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Original Article

Clinical Effectiveness of Two Commercial Fluoride Varnish Formulations on the Control of White Spot Lesion in Primary Teeth: A Pilot Study

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Abstract

Objective: To evaluate the in vivo clinical effectiveness of two commercial fluoride varnish formulations. **Material and Methods:** The sample consisted of seven children aged 2-5 years for a total of 24 active white spot lesions (WSL) in primary teeth. Children were randomly divided into two groups in accordance with the varnish used: G1 - Duraphat® - DR (n = 14 WSL); and G2 - Duofluorid XII® - DF (n = 10 WSL). Children were submitted to treatment with varnishes applied once a week for four consecutive weeks. Maximum mesiodistal and incisogengival dimensions were measured with a periodontal probe at the beginning of treatment and on the fifth week of treatment. The average between the two dimensions represented the value of the WSL dimension. The comparison of the mean final values of WSL dimensions between groups of fluoride varnishes tested was analyzed by the Mann-Whitney U test. The significance level adopted was 5%. **Results:** After five weeks, most WSL were ranked as inactive (G1 = 71.4% and G2 = 40%). No significant difference between G1 and G2 in relation to lesion activity was observed (p = 0.124). There was a significant decrease of 24% between initial (3.12 mm ± 1.49 mm) and final WSL dimension (2.35 mm ± 1.06 mm) (p = 0.012) in G1. In G2, there was a significant reduction of 40% in lesion dimension with initial value of 5.7 mm (± 3.82 mm) and final value of 3.4 mm (± 3.35 mm) (p = 0.013). Regarding the reduction in the WSL dimension, no significant difference between groups was observed (p = 0.931). **Conclusion:** Both fluoride varnish formulations tested had similar effect on the control of active white spot lesions in primary teeth.

Keywords: Topical fluoride; Primary teeth; Dental Caries.

Introduction

White spot lesions (WSL) may be the initial manifestation of incipient caries lesions from the process of tooth enamel demineralization caused by acids produced by bacteria in the cariogenic process [1]. Since clinical observations have shown that WSL are reversible, especially in an environment where there is available fluoride, remineralization has become an important mechanism for reducing enamel caries lesions [1-6].

Compared with other forms of topical application, fluoride varnish (FV) provides a prolonged exposure to fluoride [3], since it is not affected by moisture, remaining adhered to the enamel for a significant period of time. Its application is simple and fast, and its use does not require patient cooperation [1-4,7]. Although the use of FV does not completely prevent the development of caries lesions, their reduced incidence and depth should be considered (1). Previous studies have demonstrated the possibility of stoppage of incipient lesions through their inactivation after the fourth FV application, thereby excluding the need for invasive restorative treatment [8-10].

Since it is a public health problem that adversely affects the lives of many children, sometimes as soon as the eruption of primary teeth [11,12], the use of FV has been proposed as a way to prevent [7,13] and control the disease. It is vital that dentists [14] and health care planners know the true benefits that these products can provide to primary dentition [11,15].

In the permanent dentition, the evidence of the benefit of FV application is generally positive. However, the effectiveness of its application in the primary dentition is incomplete and inconsistent [16], especially in preschool children. There is a lack of studies evaluating different commercial FV formulations in the control of WSL in primary teeth. A comparison of the therapeutic effects between domestic and imported products seems to be of particular interest to public health services in Brazil [9,17].

Due to the great importance of using effective methods to control dental caries in children at preschool age, further well-designed clinical trials should be conducted involving preschool children in order to obtain evidence on the effectiveness of FV in the primary dentition [2,12,15,18-20]. Thus, the aim of this study was to evaluate the clinical effectiveness of two commercial fluoride varnish formulations on the control of white spot lesions in primary teeth.

Material and Methods

This is an intervention study developed in the form of a randomized clinical trial according to the fluoride varnish applied that evaluated 60 children of both sexes aged from 06 months to 5 years assisted in the "Só-Riso" Project - Mother and Child Care, Dental School, Federal University of Juiz de Fora (FO-UFJF) between December 2012 and May 2013. To be included in the study, children should be born and raised in Juiz de Fora, to be in primary dentition, present active WSL (rough and opaque) on the vestibular surface of non-cavitated primary teeth, whose parents and / or guardians signed the Informed Consent Form (ICF). In addition to the fluoride varnish, the fluoride sources of the study participants were consuming fluoridated water from public supply and regular

use of fluoridated toothpaste. All children examined were residents of Juiz de Fora, a city supplied with fluoridated water (0.8 ppmF). Children showing cavitation or restoration in primary teeth at evaluation, enamel development disorders (hypoplasia or fluorosis) or periodontal disease were excluded from the study [9]. Parents / guardians received guidance on practices favorable to the maintenance of oral health such as diet and oral hygiene, especially on brushing with small amount of fluoridated toothpaste twice a day. Children with caries lesions were referred for appropriate restorative treatment. Of the sixty children examined, nine were selected for a total of forty lesions.

In dry and well-lit place [21] with child sitting in the dental chair, clinical examination for diagnosis of dental caries was performed using the following criteria [22,23]:

- 0 = Healthy.
- 1 = Inactive white spot.
- 2 = Active white spot.
- 3 = Cavitated lesion.

WSL were evaluated according to the clinical characteristics of texture and shine to be classified into active lesion (rough and opaque) or inactive lesion (smooth and shiny) [9]. In addition, the mesiodistal and incisogingival dimensions of lesions were measured with the aid of a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing Inc., Chicago, USA) at the beginning and end of treatment. The WSL dimension values were represented by the mean of the largest mesiodistal and incisogingival dimensions [8,9].

Active WSL were randomly divided into two groups according to the treatment: G1 - Duraphat® (5% NaF, Colgate - Pharbil Waltrop GMBH, Im Würrigen, Germany); and G2 - Duofluorid XII® (6% NaF, 6% CaF₂, FGM, Joinville, SC, Brazil). Four applications of one of two products tested were performed once a week on active WSL. After disclosing bacterial biofilm with Replak® solution (Dentsply, Ind. e com. Ltda., Rio de Janeiro, RJ, Brazil) and mechanical control of dental biofilm performed with dental gel without fluoride Bitufo® (Itupeva, SP, Brazil) and Robinson white flat Injecta® toothbrush (São Bernardo do Campo, SP, Brazil), the surface (s) of teeth affected by WSL was (were) dried. Under relative isolation, FV was then applied with a Vigodent® microbrush (Rio de Janeiro, RJ, Brazil) [21]. These procedures were performed in four consecutive weeks [8,9]. On the fifth week [8,10], new disclosing and mechanical biofilm removal were performed, with subsequent evaluation of WSL submitted to treatment with FV, with respect to inactivation and reduction of WSL dimensions.

Initial examination procedures and treatment of WSL were performed by a single researcher previously trained and calibrated (RIC). The final examination on the fifth week of treatment was performed by an experienced researcher with no previous knowledge on the FV used (RAR). The different forms of presentation of both fluoride varnishes used in the study avoided the treatment step to be performed by a blinded investigator. The intra-examiner agreement was measured by kappa coefficient [24] in 10% of the total sample (three lesions) through two examinations performed in a period not exceeding seven days (pilot study). The kappa coefficient values obtained

indicated perfect agreement in the evaluation for the diagnosis of dental caries ($k = 100\%$), and almost perfect agreement in the assessment of the WSL dimensions ($k = 80\%$) [25]. The inter-examiner agreement was also measured by the kappa coefficient (24) and the values found indicated perfect agreement in the diagnosis of dental caries ($k = 100\%$) and almost perfect in the assessment of the WSL dimensions ($k = 80\%$) [25].

Data analysis used the Statistical Package for Social Sciences (SPSS) version 13.0 for Windows (SPSS Inc., Chicago, USA). Data were submitted to descriptive analysis. The Pearson's chi-square test was used to assess the association between treatment and WSL inactivation. The Wilcoxon test compared the initial and final mean values of WSL dimensions in groups 1 and 2. Comparison of the mean final values of WSL dimensions between groups that tested fluoride varnishes were analyzed by the Mann-Whitney U test. The significance level adopted was 5%.

This study was approved by the Ethics Committee of the Federal University of Juiz de Fora (CEP-UFJF), process number 171 463, of December 13, 2012.

Results

Seven children (mean age 3.9 ± 1.25 years) participated in the study (four girls, 57.14%, and three boys, 42.86%, totaling two losses in the sample), in which 24 active WSL (opaque and rough) were identified on the buccal surface of primary teeth randomly distributed in G1 ($n = 14$ lesions) and G2 ($n = 10$ lesions). Of the total lesions, four were present in girls (28.60%) and ten in boys (71.40%) in G1; in G2, eight lesions (80.00%) were present in girls and two (20.00%) in boys ($p = 0.013$). In G1, the mean age was 3.71 years (± 1.20) and 4.50 years (± 0.97) in G2 ($p = 0.103$).

Table 1 shows the results of the evaluation of lesions with respect to the activity classification. Of the 24 initial active WSL, 14 (58.40%) were classified as inactive after four consecutive varnish applications. In G1, ten WSL were inactivated (71.40%); in G2, four WSL became inactive (40.00%) in the final assessment. Although G1 has shown a greater number of inactivated lesions, there was no significant difference between groups ($p = 0.124$).

Table 1. Frequency of WSL classified according to activity after four consecutive fluoride varnish applications in both treatment groups (G1 and G2).

Group	Total	Activity	
		Active	Inactive
	N (%)	n (%)	n (%)
G1	14 (58.40%)	4 (28.60%)	10 (71.40%)
G2	10 (41.60%)	6 (60.00%)	4 (40.00%)
Total	24 (100.00%)	10 (41.60%)	14 (58.40%)

$p > 0.05$

The results shown in Table 2 demonstrate that, after four applications, a reduction in initial WSL dimension values was observed in both groups. To illustrate this effect, the mean difference (in mm) and the overall reduction percentage are presented. The Wilcoxon test demonstrated a

statistically significant difference ($p = 0.012$) between initial ($3.12 \text{ mm} \pm 1.49 \text{ mm}$) and final dimensions ($2.35 \text{ mm} \pm 1.06 \text{ mm}$) in G1. The same test also showed statistically significant difference ($p = 0.013$) between initial ($5.7 \text{ mm} \pm 3.82 \text{ mm}$) and final dimensions ($3.40 \text{ mm} \pm 3.35 \text{ mm}$) in G2. Although the mean WSL dimension reduction was higher in G2, the difference between groups was not statistically significant ($p = 0.931$).

Table 2. Mean (standard deviation) WSL dimension values in both treatment groups (G1 and G2) at the beginning and end of treatment and difference between S1 (first week) and S5 (fifth week).

Group	Mean WSL dimension values		Difference (S1 – S5) Reduction in mm / %	p-value
	Initial Mean in mm (\pm sd)	Final Mean in mm (\pm sd)		
G1 = 14	3.12 (1.49)	2.35 (1.06)	0.77 / 24%	0.012
G2 = 10	5.70 (3.82)	3.40 (3.35)	2.30 / 40%	0.013

$p < 0.05$ - Mann-Whitney U test.

Discussion

The occurrence of inactive white spot lesions (smooth and shiny) through the use of fluoride varnish demonstrates the possibility of stoppage of lesions without the need for invasive treatment. This result is relevant for public health services in the planning of oral health care programs, especially in children [8,26]. Thus, the effect of two commercial fluoride varnish formulations (Duraphat® and Duofluorid XII®) on active white spot lesions in primary teeth was tested.

After four fluoride varnish applications, statistical analysis showed no significant difference between groups with respect to WSL inactivation, corroborating results of previous studies [3,8,9]. The larger number of inactive lesions in G1 should not be interpreted, as well as an actual difference, although in absolute terms, it appears that treatment with Duraphat® has yielded a better therapeutic effect on WSL. However, it is noteworthy that despite the study randomization, the average number of initial lesions in G2 was higher than the average recorded in G1, with nearly significant difference between groups. In fact, it is known that a weekly regimen of fluoride varnish application may required eight weeks for a few active lesions to be classified as inactive [9]. However, some authors [17] have stated that Duraphat® is actually more effective than national fluoride varnishes, although its cost may be up to eight times higher [9].

The average lesion reduction magnitude, measured in millimeters, may be considered an important finding, since the mean dimensions reduced from $4.19 \text{ mm} (\pm 2.94)$ to $2.79 \text{ mm} (\pm 2.3)$, i.e., there was a reduction of 1.4 mm (33.4%), similar to results found in a previous study carried out in Brazil [9]. In addition, the improvement in the clinical appearance of the dental enamel can be considered a strong justification for the increased adhesion of non-cooperative patients to oral health programs [9].

The therapeutic effect observed may have been only due to the application of fluoride varnish. Although in this study, factors such as exposure to fluoride sources, residence time of

fluoride varnish in the oral cavity, guidance on diet and education to parents / guardians were controlled, there was no control over other factors related to the maintenance of general health such as adequate access to health services and sanitary conditions and interest in health-related issues [5,9,11,14,27] as well as in matters related to oral health such as adequate brushing performed by parents and healthy diet [6,13]. Although the simplified Oral Hygiene index has not been calculated, little improvement in the oral hygiene standard of children was observed.

Furthermore, the observation unit was WSL, that is, all lesions found in one child were considered, indicating that the variables are not independent, since the chance that one child who has one lesion to present another lesion is greater than the child who has no lesion. Statistical analysis should be by multiple levels (one level, the lesion, and another level, the child). However, the tests applied in this study considered variables as independent, as adopted in previous studies [8,9,11,12,14,18,28,29]. Additionally, variables age and risk for caries disease in the preventive anticariogenic effect of varnishes were not considered in this study. According to a previous study [19], the preventive effect of fluoride varnish on primary teeth varies according to age and risk of dental caries.

Fluoride varnish releases fluoride during the cariogenic challenge and spreads through the enamel, reducing the progression of carious lesions [4]. Although some authors are in agreement in relation to its effectiveness in reducing the incidence of dental caries in primary teeth of children six years old or less [12,15,30], the evidence of its inhibitory effect on this dentition is limited and evidence on its effectiveness is still insufficient [7,12,20,29,31]. Additional information regarding the control of white spot lesions in primary teeth may be obtained from further studies with larger sample sizes, longer follow-up periods and greater control of factors potentially associated to the anticariogenic effect of fluoride varnishes.

Despite these limitations, the results of this study provide relevant information on the clinical effectiveness of fluoride varnish on the control of incipient dental caries in primary teeth.

Conclusion

Both commercial fluoride varnish formulations tested produced similar clinical effects after four consecutive applications indicated for the control of caries activity and reduction in the dimension of white spot lesions at the beginning of treatment.

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