Clinical Evaluation of the Efficacy of 10% Carbamide Peroxide Bleaching Agent Used During Night-Time and Day-Time

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Abstract: This split-arch clinical study was performed to compare the effects of using 10% carbamide peroxide bleaching agent for one hour twice a day with its use for 8 hours/night on tooth color change, color stability and sensitivity.

Method: Bleaching trays, with reservoirs for the six maxillary anterior teeth, were fabricated for 12 volunteers. The trays were cut into two halves between the left and right central incisors (day-side vs. night-side) to be used with 10% carbamide peroxide for two weeks. The day-side tray was applied for one hour twice a day, while the night-side was applied for 8 hours overnight. Objective color measurements, using a colorimeter, were adopted to measure the color of the teeth of the two sides at the baseline appointment and at 1, 2, 3, 6 and 12 weeks. Total color difference (ΔE*) between two color measurements was calculated for all periods. Teeth and soft-tissue sensitivity were self-recorded for both sides during the bleaching weeks and the following week. Both Student's
t-test and Tukey's test were used to compare ΔE* between the two sides and with time at p<0.05.

**Results:** Both sides showed significant differences in ΔE* over time (p<0.05). However, no significant differences were recorded between the two sides at each measuring period (p>0.05).

**Conclusion:** At-home bleaching treatment using 10% carbamide peroxide for one hour twice daily produced similar tooth color change, stability and sensitivity with its use for 8 hours/night.

**Key words:** bleaching, carbamide peroxide, split-arch, colorimeter.

**Introduction**

Improving the color of people's teeth enhances not only their smile but also their self-esteem. Vital teeth bleaching techniques are considered the most conservative means for improving the appearance of discolored teeth. Three techniques are available for vital teeth bleaching; in-office, at-home and over-the-counter (OTC) products [1]. All of which have proven to be effective in teeth whitening. However, each technique has its pros and cons [2]. At-home vital teeth bleaching system, using 10% carbamide peroxide (CP), has become very popular as it is considered to be noninvasive and probably the safest, cost-effective, and patient-pleasing technique for teeth whitening [2].

Several researchers have compared the efficacy of 10% CP at-home bleaching agent with different in-office bleaching techniques [3-7]. Others have compared its efficacy with OTC products [7]. Researchers have addressed that teeth whitening is most effective using at-home bleaching trays with a 10% CP
bleaching agent when applied for eight hours/day for about 14 days [8,9]. However, a major drawback of this technique is patients' compliance [10]. Using the bleaching tray for several hours/day could be irritating and unendurable for some patients. Besides, patients sometimes need to reduce the insertion time, as a result of sensitivity and/or change of their lifestyle [10], without compromising the efficacy of the treatment. Reducing the time of insertion should be associated with the use of higher concentration of bleaching agent in order to get similar teeth whitening [10-12]. However, higher prevalence of tooth sensitivity can be produced with bleaching agents of higher concentrations [3,10]. Basting et al. [4] reported that teeth sensitivity may be attributed not only to the concentration of peroxide but also to the time length that the agent is in contact with the dental structures. Hence, providing the patients with an efficient, inexpensive, side-effect free and tolerable type of teeth bleaching regimen is still a challenge.

It is essential that the clinical evidence for the effects of a bleaching agent on teeth color change and stability be supported by the results of clinical studies that employs the same concentration of the bleaching agent with similar bleaching protocol or at least with a close study protocol. Few clinical studies have compared 10% CP when used overnight with other at-home bleaching agents or concentrations [13-16]. Grobler et al. [17] compared 10% CP (Opalescence PF) and 10% CP (Nite White) when used overnight. Cardoso et al. [18] compared the effect of one application of 10% CP at different timings on the teeth color change and subjects' satisfaction. However, up to date, no data is available on the effects of the same bleaching agent on the teeth color change, stability and teeth sensitivity at different timings using a split-arch design. Such studies can reduce the impact of tooth-related and patient-habit variables that may influence the results [3]. Therefore; the aim of the current study was to compare the effects of 10% CP bleaching
agent when used for one hour twice daily with its use for 8 hours overnight on teeth color change, color stability and sensitivity.

**Materials and Methods**

This study was approved by the Ethics Committee of the related university. Upon approval, 12 volunteers were enrolled. Selection criteria included: 1) The presence of six sound caries-free maxillary anterior teeth; 2) No significant periodontal disease and 3) Willingness to sign a consent form. Prior to the commencement of the study, all subjects were given a dental screening and prophylaxis. Two alginate impressions of each subject’s maxillary arch were taken and poured with dental stone to make two models. Reservoirs on the labial surfaces of the six anterior teeth of the first model were performed using a light-cured resin block-out material (LC block-out resin, Ultradent Products). Bleaching trays were later fabricated, with a 0.035-inch thick soft vinyl sheet (Ultradent Products), in a heat/vacuum tray-forming machine. The trays were trimmed just short of the gingival margin. The trays were then cut into two halves between the left and right central incisors. One half-arch tray to be used for one hour twice a day, while the other half to be used overnight for 8 hours. The sides (left side vs. right side) to be used during the daytime or nighttime were determined by flipping a coin. In order to ensure that no switching between the two half-arch trays would happen, two tray boxes (one for each half-arch tray) were given to each subject to keep the half-arch trays in. The half-arch tray to be used during the day was put in a tray box that has the word "Day" on top of it, while the other half was kept in another tray box that hold the word "Night" on it.

Three bleaching syringes of 10% CP Opalescence PF bleaching gel (Ultradent Products Inc, South Jordan, UT, USA), a commercially available home bleaching system, were given to each
subject. The subjects were instructed to place the correct amount of bleaching agent into the half-arch trays and to be used for 14 consecutive days.

Teeth color change evaluation was performed at the baseline appointment and at one, two, three, six and twelve weeks by:

1) Objective color measurements using Vita Easyshade colorimeter (Vita Zahnfabrik; H. Rauter GmbH & Co, KG, Bad Sackingen, Germany) in a standardized illumination condition. Positioning trays, with 6 mm diameter spots facing the center of the six maxillary anterior teeth surfaces, were fabricated using the second cast model to ensure a standardized position of the measuring spot of the colorimeter. The values showed by the colorimeter were recorded in reference to the CIE L*a*b* color system introduced by the Commission International de l´Eclairage in 1976. Based on the CIE L*a*b* color system, the coordinates L*, represents the lightness; while a*, represents shade and saturation in the red-green axis; and b*, represents saturation in the blue-yellow axis [3]. The color difference (ΔE*) between two color measurements was calculated as [19]:

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

2) A subjective color change evaluation was clinically performed by two independent evaluators. The evaluators, who were unaware of the study design, were required to determine if color differences present between the left and right maxillary anterior teeth as: (Yes) referring to the lighter side or (No) when there is no color difference between the two sides. Teeth and gingival sensitivity evaluations was self evaluated by the subjects for the two bleaching weeks and
the following week after treatment. The subjects were instructed to record the type of sensitivity for both sides as: 0 = none, 1 = mild, 2 = moderate and 3 = severe type of sensitivity.

At the last evaluation visit, a questionnaire was given to the subjects to record their response to the followings:
1. Which side of the two sides is lighter?
2. Satisfaction with the results at week 2 and 12 periods.
3. Which technique of the two was preferred?

The results were analyzed using SPSS program (SPSS 19.0 for windows, SPSS Inc., Chicago, USA). Both the Student's t-test and Tukey's test were used to compare means of ΔL*, Δa*, Δb* and ΔE* between the two sides and with time at p<0.05. Repeated measure of variance (ANOVA) was used to compare measurements within time and between sides. Kruskal-Wallis test was used to determine the significant differences between the two sides in lighter sides recorded by the evaluators and teeth sensitivity.

Results

Table 1 presents the means (SD) of ΔL*, Δa* and Δb* for both the day and night-sides at each evaluation period. There was an overall improvement in all of the three color coordinates (L*, a*, and b*) for both day and night-sides. No significant differences were seen between the day and night-sides at all measuring periods (p>0.05).

Table 2 shows the means (SD) of ΔE*. Both sides showed significant differences in ΔE* over time (p<0.05), however, no significant differences were seen between the day and night-sides at each measuring period (p>0.05). Repeated measure analysis of variance showed that there was a statistically significant difference in teeth color change over time (p=0.000), with no significant differences between the two sides (p=0.256).
The clinical evaluation by the independent evaluators for the differences between the two sides is shown in Table 3. No significant differences between the day and night-sides were recorded at all measuring periods (p=0.390).

This result was supported by the participants' self-evaluation at week 2 and 12 periods (Figure 1).

Teeth sensitivity recorded by the participants showed no significant difference in sensitivity between the two sides at all the recorded periods (p>0.05) (Table 4).

Five subjects reported only minor type of teeth sensitivity during the first week period. Three of them recoded the sensitivity to be in the night-side, while the other two referred to the day-side. All of them reported spontaneous disappearance of teeth sensitivity in few days. Only one subject reported a local minor gingival sensitivity at the beginning of the bleaching treatment. This discomfort, which was ignored statistically, was due to over extension of the bleaching tray that was subsided after tray adjustment.

According to the subjects' exit questionnaire, only one subject referred to the night-side to be lighter at week 2. However, this teeth color differences between the two sides was not obvious by the end of week 12. Nine of the subjects were satisfied with the teeth whitening at week 2, while only three of them were still satisfied by the end of the 12 weeks. Concerning the preference of the technique, eight of the subjects preferred the night-time use, while four of them preferred the day-time use.

Discussion

At-home bleaching technique, using 10% CP bleaching agent overnight has shown to be the most effective technique for vital teeth bleaching [8,9]. CP bleaching agent when applied onto the tooth surface degrades to hydrogen peroxide (the active
bleaching agent) and urea. As these active peroxide agents diffuse from the gel into the tooth structure, they react with the organic colored materials present within the tooth causing a reduction in tooth color [2]. Thus, these agents need to be available for extended period of time for the whitening process to occur [20]. It is well known that the required daily time of tray use depends on the percentage of the peroxide that is applied [2]. The higher the concentration of the bleaching agent, the shorter time needed for it to be in contact with the tooth surface [10]. Therefore, CP with concentration of 10% needs to be used for a long period of time (8-10 hours/day). However, such kind of treatment regimen may not be tolerable for all patients need to undergo bleaching treatment and still seeking for effective and safe results within a shorter period of time. Increasing the concentrations of bleaching agents allows a reduction in the application time of the bleaching agent, since a greater amount of active ingredient will be available [15]. However, higher concentration and/or longer time the bleaching gel is in contact with the tooth surface can be associated with higher incidence of teeth sensitivity [4], and other harsh insults to the tooth substrates.

It has been reported that clinical efficacy and safety of bleaching agents are highly influenced by peroxide-retention kinetic [20]. Kinetic cycle of a bleaching agent means the degradation rate of bleaching-active agent at a specific time. It represents the rate of physical loss of peroxide (from the bleaching tray) plus the rate of peroxide lost from the chemical break down that are combined to determine the amount of the active agent remaining at different timings. In vivo studies showed that, the mean percentage of 10% CP recovered at one hour was about 66%, while the recovered amount after 6-10 hours was about 18-6% [20]. This indicates that carbamide peroxide agent undergoes rapid initial degradation and then it slows down with time [20]. The saturation
and diffusion of peroxide and oxygen into the tooth are likely responsible for the rapid initial degradation of the product [18]. Once the tooth is saturated with these agents, the reaction slows down, reducing the benefits of longer contact between the bleaching gel and tooth structures [18]. The results of the present study showed that no significant differences in teeth color changes were seen between the two sides. These results are supported by those of the later study, since double applications of fresh agent for one hour each resulted in a similar teeth whitening compared to a single application for eight hours. This indicates that most of the bleaching effect occurred during the period of saturation of the oxidizing agent. Therefore, a day-time use of fresh bleaching gel for two separated hours produced two effective bleaching hours compared with one effective bleaching hour plus slower and less effective seven hours during the nighttime use. Up to date, two key factors have been attributed to the efficacy of teeth whitening (time and concentration) [1,10,12]. According to the present results, a third factor needs to be considered in bleaching treatment which is the frequency of applications of the bleaching agent.

Previous clinical studies have reported different measurements for ΔE* by the end of the active bleaching treatment, as well as at the follow-up periods. These variations were due to the use of different concentrations of bleaching agents and/or different treatment protocols. The results of the present study recorded no significant difference in ΔE*2 between the day and night-sides. ΔE*2 for the day and night-sides were 8.58 and 9.24, respectively. These measurements are comparable to the ΔE*2 recorded by other studies [3,14,16,18]. On the other hand, color relapse for both the day and night-sides was recorded at week 12. ΔE*12 for the day and night-sides were 6.05 and 6.51, respectively. Such result is in accordance with those reported by Zekonis et al. [6] and Bizhang et al. [7]. The results of the present study indicate that such bleaching
regimens produced teeth whitening that could be maintained for up to three months which is in accordance with other studies [6,7,17,22].

Several clinical studies have used a subjective shade matching and slide evaluation to record teeth lightness. However, some differences between subjective and objective readings were recorded [21]. These differences were attributed to be resulted from limitations of the human eye. Subjective perception of color may be affected by color adaptation, background of viewing area or the light source illuminating the color [18]. In the present study, a subjective clinical evaluation was adopted to record only the presence of differences in teeth lightness between the two sides, referring to the lighter side. This evaluation may not need much of experience in shade evaluation nor calibration. The clinical evaluation between the two sides has given a simple and direct method of comparison. However, such an evaluation cannot be used for comparison with the other periods. The result of the clinical evaluation of the present study supported the results recorded by the objective color measurements in which no significant differences were recorded between the day and night sides at all periods.

Most of the concerns attributed to at-home bleaching system are related to the adverse effects associated with it such as; teeth and gingival sensitivity. The results of the present study recorded no significant differences in teeth and gingival sensitivity between the day and night-sides. Only mild-type of teeth sensitivity was recorded during the active bleaching period that was subsided spontaneously. Several studies concluded that mild and transient tooth sensitivity might be accompanied tooth bleaching with 10% CP. These effects disappear spontaneously after the treatment period without causing sequelae or complications [13,18,22]. Besides, bleaching gels with desensitizing agent, produce lower
tooth sensitivity rates [13,18]. The results of the present study support the results of the later studies, since the bleaching agent used in this study was 10% CP (Opalescence PF), contains 0.11% fluoride ion and potassium nitrate.

According to the subjects' exit questionnaire, 75% of the subjects were satisfied with the teeth whitening immediately after the active bleaching treatment (week 2). However, by the end of the 12 weeks period, only 25% were satisfied with their teeth whitening. Cardoso et al. [18] reported that immediately after 16 days of active treatment, all the participants used the bleaching gel for 8 hours/day were satisfied with their teeth whitening, however, those bleached their teeth for only one hour/day needed longer time to reach satisfaction. Concerning preference of the technique, 66.7% of the subjects preferred the night use of the bleaching tray. However, 33.3% of the subjects stated that wearing the bleaching tray with a low concentration bleaching agent for one hour in the morning and another hour in the evening was not only well tolerated but also ensured safety and comfort. However, this technique needed double amount of the bleaching gel.

**Conclusion**

In conclusion and within the limitation of the present study, the following conclusions can be drawn:

1. At-home bleaching treatment for two weeks using 10% CP for one hour application twice daily can produce no significant difference in teeth whitening compared with 8 hours/night.

2. Both bleaching regimens produced teeth whitening that can be maintained for up to three months.
3. Teeth sensitivity accompanied two weeks at-home bleaching treatment with 10% CP (Opalescence PF), whether used for 8 hours/night or one hour twice daily, was mild and transient.

References

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**Table 1:** Mean (SD) of ΔL*, Δa*, and Δb* for day-side and night-side usage of 10% CP

<table>
<thead>
<tr>
<th>Week</th>
<th>Mean ΔL* (SD)</th>
<th>Mean Δa* (SD)</th>
<th>Mean Δb* (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day side</td>
<td>Night side</td>
<td>Day side</td>
</tr>
<tr>
<td>1</td>
<td>3.23 (2.35)</td>
<td>3.52 (2.51)</td>
<td>-1.12 (0.81)</td>
</tr>
<tr>
<td>2</td>
<td>5.41 (2.68)</td>
<td>5.62 (2.40)</td>
<td>-1.45 (0.95)</td>
</tr>
<tr>
<td>3</td>
<td>3.39 (2.49)</td>
<td>3.70 (2.10)</td>
<td>-1.16 (0.95)</td>
</tr>
<tr>
<td>6</td>
<td>2.55 (2.50)</td>
<td>2.76 (2.44)</td>
<td>-1.10 (1.11)</td>
</tr>
<tr>
<td>12</td>
<td>2.15 (2.33)</td>
<td>2.23 (2.11)</td>
<td>-1.12 (1.04)</td>
</tr>
</tbody>
</table>

**Table 2:** Means and standard deviations (SD) of ΔΕ* for the Day and Night sides

<table>
<thead>
<tr>
<th>ΔΕ*</th>
<th>Side</th>
<th>Mean*</th>
<th>S D</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΔΕ*1</td>
<td>Day</td>
<td>5.79 a</td>
<td>2.76</td>
</tr>
<tr>
<td></td>
<td>Night</td>
<td>6.84 d</td>
<td>3.00</td>
</tr>
<tr>
<td>ΔΕ*2</td>
<td>Day</td>
<td>8.58 abc</td>
<td>3.16</td>
</tr>
<tr>
<td></td>
<td>Night</td>
<td>9.24 de</td>
<td>3.40</td>
</tr>
<tr>
<td>ΔΕ*3</td>
<td>Day</td>
<td>7.01</td>
<td>3.38</td>
</tr>
<tr>
<td></td>
<td>Night</td>
<td>8.12</td>
<td>3.48</td>
</tr>
<tr>
<td>ΔΕ*6</td>
<td>Day</td>
<td>6.33 b</td>
<td>2.95</td>
</tr>
<tr>
<td></td>
<td>Night</td>
<td>7.16</td>
<td>3.51</td>
</tr>
<tr>
<td>ΔΕ*12</td>
<td>Day</td>
<td>6.05 c</td>
<td>3.36</td>
</tr>
<tr>
<td></td>
<td>Night</td>
<td>6.5 e</td>
<td>3.49</td>
</tr>
</tbody>
</table>

*Values with the same letters are significantly different at p<0.05*
Clinical evaluation of the efficacy of 10% carbamide peroxide...

Table 3: Clinical evaluation for the lighter side by the independent evaluators

<table>
<thead>
<tr>
<th>Week</th>
<th>No color Difference (# of subjects/12)</th>
<th>Lighter color (# of subjects/12)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Day-side</td>
</tr>
<tr>
<td>0</td>
<td>12/12</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>10/12</td>
<td>2/12</td>
</tr>
<tr>
<td>2</td>
<td>11/12</td>
<td>1/12</td>
</tr>
<tr>
<td>3</td>
<td>11/12</td>
<td>1/12</td>
</tr>
<tr>
<td>6</td>
<td>12/12</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>12/12</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Tooth and gingival sensitivity recorded by the subjects for the two bleaching weeks and the following week after treatment

<table>
<thead>
<tr>
<th>Week</th>
<th>No teeth sensitivity (# of subjects/12)</th>
<th>More sensitive (# of subjects/12)</th>
<th>Gingival sensitivity (# of subjects/12)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Day-side</td>
<td>Night-side</td>
</tr>
<tr>
<td>0</td>
<td>12/12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7/12</td>
<td>2/12</td>
<td>3/12</td>
</tr>
<tr>
<td>2</td>
<td>12/12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>12/12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 1: Three participants (A, B, & C) showing the Day-side vs. Night-side of the maxillary arches at week 2 and week 12 periods.
تقييم سريري لتاثير استخدام مبيض الأسنان البيتي 10% كاربومايد بيروكسايد خلال الليل أو النهار

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المستخلص

تبييض الأسنان باستخدام العلاج البيتي باستعمال 10% كاربومايد بيروكسايد لمدة 8 ساعات ليلا كل يوم لمدة أسبوعين يعمل على تبييض الأسنان بكفاءة ولكن مثل هذا النوع من النظام العلاجي قد يكون غير مناسب لجميع طالبي الحصول على تبييض امن وسهل الاستخدام.

طريقة العمل: تم تطوير 12 متطوع لتطبيق دراسة سريرية لمقارنة استخدام مادة التبييض المذكورة اعلاه لمدة اسبوعين باستخدام نظريات علاجية مختلفة والمقدمة بينها. تم عمل قوالب التبييض للفك العلوي لجميع المتطوعين ثم تم قطع القالب الى نصفين حيث يتم استخدام احد الالصاف لمدة ساعة واحدة فقط مرتين باليوم أما النصف الاخر يتم استخدامه 8 ساعات ليلا. عملية التغيير في لون الأسنان للجانبين تم قياسها باستخدام جهاز قياس الالوان قبل تبييض وبعد الاسبوع الأول والثاني والثالث والسادس والثاني عشر من التبييض. كما قام مقيم مستقلين اثنان بتقييم الجانبين ليبان إذا كان هناك فرق بين الجانبين وتحديد اي منها اكثر بياضا. كمتتم تسجيل مقدار حساسية الأسنان في الجانبين من قبل المتطوعين انفسهم.

النتائج: أظهرت النتائج وجود فرق مميز في التبييض مع الوقت لكن ليس هناك فرق في التبييض بين الجانبين. كما ليس هناك فرق في كمية حساسية الأسنان في كلا الجانبين.

الاستنتاجات: تبييض الأسنان البيتي باستخدام 10% كاربومايد بيروكسايد لمدة ساعة واحدة مرتين باليوم ينتج عنه تبييض مشابه لاستخدامه لمدة 8 ساعات ليلا.

الكلمات الرئيسية: تبييض، كاربومايد بيروكسايد، جهاز قياس الالوان.