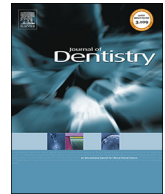




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Enhancing predicted fluoride varnish efficacy and post-treatment compliance by means of calcium-containing gummy bears

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ABSTRACT

Objectives: This study determined whether consumption of calcium-containing gummies prior to fluoride varnish application enhances plaque fluoride retention and compliance with post-varnish application instructions.

Methods: The present study followed a multi-center, parallel, randomized, and laboratory analyst-blind design. Following IRB approval, parent consent and child assent, 44 subjects (7–12 years), were randomized to either gummy or no-gummy study groups. A baseline plaque sample was obtained after a wash-out period. Fluoride varnish (5% NaF) was applied; subjects in the gummy group received two calcium-containing gummies prior to varnish application. Subjects were given two questionnaires to complete (subject and parent) to investigate adherence to post-treatment instructions. Three days later, a second plaque sample was obtained. Plaque was analyzed for plaque fluid and solid fluoride concentrations. Fluoride data were analyzed using Wilcoxon Rank Sum tests, questionnaire data using Pearson chi-square tests.

Results: Plaque fluid fluoride did not change pre- to post-treatment in the gummy group (mean \pm sd: $8.8 \pm 5.7 \mu\text{mol/l}$ vs. $10.0 \pm 6.3 \mu\text{mol/l}$; $p = 0.265$) or in the no-gummy group ($8.1 \pm 4.4 \mu\text{mol/l}$ vs. $16.1 \pm 20.0 \mu\text{mol/l}$; $p = 0.058$). Groups were not different for plaque fluid fluoride pre-treatment ($p = 1.000$), post-treatment ($p = 0.904$), or change ($p = 0.904$). Plaque solid fluoride did not change pre- to post-treatment in the gummy group ($0.89 \pm 1.10 \mu\text{mol/g}$ vs. $1.37 \pm 1.77 \mu\text{mol/g}$; $p = 0.073$) or in the no-gummy group ($0.68 \pm 0.77 \mu\text{mol/g}$ vs. $2.01 \pm 5.00 \mu\text{mol/g}$; $p = 0.190$). Groups were not different for plaque solid fluoride pre-treatment ($p = 1.000$), post-treatment ($p = 0.466$), or change ($p = 0.874$). No significant differences were found between groups for questionnaire responses.

Conclusion: This study failed to demonstrate an effect of calcium-containing gummies in enhancing plaque fluoride retention.

Clinical significance: The consumption of calcium-containing gummies prior to fluoride varnish application does not promote greater intra-oral fluoride retention or better adherence to post-treatment instructions.

1. Introduction

Several systematic reviews have concluded that fluoride varnishes are effective in preventing dental caries in children and adolescents [1–23]. However, recent caries clinical trials have demonstrated only marginal or no efficacy for fluoride varnishes in general and in particular in high-risk populations [4–7]. This highlights the need for interventions that are more efficacious and different approaches to utilize the wide array of caries-preventive agents.

Fluoride exerts its anti-caries effect primarily through small, but protracted elevations of fluoride in saliva and, in particular, in dental

plaque, the biofilm covering the teeth [8,9]. While fluoride has very good substantivity in partially demineralized enamel, the overall amount that can be retained in this reservoir is low and depends on the diffusion of fluoride through plaque, which is restricted [10]. Fluoride's retention in plaque has been shown to depend strongly on the co-presence of calcium [11]. Thus not surprisingly, several studies were able to demonstrate that ionic calcium applied to the oral cavity prior to fluoride greatly enhances fluoride retention in saliva [12], plaque and plaque fluid [13]. The mechanism of action is obvious as plaque-bound calcium presents more retention sites for a subsequent fluoride application. Similarly, the combined application of calcium and fluoride,

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either mixed immediately before [14] or during application [15], has shown great potential. However, translational approaches have thus far been largely unsuccessful due to poor consumer acceptability (two-product approach is cumbersome) or increased manufacturing costs (dual-chamber/compartiment delivery systems).

Fluoride efficacy also strongly depends on the subject's compliance with the provided (post-) treatment instructions. For fluoride toothpastes, the effects of rinsing behavior, brushing frequency and time have been shown to have marked effects on caries incidence [16–18]. While no such data could be retrieved relating to professional fluoride interventions, such as fluoride varnishes, parallels to toothpastes can be drawn nonetheless. Premature removal of fluoride varnish, motivated by its poor taste and/or cosmetic appearance, will likely limit its efficacy.

As there is still considerable scope for introducing strategies to enhance the anti-caries efficacy of fluoride, the present *in vivo* study investigated whether consumption of calcium-containing gummy bears, a dietary supplement for children, prior to fluoride varnish application can enhance not only intra-oral fluoride retention but also increase compliance with post-treatment application instructions. The null hypothesis tested was that consuming calcium-containing gummy bears prior to fluoride varnish application does not promote greater plaque fluoride retention and does not positively affect child compliance with post-fluoride varnish application instructions.

2. Subjects and methods

2.1. Study design

The present study followed a multi-center, parallel, randomized, laboratory analyst-blind design. Subjects (7–12 yrs) were randomized to either a gummy bear or no-gummy bear study group. A baseline plaque sample was obtained after a wash-out period. Fluoride varnish was applied to all teeth in both groups, with subjects in the gummy bear group receiving two calcium-containing gummy bears prior to varnish application. Subjects were given two questionnaires to complete (one for the subject, one for the parent – identical content, with the one for the parent serving as validation of their child's answers) to investigate adherence to post-treatment instructions. Three days after varnish application, a second plaque sample was obtained. Plaque samples were analyzed for plaque fluid and total plaque fluoride concentrations. Responses for each question in the questionnaire were summarized using basic frequencies and adherence to written instructions determined.

2.2. Ethical aspects

The present study was conducted in accordance with the Declaration of Helsinki. The study protocol, forms, written instructions and questionnaires were reviewed and approved by the IUPUI Institutional Review Board, #1509237792. The study was conducted at schools and community centers in Indianapolis, IN (US) and at the Oral Health Research Institute (OHRI). Written parent consent and child assent (subjects) were obtained prior to screening. Subjects received oral soft and hard tissue examinations throughout the study.

2.3. Subjects

Forty-four subjects, aged 7–12 years, who met the inclusion criteria (good general and oral health; at least 16 teeth; no oral soft tissue lesions, no periodontal disease including severe gingivitis or cavitated carious lesions; understand, willing, able and likely to comply with study instructions) were enrolled. Exclusion criteria were known or suspected allergy or hypersensitivity to fluoride varnishes (e.g. pine nut allergy); taking fluoride supplements or other fluoride products for medical purposes except for fluoride naturally occurring in diet and

Table 1
Study products.

Treatment	Product Name	Manufacturer
Fluoride Varnish	CavityShield 5% Sodium Fluoride	3 M ESPE
Calcium-containing Gummy Bear	Gummy Cuties Calcium with Vitamin D	Natural Dynamix
Toothbrush	Oral-B P40 Medium	Procter and Gamble
Fluoride-free Wash-out Toothpaste	Natural Fluoride Free Toothpaste for Children, Silly Strawberry	Tom's of Maine

toothpaste; taking any prescription antibiotics for any medical purpose. A randomization schedule, provided by the biostatistician, was used to assign subjects to the two study groups at screening.

2.4. Study products

The study products can be found in Table 1. The gummy bears had a declared calcium content of 100 mg per gummy in the form of tricalcium phosphate, with a daily serving size of two gummies. Prior to the conduct of the present study, the ability of a variety of calcium-containing gummies to release ionic calcium was evaluated (see Supplemental material). The chosen brand was selected due its superior ability to release calcium. The serving size of 200 mg calcium is somewhat comparable to the amount of calcium applied in a pre-rinse in the study by Vogel et al. [12] (20 ml of 150 mM calcium equates to 120 mg calcium).

2.5. Clinical procedures

There were three visits for all subjects. At the screening visit, parental consent and child (subject) assent were secured and the inclusion/exclusion criteria reviewed. Subjects received wash-out toothpaste and toothbrush and were instructed not to brush in the morning of the second visit which was approximately 7 d after visit one. At the second visit, a pooled, baseline interproximal and buccal surface plaque sample was collected from all teeth in the maxillary right (1) and mandibular left (3) quadrants (see *Plaque Collection*). Both groups of subjects were informed about the purpose of the fluoride varnish application and received verbal and written post-treatment instructions (Table 4). Subjects in the gummy bear group received two calcium-containing gummy bears and were asked to chew and suck the gummy bears until they dissolve rather than to just swallow them. Then, fluoride varnish was applied to all teeth (facial surfaces only). The teeth were not cleaned in any way prior to varnish application. The amount of varnish applied was standardized by the surface area of the teeth, as all facial tooth surfaces were covered by a single coating of varnish, similarly to a routine application would have been performed. Two compliance questionnaires were handed to the subjects, one for the subject to complete the next morning, the other for the parent or legal guardian to complete in the form of an interview with their child the next morning (validation of the subject's answers). Subjects were instructed not to brush their teeth in the morning of the test day (3 d later). At the third visit, the questionnaires were collected and another plaque sample collected, however from the maxillary left (2) and mandibular right (4) quadrants.

2.6. Plaque collection

Immediately before dental plaque collection, the subject was instructed to swallow all remaining saliva and cotton rolls were placed to keep their mouth dry. They were instructed to keep their mouth open. The clinical examiner then collected interproximal and buccal plaque samples. Approximately 1 mg of dental plaque was collected from the

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