A double-blind randomized clinical trial of two carbamide peroxide tooth bleaching agents: 2-year follow-up

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Objectives: This double-blind randomized clinical trial aimed to evaluate the whitening effect of two at-home tooth bleaching agents and the effect of dietary habits after 2 years. The patients’ view about bleaching longevity was also investigated.

Methods: Ninety-two subjects with mean shade of C1 or darker for the six maxillary anterior teeth were randomized into two groups (n = 46) according to the carbamide peroxide (CP) concentration: 10% (CP10) or 16% (CP16). The treatment was performed using the whitening agent in a tray for 2 h/day during 3 weeks. Shade evaluations were done with a shade guide and a spectrophotometer at baseline, 1-month, 6-month, 1-year and 2-year post-bleaching.

Results: Eighty-one (88%) of the original 92 subjects enrolled in the study were recalled at 2-year follow-up and, the tooth shade remained significantly lighter than at baseline, in both treatment groups, considering the tooth shade median values (p < 0.001) or the color parameters: L*a* (p < 0.001) for CP10 and, L*b* for CP16 group (p < 0.001). Subjects from CP10 and CP16 reported a consumption of beverage and food stains as high as at 6-month and 1-year recalls and, more than 66% of the participants from each group reported a tooth shade relapse from mild to moderate (p = 0.6).

Significance: At 2-year post-bleaching, tooth shade remained lighter than at baseline for both CP concentrations tested. Tooth shade relapse associated to increasing of a* and b* color parameters were observed for both groups when compared to the end of the treatment (CEP # 37/05).

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1. Introduction

Tooth bleaching is one of the most requested treatments by the patients, once the white and well-aligned teeth are currently considered the main factors responsible for the concept of a beautiful smile.1,2 Due to the large amount of tooth bleaching agents available in the market,3 it is difficult for the consumers to choose the agent that produces the more effective and long lasting result.

At-home dentist-supervised tooth bleaching using 10% carbamide peroxide gel with custom-trays is still considered the gold-standard treatment for tooth discoloration1,4–8 and, this bleaching agent concentration is the only one with the seal of acceptance from the American Dental Association
Office or at-home). Nevertheless, the incidence of tooth whitening effect for both concentrations and techniques (in-office or at-home) continues to introduce new products and methods for tooth bleaching, claiming that higher concentrations of hydrogen peroxide containing agents would work better than those products containing bleaching agents in lower concentration.

A number of clinical trials have compared the performance of higher and low-concentrated agents used for home or in-office tooth bleaching and the majority has showed a similar whitening effect for both concentrations and techniques (in-office or at-home). Nevertheless, the incidence of tooth sensitivity or irritation gingival is more common when the agent concentration is increased.

Few studies have evaluated the longevity of the whitening effect for more than 1 year after treatment. Besides, there is a lack of randomized clinical trials that verify the patients’ perception about the treatment’ longevity or the influence of possible factors associated to dietary habits in the shade relapse. Thus, this study aimed to evaluate the whitening effect of the at-home tooth bleaching with 10% or 16% carbamide peroxide after 2-year follow-up and the influence of the dietary habits in the bleaching longevity, as well as the patients’ perception about shade changes after a 2-year post-bleaching period.

2. Materials and methods

2.1. Examiners calibration

The design of this double-blind randomized, controlled clinical trial followed the guidelines published by Consolidated Standards of Reporting Trials (CONSORT).

The study was approved by the local Ethics Committee (# 37/05) and, prior to enrollment, each subject received an informed consent form containing all the information regarding the risks and benefits of treatment. All participants signed the consent form.

Before starting the study, 2 examiners were calibrated on shade determination of anterior teeth in 16 subjects. The study supervisor recorded shade using a digital spectrophotometer (Vitapan® Classical, Vita Zahnfabrik, Bad Säckingen, Germany). Shades were also recorded using the value-oriented shade guide (Vitapan® Classical, Vita Zahnfabrik) by two examiners. These shade selections were carried out in the afternoon with sunlight and room illumination without any communication between the examiners.

The 16 shade tabs in the guide were numbered from 1 (highest value – B1) to 16 (lowest value – C4) for statistical analysis. The visual evaluation was made by comparing the shade tabs with the middle third of the upper six anterior teeth. The scores were added and a shade mean was determined for each subject.

Analysis with a digital spectrophotometer was adopted as the gold-standard, as it can provide tooth shade via two different methods, using the 16 shade tabs in the Vita shade guide (B1–C4) or the CIEL*a*b* color system. At each evaluation period, the shade of the upper six anterior teeth was measured three times, with the active point of the instrument in the middle third of each tooth. The spectrophotometer automatically averaged the three readings for each tooth using the CIEL*a*b* color system and the Vita shade guide. These readings were used for comparison to visual assessment. The CIEL*a*b* system was defined by the International Commission on Illumination (1967) and is referred to as CIELAB. The L* represents the value (lightness or darkness). The a* value is a measure of redness (positive a*) or greenness (negative a*). The b* value is a measure of yellowness (positive b*) or blueness (negative b*). The difference between the color coordinates was calculated as: 

$$
\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}
$$

Whitening occurs mainly by increasing the lightness (higher L*) and by yellowness reduction (lower b*) and to a lesser extent by a redness reduction (lower a*).

After completing the training process, matrices were prepared to compare the degree of agreement between the examiners and the gold-standard. The kappa coefficient (κ) was calculated using either all of the colors of the shade guide (weighted kappa) or they were grouped according to chroma (simple kappa), which represents the degree of saturation of color. For kappa calculation purposes, if the gold-standard classified the color as A3.5, then the chroma value was recorded as 3. Thirteen clinical sessions in 13 days were necessary to standardize the examiners. This field study was initiated after both examiners achieved agreement with the gold-standard at greater than 70%, according to grouping by chroma.

2.2. Sample size

Sample size calculation was carried out based on a previous study. The following parameters were set for sample size calculation: mean difference between groups of 2 units or more in shade change; standard deviation of the difference between means of 2.5; beta error of 10%; and one-tailed alfa error of 5%. Based on this, a sample size of n = 80 subjects would be necessary. A 15% increase in sample size, taking into consideration potential loss or refusal, gave a total sample size of n = 92 subjects. The individuals were invited to participate in this clinical trial through advertisement in local newspapers, radio stations and University website.

2.3. Eligibility criteria, randomization and blinding

Prior to dental examination, each subject filled out a medical history sheet and a complete dental prophylaxis was performed to remove extrinsic stains. One hundred and eighty-three subjects were examined to obtain 92 individuals who met the inclusion/exclusion criteria described below. Subjects were 18–55 years of age in good general and dental health. To be included, six maxillary anterior teeth had to be present, with a mean shade of C1 or darker (Vitapan®

Classic, Vita Zahnfabrik). The anterior teeth should not have more than 1/6 of their buccal surface covered with a restorative material. Subjects with active caries, periodontal disease, previous hypersensitivity and with tetracycline-stained teeth were excluded from the study. Smokers, pregnant or lactating mothers and subjects who had used (ADA), which assures its safety and efficacy for home-use tooth bleaching. The main advantages of this technique are the easiness of use, reduced chair time and low incidence of tooth sensitivity and gingival irritation. However, manufactures continue to introduce new products and methods for tooth bleaching, claiming that higher concentrations of hydrogen peroxide containing agents would work better than those products containing bleaching agents in lower concentration.
tooth whiteners within the past 3 years and those without schedule availability were also excluded from the study (Fig. 1).¹¹

Using a protocol similar to that of the calibration exercise, initial evaluation baseline assessments were performed using the Vita shade guide and the digital spectrophotometer. Subjects were randomly assigned to two experimental groups (n = 46) according to carbamide peroxide concentration: 10% (CP10) or 16% (CP16) (Whiteness Perfect, FGM Dental Products, Joinville, Brazil). A randomization table was used to allocate the subjects in each study group. This table was prepared in advance by an epidemiologist, not directly involved with the clinical part of the study.

The concentration seal for each bleaching gel syringe was removed in order to mask treatment groups. To mask the tubes half of their plungers were covered with white adhesive tape. The same examiner responsible for subject allocation did this procedure. Thus, examiners and subjects were blinded to the agent concentration that was being delivered.

### 2.4. Bleaching procedure

Two alginate impressions (Jeltrate regular set, Dentsply International Inc., Milford, DE, USA) were taken per subject and stone molds were prepared (Durone IV, Dentsply International Inc.). The buccal surfaces of the anterior teeth on each mold 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 of thickness) for the bleaching gel. Custom trays were fabricated using a 0.9-mm thick soft vinyl material (FGM Dental Products) and a vacuum-formed process. The excess on the buccal and lingual surfaces was trimmed 1 mm above the gingival margin.

Subjects were recalled to receive the trays and three bleaching gel tubes. They were instructed to dispense gel at night into the trays and to insert them to cover at least the anterior teeth for a period of 2 h per day, over a 3-week period.¹¹ Both arches were bleached at the same time. All subjects received a hands-on practical demonstration, written instructions concerning the proper use of the bleaching agent, and advice on diet and oral hygiene control during the course of the treatment. Subjects also received toothbrushes and dentifrices without whitening agents aiming to standardize their oral hygiene regimen.

Each subject was instructed to record tooth sensitivity on a daily basis during the 3-week treatment.¹¹ Subjects who experienced more than a moderate degree of sensitivity received potassium nitrate desensitizing gel (Desensibilize KF 2%, FGM Dental Products), and they were instructed to place the desensitizing gel in their tray and wear it for 20 min once a day, as recommended by the manufacturer. During bleaching treatment, four individuals who used 16% CP and one who

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**Fig. 1 – Flow-chart of the trial.**
used the 10% CP concentration requested the desensitizing agent. In order to measure the compliance regarding bleaching usage, tubes containing bleaching agents were weighed before and after usage in a digital precision balance.11

Subjects were evaluated at the following times: baseline, 1 month, 6-month, 1-year and, 2-year post-bleaching. Examiners were blind to the status of participants regarding to the study group they belonged. At each evaluation period, subjects were recalled for tooth shade determinations, which were made following the same protocol carried out at baseline. However, at 2-year recall the method used to record teeth shade was the digital spectrophotometer, once the examiners responsible for visual assessment have graduated from the University and moved to distant cities. At 2-year recall, shade measurements were compared to the tooth shade values recorded at baseline, 1-month, 6-month and 1-year post-bleaching.

A standardized questionnaire related to diet and oral hygiene behavior was specifically prepared for the study subjects. Interviewers were trained in advance to apply the questionnaire. Subjects from both treatment groups were questioned regarding: (1) whitening toothpaste use; (2) re-bleaching after the end of the active treatment phase and, (3) daily frequency and type of beverage and food staining intake, such as: coffee, tea, wine, fresh or artificial fruit juices, cola.

To assess the patients’ opinion about the whitening effect at 2-year recall, the following three questions were included: (1) Are you satisfied with your teeth appearance? (2) Considering the longevity of the whitening treatment, could you please score from 1 to 5 the tooth shade relapse? The possible answers were: 1 = no shade relapse, 2 = mild, 3 = moderate, 4 = considerable or 5 = total shade relapse. (3) Would you indicate at-home tooth bleaching to your friends/family?

2.5. Statistical analysis

Data were checked for normal distribution using the Kolomogorov Smirnov test. As the distribution was not normal, the Wilcoxon Signed Rank test was used to determine significant differences in tooth shade within the same treatment group. Mann–Whitney-U test for independent samples was applied for statistical comparison between the two groups at baseline and after treatment results. Chi-Squared and McNemar tests were used to compare the significant differences in categorical variables. Differences were considered statistically significant when \( p < 0.05 \).

3. Results

Eighty-one of the 92 subjects enrolled in the study (88%) completed the 2-year evaluation, which is above the sample size calculated for the experiment, excluding the potential loss during follow-ups. One subject from the CP16 group failed to continue the treatment at the beginning of the trial; at 6-month recall, two more subjects were missed (one from each group). At 1-year, there were no additional misses and, at 2-year, three subjects from CP10 group and five from CP16 were missed. The subjects reasons for not showing up at the 2-year recall were as follows: starting of orthodontic treatment (\( n = 4 \)), moving to another city (\( n = 2 \)) and refusal (\( n = 2 \)). Demographic characteristics of the sample, reasons for participant loss and results of the study at 1-month, 6-month and, 1-year post-bleaching have been reported previously.7,11,24

3.1. Spectrophotometer data

At 2-year recall, the median value of tooth shade was lighter than at baseline for both groups (\( p < 0.001 \)) and there was no statistical difference between treatment groups (\( p = 0.1 \)) (Table 1).

After 2-year evaluation, the 10% and 16% carbamide peroxide concentrations showed no significant difference for \( L^* \) (\( p = 0.1 \)), \( a^* \) (\( p = 0.2 \)) or \( b^* \) (\( p = 0.8 \)). When compared to baseline, both treatment groups showed higher \( L^* \) values (\( p < 0.001 \)), lower values in \( a^* \) for CP10 (\( p < 0.001 \)) and in \( b^* \) (\( p < 0.001 \)) for CP16 (Table 2). Data for \( \Delta L^* \), \( \Delta a^* \), \( \Delta b^* \) and, \( \Delta E^* \) are graphically represented in Figs. 2–5. The tested concentrations were not statistically different in \( \Delta L^* \), \( \Delta a^* \), \( \Delta b^* \) and, \( \Delta E^* \) for each evaluation period (\( p > 0.1 \)).

There was no statistical difference into the same treatment group for \( \Delta L^* \) values when compared 2-year with other evaluation periods (\( p > 0.5 \)), except for CP10 at 6-month (\( p = 0.01 \)) (Fig. 2). At 2-year follow-up, CP10 and CP16 showed higher \( \Delta a^* \) values than at 1- and 6-month evaluations (\( p < 0.001 \)) (Fig. 3). An increasing of \( \Delta b^* \) value was observed

<table>
<thead>
<tr>
<th>Table 1 – Median change values of tooth shade and 95% confidence interval (CI) for all evaluation periods and treatment groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation periods</td>
</tr>
<tr>
<td>Baseline (Bas)</td>
</tr>
<tr>
<td>1-Month (1M)</td>
</tr>
<tr>
<td>6-Month (6M)</td>
</tr>
<tr>
<td>1-Year (1Y)</td>
</tr>
<tr>
<td>2-Year (2Y)</td>
</tr>
<tr>
<td>Significant ( p )-values (2-year vs. periods)</td>
</tr>
</tbody>
</table>

* Differences were considered statistically significant when \( p < 0.05 \).
for CP10 group when compared 2-year with 1- and 6-month (p < 0.001) and, 1-year (p < 0.02) evaluations. The CP16 also showed higher Δb* value at 2-year than at 1- and 6-month evaluations (Fig. 4).

At 2-year recall, there was not statistical difference into the same treatment group for ΔE* values than the others measurement periods (p > 0.2) (Fig. 5).

### 3.2. Diet and hygiene behavior

None of the participants reported re-bleaching within the 2-year post-bleaching period. Regarding to the use of whitening toothpaste, 32 subjects from CP10 (76.2%) and 30 from CP16 group (76.9%) reported the use of toothpaste without whitening agents. Only 8 (19.0%) subjects from CP10 and 8 (20.5%) from CP16 used whitening toothpaste. Three subjects (two from CP10 and one from CP16) did not know if the toothpaste contained whitening agents in the composition.

Overall, more than 76% subjects from each treatment group reported a consumption of beverages or food containing stains. At least 69% of participants from CP10 or CP16 reported drinking staining beverages more than twice daily. It could be observed that subjects from CP16 reported a daily frequency of staining food higher than CP10 group (p < 0.03). Details from diversity and daily frequency of beverage and food staining consumption are shown in Table 3.
3.3. Participants’ satisfaction

All participants completing the 2-year evaluation reported that they would indicate the at-home tooth bleaching to their friends and family. Considering this topic, 30 (71.4%) subjects from CP10 and 28 (71.8%) from CP16 group reported being satisfied, 2 (4.8%) from CP10 and 1 (2.6%) from CP16 reported being unsatisfied and 10 subjects from each treatment group reported being reasonably satisfied with teeth appearance ($p = 0.9$). Regarding the longevity of the whitening effect, the mean score values reported by subjects from CP10 was 2.7 ($\pm 1.0$) and, 2.5 ($\pm 1.0$) from CP16 group ($p = 0.6$), which represents a tooth shade relapse from mild to moderate. There was no statistical difference between treatment groups regarding to frequency of the answers related to bleaching longevity ($p = 0.8$). Data from participants’ perception about bleaching longevity are shown in Table 4.

Fig. 5 – Delta $E^*$ for 10% and 16% carbamide peroxide concentrations.

<table>
<thead>
<tr>
<th>Variables related to dietary behavior</th>
<th>2-year evaluation</th>
<th>$p$ 10–16</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CP10 ($n = 42$)</td>
<td>CP16 ($n = 39$)</td>
</tr>
<tr>
<td>Staining beverage consumption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>36 (85.7%)</td>
<td>36 (92.3%)</td>
</tr>
<tr>
<td>No</td>
<td>2 (4.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Sometimes</td>
<td>4 (9.5%)</td>
<td>0 3 (7.7%)</td>
</tr>
<tr>
<td>Diversity of staining beverages intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One type</td>
<td>3 (7.1%)</td>
<td>3 (7.7%)</td>
</tr>
<tr>
<td>Two types</td>
<td>8 (19.0%)</td>
<td>8 (20.5%)</td>
</tr>
<tr>
<td>Three types</td>
<td>12 (28.6%)</td>
<td>13 (33.3%)</td>
</tr>
<tr>
<td>Four types</td>
<td>9 (21.4%)</td>
<td>9 (23.1%)</td>
</tr>
<tr>
<td>Five types</td>
<td>8 (19.0%)</td>
<td>6 (15.4%)</td>
</tr>
<tr>
<td>None</td>
<td>2 (4.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Daily frequency of staining beverage intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once a day</td>
<td>13 (31.0%)</td>
<td>12 (30.8%)</td>
</tr>
<tr>
<td>Two or three times/day</td>
<td>25 (59.5%)</td>
<td>21 (53.8%)</td>
</tr>
<tr>
<td>Four or more times/day</td>
<td>4 (9.5%)</td>
<td>6 (15.4%)</td>
</tr>
<tr>
<td>Staining food consumption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32 (76.2%)</td>
<td>33 (84.6%)</td>
</tr>
<tr>
<td>No</td>
<td>10 (23.8%)</td>
<td>6 (15.4%)</td>
</tr>
<tr>
<td>Diversity of staining food intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One type</td>
<td>3 (7.1%)</td>
<td>8 (20.5%)</td>
</tr>
<tr>
<td>Two types</td>
<td>8 (19.0%)</td>
<td>2 (5.1%)</td>
</tr>
<tr>
<td>Three types</td>
<td>14 (33.3%)</td>
<td>9 (23.1%)</td>
</tr>
<tr>
<td>Four types</td>
<td>17 (40.5%)</td>
<td>20 (51.3%)</td>
</tr>
<tr>
<td>Daily frequency of staining food intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once a day</td>
<td>35 (83.3%)</td>
<td>24 (61.5%)</td>
</tr>
<tr>
<td>Two or three times/day</td>
<td>7 (16.7%)</td>
<td>15 (38.5%)</td>
</tr>
<tr>
<td>Four or more times/day</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Differences were considered statistically significant when $p < 0.05$.

<table>
<thead>
<tr>
<th>Treatment groups</th>
<th>Scores attributed for longevity of whitening effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (no shade relapse)</td>
</tr>
<tr>
<td>CP10</td>
<td>4 (9.5%)</td>
</tr>
<tr>
<td>CP16</td>
<td>6 (15.4%)</td>
</tr>
</tbody>
</table>

Table 4 – Scores attributed for participants’ perception about longevity of whitening effect at 2-year follow-up.
4. Discussion

Dental bleaching has become a more popular treatment and a
crescent number of bleaching agents are available in the
market, for either professional use or self-application.\textsuperscript{3,10,11} Manufacturers have commonly claimed that higher hydrogen
peroxide-based agents are more effective and have a long-
lasting whitening effect than low-concentrated gels. However,
this study demonstrated that the use of 16% carbamide
peroxide did not increase the efficacy or longevity of the
whitening effect when compared to the gel with 10%
carbamide peroxide. Other studies have also shown that the
increase of bleaching agent concentration seems not to
enhance the treatment’s effectiveness or longevity.\textsuperscript{4,6,13,14,16}

In dental clinics, generally when the patients ask practi-
tioners when they should perform a re-bleaching treatment,
the usual answer is “about 2 years after the first treatment”.
Considering the tooth shade medians, in our study at the 2-
year follow-up no significant color relapsing was observed for
both carbamide peroxide concentrations tested. The number
of patients who maintained a shade change of four or more
shade units from baseline was 81% for CP10 and 87% for CP16,
which is in accordance with the efficacy levels established by
ADA\textsuperscript{23} for 6 months post-initiating treatment. Long-term
clinical trials with 10% carbamide peroxide have shown that
83.3% of the patients had a shade change of two or more units
after 2 years post-bleaching\textsuperscript{17} or a color stability of 43% at
approximately 10 years post-treatment.\textsuperscript{18} When comparing
10% carbamide peroxide with high concentrated bleaching
agents, short-term clinical trials have shown that the efficacy
and longevity of home-use technique is better than\textsuperscript{4} or
similar\textsuperscript{6,13,14} to in-office treatments.

When analyzed the CIELAB parameters, $\Delta E^*$ values
remained at least four units greater than at baseline from
both concentrations tested, which indicates that there is still
color change perceptible clinically.\textsuperscript{23} However, it was observed
an increasing of $a^*$ (redness) and $b^*$ (yellowness) values for
both CP10 and CP16 groups when compared to the end of the
treatment. These findings can indicate the beginning of the
tooth color reversal, since that more positive changes in $a^*$ or
$b^*$ will result in more intensity of chroma.\textsuperscript{23,27}

Despite the fact that the consumption of staining beverages
and foods is frequently associated to tooth discoloration,\textsuperscript{7,28}
most of the studies have not reported the patients’ dietary
habits after tooth bleaching treatment. This study demonstrat-
ed that although the participants have reported a consumption
of staining beverages and foods as high as the previous
evaluations periods,\textsuperscript{7,24} the influence of dietary aspects in tooth
bleaching longevity seems to have been slight and gradual.

After 2 years post-bleaching, more than 71% of participants
for each treatment group reported being satisfied with tooth
appearance. Previous studies have also reported that home
bleaching treatment is more accepted by patients than the in-
oneffice techniques.\textsuperscript{5,14} Although the spectrophotometer analy-
sis has not demonstrated a larger tooth color relapse, more
than 66% of participants reported to notice a tooth color
relapse ranging from mild to moderate. Such finding could be
expected once this questionnaire was applied after 2 years and
generally the patients will attain the memory of their former
tooth color for only a few weeks.

The results of this study indicate that at-home tooth
bleaching with custom trays associated with low-concentrat-
ed agents is an effective treatment keeping the whitening
effect for the evaluated period. Overall, the findings of this
study demonstrated that it is not necessary to increase the
bleaching agent concentration to enhance the whitening
effect and the longevity of the treatment.

5. Conclusion

After 2 years post-bleaching, both carbamide peroxide con-
centrations tested sustained a lighter tooth shade than at
baseline evaluation and there was no difference between
treatment groups. Tooth shade relapse associated to increas-
ing of $a^*$ and $b^*$ color parameters could be observed for both
CP10 and CP16 groups when compared to 1-month evaluation.

Although most of the participants reported being satisfied
with tooth shade appearance, approximately 66% of the
subjects from each treatment group reported a tooth shade
relapse from mild to moderate.

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