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SEAL Cambodia—Evaluation of a modified protocol for placement of Fuji VII® Fissure Sealants at one and two years

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ABSTRACT

Objectives: In order to address the severe caries burden among Cambodian children and limited access to dental care this study had two objectives: (1) To evaluate the caries preventive effect of hand-mixed GIC Fissure Sealants (FS) placed on first permanent molars of 6–8 year-old Cambodian children using two protocols in the SEAL Cambodia Project and (2) validate the SEAL Cambodia population-based intervention.

Methods: The study had four groups, two cohorts, and investigated two clinical protocols (original and modified) for FS placement to compare caries preventive fraction. Three groups were followed up at 1y and two were followed up at 2y. The modified protocol involved control of the temperature of the material, the timing of mixing and placement, and adjustment of the occlusion. Data analysis examined differences in caries incidence by group.

Results: At 1 and 2 y, 62.8%, and 68.0% follow-up rates were achieved, respectively. The baseline mean dmft for the first and second cohorts was 8.0 (SD 3.9) and 9.9 (SD 4.3) respectively. The original protocol did not render a statistically significant preventive benefit. A preventive fraction of 89.1% at 1 y and 32.3% at 2 y was achieved using the modified protocol in the second cohort ($P < 0.05$). Children with baseline dmft $\geq$ 8 realised half the preventive fraction at 2 y compared to those with dmft < 8 (22.3% and 45.8% respectively).

Conclusions: The modified FS protocol increased the caries preventive effect, although it was lower than that reported in other studies.

Clinical significance: This study builds evidence for the use of glass ionomer cement Fissure Sealants (FS) for the prevention of caries at a population level. It showed that improving the field-based clinical protocol for application of FS had a large impact on clinical success.

1. Introduction

Cambodian children have a severe burden of dental caries (dmft at age 6 = 9.0) and fewer than 1% of primary school children receive any dental care [1]. In 2011 the Global Child Dental Fund (GCDF) initiated a meeting of local and international dental experts to consider a strategy for addressing the high rate of dental caries in Cambodian children. This resulted in the SEAL Cambodia project with an aim to place Fissure Sealants (FS) on the first permanent molars (FPM) of 60,000 6–8 year-old Cambodian children over three years using low viscosity glass-ionomer cement (GIC; Fuji VII®, GC Corp, Tokyo, Japan). The rationale for the project was that by sealing the most susceptible permanent teeth (FPM) soon after eruption, the proportion of permanent teeth affected by carious lesions could be dramatically reduced.

Fissure sealants are an evidenced-based intervention next in preventive efficacy to tooth-brushing with fluoridated toothpaste [2]. Resin-based sealants are considered to be the gold standard for prevention of caries on FPM due to their higher retention rates over time; however, the method is technique sensitive and requires dental equipment such as air/water spray and suction. Meta-analysis suggested that there was insufficient evidence to support the use of GIC FS since the estimated preventive fractions are between 39% and −3% over 2-years [3]. Few high-quality studies have examined the success of these interventions in a developing world context and in a population with such a severe caries experience as children in Cambodia.

The aim of the SEAL Cambodia intervention was to seal the first permanent molars of 60,000 6- to 8-year-old children with GIC over a 3-year period in three provinces of Cambodia. Initially a protocol was developed and field-tested. However, the original protocol did not render the expected1-year caries preventive effect and so the clinical

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protocol was reviewed and changed in order to increase retention [4]. It was hypothesised that the limited preventive-effect of the original protocol was probably due to lack of control of the temperature of the GIC before application, problems with moisture control, lack of adherence to recommended mixing and placement times, and lack of occlusal adjustment. Following discussions within the research team, several steps in the protocol were revised and the new protocol was subsequently implemented for the remainder of the SEAL Cambodia program [4].

The aims of this study were: (1) to evaluate the caries prevention achieved among 6–8 year-old Cambodian children participating in the SEAL Cambodia population based intervention using a modified GIC FS protocol compared with the original protocol, and (2) to validate the SEAL Cambodia population-based intervention. Such a study will add to the quality of evidence around the benefits of GIC FS to reduce the burden of caries in vulnerable populations.

2. Methods

The present study is a program evaluation of a population-based caries preventive intervention that used two different clinical protocols to apply FS. There were four groups involved belonging to two different cohorts and the primary outcome of interest was caries preventive fraction. Ethics approval was provided by the National Ethical Committee for Health Research, Ministry of Health, Cambodia. Clinical examinations at baseline and follow-up as well as clinical procedures were conducted in a school-yard setting with children in a supine position and illumination from battery-powered head-lights. Consent was established by sending the consent forms to the school the week prior to the examination and parents were given an opportunity to withdraw their child's participation should they wish. Children were free to refuse assent at the time of examination with no consequences.

Group A and Group B made up the first cohort and were recruited contemporaneously and targeted based on grade. Group C and Group D made up the second cohort who were recruited contemporaneously and targeted for both grade of school as well as age (not older than 7 y). Group A was the negative control group of the first cohort who did not receive any FS. Group B was the original protocol (intervention) group of the first cohort who received FS using the original protocol. Group C was the modified protocol (intervention) group of the second cohort and they received FS using the modified protocol. Group D was recruited to be a negative control however, ended up as a positive control group in the second cohort: dental care for children in Cambodia is often provided by not-for-profit groups which are not coordinated and on review it was discovered Group D had been sealed using the original protocol by another organisation. All groups were selected based on randomised cluster sampling using the list of eligible schools provided by the School Health Department. The sample was powered to have a 95% chance of detecting medium effect size differences among clusters groupings. G*power (version 3.1.9.2) was used to calculate the required sample size 96 children per cluster. Therefore at least 96 children were recruited from each school cluster based on school district. A 2:1 allocation ratio was used and so four clusters were recruited for intervention groups (Group B and Group C) while two clusters were recruited for control groups (Group A and Group D). This calculation confers an 80% chance of detecting a small effect among groups or a 99% chance of detecting a medium effect among groups. Group A, Group B, and Group C were followed-up at 1 y. Group C and Group D were followed up at 2 y.

Two-year follow-up rates were maximised by working with school administrators and teachers to identify children who were part of the cohort, and by having more than one 'wave' of data collection. Examiners examined the original hand-written hard copy of the school roll based on the first day of school enrolment as well as electronic versions with school administrators to account for those children who might have modified their names between base-line and follow-up visits. There were two waves of data-collection with examiners returning to schools two weeks later to capture any additional children who might have been absent during the first wave of data collection. In addition, teachers and classmates who may have taught the child at baseline were asked to identify children who were not able to be found using the previously described means.

Full-mouth intra-oral dental charting was conducted at each follow-up. The DMF index was recorded at surface level according to the WHO Basic Survey Methods [5]. Each tooth was also given a score using the PUFA Index [6]. Examiners were calibrated against an experienced dental epidemiologist (BT) and achieved kappa scores higher than 0.85. All participants were given oral hygiene education (with a ratio of one instructor to five children) and a toothbrush. Those in the intervention group brushed their teeth prior to placement of GIC FS. All participants were asked a set of questions at each examination including questions on oral hygiene, and four questions from the Oral Symptoms Domain of the Child Perceptions Questionnaire which had been previously validated for use in a Cambodian Setting [7]. The questions were about mouth pain, sores (ulcers), bad breath and food impaction in the context of the previous 3 months. The response options for each item were "Never" (scoring 0), "Once or twice" (scoring 1), "Sometimes" (scoring 2), "Often" (scoring 3), and "Every day or almost every day" (scoring 4). Children were said to have an 'impact' if they scored 3 or higher on any of the four questions.

The original protocol (Groups B & D) for placing FS involved up to two teeth (opposing arches) being treated simultaneously and use of materials at ambient temperature (25–35 °C): (1) the dentine conditioner was applied to a clean dry tooth and then removed with a wet cotton pellet; (2) the tooth was dried using cotton pellets; (3) hand-mixed Fuji VII® was placed onto the occlusal surface of the tooth and pressed into the fissures using the operators' finger (no defined duration) lubricated with cocoa butter or petroleum jelly No subsequent occlusal adjustments were made. Tthe modified protocol (Group C) involved the same work flow but with several modifications: (a) cooling of the GIC liquid (Fuji VII® Liquid) in a cup of ice prior to mixing; (b) timing the mixing (20 s) and placement of the material (60 s) using a digital timer according to the manufacturer's instructions; (c) placing one sealant at a time; (d) placing the finger over the sealant for one minute using a timer; and (e) checking the occlusion with articulating paper and adjusting if necessary.

2.1. Data analysis

Data were entered into SPSS Ver. 20 (IBM Corp., NY, USA) and analysed to produce descriptive statistics on baseline caries experience and caries incidence. Data collected on oral symptoms were analysed to generate information on the prevalence of impacts. A child was said to have an impact in oral symptoms if they responded with score 3 or higher to any of the oral symptoms items. Descriptive analyses were performed as well as bivariate analysis to examine differences in caries experience and FS retention by group membership. Caries groups were defined using the Significant Caries Index (8) whereby the overall group was divided into terciles based on caries experience in the primary dentition (dmft). Differences in means among groups were compared using the Kruskal-Wallis test and differences in proportions among groups were compared using chi-squared test. Differences in means among related samples were examined using the Wilcoxon signed rank test.

Three logistic regression models were built. Model 1 and Model 2 examined the odds ratio for developing both occlusal and approximal cavitated lesions on FPM after controlling for school of attendance and baseline caries experience. Model 3 excluded approximal lesions and controlled for the same variables.

Table 1
Clinical Characteristics of participants at baseline.

	DMFT Mean (SD)	P-value	dmft Mean (SD)	P-value	Any caries N (Row %)	P-value
Sex						
Male	1.8 (2.1)	0.397	9.1 (4.2)	0.010	520 (97.4)	0.318
Female	1.9 (2.0)		8.4 (4.2)		497 (96.7)	
Group membership						
Group A Negative Control	2.2 (2.1)	< 0.001	7.5 (4.1)	< 0.001	240 (95.6)	0.209
Group B Original Protocol	2.3 (2.2)		8.3 (3.8)		420 (97.0)	
Group C Modified Protocol	1.2 (1.6)		10.2 (4.3)		357 (98.1)	0.186
Group D Positive Control	1.7 (2.1)		9.5 (4.2)		261 (99.2)	
TOTAL	1.9 (2.0)		8.8 (4.2)		1017 (97.0)	

3. Results

A total of 1284 children were included in the program evaluation with an even gender distribution (51.7% female). The mean age was 8.1 y (SD 1.2) for groups A and B, and 6.6 y (SD 0.6) for Groups C and D. There was a significant difference in the severity of caries by group membership; those in Group C and Group D (the second cohort) had a lower DMFT and a higher dmft than other groups. This was consistent with the difference in mean age (Table 1). There was no statistically significant difference at the one-year follow-up by gender, group membership, or baseline caries experience (Table 2). Overall a 62.8% follow-up was achieved at 1 y.

Children in Group A and Group B had a greater than six times greater chance of developing new lesions on FPM when compared with Group C, once baseline caries experience, school, and gender were adjusted for (Table 3). Overall, just over one in four (27.1%) participants had one or more new cavitated lesions on FPM.

Within Group D a higher proportion of females were followed-up at two years ($p < 0.05$; Table 4). There were no gender differences in follow-up within Group C and there were no differences in follow-up by caries risk group.

Children in Group C had a one-third lower chance of having an impact in oral symptoms or developing a new carious lesion on FPM (Table 5). Differences were further amplified after participants were stratified by baseline caries experience. Children in the high caries group had twice the caries preventive increment compared with the two more extreme risk groups. There was no significant difference in

Table 2
Participant attrition analysis for the one-year Follow-up by group membership and baseline caries experience.

	Total N (Column %)	Lost N (Row %)	1 year Follow-up N (Row %)
Group A Negative Control	251 (24.0)	88 (35.0)	163 (64.9)
Male	116 (46.2)	42 (36.2)	74 (63.8)
Female	135 (53.8)	46 (34.1)	89 (65.9)
Group B Original Protocol	433 (41.3)	171 (39.5)	262 (60.5)
Male	237 (54.7)	98 (41.4)	139 (58.6)
Female	196 (45.3)	73 (37.2)	123 (62.8)
Group C Modified Protocol	364 (34.7)	131 (36.0)	233 (64.0)
Male	181 (49.7)	68 (37.6)	113 (62.4)
Female	183 (50.3)	63 (34.4)	120 (64.6)
Baseline caries			
High (dmft 0–5)	318 (30.3)	108 (34.0)	210 (66.0)
Very High (dmft 6–9)	356 (34.0)	136 (38.2)	220 (61.8)
Extreme (dmft ≥ 10)	374 (35.7)	146 (39.0)	228 (61.0)
Total	1048 (100.0)	390 (37.2)	658 (62.8)

Table 3
Logistic regression model (model 1) for risk of developing new carious lesions on FPM at one-year based by group membership.[a].

	B(SE)	Odds Ratio (95% CI)	P-value
Constant	−2.37 (0.23)	–	< 0.001
Group A Negative Control	1.80 (0.29)	6.04 (3.46, 10.56)	< 0.001
Group B Original Protocol	1.87 (0.27)	6.47 (3.84, 10.90)	< 0.001
Group C Modified Protocol	0.0[b]		

[a] Adjusted for school of attendance and baseline caries experience; Cox and Snell – 0.102; Nagelkerke – 0.148; McFadden – 0.092.

Table 4
Participant attrition analysis for the Two-year follow-up of the second cohort.

	Lost N (%)	2-year follow up N (%)	Total N (Column %)	P-value
Group C Modified Protocol	121 (33.2)	243 (66.8)	364 (57.5)	
Male	62 (34.3)	119 (65.7)	181 (49.7)	0.284
Female	59 (32.2)	124 (67.8)	183 (50.3)	
Group D Positive Control	85 (32.3)	178 (67.7)	263 (42.5)	
Male	45 (39.8)	68 (60.2)	113 (43.0)	0.017
Female	40 (26.7)	110 (73.3)	150 (57.0)	
Baseline Caries				
High (dmft ≤ 8)	61 (35.3)	112 (64.7)	173 (27.6)	0.576
Very High (dmft 8-10)	70 (30.4)	160 (69.6)	230 (36.7)	
Extreme (dmft > 10)	75 (33.5)	149 (66.5)	224 (35.7)	
Total	201 (32.5)	421 (68.0)	619 (100.0)	

Table 5
Proportion of children with new carious lesions on occlusal of FPM and sealant retention at 2 years by group membership.

	Group D Positive Control N (%)	Group C Modified Protocol N (%)	Preventive fraction (%)	P-value
≥ 1 new lesions FPM	70 (39.3)	72 (29.6)	32.3	0.024
≥ 1 new pulpally involved FPM	57 (32.0)	64 (26.3)	17.8	0.122
≥ 1 impacts in oral symptoms	122 (68.5)	117 (48.1)	29.8	< 0.001
Baseline Caries				
High (dmft ≤ 8)	16 (30.8)	10 (16.7)	45.8	0.062
Very High (dmft 8–10)	28 (39.4)	27 (30.3)	23.1	0.150
Extreme (dmft > 10)	26 (47.3)	35 (37.2)	21.4	0.152

Table 6
Logistic regression models showing odds ratio for the chance of developing one or more occlusal lesions on FPM at two-years.[a].

Model 2 – All new lesions involving the occlusal and approximal lesions[b]			
	B(SE)	Odds Ratio (95% CI)	P-value
Constant	0.86 (0.14)	–	< 0.001
Group C Modified Protocol	−0.431 (0.208)	1.54 (1.02, 2.314)	0.038
Group D Positive Control	0		
Model 3 – new lesions involving only occlusal surface[c]			
	B(SE)	Odds Ratio (95% CI)	P-value
Constant	−1.227	–	< 0.001
Group C Modified Protocol	0.675 (0.221)	1.96 (1.27, 3.03)	0.002
Group D Positive Control	0		

[a] Adjusted for school of attendance and baseline caries experience.
[b] Cox and Snell – 0.010; Nagelkerke – 0.014; McFadden – 0.008.
[c] Cox and Snell – 0.022; Nagelkerke – 0.032; McFadden – 0.019.

the prevalence of new pulpally involved lesions; however, those in Group C had a significantly lower chance of experiencing oral symptoms (Table 5). The mean number of new approximal lesions on FPM was 0.3 (SD 0.6) with a significantly higher mean number of approximal lesions (P = 0.037; Kruskal-Wallis) in Group C (0.3; SD 0.7) compared with Group D (0.2; SD 0.5). One in five children (N = 83) within these groups developed new approximal lesions over the study period. Overall, the mean number of new lesions in FPMs was 0.5 (SD 0.8) for both groups; therefore, approximal lesions accounted for over half of the FPM increment in the intervention group and a lower proportion in the control group.

The second and third models were created using logistic regression. When all lesions involving the occlusal surface were considered, those in the control group had a 1.54 times greater chance of developing a new lesion over two years (Table 6). After the teeth with both occlusal and approximal surfaces were excluded, children in the control group had twice the chance of developing new lesions on the occlusal surface.

4. Discussion

The present study validated the clinical application of GIC FS in the SEAL Cambodia population-based intervention. The effectiveness of the original SEAL Cambodia clinical protocol was tested against a modified protocol at one and two years. This study represents an important contribution to the limited body of evidence around the prevention of caries using GIC FS given that the most recent meta-analysis reported insufficient evidence for this technology. The modified protocol produced a large preventive increment at one year and a moderate preventive increment at two years. Child participants had an extreme experience of dental caries resulting a high incidence of cavitated approximal lesions on FPM that extended onto the occlusal surface. The preventive benefit of the program, in the particular protocol considerations that led to differences in preventive increments and differences in oral symptoms needs to be carefully interpreted; as these issues will inform the consideration of such an intervention as a preventive strategy for children in a Cambodian environment.

Before detailed examination of the findings of the study, it is appropriate to first examine the study strengths and limitations. The strengths were associated with the robust sampling procedure; however, the follow-up rates fell short of the ideal. Further measures were put in place at the two year follow-up which resulted in a 5% increase in numbers. As a program evaluation, the children in the study were representative of the wider SEAL Cambodia project and representative of those in their respective provinces based on data from the Cambodia National Oral Health Survey (CNOHS) [1]. Despite this, it appears that the rate of approximal lesion development on FPM was higher in Group C who were based in Phnom Penh compared with Group D who were based in the semi-urban schools of Kampot Province and this may have limited some of the comparability within the second cohort.

This is the first study to report caries preventive fractions of GIC FS among a group of children with a disproportionately severe caries experience. It has been reported in other studies that the higher caries risk was associated with lower preventive increments, as observed in the present study [3]. Children in the lower tercileof caries experience had a comparable caries experience to those considered to be in the 'high risk' group of published investigations.

4.1. Preventive benefit of the SEAL Cambodia intervention

The baseline caries experience played an important role in explaining the overall caries preventive effect at two years. Those in the extreme caries risk groups did not realise a significant reduction in the incidence of new carious lesions on FPM. The 38% preventive fraction achieved was at the higher end of the confidence interval reported in the most recent Cochrane Review which examined the benefits of GIC FS, and it is clear that this preventive increment would not have been possible without the use of the modified protocol [4]. It is also worth commenting that one in five of the children in the modified intervention group developed new carious lesions on approximal surfaces during observation. This level of disease by far exceeds that experienced among participants of other GIC FS studies where less than 1% of sealed teeth developed cavitation on the approximal surfaces [9].

Although caries prevention was observed among these children, this intervention did not address the drivers of dental caries such as dietary or oral hygiene practices; meaning that the same teeth which may have realised some benefit on the occlusal surface could have been compromised by the cavitated approximal lesions. As such, the value of the SEAL Cambodia intervention lies more in its place as the first step that a community of dentists undertook to re-orientate services towards preventive interventions. That partnerships were established across government agencies, Non-Governmental Organisations, academic institutions and dental professionals meant that the dental community was more connected than it had been prior to the project's inception. Furthermore, many dental students, dentists, therapists and hygienists from Cambodia and abroad participated in delivering preventively focused care. The project was a valuable demonstration of possibilities and the role dental professionals can play in preventing dental caries at population level. The SEAL Cambodia project formed a foundation upon which the dental community could better understand the target population and from there, a more comprehensive strategy can be built [10].

4.2. Protocol considerations

The key difference between the two protocols was the introduction of control measures to regulate the operators' work flow. Although GIC materials are moisture tolerant, it appears that the setting reaction is largely dependent on the temperature of the liquid. The original protocol used material at 'room temperature'. This was likely to be higher than 30 °C and associated with an average of around 70% humidity at the hottest time of year, which could have resulted in a faster setting time. As a consequence, the GIC was likely to be delivered to the tooth in the 'gelatinous' phase rather than during the initial working phase [11]. This would have resulted in the material failing to flow into the depths of pits and fissures, and failing to form a strong adhesive bond to the tooth surface. The gelatinous phase of setting is the time at which the material is most sensitive to leaching valuable ions on contact with moisture [11]. Therefore, the additional moisture control provided by the one-minute finger press was essential for protecting the material as it transitioned into the final setting phase in a controlled environment. This ensured the maximum compressive strength of the material could

be achieved. Finally, the temperature of the material affects the volume of the drop from the GIC liquid bottle. At 25–30 °C approximately 115–120 drops can be dispensed. In contrast, only 100–105 drops are dispensed from a bottle that is less than 20 °C. The temperature of the liquid had a major impact on all steps of the SEAL protocol.

It is possible that the choice of Fuji VII® rather than Fuji IX® created a scenario in which the protocol was more technique sensitive. Fuji IX® has a two minute working time compared to a working time for Fuji VII® of one minute. Although a pilot study demonstrated better retention of Fuji VII® at 6 months, it is possible that there could be some benefit to using Fuji IX® in order to allow for a more forgiving protocol [4]. In any case, the SEAL Cambodia project shows that an adjustment and strict monitoring of a protocol can make the difference between whether an intervention benefits participants or not.

While the preventive fraction at one year was comparable to that found in other studies, the two-year preventive fraction was lower than expected (40%) and the finding that sealants were being lost gradually over time leads to the question of whether GIC was the optimal choice of material [4]. It is likely that a resin sealant with a higher retention rate could have achieved higher two-year preventive results. Unfortunately, placing resin sealants would require significant equipment investment and it is unlikely that this would have been achievable at large scale or in the school environment in Cambodia. The alternative to a school environment would be to transport children to an equipped clinic but that would have been more problematic in terms of consent, transport costs, supervision, safety and time lost from class. In addition, many of the teeth that were targeted for sealants were not yet fully erupted and therefore, resin sealants, requiring meticulous moisture control, were contraindicated.

4.3. Self-reported oral symptoms

One unique aspect of this study is the inclusion of a self-reported oral health measure as an outcome. This was interesting given that there was no significant difference in the incidence of pulpally-involved lesions and there was a higher prevalence of new approximal lesions in Group C. The proportion of children in the original validation sample with impacts in oral symptoms was similar to that in Group D, and the modified protocol (Protocol 2) appeared to realise a one third reduction in the proportion of children experiencing oral symptoms. A reduction in oral symptoms among a population with such a severe caries experience is valuable and warrants further investigation into the role of dental interventions in improving the quality of life for young children in Cambodia.

4.4. The theoretical argument for SEAL Cambodia as a preventive strategy

The suggested rationale for targeting FPM in 6–8 year-old children is that (a) the majority of new lesions in the early permanent dentition occur on occlusal surfaces of FPMs, (b) that there is a window of 6–12 months after eruption when enamel is less mature, and (c) that diet and oral hygiene may improve across the primary school years due to a fixed school routine and lower consumption of non-nutritious food [1]. Unfortunately, the natural history of caries among Cambodian children did not follow the pattern described in other sealant studies carried out in mostly western populations. Those children often have lower rates of caries, greater exposure to fluorides, lower consumption of cariogenic foods and drinks, and more access to dental care compared with Cambodian children [3,9].

Those differences in caries experience and exposures to risk and protective factors mean that some of the underlying justifications for population wide sealant interventions do not hold. As Cambodian children develop towards a permanent dentition, a large number of carious lesions develop in permanent teeth other than FPM and analysis of the NOHS data shows that two in five 12-year-old children have cavitated carious lesions on maxillary anterior teeth. This suggests that the underlying precept that most carious lesions in this age group occur on occlusal surfaces of FPM does not hold. In addition, improvements in oral hygiene routines and dietary practices don't appear to occur until the children are older and reach secondary or high school [1]. Part of this could be related to differences in daily routine whereby children attend primary school in Cambodia for only four hours-per-day and 180 days-per-year. Although there is a 'healthy food' policy promoted by the School Health Department, anecdotal evidence would suggest that most schools earn revenue by allowing vendors onto the school grounds to sell (often non-nutritious) foods and drinks to children. Therefore, it appears that theories based on 'at risk' populations in a western setting, do not apply well in a Cambodian setting.

5. Conclusion

The Seal Cambodia population-based intervention was able to realise caries prevention using a modified protocol for GIC FS. The modified FS protocol had a significant caries preventive effect, although it was lower than that reported in other studies. Although the benefits at one-year were large, the two year preventive increment was not as high as expected. Further investigations are needed to better understand how preventive therapies and interventions operate in populations with extreme caries experience.

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Data statement

Data are available upon reasonable request from the corresponding author.

Declaration of interest

The authors declare that there could be a perceived conflict of interest given that materials for the study were provided free of charge by the manufacturer (GC Asia Corporation). In addition the company paid for logistic and administrative costs to conduct the field-based data collection activities to a total of around USD10,000. The authors did not receive any financial incentive for conducting the investigation. GC Asia Corporation had no role in the design, conduct, or reporting of the research.

Declaration of competing interests statement

The authors would like to declare that part of the funding for the SEAL Cambodia project came from GC Asia and this may present a perceived conflict of interest given that the named company is the manufacturer of the material tested in the present study. However, GC had no role in the design, conduct, or reporting of the research.

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