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EFFECT OF HIGH-FLUORIDE TOOTHPASTE AND MOUTH RINSE ON THE PREVENTION OF DEMINERALIZED LESIONS DURING ORTHODONTIC TREATMENT

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ABSTRACT

Objectives: *To evaluate the impact of using high-fluoride toothpaste and mouth rinse in preventing demineralized lesions (DLs) during orthodontic therapy.*

Materials and Methods: *This randomized controlled trial included 250 patients of both gender and were divided into three groups (A=FMR, B=HFT and C=FT). The FMR group, which received a 0.2% sodium fluoride (NaF) mouth rinse in addition to 1450 ppm fluoride (F) toothpaste; the HFT group, which used a 5000 ppm F toothpaste; and the Control (CTR) group, which utilized 1450 ppm F toothpaste. Non-probability purposive sampling was used for the recruitment of patients. A blinded healthcare professional evaluated digital images obtained before and after treatment to determine the percentage of individuals with at least one new demineralized lesion. SPSS version 25 was used for analysis.*

Results: *A total of 250 patients with a mean age of 16.82±2.21 years participated, comprising 95 males (38.0%) and 155 females (62.0%). Group A (n=83) had a mean age of 17.01±2.17 years, Group B (n=84) 16.46±2.19 years, and Group C (n=83) 17.00±2.26 years. Health status varied, with Group A having 73.5% with no disease, Group B 83.3%, and Group C 90.4%. the study presents unadjusted relative risks for increases in demineralized lesions (≥1, ≥2, ≥3) in all teeth and the aesthetic zone, comparing High-Fluoride Toothpaste (HFT) vs. Control (CTR), Fluoride Mouth Rinse (FMR) vs. CTR, and FMR vs. HFT. Pretreatment, white spot lesions (WSL) were distributed across groups, with Group A and B showing different prevalence rates. Post-treatment, Group A had 30.1% with 0 lesions, Group B 33.3%, and Group C 20.5%. Statistically significant differences were observed for increases in ≥1 WSL post-treatment (p=0.01), but not for ≥2 WSL (p=0.50) or ≥3 WSL (p=0.11).*

Conclusion: *It has been shown that using high fluoride toothpaste and mouthwash can help prevent dental caries on canines, lateral incisors, and central incisors when undergoing orthodontic treatment. A mouthwash and toothpaste with high fluoride content may be advised to prevent DL in the aesthetic zone.*

Key words: *High-fluoride toothpaste, white spot lesion, demineralization, orthodontics*

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INTRODUCTION

Using mouthwash and toothpaste with high fluoride content can help stop demineralized lesions, particularly when receiving orthodontic treatment.

Early demineralized lesions (DLs), also called white spot lesions (WSLs) continue to be a difficult clinical concern during fixed appliance orthodontic therapy. Reported incidence rates of WSL range widely, from 15% to 85%[1,2]. In a study by AK Jha et al[3] stated that the prevalence of white spot lesions (WSL) in patients after 12 months of orthodontic treatment was 46.57%, compared to 11.86% in patients who had just begun orthodontic treatment. These lesions are areas of demineralization on the tooth surface, appearing as white or chalky spots. The development of WSL is associated with the accumulation of dental plaque, which contains bacteria that produce acids as they metabolize sugars. Orthodontic treatment using fixed appliances introduces challenges in maintaining good oral hygiene. The presence of fixed appliances is associated with elevated levels of cariogenic bacteria[4,5] leading to an increased accumulation of plaque[6,7] and a heightened susceptibility to early tooth decay. Among the various preventive measures, the use of topical fluoride in different forms has shown promise in reducing the incidence and severity of WSL. Strong scientific data suggests that fluoride regulates the metabolism of microorganisms that cause dental cavities, encourages remineralization and impedes demineralization[8]. Fluoride is a mineral that has been shown to be effective in preventing dental cavities through various mechanisms. Fluoride has proven benefits for dental health[9]. As a result, public health organizations often provide guidelines for optimal fluoride levels in drinking water and oral care products to maximize the benefits while minimizing potential risks. For those who are more susceptible to dental caries, high-fluoride mouth rinses are typically advised. These mouth rinses typically include 0.2% sodium fluoride (NaF)[10]. These rinses are a form of topical fluoride application and are designed to provide additional protection to the teeth, especially for those who may be more susceptible to cavities.

The use of fluoride in dentistry has been a subject of extensive research, and the consensus in the scientific community is that, when used appropriately, fluoride is a valuable tool in preventing and controlling dental caries (cavities). However, individual responses to fluoride may vary, and professional guidance should be sought to determine the most suitable fluoride regimen for an individual's oral health needs.

Orthodontic treatment, particularly involving fixed appliances like braces, can increase the risk of demineralized lesions (white spot lesions) due to plaque accumulation around brackets and wires. These lesions represent early stages of tooth decay and can lead to cavities if left untreated. Therefore, there is a clinical need to explore preventive measures to reduce the incidence of demineralized lesions during orthodontic treatment. The current study's objective is to assess the effectiveness of fluoride-rich mouthwash and toothpaste in preventing demineralized lesion (DL) during orthodontic therapy. By evaluating the effectiveness of high-fluoride toothpaste and mouth rinse, the study aims to improve patient outcomes and quality of care during orthodontic treatment. This study helps in exploring the potential benefits of fluoride-based interventions, filling gaps in existing evidence, and ultimately promoting patient well-being, and treatment success during orthodontic care.

To examine the impact of using high-fluoride toothpaste and mouth rinse in preventing demineralized lesions (DLs) during orthodontic therapy.

Sampling Technique: Non-probability purposive sampling was used for the recruitment of patients.

Sample size: Sample size of 250 patients was calculated by using WHO sample size calculator by keeping the following parameter infront: i.e. Confidence level, 95%, power of test 80% and Anticipated population proportion of 60%[8].

MATERIALS AND METHODS

In this study 250 patients were enrolled after fulfilling the inclusion criteria. An informed consent was taken from each enrolled individual. Following a clinical evaluation, each patient was split into three groups. (Group A=FMR, Group B=HFT and Group C=FT) by block randomization method. Group A patients used regular toothpaste (1450 ppm F, Colgate Caries Control; Colgate Palmolive, Lyngby, Denmark) and rinse with a fluoride mouth rinse (FMR) (0.2% NaF, equating to 900 ppm F, Flux; Actavis, Stockholm, Sweden) twice a day. After brushing their teeth, all the group A patients were instructed to use the fluoride mouthwash. Group B patients brush teeth twice a day with a toothpaste that contains a high concentration of fluoride (HFT) (5000 ppm F, Duraphat; Colgate-Palmolive). And the control

Group patients uses standard toothpaste (1450 ppm F, Colgate Caries Control; Colgate-Palmolive) twice daily. All the three groups' patients were advised to apply 1 g of toothpaste to the brush and brush the teeth for about 2 min. The timing of brushing was right before bed and right after breakfastThe FMR group was instructed to rinse their mouths for two minutes with 10 mm of fluoride mouthwash. The patients were instructed not to use water during or after tooth brushing, and they were also instructed to refrain from eating or drinking anything for at least an hour after these treatments. Additionally, every three months, the patients received a toothbrush to use for the duration of their treatment. A predesign questionnaire was used to collect the data. Digital photos were taken before and after treatment for outcome analysis. This study was a double blinded study. A Gorelick et al. score of 1 denoted no white spot formation, 2 slight white spot formation (thin rim), 3 severe white spot formation, and 4 white spot formation with cavitation was used to evaluate the DL.

At the initial stage, the teeth underwent polishing using a rubber cup and pumice paste, followed by gentle drying before capturing photographs. During the debonding process, the composite material that was on the teeth surfaces was carefully removed with a carbide bur that rotated gently.

Subsequently, the teeth were polished once again, this time utilizing a rubber cup. Following a gentle air-drying process, a fresh set of frontal and lateral digital images were captured. These photographs were then displayed on a screen in a darkened room, where one of the authors (HE) evaluated the DL. In cases of uncertainty during scoring, the lower scores were selected.

All participants were requested to provide written responses to the questionnaire, to determine compliance with regard to fluoride intake during treatment, including questions such as : How frequently do you floss your teeth? How often do you use toothpaste? Do you utilize any additional fluoride products? Mouthwash and toothpaste with high fluoride content were included in the list of extra fluoride items.

Additionally, participants were queried about their overall health status, any existing diseases, and their use of medications."

Statistical analysis: For statistical analysis SPSS Version 25 were used. Continuous variables were presented as mean (SD). Categorical variables were presented as n (%). Chi-square test or fisher's test was used for group comparisons.

RESULT

A total of 250 patients with mean age of 16.82±2.21 years, were enrolled. The number of male patients were 95(38.0%) and that female patients were 155(62.0%) (Table 1). Group A (n = 83) had a mean age of 17.01±2.17 years, Group B (n = 84) had a mean age of 16.46±2.19 years, and Group C (n = 83) had a mean age of 17.00±2.26 years. Health status varied among the groups: in Group A, 61 participants (73.5%) had no disease, 13 (15.7%) had asthma and/or allergies, 2 (2.4%) had epilepsy, 1 (1.2%) had migraine, 5 (6.0%) had depression or anxiety, and 1 (1.2%) had autism. In Group B, 70 participants (83.3%) had no disease, 10 (11.9%) had asthma and/or allergies, 2 (2.4%) had epilepsy, 2 (2.4%) had migraine, and none reported depression, anxiety, or autism. In Group C, 75 participants (90.4%) had no disease, 7 (8.4%) had asthma and/or allergies, 1 (1.2%) had epilepsy, and none had migraine, depression, anxiety, or autism (Table 2).

Table 3 shows the unadjusted relative risks (risk ratios) for increases of ≥1, ≥2, and ≥3 demineralized lesions (DL) in all teeth and in the aesthetic zone, comparing High-Fluoride Toothpaste (HFT) vs. Control (CTR), Fluoride Mouth Rinse (FMR) vs. Control, and FMR vs. HFT. For all teeth, the risk ratios for an increase of ≥1 DL were 0.85 (95% CI: 0.65–1.10) for HFT vs. CTR, 0.90 (95% CI: 0.70–1.16) for FMR vs. CTR, and 1.06 (95% CI: 0.82–1.36) for FMR vs. HFT. For an increase of ≥2 DL, they were 0.78 (95% CI: 0.55–1.09), 0.95 (95% CI: 0.67–1.34), and 1.22 (95% CI: 0.85–1.74), respectively. For an increase of ≥3 DL, they were 0.72 (95% CI: 0.47–1.10), 1.10 (95% CI: 0.75–1.62), and 1.53 (95% CI: 1.01–2.31), respectively. In the aesthetic zone, the risk ratios for an increase of ≥1 DL were 0.82 (95% CI: 0.60–1.12) for HFT vs. CTR, 0.88 (95% CI: 0.63–1.23) for FMR vs. CTR, and 1.07 (95% CI: 0.76–1.50) for FMR vs. HFT. For an increase of ≥2 DL, the ratios were 0.75 (95% CI: 0.51–1.10), 0.93 (95% CI: 0.64–1.36), and 1.24 (95% CI: 0.82–1.88), respectively. For an increase of ≥3 DL, they were 0.68 (95% CI: 0.40–1.17), 1.02

(95% CI: 0.60–1.75), and 1.50 (95% CI: 0.82–2.75), respectively.

At the patient level, demineralized lesions (DLs) were assessed across three groups (n=250). Group A (FMR, n=83) and Group B (HFT, n=84) showed a pretreatment distribution of white spot lesions (WSLs) as follows: 0 lesions in 21 (25.3%) of Group A, 27 (32.1%) of Group B; 1-3 lesions in 32 (38.6%) of Group A, 38 (45.2%) of Group B; 4-8 lesions in 26 (31.3%) of Group A, 10 (11.9%) of Group B; and more than 9 lesions in 4 (4.8%) of Group A, 9 (10.7%) of Group B. Post-treatment, 0 lesions were found in 15 (18.1%) of Group A, 9 (10.7%) of Group B; 1-3 lesions in 20 (24.1%) of Group A, 20 (23.8%) of Group B; 4-8 lesions in 32 (38.6%) of Group A, 37 (44.0%) of Group B; and more than 9 lesions in 16 (19.3%) of Group A, 18 (21.4%) of Group B. Comparatively, Group C showed slightly different results. There was no significant difference in the increase of ≥1 WSL between the groups (p=0.46), nor in the increase of ≥2 WSL (p=0.53), while an increase of ≥3 WSL approached significance (p=0.22). For pretreatment WSLs, Group A had 66.3% with 0 lesions, Group B had 67.9%, and Group C had 64.6%. Post-treatment, Group A showed 30.1% with 0 lesions, Group B had 33.3%, and Group C had 20.5%. The increase of ≥1 WSL post-treatment was significantly different among groups (p=0.01), while increases of ≥2 WSL (p=0.50) and ≥3 WSL (p=0.11) did not show significant differences (Table 4).

Table 1: Patient characteristics of enrolled patients (n=250)

Variables	
Age (Years)	16.82±2.21
Gender	
Male	95(38.0%)
Female	155(62.0%)

Table 2: Distribution of effected individuals on the basis of sex, age, and health conditions between the groups at baseline (n=250)

	Group A (n = 83)	Group B (n = 84)	Group C (n = 83)
Age (years)	17.01±2.17	16.46±2.19	17.00±2.26
Health			
No disease	61(73.5%)	70(83.3%)	75(90.4%)
Asthma and/or allergy	13(15.7)	10(11.9%)	7(8.4%)
Epilepsy	2(2.4%)	2(2.4%)	1(1.2%)
Migraine	1(1.2%)	2(2.4%)	0
Depression, anxiety	5(6.0%)	0	0
Autism	1(1.2%)	0	0

DISCUSSION

Using mouthwash and toothpaste with high fluoride content can help stop demineralized lesions, particularly when receiving orthodontic treatment. White spot lesions (WSL) continue to be a difficult clinical concern during fixed appliance orthodontic therapy. This implies a systematic exploration of the effects or outcomes resulting from a specific action

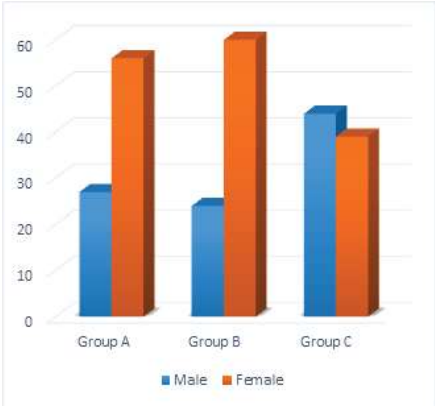

Fig 1: Bar graph showing gender distribution in all three groups

Table 3: Unadjusted relative risks (risk ratios) for increases of ≥1, ≥2, and ≥3 demineralized lesions (DL) in all teeth and in the aesthetic zone, presented as pairwise comparisons with corresponding 95% confidence intervals (CIs).

		RR (95% CI)		
Teeth	**Increase in WSL**	**HFT vs CTR**	**FMR vs CTR**	**FMR vs HFT**
All teeth	≥1 WSL	0.85 (0.65–1.10)	0.90 (0.70–1.16)	1.06 (0.82–1.36)
	≥2 WSL	0.78 (0.55–1.09)	0.95 (0.67–1.34)	1.22 (0.85–1.74)
	≥3 WSL	0.72 (0.47–1.10)	1.10 (0.75–1.62)	1.53 (1.01–2.31)
Aesthetic zone	≥1 WSL	0.82 (0.60–1.12)	0.88 (0.63–1.23)	1.07 (0.76–1.50)
	≥2 WSL	0.75 (0.51–1.10)	0.93 (0.64–1.36)	1.24 (0.82–1.88)
	≥3 WSL	0.68 (0.40–1.17)	1.02 (0.60–1.75)	1.50 (0.82–2.75)

or intervention. In this study, we want to thoroughly examine and understand what happens as a result of using high-fluoride toothpaste and mouth rinse. Demineralized lesions are areas on the teeth where minerals, such as calcium have been lost. These lesions can lead to the development of cavities. The present study focused on assessing whether the use of high-fluoride toothpaste and mouth rinse is effective in preventing the formation or progression of these demineralized lesions.

In the present study the mean age was 16.82±2.21 years of all the 250 enrolled patients. And the mean age of all the three groups individually were 17.01±2.17, 16.46±2.19 and 17.00±2.26 years respectively. The same results were also stated by another study conducted by Hanna et al[7]. Age can be a significant factor in oral health, as dental conditions and susceptibility to certain issues may vary across different age groups. In our study most of the participants were in good health while few had Asthma and/or allergy, epilepsy, migraine, depression, anxiety and autism. In this regards our study resembled the study of Hanna et al[8]. White spot lesions (WSLs) refer to areas of demineralization on the tooth enamel that appear as chalky white patches. These lesions are often an early sign of tooth decay and are commonly associated with dental caries. In our study the WSL before treatment were assessed and when it was compared among the groups a significant p-value was found. And when post treatment WSL was assessed there, we found insignificant p-value. The beneficial impact of using high-fluoride toothpaste and fluoride rinse on the development of DL aligns with the results reported in prior clinical research[11-13].

Our study indicates that there were initially more participants in the range of 0 and 1-3 WSL while low number of participants in the range of 4 to 8 and >9 WSL. But after treatment the amount of

Table 4: Demineralized lesions (DLs) at the patient level, and comparisons between groups (n=250)

All teeth included WSL pretreatment	Group A FMR (n = 83)	Group B HFT (n = 84)	Group C (n = 83)	P-value
0	21(25.3%)	27(32.1%)	17(20.5%)	0.01
1-3	32(38.6%)	38 (45.2%)	40(48.2%)	
4-8	26(53.1%)	10(11.9%)	13(15.7%)	
>9	4(4.8%)	9(10.7%)	13(15.7%)	
WSL post-treatment				
0	15(18.1%)	9(10.7%)	7(8.4%)	0.11
1-3	20(24.1%)	20(23.8%)	25(30.1%)	
4-8	32(38.6%)	37(44.0%)	24(28.9%)	
>9	16(19.3%)	18(21.4%)	27(32.5%)	
Patients with an increase of				
≥1 WSL	55(66.3%)	63(75.0%)	58(69.9%)	0.46
≥2 WSL	44(53.0%)	49(58.3%)	51(61.4%)	0.53
≥3 WSL	28(33.7%)	34(40.5%)	39(47.0%)	0.22
WSL retreatment				
0	55(66.3%)	57(67.9%)	53(64.6%)	0.74
1-3	26(31.3%)	22(26.2%)	26(31.7%)	
>4	2(2.4%)	5(6.0%)	3(3.7%)	
WSL post-treatment				
0	25(30.1%)	28(33.3%)	17(20.5%)	0.18
1-3	32(38.6%)	33(39.3%)	30(36.1%)	
4-8	31(31.3%)	23(27.4%)	36(43.4%)	
Patients with an increase of				
≥1 WSL	49(59.0%)	56(66.7%)	65(79.3%)	0.01
≥2 WSL	40(48.2%)	47(56.0%)	46(56.1%)	0.50
≥3 WSL	27(32.5%)	36(42.9%)	40(48.2%)	0.11

participant increases in the 4 to 8 and >9 WSL among the three groups. In the esthetic zone most of the participants had no WSL while the range 1-3 and >4 range indicate that some participants had WSL. The CTR group exhibited a notably higher incidence of patients experiencing a ≥1 DL When concentrating on the central, lateral, and canine incisors in the analysis, there was an increase throughout orthodontic treatment in comparison to both the HFT and FMR groups. Consequently, patients benefited more from using fluoride mouthwash and high-fluoride toothpaste in the aesthetic zone than from using regular fluoride toothpaste.

The protective effect of fluoride rinse and toothpaste with high fluoride content on the development of dental caries is consistent with findings from earlier clinical trials[8,11,14]. Nevertheless, no discernible impact was observed at the patient level when considering all teeth in the analysis. Numerous clinical studies with comparable designs similarly overlook the inclusion of the first molar in their analyses[15,16]. In a study conducted by Hanna et al[8] found no discernible impact at the patient level. Various methods exist for administering fluoride. Recent randomized controlled trials (RCTs) have demonstrated encouraging results in preventing demineralization during orthodontic treatment with high-frequency vibration (HFT), fixed orthodontic retainers (FMR) and fluoride varnish[13,15,17]. Nevertheless, there is variability in the number of teeth assessed in these studies, and a comprehensive evaluation of the preventive effects on the central incisors, lateral incisors, and canines during orthodontic treatment has not been conducted previously. Fluoride mouth rinse is notably more economical compared to high-fluoride toothpaste. In this current research, the participants received the products without any cost. Nonetheless, when patients are required to cover the expenses, it might impact their adherence or compliance. DL can endure and give rise to aesthetic concerns for patients even a 12 years following treatment[18]. Numerous clinical investigations support the current study's findings by showing that DL frequently affects the lateral incisor in the upper arch[12,19,20].

Teeth in the aesthetic zone showed the highest incidence of dental caries (DLs) throughout treatment in the present investigation, indicating that high-fluoride solutions had a more beneficial effect on caries-prone teeth. The results of high-fluoride therapies were enhanced by the presence of DLs. These findings imply that creating a novel teeth index would be a worthwhile area of study in the future. To more precisely target and assess the effectiveness of various caries preventative measures, this index should consider the teeth in the aesthetic zone, with a focus on surfaces that are prone to caries.

CONCLUSION

During orthodontic therapy, high fluoride toothpaste and mouthwash have been shown to have a beneficial effect in preventing dental caries on canines, lateral incisors, and central incisors. But DLs continue to be a problem with orthodontic treatments. Thus, more research should be done to create guidelines for avoiding DL while receiving orthodontic treatment.

LIMITATION

This study has several limitations. The sample size, while adequate, might not be large enough to detect minor differences between the intervention groups, affecting the generalizability of the findings. The follow-up period may be insufficient to fully assess the long-term impact of the interventions, especially since orthodontic treatments often last several years. Patient compliance with the high-fluoride products varied, which could have influenced the results. The visual assessment of demineralized lesions, though standard, may lack precision in detecting early or subtle lesions. Additionally, the absence of blinded outcome evaluation could introduce bias, and the study did not account for confounding factors such as differences in oral hygiene, diet, and fluoride exposure from other sources.

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