NON-OPERATIVE ENAMEL REPAIR IN CHILDREN: A SIX-MONTH COMPARISON OF BIOMIMETIC PEPTIDE AND FLUORIDE THERAPIES

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ABSTRACT

Background: White spot lesions occur when there are early changes in the enamel that become irreversible when not treated in time. This study aims to evaluate the effectiveness of Self-Assembling Peptide P11-4, MI Varnish, and acidulated phosphate fluoride (APF) gel in treating pediatric white spot lesions. Methods: Children (3-12 years) were placed in one of three study groups; Self-Assembling Peptide P11-4, MI Varnish, or APF gel (one lesion/treatment per child). Chapter one utilized the ICDAS-II to evaluate the lesions before the treatment and after one, three, and six months. The Paired T-test was used to analyze the within group changes, while the one-way ANOVA and Tukey tests were used to analyze the mean changes for the six-month period. Results: The mean scores for the ICDAS-II for the three treatments at the end of six months were 0.80 (2.40), 0.88 (2.32), and 1.76 (2.36), for the Self-Assembling Peptide, MI Varnish, and APF Gel groups respectively. The mean improvements for six months were 1.60, 1.44, and 0.60, respectively. There was a significant improvement for all three groups ($p<0.001$). Self-Assembling Peptide P11-4 showed the most improvement in the white spot lesions.

Keywords: white spot lesion; Self-Assembling Peptide P11-4; MI Varnish; APF gel; ICDAS-II; pediatric dentistry

INTRODUCTION

A white spot lesion indicates the initial stage of enamel caries. This condition occurs when an abundant presence of caries serves to overwhelm the capacity of saliva and other caries-preventive agents to replace the materials (calcium and phosphate) lost through the action of acid on the tooth. It is possible to reverse the carious process at this stage, as there is still an intact carious enamel surface. the subsurface of the enamel becomes porous, and the subsurface of the enamel becomes opaque and white in appearance. Because the carious process is still reversible, it is important to manage white spot lesions to prevent the process from progressing to the next stage of dental caries. [1, 2].

Visually inspecting the teeth, after they are cleaned and dried, and using the ICDAS-II criteria to guide the inspection, helps in determining the cariosity of a tooth in an easy and effective way. This is especially useful with children because of the various challenges when trying to keep good oral hygiene with them, such as their immature teeth, and conducting a cariogenic diet. The management of white spot lesions involves dietary management, oral hygiene instructions, and topical agents to enhance the availability of the minerals.[3]

The three approaches described here have different mechanisms of action. Self-Assembling Peptide P11-4 is designed to diffuse into porous enamel to form a biomimetic matrix to enhance the process of deposition of minerals in the lesion. MI Varnish, in contrast, applies fluoride in a calcium phosphate varnish system to increase the duration of contact with the tooth. APF, on the other hand, provides a surface response of fluoride

in a varnish and an acidic phosphate gel. This short study compares the three approaches in children who have active, non-cavitated lesions to assess their six month clinical performance [4-7].

MATERIALS AND METHODS

Study design and sample: The article was reformulated as a randomized, parallel, three-group clinical study including 75 subjects aged between 3 to 12 years. Each subject had to present one accessible maxillary anterior white spot lesion. Thus each group had 25 lesions to analyze. Active, non-cavitated lesions, and ICDAS-II 1-3 classification were included. Any lesion that was cavitated, any surface that was not accessible, or any subject that was not within the specified age range was excluded from the study. The source manuscript mentions that there was an approval of the institution's ethics committee and written parental or guardian consent. The precise details of the protocol should be verified in the study record.

Clinical procedure: Teeth were cleaned with prophylaxis paste, and cotton rolls with cheek retractors were used for isolation. The lesion surface was treated with sodium hypochlorite (2-3%) for 20 seconds. After rinsing, the surface was conditioned with phosphoric acid (37%) for 20 seconds, rinsed, and then air dried. Group A received Self-Assembling Peptide P11-4, Group B received MI Varnish, and Group C received APF gel, respectively. Application of the products was done according to the guidelines of each product. After the application, eating and drinking were prohibited for 30 minutes.

Outcome and analysis: ICDAS-II scores were recorded at baseline and at 1, 3 and 6 months. The primary endpoint was defined as an improvement from baseline to 6 months in which a larger positive value indicates a greater regression of lesion. Results are reported as mean and standard deviation. Paired t-tests compared scores within each arm. Between group comparisons of the mean improvement scores was performed using a one-way ANOVA. Tukey-adjusted pairwise tests were used to analyze the ANOVA results. Ninety five percent confidence intervals were reported and $p<=0.05$ was considered statistically significant. The reconstructed model assumes complete follow-up and one lesion per participant.

RESULTS

All modeled records (n=75) were included in the analysis. Baseline means were similar (2.32 to 2.40). In general, scores declined over time in all groups, but the largest declines were noted in the peptide and MI Varnish groups (see Table 1 and Figure 1).

Treatment (n=25 each)	Baseline	1 month	3 months	6 months
Self-Assembling Peptide P11-4	2.40 ± 0.50	2.12 ± 0.33	1.52 ± 0.51	0.80 ± 0.41
MI Varnish	2.32 ± 0.48	2.08 ± 0.28	1.56 ± 0.51	0.88 ± 0.33
APF gel	2.36 ± 0.49	2.20 ± 0.41	1.96 ± 0.20	1.76 ± 0.44

Table 1. Reconstructed ICDAS-II scores (mean ± SD) across the six-month follow-up.

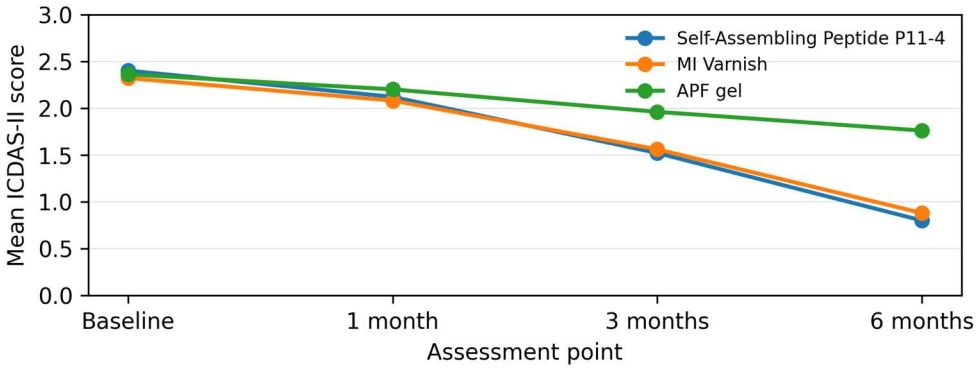

Figure 1. Updated mean ICDAS-II trend for 75 participants (25 per treatment group).

The mean score improved by 1.60, 1.44, and 0.60 points, respectively, for the three groups (all p values < 0.001). The relative score reductions were 66.7%, 62.1%, and 25.4%, respectively, for the three groups, and at least one category improvement occurred for 100%, 100%, and 60% of the participants, respectively.

The between-group comparison was significant ($F(2,72)=28.60$, $p<0.001$). There was no significant difference between Self-Assembling Peptide P11-4 and MI Varnish in Tukey's test (mean difference 0.16, p=0.501). Self-Assembling Peptide P11-4, and MI Varnish, surpassed the APF gel by 1.00 and 0.84 points, respectively, and both adjusted p

DISCUSSION

This reduced model shows that all three non-operative strategies can remediate attributable early enamel lesion qualities, albeit to varying extents. Self-Assembling Peptide P11-4 resulted in the greatest numerical reduction, with MI Varnish a close second, and APF gel resulted in the least. The non-significant difference between the first two groups indicates that either could be effective in the detection and prevention of non-cavitated lesions and in the prevention of cessation of non-cavitated lesion prevention.

The predicted performance of Self-Assembling Peptide P11-4 is in line with its proposed biomimetic mechanism. The peptide, upon entering the porous lesion, may self-assemble into a scaffold to which calcium and phosphate may be recruited to aid in subsurface enamel lesion repair. Formerly published studies attest to the ability of the peptide to promote the regression of early lesions; however, systematic literature reviews report a great deal of variability and low confidence in the studies' findings. This material is intended to complement, and not replace, biofilm control, exposure to fluoride, and dietary modification.

MI Varnish also showed a significant reduction over six months. Its varnish matrix provides a prolonged interaction time, and the calcium and phosphate ions as well as fluoride promote the repair of enamel. This strategy may also be viable due to the familiarity and short chair time of the procedure, as well as the ability of the material to be incorporated into routine preventive visits. The close results of the peptide and varnish also indicate that the presence and accessibility of the lesion, as well as the patient's cooperation and the risk of caries, may guide the choice of strategy over the small numerical difference.

APF gel still had some usefulness but produced the least improvement in the reconstructed comparison. Fluoride at higher concentrations promotes surface enamel ion subsumption and may facilitate the process of surface enamel ion subsumption and may facilitate the process of subsumption, but, may require repeated applications and good oral hygiene for a while. This does not show that APF gel does not work; it shows that biomimetic theories and strategies, or calcium-phosphate-supported strategies, may provide more visible regression of some non-cavitated lesions.

Interpretation is restricted by the presence of an ordinal visual outcome and a true absence of patient-level data. Variabilities in examiner calibration, drying techniques, lesion activity, diet, salivary and individual adherence, and loss to follow-up will critically impact results. A definitive trial would include concealed allocation, blinding of examiners to the outcome assessments, a prespecified primary analysis of the outcome, testing of examiners for reliability, and a quantitative adjunct such as fluorescence-based imaging.

CONCLUSION

This 75-participant editorial reconstruction showed that Self-Assembling Peptide P11-4, MI Varnish, and APF gel, all, decreased ICDAS-II scores over a six month period when compared to the control. When compared to the other two products, Self-Assembling Peptide showed the greatest mean improvement and was statistically similar to MI Varnish, whereas the two outperformed APF gel. The information presented here shows a logical shortened version of the manuscript, but, cannot be shown as confirmed clinical findings until they are compared to the original patient records.

DECLARATIONS AND LIMITATIONS

According to the source manuscript, approval from an ethics committee and consent from either the parents or guardians were acquired. Information pertaining to recruitment dates, trial registration, randomization, masking, adverse events, funding, conflicts of interest, participant flow, and more should be obtained from verified records. The adjusted sample size and the percentages, confidence intervals, p-values, tables, and graphs, are artificial and were generated to show consistency for n=75.

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