

## OFFICIAL STUDY SUMMARY

### *Objective and Subjective Scientific Clinical Study of Safety and Efficacy:* **Effectiveness of Smyle Teeth Whitening Gel V1 on Teeth Whitening and Gum Health**

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- CLAIMS TESTED:
- 1) Smyle Teeth Whitening Gel V1 safe to use.
  - 2) Smyle Teeth Whitening Gel V1 causes no adverse reactions and causes no visible clinical oral hard tissue / soft tissue irritation, damage, or pathology.
  - 3) Smyle Teeth Whitening Gel V1 causes no tooth sensitivity.
  - 4) Smyle Teeth Whitening Gel V1 whitens teeth significantly after just one week of use (8 shades)
  - 5) Smyle Teeth Whitening Gel V1 improves gum health significantly after just one week of use.

STUDY METHODS: **20 Subjects; Each Subject received**  
a. Smyle Teeth Whitening Gel V1 (morning and evening use)

The subjects were given verbal and written instructions and the materials; product os designed for daily home use.

#### **Tests Performed:**

- a. (Visual) Vita Shade Score by experienced and calibrated examiners
- b. (Machine) L\* spectrophotometer measurement
- c. Clinical assessment of oral soft tissue / hard tissue Assessment of Adverse Reactions (if any) by experienced examiners
- d. Loe and Silness Gingival Index by experienced and calibrated examiners
- e. VAS Sensitivity Index data collected by experienced examiner
- f. Pre-Use and Post-Use Consumer Survey Instrument administered by examiners

#### **Data Collection Intervals:**

Baseline and post-treatment day +7

#### **Statistical Methods Used:**

All statistical analyses were conducted using standard statistical software using a level of significance of  $p < 0.05$ . Data collected at each examination interval was compared between groups using a two-group 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. There were 20 subjects enrolled in the study. The mean age for Test Group was  $57.1 \pm 16.0$ .

**ORAL HEALTH AND SAFETY:** We judged safety of the new product 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 20 subjects entered in the study.

We found that there were no ill effects caused by the use of the products in all subjects tested. There were no adverse reactions and no tissue changes found except for mild reversible blanching / bleaching of the marginal gingival in about 10% of the subjects studied. There was also a statistically significant decrease in gingival irritation (redness / bleeding) noted in the study group ( $p > 0.05$ ).

ASSEMENT OF GINGIVAL IRRITATION OF SUBJECTS ENROLLED (Loe & Sillness Gingival Index: 0= No Inflammation; 1= Mild; 2= Moderate; 3= Severe)	
	X5 GROUP (n=20)
<i>Before Treatment</i>	1.26
<i>After Treatment</i>	1.08
<i>Gingival Change</i>	0.18 (significant)
<i>Standard Deviation</i>	$\pm 0.2$
<i>Significance</i>	0.0413

Significantly less  
gingival redness and  
bleeding  $p < 0.05$

We also found, using V.A.S. Teeth Sensitivity Index studies that all subjects experienced no statistically increased significant tooth sensitivity (compared to baseline) when using the test products ( $p > 0.05$ ). Interestingly, There was a statistically significant decrease in teeth sensitivity noted in the study group ( $p > 0.05$ ).

ASSEMENT OF TEETH SENSITIVITY OF SUBJECTS ENROLLED (VAS Sensitivity Index: 0= absolutely no sensitivity; 10=most severe sensitivity)	
	X5 GROUP (n=20)
<i>Before Treatment</i>	0.50
<i>After Treatment</i>	0.25
<i>Sensitivity Change</i>	0.25 (significant)
<i>Standard Deviation</i>	$\pm 0.4$
<i>Significance</i>	0.0358

Significantly less  
dental hypersensitivity  
 $p < 0.05$

**WHITENING EFFICACY:** We judged whitening efficacy based on both human sensory and machine measurements of teeth whiteness using both Vita Shade Score and Colorimeter L\* Measurement of the 20 subjects entered in the study. The mean Vita shade improvement of the Test Group was 8.05 shades ( $p < 0.0001$ ) after just one week of testing. The results for the colorimeter L\* machine measurement was similar to what we found with the visual Vita analysis. The mean L\* improvement of the Test Group was 12.11 units ( $p < 0.0001$ ); again, it is conclusive that teeth become visibly whiter after just one week of use. Also we measured that after one day, the mean shade improvement was 4.20 shades.

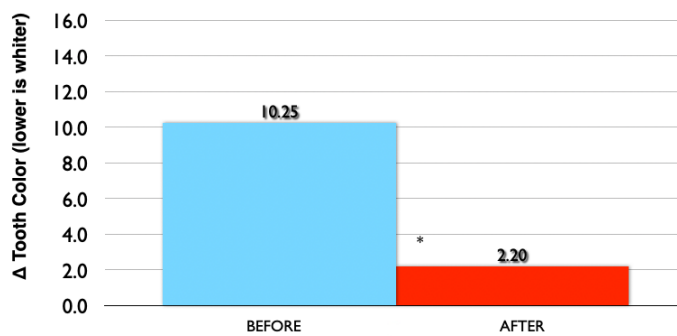
VITA SHADE SCORES	
	X5 Gel GROUP (n=20)
Before Treatment	10.25
After Treatment	2.20
Vita Shade Change	-8.05
Standard Deviation	± 0.9
Significance	0.0001

Significantly Whiter Teeth; 8.05 Vita Shades  
p < 0.05

COLORIMETER SCORES	
	X5 Gel GROUP (n=20)
<i>Before Treatment</i>	<i>64.57</i>
<i>After Treatment</i>	<i>76.68</i>
<i>L* Measure Change</i>	<i>12.11</i>
<i>Standard Deviation</i>	<i>± 1.9</i>
<i>Significance</i>	<i>0.0001</i>

Significantly Whiter Teeth; 12.11 Colorimeter Shades.  
p < 0.05

### Change in VITA® Shade Scores



Significantly Whiter Teeth; 8.05 Shades  
p < 0.05

### EXAMPLE BE

BEFORE

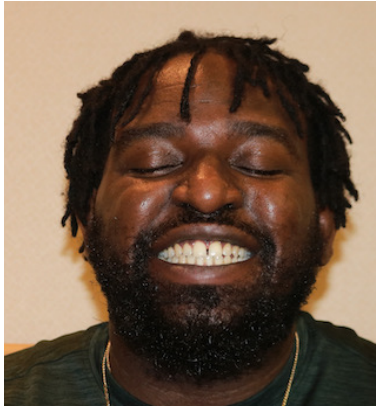
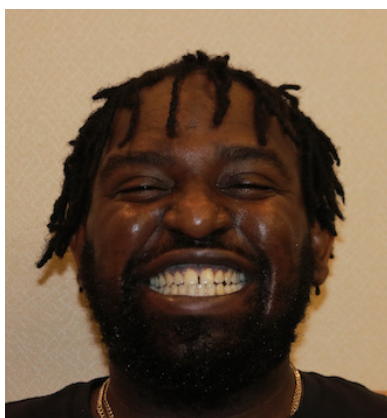


AFTER





Subjects exhibited clear and obvious oral health improvement and increased teeth whiteness.



### Survey Instrument Results

- 1) Have you been using toothpaste with fluoride and found you still get cavities and other oral care decay issues?
  - Yes 90%
  - No 5%
  - Not Sure 5%
  
- 2) Do you use honey as a natural ingredient to optimize your general health?
  - Yes 75%
  - No 25%
  - Not Sure 0%

- 3) What do you see as the benefits of our unit-dose delivery system to apply your anti-decay and teeth whitening applications?
- Just like the Keurig system the unit dose avoids waste. 70%
  - No need to saturate product with preservatives and fillers to prolong shelf life. 10%
  - Being hermetically sealed outside elements cannot get into the product to compromise its effectiveness. 20%
- 4) Do you feel you have less plaque on your teeth?
- Yes 100%
  - No
  - Not Sure
- 5) Do you feel your teeth are whiter?
- Yes 100%
  - No
  - Not Sure
- 6) Did you find the products to be user friendly?
- Yes 100%
  - No
  - Not Sure
- 7) Have you noticed that the use in people having significant oral care problems leading to Implants crowns, root canals, and bone grafts has skyrocketed in recent years?
- Yes 100%
  - No
  - Not Sure
- 8) Considering the average cost today to replace a tooth is about \$3,000 can you appreciate the need for a monthly user-friendly oral care dub that concentrates on reducing and eliminating tooth decay?
- Yes 100%
  - No
  - Not Sure

CONCLUSIONS:

We found that Smyle Teeth Whitening Gel V1 to be extremely safe and effective. We conclude and confirm:

- Smyle Teeth Whitening Gel V1 *is safe to use*
- Smyle Teeth Whitening Gel V1 *causes no adverse reactions, and causes no visible clinical oral hard tissue / soft tissue irritation, damage or pathology.*
- Smyle Teeth Whitening Gel V1 *causes no tooth sensitivity.*
- Smyle Teeth Whitening Gel V1 *visibly enhances the whiteness of teeth after approximately 8.05 shades in one week and 4.2 shades in one day.*
- Smyle Teeth Whitening Gel V1 *significantly improves gum health.*

All the claims that were requested to be tested 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 14, 2021

Martin Giniger, DMD, PhD, FICD  
Principal Investigator