Clin Oral Invest (2007) 11:321–329
DOI 10.1007/s00784-007-0128-x

ORIGINAL ARTICLE

Efficacy and tolerability of two home bleaching systems having different peroxide delivery

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Received: 4 September 2006 / Accepted: 15 May 2007 / Published online: 26 June 2007

Abstract The aim of this study was to investigate tooth whitening efficacy and oral side effects during bleaching with Whitestrips® (WS) (6% hydrogen peroxide H_2O_2 gel) and Vivadent Vivastyle® (VS) (10% carbamide peroxide gel). Forty-seven subjects were included in this single blind, randomized, parallel group study. Application of WS was performed twice a day for 30 min. Trays filled with VS were worn for 60 min once a day. Tooth color was evaluated by measuring *L*a*b** values before the study and after completion of the bleaching. Treatment tolerability was monitored throughout bleaching with an 8-week follow-up after completion of therapy. After 2 weeks both treatment groups demonstrated significant improvements in tooth color compared to baseline. A shift toward less yellow (−Δb) and brighter (+ΔL) tooth color was observed. Δb amounted to −1.69±0.38 for WS and −1.20±0.34 for VS (mean value± SE). ΔL was +1.55±0.41 for WS and +1.20±0.37 for VS. There was no significant difference between the two systems. No significant differences between the two bleaching systems were recorded for clinically observed signs or reported symptoms. Gingival irritation was observed in 13%, reported tooth hypersensitivities in 22% and reported gum irritation in 20% of the total study population. At an 8-week follow-up visit no adverse effects were observed. Both WS and VS demonstrated significant and comparable levels of tooth color improvement after 2 weeks. Each treatment caused similar levels of transient oral side effects.

Keywords Bleaching · Side effects · *Lab* value · Efficacy · Hypersensitivities · Gingival irritation · Tolerability

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Introduction

Home bleaching with custom-tray-based systems is the method most frequently applied by dental professionals to intrinsically whiten vital teeth in Germany. Treatment responses are typically good with both examiner and subjects reporting noticeable improvement in tooth color [3, 21]. A meta-analysis of seven clinical studies indicated that a significant mean change from baseline of 6.4 shade guide units according to the Vitapan Vita guide scale was achievable by adoption of tray-based bleaching systems utilizing 10% carbamide peroxide gels [32].

Custom-fit trays are typically filled with bleaching gel and can be worn for at least 1 h daily for several days until desired whitening of the teeth is achieved. A variety of gel systems with varying peroxide concentrations, flavors, desensitizing agents, or other modifications to the formulation are available [9, 19, 20].

An alternative approach to vital tooth bleaching is based on thin polyethylene foils, covered with a hydrogen-peroxide-containing gel [15, 16, 18–20, 34]. These strips deliver a controlled and relatively low dose of bleaching

active to the anterior dentition only [15, 16, 18–20, 34]. Numerous investigations have been published attesting to the clinical efficacy and safety-in-use of this new technology relative to both placebo and marketed controls [12, 15, 16]. Given the increasing diversity of tooth whitening products on the market it is important to understand how new methods of tooth bleaching compare with classical custom-tray-based systems with respect to efficacy and tolerability.

A number of methods are available for evaluating the efficacy of bleaching products [11, 32]. Essential components of an effective evaluation tool are the ability to perform reproducible, objective, and precise measurement of tooth color [11, 15, 16, 32]. Tooth color determination using the commonly cited shade-based guides have limitations given they are subject to examiner and environmental factors that can potentially influence classification of colors [12, 26]. The use of instrumentation to measure tooth color has a number of advantages over examiner-based evaluation techniques [3, 13, 15, 16, 24]. Specifically, it provides objective, linear, and quantitative means of evaluating color change where the use of common standards allows for instrument calibration and reproducibility overtime [3, 8, 11, 38]. The $L^*a^*b^*$ CIE (Centre Internationale De L'Eclairage) three-dimensional color space scale is the most frequently quoted index used in vital bleaching research and can be generated from colorimetric, spectrophotometric, or digital image analysis [8, 10, 12, 13, 15, 16]. Digital image capture of the anterior facial dentition offers some advantages over the other techniques as it captures the region of interest clearly most relevant to the bleaching outcomes—the "smile" teeth of a subject [12, 13, 15, 16]. For image analysis, red–green–blue values for the anterior teeth are obtained with reference to calibration standards. The average values of these teeth are transformed to yield CIE-LAB tooth color values for b^* (yellow-blue), L^* (lightness), and a^* (red-green) according to CIE [5]. The color measurement corresponds to the measurement performed with a noncontact spectrophotometer [10, 13]. A number of publications report the relevance of this approach in the context of visually perceived whitening and a positive correlation established between change in tooth yellowness and subject satisfaction after bleaching treatment [10–12, 14, 39].

Tolerability issues associated with peroxide-based bleaching therapies are well-documented and well-characterized with transient tooth sensitivity and gingival irritation described as the most commonly reported side effects [2, 3, 15, 16, 22, 23, 29–31, 33]. Up to 65% of individuals have been reported to be affected at least once during the bleaching regimen. Such events are generally mild in nature and resolve either during or upon completion of treatment [2, 3, 15, 16, 22, 23, 29–31, 33]. These effects have been reported for virtually all delivery systems and peroxide concentrations although recent research suggests that professionally administered, in-office treatments may elevate tooth sensitivity further still [31].

Dental hypersensitivity may be a result of penetration of bleaching agents into the pulp chamber, resulting in transient inflammatory reactions [4, 6, 17, 28, 36]. Furthermore, dehydration of the teeth during application of bleaching gels is also proposed as a reason for dental hypersensitivity [1]. Other oral soft tissue side effects have also been reported. Pohjola et al. [33] observed gingival irritation in 20–30% of the participants in a recent study, while in another study gingival irritations were observed in 31% of the cases during home bleaching [22].

The aim of this study was to compare the efficacy of a 6% hydrogen peroxide whitening strip system [Blend-a-Med Whitestrips (WS), Procter & Gamble, Cincinnati, USA] vs a 10% carbamide peroxide custom tray bleaching system designed also for short time application [Vivastyle (VS), Vivadent, Schaan, Liechtenstein]. In addition, the range and frequency of oral adverse side effects were recorded for evaluation of tolerability and safety parameters.

Materials and methods

The investigation was a monitored clinical trial performed following the ICH Good Clinical Practice Guidelines [25]. The study was reviewed and approved by the Ethics Committee of the University of Göttingen (proposal 4/9/01).

Products used in the study

The two bleaching systems tested in this study were Blend-a-Med WS and VS. Bleaching was performed for 14 days as per the manufacturers' instruction with subjects assigned to the tray group undergoing one application of 1 h/day and those assigned to the whitening strips undergoing two applications a day of 30 min each. Twenty-three subjects were treated with the tray system and 24 with the whitening strip system. Subjects were advised to use no other bleaching products throughout the study and were provided with toothbrushes (Oral B, Gillette, IR) and toothpaste (Blend-a-Med Kariosan, Procter & Gamble, Weybridge, UK) to ensure standardized oral hygiene procedures for the period of the study.

Bleaching systems

1. Maxillary Blend-a Med WS (6%) were used (lot no. PLN/64/0430). The strips were placed on the upper incisors and canines.
2. VS is a 10% carbamide peroxide gel (lot no. D95016). About 200–300 mg of gel were used for one charge of

the tray. Maxillary trays were vacuum formed from 1.5-mm-thick soft acrylate foils on plaster models. The canines and incisors were blocked out with composite (1.5 mm thickness) before manufacturing of the tray to achieve a reservoir. The tray was filled with VS in the area of incisors and canines only as to reflect a similar zone of treatment to the strip system. The time flow of the study is given in Table 1.

Subjects

Forty-seven volunteers with restored or caries-free teeth, anterior tooth color Vita shade A2 or darker, and with no crowns on upper cuspids or incisors were enrolled in the study at baseline. Patients with prior tooth hypersensitivities, anterior restorations, poor oral hygiene, generalized gingival recession, caries, heavy structural alteration of the tooth structure, and tetracycline or fluorosis staining were not included in the study. Furthermore, patients with infectious diseases, high risk for endocarditis, allergic reactions vs components of the bleaching agents, and xerostomia as well as pregnant or breast-feeding women were excluded in accordance with the regulations of the University of Göttingen Ethics Committee.

Subjects were stratified according to the baseline anterior maxillary tooth brightness (L^*) as determined by digital image analysis system and by the criteria of smoker/nonsmoker. Randomization to treatment was performed within each strata (Table 2).

Evaluation of efficacy: digital imaging and color determination

Maxillary anterior incisor facial surfaces were measured for tooth color using the digital image analysis technology (software: OmniGrab version 1.113, Procter & Gamble, Cincinnati, USA). The adopted system has previously been used in several bleaching studies to evaluate the efficacy of different bleaching products precisely and effectively [15, 16].

Imaging was carried out at baseline and day 15 after dental prophylaxis.

Before daily use, the system was calibrated to assure proper operation. In addition, a color standard was centered and imaged every hour and before imaging the subjects.

Digital images were captured with a high resolution digital color camera (Fuji HC 2500, Fuji Photo Film USA, Carlstadt, NJ, USA) connected to a conventional computer (software: OmniGrab version 1.113). The camera was equipped with a Fujicon lens and a linear polarizer to permit cross-polarized light. Two 150-W lights located on each side of a CCD camera provided the lighting. The lights were equipped with incandescent blue filters to use the camera at a constant color temperature (around 5,000 K). Linear polarizers mounted on the lights allowed the camera-mounted linear polarizer to be adjusted for extinction of highlights (specular reflection).

For each examination period, extrinsic lighting in the examination room was minimalized. Subjects were positioned on a chair in front of a chin rest used to fix the head in a reproducible position. The subject placed their chins on the chin rest, and then two plastic retractors were placed into the mouth to retract lips and cheeks. The tips of the front teeth were placed together and the operator positioned the subject to bring the teeth into the plane of focus and ensure the image was centered.

For image analysis, red–green–blue values for the six anterior maxillary teeth were obtained with reference to calibration standards. For this purpose, the corresponding areas were marked on the images. These average values of the teeth were transformed to yield CIE-LAB tooth color

Table 1 Time flow of the study

Time lapse	VS and WS
Preliminary investigation of subjects	
Day 0A	Screening of subjects, determination of initial $L^*a^*b^*$ values according to digital images, randomization
Day 0B	Impressions for manufacturing of the trays[a]
Bleaching period	
Day 1	Instruction of subjects on adoption of bleaching systems, gingival index (PBI); subject questionnaires, hand out of bleaching materials
Day 3	Gingival index (PBI), subject questionnaires
Day 7	Gingival index (PBI), subject questionnaires
Day 14	Gingival index (PBI), detailed subject questionnaires; determination of $L^*a^*b^*$ values according to digital images
Control period	
8 weeks	Oral examination, gingival index (PBI), detailed interrogation of subjects

[a] For VS only

Table 2 Characteristics of subjects at baseline

	WS	VS
Number of subjects	24	23
Male/female	12/12	13/10
Age	29.8±10.24 (21–60)[a]	28.9±7.69 (18–52)[a]
Smoker	10	9
L value	73.55±1.83[a]	73.22±1.59[a]
b value	19.93±2.10[a]	20.27±1.88[a]

[a] Mean±SD, maximum–minimum

values for *b** (yellow-blue), *L** (lightness), and *a** (red-green) according to Commission Internationale de Léclairage [5]. The color measurement corresponds to the measurement performed with a noncontact spectrophotometer [10, 13].

A mean set of color values (*L**, *a**, and *b**) was generated from the complete surface of all measured teeth [5]. In addition, the whitening efficacy on the teeth was evaluated with the classical Vita shade guide under standardized conditions by the blinded examiner.

Subjective evaluation of tooth

On each appointment during the bleaching period, subjects were asked to classify subjectively the degree of tooth whitening benefit they perceived. Whitening efficacy was classified using a gradation scale from 0 to 10 (0=no whitening, 10=maximal satisfying whitening effect).

Evaluation of tolerability

At baseline, days 3, 7, and 15 a full examination of oral hard and soft tissues was undertaken by a trained examiner. Furthermore, 8 weeks after study completion an additional examination of the oral cavity was carried out to check if any ongoing side effects had resolved fully. Any abnormal findings such as redness, edema, or epithelial irritation of soft tissues were recorded. Irritation was defined as desquamation of the outer layers of the gingival epithelium appearing as a white layer. Subjects were also asked questions with regard to any self-perceived symptoms at each study visit and all reported adverse effects were recorded by the examiner.

Moreover, a gingivitis index was recorded: for upper and lower anterior teeth, the modified papillary bleeding index (PBI) was performed [27, 35].

Evaluation of acceptability

After completion of bleaching treatment, subjects were asked about the acceptance of their assigned bleaching system. They were questioned as to whether the treatment was comfortable, slightly disturbing, uncomfortable, or very uncomfortable. On day 14 and on the following appointments, subjects were asked if they would recommend the therapy to associates/friends and if they were disposed to repeat therapy in the event of the teeth losing any whitening benefit received as a result of their participation in the study.

Statistical analysis was performed with analysis of covariance (ANCOVA), Fisher's exact test, and Mantel–Haenszel mean score ranks statistic. Analysis was carried out in SAS 8.1 using PROC Mixed. Tooth color changes compared to baseline were evaluated with a Student's *t* test.

Results

Efficacy: digital imaging

After bleaching for 14 days, tooth color had changed significantly compared to baseline in both treatment groups (*t* test, $p \leq 0.05$). A shift toward less yellow (−Δb) and brighter (+ΔL) tooth color was observed for both whitening strip and custom tray group. Δb was −1.69±0.38 for the whitening strip group and −1.20±0.34 for the tray group (least mean squares±SE). ΔL values estimated to +1.55±0.41 for the whitening strip groups and +1.20±0.37 for tray group (least mean squares±SE). There was no significant difference between treatments at the day 15 time point (ANCOVA; Fig. 1). A typical example for the efficacy of the trayless WS system is given in Fig. 2.

Graded in Vita shades the whitening effect amounted to 3.85±0.49 shades irrespective of the bleaching system (mean±SE).

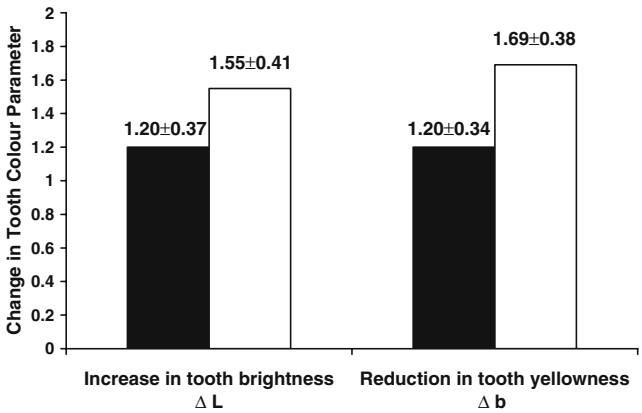

Fig. 1 Change in tooth brightness (*L**) and yellowness (*b**) after 14 days of bleaching with WS or VS, respectively, compared to baseline. Adjusted least mean squares±SE (90% confidence intervals). *Filled box* VS tray system, *open box* WS

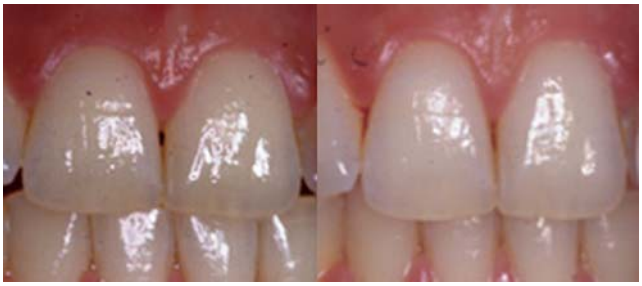

Fig. 2 Bleaching of anterior teeth with WS. *Left image* baseline, Vita shade B3; *right image* end of treatment after 14 days, Vita shade A1

Efficacy: subjective color score as observed by the subjects

During the bleaching period the tooth color improved as perceived by the subjects (Table 3). There was no significant difference between the two groups at any time point (Cochran–Mantel–Haenszel test). At day 14 the mean subjective color score within each treatment group was greater than a score value of 4. There were a number of subjects who reported no change in tooth color despite the bleaching therapy (score value of 0). However, the numbers decreased steadily as bleaching treatment progressed. At day 14 only two subjects (1 from WS group and 1 from VS group) reported no perceivable change in tooth color. Eight weeks after the end of bleaching, there was a slight decrease in subjective color score to a mean score value of about 3 for both treatment groups.

Tolerability

Gingival irritation was observed during bleaching therapy in 13% of the patients while 22% of the subjects reported tooth sensitivity and 20% reported gum irritation. Details on the number of patients from the different treatment groups with observed side effects on the different days are given in Table 4.

There were no significant differences in observed or reported evaluations of tolerability between the two bleaching systems (Cochran–Mantel–Haenszel test, Table 4). The number of subjects reporting symptoms on different days differed considerably in the two groups. In all cases the gingival irritation observed was mild and desquamative in nature being localized to the gingival margin. These events were transient and fully resolved after the end of the bleaching regimen.

Papillary bleeding index

No significantly different PBI scores (Table 5) were observed at baseline between the two groups. A significant decrease in PBI values was recorded for both groups during the bleaching therapy. In the custom tray group all postbaseline PBI values were significantly lower than at baseline. In the WS group only at day 14 was a significantly lower PBI than at baseline ($p<0.05$) recorded. On days 1, 3, and 7 of the bleaching therapy, there were significantly lower PBI values in the custom tray group ($p<0.05$) vs the whitening strip group. At the 8-week follow-up visit the VS group showed significantly lower PBI values compared to WS.

Recommendation and repetition of the bleaching regimen

Ninety-one percent of the volunteers using VS stated that they would recommend it to an associate/ friend compared to the WS group where 62% of the subjects would

Table 3 Number of subjects stating a certain color on the different days

Grades of subjective color score	Number of subjects							
	Day 3		Day 7		Day 14		8 weeks	
	VS	WS	VS	WS	VS	WS	VS	WS
0	13	11	6	4	1	1	2	4
1	1	3	4	2	1	1	1	0
2	2	0	3	2	2	1	3	2
3	2	5	3	4	5	7	3	2
4	0	0	4	3	4	4	2	4
5	0	1	1	3	4	2	3	5
6	0	0	1	1	0	0	2	2
7	0	1	0	1	1	3	1	1
8	0	1	0	1	1	2	1	1
9	0	0	0	0	1	0	2	0
10	1	0	1	0	2	0	1	0
Mean score±SD	1.11±2.40	1.73±2.39	2.44±2.45	3.14±2.35	4.55±2.74	4.14±2.19	4.48±2.83	3.71±2.35

Subjective color score as observed by the subjects. The subjects had to graduate color score on the different days compared to baseline: 0=no changes in tooth color observed, 10=optimal, fully satisfying advancement of tooth color.

Table 4 Number of subjects with irritation of the gingiva as observed by the examiners

Number of subjects with irritation of the gingiva as observed by the examiners and number of subjects stating self-observed side effects (tooth hypersensitivity, gum irritation) during (days 3-14) and postapplication (control after 8 weeks) of VS and WS		Day 3	Day 7	Day 14	Control (8 weeks)
Observed gingival irritation	WS	3	0	2	0
	VS	1	4	5	0
Reported tooth hypersensitivity	WS	6	6	2	0
	VS	4	3	2	0
Reported gum irritation	WS	6	5	3	0
	VS	3	2	3	0

recommend the product to an associate/friend (Table 6). This value increases to 71% after 8 weeks. The difference between the treatments was significant at day 14 ($p<0.05$, Cochran–Mantel–Haenszel test). For the disposal to repetition of the assigned therapy, a directionally higher number of subjects from the VS group claimed to be interested in repetition of the therapy compared to the WS group.

Comfort of the bleaching regimen

In both groups a similar proportion of subjects reported a foreign body feeling due to the applied bleaching regimens (Table 7). Significantly more subjects in the WS group (up to five subjects) complained about the taste during bleaching compared to VS group (one subject). This reduced to three subjects after 14 days.

The majority of subjects, more than 93%, accepted their assigned regimen, and rated it as comfortable or only slightly disturbing at each visit (Table 8). On days 7 and 14 of bleaching regimen, comfort rating in the two groups differed significantly. More subjects from the WS group rated the treatment as slightly uncomfortable, whereas most users of VS rated the bleaching therapy as comfortable. On day 3, there was no significant difference.

Withdrawals

Five subjects dropped out of the study due to reasons not related to bleaching therapy at different stages. Two subjects from the WS group withdrew after 5 days of treatment because of product-related side effects. These were reported by the subjects as severe tooth hypersensitivity and gum irritation. No corresponding clinical signs of gum irritation were observed by the examiner.

Table 5 Modified PBI (mean±SD) in the course of the study

	Baseline	Day 1	Day 3	Day 7	Day 14	Week 8
WS	0.43±0.37	0.30±0.22	0.25±0.27	0.37±0.31	0.22±0.29	0.49±0.24
VS	0.41±0.37	0.11±0.12	0.07±0.13	0.10±0.14	0.13±0.19	0.18±0.29

Subjects treated with WS or VS

Discussion

Until recently, the bulk of research published on vital tooth whitening products demonstrating consistent efficacy and tolerability utilizes 10–15% carbamide peroxide gels loaded into custom-fabricated trays. It was therefore considered appropriate to use a tray-based carbamide peroxide system as a control and positive reference for standard at-home bleaching [1, 32].

There are different ways to determine the magnitude of bleaching efficacy [13, 22, 26, 32]. In earlier studies, product effects were largely characterized by relating changes in tooth color against individual shades such as the tabs of the Vita-System [32]. While this approach offers a reasonable assessment of the qualitative bleaching effect of a product based upon the change from pretreatment score, the influence of examiner subjectivity and other environmental factors limit its application in comparative research. More recent studies are based on the use of digital imaging systems to generate $L^*a^*b^*$ values as a means of quantifying tooth color [5]. This allows direct comparison

Table 6 Product acceptability of the two treatment groups (VS and WS)

	VS		WS	
	Yes (%)	No (%)	Yes (%)	No (%)
Treatment recommendation				
Day 14	90.91	9.09	61.90	38.10
8 weeks	90.48	9.52	71.43	28.57
Repetition of therapy				
Day 14	88.24	11.76	71.43	28.57
8 weeks	93.75	6.25	66.67	33.33

Percentage of subjects disposed to give treatment recommendation to friend or to repeat the therapy as answered at day 14 and after 8 weeks

Table 7 Acceptance of VS and WS during application

	Day 3	Day 7	Day 14
Foreign body feeling			
WS	2	3	3
VS	4	1	1
Bad taste of bleaching gel			
WS	5	4	3
VS	1	–	–

Number of subjects with self-registered foreign body feeling and bad taste of bleaching gel (yes/no criteria) at days 3, 7, and 14, respectively.

between products and as it satisfies the conditions of being an objective, linear, and reproducible method [10, 13, 14].

Using this method, it was shown in the study that WS and VS are not statistically different in bleaching efficacy. This corresponds well to the results of other investigations, confirming the efficacy of WS as being similar in its whitening benefits as tray-based systems [10, 13, 26]. Despite this fact, the tendency was observed that WS was directionally more effective at tooth whitening than the tray-based system. The lack of statistical significance may be attributed to the large range of responses within each treatment group.

Tolerability aspects of home bleaching regimens, like gingival irritation and tooth hypersensitivity, are correlated with the peroxide concentration of the bleaching gel and with the number and length of daily applications [12, 13, 28]. WS are applied twice a day for 30 min each, VS only once per day, typically for 1 h, as in this study. The safety data from this study correlates well with that previously reported in the literature and further supports the favorable tolerability of peroxide-based, at-home bleaching products [2, 3, 15, 16, 22, 23, 29–31, 33]. All of the observed and the majority of reported oral adverse effects were mild and transient in nature. Overall, a lower percentage of oral side effects were observed compared to other studies with tray-based home bleaching systems. For example, Haywood et al. [22] observed hypersensitivity in 52% of the cases and gingival irritation in 31%. It should be noted that two subjects from the whitening strip group withdrew from the study after 5 days because of product-related oral side effects. Such events are rare for any home bleaching system with low peroxide concentrations (up to 6%) and the majority of those individuals who do report tooth sensitivity or irritation complete the bleaching process [15, 16]. However, it is important to acknowledge that for a small proportion of subjects the severity of adverse effects associated with peroxide bleaching is sufficient for them to stop treatment.

Table 8 Number subjects in the WS and VS group according to comfort rating (1–4) during the bleaching regimen

Time	Treatment	Discomfort score				*p* value
		1	2	3	4	
Day 3	VS	12	6	1	0	0.1178
	White Strips	8	13	0	1	
Day 7	VS	20	2	1	0	0.0009
	White Strips	8	12	1	1	
Day 14	VS	18	2	2	0	0.0253
	White Strips	9	12	0	0	

The *p* values of the comparison between VS and WS are given ($p < 0.05$). 1=comfortable, 2=slightly uncomfortable, 3=uncomfortable, 4=very uncomfortable. Cochran–Mantel–Haenszel statistics was used to compare the means of ranked scores for the different bleaching products.

No statistically significant differences were observed between the whitening strip group and the tray group with respect to subject-perceived tooth sensitivity or gum irritation (Table 4). In the tray group, irritation of the gingiva was observed by the examiners in 10 cases over the 14-day treatment course of the study compared to 5 cases in the WS group. In all cases, erythema or desquamation of the papilla correlated to areas covered by the bleaching tray. This type of irritation is common to tray-based systems representing mechanical compression of the papilla, as reported elsewhere [29]. All reported and observed side effects had a transient character and resolved completely after completion of the bleaching regimen, thus supporting the tolerability of home bleaching with WS and the carbamide-peroxide-charged trays.

It is discussed in the literature whether peroxides from bleaching gels function as a disinfectant consistent with their application in periodontal treatment or if they enhance inflammation and irritation of periodontal cells and structures [4, 7, 16, 37]. Carbamide peroxide (10%) caused an augmentation in the proliferative activity within the basal and parabasal layers of the gingival epithelium, resulting in a change in tissue morphometry in an in vivo study evaluating the influence of carbamide peroxide on gingival structures [7]. Therefore, it was of interest to evaluate the papillary bleeding index (PBI) as indicator for gingival or periodontal inflammation [35]. During the bleaching regimen, papillary bleeding index decreased significantly in both treatment groups, but a larger improvement was recorded in the VS group during the bleaching phase of the study. It is speculated that the observed differences between treatments are a result of the differences in the brushing ability of the two populations as the subjects were not randomized according to toothbrushing ability. Significantly more subjects in the whitening strip group commented about the in-use product taste compared with the tray group (Table 7). This may be a result of the higher release of bleaching gel into saliva, which has been

previously reported for WS [18–20]. However, in both groups the majority of subjects stated that the bleaching regimen was comfortable or only slightly disturbing.

Significantly less subjects from the whitening strip group compared to the tray group claimed to be interested in repeating this certain bleaching therapy or recommend it to friends. This may be explained by the fact that subjects of the VS group reported fewer complaints with respect to taste and foreign body feeling. The application of polyethylene foils onto the teeth was a quite unknown and uncommon practice in Germany, whereas many of the study subjects were dentally aware individuals familiar with the application of intraoral trays for bleaching or had prior experience with application of trays for fluoridation or therapy for temporo-mandibular joint disease. Further research with a larger and more representative population would help in clarifying the acceptability of different bleaching product forms.

Conclusions

1. Both bleaching systems demonstrated significant tooth color improvement after 2 weeks usage according to the manufacturers' instructions.
2. There was no statistically significant difference between the two systems.
3. Both systems were well tolerated and caused comparable levels of transient tooth sensitivity and oral soft tissue irritation. More than 90% of subjects accepted their assigned regimen, and rated it as comfortable or only slightly disturbing.

Acknowledgement The study was sponsored by a grant from Procter & Gamble. We would like to thank Dr. Catherine Mahony and Mr. Ashley Barlow for their helpful comments, Sarah O'Mahony for monitoring the study according to Good Clinical Practice Guidelines, Kieran Brennan for statistical evaluation of the data, and Robin Harris for taking and helping to analyze the digital images.

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