KöR® Whitening

STUNNINGLY WHITER TEETH™

Through the advanced science of whitening, the vast majority of patients can now obtain truly white teeth.

THE SCIENCE OF WHITENING

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A KöR Whitening
Science Paper

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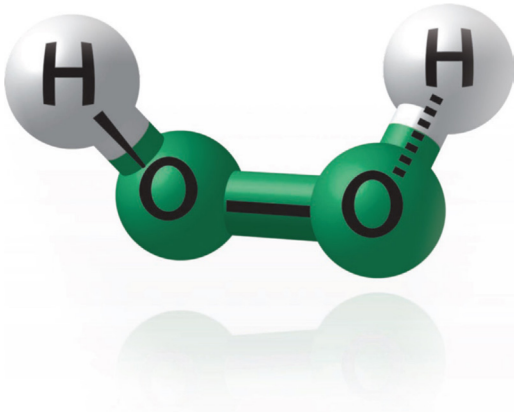
INTRODUCTION

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.[1,2]

These problems and frustrations are overcome by formulating high potency vigorous whitening gels, maintained at high potency until dental offices receive them; used in combination with well researched and scientifically based methods of application. This ensures total acceptance of whitening gel byproducts by tooth structure – in short, the ability to drive high concentrations of whitening chemistry deeply into the microstructure of teeth for extended periods of time.[4-13]

Vigorous whitening chemistry maintained at high potency + **Whitening chemistry driven deeply into tooth microstructure for extended periods** = **1. Intense whitening 2. Consistent predictability 3. Stability of whiteness**



HOW WHITENING WORKS

Intrinsic tooth color is a result of large, long-chain natural pigment and stain molecules trapped within the microstructure of teeth.[14,15] These color molecules have magnetic molecular bonds between atoms referred to as chromophores, which are responsible for the absorption of various wavelengths of light. The larger these molecules are, the more chromophores they contain, the more light they absorb and the darker they appear.[5,16-19]

As with eye, hair and skin color, there is a wide variance of inherited tooth color.[14,15] In addition to natural color, all teeth darken with time. Teeth darken in two ways: 1) Additional stain is absorbed into the microstructure of teeth, becoming intrinsic stain; and 2) color molecules within tooth structure continuously join together forming larger, and therefore darker, molecules.[14,15,20,21]

All peroxide gels work by forming hydrogen peroxide as their end product.[21] Hydrogen peroxide breaks down to water and numerous byproducts including: molecular oxygen, oxygen ions, hydrogen ions and free radicals.[22-26] 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 – 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 of these molecules from tooth structure via diffusion.[16,17]

2. Conversion – is the breakdown of large, dark color molecules to ultra-small white molecules. Bleaching factor free radicals break the chromophore bonds of large color molecules, resulting in tiny molecules with no chromophore bonds. With no chromophore bonds to absorb light, these tiny molecules are white. (Fig. 2)[16-19,24-27]

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

A. Fully potent[2,4-13]

B. Chemically influenced to produce a high percentage of free radicals (instead of simply oxygen and water)[4-13]

C. Allowed extended time for bleaching factors to diffuse deeply into the microstructure of teeth[4-13]

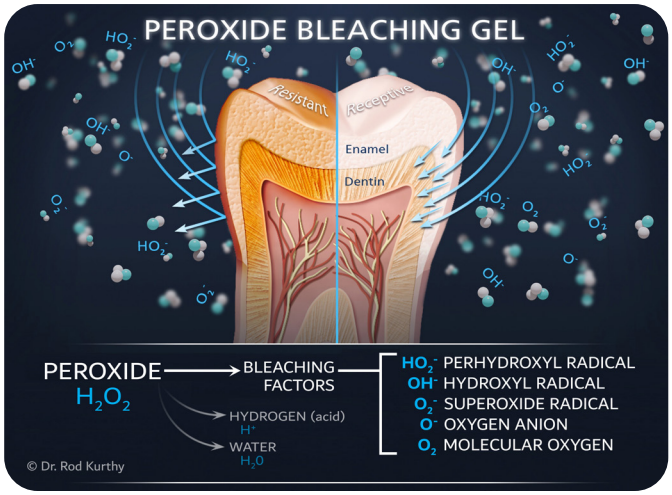


Fig. 1

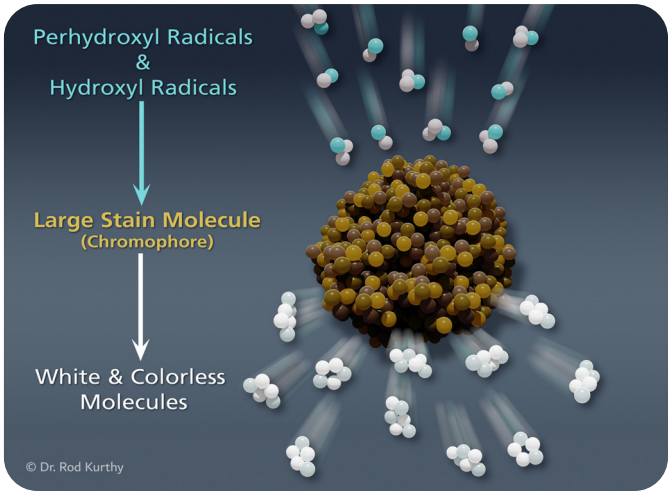


Fig. 2

PROBLEMS WITH WHITENING

Low Potency of Peroxide Whitening Gels

Peroxides are unstable chemicals[21,28] – 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 whitening gels, starting immediately following manufacture. Even at room temperature peroxide gels slowly degrade, gradually losing potency.[2,21]

Higher temperatures accelerate this degradation process.[2] Warm and hot temperatures are often encountered during warehouse storage at chemical manufacturers. Even higher temperatures (typically 125°F – 165°F) are encountered during freight truck shipment of gels from the chemical factories to whitening product companies. Just think of how hot your parked car gets inside on a sunny day.

Warehouse storage at whitening 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.[2]

Though refrigeration virtually stops the degradation process of carbamide peroxide and hydrogen peroxide, constant refrigeration of whitening gels throughout all phases of storage and shipping is quite costly for whitening system companies. The more cost-effective method of lengthening shelf-life of whitening gels involves the addition of chemical stabilizers 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 damaging degradation of whitening gels.

Stability-Enhancing Whitening Gel Ingredients

Common methods of increasing peroxide gel stability include the use of anhydrous gel bases and creation of an acidic pH by adding phosphoric acid.[21] However, such whitening gel formulations result in less effectiveness and higher sensitizing properties of whitening gels.[21,29] The more chemical stabilizers in peroxide gels, 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 "pull" on dentinal tubular fluid, resulting in more forceful tubular fluid flow within the dentinal tubules and acute pulpal whitening sensitivity.[21,29]

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.[5,28,30] 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 oxygen instead of ions and radicals, leading to less effectiveness of the whitening process.[30]

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.[5,30]

Short Time of Bleaching Factor Release

In-office whitening: In-office 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 whitening: 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.[3]

Conventional at-home whitening trays do not effectively seal peroxide gels within the trays and whitening gels are lost. More importantly, conventional trays allow rapid ingress of damaging saliva and sulcular fluids into the whitening gel within the trays.[21]

During oxygen metabolism of all animals, hydrogen peroxide is formed by the mitochondria in the cells. Every day our bodies produce nearly 100 times more peroxide than would be placed in whitening 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 immediate 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.[31-34] When saliva and sulcular fluid are allowed to enter the whitening tray, peroxidase decomposes and destroys peroxide on contact. This happens first in the cervical region of teeth, resulting in rapid exhaustion of active whitening. This is one reason why cervical areas of teeth are often seen to be more problematic in the whitening process.

Whitening tray designs that cover the marginal gingiva may help seal in whitening gel and seal out saliva, however the design covering the marginal gingiva forces gingival crevicular fluid, containing a high concentration of peroxidase, directly into the cervical portion of whitening trays, followed by rapid destruction of whitening 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 Whitening Lights And Lasers

Certainly whitening lights and lasers generate public appeal.[2] But do they really do anything? For a full explanation of the science related to whitening lights and lasers, including their significantly negative effect on the dental pulp, see the KöR Science Paper, The Myth of Whitening Lights and Lasers, by the same author.

THE SOLUTIONS

Maintaining Potency of Peroxide Whitening Gels

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

When continuous refrigeration is used to stabilize peroxides during storage and shipping, whitening 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 removed from refrigeration and placed into the warm mouth, the degradation of this unstable peroxide is highly effective and thorough. [21,30] With a fully aqueous base and neutral or slightly basic pH, gel osmolarity is much lower, and pulpal whitening sensitivity is significantly reduced.[21,29,38-40]

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.[30]

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.

Extending Time of Bleaching Factor Release

A whitening tray design that prevents loss of whitening gel from whitening trays, and at the same time prevents damaging saliva and sulcular fluid from entering the whitening tray, will result in a much longer duration of whitening activity. A longer duration of whitening 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 molecules.

Alteration of Whitening Gel Viscosity and Solubility

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

In-office whitening 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 whitening 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 whitening gels with low surface tension/low viscosity that will not run off the teeth will provide enhanced bleaching factor absorption by tooth structure.

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 whitening sensitivity.[19,21]

KÖR WHITENING SYSTEMS

Evolve Dental Technologies is the first company in the world to refrigerate a full line of whitening products from the instant of manufacture until received cold by the dental practice as the primary method of potency stabilization. Stabilization via constant refrigeration enables the formulation of whitening gels that are fully aqueous with a neutral pH and maintain that neutral pH throughout storage and shipping. 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 acidic pH, which results in significantly less sensitivity.

The unique design of proprietary at-home KöR-Seal™ Whitening Trays effectively creates a seal at the cervical 1-1.25mm of the teeth, avoiding the loss of whitening 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 whitening gels with a lower viscosity and a higher water solubility – resulting in enhanced ability of the bleaching factors to exit the aqueous whitening gel and enter the aqueous tooth.

The result is unusually active, effective whitening gels within the trays for 6+ hours, with some activity seen beyond 10 hours,[41] instead of the typical 25-35 minutes seen with conventional trays.[2] Not only is there an exceedingly increased duration of action; but the neutral pH, 100% aqueous gel and exclusion of salivary and sulcular fluid peroxidase result in a high concentration of effective ions and radicals.

KöR Refrigeration, Formulation and Science Based Protocols Result in Meticulous, Deep Cleansing

Dentists who have whitened the teeth of patients between the ages of fourteen and sixteen have routinely seen those teeth whiten extremely fast and extremely well.[41] Yet when whitening the teeth of geriatric patients in their 80's, it may seem nearly impossible. Enamel is far less dense than many think. There is interprismatic space between enamel prisms, and space between the core and periphery of each enamel prism. And there is even significant space between the individual hydroxyapatite crystals that make up the enamel prisms.

Over time, extrinsic stain molecules penetrate deeper and deeper into these microscopic spaces throughout the tooth microstructure, becoming intrinsic stain. These intrinsic stain molecules become more and more tightly condensed into and throughout the microstructure; and also join together, resulting in a tightly woven mass of organic stain blocking the penetration of bleaching factors into teeth. This is why teeth become more difficult to whiten as patients become older.

KöR-Seal Whitening Trays and extended-release KöR Whitening gels provide 6+ continuous hours of active "oxygenation" removal of this tightly woven mass of stain from within the microstructure of teeth; resulting in rejuvenation of tooth structure to its youthful ability to rapidly absorb bleaching factors.

After at-home KöR Whitening, when higher concentration KöR in-office gel is placed on the teeth, high concentrations of radicals are rapidly absorbed, virtually flooding all remaining resistant chromophores, breaking them apart, providing a final burst of whiteness – even in difficult cases such as tetracycline staining.

Dual-Activated, Tri-Barrel™ Hydremide® Peroxide Technology

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

Many of the ideal properties of whitening 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, whitening gel properties have therefore been a series of compromises.

To overcome these obstacles required a more elaborate formulation, which meant additional ingredients. However, there are many chemicals that may not be mixed together until ready for use. Conventional dual-barrel delivery systems only provided two individual chambers to separate the chemistry into.

Developing the KöR Tri-Barrel delivery system provided the ability to keep the more elaborate chemistry separated into three separate barrels until mixing immediately prior to use. The more complex formulation has enabled KöR to overcome previous obstacles, and the desired ideal properties have been achieved across the board, as discussed below.

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 instability of the whitening 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 acidic pH, resulting in significantly less sensitivity.

C) An aggressive release of effective ions and radicals instead of simply water and molecular oxygen.

D) Whitening 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 whitening gel surface tension:

A) Lower surface tension greatly enhances the ability of the tooth microstructure to absorb bleaching factors.

B) Whitening 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 more 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 effective 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 greatly reduced. 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.

All dentists have found that any patient asking for teeth whitening not only wants, but expects to have truly white teeth. Anything less than truly white teeth often disappoints and frustrates patients, which affects the dental practice in terms of fewer referrals, less interest in additional cosmetic dentistry and less follow-through by patients regarding treatment recommendations.

Through the advanced science of KöR Whitening, the vast majority of patients may now obtain truly white teeth. These patients routinely become infatuated with their newly white teeth, as well as receiving frequent compliments because of how noticeable the tooth color change is with KöR Whitening. This certainly affects the patients' confidence, loyalty and fondness of their dentist.

Reports of patient excitement, resulting in increased referrals, heightened interest in additional cosmetic dentistry such as orthodontics, composite bonding, reshaping of teeth, replacement of old crowns and other restorations that now appear dark, as well as occasional full porcelain veneer "makeovers" are regularly reported.

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. There is a KöR Whitening system specially formulated for any whitening need.

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