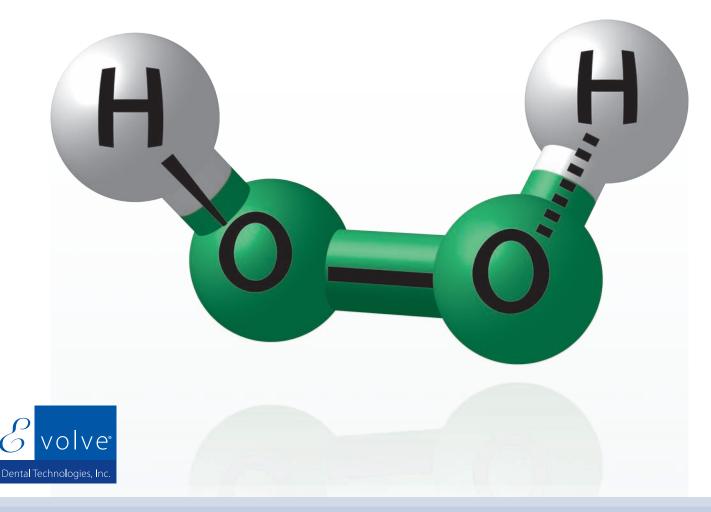
WHITE PAPER



Solving Teeth Whitening Frustrations By Rod Kurthy, DMD



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{ Introduction }

Teeth whitening can be frustrating, problematic and unpredictable. Historically whitening system companies have promised ease of use, outstanding results and happy patients. Dentists routinely have not found truth in these claims.

Frustrating problems often encountered by dentists include: receiving ineffective products, inconsistent results, rapid rebound, ineffective techniques, acute sensitivity and embarrassed staff.^{1,2a}

These problems and frustrations are overcome by formulating high potency vigorous bleaching gels, maintained at high potency until dental offices receive them; used in combination with well researched and designed methods of application. This ensures total acceptance of bleaching gel byproducts by tooth structure – in short, the ability to drive high concentrations of whitening chemistry deeply within the microstructure of teeth for extended periods of time.^{3,4,5,6,7,8,9,10,11,12}

Uncompromising, dynamic bleaching chemistry ability to propel bleaching chemistry INTO tooth microstructure Intense whitening
Consistent predictability
Stability of whiteness

{ How Bleaching Works }

Intrinsic tooth color is a result of large natural pigment and stain molecules trapped within the microstructure of teeth.^{13,14} These color molecules have bonds between atoms referred to as chromophores, which are responsible for the reflectance of color. The larger these molecules are, the more chromophores they contain and the darker they appear.^{4,15,16,17,18}

As with eye, hair and skin color, there is a wide variance of inherited tooth color.^{13,14} In addition to natural color, all teeth darken with time. Additional stain is absorbed into

the microstructure of teeth, and color molecules within tooth structure continuously join together forming larger and therefore darker molecules.^{13,14,19,20}

All peroxide gels work by forming hydrogen peroxide as their end product.²⁰ Hydrogen peroxide breaks down to water and numerous byproducts including: molecular oxygen, oxygen ions, hydrogen ions and free radicals.^{21,22,23,24,25} We will refer to the peroxide byproducts that lighten teeth as "bleaching factors." (Fig. 1)





There are two distinct modes of action by bleaching factors:

1) Oxygenation - which may be thought of as "scrubbing bubbles." All of the bleaching factors work together to cause aggressive microscopic physical and chemical disintegration of the large color molecules and physical removal via diffusion.^{15,16}

2) Chemical Conversion - which is the breakdown of large, dark color molecules to ultra-small colorless or white molecules. Bleaching factors, especially free radicals, attack large color molecules breaking them up into small molecules that have no chromophores, and therefore become colorless or white. (Fig. 2)^{15,16,17,18,23,24,25,26}

The 2 methods of whitening are successful only when peroxide products are:

A) Fully potent

B) Chemically influenced to produce a high percentage of free radicals (instead of simply oxygen and water)C) Allowed extended time for bleaching factors to diffuse into the microstructure of teeth



{ Problems With Bleaching }

A) Low Potency of Peroxide Bleaching Gels

Peroxides are unstable chemicals^{20,27} – they're supposed to be. This is why they are able to decompose quickly in the mouth releasing bleaching factor byproducts. The downside of this instability is the constant decomposition of bleaching gels, starting immediately following manufacture. Even at room temperature peroxide gels slowly degrade, gradually losing potency.^{2a,20}

Higher temperatures accelerate this degradation process.^{2a} Warm and hot temperatures are often encountered during warehouse storage at chemical manufacturers. Even higher temperatures are encountered during freight truck shipment of gels from the chemical factories to bleaching product companies.

Warehouse storage at bleaching product companies and heat during final shipment to dental practices create even more opportunity for additional heat degradation of peroxides.

The above scenario is often responsible for dentists' perception that some batches of whitening gels have less, and sometimes no effectiveness.^{2a}

Though refrigeration virtually stops the degradation process of carbamide peroxide and low concentrations of hydrogen peroxide, and greatly slows the degradation of high concentration hydrogen peroxides; constant refrigeration of bleaching gels throughout all phases of storage and shipping is quite costly for bleaching system companies. The more cost-effective methods of lengthening shelf-life of bleaching gels involve alteration of bleaching gel formulations to render them more stable. Even with more chemically stable gels, the decomposition process is not stopped, but simply slowed. Warmth and heat still result in degradation of bleaching gels.

Stability-Enhancing Bleaching Gel Ingredients

Common methods of increasing peroxide gel stability are the use of anhydrous gel bases and acidic pH.²⁰ However, such bleaching gel formulations result in less effectiveness and higher sensitizing properties of bleaching gels.^{20,28} The more stable peroxide gels are, the less effective is their decomposition and release of bleaching factors when placed in the mouth. Anhydrous and acidic gels also have a much stronger osmolarity, causing more osmotic force on dentinal tubules, resulting in more forceful tubular fluid flow within the dentinal tubules and acute pulpal bleaching sensitivity.^{20,28}

B) Lack of Chemically Influenced Production Of Free Radicals

Un-influenced decomposition of peroxide leads to a high percentage of breakdown to molecular oxygen and water, with less volume of ions and free radical formation.^{4,27,29} Molecular oxygen does have an oxidative effect, but not nearly as effective as ions and especially radicals.

When peroxide gels maintain an acidic pH (for the purpose of shelf-life) not only is the degradation of peroxide slowed significantly, but the tendency of the reaction is to produce more water and molecular

C) Short Time of Bleaching Factor Release

In-office whitening: Peroxide contact time with tooth structure is typically only 15-45 minutes. This provides little time for diffusion of bleaching factors into the microstructure of teeth.

At-home whitenig: It has been shown that peroxides in conventional at-home whitening trays lose 60% - 95% potency in 25-35 minutes, and are virtually ineffective shortly thereafter.^{2b}

Conventional bleaching trays

25-35 MINUTES of active bleaching action

Conventional at-home bleaching trays do not effectively seal peroxide gels within the trays and bleaching gels are lost. More importantly, conventional trays allow ingress of damaging saliva and sulcular fluids into the bleaching gel within the trays.²⁰

oxygen, and less ions and radicals, leading to less effectiveness of the whitening process.²⁹

As peroxides degrade, giving off radicals, hydrogen ions are also produced causing the pH of the peroxide gels to become more and more acidic with a pH as low as 3.5. As they become more acidic the reaction greatly slows, and the reaction shifts to producing higher percentages of water and oxygen, instead of effective radicals.^{4,29}

During oxygen metabolism, hydrogen peroxide is formed by the mitochondria in our cells. Every day our bodies produce nearly 100 times more peroxide than would be placed in bleaching trays. As a protective mechanism against continuous daily endogenous production of free radicals, several types of antioxidants are produced by the body. These antioxidants (such as peroxidase) force the decomposition of hydrogen peroxide to result in ONLY water and molecular oxygen, without formation of ions or radicals.

Peroxidase is found in high concentration in both saliva and sulcular fluids.^{30,31,32,33} When saliva and sulcular fluid are allowed to enter the bleaching tray, peroxidase decomposes and destroys peroxide on contact. This happens first in the cervical region of teeth, resulting in rapid exhaustion of active bleaching. This is one reason why cervical areas of teeth are seen to be more problematic in the whitening process. Whitening tray designs that cover the marginal gingiva may help seal in bleaching gel and seal out saliva, however the design covering the marginal gingiva forces gingival crevicular fluid/peroxidase directly into the cervical portion of whitening trays, followed by rapid destruction of bleaching gels. Even when the peroxide is rapidly decomposing in response to saliva and sulcular fluid peroxidase, the byproducts of water and molecular oxygen are not nearly as effective in the whitening process as ions and radicals.

The Fallacy Of Bleaching Lights And Lasers

Certainly bleaching lights and lasers generate public appeal.^{2a} But do they really do anything? Manufacturers of these lights and lasers continue their claims, however the consensus of research studies not funded by bleaching light manufacturers indicate lights and lasers are of no practical benefit to the process of teeth whitening.^{2a,34,35}

Lights and lasers hypothetically accelerate the break-down reaction of peroxide via transmission of photon energy to the reaction, releasing bleaching factors faster. However, the majority of clinical researchers utilizing split-arch clinical test design indicate that bleaching lights and lasers result in no additional lightening of the teeth, yet may contribute to bleaching sensitivity via heat and dehydration.^{2a,34,35,36}

The degradation reaction of hydrogen peroxide to water, hydrogen ions and bleaching factors is an exothermic reaction, generating heat. The continuous addition of heat or photon energy into an exothermic reaction (trying to force energy back into the reaction) may actually impede the reaction.

Even exothermic reactions typically do require initiation, and the breakdown of peroxide is no exception. Though the addition of energy (heat or photon energy) may initiate the reaction, it is incapable of accelerating the reaction at a rate necessary for in-office bleaching.

The chemical breakdown reaction of hydrogen peroxide is best directed via appropriate pH as discussed above^{18,29} with additional true chemical catalysts added when rapid reaction time is critical,²⁰ such as during in-office whitening. In fact, it is true that even in-office whitening gels intended for use with lights and lasers still utilize chemical acceleration. One would assume if bleaching lights and lasers were genuinely effective, the addition of chemical accelerators would be unnecessary.

{ The Solutions }

A) Maintaining Potency Of Peroxide Bleaching Gels

The solution to maintaining peroxide gel potency and the desired <u>instability</u> of the peroxide lies in constant refrigeration of peroxide products, from the instant of manufacture until the time of use. Refrigeration nearly stops the breakdown of peroxides, circumventing the need to use anhydrous gels and acidic pH.

When continuous refrigeration is used to stabilize peroxides during storage and shipping instead of chemical stabilization of the gel itself, bleaching gels are received by the dental practice at virtually 100% of their original potency and may be formulated with a fully aqueous base and pH at or above 7. When placed in the warm mouth, the degradation of this unstable peroxide is highly effective and thorough.^{20,29} With a fully aqueous base and neutral or slightly basic pH, gel osmolarity is much lower, and pulpal bleaching sensitivity is significantly reduced.^{20,28,37,38,39}

B) Chemically Influenced Production Of Free Radicals

Refrigeration affords the ability to provide fully aqueous gels with a higher pH allowing not only a much more thorough degradation, but a high concentration of radicals, instead of water and molecular oxygen, ensuring greatly enhanced whitening effectiveness.²⁹

Utilization of chemical accelerants that not only catalyze and hasten the reaction, but specifically direct the reaction to result in aggressive ions and radicals throughout the entire application time also greatly increases whitening results.

C) Extending Time Of Bleaching Factor Release

A bleaching tray design that prevents loss of bleaching gel from bleaching trays, and at the same time prevents damaging saliva and sulcular fluid from entering the bleaching tray, will result in a much longer duration of bleaching activity. A longer duration of bleaching activity provides more time for both oxygenation removal of organic debris from tooth microstructure and conversion of dark long-chain stain molecules to ultra-small white and colorless molecules.

D) Alteration Of Bleaching Gel Viscosity And Solubility

Currently at-home bleaching gels are made with ultra-high viscosity and low solubility to retard the damaging effects of saliva and sulcular fluid peroxidase. If the design of the bleaching tray can prevent saliva and sulcular fluid from entering the bleaching tray, the at-home gels may be made with lower viscosity and higher solubility, allowing more thorough release of bleaching factors from the gel into the teeth.

In-office bleaching gels are also typically made with high viscosity to prevent the gel from running off the teeth. The high viscosity provides a high surface tension which does not allow close microscopic adaptation of the bleaching gel to the teeth; preventing a rapid, thorough release of bleaching factors into the teeth (less absorption of bleaching factors by the teeth). Formulation of bleaching gels with low surface tension/low viscosity that will not run off the teeth will provide enhanced bleaching factor absorption by tooth structure.

E) pH Control

The addition of buffering agents to scavenge hydrogen ions released when free radicals are produced will maintain the desired non-acidic pH. The results are: 1) rapid breakdown of peroxide during the entire application period, 2) continued production of free radicals instead of a shift toward production of water and molecular oxygen throughout the entire application and 3) considerably lower osmolarity, resulting in much less bleaching sensitivity.^{18,2}

$\{ K\ddot{o}R^{\circ} Whitening Deep Bleaching^{\mathsf{M}} \}$

Dr. Rod Kurthy's Evolve Dental Technologies is the first company in the world to refrigerate a full line of bleaching products from the instant of manufacture until received by the dental practice as the primary method of potency stabilization. Stabilization via constant refrigeration enables the formulation of bleaching gels that are fully aqueous with a neutral pH. The result is an unusually unstable gel when placed in the warmth of the mouth, resulting in a more thorough breakdown as well as an osmolarity as low as 1/11th that of anhydrous gels with acidifiers. Of course this means significantly lower bleaching sensitivity.

The unique design of proprietary at-home KöR Deep Bleaching[™] Trays effectively creates a seal at the cervical 1-1.25mm of the teeth, averting the loss of bleaching gels. The same seal is responsible for preventing the rapid, damaging ingress of both saliva and sulcular fluid. This physical seal enabled the formulation of KöR at-home bleaching gels with a lower viscosity and a higher

solubility – resulting in enhanced ability of the bleaching factors to exit the bleaching gel and enter the tooth.

The result is unusually active, effective bleaching gels within the trays for 6+ hours, with some activity seen beyond 10 hours,⁴⁰ instead of the typical 25-35 minutes seen with conventional trays.^{2b} Not only is there an exceedingly increased duration of action, but the neutral pH, 100% aqueous gel and exclusion of salivary and sulcular fluid peroxidases result in a high concentration of ions and radicals.



The extended activity time of bleaching factors provides the required daily intervals necessary to thoroughly disintegrate and remove color molecules via diffusion, enabling penetration deeply within tooth microstructure resulting in thorough conversion of large, dark color molecules to ultra-small colorless and white molecules.⁴ within the microstructure of teeth rejuvenates the tooth structure to its youthful ability to rapidly absorb bleaching factors deeply into the tooth microstructure. After at-home whitening, when the higher concentration in-office peroxide gel is then placed on the teeth, high concentrations of radicals virtually flood any remaining resistant chromophores, providing a final burst of whiteness, even in resistant cases such as tetracycline staining.

Meticulous "oxygenation" removal of built-up debris

Dual-Activated, Tri-Barrel Hydremide® Peroxide Technology

As discussed above, there are numerous additional obstacles to achieving ideal results from in-office whitening gels. The culmination of years of Dr. Kurthy's research, development and clinical testing is Evolve's Dual-Activated, Tri-Barrel Hydremide[®] Peroxide formulation and delivery system.

Many of the ideal properties of bleaching gels discussed in this paper have previously been mutually exclusive – the more of one property you want, the more of another property you must give up. Traditionally, bleaching gel properties have therefore been a series of compromises. By keeping the chemistry separated into three separate barrels until mixed immediately prior to use, the previous obstacles have been overcome, and the desired ideal properties have been achieved across the board.

The combination of continuous refrigeration and Evolve's KöR Dual-Activated, Tri-Barrel Hydremide[®] Peroxide technology has resulted in the following critical benefits:

1) Stability of effectiveness and a long shelf life, yet still achieving:

- A) The desired chemical <u>in</u>stability of the bleaching gels in the mouth, resulting in aggressive, rapid, thorough release of bleaching factors.
- B) An osmolarity as low as 1/11th that of anhydrous gels with acidifiers, resulting in significantly less sensitivity.
- C) An aggressive release of ions and radicals instead of simply water and molecular oxygen.
- D) Bleaching gels that are received by dental offices at virtually 100% of their original effectiveness.

2) Chemically influenced production of free radicals:

- A) Dual methods of activation, both of which force peroxide breakdown to aggressive ions and radicals.
- B) Use of neutral, fully aqueous gels that degrade to a higher percentage of ions and radicals.
- 3) Lowering bleaching gel surface tension:

A) Lower surface tension greatly enhances the ability of the tooth microstructure to absorb bleaching factors.B) Bleaching gel that will not run off the teeth, even with the lower surface tension.

- 4) Addition of a buffering agent to scavenge hydrogen ions:
 - A) The buffering system allows aggressive release of ions and radicals, yet neutralizes the hydrogen ions produced, keeping the pH stable and therefore preventing the continued breakdown from slowing. The result is not only aggressive bleaching factors released, but a reaction rate that continues rapidly throughout the entire application time.
 - B) By maintaining a stable neutral pH, the reaction continues to produce ions and radicals instead of shifting to production of only water and molecular oxygen.
 - C) By maintaining a stable neutral pH, the rise in osmolarity is prevented and sensitivity is reduced greatly.

Though no system is perfect, and there can always be exceptions, for the first time ever, even super resistant stains like tetracycline and fluorosis can be flooded with concentrations of bleaching factors necessary to break down even these stains significantly. The vast majority of patients may now obtain truly white teeth. Gone are the days of keeping your fingers crossed behind you during in-office whitening, hoping the patient will be pleased with the result. No longer is there embarrassment by dental staff when patients complain about lack of success.

With occasional at-home maintenance, patients can be promised permanent whiteness while still allowing their enjoyment of coffee, tea and red wine. KöR Whitening is available for any whitening need, including at-home-only whitening, as well as Dr. Kurthy's full Deep Bleaching[™] system, involving both at-home and in-office whitening.

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