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COMPARATIVE EVALUATION OF TWO MOUTHWASHES IN PREVENTING WHITE SPOT LESIONS DURING FIXED ORTHODONTIC TREATMENT: A RANDOMIZED CLINICAL STUDY

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ABSTRACT

Objective: White spot lesions (WSLs) are a common adverse effect of fixed orthodontic therapy. This study compared the efficacy of two commercially available mouthwashes-Colgate Phos-Flur (0.04% sodium fluoride) and Oradox Enamel Care (hydroxyapatite + sodium fluoride)—in preventing white spot lesions in orthodontic patients. **Materials and Methods**: This randomized clinical trial (registered at CTRI/2024/05/019523 on 15 May 2024. Fifty patients undergoing fixed orthodontic treatment were randomly allocated into two groups (n=25 each): Group A—Colgate Phos-Flur; Group B—Oradox Enamel Care. Patients used the assigned mouthwash once daily for 6 months in addition to standard oral hygiene with fluoridated toothpaste. Standardized digital photographs of maxillary anterior and premolar teeth were analyzed using ImageJ software to quantify WSL area pre- and post-intervention. **Results:** After 6 months, Group B (Oradox Enamel Care) showed a significant reduction in mean WSL area compared to baseline (1.16 ± 0.29 to 0.54 ± 0.22), while Group A showed a mild decrease in WSL area (1.42 ± 0.32 to 0.92± 0.37). Between groups, Group B exhibited significantly fewer and milder WSLs at 6 months ($p<0.001$). **Conclusion:** Oradox Enamel Care containing hydroxyapatite and sodium fluoride demonstrated superior preventive and therapeutic efficacy against white spot lesions compared to Colgate Phos-Flur. The biomimetic hydroxyapatite component likely enhanced enamel remineralization synergistically with fluoride. **Trial Registration:** CTRI/2024/05/019523./

KEYWORDS: white spot lesions, orthodontics, hydroxyapatite, fluoride mouthwash, enamel remineralization.

INTRODUCTION

White spot lesions (WSLs) represent the earliest clinically detectable form of enamel demineralization and are among the most frequent complications of fixed orthodontic treatment. Their prevalence ranges widely, from 2% to 97%**,** depending on oral hygiene practices, fluoride exposure, and appliance design.[1,2] Fixed orthodontic brackets create retentive areas that harbor cariogenic biofilm, facilitating sustained acidic conditions conducive to demineralization.[3] Such enamel porosities compromise esthetics and may progress to cavitation if untreated. Demineralization around orthodontic appliances is exacerbated by increased colonization of *Streptococcus mutans* and *Lactobacillus* species, accompanied by reduced natural cleansing by saliva and oral musculature.[4,5] Effective remineralization strategies include fluoride toothpastes, varnishes, high-fluoride rinses, and enamel-strengthening agents.[6] Fluoride enhances remineralization by forming fluoroapatite and calcium fluoride reservoirs, thereby increasing resistance to acid attack.[7] However, recent advances highlight the role of biomimetic hydroxyapatite as an adjunct capable of integrating into demineralized enamel prisms and restoring mineral density more physiologically.[8,9] Although sodium fluoride mouth rinses (e.g., 0.04% NaF) have demonstrated benefit in reducing WSL incidence, limited clinical evidence compares them directly with hydroxyapatite-based mouthwashes that claim superior enamel repair. Thus, this study aimed to compare the effectiveness of Colgate Phos-Flur (0.04% NaF) with Oradox Enamel Care (hydroxyapatite + sodium fluoride) in preventing white spot lesion development in patients undergoing fixed orthodontic treatment.

MATERIAL AND METHODOLOGY

This randomized clinical study was conducted in Department of Orthodontics and Dentofacial Orthopaedics at Sharad Pawar Dental College, Maharashtra between July 2024- June2025, included

fifty participants aged 12 to 25 years undergoing fixed appliance therapy with MBT 0.022-inch slot brackets. This randomized clinical trial followed the Consolidated Standards of Reporting Trials (CONSORT) 2025 guidelines. Participants with sound enamel surfaces and good oral hygiene were included, whereas those with fluorosis, hypoplastic defects, restorations on labial surfaces, or recent professional fluoride applications were excluded. Study participants were randomly allocated into two equal groups. Group A received Colgate Phos-Flur (0.04% NaF), while Group B received Oradox Enamel Care, which contains biomimetic hydroxyapatite and sodium fluoride. All participants were instructed to brush twice daily using fluoridated toothpaste, while additionally using 15mL of assigned mouth rinse once daily for 30 seconds before bedtime. Dosimeter was provided to measure mouthwash quantity. Compliance was monitored during monthly follow-up visits. Participants were asked to note down the days they did not follow this regime. Standardized digital intraoral photographs were captured at baseline and after six months. The labial surfaces of maxillary anterior teeth and premolars were analyzed using ImageJ software to quantify the percentage of enamel surface affected by white spot lesions. WSL severity was assessed using a four-point ordinal scale ranging from no lesion to severe chalky opacity. Statistical analyses included normality testing, paired comparisons within groups, and independent comparisons between groups, with significance set at $p < 0.05$.

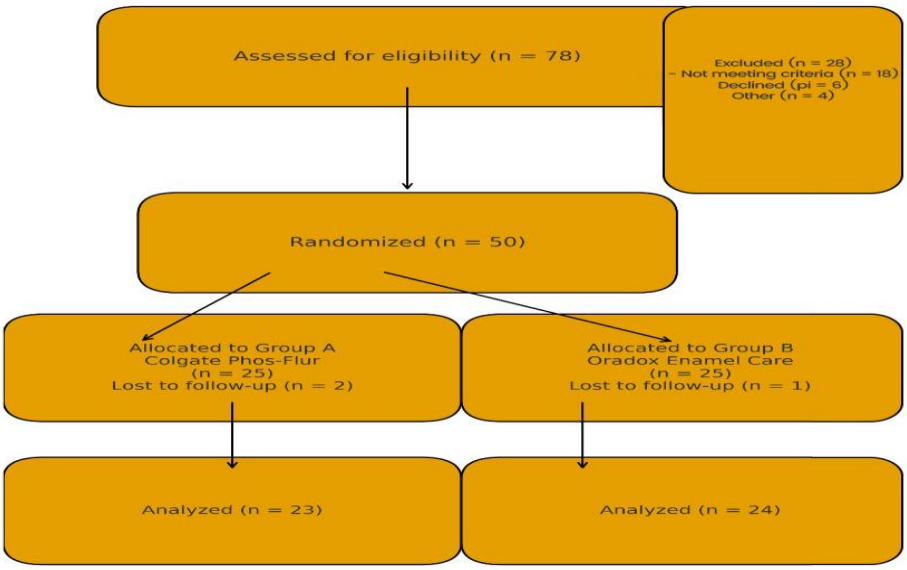

Figure 1: Randomized controlled trial design.

RESULTS

At baseline, the mean WSL scores did not significantly differ between the groups. After six months, Group A (Colgate Phos-Flur) demonstrated a mild but statistically significant decrease in WSL severity, with a mean WSL score rising from 1.42 ± 0.32 to 0.92 ± 0.37 (mean decrease -0.50 ± 0.19, $p = 0.032$). Conversely, Group B (Oradox Enamel Care) showed a significant reduction in WSL severity, with mean scores decreasing from 1.16 ± 0.29 to 0.54 ± 0.22 (mean reduction −0.62 ± 0.21, $p < 0.001$). A direct comparison revealed that Group B had significantly lower WSL scores at six months than Group A ($p < 0.001$). These findings clearly indicate that Oradox Enamel Care outperformed Colgate Phos-Flur both in preventing new WSLs and in promoting the remineralization of incipient lesions.

Figure 2: The area of WSL measured using the tools of the software, full area versus affected area to calculate the percentage.

Table 1: Baseline Characteristics.

Parameter	Group A (Colgate Phos-Flur)	Group B (Oradox Enamel Care)	p-value
Sample Size (n)	25	25	N/S
Mean Age (years)	20.6 ± 4.8	19.2 ± 4.5	0.28
Gender (M/F)	13/12	13/12	1.00
Baseline WSL Score (Mean ± SD)	1.42 ± 0.32	1.16 ± 0.29	0.76

Table 2: Outcome Results.

Outcome Measure	Group A	Group B	p-value
6-Month WSL Score (Mean ± SD)	0.92 ± 0.37	0.54 ± 0.22	<0.001
Change From Baseline	-0.50 ± 0.19	-0.62 ± 0.21	<0.001
WSL Surface Area (%)	8.6 ± 2.3	3.1 ± 1.4	<0.001

DISCUSSION

The present randomized clinical study compared the efficacy of hydroxyapatite-based Oradox Enamel Care mouthwash with a conventional 0.04% sodium fluoride mouthwash (Colgate Phos-Flur) in preventing and reversing white spot lesions (WSLs) during fixed orthodontic treatment. The findings demonstrate that Oradox Enamel Care outperformed Colgate Phos-Flur, both in reducing the severity of existing early enamel lesions and in preventing the formation of new WSLs. This superior performance is consistent with emerging evidence supporting the remineralization potential of biomimetic hydroxyapatite formulations. Hydroxyapatite is structurally analogous to the natural enamel mineral and has been shown to integrate directly into the enamel surface, thereby filling porosities characteristic of early WSLs. Tschoppe et al. reported that nano-hydroxyapatite significantly improved remineralization of both enamel and dentin substrates, producing mineral gains comparable to or better than standard fluoride formulations.[10] The ability of hydroxyapatite to deposit onto demineralized enamel, forming a new mineral layer that resembles natural tooth structure, may explain the greater reduction in lesion area observed in the Enamel Care group. Further supporting this effect, Chen et al. demonstrated that hydroxyapatite-containing toothpaste significantly reduced enamel calcium loss and increased surface microhardness compared to fluoride toothpaste alone.[11] These results align with the mechanisms proposed in the present study, where hydroxyapatite nanoparticles likely served as nucleation centers for mineral deposition, accelerating the repair of subsurface lesions. Enax and Meyer also highlighted that biomimetic hydroxyapatite can create a persistent protective layer on enamel, improving resistance to acid attack and contributing to long-term stabilization of demineralized areas.[12] This is particularly relevant for orthodontic patients, in whom plaque accumulation around brackets creates a chronic acidic environment that challenges enamel integrity. By contrast, although fluoride remains the cornerstone of enamel remineralization strategies, its primary mechanism—promoting fluoroapatite formation and enhancing surface-level mineral deposition—may be insufficient for deeper remineralization of WSLs. Geiger et al. demonstrated that conventional fluoride rinses reduced WSL incidence compared to no fluoridation, but these rinses did not significantly reverse established lesions.[13] Moreover, García-Godoy and Hicks noted that high fluoride concentrations may lead to rapid mineral deposition at the enamel surface, potentially blocking ion penetration into deeper lesion zones and limiting overall

remineralization effectiveness.[14] This phenomenon may help explain why Colgate Phos-Flur, despite containing sodium fluoride, resulted in modest reduction in WSL scores in the present trial. The findings from the current study are also in agreement with Huang et al., who demonstrated that MI Paste Plus (containing CPP-ACP and fluoride) and PreviDent varnish were effective in treating WSLs, suggesting that multiple-ion systems outperform fluoride-only products by addressing deeper lesion repair.[15] Such evidence corroborates the superior outcomes observed with hydroxyapatite-based Oradox Enamel Care, which also functions as a multi-mineral delivery system. Similarly, Najibfard et al. reported that daily use of nano-hydroxyapatite dentifrice promoted significant remineralization of early enamel lesions and improved surface appearance compared to standard fluoride toothpaste.[16] These collective findings reinforce the conclusion that hydroxyapatite offers valuable clinical advantages in orthodontic settings where enamel is frequently challenged by plaque retention and acidogenic bacteria. From a clinical standpoint, the enhanced remineralization seen in the Oradox group indicates that hydroxyapatite-containing mouthwashes may serve as a superior adjunct to routine oral hygiene for orthodontic patients. The ability of hydroxyapatite to visibly improve enamel opacity and lesion size may also provide immediate esthetic benefits, addressing patient concerns related to the cosmetic impact of WSLs. Moreover, hydroxyapatite products are non-irritating, safe for daily use, and do not carry the risk of fluorosis, making them suitable for long-term application. However, despite the encouraging findings, some limitations must be acknowledged. The follow-up period of six months, although clinically relevant, does not provide insights into long-term lesion stability or recurrence. Additionally, the analysis was limited to the maxillary anterior and premolar region; posterior teeth were not evaluated, although they are also susceptible to WSL formation. Compliance was monitored indirectly through self-reported measures, which may introduce bias. Future research should incorporate longer follow-up periods, objective compliance monitoring, and comparisons with other remineralization systems such as bioactive glass, CPP-ACP, and high-fluoride gels.

CONCLUSION

In conclusion, the results of this study, supported by existing evidence, demonstrate that hydroxyapatite-based Oradox Enamel Care mouthwash offers significantly greater benefits in preventing and reversing white spot lesions compared to traditional sodium fluoride mouthwash. Its biomimetic remineralization mechanism, superior lesion repair capabilities, and patient-friendly profile make it a promising preventive solution for orthodontic patients at high risk of enamel demineralization.

Declaration of Conflicting Interests

The author declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval Institutional Statement

The institutional ethical committee, in its meeting held on 15/5/2024, has reviewed and discussed your application to conduct the dissertation proposal titled "Comparative Evaluation of Two Mouthwashes in Preventing White Spot Lesions During Fixed Orthodontic Treatment: A Randomized Clinical Study " Registration Number: PMT/RDC/IEC/2024/07. Decision of the Committee: Approved, Recommended for a period of 1 year.

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Patient Consent

Consent was taken before beginning the procedure.

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