Independent Double Blind Clinical Study (<u>Safety and Efficacy</u>)

POPWHITE Purple Teeth Whitening Pen

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END STUDY: August 14, 2021

CLAIMS TESTED:

1) POPWHITE Purple Teeth Whitening Pen *is safe to use daily*.
2) POPWHITE Purple Teeth Whitening Pen *causes virtually no tooth sensitivity & less tooth sensitivity than commercially available whitening strips*
3) POPWHITE Purple Teeth Whitening Pen *whitens teeth significantly better than traditional, commercially available whitening strips*

SUMMARY FINDINGS:

POPWHITE Purple Teeth Whitening Pen was tested to determine the safety and efficacy of product supplied to our labs.

We found that the POPWHITE Purple Teeth Whitening Pen subjects had significantly ($P < 0.05$) lighter teeth compared to the WhiteStrips subjects using both subjective and objective methods. Immediately after treatment the test group subjects subjective shade improvement was 8.3 shades; the control group improvement was 5.7 shades. On post treatment day re-examination, the fade-back for the test group was only 0.3 shades compared to 0.7 shades for the control group. Objective colorimeter measurements confirmed the superiority of the POPWHITE Purple whitening gel over the control with regards to both overall shade improvement from baseline and decreased tooth color relapse. Additionally, the POPWHITE Purple whitening gel subjects reported 73% less tooth sensitivity immediately after treatment ($P < 0.01$) and there were 67% fewer subjects with any tooth sensitivity at the conclusion of the study compared to "strips" subjects.

CONCLUSIONS:

We found that the POPWHITE Purple Teeth Whitening Pen was extremely safe and effective. No adverse reactions were found. A clinical trial of 50 subjects found that the "" outperformed traditional, commercially available whitening "strips." After one (1) week, the teeth treated with POPWHITE Purple Teeth whitening gel appeared to be about 8 shades whiter and approximately almost 3 shades lighter than the teeth treated with "strips." All of the claims that were requested to be tested were "verified to be true" by our clinical scientists.

VERIFIED X Mark Granger Date: 08/21/2021

ABSTRACT

A randomized, parallel, double-blind clinical trial was conducted to compare a novel peroxide-free, POPWHITE Purple Teeth whitening gel to a commercially available, peroxide-based bleaching gel. The objective was to test the safety and efficacy of a new peroxide-free gel whitening gel that relied on an anionic detergent cleaning formulation. A total of 50 subjects were assigned randomly to receive either the peroxide-free experimental gel) or the control original bleaching gel (Original WhiteStrips; Procter & Gamble, Cincinnati, OH) balancing for baseline tooth color and mean age. Qualified subjects received treatment using the manufacturer's instructions printed for each gel. Accordingly each subject group received their kits and the used the product at home, twice daily for 7 days. The exposure time for the WhiteStrips group was fourteen 30-minute cycles (7 hours of treatment) while the experimental gel subjects received fourteen two-minute cycles (28 minutes of treatment). Immediately before and after completion of the treatment, and on post-treatment day +7, visual examinations were performed. At each examination interval, the following measurements were collected: visual shade score, colorimeter L* values, gingival index score, self-reported visual analog sensitivity score and overall oral tissue health assessment. Compared with baseline, both whitening gels exhibited statistically significant increases in tooth whiteness ($P < 0.001$). However, throughout the study, the whitening pen subjects had significantly ($P < 0.05$) lighter teeth compared to the WhiteStrips subjects using both subjective and objective methods. Immediately after treatment the test group subjects subjective shade improvement was 8.3 shades; the control group improvement was 7.7 shades. On post treatment day re-examination, the fade-back for the test group was only 0.3 shades compared to 0.7 shades for the control group. Objective colorimeter measurements confirmed the superiority of the Test whitening gel over the control with regards to both overall shade improvement from baseline and decreased tooth color relapse. Additionally the perborate gel subjects reported 73% less tooth sensitivity immediately after treatment ($P < 0.01$) and there were 67% fewer subjects with any tooth sensitivity at the conclusion of the study. Both gels were generally well tolerated, and none of the subjects experienced an adverse event or significant change in oral tissues health. Hence it is concluded that treatment with the new POPWHITE Purple Pen whitening gel resulted in superior whitening efficacy and greatly decreased tooth sensitivity. Additionally, the new gel was found to be safe and the exposure time to any oxidizing agent was greatly reduced.

INTRODUCTION

Tooth whitening is one of the most popular aesthetic procedures used in modern day dentistry due to its relative ease, efficacy and safety.[1,2] The most rapid commercially available method to whiten teeth typically involves applying a nylon strip onto teeth that contains hydrogen peroxide on its inner aspect. The bleaching strips generally work well but have several major drawbacks, including: 1) the need to wear the strips for a relatively long period of time; 2) poor adaptation to teeth with poor orthodontic alignment; and 3) inducement of uncomfortable tooth sensitivity in as many as 50% of people that use this method.[2]

In general, hydrogen peroxide whitens teeth via a two-step oxidative process. In the first step, the hydrogen peroxide molecule is degraded and splits into multiple components, most often water and an oxygen singlet free radical.[3] This occurs spontaneously, but, can be a fairly slow process. This is similar to the way that chlorine bleach would act if used alone to bleach clothes in a laundry washing machine. In either case, it would take at least 7-8 hours to see a difference and some damage would occur (i.e. manifested as tooth sensitivity in teeth and fabric disintegration in laundry). It is also to note that peroxide does not remove any stain, its simply lightens the color of stains, rendering them clear, instead of colored over time.

MATERIALS AND METHODS

A total of 50 subjects were enrolled into the study and the protocol and study were approved by an Institutional Review Board. Subjects were examined before the whitening treatment, immediately after treatment (seven days later), and then another one week after treatment. At each exam, a brief medical and dental history was reviewed, the oral tissues were examined and the following measurements were recorded: gingival index; visual shade of maxillary anterior teeth; triplicate colorimeter L* measurement and dentinal hypersensitivity self-assessment. In addition, any complications and adverse events were recorded.

Inclusion Criteria*:* Male and female Subjects in good general health and between the age 18 to 70 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. Subjects had to be willing to not use any other dental whitening product, with the exception of tootSodium Percarbonateaste, during the course of the study and refrain from

smoking, and to not consume any coffee, cola drinks, grape juice or other drinks or foods that may stain teeth for seven days after treatment.

Exclusion Criteria: Subjects with fewer than 6 gradable anterior maxillary teeth or subjects whose anterior maxillary teeth had restorations, dentures or dental implants. Subjects who reported current sensitivity on maxillary anterior teeth. 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. Subjects with a history of diabetes or any other gelic disease, which in the Investigator's opinion could have interfered with the assessment of the oral soft/hard tissue were excluded as were subjects with a history of photosensitivity or subjects receiving photo-chemotherapy, PUVA therapy, gelic anti-infective, anti-inflammatory or immunosuppressive therapy or who had a known history of tetracycline use and/or the presence of tetracycline-staining on any teeth. We also excluded subjects taking any photo-reactive medications and subjects who had previously used professionally dispensed take-home or in-office professionally-dispensed bleaching products (excluding over-the-counter whitening strips or tooth pastes or gels).

Treatment Methods: Subjects meeting the Inclusion/Exclusion criteria were asked to sign consent forms in order to be included in the study. The starting shade of the six maxillary teeth of each subject was assessed and that shade was considered the qualifying shade for study entrance. Both mean tooth shade and age were used for subject stratification. Each subject was dispensed an unmarked tube of tootSodium Percarbonateaste (Tooth Gloss® Whitening TootSodium Percarbonateaste for Experimental Group and Crest Whitening TootSodium Percarbonateaste for the Control Group) and a soft flat, trim bristle toothbrush for use during the one week study. Non-whitening dental floss use was permitted during the study but the use of other tootSodium Percarbonateastes, toothbrushes, whitening chewing gums or any mouthwash was prohibited.

On the day of the whitening treatment, prior to treatment with either the test or control whitening gel, each subject's medical history was again reviewed and his or her oral soft and hard tissues were examined.

Additionally for teeth # 6 though #11, the following baseline data was recorded: shade scores, triplicate colorimeter L* values, gingival index scores and dentinal hypersensitivity self-assessment scores..

During the treatment phase, the investigator was blinded as to which product any particular subject had been assigned. The subjects were also blinded as they were not told which product was the “new” improved product and which product was a standard, commercially available product.

All subjects were instructed to carefully follow manufacturers instructions. Both products were to be used for a total of fourteen cycles over seven days, The “bleaching strips” subjects used their product for 30 minutes per cycle. The “ Pens” subjects used their product for 2 minutes per cycle as directed by the manufacturer’s instructions. They were also instructed to use the product over all teeth even though they were unaware that only their six maxillary teeth would be the focus of the study. This added another element of subject “blinding.”. The total exposure of the Control group was 7 hours and the total exposure time of the experimental group was 28 minutes. The pH of the experimental product (both Pens) was between pH 6.1 and 6.8. The pH of the control group was considerably more acidic, with the bleaching strips having a pH of 4.5. At the completion of the seven (7) day whitening regimen, the subjects of both groups returned to the study clinic to assess results.

Tooth Color

Vita Shade Assessment: The same examiner assessed tooth color change at each study visit 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 were 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.[7] Two or more calibrated examiners assessed the shades throughout the study in order to verify accuracy. 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.[7]

Spectrophotometer Assessment of Tooth Lightness: As described in the literature[8] , we used a Vita Easyshade® (Vident Inc., Brea, CA) spectrophotometer to record triplicate L* measurements of the baseline and treated maxillary anterior teeth at each examination interval. The meter was calibrated according to manufacturer's instructions using a known color standard before each subject was seated in the treatment room. 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 was obtained, the meter tip was repositioned carefully in a similar manner. The mean of the three-recorded L* values for each tooth were 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.[9] We also believed that using L* would yield the most accurate and objective assessment of bleaching gel efficacy because L* vector that is the only one that is visually uniform. Furthermore, small movements in L* value are more clinically visible [9] than a* or b*, and hence likely to be the most clinically relevant. Finally, we believed L* to be a good choice since the overall objective of tooth bleaching is to visibly "lighten" the color of teeth.

Measurement of Dentinal Hypersensitivity: Subjects were asked to self-assess sensitivity (without exogenous stimuli) by recording their perceived sensitivity on each of the six maxillary teeth using a 0-10 scale[10] with the pain following pan definitions:

0-1 No pain or barley noticeable tooth sensitivity

2-3 Mild pain

4-6 Moderate pain

7-8 Severe pain, not constant

9-10 The most excruciating pain, constant

Subjects were given a maximum of three minutes to complete the self-assessment.

Oral Soft Tissue Assessment: Presence of erythema, desquamation or ulceration of soft tissues and gross changes in teeth or restorations were documented if present. The Löe & Sillness Gingival Index[11] was used to record the extent of inflammation and bleeding of the gingival surrounding the six maxillary teeth being treated using a scale of 0 (no gingival irritation) to 3 (severe gingival irritation).

Sample Size & Statistical Analysis: 50 subjects (25 subjects in each subject group) were enrolled so that the power calculation for the study would be greater than 90% and therefore would be sufficient to detect a difference in mean tooth shades of 0.50 assuming that the common standard deviation is 1.00 using a two group t-test with a 0.050 two-sided significance level. Mean shade changes at each examination interval were compared between groups using a two-group t-test for independent samples. All statistical analyses were conducted using standard statistical software using a level of significance of $P<0.05$.

RESULTS

(Popwhite Pen Users = TEST Group; WhiteStrips Users = CONTROL Group)

A total of 50 subjects were enrolled and treated in the study, and all subjects completed all study exams. Subject demographics are displayed in **Table 1**. We did not find a statistically significant differences in the mean pretreatment tooth shade or mean age of subjects enrolled into each group ($P > 0.20$ in both cases).

Change in Vita Tooth Shade*:* **Table 2** shows the complete summary of Vita shade score data compiled for the two subject groups. The mean shade change immediately after treatment was significantly greater for subjects in the TEST Group (8.3 shades) compared to the CONTROL Group (7.7 shades, $P < 0.05$). At seven days post-treatment, some rebound was seen with the average shade change being reduced to 8.1 and 7.0 Vita shades, respectively. The difference in the rebound was statistically significant, indicating subjects in the CONTROL group had more rebound shade loss (0.2 vs. 0.7 units; $P < 0.01$). Considered

as a percentage, shade change results with TEST treatment were 15.5% better than the CONTROL treatment as shown in the line graphs of **Figure 5.**

Change in Chromameter L*: Table 3 shows a summary of the objectively measured L* values that were collected in triplicate for each tooth, for each examination. The mean ΔL immediately after treatment was significantly greater for subjects in the TEST Group (4.7 L* units) compared to the CONTROL Group (3.5 L* units, $P < 0.01$). At seven days post-treatment, some rebound was seen with the average shade change being reduced to 4.3 and 2.5 L* units respectively. Just as was seen in the shade guide evaluation, there was significantly less color fade back ($P < 0.01$) in the TEST group as shown in **Figure 6**.

Dentinal Sensitivity: Table 4 shows the complete summary of self-reported sensitivity data compiled for the two subject groups. At baseline (pre-treatment), the mean scores for self-reported dentinal hypersensitivity were similar for subjects enrolled in both the TEST and CONTROL Groups (0.17 and 0.25, respectively, $P=0.15$). Subjects in both groups reported significantly higher mean sensitivity scores immediately after treatment ($P < 0.01$) compared to baseline. However, the TEST group experienced 73% less tooth sensitivity immediately post treatment and this was also highly statistically different (0.54 vs 2.01 units; $P < 0.01$). At post treatment day +7, tooth sensitivity for the TEST group was not significantly different from baseline levels ($P > 0.05$). The CONTROL group tooth sensitivity was much less on post treatment day 7, 0.47 units, but this was still significantly higher than baseline ($P < 0.05$). Additionally, at the post-treatment examination, there were only three (3) subjects with mild or greater tooth sensitivity in the TEST group. At the same time, nine (9) CONTROL group subjects reported some mild transient dentinal pain. Therefore at the conclusion of the study, there were 67% fewer TEST group subjects complaining of a sensitivity side effect compared to the control.

Oral Soft Tissue, Gingival Index and Sensitivity Evaluation*:* At all examination intervals there were no reports of erythema, desquamation or ulceration of soft tissues and gross changes in teeth or restorations were documented at any of the study exams by either investigator. Furthermore, the Löe & Sillness Gingival Index scores were essentially unchanged before treatment (TEST group = 1.2 ± 0.5; CONTROL

group = 1.3 ± 0.4) compared to immediately after treatment and at one week post-treatment (see **Table 5**). None of the study subjects reported a score of 3 at any examination.

DISCUSSION

The goal of any whitening treatment is to rapidly enhance the appearance of tooth whiteness, in the shortest time possible, while maximizing patient comfort and safety. The present study shows that the new whitening gel tested is a significant step forward in tooth whitening technology as it enhances all aspects of the goal, plus it actually removes stains. See **Figure 4** for a diagram showing how the cleaning Pens containing an anionic detergent works with neutral soap bubbles, solvents and chelators to rapidly remove enamel discolorations. In fact, the combination of cleaning and whitening Pens are so efficient it reduces whitening time by as much as 84%. Moreover the TEST gel increased the appearance of tooth whiteness immediately after treatment and reduced the amount of color rebound experienced. Additionally the new gel greatly reduced transient dentinal hypersensitivity by as much as 73% and there were 67% fewer subjects with any tooth sensitivity at the conclusion of the study.

The statistical and clinical superiority of the test gel is likely caused by a combination of factors: 1) the use of Mass Action Cleaning ingredients in the cleaning Pen that yields an effective way to remove most stain particles rapidly, 2) the use of physical action caused by rubbing the Pen against the teeth during the treatment process 3) the use of specially selected peroxide-fee oxidizer gel that is orally safe and takes advantage of the cleaning + whitening regimen.

The major advancement of the gel is use of new Aqueous Cleaning Technology. At its core, this new "aqueous" technology has been developed around the concept known as the "Law of Mass Action Cleaning" that heretofore has not yet been applied in dentistry or oral care, and serves as the basis for many of its United States and Foreign patent applications. Although this technology is novel and certainly very useful in the realm of the oral cavity, in fact the Laws of Mass Action Cleaning have been proven to be a successful method for formulation of many other product segments including almost all commercially available surface and fabric cleaners. One possible reason why this well-known cleaning principal has not been used in oral care products to date may be because the chemical ingredients generally used in these class of cleaners have not been safe for use in the mouth. However the developers of the TEST gel have addressed this problem by creating a true stain cleanser that uses all ingredients that the United States of America Food

and Drug Administration (FDA) lists as being generally regarded as safe (GRAS) for the food and cosmetics industries. In fact, as currently applied, the ingredients of the TEST gel are derived from naturally-occurring foodstuffs and elements naturally safe to ingest in reasonably small quantities.

Hence the TEST gel can be considered as the first to use an orally acceptable “tooth detergent agent” combined with a mild oxidizer that can be used in many oral care whitening products in place of traditional peroxide-containing, teeth bleaching agents. Thus the new gel has the ability to remove both surface stain and lighten teeth and even reach the heretofore unreachable subsurface stains between the enamel rods – thoroughly, deeply and rapidly, without many of the negative attributes of bleaching agents.

Thus the overall efficiency of the new gel Pen cleaning and whitening gel was demonstrated by both increased tooth whiteness and a decrease in transient dentinal hypersensitivity. With regard to tooth color enhancement, both whitening gels exhibited statistically significant increases in tooth whiteness compared to baseline color, however throughout the study, we measured significantly lighter teeth for the TEST subjects compared to the teeth of subjects using a whitening gel lacking the new technologies and containing only peroxide bleach. As an example, **Figure 8** shows a typical excellent response of subjects who were assigned to the test group. Furthermore, objective colorimeter measurements confirmed the superior results achieved with the new gel. In fact, the post-treatment ΔL* color fade back measurement, was 70% better in the test group than the readings found for subjects in the control group.

Both whitening gels were generally well tolerated, and none of the subjects experienced an adverse event or significant change in oral tissues health. However the TEST group gel Pen subjects reported 73% less tooth sensitivity immediately after treatment and at the end of the study, 67% fewer subjects complained of mild transient dentinal hypersensitivity. It was therefore our observation that persons undergoing Teeth Whitening System treatment had significantly fewer sensitivity complaints (3 out of 25) than those subjects receiving the control treatment (9 out of 25).

CONCLUSIONS

We conclude that the Teeth Whitening Pen (peroxide-free with anionic detergent) yields significantly better color improvement, significantly less color fade back and significantly reduced tooth sensitivity than

the control whitening strips. Additionally, considerable time savings are accrued by including “detergent cleaning” with a mild oxidizer gel, providing a considerable advantage to the user, yielding less tooth sensitivity and whiter, cleaner teeth.

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TABLES AND FIGURES

DATA TABLES

Table 1. Summary of baseline demographics of the two groups

DEMOGRAPHIC DATA

	TEST GROUP (POP GEL)	CONTROL GROUP (WHITESTRIPS)
Number	25	25
Location	Florida	Florida
Mean Age	46.8 ± 13.7	45.8 ± 14.2
M:F Ratio	12:13	13:12
% Smoke	24%	28%
Mean Shade	10.4 ± 1.1	10.6 ± 1.1

Table 2. Summary of Vita Shade Data. Means ± SD for each group are reported. Change means change from baseline P value is derived from T-test comparison of two groups.

CLINICAL WHITENING DATA - VITA SHADE SCORE

	TEST GROUP (POP GEL)		CONTROL GROUP (WHITESTRIPS)		T-TEST BETWEEN GROUPS
	MEAN	CHANGE	MEAN	CHANGE	
PRE-TREATMENT	10.6 ± 1.1	--	10.4 ± 1.1	--	P = 0.18
AFTER TX	2.3 ± 0.8	8.3 shades	4.7 ± 0.9	5.7 shades	P < 0.05
1 WEEK POST TX	2.5 ± 1.2	8.1 shades	5.4 ± 1.0	5.0 shades	P < 0.01
REBOUND SHADE LOSS	-	0.2 shades	-	0.7 shades	P < 0.01

Table 3. Summary of L* Chromameter Data Means ± SD for each group are reported. Mean change from baseline. P value is derived from T-test comparison of two groups.

CLINICAL WHITENING DATA – SPECTROPHOTOMETER MEASUREMENT

	TEST GROUP (POP GEL)		CONTROL GROUP (WHITESTRIPS)		T-TEST BETWEEN GROUPS
	MEAN	CHANGE	MEAN	CHANGE	
PRE-TREATMENT	75.2 ± 2.2	--	76.1 ± 2.1	--	P = 0.07
AFTER TX	79.9 ± 2.0	4.7	79.9 ± 2.0	3.5	P < 0.01
1 WEEK POST TX	79.5 ± 2.1	4.3	78.5 ± 2.0	2.4	P < 0.01
REBOUND SHADE LOSS	-	0.4	-	1.1	P < 0.01

Table 4. Summary of Visual Analog Sensitivity Scoring. Means ± SD for each group are reported. Change means change from baseline. P value is T-test comparison between the two groups.

CLINICAL SAFETY DATA – VAS SENTIVITY SCORES

	TEST GROUP (POP GEL)		CONTROL GROUP (WHITESTRIPS)		T-TEST BETWEEN GROUPS
	MEAN	CHANGE	MEAN	CHANGE	
PRE-TREATMENT	0.17 ± 0.4	--	0.25 ± 0.3	--	P = 0.15
AFTER TX	0.72 ± 0.8	0.54	2.26 ± 1.1	2.01	P < 0.01
1 WEEK POST TX	0.28 ± 0.3	0.11	0.47 ± 0.5	0.22	P < 0.05

0.54/2.01 - 100 = 73% less sensitivity

Table 5. Summary of Löe & Silness Gingival Index Scoring. Means ± SD for each group are reported. Change means change from baseline. T-test comparison is between the two groups.

	TEST GROUP		CONTROL GROUP		T-TEST BETWEEN GROUPS
	MEAN	CHANGE	MEAN	CHANGE	
PRE-TREATMENT	1.2 ± 0.5	--	1.3 ± 0.4	--	P = 0.44
IMMEDIATE POST TX	1.4 ± 0.6	0.2	1.4 ± 0.7	0.1	P = 0.28
7 DAYS POST TX	1.3 ± 0.6	0.1	1.3 ± 0.4	0.0	P = 0.41

FIGURES

Figure 1 - **Test Product Image.**

Image of Test System Studied (POPWHITE Purple Teeth Whitening Pen)

Figure 2. The Test System relies on Aqueous Cleaning Technology. This based on the physical universal laws of “Mass Action Cleaning” which states that the 8 “factors” listed below must be in balance for optimum cleaning and whitening to occur.

UNIVERSAL LAWS OF MASS ACTION CLEANING RELY ON BALANCE OF 8 FACTORS

TEMPERATURE (higher temp speeds cleaning)	SOLVENTS (breaks up stains)	CHELATORS (mineral binder)	NEUTRAL SOAP (foaming + wetting agent)
ANIONIC DETERGENT (negatively charged stain lifter)	SAPONIFIERS (grease remover)	ACTION (agitation or abrasion)	OXIDIZING Agent (for maximum whitening)

Figure 3. A Line graph comparing the change in tooth color for the Test and Control Groups at the day of treatment and (1) WEEK post-treatment. Immediately after the seven (7) days of treatment, the Test Group tooth color was marginally significantly better (P=0.05). However at day +7, the Test Group subjects' teeth did not experience as much color fade-back, causing the differences between the two groups to be more clinically evident and more statistically different (P < 0.01).

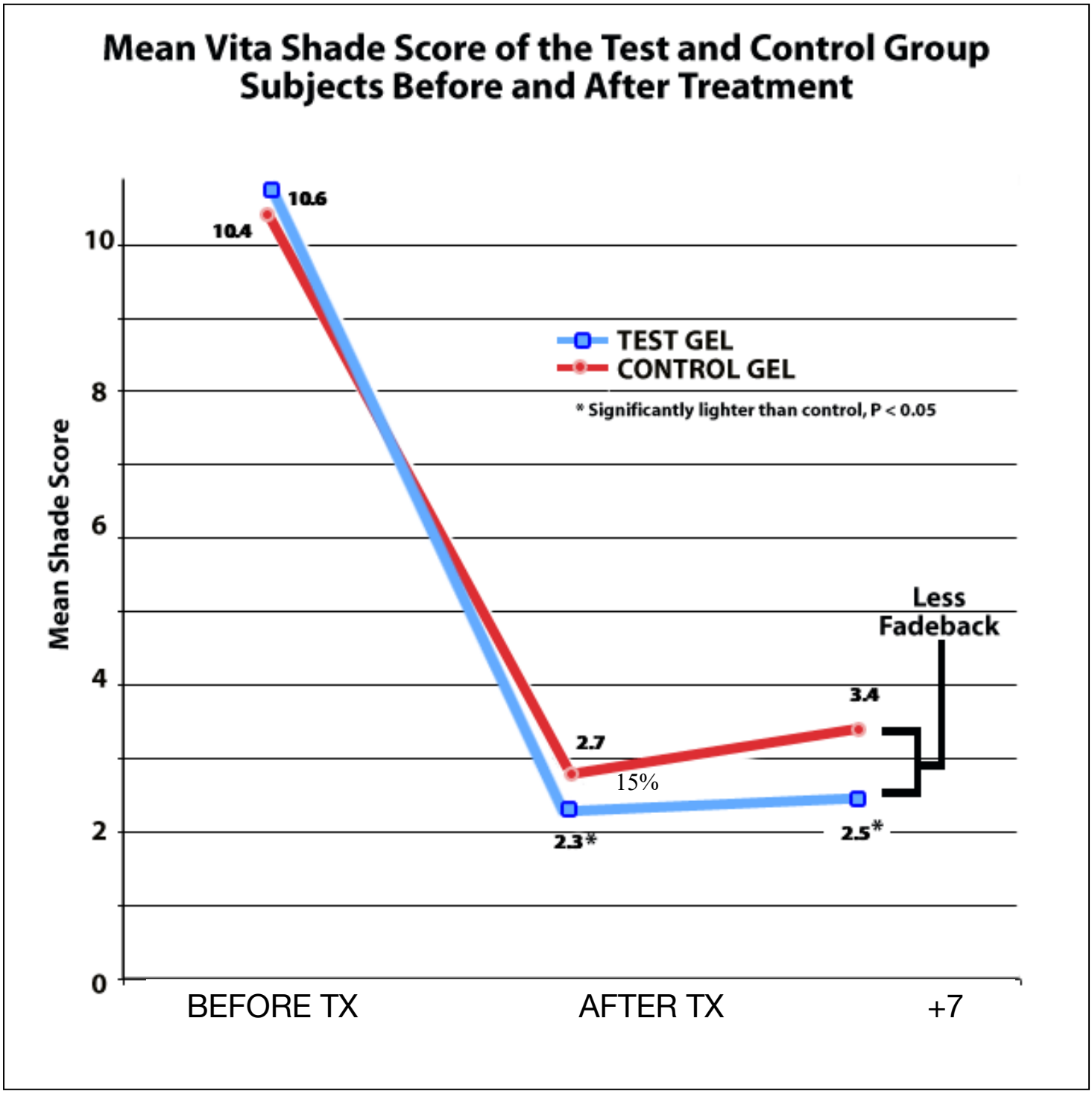

Figure 4. Bar graph comparing colorimeter reading mean change in tooth lightness (ΔL*) of the Test and Control Groups at two time points: immediately after treatment and seven days later. (Taller bars are better) (Higher number is better for color)

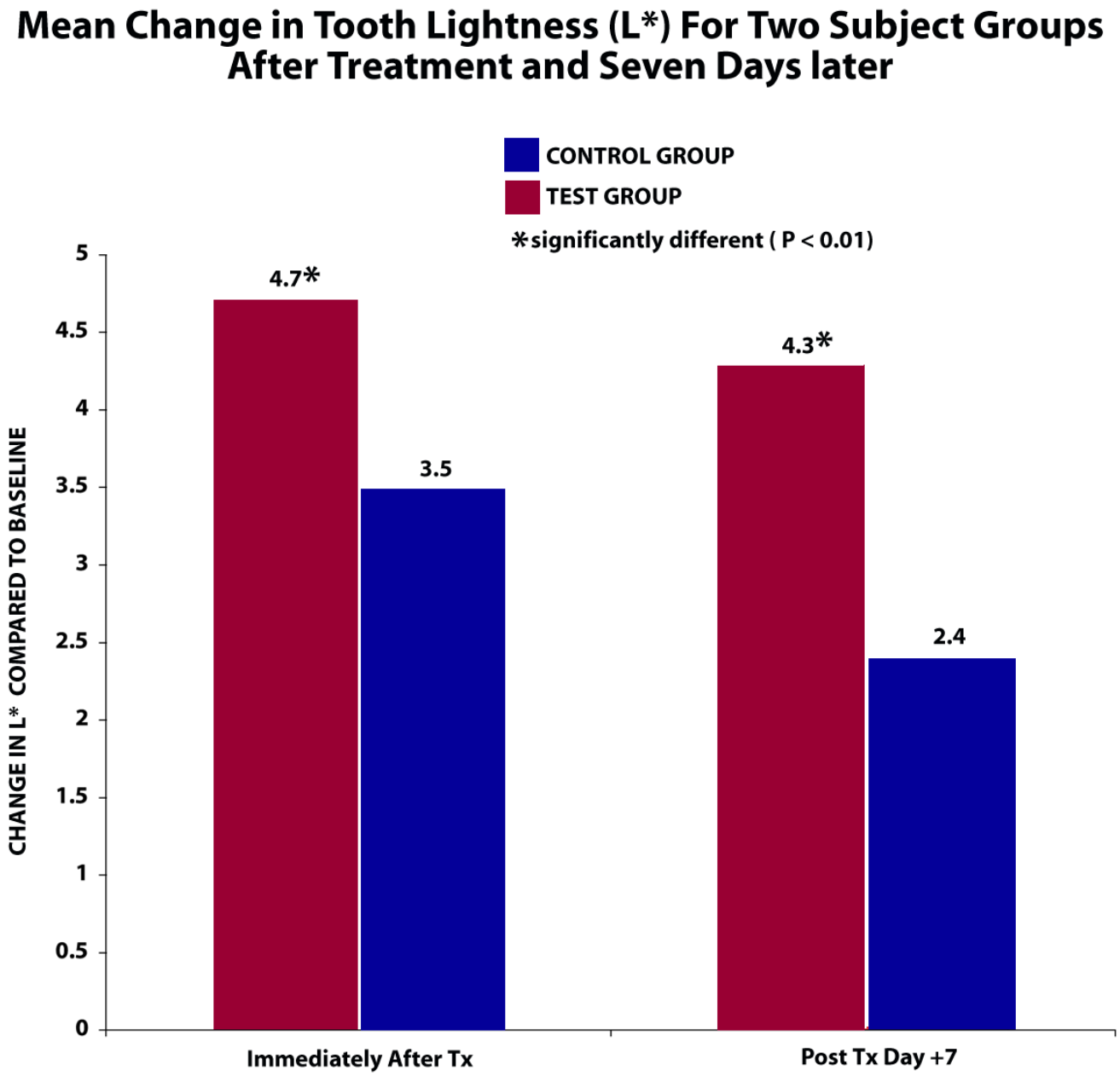

Figure 5. Bar graph comparing the mean change in self-reported tooth sensitivity of the Test and Control Groups at two time points: immediately after treatment and seven days later. The POPWHITE Purple Teeth Whitening Pen group had 73% less transient dentinal hypersensitivity immediately after treatment.