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ORIGINAL RESEARCH

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Application of a novel medical fluoride applicator device to coat enamel

Wenwei Hong[1], Limin Zhang[1], Changxiu Fan[1], Liuhui Liu[1,*]

[1]Department of Stomatology, Shanghai Fifth People's Hospital, Fudan University, 200240 Shanghai, China

***Correspondence**
liuliuhui@fudan.edu.cn
(Liuhui Liu)

Abstract

Background: Current methods for applying fluoride to deciduous teeth have limitations, such as uneven distribution and patient discomfort, highlighting the need for improved techniques. This study was designed to explore the fluorination efficacy of a newly designed medical fluoride applicator on deciduous teeth, aiming to establish a theoretical foundation for its clinical application. **Methods**: In total, 120 extracted deciduous teeth were randomly assigned to experimental (M10, M20) and control groups (T10, T20). In the experimental groups, a medical fluoride applicator was used to apply 3M ESPE Clinpro™ White Varnish (5% sodium fluoride), while the control groups employed a traditional small brush. Groups M10 and T10 received fluoride application for 10 seconds, whereas groups M20 and T20 were treated for 20 seconds. Six teeth from each group were randomly selected and analyzed at 12, 24 and 48 hours post-application. Scanning electron microscopy were observed enamel surfaces and energy-dispersive X-ray spectroscopy were analyzed the atomic percentages (at%) of carbon (C), oxygen (O), fluoride (F), sodium (Na), magnesium (Mg), silicon (Si), phosphorus (P) and calcium (Ca). **Results**: Enamel surfaces in the experimental groups exhibited rougher textures, with mineral deposits occluding most pore structures. In contrast, control group specimens displayed numerous open pores. Fluoride concentration on the enamel surface was significantly higher in the experimental groups compared to controls ($p < 0.05$), with greater fluoride retention observed at 24 and 48 hours relative to 12 hours ($p < 0.05$). Additionally, samples treated for 20 seconds demonstrated higher fluoride content than those treated for 10 seconds ($p < 0.05$). **Conclusions**: The novel medical fluoride applicator significantly enhances fluoride deposition on enamel compared to traditional methods. Its potential advantages in application efficiency, user comfort, and clinical feasibility warrant further validation and broader implementation in dental practice.

Keywords

Medical fluoride applicator device; Deciduous teeth; Fluoride coating; Fluoride content in enamel; *In vitro* experimental study

1. Introduction

Dental caries, classified as the third most prevalent form of chronic non-infectious disease by the World Health Organization (WHO) after cancer and cardiovascular conditions, is a multifactorial disorder primarily driven by bacterial activity [1]. It leads to the progressive demineralization of dental hard tissues, manifesting as alterations in tooth color, structure and integrity [2]. Despite preventive efforts through fluoride supplementation in water and various consumer products that have contributed to reductions in prevalence in some countries [3], dental caries remains a global health concern, affecting approximately 2.3 billion individuals worldwide, including 530 million children with primary tooth decay [4]. The search for effective preventive strategies thus remains critical to reducing its public health burden.

Among available preventive approaches, fluoride-based interventions are widely regarded as the most effective [5, 6]. Fluoride can be administered systemically or topically, with the latter proving more effective in caries prevention [7, 8]. The appropriate application of fluoride during the mineralization stage of tooth development can help effectively prevent caries formation, with local fluoride application substantially outperforming systemic fluoride delivery [9]. An umbrella meta-analysis demonstrated the efficacy of fluoride interventions as a means of reducing white spot lesion formation during orthodontic treatment [10]. Topical fluoride treatments through which fluoride is directly applied to the tooth surface are particularly effective, curing within 1–4 minutes and forming a transparent film that readily protects deciduous teeth from invasion by bacteria [11].

Traditionally, fluoride varnish is applied using a small brush or cotton swab (Fig. 1). However, this technique has several limitations [12, 13]. Indeed, several studies have demonstrated

that it is limited by issues including uneven fluoride distribution, operator experience, and reduced efficacy due to saliva interference or instrument wear such that large amounts of fluoride are not effectively deposited [14, 15]. Clinical studies indicate that this traditional method achieves low enamel coverage and poor fluoride retention, especially in pediatric and special-needs populations, limiting its anti-caries utility [16, 17].

FIGURE 1. 3M ESPE Clinpro™ white varnish and traditional brush.

Device design limitations have been identified as a major obstacle in optimizing fluoride application efficacy. Valentine Berger *et al*. [18] demonstrated that localized fluoride delivery via personalized 3D-printed mouthguards enhances fluoride incorporation into the enamel matrix, slowing lesion progression. While researchers have explored material innovations such as porous sponge carriers and digital positioning devices, the conventional approach of single-point contact and passive penetration remains largely unchanged [19–21]. To solve the above problems, a novel medical fluoride applicator (patent number: ZL201821815815.5) was designed in 2019 [22]. This device features a U-shaped brush head designed based on the dental arch surface database to simultaneously coat the occlusal, buccal and lingual surfaces of teeth (Fig. 2), increasing fluoride contact area compared to conventional brushes.

We hypothesize that this applicator will enhance fluoride distribution to multiple tooth surfaces, shorten application time, improve operator efficiency, and alleviate patient discomfort and fear—particularly in children. The multi-bristle design is expected to provide more uniform fluoride coverage. However, no *in vitro* or clinical studies have yet been conducted evaluating this device. Therefore, this study was devised with the aim of assessing its efficacy by comparing the fluoride deposition achieved with the novel applicator on deciduous incisors to that achieved using a traditional small brush. Together, the findings from this study will help clarify the relative strengths and limitations of this applicator, providing a scientific basis for its potential clinical adoption while addressing a gap in current research.

2. Materials and methods

2.1 Sample collection and inclusion criteria

In total, 120 exfoliated deciduous teeth were obtained from the Department of Pediatric Dentistry at Shanghai Fifth People's Hospital from August 2022 through September 2023, with informed consent having been provided by legal guardians (Ethics Approval No. 2022 EC (097)).

Exclusion criteria:

(1) Macroscopic defects: Presence of caries, cracks, hypoplasia or enamel fractures.

(2) Microscopic defects: Evidence of demineralization, white spot lesions, or abnormal prism structures, confirmed via stereomicroscopy (Olympus SZX16, 25× magnification, Olympus Corporation, Tokyo, Japan).

Selected teeth underwent ultrasonic cleaning using a 10% Sodium Bicarbonate ($NaHCO_3$) solution for 15 minutes, followed by disinfection in 0.5% chlorhexidine for 24 hours. Samples were subsequently stored in artificial saliva (pH 6.8) at 37 °C until experimentation.

2.2 Stratified randomization and group allocation

2.2.1 Sample size calculation

Based on a pilot study (α = 0.05, β = 0.2, effect size = 1.6), a minimum of 6 teeth per group was required, as determined using G*Power 3.1 software (University of Düsseldorf, Düsseldorf, NRW, Germany).

Randomization protocol:

(1) Stratification: Samples were categorized into incisors (n = 48), canines (n = 24) and molars (n = 48).

(2) Block randomization:

• Using R (v4.3.1, randomize R package, seed = 2023), teeth were assigned into 12 blocks (10 teeth per block), ensuring proportional representation of incisors, canines and molars (2:1:2 ratio), as illustrated in Fig. 3.

• Each block was randomly assigned to:

(1) Experimental groups (n = 6 groups): Fluoride was applied using the novel medical fluoride applicator (5% sodium fluoride, 3M ESPE Clinpro™ White Varnish).

• M10: 10 s application (n = 30 teeth).

• M20: 20 s application (n = 30 teeth).

(2) Control groups (n = 6 groups): Fluoride was applied using a traditional brush (5% sodium fluoride, 3M ESPE Clinpro™ White Varnish).

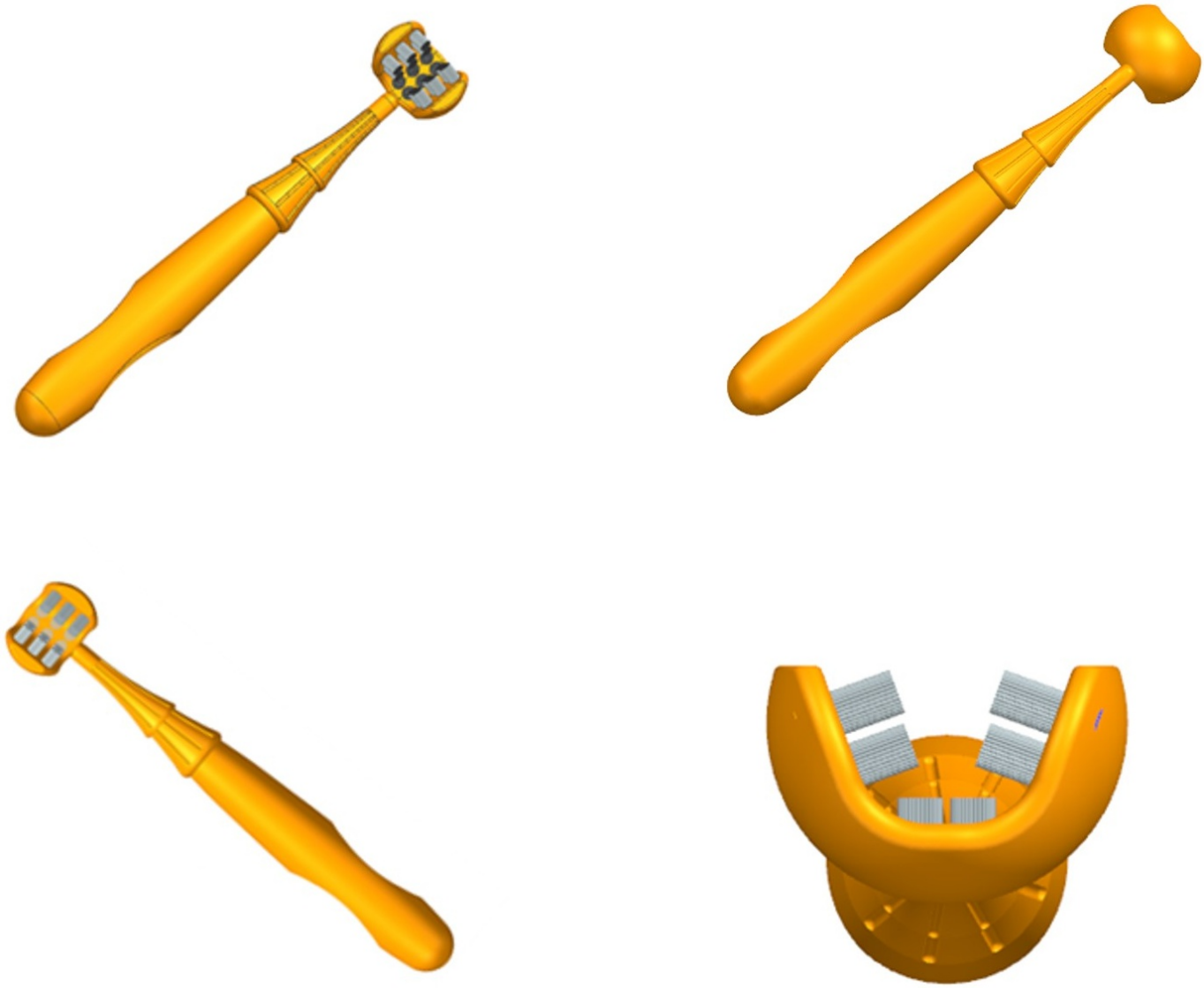

FIGURE 2. Diagrammatic overview of the newly developed medical fluoride applicator.

FIGURE 3. Representative image of simulated dental arches.

• T10: 10 s application (n = 30 teeth).
• T20: 20 s application (n = 30 teeth).
(3) Allocation concealment: Group assignments were sealed in opaque envelopes to ensure blinding.

2.2.2 Rationale for timing

• 10-second application: Preliminary tests demonstrated that the novel medical fluoride applicator effectively covered all teeth in the single jaw within 10 seconds.
• 20-second application: Pilot data indicated that the traditional brush required 20 seconds to achieve comparable coverage.

2.2.3 Fluoride application protocol

(1) Experimental groups: 0.125 mL of fluoride varnish was applied using the novel medical fluoride applicator.
(2) Control groups: The same fluoride volume was applied using a standardized brushing technique.
(3) Environmental Conditions: Procedures were conducted at 23 ± 1 °C and 50 ± 5% relative humidity (RH).

2.3 Post-treatment analysis

Sampling timeline: Following fluoride application, treated teeth were placed in 24-well plates (one tooth per well) containing 1 mL of deionized water and incubated in a 37 °C water bath oscillator. At 12, 24 and 48 hours post-application, 6 teeth from each group (M10, M20, T10, T20) were randomly selected for analysis (two incisors, two canines and two molars). Each sample was assessed at a single time point to prevent structural damage from repeated measurements.

The detailed sample size distribution and experimental workflow was depicted in Fig. 4.

2.4 Scanning electron microscopy (SEM)

Prior to scanning electron microscopy (SEM) examination, all samples rinsed in double de ionized water for 12 h at room temperature followed by blotting it dry with a blotting paper. Specimens were fixed to aluminium stubs with double-sided adhesive carbon tape (SPI Supplies, USA). Since we performed the analysis in the Low Vacuum Mode (25 Pa of chamber pressure), the application of a conducting coating was not necessary. Randomly selected buccal enamel surfaces were observed with Nova NanoSEM 230 (FEI Company, Hillsboro, OR, USA) at three different magnifications (×1000, ×2000 and ×3000), with an electron acceleration voltage of 15–20 kV and using the backscattered electrons detector.

2.5 Energy-dispersive X-ray spectroscopy (EDS) analysis

The same buccal surface of each tooth was visualised under SEM at a standardised magnification of ×100 with a working distance of 10 mm and the whole image area was selected to determine the atomic percentages (at%) of carbon (C), oxygen (O), fluoride (F), sodium (Na), magnesium (Mg), silicon (Si), phosphorus (P), and calcium (Ca), using an X-ray detector system (Oxford Instruments, 7582, Abingdon, U.K.) attached to the scanning electron microscope.

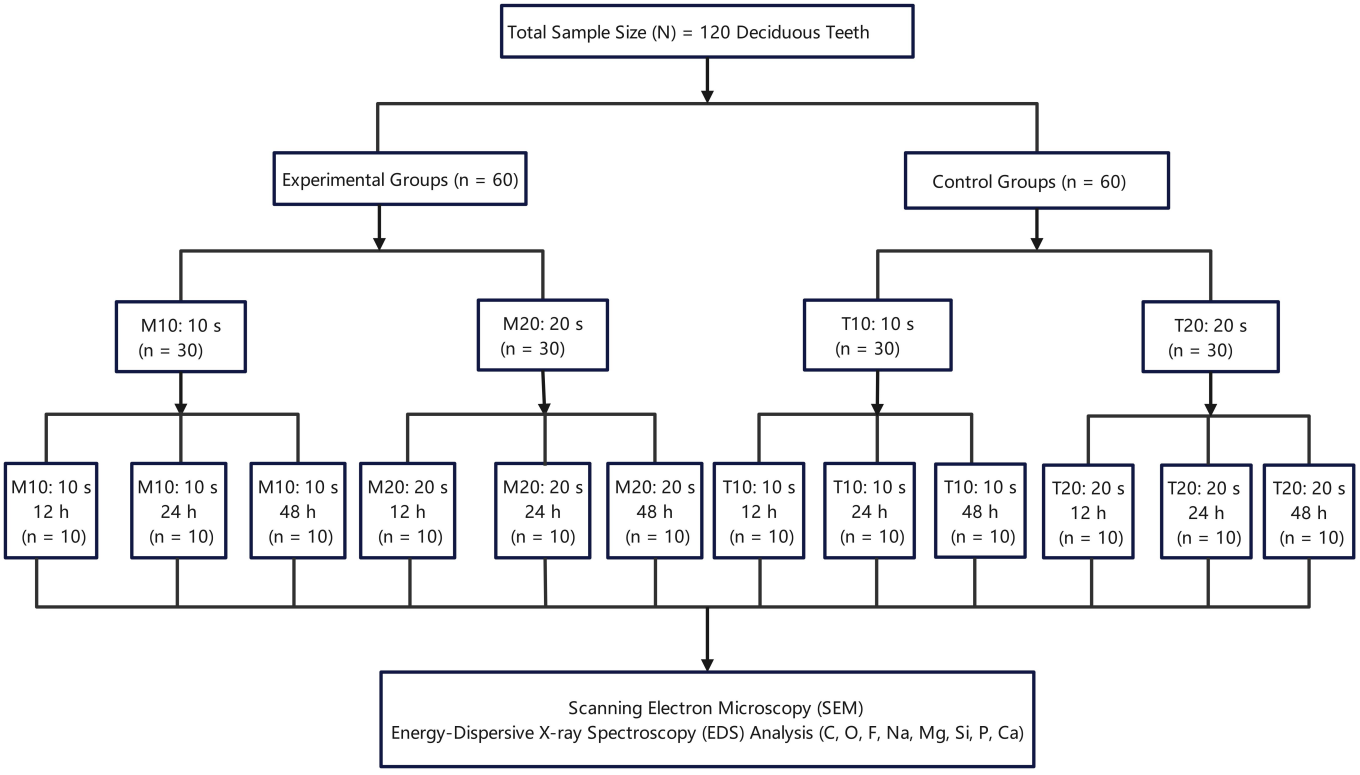

FIGURE 4. Sample size distributions and experimental workflow. C: carbon; O: oxygen; F: fluoride; Na: sodium; Mg: magnesium; Si: silicon; P: phosphorus; Ca: calcium; n: the number of samples per group.

2.6 Statistical analysis

SPSS 25.0 (IBM Corp., Armonk, NY, USA) was used for all analyses. Continuous variable normality was evaluated with the Shapiro-Wilk test ($n < 50$) and the Kolmogorov-Smirnov test ($n \geq 50$). When normally distributed they were reported as the means ± standard deviation ($\bar{x} \pm s$) and compared with Student's *t*-tests (two groups) or one-way analysis of variance (ANOVAs) (three or more groups). When non-normally distributed, data were reported as medians (interquartile range, IQR) and assessed with Mann-Whitney U tests (two groups) or Kruskal-Wallis H tests (three or more groups), assessing significance with the Dunn-Bonferroni *post hoc* test. Categorical variables were reported as frequencies (%) and compared with chi-square tests or Fisher's exact test (expected count <5). Effect size calculations for chi-square and Student's *t*-tests were performed with Cramer's V and Cohen's *d*, respectively. A two-tailed $p < 0.05$ was considered significant (95% confidence interval).

3. Results

3.1 Enamel surface morphology analyses

The enamel surface morphologies of experimental and control groups were examined at 12, 24 and 48 hours post-application under varying magnifications (Figs. 5,6,7,8,9,10; Fluoride application for 10 s: M10 (12 h/24 h/48 h, a–c) and T10 (12 h/24 h/48 h, d–f); Fluoride application for 20 s: M20 (12 h/24 h/48 h, a–c) and T20 (12 h/24 h/48 h, d–f)).

Overall, enamel surfaces in the experimental groups (M10, M20) exhibited rough textures with extensive pore occlusion by newly formed mineral crystals. The crystal structures were relatively uniform, and a distinct crystalline morphology was observed. These findings indicate a high degree of mineralization with minimal microporosity. In contrast, control group samples (T10, T20) displayed irregular, rough enamel surfaces with numerous visible pores and a less structured crystalline arrangement.

3.2 Enamel fluoride content—10-second application

The fluoride concentration on the enamel surface in the experimental groups was significantly higher than that observed in the control groups at all three time points—12 h, 24 h and 48 h. These differences were statistically significant ($p = 0.002$, $p = 0.001$ and $p = 0.024$, respectively), as shown in Table 1. Within the experimental groups subjected to a 10-second fluoride application, fluoride levels at 24 h and 48 h were significantly greater than those at 12 h ($p = 0.013$, $p = 0.002$). However, no statistically significant difference was observed between 24 h and 48 h ($p = 1.000$), as depicted in Fig. 11.

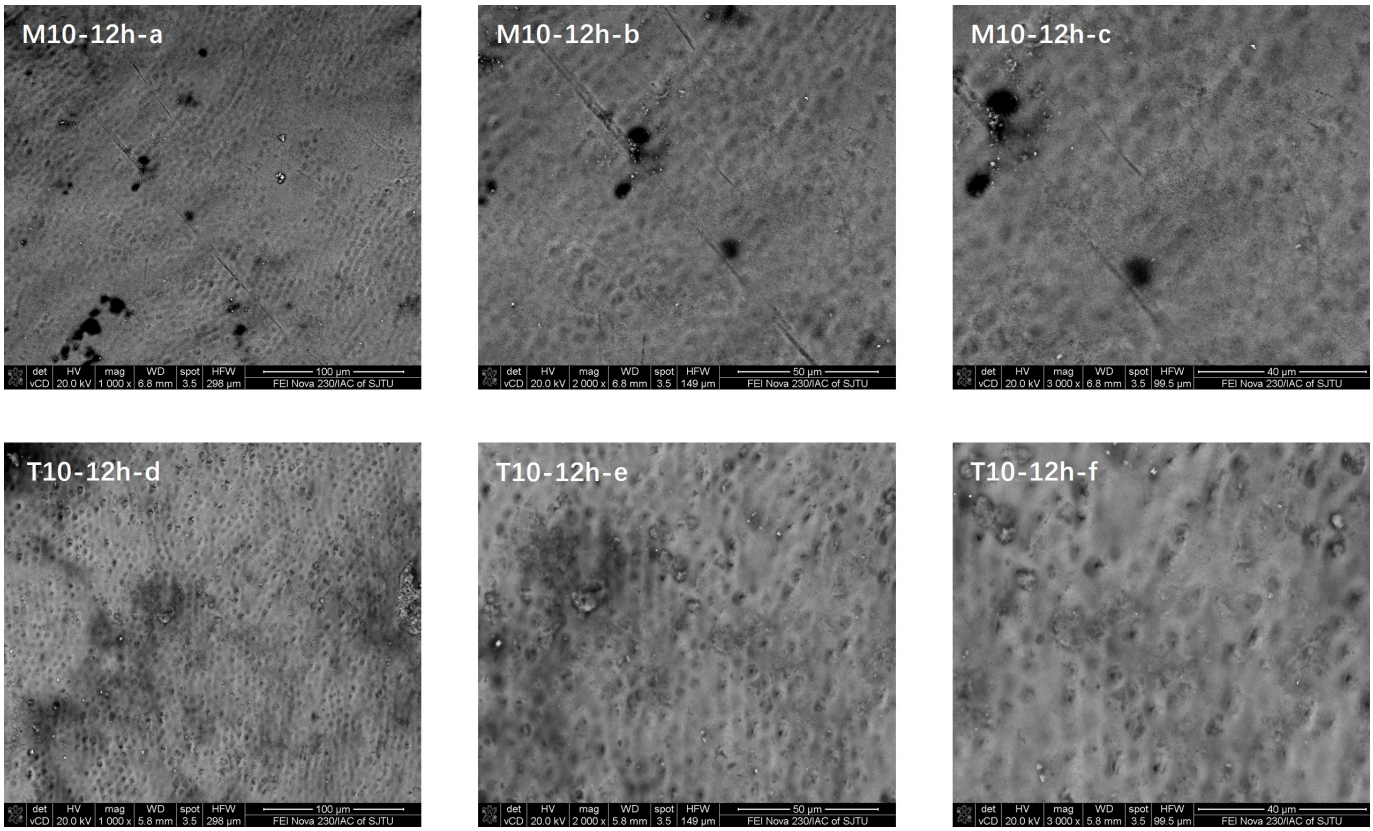

FIGURE 5. Enamel surface morphology comparisons in the M10 and T10 (control) groups 12 hours after the 10-second application of fluoride. M10-12h-a–c: Analyses of enamel surface morphology 12 h following fluoride application for 10 s using the novel medical fluoride applicator. T10-12h-d–f: Analyses of enamel surface morphology 12 h following fluoride application for 10 s using a traditional brush. a: ×1000; b: ×2000; c: ×3000; d: ×1000; e: ×2000; f: ×3000.

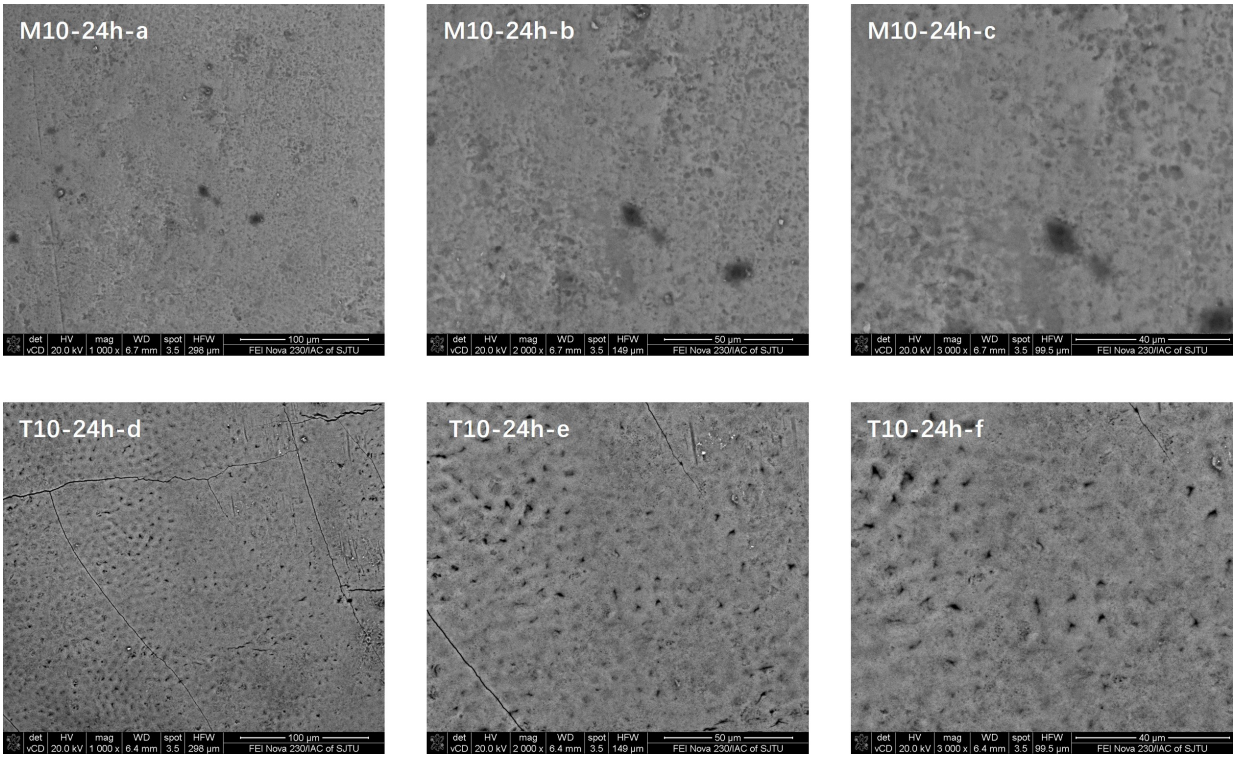

FIGURE 6. Enamel surface morphology comparisons in the M10 and T10 (control) groups 24 hours after the 10-second application of fluoride. M10-24h-a–c: Analyses of enamel surface morphology 24 h following fluoride application for 10 s using the novel medical fluoride applicator. T10-24h-d–f: Analyses of enamel surface morphology 24 h following fluoride application for 10 s using a traditional brush. a: ×1000; b: ×2000; c: ×3000; d: ×1000; e: ×2000; f: ×3000.

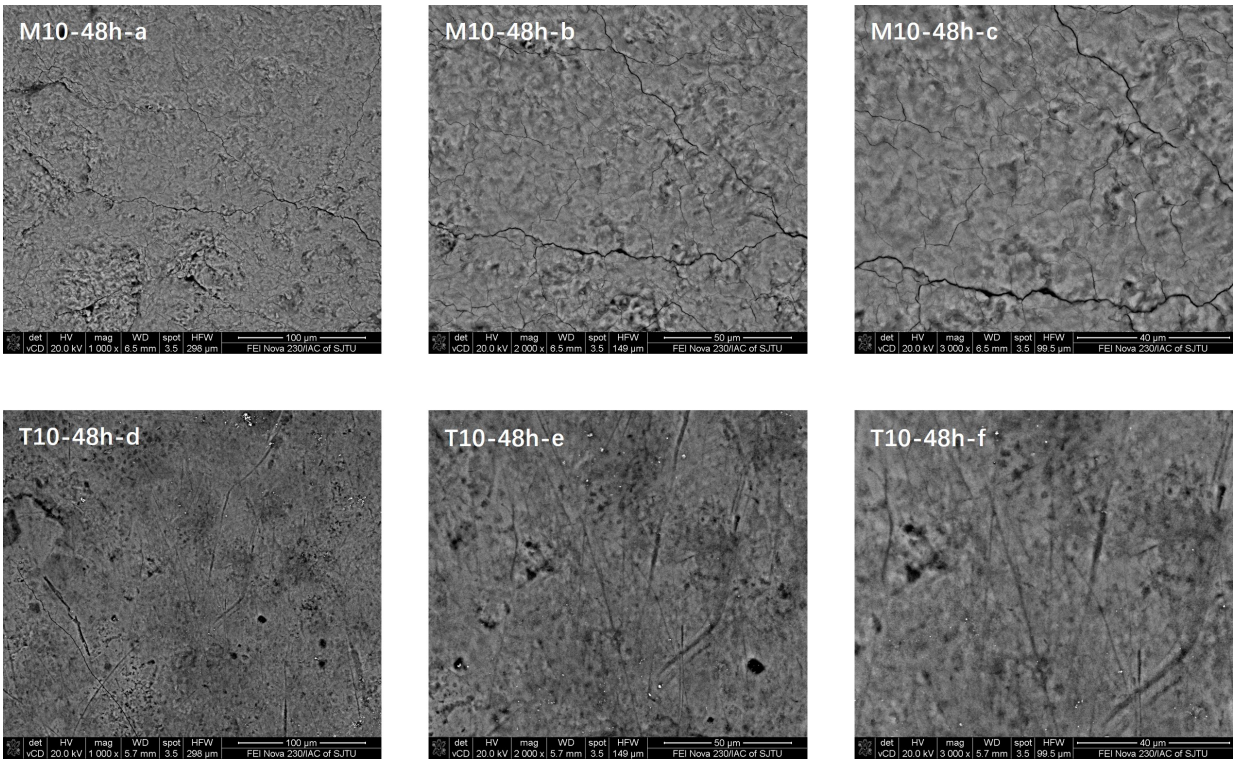

FIGURE 7. Enamel surface morphology comparisons in the M10 and T10 (control) groups 48 hours after the 10-second application of fluoride. M10-48h-a–c: Analyses of enamel surface morphology 48 h following fluoride application for 10 s using the novel medical fluoride applicator. T10-48h-d–f: Analyses of enamel surface morphology 48 h following fluoride application for 10 s using a traditional brush. a: ×1000; b: ×2000; c: ×3000; d: ×1000; e: ×2000; f: ×3000.

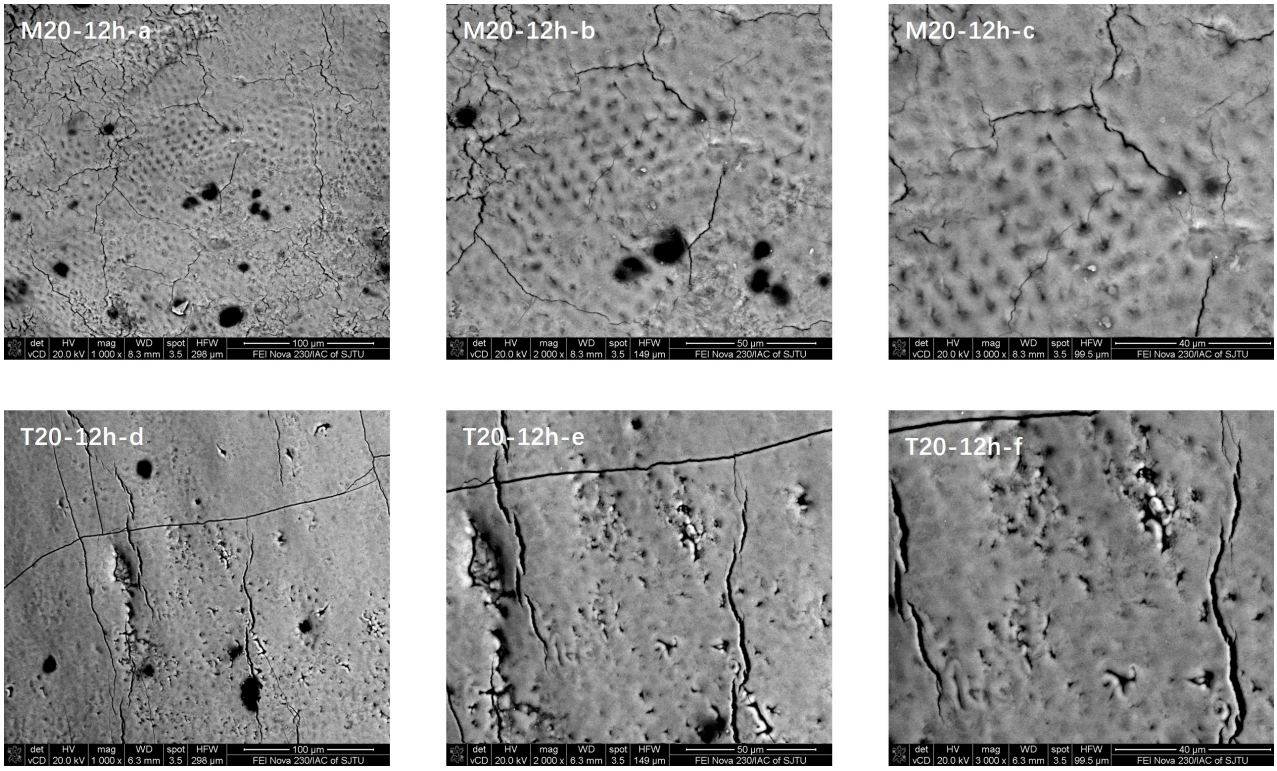

FIGURE 8. Enamel surface morphology comparisons in the M20 and T20 (control) groups 12 hours after the 20-second application of fluoride. M20-12h-a–c: Analyses of enamel surface morphology 12 h following fluoride application for 20 s using the novel medical fluoride applicator. T20-12h-d–f: Analyses of enamel surface morphology 12 h following fluoride application for 20 s using a traditional brush. a: ×1000; b: ×2000; c: ×3000; d: ×1000; e: ×2000; f: ×3000.

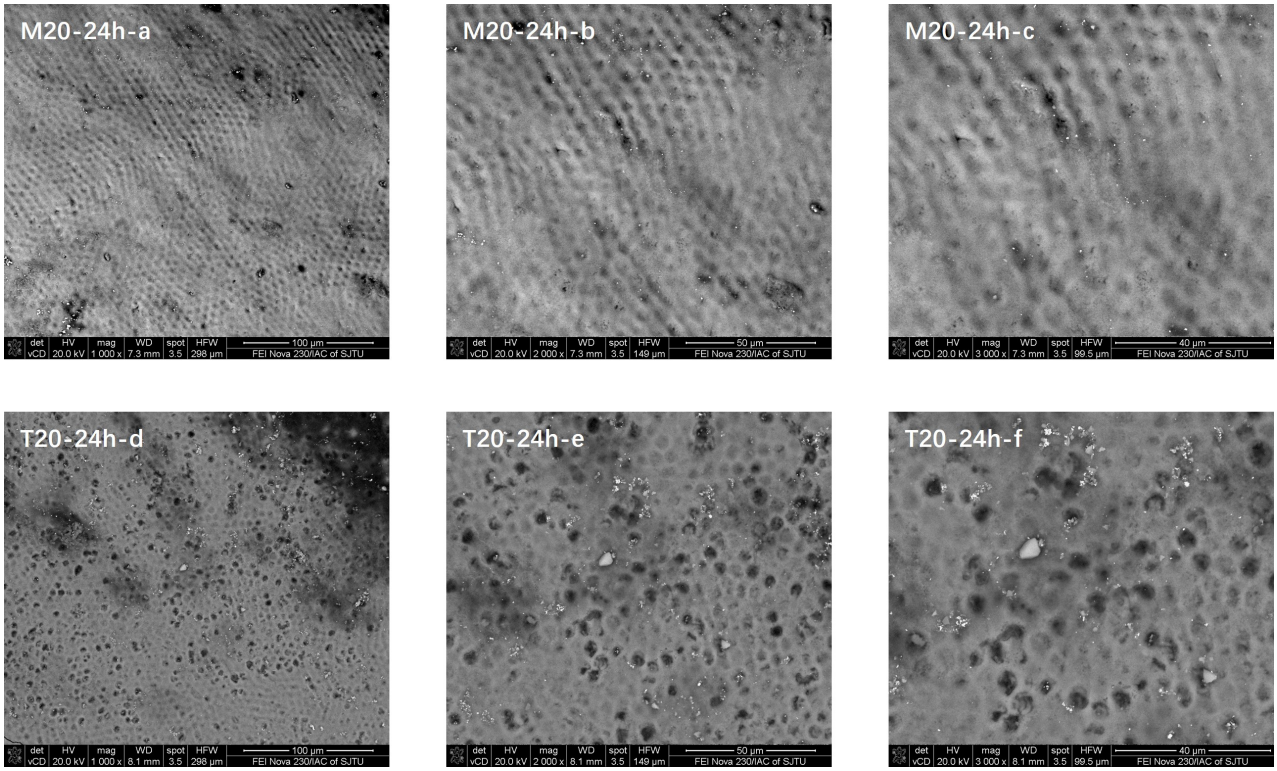

FIGURE 9. Enamel surface morphology comparisons in the M20 and T20 (control) groups 24 hours after the 20-second application of fluoride. M20-24h-a–c: Analyses of enamel surface morphology 24 h following fluoride application for 20 s using the novel medical fluoride applicator. T20-24h-d–f: Analyses of enamel surface morphology 24 h following fluoride application for 20 s using a traditional brush. a: ×1000; b: ×2000; c: ×3000; d: ×1000; e: ×2000; f: ×3000.

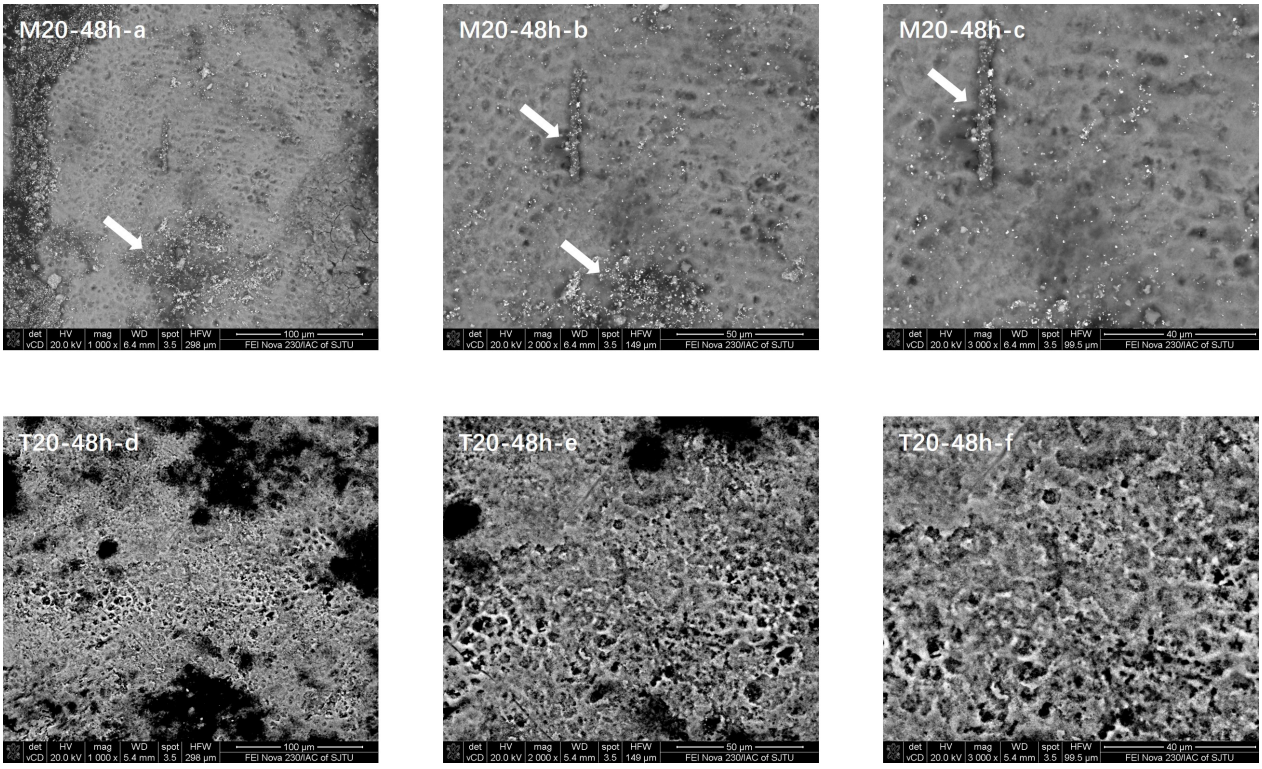

FIGURE 10. Enamel surface morphology comparisons in the M20 and T20 (control) groups 48 hours after the 20-second application of fluoride. M20-48h-a–c: Analyses of enamel surface morphology 48 h following fluoride application for 20 s using the novel medical fluoride applicator. T20-48h-d–f: Analyses of enamel surface morphology 48 h following fluoride application for 20 s using a traditional brush. a: ×1000; b: ×2000; c: ×3000; d: ×1000; e: ×2000; f: ×3000. Areas with crystal structures are marked with white arrows.

TABLE 1. Enamel surface element composition analyses for the experimental and control groups over time following fluoride application for 10 s (%).

	C	Na	Mg	Si	P	O	Ca	F
12 h								
M10	10.09 ± 0.91	0.57 ± 0.04	0.14 ± 0.03	0.13 ± 0.03	15.57 ± 0.31	32.77 ± 1.74	39.47 ± 0.94	1.27 ± 0.14
T10	9.47 ± 1.02	0.52 ± 0.04	0.15 ± 0.02	0.14 ± 0.03	16.12 ± 0.68	34.05 ± 1.18	38.64 ± 1.04	0.90 ± 0.65
p	0.292	0.066	0.598	0.556	0.101	0.163	0.180	0.002
24 h								
M10	11.32 ± 2.25	0.41 ± 0.21	0.18 ± 0.15	0.92 ± 0.92	14.21 ± 1.62	30.72 ± 2.08	40.60 ± 2.98	1.74 ± 0.13
T10	11.48 ± 0.84	0.59 ± 0.10	0.28 ± 0.07	0.18 ± 0.09	13.34 ± 1.39	31.55 ± 2.90	41.23 ± 2.34	1.15 ± 0.28
p	0.871	0.082	0.163	0.083	0.486	0.580	0.688	0.001
48 h								
M10	9.57 ± 3.57	0.46 ± 0.16	0.15 ± 0.11	0.32 ± 0.52	15.48 ± 0.64	31.87 ± 0.74	40.26 ± 3.38	1.89 ± 0.38
T10	11.76 ± 0.77	0.47 ± 0.05	0.35 ± 0.21	0.27 ± 0.25	12.88 ± 0.71	30.42 ± 1.05	42.67 ± 2.33	1.16 ± 0.55
p	0.172	0.865	0.064	0.846	<0.001	0.021	0.180	0.024

Independent Samples t-tests were utilized to compare means between two groups (e.g., M10-12 h vs. T10-12 h). C: carbon; O: oxygen; F: fluoride; Na: sodium; Mg: magnesium; Si: silicon; P: phosphorus; Ca: calcium.

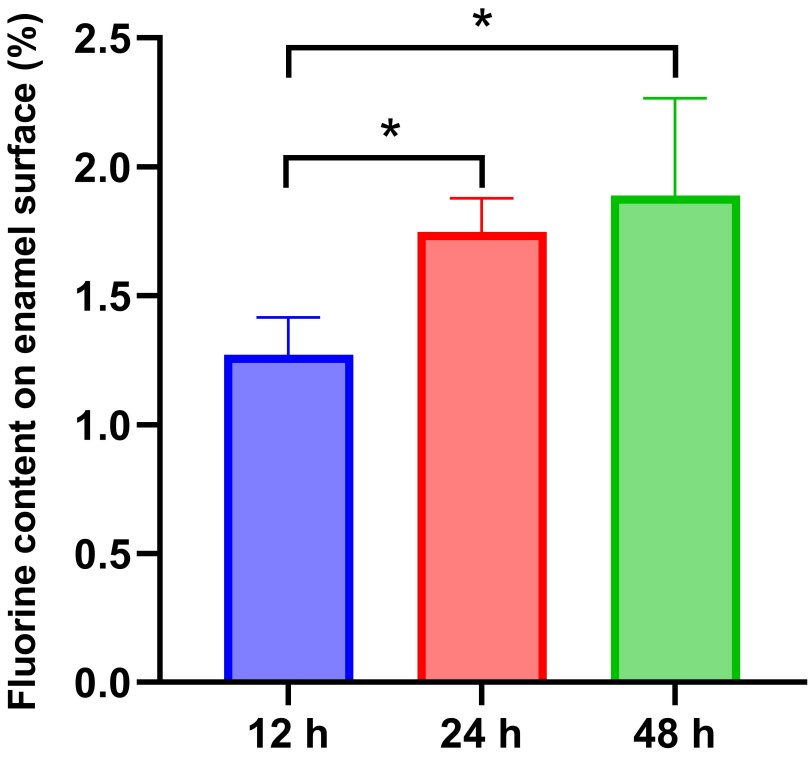

FIGURE 11. Measurement of enamel surface fluoride content at 12, 24 and 48 hours following fluoride application for 10 seconds. Data were compared via one-way ANOVA with Dunn-Bonferroni *post-hoc* test. M10-12 h *vs.* M10-24 h *vs.* M10–48 h. *: $p < 0.05$.

3.3 Enamel fluoride content—20-second application

In the experimental groups where fluoride was applied for 20 seconds, fluoride levels on the enamel surface remained significantly elevated compared to the control groups at 12 h, 24 h and 48 h ($p = 0.032$, $p < 0.001$, $p = 0.001$), as shown in Table 2. Additionally, within the experimental groups subjected to a 20-second application, fluoride concentrations at 24 h and 48 h were significantly higher than at 12 h ($p = 0.007$, $p = 0.002$). However, the difference between 24 h and 48 h was not statistically significant ($p = 1.000$), as illustrated in Fig. 12.

3.4 Comparison of fluoride content between 10-second and 20-second applications

When comparing fluoride retention between the 10-second and 20-second application groups, the 20-second application consistently resulted in higher fluoride content across all time points ($p \leq 0.001$), as shown in Fig. 13.

4. Discussion

Recent research on human subjects has demonstrated that customized 3D-printed mouthguards can enable controlled intraoral release of active compounds by modifying their matrix composition [23]. Building on this concept, the novel three-sided U-shaped fluoride applicator detailed herein represents a significant advancement in pediatric caries prevention, integrating morphological innovation with engineering optimization. Its potential for clinical translation could greatly enhance global oral health. Compared to conventional small-brush application methods, this device offers distinct advantages across three key dimensions discussed below.

First, the device has an innovative design for superior coverage. Developed based on a comprehensive dental arch morphology database, the device features a three-sided U-shaped brush head that simultaneously covers the occlusal, buccal and lingual surfaces of the teeth. This contrasts with traditional small brushes, which provide only partial coverage. Our *in vitro* experiments revealed that the new device significantly increased the contact area with deciduous teeth, facilitating a more uniform and thorough fluoride application. Prior studies support the correlation between increased contact area and enhanced fluoride uptake, reinforcing the effectiveness of this design [24, 25].

Second, the streamlined fluoride application process offers dual benefits: reducing overall clinical treatment time while improving patient experience, particularly among young and uncooperative children. Shorter chair time is crucial in pediatric dentistry, where patient compliance remains a significant challenge. By aligning with the American Academy of Pediatric Dentistry's (AAPD) behavioral management guidelines, the device addresses common obstacles related to procedural efficiency and treatment adherence [26].

Third, designed for ease of use, the device's simple "point-and-shoot" design enables non-dental professionals to achieve proficiency within an hour of training. This feature supports widespread adoption in community healthcare settings, where dental services may be limited. By allowing trained nurses and healthcare workers to apply fluoride effectively, the device en-

TABLE 2. Enamel surface element composition analyses for the experimental and control groups over time following fluoride application for 20 s (%).

	C	Na	Mg	Si	P	O	Ca	F
12 h								
M20	11.80 ± 1.53	0.37 ± 0.06	0.15 ± 0.02	0.29 ± 0.09	12.38 ± 1.12	34.31 ± 3.14	38.52 ± 2.67	2.20 ± 0.25
T20	11.17 ± 0.74	0.22 ± 0.14	0.16 ± 0.13	0.29 ± 0.06	11.56 ± 0.48	34.96 ± 1.83	40.42 ± 1.42	1.21 ± 0.93
p	0.388	0.042	0.785	0.884	0.134	0.671	0.155	0.032
24 h								
M20	11.57 ± 0.99	0.86 ± 0.27	0.35 ± 0.14	0.15 ± 0.06	13.34 ± 1.39	33.02 ± 3.81	37.82 ± 3.07	2.89 ± 0.29
T20	10.61 ± 1.37	0.50 ± 0.04	0.34 ± 0.13	0.08 ± 0.02	14.13 ± 1.28	34.62 ± 1.08	38.14 ± 0.98	1.58 ± 0.27
p	0.203	0.009	0.915	0.015	0.329	0.344	0.813	<0.001
48 h								
M20	10.93 ± 0.62	0.47 ± 0.05	0.35 ± 0.21	0.27 ± 0.25	12.88 ± 0.71	33.59 ± 0.78	38.51 ± 1.44	3.01 ± 0.43
T20	11.49 ± 0.57	0.26 ± 0.15	0.15 ± 0.05	0.45 ± 0.40	12.35 ± 0.77	34.86 ± 1.06	38.51 ± 0.79	1.94 ± 0.20
p	0.137	0.008	0.044	0.381	0.250	0.040	0.998	0.001

Independent Samples t-tests were utilized to compare means between two groups (e.g., M20-12 h vs. T20-12 h). C: carbon; O: oxygen; F: fluoride; Na: sodium; Mg: magnesium; Si: silicon; P: phosphorus; Ca: calcium.

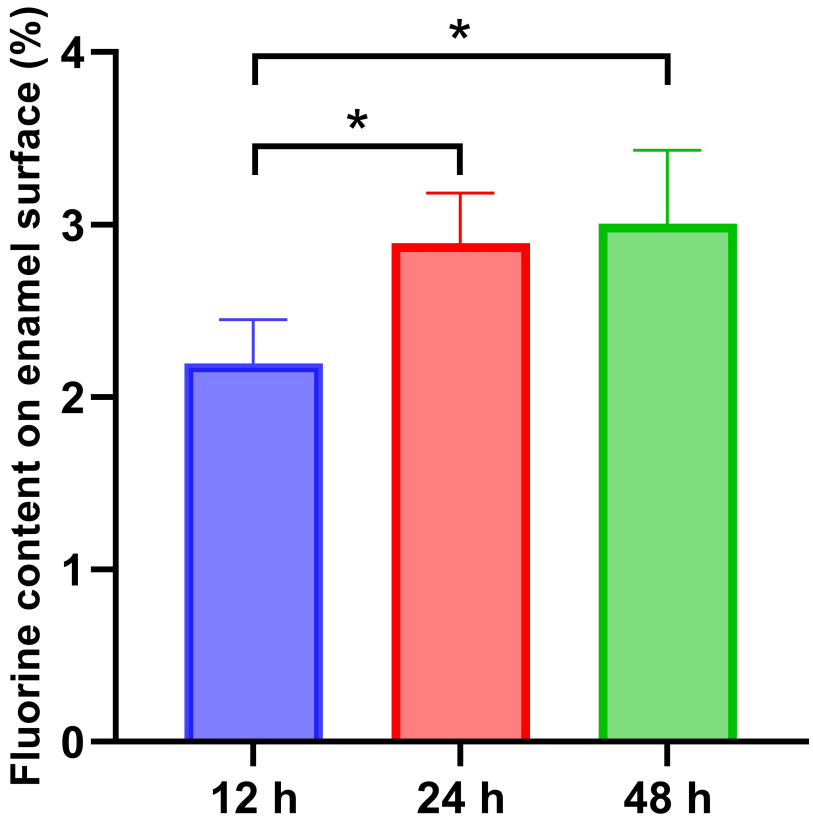

FIGURE 12. Measurement of enamel surface fluoride content at 12, 24 and 48 hours following fluoride application for 20 seconds. Data were compared via one-way ANOVA with Dunn-Bonferroni *post-hoc* test. M20-12 h *vs.* M20-24 h *vs.* M20-48 h. *: $p < 0.05$.

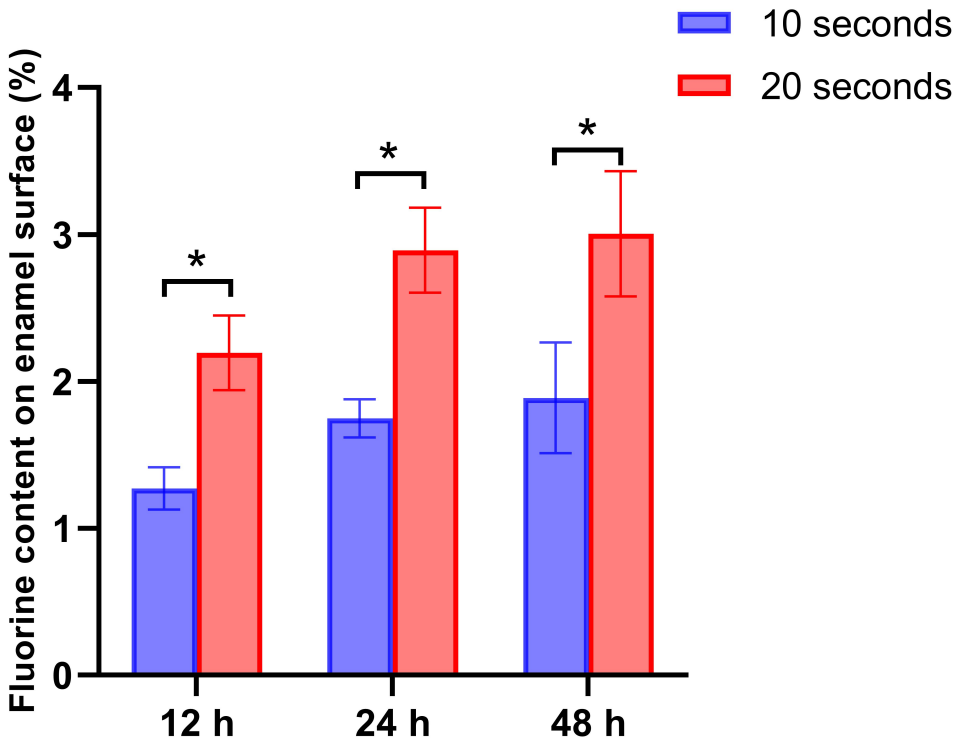

FIGURE 13. Evaluation of the fluoride content on enamel surfaces over time in different groups following fluoride application for 10 or 20 seconds. Independent Samples *t*-test: Used for comparing means between two groups (*e.g.*, M10 *vs.* M20). *: $p < 0.05$.

hances accessibility in underserved populations, contributing to global efforts toward equitable oral healthcare.

While this study did not quantify fluoride coating thickness directly, enamel surface morphology assessments provided valuable insights into the device's efficacy. Post-application observations revealed a smoother, more uniform enamel surface, characterized by spherical, granular, flaky and strip-like crystalline deposits, along with U-shaped crystal growth patterns. These findings align with previous research by Brar *et al.* [27], who demonstrated that homogenous fluoride deposition promotes the formation of well-structured fluorapatite crystals, thereby reinforcing enamel resistance to demineralization. The improved enamel surface integrity in the experimental groups suggests that the new device achieves an optimal fluoride distribution, potentially linked to an ideal coating thickness [28]. Prior studies have established that achieving a specific fluoride layer thickness enhances fluorapatite formation, maximizing enamel protection against caries [29]. The observed enamel modifications following fluoride application with the novel device imply that it may effectively deliver fluoride in a manner conducive to long-term enamel strengthening.

The fluoride concentration on the enamel surfaces of deciduous teeth treated with the novel applicator device was significantly higher than that achieved using the conventional small-brush method. This finding aligns with previous research by Berger *et al.* [18], who demonstrated that sustained localized fluoride release at the enamel-device interface through personalized 3D-printed mouthguards enhances fluoride incorporation into the tooth matrix and slows lesion progression. Our results further underscore the device's potential to improve both enamel mineralization and fluorination, reinforcing its promise in pediatric dental care. Regarding fluoride release dynamics, prior studies have consistently shown that fluoride coatings release ions in a controlled, gradual manner over time [30]. The most substantial fluoride ion release occurs within the first hour following application, accounting for approximately 14% of the total fluoride content [31]. Thereafter, the release rate declines, yet fluoride ions remain detectable on the enamel surface even 10 days post-application [30, 31]. Our findings revealed a significant increase in enamel fluoride levels at 24 and 48 hours compared to the 12-hour mark. However, no statistically significant difference was observed between the 24-hour and 48-hour time points. This plateau effect may indicate that the enamel reaches a fluorination saturation threshold, aligning with established ion diffusion principles [32–34].

Comparing fluoride retention across different application durations, enamel surfaces in the 20-second fluoride application groups exhibited significantly higher fluoride content than those in the 10-second groups. This suggests that extending the application time leads to greater fluoride deposition, as evidenced by significant increases in fluoride concentration at 12, 24 and 48 hours. A substantial body of *in vivo* and *in vitro* research has demonstrated that fluoride coatings facilitate substantial fluoride retention on the enamel surface [35–37]. As external fluoride concentrations rise, fluoride ions interact with enamel components via ionic bonding, promoting a dynamic equilibrium [38]. Hydroxyapatite crystals within the enamel, which have a natural affinity for fluoride, integrate these ions into their structure [24]. The chemical potential gradient between the coating-associated external high-fluoride environment created by the coating and the lower-fluoride

interior of the enamel drives this process [39]. By precisely controlling coating duration, the novel applicator device optimizes fluoride deposition, thereby enhancing its preventive effects against caries.

The single-use cartridge of the applicator provides a premeasured 0.125 mL dose of 5% sodium fluoride gel (22,600 ppm F^-), consistent with the WHO recommended maximum pediatric dosage ($\leq$0.25 mL per session) [13]. Given that this study was conducted *in vitro*, potential acute toxic effects could not be assessed. Future clinical applications should consider certain risks, including the possibility that increased enamel surface roughness in the experimental group may heighten susceptibility to mechanical gingival irritation. Additionally, soft tissue reactions following prolonged use warrant further investigation through clinical trials. To minimize potential adverse effects, clinical application should incorporate protective measures such as rubber dam isolation and swallowing risk assessments.

This study has several limitations. First, *in vitro* conditions cannot fully replicate the complex environment of the oral cavity. Differences in fluoride retention, anti-caries effectiveness, and mineralization potential may exist between *in vitro* and *in vivo* settings. Successful crystal growth and deposition require the presence of seed crystals or nucleation sites, which are relatively sparse and less active under natural oral conditions. Furthermore, biological factors such as salivary proteins, pyrophosphate inhibitors, and variations in calcium-to-phosphate (Ca/P) ratios in saliva may influence fluoride deposition and mineralization. Second, due to the irreversible nature of sample processing for acid-etching and SEM analysis, baseline mineral content (*e.g.*, calcium and phosphate levels) could not be retrospectively quantified. While rigorous stratified randomization was employed to minimize potential confounding variables (*e.g.*, tooth type, arch position), variations in initial mineralization status that were not assessed may have contributed to residual confounding. Subsequent studies should incorporate non-destructive baseline characterization strategies, such as micro-computed tomography (micro-CT) or Raman spectroscopy, to enhance the accuracy of fluoride efficacy assessments prior to experimental interventions. Further clinical investigations are necessary to validate the safety and efficacy of this fluoride coating device, with the ultimate goal of refining its design to maximize fluoride retention, reduce clinical workload, and enhance caries prevention.

5. Conclusions

This *in vitro* study compared the effectiveness of a novel fluoride applicator device with traditional small-brush methods in enhancing enamel fluoride uptake in deciduous teeth. The results demonstrated significant advantages of the new device, including superior fluoride retention, improved structural integrity, and greater fluorination efficiency. Notably, a 20-second application yielded better outcomes than a 10-second application. Additionally, the device's ease of use, enhanced patient comfort and operational efficiency highlight its clinical potential. These findings provide a strong theoretical foundation for clinical implementation, suggesting that this technology could play a pivotal role in pediatric dentistry by improving oral health outcomes, reducing caries incidence, and alleviating financial burdens on families and overall healthcare systems. Additional clinical trials are necessary to validate these findings and facilitate the broader adoption of this promising technology for pediatric oral health management.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

WWH—conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing–original draft. LMZ—conceptualization; formal analysis; funding acquisition; investigation; methodology; resources; software; supervision; validation; visualization. CXF—conceptualization; formal analysis; funding acquisition; investigation; methodology; resources; software; supervision; validation; visualization. LHL—conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing–review and editing.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The studies involving human participants were reviewed and approved by the Ethics Committee of the Shanghai Fifth People's Hospital, Fudan University (Approval document Number: 2022 EC (097)). The patients/participants provided their written informed consent to participate in this study.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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