Review

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

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A B S T R A C T

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 (mm2) 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. 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. This condition may affect the quality of life and have psychosocial effects on patients, and thus it is important to find effective, minimally invasive and low-cost treatments for patients with dental fluorosis.

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. The microabrasion technique was first proposed by Croll and Cavanaugh 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.

The replacement of HCl by phosphoric acid in microabrasive treatments was first proposed by Mondelli et al. 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. 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. Another study that evaluated the same techniques in vitro showed that enamel loss was significantly higher with HCl than with phosphoric acid.

Tooth bleaching techniques have often been associated to enamel microabrasion in order to reduce the contrast between white spotted lesions and the remaining tooth surface. 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. 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).

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).

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 ($\kappa$) 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 ($\kappa > 0.70$) 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. 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. 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...
scanty rainfall. This area has an increased level of fluoride in its groundwater beds, which has led to a high number of cases of severe fluorosis.²⁰

2.4. Eligibility criteria and randomization

Before the dental examination, each participant filled out a medical history sheet and complete dental prophylaxis was performed for removal of extrinsic stains. A hundred and thirty individuals were examined to obtain 70 participants who met the inclusion/exclusion criteria.

Participants were 15–39 years old, all in good oral and general health. To be included, they had to have at least four maxillary anterior teeth with dental fluorosis ranging from 1 to 7 according to the TF index.¹⁹ Individuals with loss or fracture of some maxillary anterior teeth, with evident malocclusion or with more than 1/6 of their buccal surfaces restored were excluded from this study. Participants under orthodontic treatment, with previous hypersensitivity or who had nonvital incisors or canines, smokers, pregnant or lactating women were also excluded (Fig. 1).

After the initial examination, the tooth surfaces were clean and dry and baseline enamel staining was recorded using a digital camera (Canon EOS Rebel XTi, Ohta-ku, Tokyo, Japan), with lens (Canon EF 100 mm Macro Lens) and default settings (ISO 100, 1/200 speed and F/20 aperture), always under the same flash (Macro Ring Lite MR-14EX), and natural and room illumination conditions.

Teeth were dried naturally and photos were taken after 90 s. A calibration scale (in millimetres) was included at the side of each photo, adjacent to the affected teeth (Fig. 2). The camera was positioned according to the recommendations of Cochran et al.,²¹ at the 12 o’clock position and the flash angled at 45° to reduce specular reflection and lip shadow. The images were loaded into the Image Tool software (v. 3.0, San Antonio Dental School, University of Texas Health Science, TX, USA) and two blinded and experienced examiners measured the areas of fluorosis stains (mm²). These evaluations were carried out after the examiners had undergone calibration training to ensure uniformity in measuring the areas of staining. The

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Fig. 1 – Flowchart of the trial.

Fig. 2 – A calibration scale (in millimetres) positioned at the side of each digital photo.
examiners achieved interexaminer agreement greater than 70%.

Participants were grouped according to the level of severity of fluorosis and randomized into two treatment groups (n = 35): I – enamel microabrasion with 37% phosphoric acid (Cond Ac Dental Products, FGM Dental Products, Joinville, SC, Brazil) and fine-grained pumice (Quimidrol, Joinville, SC, Brazil); II – association of microabrasion and at-home tooth bleaching (10% carbamide peroxide, Whiteness Perfect, FGM Dental Products). A randomization table to allocate participants in each treatment group was prepared in advance by an examiner not directly involved with the clinical steps of the study.

2.5. Microabrasive treatment

Participants from both groups received the microabrasive treatment on maxillary teeth affected by fluorosis stains.

Before the start of microabrasion, the mucosa was protected with solid vaseline and isolated using rubber dam. Eyeglasses were also used for eye protection.

A layer of microabrasive paste (±2.0 mm), consisting of 37% phosphoric acid/pumice (1:1), was applied to the surface of the affected teeth. A rubber cup (Microdent, KG Sorensen, Cotia, SP, Brazil) attached to a contra-angle was used to abrade lightly the tooth surface, at slow rotation (10:1 gear reduction handpiece) for 10 s. The excess paste was removed with sterile gauze and the teeth were rinsed for 20 s. This procedure was repeated 12 times during each clinical appointment and was performed in a maximum of two clinical sessions per patient.

At the end of the clinical appointment, the microbraded surface was polished with felt discs (Diamond, FGM Dental Products) and polishing paste (Diamond Excel, FGM Dental Products). Then, after the treated teeth were rinsed and dried, neutral sodium fluoride foam (Fluoride Care, FGM Dental Products) was applied for 1 min. All the patients received oral and written instructions about dietary restrictions during the course of treatment. Participants also received a toothbrush and a dentifrice without whitening agents (1.500 ppm of fluoride) to standardize the oral hygiene regimen.

A total of 58 clinical sessions of microabrasion were performed for group I (23 patients underwent two clinical sessions of treatment and 12 underwent only one session). For group II, 57 sessions of microabrasion were performed (22 patients underwent two clinical sessions and 13 had only one session of microabrasion).

2.6. Bleaching treatment

Two days after the microabrasive treatment, two alginate impressions (Jeltrate regular set, Dentsply, Petrópolis, RJ, Brazil) were taken per patient from group II and stone models were prepared. The buccal surfaces of the anterior teeth (premolar to premolar) on each mould were blocked out with five coats of nail polish, starting approximately 1.0 mm above the gingival margin. This area created a reservoir in the tray (about 1.0 mm thickness) for the bleaching gel. Custom trays were fabricated using a 1-mm thick soft vinyl material (FGM Dental Products) and a vacuum-formed process. Excess on the buccal and lingual surfaces was trimmed just short of the gingival margin.

In another clinical session, each participant in group II was given a pair of trays and two tubes of bleaching gel. Patients were instructed to use the gel simultaneously in both arches for 4 h in the evening for 2 weeks. All patients were given a hands-on practical demonstration and written instructions on the proper use of the bleaching agents and restrictions regarding diet during the course of treatment. The participants also received toothbrushes and dentifrices without whitening agents to standardize their oral hygiene regimen.

Compliance of participants in group II was evaluated based on the amount of gel used. Participants returned all used and unused syringes containing bleaching gels to ensure completion of the treatment. The syringes were weighed before and after bleaching (analytical balance AG 200, Gehaka Ltda, São Paulo, SP, Brazil).

2.7. Clinical evaluation

Patients were evaluated one month after treatment and the area of fluorosis stains was measured by the same two blinded and experienced examiners following the protocol that was conducted at the baseline evaluations. At the 1-month recall, the remaining areas of fluorosis in each patient were compared with the areas at baseline to verify the reduction.

The same examiners evaluated dental aesthetic improvement using a visual analogue scale (VAS) ranging from 1 (no improvement in aesthetic appearance or stain not removed at all to 7 (exceptional improvement in aesthetic appearance or stain totally removed). The same VAS was given to the patients or their parents to assess their opinion about the aesthetic appearance of the teeth after treatment.

Each participant was instructed to record tooth sensitivity and gingival irritation during the treatment and one week after the treatment ended. They used a VAS ranked as follows: 1 (no tooth or gingival sensitivity), 2 (mild sensitivity), 3 (considerable sensitivity) and 5 (severe tooth or gingival sensitivity). Participants who reported more than a moderate degree of sensitivity received potassium nitrate and sodium fluoride at 0.2% desensitizing (Desensibilize KF 2%, FGM Dental Products). They were instructed to place the desensitizing gel in the tray and wear it for 10 min per day as recommended by the manufacturer.

2.8. Statistical analysis

Normality distribution of data was checked using the Kolmogorov Smirnov test. Data were statistically analyzed by the Wilcoxon signed rank and paired t test for comparison within the same treatment group and by the Mann–Whitney U test for comparisons between independent groups to determine significant differences in the different periods of evaluation regarding the staining area, aesthetic perception, tooth and gingival sensitivity. Differences were considered statistically significant when p < 0.05.

3. Results

All patients attended the 1-month evaluation. The age of the participants ranged from 15 to 39 years, with the mean (±SD)
age being 17.6 (±4.0) years. Forty-eight participants were female (68.6%) and twenty-two male (31.4%). At baseline, treatment groups were balanced with regard to age, gender, education level and TF index (Table 1). The mean weight of the syringes (with whitening gel) was 7.8 ± 0.1 g. At the end of the treatment, the weight was reduced to 5.0 ± 0.2 g, demonstrating consumption of the whitening gel.

3.1. Enamel opacity areas

At baseline, means of fluorosis staining areas were 32.0 ± 10.1 mm² for group I (MAB) and 31.4 ± 9.3 mm² for group II (MAB + BL) and there was no statistical difference between treatment groups (p = 0.8).

At 1-month follow-up, both treatment groups showed a significant reduction in stained areas (p < 0.0001). However, no significant difference between the groups was observed (p = 0.7) (Table 2).

3.2. Visual analogue scale

At 1-month follow-up, participants from group II reported that they were happier with their dental appearance than participants from group I (p = 0.004) (Table 3). Nineteen (54.3%) participants who received microabrasive treatment and 30 (85.7%) who received microabrasion and home bleaching reported an improvement in appearance of their teeth from moderate to excellent.

Regarding the visual evaluation carried out by the examiners, 24 (68.6%) participants from group I and 26 (74.3%) from group II showed improvement in the appearance of the teeth from moderate to excellent. However, no significant differences between treatment groups were observed (p = 0.8) (Table 3).

3.3. Tooth sensitivity and gingival irritation

Medians and 95% confidence intervals for tooth sensitivity and gingival irritation reported by participants were 1.1 (1.0–2.0) and 1.0 (1.0–2.3) for group I and 1.1 (1.0–1.8) and 1.0 (1.0–2.7) for group II. There was no statistical difference between the groups for tooth sensitivity (p = 1.0) or gingival irritation (p = 0.3).

4. Discussion

Although dental fluorosis is usually reported as a developmental disturbance of enamel, there is a lack of clinical trials evaluating the efficacy of the techniques available to treat this condition. Most studies are clinical case reports, which makes it difficult to compare our findings with those available in the literature.

VAS is still the most common method used to evaluate the effectiveness of dental fluorosis treatments, and qualitatively verify the improvement in dental appearance and the reduction of fluoride stains. In this study, the VAS was used to verify the improvement in dental appearance and to observe the potential side effects of the treatments such as tooth sensitivity and/or gingival irritation. To provide objectivity, stained areas were measured before and after treatment using software and digital images.

Previous studies have used software to measure the depth and area of enamel demineralization or reduction in the fluorosis stained areas after using different microabrasive

### Table 1 - Demographic characteristics and TF index, according to treatment groups.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Categories</th>
<th>Treatment groups</th>
<th>PMAB - MAB + BL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MAB (n = 35)</td>
<td>MAB + BL (n = 35)</td>
</tr>
<tr>
<td>Gender n (%)</td>
<td>Female</td>
<td>22 (62.9)</td>
<td>26 (74.3)</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>13 (37.1)</td>
<td>9 (25.7)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td>17.4 (±6.5)</td>
<td>17.7 (±4.2)</td>
</tr>
<tr>
<td>Education level (years of study)</td>
<td></td>
<td>8.8 (±2.1)</td>
<td>9.2 (±2.1)</td>
</tr>
<tr>
<td>TF index</td>
<td></td>
<td>4.0 (1.8-7.0)</td>
<td>3.3 (1.7-6.7)</td>
</tr>
</tbody>
</table>

Difference statistically significant between groups (p < 0.05).

a MAB = microabrasion.

b MAB + BL = microabrasion and bleaching.

### Table 2 - Means (SD) of fluorosis staining areas (mm²) at different evaluation periods for groups treated with enamel microabrasion or microabrasion and at-home tooth bleaching.

<table>
<thead>
<tr>
<th>Evaluation periods</th>
<th>Fluorosis staining areas (mm²)</th>
<th>PMAB - MAB + BL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MAB (n = 35)</td>
<td>MAB + BL (n = 35)</td>
</tr>
<tr>
<td>Baseline</td>
<td>32.0 (±10.1)</td>
<td>31.4 (±9.3)</td>
</tr>
<tr>
<td>1-Month</td>
<td>20.4 (±1.8)</td>
<td>19.8 (±8.0)</td>
</tr>
<tr>
<td>Post-1 month</td>
<td>0.0001</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

* Difference statistically significant between groups (p < 0.05).

### Table 3 - Aesthetic perception medians and 95% Confidence Interval (CI) of patients and examiners after enamel microabrasion or microabrasion and at-home tooth bleaching.

<table>
<thead>
<tr>
<th>Evaluation of aesthetic perception</th>
<th>Treatment groups</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MAB (n = 35)</td>
<td>MAB + BL (n = 35)</td>
</tr>
<tr>
<td>Subjects</td>
<td>5.0 (2.0-7.0)</td>
<td>6.0 (3.0-7.0)</td>
</tr>
<tr>
<td>Examiners</td>
<td>5.0 (3.0-7.0)</td>
<td>5.0 (2.0-7.0)</td>
</tr>
</tbody>
</table>

* Difference statistically significant between groups (p < 0.05).
techniques. A clinical trial compared the efficacy of microabrasion performed using a paste consisting of 37% phosphoric acid or 18% HCl and pumice in reducing fluorosis stains. The authors reported a significant reduction of the stained areas after six applications of both products.6,14 We also observed a significant reduction in stained areas after microabrasion with 37% phosphoric acid and pumice or after the association of this technique with home bleaching, with no statistical difference between the groups. These findings show that tooth bleaching may not influence the reduction in enamel opacity and this decrease could be the result of the microabrasive treatment performed previously. Some studies that have combined microabrasion with tooth bleaching for fluorosis treatment evaluated the improvement in tooth appearance using qualitative methods such as VAS and/or questionnaires of aesthetic perception.6,7,15,16 However, it is not possible to correlate these findings objectively with the improvement in tooth appearance due to decrease in stained areas.

Another study evaluated the effectiveness of a microabrasive compound containing 18% HCl in reducing yellow, white and brown fluoride stains. Four examiners used a standardized questionnaire and a VAS and observed an improvement in the appearance of the teeth and a decrease in the stained areas.11 In this study, the same VAS used by the examiners was used by the participants. However, although the patients in group II who underwent microabrasion and home bleaching reported an improvement in dental appearance significantly greater than the patients in group I who underwent microabrasion only, the examiners, blinded about the treatment used, did not observe any differences between the groups after treatment. Some factors may explain the difference between the visual evaluations of examiners and patients. While the examiners were trained to verify the staining reduction area after treatments, without regard tooth base shade, the participants were providing a much more subjective and possibly broader opinion. Additionally, a possible decrease in the contrast between fluorosis stains and the adjacent enamel, making teeth lighter and more uniform. This characteristic was emphasized by studies that recommend bleaching treatment combined with enamel microabrasion.6,7,9,15,16 Another possible explication could be that patients who did not receive the home bleaching treatment came into contact with participants who did and, now that tooth whitening is a widespread and desirable aesthetic treatment, there may have been a negative judgement about the efficacy of the microabrasion treatment. Mild or moderate tooth sensitivity and gingival irritation are the most frequent side effects reported after home tooth bleaching treatments.6,22–25 Additionally, increase of these side effects are generally associated to increase of bleaching gels concentrations.24,25 Most of our patients reported no or mild tooth sensitivity and/or gingival irritation and there was no difference between the treatment groups. These side effects were reported in the first days after the microabrasive treatment and/or during the bleaching treatment. However, patients reported that this tooth sensitivity was transitory and stopped within a short period of time after microabrasive treatment and after the use of the whitening agent finished. A study evaluated the efficacy of bleaching with 7.5% hydrogen, 10% or 20% carbamide peroxide in patients with mild fluorosis. The results showed that patients treated with carbamide peroxide gels reported a lower incidence of tooth sensitivity than those who were treated with hydrogen peroxide.5

VAS scales have been used by several studies to measure frequency and severity of various symptoms in epidemiologic and clinical studies including dental fluorosis appearance.5,11 In spite of its accepted sensibility, VAS scales are influenced by individuals choice. For instance, a study may include some patients with reduced ability to quantify tooth appearance, and treatment improvement can be reported by placebo groups in many situations.26 However, these limitations are also found in other studies.

Both treatment protocols tested in this clinical trial resulted in a significant decrease of enamel fluorosis stained areas. Therefore, the present study suggests that the association of microabrasion with home tooth bleaching with 10% carbamide peroxide is the best choice for treating mild to moderate fluorosis (TF 1–7), because tooth bleaching minimizes the contrast between the areas of healthy and stained enamel. Further longitudinal and clinical trials comparing these treatment protocols for dental fluorosis are needed to investigate the efficacy, tooth colour changes and risk factors associated with a shade rebound effect.

5. Conclusions

Microabrasion with 37% phosphoric acid and pumice and the association of this technique with at-home bleaching were effective in reducing the enamel fluorosis staining (TF 1–7) and improving the appearance of the teeth. However, patients who used home bleaching after microabrasive treatment reported that they were happier with dental aesthetics without any increase in the incidence of side effects such as tooth sensitivity or gingival irritation.

References

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