



Resin-Modified Glass Ionomer Varnish Versus Acidulated Phosphorus Fluoride Gel in Prevention of White Spot Lesions During Comprehensive Orthodontic Treatment (Split Mouth Randomized Clinical Trial) (A Comparative Study)

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Abstract

Statement of the Problem: Although fluoride varnish has been investigated and recommended by many studies for the prevention of white spot lesion, its effective use over the course of 3 months from a single application is not considered enough especially when it is compared to newly proposed material. These materials such as resin-modified glass ionomer have not been studied enough throughout literature to evaluate their real effect.

Purpose: The aim of this study was to evaluate the effect of a Clinpro XT varnish single application on enamel demineralization near orthodontic brackets during fixed orthodontic treatment in comparison with acidulated phosphorus fluoride gel.

Materials and Methods: Eighteen patients were seeking orthodontic treatment. They were selected from the out-patients clinic of the Orthodontic Department, Faculty of Dentistry, Cairo University. For each patient the maxillary anterior teeth (from canine to canine) were divided into right and left sides. The two quadrants were randomly divided into two groups: Group I (54): Teeth were treated by Clinpro XT. Group II (54): Teeth were treated with Acidulated Phosphorus Fluoride gel which was assessed immediately before application (T0), after three months (T1) and after six months (T2) application. The outcome of treatment was assessed by color change using spectrophotometer and patient satisfaction using Visual Analogue Scale (VAS).

Result: Show a statistically insignificant difference in the color change was found between the intervention and comparator groups after 3 months of the beginning of orthodontic treatment while the difference between the 2 groups was statistically significant after 6 months. Regarding the Visual Analogue Scale results there was statistically significant difference between the 2 groups at both 3-month and 6-month follow up period.

Conclusion: Clinpro XT varnish outperformed acidulated Phosphorus Fluoride gel in preventing white spot lesions during orthodontic treatment hence it is recommended to be used as a preventive material at 6-month of administration.

Keywords: Resin Modified Glass Ionomer; Acidulated Phosphorus Fluoride; Prevention and White Spot Lesions

Introduction

Demineralization or white spot lesion (WSL) development in the enamel in association with orthodontic treatment with fixed appliances remains a well-known clinical problem for dental specialists [1]. Various methods how to prevent formation of it are discussed in the literature, but not yet determined which one is the most effective. WSLs can become visible around fixed appliances within one month of bracket placement; although regular caries formation usually takes at least 6 months (Figure 1) [2]. Individuals with malocclusion usually have difficulty in performing proper oral hygiene because of many retention sites. In addition, bonding attachments to teeth make conventional oral hygiene more difficult and can prolong plaque accumulation on tooth surfaces [3,4]. WSLs mainly appear on buccal surfaces of the maxillary teeth in the following order: lateral incisors, canines, premolars, and central incisors [5,6]. According to the literature the prevalence of WSLs after orthodontic treatment is about 50% and its prevention is the goal of every orthodontist [7-12]. Primary prevention of white spot lesions can be done near fixed appliances and secondary prevention (treatment) is done when the braces are removed. White spot lesions can be very difficult or sometimes even impossible to improve when fixed appliances are removed, and entire resolution of the lesions can rarely be achieved, the aesthetics is effected and the patients' satisfaction with their smile [13]. Moreover, white spot lesions that are untreated can lead to the formation of dental caries and restorative treatment. White spot lesions can be re-mineralized by saliva to some degree, although this process is faster during the first few months, and later it becomes slower [14]. Thus, an early prevention of the white spot lesions is one of the aims of modern orthodontic treatment.

Earlier studies have shown that the use of fluoride, casein phosphopeptide amorphous calcium phosphate, or a combination of both gave very little or insignificant results to the white spot lesion prevention. Fluoride gels often referred to as acidulated phosphate fluoride or (APF) are used as both treatment and prevention of white spot lesions. It is claimed that because of its acidity large amount of fluoride is absorbed by the teeth and helps to prevent caries initiation.

Resin-modified glass ionomer (Clinpro XT) varnish was introduced as a dentin desensitizing agent and for the prevention of



Figure 1: White spot lesions after orthodontic treatment with fixed appliances.

white spot lesions. Few studies have been conducted clinically to show the durability and effectiveness of this material in white spot lesions prevention. Thus, this research study was performed to evaluate the effectiveness and durability of ClinproXT varnish compared to acidulated phosphorus fluoride gel in preventing white spot lesions.

Materials and Methods

Study design

The project employed a split-mouth randomized clinical trial. The primary outcome was Color change using a spectrophotometer. Secondary endpoints were Patient satisfaction using Visual Analogue Scale (VAS). The study was ethically approved by the research ethics committee, faculty of dentistry, Cairo University. (2019) and registered in Clinical Trials.gov Identifier (NCT03721198).

Participants

Eighteen patients with no ethnic restriction (from thirteen to thirty years old). The patients were seeking orthodontic treatment. They were selected from the out-patients clinic of the Orthodontic Department, Faculty of Dentistry, Cairo University. For each patient the maxillary anterior teeth (from canine to canine) were divided into right and left sides. The enrolment started in June 2019 and ended in June 2020. The inclusion criteria were patient indicated for fixed orthodontic treatment with permanent dentition. Healthy gingival and periodontal condition. No visible white spot lesions on the labial enamel surfaces of the teeth. Low caries index. Exclusion criteria were Presence of enamel hypoplasia or dental fluorosis, Presence of tetracycline pigmentation, Periodontal pocketing of 3mm or greater, Presence of Smokers, carious cavities, fluoride gel Allergy being used in study (using allergy test), Patients who have systemic disease.

Intervention

The test varnish was a commercially available product, Clinpro XT varnish (3M ESPE, Pymble, New South Wales, Australia) (Figure 2). Clinpro XT varnish was applied according to the manufacturer instructions as follows: In upper right/left anterior teeth, the polished tooth surface was etched using 37% orthophosphoric acid gel, applied for fifteen seconds over the labial enamel surface extending from gingival surface of the bracket to the free gingival margin. Then, the surface was rinsed thoroughly by water spray and dried with compressed moisture and oil free air to remove the etchant. The liquid and paste components of the varnish were mixed on a paper pad for 15 seconds by a small plastic spatula. When the mix material appears glossy and smooth in consistency, it was applied as a thin layer over the etched enamel surface by a ball applicator. Care was taken to avoid long-term contact of uncured material with soft tissues. If unexpected contact occurred, the material was immediately removed with wet cotton roll. Then, the varnish was light cured with the visible light- curing unit for twenty seconds. Instructions for Oral hygiene were given to the patient e.g. tooth brushing twice daily with non-fluoridated tooth-paste.

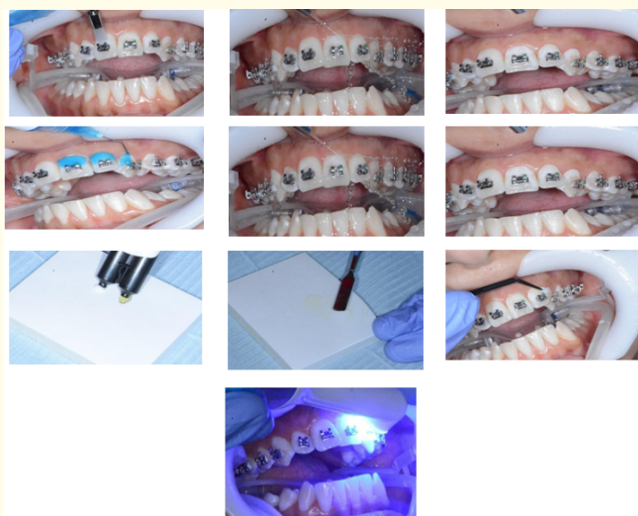


Figure 2: Intraoral photographs showing steps of Clinpro XT varnish application.

Comparator

The comparator was a commercially available product, acidulated phosphorus fluoride (Alpha-Pro®APF) gel (Figure 3). It was applied according to the manufacturer instructions.



Figure 3: Acidulated phosphorus fluoride (Alpha-Pro®APF) gel and intraoral photographs showing steps of APF gel application.

Randomization

The investigator cut out 18 slips of paper where allocation concealment was ensured by keeping them in opaque sealed envelopes. Nine slips labeled CXT/R indicated Clinpro XT on the right side and nine slips labeled CXT/L indicated resin modified glass ionomer varnish Clinpro XT on the left side. One slip of paper was randomly chosen by each participant on the day of the trial to assign either Clinpro XT to the right or left side of the upper anterior teeth where Acidulated Phosphorus Fluoride was consequently designated to the contralateral side. The groups allocated by the participants were then recorded in a separate log book to be used in the clinical session.

Blinding

The patients and the outcome assessor were blinded to the material assignment while the operator was not due to the difference in restorative material presentation and its application protocol.

Clinical procedures

Patients selected received full mouth scaling one month before bonding (to prevent bleeding during bonding procedure) in order to remove any calculus or debris on teeth to maintain healthy gin-

gival and periodontal condition. Full medical and dental history of the patients was taken. Extra-oral and intra-oral examination was made in order to alleviate any abnormalities.

The bonding of brackets was done by a single experienced orthodontist under a standardized method. pumice was used to clean teeth, rinsed and dried thoroughly. The area where the bracket was to be placed was etched with a 37% orthophosphoric acid gel for fifteen seconds and then rinsed with water. After rinsing, the enamel surface was dried with compressed moisture and oil free air. A layer of primer was applied to the tooth and bracket mesh. Adhesive paste was applied to the base of the bracket and pressed firmly onto the tooth surface. Excess adhesive was removed, and the adhesive light cured for twenty seconds (according to manufacturer instructions).

Outcome

The primary outcome was color change regarding lightness using spectrophotometer (VITA Easy shade[®]) (Figure 4). The first reading was taken using VITA Easy shade[®] before which complete dryness of the field was done. The unit was calibrated with a new anti-infection cover in order to prevent patient to patient cross-contamination. The instrument was seated in the calibration block holder so that the probe tip is flush with and perpendicular to the calibration block and depresses the calibration block. It was insured that the hand piece was fully seated in the calibration holder. A short press over the reading button then a green LED in the center of the base unit was lit and shortly afterwards the hand piece probe illuminated the calibration block. Initial calibration took a few seconds after the unit was switched on. Two short beeps indicated completion of calibration. The bleaching mode was selected to ensure a numerical value of the shade was obtained and it was ready to use. The shade of the white spot lesion (WSL) immediately before Clinpro XT varnish and APF gel and 3, 6 months follow up was measured and recorded. The scoring criteria according to the lightness scale were graded from 0 to 100. Therefore, the higher the L* value, the greater the light reflectivity of the object.

The secondary outcome was patient satisfaction using visual analogue scale (VAS) (Figure 4). Each patient was handed a VAS (visual analogue scale) scaled from 0 to 100 as 0 means not satis-

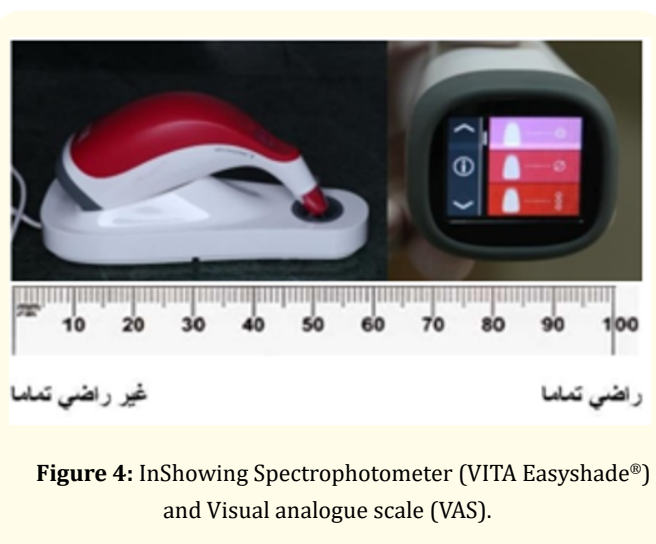


Figure 4: InShowing Spectrophotometer (VITA Easyshade[®]) and Visual analogue scale (VAS).

fied and 100 means the most satisfaction that could be obtained and the patient was instructed to look into a mirror and assess each quadrant alone. This procedure was made before the application as training to ensure the patient understood what he/she was told and was repeated after three and six months follow up.

Side-effects

All possible perceived side-effects (objective as well as subjective) in connection to the interventions were reported to the clinical investigator and the participants had the opportunity to discontinue their participation at any time without further motivation.

Statistical methods

Statistical analysis was performed using SPSS 20[®], Graph Pad Prism[®] and Microsoft Excel 2016. Data was represented as mean and standard deviation and P value was set at <0.05. Comparison between the two groups at different follow up periods was performed by the Independent T-test. On the other hand, comparison between two follow up periods was performed by Paired t-test, while comparison between three groups was performed by One Way Analysis of Variance ANOVA followed by Tukey's post hoc test. This power analysis used color change using spectrophotometer as the primary outcome. The effect size (d) = 0.898 was calculated based upon the results of Jena AK., *et al.* (2015) and Jiang H., *et al.*

(2013). Using alpha (α) level of (5%) and Beta (β) level of (20%) i.e. power = 80%; the minimum estimated sample size was 13 subjects. To compensate for a drop-out rate of 25%, the number will be increased to a total of 16 subjects. Sample size calculation was performed using G*Power Version 3.1.9.2.

Results

Mean difference in enamel lightness (ΔL) of central teeth after Clinpro XT application was (0.28 ± 0.08) and (0.50 ± 0.11) for $\Delta L1$ and $\Delta L2$ respectively, for lateral teeth it was (0.33 ± 0.19) and (0.44 ± 0.28) for $\Delta L1$ and $\Delta L2$ respectively, for canines teeth it was (0.28 ± 0.12) and (0.56 ± 0.05) for $\Delta L1$ and $\Delta L2$ respectively while for all teeth it was (0.29 ± 0.04) and (0.50 ± 0.15) for $\Delta L1$ and $\Delta L2$ respectively.

Comparison between $\Delta L1$ and $\Delta L2$ was performed by Paired t-test which revealed significant difference ($P > 0.05$) between them regarding central, lateral, canine and all teeth.

Mean difference in enamel lightness (ΔL) of central teeth after Acidulated Phosphorus Fluoride application was (0.23 ± 0.01) and (4.23 ± 0.23) for $\Delta L1$ and $\Delta L2$ respectively, for lateral teeth it was (0.33 ± 0.01) and (4.17 ± 0.31) for $\Delta L1$ and $\Delta L2$ respectively, for canines teeth it was (0.28 ± 0.06) and (4.01 ± 0.35) for $\Delta L1$ and $\Delta L2$ respectively while for all teeth it was (0.27 ± 0.05) and (4.13 ± 0.31) for $\Delta L1$ and $\Delta L2$ respectively.

Comparison between $\Delta L1$ and $\Delta L2$ was performed by Paired t-test which revealed significant difference ($P > 0.05$) between them regarding central, lateral, canine and all teeth.

Comparison between group I and II was performed by using independent t-test which revealed that; Insignificant difference between group I and II regarding $\Delta L 1$ for central, lateral, canine and all teeth as $P > 0.05$, while revealed significant difference regarding $\Delta L 2$ for central, lateral, canine and all teeth as $P > 0.05$ as presented in figure 5.

Patient's satisfaction was evaluated after three months and six months by using the visual analogue scale (VAS).

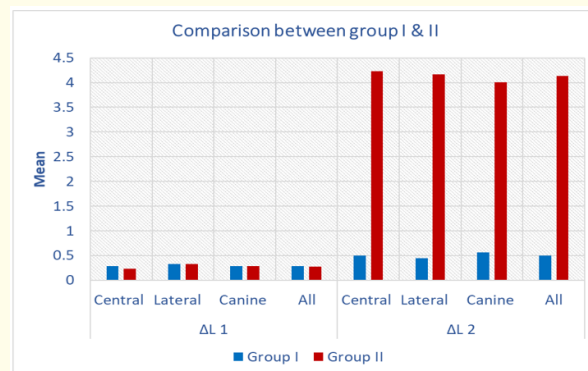


Figure 5: Bar chart showing Lightness changes (ΔL) in group I and II.

In Clinpro XT (intervention) group, the visual analogue scale recorded was (93.83 ± 7.92) and (93.82 ± 7.90) regarding 3 and 6 months respectively. In the Acidulated Phosphorus Fluoride (Comparator) group the visual analogue scale recorded was (11.66 ± 3.72) and (11.65 ± 3.77) regarding 3 and 6 months respectively.

Comparison between different follow up periods in each group separately was performed using Paired t-test which revealed insignificant difference between them in both groups as $P > 0.05$.

Comparison between both groups regarding each follow up period was performed by Independent t-test which revealed significant difference between them in both follow up periods as $P < 0.05$ as presented in figure 6.

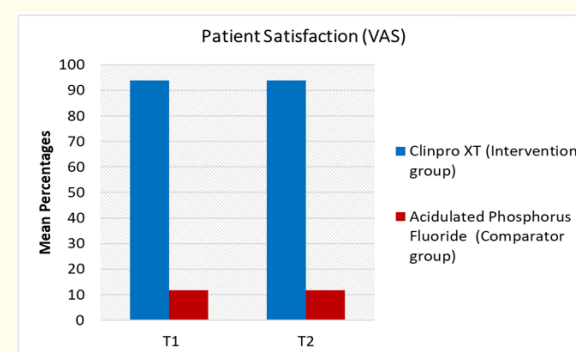


Figure 5: Bar chart showing comparison between group I and II regarding patient satisfaction using (VAS) after 3 and 6 months of application for both groups.

Discussion

Acidulated phosphate fluoride (APF) gel 1.23% is the most commonly used fluoride application agent because of its stability and commercial availability [14], so it was used in our study for the comparator group. The gel contains acid phosphate, which etches the tooth enamel; fluoride ions then replace the hydroxyapatite mineral to form fluorapatite, which is more stable and more resistant to acid [15].

On the other hand, resin-modified glass ionomer (Clinpro XT) varnish was used as the intervention material. This material is based on the patented methacrylate modified polyalkenoic acid. The liquid component consists primarily of polyalkenoic acid; the paste is a combination of HEMA, BIS-GMA, water, initiators, and fluoroaluminosilicate glass (FAS glass). Clinpro XT varnish provides the major benefits of glass ionomer materials including adhesion to the tooth structure and sustained fluoride release. In the patented resin-modified glass ionomer, chemistry in Clinpro XT varnish provides a burst of fluoride released during the first several days after placement and also long term sustained fluoride release over the life of the coating. The fluoride resides in fluoroaluminosilicate glass particles: reaction at the surface provides the immediate release, while the bulk provides a reservoir of fluoride for sustained release. Clinpro XT varnish also contains calcium glycerophosphate, which can provide calcium and phosphate release, and whose benefit in oral care has been demonstrated [16,17]. The calcium glycerophosphate in Clinpro XT varnish provides the continual release of calcium and phosphate over the life of the coating.

A split-mouth design was selected in this study to standardize the methodology and avoid bias. A split-mouth study design creates divisions within the mouth of patients who constitute the experimental units randomly assigned to treatments. This study design is very popular, particularly in the fields of periodontics and orthodontics [18,19]. In a split-mouth study design, the subjects act as their own controls, thus eliminating inter-subject variability regarding the difference in oral hygiene, habits, and enamel quality and increasing the power of the study compared to a design where a subject (whole mouth) is assigned to a treatment [19,20]. Also due to the increased statistical efficiency, fewer patients are need-

ed to detect a determined treatment effect [18,19]. Accordingly, there was no need to imply any restrictions on age or gender in the study. Association between enamel hypoplasia and caries development has been reported by many studies [21], additionally, enamel hypoplasia is associated with less probability of oral hygiene maintenance [22]. Thus, patients with this defect were excluded from the study. Also, conditions like enamel fluorosis and tetracycline pigmentation may have a negative effect on the detection of white spot lesion and evaluation of color changes so they were set as exclusion criteria.

White spot lesions can be either non-carious or carious. Cari-ous white spot lesions appear rough, opaque, and porous, whereas non-cari-ous lesions appear mostly smooth and shiny [23]. Enamel crystal dissolution begins with subsurface demineralization, creating pores between the enamel rods. The demineralized enamel surface appears whitish in color due to the difference in refractive indices (RIs) between defective and sound enamel [24]. This difference is due to the presence of micro-porosities in affected enamel lesions. These micro-porosities are filled with either water (RI = 1.33) or air (RI = 1.0), unlike sound enamel, which has a RI of 1.62. When these pores are filled with water, the lesions appear opaque compared to sound tissue, while when they are dried, they become filled with air and the lesion becomes more apparent and obvious, which causes light to scatter, resulting in a whitish opaque appearance of those lesions, especially when they are desiccated [25].

Therefore, the color change can be used as a valid outcome to assess the effectiveness of the prevention or treatment of white spot lesions.¹⁴ Color change evaluation with spectrophotometer has been proved to be more reliable than subjective shade evaluation with different shade guide systems [26]. All measurements with spectrophotometer were obtained from the tooth surface cervical to the brackets because it is the most susceptible area to caries development due to the inaccessibility to tooth brushing.

The patient-related outcomes were overlooked throughout studies during the assessment of the effectiveness of white spot lesion prevention in spite of the fact that public perception is considered as the main factor that drives the demand for the esthetic dental treatment [27] accordingly, we considered the measurement of the patient satisfaction in the present study.

A Visual Analogue Scale (VAS) is a measurement instrument that measures a characteristic or attitude. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms [28]. Visual analogue scale, among other scales used to measure patient satisfaction, has been found to be simpler and less vulnerable to confounding factors especially patient's age [29]. 18 subjects were recruited for this study after the sample size calculation which was based upon the results of Jena., *et al.* [30] and Jiang., *et al.* [31].

Taking all the previous elements into account might help to interpret the obtained results. In this study, a statistically insignificant difference in the color change was found between the intervention and comparator groups after 3 months of the beginning of orthodontic treatment while the difference between the 2 groups was statistically significant after 6 months. The mean color change of the comparator group which received acidulated phosphorus fluoride for 3 months was (0.27 ± 0.05) and for 6 months was (4.13 ± 0.31) while that of the intervention group which received Clinpro XT varnish for 3 months was (0.29 ± 0.04) and for 6 months was (0.50 ± 0.15) suggesting that the amount of demineralization the occurred in the comparator group after 6 months was higher than that occurred in the group received Clinpro XT varnish. In the same context, there was a statistically insignificant difference between the results of color change in the intervention group after 3 months and after 6 months while there was a statistically significant difference between the results of color change in the comparator group after 3 months and after 6 months. These data indicate that the amount of demineralization increased significantly from a 3-month follow-up period to a 6-month follow-up period in the comparator group which wasn't the case in the intervention group.

The data reported by our study is in accordance with previous works that investigated the preventive potential of Clinpro XT varnish. Shailesb., *et al.* [32] reported, in a split-mouth clinical trial, a significant difference between the use of Clinpro XT and daily oral hygiene measures over 6 months favoring the use of Clinpro XT for the prevention of white spot lesions.

Similar results to our study were also reported by another split-mouth study, by Jena., *et al.* [30], who investigated the development of white spot lesions during orthodontic treatment in 2 different

groups; one received Clinpro XT varnish and the other didn't with 6 months follow up. Favorable results were reported in the intervention group recommending the use of Clinpro XT for prevention. Unlike our study, a large sample size was used in the study by Jena., *et al.* [30] and this could be attributed to the use of Diagnodent in that study. The DIAGNodent readings may be affected by stains, calculus, and plaque and are based on bacterial metabolites.

Regarding acidulated phosphate fluoride, our results were in accordance with 2 published systematic reviews. Lopatiene., *et al.* [33] concluded that acidulated phosphate fluoride was effective in preventing white spot lesion up to 3 months of a single application, but concerns were addressed for longer periods.

The other review by Sardana., *et al.* [34] deduced that, based on the pooled results, acidulated phosphate fluoride could achieve a relative risk reduction from 25% to 30% after 3 months of a single application. These results are concomitant with our results which support the effectiveness of acidulated phosphate fluoride in preventing white spot lesion after 3 months of a single application.

Regarding the VAS results, in the intervention group, the visual analogue scale recorded was (93.83 ± 7.92) after 3 months and (93.82 ± 7.90) after 6 months with a statistically insignificant difference within this group. Whereas the Acidulated Phosphorus Fluoride the recorded data were (11.66 ± 3.72) and (11.65 ± 3.77) regarding 3 and 6 months respectively with also statistically insignificant differences within this group. On the other hand, there was a statistically significant difference between the 2 groups at both 3-month and 6-month follow up period. From these data we can interpret that patient satisfaction in the group received Clinpro XT varnish is higher than the other comparator group. As locators transfer much less stresses to flexible caps. That indicated longer life time and longer periods between successive maintenance. This observation could be related to that this locator's high-density resin cap that is originally designed to be incorporated into the denture base to help managing stresses. It acted as if it helped by carrying a big share of stresses to protect the simulated supporting structures; cortical and cancellous bone as well as the implant body from being stressed [35].

As the vertical load increase the total deformation and Von Mises stress increase as the used materials were assumed to linear elastic, homogenous and isotropic. In addition, as the resultant stresses are within the linear part of stress strain curve the results will be correct and the same as what was obtained in this study even if we used full stress strain curve in defining all materials (non-linear materials).

To the best of our knowledge, no study reported the patient-reported outcomes while investigating methods of prevention of white spot lesions in patients undergoing orthodontic treatment.

Conclusion

According to the results of the present study, the following conclusions could be drawn:

- There was an insignificant difference in color change between resin-modified glass ionomer (Clinpro XT) varnish and acidulated Phosphorus Fluoride gel after 3 months of application. On the contrary, after 6 months there was a significant difference between the 2 groups favoring the use of Clinpro XT varnish.
- Significant difference in patient satisfaction records using (VAS) between both groups after 3 and 6 months favors the use of Clinpro XT varnish.

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