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A Clinical Evaluation of a Bleaching Agent Used With and Without Reservoirs

BA Matis • M Yousef
MA Cochran • GJ Eckert

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Clinical Relevance

There is no clinical difference in tooth whitening after two hours of tray use whether or not reservoirs are present.

SUMMARY

This *in vivo* study evaluated the variation of tray fabrication (trays constructed with or without reservoirs) on the degree of color change of teeth and sensitivities associated with using a 15% carbamide peroxide bleaching agent for two hours once daily for 14 days.

Patients returned in one, two, three, six and 12 weeks. Color changes were evaluated by subjective shade matching, comparing clinical photographs and through measurements obtained using a color-measuring device. Subjects were asked to keep a daily record of any tooth and gingival sensitivity on the right and left side of their maxillary dental arch for three weeks.

Indiana University School of Dentistry, Clinical Research Section, 1121 West Michigan Street, Indianapolis, IN 46202

Bruce A Matis DDS, MSD, director, Clinical Research Section

Yaser S Hamdan BDS, MSD, graduate student, Operative Dentistry

Michael A Cochran DDS, MSD, director, Graduate Operative Dentistry Program

George J Eckert MS, biostatistician, School of Medicine

Colorimeter data showed that teeth lightened with agent with reservoirs were significantly lighter than teeth lightened with the same agent without reservoirs. However, the amount of lightening was below the threshold of visual differentiation. Shade guide and slide photography data showed no significant differences between teeth lightened with agent with reservoirs compared to teeth lightened with the same agent without reservoirs. In addition, no significant differences in tooth and gingival sensitivity were found between the tray side with reservoirs and those without reservoirs.

INTRODUCTION

At-home tooth bleaching using peroxide-containing materials has become very popular (*Clinical Research Associates*, 1997; *Dental Advisors*, 2000), and currently, more than 45 different products are available. Palmer (1995) showed that among dental practitioners in the US, those providing professional in-office tooth bleaching had decreased from 56% in 1993 to 44% in 1995; however, dentists dispensing at-home whitener had increased from 79% to 95% during the same period.

A very relevant question in the science of bleaching is whether reservoirs are necessary. In 1997, Haywood concluded in a pilot study that there was no apparent difference in the bleaching rate with or without reservoirs. Without using reservoirs in the bleaching tray,

the amount of bleaching material used to lighten teeth would be reduced as well as the time for tray fabrication.

This *in vivo* study evaluated the effect of using reservoirs vs not using them on the degree of color change, rebound effects and sensitivities associated with the daytime use of an at-home bleaching agent. A half-arch design with reservoirs on one side of each subject's bleaching tray and no reservoirs on the other was used.

METHODS AND MATERIALS

The manufacturer (Rembrandt Xtra-Comfort Non-Sensitizing Bleaching Gel Regular Strength, Den-Mat Corp, Santa Maria, CA 93456, USA) supplied the bleaching agent used in this double-blind study. It had a 15% concentration of carbamide peroxide.

Subjects who met the inclusion/exclusion criteria (Table 1) were randomly divided into two groups. Two alginate impressions of each subject's maxillary arch were taken. The first model was used to fabricate the bleaching tray. Paint-On Dental Dam (Den-Mat Corp) was applied as a block-out material to the central and lateral incisor and the canine on one side of the arch to create tray reservoirs on these teeth. The block-out was applied so that the labial surface was covered with the exception of 1 mm mesially, distally and cervically. The other half arch had no reservoirs (Figure 1). A study monitor randomly assigned which side of the maxillary arch would have reservoirs. The trays were made by a vacuum-formed process using Sheet Resin (Den-Mat Corp). As recommended by the manufacturer, the excess was trimmed on the labial and lingual surfaces to the gingival junction. The subjects were instructed by the study monitor regarding how to place the correct amount of whitening agent in the tray.

The second study model was used to construct a positioning jig with full palatal coverage. The jig was indexed with a dual-prong precision attachment (Coltene/Whaledent Mahwah, NJ 07430, USA) to ensure that the light-measuring device could be precisely repositioned at each evaluation. Extrinsic stains of the teeth were removed with a dental prophylaxis using Nupro prophylaxis fluoride paste (Dentsply, Preventive Care, York, PA 17404, USA). The prophylaxis was performed at least two weeks prior to initiating the active study phase. Preoperative evaluation was done on the maxillary anterior teeth and their surrounding soft tissues. During the preoperative evaluation, a Loe & Silness Gingival Index was conducted to qualify patients for the study. The maxillary teeth were then evaluated by: 1) clinical photographs recorded with Ektachrome Elite 100, 35 mm color slide film (Kodak, Rochester, NY 14650, USA) with a shade tab of B-54 in each slide frame as a constant color; 2) shade matching of right and left anterior teeth with Trubyte Bioform Color Ordered Shade Guide (Dentsply, Trubyte, York, PA 17405, USA) and 3) Colorimeter

Table1: Inclusion/Exclusion Criteria to Qualify for Study

| Inclusion Criteria |
|--|
| <ul style="list-style-type: none"> • Have all six maxillary anterior teeth. • None of the maxillary anterior teeth can have more than 1/6 of the labial surfaces of the natural tooth covered with a restoration, and the location must not interfere with colorimeter placement. • All six anterior teeth must be darker than B54 and lighter than B85 on the Trubyte Bioform Color Ordered Shade Guide. • None of the maxillary anterior teeth can be excessively rotated, such as mesiorotation or distorotation, which interferes with colorimeter placement. • Be willing to sign a consent form. • Be at least 18 years of age. • Be able to return for periodic examinations. • Be willing to refrain from the use of tobacco products during the study period. |
| Exclusion Criteria |
| <ul style="list-style-type: none"> • A history of any medical condition that may interfere with the study or require special attention, such as tuberculosis, hepatitis, AIDS, AIDS-related disease, other infectious disease, blood disorders, pacemaker, any other condition requiring pre-medication and other conditions left up to the judgment of the principal investigator. • Use of any kind of tobacco products during the preceding 30 days. • Subjects who have used professionally applied or prescribed tooth whiteners, whether in-office or at-home, in the preceding five years. • Gross pathology in the oral cavity (excluding caries). • Gingival index score greater than 1.0. • Intrinsic discolored teeth due to tetracycline staining. • Pregnant or lactating women. |

readings (Chroma Meter Model SR-321 Minolta, Ramsey, NJ 07446, USA) to measure L*, a* and b* of the six maxillary anterior teeth using the custom-fitted positioning jig (Figure 2).

The L*, a* and b* color space system was defined by the Commission International de l'Eclairage in 1979 and is referred to as CIELAB (International Commission on Illumination, 1978). The L* represents the value where white is 100 and black is 0. A positive a* value indicates the red direction, a negative a* value the green direction, a positive b* value the yellow direction and a negative b* value the blue direction (Matis & others, 1998). Total color differences between two colors (ΔE) are calculated using the formula (International Commission on Illumination, 1978): $\Delta E_{ab*} = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

All subjects were instructed to insert the mouth guard containing the bleaching agent for two hours, once a day for 14 days. They were told to brush their teeth at least twice daily for oral hygiene standardization. Subjects were also asked to keep a daily record in five categories (1: no sensitivity; 2: slight sensitivity; 3: moderate sensitivity; 4: considerable sensitivity; 5: severe sensitivity) of any tooth or gingival sensitivity.



Figure 1. Maxillary arch with one side blocked out to fabricate reservoirs in trays.



Figure 3. Standard B-54 shade tab positioned in place during baseline photograph of maxillary arch.

During the active phase of treatment and for seven days after the cessation of bleaching, they were to indicate whether any sensitivity was present on the left or right side. Subjects experiencing more than a moderate degree of sensitivity after using the bleaching agent were asked to notify the study monitor. They were to be given Desensitizing Gel (Den-Mat Corp) containing 5% potassium nitrate to use in their tray to reduce sensitivity.

Patients were recalled at one, two, three, six and 12 weeks. Identical three-step examinations were conducted at each recall by the same examiners who conducted the pre-operative evaluation.

The photographs were compared by two experienced independent evaluators for color changes on the right and left sides of the maxillary arch. The evaluators categorized each side of the maxillary arch into one of four gradients (0: no difference; 1: slight; 2: moderate; 3: significant). While taking photographs, the subjects held a standard shade guide (B-54) beside their anterior teeth (Figure 3). If differences existed between the right or left sides, the evaluators were required to develop a consensus to determine the lighter side. The

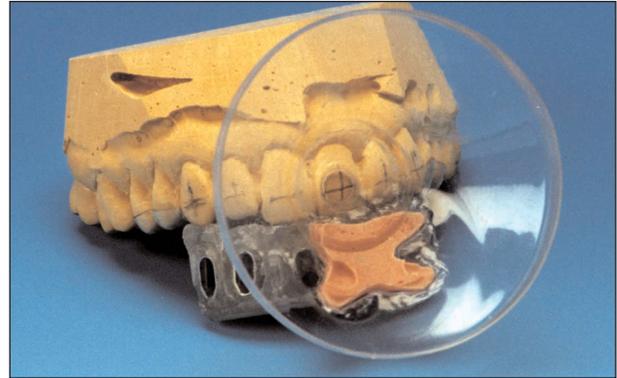


Figure 2. Custom-made jig on the maxillary arch with the cone head, which fits on the colorimeter, seated in place.

colorimeter was connected to a PC running Spectra QC software (Minolta, Ramsey, NJ 07446, USA) capable of directly recording and analyzing the readings, similarly to what had been accomplished in a previous study (Mokhlis, 1998).

Statistical Methods

Assignment to half-tray type (half with reservoirs and the other half without) was examined for baseline differences in colorimeter measurements and shade guide rank order using analysis of variance (ANOVA). The ANOVA models included fixed effects for tooth type, half-tray and tray-by-tooth interaction, and a random subject effect to correlate multiple measurements from each subject.

Change in colorimeter measurements and shade guide rank orders were computed by subtracting the baseline from the follow-up measurements. The ΔL^* , Δa^* , Δb^* , ΔE and change in shade guide comparisons were made using ANOVA. The ANOVA included fixed effects for tooth type, half-tray type, examination and interactions between those effects. Baseline values were included as covariates. Random subject effects were included to correlate measurements on multiple teeth and to correlate measurements on the same teeth at multiple examinations. Pairwise comparisons between half-tray types were made using Tukey's multiple comparisons procedure to control the significance level for each comparison at 5%.

At each exam, Wilcoxon Signed Rank tests were used to determine whether using the reservoir resulted in significantly lighter shades according to the clinical slide assessments.

Gingival and tooth sensitivity comparisons were performed using ANOVA with fixed effects for half-tray type, day, half-tray type by-day interaction and random subject effects to correlate the sensitivities within and between days.

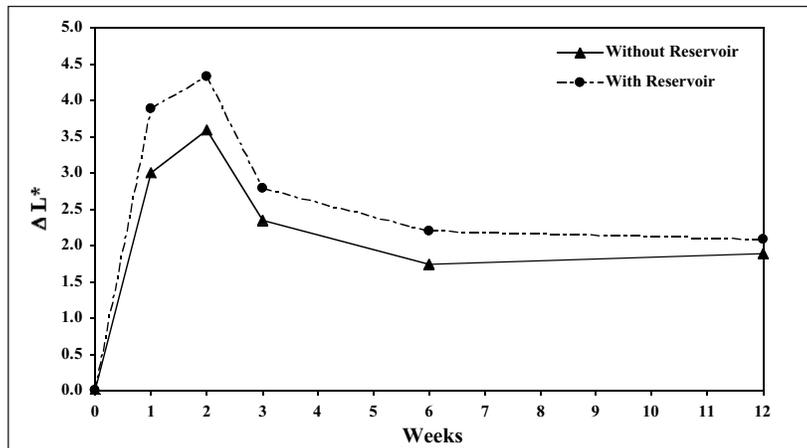


Figure 4. Change in ΔL^* over 12 weeks for teeth in quadrant lightened with agent in tray with reservoirs and the adjacent quadrant without reservoirs.

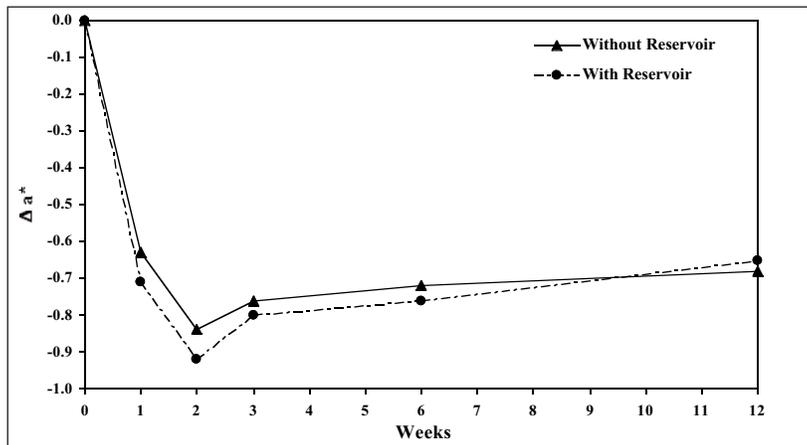


Figure 5. Change in Δa^* over 23 weeks of teeth in quadrant lightened with agent in tray with reservoirs and the adjacent quadrant without reservoirs.

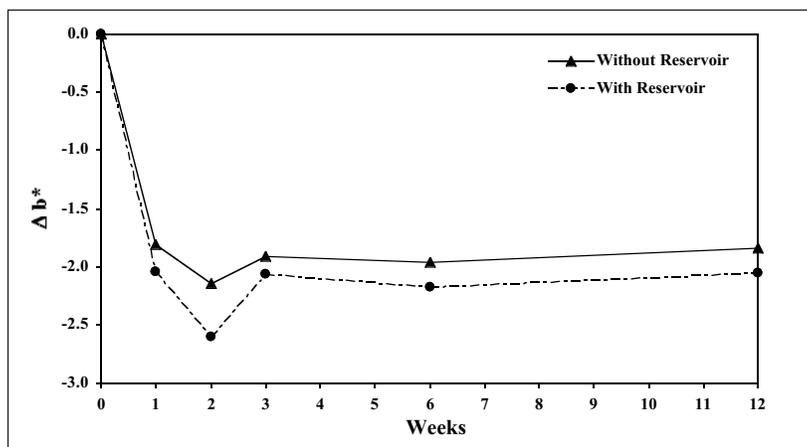


Figure 6. Change in Δb^* over 12 weeks for teeth in quadrant lightened with agent in tray with reservoirs and the adjacent quadrant without reservoirs.

RESULTS

Twenty-seven subjects were enrolled and completed the study, including 12 males and 15 females ranging in age from 23 to 68 years (average age being 48.3). Thirteen patients were assigned custom trays with reservoirs on the left anterior quadrant and 14 patients were assigned custom trays with reservoirs on the right anterior quadrant of their maxillary arch.

Chroma Meter Data

Neither side had a significantly different baseline L^* ($p=0.20$), a^* ($p=0.57$), b^* ($p=0.24$) or shade guide ($p=0.77$).

ΔL^*

Quadrants lightened with agent in a tray with reservoirs had significantly higher ΔL^* than quadrants lightened with agent without reservoirs overall ($p=0.0045$) and for week 1 ($p=0.0006$), week 2 ($p=0.0063$), week 3 ($p=0.0367$) and week 6 ($p=0.0271$), but not for week 12 ($p=0.33$). ΔL^* continued to change over time until week 6, but there was no significant change between week 6 and 12 ($p=0.93$) (Figure 4).

Δa^*

Quadrants lightened with agent in a tray with reservoirs and adjacent quadrants lightened without reservoirs had significantly different Δa^* for week 2 ($p=0.0424$) and marginally different Δa^* for week 1 ($p=0.06$). No significant difference between quadrants lightened with reservoirs and without reservoirs was found for Δa^* overall ($p=0.14$) or for week 3 ($p=0.20$), week 6 ($p=0.15$) or week 12 ($p=0.92$) (Figure 5).

Δb^*

Quadrants lightened with agent in a tray with reservoirs had significantly different Δb^* than an adjacent quadrants lightened without reservoirs overall ($p=0.0055$) and for week 1 ($p=0.0418$), week 2 ($p=0.0031$), week 6 ($p=0.0063$) and week 12 ($p=0.0203$). Quadrants lightened in a tray with reservoirs had marginally different Δb^* than adjacent quadrants lightened without reservoirs for week 3 ($p=0.07$). Δb^* continued to change over time until week 3, but there were no significant changes after week 3 ($p>0.08$) (Figure 6).

ΔE

Quadrants lightened with agent in trays with reservoirs had significantly higher ΔE than adjacent quadrants lightened without reservoirs overall ($p=0.0028$) and for week 1 ($p=0.0006$), week 2 ($p=0.0035$), week 3 ($p=0.0326$) and week

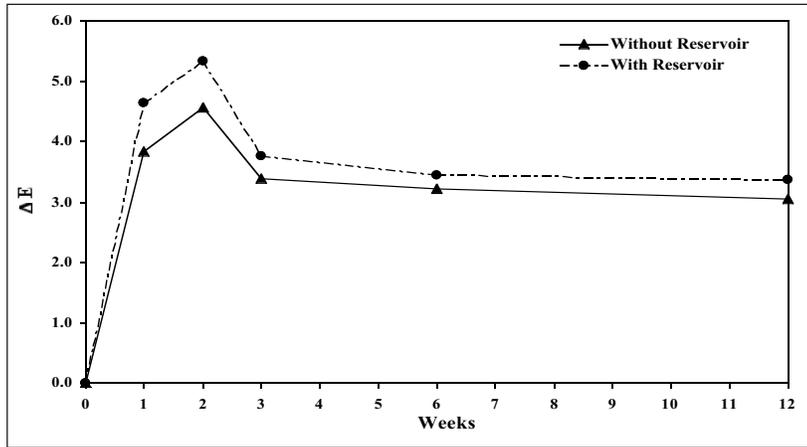


Figure 7. Change in ΔE^* over 12 weeks of teeth in quadrants and lightened with agent in tray with reservoirs and the adjacent quadrant without reservoirs.

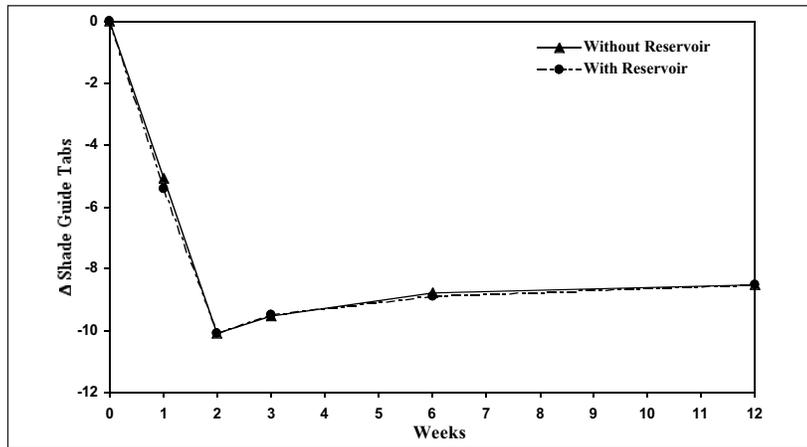


Figure 8. Change in Δ Shade Guide Tabs over a 12 week period with and without reservoirs.

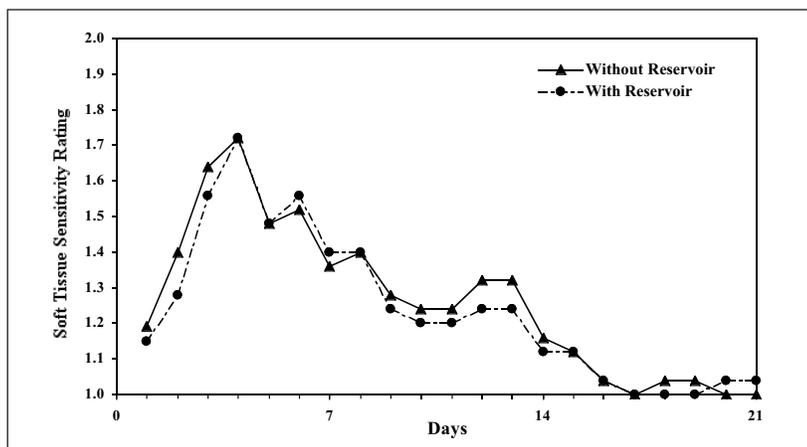


Figure 9. Change in soft tissue sensitivity over 14 days of bleaching and 7 days post-bleaching of teeth with and without reservoirs

12 ($p=0.0188$), but not for week 6 ($p=0.11$). ΔE continued to change over time until week 6, but there was no significant change between weeks 6 and 12 ($p=0.30$) (Figure 7).

Shade Guide Data

Figure 8 shows shade guide readings with and without reservoirs. No significant difference between teeth lightened with reservoirs and adjacent teeth lightened without reservoirs was present for shade guide readings overall ($p=0.78$) or at any specific exam ($p>0.25$). Shade continued to change over time until week 6; however, there was no significant change between week 6 and 12 ($p=0.27$) (Figure 7).

Slide Data

The presence of the reservoir did not have a significant effect on lightness, as determined by the clinical slide assessments at baseline ($p=1.00$) or any follow-up exam ($p>0.62$) (Table 2). Due to an overexposure of film during processing, only 11 of the 27 patients had slides that were of diagnostic value at week 2.

Sensitivity Data

No significant difference was present between a maxillary quadrant lightened with reservoirs and an adjacent quadrant lightened without reservoirs for either gingival sensitivity ($p=0.46$) (Figure 9) or tooth sensitivity ($p=0.90$) (Figure 10).

DISCUSSION

Few studies have evaluated the effects of tray fabrication design (Haywood, Leonard & Nelson, 1993; Javaheri & Janis, 2000; Bosma & others, 2000). Those studies used subjective shade guide matching and clinical photographs without the inclusion of an objective color-measuring device. Colorimeter data in this study showed that quadrants lightened with reservoirs produced significantly higher ΔL^* , Δb^* and ΔE than adjacent quadrants lightened without reservoirs. However, the subjective shade matching and slide evaluation showed no significant difference between teeth lightened with reservoirs and those lightened without reservoirs. The difference between subjective and objective readings probably resulted from limitations of the human eye. The colorimeter expresses minute differences in color in numerical form, while subjective perception of color may be affected by color adaptation, background of viewing area or the light source illuminating the color. Colorimeters have sensitivities corresponding to those of the human eye, but, because they always take measurements using the same light source and illumination method, the measurement conditions are much more standardized.

| Weeks | Without Reservoir Slightly Lighter | No Difference | With Reservoir Slightly Lighter | Total |
|-------|------------------------------------|---------------|---------------------------------|-------|
| 0 | 0 | 26 | 1 | 27 |
| 1 | 1 | 23 | 3 | 27 |
| 2 | 1 | 8 | 2 | 11 |
| 3 | 2 | 23 | 2 | 27 |
| 6 | 0 | 26 | 1 | 27 |
| 12 | 1 | 26 | 0 | 27 |

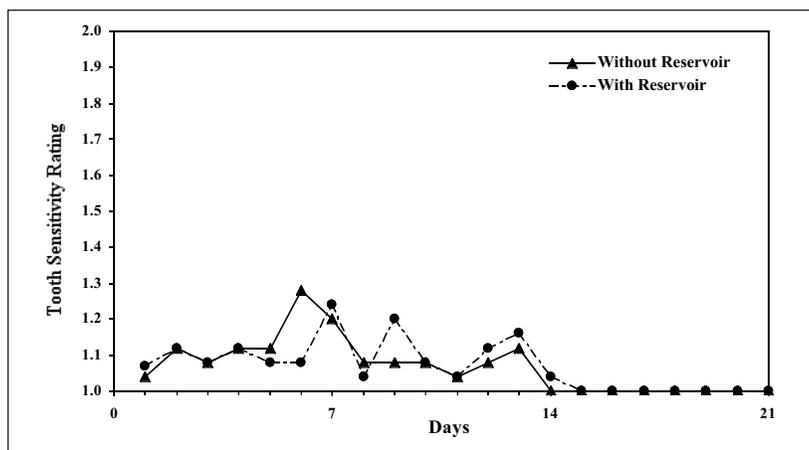


Figure 10. Change in tooth sensitivity over 14 days of bleaching and 7 days of post-bleaching of teeth with and without reservoirs.

A recent crossover study by Yousef (2002) compared degradation of nine different products. Six used no reservoirs and three used reservoirs. The results showed that the percentage of carbamide peroxide recovered after two hours (50%) was significantly higher for trays designed with reservoirs than for trays designed without them (19%). However, the carbamide peroxide percentage in teeth samples in Yousef's study were not affected by whether or not reservoirs were used, within the same concentration (3.5 +/- 1.0 without reservoir vs 3.7 +/- 0.4 with reservoir for 10% CP, 5.2 +/- 1.4 vs 6.9 +/- 0.6 for 15% or 16% CP, 7.5 +/- 1.6 vs 7.5 +/- 0.9 for 20% or 22% CP). Similar results were obtained for the carbamide peroxide percentage in tray samples. This indicates that the availability of gel and not the bulk of material present is important.

A study by Panich (1999) compared 15% carbamide peroxide and 5.5% hydrogen peroxide applied for a half-hour, twice daily for 14 days. In that study, all trays were designed with reservoirs. They reported a mean ΔE of 4.42 and 3.44, at 2 weeks and 6 weeks, respectively. In this study, the mean ΔE for two-hour daily exposure of 15% carbamide peroxide at 2 weeks was 4.56 without reservoirs, 5.33 with reservoirs. At 6 weeks, ΔE in this study was 3.21 for trays without

reservoirs and 3.43 with reservoirs. The current study used the same shade guide as the aforementioned study, and the same evaluators performed all subjective color evaluations. Panich reported a mean Δ shade of -10.5 and -8.90 at 2 weeks and 6 weeks, respectively. In this study, the mean shade at 2 weeks was -10.10 for both reservoir and non-reservoir sides. At 6 weeks the mean shade guide value was -8.91 with reservoirs and -8.80 for the sides without reservoirs. Comparing the values of ΔE and Δ shade from both studies gives an indication that using 15% concentration of carbamide peroxide applied for one half-hour, twice daily for 2 weeks can give results similar to the two-hour application of 15% carbamide peroxide for the same time period.

The ΔL^* , Δa^* , Δb^* and ΔE for the reservoirs group showed color relapses at a higher rate when compared to the non-reservoirs group during the first four weeks after termination of bleaching. Trays with reservoirs had significantly higher ΔE than trays without reservoirs at weeks 1, 2, 3 and 12, but not for week 6. ΔE continued to change over time until day 46.

There was no significant difference between quadrants lightened with reservoirs and those lightened without reservoirs for shade guide readings overall or at any specific exam. This agrees with three other studies (Bosma & others, 2000; Javaheri & Janis, 2000; Haywood & others, 1993) that evaluated the design of bleaching trays using shade guides, but their results do not agree with those obtained with the colorimeter values in the current study, which indicated that trays with reservoirs had significantly higher Δb^* , ΔL^* and ΔE overall.

The question then is, does objective statistical difference always translate to clinical significance? Ruyter, Nilner & Moller (1987) and Um & Ruyter (1991) suggest that a ΔE of 1 unit is visually perceptible and 3.3 units is clinically acceptable. In this study, change in colorimeter measurements with and without reservoirs for ΔE value was 0.77 at 2 weeks and 0.30 at 12 weeks. Statistical difference was documented, but clinical difference was below visual perception in this study.

The shade guide data agreed, however, with colorimeter data in the sense that, for both sides, the majority of lightening occurred during the first week

and to a lesser extent during the second week of active bleaching. The shade guide rank data showed that color relapse started following discontinued bleaching, with most of the relapse taking place during the first week postbleaching.

During all visits, use of the reservoirs did not have a significant effect on lightness determined by the clinical slide assessments. This agrees with the finding of Bosma & others (2000) in a similar study, and the subjective shade matching in this study.

There was no significant difference between quadrants lightened with reservoirs and adjacent quadrants lightened without reservoirs for gingival sensitivity or tooth sensitivity. None of the participating subjects experienced greater than mild gingival or tooth sensitivity, and none was given a desensitizing gel.

An exit questionnaire for this whitening study included the question, "Did you notice a difference in the color between your upper and lower teeth?" Twenty-four subjects answered yes, and three responded no. Another question was, "Did you notice a difference in the color of your upper teeth between the right and the left side? If yes, which side is lighter in color?" Twenty-four subjects answered no, three subjects replied yes. Two of the three subjects who answered yes pointed to the side with the reservoirs.

CONCLUSIONS

This three-month, double-blind clinical study was conducted to evaluate the effects of tray design on the degree of color change, rebound effects and sensitivities associated with using a daytime at-home bleaching agent containing 15% carbamide peroxide. The degree of color change and color relapse was evaluated objectively by using a colorimeter and subjectively by using a shade guide and photographs. Patients self-evaluated any tooth and gingival sensitivity they experienced by recording maxillary right or left side sensitivity during the first 21 days of the study.

This study concluded:

1. Objective measurements with a colorimeter indicated the bleaching with tray reservoirs produced significantly greater tooth lightening than bleaching without reservoirs.
2. Subjective evaluations using the shade guide, slide photography and subject feedback indicated no significant difference between teeth lightened with or without using reservoirs in the tray.
3. There was no significant difference for tooth and gingival sensitivity in the sides with or without reservoirs.

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