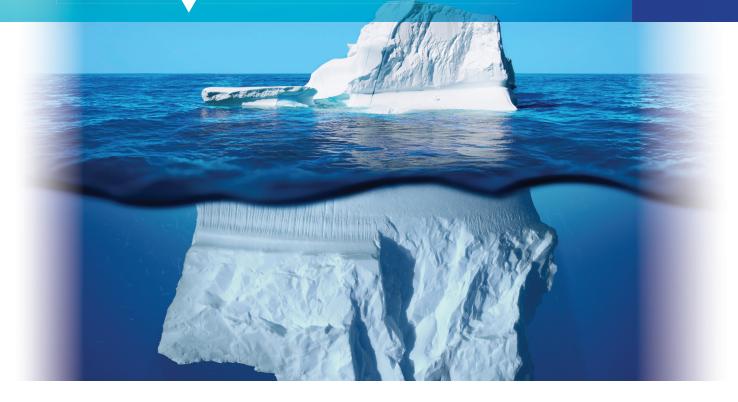


The wide-ranging benefits of constant refrigeration of whitening gels apply to both whitening effectiveness and sensitivity reduction of whitening products.

THE SCIENCE OF WHITENING GEL REFRIGERATION

By Rod Kurthy D.M.D.



A Kör Whitening Science Paper

Illustrations By Dr. Rod Kurthy



INTRODUCTION

The two most significant problems seen with teeth whitening are:

- 1) Lack of effectiveness and predictability,¹⁻⁸ and
- 2) Teeth sensitivity and pain during and after teeth whitening. 2-8

Refrigeration - or rather, lack of refrigeration - plays a very large role in the causation of both of these problems.¹⁻⁸

Most dentists providing professional tooth whitening for their patients have found that some batches of whitening gels they receive work much better than others, even when using the same brand.⁹ Some batches even seem to not work much at all.⁹ Long periods of <u>NON</u>-refrigerated storage and/or intense heat exposures are the primary reasons for this uncontrolled chemical degradation of whitening gels, prior to being received by the dental practice.^{9,10}

As you will learn below, all whitening gels received by dental practices have undergone significant degradation by the time they are received by the dental practices, unless they have been refrigerated constantly since the time of manufacture.¹⁰



All peroxide-based whitening gels are unstable chemicals^{11,12} – they're supposed to be. This is why they are able to break down quickly in the mouth, releasing bleaching factor byproducts. However, the disadvantage of this chemical instability is that all whitening gels start degenerating immediately after manufacture if not kept under constant refrigeration.^{9-11,13} Even at room temperature, peroxide gels degrade, gradually losing potency.^{9-11,13}

Higher temperatures accelerate this degradation process.^{9,10} Warm and hot temperatures are often encountered during warehouse storage at chemical manufacturers.^{10,14-16} Even higher temperatures (125°F - 165°F) are encountered during freight truck shipment of gels from the chemical factories to whitening product companies.^{10,14-16} Just consider how hot your parked car gets inside on a warm, sunny day.

Warehouse storage at whitening product companies and high heat again during final shipment to dental practices create even more heat degradation of peroxides.^{10,14-16}

The above scenario is often responsible for dentists' common perception that some batches of whitening gels have less, and sometimes no effectiveness.⁹

There are only two ways to stabilize whitening gels:

- Chemical Stabilizers: The addition of chemical stabilizers, such as phosphoric acid and an anhydrous base, will partially stabilize whitening gels.^{10,11,18} These chemical stabilizers are only partially effective, because if they were to result in more stability, the whitening gels would not break down at all in the mouth (would have no effectiveness).^{9-11,13}
- Refrigeration: Constant refrigeration of whitening gels, from the moment of manufacture until received cold by the dental practice, greatly stabilizes whitening gels, preventing their breakdown for long periods of time, even in the total absence of chemical stabilizers.¹⁰



HOW TYPICAL WHITENING COMPANIES HANDLE WHITENING PRODUCTS

Whitening gel formulations are typically manufactured at an offsite chemical manufacturing center. The whitening gels then go into a warehouse, which is not only NON-refrigerated, but not even air conditioned. Temperatures can be quite warm.¹⁰

The whitening products are at some point shipped to the whitening product company in freight trucks, which most often reach temperatures of $125^{\circ}F - 165^{\circ}F^{10,14-16}$ The products are then stored in a warehouse again at the whitening company, which can also be quite warm.¹⁰

The products are then shipped to dental practices in trucks such as UPS that again most often reach temperatures of $125^{\circ}F - 165^{\circ}F$.^{10,14-17}

There are a small number of whitening product companies that do refrigerate only their highest concentration hydrogen peroxide in-office whitening gels when shipping to dental practices; however, rarely are these in-office whitening gels refrigerated at any time prior to shipping.

Because the whitening products are not refrigerated, or not constantly refrigerated, chemical stabilizers are added to reduce breakdown of the whitening gels during storage and shipping. These chemical stabilizers typically include fully or partially anhydrous bases, plus "acidifiers" such as phosphoric acid.^{10,11,18}

HOW KÖR® WHITENING PRODUCTS ARE HANDLED

Evolve Dental Technologies, Inc. (KöR Whitening) is the first company to constantly refrigerate a full line of teeth whitening products from the instant of manufacture – until received cold by the dental practice. Evolve's manufacturing facility immediately places all KöR Whitening products into refrigeration. The products are then shipped to Evolve headquarters in a refrigerated truck maintained at 34-36°F.

When the products arrive at Evolve, they are immediately transferred to Evolve's large industrial refrigerators, also maintained at 34-36°F. (Fig. 1)







Fig. 2 – All KöR Whitening products are shipped to dental practices in cold pack containers with cold packs that have been frozen down to a negative $(-)40^{\circ}C/(-)40^{\circ}F$.

Prior to shipping, scheduled arrival dates are confirmed with each dental practice to ensure the dental practice will be open when the product arrives, and to remind the office to place the KöR Whitening products into the refrigerator upon arrival. Large red labels are also placed on the outside of the boxes to remind the dental staff to open and place the products into the refrigerator.

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DISADVANTAGES OF CHEMICAL STABILIZERS

The more UN-stable a whitening product is when placed into the mouth, the more effectively and completely it will break down.^{11,12} Of course this is our goal for the most effective whitening results.

However, when chemical stabilizers are used in whitening gels to reduce degradation caused by non-refrigerated temperatures, they become <u>more stable</u>.^{10,11,18} That means that when placed into the mouth, they are not as UN-stable as we would like, and therefore, will not break down as effectively or completely in the mouth.^{11,12,19}

Even with chemical stabilizers, whitening products still experience significant degradation when not refrigerated.^{9-11,13} If enough chemical stabilizer were incorporated into whitening gels to fully protect against adverse temperatures, they would be too stable to break down at all when placed in the mouth. Chemical stabilizers are therefore minimally effective in protecting against temperature degradation of whitening gels.^{9-11,13}

Acidifier chemical stabilizers create an acidic environment. An acidic environment stabilizes the gel somewhat, but is detrimental in several ways:

- 1) Slows the breakdown of peroxide when in the mouth (reduces effectiveness).^{10,11,18,19}
- Acidic (low) pH results in breakdown of whitening gels to more oxygen (which is not effective for whitening), instead of highly effective perhydroxyl radicals that are given off when the whitening gel is maintained with a higher (non-acidic) pH.^{10,20}
- 3) Demineralizes enamel and dentin. Acids in whitening gels cause detrimental effects such as erosion of enamel resulting in reduced microhardness, and demineralization of dentin.^{10,18-33} Any solution with a pH value lower than pH5.5 may cause erosion; particularly if it is applied for long periods and repeated over time (such as in teeth whitening).^{10,31}
- 4) Removes smear plugs, resulting in increased sensitivity.^{10,21,23,26,27,30} (Figs. 3-6)
- 5) Enlarges orifices of dentinal tubules, also resulting in increased sensitivity.^{10,19,23,26,27,30} (Fig. 7)
- 6) Flares orifices of dentinal tubules, again resulting in increased sensitivity.^{10,19,23,26,27,30} (Fig. 7)
- Increases osmolarity, causing up to eleven times greater osmotic "pull" on dentinal tubular fluid; resulting in more forceful tubular fluid flow within the dentinal tubules and acute pulpal whitening sensitivity.^{10,11,19,26,34-36} (Fig. 4)



Fig. 3 – Acidic pH whitening gel removing dentinal tubular smear plugs, resulting in sensitivity due to Brännström's Hydrodynamic Theory of dentinal sensitivity.



Fig. 4 – Open dentinal tubules with high osmolarity acidic and anhydrous whitening gel "pulling" on dentinal tubular fluid, resulting in outward flow of tubular fluid away from pulp.

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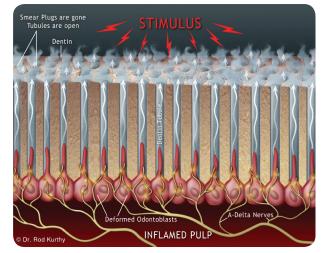


Fig. 5 – Open dentinal tubules with external stimulus (high osmolarity acidic whitening gel) "pulling" on dentinal tubular fluid, resulting in outward flow of tubular fluid away from pulp.

Outward flow of tubular fluid results in the odontoblastic processes of odontoblasts lining the pulp chamber being sucked into the dentinal tubules, deforming and triggering the A-Delta nerves, causing pulpal sensitivity and pain.

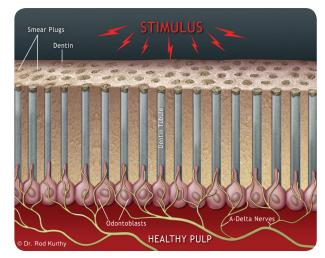


Fig. 6 – Natural and/or synthetic smear plugs are in place, and have not been removed by acid challenges. Even though a stimulus (such as whitening gel) is applied externally, smear plugs block the flow of dentinal tubular fluid.

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Odontoblasts lining the pulp chamber are unaffected and
A-Delta nerves are not distorted.
There is no sensitivity or pain felt by the patient.
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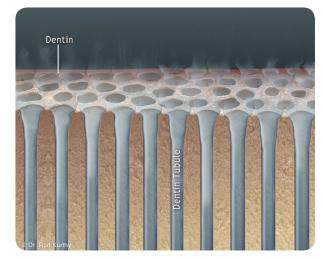


Fig. 7 – Acidic effects on dentin. The diameters of dentinal tubular orifices have been greatly enlarged by acid challenges. Orifices of enlarged dentinal tubules have also been flared like a trombone.

Larger, flared dentinal tubules are significantly more difficult to naturally or synthetically fill with smear plugs, and any smear plugs formed are much more easily displaced again.

Anhydrous base chemical stabilizers are also detrimental in several ways:

- 1) Slows the breakdown of peroxide, reducing the whitening effectiveness.^{11,19}
- 2) Is more difficult for bleaching factors to get out of an anhydrous base and move into the aqueous base of teeth, again reducing whitening effectiveness.
- Increases osmolarity of whitening gels, causing more osmotic "pull" on dentinal tubular fluid; resulting in more forceful tubular fluid flow within the dentinal tubules and acute pulpal whitening sensitivity.^{10,11,19,26,34-36} (Fig. 4)

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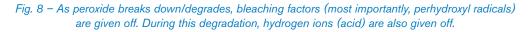


DISADVANTAGES OF NON-REFRIGERATION

When whitening products are not refrigerated during storage and shipping, they are constantly exposed to temperatures ranging anywhere from room temperature to 165°F.^{9-11,13-17} All NON-refrigerated whitening products are therefore degraded, less potent and less effective when received by the dental practice compared to the day the products were manufactured.¹⁰

As NON-refrigerated whitening products degrade during storage and shipping, hydrogen ions are produced.^{10,37-41} (Fig. 8)





Hydrogen ions are acid (pH = "power" or "potential" of Hydrogen). Even whitening gels originally manufactured with a neutral pH therefore become more and more acidic as they break down during storage and shipping.^{10,11 13} By the time they are used on patients, the pH has become acidic.^{10,11,13}

NON-refrigeration of whitening products therefore results in degradation of whitening gels as well as an acidic pH by the time they are used on patients.^{10,11,13,37-41} The disadvantages of this include:

1) Less effectiveness

- a. Depending on the length of time in storage and the temperatures exposed to, NON-refrigerated whitening products may be almost completely inactive by the time they are received and used.
- b. Acidic (low) pH of whitening gels results in more oxygen (which is far less effective for whitening), whereas a neutral and higher pH results in more perhydroxyl radicals, which are far more effective in whitening.^{10,20}

2) Damage to tooth structure

Low pH whitening gels cause demineralization of dentin and enamel, leading to erosion of tooth structure and lower microhardness.^{10,11,13,21,23,26,27,30}

3) Greater whitening sensitivity and pain

Low pH whitening gels cause:

- a. Removal of dentinal tubular smear plugs, resulting in open tubules and increased sensitivity.^{10,21,23,26,27,30} (Figs. 3-6)
- b. Enlargement of the diameter of dentinal tubules,^{10,21,23,26,27,30} resulting in greater difficulty in forming and maintaining natural or synthetic smear plugs. (Fig. 7)
- c. Flaring of the orifices of dentinal tubules (like a trombone).^{10,21,23,26,27,30} The greater the flare of dentinal tubular orifices, the easier smear plugs are lost, and the more difficult it is to reform smear plugs. (Fig. 7)
- d. Lower pH results in significantly stronger osmolarity, causing much more osmotic "pull" on dentinal tubular fl uid in these open dentinal tubules, resulting in far more whitening sensitivity.^{11,19,34-36} (Fig. 4)

ADVANTAGES OF CONSTANT REFRIGERATION

Constant refrigeration virtually stops the breakdown of whitening gels without the need for chemical stabilizers.^{10,11,42} Even more importantly, refrigeration protects whitening gels against the extremely damaging high heat encountered during shipping.^{9,10,14-16}

Benefits of Constant Refrigeration Include:

- 1) Provides a very long shelf life (18-24 months), even with no chemical stabilizers.¹⁰
- 2) Whitening gels are received by the dental practice at virtually the same potency as the day they were manufactured.^{10,11,42}
- 3) Whitening gels received with a neutral pH.
 - a. With no chemical stabilizer such as phosphoric acid, the pH can be made neutral and not acidic.^{10,11,13}
 - b. Because refrigeration blocks breakdown of peroxide during storage and shipping, hydrogen ions (acid) are not produced,³⁷⁻⁴¹ resulting in product received still at a neutral pH.
- 4) Greater effectiveness.
 - a. With no chemical stabilizers, the very fresh/potent whitening products are extremely UN-stable when placed in the mouth.^{11,12} These whitening gels, therefore, break down very effectively and completely.^{11,42}
 - b. With a higher pH base, the breakdown of peroxide results in a high concentration of extremely effective perhydroxyl radicals instead of ineffective oxygen and water.^{11,42}
- 5) No damage to tooth structure. With a neutral pH, enamel and dentin are not demineralized.^{10,18-33}
- 6) Lower sensitivity.
 - a. With a neutral pH, dentinal tubule smear plugs are not removed by acid.^{10,18-33}
 - b. With a neutral pH, dentinal tubule orifices are not enlarged and are not flared.^{10,19,23,26,27,30} This helps form and maintain dentinal tubular smear plugs.^{10,19,23,26,27,30}
 - c. With no chemical stabilizers needed (no anhydrous base or acidifiers),^{10,11,18} the osmolarity is as little as 1/11th of typical whitening gels, resulting in 1/11th the "pull" on dentinal tubular fluid.^{10,11,19} Therefore, experiencing far less whitening sensitivity.^{11,19,34-36}

Discussion

Given the obvious benefits of refrigeration, you may be wondering why all whitening companies don't constantly refrigerate all of their whitening gels. Realize that there are significant financial pressures on any company, including whitening product companies. We are all familiar with the concept of profit.

The cost and time-consuming handling required to achieve constant refrigeration of an entire line of whitening products is very burdensome for whitening product companies. As a consultant, it was Dr. Rod Kurthy's mission for several years to promote refrigeration to whitening companies. His realization that whitening companies were resistant to the idea of constant refrigeration due to profitability concerns was one of the primary reasons for his decision to start his own whitening company.

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