

EFFECTIVENESS OF SELF-ASSEMBLING PEPTIDE (P11-4) ON THE REMINERALIZATION OF WHITE SPOT LESIONS IN PRIMARY TEETH (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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INTRODUCTION

Regenerative medicine-based dental approaches for caries treatment are being widely adopted and accepted as a novel shift from reparative to regenerative dentistry, where they focus on biomimetic remineralization of initial carious lesions as a minimal invasive therapy and replacing the damaged dental tissues with biologically similar tissues ⁽¹⁾. Self-assembling peptide p11-4 might be a promising approach in micro-invasive technology allowing regeneration of the carious lesion by substituting the enamel matrix by a biomimetic scaffold, which has a high affinity to ions from saliva like calcium and phosphate, and acts as a nucleator for de-novo hydroxyapatite formation. This in turn should arrest the initial caries and trigger natural three-dimensional regeneration of the enamel.^(2,3) **Aim of the study:** To assess clinically the effect of Self-assembling peptide P11-4 (SAP) in conjunction with 5% sodium fluoride (NaF) varnish versus a 5% NaF only in the remineralization of enamel white spot lesions (WSL) in primary teeth.

METHODOLOGY

The study was a randomized controlled clinical trial, that was set up and reported according to the CONSORT statement⁽⁴⁾. The trial was conducted on 24 healthy children aged 3 to 6 years, with at least one visible active WSL in primary teeth with ICDAS II score of 1, 2 or 3⁽⁵⁾. At the first visit, the teeth were professionally cleaned with non-fluoridated prophylaxis paste, followed by complete isolation using rubber dam. Baseline assessments of WSLs were recorded using diagnodont scores and ICDAS II scoring system. In the study group (n=12): the affected tooth surface was cleaned with sodium hypochlorite 2% for 20 seconds, then phosphoric acid gel 35–37% was used to etch the surface for 20 seconds, followed by rinsing and drying of the tooth and the solution of SAP was allowed to diffuse for 5 minutes to dry. Finally a thin coat of the 5%NaF varnish was applied by a thin brush, which was then allowed to dry for 10 seconds. The control group (n=12): received 5% NAF only. Oral health instructions were given to all patients (study and control), and were instructed not to eat, drink or brush their teeth for 45 min. In the second visit:(after 3 month) the outcome of the study : diagnodont and ICDAS II scores of the lesions were recorded. 5%NaF was finally applied on all lesions, according to the AAPD guidelines.

RESULTS AND DISCUSSION

The mean diagnodont readings in both groups decreased when compared to baseline, the decrease was greater in the study group with no statistically significant difference between them (table1). The mean percent reduction in diagnodont readings from baseline to 3 months showed a statistically significant difference between the 2 groups, where in the study group the reduction was (22,28%) and in the control group the mean reduction was (4,18%) with **p=0.026** (table2). However, there was no significant difference in ICDAS scores between the 2 groups at

baseline and after 3 month.(figure1). The results of the present study are in concordance with the conclusions of the previous studies by Alkilzy et al and Metwally N et al ⁽²⁾⁽⁶⁾, that were performed on permanent teeth, this study shows the significance of SAP on remineralization of WSL in primary teeth.

Table 1: Diagnodont values at different time intervals

Baseline	Mean (SD)	Study (n=12)	Control (n=12)	Test (P value)
	Median (IQR)	15.08 (8.97)	16.75 (9.36)	
Min – Max	3.00 – 30.00	2.00 – 36.00		
3 Months	Mean (SD)	12.33 (8.44)	15.42 (8.12)	1.042 (0.297)
	Median (IQR)	12.00 (11.00)	15.00 (9.25)	
	Min –Max	1.00 – 30.00	2.00 – 33.00	

Table 2: Percent reduction in Diagnodont values from baseline to 3 months

Baseline–3 Months	Mean (SD)	Study (n=12)	Control (n=12)	Test (P value)	
	Median (IQR)	-22.28 (23.86)	-4.16 (13.29)		2.234 (0.026*)
	Min – Max	-66.67 – 25.00	-20.00 – 25.00		

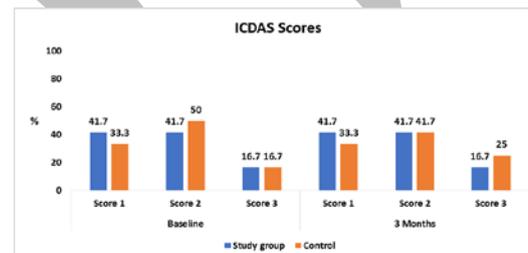


Figure 1: Distribution of ICDAS II scores at baseline and 3 months

CONCLUSION

Self-assembling peptide P11-4 in conjunction with 5% NaF varnish is superior to 5% NaF varnish only in the remineralization of white spot lesion.

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