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Clinical Research

Clinical Effectiveness of Two Microabrasion Materials for the Removal of Enamel Fluorosis Stains

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Clinical Relevance

PREMA and Opalustre are effective, conservative methods for improving the appearance of fluorosis-affected teeth; however, faster results can be obtained with Opalustre. The results of this study show that the majority of subjects reported being satisfied after microabrasion treatment.

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SUMMARY

This study evaluated the effectiveness of two microabrasion products for the removal of enamel fluorosis stains. Using a split-mouth study design, two operators used PREMA (PM) and Opalustre (OP) to remove fluorosis-like stains from 36 subjects (10-12 years old). Both products were rubbed onto the surface of the affected teeth for 30 seconds. This procedure was repeated five times during each clinical appointment. A maximum of three clinical appointments were scheduled. The subjects and/or their parents were questioned about their satisfaction with the treatment. Two blinded evaluators appraised both sides of the mouth using a visual scale system. The data were analyzed by Friedman repeated measures ANOVA and Wilcoxon test. The majority of the subjects (approximately 97%) reported satisfaction at the end of the treatment (p=0.0001). A significant improvement in appear-

ance was detected after the second clinical appointment when using PREMA and Opalustre ($p<0.002$). After the first clinical appointment, OP showed a statistically higher mean rating for improvement in appearance (3.4 ± 0.7) than PM (2.4 ± 0.5) ($p=0.002$).

INTRODUCTION

The prevalence of dental caries in children and adolescents has decreased over the last two decades.[1-2] Oral Health Research and Epidemiology (FDI/WHO works group) has indicated that the most common factor in the reduction of caries prevalence was fluoride.[2] However, in addition to its considerable benefits, using fluoride increases the risk of dental fluorosis, a condition that has been observed in several populations.[3] The use of excessive fluoride during tooth development can result in mottled, pitted enamel, frequently known as fluorosis. Recently, Levy and others[4] indicated that fluorosis was associated with increased parental dissatisfaction with the overall appearance and color of their children's teeth.

It was concluded at the International Symposium on Non-Restorative Treatment of Discolored Teeth[5] that microabrasion was a safe, conservative and effective atraumatic method of removing superficial enamel defects, such as the ones resulting from fluorosis. Croll and Cavanaugh[6] have successfully removed white enamel opacities with five-second wooden stick pressure applications of 18% hydrochloric acid and pumice, with intermittent water rinsing between applications. However, a high concentration of HCl has some chief disadvantages. The inherent danger of using a powerful acid in the mouth and the inconvenience and time taken to compress the mixture against enamel surfaces using finger pressure and a hand-held applicator have led to the search for a safer, quicker and easier method for correcting fluorosis and fluorosis-like defects.

After extensive experimentation on extracted human teeth with various acids at different concentrations, combined with manual abrasive agents and certain gel solutions, an enamel microabrasion kit (PREMA Compound, Premier Dental Products, Plymouth Meeting, PA, USA) was developed and introduced for use by dentists.[7-8] More recently, a new microabrasion compound was also developed and is commercially available on the market (Opalustre, Ultradent Products, Inc, South Jordan, UT, USA).[9]

Although numerous case reports have been published about these products, the literature still lacks clinical evidence comparing the effectiveness of these compounds with removal of fluorosis-like defects.[10-13] The few clinical trials available in the literature employed a limited-size sample.[6,14-17] For example, Ashkenazi and Sarnat[16] reported the successful outcome of a two-to-four-year follow-up study of the microabrasion technique, but the sample only involved five children.

Therefore, the purpose of this split-mouth randomized clinical study was to compare two compounds for microabrasion (PREMA and Opalustre) in terms of their ability to remove enamel fluorosis stains. The authors of this study hypothesized that both compounds were effective in removing fluorosis and fluorosis-like stains from enamel.

METHODS AND MATERIALS

Experimental Design and Subject Selection

The microabrasion compounds studied were PREMA (Premier Dental Products) and Opalustre (Ultradent Products Inc) (Table 1).

The protocol and consent form for this study were reviewed and approved by the University of Oeste of Santa Catarina Committee on Investigations Involving Human Subjects. Written informed consent was obtained from all participants prior to the beginning of the clinical study. Patient screening and pretreatment selection of teeth with fluorosis were performed by two clinical investigators. The investigators screened the patients initially to determine whether they met the study entry criteria (described below) and enrolled the qualified patients in the study for the evaluation visit. Qualified patients were recruited in the order in which they reported for the screening session, thus forming a convenience sample. The investigators carried out the evaluations using a mouth mirror, an explorer and a periodontal probe.

According to the treatment rules at the School of Dentistry, Department of Dental Materials and Operative Dentistry, University of Oeste de Santa Catarina, all subjects were given oral hygiene instructions before starting the treatment. Subjects with extremely poor oral hygiene or periodontal disease were excluded.

Each participant had to have at least four maxillary incisors with fluorosis, according to Dean's classification system (Table 2).[18] These teeth were cleaned with

Table 1: *Materials, Composition and Range of Particle Size*

Materials	Composition	Range of Particle Size
PREMA	10% hydrochloric acid, silicon carbide and silica gel	30-60 µm
Opalustre	6.6% hydrochloric acid, 6.6% silicon carbide	20-160 µm

Font: Manufacturer's information

Table 2: *The Dean's Index for Classification of Dental Fluorosis(*)*

Classification (Score)	Criteria
Normal (0)	The enamel represents the usual translucent semivitriform type of structure. The surface is smooth, glossy and usually a pale, creamy white color.
Questionable (0.5)	The enamel discloses slight aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is used in those instances where a definitive diagnosis of the mildest form of fluorosis is not warranted and a classification of "normal" is not justified.
Very mild (1)	Small, opaque, paper-white areas scattered irregularly over the tooth, but involving less than 25% of the tooth surface. Frequently included in this classification are teeth showing no more than about 1-2 mm of white opacity at the bicuspids or second molars.
Mild (2)	The white opaque areas in the enamel of the teeth are more extensive but involve less than 50% of the tooth.
Moderate (3)	All enamel surfaces of the teeth are affected, and surfaces subject to attrition show wear. Brown stain is frequently a disfiguring feature.
Severe (4)	All enamel surfaces are affected and hypoplasia is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is confluent pitting. Brown stains are widespread and teeth often present a corroded-like appearance.

(*) Adapted from Dean[18] and Train and others.[10] Only subjects with questionable, very mild and mild fluorosis were included in this study.

Figure 1. *Normal fluorosis according to Dean's classification.[18]*

Figure 2. *Questionable fluorosis according to Dean's classification.[18]*

Figure 3. *Very mild fluorosis according to Dean's classification.[18]*

pumice and water to remove extrinsic stain. As determined by this method, each individual received a score corresponding to the clinical appearance of the most affected teeth in the mouth. In this study, the four maxillary incisors were compared before a score was given. The criteria have been defined as follows: normal, questionable, very mild, mild, moderate and severe (Figures 1-4).

Fifty subjects were examined by two independent examiners (EN, LC) in order to classify the degree of fluorosis involvement. Only subjects with questionable, very mild and mild fluorosis were included in this study. Therefore, any child with an incisor with a fluorosis score of 3 or more was excluded from this study. After classification of the degree of fluorosis, two other examiners (ADL, AR) assessed the clinical aspect of the teeth before beginning treatment. Photographs of the teeth were taken at baseline, before starting the study. All participants were informed of the nature and objectives of this study; however, they were unaware of the location of each material.

Figure 4. *Mild fluorosis according to Dean's classification.*[18]

The success rate for removing questionable-to-mild fluorosis stains was considered to be 90% for PREMA. Using an α of 0.05, a power of 80% and a one-sided test, the minimal sample size should be 59 teeth in each group in order to detect a difference of 20% between groups. Out of 50 subjects, 36 participants were selected (19 male and 17 female), ranging in age from 10 to 12 years, each having at least four teeth with fluorosis stains. The 14 subjects who were excluded from the study showed moderate and severe fluorosis.

Microabrasion Procedure

The microabrasion procedure was carried out by two other calibrated operators (DT, CZ). For the calibration procedure step, one experienced clinician (DB) treated two patients with both techniques in order to identify all steps involved in the microabrasion technique. Then, each operator treated two patients with both materials under direct supervision of the experienced clinician. Only subsequent to this were the operators considered capable of initiating the microabrasion procedures. These patients were not included in the study.

The method of application followed the "split-mouth" study design. For each subject, two compound systems were randomly selected and designated "left" or "right" (OM). Both microabrasion materials were used on the same participant. A coin was tossed to determine whether Opalustre or PREMA would be used on the left or right side. Before placement of the rubber dam and clamps, gingival tissue was protected with solid Vaseline. The subject was protected with eyeglasses. A thin layer of Opalustre or PREMA was applied (± 1 mm) over the localized opacities on the facial surface of the affected teeth. After 10 seconds, the compound was rubbed lightly (20 ± 5.2 g)[19] onto the surfaces using a contra-angle handpiece in slow rotation (10:1 gear reduction handpiece) fitted with a synthetic rubber rotary application tip (KG Sorensen, Barueri, SP, Brazil) for 30 seconds.

This procedure was repeated five times during each clinical appointment. A maximum of three clinical appointments were scheduled for the microabrasion procedure. The compound was rinsed, and the teeth were then examined wet to allow for the assessment of treatment progress. The rubber dam was removed and the following questions were posed to the subjects:

1) Are your treated teeth as smooth as the non-treated ones? If the answer was no, a second question was posed.
2) Which side is smoother?

Clinical Evaluation

The subjects were examined by two independent examiners (ADL, AR), both of whom assessed the clinical aspect of the teeth before starting the treatment. The clinical aspect resulted from the microabrasion technique, which was evaluated at least 48 hours after completion of the clinical appointment in order to avoid the influence of dehydration caused by rubber dam isolation. The independent examiners evaluated both sides of the mouth using a visual scale ranging from 1 (no improvement in appearance or stain not removed at all) to 7 (exceptional improvement in appearance or stain totally removed), as described by Price and others[13] (Table 3, Figures 5-7). Post-operative photographs were taken before each clinical appointment and upon completion of the microabrasion technique. For training purposes, photographs of teeth subjected to the microabrasion technique that were representative of each score were observed. Then, both examiners reviewed approximately 10 patients subjected to the microabrasion procedure at baseline and after completing the treatment (they were not included in the sample) on two different occasions. A score was given for each case. An initial intra- and inter-examiner agreement of at least 85% was necessary before the clinical evaluation in this study could begin.

A second and a third appointment were scheduled in case the stains were not fully removed (a score of 5 or less). Only upon completion of the final treatment were the teeth polished with Sof-Lex Pop-On ultra-fine discs (3M ESPE, St Paul, MN, USA) and a topical applica-

Table 3: *Visual Scale Used to Evaluate the Rate of Improvement in Appearance*

No Improvement		Slight		Moderate		Exceptional Improvement
1	2	3	4	5	6	7

Adapted from Willis and Arbuckle[14] *and Price and others*[13]

Figure 5. *Mild fluorosis before (a) and after treatment (b). This case was scored as slight improvement (Price & others[13]).*

Figure 6. *Very mild fluorosis before (a) and after treatment (b). This case was scored as moderate improvement (Price & others[13]).*

Figure 7. *Very mild fluorosis before (a) and after treatment (b). This case was scored as exceptional improvement (Price & others[13]). Note that the white spots diagnosed as trauma-induced stains in the incisal third of the central incisors were not taken into account during the evaluation, since these stains are too deep to be removed by microabrasion procedures.*

tion of a 1.23% fluoride gel solution (DFL, Rio de Janeiro, RJ, Brazil) was applied for four minutes after the polishing procedure. A third question was posed to the subjects and/or their parents in order to assess their opinion about the esthetic improvements upon completion of the treatment. Are you: a) very satisfied? b) satisfied? or c) non-satisfied?

Statistical Analysis

Descriptive statistics were used to describe the means of the evaluated criteria. The smoothness and the degree of satisfaction were analyzed by the Fisher's exact test (α=0.05). The number of appointments required to remove the fluorosis stains were analyzed with the Friedman repeated measures analysis of variance by rank and the Wilcoxon signed rank test for pairwise comparisons (α=0.05). As a measure of agreement between the examiners, Cohen's Kappa statistics was used.

RESULTS

Cohen's Kappa statistics (0.86) showed strong agreement between the examiners. The majority of the subjects (81.5%) showed very mild and mild fluorosis. All subjects had three clinical treatments. After the microabrasion procedure, 83.4% of the subjects reported that their abraded teeth were rougher than the non-treated ones. The side treated with Opalustre was considered rougher than the side treated with PREMA for 77.7% of the subjects (Fisher exact, p=0.001); 83.3% of the subjects reported being very satisfied; 14% reported being satisfied and only 2.7% of the subjects reported being unsatisfied with their treatment outcomes. Therefore, the majority of the subjects (approximately 97%) reported being very satisfied/satisfied at the end of the treatment (Fisher exact, p=0.0001).

The materials results are summarized in Table 4. Significant differences were observed for materials and time (Friedman test, p=0.00001). On a scale of 1 to 7, the mean ratings for improvement in appearance were significantly improved after the second clinical appointment for both compounds (Wilcoxon test, p=0.002). When the performance of both materials was compared after the first clinical appointment, the Opalustre compound showed a statistically higher mean rating for improvement in appearance (3.4 ± 0.7) than the PREMA compound (2.4 ± 0.5) (Wilcoxon test, p=0.002).

DISCUSSION

As pointed out by Wong and Winter,[12] esthetics is a subjective perception. Some authors who used an index with an arbitrary cutoff to designate classes of defects as esthetically objectionable may not reflect the communities' nor the individuals' perception of cosmetic acceptability.[20] Hence, this study has not attempted to employ any esthetic index. Instead, the participants' and their parents' satisfaction related to the improvement was regarded as a successful outcome. The degree of satisfaction in this study was very high (97%) and was the same rate of satisfaction as reported in the Willis and Arbuckle study,[14] contrary to what was reported in another clinical investigation.[12] For instance, Wong and Winter[12] found that only 65.6% of the subjects were satisfied after microabrasion with the PREMA compound.

This difference could be attributed to the degree of fluorosis stains abraded in each study. Wong and Winter[12] demonstrated that the subject's satisfaction degree was lower when the microabrasion procedure was performed in multi-line (with multiple horizontal line defects, with each line less than 2 mm in width) or diffused (with small, discontinuous areas) enamel defects. According to the Dean scale,[18] these two defects could be considered moderate or severe fluorosis, which was not a criterion for eligibility in this study. If the multi-line and diffused defects were classified following the Thylstrup and Fejerskov scale,[21] they would be probably scored as 4. According to the aforementioned authors, lesions scored as 4 have a pore volume of about 10%–25%, which is considered too deep to be effectively removed by the microabrasion procedure.

These findings are also in agreement with a study by Train and others.[10] They compared the effectiveness of the microabrasion procedure with PREMA in mild, moderate and severe fluorosis enamel stains. The authors found that mildly stained teeth achieved the best esthetic results, moderately stained teeth improved but continued to demonstrate white spots and staining and severely stained teeth showed only slight improvement. Therefore, it seems that the degree of satisfaction, which indirectly indicates the effectiveness of the microabrasion procedure, is high when the initial diagnosis of severity falls within certain parameters. The microabrasion technique can be considered to be a definitive treatment for teeth with questionable to mild fluorosis stains.[12,14]

Two uninformed examiners, uninformed as to which product was used on which subjects, attempted to evaluate the clinical performance of both compounds after each clinical appointment. After the second and third clinical appointments, both compounds were equally effective at removing very mild to mild fluorosis stains. Previous studies that evaluated the effectiveness of PREMA for the removal of enamel stains have observed similar results.[12-13,15] A case report found that the compounds Opalustre and PREMA were effective at removing white enamel stains.[22] Good clinical outcomes were also reported by Allen and others[23] after the application of

Table 4: *Means and Standard Deviations of the Scores Attributed for the Rate of Improvement in Appearance for Materials in Each Clinical Appointment (one week after the treatment)*

	1st	2nd	3rd
PREMA	2.4 ± 0.5[c]	3.5 ± 0.7[b]	5.1 ± 0.8[a]
Opalustre	3.4 ± 0.7[b]	3.9 ± 0.6[a,b]	5.3 ± 1.1[a]

Same superscript letters indicate no significant difference between means (p>0.05).

Opalustre in another case report. To date, no prospective clinical study was conducted to evaluate the performance of Opalustre.

However, when the compounds were compared at the end of the first clinical appointment or after five 30-second applications, Opalustre was more effective at removing stains. The action of microabrasion is based on removal of the first 100-200 µm of the enamel surface. The amount and ease of white stain removal depends on the type of acid and abrasive employed, as well as the application time and pressure.[19,24-26] Studies that evaluated the amount of enamel loss after the application of PREMA and Opalustre found that these compounds led to a lower removal of enamel when compared to the use of an 18% HCl/pumice mixture.[19,24-26]

Numerous studies have been conducted in order to evaluate the amount of enamel loss after microabrasion techniques. The use of 18% HCl and pumice mixture for 10 five-second successive applications resulted in an initial removal of 12 µm of enamel and 50 five-second applications removing approximately 36-100 µm of enamel.[24-25]

Another study examined the effect of an 18% HCl-pumice mixture at time intervals of 5, 10 and 20 seconds and 5, 10 and 15 applications under pressures of 10, 20 and 30 g. They concluded that the combination of ten 10-second or fifteen 5-second applications with 20 g of pressure resulted in enamel removal slightly less than 250 µm.[19] Croll[8] indicated that the reduction in the number of applications and the increase in application time (ten 30-second applications) of PREMA compound resulted in enamel loss of less than 200 µm.

These findings highlight the fact that the concentration of acid employed plays a role in the amount of enamel reduction.[19,24-25] Following this rationale, it was surprising to observe that PREMA (10% HCl) was less effective than Opalustre (6.6% HCl) after five 30-second applications.

Differences in the type of abrasive, abrasive grits and hardness affect the performance of a microabrasion compound. It was already demonstrated that the association of abrasives and acid increases the ability of the acid to remove enamel white spots and stains.[27] This is somewhat true, as Tong and others[26] observed that the sole use of HCl for microabrasion purposes caused an enamel loss of 100 µm, which was approximately four times lower than the amount of enamel loss after the association of HCl with pumice. This synergism between HCl and pumice was also observed in other studies.[19,24-26]

Although the same abrasive (silicium carbide) is presented in both compounds, the size of the abrasive particles from Opalustre compound (20-160 µm) was greater than that of PREMA (30-60 µm). This could have been responsible for the faster efficiency of Opalustre and the greater roughness reported by subjects in the Opalustre-treated side.

However, it seems that the greater roughness of the enamel after microabrasion treatment is not a matter for clinical concern, as the treated tooth surface becomes smooth and lustrous over time.[15] Apart from that, Segura and others[28-29] have shown that the enamel surfaces abraded with PREMA compound better resist acid challenge and bacterial colonization than untreated enamel. Histological studies have shown that, after microabrasion, the enamel surface appears as a layer of mineralized tissue without the natural external prism morphology, which is referred to as the *abrasion effect*.[30] Polishing with superfine abrasive disks, such as Sof Lex Pop On, can minimize the subject's experiencing roughness on the enamel surfaces.

CONCLUSIONS

The results of this study showed that:

1. Enamel microabrasion using PREMA or Opalustre compounds is effective and safe for removing white enamel stains and improves the appearance of the teeth; however, faster results are obtained with Opalustre.
2. The majority of subjects (approximately 97%) reported to be very satisfied/satisfied upon completion of the microabrasion treatment.

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