Efficacy, Side-effects and Patients' Acceptance of Different Bleaching Techniques (OTC, in-office, at-home)

TM Auschill • E Hellwig • S Schmidale • A Sculean • NB Arweiler

Clinical Relevance
The outcome of this clinical study suggests that the three evaluated bleaching techniques resulted in the desired whitening of teeth within the recommended application time periods. Each method was also well accepted by the patients. The side effects that occurred were reversible and none of the products tested resulted in detectable changes in the enamel surface.

SUMMARY
This clinical study compared the efficacy of three different bleaching techniques with respect to the bleaching times required in order to achieve six grades of whitening in human teeth. Any side effects that were noted and the patients' acceptance of the method were recorded by a visual analog scale ranging from 0 to 10. Moreover, epoxy casts from the study teeth were analyzed by scanning electron microscopy in order to detect any potential changes in the enamel surface due to treatments.

Thirty-nine volunteers participated in the study and were allocated randomly to one of three different bleaching treatments: Group A (n=13) used Whitestrips (over-the-counter technique; one cycle=30 minutes), Group B (n=13) used Opalescence PF 10% (at-home bleaching technique; one cycle=8 hours) and Group C (n=13) used Opalescence Xtra Boost (in-office bleaching technique; one cycle=15 minutes) until a defined whitening of six tabs compared to the baseline were reached (assessed by the VITA shade guide).

All three methods achieved six grades of whitening. The mean treatment time required to reach the defined level of whitening was 31.85 ± 6.63 cycles in Group A, 7.15 ± 1.86 cycles in Group B and 3.15 ± 0.55 cycles in Group C. All products differed significantly from each other in terms of treatment cycles and required treatment time (p<0.001 by ANOVA and Mann-Whitney-U-test). Using the VA scale, side effects noted within the three groups were minimal. Tooth hypersensitivity ranged from 2.62 (Whitestrips) to 3.38 (Opalescence PF), and gingival irritation ranged...
between 0.23 (Opalescence Xtra Boost) and 0.85 (Whitestrips). The most accepted method was the in-home bleaching technique. None of the teeth studied showed detectable enamel surface changes in the subsequent SEM analysis using 200x and 2000x magnification.

INTRODUCTION

Tooth bleaching has been described in the literature as early as 1889. Many of these early attempts were not very successful (Kirk, 1889). The most effective methods involve the use of hydrogen peroxide (Haywood, 1992). This bleaching agent enables the treatment to be efficient at removing intrinsic staining, and most of the current vital bleaching materials contain hydrogen peroxide in some form, either as carbamide peroxide or hydrogen peroxide per se (Fasanaro, 1992). Carbamide peroxide solutions are unstable and dissociate into their constituent parts on contact with tissue or saliva (Haywood, 1992; Haywood & Heymann, 1989). Carbamide peroxide solution (H₂O₂) breaks down into hydrogen peroxide (H₂O₂) and urea (Ca[NH₂]₂), after which the urea degrades into ammonia (NH₃) and carbon dioxide (CO₂). The active agent (H₂O₂) has to be in contact with the outer enamel surface for a period of time in order to develop its bleaching potential. Hydrogen peroxide breaks down into oxygen and water, which then penetrate the tooth and liberate the pigment molecules.

The most common methods used to remove discoloration from teeth consist of two clinical and a non-clinical technique. At-home bleaching is a method where the patient fills a custom-designed tray with bleaching material (10% to 20% carbamide peroxide resulting in 3.35-7% hydrogen peroxide) that is then worn for several hours. Since its introduction by Haywood and Heymann (1989), the original technique has undergone some modifications. For example, there have been changes in tray material, tray design and the use of reservoir and ingredient concentration (Leonard, Shina & Haywood, 1998; Matis & others, 2002). This technique has become an efficient, safe method for lightening discolored teeth. Over-the-counter (OTC) bleaching products (5.3% to 5.6% hydrogen peroxide) are sold as cosmetics and are freely available through stores, pharmacies and the Internet. They can be sold, for example, as either strip or varnish systems and may cause patients problems, because a dentist does not monitor the bleaching procedure. The efficacy and structural side effects of this system have not been fully studied (White & others, 2003). In-office bleaching is suitable for removing stains by using a high concentration of hydrogen peroxide (35% to 38%). The dentist is in complete control of the process throughout the treatment. This provides the advantage of being able to terminate the discoloring process at any time. Studies have shown that higher concentration materials may bleach teeth faster (Leonard & others, 1993). They usually work so rapidly that visible results can be observed after only a single visit.

Each of the described techniques has certain advantages and disadvantages (Leonard & others, 2001b; Dahl & Pallesen, 2005). A common clinical side effect is thermal sensitivity of individual teeth. This may occur during the bleaching procedure and usually stops when treatment is suspended. Gingival irritation caused by bleaching agents has also been reported. With the in-office technique, making use of a dam and with the at-home bleaching technique, using an individually designed guard, the agent only has minimal contact with soft tissue. Additionally, several studies have evaluated such adverse events as carcinogenicity (Dadoun & Bartlett, 2003) and effects on restorative materials (Langsten & others, 2002; Turker & Biskin, 2003). In vitro scanning electron microscopic evaluations of the surface texture of dentin (de Freitas & others, 2002) and enamel treated with different bleaching agents showed little to no changes (Haywood, Houck & Heymann, 1991; Leonard & others, 2001a; Auschill & others, 2002).

Because of the different techniques available and their varying peroxide concentrations, individual exposure times are necessary in order to achieve the same level of whitening. This allows for individually tailoring the bleaching program for each patient, but which technique is the best? Which technique does the patient prefer/accept most? Because the observations regarding effectiveness and adverse effects are still controversial and only a few studies have been carried out under intraoral conditions (Leonard & others, 2001b; Zekonis & others, 2003), there is a need for additional research on the impact of currently available bleaching techniques.

Thus, the aim of this study was to evaluate the efficacy of the three bleaching techniques in vivo, possible side effects such as tooth sensitivity and gingival irritations, patients’ acceptance and any effects on enamel surface morphology studied by scanning electron microscopy (SEM).

METHODS AND MATERIALS

This randomized, examiner blind clinical study used a parallel group design. It assessed intrinsic stain removal and the occurrence of intraoral adverse effects after bleaching with three different bleaching techniques in vivo. In addition, their effect on enamel surface morphology was investigated by SEM.

Thirty-nine human subjects in good health were recruited for this study. Subjects with poor general or dental health, fixed orthodontic appliances or known hypersensitivity were not permitted to participate. An
inclusion criterium was the presence of the right unre-
stored upper canine, which was initially of grade A3 or
darker according to the VITA shade guide (VITAPAN
classical; VITA Zahnfabrik, Bad Säckingen, Germany).
The degree of color change was evaluated by using color
slide photography. All subjects gave their written con-
sent and completed a medical history form.

The subjects received a professional tooth cleaning
prior to the start of the study and were asked to brush
their teeth twice daily with the allocated toothbrush
(elmex inter X, GABA International AG, Basel, CH) and
two toothpastes (aronal/elmex, GABA International AG, Basel, CH) in order to standardize
both cleaning during the study.

Two trained, qualified examiners, who were blind as
to treatment assignment and period, measured the
baseline tooth color by using the VITA shade guide
(VITAPAN classical; VITA Zahnfabrik, Bad Säckingen,
Germany) on the facial surface of the right upper
canine. Prior to starting the study, a calibrating session
was held to review shade matching using the VITA
system.

The tabs of the shade guide were arranged from B1 to
C4, corresponding to a grade of whitening from 1 to 16
(Table 1) (Leonard & others, 2001b; Pohjola & others,
2002; Auschill & others, 2002), in which a smaller number
means the tooth is lighter.

Participants were randomly assigned to three groups
of 13 volunteers each (n=13 upper right canine). Group
A was treated with the over-the-counter technique,
Group B with the at-home bleaching technique and
Group C with the in-office technique. The three groups
were screened, then treated according to the specific
bleaching technique:

For Group A, the strips (Whitestrips, 5.3% hydrogen
peroxide, Procter & Gamble Technical Centres Ltd,
Egham, UK) were distributed and their application
demonstrated. The recommended wearing regimen was
30 minutes twice a day, and the participants were
asked to rinse their mouth with water after wearing in
order to remove any remaining gel from the teeth.

For Group B, a maxil-

ary alginate impression was taken from the subjects and a
model was cast for fab-

rication of the whitening tray. A 1-mm buccal reservoir from the
right to the left upper canine was formed

using block-out com-

posite (L.C. Block-Out,

Resin, Ultradent

Products, Inc, South

Jordan, UT, USA). An
ethyl-vinyl-acetate-tray (Soft-TRAY, Ultradent) was
made with the press-down machine. The participants
were asked to wear their tray filled with the bleaching
solution (Opalescence Xtra Boost, 10% carbamide peroxide,
Ultradent) for eight hours per night.

In Group C, the teeth to be bleached were isolated
using a conventional dam (FlexiDam, Coltene,
Langenau, Germany). With a syringe-to-syringe mixing
process, the bleaching agent (Opalescence Xtra Boost,
38% hydrogen peroxide, Ultradent) was activated and a
1-mm thick layer of the material was applied on the
labial surface of each tooth. The gel was removed 15
minutes after application (one cycle per appointment).
This product contains hydrogen peroxide, which is
chemically activated when mixed and does not need
light activation.

Within each group, the whiteness of the study teeth
from every subject was inspected 24 hours after the
bleaching session, and the individual bleaching steps
were repeated until the expected result was reached; in
the case of this study, six tabs lighter than the baseline
value. The examiner scored the shade of each test tooth
by selecting the closest matching shade tab on the
guide. If the examiners disagreed during the session,
differences were discussed and an agreement reached.
Intraoral color slides were taken in order to record the
tooth shade for documentation of the baseline shade
and to compare whether a change in shade occurred.
Shade determinations were always performed under
the same conditions (for example, no lipstick, same
light source).

For safety and acceptance monitoring of gingival-irri-
tations and tooth-hypersensitivity, participants were
asked to record the total hours of wear daily and any
intraoral adverse events in their teeth and gingiva.
Subjects completed their questionnaires seven days
after treatment, recording their personal response to
the above mentioned side effects and their overall
impression of the treatment (patients' acceptance
(Zekonis & others, 2003). Table 2 shows abnormalities

| Table 1: The VITA Value-oriented Shade Guide with 16 Shades Ranked From the Lightest Color on the Left to the Darkest Color on the Right |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| B1 | A1 | B2 | D2 | A2 | C1 | C2 | D4 | A3 | D3 | B3 | A3.5 | B4 | C3 | A4 | C4 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |

| Table 2: Side Effects and Patients' Acceptance Evaluated by Visual-analog Scale |
|---|---|---|
| Tooth sensitivity | 2.62 ± 1.46 | 3.38 ± 1.66 | 2.85 ± 1.41 |
| Gingival irritations | 0.85 ± 1.82 | 0.38 ± 0.87 | 0.23 ± 0.44 |
| Patients acceptance | 2.31 ± 1.93 | 1.46 ± 1.33 | 3.31 ± 1.75 |

* statistically significantly different from each other (p<0.01; Mann-Whitney-U-test).
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not present at baseline or which worsened during the bleaching process.

baseline and after reaching the defined level of whiteness, impressions (Dimension Garant L, ESPE, Seefeld, Germany) of the upper right canine were taken. They were rinsed, dried and epoxy resin casts (Blue Star, Girrbach Dental GmbH, Pforzheim, Germany) made. The cast was removed from the impression, trimmed, dried for 24 hours, fastened on a carrier, sputter coated with gold palladium and examined under scan electron microscope SEM (REM Leo 430 VP, LEO Electron Microscopy Ltd, Cambridge, GB) at 15kV. SEM pictures at baseline and after treatment of the upper canine at 200x and 2000x magnification were obtained in order to evaluate enamel texture changes. SEM photographs of each replica were taken 4-mm labially from the incisal edge and half mesiodistally in order to ensure the same location on the tooth was used. Three examiners compared each of the picture-pairs to find out whether a difference between the photographs evaluating enamel texture could be seen.

Statistical Analysis

Although the shade tab used was not linear between the different tabs, a statistical analysis could still be performed since the baseline data were similar and did not differ significantly from one another (p>0.05; by ANOVA).

The average values of the bleaching cycles, required time for the individual products and the visual analogue scale were calculated using the statistical program SPSS 11.0. First, the data records were checked for normal distribution using the Kolmogorow Smirnov test. Since they were not normally distributed and significant differences between the products were found using ANOVA (analysis of variance), the Mann-Whitney-U test for independent samples was applied for statistical comparison among the three groups.

RESULTS

All 89 participants completed the study. The volunteers ranged in age from 21 to 68 years, with the average age being 29.82 years. The participants were randomized into three groups. There were no statistically significant differences in the mean baseline shade, age or gender of the participants.

Efficacy of Shade Change

The shades of the three groups did not differ significantly at baseline. Their values ranged from grade 9-15, with a mean value of 11.2±1.8 in Group A, 11.5±2.0 in Group B and 11.4±2.1 in Group C (p>0.05 by ANOVA). All three techniques proved to be effective at whitening. The mean treatment time required to achieve the defined shade was 31.85 ± 6.63 cycles (= 958.46 ±
Figure 3a. Clinical photograph before over-the-counter treatment.

Figure 3b. Clinical photograph after 16 days of over-the-counter treatment.

Figure 4a: SEM photograph of enamel before over-the-counter treatment (2000x).

Figure 4b: SEM photograph of enamel after over-the-counter treatment (2000x).

Figure 5a: SEM photograph of enamel before at-home treatment (2000x).

Figure 5b: SEM photograph of enamel after at-home treatment (2000x).

194.80 minutes) in Group A, 7.15 ± 1.86 cycles (= 3043.85 ± 982.16 minutes) in Group B and 3.15 ± 0.55 cycles (= 47.08 ± 8.43 minutes) in Group C (Figures 1 and 2). Photographs of one participant (representing the pre- and post-bleaching situations) are shown in Figure 3a and b.

Side-effects and Patients' Acceptance
In order to record side effects and patients' acceptance, a visual analogue scale was used in which the extremes represented the limits of pain and acceptance. One end was labeled "no discomfort" or "best acceptance" (0), whereas, the other end was labeled "severe discomfort" or "no acceptance" (10). Subjects were asked to mark
the position that best indicated their current opinion. All products yielded minimal side effects in the volunteers. Transient problems documented by the patients were initial gingival irritation and slight thermal tooth sensitivity (Table 2). These symptoms were mild, transient and reversible. Additionally, Table 2 shows the average values of patients’ acceptance.

Statistical Analysis of these data demonstrated that there was only one significant difference between Opalescence PF 10% and Opalescence Xtra Boost concerning acceptance (p ≤ 0.05, by Mann-Whitney-U-Test). All other comparisons detected no significant differences (p > 0.05 by ANOVA).

**DISCUSSION**

The second part of the study showed that teeth treated with bleaching agents had no observable enamel surface texture changes when evaluated by the three examiners. No differences outside normal tooth variations were visible when the texture of the epoxy resin replica surface at baseline was compared with its corresponding cast after bleaching, regardless of whether 200x or 2000x magnification was used. Figures 4 through 6 present pre- and post-treatment SEM photographs of the enamel surface of each group.

Efficacy

The precondition was to bleach six grades lighter than baseline value, which was achieved in each of the 39 study teeth (Figures 3a and 3b). Thus, the clinical efficacy rate for the volunteers in the groups was 100%. Different methods of determining this tooth shade change can be used (colorimeter, shade guide). In this study, the VITA shade guide was used, because it is still the most commonly used method and is predictable when whitening teeth (Freedman, 1997).

Side Effects

An additional objective of this study was to determine possible side effects. Teeth and gum sensitivity were self-evaluated by the volunteers. Penetration of bleaching agents into tooth hard tissue results in different changes in vital teeth. Numerous studies have shown that pulpal reactions to bleaching agents are reversible (Cohen, 1979; Robertson & Melfi, 1980). They reported no histological changes in the treated teeth when compared with the controls and concluded that vital bleaching was harmless to pulpal tissues. A study by Seale, McIntosh and Taylor (1981) showed that treatment in dogs with 33% hydrogen peroxide alone or with heat caused obliteration of odontoblasts, hemorrhage, resorption and inflammatory infiltration, while heat alone was not detrimental. Pulpal changes demonstrated evidence of reversibility after 60 days.

In this study, none of the three tested products needed light for activation of the bleaching process. This may explain the low sensitivity values. The at-home treatment caused slightly higher tooth sensitivity compared to the over-the-counter and in-office treatments but this was not significant and had no consequence in patients’ acceptance. This higher value could be explained by the longer application time (in minutes).
Similar general observations could be made regarding gingival irritation. The over-the-counter treatment caused higher gingival irritation compared to the at-home or in-office treatments, but again, no significant differences existed between the groups (Li & others, 2003). These higher irritations could be due to the fact that there was no monitoring of the over-the-counter technique by a dentist. The strips were more irritating to the gingiva than the in-office treatment, which used a dam, and the at-home treatment, with its individually designed guard. However, it should be kept in mind that the irritation was mild and reversible in each case and none of the volunteers had to resign. Additionally, visual inspection by the examiners showed no signs of gingival inflammation or necrosis after clinical treatment. The fact that, for many years, carbamide peroxide and hydrogen peroxide solutions have been investigated and used clinically to bleach vital teeth without incurring pulpal and gingival damage is an indication of its safety to these tissues.

Patients’ Acceptance

The at-home bleaching treatment was significantly more accepted by patients compared with the in-office method. When asked for reasons, the volunteers indicated that the at-home technique required less chairtime despite the in-office method being under the dentist’s control. It should be emphasized that values between zero and five indicate wide acceptance for all three techniques. Thus, in principle, all products are recommendable.

SEM

The second part of the study examined the effect of tooth bleaching agents on enamel surface. These observations were based on scanning electron microscopic evaluations of epoxy casts of replicas made of the study teeth (Leonard & others, 2001a). All evaluations were performed by three examiners blinded to the status of the tooth. After the respective treatment times in each group (16 days of active treatment in Group A, seven days in Group B and one day in Group C), the surface morphology showed no noticeable changes compared to baseline (Figures 4-6). Leonard and others (2001a) demonstrated that a regimen using a 10% carbamide peroxide solution had minimal to no effect on the enamel surface. This is in accordance with other SEM findings (Haywood & others, 1991; Spalding, Taveira & de Assis, 2003; White & others, 2003), where bleaching was considered to be safe for enamel. In contrast, Bitter (1992) and McGuckin, Babin and Meyer (1992) found some grooves on the enamel surface in their studies. Similar results were presented by Hegedüs and others (1999), where atomic force microscopy pictures showed that several grooves present in the enamel surface of untreated teeth became deeper after the bleaching procedure. The increase in depth of the grooves was more pronounced in the case of the higher concentrated solution (30% HP) after 28 hours of treatment. It was presumed that the differences in groove depth after treatment were caused by the difference in hydrogen peroxide concentration. However, in this study, the treatment with 38% hydrogen peroxide took 60 minutes in order to reach the desired result. Thus, in addition concentration, the major difference among the study designs was the time of application of the active agent. In summary, the SEM results of this study showed that no differences between the tested bleaching methods could be observed with regards to surface texture changes. However, it should be kept in mind that peroxide could have not only affected the surface but at the inner structure of the tooth. Without penetrating through hard tooth tissues, it would be impossible to treat the intrinsic discolorations (Seale & others, 1998; Chemical release of calcium and other minerals was observed (McCracken & Haywood, 1996), whereas, clinical significance of this small amount was assumed not to be significant. It was not possible in the course of this in vivo study to evaluate these internal areas and more investigations are needed on this topic.

The results of this study indicate that each of these treatments has certain advantages and disadvantages. The dentist should be familiar with all of them in order to serve patients best. The patient can be treated with a single technique or a combination. For example, the patient can start with the in-office technique to receive immediate results and continue with one of the other to save or extend the whitening.

CONCLUSIONS

It can be concluded that all three tested techniques are effective in removing intrinsic staining. In principle, the higher the concentration of the active ingredient, the faster tooth lightening occurs (in minute). Following the manufacturers’ instructions (cycles), took an average of 16 days with the over-the-counter bleaching technique, seven days when using the at-home bleaching technique and, with the in-office bleaching technique, the result may be achieved in one day. The side effects that appeared were reversible, none of the volunteers had to resign and there were statistically significant differences among the groups. All techniques were well accepted, with a slight preference for the home bleaching method. Additionally, tested products had no evident effect on the surface morphology of teeth when viewed under SEM at 2000x magnification.
References


Cohen SC (1979) Human pulpal response to bleaching procedures on enamel surface Schweizer Monatsschrift für Zahnmedizin 112(9) 394-399.


Kirk CE (1889) The chemical bleaching of teeth Dental Cosmos 31 273-283.


