

Home Bleaching Products

**An Evidence Based Study
On the Benefits and Risks of Home Bleaching Products**

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Abstract

The benefits and risks of using at home bleaching products were investigated by conducting an evidence-based review of the literature. The review was based on evidence from articles found using three electronic databases (PubMed, Cochrane, and Medline). In total, 21 articles were read in full, however, only 19 were deemed to be relevant and were assessed using the “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”⁸, which included 17 questions. Of these, the five studies with scores of 14 or greater (out of 17) were selected and critically appraised. Of these five studies, one looked at the differences between bleaching with Carbamide Peroxide (CP) and Hydrogen peroxide (HP) (Mokhlis et al. 2000), one compared 10% to 15% CP¹², one looked at safety of HP (Kugel et al. 2000) and two looked at safety of CP (Rosensteil et al. 1996 and Matis et al. 2000). All studies showed statistically significant shade reduction as a result of using bleaching products. The question of safety of bleaching products was assessed in all five studies, however, only one study showed statistically significant adverse effects including transient gingival and tooth sensitivity as well as an increase in gingival index of inflammation. Conclusions about adverse effects cannot be drawn from the remaining four studies because either powers were not given for insignificant results or statistical analyses were not performed. Overall, the evidence shows that both hydrogen peroxide and carbamide peroxide are effective bleaching products and there is insufficient evidence regarding the adverse effects of these products.

Introduction

Since the advent of applying chemicals to specifically whiten teeth in 1937¹, tooth whitening has become the most frequently requested dental treatment². Research has led to more convenient, efficient and patient friendly products which allow patients to whiten their teeth in the comfort of their own homes³. Home whitening systems are either dentist prescribed and supervised or purchased over the counter⁴. The CRA has compiled research demonstrating that the use of at home tooth whiteners of low concentrations for a longer duration are comparable to tooth whiteners applied in the dental office at a higher concentration for a shorter duration³, allowing for increased flexibility in patient care.

Haywood and Heymann⁵, introduced the first dentist supervised at home bleaching system called 'Nightguard Vital Bleaching', using the product carbamide peroxide in a night guard to whiten dentin and enamel as the patient slept⁶. This led to the introduction of many at home whitening products which differ in the chemicals used, the concentrations of these chemicals, and the delivery methods. The dental community responded with fear of possible adverse effects and the Council on Dental Therapeutics⁷ acted by developing safety and efficacy guidelines for home whitening products.

A review of the current literature on home tooth whitening products was executed to answer the following questions: What are the benefits of tooth whitening products? Do adverse effects occur with the use of tooth whiteners? Which tooth whitening product is best? The three null hypotheses included: There are no aesthetic benefits associated with the use of home bleaching products when compared to using no bleaching products.

There are no physiological risks associated with the use of home bleaching products when compared to using no bleaching products. There is no difference between various home bleaching products with respect to physiological risks or aesthetic benefits. This literature integrates the strongest evidence regarding the effects of tooth whitening products.

Methods

Relevant studies were found and critically appraised using a systematic search strategy that excluded articles based on set criteria.

Search Strategy

The search for scientific evidence on the research questions was performed using three different databases. Three computerized literature searches were conducted. The search was limited to *in vivo* human studies published in English between 1990 and 2005. “Home tooth bleaching OR home tooth whitening” were the key words entered in the abstract or title fields in PubMed, Cochrane Central Register of Controlled Trials and Medline search engines. The first stage of screening was the title screening stage, in which studies where the bleaching was done (fully or partially), in a dental office setting as well as studies that clearly were not *in vivo* studies or were not at least randomized controlled trials (RCTs) were excluded. Two studies were removed from the Medline search because they were duplicates. The second stage was the abstract reading stage that further excluded all studies that were not at least RCTs, or that were *in vitro*. (Table 1).

The next step was to combine the searches from the three databases, removing duplicates, in order to form a master list. After these three steps, 18 articles remained. Upon reading the full copy of each article, two were found not to be RCTs, leaving 16 articles. The references of these articles were scanned and another 3 articles were added, making a total of 19 articles.

Each of the 19 articles was scored independently by 3 members of the research team using the “Checklist to Assess Evidence of Efficacy of Therapy or Prevention”⁸ (Figure 1). The scores for each checklist were tallied and compared. Where there were any discrepancies in the scoring, the research team met and re-evaluated the checklist until a final score was established. The articles that had scores of less than 14 (out of 17) were excluded. The five articles that remained were used to construct a table of evidence to show the relevant findings in a concise manner (Table 2).

Results

The 5 relevant studies each looked at different aspects of the research question being evaluated. Each study had a score of at least 14 (out of 17), with the findings consistently indicating that both carbamide peroxide (CP) and hydrogen peroxide (HP) are effective products for tooth whitening (Table 2). However, in three of the studies^{9, 10, 11} the interventions were not monitored, two studies were of insufficient duration to test for colour rebound^{12,13}, and four studies did not control for outside dental care received by the study subjects^{9, 10, 11, 13}. Considering all of these factors, there is an overall lack of evidence on which to base conclusions regarding the benefits and especially the risks of home bleaching products.

Discussion

Carbamide Peroxide (CP): Benefits and Risks

Of the five studies, four of them tested the efficacy of various concentrations of CP using custom made trays as the delivery method. CP concentrations ranged from 10% to 20% and all were found to provide statistically significant improvements in tooth shade^{9, 10, 11, 12}.

Shade change was evaluated via the following methods: shade guide, colorimeter/ chromameter, photographs, and colour slides. While some studies used a number of these techniques to determine changes in shade^{9, 11}, others used only one^{10, 12}.

Tooth sensitivity was the major adverse effect observed in the studies using CP. In fact, this was the only adverse effect observed by Kihn et al.¹² and Mokhlis et al.⁹. In addition, Matis et al.¹¹ looked at the gingival index and Rosenstiel et al.¹⁰ used electrical pulp tests to assess vitality and probing to assess sulcus depth. Tooth sensitivity was based solely on subjective reports with the exception of Kihn et al.¹² who also used a statistically analyzed analogue scale to measure tooth sensitivity. In all cases of reported sensitivity, it was found to be transient and only found during the application of the treatment. Cessation of the application of CP resulted in removal of sensitivity in all cases.

Kihn et al. looked at the efficacy of 10% versus 15% CP and found 15% CP to have a slightly greater decrease in shade than 10% CP, however this was only by about 1.5-2 shades¹². Sensitivity was not found to be different among the two different concentrations of CP.

Matis et al.¹¹ and Rosentiel et al.¹⁰ both compared CP with control groups receiving a placebo and both found the respective 10% and 15% CP to provide statistically significant colour change as compared with the placebo group.

Mokhlis et al.⁹ compared 20% CP with 7.5% HP (which yield the same concentration of active ingredient once in the mouth) and found that while initially the CP resulted in significantly more shade change than the HP, at the end of the treatment time of 14 days, there was no statistically significant difference between them with regard to tooth lightness.

Hydrogen Peroxide (HP): Benefits and Risks

Both studies that used HP as the bleaching agent found that HP was effective^{9, 13}. The main difference between the studies was the concentrations of HP used (5.3%¹³ versus 7.5%¹¹). Using a shade guide, colour slides, photographs, and a colorimeter⁹ found that the 7.5% HP daytime treatment resulted in a significant change in tooth lightness and did not demonstrate colour relapse for up to 10 weeks after the study was completed. Kugel et al. used a polyethylene film with 5.3% HP gel (i.e. strips). Colour was determined using the Vita shade guide and an increase of tooth whiteness by approximately four Vita shades was observed¹³. They also found that the group experienced a significant reduction in both gingivitis, measured using the gingival index, and in plaque scores, measured by the plaque index, over the treatment period¹³.

The main risks associated with the use of HP in both concentrations were tooth and gingival sensitivity. Both studies found that the amount of tooth or gingival sensitivity reported by the patients was not significant enough to make them harmful to

the user, however no powers were given to substantiate these claims. Mokhlis et al. used self reports to rate sensitivity experienced by the patients⁹. In the Kugel et al. study, oral soft and hard tissues were examined visually and sensitivity was self reported¹³. Neither of these studies conducted statistical analysis for the adverse effects, so no conclusions can be drawn.

Both studies reveal that HP in at-home bleaching systems shows clinically significant effects while nothing can be said for adverse effects. However, there were several factors that were not taken into account in these studies. In the Mokhlis et al. study, patient compliance was not monitored or recorded⁹. In the Kugel et al. study, patient compliance was not monitored and the study was of short duration, making it impossible to determine whether colour rebound occurred¹³.

Mode of Application: Benefits and Risks

In order to achieve successful tooth bleaching, the bleaching product must stay in contact with the tooth surface for a certain amount of time. The two most common ways to achieve this are using custom trays that hold the bleaching solution on and around the teeth and using plastic strips that are coated in the bleaching solution. Kugel et al. conducted a study that compared polyethylene film (strips) coated 5.3% HP to polyethylene film coated with placebo gel¹³. Compared to the control, Kugel et al. found that the use of the whitening strips over a two week period resulted in a significant ($p < 0.0001$) decrease in tooth colour by 2.85 ± 0.41 shades according to the Vitapan¹³ Classical shade guide. In both the treatment and control groups there were abnormal soft-tissue findings at baseline and after treatment completion¹³. At the end of treatment

there were no new cases of soft tissue damage nor was there deterioration of any of the existing cases of soft tissue damage¹³. In comparison to other whitening methods, such as those requiring the use of trays, whitening strips offer better ease of use, shorter duration of application, and greater comfort which would all lead to better patient compliance¹³. The results by Kugel et al.¹³ would have been stronger had colorimetry been used to assess tooth shades, and had the study been lengthened to examine tooth shades after completion of treatment in order to examine possible rebounds in tooth whiteness. Furthermore, the degree of patient compliance is not known since a daily log was not kept by the study subjects¹³. The remaining 4 studies all used custom trays to apply the bleaching solution to the teeth.

Conclusions

According to this literature review, the at home bleaching products on the market today have shade reduction benefits. All products show effective whitening.

Adverse effects were investigated in all studies, yet in most cases insufficient evidence is available to draw any conclusions. According to Matis et. al¹¹, however, 10% CP gel appears physiologically acceptable since any statistically significant adverse effects were transient.

In regards to making a decision as to which product is best, it has been shown that a concentration of 15% CP gel is more effective at whitening than a 10% CP gel (9.4 vs 7.7 shades) and that 20% CP and 7.5% HP gels are similarly effective at whitening (Note that 20% CP breaks down into HP and urea, yielding the same concentration of active ingredient as 7.5% HP). Overall, there is ample research available on the topic of at-home

tooth bleaching; however, the quality of evidence is insufficient to assess adverse effects. Oftentimes, adverse effects were only subjectively measured (no statistics) and powers were not stated when applicable. Beyond these numerical shortcomings, the interventions were usually not thoroughly monitored and dental care outside of the study was not fully controlled for. Several studies used only a shade guide (subjective) to assess colour change, while a more objective method involving a chromameter is currently available. The duration of study was often not sufficient to assess colour rebound and should be at least four weeks post-treatment ¹¹ in order to fully evaluate the bleaching effects. The results found by many researchers were not always generalizable. For example, studies often excluded: heavily restored dentition, Gingival Index greater than 1, Tetracycline stained teeth, teeth with fluorosis, teeth with mild discolourations and tobacco users. The exclusion of tobacco users may be the most clinically relevant, since tobacco users likely consist of a large proportion of the people who seek this treatment.

Future research should address the limitations previously described (power, duration, outside care, intervention monitoring, chromameter, and target population), and should focus on increasing the quality of evidence on adverse effects of at-home tooth bleaching systems.

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Table 1. Search Strategy

	Medline	Cochrane	PubMed
Initial Search:	23	8	23
Title:	13	8	19
Not RCT	5	-	-
In-office	1	-	3
<i>In vitro</i>	2	-	1
Duplicates	2	-	-
Abstract:	6	6	18
Not RCT	6	2	1
<i>In vitro</i>	1	-	-

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Checklist to Assess Evidence of Efficacy of Therapy or Prevention

Citation:

1. Was the study ethical? _____
2. Was a strong design used to assess efficacy? _____
3. Were outcomes (benefits and harms) validly and reliably measured? _____
4. Were interventions validly and reliably measured? _____
5. What were the results? _____
 - Was the treatment effect large enough to be clinically important? _____
 - Was the estimate of the treatment effect beyond chance and relatively precise? _____
 - If the findings were “no difference” was the power of the study 80% or better _____
6. Are the results of the study valid? _____
 - Was the assignment of patients to treatments randomised? _____
 - Were all patients who entered the trial properly accounted for and attributed at its conclusion? _____
 - i) Was loss to follow-up less than 20% and balanced between test and control _____
 - ii) Were patients analysed in the groups to which they were randomised? _____
 - Was the study of sufficient duration? _____
 - Were patients, health workers, and study personnel “blind” to treatment? _____
 - Were the groups similar at the start of the trial? _____
 - Aside from the experimental intervention, were the groups treated equally? _____
 - Was care received outside the study identified and controlled for _____
7. Will the results help in caring for your patients? _____
 - Were all clinically important outcomes considered? _____
 - Are the likely benefits of treatment worth the potential harms and costs? _____

Adapted from: Fletcher, Fletcher and Wagner. Clinical epidemiology – the essentials. 3rd ed. 1996, and Sackett et al. Evidence-based medicine: how to practice and teach EBM. 1997

Figure 1. **Checklist to Assess Evidence of Efficacy of Therapy or Prevention**

Table 2. Evidence Based Table for the Efficacy of at Home Tooth Bleaching Products

Author, Date	Population	Test Tx	Control Tx	Outcome	Critical Appraisal	Conclusion/ Strength of Evidence (efficacy/ adverse effects)
Kihn PW et al., 2000	56 subjects, 6 Mx ant shade A3 or darker (VITA), good general and dental health, 18-65 yrs old	15% CP (NUPRO Gold tray)	10% CP (NUPRO Gold tray)	Shade Change (S; p<0.05): -15% CP = 9.4 -10% CP = 7.7 Adverse Effects (NS; p>0.05): -Transient sensitivity	Score: 14.5 -Only shade guide (1/2) -No power (1) -Loss to follow-up (1/2) unaccounted for -Short duration (1/2)	Study Design: I (Double-blind RCT) Evidence: A/I -15% CP more effective whitening than 10% CP (9.4 vs 7.7 shades)
Kugel G et al., 2000	70 adults, 3 or more Mx teeth shade A2 or darker (VITA) Excluded: -fixed ortho -atypical stains -perio disease/oral pathoses -dentinal hypersensitivity	5.3% HP (Crest White Strips)	Placebo (Crest White Strips)	Shade Change (S; p<0.0001): -5.3% HP = 4 -Placebo = 1 Adverse Effects: -No notable findings	Score: 14 -Outcome measurement unreliable (1) (shade guide only and adverse effects) -Short duration (1) -Uncontrolled outside care (1)	Study Design: I (Double-blind RCT) Evidence: A/I -5.3% HP gel effective whitening (4 vs 1 shades)
Author, Date	Population	Test Tx	Control Tx	Outcome	Critical Appraisal	Conclusion/ Strength of Evidence (efficacy/adverse effects)

Matis BA et al., 1998	60 subjects, 6 Mx ant shade A3 or darker (VITA), and < 1/6 of facial surface restored Excluded: -smokers -sig. soft/hard tissue pathoses -GI > 1	10% CP (Opalescence Gel)	Placebo (Opalescence Gel)	Shade Change (S; p=0.0001): -10% CP = 14.1 -Placebo = 1.9 -10% CP > ΔE* Adverse Effects: -Transient gingival (S; p=0.0001) and tooth sensitivity (S; p=0.001), and GI (S; p=0.01) -No sig. gastro-intestinal sensitivity (NS; p=0.427)	Score: 14.5 -Interventions not monitored (1/2) -No power (1) -Uncontrolled outside care (1)	Study Design: I (Double-blind RCT) Evidence: A/B -10% CP gel effective whitening (14.1 vs 1.9 shades) -10% CP gel appears physiologically acceptable
Mokhlis GR et al., 2000	24 subjects, all 6 Mx ant less than 1/6 of facial surface restored and shade b/w B54 and B85 (TRUBYTE), 18 yrs, no tobacco use during study Excluded: -any medical condition, gross oral pathology, tetracycline stain, endo on Mx ant, prof. whitening in last 5 years, tobacco in last 30 days, pregnant or lactating, GI > 1	20% CP (Opalescence gel PF)	7.5% HP (Day White gel)	Shade Change (p=0.0321): -20% CP → sig. higher ΔE* at end of treatment, but no sig. difference 10 wks post tx (p=0.99) Adverse Effects: -No sig. tooth (p=0.19) or gingival sensitivity (p=0.12)	Score: 15 -Interventions not monitored (1/2) -No Power (1) -Outside care partially controlled (1/2)	Study Design: I (Double-blind, split-mouth RCT) Evidence: A/I -20% CP and 7.5% HP gels similarly effective whitening
Author, Date	Population	Test Tx	Control Tx	Outcome	Critical Appraisal	Conclusion/ Strength of Evidence (efficacy/adverse effects)

Rosenstiel SF et al., 1996	52 adults, 6 Mx ant free of restorations and caries Excluded: -noticeable intrinsic staining -hypoplasia -fluorosis	10% CP (Opalescence gel)	Placebo (Opalescence gel)	Shade Change (S; $p < 0.05$): -10% CP $\Delta E^* = 3.6$ -Placebo $\Delta E^* = 2.0$ Adverse Effects: -No sig. vitality ($p = 0.76$), sulcus depth ($p = .94$) or GI changes ($p = .81$)	Score: 14.5 -Intervention not monitored (1/2) -No power (1) -Outside Care not controlled (1)	Study Design: I (Double-blind RCT) Evidence: A/I -10% CP gel effective whitening (3.6 vs 2.0 ΔE^*)
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