

Effectiveness of a New Dentifrice with Baking Soda and Peroxide in Removing Extrinsic Stain and Whitening Teeth

A. Ghassemi, PhD W. Hooper, PhD L. Vorwerk, BS T. Domke, BS

Church & Dwight Co., Inc.
Princeton, NJ, USA

P. DeSciscio, DMD S. Nathoo, DDS, PhD

Oral Health Clinical Services, LLC
Piscataway, NJ, USA

Abstract

- **Objective:** The primary purpose of this randomized, controlled, six-week clinical trial was to determine the effectiveness and safety of a new whitening dentifrice in removing extrinsic tooth stain and whitening teeth. An additional two-week exploratory study was conducted to determine whether the whitening or stain-prevention activity of the dentifrice would persist following cessation of use.
- **Methods:** In the first study (Phase I), one-hundred and forty-six qualifying subjects were randomly assigned to either a sodium bicarbonate whitening dentifrice group (Arm & Hammer® Advance White® Extreme Whitening Baking Soda and Peroxide Toothpaste) or a silica-based negative control dentifrice group, and brushed twice daily with their assigned dentifrice for six weeks. Tooth shade on the labial surfaces of the eight incisors was assessed using a Vita Classic shade guide, and extrinsic tooth stain was scored using a Modified Lobene Stain Index (MLSI) at baseline, week 4, and week 6. In Phase II (after the week 6 examination), volunteers from the Arm & Hammer whitening dentifrice group were randomly assigned to continue using the whitening dentifrice or to use the negative control dentifrice twice daily for two weeks. The six-week shade and stain index scores served as the baseline for this exploratory phase and were rescored after two weeks.
- **Results:** The whitening dentifrice group had statistically significant ($p < 0.0001$) mean shade score reductions of 1.82 and 2.57 from baseline to weeks 4 and 6, respectively. For the same periods, the negative control dentifrice group was virtually unchanged from baseline. For tooth stain, the MLSI total mean scores for the whitening dentifrice group showed statistically significant ($p < 0.0001$) decreases from baseline of 1.42 (41.6%) and 2.11 (61.6%) at weeks 4 and 6, respectively. In contrast, the negative control dentifrice group had a MLSI reduction of 0.07 at week 4 and a 0.06 increase at week 6. Between-group analyses using baseline-adjusted ANCOVA showed the whitening dentifrice to be statistically significantly more effective ($p < 0.0001$) than the negative control for shade and tooth stain reductions for all index comparisons. Compared to the six-week (baseline) scores, subjects who continued to use the whitening dentifrice for the additional two weeks experienced statistically significant ($p < 0.0001$) further mean reductions of 0.88 in shade score and 0.46 in MLSI score, while subjects who switched to the negative control dentifrice experienced smaller, statistically significant ($p < 0.05$) reductions of 0.34 in shade score and 0.13 in total MLSI score.
- **Conclusion:** The Arm & Hammer whitening dentifrice tested in this study is effective for removing extrinsic tooth stain and whitening teeth. While the results also suggest that this dentifrice may have stain-prevention activity that persists following cessation of product use, such activity would need to be confirmed with further studies.

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Introduction

Consumers' desire for healthy looking teeth has led to the development and marketing of dentifrices specifically formulated to help whiten teeth, primarily by the removal and prevention of extrinsic tooth stain. While the primary stain removal ingredient in these formulations is the abrasive, additional components are often added to augment stain removal and prevention efficacy, including sources of peroxide to provide bleaching activity and phosphate compounds that are thought to desorb stain components.¹

Dentifrices containing sodium bicarbonate as the sole abrasive have been shown to be effective in stain removal in clinical trials²⁻⁴ and *in vitro* studies.^{5,6} It is noteworthy that in these studies, the sodium bicarbonate dentifrices have been

significantly more effective than the negative control dentifrice containing silica abrasives, even though the dentifrices had similar relative dentin abrasivity (RDA) values. This suggests that the mechanism by which sodium bicarbonate reduces and prevents stain may include a chemical, as well as a mechanical component.

A new whitening dentifrice has been recently introduced (Arm & Hammer® Advance White® Extreme Whitening Baking Soda & Peroxide Toothpaste, Church & Dwight Co., Inc., Princeton, NJ, USA) that is a single-phase anhydrous dentifrice containing 50% sodium bicarbonate, 0.243% sodium fluoride, tetrasodium pyrophosphate, and 1% peroxide as sodium carbonate peroxide. The primary objective of this six-week clinical trial was to evaluate the efficacy of this dentifrice in

whitening teeth with pre-existing extrinsic stain, using both a stain index and a tooth shade determination to provide additional clinical relevance to the outcomes. At the end of the six-week period, an additional two-week exploratory study was conducted to determine whether the whitening or stain-prevention activity of the test dentifrice may persist following cessation of its use.

Materials and Methods

Summary of Study Design

This was a randomized, controlled, double-blind, parallel-group, prospective clinical trial to investigate the safety and effectiveness of a novel dentifrice for both extrinsic stain removal and tooth whitening. The study protocol was reviewed and approved by the Concordia Clinical Research, Inc. IRB, Cedar Knolls, NJ, USA. All subjects provided informed consent prior to entering into the study.

In the first phase of the study, subjects were required to have extrinsic stain on the labial surfaces of the eight anterior teeth, with a mean Modified Lobene Stain Index (MLSI)⁷ ≥ 1.5 and a tooth shade corresponding to shades A2 to B4 on the Vita Classical shade guide (Vident, Brea, CA, USA). Qualifying subjects were randomly assigned to either the test group (Arm & Hammer[®] Advance White[®] Extreme Whitening Baking Soda & Peroxide Toothpaste [Whitening Dentifrice]) or a conventional dentifrice group (Crest[®] Cavity Protection Regular Toothpaste [Negative Control], Procter & Gamble Co., Cincinnati, OH, USA) and instructed to brush twice daily with their assigned dentifrice for six weeks. Extrinsic stain and tooth shade were evaluated at baseline, four, and six weeks. In addition, all subjects received an oral soft tissue examination at each visit to monitor product safety.

In order to evaluate the persistence of stain reduction and whitening following discontinuation of test product use, volunteers from the whitening dentifrice group were enrolled in an additional two-week use study (Phase II). These subjects were randomly assigned to either continue using the whitening dentifrice or to use the negative control dentifrice, with approximately half of the subjects assigned to each group. The final (six-week) stain index and shade scores from the first phase served as the baseline scores for this second study, with subjects re-evaluated at two weeks. Since the purpose of the final two weeks was to measure persistence of stain and shade improvement, only those subjects who showed any improvement in both extrinsic stain and shade at week 6 were included in the data analysis for Phase II.

Study Population

One-hundred and forty-six qualifying male and female subjects between the ages of 19 and 70 were recruited and enrolled into the study. Subjects were required to be in good general health with adequate oral hygiene, have extrinsic stain on the labial surfaces of the eight incisor teeth with a mean MLSI ≥ 1.5 , have labial surfaces of the eight incisor teeth with a shade corresponding to tabs A2 to B4 on the Vita Classical shade guide, and agree to refrain from using any oral care product other than their assigned product for the duration of the study.

Subjects were excluded from the study if they had evidence of neglected dental health and need of prompt professional attention, a serious medical condition or transmittable disease, non-scoreable anterior teeth, a history of allergy to oral care products or known sensitivity to peroxide, a dental prophylaxis within the previous three months, professional or self-applied bleaching during the previous six months, or were pregnant or lactating.

Clinical Procedures

Qualifying subjects received a baseline oral soft and hard tissue examination, after which the shade of the labial surface of the eight incisors was determined by visual assessment using a tooth shade guide,⁸ and the extrinsic stain on these surfaces was scored using the MLSI. Subjects also completed a subjective sensory questionnaire to record any oral symptoms they may have been experiencing. Subjects were randomly assigned to either the test or negative control group by a computer-generated random code. Of the 146 subjects enrolled in the study, 93 were assigned to the whitening dentifrice group and 53 were assigned to the negative control group. This initial disparity in number of subjects per group allowed for appropriate subject numbers in the subsequent exploratory study phase (see below). Subjects were given their assigned dentifrice, a soft toothbrush (Oral-B[®] 35 Indicator[®], Procter and Gamble Co., Cincinnati, OH, USA), a timer, daily diary, and instruction sheet, and instructed to apply the dentifrice to the full length of the toothbrush head and brush for one minute twice daily at home for the six-week duration of the study, with the first use performed under supervision at the clinical site. The dentifrices were dispensed in identical-appearing, white-labeled tubes. The subjects returned to the clinical site after four and six weeks, at which time they received an oral soft tissue examination, were rescored for tooth shade and extrinsic stain, and completed a sensory evaluation form. They also brought their diaries and toothpaste tubes. Compliance with dentifrice use was monitored by comparing the difference in weights of the dentifrice tube at the time it was dispensed and the time it was returned, and by monitoring subject diaries at the four- and six-week examinations.

At the end of the six-week study, subjects in the whitening dentifrice group who volunteered were enrolled in a two-week study to assess the persistence of the whitening effect. Approximately half of these subjects were randomly assigned to continue using the whitening dentifrice and the remaining subjects switched to the negative control dentifrice. The six-week means for these subjects served as the baseline means for this study, with assessments repeated after two weeks.

Clinical Assessments

All the clinical assessments were made by a single, experienced dental examiner who was blinded to the dentifrice used by a given subject. Separate case report forms were used at each examination period for recording the clinical data. The clinical examinations were all conducted under uniform conditions using a standard color-corrected operatory light in a room with a neutral colored decor.

Extrinsic Stain. The labial surfaces of the eight incisors were scored using the Macpherson Modification⁷ of the Lobene Stain Index (MLSI)^{9,10} after any plaque or food debris was removed with a cotton swab. The MLSI was scored by dividing the labial tooth surface into four regions and assessing stain intensity and extent in each of these regions, as follows:

- Gingival (G): 2-mm wide strip running parallel to the gingival margin between the mesial and distal line angles with the tip of the papillae demarcating the upper limit.
- Mesial (M): Visible area between the mesial line angle and adjacent tooth, ending at the interdental papilla.
- Distal (D): Visible area between the distal line angle and adjacent tooth, ending at the interdental papilla.
- Body (B): Central area of the labial tooth aspect, between the gingival and distal/mesial sites, extending to the incisal edge.

The stain intensity in each of these regions was scored according to the following criteria:

- 0 = no stain, natural tooth coloration
 1 = faint stain seen with close examination
 2 = clearly visible orange to brown stain
 3 = dark stain, deep brown to black

For mesial, distal, and gingival regions with intensity scores > 0, the stain area (extent) was scored according to the following criteria:

- 1 = thin line of stain, which can be discontinuous
 2 = thick line or band of stain
 3 = stain covering the entire area

For body regions with intensity scores > 0, the stain area (extent) was scored according to the following criteria:

- 1 = stain limited to pits/grooves
 2 = stain outside pits/grooves, with up to 10% of the area affected
 3 = stain outside pits/grooves, with more than 10% of the area affected

The total MLSI for each tooth was obtained by multiplying the corresponding area and intensity scores from each region. The mean per-subject index score was obtained by averaging the total scores over the number of sites scored.

Tooth Shade. The tooth shade of the labial surface of each of the eight incisors was graded using the Vita Classical shade guide as the reference standard. For each assessment, the tooth was wiped dry and the tooth surface compared with the shade guide tab that most closely corresponded to it. For purposes of analysis, the sixteen shade tabs were arranged from lightest (B1) to darkest (C4) shade, with each shade given a sequential numerical ranking from 1 to 16. A mean subject shade score was obtained by adding the color ranking values and dividing the sum by the number of teeth examined.

Oral Soft Tissue. The buccal, labial, and sublingual mucosa, lips, attached gingiva, tongue, hard and soft palates, uvula, and oropharynx were examined at baseline and at four and six weeks for signs of inflammation, infection, ulceration, or other pathology. Any changes in the course of the study

were recorded and an assessment made by the examiner as to whether or not they could be attributable to the test dentifrice.

Statistical Analyses

The study outcome variables were tooth shade, stain area, stain intensity, and total stain (area x intensity). Within-group comparisons were performed by comparing baseline to four- and six-week scores using paired t-tests. Between-group comparisons were performed using an analysis of covariance (ANCOVA) model with baseline values as the covariate. Post-ANCOVA treatment comparisons were made using t-tests. All treatment comparisons were based on two-sided tests with a level of significance of $\alpha = 0.05$. The same analytic plan was used to compare baseline and two-week values for the exploratory study.

Results

One-hundred and forty-six subjects were randomized into the initial six-week study, of whom one-hundred and thirty-five (86 in the whitening dentifrice group, 49 in the negative control group) satisfied all the protocol requirements and constituted the evaluable subject population. The eleven subjects not completing the study were exited for reasons unrelated to the study dentifrices. The baseline demographic and clinical characteristics for the per-protocol study population are shown in Table I.

Table I
 Baseline Characteristics of Subjects Completing the Six-Week Clinical Trial (Phase I)

	Whitening Dentifrice n = 86	Negative Control n = 49
Gender		
Male	40 (47%) [#]	18 (37%)
Female	46 (53%) [#]	31 (63%)
Age (Years)		
Mean	40.14	37.80
Range	19-70	19-67
Tooth Shade*	9.77 (2.26)	9.17 (2.14)
Extrinsic Stain**		
Area	2.07 (0.40) [#]	1.93 (0.28)
Intensity	1.58 (0.32)	1.50 (0.28)
Total	3.43 (1.06) [#]	3.03 (0.79)

*Mean (SD) Vita Classic shade guide tab number.

**Mean (SD) MLSI score.

[#]Significantly different from negative control, $p < 0.05$.

The oral mucosal examinations and subjective sensory responses indicated that there were no clinically significant findings or product-related adverse events during the course of the study. Statistical comparison of mean usage rates estimated from dentifrice tube weights indicated comparable daily usage by both groups, with mean usage for the test and negative control of 1.39 (0.77) and 1.51 (0.92) gm, respectively ($p = 0.775$).

Tooth Shade

The mean Vita Classic shade guide scores at weeks four and six are presented in Table II. Within-group analyses indicated that the whitening dentifrice group had statistically

Table II
Summary of Mean Shade Scores for Subjects Completing the Six-Week Clinical Trial (Phase I)

Group	n	Mean Shade Score (SD)	Within-Treatment Analysis		Between-Treatment Comparison ³	
			Reduction in Score ¹ (Mean SD)	p-value ²	Difference	p-value
Week 4						
Whitening Dentifrice	86	7.95 (2.30)	1.82 (0.80)	< 0.0001	1.74	< 0.0001
Negative Control	49	9.10 (2.26)	0.07 (0.42)	0.4298	----	----
Week 6						
Whitening Dentifrice	86	7.20 (2.22)	2.57 (0.99)	< 0.0001	2.57	< 0.0001
Negative Control	49	9.21 (2.29)	-0.04 (0.69)	0.9137	----	----

¹Reduction in mean shade score between baseline and four- and six-week assessments.

²Significance level of paired t-tests comparing baseline mean with four- and six-week means.

³Difference in mean shade score reductions and significance of ANCOVA comparison using baseline-adjusted means.

significant ($p < 0.0001$) mean shade score reductions of 1.82 and 2.57 from baseline to four and six weeks, respectively. The negative control group was virtually unchanged during this period, with a non-significant decrease of 0.07 at week 4 and a slight increase of 0.04 at week 6. An ANCOVA using adjusted mean differences from baseline revealed that the whitening dentifrice was statistically significantly more effective than the negative control ($p < 0.0001$) at both examination periods, with a 1.74 lower tooth shade score at week 4 and a 2.57 lower tooth shade score at week 6.

Tooth Stain

Intensity. The mean MLSI intensity, area, and total scores at weeks 4 and 6 are presented in Table III. Within-group analyses indicated that the whitening dentifrice group had statistically significant ($p < 0.0001$) stain intensity score reductions from baseline of 0.36 (22.9%) and 0.56 (35.6%) at four and six weeks, respectively. In contrast, the negative control had an unchanged intensity score at week 4 and a slight increase of 0.04 (2.4%) at week 6. An ANCOVA using adjusted mean differences from baseline revealed that the whitening dentifrice was statistically significantly more effective than the negative control ($p < 0.0001$) at both examinations.

Area. Within-group analyses indicated that the whitening dentifrice group had statistically significant ($p < 0.0001$) stain area score reductions from baseline of 0.49 (23.6%) and 0.91 (43.8%) at four and six weeks, respectively. In contrast, the negative control group had a smaller, but statistically significant reduction of 0.07 (3.4%) at week 4 and a non-significant reduction of 0.02 (0.9%) at week 6. An ANCOVA using adjusted mean differences from baseline revealed that the whitening dentifrice was statistically significantly more effective than the negative control ($p < 0.0001$) at both examinations.

Total Stain. Within-group analyses indicated that the whitening dentifrice group had statistically significant ($p < 0.0001$) total stain score reductions from baseline of 1.42 (41.6%) and 2.11 (61.6%) at four and six weeks, respectively. In contrast, the negative control group had a smaller, but statistically significant reduction of 0.07 (2.2%) at week 4 and non-significant increase of 0.06 (1.9%) at week 6. An ANCOVA using adjusted mean differences from baseline revealed that the whitening dentifrice was statistically significantly more effective than the negative control ($p < 0.0001$) at both examinations.

Table III
Summary of MLSI Scores for the Six-Week Clinical Trial (Phase I)

Group	n	Mean MLSI Score (SD)	Statistical Significance vs. Negative Control ¹
Stain Intensity - Week 4			
Whitening Dentifrice	86	1.22 (0.24)	$p < 0.0001$
Negative Control	49	1.50 (0.27)	
Stain Intensity - Week 6			
Whitening Dentifrice	86	1.02 (0.24)	$p < 0.0001$
Negative Control	49	1.54 (0.30)	
Stain Area - Week 4			
Whitening Dentifrice	86	1.58 (0.35)	$p < 0.0001$
Negative Control	49	1.87 (0.28)	
Stain Area - Week 6			
Whitening Dentifrice	86	1.16 (0.35)	$p < 0.0001$
Negative Control	49	1.92 (0.33)	
Stain, Total - Week 4			
Whitening Dentifrice	86	2.00 (0.79)	$p < 0.0001$
Negative Control	49	2.96 (0.82)	
Stain, Total, Week 6			
Whitening Dentifrice	86	1.32 (0.63)	$p < 0.0001$
Negative Control	49	3.09 (0.92)	

¹Result of ANCOVA comparison of baseline-adjusted means.

Persistence of Whitening

Eighty-three subjects from the original whitening dentifrice group completed the two-week study, with 39 randomly assigned to continue using the whitening dentifrice and 44 randomly assigned to the negative control. The six-week mean shade and MLSI scores for the randomized participating subjects served as the baseline scores for this study. The demographic characteristics and baseline scores of the population are presented in Table IV. The two groups were comparable demographically and with respect to clinical parameters. The mean two-week shade guide and MLSI scores are presented in Tables V and VI, respectively. Compared to the six-week (baseline) scores, subjects who continued to use the whitening dentifrice for the additional two weeks experienced statistically significant ($p < 0.0001$) further mean reductions of 0.88 (12.4%) in shade score and 0.46 (36.8%) in total MLSI score; subjects who switched to the negative control also

experienced statistically significant ($p < 0.05$), though smaller reductions of 0.34 (4.6%) in shade score and 0.13 (9.9%) in total MLSI score.

Table IV
Persistence of Effect Study (Phase II): Demographic Characteristics and Baseline Scores

	Whitening Dentifrice n = 39	Negative Control n = 44
Gender		
Male	19 (49%)	21 (48%)
Female	20 (51%)	23 (52%)
Age (Years)		
Mean (S.D.)	41.66 (12.77)	39.95 (15.46)
Tooth Shade*	7.04 (2.34)	7.42 (2.07)
Extrinsic Stain**		
Area	1.12 (0.32)	1.19 (0.34)
Intensity	1.00 (0.24)	1.02 (0.25)
Total	1.26 (0.54)	1.35 (0.66)

*Mean (SD) Vita Classic shade guide tab number.

**Mean (SD) MLSI score.

Discussion

In view of consumers' desire for white, healthy looking teeth, there is an ongoing effort to develop new dentifrice formulations that deliver enhanced stain removal efficacy without increased abrasivity. This often results in the inclusion of chemical agents in formulations to augment the stain removal and prevention activity of the abrasive. Accordingly, the new whitening dentifrice tested in this study contained, in addition to sodium bicarbonate, both a hydrogen peroxide source and a pyrophosphate component. The effectiveness of this dentifrice was tested using a regular (non-whitening) dentifrice having a silica-based abrasive system as a negative control. Of note is the fact that although the test and control dentifrices had similar relative dentin abrasivity values (whitening dentifrice RDA = 88; negative control dentifrice RDA = 95), there were marked differences in effectiveness between the two products.

The results of this study demonstrate that Arm & Hammer Advance White Extreme Whitening Baking Soda & Peroxide Toothpaste is both effective and safe for removing extrinsic tooth stain and whitening teeth. Over the six-week test period, this dentifrice produced a statistically significant 61.6% reduction from baseline in total stain compared to a non-significant slight increase in stain in the negative control group. Compared to the negative control, the whitening dentifrice produced 61.1%

Table VI
Persistence of Effect Study (Phase II): Summary of Mean MLSI Scores

Group	n	Mean MLSI Score (SD)	Statistical Significance vs. Negative Control ¹
Stain Intensity - Week 2			
Whitening Dentifrice	39	0.72 (0.25)	$p < 0.0001$
Negative Control	44	0.96 (0.26)	
Stain Area - Week 2			
Whitening Dentifrice	39	0.77 (0.33)	$p < 0.0001$
Negative Control	44	1.09 (0.41)	
Stain, Total - Week 2			
Whitening Dentifrice	39	0.80 (0.36)	$p < 0.0001$
Negative Control	44	1.21 (0.70)	

¹Result of ANCOVA comparison of baseline-adjusted means.

lower total stain scores by six weeks. The tooth shade findings are indicative of the clinical relevance of the extrinsic stain reductions. That is, over the six-week period the whitening dentifrice group experienced a statistically significant mean shade reduction of 2.57 Vita Classic shade guide tabs while the mean shade of the negative control group remained essentially unchanged.

It is interesting that during the subsequent two-week study period, the subjects initially on the whitening dentifrice (for six weeks) who continued brushing with the same whitening dentifrice, as well as those who switched to brushing with the negative control dentifrice experienced additional extrinsic stain reductions from the baseline (original six-week) scores. Subjects who continued using the whitening dentifrice had an additional statistically significant total stain reduction from the week-six baseline of 36.8% as compared to a mean 9.9% reduction in subjects who were randomized to the negative control dentifrice. The finding of continued stain reduction, rather than increase, in the negative control group over the two-week period suggests that the whitening dentifrice may have stain reduction and prevention activity that persists following cessation of product use. However, a further longer-term study would be needed to confirm this.

Acknowledgement: This study was funded by the Church & Dwight Co., Inc.

Table V
Persistence of Effect Study (Phase II): Summary of Mean Shade Scores

Group	n	Mean Shade Score (SD)	Within-Treatment Analysis		Between-Treatment Comparison ³	
			Mean Reduction in Score ¹ (SD)	p-value ²	Difference	p-value
Week 2						
Whitening Dentifrice	39	6.17 (2.31)	0.88 (0.75)	< 0.0001	0.55	0.0009
Negative Control	44	7.08 (2.21)	0.34 (0.69)	0.0030	-----	-----

¹Reduction in mean shade score between baseline and two-week assessment.

²Significance level of paired t-test comparing baseline mean with two-week mean.

³Difference in mean shade score reductions and significance of ANCOVA comparison using baseline-adjusted means.

For further correspondence with the authors of this paper, contact Annahita Ghassemi—annahita.ghassemi@churchdwright.com.

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