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Clinical Research

A Clinical Study Comparing the Efficacy and Sensitivity of Home vs Combined Whitening

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Clinical Relevance

Although pressured to provide easier and more efficacious methods of whitening patients' teeth, clinicians must exercise caution in ensuring that the systems used do actually confer a benefit.

SUMMARY

This randomized clinical study assessed efficacy in terms of color change and production of sensitivity after home whitening alone and home whitening supplemented with in-office bleaching. Thirty-six subjects (aged 19 to 58 years) were randomly assigned to one of three different treatment groups: (A) home whitening for two weeks, with 16% carbamide peroxide in custom-made trays; (B) home whitening for two weeks, with 16% carbamide peroxide in custom-made trays supplemented with in-office bleaching with 9% hydrogen peroxide (in the same trays); or (C) home whitening for two weeks, with 16% carbamide peroxide in custom-made trays supplemented with in-office bleaching with 27% hydrogen peroxide (in the same trays). The efficacy of tooth whitening was assessed by determining the color change associated with the six upper anterior teeth using a value-ordered shade guide. Sensitivity was self-assessed with the use of a visual analog scale (VAS). Tooth shade and sensitivity were assessed at the following points: pretreatment; immediately after the home whitening phase; immediately after the in-office phase (groups B and C); and one week post active treatment. At the one week follow-up visit, subjects in group A had a mean (SD) color change of 5.9 (1.83) (teeth were lighter) immediately after cessation of treatment ($p<0.01$). Subjects in groups B and C experienced a greater change in mean (SD)

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shade immediately following their respective in-office treatments of 5.1 (1.53) and 5.4 (1.55). However, within one week, the shade of these teeth regressed to a similar degree to that achieved by subjects treated in group A. Overall, no significant difference in shade change or sensitivity was produced between the three groups. Investigators concluded that the in-office element of combined whitening produced no significant difference in tooth color or sensitivity when compared with home whitening alone.

INTRODUCTION

Color is central to the appearance of teeth; the discoloration of teeth understandably is a cause of great concern to a large number of subjects[1] who seek dental treatment to improve the appearance of their teeth. The cause of discoloration is multifactorial,[2,3] and an appropriately prescribed tooth whitening regimen offers a safe, non invasive, and predictable approach to improving appearance.[4] Methods for achieving chemical whitening of teeth can be divided into four categories as follows:

1. Home whitening: This is undertaken by the patient at home with the use of custom-made trays under the direction of a dentist.
2. Assisted whitening: Hydrogen/carbamide peroxide is applied in trays in-office.
3. Power whitening: This practice-only treatment requires gingival protection because of the high concentrations of hydrogen peroxide used; it may or may not be used in conjunction with a light or heat source.
4. Over-the-counter products: These may include toothpastes or whitening strips.[5]

Tooth sensitivity is the most common side effect of vital tooth whitening[6]; its prevalence has been reported to lie between 11% and 93%.[7-10] This huge variation in reported levels of sensitivity can be explained by the subjective nature of sensitivity, but also by the variation in concentrations of whitening agents used in these studies. Although sensitivity is very common, robust research investigating the severity of sensitivity associated with different whitening regimens is lacking.

Both at-home and in-office whitening techniques have been shown to produce favorable changes in tooth color,[11-18] and several manufacturers have attempted to combine the two techniques to develop a more efficacious procedure. Available research suggests that this combination technique produces significantly greater tooth whitening when compared with in-office whitening alone.[12] However, the effect of combined whitening vs that of home whitening alone has not been studied to date. Similarly, no study to date has examined the sensitivity associated with concentrations of carbamide peroxide used in assisted whitening, which are up to 22%. Tooth sensitivity studies related to the use of carbamide peroxide in at-home systems, however, report a higher level of sensitivity associated with higher concentrations as opposed to lower concentrations.[13]

Over-the-counter whitening treatments have been extensively evaluated in contrast to power whitening or office whitening, which has not.[4] Although it is accepted that over-the-counter whitening products are effective, the outcome is short-lived.[4] Regression of whitening in the period immediately following whitening, however, is recognized as a problem for all whitening agents, but this is a particular problem with over-the-counter products.[5] Because of the paucity of good quality evidence, it is difficult to comment further on the effectiveness of power or in-office whitening.

This randomized clinical study, therefore, aimed to assess the efficacy of color change and production of sensitivity after home whitening alone, and after two different regimens of in-office assisted whitening. Color change was assessed by visual comparison with a modified shade guide, which is a widely accepted technique for studies of this type,[19-23] whereas sensitivity was evaluated with a visual analog scale (VAS).

METHODS AND MATERIALS

This randomized clinical study assessed efficacy in terms of color change and production of sensitivity after home whitening alone and home whitening supplemented with in-office bleaching.

Study Design

This study included 36 subjects aged 19 to 58 years (mean, 29.8 years). Subjects were assigned with the use of a randomly generated allocation table to one of three treatment groups: (A) home whitening (n=12); (B) home whitening combined with 9% hydrogen peroxide (n=12); or (C) home whitening combined with 27% hydrogen peroxide (n=12).

Inclusion Criteria

1) Adult (18–70 years). 2) Available for the duration of the study. 3) Minimum of 20 uncrowned natural

teeth. 4) Minimum of upper six anterior teeth without crowns or large restorations. 5. Minimum baseline shade of A3 for all upper six front teeth.

Exclusion Criteria

1) Presence of orthodontic bands/brackets. 2) Presence of removable partial dentures. 3) Tumor(s) of the soft or hard tissues of the oral cavity. 4) Advanced periodontal disease (consisting of purulent exudate, tooth mobility, and/or extensive loss of periodontal attachment or alveolar bone). 5) Five or more carious lesions requiring immediate restorative treatment. 6) History of allergy to consumer or) personal care products. 7) Participation in any other clinical study or test panel up to one month before the start of the study. 8) Use of a tooth whitening procedure up to one month before entry into the study. 9) Pregnant women or women who are breast-feeding. 10) Medical condition that the investigator believed may compromise the subject's safety.

Methods

This study was reviewed by Leeds Dental Institute Ethics Committee; all subjects were provided with a patient information sheet and were required to sign informed consent forms before they were enrolled into the study.

Once subjects were enrolled into the study, upper and lower alginate impressions were made to allow custom whitening trays to be made, and tooth shades were assessed. Before active treatment was begun, the following baseline measurements were recorded at this appointment ("Baseline visit"): tooth shade (upper six anterior teeth), sensitivity, full intraoral examination, and digital color images of the upper anterior teeth.

All tooth shades were assessed visually by one examiner and the examiner's dental nurse independently with reference to a value-ordered shade guide—the Vitapan Classical Shade Guide (Vita Zahnfabrik, Bad Säckingen, Germany)—and for shades lighter than Vita B1, a "bleaching" shade guide was used (Ivoclar Vivadent, Leicester, UK) (Figure 1). Following independent assessment, an agreed tooth shade was recorded. According to the scale shown in Figure 1, each shade was then assigned a numeric value.

Sensitivity was self-assessed with the use of a VAS, with 1 correlating to no sensitivity and 10 correlating to unbearable sensitivity.

Different treatment regimens were randomly allocated, as explained in the following paragraphs.

Group A: Home Whitening With 16% Carbamide Peroxide (Enlighten, London, UK)

Subjects were advised to wear the trays with the whitening product for 14 consecutive nights for at least seven hours per night. This was in keeping with the manufacturer's instructions.[14] After a two week period of active treatment, the subjects were recalled, and information recorded at baseline was updated at the post home bleach visit.

Group B: Home Whitening With 16% Carbamide Peroxide Supplemented With an In-Office Course of Assisted Whitening With 9% Hydrogen Peroxide (Enlighten)

Subjects were advised to wear the trays as per group A, and at the two week point, subjects were recalled, and the information recorded at baseline was updated at the post home bleach visit. However, soon after this (within 24 hours), treatment of the upper and lower front teeth using the chairside whitening system (two 20 minute applications of 9% hydrogen peroxide) was performed at the post office bleach visit. Information recorded at baseline and before chairside treatment was then updated.

Group C: Home Whitening With 16% Carbamide Peroxide Supplemented With an In-Office Course of Assisted Whitening With 27% Hydrogen Peroxide (Enlighten)

Subjects were advised to wear the trays as per group A, and at the two week point, subjects were recalled, and information recorded at baseline was updated at the post home bleach visit. However, soon after this (within 24 hours), treatment of the upper and lower front teeth using the chairside whitening system (two 20 minute applications of 27% hydrogen peroxide) was performed. Information recorded at baseline and before chairside treatment was then updated.

All Treatment Groups

All groups returned one week after their respective active treatment was completed. At this visit, all information taken at baseline was updated ("1 week follow-up visit").

Statistics

The average tooth shade was calculated for each patient based on data from the upper six anterior teeth. Given the fact that the Vitapan Classical Shade Guide produces ordinal scores, the data for tooth shade nonparametric statistics were used for

Figure 1. *Vitapan and Ivoclar shade guides arranged in value order. These shade tabs were assigned numeric values of 1 to 18, starting from BL1 with increasing values moving to the right.*

the analysis. Kruskal-Wallis tests were used to evaluate differences in shading between the three treatment groups at baseline and at the end of treatment. The Wilcoxon Signed Ranks test was used to assess changes in shade within each treatment group (from post home bleach visit compared with baseline visit; from 1 week follow-up visit compared with visit 2 for ALL groups; and from post office bleach visit to post home bleach visit, and from 1 week follow-up visit to post office bleach visit for groups B and C only). The Mann-Whitney test was used to determine differences between groups at each time point.

Sensitivity data were analyzed using one-way analysis of variance (ANOVA) to evaluate differences between groups at baseline and at the end of treatment. Paired *t*-tests were used to evaluate differences in sensitivity within treatment groups for each time point. All results were analyzed using the Statistical Package for the Social Sciences (SPSS), version 15 (SPSS Inc, Chicago, IL, USA). Statistical significance was set at the 5% level, or α=0.05.

RESULTS

Table 1 shows the mean tooth shade by treatment group at various time points. All 36 subjects evaluated at baseline returned for all planned visits. At baseline, no significant differences between groups in terms of tooth shade were noted ($X^2_{[2]} = 2.05$; p=0.36).

All groups showed a significant change in tooth color when baseline shades were compared with those at final recall (Table 1). Home whitening, which was used in all treatment groups, resulted in an improvement in tooth color of the order of eight shade tabs when measured immediately after the home whitening stage of treatment (Table 2). The additional use of in-office assisted whitening resulted in a statistically significant shade change imme-

Table 1: *Mean (Standard Deviation) Shading by Group and Time Point*

Group	Baseline	Post Home Bleach	Post Office Bleach	1 Week Follow-up
A	14.1 (3.13)	5.4 (1.79)		5.9 (1.83)
B	13.1 (2.95)	5.6 (1.78)	5.1 (1.53)	5.4 (1.91)
C	14.7 (2.76)	6.5 (1.91)	5.7 (1.59)	6.2 (1.30)
Total	14.0 (2.95)	5.8 (1.83)	5.4 (1.56)	5.8 (1.68)

diately post treatment (ie, post office bleach visit) (9% hydrogen peroxide, p=0.002; 27% hydrogen peroxide, p=0.002). However, clinically, this was insignificant because the mean difference was less than one shade tab. Also, no statistically significant difference was noted in shade change immediately post treatment (ie, at post office bleach visit) when 9% hydrogen peroxide was used in comparison with 27% hydrogen peroxide (p=0.25). In all groups, the shade change was found to have regressed somewhat when assessed at final recall (ie, one week follow-up visit); this regression occurred to such a degree that no significant difference in shade change was observed between any of the treatment groups ($X^2_{[2]} = 2.05$; p=0.359).

No significant differences in sensitivity were observed between the three groups at baseline according to ANOVA (p=0.23) (Table 3). In general, sensitivity increased during the course of the study; the maximum increase was noted immediately after the home whitening stage (ie, post home bleach visit). These findings were statistically significant

Table 2: *Shade Changes at Start and End of Home Whitening Phase*

Group	Mean Shade at Baseline	Mean Shade at 1 Week Follow-up	Mean Difference	Wilcoxon Test Between Visits, *p* Value
A	14.1	5.4	8.7	<0.05
B	13.1	5.6	7.5	<0.05
C	14.7	6.5	8.2	<0.05

Table 3: *Mean (Standard Deviation) Sensitivity by Group by Visit*

Group	Visit 1	Visit 2	Visit 3	Visit 4
A	3.1 (1.86)	4.5 (2.41)		2.9 (1.68)
B	2.1 (1.00)	3.6 (2.54)	4.0 (2.52)	2.2 (1.47)
C	2.8 (1.42)	4.2 (2.17)	4.4 (2.19)	2.8 (1.53)
Total	2.7 (1.49)	4.1 (2.34)	4.2 (2.32)	2.6 (1.55)

according to the t-test (group A, p=0.003; group B, p=0.016; group C, p=0.008).

For subjects treated with in-office assisted whitening, an additional increase in sensitivity was recorded, although this was not statistically significant ($p>0.05$). At the completion of the study, all sensitivity levels had returned to baseline levels. This sensitivity increase may be regarded as transient, in that comparison of sensitivities at baseline and at final recall revealed no significant differences between the three groups (p=0.47), or when final levels of sensitivity were compared with baseline scores of each group (group A, p=0.46; group B, p=0.67; group C, p=0.75).

DISCUSSION

This study showed that significant improvement in tooth color, in terms of whitening, occurs when 16% carbamide peroxide is used in a nightguard vital bleaching procedure; this is consistent with the findings of previous research.[7,11,15-17] Supplemental use of in-office whitening with 9% and 27% hydrogen peroxide was shown to result in a further degree of whitening, which is thought to be due to higher levels of oxygen within the tooth immediately after the supplemental use of in-office whitening agents.[11,17] However, no statistical difference was observed in the degree of additional whitening produced with 9% and 27% hydrogen peroxide. The whitening effect seen in all groups regressed somewhat, such that comparison of whitening from baseline to final recall showed no significant differences between the three groups. This regression is well recognized,[10,18] and it is thought that oxygen within the tooth from the oxidative process initially alters the optical properties of the tooth. Oxygen then dissipates over the following week(s), and the tooth takes on the actual lightened shade.[5]

Tooth sensitivity is a recognized complication of tooth whitening with peroxide,[5-7,10,11,19] and so its occurrence in this study was to be expected. The greatest increase in sensitivity levels was reported immediately after the home whitening phase (ie, at the post home bleach visit). Subjects receiving supplemental in-office whitening reported a further increase in sensitivity immediately after the application of in-office hydrogen peroxide. However, this was not significant, and overall, changes in sensitivity from baseline to final recall for all groups were found to be not significant.

Several modes of measuring tooth shade are available in dentistry, including shade guides, colorimeters, and spectrophotometers, to name a few. For this study, the Vitapan Classical Shade Guide (Vita Zahnfabrik) and the four-tab "bleaching" shade guide (Ivoclar Vivadent) were used. They are familiar to practicing dentists and are practical and economical; the Vitapan guide is often used in research studies.[20-22] Furthermore, when the Vita guide is arranged in value order, this has been shown to make shade selection easier and more predictable when used for whitening teeth.[23] In addition, in this study, shade was measured independently and was subsequently agreed upon by two independent examiners before the shade was recorded. However, a greater degree of standardization could have been achieved (ie, shades taken under the same lighting conditions, at the same time of day, etc.), and this may have enhanced the accuracy of results. It is important to note though that the "random" nature of result collection mirrors the situation encountered in day-to-day practice.

There is always a potential problem when statistical analyses are translated into the clinical situation. For instance, in this present study, the additional use of in-office whitening resulted in a statistically significant shade change immediately post treatment (9% hydrogen peroxide; 27% hydrogen peroxide); clinically, though, this was insignificant, because the mean difference was less than one shade tab. Measurement of sensitivity is also subjective. To reduce this subjectivity (although it could not be eliminated), the study focused on changes in sensitivity within the same subjects.

To more fully assess the combination of home whitening and assisted whitening, further research could investigate the effect of using in-office whitening before home whitening. This would assess the impact of high-strength hydrogen peroxide in-office treatments on subsequent home whitening, rather than the converse. Future research could also investigate the effect of increasing the frequency of in-office hydrogen peroxide application, and its effect on tooth whitening and/or sensitivity. However, it would appear from the results of this study that there is likely to be no statistically significant difference in whitening outcomes or clinical indications to support combining home whitening and assisted whitening, because the results are not significantly different from those produced by home whitening alone.

CONCLUSION

Within the limitations of the study, it was concluded that home whitening with 16% carbamide peroxide produces changes in mean tooth shade that result in significant tooth whitening. The addition of a supplemental in-office whitening phase (9% and 27% hydrogen peroxide) produces no significant change ($p>0.05$) in tooth color when compared with home whitening alone (at the final recall). No significant difference ($p>0.05$) in changes in sensitivity was noted for any of the three groups; any change in sensitivity from baseline to final recall was deemed to be not statistically significant.

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