

## Effectiveness of treatment with carbamide peroxide and hydrogen peroxide in subjects affected by dental fluorosis: a clinical trial

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*Dental fluorosis is an endemic dental health problem around the world; so, it is important to develop clinical alternatives that are non-invasive and inexpensive. In this study, nightguard vital bleaching technique (NVBT), using carbamide and hydrogen peroxide as active agents, has shown itself to be effective in whitening teeth affected by dental fluorosis. Carbamide peroxide at 10 and 20% and hydrogen peroxide at 7.5% showed good clinical effectiveness in improving clinical appearance, but it is important to point out that clinical success is only in cases of class 1 to 3 of the Tooth Surface Index of Fluorosis. When comparing 10 and 20% concentrations of carbamide peroxide, there was no difference in the clinical effectiveness ( $p > 0.05$ ); but when comparing both concentrations of carbamide peroxide against hydrogen peroxide, results showed that carbamide peroxide was more effective in whitening in cases of dental fluorosis, the difference being statistically significant ( $p < 0.05$ ). NVBT has two advantages: it is a non-invasive technique and the relationship cost/benefit is excellent; only a few patients reported tenderness or mild tooth sensitivity.*

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### INTRODUCTION

The decline in prevalence and incidence of dental caries in developed countries over the last two decades is considered to be largely due to the widespread use of fluoride in different forms, but simultaneously with decline in caries, an increase in dental fluorosis has been reported.<sup>1</sup> An endemic dental health problem in several countries around the world, dental fluorosis, has dramatically increased in frequency in developing countries in Latin America in recent years.<sup>2-8</sup> Since Mexico is a major producer of fluorospar in the world, the two states associated with this productivity, San Luis Potosi and Coahuila, have great amounts of fluoride in the sources of drinking water and the populations have a high incidence and prevalence of

dental fluorosis.<sup>9</sup> Recently, there have been several reports showing that a wide area in central and northern states of Mexico is affected by an endemic dental fluorosis that affects both primary and permanent dentitions.<sup>6,10</sup> Therefore, conservative and inexpensive methods to treat dental fluorosis are necessary. The proposals should consider the following aspects: 1. There should be a conservative approach to obtain good esthetic and cosmetic results; and 2. Treatment alternative should be at a low cost.

It has been reported that dental fluorosis in adolescents and adults affects mainly anterior teeth, so this is a main concern from an esthetic point of view for populations affected by dental fluorosis. There are several treatment possibilities from a conservative approach from non-invasive techniques such as bleaching, to aggressive methods such as veneering, crowding or bonding. Nightguard vital bleaching technique (NVBT) with carbamide peroxide or hydrogen peroxide has enjoyed great popularity to enhance esthetics in anterior teeth, since it was first introduced to the dental profession by Haywood and Heyman in 1989.<sup>11</sup> It has been reported that NVBT is a safe and effective method that provides a less invasive and less costly alternative than crowns or laminate veneering.<sup>12</sup> There are several brands of carbamide peroxide available on the dental market with different

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Table 1. Bleaching results using a 10% carbamide peroxide (Nuprogold)

Baseline Score TSIF	Frequency	Relative Frequency	Final Score TSIF	Frequency	Relative Frequency
0-5	0	0.00%	0-5	0	0.00%
6-10	0	0.00%	6-10	0	0.00%
11-15	0	0.00%	11-15	0	0.00%
16-20	20	52.63%	16-20	36	94.73%
21-25	13	34.21%	21-25	2	5.26%
26-30	3	7.89%	26-30	0	0.00%
31-35	2	5.26%	31-35	0	0.00%
36-40	0	0.00%	36-40	0	0.00%
<b>Total</b>	<b>38</b>	<b>100.00%</b>		<b>38</b>	<b>100.00%</b>

TSIF (Tooth Surface Index of Fluorosis).

Table 2. Bleaching results using a 20% carbamide peroxide (Opalescence)

Baseline Score TSIF	Frequency	Relative Frequency	Final Score TSIF	Frequency	Relative Frequency
0-5	0	0.00%	0-5	0	0.00%
6-10	0	0.00%	6-10	0	0.00%
11-15	0	0.00%	11-15	1	2.63%
16-20	19	50.00%	16-20	34	89.47%
21-25	15	39.47%	21-25	3	7.89%
26-30	4	10.52%	26-30	0	0.00%
31-35	0	0.00%	31-35	0	0.00%
36-40	0	0.00%	36-40	0	0.00%
<b>Total</b>	<b>38</b>	<b>100.00%</b>		<b>38</b>	<b>100.00%</b>

TSIF (Tooth Surface Index of Fluorosis).

concentrations. Different companies make hydrogen peroxide too, so it is important to carry out clinical studies to determine their clinical effectiveness.

This study focuses on testing Nightguard vital bleaching technique on teeth affected by dental fluorosis, comparing carbamide peroxide and hydrogen peroxide in a double-blind clinical trial.

**PATIENTS AND METHODS**

The Ethics Committee of the Faculty of Dentistry at San Luis Potosí University, approved this study. This clinical trial involved 114 subjects, who desired to lighten the appearance of anterior teeth due to effects of dental fluorosis; indications, contra-indications, risks and benefits of bleaching were written into a consent form and discussed with each subject. The inclusion criteria were as follows: dental fluorosis in degrees 1 to 3 in accordance with Tooth Surface Index of Fluorosis (TSIF); 8 maxillary teeth (from central incisor to first premolar both sides) had to be present, bucal and lingual faces were evaluated before and after treatment with NVBT; all teeth had to be free of dental caries and restorations.<sup>13</sup> The exclusion criteria were as follows: all

patients who had had previous bleaching treatment were excluded; dental fluorosis in degrees 4-5 of TSIF; patients with severe periodontal disease; tetracycline-stained teeth; patients with teeth with history of dental trauma. A double blind clinical trial was done, patients were randomized into three groups of treatment, sample size was 38 subjects per group: group A, 10% carbamide peroxide; group B, 20% carbamide peroxide; group C, 7.5% hydrogen peroxide.<sup>14</sup> Both subjects and dentist were unaware of which treatment was involved; clinical evaluations were done using TSIF index at baseline and 1 week after treatment. A pilot study to calibrate all evaluators was done, the results of Kappa being 0.86.

Nightguard vital bleaching was used in this study. An irreversible hydrocolloid impression (Jeltrate Plus, Caulk, USA) was taken of the upper arch and poured with hydrocol, the resultant cast having to be free of voids. The cast was trimmed on a model trimmer to achieve a base parallel to the occlusal plane of the posterior teeth. Minor voids were blocked out. Reservoirs on the facial aspect of all teeth of approximately 0.5 to 1.0 mm thick, for the bleaching agent,

**Table 3.** Bleaching results using a 7.5% hydrogen peroxid (DayWhite)

Baseline Score TSIF	Frequency	Relative Frequency	Final Score TSIF	Frequency	Relative Frequency
0-5	0	0.00%	0-5	0	0.00%
6-10	0	0.00%	6-10	0	0.00%
11-15	2	5.26%	11-15	1	2.63%
16-20	11	28.94%	16-20	6	15.78%
21-25	17	44.73%	21-25	22	57.89%
26-30	8	21.05%	26-30	9	23.68%
31-35	0	0.00%	31-35	0	0.00%
36-40	0	0.00%	36-40	0	0.00%
<b>Total</b>	<b>38</b>	<b>100.00%</b>		<b>38</b>	<b>100.00%</b>

TSIF (Tooth Surface Index of Fluorosis).

**Table 4.** Comparison of NVBT among groups.

Treatment	p value
10% carbamide peroxide vs. 20% carbamide peroxide	0.9296
10% carbamide peroxide vs. 7.5% hydrogen peroxide	0.0194*
20% carbamide peroxide vs. 7.5% hydrogen peroxide	0.0336*

Nightguard Vital Bleaching Technique (NVBT)

\* Difference statistically significant by Mann Whitney U Test

were made to make space for gels to be tested, using a blocking out resin (LC Block-Out, Ultradent). A heat/vacuum tray-forming machine (Sta-Vac, Buffalo Manufacturing, USA) and 0.035-inch Soft-tray (Opalescence, Ultradent, USA) were used to fabricate the Nightguard. The tray was trimmed in a horseshoe-shaped design, the edge was 2mm from gingival crest onto gingival tissue, periphery edges should allow unrestricted movement from labial frenum attachment. The bleaching systems under investigation were NuProgold (Dentply, USA); Opalescence (Ultradent, USA); DayWhite (Discus Dental, USA). These were used as per instructions of the manufacturer. For each patient, three bleaching systems were randomly selected and a photograph study of anterior teeth was taken under standardized lighting conditions using the same camera and dental operatory light. Patients were instructed as to how to place the bleaching agents into the trays, each patient wearing the tray at night for a period of seven days. After that a photograph study was taken and final evaluations were estimated.

The data on the onset of tooth whitening were analyzed by Kruskal-Wallis test to compare the differences among the three groups; Mann Whitney U

test was used to compare differences between two groups, and baseline and after treatment results for each material tested are shown. JMP version 4.0 statistical program was used to do statistical analysis of data.

## RESULTS

Seventy-four (74) women and 40 men participated, the mean age being 17.6 years old (range from 12 to 29). All patients had a baseline score from 16 to 35, using the TSIF. After treatment with 10% carbamide peroxide material (Nuprogold) tooth whitening indicated a clinically significant result: 94.73% of patients moved to a score of 16 to 20; there was a significant statistical difference ( $p < 0.05$ ) (Table 1). A similar pattern was shown in patients treated with 20% carbamide peroxide (Opalescence): All subjects had a baseline score of dental fluorosis from 16 to 30. After treatment there was a significant clinical improvement: 92.1% of patients had a score between 11 and 20; statistically, there was a significant difference ( $p < 0.05$ ) (data shown in Table 2).

The group that used 7.5% of hydrogen peroxide material (DayWhite) showed similar response to treatment as other groups named above. This group began with a dental fluorosis score from 11 to 30, after treatment most patients having grouped in a score from 11 to 25. This clinical change had a statistically significant difference (Table 3). Data from these groups showed that all treatments were effective in whitening teeth in cases of dental fluorosis in conditions described above. Side effects of bleaching treatment were minimal for the patients: 3 (8%) patients of group A, 5 (13%) patients of group B, and 6 (16%) patients of group C reported gum tingling and tenderness or mild tooth sensitivity for one or two days.

When comparing all groups, there was a statistical difference ( $p < 0.05$ ), analyzing data by Kruskal-Wallis test. To find out where the differences were among groups, Mann Whitney U test was used. Results were as follows: when comparing 10% and 20% of peroxide

carbamide in one week of treatment, there was no statistical difference ( $p > 0.05$ ). This indicated that both treatments had similar clinical whitening improvement; when comparing treatments with 10% carbamide peroxide and 7.5% hydrogen peroxide, there was a statistically significant difference ( $p < 0.05$ ). These results show that 10% carbamide peroxide was more efficient clinically; when comparing treatments with 20% carbamide peroxide and 7.5% hydrogen peroxide, there was a statistically significant difference ( $p < 0.05$ ). These clinical data show that 20% carbamide peroxide was more efficient clinically. Comparative results are shown in table 4.

## DISCUSSION

Nightguard vital bleaching technique (NVBT) with carbamide peroxide or hydrogen peroxide used in teeth affected by dental fluorosis is an effective method of treatment for these subjects. It has several advantages: it is a non-invasive technique in which the enamel keeps its structure; it is easily handled by patients, and it is low-cost. Considering that most affected people have a low income and the social medical system in Mexico does not cover this health problem, NVBT is an excellent approach to deal with teeth stained by dental fluorosis.

Carbamide peroxide (10 and 20%) and 7.5% hydrogen peroxide showed good clinical effectiveness to improve clinical appearance of teeth affected by dental fluorosis, but it is important to point out that the clinical success is only in cases of class 1-3 of the TSIF index. In other words, NVBT is a useful method for teeth that have not lost any enamel. For cases that showed irregular areas in enamel surface, there are other effective treatment methods, such as composites, laminate veneers or esthetic crowns. When comparing 10 and 20% concentrations of carbamide peroxide, there was no difference in clinical effectiveness, but when comparing both concentrations of carbamide peroxide against hydrogen peroxide, results showed that carbamide peroxide was effective in whitening teeth affected by dental fluorosis. NVBT procedure could also be used in conjunction with restorative dentistry to complement or improve the overall esthetic result. Special care should be addressed to unrestored carious lesion and pre-existing sensitivity as contra-indications to using it.

Although, NVBT has been very effective in whitening teeth, some researchers consider that the need to make an impression to fabricate plastic trays and the necessity to wear them overnight produce some inconvenience to the patient and to the dentist. The use of whitening strips is used containing hydrogen peroxide in children and adolescents in teeth without fluorosis.<sup>15</sup> Considering that both deciduous and permanent dentitions are affected by fluorosis, it is important to have different alternatives to deal with this health problem.

It has been reported that different bleaching materials at different concentrations have side-effects when used for a long time on enamel and dental restorative materials. These studies have shown changes in surface hardness and roughness in restorative materials and color change in enamel surfaces.<sup>16</sup> There is also concern that long-term use of carbamide peroxide could result in dissolution of enamel matrix, but reports to date have not supported this theory.<sup>17</sup> It has been shown *in vitro* that 10% or 16% carbamide peroxide did not affect enamel structure, whereas 35% carbamide peroxide did affect enamel, so these lower concentrations are recommended in the overnight technique.<sup>18</sup> In this study the best results were after 1 week treatment; there is a report that suggests that efficacy is much better at 2 weeks. After that no significant difference was found in clinical effectiveness. In all cases, more overall color change occurred with the 15% product, but the differences were not significant at the end of the study. These results agree with our clinical evaluation of bleaching agents at different concentrations.<sup>19</sup>

Several studies have shown that carbamide peroxide bleaching agents in the range of 10 to 35% adversely affect the bond strength of composites to acid-etched enamel when bonding is performed immediately after bleaching procedure, especially when acetone-based adhesives are used.<sup>20-22</sup> A very important point in operative dentistry and orthodontics is that a period of up to three weeks is required before resin-enamel bond strengths return to values such as have unbleached teeth.<sup>23</sup> It has been reported that bond strength of adhesives is improved when sodium ascorbate treatment is used on enamel surfaces. It is hypothesized that the reduction of resin-enamel bond strength is caused by a delayed release of oxygen that affects the polymerization of resin components.<sup>24</sup> Recently, it was reported that carbamide peroxide caused an augmentation within the basal and parabasal layers of the gingival epithelium, resulting in a change in its morphometry.<sup>25</sup> It has been known for long time that hydrogen peroxide has the capability of inducing alterations associated with preneoplastic lesions and the possibility of being a risk factor for carcinogenic lesion in the mouth.<sup>26</sup>

Our results suggest that 10% carbamide peroxide is the best choice for whitening teeth. This material has two additional advantages: 1. It is less aggressive than a concentration of 20%; and 2. The cost is low with a better relationship of cost/benefit. Likewise, only a few patients reported tenderness or mild tooth sensitivity for one or two days. All this taken together the cost/benefit, the small possibility of side effects and easy handling by patients make NVBT an excellent approach to treat anterior teeth affected by dental fluorosis. NVBT is effective as a tooth-whitening system under supervision of dentist, with few reported side effects such as transient tooth sensitivity and minimal gingival sensitivity.

Additional studies are necessary to determine the stability of color changes in anterior teeth treated with NVBT and to explore side effects in the long term on enamel surfaces and soft mouth tissues.

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