The science behind Philips Zoom whitening
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At Philips, we’re passionate about creating innovative products for a lifetime of better oral health, a commitment that extends into the research we conduct and the partnerships we build with dental professionals. By providing products that are clinically proven safe and effective, we ensure that clinicians are confident recommending them and their patients are satisfied with the experience and results.

We have consistently raised the bar and set new industry standards. Philips Zoom is a widely recognized technology and is the #1 patient-requested professional whitening brand in the United States. The results are clinically validated, the technology is safe and reliable and the variety of formulas offers a range of options from which practices and patients may choose.

The advanced formulas of our take-home whitening products are clinically proven to whiten safely and effectively. It’s our power of three advantage that sets our whitening treatments apart from the rest, formulated with amorphous calcium phosphate (ACP), potassium nitrate and fluoride to minimize sensitivity and improve whitening luster. And our innovative light-accelerated procedures take whitening to new levels of clinical excellence: truly a bright future for Zoom.

The studies presented in this booklet focus equally on the safety and efficacy of Zoom to provide a convincing example of our ongoing commitment to independently conducted clinical research. This compilation is an evolving library of clinical evidence showing the efficacy, safety and results you and your patients can expect to experience. We trust that the findings presented in this brochure will convince you that Philips Zoom is the superior whitening solution for a lifetime of improved oral health.
Comparison of the tooth shade reduction and color change effects of 6% hydrogen peroxide with and without Philips Zoom WhiteSpeed led acceleration followed by use of Philips Zoom NiteWhite 16% carbamide peroxide

in vivo study
University of Texas Health Science Center School of Dentistry; Houston, TX, USA

Objective
The primary objective of this study was to compare tooth shade reduction following application of 6% hydrogen peroxide with and without Philips Zoom WhiteSpeed LED acceleration, immediately and seven days following treatment.

Secondary objectives included an evaluation of safety, tooth color at all timepoints, and tooth shade at Day 14 post in-office bleaching, which included three-dose use of Philips Zoom NiteWhite 16% carbamide peroxide.

Methodology
This was a randomized, single-blind, split-mouth (opposing arch) design clinical trial. The IRB-approved study was conducted in generally healthy subjects, at least 18 years of age, who presented with a minimum of four of six anterior facial-maxillary teeth assessed as 2.5M2/3M2 per VITA BleachedGuide 3D Master Shade Guide. Subjects with intrinsic tooth staining (tetracycline exposure, fluorosis) or with visible supragingival calculus on anterior teeth, or with a contraindicating medical or dental condition, were excluded from the study. Enrolled subjects were fitted with a custom jig (one for each arch) for all CIE (ΔE) color measurements using the VITA EasyShade spectrophotometer. Tooth shade matching was performed using the VITA BleachedGuide 3D-Master (VBG) by calibrated examiners, according to ISO/TR 28642, under controlled lighting conditions, at a distance of approximately 25 cm. Shade change was expressed in terms of shade guide units (SGU), computed as the difference from Baseline in the absolute number of shade guide “steps”. Per ISO/TR 28642, color difference values above ΔE* = 2.7 were considered to represent a color mismatch beyond the 50:50% acceptability threshold (AT), and above ΔE* = 1.2 beyond the 50:50% perceptibility threshold (PT).

Study subjects were randomly assigned to opposing arch (maxillary versus mandibular arch) in-office tooth bleaching with 6% hydrogen peroxide (HP) with and without Philips Zoom WhiteSpeed LED acceleration. The facial surface of the anterior teeth in each arch were isolated and treated with 6% HP for 15 minutes, in four cycles. Efficacy (VBG, ΔE) of 6% HP with and without LED acceleration was assessed at Baseline, immediately following, and at Day 7 and Day 14 following in-office bleaching. At the Day 7 visit, all subjects were dispensed a take-home Philips Zoom NiteWhite 16% carbamide peroxide kit to be used over a three-dose period (three overnight applications). All study subjects used a soft-bristle manual toothbrush with Sensodyne True White dentifrice for the duration of the study.

Results
Of 82 subjects consented and enrolled, 77 subjects completed the study, (mean age: 49 years, 43 females, 34 males).

VITA BleachedGuide 3D Master, Shade Guide Units (SGU)
Immediately following in-office bleaching, the mean (SD) reduction in SGU for the 6% HP with Philips Zoom WhiteSpeed LED acceleration group was 6.9 (3.1), and 5.3 (2.5) for the 6% HP without LED acceleration group. This difference was statistically significant, p-value = 0.0001.

At Day 7 following in-office bleaching, the mean (SD) reduction in SGU for the 6% HP with Philips Zoom WhiteSpeed LED acceleration group was 4.4 (2.8), and 3.6 (2.5) for the 6% HP without LED acceleration group. This difference was statistically significant, p-value = 0.0089.

At Day 14 following in-office bleaching, and including three-dose use of Philips Zoom NiteWhite 16% carbamide peroxide application, the mean (SD) reduction in SGU for the 6% HP with Philips Zoom WhiteSpeed LED acceleration group was 6.9 (2.9), and 6.2 (2.6) for the 6% HP without LED acceleration group. This difference was statistically significant, p-value = 0.0148.

VITA EasyShade, ΔE
Immediately following in-office bleaching, the mean (SD) ΔE for the 6% HP with Philips Zoom WhiteSpeed LED acceleration group was 7.3 (3.5), and 6.8 (3.6) for the 6% HP without LED acceleration group, p-value = 0.3146.

At Day 7 following in-office bleaching, the mean (SD) ΔE for the 6% HP with Philips Zoom WhiteSpeed LED acceleration group was 7.7 (4.0), and 6.7 (3.7) for the 6% HP without LED acceleration group, p-value = 0.0566.

At Day 14 in-office bleaching, and including three-dose use of Philips Zoom NiteWhite 16% carbamide peroxide application, the mean (SD) ΔE for the 6% HP with Philips Zoom WhiteSpeed LED acceleration group was 7.4 (2.8), and 7.4 (3.2) for the 6% HP without LED acceleration group, p-value = 0.9716.

Safety
The incidence and severity of tooth sensitivity was reported as low following chairside 6% hydrogen peroxide treatment, with mild sensitivity reported during the home use period of Philips Zoom NiteWhite 16% carbamide peroxide.
Conclusions:
In-office tooth bleaching with a 4x15-minute regimen of 6% hydrogen peroxide exceeded the ISO/TR 28642 defined ΔE* perceptibility thresholds (AT and PT) at all timepoints, compared to Baseline. By this definition, the addition of a three-dose treatment with 16% carbamide peroxide was similarly effective, and helped prevent color rebound.

In-office tooth bleaching with 6% hydrogen peroxide with Philips Zoom WhiteSpeed LED acceleration was statistically significantly superior to in-office bleaching with 6% hydrogen peroxide without LED acceleration, per VITA BleachedGuide 3D Master shade matching assessment at all study time points: Immediately, Day 7 and Day 14 following treatment. There was no statistical differentiation discerned between treatment groups per VITA EasyShade ΔE* measurement, at any time point.

All tooth-bleaching products used in this study were safe.

Shade Guide Unit Reduction, VITA BleachedGuide 3D Master - LED versus no LED
Change Immediately, Day 7 and Day 14 Following Treatment

<table>
<thead>
<tr>
<th></th>
<th>Immediately Post</th>
<th>Day 7</th>
<th>Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>6% HP + LED</td>
<td>6.9</td>
<td>5.3</td>
<td>4.4</td>
</tr>
<tr>
<td>6% HP - LED</td>
<td>6.9</td>
<td>6.2</td>
<td></td>
</tr>
</tbody>
</table>

Color Change ΔE*, VITA EasyShade - LED versus no LED
Change Immediately, Day 7 and Day 14 Following Treatment

<table>
<thead>
<tr>
<th></th>
<th>Immediately Post</th>
<th>Day 7</th>
<th>Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>6% HP + LED</td>
<td>7.3</td>
<td>7.7</td>
<td>7.4</td>
</tr>
<tr>
<td>6% HP - LED</td>
<td>6.8</td>
<td>6.7</td>
<td>7.4</td>
</tr>
</tbody>
</table>
Significant differences in tooth shade were also observed at Day 7 per VCS, with LS Mean (SE) reductions of 4.92 (0.20) for PZW, and 4.19 (0.20) for UOB, p-value = 0.0106.

Significant differences in tooth shade at Day 7 were also observed per VBG, with LS Mean (SE) reductions of 2.41 (0.13) for PZW, and 2.06 (0.12) for UOB, p-value = 0.0489.

Phase II efficacy

On Day 90, the SDC was statistically superior to MTB in maintaining shade per VCS, with LS Mean (SE) reduction of 0.77 (0.22) for SDC and 0.47 (0.22) for MTB, p-value = 0.0001.

For VBG at Day 90, the LS Mean (SE) reduction was 0.29 (0.12) for SDC and 0.15 (0.12) for MTB, p-value = 0.0108.

No tooth color differences were observed per $\Delta E$.

Safety

The percentage of subjects who reported “no sensitivity” immediately post-bleaching was 98.5% for PZW, and 98.6% for UOB. At Day 7, these values were 82.1% for PZW, and 79.4% for UOB. Of those who did experience sensitivity, one subject rated sensitivity as “moderate.” All other reports were characterized as “mild.”

There was a total of 41 adverse events reported among 34 subjects. In general, these events were associated with sensitivity. Subject use of post-bleaching sensitivity gel (Relief ACP for PZW subjects, or UltraEZ for UOB subjects) applied per manufacturer’s instructions. All subjects used a standard manual toothbrush during study Phase I. On Day 30, approximately equal numbers of subjects from the PZW and UOB treatment groups were then randomized to long-term tooth-bleaching maintenance with either a Philips Sonicare DiamondClean (SDC) powered toothbrush, or a manual toothbrush (MTB). All subjects were provided a standard dentifrice. Subjects returned to clinic at Day 90 for final tooth shade and color assessments.

Results

Demographics

Of 394 subjects screened, 136 were enrolled and randomized in Phase I. 67 to PZW and 69 to UOB (mean age, 50 years). Of these, 134 were randomized in Phase II. 67 to SDC and 67 to MTB. One hundred thirty-three subjects completed the study.

Phase I efficacy

For the primary endpoint, $\Delta E$ at Day 7, a significantly larger reduction was observed for PZW than UOB, with Kruskal-Wallis median $\Delta E$ values of 6.34 and 4.08, respectively, p-value = 0.0059.

Significant differences in tooth shade were also observed at Day 7 per VCS, with LS Mean (SE) reductions of 4.92 (0.20) for PZW, and 4.19 (0.20) for UOB, p-value = 0.0106.

Significant differences in tooth shade at Day 7 were also observed per VBG, with LS Mean (SE) reductions of 2.41 (0.13) for PZW, and 2.06 (0.12) for UOB, p-value = 0.0489.

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Conclusions

At Day 7 following tooth bleaching, Philips Zoom WhiteSpeed showed statistically greater change in overall tooth color and shade than Ultradent Opalescence Boost PF.

At Day 90 following tooth bleaching, Philips Sonicare DiamondClean powered toothbrush maintained tooth shade significantly better than a manual toothbrush.

Both chairside tooth bleaching products and the toothbrushing regimens are safe for use.
### Median ΔE

<table>
<thead>
<tr>
<th></th>
<th>Post-bleaching</th>
<th>Day 7</th>
<th>Day 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoom WhiteSpeed</td>
<td>5.12</td>
<td>2.55</td>
<td>3.44</td>
</tr>
<tr>
<td>Opalescence Boost</td>
<td>6.34</td>
<td>4.08</td>
<td>6.03</td>
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</table>

### LS Mean Shade Reduction at Day 90

#### VITA Classical Shade Guide and VITA Bleached Guide

<table>
<thead>
<tr>
<th></th>
<th>VCS</th>
<th>VBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoom WhiteSpeed</td>
<td>0.77</td>
<td>0.29</td>
</tr>
<tr>
<td>Opalescence Boost</td>
<td>0.47</td>
<td>0.15</td>
</tr>
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</table>

### LS Mean VITA Classical Shade Reduction

<table>
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<th>Day 7</th>
<th>Day 30</th>
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<tr>
<td>Zoom WhiteSpeed</td>
<td>5.86</td>
<td>4.47</td>
<td>4.45</td>
</tr>
<tr>
<td>Opalescence Boost</td>
<td>4.92</td>
<td>4.19</td>
<td>4.11</td>
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</tbody>
</table>

### LS Mean VITA Bleached Guide Shade Reduction

<table>
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<th></th>
<th>Post-bleaching</th>
<th>Day 7</th>
<th>Day 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoom WhiteSpeed</td>
<td>3.24</td>
<td>2.05</td>
<td>2.25</td>
</tr>
<tr>
<td>Opalescence Boost</td>
<td>2.41</td>
<td>2.06</td>
<td>2.03</td>
</tr>
</tbody>
</table>

### Maximum Sensitivity Rating Reported by Study Subjects

<table>
<thead>
<tr>
<th></th>
<th>Zoom WhiteSpeed</th>
<th>Opalescence Boost</th>
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<tbody>
<tr>
<td>No sensitivity</td>
<td>82%</td>
<td>79%</td>
</tr>
<tr>
<td>Mild sensitivity</td>
<td>16%</td>
<td>21%</td>
</tr>
<tr>
<td>Moderate sensitivity</td>
<td>1%</td>
<td>0%</td>
</tr>
</tbody>
</table>

A two-phase, three-month clinical evaluation comparing two chairside tooth bleaching treatments, with tooth shade maintenance by powered or manual toothbrushing.
The basic chemistry behind hydrogen peroxide tooth whitening

in vitro study
Philips Research Laboratories, Cambridge, UK

Objective
To examine the basic interactions between whitening agents and stain molecules in simple solutions and to give clarity on the basic chemistry and photochemistry that occurs during the process.

Materials
• Black tea stain solution
• Whitening agents of various compositions including hydrogen peroxide, ferrous gluconate, and potassium hydroxide (based on Zoom treatment, Discus Dental, Inc., Culver City, CA, USA)
• Blue light (465nm)
• Infrared light (850nm)

Methodology
The absorbance of tea stain solution at 450nm was measured over a period of 40 minutes, with various compositions of whitening agent added (including hydrogen peroxide, ferrous gluconate and potassium hydroxide in the formulations) and at the same time the samples were subjected to blue light (465nm) or infrared light (850nm) irradiation, or alternatively were heated.

Results
The reaction rates between chromophores in the tea solution and hydrogen peroxide can be accelerated significantly using ferrous gluconate activator and blue light irradiation. Infrared irradiation was not found to increase the reaction rate through photochemistry but increases the temperature. While raising the temperature can give a slight increase in reaction rate, it can easily lead to inefficiency through the acceleration of exothermic decomposition reactions of hydrogen peroxide.

Conclusion
By carrying out work in simple solution, it was possible to separate the basic chemistry of tooth whitening from the complex physical processes which occur in the tooth during whitening. Ferrous activators and blue light irradiation were shown unambiguously to significantly enhance the whitening process, whereas infrared irradiation or heating has a smaller effect.
Objective
To evaluate the whitening efficacy of four in-office whitening systems using a direct measurement method, which evaluated the discoloration of a stain solution prepared with the most common food color used in beverages and industrial food.

Materials
- Caramel solution
- 25% hydrogen peroxide
- 25% hydrogen peroxide + ferrous complex
- UVA lamp

Methodology
A caramel solution (CS) was prepared in water, using Caramel Class IV AP 100 (Sethness Products Company, USA), at a proportion of 0.1% in weight (w/v). Five experimental groups were designed:
Group 1. Control: caramel solution (CS) not submitted to any discoloration process; Group 2. CS+HP 25% (Lase Peroxide, DMC, Brazil); Group 3. CS+HP 25% + visible light LED for 45 min (480nm, Whitening Lase Plus, DMC, Brazil); Group 4. CS+HP 25% and Fe2+ (Zoom 2 gel, Discus Dental, USA); 5. CS + HP 25% and Fe2+ + UVA light (360–400nm) during 45min (Zoom AP lamp, Discus Dental). Five repetitions were conducted for each experimental group and the results were measured using a Shimadzu spectrophotometer UV-1650PC (Shimadzu Scientific Instruments, Japan) and converted into a percent that indicates the color that remained in the solution.

Results
One-Way ANOVA showed all groups were statistically different except for Groups 1 and 2, which were statistically similar.

Conclusion
The 25% hydrogen peroxide gel associated with ferrous complex reached higher discoloration than the 25% hydrogen peroxide gel. The 25% hydrogen peroxide gel associated with ferric complex submitted to UVA light emission offered the highest whitening potential when compared to all the other groups.
Whitening treatment combined with bioactive materials

in vitro study


Objective
To investigate the influence of bioactive materials on whitened surfaces and dentin using Knoop hardness test

Materials
• Eight human teeth
• 15% carbamide peroxide, potassium nitrate, fluoride (Opalescence PF, Ultradent)
• 16% carbamide peroxide, potassium nitrate, fluoride, calcium, phosphate (NiteWhite ACP, Discus Dental)
• 15% carbamide peroxide, potassium nitrate, fluoride & glass-ceramic crystallized glass P₂O₅–Na₂O–CaO–SiO₂ (Opalescence PF, Ultradent & Biosilicate, VitroVITA)
• 15% carbamide peroxide, potassium nitrate, fluoride + potassium nitrate, fluoride, calcium, phosphate (Opalescence PF, Ultradent + Relief ACP, Discus Dental)

Methodology
Eight human teeth were sectioned into five wafers per tooth and divided into five experimental groups (n=8). The specimens were treated and mounted in intra-oral palatal retainers. Whitening treatments were performed for 14 days according to manufacturer’s instructions. Six Knoop hardness measures were taken for each specimen, three before and three after treatments. The data were compared by Student’s t-test (α = 0.05).

Results
Opalescence PF caused hardness decrease on enamel and dentin (p<0.05). NiteWhite ACP and the bioactive materials had a positive influence on the hardness of bleached enamel and dentin, except for the effect on enamel of the Biosilicate material when applied for five minutes one time per week, which showed a decrease in KHN.

Conclusion
Whitening treatment can lead to alterations in the dental structure. Minimizing or eliminating the alterations in the whitened dental structure could bring benefits to patients. Adding bioactive materials to whitening treatments can minimize or eliminate the alterations in the dental structure.
Pre- and Post-Treatment Enamel Hardness

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>NiteWhite ACP</td>
<td>279.7</td>
<td>279.6</td>
</tr>
<tr>
<td>Opalescence PF</td>
<td>281.4</td>
<td>267.8</td>
</tr>
<tr>
<td>Opalescence PF + Bio Mixed</td>
<td>289.1</td>
<td>289.6</td>
</tr>
<tr>
<td>Opalescence PF + Bio</td>
<td>279.3</td>
<td>265.8</td>
</tr>
<tr>
<td>Opalescence PF + Relief ACP</td>
<td>277.0</td>
<td>278.5</td>
</tr>
</tbody>
</table>

Pre- and Post-Treatment Dentin Hardness

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>NiteWhite ACP</td>
<td>45.2</td>
<td>42.5</td>
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<tr>
<td>Opalescence PF</td>
<td>47.2</td>
<td>38.9</td>
</tr>
<tr>
<td>Opalescence PF + Bio Mixed</td>
<td>46.4</td>
<td>44.3</td>
</tr>
<tr>
<td>Opalescence PF + Bio</td>
<td>43.0</td>
<td>40.5</td>
</tr>
<tr>
<td>Opalescence PF + Relief ACP</td>
<td>45.2</td>
<td>41.4</td>
</tr>
</tbody>
</table>

Whitening treatment combined with bioactive materials

Take-home whitening

Benefits of ACP
Influence of bioactive materials on whitened human enamel surface

in vitro study
Pinheiro HB, Cardoso PEC, Universidade de São Paulo, São Paulo, Brazil
Academy of Dental Materials Meeting, 2011

Objective
To investigate the influence of bioactive materials on whitened human enamel surface using Knoop hardness test.

Materials
- Five human teeth
- 16% carbamide peroxide, potassium nitrate, fluoride (Opalescence PF, Ultradent)
- 16% carbamide peroxide 16%, potassium nitrate, fluoride, calcium, phosphate (NiteWhite ACP, Discus Dental)
- 15% carbamide peroxide 15%, potassium nitrate, fluoride + potassium nitrate, fluoride, calcium, phosphate (Opalescence PF, Ultradent + Relief ACP, Discus Dental)
- 15% carbamide peroxide, potassium nitrate, fluoride + potassium nitrate, fluoride, calcium, phosphate (Opalescence PF, Ultradent & Relief ACP, Discus Dental)

Methodology
Five human teeth were sectioned into four slices per tooth. Whitening treatments were performed for 14 days according to manufacturers’ instructions. Six Knoop hardness measures were taken for each specimen, three before and three after treatments. The data were compared by Student’s t-test (α=0.01).

Results
OPF and OPF + Relief ACP presented statistically significant hardness decrease; NiteWhite ACP and OPF & Relief ACP mixed at the time of application showed that enamel hardness was maintained.

Conclusion
Whitening treatment can lead to alterations in the dental structure. Minimizing or eliminating the alterations in the whitened dental structure could bring benefits to patients. With the purpose of increasing the mineral deposition on the tooth, amorphous calcium phosphate (ACP) biomaterial has been added to toothpastes, mouth rinses, chewing gums, and more recently to whitening products. This study indicates that the use of ACP simultaneously with the whitening treatment is beneficial.
Influence of five home whitening gels and a remineralizing gel on the enamel and dentin ultrastructure and hardness

in vitro study


Universidade de São Paulo, São Paulo, Brazil

Objective

To investigate the influence of calcium phosphate–enhanced home whitening agents on human enamel and dentin surface microhardness and ultramorphy.

Materials

• 10 intact molar crowns
• 15% carbamide peroxide + potassium nitrate + fluoride (Opalescence PF, Ultradent)
• 16% carbamide peroxide + potassium nitrate + fluoride (Whiteness Perfect, FGM)
• Potassium nitrate + fluoride + calcium + phosphate (Relief ACP, Discus Dental)
• 16% carbamide peroxide + potassium nitrate + calcium + phosphate (NiteWhite ACP, Discus Dental)
• 7.5% hydrogen peroxide + potassium nitrate + calcium + phosphate (DayWhite ACP, Discus Dental)
• 7.5% hydrogen peroxide + potassium nitrate + fluoride + calcium (White Class Ca, FGM)

Methodology

Five intact molar crowns were used for ultrastructural analysis and five for microhardness tests. Each resulting coronal structure was cut in slices. After measuring the baseline Knoop Hardness Number (KHN) of the enamel and dentin, the slices were divided into six experimental groups and one control group (n=5). The groups were as follows: G1 = 15% CP; G2 = 16% CP; G3 = Ca and PO\(_4\); G4 = 16% CP with Ca and PO\(_4\); G6 = 7.5% HP with Ca.

Results

Conventional whitening agents (G1, G2) and the gel with calcium (G6) cause KHN decrease (p = <0.05). The remineralizing and whitening agents with calcium and phosphate (G3, G4, G5) did not change KHN. A change in morphology was observed on dentin surfaces in G1, G2, and G5.

Conclusion

The results indicated that the gels with calcium and phosphate added did not change the superficial enamel and dentin hardness nor did it change the tooth morphology. The conventional whitening gels that did not have remineralizing agents added to the formulation showed decreases on superficial hardness of enamel and dentin as well as morphological changes on tooth structure.
Mean Enamel Hardness Before and After Treatment

<table>
<thead>
<tr>
<th>Product</th>
<th>Baseline (KHN)</th>
<th>Final (KHN)</th>
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<tbody>
<tr>
<td>DayWhite ACP</td>
<td>320.7</td>
<td>316.2</td>
</tr>
<tr>
<td>NiteWhite ACP</td>
<td>313.7</td>
<td>315.7</td>
</tr>
<tr>
<td>Opalescence PF</td>
<td>308.9</td>
<td>278.5</td>
</tr>
<tr>
<td>Relief ACP</td>
<td>310.1</td>
<td>314.8</td>
</tr>
<tr>
<td>Whiteness Perfect</td>
<td>316.8</td>
<td>291.2</td>
</tr>
<tr>
<td>White Class Ca</td>
<td>315.7</td>
<td>289.7</td>
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</table>

Mean Dentin Hardness Before and After Treatment

<table>
<thead>
<tr>
<th>Product</th>
<th>Baseline (KHN)</th>
<th>Final (KHN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DayWhite ACP</td>
<td>53.7</td>
<td>52.6</td>
</tr>
<tr>
<td>NiteWhite ACP</td>
<td>51.7</td>
<td>48.2</td>
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<tr>
<td>Opalescence PF</td>
<td>51.7</td>
<td>44.1</td>
</tr>
<tr>
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<tr>
<td>Whiteness Perfect</td>
<td>50.3</td>
<td>34.8</td>
</tr>
<tr>
<td>White Class Ca</td>
<td>52.1</td>
<td>44.8</td>
</tr>
</tbody>
</table>
Microhardness and ultramorphological changes after whitening: calcium and phosphate benefits

in vitro study


Objective
To investigate the influence of home bleaching agents with and without calcium and phosphate on human enamel and dentin surface microhardness and ultramorphology.

Materials
- Five human molars
- 15% carbamide peroxide with potassium nitrate and fluoride (Opalescence PF, Ultradent)
- 16% carbamide peroxide with potassium nitrate and fluoride (Whiteness Perfect, FGM)
- 16% carbamide peroxide with potassium nitrate and ACP (NiteWhite ACP, Discus Dental)
- 7.5% hydrogen peroxide with potassium nitrate and ACP (DayWhite ACP, Discus Dental)
- 7.5% hydrogen peroxide with potassium nitrate, fluoride, and calcium (White Class Ca, FGM)

Methodology
Five intact human third molars were sectioned into five wafers. All wafers had their baseline Knoop Hardness Number (KHN) of the enamel (E0) and dentin (D0) measured. Each wafer of the tooth was assigned to a group (n=5). G1=15% carbamide peroxide (CP) (Opalescence PF-Ultradent) applied for four hours per day; G2=16% CP (Whiteness Perfect, FGM), G3=16% CP with Ca and PO4 (NiteWhite ACP-Discus Dental), G2 and G3 followed same application time of group 1; G4=7.5% hydrogen peroxide (HP) with Ca and PO4 (Day White ACP-Discus Dental); G5=7.5% HP with Ca (White Class Ca-FGM), G4 and G5 were applied for one hour per day. After each session of bleaching treatment, specimens were stored in distilled water (37°C). The products were applied for two weeks, according to manufacturers’ instructions. Subsequent measurements of KHN were taken in the enamel (E1) and dentin (D1). Two specimens from each group were selected for ultramorphological investigation after final tests.

Results
Conventional bleaching agents and the gel with calcium (Group 1 and Group 2) caused KHN decrease. Bleaching agents with calcium and PO4 (Group 3 and Group 4) did not change KHN. The obvious change of morphology was observed on enamel and dentin surfaces in Group 1, Group 2 and Group 5.

Conclusion
The bleaching agents with calcium and ACP did not change the superficial enamel and dentin microhardness and ultramorphology. Conventional bleaching agents and the gel with calcium caused microhardness decrease and ultramorphology changes on enamel and dentin.
Microhardness and ultramorphological changes after whitening: calcium and phosphate benefits

<table>
<thead>
<tr>
<th>Enamel</th>
<th>Opalescence PF</th>
<th>Whiteness Perfect</th>
<th>NiteWhite ACP</th>
<th>DayWhite ACP</th>
<th>White Class Ca</th>
</tr>
</thead>
<tbody>
<tr>
<td>KHN (Baseline)</td>
<td>308.9 (15.5)</td>
<td>316.8 (8.0)</td>
<td>313.8 (14.7)</td>
<td>320.7 (10.4)</td>
<td>315.7 (16.0)</td>
</tr>
<tr>
<td>KHN (After Treatment)</td>
<td>278.5 (12.8)</td>
<td>291.2 (12.9)</td>
<td>315.7 (16.0)</td>
<td>316.2 (6.6)</td>
<td>289.7 (6.0)</td>
</tr>
</tbody>
</table>

- Control
- Opalescence PF
- Whiteness Perfect
- NiteWhite ACP
- DayWhite ACP
- White Class Ca

Original magnification: 50,000X
Insets: 100,000X

Benefits of ACP

Take-home whitening
Dentin

Original magnification: 10,000X
Insets: 20,000X

<table>
<thead>
<tr>
<th>Product</th>
<th>KHN (Baseline)</th>
<th>KHN (After treatment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opalescence PF</td>
<td>(5.3)</td>
<td>(3.2)</td>
</tr>
<tr>
<td>Whiteness Perfect</td>
<td>(5.7)</td>
<td>(4.6)</td>
</tr>
<tr>
<td>NiteWhite ACP</td>
<td>(6.0)</td>
<td>(5.0)</td>
</tr>
<tr>
<td>DayWhite ACP</td>
<td>(5.8)</td>
<td>(4.9)</td>
</tr>
<tr>
<td>White Class Ca</td>
<td>(6.9)</td>
<td>(5.7)</td>
</tr>
</tbody>
</table>

**Microhardness and ultramorphological changes after whitening: calcium and phosphate benefits**

**Take-home whitening**

**Benefits of ACP**
Effect of Relief ACP on dentin microhardness and surface morphology
in vitro study


Objective
To investigate effects of Relief ACP on dentin microhardness and surface morphology of extracted human teeth compared to that of Satin Finish.

Materials
- 20 dentin specimens
- Relief ACP (Discus Dental)
- Satin Finish (Discus Dental)

Methodology
Twenty dentin specimens were prepared by grinding the enamel from the surface of human molars until the dentin was exposed. The sample surface was measured for Knoop Hardness Number (KHN) with a Leco Microhardness Tester (M-400-H1, St. Joseph, MI). The specimens were randomly assigned to three groups. Group A (N=4) served as the Control (100% humidity). Group B (N=8) was treated with Relief ACP (Discus Dental), while Group C (N=8) received treatments with Satin Finish (Discus Dental). The samples received 28 treatments of 30 minutes each. Prior to each treatment the samples were immersed in pooled human saliva for 20 minutes. The KHN was measured after the last treatment, and the specimens were then processes for the SEM evaluation. The KHN data were analyzed using the One-way ANOVA and Student-Newman-Keuls methods.

Results
There were no significant differences in the KHN values among the three groups before and after treatments. The changes in KHN were statistically different (p=0.032); however, there were no significant within-treatment differences for any of the three groups. The SEM evaluation showed deposits inside of the exposed dentin tubule openings in the specimens treated with Relief ACP, and most of the openings appeared fully blocked by the deposits. Such deposits were not observed in the Control samples and they were less evident in the Satin Finish group.

Conclusion
The treatment with Relief ACP or Satin Finish does not change surface microhardness of human dentin, and treatments with Relief ACP produce deposits inside of the exposed dentin tubule openings.
Fluoride and potassium nitrate-fluoride whitening agents: in vitro caries study

in vitro study


Objective

To evaluate the effects of whitening agents containing amorphous calcium phosphate with fluoride (ACP–Fl) and potassium nitrate with fluoride (KN–Fl) on enamel caries initiation and progression.

Materials

- 15 human teeth
- 16% carbamide peroxide, ACP and fluoride (NiteWhite, ACP–Fl, Discus Dental)
- 15% carbamide peroxide with potassium nitrate and fluoride (Opalescence, KN–Fl, Ultradent)

Methodology

Fifteen human teeth with sound enamel surfaces were divided into three portions. Each tooth portion was assigned to a treatment group: Group 1) No Treatment Control; Group 2) NiteWhite 16% carbamide peroxide, ACP and fluoride (ACP–Fl, Discus Dental); Group 3) Opalescence 15% carbamide peroxide with potassium nitrate and fluoride (KN–Fl, Ultradent Products). The teeth were treated according to the manufacturer’s guidelines followed by synthetic saliva rinsing on a daily basis for 14 days. Control tooth portions were exposed only to synthetic saliva rinsing. A modified ten Cate solution was used for in vitro enamel caries initiation and progression. The teeth were treated prior to lesion initiation and before lesion progression. Longitudinal sections were taken after the lesion initiation period and the lesion progression period for polarized light study and statistical analysis (ANOVA, DMR).

Results

For both the lesion initiation and progression periods, significant differences were found between ACP–Fl and KN–Fl.

Mean lesion depths:

- Lesion Initiation Period: Control 156±17um; KN–Fl 95±12um (P<.05); ACP–Fl 72±14um (P<.05)
- Progression Period: Control 306±29um; KN–Fl 172±18um (P<.05); ACP–Fl 108±14um (P<.05).

Mean Lesion Depths

<table>
<thead>
<tr>
<th></th>
<th>Group 1: Control</th>
<th>Group 2: NiteWhite — 16% carbamide peroxide, ACP and fluoride</th>
<th>Group 3: Opalescence — 15% carbamide peroxide with potassium nitrate and fluoride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion initiation period</td>
<td>156±17um</td>
<td>72±14um (P&lt;.05)</td>
<td>95±12um (P&lt;.05)</td>
</tr>
<tr>
<td>Lesion progression period</td>
<td>306±29um</td>
<td>108±14um (P&lt;.05)</td>
<td>172±18um (P&lt;.05)</td>
</tr>
</tbody>
</table>

Conclusion:

Fluoride–containing whitening agents significantly reduce the susceptibility of enamel surfaces to in vitro caries initiation and progression compared with matched no treatment controls. When both ACP and fluoride (ACP–Fl) are present in the whitening agents, caries resistance was markedly improved over the whitening agent containing fluoride, but lacking ACP.

Take-home whitening

Benefits of ACP

Fluoride and potassium nitrate-fluoride whitening agents: in vitro caries study
Effect of take-home whitening agent on enamel microhardness

in vitro study


**Objective**
To evaluate the effect of remineralizing agents such as fluoride or amorphous calcium phosphate (ACP) during bleaching on surface enamel microhardness.

**Materials**
- 16% carbamide peroxide with ACP (NiteWhite ACP, Discus Dental)
- 15% carbamide peroxide with fluoride (Opalescence PF, Ultradent)
- 9% hydrogen peroxide with fluoride (Tres White, Ultradent)

**Methodology**
Nine human central incisors were cut in half longitudinally for a total of 18 surfaces. The sections were embedded into acrylic with the facial surfaces exposed. The prepared specimens were randomly divided into three groups (six specimens each), and assigned treatment with one of the three whitening agents being tested. Group 1 was treated with 16% carbamide peroxide with ACP (NiteWhite ACP); Group 2 was treated with 15% carbamide peroxide with fluoride (Opalescence PF); Group 3 was treated with 9% hydrogen peroxide with fluoride (Tres White).

Before bleaching was initiated, baseline data were collected on the Vickers surface hardness (VHN) of the enamel using a MicroMet 2100 series tester (Buehler, Lake Bluff, IL). Six hardness tests were conducted with 500 gm load for 15 seconds on each specimen for a total of 36 measurements per group. The specimens then underwent six consecutive one-hour cycles of bleaching with the assigned whitening agent. At the completion of the bleaching, another six enamel hardness readings were taken for each specimen. The data gathered were analyzed using ANOVA with p < 0.05 for significant differences.

**Results**
All whitening systems produced a decrease in enamel hardness after six bleaching cycles. The VHN of Group 1 (NiteWhite ACP) decreased by 5.57%, the VHN of Group 2 (Opalescence PF) decreased by 10.49% and the VHN of Group 3 (Tres White) decreased by 11.91%. The decrease in enamel hardness for Group 1 specimens treated with 16% carbamide peroxide with ACP (NiteWhite) was significantly less than the decrease seen in other groups.

**Conclusion**
Bleaching with NiteWhite ACP resulted in the least decrease in hardness compared with Opalescence PF and Tres White under the conditions of this study.
Effect of remineralizing agents on enamel microhardness after bleaching

in vitro study


Objective
To determine the potential of remineralizing agents to increase microhardness of enamel after bleaching

Materials
- Five human incisors
- 15% carbamide peroxide (Opalescence, Ultradent)
- MI Paste (Ultradent)
- Relief ACP (Discus Dental)

Methodology
Five human incisors were sectioned in half superior inferiorly. The halves were then mounted on cold cure acrylic for ease of manipulation. Six VH readings were then done per specimen on Micromet 2100 (Buehler, Lake Bluff, IL) with 500 gm load to establish baseline. Six cycles of bleaching with 15% carbamide peroxide (Opalescence, Ultradent) were then performed. Each cycle lasted one hour prior to placement of new solutions. The teeth again were tested for VH hardness with six readings per specimen. Upon completion of bleaching, the halves of the teeth were divided into either Group A (MI Paste, Ultradent) or Group B (Relief, Discus Dental). The systems were applied for 30 minutes then rinsed with tap water. The specimens again were tested for VH hardness with 6 readings per specimen. The procedure was repeated for a total of three remineralization cycles. All data gathered were analyzed using ANOVA with \( p<0.05 \) for significant differences.

Results
After six cycles of bleaching, there was a significant decrease in hardness on all specimens from a VH of 313.1 to 280.8. After three applications of remineralization agents in both groups, all hardness measurements returned to baseline.

Conclusion
There was a statistically significant decrease in enamel hardness for the bleaching system tested in this study. The application of remineralization agents reversed the decrease in enamel hardness to baseline after three applications.
Whitening agents with ACP: enamel caries formation and progression

in vitro study


Objective
To evaluate the effect of whitening agents containing amorphous calcium phosphate (ACP) on human enamel caries formation and progression

Materials
- 15 human teeth
- 9.5% hydrogen peroxide ACP (DayWhite Excel 3, Discus Dental)
- 6% hydrogen peroxide ACP (NiteWhite Turbo, Discus Dental)
- 16% carbamide peroxide ACP (NiteWhite, Discus Dental)

Methodology
Fifteen teeth with sound enamel surfaces were divided into four portions. Each tooth portion was assigned to a treatment group: Group 1) No Treatment Control; Group 2) DayWhite Excel 3 9.5% hydrogen peroxide ACP; Group 3) NiteWhite Turbo 6% hydrogen peroxide ACP; Group 4) NiteWhite 16% carbamide peroxide ACP. The teeth were treated according to the manufacturer’s recommendations followed by synthetic saliva, on a daily basis for 14 days. Control tooth portions were exposed only to synthetic saliva. A modified ten Cate solution was used for in vitro enamel caries formation and progression. The teeth were treated prior to lesion formation, and before lesion progression 1 and lesion progression 2 periods. Longitudinal sections were taken after lesion formation, lesion progression 1 and lesion progression 2 periods for polarized light study and statistical analysis (ANOVA, DMR).

Results
Mean lesion depths were:
- Lesion Formation Period: Control 108±15um; DayWhite 93±11um; NiteWhite Turbo 48±7um (P<.05); NiteWhite 16% 105±12um.
- Progression Period 1: Control 171±18um; DayWhite 126±13um (P<.05); NiteWhite Turbo 96±9um (P<.05); NiteWhite 16% 132±12um (P<.05).
- Progression Period 2: Control 228±20um; DayWhite 165±17um (P<.05); NiteWhite Turbo 129±11um (P<.05); NiteWhite 16% 152±16um (P<.05).

Mean Lesion Depths

<table>
<thead>
<tr>
<th></th>
<th>Group 1: Control</th>
<th>Group 2: DayWhite Excel 3 - 9.5% hydrogen peroxide ACP</th>
<th>Group 3: NiteWhite Turbo 6% hydrogen peroxide ACP</th>
<th>Group 4: NiteWhite 16% carbamide peroxide ACP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Formation</td>
<td>108±15um</td>
<td>93±11um(P&lt;.05)</td>
<td>48±7um (P&lt;.05)</td>
<td>105±12um(P&lt;.05)</td>
</tr>
<tr>
<td>Period</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Progression Period</td>
<td>171±18um</td>
<td>126±13um(P&lt;.05)</td>
<td>126±13um (P&lt;.05)</td>
<td>132±12um (P&lt;.05)</td>
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<td>1</td>
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<tr>
<td>Progression Period</td>
<td>228±20um</td>
<td>165±17um (P&lt;.05)</td>
<td>129±11um (P&lt;.05)</td>
<td>152±16um (P&lt;.05)</td>
</tr>
<tr>
<td>2</td>
<td></td>
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</table>

Conclusion
Whitening agents containing calcium phosphate have a reduced susceptibility to in vitro enamel caries lesion initiation and progression.
A 180-day clinical investigation of the tooth whitening efficacy of a bleaching gel with added amorphous calcium phosphate

in vivo study


1 - Martin Giniger & Company, New York, NY, USA, 2 - Discus Dental, Culver City, CA, USA

**Objective**

To determine if there are any significant long-term clinical benefits or side effects caused by the addition of amorphous calcium phosphate (ACP) to a professional 16% carbamide peroxide bleaching gel.

**Materials**

- 16% carbamide peroxide gel containing ACP (NiteWhite ACP, Discus Dental)
- 16% carbamide peroxide gel without ACP (NiteWhite Excel 3, Discus Dental)

**Methodology**

This study examined the effect of bleaching gel with added ACP in a subset of subjects (n=27) from a previously published short-term (n=50) study, in which two groups were assigned to use either an experimental ACP-containing gel or a similar "control" gel. Both groups used the product for four hours (or overnight) daily for 14 days. In the present study, the long-term ACP effects on tooth color, gingival health and three measures of dentinal hypersensitivity at post-treatment days +90 and +180 were assessed.

**Results**

In the previously published study, the difference in tooth whitening efficacy at day +5 between the test group and the control group was only 0.19 shades relative to baseline, and was not statistically significant. In the present study, the differences between the groups had almost doubled at day +90, and were calculated to be 0.34 shades (statistically different t-test p=0.002). Furthermore, the differences had more than doubled again at day +180, with the ACP group subjects’ teeth being 0.78 shades lighter than the control group’s teeth (statistically different t-test p=0.002). Considered as a percentage, at day +180 the ACP group had retained nearly 10% more of their original whitening treatment result compared to control. There were no other significant differences found between the two groups. Tooth sensitivity, soft tissue health and gingival health remained similar to baseline levels.

**Conclusion**

This study demonstrated that the 16% carbamide peroxide product with ACP offers 10% better long-term (six months) whitening efficacy than the traditional bleaching gel tested. The long-term safety of the product has also been demonstrated, as there were no adverse gingival or other effects seen at either day +90 or day +180.

**Improvement in Tooth Color from Baseline**

<table>
<thead>
<tr>
<th>Day 3</th>
<th>Day 7</th>
<th>Day 14</th>
<th>Post-Tx Day +5</th>
<th>Post-Tx Day +90</th>
<th>Post-Tx Day +180</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.03</td>
<td>5.35</td>
<td>5.45</td>
<td>6.07</td>
<td>6.41</td>
<td>6.23</td>
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<td>6.59</td>
<td>6.99</td>
<td>7.73</td>
<td>7.84</td>
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</tr>
<tr>
<td>8.17</td>
<td>8.03</td>
<td>6.41</td>
<td>6.07</td>
<td>5.45</td>
<td></td>
</tr>
</tbody>
</table>

- 16% CP with ACP
- 16% CP without ACP