

Randomized Clinical Trial on the Efficacy of a New Bleaching Lacquer for Self-application

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Clinical Relevance

After application once a day for two weeks, a new bleaching lacquer for self-application, containing 8% carbamide peroxide without the use of any mouth guards (cellulose based), revealed a tooth shade improvement of least two shades.

SUMMARY

Background: This study evaluated the clinical efficacy and duration of effectiveness of a new bleaching lacquer for self-application without the use of mouth guards. It compared two different application times. **Methods:** Forty-six adult subjects who requested bleaching treatment

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were selected to participate in this randomized, single-blind (examiner-blinded), single center, two-group trial. The subjects were randomly divided into two groups (n=23 each), each being instructed to bleach (8% carbamide peroxide) their six maxillary anterior teeth for two weeks. Daily contact time in Group 1 was 20 minutes once a day and, in Group 2, the time was 20 minutes twice a day. Efficacy was measured subjectively using the Chromascop Complete shade scores obtained at baseline and after one, two and three weeks, as well as after one, three, six and nine months. **Results:** After two weeks of treatment, the teeth in the Group 1 subjects exhibited a 2.4 ± 0.2 mean shade scores improvement compared to baseline ($p < 0.001$; t -test for paired samples), and the subjects' teeth in Group 2 exhibited a 3.5 ± 0.1 mean shade scores improvement ($p < 0.001$). However, the difference between both groups was not statistically significant ($p > 0.05$). The observed effects were stable for six months.

Conclusions: It can be concluded that the new bleaching lacquer is efficacious; however, a double application does not seem to be obligatory.

INTRODUCTION

Tooth discoloration is a common problem. People of various ages may be affected, and it can occur in all teeth. The etiology of dental discoloration is multifactorial, as has been recently reviewed extensively (Watts & Addy, 2001). However, the most important issue for treatment is the type of discoloration. Many researchers classify discoloration as either being extrinsic or intrinsic (Dayan & others, 1983; Hayes, Full & Pinkham, 1986; Teo, 1989). Extrinsic staining is defined as staining that can be removed with a casual prophylactic cleaning procedure (Dayan & others, 1983). Intrinsic staining is incorporated into the tooth matrix and can only be removed with bleaching procedures. Some discoloration is a combination of both types of stain. For example, nicotine stain on teeth is extrinsic and may become intrinsic (Greenwall, 2001).

Most of the bleaching agents used for treatment contain hydrogen peroxide in some form. The hydrogen peroxide breaks down into water and oxygen. It is the oxygen molecule that penetrates the tooth and liberates or chemically alters the pigment molecule, causing the tooth to appear whiter. The predominant types of peroxide used for vital bleaching that uses mouth guards are pure hydrogen peroxide or carbamide peroxide. Ten percent carbamide peroxide breaks down to a 3.4% solution of hydrogen peroxide (H_2O_2) and a 6.6% solution of urea (CH_4N_2O) (Fasanaro, 1992).

Traditionally, vital teeth have been whitened using two different treatment methods. A well-known method is the in-office procedure commonly known as "power bleaching," which uses a 30% to 35% hydrogen peroxide solution in conjunction with heat and/or light to increase the kinetics of stain removal (Feinman, Goldstein & Garber, 1987). A more recent method involves the fabrication of a mouth guard, in which a peroxide preparation is placed and worn over the teeth to obtain the desired bleaching effect. This is often referred to as "home bleaching" or "night guard vital bleaching" and is the most common whitening procedure dentists offer their patients (Christensen, 1997). The predominant type of peroxide used for home bleaching with mouth guards is 10% to 16% carbamide peroxide (Christensen, 1997). The first paper discussing the concept of night guard vital tooth bleaching was published in 1989 by Haywood and Heymann. Since that landmark publication, numerous studies have considered this treatment to be safe and effective.

In recent years, the demand for bleaching has grown significantly, as people seek to improve the appearance of their smile. Moreover, dentists use bleaching therapies as a minimally invasive treatment to improve the esthetics of their patients. However, due to the high cost of individually prepared mouth guards, the night guard bleaching procedure is expensive. Therefore, it

would be desirable for many patients to develop a new generation of bleaching material that does not require any mouth guards. Thus, the purpose of this study was to evaluate the efficacy of a new bleaching lacquer based on cellulose and 8% carbamide peroxide. This lacquer has been developed for self-application without mouth guards; a once a day versus twice daily application was evaluated. Moreover, the duration of effectiveness should be determined.

METHODS AND MATERIALS

Protocol

Forty-six adult subjects requesting bleaching treatment were selected to participate in this randomized, single blind (examiner-blinded), single center, two-group trial. The examiner and all study personnel were blinded to the treatment assignment for the duration of the study. Only the study statisticians and the data monitoring committee (Department of Medical Informatics, Biometry and Epidemiology, Charité—Universitätsmedizin Berlin) saw the unblind data, but no one from that department had any contact with the study subjects or clinicians. The research protocol was approved by the Ethical Committee at the Charité—Universitätsmedizin Berlin (vote number 32/2003). All subjects received detailed information (verbal and written) on the principles of treatment and the purpose of the study and signed appropriate informed consent forms. The subjects were also asked to contact the doctor in attendance (examiner) in the advent of any adverse reactions or if the treatment failed, so that they could be given an alternative therapy. The examiner in this study was a dentist experienced in the therapy of tooth discoloration.

The subjects received bleaching lacquer in single doses, along with lip retainers, cotton tissues, application protocols and verbal and written instructions.

Selection of Subjects

All patients who requested a home bleaching treatment of the maxillary incisors and canines at the Department of Operative Dentistry and Periodontology (University School of Dental Medicine, Campus Benjamin Franklin, Charité—Universitätsmedizin Berlin, Germany) and who were at least 18 years old, had good general health and at least their upper canines with a tooth color of 3A (or darker) as measured with the tooth shade guide Chromascop Complete (Ivoclar Vivadent, Liechtenstein) were candidates for the study. They were not admitted to the study if any of the following criteria was present: (1) a known allergy to any of the ingredients in the bleaching lacquer used, (2) systemic diseases, (3) tooth discoloration removable with prophylaxis paste, (4) inhomogeneous tooth discolorations, such as tetracycline discoloration, (5) tooth structure anomalies, including dentinogenesis imper-

fecta, (6) non-vital front teeth, (7) one or more caries lesions, (8) crowns and fillings on one or more anterior teeth, (9) insufficient oral hygiene (Approximal Plaque Index indicating more than 25% plaque; [Lange, Plagmann & Baumann, 1977]), (10) untreated periodontitis, (11) orthodontic appliances on the incisors, (12) pregnant or breast feeding women or (13) residence outside the city of Berlin, insufficient address for follow-ups or an unwillingness to return for follow-up appointments.

Treatment Regimen

The panelists were interviewed in order to exclude criteria 1 through 13 above, and their teeth were thoroughly examined. If necessary, radiographic investigation was performed. Following assignment, before treatment and before each measurement of the tooth color, all incisors were professionally cleaned again, using a prophylaxis paste with fluoride (Hawe Cleanic, Art no 3130, Hawe-Neos Dental, Bioggio, Switzerland) and a polishing cup (Hawe Pro-Cup, Art no 990/120, Hawe-Neos Dental) to avoid measuring any extrinsic tooth discoloration. The polishing paste was removed using water spray.

The determination as to whether the subjects should use the lacquer once or twice a day was made by referring to a randomization list created in the Department of Medical Biometry and Clinical Epidemiology; details of the randomization list were known to the person who gave the bleaching material to the subjects, but the randomized list was unknown to the examiner. In Group 1, the subjects used the new bleaching lacquer based on ethyl cellulose containing 8% carbamide peroxide once a day for 20 minutes (Viva Style Paint on; Ivoclar Vivadent) for two weeks, while the subjects in Group 2 used the same bleaching lacquer twice a day for 20 minutes for two weeks. The subjects were instructed by the examiner to brush their teeth, insert the labial retainer, dry the labial surfaces using a cotton tissue, then paint the bleaching lacquer on the labial surfaces of all six maxillary anterior teeth. For ethical reasons and individual aspects, all subjects bleached their complete upper incisors and canines, and there was no randomization of upper and lower front teeth. The subjects were instructed to wait 60 seconds, until the lacquer was dry, before removing the labial retainer. They were instructed to avoid speaking, drinking and eating during the 20 minutes and to record the time of application in the application protocol. After 20 minutes, the subjects removed the lacquer using a toothbrush and dental floss. Finally, they returned the remaining bleaching material to the person who gave them the material. After two weeks of applications (third visit), the subjects were asked to fill out a questionnaire concerning side effects and satisfaction and how they handled the bleaching lacquer. After the three month follow-up visit, the subjects received a diary to record their

daily intake of cigarettes, red wine, coffee and black tea for two weeks.

Measurements

The tooth shade guide Chromascop Complete (Ivoclar Vivadent) was used to determine the tooth color of the anterior teeth of the mandible and maxilla in the middle third of the labial surface. The tooth shades were noted on a separate sheet for each visit in order to exclude the chance that the examiner could be influenced by the last color measurement. All measurements of tooth color were taken in the same room at the same location in daylight by the same experienced examiner. After the tooth color was determined, the examiner took a photograph using the evaluated tooth shades of the tooth shade guide.

The study took nine months to complete. Within this time period, five follow-up visits were conducted. The tooth color of all anterior incisors and canines was evaluated immediately before treatment at baseline (after tooth cleaning), after one week \pm 1 day (during application period) and after two weeks \pm 1 day (directly after application). The follow-up visits for tooth color determination of the upper anterior teeth took place one week \pm 1 day, one month, three months, six months and nine months (each \pm 7 day) after baseline. The tooth color of all mandibular anterior teeth was also evaluated immediately before treatment at baseline (after tooth cleaning), after two weeks (directly after application) and at final evaluation after nine months. All follow-up visits were performed under the same conditions compared to the baseline measurements and only within the mentioned period of time.

Additionally, all teeth were investigated in terms of sensitivity to cold air caused by the bleaching treatment at baseline and all the seven subsequent visits. The examiner used a cold air stimulus (20°C) for approximately 1 second in order to quantify the subjects' responses. The air was directed perpendicular to the cemento-enamel junction of the tooth from a distance of 10 mm, and sensitivity was assessed by subjective means utilizing the responses "yes" and "no" for sensitivity. Moreover, all side effects observed by the examiner during the eight visits were noted on the sheet for tooth color determination.

Tooth Shade Ranking

For the statistical analysis, the differences in lightness between the 24 Chromascop Complete shade tabs (CCS; Ivoclar Vivadent) were measured using a spectrophotometer (SpectroShade, MHT, Niederhasli, Switzerland) and subsequently ranked corresponding to the ΔL values obtained (Judd & Wyszecki, 1975) numerically from lightest (1) to darkest (24) color (Table 1). The ranking of the Chromascop Complete shade tabs in this study was compared to the commonly known ranking (Greenwall, 2001) of the Vita Classic

shade guide (VCS; Vita, Bad Säckingen, Germany) by evaluating the smallest ΔE for each Chromascop Complete shade compared to the Vita Classic shade guide (SpectroShade).

Statistical Procedures

Subject size had been calculated by referring to previous clinical studies that evaluated the effectiveness of home bleaching products containing carbamide peroxide (10% to 16%) to treat tooth discolorations.

In the descriptive analysis, the means and standard deviations were computed at baseline and for all follow-up visits. Missing values were indicated as 999. Measurement values were averaged over all maxillary and mandible incisors and canines for each patient. In the descriptive analysis, the means and standard deviations were computed at baseline and for all follow-up visits. Comparisons between different time points were performed using the *t*-test for dependent samples; comparisons between study legs were performed using the *t*-test for independent samples. Data from subjects' diaries were analyzed using non-parametrical tests (Mann-Whitney U-test), and data from questionnaires were computed using the chi-square test. The level of significance was 0.05 (two-sided) for all statistical tests. Commercially available statistical software (SPSS-WIN, Release 12.0, SPSS Inc, Chicago, IL, USA) was used.

RESULTS

Regarding the demographic characteristics of this study, the 46 adult subjects selected were 11 males and 35 females ranging in age from 19 to 68 years, with a mean age of 29.1 ± 8.5 years. The age of the subjects was normally distributed. The flow of the subjects through each stage of the study, including all treatment regimes, is shown in Figure 1. A few subjects missed one or two visits due to summer vacations. According to the bleaching packages that were returned, it was clear that all the subjects had used the bleaching material completely.

The mean tooth shade values and standard deviations of all bleached teeth for all eight visits for both treatment groups are given in Table 2. At baseline, the mean tooth-shade value of Group 1 was comparable to the mean tooth shade value of Group 2. At subsequent observation times, the mean tooth shade values were slightly lower in Group 2, compared to Group 1. Differences between the two groups in terms of tooth shade values were not statistically significant at any follow-up during the study ($p \geq 0.05$; Table 2). The box-and-whisker plots for both groups and all visits can be seen in Figure 2.

After two weeks of application, the subjects in Group 1 exhibited a 2.4 mean tooth-shade improvement compared to baseline, while the subjects in Group 2 exhib-

Table 1: The 24 Chromascop Complete shade tabs (CCS; Ivoclar Vivadent) were measured using a spectrophotometer (SpectroShade) and, subsequently, ranked corresponding to the obtained ΔL values numerically from lightest (1) to darkest (24) color. The ranking of this study was compared to the commonly known ranking of the Vita Classic shade guide (VCS) by evaluating the smallest ΔE between both shade guides. Vita Classic shades not covering the Chromascop Complete shades are given in the last line (NCC).

CCS	010	020	030	040	01	1A	2B	1C	1D	2A	1E	2C	3A	6B	4A	2E	4B	5B	6C	6D	3E	3C	4C	4D	
ΔL	17.6	17.2	16.0	14.1	14.1	12.2	11.2	11.0	10.8	10.3	9.0	7.8	7.6	7.1	6.9	6.3	6.0	5.2	4.4	4.2	2.6	2.5	2.3	0	
Rank	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
ΔE	8.5	5.8	3.4	1.0	1.3	1.6	2.7	1.8	3.3	2.1	2.5	4.4	3.9	0.9	1.0	3.6	1.2	3.0	2.1	1.2	2.3	0.9	0.8	3.2	
VCS	B1				A1	A2				C1	A3				D3		A3.5	C3				A4	C4		
NCC					B2	D2					C2	D4					B3		B4						

Table 2: Means (SD) for Bleached Maxillary Teeth, Untreated Mandible Teeth and Sensitivity of Maxillary Teeth, with Comparisons Between Groups 1 and 2 for the Bleached Maxillary Teeth and Between the Maxillary and Mandible Teeth

Visit	Bleached Maxillary Teeth			Untreated Mandible Teeth		Maxillary vs Mandible Teeth		Sensitivity of Maxillary Teeth	
	Group 1	Group 2	Group 1 vs 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
	Mean (\pm SD)	Mean (\pm SD)	<i>p</i> value	Mean (\pm SD)	Mean (\pm SD)	<i>p</i> value	<i>p</i> value	Mean (\pm SD) %	Mean (\pm SD) %
1	10.38 (\pm 2.26)	10.45 (\pm 2.09)	0.91	10.67 (\pm 2.34)	10.02 (\pm 1.92)	> 0.05	> 0.05	4 (\pm 14)	3 (\pm 6)
2	8.80 (\pm 2.32)	7.90 (\pm 2.35)	0.20					4 (\pm 13)	5 (\pm 21)
3	7.96 (\pm 2.45)	7.00 (\pm 2.14)	0.16	10.28 (\pm 1.96)	11.09 (\pm 1.87)	0.0001	0.0001	6 (\pm 19)	6 (\pm 21)
4	7.75 (\pm 2.48)	6.84 (\pm 1.83)	0.18					6 (\pm 23)	5 (\pm 22)
5	7.82 (\pm 2.64)	7.03 (\pm 2.00)	0.29					6 (\pm 21)	6 (\pm 22)
6	8.22 (\pm 2.49)	6.86 (\pm 2.00)	0.05					3 (\pm 14)	5 (\pm 21)
7	8.08 (\pm 2.58)	7.11 (\pm 2.02)	0.18					1 (\pm 4)	6 (\pm 22)
8	8.62 (\pm 2.47)	7.34 (\pm 2.20)	0.09	10.29 (\pm 1.37)	9.99 (\pm 1.44)	0.002	0.0001	4 (\pm 16)	5 (\pm 21)

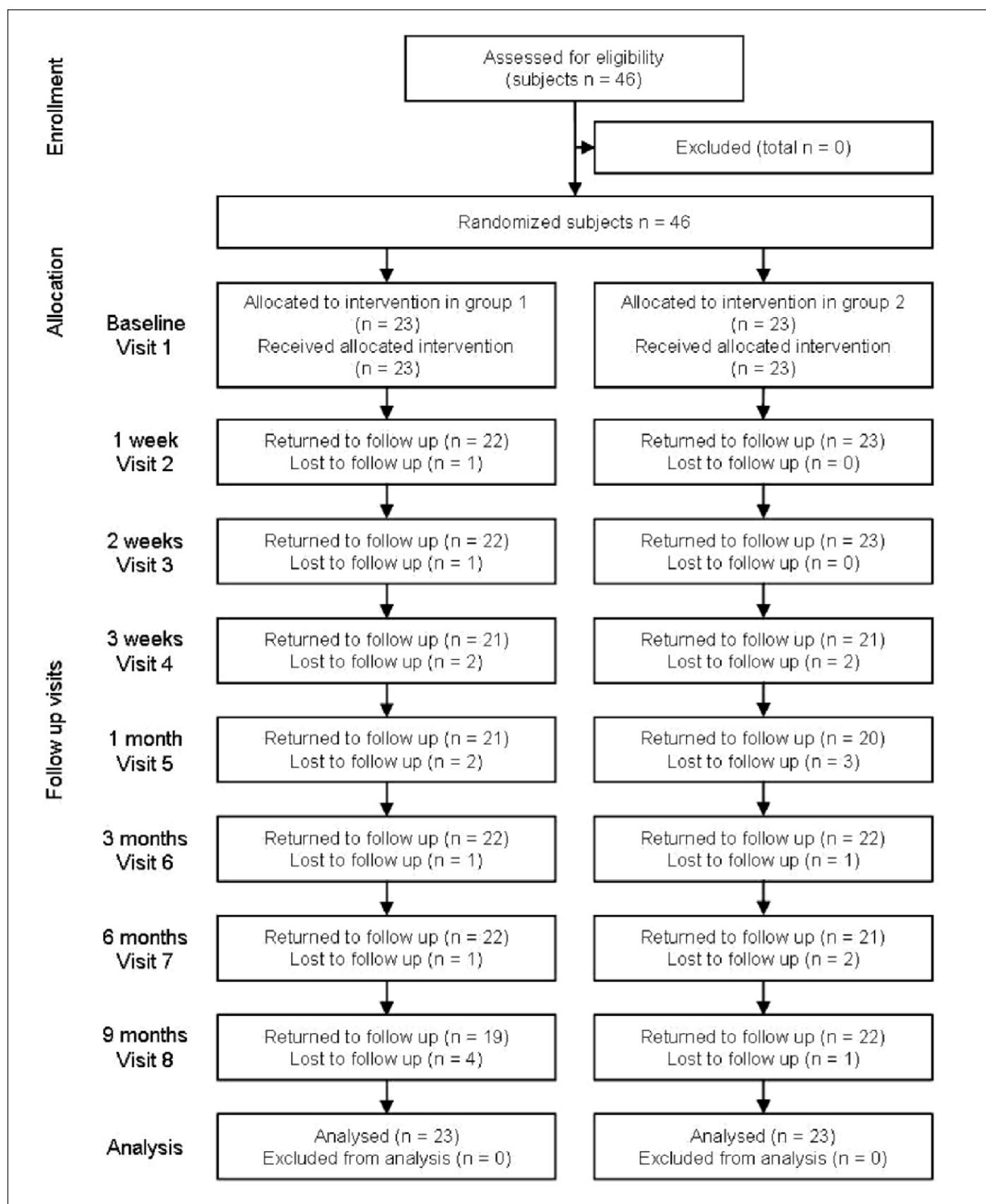


Figure 1: Diagram showing the flow of subjects through each stage of the trial.

ited a 3.5 mean tooth shade improvement. One week after completion of the bleaching treatment, the subjects' teeth in Group 1 exhibited a 2.6 ± 0.2 mean tooth shade improvement, and the subjects' teeth in Group 2 exhibited a 3.6 ± 0.1 mean tooth shade improvement. Improvements in the mean tooth shade were statistically highly significant ($p<0.001$) in both treatment groups at each visit after baseline compared to the baseline except for visit eight in Group 1 ($p=0.018$).

The results of the evaluation of the tooth shades for the untreated mandibular anterior teeth are given in Table 2, including statistical analysis comparing the bleached maxillary anterior teeth and the untreated mandibular teeth at visits one, three and eight. Regarding changes that occurred to untreated teeth in both groups during the study, a slightly significant difference was found only between visits three and eight ($p=0.03$).

Long-term shade measurements of one, three, six and nine months after the final bleaching treatment indicated that the results were stable over a period of at least six months. No significant increase in the mean tooth shade scores in Groups 1 and 2 (Figure 2) compared to visit three ($p\geq0.05$) could be demonstrated. However, tooth shade values in Group 1 increased slightly again six months after treatment.

All but three participants completed the subjects' questionnaires. The detailed questions and answers that addressed side effects and subjects' satisfaction are shown in Table 3. Statistical analysis could not reveal

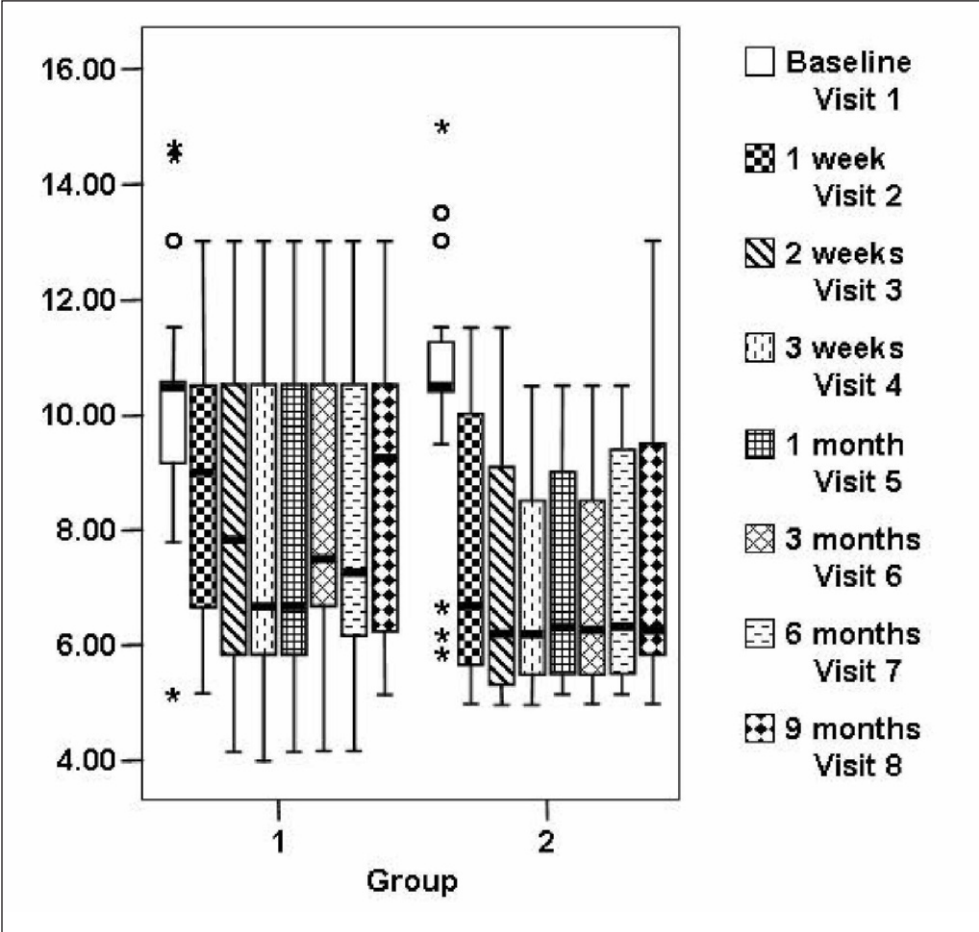


Figure 2. Box-and-whisker plots for both groups and all visits. For evaluation, the Chromascope Complete shade tabs were ranked numerically from the lightest (1) to the darkest color, as given on the y-axis.

Table 3: Evaluation of the Questionnaires (n=43) Concerning Side Effects and Subjects' Satisfactions			
Question	Yes	No	No Answer
1. Did you realize an increase of dentin hypersensitivity after bleaching?	4	39	-
2. Did you realize soft tissue irritation after bleaching?	10	32	1
3. Are you satisfied with the result of the treatment?	34	9	-
4. Would you repeat the treatment, if necessary?	35	7	1
5. Would you recommend the treatment to a friend?	34	9	-
6. Has the application of the lacquer been comfortable?	28	15	-
7. Has the taste of the lacquer been acceptable?	39	4	-
8. Do you comply with the duration and frequency of application?	34	9	-
9. Do you comply with the lip retainer?	23	17	3
10. Did you have any experience with a bleaching technique using a tray system?	3	40	-

any significant differences concerning the given answers for questions 1 to 10 ($p\geq0.05$).

After treatment with bleaching lacquer, some side effects were observed in both groups. Some teeth showed tooth sensitivity to cold air stimulus for all visits (Table 2); however, there were no significant differences either between both groups ($p>0.05$) or within the groups com-

pared to baseline data ($p>0.05$). Irritation of the gingiva was observed for 10 subjects.

The results of the patient diaries ($n=28$) regarding daily consumption of tooth staining beverages and tobacco revealed a daily average of 5.1 ± 7.6 cigarettes, 0.1 ± 0.5 glasses of red wine, 1.7 ± 1.6 cups of coffee and 0.9 ± 1.9 cups of black tea. However, no correlation between the daily amount of tobacco, red wine, black tea, coffee and the tooth-shade alterations between visits three and eight could be observed ($p>0.05$).

DISCUSSION

Regarding the effectiveness of the new bleaching lacquer used in this study, it should first be emphasized that the home bleaching product used cannot be categorized as an OTC-product, since it is only available from the dentist. Thus, it should be regarded as a trayless home bleaching product. Furthermore, this product has the lowest carbamide peroxide concentration ever reported for a home bleaching product. This should be taken into account when comparing these results with other clinical studies that have evaluated home bleaching products. A comparable product is the hydrogen peroxide strip system (blend-a-med professional, Procter & Gamble, Cincinnati, OH, USA), which is a trayless bleaching system that does not require any prefabrication or gel loading and is also available only at the dentist's office. The delivery system is a thin strip pre-coated with an adhesive 6.5% hydrogen peroxide gel (Sagel & others, 2002). While this concentration is more than twice as high as the bleaching product tested in this study, the strip system obviously does not appear to be more efficacious compared to the bleaching lacquer (Gerlach & Zouh, 2001). One reason might be that, compared to the lacquer, the strips are not as effective in coating the complete surface of the teeth.

The color and appearance of teeth is a complex phenomenon, with many factors such as lighting conditions, translucency, opacity, light scattering, gloss, texture and the human eye and brain influencing the overall perception of color (Judd & Wyszecki, 1975). The measurement of color is possible via a number of methods, including visual assessment with shade guides, spectrophotometry, colorimetry and computer analysis of digital images. All methods have been used successfully to measure longitudinal tooth color changes when the dentition has undergone tooth-whitening procedures (Joiner, 2004). However, visual color determination, by comparing the teeth with standard color shade guides, is still the most frequently applied method in dentistry (Van der Burgt & others, 1990; Paul & others, 2002). Visual evaluation is a subjective process, whereby the tooth and the shade guide are observed simultaneously under the same lighting conditions. General variables such as external light conditions, experience, age, fatigue of the human eye, and physiological variables,

such as color blindness, may lead to inconsistencies and bias (Hill, 1987; Watts & Addy, 2001). In addition, the potential for standardized verbal means for communication of the visually assessed color characteristics are limited (Seghi, Johnston & O'Brien, 1989). Despite these limitations, the human eye is very efficient in detecting even small differences in color between two objects (Paul & others, 2002). Corresponding to the findings in this study, tooth color was measured visually, obtaining significant differences by comparing tooth shades between groups and visits.

Although the Vita Classic shade guide for prostheses commonly serves as the standard to which tooth color is matched, several disadvantages have been described. For example, the range of shades available does not cover the complete space of natural and bleached tooth color (Schwabacher & Goodkind, 1990; Goodkind, Keenan & Schwabacher, 1987). Thus, for this study, the Chromascop Complete shade guide has been selected, because it has an extensive range of extremely bright tooth colors necessary to evaluate bleached teeth. It seems reliable to put this shade guide's colors in order using spectrophotometry, because this technique has shown some difficulties measuring the color of teeth *in vivo*, but not *in vitro* (Paul & others, 2002). For comparative reasons, the Vita Classic shades have been added to Table 1. However, Vita Classic shades and Chromascop Complete shades are not systematic in their color space (O'Brien, Groh & Boenke, 1990), and there is a lack of consistency among and within individual dentists in matching colors (Okubo & others, 1998). Moreover, the results cannot be transformed into the CIE Lab color scale (Van der Burgt & others, 1985), and the commercially available shade guides often failed to be identical (Paul & others, 2002).

Clinical studies using concentrations of 10% to 15% carbamide peroxide reported moderate tooth sensitivities ranging from 10% (Jorgensen & Carroll, 2002) to 13% (Gerlach, Zouh & McClanahan, 2002) of the subjects using tray systems for home bleaching. Leonard and others (2002) revealed more tooth sensitivity when using 16% carbamide peroxide compared to 10% carbamide peroxide; however, they did not find any significant differences between the two concentrations. Surprisingly, 20% of the participants in the current study reported sensitivity when wearing their treatment tray without solution, but 36% of the participants also reported sensitivity to the placebo solution. In this study, some subjects revealed tooth hypersensitivity as well during the treatment period when using a lacquer based on cellulose, which might have the same effect as the trays. The reason for this sensitivity could be dehydration of the teeth (Greenwall, 2001). Carbamide peroxide systems are aqueous gel based, and it can be speculated that dehydration of the hard tissue is less likely to occur with aqueous-based carbamide peroxide. On

the other hand, carbamide peroxide systems bleach slower and need longer exposure times (Greenwall, 2001). Additionally, they do not contain a soft tissue protectant. Thus, they may cause more soft tissue irritation, possibly due to the higher concentration of hydroxyl ions, acid urea, ammonia or carbonic acids. There is still no scientific evidence to prove this (Greenwall, 2001); however, this study, using carbamide peroxide, revealed soft tissue irritation as well.

Once bleaching has been terminated, a slight increase in brightness occurs for the next two weeks. It has been hypothesized that the tooth is filled with oxygen and is dehydrated from the oxidative process, and this changes the optical qualities of the tooth, so that it appears more opaque. After two weeks, the oxygen has dissipated and the rehydrated tooth demonstrates the actual lightened shade (Greenwall, 2001). The process of color regression towards darker shades *in vivo* is poorly described and understood in the literature (Heymann & others, 1998), but it is thought to be the opposite of the bleaching procedure. Regression occurs over a longer period of time, because some of the previously oxidized substance may become chemically reduced and causes the tooth to reflect the old discoloration of the enamel or the enamel may become remineralized with the staining molecule of the original stain (Lyons & Ng, 1998). However, a clinical trial (Leonard & others, 1999) that evaluated the color stability of tetracycline-stained teeth 54 months after bleaching treatment revealed no significant tooth color regression. Furthermore, color stability after non-vital bleaching has been reported, with 4% regression after six months (Ho & Goerig, 1989) and 10% color regression after one year of at-home bleaching (Haywood, Leonard & Nelson, 1994). These findings are in accordance with the results of this study.

Appropriate subject selection and counseling is important for patient satisfaction. In a longitudinal study by Haywood and others (1994) at 1.5 years post treatment, 74% of subjects who had responded to home bleaching were satisfied with the shade of their teeth. At three years post-treatment, the figure was 62% and at seven years post-treatment of the same patient pool, 35% were satisfied with the color of their teeth. No one reported reverting to his or her original shade (Leonard, Knight & Haywood, 1998). Patients' perceptions of the whitening technique are generally positive. Appropriate subject selection and good counseling might be one reason that the questionnaires of subjects in this study revealed subjects' satisfaction of 80% regarding the result of their treatment. However, subjects' satisfaction of 65% regarding comfort of application and 55% of subjects' satisfaction regarding use of the lip retainer was obviously lower compared to the application mode and, thus, these two aspects should be taken into account for further evaluation of the new bleaching lacquer.

CONCLUSIONS

It can be concluded that the new bleaching lacquer, based on cellulose with 8% carbamide peroxide, is safe and efficacious without the use of any mouth guards. Making application twice daily for two weeks tended to be more effective compared to the once a day application; however, no statistical difference was noted between the two different application times. Thus, it does not seem to be obligatory to use the lacquer twice daily to get a visible result. The outcome of the tooth color after two weeks of bleaching is stable for at least six months regardless of whether it was applied once or twice a day.

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