ORIGINAL RESEARCH

Effectiveness of MI Varnish™ and PreviDent® Varnish in Noncavitated Interproximal Lesions: A Randomized Clinical Trial

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Abstract

Aim: Evaluating the remineralization efficacy of noncavitated proximal incipient lesions with Colgate® PreviDent® and MI™ varnishes in comparison to the industry standard (1.23%) acidulated phosphate fluoride (APF) gel.

Study design: Parallel randomized controlled, multicenter, single-blinded trial.

Materials and methods: By flipping a coin, 18 patients with 91 lesions were divided into three groups. The Colgate® PreviDent (n = 33), MI varnish (n = 30), and control (APF gel) groups (n = 28) were identified as the three arms. We conducted an initial assessment and therapy as well as follow-ups at 3 and 6 months to evaluate the course of the caries lesion.

Results and statistics: Caries progression was significantly reduced on treated surfaces across both groups. Nine surfaces in the Colgate® PreviDent® group with white spots and dryness did not change, one surface turned into a white patch without dryness, and another surface changed to a sound surface; only two surfaces were discontinued from treatment (restored) due to a misdiagnosis by the operator (n = 2). Nine of the surfaces in the MI™ group maintained their white patches with dryness, whereas one developed a new white patch that was not dry. Only MI varnish™-treated teeth exhibited dramatic radiographic improvement. Caries on the outside enamel were either unchanged or restored to healthy levels. Caries on the inner surface of the enamel also did not change.

Conclusion: Remineralizing noncavitated early-stage lesions may be done with both MI™ and Colgate® PreviDent® varnishes. Despite this, radiographic results did not vary significantly across the three groups. In situations of rather advanced incipient caries seen on radiographs, the MI varnish™ might be recommended.

Keywords: Fluoride varnish, Interproximal, Noncavitated, Remineralization.

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Introduction

Across all populations, dental caries is the most frequent kind of chronic illness.[1] In Saudi Arabia, dental caries affects around 80% of school-aged children and 70% of adults.[2] Tooth decay is a complex illness where the etiological factors include acid-producing bacteria, fermentable carbohydrates, a porous tooth surface, and period.[3] The main causative bacteria related to dental caries is *Streptococcus* sp. (*Streptococcus mutans* and *Streptococcus sobrinus*). Dental caries are caused by pH fluctuations brought on by bacteria in the biofilm.[3–5] Pain from caries, which may lead to acute and chronic infections, can cause children to change their eating and sleeping patterns, increase treatment costs as well as cause them to miss school.

Intervention for caries treatment should be kept to a minimum while prioritizing prevention.[6] The early signs of tooth decay are called "incipient carious lesions." They may really go backward, stop, or even cavitate. If detected and treated in time, lesions of this kind may remineralize.[6,7] To initiate the remineralization process, a proper home care regimen, and precise clinical intervention are required. Treatment with fluoride has been the cornerstone of conservative dental care for early caries.[5] The demineralization of healthy enamel is slowed by low levels of fluoride, while remineralization of damaged enamel is sparked. The capacity of cariogenic bacteria to create acid is also diminished by fluoride's effects on bacterial metabolism.[8,9] Fluoride helps hydroxyapatite crystals absorb more calcium and fluoride, generating fluorapatite by temporarily forming a calcium-fluoride-like substance on the surface of the tooth when the oral pH decreases.[10] Compared to hydroxyapatite, fluorapatite has higher acid resistance.[8,9]

A variety of fluoride treatments are used across different uses, exhibiting variations in concentrations, durations, and frequency. The effectiveness of newer products is always changing, although the available data remains inadequate. White patch lesions in orthodontic patients may be treated with MI varnish™ with RECALDENT, which is made of casein phosphopeptide-amorphous calcium phosphate (CCP-ACP). CCP-ACP and 5% NaF

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(22,600 ppm fluoride) are active chemicals, and they work together to remineralize teeth more thoroughly. Colgate® PreviDent® varnish is another option containing xylitol and 5% NaF (22,600 ppm fluoride). The majority of these recently introduced items lack enough research to warrant their endorsement for widespread consumer use. This research aimed at comparing the efficacy of Colgate® PreviDent® and MI varnish™ with the conventional 1.23% acidulated phosphate fluoride (APF) gel in promoting the remineralization of noncavitated proximal incipient lesions.

Materials and Methods

ClinicalTrials.gov (NCT03925740) and the King Abdulaziz University Institutional Review Board (REC-013-01019) both approved the study for human participation on April 24, 2019. Research at King Abdulaziz University Dental Hospital (KAUDH) in Jeddah began in the new year. Each patient's legal guardian completed an informed consent form. Research procedures were conducted based on the principles articulated in the Helsinki Declaration of 1975 and in compliance with the standards set out by the King Abdulaziz University Ethical Committee.

Study Design

The consolidated standards of reporting trials (CONSORT) standards were followed in order to ensure the highest quality of reporting for this randomized controlled clinical study. In this study, 91 noncavitated interproximal caries lesions were distributed among 18 patients in three groups. To evaluate the effectiveness of three fluoride products, patients were randomly placed into each of three categories: Colgate® PreviDent® (n = 33), MI varnish™ (n = 30), or a control group (APF gel, n = 28). The students in the control group came from KAUDH's undergraduate clinics, while the other two were drawn from the hospital's postgraduate programs. Neither the patients nor their parents knew which group they had been placed in until after the clinical and radiological evaluations had been completed. However, since the ingredients were packaged differently, it was impossible to blind the doctors throughout the application process.

Sample Size Calculation

G*Power 3.1.9.7 was used to determine the necessary sample size. With an effect size of 0.38, an error of 0.05, power of 0.80, and a degree of freedom of 5, 91 caries-prone teeth were deemed adequate for this investigation. We extrapolated the impact magnitude from the primary research.[11] The study participants (patients) were enlisted from KAUDH's graduate and undergraduate student clinics.

Random Allocation and Blinding

Three treatment groups were designated as the Colgate® PreviDent®, MI varnish™, and control (APF gel) groups. Participants were placed into the three groups at random using a coin flip. Each lesion was examined clinically and radiographically, rated according to the International Caries Detection and Assessment System (ICDAS) standards, and then randomly assigned after consent and demographic information were collected. Each lesion was evaluated independently before and after randomization.[12] Each patient was given a unique two-digit code, the first digit of which stood for the serial number of the patient and the other for the group to which the patient belonged. Radiographic reevaluation using bitewing and periapical radiographs was conducted during the 6-month follow-up. Radiographs were labeled using patient's two-digit code and the medical record number. All patients' radiographs were collected and then shuffled before being interpreted blindly.

Patient Selection

Based on the inclusion/exclusion criteria, eighteen kids (aged 6–15) who visited KAUDH for dental care were assessed for possible participation in the research.

Inclusion Criteria

- The presence of proximal incipient caries may be seen in both anterior and posterior teeth regardless of whether they are primary or permanent.
- Clinical and radiographic ICDAS score of 1 or 2.

Exclusion Criteria

- Bitewing radiographs showing evidence of active beginning carious lesions (ICDAS score of 3) or deep caries through the dentinoenamel junction.[12]
- Negative dental behavior and persistent health problems.

Children who needed further dental care at the time of their first visit were referred to specialists. Only 18 individuals (91 lesions) met the inclusion and exclusion criteria (Fig. 1).

Clinical and Radiographic Examination

The clinical examination and assessment were conducted by two general dentists who had received proper training and calibration. Lesions are identified by a comprehensive examination, including visual and tactile assessment, using sufficient lighting and mouth mirrors and probes. Additionally, bitewing radiographs are used for posterior teeth, whereas periapical radiographs are utilized for anterior teeth.[12] The assessment of inter and intraexaminer reliability was conducted at two distinct time intervals, resulting in a 90% agreement rate and a κ-value of 0.613, indicating a considerable level of agreement. Any conflict between the parties involved was resolved by the intervention of a third examiner who had the necessary expertise and had undergone appropriate calibration. If the observed abnormalities align with the predetermined clinical criteria for inclusion, a standardized periapical radiograph was captured for front teeth, while a bitewing radiograph was recorded for posterior teeth. The radiographs were used for the purpose of conducting an initial radiographic examination and subsequent assessment. In order to enhance the replicability and uniformity of X-ray projection for subsequent radiographic examinations, a digital film radiograph system (MiPACS: Medicor Imaging, Charlotte, North Carolina, United States of America) was employed, along with a digital holder to precisely direct the X-ray beam at a 90° angle. The bitewing radiograph was captured using specific parameters, including a voltage of 65 kV, a current of 7 mA, and an exposure time of 0.064 seconds. In order to provide precise alignment and placement of the photostimulable phosphor (PSP) plates (Gendex Dental Systems, Hatfield, Pennsylvania, United States of America), the use of XCP Rill holder and an X-ray beam centering system was employed for the periapical radiography. The X-ray source, Orix 70, manufactured by ARDET dentistry and medical devices in Milano, Italy, was specified to operate at a voltage of 70 kV, a current of 7 mA, and an exposure period of 0.05 seconds. The PSP plates were then subjected to processing utilizing the GXPS-500 digital X-ray phosphor plate system, manufactured by Gendex Dental Systems located in Hatfield, Pennsylvania, United States of America.

MI varnish™ and Colgate PreviDent® Groups

Five participants (33 lesions) were randomized to the Colgate PreviDent group, whereas three patients with 30 lesions were given MI varnish™. Greene and Vermillion's oral hygiene index was used for the evaluation of dental hygiene.[13] A decayed, missing, and filled surfaces (DMFS) index was also recorded. Plaque was removed during the prophylaxis procedure by employing a polishing brush on a slow-speed handpiece and dental floss. X-rays revealed early signs of lesions; therefore, the patient was given orthodontic separators or wedges to insert between the teeth.

After the teeth had dried from air drying, the material was put directly in the interproximal regions with the early lesions and subsequently to the other teeth (based on the patient's group). Patients were told to wait 30 minutes before rinsing or drinking anything, and for the following 2 hours, they should adhere to soft meals and avoid anything hard or sticky. Oral care instructions and a checklist were supplied. The subsequent follow-up was arranged after 3 months.

Acidulated Phosphate Fluoride (APF) Gel (Control) Group

A total of 10 patients were selected for inclusion in the study *via* the examination of dental records. These records included radiographs of patients who had received treatment in the undergraduate clinics. The usage of the APF was conducted through the tray method in the following manner—the individual assumed a vertical posture while sitting. Following the removal of plaque using a polishing brush connected to a low-speed handpiece, an APF gel was administered into an expendable foam tray, ensuring it was filled no more than one-third of its capacity, as per the guidelines provided by the manufacturer. The patient received instructions to refrain from swallowing the gel and to apply gentle pressure utilizing the cheeks and tongue, together with mild biting force, in order to facilitate the interproximal flow of the gel for a duration of 4 minutes. A saliva ejector was used to facilitate the separation of saliva and the removal of surplus gel. The individual was provided with instructions to abstain from consuming food, beverages, or engaging in oral rinsing for a minimum duration of 30 minutes.

Follow-up Visits for the Colgate PreviDent and MI Varnish™ Groups

Caries Management by Risk Assessment (CAMBRA) guidelines dictated a 3-month (T1) and 6-month (T2) interval between follow-up visits.[14] Oral prophylaxis, including plaque cleaning, and the placement of orthodontic wedges or separators interproximally were conducted at T1 as they had been at T0. The next day, the patients were summoned back in. After the teeth had dried and any orthodontic wedges or separators had been removed, the material was first placed between the lesion of interest and adjacent teeth interproximally. The patients and their parents were given the same instructions as at T0. Patients were reminded to brush their teeth and floss daily, and a 3-month checkup was planned.

Except for two patients in the Colgate PreviDent group who stopped treatment due to a misdiagnosis from their doctor (their composite restorations having already been completed), no patients were lost to follow-up at T1 (Fig. 1). The identical operation was carried out during the 6-month checkup. Radiographs of the bitewing and periapex were also taken to evaluate the lesions. At T2, there were no cases of either loss to follow-up or intervention discontinuation in any of the study groups (Fig. 1).

Follow-up Visit for the APF Gel (Control) Group

The identical process was followed for the other two groups at the 6-month visit. Given that this was the procedure followed at the student dentistry clinics, no T1 visit was planned for the patients in this group. For this group, there was no record of loss to follow-up or terminated intervention at T2 (Fig. 1).

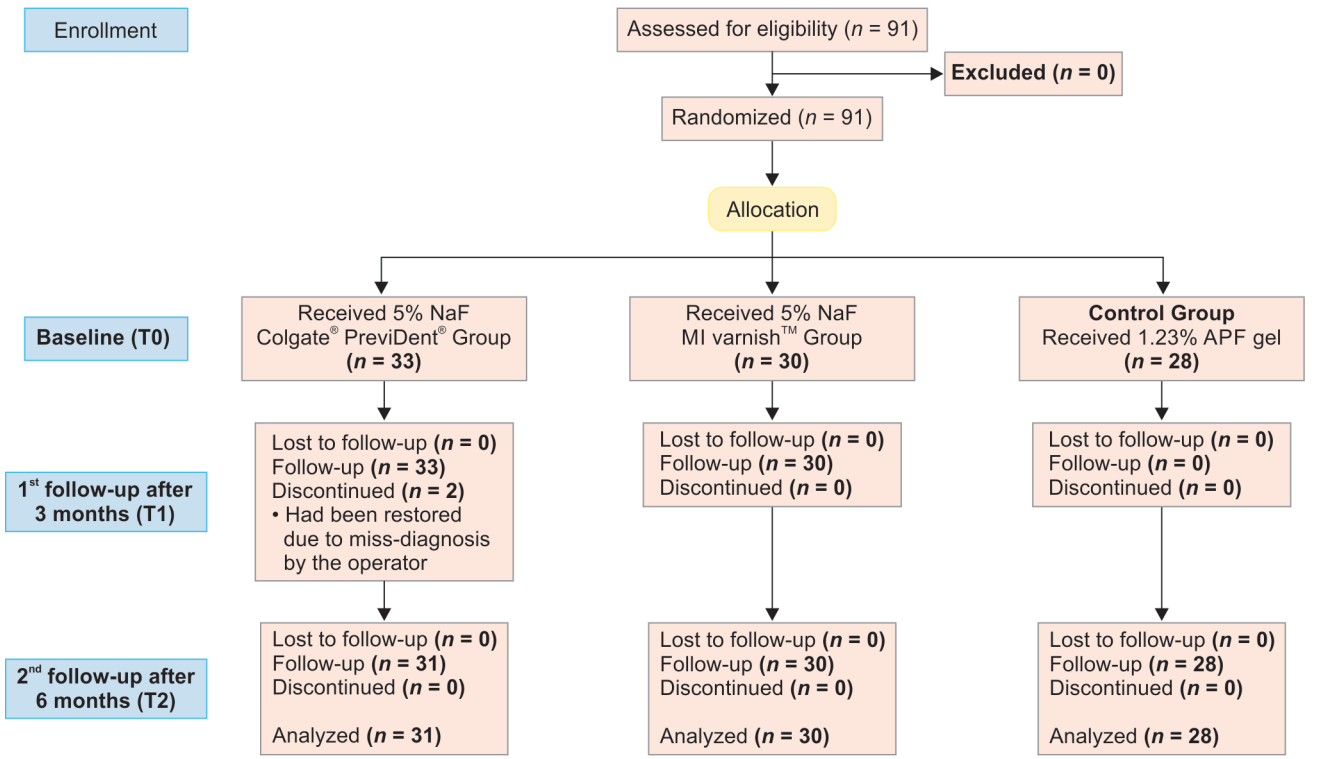

Fig. 1: Consolidated standards of reporting trials (CONSORT) flowchart

Table 1: Demographic characteristics of patients (n = 18)

Variable		*Mean ± SD or frequency (%)*
Age, years		9.3 ± 2.38
Sex	Male	8 (44.4)
	Female	10 (55.6)
Socioeconomic status	Low	4 (22.2)
	Moderate	3 (16.7)
	High	11 (61.1)
Maternal education	≤High school	8 (44.4)
	≥University	10 (55.6)
Paternal education	≤High school	5 (27.8)
	≥University	13 (72.2)

SD, standard deviation

Table 2: Characteristics of patient's dentition surfaces (n = S9)

Variable		*Mean ± SD or frequency (%)*
Oral hygiene score*		1.67 ± 0.91
DMFS		24.39 ± 11.15
Dentition	Primary	29 (32.6)
	Permanent	60 (67.4)
Site of lesion	Mesial	52 (58.4)
	Distal	37 (41.6)
Location		
Right vs left	Right	47 (52.8)
	Left	42 (47.2)
Anterior vs posterior	Anterior	11 (12.4)
	Posterior	78 (87.6)
Upper vs lower	Upper	45 (50.6)
	Lower	44 (49.4)
Oral hygiene score	Poor	64 (71.9)
	Fair	6 (6.7)
	Good	19 (21.3)

*Green and vermillion oral hygiene index; DMFS, decayed, missing, filled, surface; SD, standard deviation

Outcome Assessment Criteria

The main result was a comparison of baseline direct visual examination and ICDAS scores for caries lesions to comparisons made 6 months later. Maintaining a caries score of 0 or reducing it to a score of 0 after 6 months was regarded a clinical and radiological success.

Statistical Analysis

The IBM Statistical Package for the Social Sciences (SPSS) Statistics 20 program (Armonk, New York: IBM Crop) was used for the statistical analysis. Frequencies and percentages were used to depict descriptive statistics for categorical variables, while mean and standard deviation (±) were used to depict descriptive statistics for continuous variables. The Chi-squared test was run, and significance was determined to be at $p < 0.05$ after using the *post hoc* Bonferroni adjustment. Where there were less than five cells in a sample, the Fischer's exact test was utilized.

Results

Out of the whole sample size of 18 children included in the research, a total of eight children, accounting for 44.4% of the participants, were identified as males. The average age of the children was 9.3 ± 2.38 years, the average oral hygiene score was 1.67 ± 0.91, and the average DMFS score was 24.39 ± 11.15 (Table 1). Among the patients included in the study, it was found that 29 individuals (32.6%) had primary dentition. Out of the total number of primary molars analyzed, which amounted to 78 teeth (89%), it was seen that 52 lesions (58.4%) were located mesial as shown in Table 2.

International Caries Detection and Assessment System (ICDAS) ratings for early caries were significantly reduced in both the MI varnish™ and Colgate PreviDent groups after 6 months of treatment (T2). Five previously carious tooth surfaces were restored to health in the PreviDent group. Radiographically, one of the white patches had dryness only in the outside enamel, while the others had dryness only in the interior enamel. After applying the Bonferroni adjustment to the p-values of the Chi-squared test findings (Table 3), we found that nine of the surfaces with white patches and dryness did not change. Four surfaces were converted to sound in the MI varnish™ group. Radiographically, one of them was a white spot devoid of dryness and localized to the inner enamel, while the others were white spots with dryness in the outer enamel. Nine of the surfaces with white spots and dryness remained unaltered after Bonferroni adjustment, while one surface developed white spots but no dryness.

Based on radiographical analysis, the only group whose teeth improved significantly on X-rays was the MI varnish™ group. After accounting for Bonferroni's correction, eight of the 16 surfaces that had outer enamel caries stayed on the outer enamel surface [8/16 (50%)], five improved to sound surface [5/16 (31.3%)], and three proceeded to the inner enamel surface [3/16 (18.7%)] ($p < 0.05$). In addition, one surface went from having inner enamel caries to having outer enamel caries (one change, 7.1%), and one surface went from having inner enamel caries to having a sound surface (one change, 7.1%). There was no development of outer dentinal caries from the surface caries (Table 4).

The results presented in Table 5 indicate the presence of disparities in the clinical results seen among varnish groups ($p = 0.004$). Following the implementation of the Bonferroni correction, it was shown that the control group exhibited a statistically significant increase in the number of failures when compared to the experimental groups ($p < 0.05$). Nevertheless, the study did not find any disparity in the radiographic results.

Discussion

This clinical trial's objective was to confirm a potentially economical treatment option for children's early proximal carious lesions. The easiest and most efficient technique to control caries development is to use dental floss to remove the biofilm from proximal regions.[15] It is true that a patient's flossing technique and frequency have an impact on how well their caries are managed.[16] In addition, cleaning the proximal regions becomes challenging due to children's noncompliance with flossing.[17] Therefore, in order to avoid cavitations, early therapies for developing carious lesions are crucial. Incipient carious lesions may be made to remineralize with fluoride treatments, and the clinical and radiographic results of incipient caries may be affected by fluoride products that include xylitol and CCP-ACP. CCP-ACP therapy for early caries has shown encouraging results in recent trials.[18–23] Fluoride and CCP-ACP together have a synergistic effect.[23] Nevertheless, some research has shown that there is no therapeutic advantage to using CCP-ACP in addition to

Table 3: Progression of caries on tooth surfaces in the three varnish groups after 6 months according to the clinical ICDAS scores

			Clinical ICDAS scores after 6 months, frequency (%)					
	Varnish groups	*Surfaces*	*Sound (A)*	*White spot with dryness (B)*	*White spot without dryness (C)*	*Shadow without catch (D)*	*Total*	*p-value*
Baseline clinical ICDAS scores	Colgate®	White spot with dryness	1 (9.1)	9 (81.8) (A, C)	1 (9.1)	0	11 (100)	<0.001*
	FreviDent®	White spot without dryness	4 (20) (B)	1 (5)	12 (60)	3 (15)	20 (100)	
	MI	White spot with dryness	3 (15)	16 (80) (C)	1 (5)		20 (100)	0.019*
		White spot	1 (10)	4 (40)	5 (50)		10	
		without dryness			(B)		(100)	
	APF gel	White spot with dryness	0	3 (42.9)	4 (57.1)	0	7¥ (100)	0.12
		White spot without dryness	2 (25)	1 (12.5)	2 (25)	3 (37.5)	8¥ (100)	

Results are based on two-sided tests with a significance level of 0.05, using the Bonferroni collection; for each significant pair, the key of the category (A, B, or C); **the frequency is significantly higher than the number under the category that appears next to it; *p-value significant at 0.05; ¥the total number of APF surfaces is less than the total included surfaces (n = 2E) because the clinical base line of 13 surfaces was not missing; APF, acidulated phosphate fluoride; ICDAS, International Caries Detection and Assessment System

Table 4: Progression of caries on tooth surfaces in the three varnish groups after 6 months according to radiographic ICDAS scores

		Clinical ICDAS scores after 6 months, frequency (%)					
Varnish groups	*Surfaces*	*Sound (A)*	*White spot with dryness (B)*	*White spot without dryness (C)*	*Shadow without catch (D)*	*Total*	*p-value*
Colgate®	Outer enamel	4 (28.6)	7 (50)	2 (14.3)	1(7.1)	14 (100)	0.17
PreviDent®	Inner enamel	4 (23.5)	3 (17.6)	7 (41.2)	3 (17.6)	17 (100)	
MI	Outer enamel	5 (31.2) (C)	8 (50) (C)	3 (18.8)	–	16 (100)	0.001*
	Inner enamel	1 (7.1)	1 (7.1)	12 (85.7) (A,B)	–	14 (100)	
APF gel	Outer enamel	2 (12.5)	10 (62.5)	3 (18.8)	1 (6.2)	16 (100)	0.086
	Inner enamel	2 (16.7)	2 (16.7)	4 (33.3)	4 (33.3)	12 (100)	

Results are based on two-sided tests with a significance level of 0.05, using the Bonferroni correction; for each significant pair, the key of the category (A, B, or C); **the frequency is significantly higher than the number under the category that appears next to it; *p-value significant at 0.05; APF, acidulated phosphate fluoride; ICDAS, International Caries Detection and Assessment System

Table 5: Clinical and radiographic outcomes after 6-month follow-up for the three varnish groups

Outcome		*Colgate® Previ Dent®*	*MI varnish™*	*APF*	*p-value*
Clinical outcome	Decreased (A)	6 (19.4)	8 (26.7)	3 (20)	0.004*
	Same (B)	21 (67.7)	21 (70)	5 (33.3)	
	Increased (C)	4 (12.9)	1 (3.3)	7 (46.7) (A)	
	Total	31 (100)	30 (100)	28 (100)	
Radiographic outcome	Decreased	11 (35.5)	7 (23.3)	6 (21.4)	0.261
	Same	14 (45.2)	20 (66.7)	14 (50)	
	Increased	6 (19.4)	3 (10)	8 (28.6)	
	Total	31 (100)	30 (100)	28 (100)	

Results are based on two-sided tests with a significance level of 0.05, using the Bonferroni correction; for each significant pair, the key of the category (A, B, or C); **the frequency is significantly higher than the number under the category that appears next to it; *p-value significant at 0.05; APF, acidulated phosphate fluoride

fluoride alone.[11,24–27] The observed heterogeneity in the research about the clinical significance of CCP-ACP may be ascribed to many factors such as the research design, length of use, changes in the lesions' severity and activity, and potential distinctions between incipient carious lesions that are not orthodontic and those that are.

Fluorides coupled with CCP-ACP have been shown in a prior systematic study to have a therapeutic benefit over fluoride monotherapy on the occlusal surface. On smooth surface lesions, however, fluoride monotherapy can have the same outcome,[28] this research demonstrated a considerable improvement in the clinical ICDAS scores of incipient carious lesions with both MI varnish™ and Colgate® PreviDent®. Only lesions treated with MI varnish™, however, demonstrated improvements in radiography. However, there were no appreciable variations in the radiography results between the three kinds of varnishes that were used. The present study's findings corroborate the findings of the prior comprehensive review[28] since we additionally examined proximal smooth surface lesions. Additional long-term research may be necessary to corroborate the findings of this study, even though there were no significant variations in the radiographic outcomes across the three kinds of varnishes. CCP-ACP is successful, according to research that assessed the effectiveness of a 3-month CCP-ACP application regimen with a 12-month follow-up period.[29]

This research has a number of limitations. Patients with early carious lesions participated in a randomized clinical study that examined three different fluoride products. Therefore, the data does not apply to those who do not have carious lesions. The fact that we had to rely on a control group culled from college health centers was a significant drawback. Therefore, the same research examiners did not conduct the first clinical caries evaluation for the control group. The lack of instrumental diagnostic tools like laser fluorescence and quantified light-induced fluorescence further hampered progress. Unfortunately, financial limitations prevented us from using such technology in our multisite experiment.

However, this clinical experiment does have some positive aspects. The result is an extremely important factor for both dentists and their patients. In addition, randomization ensured parity among groups before enrollment, and findings held true after controlling for age, gender, and severity at baseline. The evaluation period was set at 6 months to provide us sufficient time to see substantial radiographic changes while reducing the risk of losing track of the patients. Reversal of caries is not noticeable for at least 6 months.[30] Patients and examiners alike were kept in the dark throughout the evaluation. There was also a high rate of patient compliance. No participant in the study discontinued participation because of adverse effects such as allergies, gingival irritation, or plaque buildup. Future research should use quantitative light-induced fluorescence and have a longer follow-up time to corroborate the findings of this study.

Conclusion

In dentistry, preventing cavities is crucial for preserving natural teeth. Statistically substantial improvements in clinical ICDAS scores were seen for incipient carious lesions treated with both MI varnish™ and Colgate® PreviDent®. Only MI varnish™-treated teeth improved significantly in radiographic evaluations. However, none of the three intervention methods had significantly different radiological results. Adding CPP-ACP to fluoride has been reported to have a synergistic effect, and this clinical investigation confirmed those findings. Longer follow-up times and higher sample numbers are only two of the promising avenues for this continuing registered experiment. This research lends credence to the idea that pediatric dentistry has to change its focus from traditional restorative care to disease prevention and tooth structure conservation.

Why This Paper is Important to Pediatric Dentists?

- Statistically significant improvements in clinical ICDAS scores for incipient carious lesions were reported in both the MI™ and PreviDent® interventions.
- The findings of this research may provide valuable insights for the identification of the optimal varnish for clinical implementation using a personalized and tailored strategy on a case-by-case basis.
- The research may also provide guidance for future long-term investigations using a bigger sample size and other anticaries therapies in order to establish a conclusive approach for inducing caries regression.

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