

The Safety of Home Bleaching Techniques

• Laura Tam, DDS, M.Sc. •

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PRACTITIONER'S QUESTION:

How safe is home tooth bleaching?

Home bleaching is a popular dental procedure used to whiten teeth. The first clinical study of nightguard vital tooth bleaching using a carbamide peroxide product was published in 1989.¹ Carbamide peroxide is the most commonly used active ingredient in home bleaching systems. It breaks down into hydrogen peroxide and urea in aqueous solution. Although concentrations of 10% carbamide peroxide (equivalent to approximately 3% hydrogen peroxide) are most commonly used, bleaching systems containing up to 22% carbamide peroxide are available for home use.

The safety of home bleaching has been questioned. This article looks at the minor or transient adverse effects of home bleaching on oral tissues as well as the potential major long-term or systemic risks of the technique on dental and soft tissues.

Minor or Transient Effects

Tooth Sensitivity

Previously, the most common method for vital tooth bleaching used liquid hydrogen peroxide in combination with heat. This method invariably caused tooth sensitivity both during and after the procedure. Thirty-five per cent hydrogen peroxide preparations with or without the additional use of heat caused histological pulpal changes.²⁻⁴ However, the treated pulps generally showed a reversal of these changes and repair within 60 to 92 days. Hydrogen peroxide by itself has been shown to inhibit pulpal enzyme activity and may penetrate into the pulp in very minute concentrations.⁴⁻⁶

Recent clinical studies of carbamide and hydrogen peroxide tooth bleaching reported varying degrees of tooth sensitivity which persisted for up to 24 to 48 hours after the cessation of bleaching treatment.⁷⁻¹⁰ To date, irreversible pulp changes have not been attributed to the home use of carbamide peroxide. Irreversible pulp changes have been reported, however, with 35% hydrogen peroxide bleaching *in vitro*^{4,11} and *in vivo*.¹²

Altered Enamel Morphology

Carbamide peroxide bleaches create slight morphological changes in the enamel surface at various pH levels.¹³⁻¹⁵ These changes are minimal in comparison to the severe morphological changes that occur when the enamel surface is subjected to phosphoric acid. There has been one reported clinical case of significant non-reversible destruction of previously sound tooth structure after using an *acidic* over-the-counter home bleaching system for two months.¹⁶

Reduced Bonding

Carbamide peroxide can also affect the teeth by significantly reducing the bond strength of resin composite systems to treated enamel and dentin.¹⁷ It has been postulated that residual peroxide on the dentin and enamel surfaces inhibits polymerization of the resin bonding systems. As a result, any bonding procedures should be postponed for at least one week after the cessation of bleaching.

Problems with Restorative Dental Materials

Laboratory studies documenting the effects of bleaching agents on dental materials show clinically insignificant changes to most restorative dental materials after bleaching. It is interesting to note that carbamide peroxide gels increase the mercury release from dental amalgams.¹⁸ In addition, methacrylate temporary restorations become orange after carbamide peroxide exposure.¹⁹

Gingival Tissue Irritation

Patients may report soft-tissue irritation during home bleaching treatment. It has been shown that the gingival soft tissues can undergo an acute inflammatory reaction following exposure to a dilute hydrogen peroxide solution.²⁰ Higher concentrations (30%) of hydrogen peroxide will temporarily blanch the gingival soft tissues. However, when the tray is designed to avoid soft tissue contact, no significant soft tissue problems have been identified when the home bleaching technique with 10% carbamide peroxide is used. In addition, carbamide peroxide products are used as rinses for

periodontal purposes and can actually reduce plaque and gingivitis scores.

Potential Major Long-Term or Systemic Risks

In the home bleaching method, exposure to peroxide bleaching agents is not isolated to the teeth. Bleaching agents come into contact with the intraoral soft tissues and are unavoidably swallowed. Therefore, the advent of the home bleaching technique has raised concerns as to whether peroxide bleaching agents have detrimental long-term soft tissue or systemic effects.

As an oxidant, hydrogen peroxide has been adversely associated with carcinogenesis, genotoxicity, cytotoxicity, aging and lung injury.^{21,22} Many of the effects of hydrogen peroxide are attributed to its conversion to reactive oxygen radical species, the hydroxyl radical (OH) in particular. However, hydrogen peroxide is a normal intermediate metabolite in humans that eventually breaks down into water and oxygen. The human body is equipped with a protective barrier of salivary constituents and the oral mucosa as well as various defence mechanisms to effectively metabolize hydrogen peroxide both extracellularly and intracellularly. Well-conducted *in vivo* studies are needed to determine the true effects of the current home bleaching technique on the human body.

Significant systemic and soft tissue consequences following exposure to hydrogen and carbamide peroxide have been demonstrated in animal and *in vitro* studies. For example, acute toxicological effects have been demonstrated in rats that have ingested carbamide peroxide.^{23,24} These studies infer that a very large ingestion of carbamide peroxide is potentially hazardous for humans. However, the estimated total ingestion of 10% carbamide peroxide by humans during a typical bleaching treatment provides a calculated safety factor of 239 for the no-observable-adverse-effect level.²⁵ Acute toxicity following material ingestion should therefore not be a clinical problem when adults use home bleaching products with 10% carbamide peroxide as directed.

Potential carcinogenicity of the peroxides used in bleaching agents remains the most controversial safety issue. Studies have suggested that, when ingested, 0.1 and 0.4% hydrogen peroxide increased the incidence of duodenal carcinomas in mice,²⁶ that 1.5% hydrogen peroxide increased the carcinogenicity of a known carcinogen in rat duodenum and jejunum,²⁷ and that 3% and 30% hydrogen peroxide increased the incidence of carcinomas in hamster cheek mucosa when applied topically along with a known carcinogen.²⁸ However, Marshall and others reported that low concentrations (0.75% to 3%) of hydrogen peroxide-formulations actually delayed the onset, reduced the rate of tumour formation and/or reduced the incidence of tumour formation in hamster cheek mucosa.²⁹ These studies were reviewed along with others by Li³⁰ who concluded that the overall evidence suggests that the use of peroxide-containing home bleaching materials is safe when used as prescribed.

Regulations

In Canada, carbamide- and hydrogen peroxide-based bleaching systems are considered cosmetic preparations that

are subject to the provisions of the Food and Drugs Act (FDA) and its regulations regarding composition, safety, labelling and advertising. A cosmetic is defined as "any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving, altering the complexion, skin, hair or teeth." Carbamide and hydrogen peroxide are ingredients that present an avoidable hazard and are therefore on the Cosmetic Notification Hot List. This list states that carbamide or hydrogen peroxide may be used as a tooth bleaching agent at a concentration limited to 10% and 3% respectively and must be labelled for use for no more than 14 days unless *under the supervision of a dentist*. Bleaching systems that contain fluoride would be considered a drug. Consequently, they are not commercially available in Canada at this time.

In the United States, hydrogen peroxide products containing 3% or less hydrogen peroxide are approved by the Food and Drug Administration and are generally recognized as safe. Dentifrices delivering low concentrations of hydrogen peroxide (0.75%) or calcium peroxide (0.5%) are available over the counter. The Council on Scientific Affairs of the American Dental Association (ADA) developed *Guidelines for the Acceptance of Peroxide-Containing Oral Hygiene Products* in 1994 to consider the safety and efficacy of bleaching products. If the data submitted by the manufacturers of peroxide-containing home use whitening agents met the guideline requirements, the product was awarded the ADA Seal of Acceptance. The Council recommends using only whitening agents displaying the ADA Seal of Acceptance. Currently, these are Opalescence Whitening Gel (Ultradent), Platinum and Platinum Overnight Professional Toothwhitening System (Colgate), Nite White Classic (Discus Dental), Patterson Brand Toothwhitening Gel (Patterson Dental Co.) and Rembrandt Lighten Bleaching Gel (DenMat).

In light of the estimated millions of cases of home bleaching using 10% carbamide peroxide, the lack of documented serious adverse effects attributed directly to this technique has contributed to its acceptance as a conservative option for tooth whitening. However, definitive conclusions regarding the safety of the carbamide peroxide bleaching method from clinically relevant in-depth bleaching studies are lacking. Dentists must therefore be wary of the inappropriate use of application of products by patients that could potentially lead to serious adverse effects not anticipated from the short-term use of 10% carbamide peroxide bleaching products. There are reported cases of home bleaching of longer duration (up to 6 months³¹) with minimal side effects. However, the majority of clinical studies have been based on a shorter-term bleaching regimen. The regulations suggest that if the bleaching treatment is to be extended, the dentist should be regularly assessing the patient after two weeks.

The emphasis on dentist supervision is critical. The dentist plays a key role in the safe use of home bleaching materials, diagnosing the condition of the dentition and the etiology of the tooth discoloration, deciding if the home bleaching method is the treatment regimen to prescribe, providing the most appropriate type and amount of bleaching materials,

educating and supervising the patient during bleaching treatment, assessing the effectiveness of the treatment, and treating any adverse effects.

An *in vitro* study concluded that lower concentrations (5%) of carbamide peroxide take longer to whiten teeth but eventually achieve the same result as higher concentrations (16%).³² Given the current regulations for approval in Canada and the United States, which suggest that 10% is the upper limit of tolerance for safety for unprotected use, and the paucity of available safety data and clinical trials for bleaching systems containing more than 10% carbamide peroxide, bleaching systems containing more than 10% carbamide peroxide should not, at least from a medico-legal standpoint, be used at this time for home bleaching. The use of the home bleaching technique should also be avoided in children, pregnant and lactating women, and patients suffering from pathological conditions affecting the oral tissues. ✦

Dr. Tam is an assistant professor in the faculty of dentistry, University of Toronto.

Reprint requests to: Dr. Laura Tam, Faculty of Dentistry, University of Toronto, 124 Edward St., Toronto, ON M5G 1G6
The author has no declared financial interest in any company manufacturing the types of products mentioned in this article.

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