permanent molar was selected from each participating child. Sample size estimation, based on a previous study [8], indicated that 72 teeth were required to achieve a type I error of 0.05 and a statistical power of 0.8. During the 12-month evaluation period, outcomes including total retention, partial retention, and total loss were examined as proportional measures of the variables. Considering a potential dropout rate of 20%, the final target sample size was increased to 88 teeth, corresponding to 88 children.

2.4 Grouping

The erupting permanent molars were randomly assigned to two groups: Group GS included 44 permanent molars sealed with self-etching sealants (BeautiSealant; Shofu, Japan), while Group RS included 44 permanent molars sealed with etch-and-rinse sealants (Clinpro Sealant, 3M ESPE, USA).

2.5 Randomization

Stratified randomization according to sex and age was performed by generating numbers for each group using an online tool (www.randomizer.org). Randomization was performed by a research team member (TDT) who was not involved in any phase of the clinical trial. The participants were then sequentially assigned to one of the two groups by the same researcher based on their assigned numbers until the required sample size was reached. For children with multiple teeth requiring sealant intervention, one tooth was randomly selected for evaluation. This approach ensured the independence of the statistical observations and minimized potential confounding from data clustering, as multiple teeth from the same participant cannot be considered independent units.

2.6 Clinical procedures

Following oral prophylaxis with pumice and water, and isolation with a rubber dam, the selected teeth underwent the respective interventions. A clinician (TDT) then applied sealants to the pits and fissures of the occlusal surface of the permanent molars according to the manufacturers' clinical protocols.

In the GS group, primer was applied to the enamel surface using a microbrush for 5 s, followed by gentle air-drying. Subsequently, BeautiSealant was applied to the pit and fissure region and light-cured (LED.B, Guilin Woodpecker Medical Instrument Co., Ltd, Guilin, Guangxi, China) at 1200 mW/cm^2 for 20 s.

In the RS group, the occlusal surface was etched using 37% phosphoric acid (Coltene, Brazil) for 20 s, washed, and dried. The Clinpro Sealant was then applied and light-cured using the

same device at 1200 mW/cm^2 for 20 s.

2.7 Follow-up

The primary clinical outcome for this trial was sealant retention. The secondary outcomes included the incidence of new caries lesions and the quality of the sealant. Follow-up examinations were conducted to clinically evaluate all children at 3-, 6-, and 12-months post-intervention. At each visit, two calibrated evaluators (VNTL and TTT) performed the clinical assessments.

Sealant retention was recorded using Simonsen's criteria of total retention, partial retention, and total loss [6]. Caries status was recorded using the ICDAS system, with scores of 0 and $\geq$1 indicating sound and fully sealed teeth and a new caries lesion, respectively [10, 11]. Sealant quality was assessed using the United States Public Health Service (USPHS) criteria, and considered the anatomical form, marginal adaptation, superficial texture, and marginal discoloration [14].

2.8 Blinding

Both types of sealants were opaque and indistinguishable in appearance. The evaluators (VNTL and TTT) were blinded to the group allocation at each follow-up. Additionally, the participants were blinded to the treatment materials. The investigator who performed the statistical analyses (HUT) was also blinded to the intervention allocation.

2.9 Statistical analysis

The analysis was conducted on an intention-to-treat basis, with all 88 teeth analyzed according to their original randomization groups, regardless of follow-up completion. For the five teeth lost to follow-up at 12 months, a last-observation-carried-forward (LOCF) approach was applied, using their 6-month data as the final value. This approach was considered appropriate because retention and caries outcomes typically change gradually over time, and LOCF provides a conservative estimate that minimizes bias over a relatively short follow-up period.

IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA) was used to perform the statistical analyses. For continuous variables, data are presented as means $\pm$ standard deviation (SD). Student's *t*-test was used to compare differences between the groups. Categorical variables are presented as numbers of samples and percentages, N (%). Chi-square or Fisher's exact tests were used to compare sample proportions, as appropriate. Bonferroni correction was applied to adjust for multiple comparisons across different time points for the primary and secondary outcomes (retention, caries incidence, and sealant quality). The significance level for each family of tests was set at an adjusted α level. Spearman's rank correlation coefficients were used to explore the relationships between variables. A p-value < 0.05 was considered statistically significant.

3. Results

3.1 Participants

Among 122 patients assessed for eligibility, 88 (88 teeth) were enrolled in this RCT after excluding 34 patients who did not meet the inclusion criteria. Five participants (accounting for 5 teeth) could not be contacted at the 12-month follow-up examination, resulting in a 5.7% loss to follow-up. The 12-month follow-up period was conducted within a permitted time window of 360–367 days. No deviations in the study protocol were observed. The study flow diagram is shown in Fig. 1.

3.2 Baseline characteristics

This study included 37 (42%) males and 51 (58%) females ranging in age from 6.93 to 12.11 years. Table 1 presents the baseline characteristics of the study population. Age, sex, eruption stage, ICDAS scores, permanent molar type, and dental arch did not differ significantly between participants in the RS and GS groups ($p > 0.05$). Examiner reliability was assessed before clinical evaluations showed excellent inter-rater reliability between the two calibrated evaluators for all clinical criteria (kappa > 0.9). Intra-rater reliability for each examiner was also confirmed to be excellent, with kappa values exceeding 0.9.

3.3 Sealant retention

Table 2 presents the comparison of sealant retention between both groups across follow-up intervals. Both groups exhibited a progressive decline in sealant retention over time. At 3 months, retention rates did not differ significantly between the RS and GS groups ($p = 0.281$). However, at 6 months, the RS group showed significantly higher retention than the GS group ($p = 0.002$). This difference was even more pronounced at 12 months ($p < 0.001$), indicating a substantially better long-term retention rate in the RS group.

3.4 Caries incidence

At both 6-month and 12-month follow-ups, the ICDAS scores did not differ significantly between the RS and GS groups ($p = 1$ and $p = 0.241$, respectively) (Table 3).

In the GS group, no cases of dental caries were detected at the 3-month follow-up. Only one permanent molar (2.3%) had an ICDAS score $\geq$1 at 6 months, increasing to two (4.9%) at 12 months. None of the mandibular molars exhibited an ICDAS $\geq$1 score.

In the RS group, no cases with an ICDAS score $\geq$1 were observed at the 3-, 6-, and 12-month follow-ups.

3.5 Sealant quality

Assessment of the quality of the remaining sealant showed no significant differences in the anatomical form (at 3 months), marginal adaptation (at 6 and 12 months), superficial texture (at 12 months), and marginal discoloration (at 3, 6, and 12 months) between the groups ($p > 0.05$) (Table 4). After Bonferroni correction, the anatomical form score of the RS remained significantly higher than that of the GS at both 6 and 12 months. By contrast, the previously observed difference in superficial texture at 6 months was no longer statistically

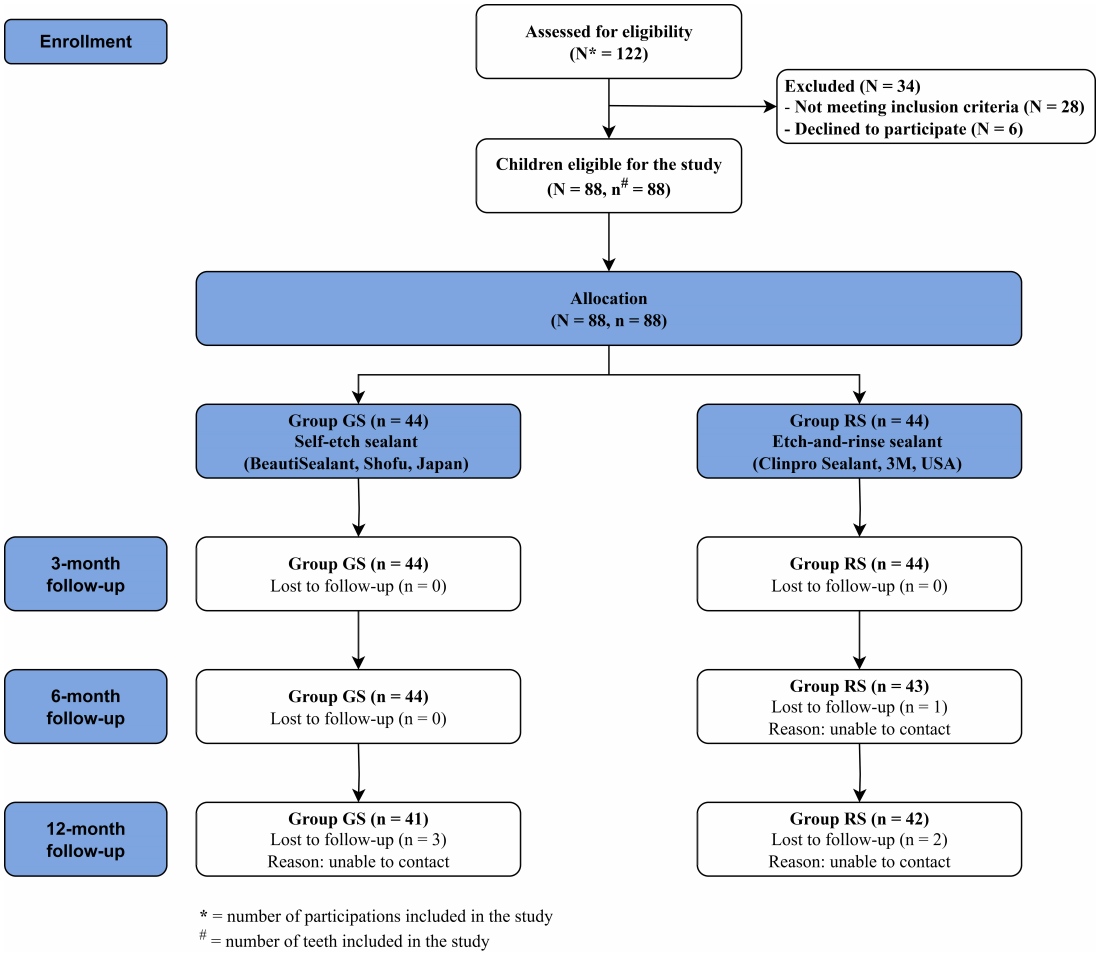

FIGURE 1. CONSORT flow diagram of participants up to 12 months. CONSORT, Consolidated Standards of Reporting Trials; GS, giomer-based sealant; RS, resin-based sealant.

TABLE 1. Baseline participant characteristics.

	Group GS (n = 44)	Group RS (n = 44)	*p*-value
Age (yr) (mean ± SD)	9.07 ± 2.11	9.52 ± 2.59	0.369
Sex			
Male (n = 37)	17	20	0.517
Female (n = 51)	27	24	
Eruption stage			
2	11	16	0.248
3	33	28	
ICDAS			
1	1	1	1.000
2	43	43	
Type of permanent molar			
First	36	31	0.211
Second	8	13	
Dental arch			
Upper	29	34	0.237
Lower	15	10	

GS, giomer-based sealant; RS, resin-based sealant; ICDAS, International Caries Detection and Assessment System.

TABLE 2. Comparison of retention scores between the two groups at 3, 6, and 12 months.

Follow-up interval	Retention	Group GS n (%)	Group RS n (%)	*p*-value
3 months				
	Total retention	40 (90.9)	43 (97.7)	0.281
	Partial retention	3 (6.8)	1 (2.3)	
	Total loss	1 (2.3)	0	
6 months				
	Total retention	26 (59.1)	39 (90.7)	0.002
	Partial retention	13 (29.5)	2 (4.7)	
	Total loss	5 (11.4)	2 (4.6)	
12 months				
	Total retention	7 (17.1)	26 (61.9)	<0.001
	Partial retention	17 (41.5)	13 (31.0)	
	Total loss	17 (41.5)	3 (7.1)	

GS, giomer-based sealant; RS, resin-based sealant.

TABLE 3. Comparison of caries scores between the two groups at 3, 6, and 12 months.

Follow-up interval	New caries	Group GS n (%)	Group RS n (%)	*p*-value
3 months				
	No	44 (100)	44 (100)	-
	Yes	0	0	
6 months				
	No	43 (97.7)	43 (100)	1.000
	Yes	1 (2.3)	0	
12 months				
	No	39 (95.1)	42 (100)	0.241
	Yes	2 (4.9)	0	

GS, giomer-based sealant; RS, resin-based sealant.

TABLE 4. Comparison of the quality of sealant remnants between the two groups at 3, 6, and 12 months.

USPHS criteria	Follow-up interval		Group GS n (%)	Group RS n (%)	*p*-value
Anatomical form					
	3 months	Alfa	40 (93.0)	43 (97.7)	0.360
		Bravo	3 (7.0)	1 (2.3)	
	6 months	Alfa	26 (66.7)	39 (95.1)	0.001
		Bravo	13 (33.3)	2 (4.9)	
	12 months	Alfa	6 (25.0)	26 (66.7)	0.001
		Bravo	18 (75.0)	13 (33.3)	
Marginal adaptation					
	3 months	Alfa	43 (100)	44 (100)	-
	6 months	Alfa	35 (89.7)	41 (100)	0.051
		Bravo	3 (7.7)	0	
		Delta	1 (2.6)	0	
	12 months	Alfa	21 (87.5)	38 (97.4)	0.150
		Bravo	3 (12.5)	1 (2.6)	

TABLE 4. Continued.

USPHS criteria	Follow-up interval		Group GS n (%)	Group RS n (%)	*p*-value
Superficial texture					
	3 months	Alfa	43 (100)	44 (100)	-
	6 months	Alfa	32 (82.1)	41 (100)	0.005
		Bravo	7 (17.9)	0	
	12 months	Alfa	23 (95.8)	39 (100)	0.381
		Bravo	1 (4.2)	0	
Marginal discoloration					
	3 months	Alfa	43 (100)	43 (97.7)	1.000
		Bravo	0	1 (2.3)	
	6 months	Alfa	38 (97.4)	40 (97.6)	1.000
		Bravo	1 (2.6)	1 (2.4)	
	12 months	Alfa	21 (87.5)	35 (89.7)	1.000
		Bravo	3 (12.5)	4 (10.3)	

USPHS, United States Public Health Service; GS, giomer-based sealant; RS, resin-based sealant.

significant.

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

No correlation was observed between sealant retention and caries development at the 6-month follow-up (Table 5). However, a statistically significant but weak positive correlation was observed between sealant retention and caries development at 12 months ($r = 0.221$; $p < 0.05$).

4. Discussion

This randomized triple-blind clinical trial evaluated and compared the effectiveness of RS and GS in preventing dental caries in erupting permanent molars over a 12-month study period. The primary outcome was sealant retention, while the secondary outcomes included caries incidence and the quality of the remaining sealant.

At 12 months, the total retention rates were 61.9% for RS and 17.1% for GS, consistent with previous RCTs. Ntaoutidou *et al.* [15] reported rates of 70.2% for RS and 8.7% for GS at 12 months, while other trials observed 62.1% for RS [16] and 26.9% for GS [6]. Collectively, these findings highlight the superior clinical reliability of RS over GS in maintaining sealant retention at 12 months, a critical factor for long-term caries prevention.

Regarding the secondary outcome, caries prevention did not differ significantly between the groups. However, only two new lesions developed during the study, severely limiting the statistical power and suggesting that the trial was underpowered for this outcome. In contrast, the difference in sealant retention was robust and clinically meaningful, underscoring a key trade-off between the two sealant systems.

Several hypotheses may explain the paradoxical finding of low caries development in the GS group (4.9% at 12 months) despite its high rate of total sealant loss (41.5%). First, the sealant may have provided protection during the vulnerable initial eruption period, potentially reducing long-term susceptibility even after material loss [17, 18]. Partial retention could leave microscopic resin tags that block bacterial invasion and maintain a resistance to caries [19], suggesting that the caries-preventive mechanism of sealants may extend beyond a mere physical barrier. If partial retention provides clinical benefits, re-evaluation of the sealant failure criteria and adjustment of clinical management strategies may be warranted. Second, the bioactive properties of the GS, including the sustained release of fluoride, strontium, and boron ions from the S-PRG fillers, may inhibit demineralization and exhibit antibacterial effects [7]. However, these potential mechanisms were not directly measured in our study and remain speculative, warranting future investigation. Third, an overall low risk of caries in the study population cannot be ruled out. When the incidence of caries is very low, detecting statistically significant differences in the actual caries-prevention effects between the two sealants may be challenging. This is an important consideration because the efficacy of sealants may be more clearly demonstrated in populations higher caries risk [20].

The lower retention rate of GS compared with RS is attributable to differences in adhesion mechanisms. RS involves 37% phosphoric acid etching to create enamel microporosities for strong micromechanical interlocking [21]. This is considered the “gold standard” for resin-based materials bonding to tooth structure [22]. In contrast, GS uses a self-etching system with milder acidic primers, resulting in less effective enamel bonding and lower retention [6, 22]. The results of this study reinforce the tradeoff between simplified clinical procedures and long-term mechanical retention.

Analysis of the correlation between sealant retention and caries development revealed a weak but statistically significant positive correlation at 12 months ($r = 0.221$, $p < 0.05$) but not at 6 months [23]. Although the statistical significance indicates

TABLE 5. Spearman's rank correlation coefficient between sealant retention and caries development.

Follow-up interval	Variables	Correlation coefficient	*p*-value
6 months	Sealant retention *vs.* Caries development	0.164	0.129
12 months	Sealant retention *vs.* Caries development	0.221	0.045*

**indicates a statistically significant correlation ($p < 0.05$).*

that this relationship is unlikely to be due to chance, its clinical importance is limited. While retention contributes to caries prevention, other factors, including oral hygiene, diet, fluoride exposure, and inherent caries risk, must also be considered [24].

For the sealant quality, the USPHS criteria provide objective quality indicators directly linked to the clinical success and longevity of sealants [8]. The superior performance of RS over GS in terms of anatomical form, marginal adaptation, and superficial texture aligns with RS's excellent retention, suggesting that despite the difference in caries incidence was not significant at 12 months, RS may have a better long-term clinical prognosis.

The findings from this 12-month clinical trial offer direct practical guidance for clinicians selecting sealant materials for erupting permanent molars. The primary clinical takeaway is the trade-off between long-term durability and application efficiency. The etch-and-rinse RS demonstrated significantly superior retention, with a total retention rate of 61.9% at 12 months, reinforcing its status as a durable and reliable choice when long-term performance is the main objective. In contrast, the GS, a self-etching system, offers a simplified and faster clinical procedure by eliminating the separate etching and rinsing steps. This can be an advantage in pediatric dentistry, particularly with anxious or uncooperative patients or in situations where achieving perfect moisture control is challenging. Therefore, clinicians must weigh the significantly lower 12-month retention rate of GS (17.1% total retention) against the practical benefits of its streamlined application and its potential bioactive properties like fluoride release, which require further follow-up. The choice of material may be situational: RS is preferable when ideal isolation can be achieved, while GS may be a valuable alternative for challenging clinical scenarios, with the understanding that more frequent monitoring for sealant loss may be required.

The strengths of this RCT include the application of standardized assessment tools (ICDAS, Simonsen's criteria, and USPHS criteria) [6, 8, 25, 26]. In addition, our triple-blind RCT provided a high level of evidence by concealing the treatment methods from participants, evaluators, and data analysts, thereby minimizing subjective bias [27, 28]. Finally, findings based on a comparison between RS and GS, which provide an optimized protocol, could help clinicians reduce chair time and avoid discomfort in pediatric patients.

However, our study has several limitations. First, the 12-month follow-up period was relatively short for evaluating caries development and progression. Therefore, longer-term studies are warranted. Second, the sample's very low caries incidence limited the generalizability of the findings to higher-risk populations and different clinical settings. Third, owing to the protocol differences, the operator could not be blinded, which may have introduced performance bias. Additionally, the dental caries assessment was primarily based on the subjective observations of examiners rather than on quantitative tools such as light-induced fluorescence [29–31]. Moreover, rubber dam isolation in erupting permanent molars is challenging; thus, Isolite or DryShield isolation systems should be used to ensure an optimal working environment for sealant retention [32]. Finally, future split-mouth RCTs are needed to reduce variability between participants to allow more precise estimates of treatment effects [33, 34].

5. Conclusions

Within the 12-month study period, RS demonstrated superior retention compared with GS. However, due to the very low incidence of caries, differences in caries prevention could not be determined. In clinical practice, RS is recommended when ideal isolation can be achieved, whereas GS may be considered in pediatric cases with moisture-control challenges, with the understanding that more frequent follow-ups are needed to mitigate the trade-off between faster placement and lower retention. Long-term studies in higher caries-risk populations are warranted to further evaluate the clinical effectiveness of these materials.

ABBREVIATIONS

RS, resin-based sealant; GS, giomer-based sealant; ICDAS, International Caries Detection and Assessment System; S-PRG, surface pre-reacted glass-ionomer; RCT, randomized controlled trial; USPHS, United States Public Health Service; LOCF, last-observation-carried-forward; SD, standard deviation; CONSORT, Consolidated Standards of Reporting Trials.

AVAILABILITY OF DATA AND MATERIALS

Data supporting the findings of this study are available from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

VNTL and DWL—designed the study methods; wrote and edited the final version of the manuscript. TDT—recruited the participants. VNTL and TDT—prepared the questionnaires. HUT—analyzed the data. VNTL and TTT—organized the ideas and wrote the initial draft. All authors revised and verified the final version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Institutional Ethics Committee of Hue University of Medicine and Pharmacy (Date: 20 February 2023, No.: H2023/012) and conformed to the recognized tenets of the Declaration of Helsinki. The trial was registered at ClinicalTrials.gov (NCT05969756). Written informed consent was obtained from the parents or legal guardians of all participants.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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