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Effects of restoring SDF-treated and untreated dentine caries lesions on parental satisfaction and oral health related quality of life of preschool children

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ABSTRACT

Objectives: To find out the effects of placement of atraumatic restorative treatment (ART) restorations on parental satisfaction and oral health related quality of life (OHRQoL) of preschool children with SDF-treated or untreated dentine caries lesions.

Methods: In a randomized controlled trial conducted in Hong Kong, preschool children who had cavitated dentine caries lesions were randomly assigned to receive application of silver diamine fluoride (SDF) solution or placebo (tonic water) on their caries lesions 10 weeks before receiving ART restorations. Parents were asked to rate their satisfaction with their child's teeth using a 5-point scale (5 = very satisfied, 1 = very dissatisfied) before and six months after the restorative treatment. Besides, the Chinese version of Early Childhood Oral Health Impact Scale (C-ECOHIS) was used to assess the children's OHRQoL.

Results: A total of 194 children participated in this study, with 101 and 93 children receiving SDF and placebo application before ART restorations, respectively. There was no significant difference in parental satisfaction and C-ECOHIS score between the SDF and placebo groups at baseline. At the 6-month follow-up, the mean parental satisfaction score regarding their child's dental health status increased significantly ($p < 0.001$) from 2.2 ± 0.7 to 2.8 ± 1.0 in the SDF group and from 2.3 ± 0.8 to 2.7 ± 0.9 in the placebo group. However, no significant changes ($p > 0.05$) in C-ECOHIS scores were found in either of the two groups after ART restoration placement.

Conclusions: Placement of ART restorations can improve parental satisfaction with the health and appearance of their child's teeth but has no significant effect on the OHRQoL.

Clinical significance: This study provides valuable information about the effects of ART restoration placement on SDF-treated or untreated dentine caries lesions regarding parental satisfaction and OHRQoL of preschool children.

1. Introduction

Dental caries of young children is common in both developing and industrialized countries [1]. In Hong Kong, the prevalence of dental caries among 5-year-old children is around 50% [2]. The decay process not only causes destruction of the dental tissues but can also cause infection and pain in the young children. The adverse effects of dental caries may impact on both children and their families, including significant health, social and economic consequences [3].

Management of dental caries in children involves both prevention and treatment of the disease. Both non-restorative and restorative approaches can be used in the treatment of carious lesion into dentine [4,5]. A non-invasive and non-restorative approach is to halt the caries process and convert an active carious lesion into an inactive one through topical applications of fluorides directly on the lesion without removal of any dental tissues. An inactive (arrested) dentine caries lesion usually is hard on gentle probing and does not cause symptoms [4]. Results from randomized clinical trials show that annual or semi-annual application of silver diamine fluoride (SDF) solution is effective in arresting dentine caries in young children [6–8]. However, a common outcome of SDF application is deposition of black stain on the arrested caries lesions which may cause aesthetic concerns of both the children and their parents [9].

Atraumatic restorative treatment (ART), in alignment with the minimal invasive philosophy of dental caries management, is a patient-friendly treatment for young children. The ART procedure involves removal of soft carious dental tissues using hand instruments without giving local anesthesia. An adhesive restorative dental material is then

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used to fill up the prepared cavity [10]. Usually a high viscosity glass ionomer cement which is a tooth-coloured chemical-cured material is used in a field setting. Results of a recent systematic review show that the ART restorations placed in primary molars have a similar survival rate compared to conventional treatment [11].

Although use of clinical parameters is important in assessing people's oral health condition, recently psycho-social influences on patients are attracting more attention. Therefore, besides clinical parameters, it is necessary to have patient-based assessment tools to evaluate oral health impacts. Oral health related quality of life (OHRQoL) has been defined as a multidimensional concept which includes a subjective evaluation of the individual's oral health, functional well-being, emotional well-being and sense of self [12]. In measuring the OHRQoL of children, it is generally believed that preschool children are too young to be capable of abstract thinking which underlies perceptions of the impacts of health and diseases, while the parents and caregivers who are responsible and making decisions for their child's oral health would be in a better position to report the physical and psychological negative impacts of their child's oral health on the child and the whole family [13]. So most of the child OHRQoL measurement tools currently available, such as ECOHIS, Michigan – OHRQoL, OH-ECQOL, were developed for parents to complete [14]. Among these tools, Early Childhood Oral Health Impact Scale (ECOHIS) is the most commonly used and was developed to measure OHRQoL of preschool children (younger than 5 years old) [13]. The ECOHIS presents with good reliability, responsiveness and interpretability. Meanwhile, it is the only tool that has been culturally adapted and translated in 14 languages, including the Chinese version ECOHIS (C-ECOHIS) [15].

Despite the high effectiveness of SDF application in treating active caries in children, the black stain on the SDF-treated lesions may cause patient and parental dissatisfaction, and affect their OHRQoL. A method to improve the esthetics of the decayed teeth is to place a tooth-colour restoration to cover the stained cavity. The shape of the decayed tooth can also be restored in the process to further enhance the overall dental appearance. However, information on how effective is the placement of ART restorations in achieving the patient's desired outcome is lacking. In this study, we aimed to find out the changes in parental satisfaction and OHRQoL of preschool children after ART treatment on untreated and SDF-treated dentine caries lesions.

2. Material and method

This study was part of a randomized controlled trial conducted in kindergartens in Hong Kong. Ethical approval was obtained from the Institutional Review Board of the University of Hong Kong (IRB reference Number: UW17-180) and the trial was registered (clinicaltrials.gov #NCT03657862). The flow of activities in the study is shown in Fig. 1.

2.1. Sample size calculation

Sample size calculation was based on the primary outcome of the randomized controlled clinical trial, which was to investigated the success of ART restorations in the untreated and SDF-treated caries lesions. An absolute difference of 10% in the success rate of restorations was regarded as clinically significant. In this non-inferior clinical trial, using one-tailed test with statistical significance set at 2.5% and a power of 80%, the calculated minimal number of restorations needed in each group was 139. Since more than one caries lesion can be found in one child's mouth, the clustering effect on sample size was considered. It was anticipated that the number of decayed teeth included per study child was 2.5. A design effect of 1.15 was calculated, using an assumed intra-class correlation roh of 0.1. Thus, the necessary sample size was increased to 160. Furthermore, to compensate for a possible drop-out rate of 15%, the sample size was increased to 188 restorations per group. Therefore, at least 76 children in each group should be recruited at baseline. The minimum sample size was 152 in total.

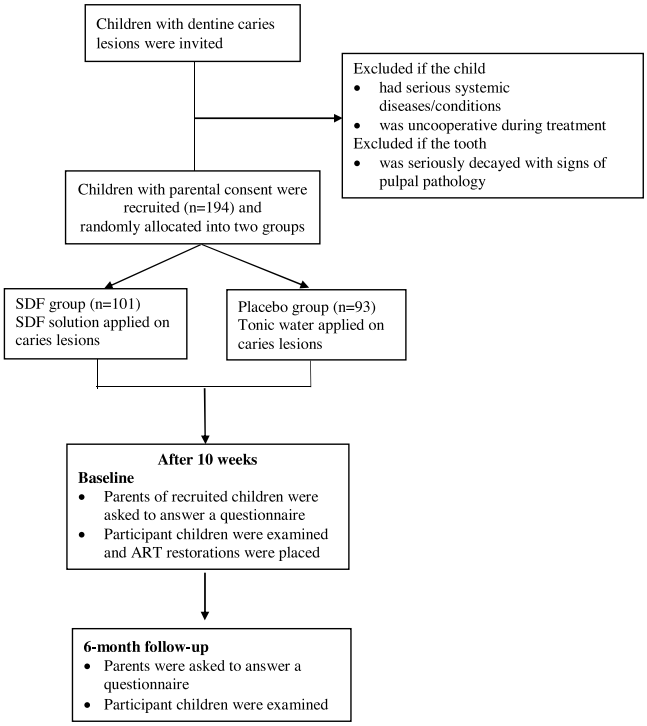

Fig. 1. Flow diagram of the study activities.

2.2. Subject recruitment and group allocation

Children attending grade 1 or 2 in nine kindergartens in Kong Hong were offered a free dental examination in the kindergarten. These kindergartens were chosen from the large (enrolment > 100) kindergartens in different districts in Hong Kong so as to increase the generalizability of the findings. An invitation letter with information on the purpose and procedures of the study was sent to the parents through the kindergarten. Written consent was obtained from parents before any clinical procedure. Children who were found to have dentine caries lesions in primary teeth were invited to join the randomized controlled clinical trial. Children with serious systemic disease/conditions and who were uncooperative during treatment were excluded. Seriously decayed teeth with signs of pulpal pathology and caries lesions which were too small to be prepared into a cavity for a filling with hand instruments were also excluded.

The recruited children were randomly allocated into two groups (SDF and placebo groups) using computer-generated random numbers. The group allocation was conducted by an independent dental assistant. Participant children, their parents and the clinical examiners were blinded to the children's group allocation.

2.3. Interventions

The study interventions were conducted in the kindergartens without the presence of the children's parents. The clinical procedures were carried out with the children in a supine position lying on a table or a bed. A disposable dental mirror attached to a handle with a LED light at the tip was used as an intraoral light source during the clinical examination and treatment.

For the children in the SDF group, a 38% SDF solution (Saforide, Toyo Seiyaku Kasei Co., Osaka, Japan) was applied onto all the caries lesions in their primary teeth using micro-brushes with isolation of teeth by cotton rolls. For the children in the placebo group, tonic water was applied in the same way. The children were then instructed not to

eat or drink for at least half an hour after the application.

Ten weeks after the application of SDF solution or placebo, ART restorations were provided to the study children in the kindergarten. The included caries lesions were restored following the standard ART procedures with the use of hand instruments [10]. No local anesthesia was given. The dental restorative material used was a hand-mix high-strength chemical-cured glass ionomer (Ketac-molar, 3 M ESPE, Germany). Isolation of the operating site was achieved with cotton rolls.

2.4. Data collection

At baseline, just before ART restoration placement (10 weeks after SDF or placebo application), children were clinically examined by two trained dentists using disposable dental mirror attached to a handle with an intra-oral LED light and a ball-ended probe. The status of each tooth was recorded and dental caries was diagnosed at the cavitation level according to the criteria recommended by the World Health Organization [16]. Meanwhile, whether there was stain on any of the anterior teeth (canine to canine) was recorded as either “yes” or “no”. Six months after placement of the ART restorations, the study children were clinically examined again to assess the stain status of their anterior teeth.

At baseline, parents were asked to complete a questionnaire. The questionnaire consisted of three parts: Part 1, general information, e.g. relationship with the child (mother, father, grandparents or others) and education level of parents; Part 2, parental satisfaction; and Part 3, children’s OHRQoL. Six months after placement of ART restorations (6-month follow-up), parents were asked to complete a follow-up questionnaire which contained the same questions in Parts 2 and 3 of the baseline questionnaire. The questionnaires were sent to the parents and returned through the kindergartens.

In the questionnaire, the parents were asked to rate their satisfaction with four different aspects of their child’s teeth using a 5-point scale (5 = very satisfied, 1 = very dissatisfied). The four aspects were: 1) their child’s dental health status which mainly focused on tooth decay; 2) colour of their child’s anterior teeth, including stain on the teeth; 3) alignment of their child’s anterior teeth; and 4) overall appearance of their child’s teeth. Questionnaires with missing response in any of the above four questions were excluded from statistical analysis.

The validated Chinese version of the Early Childhood Oral Health Impact Scale (C-ECOHIS) [15] was used to assess the OHRQoL of the participant children. The C-ECOHIS contained 13 items grouped into two sections, child impact section (CIS) and family impact section (FIS). Four domains were included in CIS: child symptom, function, psychology and self-image/social interaction. For FIS, there were two domains: parent distress and family function. For each item, the parents were asked to assess on a 5-point scale the negative impact of their child’s oral health on quality of life. Response categories were to record how often an event had occurred: 0 = never; 1 = hardly ever; 2 = occasionally; 3 = often; 4 = very often; 5 = don’t know. All ‘don’t know’ responses were recoded to missing. The total C-ECOHIS scores were derived by adding up the parents’ responses of all 13 items (total score can range from 0 to 52, with CIS and FIS ranging from 0 to 36 and 0–16, respectively). Questionnaires with more than 40% of the C-ECOHIS items missing were discarded. Otherwise, the missing responses and all ‘don’t know’ responses were imputed with the mode value so as to derive the total and domain scores. A higher C-ECOHIS score indicated greater negative impact of oral health status on OHRQoL.

2.5. Statistical analysis

Data were input into a computer using the software EpiData Manager 4.0 (EpiData Association, Denmark) with double check and analyzed with the software SPSS (IBM SPSS statistics version 25, USA). Distribution of the characteristics of the participants in the two study groups were compared using chi-square test. The changes in parental satisfaction and C-ECOHIS scores were calculated by subtracting the baseline score from the 6-month follow-up score. Due to the non-normal distribution of the scores, Wilcoxon Signed Ranks test (a non-parametric test) was used to compare the distribution of the baseline and 6-month follow-up parental satisfaction and C-ECOHIS scores. The Mann-Whitney test was adopted to compare parental satisfaction and C-ECOHIS scores of the SDF and placebo groups. The value of standardized effect size (ES) was calculated by dividing the change in score by the standard deviation of baseline scores [17]. An ES value ≤ 0.2 was interpreted as having a small effect while ES values 0.3-0.7 and ≥ 0.8 were regarded as having a moderate and a large effect, respectively [18]. The statistical significance level for all tests was set at 5%.

3. Results

A total of 194 children, aged 3–4 years, participated in this clinical trial. There were 101 children in the SDF group and 93 children in the placebo group. At baseline, 191 (98.5%) questionnaires were collected. One questionnaire was excluded from C-ECOHIS analysis because more than 40% of the C-ECOHIS questions were unanswered. Three questionnaires were input with mode value in one item in the CIS. At the 6-month follow-up, 193 (99.5%) questionnaires were collected. Two questionnaires were excluded for C-ECOHIS analysis due to over 40% of questions being unanswered.

It can be seen from Table 1 that more boys than girls were recruited in both SDF (57.4%) and placebo (61.3%) groups. Most (>80%) of questionnaires were answered by the child’s mother. More than 80% of the parents had secondary school level education or above. No significant difference in parents’ and children’s background was found between the two study groups ($p > 0.05$).

Table 2 displays the clinical features of the participant children. The mean ± SD decayed, missing and filled teeth (dmft) score of the participant children at baseline was 4.6 ± 3.4, with no significant

Table 1
Background of the participant parents and children.

	All participants n = 194		SDF group n = 101		Placebo group n = 93	
	n	%	n	%	n	%
Gender of child						
girl	79	40.7	43	42.6	36	38.7
boy	115	59.3	58	57.4	57	61.3
Relationship with child						
mother	163	84.1	87	86.1	76	81.7
father	26	13.4	11	10.9	15	16.1
grandparents/others	5	2.5	3	3.0	2	2.2
Mother’s education level						
not completed secondary school	33	17.0	17	16.8	16	17.2
completed secondary school	115	59.3	63	62.4	52	55.8
tertiary, non-degree course	25	12.9	11	10.9	14	15.1
university degree program	17	8.8	8	7.9	9	9.7
information missing	4	2.0	2	2.0	2	2.2
Father’s education level						
not completed secondary school	23	11.9	13	12.9	10	10.8
completed secondary school	113	58.3	60	59.4	53	56.9
tertiary, non-degree course	32	16.5	17	16.8	15	16.1
university degree program	21	10.8	9	8.9	12	12.9
information missing	5	2.5	2	2.0	3	3.3

Table 2
Clinical features of the participant children.

	All participants (n = 194)		SDF group (n = 101)		Placebo group (n = 93)		Children with anterior teeth restored (n = 106)		Children without anterior teeth restored (n = 88)	
Mean (SD) dmft score	4.6	(3.4)	4.6	(3.6)	4.6	(3.3)	4.5	(3.7)	4.6	(3.2)
Mean (SD) no. of restorations received	2.6	(1.6)	2.7	(1.6)	2.6	(1.7)	3.0	(1.7)	2.2	(1.4)
Mean (SD) no. of restorations placed in anterior teeth	1.1	(1.3)	1.2	(1.4)	1.0	(1.2)	2.0	(1.1)	0	0
	BL	6 m	BL	6 m	BL	6 m	BL	6 m	BL	6 m
% of children with stain	28.8	27.1	43.4*	28.4	13.0*	25.6	35.6	29.3	20.7	24.4

BL, baseline; 6 m, 6-month follow-up.
* $p < 0.001$.

difference between the SDF (4.6 ± 3.6) and placebo (4.6 ± 3.3) groups ($p > 0.05$). The mean number of restorations received per child was 2.6 ± 1.6. More than half (54.6%) of the participants received ART restorations in their anterior teeth. At baseline, proportionally more children in the SDF group had stain on their anterior teeth compared with that in the placebo group (43.4% vs 13.0%, $p < 0.001$). At 6-month follow-up, there was no significant difference in the proportion of children having stain on their anterior teeth between the SDF and placebo groups ($p > 0.05$).

At baseline, the mean ± SD parental satisfaction scores regarding dental health status and colour of anterior teeth were 2.2 ± 0.8 and 2.6 ± 1.0, respectively (Table 3). There was no statistically significant difference in the distribution of parental satisfaction scores between the SDF and placebo groups ($p > 0.05$). Whether children having anterior teeth restored or not, the distributions of parental satisfaction scores in all four aspects had no statistically significant difference ($p > 0.05$).

The mean parental satisfaction scores regarding their child's dental health status and colour of anterior teeth increased significantly at 6-month follow-up. A moderate ES was found in two aspects, dental health status (ES = 0.6) and colour (ES = 0.3). However, only a small effect (0.1) was observed in two aspects, namely 'alignment' and 'overall tooth appearance'. At baseline, only 6% and 10% of the parents in the SDF and placebo groups, respectively, gave a satisfaction score greater than 3 regarding their child's dental health status. At 6-month follow-up, proportionally more parents in both SDF (38%) and placebo (28%) groups were satisfied with their child's dental health status. A large ES (0.9) of parental satisfaction with their child's dental health status was observed in the SDF group. In the placebo group, a moderate ES (0.5) was observed in the same aspect. Results of the Wilcoxon Signed Ranks Test indicated that the parental satisfaction score of their child's anterior tooth colour at 6-month follow-up increased significantly in the SDF group ($p = 0.002$), while no significant change was found in the placebo group ($p > 0.05$). For the overall tooth appearance, parents whose child had anterior teeth restored gave significantly higher score at follow-up ($p = 0.034$) while no significant change was found among parents whose child did not receive any anterior teeth restoration ($p > 0.05$).

Table 4 displays the frequency of C-ECOHIS response (%) of the two study groups at baseline and 6-month follow-up. At baseline, 20.4% and 34.8% of the parents in the SDF and placebo groups had a zero C-ECOHIS score. More than 70% of the parents in both two groups reported that their child never or hardly ever had pain in teeth, mouth or jaws. No significant change was found at the 6-month follow-up, with about a quarter of parents still had a zero C-ECOHIS score and more than 60% of the children never or hardly ever had dental pain. Furthermore, the vast majority (>80%) of children seldom had 'function', 'psychology' or 'self-image/social interaction' problems related to their oral health. As for the FIS, around one third of the parents reported having parental distress, 'being upset' or 'feeling guilty', at least occasionally and there was not much change at the 6-month follow-up.

The mean C-ECOHIS scores at baseline and 6-month follow-up are shown in Table 5. No statistically significant changes in the mean total C-ECOHIS, CIS and FIS scores were found between baseline and 6-month follow-up ($p > 0.05$). Furthermore, results of Mann-Whitney Test indicated no significant difference in the distribution of C-ECOHIS scores between the SDF and placebo groups at both baseline and 6-month follow-up ($p > 0.05$).

4. Discussion

As a noninvasive caries management method, results of clinical studies show that SDF application is accepted by parents because of its ease of application and pain free procedure [19,20]. Significant improvement in parental satisfaction with their child's dental health 18

Table 3
Mean parental satisfaction scores at baseline and 6-month follow-up, and effect size (ES).

	All participants (n = 190)			SDF group (n = 98)			placebo group (n = 92)			Children with anterior teeth restored (n = 103)			Children without anterior teeth restored (n = 87)		
	BL	6 m	ES	BL	6 m	ES	BL	6 m	ES	BL	6 m	ES	BL	6 m	ES
Dental health status	2.2	2.8***	0.6	2.2	2.8***	0.9	2.3	2.7***	0.5	2.2	2.7***	0.7	2.3	2.8***	0.6
Color	2.6	2.9***	0.3	2.6	2.9**	0.3	2.7	2.9	0.2	2.5	2.8**	0.3	2.8	3.0*	0.2
Alignment	3.2	3.3*	0.1	3.2	3.3	0.1	3.1	3.3	0.2	3.1	3.2	0.1	3.2	3.4	0.1
Overall appearance	3.1	3.2	0.1	3.0	3.2	0.2	3.2	3.3	0.1	3.0	3.2*	0.2	3.2	3.3	0.1

BL, baseline; 6 m, 6-month follow-up; ES, effect size.
***$p < 0.001$; **$p < 0.01$; *$p < 0.05$; p-value was derived by Wilcoxon Signed Ranks test to compare the parental satisfaction scores between baseline and 6-month follow-up.

Table 4
Frequency of C-ECOHIS response (%) at baseline and 6-month follow-up.

	SDF group (n = 98)						placebo group (n = 89)					
	Never or hardly ever		Occasionally		Often or very Often		Never or hardly ever		Occasionally		Often or very Often	
	BL	6 m	BL	6 m	BL	6 m	BL	6 m	BL	6 m	BL	6 m
Symptom												
a) pain in the teeth, mouths or jaws?	71.4	72.4	25.5	25.5	3.1	2.0	75.3	62.9	20.2	33.7	4.5	3.4
Function												
b) difficulty drinking beverages?	92.9	88.8	7.1	11.2	0.0	0.0	93.3	91.0	6.7	5.6	0.0	3.4
c) difficulty eating foods?	86.7	83.7	10.2	14.3	3.1	2.0	87.6	80.9	10.1	16.9	2.2	2.2
d) difficulty pronouncing any words?	84.7	82.7	9.2	16.3	6.1	1.0	88.8	91.0	6.7	6.7	4.5	2.2
e) missed school?	95.9	99.0	4.1	1.0	0.0	0.0	98.9	97.8	1.1	2.2	0.0	0.0
Psychology												
f) trouble sleeping?	95.9	91.8	4.1	8.2	0.0	0.0	94.4	91.0	5.6	9.0	0.0	0.0
g) been irritable or frustrated?	93.9	93.9	6.1	6.1	0.0	0.0	92.1	91.0	5.6	7.9	2.2	1.1
Self-image/social interaction												
h) avoided smiling or laughing?	92.9	91.8	6.1	7.1	1.0	1.0	94.4	94.4	4.5	5.6	1.1	0.0
i) avoided talking?	95.9	95.9	3.1	4.1	1.0	0.0	98.9	98.9	1.1	1.1	0.0	0.0
Parental distress												
j) been upset?	70.4	71.4	23.5	23.5	6.1	5.1	74.2	68.5	22.5	24.7	3.3	6.7
k) felt guilty?	68.4	72.4	22.4	19.4	9.2	8.2	73.0	66.3	18.0	27.0	9.0	6.7
Family function												
l) take hours or days off work?	95.9	93.9	3.1	6.1	1.0	0.0	92.1	88.8	7.9	11.2	0.0	0.0
m) affected the family's economic situation?	92.9	89.8	6.1	10.2	1.0	0.0	88.8	87.6	10.1	10.1	1.1	2.2

BL, baseline; 6 m, 6-month follow-up.
No statistically significant difference was found between groups, and between BL and 6 m.

and 30 months after SDF application has also been reported [20]. Despite this, there are limitations in what can be achieved through applications of SDF. SDF treatment can arrest active caries and prevent development of dental complications but probably does not improve chewing function and dental appearance.

A black and hard surface of a caries lesion is a clinical sign indicating that the progression of dental caries has been stopped [21], but this may not be understood by lay persons. A blackened unrestored cavity in a child's tooth may still be a concern for the parents. They may like to see that the cavity is filled with a tooth-colour material. In the present study, parental satisfaction with their child's dental health status increased significantly after ART restoration placement in both study groups and no matter whether there were restorations placed in the child's anterior teeth. At baseline, before the placement of ART restorations, most of the parents were probably aware of their child's dental health problems and were generally dissatisfied (mean satisfaction score <3) regardless whether their child's decayed teeth had been treated with SDF or not.

In this study, stain could be found on the anterior teeth of children in both groups. As one of the outcomes of SDF application was staining on the arrested caries lesion, the prevalence of stain was much higher in the SDF group compared with the placebo group before placement of ART restoration. Even without SDF application, some children in the placebo group had stain on their anterior teeth. It is probably because of the deposit of dietary chromogens and other substances on the tooth surfaces. The actual mechanism of staining is not fully understood but it is associated with poor oral hygiene and some dietary habits, e.g. drinking tea, coffee, or cola [22]. After ART restoration placement, the cavities with black stain caused by SDF application were restored and covered by glass ionomer cement. The prevalence of stain dropped in the SDF group with no significant difference compared with that in the placebo group at the 6-month follow-up. Consequently, parental satisfaction with the colour of their child's anterior teeth (including stain) increased in the SDF group at 6-month follow-up.

Regarding satisfaction with the overall appearance of their child's teeth, parents whose child had anterior teeth restored reported significantly increased satisfaction while the other parents did not. Very likely, the parents were more sensitive about an improvement in the appearance of their child's anterior teeth compared to that in the posterior teeth. However, no significant change in parental satisfaction with the overall dental appearance of their child was found in either the SDF or placebo group 6 months after the placement of ART restorations. It is noted that many factors of the teeth, e.g. tooth colour, shape, alignment and occlusal relationship, as well as individual perception of aesthetics can affect parental satisfaction with overall dental appearance. It is not surprising that provision of restorative treatment alone

Table 5
Mean (SD) of C-ECOHIS score at baseline and 6-month follow-up.

	All participants (n = 187)				SDF group (n = 98)				Placebo group (n = 89)			
	BL		6 m		BL		6 m		BL		6 m	
CIS	4.0	(4.6)	4.3	(4.9)	4.1	(4.6)	4.2	(4.6)	3.8	(4.6)	4.3	(5.1)
FIS	2.6	(2.9)	2.7	(2.9)	2.6	(2.7)	2.6	(2.7)	2.5	(3.1)	2.8	(3.1)
C-ECOHIS	6.5	(7.0)	7.0	(7.3)	6.8	(6.7)	6.9	(6.8)	6.3	(7.2)	7.1	(7.8)

BL, baseline; 6 m, 6-month follow-up; CIS, child impact section; FIS, family impact section.
No statistically significant difference was found between groups, and between BL and 6 m.

may not be sufficient to significantly improve the parents' overall satisfaction.

Regarding the OHRQoL of the participant children in this study, it is noted that the mean ECOHIS score at baseline is lower than those in studies conducted in other countries [13,18,23–25], but similar to that found in a survey conducted in Hong Kong [26]. One of the reasons is that the source of study children was different. Participants in this study were recruited from kindergartens while those in the studies conducted in other countries were from dental clinics or hospitals. Children who seek dental treatments probably have poor oral health. Thus, low level of OHRQoL reported was due to the impacts from their oral health problems. Besides, due to cultural differences, Chinese parents may perceive less impact from their child's dental problems compared to the parents influenced by other cultures.

The clinical success of ART restorations has been reported in many clinical studies [27], but information from patient-based assessment of the impacts of ART restorations on physical, social and psychological well-being is needed to supplement the clinical findings. A few studies were conducted in this area but their results were not consistent. A study conducted in Australia reported that the MID-ART approach improved ECOHIS scores of children compared to standard care approaches [24]. However, in the present study, the OHRQoL of the study children as measured by the ECOHIS did not change significantly after placement of ART restorations, which is consistent with the findings of a study conducted in Brazil [28]. This finding can be explained in several ways. Firstly, the low C-ECOHIS score at baseline indicates a low level of negative influences of oral health problems on the daily life of the study children and their families. Thus, there was little room for improvement in the children's OHRQoL after receiving ART restorations. Secondly, although ART as a minimally invasive caries treatment might have caused some subtle changes in the OHRQoL of the study children, these might not be perceived and reported by their parents. It has been reported that there is an association between the responsiveness of the ECOHIS and the complexity of dental treatment received by preschool children. A study found that children who received more complicated dental treatment such as endodontic treatment and tooth extraction had more changes in their ECOHIS score than those who received non-operative treatment only [29]. In addition, a number of studies found marked decrease in ECOHIS scores in the children after they had received dental treatments under general anesthesia [23,25,30,31]. Thirdly, in this study, the ART restorations were provided to the children in the kindergarten without the presence of their parents. Without involving the parents, their perceived changes in the OHRQoL of their child after receiving dental treatment may be different from the situation where a dentist-child-parent relationship is established [32].

The present study had a high response and retention rate, and provides valuable information about the changes in OHRQoL of preschool children after receiving ART restorations. Nevertheless, limitations of the present study should also be noted. The ART restorations in this study were provided to Chinese preschool children in a kindergarten setting in Hong Kong, so the results may not be generalizable to other ethnic populations or to preschool children receiving restorations in a clinic setting. In addition, 6 months may not be long enough to fully evaluate the impacts of ART restoration placement on children's OHRQoL. Long-term changes should be investigated in future studies. Moreover, measurement tools of preschool children's OHRQoL that solely rely on parental report may not be able to fully reflect the benefits of dental treatments because the parents may not perceive all the impacts of oral health problems on their child.

Within the limitations of this study, it is concluded that placement of ART restorations regardless whether the decayed teeth have previously received application of SDF solution or not can improve parental satisfaction with their child's dental health status. In addition, placement of ART restorations on SDF-treated anterior primary teeth can lead to higher parental satisfaction with the colour of their child's teeth. However, this minimal invasive restorative treatment has no significant effect on the OHRQoL of preschool children.

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