Background. The authors tested the adjunctive use of light with a 15 percent peroxide gel as a single-visit, in-office tooth whitening system.

Methods. Subjects (N = 87) with stained (> shade D4, Vita Zahnfabrik, Bad Säckingen, Germany) anterior teeth were randomly assigned to test (peroxide and light), peroxide control (peroxide gel) or light control (placebo gel and light) groups and were treated for one hour. The researchers evaluated tooth shade, color and subject response at baseline and post-treatment and at three and six months posttreatment.

Results. The initial shade unit reduction of combined light and peroxide treatment (8.4) was greatest compared with that of peroxide alone (5.9) and of light alone (4.9). Approximately 88 percent of these effects persisted for six months. Lightness was increased and yellowness decreased to a significantly greater extent in the test group than in either control. These findings were corroborated by subject evaluation. One week after treatment, moderate to greatly increased tooth sensitivity occurred in 20 percent of test subjects, 21.7 percent of peroxide control subjects and none of the light control subjects. Neither tooth sensitivity nor gingival redness was present at the three- and six-month visits.

Conclusions. Peroxide and light treatment significantly lightened the color of teeth to a greater extent than did peroxide or light alone.

Clinical Implications. Light can increase the tooth-whitening effect of peroxide, thereby increasing the effectiveness of tooth-whitening procedures.
Concentrations of hydrogen peroxide vary. Typically, light sources designed specifically for tooth whitening are used as the adjunctive bleaching agent. To date, neither the efficacy nor the safety of light used in this fashion as an adjunctive to tooth-whitening agent has been investigated in a controlled clinical trial.

Evaluating the efficacy and safety of tooth whitening systems has received considerable attention. Concern has been expressed about efficacy limitations such as the time for color rebound; the intensity of the stain that can be removed; and safety limitations, including tooth sensitivity, soft-tissue irritation and systemic effects. The ADA Council on Dental Therapeutics’ 1998 guidelines for evaluating the effectiveness and safety of tooth-whitening systems stipulate conditions for conducting effective clinical evaluations.

This article reports the results of a six-month parallel-design, blinded clinical evaluation of a one-time, in-office, combination peroxide-and-light tooth-whitening procedure conducted in accordance with ADA guidelines.

**METHODS AND MATERIALS**

**In-office tooth whitening system.** The light used (BriteSmile 2000, BriteSmile, Walnut Creek, Calif.) was a stationary, short-arc gas plasma lamp emitting light in the blue-green (400-505 nanometers) portion of the color spectrum. The lamp simultaneously illuminated all the incisors. One of the researchers calibrated light irradiance daily using a standard light meter, set to a level of 130 to 160 milliwatts per square centimeter measured at a standard working distance of 1.75 inches. Although irradiance was measured on only one portion of the emitter, all anterior teeth received approximately the same irradiance.
because the shape of the emitting surface approximated that of the dental arch. The bleaching agent was the commercial product that contains 15 percent hydrogen peroxide in a pH 6.5 hydrogel. The placebo gel was the same hydrogel vehicle without peroxide.

**Experimental design.** All subjects had at least four maxillary incisors. Inclusion criteria included a willingness to provide informed consent, good general health, age between 18 and 65 years, availability for six months, no history of prior tooth whitening and a minimum shade of D4 or darker according to the Vitapan system (Vita Zahnfabrik, Bad Säckingen, Germany) (Table 1) on all four maxillary central incisors. Exclusion criteria included pregnancy, breastfeeding and participation in another clinical study or panel test. No subject with orthodontic appliances, soft- or hard-tissue tumors of the oral cavity, carious lesions requiring immediate treatment, restorations on any anterior teeth, congenital tooth stains or dental defects, or advanced periodontal disease was included in the study.

All subjects received a detailed informed consent form that outlined all procedures, defined alternatives and indicated that they could be assigned to a placebo group. To make placebo assignment more tolerable, all subjects in either the peroxide-alone or light-alone groups were offered supplemental treatments after the six-month experimental period had passed. Eighty-seven subjects (38 male and 49 female) with an average age of 44 years (20-67 years) were randomly assigned by the study coordinator (M.N.) to three experimental groups of 29 from a prepared (J.M.G.) randomization sequence. These groups were the test group (Group 1), which used 15 percent hydrogen peroxide gel plus light; the per-
oxide control group (Group 2), which used 15 percent hydrogen peroxide gel alone; and the light control group (Group 3), which used light with placebo gel.

Treatment assignment was by randomization in strata of three, as was the sequence of treatments. Treatments were blinded to both the examiner and subject to the extent possible (the lack of a light in Group 2 could not be blinded to the subject). Otherwise, all subjects were treated identically. Treatment visits included tooth brushing with a nonfluoridated nonwhitening dentifrice, baseline clinical measurements, tooth isolation, whitening and posttreatment clinical and color measurements (Figure 1, page 168).

One examiner (M.T.) measured whole-tooth enamel color, gingival health and safety at four checkpoints (baseline, immediately posttreatment, at three months and at six months). The examiner subjectively evaluated tooth shade on the four maxillary central and lateral incisors using the Vita shade guide (Vita Zahnfabrik) and a research hygienist (J.S.) quantitatively measured color using a CR-321 Chromameter (Minolta, Ramsey, N.J.) in accordance with ADA recommendations for submissions of whitening products.20 (Authors’ note: The chromameter scale has one lightness and two color components used to measure color differences. The lightness, or \( L^* \), value represents the spectrum between black and white. The two color ranges are \( a^* \), capturing the spectrum between red and green, and \( b^* \), capturing the spectrum between yellow and blue.21) The same investigator conducted all shade-guide color evaluations under standard color-corrected full-spectrum operatory light that remained the same for all measurements. Chromameter measurements were made using custom-fabricated maxillary color measurement stents as described in Rustogi and Curtis.21 We also maintained a 35-mm photographic and digital image record of the whitening process. To meet the criteria for a blind clinical trial, the examiner responsible for measuring color was required to leave the operatory while the treatments were performed and to return subsequently for the posttreatment color measurements, so that she was unaware of the actual treatment administered (Figure 1).

In accordance with ADA guidelines, examiners measured gingival health using the Gingival Index and Plaque Index.22 The examiners recorded readings on all maxillary and mandibular teeth from the first molar forward at each evaluation period. Safety was evaluated by both professional oral examination and a subject questionnaire. To ensure protection of the maxillary and mandibular gingiva, examiners applied a brush-on isolation material (Opaldam, Ultradent Products, South Jordan, Utah) extending approximately 1 millimeter onto all tooth surfaces in the treatment area before whitening. Examiners placed a cheek retractor to hold the skin and lips away from the treatment area, and placed cotton rolls in the cheek vestibules to control saliva buildup. Bite blocks were used as a jaw rest. Examiners applied sunblock to the lips. The subject and the operatory staff wore orange-tinted protective eyewear during the whitening procedure.

The research hygienist applied a 2-mm strip of peroxide or placebo gel to the buccal surfaces of all maxillary and mandibular anterior teeth. She covered all the incisors, canines and premolars fully to ensure a uniform effect. She positioned

Figure 2. Shade scores for individual teeth before and immediately after each of three treatments. Baseline scores for the teeth in each of the three groups averaged approximately 10 (Vita [Vita Zahnfabrik, Bad Säckingen, Germany] shade D3). The peroxide-and-light-treatment (A) appeared to exceed the range of the shade guide as indicated by the sharply attenuated posttreatment distribution and the largest modal value of 1 (Vita shade B1). Teeth treated by peroxide alone (B) or by light alone (C) had a clear bleaching result, albeit less than with the peroxide-light combination.
the light according to the manufacturer’s instructions using the integral bite appliance guide to set the distance between the teeth and the light source. All treatments lasted one hour. Desiccation of the tooth surface was minimized by reapplication of hydrogel every 20 minutes so that the tooth surface was never dry.

Statistical analysis. One of the researchers (R.K.) analyzed all subjects as part of the groups to which they were randomized. For each subject, he evaluated values from the four maxillary incisors for shade (Table 2, page 169). He calculated ordinal changes in shade guide values using the conversion defined in Table 1 (page 168), which represents the ordered brightness sequence recommended by the manufacturer. He calculated differences, means and standard errors on the basis of this numeric assignment. Evaluation of differences between treatments was done by Kruskal-Wallis nonparametric analysis. He evaluated differences from baseline and color values from the chromameter by the Friedman test. He did not tabulate the small and not statistically significant changes in the a* parameter, and these are not illustrated. He evaluated questionnaire results by χ² and Fisher exact test.

RESULTS

We randomly assigned subjects ranging in age from 17 to 64 years to three treatment groups. Group assignments were concealed from both investigators and subjects by a study coordinator (M.N.) who did not participate in treatment or evaluation. All 87 subjects completed the study. The baseline shade values of each treatment group were approximately D3 (shade 10) (Figure 2, Table 1) and did not significantly differ from each other.

As indicated in Figure 3, the initial effects of treatment on shade were greatest with the peroxide-and-light treatment. This effect was significantly greater than either of the other two treatments, up to and including the final six-month evaluation. Although the effects of peroxide-alone treatment were significantly greater than those of the light-alone treatment, both were significantly lighter at six months than at baseline. The magnitude of these effects is illustrated by the intraoral image representing the largest change seen, 13 shade steps in one subject treated with peroxide and light (Figure 4).

Evaluation of color change using a chromameter and an individualized stent corroborated the shade response by revealing a significant decrease in yellowness (b*) and an increase in lightness (L*) associated with the combination of peroxide and light treatment (Table 2). Changes in redness (a*) were small and not statistically significant. These were omitted to simplify the presentation.

In responding to the questionnaire item, “How much did the product increase the whiteness of your teeth?” immediately after undergoing the whitening treatment, 96.6 percent of those treated with the peroxide-and-light combination responded either “Greatly” or “Moderately.” In comparison, 39.3 percent of the subjects treated with peroxide alone and 53.5 percent of the subjects treated with light alone responded “Greatly” or “Moderately.” These relationships are summarized in Table 2. With follow-up questionnaires, an average of 81 percent (at three months) and 74 percent (at six months) reported that there had been a “None to slight” decrease in tooth whiteness irrespective of their treatment group (data not shown).

Soft-tissue irritation was evaluated by professional oral examination and by recording Gingival Index measurements. Although signs of mild irri-
therapy with no change in Plaque Index (Table 3). The Gingival Index in all treatment groups was significantly less than baseline at three months. The Gingival Index reduction of the peroxide and light subjects was significantly less than that of the light-alone treatment group at six months.

We evaluated tooth sensitivity by questionnaires at four points in time: immediately after treatment, one week after treatment with a mailed questionnaire, and at the three-month and six-month follow-up visits (Table 4). These responses indicated that in the peroxide-and-light and peroxide-alone treatment groups both produced a greater incidence of sensitivity than the light-alone treatment group. Sixty percent of subjects treated with peroxide and light, 52 percent treated with peroxide alone and 9 percent treated with light alone reported some level of sensitivity one week after treatment. These results clearly associate tooth sensitivity with peroxide rather than light. Combining only reports of moderate and greatly increased sensitivity for the immediate posttreatment and one-week follow-up periods, among the subjects receiving the peroxide-and-light treatment, 13.7 percent reported sensitivity at the immediate posttreatment check-point and 20 percent reported it at the one-week checkpoint. Of the subjects treated with peroxide alone, 3.4 percent reported sensitivity immediately after treatment and 21.7 percent did so after one week. None of the subjects treated by light alone reported either moderately or greatly increased tooth sensitivity associated with treatment. We did not observe this level of sensitivity response in peroxide-treated and light-treated subjects in all groups immediately after treatment (11.6 percent of subjects), no significant differences between groups were noted by oral examination (data not shown). The Gingival Index of all groups decreased significantly after

**TABLE 3**

<table>
<thead>
<tr>
<th>MEASUREMENT</th>
<th>TREATMENT</th>
<th>SCORE (± SEM*) AT MEASUREMENT PERIOD</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>Gingival Index</td>
<td>Peroxide and light</td>
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</tr>
<tr>
<td></td>
<td>Peroxide</td>
<td>0.65 ± 0.37</td>
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<tr>
<td></td>
<td>Light</td>
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<tr>
<td>Plaque Index</td>
<td>Peroxide and light</td>
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<tr>
<td></td>
<td>Peroxide</td>
<td>0.12 ± 0.03</td>
</tr>
<tr>
<td></td>
<td>Light</td>
<td>0.08 ± 0.03</td>
</tr>
</tbody>
</table>

* SEM: Standard error of the mean for 29 subjects.
† Significantly different from baseline (P < .01, Friedman analysis).
‡ Significantly different from light alone (P < .005, Kruskal-Wallis analysis).
subjects in the three-month and six-month questionnaire responses. Statistical testing by $\chi^2$ indicated there were significant sensitivity differences between treatment groups immediately after treatment and one week later, but no significant differences between groups in their sensitivity responses are seen in the three- and six-month visit data.

**DISCUSSION**

The question addressed in this study is whether light can augment the effects of peroxide tooth whitening. The short answer is yes. The blinded shade evaluator scored the whitening effect; the electronic apparatus for evaluating color change measured it; and, the subjects treated with light reported it. In this study, the direct in-office application of a gas-plasma light for three 20-minute periods in conjunction with application of a relatively low-concentration (15 percent) hydrogen peroxide gel produced a significantly greater tooth whitening effect than did either light or peroxide alone. On average, the change in tooth color was at least 8.35 shades of whitening with the peroxide-and-light treatment. The distribution of Figure 2A suggests that with additional lighter shade tabs, an even greater effect would have been achieved. The chromameter measurements indicate that the reduction in yellowness ($b^*$) was the most significant color change effect of the tooth-whitening procedures. Hence, the major effect of the procedure appeared to be reduction in the tooth yellowing associated with aging.

The ADA guidelines stipulate that at least 50 percent of the treated population recalled at three and six months should maintain a perceptible color change. In this study, 93 percent of the peroxide-and-light group, 79 percent of the peroxide-alone group and 48 percent of the light-alone groups maintained a change of at least four
shade units for six months. By linear extrapolation of these data, a residual tooth-whitening effect in the peroxide-and-light treatment group should be maintained for 3.6 years if this rate of decline were maintained.

One surprising observation from this study was that light by itself appeared to have a bleaching effect. This is illustrated in the largest change observed by light-alone treatment, a change of nine shade steps (Figure 5). Shade values remained significantly lower in light-treated teeth throughout the six-month observation period (Table 2). More than one-half (53.5 percent) of subjects treated by light alone, when asked immediately after treatment, considered the result to be a moderate to great increase in tooth whiteness. Measurement of both increased lightness (L*) and decreased yellowness (b*) were statistically significant immediately after treatment. Although not statistically significant, these changes persisted throughout the six-month observation period. Art museum curators recognize that colored surfaces are bleached when exposed to light and for that reason forbid flash photography of artwork. Since chemical bleaching is the result of breaking chemical double bonds in a chromophore, strong absorption of light might be expected to do the same to teeth.

Tooth sensitivity has been recognized as a common side effect of peroxide-based whitening procedures.5,19 Levels of 54 percent mild and 10 percent moderate sensitivity reported for home whitening treatment with 15 percent carbamide peroxide are approximately the same as those reported in this study.24 Our results indicate that tooth sensitivity with these treatment procedures was mild, transient (vanishing after one week posttreatment) and primarily associated with peroxide and not with light.

Evaluation of soft-tissue irritation was similarly mild and transient. This may be the result of the close professional control in application and protection of surrounding tissues that are an integral part of the procedure. We recorded Gingival Index values as a measure of tissue irritation. Rather than increasing as might be expected after topical application of potentially irritating substances, Gingival Index measurements significantly decreased over the three- and six-month periods, suggesting that the tooth-whitening procedures reduced gingivitis. This effect also has been reported by investigators studying home tooth-whitening procedures.24-26

CONCLUSION

These data indicate that light augments the effect of peroxide tooth whitening and indeed, appears to have a tooth whitening effect by itself. In testing a single-visit, in-office whitening treatment with relatively low-concentration hydrogen peroxide (15 percent) augmented by light for a treatment period of one hour, we were able to achieve a high level of tooth whitening that persisted for a minimum of six months with minor transient tooth sensitivity.

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18. Li Y. Toxicological considerations of tooth bleaching using peroxide-containing agents. JADA 1997;128(supplement):31S-6S.