

OFFICIAL CLINICAL STUDY REPORT

Independent Scientific Clinical Study of Safety and Efficacy

A Comparative Study of POPWHITE® Medium Grit Prophy Paste Against NuPro® Market Leader

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- CLAIM TESTED:
- POPWHITE® Medium Grit Prophy Paste whitens teeth
 - POPWHITE® Medium Grit Prophy Paste removes stains
 - POPWHITE® Medium Grit Prophy Paste is safe to use
 - POPWHITE® Medium Grit Prophy Paste causes no teeth sensitivity
 - POPWHITE® Medium Grit Prophy Paste causes no gingival irritation
 - POPWHITE® Medium Grit Prophy Paste whitens teeth better than NuPro® (Market Leader)
 - POPWHITE® Medium Grit Prophy Paste whitens teeth at least six shades
 - POPWHITE® Medium Grit Prophy Paste removes stains better than NuPro® (Market Leader)
 - POPWHITE® Medium Grit Prophy Spatters less than NuPro® (Market Leader)

- MAJOR OBJECTIVES:
- 1) Determine safety of POPWHITE® Medium Grit Prophy Paste
 - 2) Determine stain removal and whitening efficacy of POPWHITE® Medium Grit Prophy Paste
 - 3) Compare performance of POPWHITE® Medium Grit Prophy Paste to market leader
 - 4) Compare spatter performance of POPWHITE® Medium Grit Prophy Paste to market leader

STUDY METHODS: **20 Subjects in each of two (2) groups:**
POPWHITE® Medium Grit Prophy Paste (n=20); TEST GROUP
NuPro® Medium Grit Prophy Paste (n=20); CONTROL GROUP

Experimental Plan Used:

Subjects were treated only with one-time use of their assigned product, comprising a complete dental prophylaxis of each subjects maxillary and mandibular teeth by a licensed dental hygienist.

Vita Shade Score and L* Colorimeter Data was collected on maxillary anterior tooth #8 before and after treatment. Vita Shade Score and L* Colorimeter Data were collected by experienced and calibrated examiners. The study followed a parallel, double-blind research protocol that complied with industry and ADA standards.

Statistical Methods Used:

All statistical analyses were conducted using standard statistical software using a level of significance of $p < .05$. Data collected at each examination interval was compared between groups using a two-group Student's t-test for independent samples.

SUMMARY FINDINGS:

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 on tooth #8. There were twenty (20) subjects in each group and each group was balanced for mean age and gender. The mean age for the Control Group was 35.7 ± 14.2 ; the mean age of POPWHITE® Test Group was 35.7 ± 14.3 . The male: female ratio of each group was kept as balanced as possible. See **Table 1** for a summary of the demographic data.

TABLE 1 - DEMOGRAPHICS				
DEMOGRAPHICS OF STUDY SUBJECTS ENROLLED IN PROPHY PASTE STUDY				
STUDY GROUP	MEAN AGE	STANDARD DEVIATION	RACE	M:F RATIO
CONTROL (n=20)	35.7	14.3	12 W 4 B 3 H 1 A	10:10
TEST (n=10)	35.7	14.2	13 W 3 B 2 H 2 A	10:10
<i>Note: There was no statistical difference in age, sex or race (p < 0.05)</i>				

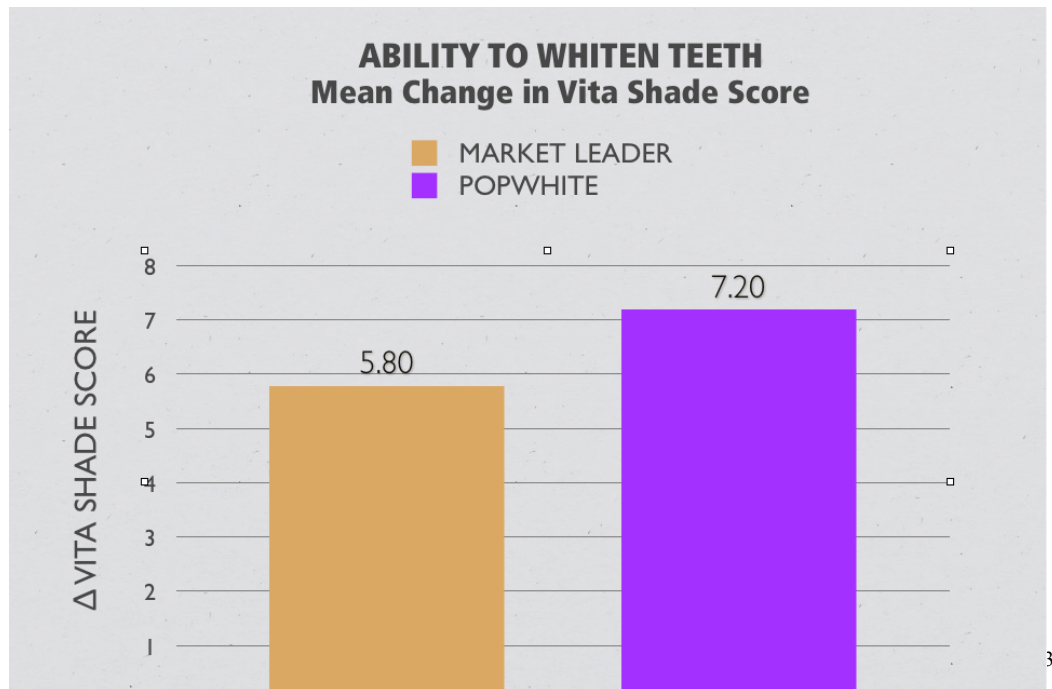
SUMMARY FINDINGS:

WHITENING EFFICACY RESULTS: We judged the stain removal and whitening efficacy of the POPWHITE® Medium Grit Prophy Paste against the Market Leading NuPro® Medium Grit Prophy Paste using Vita Shade Score analysis according to ADA Guidelines and industry standards.

Table 2 below shows the mean Vita Shade Score for all subject groups before and after professional dental prophylaxis by a licensed hygienist. As shown in the table, all test subjects who were treated with POPWHITE® product had statistically significant whiter teeth than the CONTROL subjects teeth ($p < 0.05$) even though at baseline all teeth were statistically the same color.)

TABLE 2 – VITA SHADE SCORE			
VITA SHADE SCORE FOR ALL SUBJECTS BEFORE AND AFTER PROPHYLAXIS			
STUDY GROUP	BASELINE	AFTER	CHANGE
CONTROL (n=20)	10.05 ± 0.6	4.25 ± 1.0	-5.80 ± 1.1
TEST (n=20)	10.00 ± 0.6	2.80 ± 0.9	-7.20 ± 1.1

*Note: There was no statistical difference in tooth color at baseline.
After Treatment – All test subjects teeth remained statistically significantly whiter than control subjects teeth all time points ($p < 0.05$)*

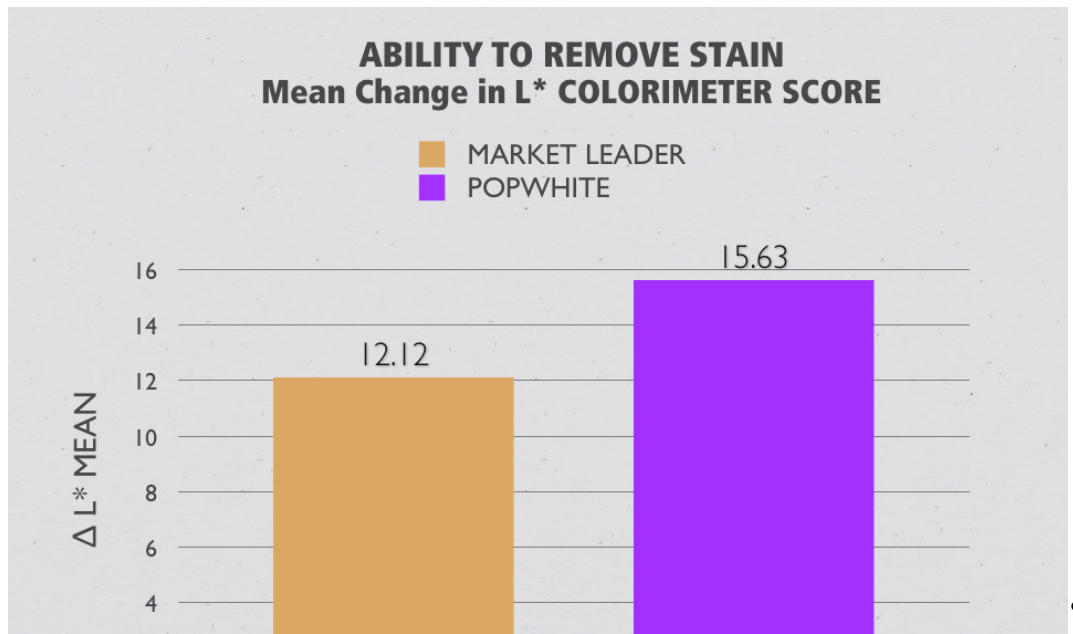


SUMMARY FINDINGS:

STAIN REMOVAL EFFICACY RESULTS: We judged the stain removal efficacy of the POPWHITE® Medium Grit Prophy Paste against the Market Leading NuPro® Medium Grit Prophy Paste using Objective Minolta Colorimeter analysis (L*) according to ADA Guidelines and industry standards.

Table 3 below shows the mean L* Colorimeter measurement for all subject groups before and after professional dental prophylaxis by a licensed hygienist. As shown in the table, all test subjects who were treated with POPWHITE® product had statistically significant brighter teeth than the CONTROL subjects teeth ($p < 0.05$) even though at baseline all teeth were statistically the same color.) Furthermore the bar graph below shows that POPWHITE removed stains and brightened teeth 22% better than the control prophy paste.

TABLE 3 – COLORIMETER STAIN REMOVAL ANALYSIS			
L* SCORE FOR ALL SUBJECTS BEFORE AND AFTER PROPHYLAXIS			
STUDY GROUP	BASELINE L*	AFTER L*	CHANGE
CONTROL (n=20)	66.56 ± 0.8	78.68 ± 2.0	12.12 ± 2.2
TEST (n=20)	66.73 ± 1.2	82.36 ± 2.1	15.63 ± 2.6
<p><i>Note: There was no statistical difference in tooth color at baseline.</i> <i>After Treatment – All test subjects teeth remained statistically significantly brighter than control subjects teeth all time points ($p < 0.05$)</i></p>			



SUMMARY FINDINGS:

We judged safety of the Control and Test products based on the results of Loe and Silness Gingival Index scoring, VAS Sensitivity Index scoring and through thorough monitoring the hard tissue / soft tissue oral health of the 40 subjects entered in the study. In general we found no adverse reaction or serious side effects in any of the subjects tested. All Control and Test products were judged by us to be very safe. The instructions were easy to follow and the subjects found the product easy to apply. This also contributed to the safety profile of the products.

Gum Irritation

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 except for very mild gingival irritation in about 5% of subjects treated. We found by using the Loe and Silness Gingival Index that all subjects experienced no statistically increased significant gum irritation (compared to baseline) when using any of the test or control products ($p > 0.05$), even though the results showed that POPWHITE® did perform somewhat better. See **Table 4** below.

TABLE 4 – GUM IRRITATION			
LOE & SILNESS GINGIVAL INDEX FOR ALL SUBJECTS BEFORE AND AFTER PROPHYLAXIS			
STUDY GROUP	BASELINE GI	AFTER GI	CHANGE
CONTROL (n=20)	1.28 ± 0.2	1.48 ± 0.3	0.2 ± 0.2
TEST (n=20)	1.23 ± 0.2	1.28 ± 2.1	0.05 ± 0.1
<p><i>Note: There was no statistical difference in gingival irritation at baseline. After Treatment – There was no statistical difference in gingival irritation ($p < 0.05$) even though POPWHITE did perform 0.15 GI units better.</i></p>			

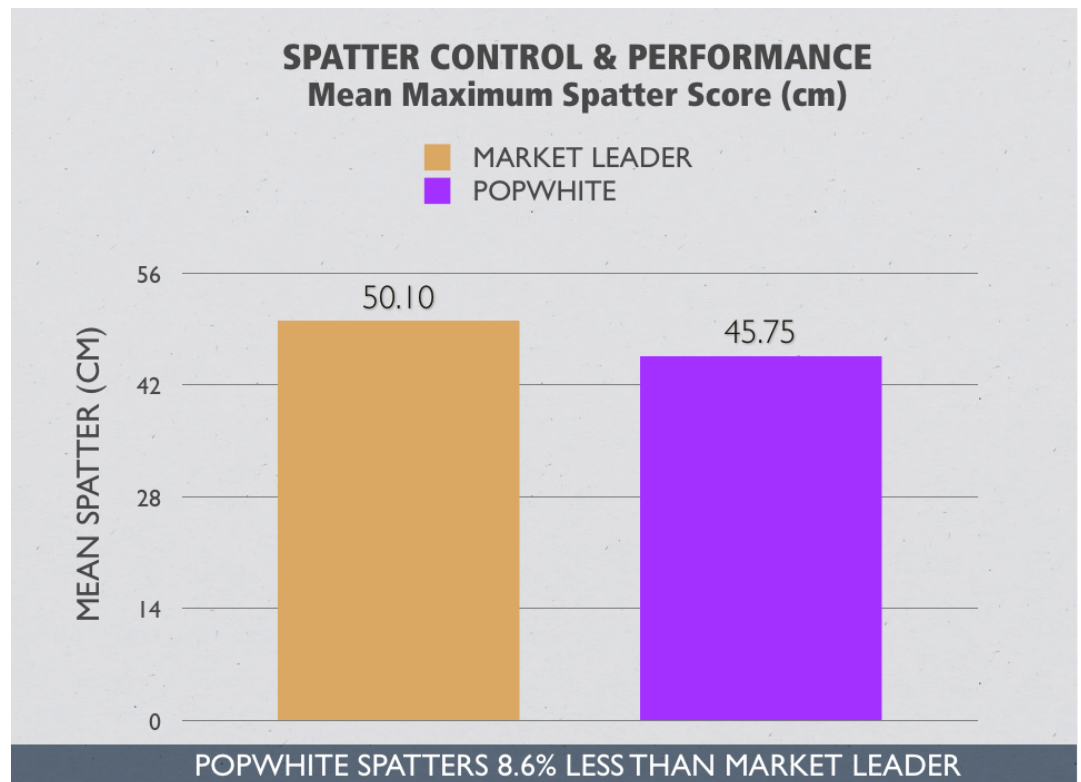
Teeth Sensitivity

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 except for very teeth sensitivity in about 5% of subjects treated. We found by using a Visual Analog Score (VAS) Sensitivity Index that all subjects experienced no statistically increased significant teeth sensitivity (compared to baseline) when using any of the test or control products ($p > 0.05$) even though the results showed that POPWHITE® did perform somewhat better. See **Table 5** below.

TABLE 5 – TEETH SENSITIVITY

VAS SENSITIVITY INDEX FOR ALL SUBJECTS BEFORE AND AFTER PROPHYLAXIS			
STUDY GROUP	BASELINE GI	AFTER GI	CHANGE
CONTROL (n=20)	0.10 ± 0.02	0.40 ± 0.04	0.3 ± 0.03
TEST (n=20)	0.20 ± 0.03	0.25 ± 0.03	0.05 ± 0.01
<p><i>Note: There was no statistical difference in gingival irritation at baseline. After Treatment – There was no statistical difference in gingival irritation (p < 0.05) even though POPWHITE did perform 0.25 VAS Sensitivity units better.</i></p>			

SUMMARY FINDINGS: **SPATTER** – We judged spatter performance of both the Control and Test products based on the results of measurements of maximum spatter during routine prophyllaxis using digital imaging of white drapes covered with spatter after dental prophyllaxis for 20 minutes. The mean maximum spatter for the control market-leading product was 50.10 cm ± 4.0 and the mean maximum spatter for the POPWHITE® 45.75 cm ± 4.1. This means that POPWHITE® spatters 8.6% less than the market leader. See graph below.



CONCLUSIONS:

- POPWHITE® Medium Grit Prophy Paste whitens teeth
- POPWHITE® Medium Grit Prophy Paste brightens teeth
- POPWHITE® Medium Grit Prophy Paste removes stains
- POPWHITE® Medium Grit Prophy Paste is safe to use
- POPWHITE® Medium Grit Prophy Paste causes no teeth sensitivity
- POPWHITE® Medium Grit Prophy Paste causes no gingival irritation
- POPWHITE® Medium Grit Prophy Paste whitens teeth 1.4 shades better than the Market Leader
- POPWHITE® Medium Grit Prophy Paste removes 22% more stain than the Market Leader
- POPWHITE® Medium Grit Prophy Paste whitens teeth on average 7.2 Vita shades
- POPWHITE® Medium Grit Prophy Paste brightens teeth on average 15.63 L* shades
- POPWHITE® Medium Grit Prophy Paste removes stains better than NuPro® (Market Leader)
- POPWHITE® Medium Grit Prophy Spatters 8.6% less than NuPro® (Market Leader)

TESTIMONIAL:

The claims that were requested to be tested by POPWHITE were “verified to be true” by our clinical scientists and we stand behind these findings under the testing conditions described above.

VERIFIED:

X 

Date: August 30, 2014

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