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Review

Acceptability, efficacy and safety of two treatment protocols for dental fluorosis: A randomized clinical trial

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ABSTRACT

Objectives: This parallel randomized clinical trial evaluated the efficacy of two treatments for removing fluorosis stains.

Methods: Seventy individuals living in an area endemic for fluorosis, with at least four maxillary anterior teeth presenting fluorosis with a Thylstrup and Fejerskov index from 1 to 7, were randomized into two treatment groups ($n = 35$): GI – enamel microabrasion or GII – microabrasion associated with at-home bleaching. Microabrasion was performed using 37% phosphoric acid and pumice and, at-home tooth bleaching was performed with 10% carbamide peroxide. Areas of enamel opacities were recorded by digital camera at baseline and 1-month (1 M) after treatment. Two blinded examiners evaluated the reduction in the area (mm^2) of opacity using software. Two visual analogue scales were used: one for recording tooth sensitivity and/or gingival irritation ranging from 1 (none) to 5 (severe) and the other to evaluate participant satisfaction with the treatment used ranging from 1 (no improvement) to 7 (exceptional improvement).

Results: 1 M after treatment, both groups showed a significant reduction in the area of enamel opacity ($p = 0.0001$) and there was no difference between groups ($p = 0.1$). Most of the participants from both treatment groups reported no or mild tooth sensitivity and gingival irritation ($p > 0.05$). Participants reported that they were happy with the improvement in dental appearance, however, individuals from GII reported that they were happier than those from GI ($p = 0.004$).

Conclusions: Both treatment protocols were effective in reducing fluoride stains, however, when home bleaching was associated to enamel microabrasion, patients reported a major satisfaction with dental appearance.

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1. Introduction

Dental fluorosis is caused by excessive fluoride ingestion during tooth development.[1] It is characterized by the presence of bilateral, diffuse, thin and horizontal white striations and stained plaque areas. In the most severe cases, the enamel may become discoloured and/or pitted.[2,3] This condition may affect the quality of life and have psychosocial effects on patients,[4,5] and thus it is important to find effective, minimally invasive and low-cost treatments for patients with dental fluorosis.[6,7]

The choice of treatment depends on the severity of the disease. For less severe cases, more conservative methods such as enamel microabrasion, tooth bleaching or a combination of these techniques have been used for removing and/or reducing superficial enamel opacity.[6–9] The microabrasion technique was first proposed by Croll and Cavanaugh[10] using an abrasive paste composed by 18% hydrochloric acid (HCl) and pumice that was applied to the affected enamel. Because of the caustic potential of HCl, other microabrasion techniques have been proposed using less concentrated HCl combinations, different acids such as 37% phosphoric acid and/or different abrasive agents.[8,11,12]

The replacement of HCl by phosphoric acid in microabrasive treatments was first proposed by Mondelli et al.[13] The advantages of using 37% phosphoric acid are its availability in the dental office for routine use in bonding procedures and fewer hazards than with HCl.[12] A clinical study that compared the efficacy of microabrasion carried out with phosphoric acid or 18% HCl showed that both acids reduced enamel opacity to a similar degree.[14] Another study that evaluated the same techniques in vitro showed that enamel loss was significantly higher with HCl than with phosphoric acid.[12]

Tooth bleaching techniques has often been associated to enamel microabrasion in order to reduce the contrast between white spotted lesions and the remaining tooth surface.[6,15,16] A randomized clinical trial that evaluated the effect of in-office (30% hydrogen peroxide) or home bleaching (15% carbamide peroxide) on the colour and luminosity of fluorotic teeth, showed that although in-office bleaching did not affect the colour and luminosity of fluorotic teeth, at-home bleaching led to assimilation of the colour of the fluorotic stain with the colour of surrounding enamel areas.[9] Although microabrasion and tooth bleaching are the most conservative therapies used in the treatment of fluorosis, there is a lack of controlled, randomized and longitudinal clinical trials comparing the efficacy of these treatments. Thus, the aim of this parallel randomized clinical trial was to evaluate the acceptability, efficacy and safety of enamel microabrasion and the association of this technique with at-home tooth bleaching on the removal fluorosis stains.

2. Materials and methods

2.1. Ethical considerations

This study was approved by the local Ethics and Research Committee (#446/10). Each participant received an informational document describing the study proposal and the role performed by each participant, which also signed an informed consent form before enrolment in the study. The design of this randomized and controlled clinical trial followed the guidelines published by the Consolidated Standards of Reporting Trials (CONSORT).[17,18]

2.2. Examiner calibration

Before starting the study, calibration training sessions were performed in two steps: first using 60 dental fluorosis pictures (in lux calibration) and secondly under clinical (in vivo) conditions. The first calibration session was performed to minimized intraexaminer errors, and to ensure uniformity in the diagnosis of dental fluorosis with different degree of severity (1–9) according to the Thylstrup and Fejerskov index (TF).[19]

The (in lux) calibration was performed using coded images from a database of patients with different degrees of fluorosis and previously scored by experienced examiners. The initial kappa coefficient (κ) was $\kappa = 0.42$ when calculated for all nine individual TF severity degrees and $\kappa = 0.70$ when TF scores were grouped into three severity levels: mild (1–3), moderate (4–6) and severe (7–9). The decision to group the scores into three levels of TF was made because of the initial difficulty in obtaining good agreement between the study examiner and fluorosis pictures of all nine TF severity degrees of fluorosis from the data bank.

Only after a good agreement ($k > 0.70$) on the previous calibration step, the in vivo calibration took place. For this calibration, an experienced evaluator (gold standard) and the same pre-trained examiner analyzed the severity of fluorosis in maxillary anterior teeth ($n = 42$) of seven volunteers living in São João do Rio do Peixe, PB, Brazil, an endemic area for fluorosis.[20] These examinations were carried out in the morning, with sunlight and room illumination, and without any communication between the examiners. Four clinical sessions were necessary to calibrate the study examiner, mainly for scores 2, 3 and 4. The selection of participants for this study only began when the examiner achieved greater than 70% agreement with the gold standard examiner and $\kappa > 0.70$ for individual and grouped TF index scores. Thus the final kappa values of the study examiner were 0.73 and 0.86 for individual and grouped TF scores, respectively.

2.3. Sample size

Sample size was calculated based on a previous study.[7] To detect a difference of 20% between groups for removal of fluorosis stains with TF 1–7, with a power of 80%, alpha error of 5% and a one-tailed test, a sample size of 25 participants per treatment group was required. An additional 40% of participants were selected to take account potential losses or refusal to participate, giving a total sample size of 70 participants (35 in each treatment group). These individuals were invited to participate in this clinical trial through advertisements on a local radio station, through health personnel, and posters displayed in public schools and Family Health Units from São João do Rio do Peixe, PB, Brazil.

São João do Rio do Peixe is situated about 490 km from João Pessoa, the capital of Paraíba. It is a semiarid region with

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