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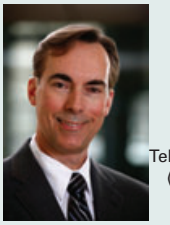

Gerard Kugel,
DMD, MS, PhD
171 Burlington St,
Lexington, MA 02420
Telephone: (B) 617-636-0870
(FAX) 781-862-2448 email:
gerard.kugel@tufts.edu

Current occupation (i.e., private practice, full-time academics, etc.):

Private practice and Associate Dean for Research.

Education (degrees, year, and institution):

Rutgers University
New Brunswick, NJ
B.S. Biology and Psychology, 1976

Cornell University Graduate School of Medical Sciences
Department of Neurobiology
New York, NY
Ph.D. candidate, 1977–1979 (transferred)

Tufts University School of Dental Medicine
Boston, Massachusetts
D.M.D., Ph.D. Program
D.M.D., 1985

Masters of Esthetic Dentistry

Clinical Trial Assessing Light Enhancement of In-office Tooth Whitening

GERARD KUGEL, DMD, MS, PHD*
SUSANA FERREIRA, DDS, DMD†
SHRADHA SHARMA, BDS, DMD‡
MATTHEW L. BARKER, PHD§
ROBERT W. GERLACH, DDS, MPH¶

ABSTRACT

Objective: Evaluate a light-enhanced in-office tooth whitening system in order to assess tooth color and safety.

Methods: Thirty-three adults were randomly assigned to one of three treatment groups. Professional treatment involved application of a 25% H_2O_2 gel (Discus Dental ZOOM!) with light enhancement, H_2O_2 gel alone, or the light alone with no peroxide. The 12 anterior teeth were treated three times for 20 minutes each. Efficacy was measured objectively as $L^*a^*b^*$ color change using digital images, tooth shade was measured, and safety was evaluated immediately after treatment and at post-treatment days 7 and 30.

Results: After adjusting for baseline and age, immediate (end-of-treatment) means (SE) for Δb^* (yellowness) were –3.1 (0.25) for the gel + light, –2.0 (0.25) for the gel-only group, and –2.4 (0.25) for the light-only group. Significant ($p < 0.05$) color rebound was evident at posttreatment day 7. By day 30, adjusted means (SE)

*Associate dean for research, professor, Department of Prosthodontics and Operative Dentistry, Tufts University School of Dental Medicine, Boston, MA, USA
†Assistant professor, Research Department, Tufts University School of Dental Medicine, Boston, MA, USA
‡Assistant professor, Research Department, Tufts University School of Dental Medicine, Boston, MA, USA
§Senior statistician, Worldwide Clinical Investigations, The Procter & Gamble Company, Mason, OH, USA
¶Research fellow, Worldwide Clinical Investigations, The Proctor & Gamble Company, Mason, OH, USA

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for Δb^* were –1.7 (0.20) for the gel + light group, –1.1 (0.20) for the gel-only group, and –0.5 (0.20) for the light-only group. Both peroxide groups differed significantly ($p < 0.05$) from light alone on Δb^* and ΔL^*. In the gel + light group, 91% of subjects experienced tooth sensitivity, the majority of which was moderate or severe. Adverse events were low in the light-only group.

Conclusion: Use of light enhancement for in-office whitening leads to immediate color change, after which there was significant color and shade rebound within 7 days as well as moderate-to-severe tooth sensitivity during and after treatment.

CLINICAL SIGNIFICANCE

Increased tooth sensitivity during treatment and appreciable short-term color rebound after treatment may impact the utility of in-office tooth whitening with peroxide and light as a stand-alone esthetic procedure.

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INTRODUCTION

Use of peroxides for tooth whitening has a lengthy history extending back nearly a century. Many of the early approaches had appreciable limitations, and as such, the technique did not gain in popularity until the introduction of night guard vital bleaching in the late 1980s.[1] Typically, subjects would wear a custom bleaching tray filled with a 10% carbamide peroxide gel overnight for several weeks. Safety and efficacy were established through a series of clinical trials, which, for the most part, showed adverse events to be limited to minor oral irritation and tooth sensitivity typically confined to the period of active treatment.[2]

With safety and efficacy established, some research focused on alternatives to conventional overnight trays. One area involved higher peroxide concentrations in the whitening gels used with custom trays to reduce treatment time and/or increase whitening response.[3] Some studies evaluated tray-based gels at higher concentrations.[4,5] For the most part, clinical research on these higher concentration tray-based systems was limited in scope and duration. Another area involved convenience, highlighted by the advent of easy-to-use whitening strips introduced in 2000, and the subject of extensive subsequent research.[6] Although these systems reduced daily treatment time, duration still extended over several days.

Peroxide reactivity can be accelerated with the use of heat or metal catalysts. From time to time, some clinicians explored the use of heat to accelerate peroxide-based whitening. An early technique, for example, used hydrogen peroxide and a handheld heating source to bleach tetracycline-stained teeth.[7] Other research evaluated combination approaches using office-based accelerated whitening with an at-home peroxide-containing tray.[8] Such methods could facilitate compliance, while limiting treatment duration. More recent research has focused on the possible role of light and peroxide activation. In general, research has been limited, and outcomes have been ambiguous. Some research suggested a positive effect of light-activated bleaching agents, while studies showed little-to-no contribution of light to whitening.[9–11]

Numerous systems are marketed today ostensibly for accelerated in-office whitening. Many of these use light or heat and higher

peroxide concentrations for immediate whitening, sometimes followed by take-home peroxide gel trays. A randomized clinical trial was conducted with one light-enhanced tooth whitening system to assess the incremental contribution of the light to tooth color and safety to in-office whitening.

METHODS AND MATERIALS

This was a randomized, examiner-blind, 1-month clinical trial. Prior to study initiation, the protocol, informed consent, and advertising were reviewed and approved by Tufts/NEMC Institutional Review Board. The target population was healthy adults with tooth discoloration (A2 or darker). Subjects who desired to undergo in-office tooth whitening were recruited from the general population at Tufts University School of Dentistry. Subjects were excluded if they had a bleaching history, severe or atypical intrinsic or extrinsic staining, dentinal sensitivity, acute dental treatment needs, or crowns or composite restorations covering one-third or more of the facial anterior teeth. Subjects were also excluded because of history of psoralen + UV radiation or other photochemotherapy, melanoma, or use of light-sensitive or photoreactive drugs or substances.

There were a total of four visits, baseline (prior to treatment), treatment, and 1 week and 1 month posttreatment. At baseline, written informed consent, demographic information, inclusion/exclusion criteria, and clinical parameters were collected. Eligible subjects were assigned to one of three groups, with randomization balanced with respect to baseline tooth color (b^* and L^*), numerical tooth shade, and age. All subjects were assigned to one of three in-office, professionally administered treatments using a high-peroxide concentration gel and/or light (ZOOM! Chairside Tooth Whitening System, Discus Dental, Inc., Culver City, CA, USA). The three treatment groups were: group 1: gel + light, group 2: gel only, and group 3: light only.

At the treatment visit, both the maxillary and mandibular anterior teeth were treated with the assigned in-office procedure (peroxide gel + light peroxide gel, or light only). Two well-trained dentists provided care, and because this was professionally administered, all treatment was open label. Prior to treatment, the oral cavity was isolated and protected using supplied lip balm, retractor, and face bib; 2 × 2 gauze squares were inserted; and the facial gingiva was covered with a liquid dam. Treatment materials were supplied by the manufacturer, stored and used following the manufacturer's instructions, as part of the chairside whitening system, and consisted of: ZOOM! Chairside Whitening System (Discus Dental, Inc.) using the ZOOM! Chairside Procedure Kit containing 25% H_2O_2 Whitening Gel and/or the ZOOM! Chairside Whitening Lamp, depending on treatment assignment.

For group 1 (gel + light), the bleaching gel was applied on the facial surfaces of teeth 6–11 and 22–27 using the supplied gel brush, positioning guides were inserted, and light treatment was initiated. After 20 minutes, the light automatically turned off, and the bleaching gel was rinsed with water. This process was repeated for a total of three applications. After the 60-minute treatment was completed, a 1.1% neutral sodium fluoride gel was applied for 5 minutes, after which the fluoride gel was rinsed with water. Other than the light application, treatment was otherwise identical for group 2 (gel only). For this group, the 20-minute application cycles were timed with a stopwatch. Group 3 (light only) received only the three 20-minute light cycle treatments. No bleaching gel was applied, but treatment was completed with the same neutral sodium fluoride used for the other two groups. All subjects were supplied with an anticavity dentifrice (Crest Cavity Protection, The Procter & Gamble Co., Cincinnati, OH, USA) and toothbrush (Crest

Extra Soft, The Procter & Gamble Co.) to standardize oral hygiene, which otherwise, was at-home and unsupervised.

Tooth color was measured at baseline (prior to treatment), on the treatment day (after treatment), and approximately 1 and 4 weeks after treatment in order to assess immediate whitening and posttreatment color rebound. In addition, clinical photographs and other ancillary data were collected.

Efficacy was assessed from digital images of the maxillary and mandibular anterior dentition using a standardized method.[12] With this method, the subjects brushed with water and an extra-soft toothbrush to remove any superficial debris, and cheek retractors were inserted to expose the maxillary and mandibular facial tooth surfaces. A single image was recorded with an HC Series 3CCD high-resolution digital camera (Fuji Film Corp., Tokyo, Japan) and a Fujinon A8x12BMD, 1:2.8/12–96 mm zoom lens under standard polarized lighting conditions. The imaging system was calibrated daily prior to use, and hourly during use, and all images were collected in a separate dental clinic by a technician who was blinded to treatment identify, period, and study design. In addition, safety was assessed at each visit from clinical examination and interview to ascertain any signs or symptoms associated with treatment.

Image analysis was used to derive red–green–blue (RGB) values for the anterior teeth. A least square discriminant analysis was used to objectively identify tooth pixels on the anterior facial surfaces of teeth 6–11 and 22–27. RGB values were counted and averaged. RGB averages were converted to CIELAB values using regression equations for MacBeth $L^*a^*b^*$ values under illuminant C conditions that were specific for this system and testing conditions.[12] With this approach, tooth color was measured at each visit as blue–yellow (b^*), lightness (L^*), and red–green (a^*). Color change was determined as the simple mathematical difference between treatment/posttreatment visits and baseline, wherein whitening was represented by decreased yellowness ($-\Delta b^*$), increased lightness ($+\Delta L^*$), and decreased redness ($-\Delta a^*$). Analysis of covariance was used for between-group comparisons of color change; and in order to control for baseline factors that might impact response, means were derived from a statistical model where age and starting tooth color served as covariates. Paired difference *t*-tests were used to investigate color changes from baseline and end of treatment. Exact Wilcoxon rank sum tests were used to compare groups on the severity occurrence (0 = none, 1 = mild, 2 = moderate, and 3 = severe) of tooth sensitivity and oral irritation. All comparisons were tested two sided at a 5% level of significance.

RESULTS

A total of 33 subjects (11 per group) provided informed consent and were randomized to treatment. The subjects ranged in age from 22 to 48 with a mean age of 30.9 years. Males and females were approximately equally represented, and only two subjects reported tobacco use. Groups were balanced ($p > 0.26$) with respect to pertinent demographic and behavioral parameters as well as baseline tooth color. All subjects attended the baseline, treatment, and day 7 visits. Three subjects (one per group) failed to attend the day 30 visit. All subject data and visits were included in data analyses.

The scatterplots illustrate individual whitening responses immediately after completion of treatment, and again 1 week and 1 month posttreatment. Immediately after completion of the in-office treatment, all subjects had measured two-parameter (Δb^* and ΔL^*) color improvement (Figure 1). A total of eight subjects had at least two units of reduction in yellowness and two units or more increased lightness, and three subjects had over three-unit change in both Δb^* and ΔL^*. One week posttreatment, all groups showed

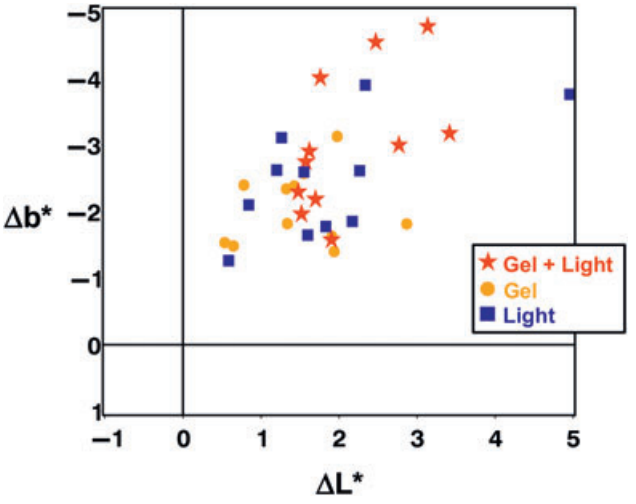

Figure 1. Scatterplot of Δb* *and* ΔL* *immediately after treatment.*

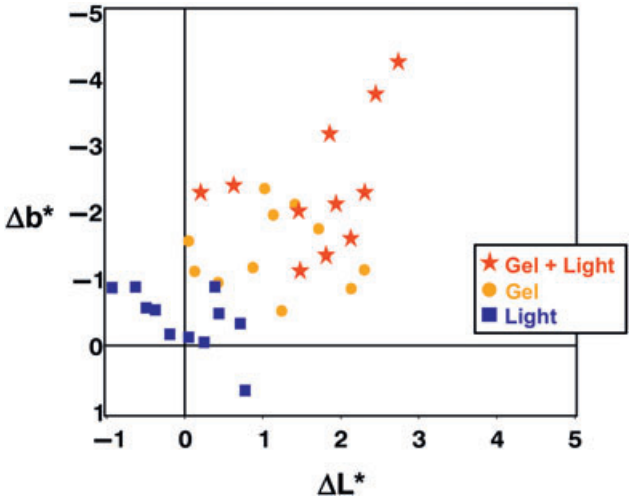

Figure 2. Scatterplot of Δb* *and* ΔL* *7 days posttreatment.*

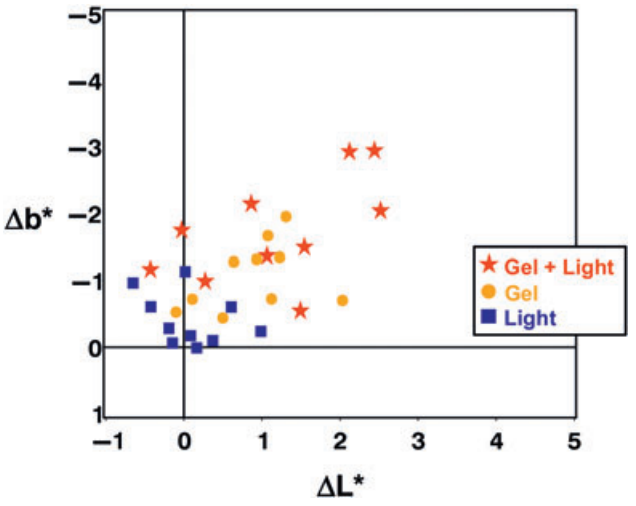

Figure 3. Scatterplot of Δb* *and* ΔL* *30 days posttreatment.*

rebound, with the light-alone group now clustering around zero (Figure 2). This rebound continued through day 30 (Figure 3). One month posttreatment, only three subjects (in the gel + light group) exhibited two or more units of color improvement in Δb^* and ΔL^*. The two peroxide groups, but not the light-only group, exhibited significant ($p < 0.05$) two-parameter (Δb^* and ΔL^*) color improvement 30 days posttreatment.

After adjusting for baseline tooth color and age, immediate (end-of-treatment) means ± SE for Δb^* (yellowness) were –3.14 ± 0.25 for the gel + light group, –2.00 ± 0.25 for the gel-only group, and –2.42 ± 0.25 for the light-only group (Table 1). Results were generally similar for ΔL^* (lightness), although the adjusted change was somewhat lower. Like Δb^*, the gel + light group had the greatest numerical color improvement, and the gel-only group had the least numerical color improvement. At this immediate posttreatment time point, the gel + light group differed statistically ($p < 0.05$) on Δb^* and ΔL^* from the gel-only group, but not the light-only group. There were no between-group differences on Δa^*.

TABLE 1. ANALYSIS OF COVARIANCE AT IMMEDIATE POSTTREATMENT.

Color/Treatment	Baseline mean (SE)	Adjusted mean change from baseline (SE)	Between-group *p* values	
			Gel alone	Light alone
Δb^*				
Gel + light	18.64 (0.38)	–3.14 (0.25)	0.0029	0.0516
Gel	19.34 (0.55)	–2.00 (0.25)		0.2484
Light	18.95 (0.47)	–2.42 (0.25)		
ΔL^*				
Gel + light	74.59 (0.62)	2.20 (0.22)	0.0289	0.2006
Gel	74.63 (0.77)	1.50 (0.21)		0.3619
Light	74.51 (0.63)	1.78 (0.22)		
Δa^*				
Gel + light	7.49 (0.27)	–0.32 (0.11)	0.6129	0.7738
Gel	7.51 (0.26)	–0.40 (0.11)		0.4279
Light	7.34 (0.29)	–0.27 (0.11)		

TABLE 2. ANALYSIS OF COVARIANCE AT DAY 7.

Color/Treatment	Baseline Mean (SE)	Adjusted Mean Change from Baseline (SE)	Between-Group *p*-values	
			Gel Alone	Light Alone
Δb^*				
Gel + light	18.64 (0.38)	–2.41 (0.22)	0.0018	<0.0001
Gel	19.34 (0.55)	–1.36 (0.21)		0.0058
Light	18.95 (0.47)	–0.44 (0.22)		
ΔL^*				
Gel + light	74.59 (0.62)	1.65 (0.21)	0.0847	<0.0001
Gel	74.63 (0.77)	1.13 (0.20)		0.0013
Light	74.51 (0.63)	0.09 (0.21)		
Δa^*				
Gel + light	7.49 (0.27)	–0.47 (0.12)	0.8715	0.0512
Gel	7.51 (0.26)	–0.44 (0.11)		0.0625
Light	7.34 (0.29)	–0.13 (0.12)		

Statistically significant ($p < 0.05$) color rebound was evident at posttreatment day 7. The greatest rebound (82% for Δb^* and 95% for ΔL^*) was measured in the light-only group. At posttreatment day 7, adjusted mean $\Delta b^* \pm$ SE was –2.41 ± 0.22, –1.36 ± 0.21, and –0.44 ± 0.22 for the gel + light, gel-alone, and light-alone groups, respectively, whereas ΔL^* was 1.65 ± 0.21, 1.13 ± 0.20, and 0.09 ± 0.21 (Table 2). Unlike the day of treatment, the light-alone group exhibited the lowest measured whitening (Table 3). Further posttreatment rebound was evident for both of the peroxide gel groups at day 30. Adjusted means ± SE for Δb^* and ΔL^* were –1.74 ± 0.20 and 1.07 ± 0.24 for the gel + light group, and –1.05 ± 0.20 and 0.89 ± 0.23 for the gel group, with two-parameter color rebound ranging from 41 to 51%. At day 30, the light group exhibited adjusted means ± SE for Δb^* of

TABLE 3. ANALYSIS OF COVARIANCE AT DAY 30.

Color/ Treatment	Baseline Mean (SE)	Adjusted Mean Change from Baseline (SE)	Between-Group *p*-values Gel Alone	Light Alone
Δb^*				
Gel + light	18.57 (0.41)	–1.74 (0.20)	0.0227	0.0002
Gel	19.42 (0.60)	–1.05 (0.20)		0.0453
Light	18.94 (0.52)	–0.45 (0.20)		
ΔL^*				
Gel + light	74.57 (0.68)	1.07 (0.24)	0.5920	0.0233
Gel	74.64 (0.86)	0.89 (0.23)		0.0494
Light	74.30 (0.65)	0.20 (0.24)		
Δa^*				
Gel + light	7.50 (0.30)	–0.36 (0.13)	0.3938	0.0692
Gel	7.62 (0.26)	–0.20 (0.12)		0.2580
Light	7.39 (0.31)	0.01 (0.13)		

TABLE 4. TOOTH SENSITIVITY AND ORAL IRRITATION SEVERITY OCCURRENCE.

Type/Treatment	Percent of Subjects 0 = None	1 = Mild	2 = Mod	3 = Sev	*p*-value vs. Gel Alone	*p*-value vs. Light Alone
Tooth Sensitivity						
Gel + light	9.1	27.3	36.4	27.3	0.0366	0.0002
Gel	45.5	27.3	27.3	0.0		0.0379
Light	90.9	9.1	0.0	0.0		
Oral Irritation						
Gel + light	72.7	18.2	9.1	0.0	1.0000	0.2143
Gel	63.6	36.4	0.0	0.0		0.0902
Light	100.0	0.0	0.0	0.0		

–0.45 ± 0.20 for Δb^* and 0.20 ± 0.24 for ΔL^*. Other than the gel + light-versus-gel comparison for ΔL^*, all three groups were statistically significantly different ($p < 0.05$) at posttreatment day 30 yellowness and lightness. Results for Δa^* were included for completeness (Table 3).

There were a total of 25 adverse events, involving 20 different study subjects. Most occurred among subjects treated with peroxide gels, with 10 subjects (91%) in the gel + light group, eight (73%) in the gel-only group, and two (18%) in the light-only group having at least one adverse event. Tooth sensitivity was the most common adverse event, reported by 10 of 11 (91%) individuals in the gel + light group, 6 of 11 (55%) in the peroxide gel group, and 1 of 11 (9%) in the light group (Table 4). A majority (55%) of subjects in the gel + light group reported the tooth pain as moderate to severe. Treatments differed significantly ($p < 0.04$) on tooth sensitivity, with occurrence severity greatest in the gel + light group and least in the light-only group (where one subject reported mild tooth pain). Oral irritation was less common (seven subjects overall),

and confined to the two peroxide gel groups. Treatments did not differ significantly on oral irritation occurrence severity. Other adverse events included posttreatment chelitis (two cases) and ulceration (two cases), one each in the gel + light and gel-only groups, and one report of dry mouth in the light group. Although no subjects dropped from the study because of treatment-related adverse events, four (three in the gel + light group and one in the gel group) failed to complete the 60-minute treatment cycle because of discomfort.

DISCUSSION

In-office tooth whitening remains a controversial treatment in contemporary dentistry. There are opinions around the appropriateness of such care and some research showing little-to-no contributions of lights to whitening.[10,11,13] Despite these concerns, some research shows long-term responses, including the paradoxical report of long-term whitening with a light, but no peroxide gel.[9] The mechanism for light activation of peroxide whitening is unknown, although some have suggested heat may accelerate diffusion and reactivity.[14] Others suggest that lights have little substantial effect on whitening response, and whereas there is a lot of conjecture, there is limited systematic evidence of tooth whitening activation via lights or other sources.[15]

We conducted this research to assess the incremental contribution of light to peroxide-based tooth whitening. Certainly, application of a 25% hydrogen peroxide gel (without any acceleration by light or other means) should result in some tooth whitening. Numerous studies with repeated application of higher concentration trays or gels show significant whitening.[3–5] Our research used a minus-one design to dimension the contribution of the light to gel whitening. Whitening was assessed with an objective and instrumental method that has previously demonstrated sufficient measurement sensitivity to detect peroxide dose-ranging effects with tray and strip delivery systems.[5,16] We also assessed the contribution of light to safety and tolerability using clinical examination and subject report to ascertain both the symptomatic and clinically apparent changes. Adverse events were coded consistent with pharmaceutical research standards, and treatments were compared statistically. To limit bias, evaluability assessment was determined, and data sets were locked prior to unblinded analysis.

In this research, the combination gel and light, gel alone, and light alone all yielded immediate posttreatment color change. That is, all subjects left the in-office treatment visit with measurable color change. We believe that dehydration during the 1-hour isolation contributed to the immediate posttreatment color change in the light-only group, which is supported by the absence of apparent two-parameter color improvement in that group 1 week or 1 month following in-office treatment. The peroxide groups, in contrast, exhibited significant whitening throughout the posttreatment period. Rebound was apparent, most noticeably in the light group, but also in the peroxide groups, where 41–51% of initial whitening was lost by day 30. Clinical photographs illustrate the color change seen throughout this trial (Figures 4–6).

Adverse events were common, particularly in the two peroxide groups, with many (44%) categorized as moderate or severe. Tooth sensitivity and oral irritation were most common. Isolation technique may have contributed to the latter outcome. We used a liquid dam to isolate the tissues from exposure to the 25% hydrogen peroxide gel, and some possible gel leakage was observed on marginal gingival tissues immediately following treatment. Better technique and/or materials may have limited these adverse events, because none were noted in the light-only group where there was no potential peroxide tissue exposure. Three subjects in the gel + light group and one in the gel-only group used rescue medications (analgesics),

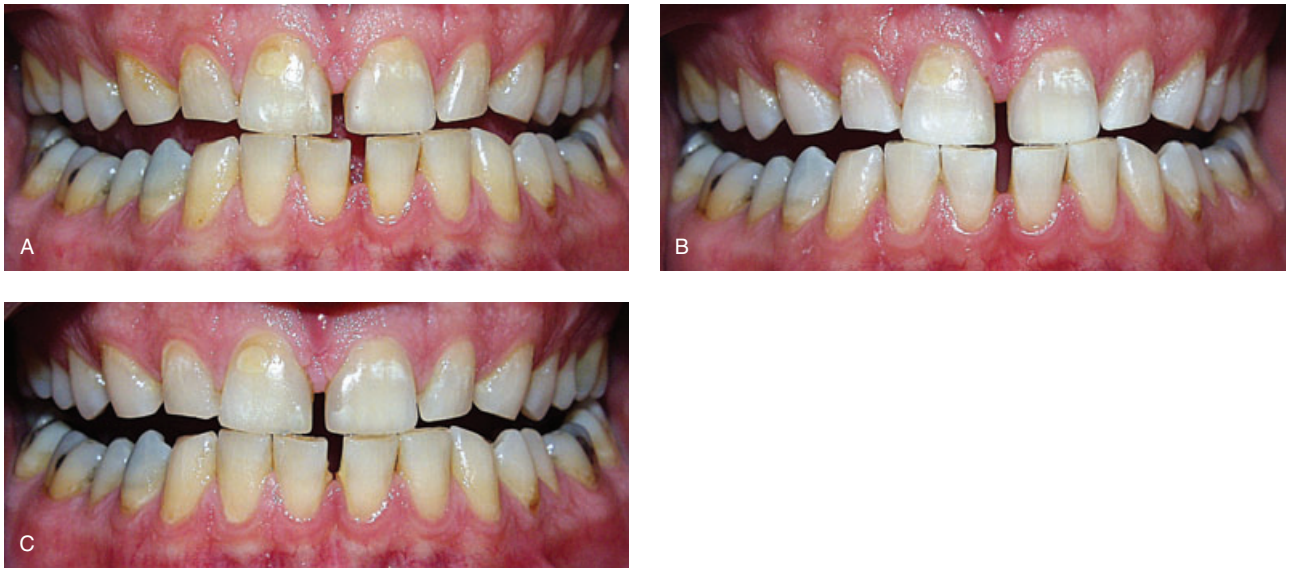

Figure 4. Clinical photographs, gel + light. A, *Baseline.* B, *Immediately after treatment.* C, *30 days posttreatment.*

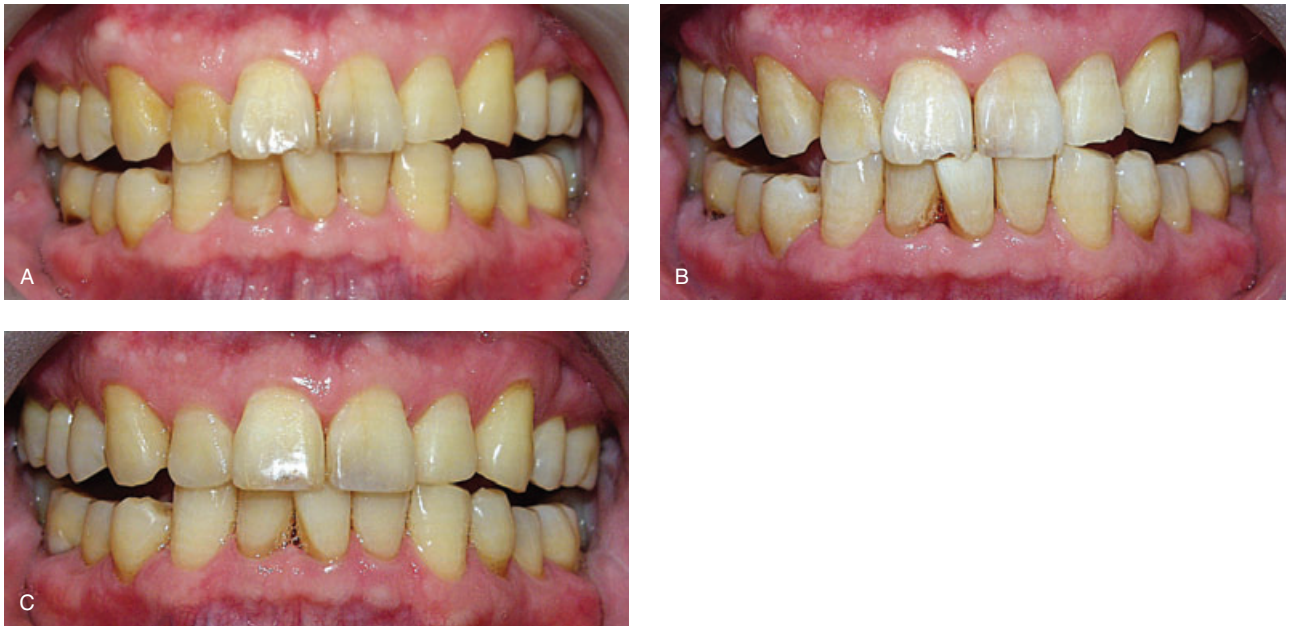

Figure 5. Clinical photographs, gel only. A, *Baseline.* B, *Immediately after treatment.* C, *30 days posttreatment.*

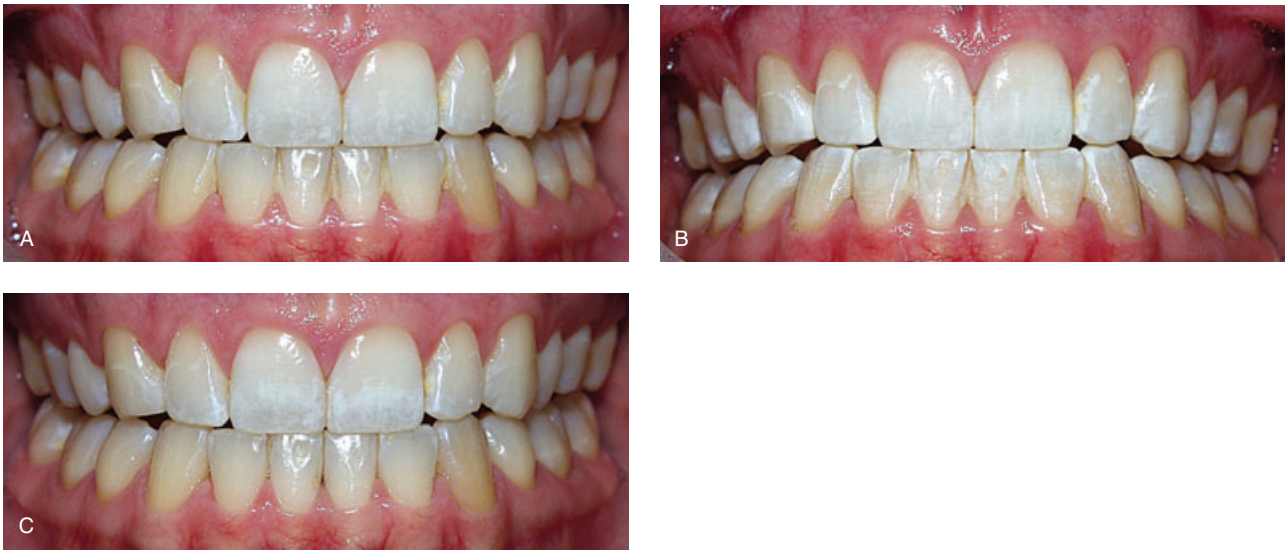

Figure 6. Clinical photographs, light only. A, *Baseline.* B, *Immediately after treatment.* C, *30 days posttreatment.*

and one subject, again in the gel + light group, telephoned approximately 8 hours posttreatment with severe tooth pain. No local anesthesia or preemptive analgesics were administered with treatment. Whether this practice would have limited postoperative pain or increased risk by blunting the pain response, is unknown.

Professionally administered treatment represents the only part of whitening that is fully under professional control.[17] In-office whitening systems, including the one tested in this study, sometimes combine professionally administered care with a take-home custom tray and peroxide bleaching gel. There is sufficient evidence on certain take-home tray systems to consider the latter approach as safe and effective.[18] This randomized clinical trial evaluated the immediate and posttreatment contribution of light to in-office peroxide gel whitening, without any adjunctive use of a take-home tray and peroxide gel. Further research would be indicated to determine whether follow-on use of a take-home tray affected immediate or sustained whitening efficacy or posttreatment tolerability. In addition, the in-office tooth whitening market is dynamic, with numerous product revisions to lights, peroxides, regimens, and the like. This research was conducted with a single light and single peroxide gel available at the time of the research. Care should be taken in extrapolating the findings from this study to other light/gel combinations.

Contrary to some opinion, this research showed that light affected the clinical response to in-office peroxide gel whitening. The combination of the peroxide gel plus light treatment differed from the peroxide gel alone in two areas. There was significant ($p < 0.05$) incremental two-parameter whitening at days 7 and 30 posttreatment for the gel + light group compared to the gel-only group. Whereas these groups differed significantly on whitening, the magnitude of the color improvement was relatively small and was accompanied by a significant ($p < 0.05$) increase in tooth sensitivity. When the light was used in combination with the

peroxide gel, virtually all (10 of 11) subjects had tooth sensitivity, more than one-half of which was moderate or severe in intensity. A remarkable 27% of gel + light subjects voluntarily discontinued treatment during the 1-hour session.

Although this study focused on the light contribution, the research provides some evidence on the durability of whitening with the in-office gel + light combination. Color rebound was extensive, even in the gel + light system, with 41–51% of initial b^*L^* color change lost over 30 days. For perspective, multiple studies of self-directed whitening strips used for up to 2 weeks had less rebound, and greater two-parameter color change several weeks posttreatment.[19–21] Use of a positive control would help further dimension the absolute magnitude of whitening with in-office light-aided treatment. Of note, three subjects in the gel + light group experienced relatively greater post-treatment whitening approaching or exceeding two-unit improvement in Δb^* and ΔL^* at day 30. (These three subjects contributed a majority of the whitening seen in this group.) Such response could be indicative of subject-based factors associated with whitening. Regrettably, there were no evident differences (age, tooth color, gender, adverse events, or early discontinuation) for these three individuals relative to their peers, so we are unable to provide a research perspective on optimal patient selection for in-office treatment.

CONCLUSION

Clinical research on the in-office use of light and a peroxide gel alone or in combination showed significant immediate color change and posttreatment color rebound in all groups. Use of the light with the peroxide gel resulted in incremental whitening, but this was largely offset by increased tooth sensitivity occurrence and severity.

DISCLOSURE AND ACKNOWLEDGMENTS

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Reprint requests: Gerard Kugel, DMD, MS, PhD, professor, Department of Prosthodontics and Operative Dentistry, Tufts University School of Dental Medicine, Boston, MA, USA 02111; Tel: 617-636-0870; email: gerard.kugel@tufts.edu