Independent Scientific Clinical Study of Safety and Efficacy:
14 Day Combined Use of New POPWHITE® Toothpaste and Oral Rinse

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DATES OF STUDY: February 08, 2019 – February 21, 2019

CLAIMS TESTED: 14-Day Use Claims:
- Use of PopWhite Toothpaste & Oral Rinse achieves an average of 6 shades or better in
- 14 days PopWhite Toothpaste & Oral Rinse whitens better than market leading whitening toothpaste

Same Day (One Use) Claims
- Use of PopWhite Toothpaste & Oral Rinse achieves an average of 2 shades or better in 1 day
- PopWhite Toothpaste & Oral Rinse whitens better than market leading whitening toothpaste

Safety Claims:
- Use of PopWhite Toothpaste & Oral Rinse causes no significant tooth sensitivity
- Use of PopWhite Toothpaste & Oral Rinse causes no significant gum irritation
- Use of PopWhite Toothpaste & Oral Rinse causes no adverse reactions or tissue pathology

Consumer Perceptions:
- PopWhite Toothpaste & Oral Rinse is easy to apply
- PopWhite Toothpaste & Oral Rinse makes teeth noticeably whiter after just one day
- PopWhite Toothpaste & Oral Rinse causes no sensitivity

MAJOR OBJECTIVES: The major objective of the study was to test the safety and effectiveness of a combined regimen of a newly manufactured version of POPWHITE® Toothpaste and Oral Rinse, which contains a patented purple tinted color correcting technology that delivers a whitening enhancement formulation to the teeth while brushing and rinsing. The recommended protocol is brushing and rinsing twice daily for 2 minutes (brushing) and 1 minute (rinsing), yielding a 6-minute daily total exposure.

The study was conducted in accordance with the Guidelines for Good Clinical Practice and ADA Guidelines for Testing of Toothpaste and Home Whitening Products.

STUDY METHODS: Fifteen (15) subjects were assigned to the experimental study group. The same toothbrushes (Oral-B Pro-Health Soft Full Head Toothbrush) were given to all 15 subjects to brush their teeth. Before starting the study, oral hygiene instruction was given to subjects, including tooth brushing times and technique. Subjects were instructed to brush and rinse their teeth twice a day with the Popwhite® Toothpaste and Oral Rinse, in the morning after breakfast and in the

evening before sleeping. Subjects were not given any instructions about drinking and eating, and were allowed to follow their previous patterns for these activities.

As per the protocol established by the American Dental Association, two experienced, trained examiners, who have achieved a 90% agreement during a pre-study calibration, performed the oral soft tissue examinations and shade assessments at baseline. Shade assessments were made by comparing the shade tabs from a Vita shade guide, with the facial aspects of the upper and lower central incisor teeth and selecting the closest matching shade.

Teeth shades of subjects were evaluated, near one window, between 10:00 am and 12:00 am in natural light, so as to simulate real life perceptions of teeth lightness. The examinations took place at the following time intervals: Baseline, Day 1, Day 7 and Day 14. All subjects were asked to sign consent forms and were asked to complete a brief baseline consumer perception survey.

Subject Demographics:
Subjects were chosen from a pool of candidate living in the South Florida area (Palm Beach and Broward Counties). All subjects will range between 18 – 85 years in age. Four (4) of the subjects identified themselves as smokers (at least ½ pack per day or use of electronic cigarettes).

Product Use Protocols:
Procedure for the study was as follows:
1. Baseline tooth shade was recorded using Vita-Shade Guide and Spectrophotometer
2. Participants were provided with a toothbrush and Popwhite® Toothpaste (4 oz. tube) and Popwhite Oral Rinse (16.9 oz. bottle).
3. Participants dispensed a bead of test toothpaste on the toothbrush and were timed as they brush for 2 minutes, and then they rinsed their mouth with a capful of oral rinse for 1 minute.
4. Participants were instructed to follow this procedure and use product twice daily for 6 minutes total exposure time each day. The product was to be used for 2 weeks (14 days).

Statistical analysis:
Data from the study were entered into statistical software (SSPS for Mac, Version 15.0; SPSS Inc., Chicago, USA). The Student's T-test, Fisher's exact chi-square test, and ANOVA analysis was used to compare the quantitative data from the study. Results were tested for significance at the ($p < 0.05$) level.

Ethics:
An Expedited IRB Study Approval application was submitted due to the non-invasive nature of the proposed study. The study was conducted in accordance with the Guidelines for Good Clinical Practice and ADA Guidelines for Testing Home Use Whitening Products. All procedures were reviewed by PSC Research Institute Principal Investigator (Dr. Martin Giniger) and followed manufacturer's published or proposed directions for treatment application. Study subjects were required to sign an informed consent form and met all entrance requirements.

Inclusion Criteria:
1. Male and female Subjects in good general health and between the age 18 to 85 years at the time of enrollment with a tooth shade greater than or equal to A3 for all six non-restored maxillary anterior teeth prior to treatment.
2. Subjects have to be willing to not use any other dental whitening product, with the exception of toothpaste, during the course of the study
3. Preference will be given to person who smoke at least ½ pack of cigarettes per day (at least 7 participants who smoke in each group)

4. Preference will be given to study participants over the age of 50 (at least 7 participants over age 50 in each group)
5. Participants will be asked to refrain from consumer dark foods / beverages that tend to stain teeth for ½ hour after the application of their assigned product during the course of the study.

Exclusion Criteria:
1. Subjects with fewer than 6 gradable anterior maxillary teeth or subjects whose anterior maxillary teeth have had restorations, dentures or dental implants.
2. Subjects who have had a dental cleaning procedure within the last 6 months.
3. Subjects who reported current sensitivity on maxillary anterior teeth.
4. Subjects with a history of sensitivity to peroxides or glycols and a documented history of untreated caries, dentin exposure, recession, abfractions, cracks or chips on the teeth to be treated or severely malposed anterior teeth.
5. Subjects with a history of diabetes or any other systemic disease, which in the Investigator's opinion could have interfered with the assessment of the oral soft/hard tissue
6. Subjects taking any photo-reactive medications
7. Subjects who had previously used teeth whitening gels or peroxide-based teeth bleaching products within the last 6 months.

Assessment of Tooth Color Change:
Two examiners were available to assess Vita Shade Score. The primary examiner was a well-experienced and calibrated dentist. The second examiner is Dr. Martin Giniger, who also served as a project director and is a published and well known, experienced authority in the measurement of teeth color. For consistency's sake, and to ensure maximum impartiality, the primary examiner determined all Vita Shade Scores. The second examiner (Dr. Martin Giniger; project director) was used when the primary examiner felt that he had become un-blinded (with regard to which product is being used), or when he felt that he could not decide on a definitive shade match. When the second examiner was called into action, the decisions of the second examiner was used as the final determination of Vita Shade Score.

Shade change was calculated by determining the change in the number of shade guide units that occurred toward the lighter end of the value-oriented list of shade tabs. Although the scale is not in the truest sense linear, the changes were treated as representing a continuous and approximately linear ranking for the purpose of analysis as is standard practice in the dental literature.

As detailed below, the Vita Shade Score was used to determine the general efficacy of teeth whitening caused by the Experimental and Control products. In order to measure the efficacy of deep set stain removal, we utilized a specially calibrated spectrophotometer (Minolta CR-321Chromameter) in accordance with ADA guidelines for acceptance of teeth whitening products (reference: Tavares et al. Light augments tooth whitening with peroxide. J Am Dent Assoc 2003;134;167-175) with the meter set at a depth of 1.5mm. We intend to report here both measures of teeth whiteness (Superficial and 1.5 mm Deep).

Vita Shade Assessment for Measurement of Surface Tooth Color:
The principal investigator assessed tooth color change of each subject's teeth in a room with color corrected lighting (5500K light bulbs). A blue bib was placed over clothing and the dental light turned off. Subjects were instructed not to wear lipstick and to sit in a position where the teeth in the maxillary arch were parallel to the floor during the evaluation. Anterior maxillary teeth #6 through #11 will be used for assessment. Gradations within the value-oriented Vita® Shade Guide (Vita Zahnfabrick GmbH,

Sackingen, Germany) were utilized. The shade guide was arranged in the chromatic rank order [1 = lightest shade; 16 = darkest shade] as recommended by the manufacturer and described in the literature. Shade change was calculated by determining the change in the number of shade guide units that occurred toward the lighter end of the value oriented list of shade tabs. Although the scale is not in the truest sense linear, the changes will be treated as representing a continuous and approximately linear ranking for the purpose of analysis as is standard practice in the dental literature.

Spectrophotometer Assessment of Tooth Lightness:
To measure the ability of the Experimental and Control Products to affect deep set stains, we used a Minolta CR-321 spectrophotometer to record triplicate L* measurements of the baseline and maxillary central incisor teeth at each examination interval. The meter was calibrated according to manufacturer's instructions and set at a depth of 1.5 mm for the measurement of deep set stains. For each measurement, the spectrophotometer tip was carefully placed in the center of each tooth, assuring that it was parallel and flush against enamel surface. After each reading obtained, the meter tip was repositioned carefully in a similar manner. The mean of the three-recorded L* values for each tooth was entered into a spreadsheet for each examination interval. The group means, standard deviation calculations and T-test statistical analyses were derived from these values. We used L* as the objective measurement of tooth lightness because it is derived from the CIE LAB perceptual color space, the most commonly used color space in studies of human tooth color. We also believe that using L* would yields most accurate and objective assessment of whitening efficacy because L* vector is the only one that is visually uniform. Furthermore, small movements in L* value are more clinically visible than a* or b*, and hence likely to be the most clinically relevant. Finally, we believe that L* to be a good choice since the overall objective of tooth bleaching is to visibly "lighten" the color of teeth.

RESULTS:

Fifteen subjects were assigned to the experimental study group. The same toothbrushes (Oral-B Pro-Health Soft Full Head Toothbrush) were given to all 15 subjects to brush their teeth. Before starting the study, oral hygiene instruction was given to subjects, including tooth brushing times and technique. Subjects were instructed to brush and rinse their teeth twice a day with the Popwhite® Toothpaste and Oral Rinse, in the morning after breakfast and in the evening before sleeping. Subjects were not given any instructions about drinking and eating, and were allowed to follow their previous patterns for these activities.

DEMOGRAPHICS:
All subjects were residents of South Florida and all major races were represented in the study groups. All subjects were healthy and had healthy, natural maxillary teeth that were judged to have a Vita shade of A3 or darker.

1. Mean age of subjects was 47.5 ± 13.2 years. Age range was 18-85 years.
2. At least 4 persons in each group identified themselves as cigarette smokers (at least 1/2 pack per day).
3. The experimental group consisted of 5 females and 10 males

WHITENING EFFICACY RESULTS:

We judged the whitening efficacy of the Control and Test products using Vita Shade Score analysis and confirming the results with a Minolta CR-321 Spectrophotometer according to ADA Guidelines and industry standards.

Table 1 and Table 2 (Whitening) below shows the "Mean Vita Shade Score" for all the subjects groups at the nine (9) measurement intervals. That data shows that combined use of POPWHITE® toothpaste and oral rinse caused a HIGHLY significant improvement (p < 0.05) after just one use. The data also shows:

1. Use of PopWhite Toothpaste & Oral Rinse achieves an average of 2 shades or better in 1 day (same-day results)

2. Use of PopWhite Toothpaste & Oral Rinse achieves an average of 4 shades or better in 7 days

3. Use of PopWhite Toothpaste & Oral Rinse achieves an average of 6 shades or better in 14 days

Table 1 shows the *Mean* Vita Shade Scores of all 15 participants after 1, 7 and 14 days of use along with standard deviations.

Table 2 shows the *CHANGE in* Vita Shade Scores of all 15 participants after 1, 7 and 14 days of use along with statistical significance. In all cases, the results were highly statistically significant.

TABLE 1				
MEAN VITA SHADE SCORES AFTER COMBINED USE OF POPWHITE® TOOTHPASTE AND ORAL RINSE				
STUDY GROUP	BASE	DAY 1	DAY 7	DAY 14
EXPERIMENTAL (n=15)	9.80	5.95	4.60	3.70
NOTES:				
Day 1 SD = ±1.3				
Day 7 SD = ±1.3				
Day 14 SD = ±1.4				

TABLE 2				
MEAN CHANGE IN VITA SHADE SCORE AFTER COMBINED USE OF POPWHITE® TOOTHPASTE AND ORAL RINSE				
STUDY GROUP	BASE	DAY 1	DAY 7	DAY 14
EXPERIMENTAL (n=15)	--	3.85	5.2	6.1
NOTES:				
Day 1 (significant; p <0.01)				
Day 7 (significant; p <0.01)				
Day 14 (significant; p <0.01)				

Table 3 (Brightening) below shows the "Mean Spectrophotometer L* Score" for all the subjects groups after the first measurement interval. It shows that PopWhite Toothpaste and Oral Rinse caused a significant improvement ($p < 0.01$) in brightening after just one use.

After just 1 day, the brightness increased 71.5 – 66.9 = 4.6 L* brightness units (equivalent to ~3.85 ± 1.0 shades)
After just 7 days, the brightness increased 75.1 – 66.7 = 8.4 L* brightness units (equivalent to ~5.2 ± 1.3 shades)
After just 14 days, the brightness increased 79.0 – 66.7 = 12.3 L* brightness units (equivalent to ~6.1 ± 1.7 shades)

TABLE 3			
MEAN COLORIMETER MACHINE MEASUREMNT OF TEETH BRIGHTNESS (L*) COMBINED USE OF POPWHITE® TOOTHPASTE AND ORAL RINSE			
STUDY GROUP BASE	DAY 1	DAY 7	DAY 14
EXPERIMENTAL (n=15) 66.7	71.5	75.1	79.0
NOTES:			
Day 1 SD = ±1.0			
Day 7 SD = ±1.3			
Day 14 SD = ±1.7			
Each measurement interval results are statistically significant (p <0.01)			

FIGURE 1

EXAMPLE OF WHAT 6 VITA SHADE IMPROVEMENT LOOKS LIKE TO SET EXPECTATIONS

6 SHADE IMPROVEMENT
ON VITA SHADE GUIDE
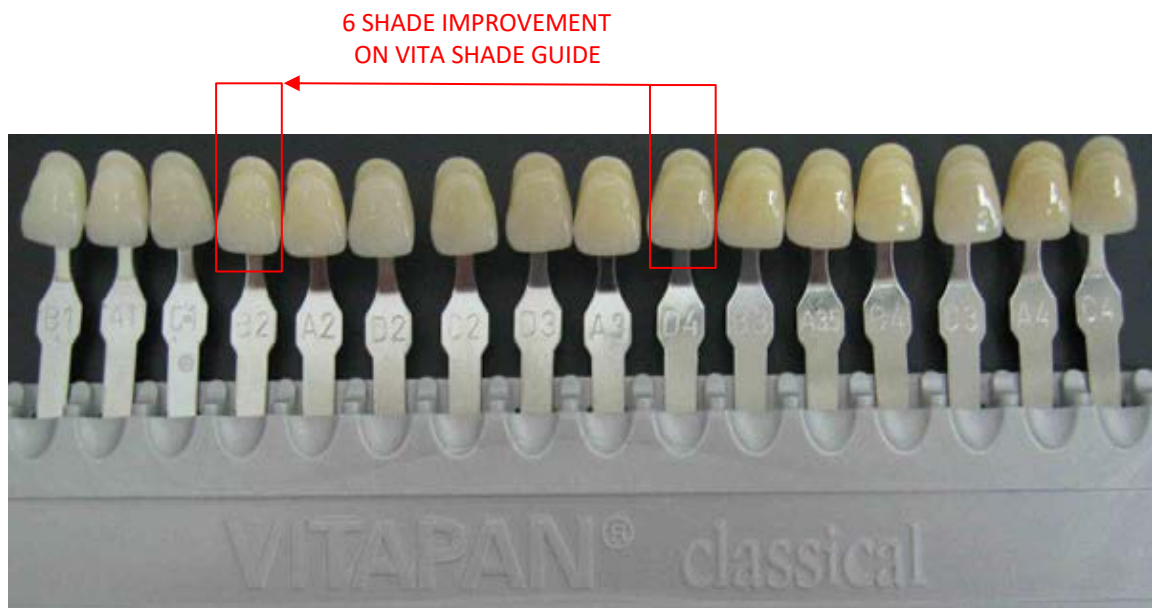
CLINICAL PHOTOGRAPHS:

Clinical Photographs of Subjects before use, and after 14 days of use of new formula PopWhite® Toothpaste & Oral Rinse. All photos show impressive natural-looking whitening and brightening of teeth using only PopWhite® Toothpaste & Oral Rinse and no other whitener. All skin tones match, as environmental brightness and lighting was carefully controlled. A Canon® EOS T6i camera was used for all clinical photographs. A Canon® EF-5 Zoom Lens was attached to camera and a ring flash was used.

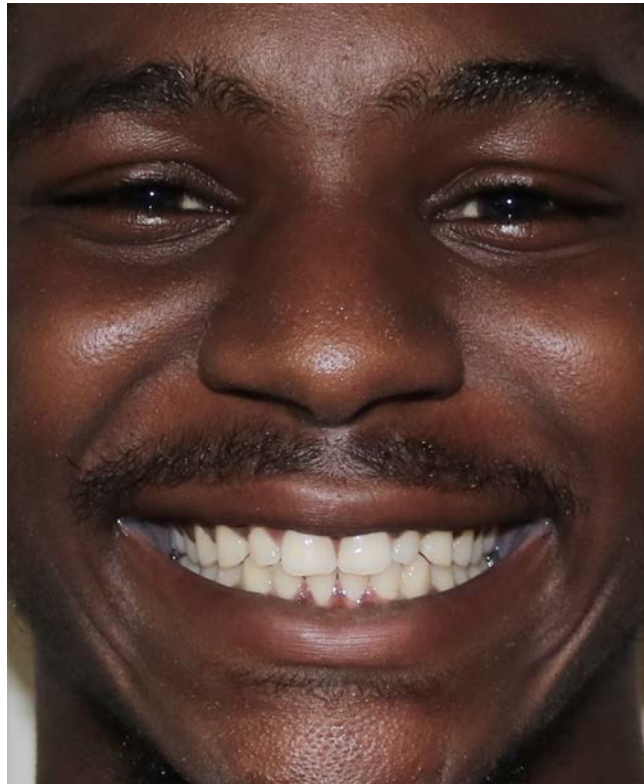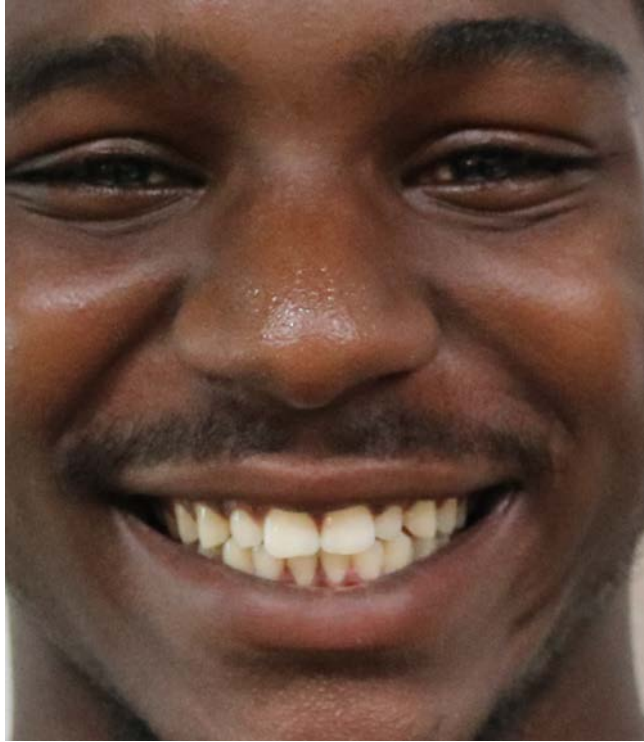**JEFF (Subject 1)**

CHRISTIAN (SUBJECT 4)

SETH (SUBJECT 5)

JAKE (SUBJECT 6)

LARRY (SUBJECT 8)

KATHERINE (SUBJECT 9)

LORI (SUBJECT 10)
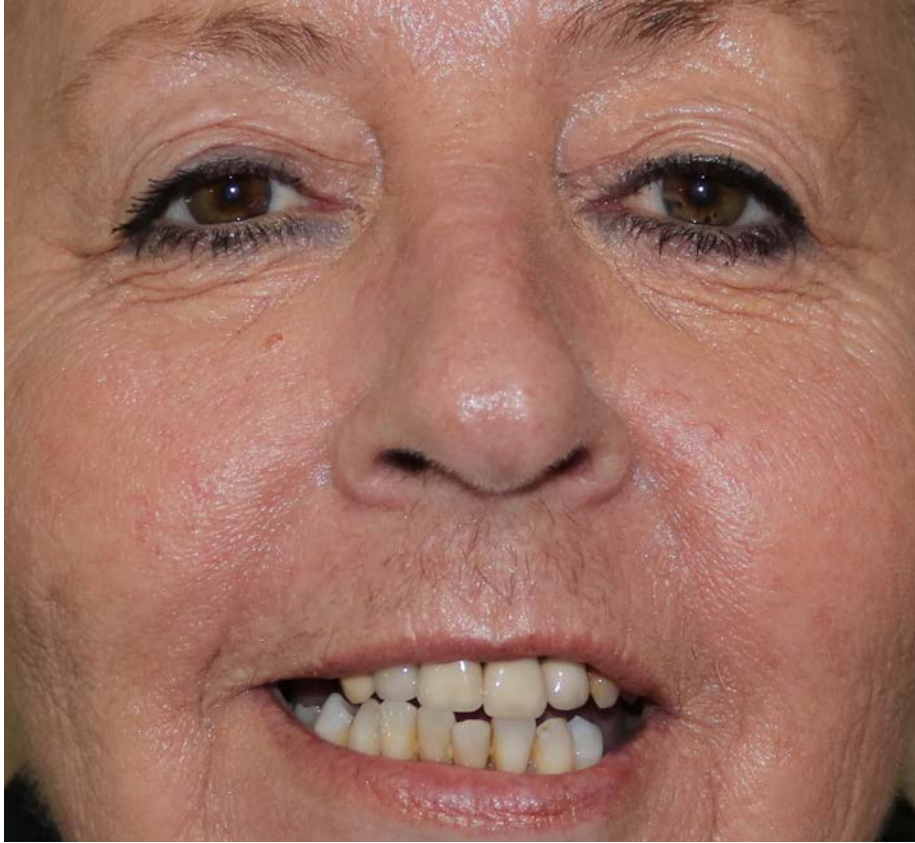
COURTNEY (SUBHECT 13)

DAVID (SUBJECT 14)

PAUL (SUBJECT 15)

SAFETY:
We judged safety of the Control and Test products based on the results of Loe and Silness Ginigival Index scoring, VAS Sensitivity Index scoring and through thorough monitoring the hard tissue / soft tissue oral health of the 60 subjects entered in the study.

Overall Safety:
We found that there were no ill effects caused by the use of any of the products in all subjects tested. There were no adverse reactions found and there were no tissue changes found.

Gum Response:
We found that the PopWhite Toothpaste & Oral Rinse was very gentle to the gingival tissue and did not cause any significant gum irritation as shown in Table 3. Scoring was as follows: 0—normal gingiva; 1—mild inflammation (slight color changes and edema; no BOP); 2— moderate inflammation (redness, edema, and glazing; BOP); 3—severe inflammation (marked redness, edema, ulceration; tendency toward spontaneous bleeding); Thus any mean reduction, can be interpreted as healthier gums. There was no significant change at day 1 and day 7 (p > 0.05), however at day 14 there was a small but significant improvement to gingival health (p < 0.05).

TABLE 3				
MEAN CHANGE IN GINGIVAL INDEX SCORE				
STUDY GROUP	BASE	DAY 1	DAY 7	DAY 14
EXPERIMENTAL (n=15)	--	-0.2	-0.3	-0.75
NOTES:				
Day 1 (significant; p <0.247)				
Day 7 (significant; p <0.145)				
Day 14 (significant; p <0.05)				

Teeth Sensitivity:
We found that the PopWhite Toothpaste & Oral Rinse did not cause any teeth sensitivity, and in fact at Day 14 is slightly reduced sensitivity, although this was no statistically significant. Subjects will be asked to self-assess sensitivity (without exogenous stimuli) by recording their perceived sensitivity on each of the six maxillary teeth using a scale of 0-10 with the pain defined as:

- 0 No pain or barely noticeable tooth sensitivity
- 1-3 Mild pain
- 4-6 Moderate pain
- 7-9 Severe pain, not constant
- 10 The most excruciating pain, constant

TABLE 4				
MEAN CHANGE IN V.A.S. TEETH SENSITIVITY SCORE				
STUDY GROUP	BAS	DAY 1	DAY 7	DAY 14
EXPERIMENTAL (n=15)	--	0	0	-0.05
NOTES:				
Day 1 - No change in teeth sensitivity				
Day 7 - No change in teeth sensitivity				
Day 7 - No significant change in teeth sensitivity (p = 0.347)				

CONSUMER PERCEPTIONS:

We were asked to administer a post-use consumer surveys to all subjects. Below is a summary of the responses:
  i.   I believe the whitening products are effective at making my smile whiter: **100% Agreed**
  ii.   I believe the whitening products are easy to use: **100% Agreed**
  iii. Using the products improve the look of my smile: **100% Agreed**
  iv.   My teeth look brighter after using the products: **100% Agreed**
  v.   The products reduced the yellowness of my teeth: **100% Agreed**
  vi.   The products removed stains on my teeth: **100% Agreed**
  vii. The products seem to help whiten my existing dental work (artificial tooth surfaces – ex. veneers, bonding caps): **100% Agreed** (of people who had dental work)
  viii. My teeth look better immediately after using the products: **100% Agreed**
  ix.   I did not experience any pain or sensitivity when using the products
  x.   The products tasted Minty or Fresh: **100% Agreed**
  xi.   The products were easy to use: : **100% Agreed**
  xii. I would recommend the products to a friend: **100% Agreed**

CLAIMS VERIFIED: **FOR SUJECTS OF ALL AGES – POPWHITE Toothpaste System:**

1. Whitens teeth 3.85 shades in just 1 day simply by brushing and rinsing 2x/day
2. Whitens teeth 5.2 shades in 7 days simply by brushing and rinsing 2x/day
3. Whitens teeth 6.1 shades in 14 days simply by brushing and rinsing 2x/day
4. Safe to use
5. Doesn't cause irritation of gums or tooth pain/sensitivity
6. Whitens better than the leading "whitening" toothpaste that doesn't contain peroxide (Crest Vivid White)
7. Whitens better than the leading whitening toothpaste that contains peroxide (Colgate Optic White)
8. Possible to see visible results within in just one day (Achieves a mean of 1.5 shades)
9. System whitens "intrinsic" as well as "extrinsic" stains such as tobacco
10. This system has no harsher abrasives than any other whitening toothpaste
11. This whitens 97% better than your typical "whitening" toothpaste.
12. This whitens 57% better than the "whitening" toothpastes that actually DO contain whitening ingredients, like peroxide.

TESTIMONIAL: All of the claims that were requested to be tested by POPWHITE Inc. was "verified to be true" by our clinical scientists and we stand behind these findings under the testing conditions described above.

VERIFIED: X _____   Date: February 21, 2019

                   Martin Giniger, DMD, MsD, PhD, FICD
                   Principal Investigator