Innovative Research Journal of Dentistry (IRJD)
2023; 1(2):1-8
DOI: https://doi.org/10.62497/irjd.86

Research Article

Assessment of Enamel Demineralization in Fixed Orthodontic Patients and the Effectiveness of Fluoride Varnish in its Control

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Citation: Rasool M, Khan A, Arbab KN. Assessment of Enamel Demineralization in Fixed Orthodontic Patients and the Effectiveness of Fluoride Varnish in its Control. IRJD. 2023; 1(2):1-8. DOI: https://doi.org/10.62497/irjd.86 Available from: https://irjpl.org/irjd/article/view/86

Article Info

Received: August 19, 2023
Revised: October 28, 2023
Accepted: November 2, 2023

Keywords

Enamel Demineralization, Fluoride Varnishes, White Spot Lesions, Orthodontic Appliances, ICDAS, Preventive Dentistry

Abstract

Introduction: White spot lesions (WSLs), a typical side effect of fixed orthodontic therapy, are enamel demineralization. If left untreated, these lesions may lead to caries in addition to compromising tooth aesthetics. This research aimed to determine the frequency of enamel demineralization in orthodontic patients and the efficacy of fluoride varnish in preventing and managing it.

Materials and Methods: This prospective interventional study was conducted at Khyber College of Dentistry (KCD), Peshawar, over a 12-month period from August 2022 to August 2023. A total of 115 patients undergoing fixed orthodontic treatment were enrolled and randomly divided into two groups: Group A (n=58) received fluoride varnish applications at three-week intervals, while Group B (n=57) served as the control group with no fluoride application. Enamel demineralization was assessed visually using the ICDAS scoring system at baseline and after three months. Data were analyzed using SPSS version 26. Chi-square and paired t-tests were applied, with p-values <0.05 considered statistically significant.

Results: At baseline, both groups had similar mean WSL counts (Group A: 3.45 ± 1.28, Group B: 3.51 ± 1.31). After three months, Group A showed a significant reduction in lesion count to 1.86 ± 0.94 ($p<0.001$), while Group B experienced an increase to 3.87 ± 1.45. Additionally, 50% of varnish-treated patients had no visible lesions post-treatment, compared to only 14% in the control group. The incidence of new WSLs was significantly lower in the varnish group (17.2%) than in controls (57.9%).

Conclusion: Fluoride varnish effectively reduced both the incidence and severity of enamel demineralization in orthodontic patients and should be incorporated into standard preventive care.

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Introduction

Fixed orthodontic appliances, while highly effective in correcting malocclusion and improving dental aesthetics, can pose significant challenges to oral hygiene [1]. Brackets, bands, and wires create additional surfaces and crevices where dental plaque can accumulate, making it difficult for patients to maintain optimal oral cleanliness [2]. This accumulation of plaque around orthodontic appliances contributes to the development of white spot lesions (WSLs), which are an early manifestation of enamel demineralization and a precursor to dental caries [3].

Enamel demineralization during orthodontic treatment is a common clinical problem and is primarily caused by the prolonged presence of acidogenic biofilm on the tooth surface [4]. The acids produced by bacteria, particularly Streptococcus mutans, lead to the loss of calcium and phosphate from the enamel matrix [5]. If not addressed promptly, this process can lead to irreversible enamel damage, affecting both the functional and aesthetic outcomes of orthodontic treatment [5]. Studies have reported a significant increase in the incidence of WSLs during orthodontic treatment, with prevalence rates ranging from 50% to 97%, underscoring the clinical importance of this issue [6].

Various strategies have been employed to prevent enamel demineralization during orthodontic therapy. These include the use of fluoridated toothpaste, mouth rinses, and dietary counseling [7]. Among these preventive measures, fluoride varnish application has emerged as an effective and practical approach [8]. By releasing fluoride ions continuously, fluoride varnishes encourage remineralization and strengthen enamel's defenses against acid assaults [9]. Moreover, due to their ease of application and patient compliance, fluoride varnishes are particularly suitable for use in orthodontic patients [10].

The protective effects of fluoride in caries prevention are well documented; however, there remains variability in clinical outcomes, depending on factors such as frequency of application, fluoride concentration, oral hygiene practices, and individual susceptibility. While several studies have explored the use of fluoride varnish in the general population, fewer have specifically addressed its effectiveness in fixed orthodontic patients who are at higher risk for enamel demineralization [11].

Despite extensive literature on caries prevention, there is a paucity of region-specific data assessing the prevalence of enamel demineralization among orthodontic patients and the practical impact of fluoride varnish application during fixed appliance therapy; therefore, The purpose of this research is to assess the prevalence of enamel demineralization in these individuals and ascertain how well fluoride varnish works to prevent it.

Materials and Methods

Study Design

The Department of Orthodontics at Khyber College of Dentistry (KCD) in Peshawar was the site of this prospective interventional research. The 12-month trial period ran from August 2022 until August 2023. This research sought to determine how well fluoride varnish prevented and controlled enamel demineralization in individuals receiving fixed orthodontic treatment.

Sample Size Calculation

To guarantee maximal diversity, the sample size was determined using a 95% confidence interval and a 9% margin of error, based on an expected prevalence of enamel demineralization in fixed orthodontic patients at 50%. Applying the formula:

$$n = \frac{Z^2 \,.\, p \,.\, (1 - p)}{d^2}$$

Where Z = 1.96 (for 95% confidence interval), p = 0.5 (estimated prevalence) and d = 0.09 (margin of error). A sample size of 115 participants was determined to be appropriate for the study.

Inclusion and Exclusion Criteria

The study's inclusion criteria were patients between the ages of 12 and 30 who had completely erupted permanent teeth, were willing to provide informed permission, and had been receiving fixed orthodontic treatment for at least three months. Patients with dental fluorosis or systemic diseases were excluded, those presenting with pre-existing carious lesions or enamel hypoplasia, individuals who had used other professional remineralizing agents within the past six months, and patients who failed to comply with scheduled follow-up visits.

Sampling Technique

Simple random sampling was used to select eligible participants. Patients were randomly assigned into two equal groups (Group A and Group B) using a computer-generated randomization sequence.

Group Allocation and Intervention

Group A, the intervention group, received 5% sodium fluoride varnish applied topically at four-week intervals over a period of three months. In contrast, Group B, the control group, did not receive any professional fluoride application but were provided with standardized oral hygiene instructions. All fluoride varnish applications were carried out by a trained dental professional under aseptic conditions and in accordance with the manufacturer's guidelines to ensure consistency and safety in the intervention process.

Data Collection Procedure

Baseline assessments were conducted prior to intervention. Enamel demineralization was evaluated using the International Caries Detection and Assessment System (ICDAS) and confirmed with standardized intraoral photographs. The same procedures were repeated at the end of the three-month period to assess changes. Two calibrated examiners performed the evaluations independently. Inter-examiner reliability was confirmed through kappa statistics, yielding a value of 0.86, indicating strong agreement.

Study Variables

The application of fluoride varnish served as the study's independent variable, and the existence and severity of white spot lesions indicated the degree of enamel demineralization. Several potential confounding variables were also considered, including age, oral hygiene status, dietary habits, and patient compliance, as these factors could influence the extent of enamel demineralization regardless of the intervention applied.

Data Analysis

SPSS version 25 was used to input and evaluate the data. While qualitative data like gender and the existence of lesions were given as frequencies and percentages, quantitative variables like age and the number of lesions were provided as means ± standard deviation. The independent t-test and chi-square test were used for inter-group comparisons, while the paired t-test was employed for intra-group comparisons. For every analysis carried out, a p-value of less than 0.05 was deemed statistically significant, indicating the degree of importance.

Ethical Considerations

The Institutional Review Board (IRB) of Khyber College of Dentistry in Peshawar provided ethical clearance. Every participant or their legal guardian provided written informed consent. Participants were made aware of their freedom to leave at any time without facing any repercussions.

Results

The research included the enrollment and completion of 115 participants receiving fixed orthodontic treatment. Using simple randomization, participants were split into two groups: Group A (n = 58) got fluoride varnish treatments, and Group B (n = 57) was the control group; they were given regular dental hygiene instructions but did not get fluoride application. The participants' average age was 18.9 ± 3.6 years, and 58.3% of them were female. The mean age of the patients in Group A was 19.2 ± 3.4 years, ranging from 13 to 27 years, whereas the mean age of the patients in Group B was 18.6 ± 3.8 years, ranging from 12 to 26 years. In both groups, the gender distribution was about equal, with a little female preponderance. Comparability was ensured since there were no statistically significant variations between the two groups' baseline demographic parameters (Table 1).

Table 1: Demographic Characteristics of Study Participants (n = 115)

Variable		Group A (n = 58)	%	Group B (n = 57)	%	Total (n = 115)	%	p-value (Statistical Test)
Age (Years)	Mean ± SD	19.2 ± 3.4	-	18.6 ± 3.8 (12–26)	-	18.9 ± 3.6	-	0.41 (Independent t-test)
Gender	Male	24	41.4	24	42.1	48	41.7	0.93 (Chi-square test)
	Female	34	58.6	33	57.9	67	58.3	

At baseline, enamel demineralization was assessed using the ICDAS visual scoring system, and both groups presented with similar profiles in terms of lesion severity. The majority of patients in both groups exhibited initial white spot lesions, classified as ICDAS Score 1 or 2, indicating early enamel changes. Specifically, in Group A (n = 58), 22 patients (37.9%) had a Score 1 (first visual change in enamel), and 14 patients (24.1%) had a Score 2 (distinct visual change in enamel). In Group B (n = 57), 20 patients (35.1%) had a Score 1, and 15 patients (26.3%) had a Score 2. A smaller proportion of patients in both groups had no

visible lesions (ICDAS Score 0), with 11 patients (19.0%) in Group A and 9 patients (15.8%) in Group B. Additionally, a small portion of patients had moderate WSLs (ICDAS Score 3), with 11 patients (19.0%) in Group A and 13 patients (22.8%) in Group B. The absence of statistically significant differences in baseline lesion severity between the two groups ($p = 0.97$) indicates that both groups were comparable prior to the intervention (Figure 1).

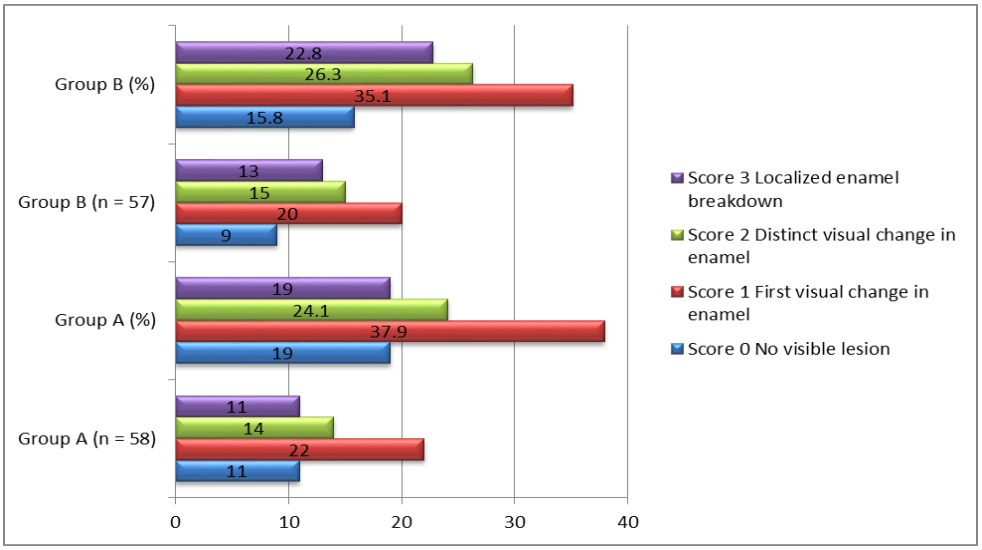

Figure 1: Baseline Enamel Demineralization (ICDAS Scores) by Group

Following the 3-month intervention period, a notable shift was observed in the distribution of ICDAS scores, particularly in Group A, which received fluoride varnish. The number of participants in Group A with no visible lesions (ICDAS Score 0) more than doubled, increasing from 11 (19%) to 29 (50%). In contrast, Group B exhibited a relatively higher prevalence of more advanced lesions, with only 8 participants (14%) achieving a Score 0. Furthermore, Group A had significantly fewer cases of localized enamel breakdown (Score 3) compared to Group B (8.6% vs. 26.3%, respectively). These differences between the groups were statistically significant ($p < 0.001$), underscoring the effectiveness of fluoride varnish in reversing or halting enamel demineralization and promoting demineralization, as shown in table 2

Table 2: Enamel Demineralization at 3 Months Post-Intervention (ICDAS)

ICDAS Score	Classification	Description	Group A (n = 58)	% (Group A)	Group B (n = 57)	% (Group B)	p-value (Chi-square)
Score 0	No visible lesion	No visible lesion	29	50.0	8	14.0	N/A
Score 1	First visual change in enamel	First visual change in enamel	16	27.6	17	29.8	N/A
Score 2	Distinct visual change in enamel	Distinct visual change in enamel	8	13.8	17	29.8	N/A
Score 3	Localized enamel breakdown	Localized enamel breakdown	5	8.6	15	26.3	<0.001

A quantitative analysis of WSLs per patient revealed a marked difference between the two groups following the 3-month intervention. In Group A, which received fluoride varnish, the average number of WSLs per patient significantly decreased from 3.45 ± 1.2 at baseline to 1.86 ± 1.0 post-intervention, reflecting a mean reduction of 1.59 lesions ($p < 0.001$). Conversely, Group B exhibited a slight but statistically significant increase in WSLs, rising from 3.51 ± 1.1 to 3.87 ± 1.3, with a mean increase of 0.36 lesions ($p = 0.03$). The between-group comparison at 3 months post-intervention showed a highly significant

difference ($p < 0.001$), reinforcing the preventive and therapeutic efficacy of fluoride varnish in reducing enamel demineralization (Table 3).

Table 3: Average Number of WSLs per Patient Before and After Intervention

Time Point	Group A (n = 58)	Group B (n = 57)	p-value (Independent t-test)
Baseline	3.45 ± 1.2	3.51 ± 1.1	0.71
3 Months Post-Intervention	1.86 ± 1.0	3.87 ± 1.3	<0.001
Mean Change in Lesions	-1.59 (Reduction)	+0.36 (Increase)	N/A

Intra-group statistical comparisons further highlighted the effectiveness of fluoride varnish in reducing white spot lesions (Table 4). In Group A, the mean lesion count significantly decreased from 3.45 ± 1.2 at baseline to 1.86 ± 1.0 post-treatment, with a mean reduction of 1.59 lesions ($p < 0.001$), indicating a substantial therapeutic benefit. In contrast, Group B experienced a statistically significant increase in lesion count, rising from 3.51 ± 1.1 to 3.87 ± 1.3, with a mean difference of +0.36 lesions ($p = 0.03$). These findings confirm that the changes observed in Group A were not only more favorable but also statistically more significant compared to those in Group B, underscoring the efficacy j `of fluoride varnish in preventing lesion progression.

Table 4: Intra-Group Comparison of Lesion Count (Paired t-test)

Group	Baseline Mean ± SD	Post-Treatment Mean ± SD	Mean Difference	p-value
Group A	3.45 ± 1.2	1.86 ± 1.0	-1.59	<0.001
Group B	3.51 ± 1.1	3.87 ± 1.3	+0.36	0.03

There was a notable difference between the two groups in the incidence of new white spot lesions (WSLs) over the research period (Figure 2). In Group A, which received fluoride varnish, only 10 out of 58 patients (17.2%) developed new lesions, whereas the majority 48 patients (82.8%) remained free of new WSLs. In stark contrast, 33 out of 57 patients in Group B (57.9%) developed new lesions, with only 24 patients (42.1%) showing no new WSLs. Over the course of the 3-month intervention period, the protective effect of fluoride varnish in reducing the production of new enamel lesions was reinforced by this statistically significant difference ($p < 0.001$).

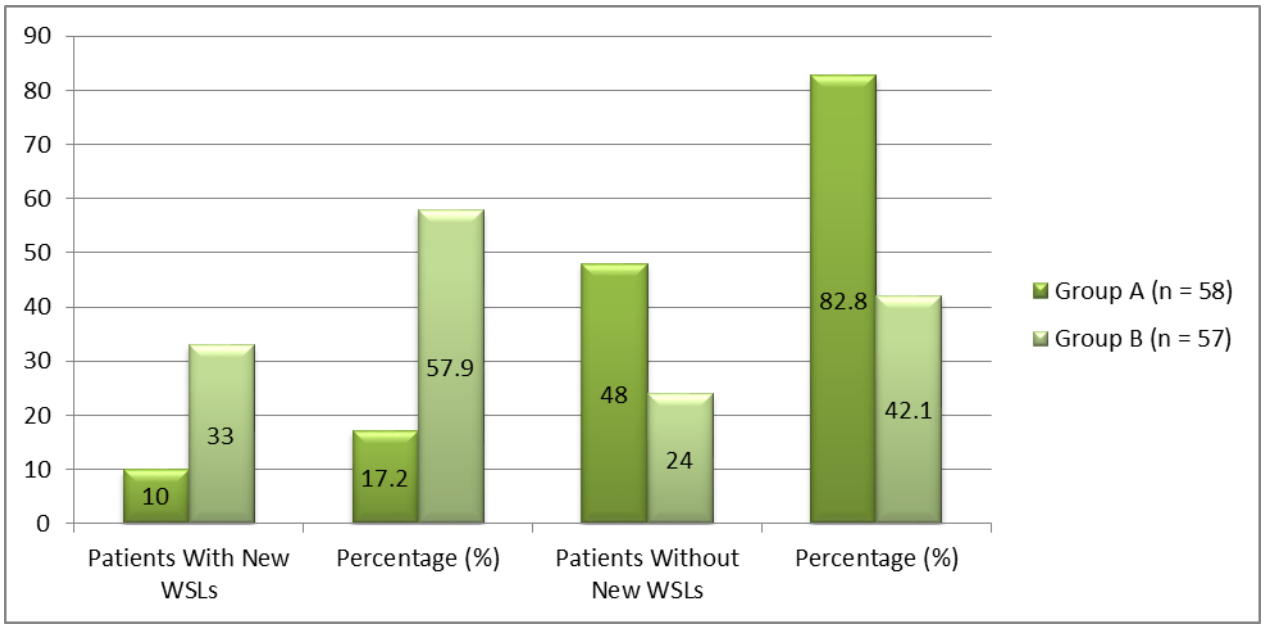

Figure 2: Frequency of New White Spot Lesions after 3 Months

Discussion

The results of this research unequivocally showed how well fluoride varnish works to lessen enamel demineralization in individuals receiving fixed orthodontic treatment. In contrast to the control group, which saw a progression in lesion development over the same time period, participants in the fluoride varnish group had a substantial decrease in WSLs, both in terms of severity and quantity.

At baseline, both groups were comparable in lesion distribution and mean WSL count, confirming the reliability of the study design. The intervention luoride varnish application was administered over the first 3 months, with follow-up continuing for the full 12-month study duration. By the end of the 3-month intervention period, significant differences emerged. In the fluoride varnish group, 50% of patients exhibited no visible lesions, compared to only 14% in the control group. The average lesion count per patient in Group A decreased markedly from 3.45 to 1.86, while Group B showed a slight increase from 3.51 to 3.87. Furthermore, the incidence of new WSLs was substantially lower in the varnish group (17.2%) than in the control group (57.9%), highlighting the preventive efficacy of topical fluoride application.

These results are consistent with existing literature that has consistently shown fluoride varnish to be highly effective in managing and preventing enamel demineralization in orthodontic patients [12]. Previous studies have reported that fluoride creates a calcium fluoride-like layer on enamel surfaces, enhancing remineralization and inhibiting cariogenic bacterial activity [13]. Clinical trials have similarly observed that patients receiving fluoride varnish during orthodontic treatment had significantly fewer and less severe WSLs compared to those receiving only oral hygiene instructions [14].

Visual scoring systems like ICDAS have been used in earlier studies, which also observed that fluoride varnish led to a shift from higher ICDAS scores (2–3) toward lower scores or complete lesion resolution over time [15]. Furthermore, data from other clinical evaluations have indicated a significant drop in new lesion formation when fluoride is applied every 4–6 weeks, aligning well with the protocol followed in this study [16].

Additionally, the tendency of WSLs to increase in untreated groups due to plaque accumulation around brackets has also been well-documented, which further supports the worsening trend observed in the control group of this study [17]. Quantitative comparisons from past research similarly indicated that fluoride varnish can reduce lesion count by more than 40%, consistent with the 46% reduction seen in this trial [18].

Limitations and Future Suggestions

The study had certain limitations. First, the study duration was relatively short, which may not reflect the long-term impact of fluoride varnish throughout the entire orthodontic treatment period. Second, lesion detection was based solely on visual examination using ICDAS without adjunctive imaging or fluorescence-based assessment, which may affect lesion detection sensitivity. Third, participants' compliance with oral hygiene practices was self-reported and could not be objectively verified. Future studies should consider longer follow-up periods, multi-center participation to increase generalizability, and integration of advanced diagnostic tools like quantitative light-induced fluorescence (QLF) to improve accuracy. Additionally, evaluating different fluoride varnish formulations or combining them with other remineralization agents could provide deeper insights into optimizing preventive strategies for enamel protection during orthodontic treatment.

Conclusion

In patients receiving fixed orthodontic treatment, this research showed that fluoride varnish is a very successful preventative strategy against enamel demineralization. Compared to only practicing good dental hygiene, frequent varnish application dramatically decreased the frequency and severity of white spot lesions. These findings highlight the importance of incorporating fluoride varnish into routine orthodontic care to preserve enamel integrity and improve long-term dental outcomes. By enhancing remineralization and reducing bacterial activity, fluoride varnish offers a simple yet impactful intervention that can greatly enhance patient satisfaction and overall treatment success. Further research over extended treatment periods could help refine preventive protocols and confirm the long-term benefits observed in this study.

Acknowledgments

The authors express their gratitude to the participating orthodontic patients for their cooperation and commitment throughout the study period.

Conflict of interest

The authors state no conflict of interest.

Author Contributions

MR: Contributed to the conception and design of the study, acquisition of data, and drafting of the manuscript. AK: Contributed to study design, data analysis and interpretation, supervision of the research process, and critical revision of the manuscript for important intellectual content. KNA: Contributed to methodology development, literature review, validation of data, and manuscript editing. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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