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Clinical Research

Comparative Clinical Study of the Effectiveness of Three Different Bleaching Methods

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Clinical Relevance

The efficacy of vital bleaching depends on the two aspects—viz, bleaching agent and the bleaching method. Results from this *in vivo* study show that 10% carbamide peroxide home-bleaching and 15% hydrogen peroxide in-office bleaching were more effective than a 6% hydrogen peroxide home-bleaching over-the-counter product up to three months after completion of the bleaching treatment.

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SUMMARY

Objective: The current study assessed the efficacy of three current bleaching methods.

Methods: Seventy-five healthy subjects (45♀; 30♂) with anterior teeth, having a Vita Shade score of A2 or darker, participated in the study. The subjects were randomly assigned to one of three treatment groups: Group A: home-bleaching (Illumine Home, 10% carbamide peroxide, trays, overnight, for two weeks), Group B: in-office bleaching (Illumine Office, 15% hydrogen peroxide, trays for 45 minutes, three times over three weeks), Group C: Whitestrips (strips, twice a day, 30 minutes each for two weeks).

Following the screening visit, three weeks prior to the baseline examination, all subjects received a dental prophylaxis.

The color of the teeth was determined using a colorimeter (ShadeEye NCC) and a custom-made stent at baseline (E_0), immediately after completion of the bleaching (E_3) and three months after treatment (E_4). All subjects received oral hygiene instructions and a toothbrush and toothpaste for oral home care during the study period.

The change of tooth color was determined for each treatment regimen between baseline and E_3 and baseline and E_4 and was statistically analyzed performing the Kruskal Wallis test and the Mann-Whitney-U test. The significance level was set at $p<0.01$.

Results: The dropout rate was 0%. Mean (SD) ΔE* (overall color change) from baseline to immediately after treatment was 6.57 (2.13) for Group A, 5.77(1.72) for Group B and 3.58 (1.57) for Group C. The mean (SD) tooth color change from baseline to three months after treatment ΔE* was: 4.98(1.34) for Group A, 4.59 (1.42) for Group B and 2.99 (1.39) for Group C. Significant differences were found between home bleaching and Whitestrips, as well as between in-office bleaching and Whitestrips, but not between home-bleaching and in-office bleaching during the same time.

Conclusion: Using an objective color measurement device, home bleaching and in-office bleaching were found to be superior to Whitestrips. Home bleaching and in-office bleaching were equally efficient for bleaching teeth and maintaining the results for up to three months.

INTRODUCTION

The increasing demand for brighter and whiter teeth by patients has led to the development of various (several) bleaching products (by the industry).

Tooth discolorations vary in etiology, appearance, localization, severity and adherence to tooth structure. They are categorized as intrinsic or extrinsic. Intrinsic discoloration is caused by the incorporation of chromatogenic material into dentin and enamel during odontogenesis or after eruption. After eruption of the tooth, aging, pulpal necrosis and iatrogenesis are the main causes of intrinsic discoloration. Pigments of coffee, tea, red wine, carrots, oranges and tobacco cause extrinsic staining of teeth.[1-2]

Scaling and professional cleaning of discolored teeth are common procedures for removing the majority of extrinsic stains. For more tenacious extrinsic discolorations and intrinsic staining, various bleaching techniques may be attempted. Three distinct bleaching approaches are available: dentist-supervised nightguard bleaching, in-office or power bleaching and over-the-counter bleaching products. Nightguard bleaching typically uses a relatively low concentration of bleaching agent applied to the teeth via a custom fabricated tray that is worn at night for at least two weeks.

The bleaching agents currently used are hydrogen peroxide at concentrations ranging from 3% to 50% and carbamide peroxide at concentrations between 1% and 45%. In-office-bleaching generally uses high concentrations of bleaching agents (15% hydrogen peroxide) applied for a shorter period of time. Over-the-counter products typically contain low concentrations of the bleaching agent (6% hydrogen peroxide), which are self-applied to the teeth via strips and normally require applications twice a day for up to two weeks. In general, the efficacy of hydrogen peroxide-containing products is similar to carbamide peroxide-containing products tested *in vivo*.[3-4]

In addition to the bleaching agent and its concentration, treatment time also affects bleaching success. Sulieman and others[5] compared the *in vitro* tooth bleaching efficacy of gels containing 5%-35% hydrogen peroxide and found that the higher the concentration, the lower the number of gel applications required to produce uniform bleaching. Similar results were found by Leonard and others,[6] who compared the *in vitro* tooth bleaching efficacy of 5%, 10% and 16% carbamide peroxide gels and found that bleaching by 16% and 10% carbamide peroxide was initially faster than by the 5% concentration. Matis and others showed that a 15% carbamide peroxide gel achieved significantly better tooth bleaching than a 10% carbamide peroxide gel after two weeks of use. However, by extending the treatment time to six weeks, the differences in tooth color or brightness were no longer of statistical significance.[7]

Common clinical adverse effects of bleaching are hypersensitivity and gingival irritation. Browning and others observed dentinal hypersensitivity in 77% of subjects and 22% soft tissue sensitivity.[8]

The aim of this study was to compare the efficacy of three vital bleaching methods (home-bleaching, in-office-bleaching and over-the counter bleaching) with different bleaching agents (carbamide peroxide or hydrogen peroxide). The products were applied according to the manufacturer's instruction, and they varied in concentration and instructions for use. In addition, the range and frequency of oral adverse side effects were recorded for evaluation of tolerability and safety parameters.

METHODS AND MATERIALS

Seventy-five generally healthy subjects participated in the current study. The eligibility for enrollment was determined in a screening examination according to the following inclusion and exclusion criteria. The subjects included were older than 18 years of age and had the desire to have their six upper and six lower anterior teeth bleached. The selected teeth were not allowed to have apparent fillings or crowns and had to have a Vita-color shade of A2 or darker.

Criteria for exclusion from the study were serious general diseases, alcoholism, heavy smoking, known hypersensitivity to the substances used in the study, pregnancy and lactation, serious oral diseases, such as acute necrotizing gingivitis, acute gingivostomatitis (for example, due to AIDS), the wearing of orthodontic appliances, hypersensitive or exposed tooth cervices, enamel cracks or crevices or a past history of bleaching therapy. Following the recruitment of subjects, the study conditions and procedures were explained and written consent was obtained from each subject. A medical and dental health history was taken and the eligibility of the subject to enter the study was decided.

During the screening examination, each subject was given oral hygiene instructions, and a professional tooth cleaning was carried out using ultrasonic and hand instruments and dental floss. Tooth polishing was done using a rubber cup and polishing paste (CleanicDent, KerrHawe, Switzerland). Three weeks after the screening examination, the baseline examination (E_0) was carried out. Each subject received a tube of toothpaste (Oral-B Advantage, Procter & Gamble GmbH, Schwalbach am Taunus, Germany) and a toothbrush (Cross Action Vitaliser 35 Soft, Procter & Gamble GmbH), as well as one of the three different bleaching treatments. At the baseline visit (E_0), immediately after completion of the bleaching (E_3) and three months after bleaching (E_4), digital imaging and oral tissue examinations were conducted. All bleaching procedures were performed by the same dentist (KD).

Of the 75 total subjects, 45 participants were female and 50 were non-smokers (Table 1). Table 2 provides the mean age of the subjects for each group.

Accounting for baseline tooth color and age, the subjects were randomly assigned to one of three treatment groups: 10% carbamide peroxide custom tray (Illumine Home 10%, Dentsply Detrey GmbH, Konstanz, Germany), 15% hydrogen peroxide custom tray (Illumine Office, Dentsply Detrey GmbH) or 6% hydrogen peroxide whitening strips (Blend-a-Med Whitestrips, Procter & Gamble, Cincinnati, OH, USA). Subjects assigned to the Illumine Office groups were treated three times over three weeks for 45 minutes each.[9] The subjects from the Illumine Home group were treated overnight for two weeks. The Whitestrips group subjects applied them twice a day for 30 minutes each for two weeks.

The effectiveness of bleaching was measured by a change in tooth color using a colorimeter (ShadeEye NCC, Shofu, Ratingen, Germany). ShadeEye NCC is an intraoral contacting colorimeter designed to measure the shades of natural teeth through a disposable contact tip. The color is often expressed in terms of the Commission Internationale de I'Éclairage (CIE) Lab* color space. The CIE Lab* system provides the advantage that color differences are expressed in units directly related to visual perception and clinical significance.[10]

The following formula was used to determine the overall color change ΔE^*, $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

ShadeEye NCC identifies the L* a* b* value at each measurement. These are values from the three-dimensional color space. The L* value stands for brightness, that is, the black-white axis. The higher the L* value, the "whiter" the object. The a* value provides a value on the red-green axis, for which higher values mean more red in the object. The b* value represents the blue-yellow axis, for which higher values signify more yellow. At each visit, three measurements were made for each tooth and the average L*, a* and b* values were calculated. The data records of each subject were transferred to a patient-oriented Excel file directly following the measuring cycle, from which the data was transferred to the SPSS statistics program. In addition to the electronic color determination, an individual color determination was made at each session using a Vita Lumin shade guide as a reference to the clinical situation. The Vita shade guide is a widely used system for color determination in daily dental practice. It consists of the 16 most common tooth colors sorted according to shade (Table 3).

Table 1: *Distribution of Subjects by Gender and Smoking Status to Bleaching Modalities*

	Illumine-Home	Illumine-Office	Whitestrips
female	15	14	16
male	10	11	9
non-smoker	15	17	18
smoker	10	8	7

Table 2: *Number of Subjects (N) and Age Distribution at Baseline Examination*

	Age in Years					
Product	N	Minimum	Maximum	Median	Mean	Standard Deviation
Illumine-Home	25	20.21	64.22	38.27	38.71	13.02
Illumine-Office	25	18.63	65.63	45.94	43.27	17.25
Whitestrips	25	19.16	66.97	41.40	40.65	14.43

Table 3: *Vita Shade Designations and Corresponding Scores*

Vita	B1	A1	B2	D2	A2	C1	C2	D4	A3	D3	B3	A3,5	B4	C3	A4	C4
Rank	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

The color determination was made directly following the electronic measurement, without the bleaching tray, under the same conditions and was always carried out by the same dentist using the same shade guide. The tooth colors were recorded manually by an assistant on prepared forms and were later entered into the SPSS file by the examiner, together with all other data.

Impressions of the upper and lower jaws were taken. Plaster models were made from the impressions and used to fabricate customized bleaching trays for the upper and lower jaws for each subject. The trays were made from transparent, soft plastic (Opalescence, Ultradent Products, South Jordan, UT, USA) using a heat and vacuum tray-forming procedure. The models were analyzed for the purpose of finding a suitable, reproducible reference point on each of the 12 selected teeth (incisors and canines; upper and lower jaws) for a comparative color analysis. The measuring points were four millimeters coronal to the free gingival margin in an area as flat as possible to allow a precise and reproducible positioning of the contact tip (with 5 mm diameter) of the color measuring instrument. For this purpose, holes matching the dimensions of the contact tip were drilled into the splint for each tooth selected for bleaching. The hole at the designated reference point corresponded exactly to the dimensions of the contact tip (ShadeEye Contact Tip) of the colorimetric instrument. These prepared splints allowed the examiner to access the determined measuring point reproducibly (Figure 1).

The bleaching trays were checked in terms of their seat on the teeth. Subjects were asked at every session about experiencing any discomfort during and/or after the bleaching sessions.

Data Analysis

All recorded data were entered into a statistics program. The statistical analysis was executed with the SPSS computer program for Windows 12.0.

Analysis of the secondary data was exclusively of a descriptive nature: the median, quartiles, minimum, maximum, mean and standard deviation were calculated.

In addition, changes in the L*, a*, and b* values in each group were compared using the Kruskal Wallis and the Mann-Whitney U-tests. The significance level was set at $p<0.05$. In order to maintain the probability of error at 5%, the p-values were adjusted accordingly for individual tests.

RESULTS

The data were normally distributed; therefore, mean values were used for the statistical analysis.

Significant differences in color changes were found among the various bleaching modalities at the time

Figure 1. *Inserted individual splint with reference points for colorimeter tip.*

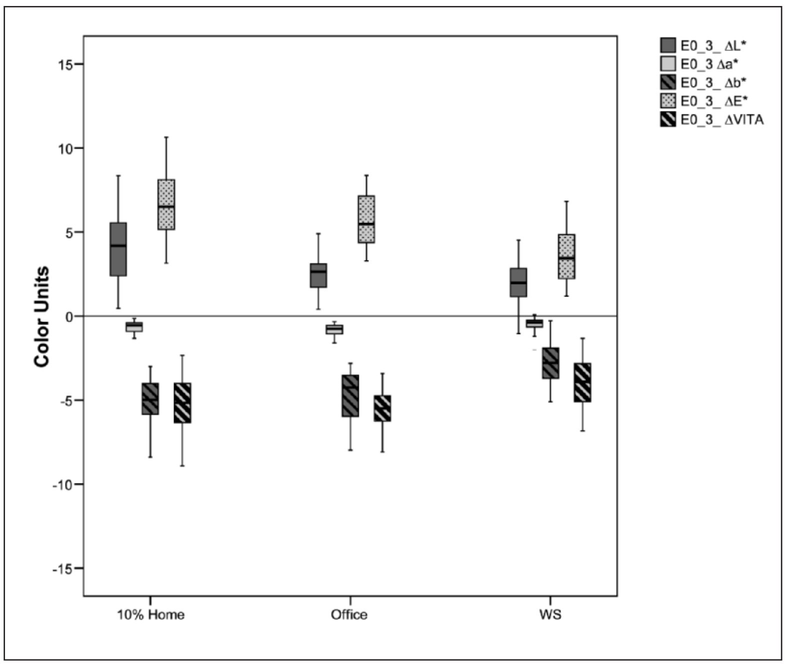

Figure 2. *Change in ΔL*, Δa*, Δb*, ΔE*, and ΔVita*
Color change between baseline examination and completion of bleaching (E_0-E_3)
*(Horizontal lines indicate significant differences between the groups at *p<0.05, ***p<0.001).*
(10% Home: Home-bleaching; Office: in-office bleaching; WS: Whitestrips)

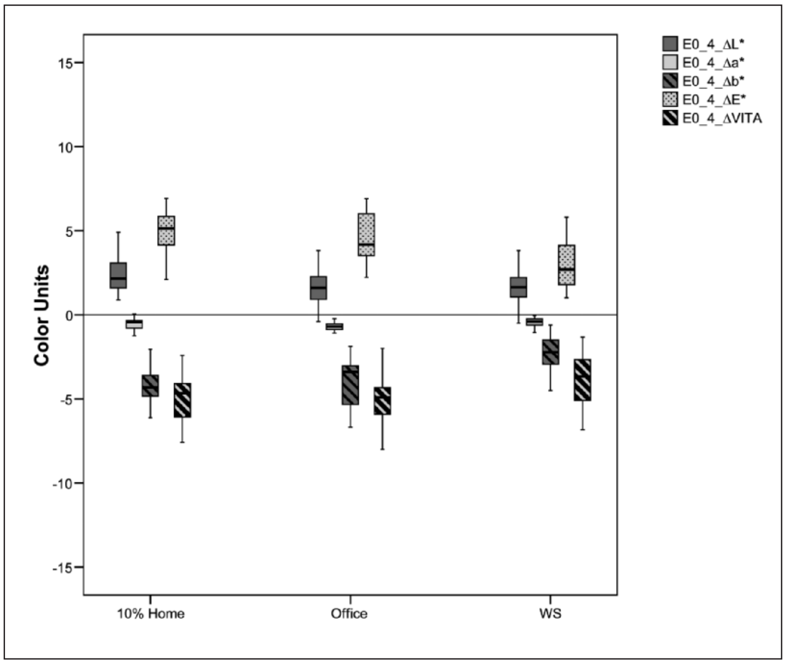

Figure 3. *Change in ΔL*, Δa*, Δb*, ΔE* and ΔVita*
Color change between baseline examination and follow-up three months after completion of bleaching (E_0-E_4).
*(Horizontal lines indicate significant differences between the groups at *p<0.05, ***p<0.001).*
(10% Home: Home-bleaching; Office: in-office bleaching; WS: Whitestrips)

interval baseline to immediately after completion of the bleaching (E_0-E_3) (Δb*, ΔL*, Δa* and ΔE*) and at baseline to three months follow-up interval (E_0-E_4) (ΔL*, Δb* and ΔE*) (Kruskall-Wallis test).

The color changes Δb* determining the degree of yellowness and blueness between baseline and completion of bleaching (E_0_3) and at the three month follow-up (E_0_4) treatment using home-bleaching and in-office bleaching were significantly more efficacious than Whitestrips (Mann-Whitney U-test) (Figures 2 and 3). No significant differences were found between home bleaching and in-office bleaching in b*.

The changes in brightness ΔL* between baseline and completion of bleaching (E_0-E_3) were significantly greater for the bleaching treatment using home bleaching in comparison to in-office bleaching and Whitestrips (Mann-Whitney U-test). No significant differences were found between in-office bleaching and Whitestrips (Figure 2). At the three month follow-up (E_0-E_4) for the bleaching treatment using home-bleaching, the color changes ΔL* remained significantly greater compared to in-office bleaching and Whitestrips (Mann-Whitney U-test). No significant differences were found between in-office bleaching and Whitestrips in L* (Figure 3).

The color changes along the red-green axis Δa* between baseline and after the final examination (E_0-E_3) for the bleaching treatment using home-bleaching and in-office bleaching were significantly greater compared to Whitestrips (Mann-Whitney U-test). No significant differences between home bleaching and in-office bleaching (Figure 2) were found. The bleaching outcome for in-office bleaching was unchanged at the three month follow-up (E_0-E_4), which was revealed in the significant color change Δa* in contrast to home bleaching and Whitestrips (Mann-Whitney U-test). No significant differences between home bleaching and Whitestrips (Figure 3) were found in a*.

The color changes ΔE* and ΔVita between baseline and after the final examination (E_0-E_3) and ΔE* and ΔVita between baseline and three months after completion of bleaching (E_0-E_4) revealed significantly better bleaching results when home bleaching was provided (Mann-Whitney U-test). Neither treatment with in-office bleaching nor Whitestrips resulted in a significant ΔE* or ΔVita change in E* (Figures 2 and 3).

Table 4 demonstrates the hypersensitivity and gingival irritation reported by patients after bleaching. Tooth sensitivity was similar in all groups and ranged from 60% to 72% of all patients. Gingival irritation was low, with 7% to 13%. All bleaching treatments were well tolerated. Adverse reactions were frequent but mild in severity and did not contribute to any treatment modification or early withdrawal.

Table 4: *Treatment-related Adverse Effects Experienced During Bleaching Procedures*

Subjects-Reported			
Adverse Effects	**10% Home (n = 25)**	**Office (n = 25)**	**WS (n = 25)**
Tooth Sensitivity			
Occurrence (n, %)	18 (72.0%)	16 (64.0%)	15 (60.0%)
Average duration (days)	5	1	5
Gingival Irritation			
Occurrence (n, %)	7 (28.0%)	13 (52.0%)	7 (28.0%)
Average duration (days)	1	1	1

DICUSSION

The more yellow the teeth at baseline, the better the outcome of tooth bleaching.[11] The analysis by Gerlach and Zhou, including 600 subjects, demonstrated a significant relationship between the subject's age and the magnitude of bleaching response, with younger subjects experiencing better tooth bleaching results.[11] The bleaching groups of the current study were balanced for baseline tooth color and age.

The subjective determination of tooth color is challenged by high variability. Interference by surrounding light is a disadvantage of the subjective color determination, as is the variability of the subjective color impression. The color impression of a tooth depends on the translucency, reflection and adsorption of light on the tooth surface. In various *in vivo* studies, the tooth color sample of the shade guide was related to a specific ranking on a light-dark scale.[12-15] The advantage of the objective color determination in the current study is the exclusion of all confounding factors and the generation of precisely and objectively measured data. The values recorded are more sensitive to color change than those obtained by trying to match the tooth color to the closest Vita shade. The intraoral dental colorimeter (ShadeEye NCC) produces acceptable reproducibility from readings of natural teeth.[14]

Color measuring instruments have been used to determine the color of teeth in several studies.[16-19] In the current study, the authors used two techniques of color measurement.

Recordings with the colorimetric device are sensitive to handling. Haase identified significant color changes when the tip of the measuring instrument lacked complete contact with the tooth surface.[20] In the current study, reproducible reference points were generated by using an individual measuring split as a reference to record the tooth color in the same place and at the same distance at each measurement.

Heymann[21] has suggested that the concentration and contact time of the bleaching agent to the tooth are very important for the bleaching outcome. The study by Matis and others agreed that the contact time of the bleaching agent appears to be an important factor,[22] but that the concentration is not as important a factor for the bleaching outcome. The current study confirmed that the contact time, as well as the concentration of the bleaching agents, was important for the bleaching effect. Home bleaching with a low concentration of bleaching agent but with a longer contact time was as effective as the in-office-bleaching with a highly concentrated bleaching agent but with a shorter contact time. Leonard and others concluded that higher concentrations achieved faster bleaching, but the results were equivalent if lower concentrations were used for a longer time.[23] The results of the current study showed that 10% carbamide peroxide applied for two weeks for eight hours daily (total 112 hours), as well as three times 15% hydrogen peroxide for 45 minutes (total 2 hours and 15 minutes), were more effective than 6% hydrogen peroxide for 14 hours. One *in vitro* study investigated 11 different bleaching regimens: home bleaching using 10%, 15%, 16% or 20% carbamide peroxide, power bleaching using 15% hydrogen peroxide, 30% hydrogen peroxide or 25% carbamide peroxide with or without light activation and over-the-counter bleaching strips containing 5.3% hydrogen peroxide. The study showed that all the products had a similar bleaching effect on enamel, but only the home bleaching regimen was more effective in lightening dentin. The authors suggested that the in-office bleaching technique proved to be less efficient than home bleaching for removing stains deposited in dentin.[24] The current study, in which the bleaching effect on enamel was measured, showed the greatest bleaching effect for home bleaching and in-office-bleaching compared to Whitestrips.

The current study showed that home bleaching was more effective than the study by Gerlach and others (2000).[25] In the Gerlach and others study, home bleaching was applied for two hours per day. In contrast, the subjects in the current study were instructed to use home bleaching for eight hours and longer per day (overnight). Gerlach and others found that the bleaching effects of a 5.3% hydrogen peroxide bleaching strip compared to a 10% carbamide peroxide tray-based home bleaching system did not differ statistically with respect to any of the color measurements used in the current study.

A study[26-28] showed the advantages of colorimeter measurements over the shade guide[25-27] for determining the efficacy of tooth-whitening products. The colorimeter evaluation of color change is a more objective measurement procedure that eliminates the potential for human bias and variability.

Comparing bleaching with in-office bleaching (38% hydrogen peroxide), home bleaching (10% carbamide peroxide) and Whitestrips (6% hydrogen peroxide), all groups achieved six grades of bleaching assessed by the VITA shade guide. The most accepted method among subjects was the home bleaching technique.[29] The results of the current study are similar to four or five grades of bleaching assessed by the VITA shade guide for all groups.

Adverse effects in conjunction with bleaching, such as hypersensitivity or gingival irritation, have been reported under similar conditions.[12,30,32] In the current study, hypersensitivity and gingival irritation were minor and disappeared spontaneously without requiring an interruption of the treatment.

CONCLUSIONS

In summary, clinical tooth bleaching with home bleaching with 10% carbamide peroxide for two weeks for eight hours per day or in-office bleaching three times for 45 minutes each revealed a bleaching effect superior to Whitestrips for up to three months after bleaching.

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