

PREVENTIVE EFFECT OF FLUORIDE VARNISH ON WHITE SPOT LESIONS AROUND CLEAR ALIGNER ATTACHMENT

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ABSTRACT

Aim: The aim of this in vitro study was to evaluate the fluoride varnish effectiveness in preventing white spot lesions (WSLs) around clear aligner attachments.

Materials and methods: Two similar samples of extracted human premolar teeth, with bonded composite attachment on the facial surface, were divided into two groups: Group 1 (control), which received no fluoride varnish, and Group 2 (F. varnish), in which fluoride varnish was applied, to evaluate the preventive effect of fluoride varnish on the development of white spot lesions (WSLs) around the clear aligner attachments. The teeth in both the fluoride varnish and control groups had been exposed to an acid-base challenge protocol. Enamel demineralization was evaluated using the DIAGNOdent pen. The obtained DIAGNOdent scores were subjected to a classification system to estimate the depth of demineralization in each group.

Results: Statistically significant difference was found between the two groups ($p < 0.01$) regarding change in DIAGNOdent scores. Teeth in group 1 (control) demonstrated a higher increase in the mean DIAGNOdent score values in comparison to the teeth that received preventive fluoride varnish application. The control group exhibited significantly deeper enamel demineralization, with 93.7% of the samples displaying demineralization reaching the inner half of the enamel, whereas this extent was observed in only 12.5% of the samples in the fluoride varnish group.

Conclusion: Preventive fluoride varnish application was found to be effective in reducing both the incidence and severity of enamel demineralization around the clear aligner attachments.

KEYWORD: Clear aligners, fluoride varnish, white spot lesions.

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INTRODUCTION

Clear aligner therapy is an orthodontic treatment modality that utilizes a series of transparent, custom-fabricated thermoplastic sheets to achieve progressive dental movement. Compared with conventional fixed braces, clear aligners offer several clinical advantages, including superior aesthetics due to their near invisibility, enhanced patient comfort, and the convenience of removability, which facilitates optimal oral hygiene and unrestricted dietary habits.¹

However, the exclusive use of clear aligners without the incorporation of auxiliary attachments presents inherent biomechanical limitations. Primarily due to their restricted capacity to exert controlled forces, limiting the range and predictability of certain tooth movements.² The incorporation of composite attachments enhances the control and predictability of tooth movement by increasing the surface area for aligner engagement and enabling more precise force application nearer to the center of resistance. This facilitates more effective translation movement of teeth, which is essential for effective clear aligner therapy.³

Although reduced incidence of WSLs in clear aligners relative to conventional fixed orthodontic appliances, enamel demineralization persists as a significant adverse effect, especially in cases of extended aligner wear time.⁴ Also, clear aligner attachments may serve as plaque-retentive sites, potentially increasing the risk of biofilm accumulation and subsequent enamel demineralization, particularly in patients with suboptimal oral hygiene.⁵

Incipient enamel carious lesions are characterized by subsurface demineralization that occurs beneath a relatively preserved outer enamel layer. The altered refractive properties of the demineralized area result in increased light scattering and reduced

translucency, which clinically manifests as a chalky white appearance.^{6,7}

WSLs require a comprehensive, multifactorial management. The primary objective should be the prevention of enamel demineralization and biofilm accumulation. In addition, therapeutic strategies may include promoting remineralization, performing enamel thinning or micro-abrasion, applying resin infiltration techniques, and restoring affected areas with adhesive composite resins.⁸

Preventive strategies are widely regarded as superior and more favorable approaches than therapeutic interventions.^{9,10} Fluoride varnish is widely regarded as a gold standard in non-invasive caries prevention and early enamel lesion management; topical fluoride applications elevate fluoride ion levels in saliva, promoting the development of fluorapatite, which is highly resistant to acidic dissolution and demineralization. Moreover, higher fluoride concentrations can suppress bacterial metabolic activity, contributing to caries prevention.¹¹

Based on this knowledge, fluoride varnish was applied onto the sound tooth surface around the composite clear aligner attachment as a preventive measure, and its effectiveness in reducing enamel demineralization around the attachments was evaluated.

MATERIALS AND METHODS

Sample size calculation

According to the methodology of a prior study by Demito et al.¹², a total sample size of 32 teeth provides 80.5% statistical power to detect differences between group means, assuming a large effect size (Cohen's $d = 0.9$), at a 0.05 significance level using an independent samples t-test. The sample size calculation was performed using G*Power software (version 3.1.9.7).

Sample selection

Only sound human premolars that were extracted for orthodontic purposes were included in this study. Teeth exhibiting signs of previous demineralization, discoloration, or surface irregularities were excluded. Each tooth was carefully examined under magnification and illumination to ensure the absence of surface damage or defects.

Methodology

32 sound human premolar teeth that were extracted for orthodontic purposes were collected. Residual soft tissue was removed using a scalpel blade. The enamel surface of the teeth was cleansed with pumice and distilled water using slow-speed handpiece. Finally, teeth were rinsed with distilled water and divided randomly into two equal groups of 16 teeth.

The facial enamel surface was covered with a piece of adhesive tape to confine acid etching. Enamel etching was done using 37% phosphoric acid gel, that was applied through the exposed window for 30 seconds, rinsed with distilled water for the same amount of time, and dried with compressed air.

Composite attachments using conventional composite (Filtek Z350XT, 3M, California, USA) were bonded to the middle of the facial surfaces of all teeth using a plastic mold. Excess composite was removed with a dental scaler.

Specimen preparation

Each tooth was inserted into an acrylic block; crowns were coated with a nail varnish, leaving a window around the attachment for pH-cycling and DIAGNOdent measurements to be done through it. Fluoride varnish (Profluoride, VOCO, Cuxhaven, Germany) was applied to group 2 teeth, whereas the control group didn't receive any preventive material.

Measurement

Prior to any intervention, all samples were assessed using DIAGNOdent® pen (Kavo, Biberach, Germany) (Figure 1). The device was calibrated on its calibration ceramic disc, with the number on the DIAGNOdent pen screen matching the number on the calibration disc. For each sample, four readings were taken through the designated window in accordance with the manufacturer's instructions, and the average value was calculated for analysis. Following the pH cycling protocol, post-intervention readings were also recorded.



Fig. (1) DIAGNOdent pen used in the study.

The recorded scores were subjected to a specific classification system.¹³

- D0 (demineralization -free) = 0-7.
- D1 (demineralization in the outer half of enamel) = 7.1-14.
- D2 (demineralization in the inner half of enamel) = 14.1-24.
- D3, D4 (demineralization reached dentine) > 24.

pH-cycling

Teeth were exposed to a 14 days pH-cycling protocol, involving the exposure to a series of demineralizing solution with pH = 4.8 for 8 hours and artificial saliva with pH = 7 for 16 hours.

Solutions pH was adjusted using pH-meter (Figure 2). The cycling was done in an incubator (Figure 3) adjusted at 37°C.



Fig. (2) pH meter used in the study.



Fig. (3) Incubator used in the study.

Statistical analysis

Data entry and statistical analysis were performed using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA, 2020). *Qualitative data* was presented as count (N) and percentage (%) and analyzed using the chi-square test. Normality test for *Quantitative data* was initially performed using Shapiro-Wilk’s test (normally distributed data has $p > 0.050$) and Q-Q- plots. The significant outliers were identified through examination of boxplots. Data was described as means and standard deviations and compared by using the independent samples t-test. A p-value of ≤ 0.050 was considered statistically significant for all tests.

RESULTS

Fluoride varnish group exhibited significantly lower post-intervention DIAGNOdent values compared to the control group ($p < .001$). Regarding the difference between the measured pre-intervention and post-intervention DIAGNOdent scores, results showed that the mean and standard deviation for group 1 (control) were (16.44 ± 3.71) , and for group 2 (F. varnish) were (8.13 ± 2.06) . Control group exhibited a statistically significant higher change in the mean Diagnodent score values between pre-intervention and post-intervention measurements than fluoride varnish group ($p < .001$) (Table 1).

TABLE (1) Difference of Diagnodent scores between groups:

Diagnodent score	Group 1		Group 2		Sig.	Cohen’s d
	Mean	SD	Mean	SD		
Pre-intervention	2.56	0.814	3.94	1.340	.001	1.2
Post-intervention	19.25	3.568	12.06	2.294	<.001	2.4
Difference	16.44	3.705	8.13	2.062	<.001	2.8

Note: SD = standard deviation. Sig. = statistical significance (p-value). Cohen’s d = effect size measure (0.2, 0.5, and 0.8 = small, medium, and large effect sizes, respectively). Difference = post-intervention value – pre-intervention value. The test of significance is independent samples t-test.

All samples in both groups demonstrated pre-intervention DIAGNOdent scores corresponding to D0 (0-7). Regarding post-intervention DIAGNOdent scores, group 1 (control) demonstrated significantly

deeper enamel demineralization ($p < .001$), with 93.7% of the samples exhibiting scores in the D2 range. In contrast, only 12.5% of the samples in group 2 (F. varnish) reached the D2 level (Table 2).

TABLE (2) Diagnodent scores comparison between groups:

Diagnodent score	Group 1		Group 2		χ^2	Sig.
	N	%	N	%		
Pre-intervention D0 (0-7)	16	100	16	100	-	-
Post-intervention D1 (>7-14)	1	6.3	14	87.5	21.208	<.001
D2 (>14-24)	15	93.7	2	12.5		

Note: Sig. = statistical significance (p-value). The test of significance is Chi-Square (χ^2) test.

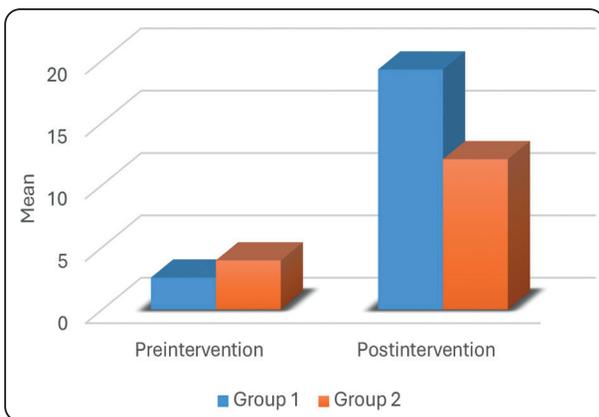


Fig. (4) Mean of pre-intervention and post-intervention Diagnodent scores of both groups.

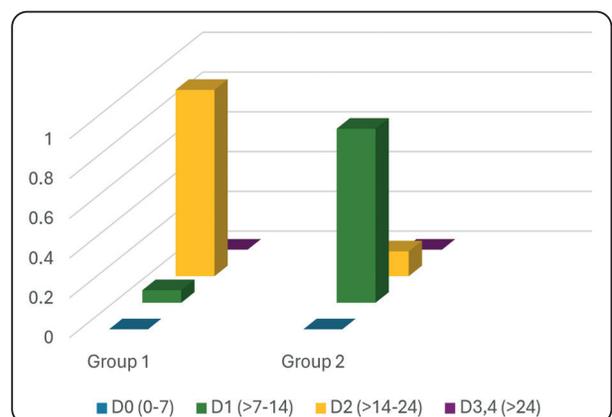


Fig. (6) Distribution of post-intervention Diagnodent scores between groups.

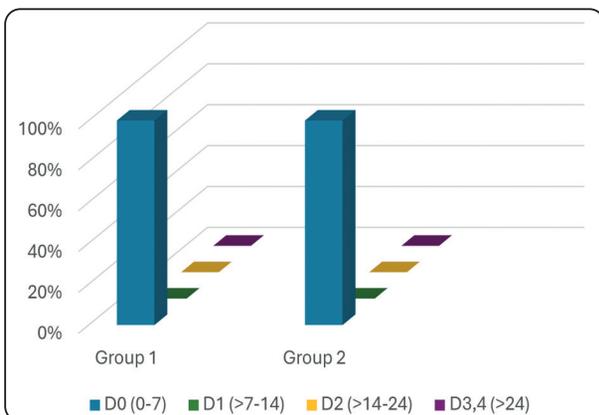


Fig. (5) Distribution of pre-intervention Diagnodent scores between groups.

DISCUSSION

Clear aligners have emerged as a highly aesthetic and comfortable alternative to traditional orthodontic appliances, contributing to their widespread adoption and growing popularity.¹⁴ WSLs represent one of the most prevalent complications associated with orthodontic treatment.¹⁵ The removable nature of clear aligners facilitates more effective oral hygiene practices compared to fixed appliances, as they can be taken out during tooth brushing and flossing.¹⁶

However, a recent investigation reported that there is no difference in the incidence or the severity of WSLs between clear aligners and conventional brackets, as well as self-ligating brackets.¹⁷ The prevalence of WSLs among individuals undergoing clear aligner treatment reached 41.18%.¹⁷

With clear aligners in place, the mechanical cleansing actions of the lips, cheeks, and tongue are restricted.¹⁸ Additionally, prolonged wearing time of clear aligners has been shown to reduce salivary flow, thereby diminishing the saliva's natural cleansing, buffering, and remineralizing functions.^{18,19} WSLs tend to develop more frequently around bonded composite attachments, as these protruding structures act as plaque-retentive sites that facilitate the accumulation of food debris and bacteria.¹⁹

Fluorescence-based diagnostic technologies like DIAGNOdent demonstrated reliable performance in the monitoring of early-stage, non-cavitated carious lesions on smooth enamel surfaces under controlled *in vitro* conditions.²⁰ Different studies^{21,22} have shown that DIAGNOdent® (KaVo) is effective in assessing enamel demineralization.

Profluorid varnish was selected for this study owing to its ease of application and its compatibility with moist environments, eliminating the need for complete drying prior to its usage. Fluoride varnish was applied to the intact enamel surrounding the composite clear aligner attachments as a preventive intervention, and its efficacy in minimizing enamel demineralization in these regions was subsequently assessed.

The fluoride varnish group demonstrated significantly lower post-intervention DIAGNOdent scores compared to the control group ($p < 0.001$), indicating a notable reduction in enamel demineralization. Furthermore, the change in DIAGNOdent scores between pre-intervention and post-intervention was significantly higher in the control group (16.44 ± 3.71) than in the fluoride varnish group (8.13 ± 2.06), reinforcing the protective effect of fluoride

application. These results are in agreement with the reported limited mineral loss and maintained enamel integrity associated with fluoride varnishes under pH cycling conditions.²³ Also, these results are consistent with the findings of Reddy et al.²⁴, where the efficacy of different fluoride varnishes in preventing enamel demineralization adjacent to orthodontic brackets was proved. The reduced change in DIAGNOdent score values in group 2 (F. varnish) may be attributable to the formation of CaF₂-like deposits on the tooth surface, which increase fluoride availability and serve as a reservoir for sustained fluoride release, enhancing remineralization and inhibiting acid penetration.¹⁰

All samples in both groups demonstrated pre-intervention DIAGNOdent scores corresponding to D0 (0-7): caries free, indicating sound, non-demineralized enamel with no evidence of WSLs. Post-intervention DIAGNOdent scores for both groups ranged between D1 and D2, reflecting varying degrees of enamel demineralization. In the control group (Group 1), 93.7% of the samples exhibited scores in the D2 range, indicating deeper demineralization. In contrast, only 12.5% of the samples in the fluoride varnish group (Group 2) reached the D2 level, suggesting a substantial protective effect of the varnish against lesion progression.

The significantly lower incidence of D2-level DIAGNOdent scores in the fluoride varnish group compared to the control group ($p < 0.001$) highlights the effectiveness of fluoride varnish in preventing enamel demineralization around clear aligner attachments. These findings align with the showed significantly lower DIAGNOdent values and maintained enamel hardness associated with fluoride varnish, indicating its effectiveness in decreasing both enamel demineralization and the rate of lesion progression.²⁵ In addition, Shivananda et al.²⁶ demonstrated that Profluorid varnish significantly enhances fluoride penetration and retention within the enamel's microscopic structures, which may explain enhanced post-intervention DIAGNOdent scores.

Conversely, it was claimed that fluoride varnish has only surface remineralization potentials with limited penetration into deeper lesion body, especially under dynamic acid challenges.²⁷ This could explain the observation that a small percentage (12.5%) of group 2 (F. varnish) samples in the current study still reached D2 levels.

Nonetheless, the statistically significant difference in mean DIAGNOdent score changes and final DIAGNOdent values between groups strongly supports the substantial preventive anti-demineralization efficacy of fluoride varnish when applied around clear aligner attachments.

Limitations

This study has several limitations that should be considered. First, the adopted in vitro design, that lacks the complexity of oral environment of in vivo conditions, such as salivary flow, biofilm dynamics, dietary habits, and oral hygiene variations. Second, DIAGNOdent readings, though useful for detecting initial demineralization, still have the limitation of fluorescence-based measurements and lack any detailed histological data. Finally, the study evaluated only one type of fluoride varnish and composite attachment material, which may limit the validity of the findings across different clinical scenarios or product formulations.

CONCLUSION

The findings of this study support the anti-demineralization efficacy of fluoride varnish in reducing both the incidence and severity of WSLs around clear aligner attachments. Since composite attachments can serve as plaque-retentive sites and elevate the risk of demineralization, the preventive application of fluoride varnish around these regions may offer a straightforward and effective approach to minimize enamel demineralization during clear aligner clinical practice, particularly among patients with inadequate oral hygiene.

ACKNOWLEDGEMENT

Not applicable.

Funding

The author received no funding for this research.

Conflict of interest

Authors declare no conflict of interest or financial interest

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