

# Comparison of the Tooth-Whitening Effects of a Direct Application Percarbonate Bleaching Film and Two Commercially available Whitening Dentifrices

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## ABSTRACT

Whitening toothpastes represent the most accessible and widely used approach for improving tooth color. **Objective:** A randomized, placebo-controlled clinical trial was conducted to compare the clinical response of a novel self-directed bleaching film vs two currently marketed whitening toothpastes. **Methods:** Adult volunteers were randomized to: 1) A 19% sodium percarbonate bleaching film + a marketed regular NaF toothpaste or 2) placebo film + PVM/MA copolymer/pyrophosphate whitening toothpaste or 3) placebo film + triclosan/copolymer whitening toothpaste. Once per day for 14 days subjects applied their film, using an applicator brush, to the facial surfaces of their anterior teeth whilst maintaining a regular brushing regimen with their assigned toothpaste. After two weeks use of the bleaching film ceased and subjects continued to use their assigned toothpaste for a further 10 weeks. Digital Image Analysis was used to measure tooth color at baseline, 2, 6 and 12 weeks. **Results:** Of the 79 subjects completing the study only those assigned to the percarbonate bleaching film showed a meaningful change in tooth colour. At two weeks an adjusted mean with standard error for  $\Delta W^*$  of  $-2.75 \pm 0.264$  was recorded for subjects using the bleaching film versus  $-0.42 \pm 0.061$  and  $-0.42 \pm 0.077$  for each of the whitening toothpastes. At 6 weeks an adjusted mean  $\Delta W^*$  of  $-2.46 \pm 0.251$  was observed in the bleaching film group versus  $-0.38 \pm 0.073$  and  $-0.33 \pm 0.06$  for whitening toothpaste groups (2) and (3) respectively. The bleaching film group exhibited superior whitening efficacy to the whitening dentifrices at all post-baseline visits ( $p < 0.0001$ ). **Conclusion:** This research establishes the superior whitening efficacy of a self-applied 19% sodium percarbonate bleaching film compared to two currently marketed whitening toothpastes.

## OBJECTIVE

This randomized clinical trial was conducted to evaluate the efficacy response of a novel bleaching system versus two leading whitening dentifrices.

## MATERIALS AND METHODS

**Study Design:** 79 healthy adult volunteers were randomized, after balancing for age and tooth color, to one of the following treatments:

- 1) Bleaching Film (19% Sodium Percarbonate) with Crest Cavity Protection Dentifrice\*.
- 2) Placebo Control (0% Sodium Percarbonate) with Colgate Total Plus Whitening Dentifrice†.

## MATERIALS AND METHODS (Cont.)

3) Placebo Control (0% Sodium Percarbonate) with Colgate Whitening Dentifrice‡

\* - The Procter & Gamble Company, US

† - Colgate Palmolive Company, US

‡ - Colgate Palmolive Company, Poland.

The Bleaching film and its control were applied using a applicator brush on the anterior facial surfaces of the teeth. The film was kept overnight and application repeated for 2 weeks. The subjects maintained twice a day brushing routine for a further 10 weeks with evaluations 4 and 10 weeks after the bleaching regimen ceased.

**Method:** The color of 6 maxillary and 6 mandibular anterior teeth was measured objectively at baseline, 2, 6 and 12 week visits using digital imaging analysis. Tooth color change from baseline was measured in  $\Delta W^*$  as the difference between  $W^*$  at end-of-treatment and baseline.  $W^*$  measured the overall colour change relative to pure white ( $L^*=100$ ,  $a^*=0$ ,  $b^*=0$ ) and was derived from  $W^* = (a^{*2} + b^{*2} + (L^* - 100)^2)^{1/2}$ .

**Statistical Analysis:** Analysis of covariance was used to determine the mean color change from baseline and treatment differences. Baseline tooth color was used as the covariate in the model.

## RESULTS

Of a total of 79 subjects completing the study, 71 were found to be evaluable. Of these, there were 39 females and 32 males. The subjects ranged from 18 to 38 years of age and the overall mean age was 22 years.

Treatment	Bleaching Film+Crest Cavity Protection	Placebo+Colgate Total Plus Whitening	Placebo+Colgate Whitening
$\Delta W^*$ 2 wk (std error, p-values)	-2.75 (0.26, <0.0001)	-0.42 (0.06, <0.0001)	-0.42 (0.07, <0.0001)
$\Delta W^*$ 6 wk (std error, p-values)	-2.46 (0.25, <0.0001)	-0.33 (0.06, <0.0001)	-0.38 (0.07, <0.0001)
$\Delta W^*$ 12 wk (std error, p-values)	-2.12 (0.20, <0.0001)	-0.09 (0.12, 0.46)	-0.08 (0.12, 0.49)

## DATA

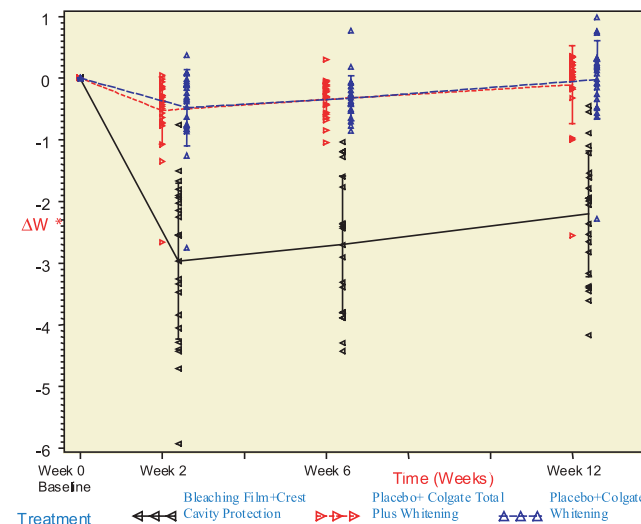
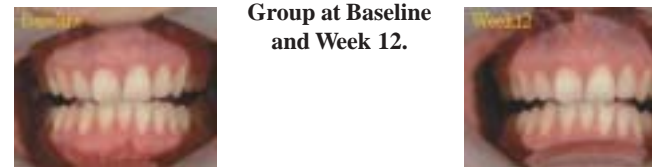


Figure 2 : Digital Images of a Subject in Bleaching Film Group at Baseline, Week 2 and Week 12.



Figure 3 : Digital Images of a Subject in Colgate Whitening Group at Baseline and Week 12.



## CONCLUSION

Objective comparison showed the peroxide containing bleaching film to be more efficacious than two marketed whitening dentifrices.