

# **Tooth Whitening/Bleaching: Treatment Considerations for Dentists and Their Patients**

ADA Council on Scientific Affairs

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### **Introduction**

Over the past two decades, tooth whitening or bleaching has become one of the most popular esthetic dental treatments (*Note: this paper uses the terms "whitening" and "bleaching," interchangeably*). Since the 1800s, the initial focus of dentists in this area was on in-office bleaching of non-vital teeth that had discolored as a result of trauma to the tooth or from endodontic treatment. By the late 1980s, the field of tooth whitening dramatically changed with the development of dentist-prescribed, home-applied bleaching (tray bleaching) and other products and techniques for vital tooth bleaching that could be applied both in the dental office and at home.

The tooth whitening market has evolved into four categories: professionally applied (in the dental office); dentist-prescribed/dispensed (patient home-use); consumer-purchased/over-the-counter (OTC) (applied by patients); and other non-dental options. Additionally, dentist-dispensed bleaching materials are sometimes used at home after dental office bleaching to maintain or improve whitening results.

Consumer whitening products available today for home use include gels, rinses, chewing gums, toothpastes, paint-on films and strips. The latest tooth whitening trend is the availability of whitening treatments or kits in non-dental retail settings, such as mall kiosks, salons, spas and, more recently, aboard passenger cruise ships. Non-dental whitening venues have come under scrutiny in several states and jurisdictions, resulting in actions to reserve the delivery of this service to dentists or appropriately supervised allied dental personnel.

Current tooth bleaching materials are based primarily on either hydrogen peroxide or carbamide peroxide. Both may change the inherent color of the teeth, but have different considerations for safety and efficacy. In general, most in-office and dentist-prescribed, at-home bleaching techniques have been shown to be effective, although results may vary depending on such factors as type of stain, age of patient, concentration of the active agent, and treatment time and frequency. However, concerns have remained about the long-term safety of unsupervised bleaching procedures, due to abuse and possible undiagnosed or underlying oral health problems.

Although published studies tend to suggest that bleaching is a relatively safe procedure, investigators continue to report adverse effects on hard tissue, soft tissue, and restorative materials.<sup>1-3</sup> The rate of adverse events from use or abuse of home-use OTC products is also unclear because consumers rarely report problems through the U.S. Food and Drug Administration (FDA) Medwatch system. Based on these factors, the American Dental Association (ADA) has advised patients to consult with their dentists to determine the most appropriate whitening treatment, particularly for those

with tooth sensitivity, dental restorations, extremely dark stains, and single dark teeth.<sup>4</sup> Additionally, a patient's tooth discoloration may be caused by a specific problem that either will not be affected by whitening agents and/or may be a sign of a disease or condition that requires dental therapy.

The purpose of this report is to outline treatment considerations for dentists and their patients prior to tooth whitening/bleaching procedures so that the potential for adverse effects can be minimized. This report does not address agents used for non-vital intracoronal bleaching procedures.

### **Safety Concerns with Tooth Bleaching Materials**

Concerns regarding the safety of all bleaching treatments and products have long existed, but were heightened since the introduction of at-home bleaching.<sup>5-8</sup> Discussions in this section focus on peroxides and their use as active ingredients in tooth bleaching materials. Important concerns related to patient examination and diagnoses are addressed elsewhere in this report.

A variety of peroxide compounds, including carbamide peroxide, hydrogen peroxide, sodium perborate and calcium peroxide, have been used as active ingredients for bleaching materials; however, essentially all extracoronal bleaching materials currently available for whitening of vital teeth in the United States contain carbamide peroxide and/or hydrogen peroxide. Recently, products containing chlorine dioxide were introduced in the United Kingdom, but there is no evidence that tooth bleaching products using chlorine dioxide as the active ingredient are safer than peroxide-based materials. In fact, safety concerns have been documented with chlorine dioxide and its use for tooth bleaching treatment due to the low pH of the material and resultant tooth etching.<sup>9</sup>

Most OTC bleaching products are hydrogen peroxide-based, although some contain carbamide peroxide. Carbamide peroxide decomposes to release hydrogen peroxide in an aqueous medium: ten percent carbamide peroxide yields roughly 3.5% hydrogen peroxide. In-office bleaching materials contain high hydrogen peroxide concentrations (typically 15-38%), while the hydrogen peroxide content in at-home bleaching products usually ranges from 3% to 10%; however, there have been home-use products containing up to 15% hydrogen peroxide.

Safety issues have been raised regarding the effects of bleaching on the tooth structure, pulp tissues, and the mucosal tissues of the mouth, as well as systemic ingestion. Regarding mucosal tissues, safety concerns relate to the potential toxicological effects of free radicals produced by the peroxides used in bleaching products. Free radicals are known to be capable of reacting with proteins, lipids and nucleic acids, causing cellular damage. Because of the potential of hydrogen peroxide to interact with DNA, concerns with carcinogenicity and co-carcinogenicity of hydrogen peroxide have been raised, although these concerns so far have not been substantiated through research.<sup>5,10,11</sup> However, studies have shown that hydrogen peroxide is an irritant and also cytotoxic. It is known that at concentrations of 10% hydrogen peroxide or higher,

the chemical is potentially corrosive to mucous membranes or skin, and can cause a burning sensation and tissue damage.<sup>5,12,13</sup> The amount of products applied during office bleaching treatment and other formulation variables can change the potential to cause damage. However, severe mucosal damage can occur if gingival protection is inadequate with high strength tooth whitening products. Clinical studies have also observed a higher prevalence of gingival irritation in patients using bleaching materials with higher peroxide concentrations.<sup>14,15</sup>

Data accumulated over the last 20 years, including some long-term clinical study follow up<sup>16,17</sup>, indicate no significant, long-term oral or systemic health risks associated with professional at-home tooth bleaching materials containing 10% carbamide peroxide (3.5% hydrogen peroxide). However, these data were collected from studies which include examinations by dental professionals, and there is no safety evidence on bleaching materials that do not involve such examinations by dental professionals, regardless of hydrogen peroxide concentration or application venue. Additionally, consumers are not generally aware of how to report adverse events through FDA's Medwatch system. If a licensed dental professional is not consulted when patients use OTC bleaching products, adverse effects due to product abuse may go unreported.

Regarding hard tissues, transient mild to moderate tooth sensitivity can occur in up to two-thirds of users during early stages of bleaching treatment.<sup>18</sup> Sensitivity is generally related to the peroxide concentration of the material and the contact time; it is most likely the result of the easy passage of the peroxide through intact enamel and dentin to the pulp during a five- to 15-minute exposure interval. However, there have been no reported long-term adverse pulpal sequelae when proper techniques are employed. The incidence and severity of tooth sensitivity may depend on the quality of the bleaching material, the techniques used, and an individual's response to the bleaching treatment methods and materials. To date, there is little published evidence documenting adverse effects of dentist-monitored, at-home whiteners on enamel, but two clinical cases of significant enamel damage have been reported, apparently associated with the use of OTC whitening products.<sup>19,20</sup> This damage may be related to the low pH of the products and/or overuse.

*In vitro* studies suggest that dental restorative materials may be affected by tooth bleaching agents.<sup>1,21</sup> These findings relate to possible physical and/or chemical changes in the materials, such as increased surface roughness, crack development, marginal breakdown, release of metallic ions, and decreases in tooth-to-restoration bond strength. Such findings have not appeared in clinical reports or studies. To address the safety of bleaching materials, the ADA convened a panel of experts in 1993. The ADA subsequently published its first set of guidelines for evaluating peroxide-containing tooth whiteners.<sup>22</sup> These guidelines have been revised periodically.

In March 2005, the European Scientific Committee on Consumer Products (SCCP) concluded the following: "The proper use of tooth whitening products containing >0.1 to 6.0% hydrogen peroxide (or equivalent for hydrogen peroxide-releasing substances) is considered safe after consultation with and approval of the consumer's dentist."<sup>13</sup> The

SCCP, in January 2008, again recommended that up to 6% hydrogen peroxide is a safe limit to use for at-home tooth bleaching; however, it did not recommend use of such products without dental consultation.<sup>23</sup>

In summary, available data indicate that extracoronal bleaching treatment in the dental office or at home may cause short-term tooth sensitivity and/or gingival irritation. More severe mucosal damage is possible with high hydrogen peroxide concentrations. While available evidence supports the safety of using bleaching materials of 10% carbamide peroxide (3.5% hydrogen peroxide) by dental professionals, there are concerns with the use of at-home bleaching materials with high hydrogen peroxide concentrations. Studies designed specifically to assess the long-term safety of high hydrogen peroxide concentration in at-home bleaching materials are needed, especially for repeated use of these products. There appears to be insufficient evidence to support unsupervised use of peroxide-based bleaching materials.

Similar to other dental and medical interventions, questions have been raised about the safety of tooth whitening treatments during pregnancy. In the absence of such evidence, clinicians may consider recommending that tooth whitening be deferred during pregnancy.

The safety of tooth bleaching for children and adolescents is also a consideration. More research is needed to establish appropriate use and limitations for these patients. However, bleaching is a conservative approach compared with restorative options when tooth discoloration causes significant concern. If possible, delaying treatment until after permanent teeth have erupted is recommended, as is use of a custom-fabricated bleaching tray to limit the amount of bleaching gel.<sup>24</sup> Close professional and parental/guardian supervision are needed to maximize benefits and minimize adverse effects and overuse.

## **Bleaching Treatment Considerations**

### ***General Considerations***

A typical dental examination begins with a health and dental history. Intra-oral examination of the hard and soft tissues of the mouth and extra-oral examination of the head and neck are also conducted to assess the patient for oral health problems as well as lumps, sores, or other signs of disease such as cancer or infection.. Seminal to decisions regarding tooth bleaching, the patient history would include the patient's opinions regarding the cause of tooth discoloration, a history of allergies (which may include ingredients in bleaching materials), and information regarding any past problems with tooth sensitivity. Some tooth discolorations may be the result of a disease or condition that requires endodontic therapy, restorations or dental surgery. Such diagnoses can only be made by a dentist or another licensed health care professional, depending on local licensing regulations. In light of these and additional factors noted below, a dental examination with appropriate radiographs or other screening or diagnostic tests is recommended prior to considering tooth bleaching.

Bleaching discolored teeth in which the color change is the only visible indication of an underlying abnormality may change tooth color, but will not remove any underlying abnormality. This masking effect can result in tooth loss or other complications depending on the underlying condition since the true cause of the discoloration may go untreated. Dental caries or leaking restorations are two common conditions that may cause teeth to appear dark. Patients should be advised that bleaching treatments will not remove tooth decay that may subsequently progress and result in the need for more extensive and expensive treatments.

Examination of tooth function and para-function may reveal conditions such as bruxism or temporomandibular dysfunction that may be aggravated by use of bleaching trays.<sup>25</sup> Radiographs may be necessary to aid in screening and diagnosis of diseases or conditions that may manifest as tooth discoloration, such as pulp necrosis with or without infection, anomalous pulp chamber size and anatomy, calcific metamorphosis, root resorption, etc. A history of tooth sensitivity should be investigated carefully to determine the cause(s) and whether treatment before tooth bleaching will benefit the patient.

A dental examination will help to identify and record the presence and locations of existing tooth restorations. This step may be quite important to an acceptable tooth bleaching outcome, since restorations do not change color. Dental restorations can also be a cause of tooth discoloration: metallic and other restorative materials may influence tooth color significantly depending on the translucency and thickness of the remaining tooth structure.

Patient expectations may be unrealistic unless cosmetic issues with existing restorations are addressed initially. Additional examination considerations include: tooth/enamel cracks and related sensitivity; exposed root surfaces (that resist bleaching); and other smile considerations such as translucency or defects in tooth form or anatomy.

Patient habits and lifestyle, as well as the presence of removable or fixed appliances or prostheses, should also be considered during an examination. Pre-treatment photographs and shade guides are often helpful to record a baseline to better assess treatment success.

Upon completion of the dental examination and diagnosis, treatment may be recommended and prioritized. Although the patient's primary concern may be tooth discoloration, bleaching procedures may not be recommended (or effective) until other problems are addressed. If dental restorations are present, often the expense and/or the risks related to the replacement fillings or crowns to match post-bleaching tooth color may contraindicate bleaching.

When bleaching is pursued, the dental team will consider and recommend the appropriate materials, techniques, and delivery systems to best serve the patient's

needs and desires (see next section for further discussion of method-specific considerations). These factors affect the costs and may influence treatment decisions.

The length of treatment and expected outcome will depend on the cause of the discoloration, as well as the chosen product and technique. Dentists can discuss these concerns with their patients in the treatment plan development process. Success will vary when tooth discoloration is related to inherited/developmental aspects, age-related tooth changes, extrinsic staining (e.g., from diet or smoking), or intrinsic staining such as tetracycline-associated stain or color change secondary to tooth trauma.

If a patient has a history of sensitive teeth due to thermal or mechanical stimulation, or experiences sensitivity during tooth bleaching, the benefits and risks of various tooth sensitivity treatment options can be discussed with the patient. Options to help manage tooth sensitivity may include use of non-steroidal anti-inflammatory drugs (NSAIDs), fluoride, casein phosphopeptide-amorphous calcium phosphate or potassium nitrate. During treatment, it may be necessary to select an alternate bleaching product, or change the delivery system, treatment duration or treatment interval. Depending on the patient's response, side effects or other issues, it may be in the patient's best interest to discontinue treatment.

### ***Method-Specific Considerations***

Dentist-managed bleaching treatments may include in-office bleaching, at-home use of bleaching trays at night or during the day, strip-based materials, or a combination of these treatment methods. The choice between the methods and types of products relate to many factors, including the patient's lifestyle, caries history, tooth sensitivity, and discoloration type. Additionally, the need for and effectiveness of maintenance or periodic re-treatment varies widely. This can be addressed depending on the patient's individual response to tooth whitening. A dental examination, including any necessary radiographs, should precede re-treatment.

Other considerations consistent with those covered previously, such as the presence or history of sensitivity, presence of dental restorations, and occlusal/temporomandibular dysfunction may raise method-specific concerns that merit attention as well. Allergies to bleaching tray materials, isolation barriers, or bleaching materials may also limit treatment options.

With the tray bleach method, if tooth sensitivity is problematic, the tray may be used in advance for the application of potassium nitrate for 10 to 30 minutes<sup>26,27</sup>, unless the bleaching material includes a desensitizing agent. Use of potassium nitrate-containing toothpaste before bleaching and throughout the bleaching therapy can also help patients manage tooth sensitivity.<sup>28</sup> Higher peroxide concentrations result in more sensitivity but may not shorten the treatment time<sup>29</sup>, since individual teeth can respond at different rates.

Although brown discolorations respond well to bleaching, white discolorations remain unchanged, though the background may be lightened to make the white areas less

noticeable. Occasionally, bleaching may need to be combined with abrasion techniques or bonded restorations to address non-esthetic white areas. With tray bleaching, teeth normally lighten in 3 days to 6 weeks. However, whitening of nicotine-stained teeth may take 1-3 months. Tetracycline-stained teeth may not respond or adequate response may require 2 to 6 months (or more) of dentist supervised nightly treatment. Diagnosis of the cause(s) of tooth discoloration followed by an explanation of the projected treatment time, benefits and risks are important considerations to address patient concerns and set reasonable expectations.

With in-office bleaching, both proper isolation and protection of mucosal tissues are essential. Dentists may also wish to consider prescribing NSAIDs prior to treatment,<sup>30</sup> since post-treatment sensitivity is unpredictable. The treatment schedule may also be a useful method to help minimize tooth sensitivity. Multiple appointments are typically scheduled 1 week apart to allow sensitivity to abate. A “bleaching light” is sometimes used with in-office bleaching procedures as well. Some reports suggest that pulpal temperature can increase with bleaching light use, depending on the light source and exposure time. An *in vitro* study suggests that use of some lights may result in light radiation exposure levels approaching or exceeding safety limits.<sup>31</sup> Pulpal irritation and tooth sensitivity may be higher with use of bleaching lights or heat application, and caution has been advised with their use.<sup>32,33</sup>

There is conflicting evidence on the effects of bleaching lights on tooth color change. Most studies comparing effectiveness of in-office bleaching with or without light application were conducted *in vitro*.<sup>32</sup> The effects on tooth color change were variable, and some differences detected electronically were not detectable visually. This observation was reported in a recent clinical study report as well.<sup>34</sup> Of studies conducted *in vivo*, most found no added benefit for light-activated systems.<sup>32,35</sup> Heat and light application may initially increase whitening due to greater dehydration, which reverses with time. Actual color change will not be evident until 2 to 6 weeks after bleaching treatment.

The average number of in-office visits for maximum whitening is three,<sup>36</sup> with a range of 1 to 6 visits, so the patient should be prepared for additional in-office treatments or for a combination of office visits and tray delivery to complete the process.<sup>37</sup>

As noted previously, the unsupervised use of OTC whitening products raises concerns about possible masking of undiagnosed or underlying disease (whether related to tooth discoloration or not), cosmetic or functional aspects of existing dental restorations, and unknown allergies or other untoward responses. In addition to these safety concerns, absent a dental examination and consultation, user expectations may not be realistic.

Finally, bleaching offered in a mall kiosk or other non-dental venue may present the image of a dental practice and professional supervision without providing the benefits of care from fully trained and licensed oral health care providers.



## **Regulatory and Scope of Practice Aspects of Bleaching Treatment**

Presently, all extracoronal tooth bleaching products remain unclassified by the FDA. This includes all peroxide-based products used in the in-office, dentist-dispensed products for at-home use, OTC (patient-purchased) products, as well as products used in non-dental settings.

In the early 1990s, the FDA proposed regulating the peroxide-based bleaching materials as drugs and sent warning letters to manufacturers.<sup>38</sup> The FDA's position was challenged legally, and in alignment with court decisions, the FDA suspended attempts to classify the bleaching materials. To date, the FDA has taken no further action to classify tooth bleaching products.

Tooth whitening products are developed and marketed according to U.S. "cosmetic" regulations. These regulations are more limited than those for drugs or medical devices. This may lead to the perception that the products are innocuous, though they have the potential to cause harm and may result in undesirable effects to the teeth or oral mucosa.<sup>3</sup> Such adverse effects are generally related to low pH and poor product quality.

The recent appearance of tooth-bleaching businesses in non-dental settings has led to state dental board decisions, attorney general opinions, and legislation in some states. Some jurisdictions have taken recent action to better limit patient risks associated with tooth bleaching. These include: Florida, Iowa, Massachusetts, Nevada, New Jersey, Tennessee, and the District of Columbia.

Concerns regarding tooth bleaching in non-dental settings have been raised. Non-dental personnel are not educated in the use of disease screening or diagnostic tests (such as radiographs), and are not licensed or qualified to provide dental examinations. Dental and other healthcare workers receive required education and training in infection control procedures to protect patients and themselves from infectious diseases that may be spread by blood or saliva. The staff in non-dental facilities are not licensed and the level of education and training in infection control or other important emergency and safety procedures is unknown.

Tooth bleaching in the United Kingdom (U.K.) emerged in conflict with existing regulations that applied to hairdressers and the use of hydrogen peroxide. Steps toward resolution of this conflict are underway, including an extensive review of tooth bleaching safety data. As noted previously, the Scientific Committee for Consumer Products (SCCP) in Europe supported the safety of tooth bleaching materials containing up to 6.0% hydrogen peroxide for use by dental professionals.<sup>13,23</sup> It is expected that this SCCP recommendation will eventually be ratified by the European Council and by the U.K. government. The timeline for these actions is unclear at present.

## **Rationale for Dental Professional Involvement in Extracoronal Bleaching Treatment**

Dental professionals are responsible for managing patient care, and are a key resource on oral health to the public at large. Consumers may pursue tooth bleaching without

understanding the risks of treatment or the factors that may affect treatment success or failure. For optimal safety and to ensure proper diagnosis and treatment, examination by a dentist is necessary. To aid in patient communication on whitening/bleaching, a helpful summary of considerations is available that can also be used as a resource for the public at large.<sup>39</sup>

As discussed previously, tooth discoloration, particularly intrinsic discolorations, may not be amenable to bleaching. Bleaching materials can affect filling materials, and may also result in color mismatch of teeth with existing fillings or crowns. Therefore, pre-treatment examination and routine monitoring of bleaching by dentists allow for professional assessment of each patient's situation, recommendations for methods and/or materials to help minimize problems, as well as earlier detection and better management of any adverse effects. Professionally performed or supervised bleaching reduces the risk of patients selecting and using inferior products, inappropriate application procedures, product abuse and/or the ongoing oral health effects of undiagnosed or underlying disease.

## **Summary**

Tooth bleaching is one of the most conservative and cost-effective dental treatments to improve or enhance a person's smile. However, tooth bleaching is not risk-free and only limited long-term clinical data are available on the side effects of tooth bleaching. Accordingly, tooth bleaching is best performed under professional supervision and following a pre-treatment dental examination and diagnosis.

In consultation with the patient, the most appropriate bleaching treatment option(s) may be selected and recommended based on the patient's lifestyle, financial considerations, and oral health. Patients considering OTC products should have a dental examination, and should be reminded that they may unknowingly purchase products that may have little or no beneficial effect on the color of their teeth and may also have the potential to cause harm.

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