Abstract: ABSTRACT
Introduction: The purpose of this study was to compare the efficacy of fluoride gel vs. fluoride varnish in treating white spot lesions (WSLs) following fixed orthodontic appliances. Methods: This study was a randomized, parallel group study consisting of 38 subjects (12-16 years old), with participants being randomly assigned to either the fluoride gel group (group 1) or the fluoride varnish group (group 2). Fluoride gel (Pediagel® 1.23% APF, Preventech) or fluoride varnish (Vanish®TM, 3M ESPE, 5% sodium fluoride, with tri-calcium phosphate) was applied onto tooth surfaces with WSLs once at baseline after orthodontic debonding. The labial (buccal) surfaces of the anterior maxillary teeth were assessed with a DIAGNOdent pen (DD) (KaVo) at baseline (T1), 3-month (T2), and 6-month (T3) follow-up visits. The DD readings were analyzed using IBM SPSS statistics V.22 (IBM, Armonk, NY). Independent sample t-tests were used to compare differences in mean percentage changes in DD readings between treatment groups (gel vs. varnish fluoride) at 3 and 6-months intervals. One sample t-tests were used to compare within group (gel or varnish fluoride) percentage change from baseline to 3 and 6-month intervals with baseline equal to zero. Results: A trend towards higher mean baseline DD readings as teeth moved away from the midline was observed. The mean percentage change in DD readings varied greatly both within treatment groups and across individual tooth location for the 3-month assessment interval (T2). The mean percentage change in DD readings exhibited variability across individual tooth locations within each treatment group, but a trend of lower DD readings was demonstrated for both treatment groups for the 6-month assessment interval (T3). However, there was no significant difference between the two study groups (fluoride gel vs. fluoride varnish) in reverting white spot lesions. Conclusions: We found no conclusive evidence that either fluoride treatment group is superior to the other in remineralizing white spot lesions.

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INTRODUCTION

The development of white spot lesions (WSLs) during fixed appliance treatment continues to be major concern in Orthodontics. WSLs are areas of enamel decalcification typically found around the periphery of bracket bases and have been described as “subsurface enamel porosities from carious demineralization” which present as “milky white opacities when located on smooth surfaces.”1 WSLs tend to develop on areas of tooth surfaces that are both difficult to access with a toothbrush and not easily detectable by patients.2 Once formed, WSLs remain relatively unimproved in structure and appearance after orthodontic appliances have been removed.3,4

Most patients seek orthodontic treatment for an improvement in appearance and smile esthetics. Uniform tooth color is a major component of esthetics and includes both intrinsic and extrinsic properties.5 Extrinsic color is associated with the absorption of materials on the enamel surface, and intrinsic color is dependent on the light absorption and scattering properties of enamel and dentin.5 The light-scattering properties of enamel are particularly associated with hydroxyapatite crystals. In demineralized enamel, minerals are primarily replaced by water, which causes a decrease in the light passage, thus a reduction in light absorption by enamel.6 Demineralization of enamel around orthodontic appliances can increase the light-scattering coefficient by a factor of 3.5,7 The diffuse backscattering of light explains the dull white appearance of WSLs.8 Unfortunately, WSLs often occur in the anterior teeth and can be a detriment to the esthetic result of orthodontic treatment.

Prior studies have determined that the risks of WSL formation vary depending on factors that are unique to each individual orthodontic patient. These factors include the
mineral content of enamel, bacterial plaque accumulation, and the diet of the patient. Plaque accumulation and diet are associated with compliance, which varies greatly among orthodontic patients. Direct bonded orthodontic brackets have largely replaced bands in contemporary orthodontic treatment, and therefore a larger portion of the tooth surface is exposed to acid attacks by bacterial plaque. Previous studies have concluded that orthodontic patients treated with fixed appliances had greater difficulty removing plaque and a significantly higher incidence of WSLs compared with non-orthodontic patients.

Routine measures such as adequate brushing with fluoride-containing toothpastes and the use of mouth rinses can be effective in preventing WSLs, however, non-compliance with oral hygiene is a persistent problem with our adolescent patient population. Recent attempts to prevent or reduce WSL formation involve reducing the role of patient compliance. Some examples of preventive measures include the application of enamel sealants around orthodontic brackets and use of concentrated topical fluoride. Practitioners continue to search for efficient and cost-effective preventive measures to avoid WSLs.

There has been a paradigm shift in modern dentistry to focus on preventive measures rather than invasive treatment. Fluoride is the most important agent in the prevention of demineralization and development of carious lesions. Along with routine measures such as fluoridated toothpastes, mouth rinses, and fluoridated public water supplies, topical fluoride gels and varnishes have become common delivery methods. A systematic review by Bergstrand and Twetman reported the most effective method of
reducing the incidence of WSLs in patients undergoing fixed orthodontic treatment was regular application of fluoride varnish around the bracket base.\textsuperscript{17}

Vanish\textsuperscript{TM}, ESPE, 5\% Sodium Fluoride white varnish with Tri-Calcium Phosphate (TCP) is a formula that contains fluoride in combination with calcium and phosphate, which are also found in saliva. According to the manufacturer, the TCP technology creates a protective barrier around the calcium allowing it to coexist with fluoride and deliver sustained fluoride and calcium release.\textsuperscript{18} Once applied, the varnish comes in contact with saliva causing the release of calcium and fluoride. This product is proposed to achieve the continued release of fluoride and calcium over the life of the varnish, up to 24 hours.

The method of assessing WSLs varies widely. In 2008, Benson described the various methods of macroscopic and microscopic assessment of WSLs and enumerated their advantages and disadvantages.\textsuperscript{19} Macroscopic methods evaluate changes in optical properties of enamel and include clinical examination, photographic examination and light scattering by the optical caries monitor. Additional macroscopic methods evaluate optical fluorescence by utilizing fluorescent dye, ultraviolet light, laser fluorescence and quantitative light fluorescence. Microscopic assessment techniques include the caries model and the in situ caries model. Benson emphasized the importance of validity, reproducibility and ease of use in analytical methods for the assessment of WSLs.

The DIAGNOdent pen (KaVo, Biberach, Germany) provides an indication of bacterial activity by analyzing the fluorescence of porphyrins, which are bacterial metabolites. Moriyama et al. concluded that both the DIAGNOdent and DIAGNOdent pen (DD) devices were effective in detecting demineralization and remineralization on
smooth surfaces of enamel. Other studies have shown good correlation between the DD and other commonly used assessment methods such as the International Caries Detection and Assessment System (ICDAS-II). The DD emits a red laser beam at wavelength of 655 nm. and is the more portable of the DIAGNODent devices.

Compared with the evidence on the prevention of WSLs during fixed orthodontic treatment, much less is known about the remineralizing effects from concentrated fluoride application and other agents after orthodontic therapy. The aim of this study was to determine if there is a difference in efficacy between two different topical fluoride treatments in reverting WSLs. The null hypothesis to be tested was no difference in effectiveness of WSL remineralization between the two fluoride intervention groups (gel vs. varnish) over a 6-month interval.

MATERIALS AND METHODS

Patients in the graduate clinic of the Department of Orthodontics in the College of Dentistry, were recruited for this study. Eligible participants included both males and females with ages ranging from 12 – 16 years, in good general health (without systemic diseases), who had recently completed orthodontic treatment with fixed appliances and had a minimum of two WSLs present on the labial surfaces of maxillary anterior teeth. Subjects with enamel hypoplasia, dental fluorosis, tetracycline pigmentation, periodontal pockets (≥ 3 mm), currently prescribed to antibiotics or carious lesions on the anterior maxillary teeth were excluded.

Before participation in this study, the subject and their legal guardian were informed of the purpose, design, and procedures involved with this trial and written
consent was obtained from both the subject and the legal guardian prior to study implementation. The institutional review board at the [Institutional Review Board] approved of this clinical trial, IRB#: 11-01483-XP.

This study was a randomized, parallel group, clinical trial in which subjects were randomly assigned to receive one of two treatments. Group 1 received application of fluoride gel (Pediagel® 1.23% Acidulated Phosphate Fluoride (APF); (Preventech). Group 2 received application of fluoride varnish (Vanish™, 3M ESPE, 5% Sodium Fluoride with Tricalcium Phosphate). Both of the applied products were available for over-the-counter purchase outside of this study, and it was not known whether either treatment was superior to the other in the treatment of white spot lesions following fixed orthodontic appliances. A random number table was used to assign subjects to one of the test groups. Both the subject and the principal investigator knew which of the two treatments the subjects received. However, the individual who acquired and recorded the DD measurements was blinded to the subject’s treatment.

There were a total of three (3) visits. The first was the baseline visit (T1), which occurred within 60 days of removal of fixed orthodontic appliances for all subjects. Additional visits occurred at 3 months (T2) and 6 months (T3) from the baseline visit. At the baseline visit, the principal investigator verified that the subject qualified and consented for the study. First, the subject was instructed to brush their teeth with a toothbrush and fluoride toothpaste which was supplied to them. Digital photographs of the maxillary anterior teeth were taken prior to assessment with the DD. The WSLs on the labial surfaces of the anterior maxillary teeth (canine to canine) were assessed using a DD. The pen was calibrated according to the manufacturer’s instructions before each
subject’s assessment and the teeth were dried with cotton gauze before readings were taken. The entire labial surface of each of the anterior maxillary teeth was scanned by rocking the pen slowly in a pendulous motion using probe tip B. The peak reading displayed on the device was recorded for each tooth surface. Higher readings were interpreted to correlate with increased presence of fluorescing bacterial porphyrins indicating reduced mineralization of the tooth surface. Three readings were taken per tooth and the average was recorded for analysis. The same operator, who was blinded to the group allocation of the subjects, carried out the assessments at all of the visits. Each subject was randomly assigned to a treatment group using a 60 space random number table, and received the assigned fluoride treatment at the end of the baseline visit only. Manufacturer’s instructions were discussed and given to the subject following the application. At both of the follow-up visits (T2 and T3), the subject brushed their teeth as instructed at the baseline visit. Then, digital photographs were taken and the subjects’ maxillary anterior teeth were assessed in the same manner as at T1, using the DD.

Data was collected and entered into an Excel data file (Microsoft, Redmond, WA) and was converted into an SPSS (IBM, Armonk, NY) data file. All analysis was conducted with IBM SPSS Statistics V22. Analysis was conducted separately for each tooth with WSLs. The percent change in the DIAGNOdent readings of WSLs from baseline and at 3 and 6 months was calculated. Independent sample t-tests were used to compare WSLs between treatment groups at 3 and 6 months with baseline equal to zero. One sample t-tests were used to compare within group (gel or varnish) percent change from baseline at 3 and 6 months with baseline equal to zero. P values < .05 were considered to be statistically significant.
RESULTS

Of the 38 participants recruited, 7 failed to return for the T2 and/or T3 visit and were eliminated from the study. A total of 16 participants in group 1 (10 males; 6 females) completed the study. In group 2, 15 participants (8 males; 7 females) completed the study. The overall dropout rate was 18.4% and all participants lost-to-follow-up were from group 1. In the 31 remaining subjects (16 in group 1, 15 in group 2), a total of 129 teeth with WSLs were analyzed (65 in group 1, 64 in group 2). A total of 3 teeth with WSLs were excluded from the results analysis, and all were from group 1 (gel fluoride). Two of the excluded teeth had small amounts of adhesive remaining, which was detected at the completion of the study and during review of photographs. One tooth had a visible carious lesion form during the trial interval and therefore did not meet the original exclusion criteria. Figure 1 shows the flow diagram of the recruitment and participation for this clinical trial.

Table 1 shows comparisons of the DD readings within each group, by tooth number, and at each time point. Figure 2 shows the mean baseline DD readings for both fluoride intervention groups and by individual tooth number across the maxillary anterior teeth (teeth #6 thru #11). The mean baseline DD readings were similar for the two groups (t test, $P > 0.05$). A trend of higher mean DD readings at increasing distance from the midline was observed. Figure 3 shows the mean percentage change in DD readings from baseline (T1) to 3-months (T2) interval for both fluoride treatment groups. With baseline (T1) equal to zero, the mean percentage change in DD readings varied greatly both within treatment groups and across individual tooth location for the time interval at
3-months (T2). Figure 4 shows the mean percentage change in DD readings from baseline (T1) to 6-months (T3) interval for both fluoride treatment groups. With baseline (T1) equal to zero, the mean percentage change in DD readings exhibited variability across individual tooth locations within each treatment group, but a trend of lower DD readings was demonstrated for both treatment groups at 6-months (T3). There were no statistically significant differences between treatment groups for any tooth location (P > .05). Within group analyses showed that only tooth #6 and tooth #11 in the group 2 (varnish) had statistically significant differences in mean percentage change in DD readings at 6 months (T3) compared to baseline (T1) (P < .05). No adverse responses or safety concerns with either fluoride were reported by any of the participating subjects in this clinic trial.

DISCUSSION

According to the baseline (T1) data as seen in Figure II, there was a trend towards higher mean DD readings for teeth more distant from the midline. Therefore, the interpretation that the lateral incisor and canine teeth were more affected by WSLs than the central incisors could be made. In this study, we evaluated the maxillary six anterior teeth, but others have also reported that the greatest prevalence of WSLs is on the cervical and middle thirds of the crowns of the first molar, lateral incisor, and canine.\textsuperscript{23-27} A recent study conducted by Sonesson et al. demonstrated similar results that maxillary lateral incisors and canines are the teeth most commonly affected with WSLs.\textsuperscript{28} In that multicenter randomized controlled trial, 424 healthy 11-16 year-old patients were assigned to either a regular toothpaste group (1450 ppm) or a high fluoride toothpaste
group (5000 ppm). The investigators measured the prevalence and incidence of WSLs at maxillary incisors, canines, and premolars with pre and post-treatment digital photographs. Their conclusion agreed with other studies that daily use of high fluoride toothpastes may be recommended to prevent WSLs during fixed appliance orthodontic treatment.

Figure 3 shows the mean percentage change in DD readings at the 3-months interval (T2) as compared with the baseline (T1) assessment. A moderate amount of variability was seen both within treatment groups and across individual tooth location. Several possible factors could explain this finding. First, the DD is an indirect measuring device in the assessment of WSLs and could be responsible for some degree of variability seen. Bacterial porphyrins are measured rather than actual mineral content of enamel. In-vitro studies have concluded that the DD pen may be helpful in assessing both demineralization and remineralization in smooth surface lesions. However, other factors may need to be taken into account in a clinical setting. A previous study reported that the readings can be affected by stains, calculus, plaque, or remnants of adhesive or sealant left on the enamel surface. However, measures were taken in this study in an attempt to control for such confounding variables by (1) excluding teeth from analysis which had visible remnants of adhesive and by (2) allowing the subject to brush their teeth with toothpaste before each assessment was made. Several teeth in both treatment groups showed slightly higher mean DD readings at T2 as compared to baseline. The timing of the baseline assessment could have influenced this finding. For example, 25 of the 31 subjects who completed the study were enrolled and had their baseline DIAGNOdent readings taken on the day of appliance removal, at which time, any
gingival inflammation and/or hypertrophy could have masked some of the WSLs. Exclusion of patients with probing depths of greater than 3 mm. was an attempt to minimize the masking of lesions by gingival inflammation. As mentioned in a similar study by Huang et al. (published after the beginning of our current study), it may have been wise to delay baseline DD readings and treatment intervention for several days after debonding in order to allow for resolution of gingival inflammation and physiologic hydration levels of enamel following removal of orthodontic adhesives.

Figure 4 shows the mean percentage change in DD readings at 6-months interval (T3) as compared with the baseline (T1) assessment. All teeth for both fluoride intervention groups demonstrated lower mean DD readings at T3 compared to baseline (T1), with the exception of tooth #10 in group 1 (gel) which exhibited a negligible change from baseline. The lower mean DD readings for both fluoride treatment groups could be interpreted as improvement in the WSLs over time. However, only teeth #6 and #11 in group 2 (varnish) had statistically significant lower mean DD readings from baseline (Table III). There was no significant difference in the percentage change from baseline between the two fluoride groups and therefore the null hypothesis was not rejected. Despite our finding of no difference between the two fluoride delivery products in reverting WSLs, the clinical advantages of the varnish may make it more attractive to practitioners. First, it has a high concentration of fluoride, yet it is controlled due to its rapid setting time and smaller application doses, which lower the risk of ingestion. In addition, the varnish avoids the use of an application tray, and it can be applied by a trained assistant. These factors could result in shorter clinical chair time and increased application safety.
A recent similar in-vivo study by Du and colleagues also showed improvement in WSLs from baseline to 6-month follow-up with the use of 5% fluoride varnish applications after orthodontic treatment.\textsuperscript{31} This study was a randomized controlled trial using saline solution as the control and 5% sodium fluoride varnish (Duraphat, Colgate Oral Pharmaceuticals, USA) as the treatment intervention for comparison in reverting WSLs on debonded teeth. Their analysis included 96 subjects with a total of 209 teeth with WSLs. The method of assessment with DD was the same, and their results showed a statistically significant difference between mean DD readings of the two groups at 3-month and 6-month follow-up visits. The principal differences between that study and the present study were the amount of topical fluoride applications and the use of a saline control group. In Du et al, fluoride varnish (Duraphat) was applied monthly for 6 months after orthodontic treatment, while our study consisted of only one fluoride application at the baseline visit. Du et al concluded that their greater decrease in DD readings in the test group may be taken to imply improvement in the WSLs and thus topical fluoride varnish application may be advocated as a routine measure in treating WSLs after orthodontic treatment. Another study by Baeshen et al used a similar method of assessment and intervention with a split mouth control design.\textsuperscript{32} The investigators compared 0.5% sodium fluoride chewing sticks with non-fluoridated chewing sticks by using visual inspection (International Caries Detection and Assessment System II index criteria) and the DD. The fluoride treatment group demonstrated favorable results at the end of the 6-week follow-up with significant decreases in both the DD readings and the ICDAS II scores as compared to the control.
There were several limitations in this prospective pilot study. First, is the lack of a control group. Comparison data for a control group could have provided more information about the process of remineralization and the effect magnitude from the fluoride intervention. However, this study was planned and intended to evaluate the difference in two commonly used fluorides rather than the effect of the fluoride on WSLs after fixed orthodontic appliance therapy. Previous studies have concluded that using a DIAGNOdent pen may be helpful in the assessment of smooth surface lesions, but the results should be interpreted with caution. \(^{22,33,34}\) Statistically significant results may not translate to clinical significance. As mentioned previously, organic stains, plaque, calculus, or remnants of adhesive or sealant could affect the readings. Even though the subjects were randomly assigned to a treatment group, the dropout rate for group 1 compared to group 2 appeared to be a non-random experience. We attribute this to the randomization process in our study. We had an initial goal of recruiting 60 subjects, however only 38 subjects were enrolled. Therefore, not all assignments for the random number table were allocated and this could explain the difference in the number of subjects enrolled in each group, as well as explaining the high dropout rate in only group 1.

CONCLUSIONS

1. The baseline DIAGNOdent pen results demonstrated higher readings on canines and lateral incisors, establishing a trend of lateral incisors and canines being more affected by WSLs than central incisors.
2. Within the limitations of this study, we found no conclusive evidence that either of the fluoride vehicles was superior to the other in remineralizing white spot lesions.

3. Topical applications of fluoride gel or varnish may be beneficial in the treatment of WSLs following orthodontic therapy.

4. Additional high quality intervention studies employing specific and sensitive detection methods could contribute valuable information to this area of research.
REFERENCES


18. ESPE M Vanish 5% sodium fluoride white varnish with tri-calcium phosphate. [http://multimedia.3m.com/mws/mediawebserver?mwsId=66666uZjeFSLXTtnx f6mXMXEVuQEcUZgV6EV666666---&fn=vanish_tpp.pdf]. Accessed February 12 2013.


Figures Captions:

**Figure 1.** Flow Diagram of Study.

**Figure 2.** Mean baseline DIAGNOdent pen readings by treatment group and tooth number.

**Figure 3.** Mean percent change in DIAGNOdent pen readings from baseline (T1) to 3-months interval (T2) with baseline (T1) equal to zero. Error bars represent standard error.

**Figure 4.** Mean percent change in DIAGNOdent pen readings from baseline (T1) to 6-months interval (T3) with baseline (T1) equal to zero. Error bars represent standard error.
**Enrollment**
- Eligible for randomization: n = 38

**Allocation**
- Group 1: Fluoride Gel, n = 23
- Group 2: Fluoride Varnish, n = 15

**Follow-up**
- Lost to follow-up: Group 1, n = 7; Group 2, n = 0

**Analysis**
- Subjects completing study: Group 1, n = 16; Group 2, n = 15
- Number of teeth with WSLs:
  - Excluded from analysis: Group 1, n = 3; Group 2, n = 0
  - Analyzed: Group 1, n = 65; Group 2, n = 64
Table I. Baseline demographic characteristics for each treatment group.

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Table II. Diagnodent Pen Readings: means and standard deviations by treatment group, tooth number and time period.

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Table III. Mean percentage change in DD readings from baseline by treatment group, tooth number, and time period. Baseline is equal to zero.

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<td>28.6</td>
<td>20.9</td>
<td>16.2</td>
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<td>-16.5</td>
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<tr>
<td>T3 (Gel)</td>
<td>SE</td>
<td>16.1</td>
<td>18.2</td>
<td>18.7</td>
<td>17.6</td>
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<td>23.7</td>
</tr>
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<td>-32.0*</td>
<td>-5.4</td>
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<td>6.7</td>
</tr>
</tbody>
</table>

SE, Standard Error; T2, 3-month interval; T3, 6-month interval
*Statistically significantly difference from baseline (P < 0.05), within group analysis (One sample t-test)
There were no statistically significant differences between treatment groups at either T2 or T3 (P <0.05), between group analysis (Independent t-test)
Figure 3

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Figure 3

Mean % Change in DD Reading

Tooth Number

- Treatment 1 (Gel)  - Treatment 2 (Varnish)
Figure 4

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Figure 4

Tooth Number

- Treatment 1 (Gel)
- Treatment 2 (Varnish)