

# The science behind Philips Zoom whitening



ZOOMI

## Table of contents

## In-office whitening

#### Benefit of light vs. no light

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
The basic chemistry behind hydrogen peroxide tooth whitening <b>6</b>

## Take-home whitening

#### Benefits of ACP

Whitening treatment combined with bioactive materials
Influence of bioactive materials on whitened human enamel surface
Effect of Relief ACP on dentin microhardness and surface morphology <b>10</b>
Fluoride and potassium nitrate-fluoride whitening agents: in vitro caries study 11
Effect of remineralizing agents on enamel microhardness after bleaching
A 180-day clinical investigation of the tooth whitening efficacy of a bleaching gel with added amorphous calcium phosphate <b>13</b>



## Notes from Marilyn Ward, DDS

Director, Clinical and Dental Scientific Affairs Philips Oral Healthcare

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

Ontiveros J, Eldiwany MS, Arriaga DM, Fay RM, Gonzalez MD, Pereira Sanchez NA, Sly MM, Paravina R. Clinical efficacy & sensitivity on in-office tooth whitening with & without light treatment combined with at-home bleaching. J Cosmetic Dent. Winter 2019. Vol 34 (4): 70–79.

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 ( $\Delta$ E) 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<sup>2</sup>, 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  $\Delta E^* = 2.7$  were considered to represent a color mismatch beyond the 50:50% acceptability threshold (AT), and above  $\Delta E^*$  = 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,  $\Delta$ E) 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, ∆E

Immediately following in-office bleaching, the mean (SD)  $\Delta E$  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)  $\Delta E$  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)  $\Delta E$  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. 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

#### **Conclusions**:

In-office tooth bleaching with a 4x15-minute regimen of 6% hydrogen peroxide exceeded the ISO/TR 28642 defined  $\Delta E^*$  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.

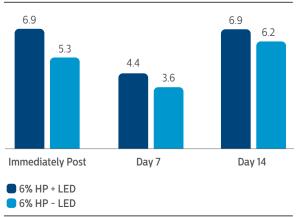
In-office tooth bleaching with 6% hydrogen peroxide with Philips Zoom WhiteSpeed LED acceleration was statistically significantly superior to in-office bleaching with 6% hydrogen peroxide without LED acceleration, per VITA BleachedGuide 3D Master shade matching assessment at all study time points: Immediately, Day 7 and Day 14 following treatment.

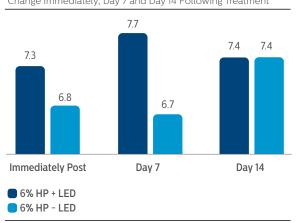
There was no statistical differentiation discerned between treatment groups per VITA EasyShade  $\Delta E^*$  measurement, at any time point.

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





#### Color Change ∆E\*, VITA EasyShade - LED versus no LED Change Immediately, Day 7 and Day 14 Following Treatment

## The basic chemistry behind hydrogen peroxide tooth whitening

#### in vitro study

Young N, Fairley P, Mohan V, Jumeaux C. The chemistry behind hydrogen peroxide tooth whitening, J Dent Res 91(Spec Iss B):147, 2012.

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.

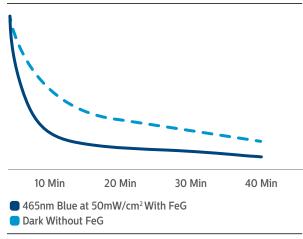
#### Results

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.

## Effect of Ferrous Activators and Blue Light Irradiation on Whitening Process



### Whitening treatment combined with bioactive materials

in vitro study

Pinheiro HB, Cardoso J and Cardoso PEC. Whitening treatment combined with bioactive materials - in situ study. (Spec Iss A), 0801, 2012.

#### 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 & glassceramic crystalized glass P<sub>2</sub>O<sub>5</sub>-Na<sub>2</sub>O-CaO-SiO<sub>2</sub> (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 ( $\alpha = 0.05$ ).

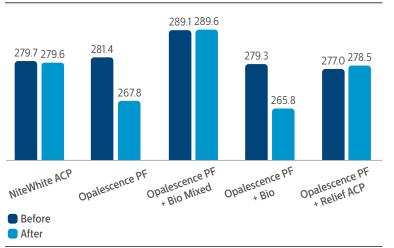
#### Results

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.

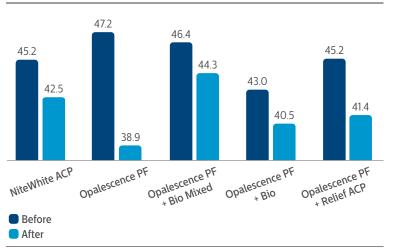
#### Conclusion

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



Pre- and Post-Treatment Dentin Hardness



### 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

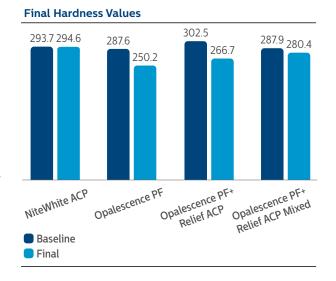
Five human teeth were sectioned into four slices per tooth. Whitening treatments were performed for 14 days according to manufacturers' instructions. Six Knoop hardness measures were taken for each specimen, three before and three after treatments. The data were compared by Student's t-test ( $\alpha$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



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## Effect of Relief ACP on dentin microhardness and surface morphology

#### in vitro study

Li Y, Lu H, Zhang W, Hou J, Devaraj A. Effect of relief ACP on dentin microhardness and surface morphology. J Dent Res 86 (Spec Iss A), 1776, 2007.

#### 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

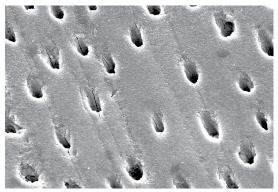
Twenty dentin specimens were prepared by grinding the enamel from the surface of human molars until the dentin was exposed. The sample surface was measured for Knoop Hardness Number (KHN) with a Leco Microhardness Tester (M-400-H1, St, Joseph, MI). The specimens were randomly assigned to three groups. 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

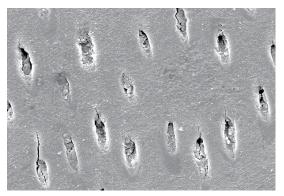
There were no significant differences in the KHN values among the three groups before and after treatments. The changes in KHN were statistically different (p=0.032); however, there were no significant within-treatment differences for any of the three groups. The SEM evaluation showed deposits inside 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.



Dentin treated with potassium nitrate and fluoride



Dentin treated with potassium nitrate, fluoride and Relief ACP

## Fluoride and potassium nitrate-fluoride whitening agents: in vitro caries study

#### in vitro study

Hicks J and Flaitz C. Effects of whitening agents with ACP-fluoride and potassium nitrate-fluoride on in vitro enamel caries initiation and progression. J Dent Res 86 (Spec Iss A), 0497, 2007.

#### 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-FI, 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-FI, Discus Dental); Group 3) Opalescence 15% carbamide peroxide with potassium nitrate and fluoride (KN-FI, 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)</li>
- Progression Period: Control 306±29um; KN-Fl 172±18um (P<.05); ACP-Fl 108±14um (P<.05).</li>

#### Mean Lesion Depths

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

#### **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.

## Effect of remineralizing agents on enamel microhardness after bleaching

#### in vitro study

Ochiai K, Sung EC, Chung J, Caputo AA. Effect of remineralizing agents on enamel microhardness after bleaching. J Dent Res 86 (Spec Iss A), 2007.

#### 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.

## A 180-day clinical investigation of the tooth whitening efficacy of a bleaching gel with added amorphous calcium phosphate

#### in vivo study

Giniger M1, Spaid M1, MacDonald J2, Felix H2. A 180-day clinical investigation of the tooth whitening efficacy of a bleaching gel with added amorphous calcium phosphate. J Clin Dent 1611-16, 2005.

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.

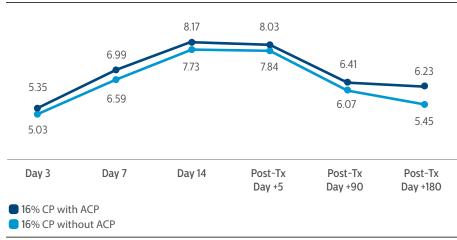
#### Results

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





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