



Statistical Report:

**ASSESSMENT OF THE IN USE ACCEPTABILITY AND EFFICACY OF A PRODUCT
THROUGH SELF-ASSESSMENTS COMPLETED BY STUDY SUBJECTS AND DENTAL
CLINICAL ASSESSMENTS UNDER NORMAL USE CONDITIONS**

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1 – INTRODUCTION

In this study, 35 subjects have been followed up during 21 days.

The objective of the study was:

- To verify the oral cavity acceptance of a topical use product cosmetic product, by observing the non-occurrence of adverse events and discomfort sensations on subjects with sensitive teeth and gums, when used under normal use conditions;
- To verify the efficacy of the product through a dental clinical assessment and subjective perception of the study subject under normal use conditions.

2 – STATISTICAL ANALYSIS

Exploratory data analysis (summary tables and graphs) was performed. The normality of data was verified through Shapiro-Wilk's test. Time-points were compared through Wilcoxon signed-rank test for VITA Scale, Gengivitis and Bacterial Plaque. Frequency and percentage were calculated for Self-Assessment and Profile Assessments.

The confidence level used on the comparative analysis was 95%.

Software: MINITAB 14 and XLSTAT 2021.

3 – RESULTS

3.1 – Expert clinical grading of teeth color (Vita Scale)

Four groups of colors can be assigned to subject for the assessment of teeth whitening, as follows:

- A: Reddish - Brown
- B: Reddish - Yellow
- C: Shades of gray
- D: Reddish - Gray

Note that the majority of subjects have a A shade followed by a B shade. None of the subjects had a D shade.

Table 1: Frequency and percentage

Shade	n	%
A: Reddish - Brown	27	77.1%
B: Reddish - Yellow	6	17.1%
C: Shades of gray	2	5.7%
D: Reddish - Gray	0	0.0%

The assessments were performed to Upper Incisors, Upper Canines, Upper Posterior Teeth, Lower Anterior Teeth, Lower Canines and Lower Incisors. The intensity of the assessments within each group can vary from 1 to 4. The following table illustrates the results for the average of all evaluated teeth.

No significant difference in the intensity of the color of the teeth was observed after 21 days of using the product Perfect Smile Portable Water Flosser in relation to initial time-point T0 (before product use).

Table 2: Descriptive statistics and results of comparison

Statistics	T0	T21	$\Delta(T7 - T0)$
Mean	2.7	2.7	0.0
Standard error	0.1	0.1	0.0
$\Delta(\%)$ improvement on the mean			0.0
% of subjects with reduction			5.7
P-value			0.186

* significant at 5% (Wilcoxon signed-rank test).

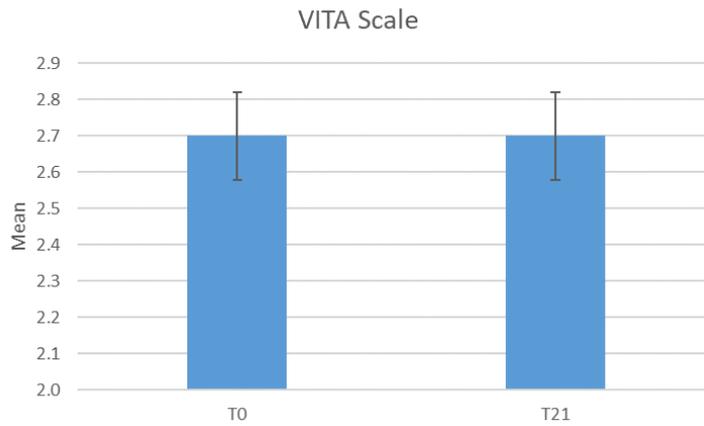


Figure 1. Mean ± standard error for intensity of color by time-point

3.2 – Profile Assessments

Table 3: Percentage, frequency (), mean and standard error

1. How many times a week do you use dental floss?	T0
1	2.9% (1)
2	5.7% (2)
3	2.9% (1)
4	5.7% (2)
5	2.9% (1)
6	2.9% (1)
7	28.6% (10)
10	2.9% (1)
12	2.9% (1)
14	37.1% (13)
21	5.7% (2)
Mean	9.8
Standard error	0.9

Table 4: Percentage and frequency ()

Question	% of agreement
	T0
2. Your current dental floss causes damage to your teeth or gums.	62.9% (22)
3. Your current dental floss cleans well between your teeth.	91.4% (32)
4. Your current dental floss helps to clean your teeth.	91.4% (32)
5.1. You are satisfied with your current dental floss.	77.1% (27)

3.3 – Self-Assessments

Table 5: Percentage and frequency () of positive answers by question

Question	% Positive answers
	T21
1. I feel my teeth and gums cleaner after using the Perfect Smile Portable Water Flosser than after using the dental floss.	91.4% (32)
2. My teeth and gums look healthier after using the Perfect Smile Portable Water Flosser than after using the dental floss.	94.3% (33)
3. The Perfect Smile Portable Water Flosser is gentler on my gums than the dental floss.	91.4% (32)
4. The Perfect Smile Portable Water Flosser cleans better the areas that are hard to reach of my mouth than the dental floss.	97.1% (34)
5. My breath is fresher after using the Perfect Smile Portable Water Flosser.	88.6% (31)
6. The Perfect Smile Portable Water Flosser is easy to use.	94.3% (33)
7. The Perfect Smile Portable Water Flosser is safe to use.	97.1% (34)
8. After 7 days, the Perfect Smile Portable Water Flosser left my teeth with a cleaner sensation.	94.3% (33)
9. After 14 days, the Perfect Smile Portable Water Flosser left my teeth with a lighter aspect.	77.1% (27)
10. My teeth look noticeably lighter after using the Perfect Smile Portable Water Flosser.	74.3% (26)
11. One minute a day for brighter teeth, healthier gums and fresher breath.	94.3% (33)
12. My teeth and gums look healthier and more protected from dental plaque and other bad bacteria after using the Perfect Smile Portable Water Flosser than the dental floss.	91.4% (32)
13. The Perfect Smile Portable Water Flosser helped to remove stains like coffee or red wine from my teeth.	75.0% (24)
14. My friends and family noticed that my teeth were lighter after I used the Perfect Smile Portable Water Flosser.	60.0% (21)
15. My friends and family noticed that my gums were healthier after I used the Perfect Smile Portable Water Flosser.	62.9% (22)
17. How likely are you to recommend the Portable Water Flosser?	97.1% (34)
18. I prefer the Perfect Smile Portable Water Flosser to other oral water flossers I've used.	91.4% (32)
20. I prefer the Perfect Smile Portable Water Flosser to dental floss.	82.9% (29)
21. The Perfect Smile Portable Water Flosser gives me confidence that my gum recession has improved compared to when I used dental floss.	91.4% (32)
22. The Perfect Smile Portable Water Flosser makes my teeth feel less sensitive than when I used the dental floss.	94.3% (33)
23. I think the Perfect Smile Portable Water Flosser would be easier for my kids and the whole family to use.	85.7% (30)
24. The Perfect Smile Portable Water Flosser helps achieve the same level of cleanliness as flossing, but doesn't scrape my teeth or gums.	85.7% (30)
25. The Perfect Smile Portable Water Flosser allows me to clean behind (in the back) of my mouth better than with dental floss.	94.3% (33)
26. My gums presented less bleeding when using the Perfect Smile Portable Water Flosser.	88.6% (31)
27. The Perfect Smile Portable Water Flosser cleans better than just brushing.	91.4% (32)
28. Using the Perfect Smile Portable Water Flosser is an easier and more effective way to clean between your teeth than with dental floss.	88.6% (31)

19. The Perfect Smile Portable Water Flosser cleaned my mouth better than other oral water flossers.	T21
5x	31.4% (11)
4x	20.0% (7)
3x	28.6% (10)
2x	11.4% (4)
1x	8.6% (3)

3.4 – Gingivitis index

Product Perfect Smile Portable Water Flosser promoted a significant reduction on gingivitis index after 21 days of use in relation to initial time-point T0 (before product use).

Table 6: Descriptive statistics and results of comparison

Statistics	T0	T21	$\Delta(T7 - T0)$
Mean	1.0	0.5	-0.5
Standard error	0.1	0.1	0.1
$\Delta(\%)$ improvement on the mean			50.0
% of subjects with reduction			45.7
P-value			<0.001*

* significant at 5% (Wilcoxon signed-rank test).

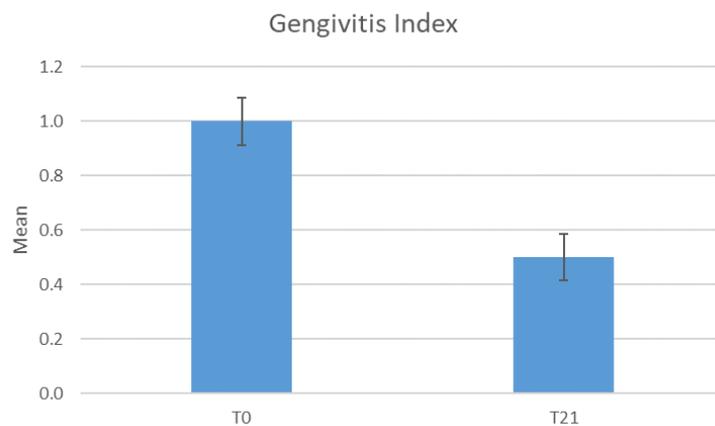


Figure 2. Mean \pm standard error of gingivitis index by time-point

3.5 – Bacterial plaque number

Product Perfect Smile Portable Water Flosser promoted a significant reduction in bacterial plaque number after 21 days of use in relation to time-point T0 (before product use).

Table 7: Descriptive statistics and results of comparison

Statistics	T0	T21	$\Delta(T7 - T0)$
Mean	88.8	55.0	-33.8
Standard error	4.0	3.8	3.5
$\Delta(\%)$ improvement on the mean			38.1
% of subjects with reduction			100.0
P-value			<0.001*

* significant at 5% (Wilcoxon signed-rank test).

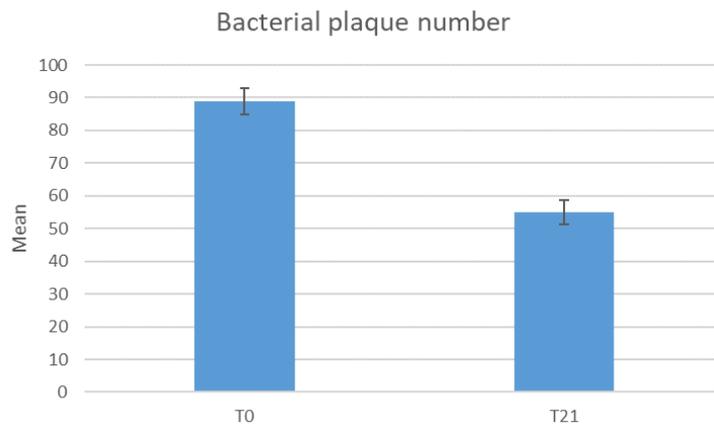


Figure 3. Mean \pm standard error of bacterial plaque number by time-point

3.6 – Percentage of surface with bacterial plaque

Product Perfect Smile Portable Water Flosser promoted a significant reduction in the percentage of surface with bacterial plaque after 21 days of use in relation to time-point T0 (before product use).

Table 8: Descriptive statistics and results of comparison

Statistics	T0	T21	$\Delta(T7 - T0)$
Mean	80.5	50.0	-30.5
Standard error	3.3	3.4	3.0
$\Delta(\%)$ improvement on the mean			37.9
% of subjects with reduction			100.0
P-value			<0.001*

* significant at 5% (Wilcoxon signed-rank test).

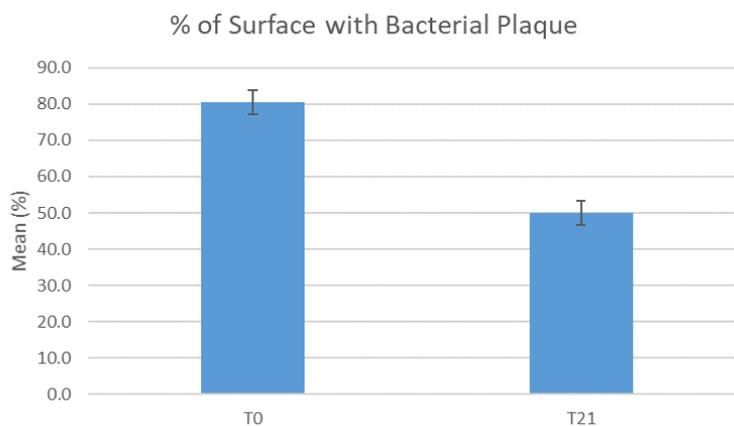


Figure 4. Mean \pm standard error of the percentage of surface with bacterial plaque by time-point

3.7 – Visual Analogue Scale - EVA - Degree of pain

Product Perfect Smile Portable Water Flosser promoted a significant reduction in degree of pain after 21 days of use in relation to initial time-point T0 (before product use).

Table 9: Descriptive statistics and results of comparison

Statistics	T0	T21	$\Delta(T7 - T0)$
Mean	2.4	1.3	-1.1
Standard error	0.2	0.2	0.3
$\Delta(\%)$ improvement on the mean			45.8
% of subjects with reduction			71.4
P-value			0.001*

* significant at 5% (Wilcoxon signed-rank test).

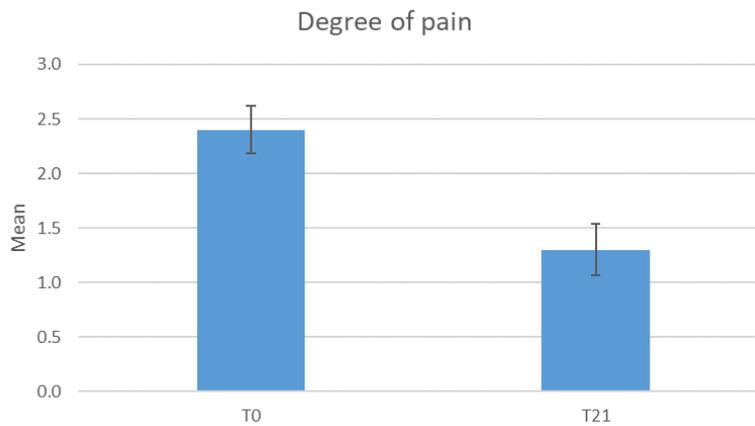


Figure 5. Mean \pm standard error by time-point

Table 10: Percentages and frequencies

Degree of pain	T0	T21
0	0% (0)	25.7% (9)
1	25.7% (9)	48.6% (17)
2	31.4% (11)	8.6% (3)
3	28.6% (10)	14.3% (5)
4	8.6% (3)	0% (0)
5	0% (0)	0% (0)
6	5.7% (2)	0% (0)
7	0% (0)	2.9% (1)
8	0% (0)	0% (0)
9	0% (0)	0% (0)
10	0% (0)	0% (0)
light (0+1+2)	57.1% (20)	82.9% (29)
moderate (3+4+5+6+7)	42.9% (15)	17.1% (6)
severe (8+9+10)	0% (0)	0% (0)

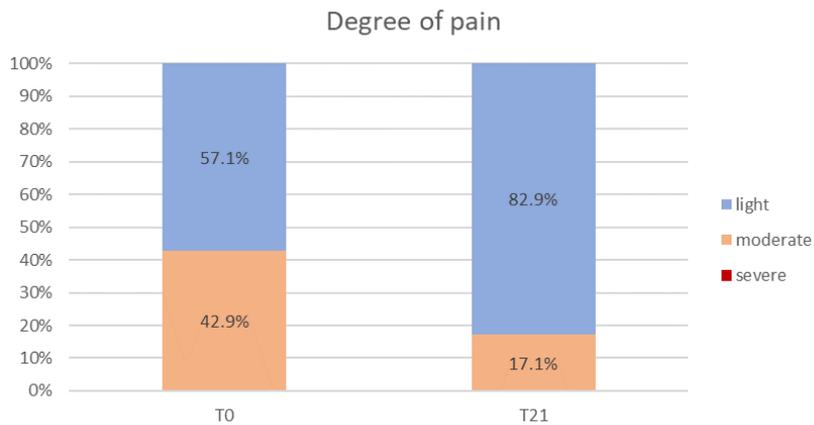


Figure 6. Percentage of results by time-point

3.8 – Claims

Thus, the following claims can be supported:

- *Assessed by a Dentist;*
- *Clinically Tested;*
- *Easy and more effective way to clean between teeth than string floss;*
- *More effective than string floss for removing plaque and improving gum health;*
- *Removes up to 90.0% of plaque from treated areas; (please check subject 027 data)*
- *100% of consumer presented reduction of plaque;*
- *A minute a day for brighter teeth, healthier gums and fresher breath;*
- *More effective than string flossing;*
- *Clinically shown to brighten teeth;*
- *Clinically shown to make gums healthier;*
- *Freshen breath;*
- *Clinically shown to remove stains;*
- *Visibly removes stains like coffee or red wine from my teeth;*
- *Teeth and gums look healthier than when I use traditional string floss;*
- *Feel healthier after using the Perfect Smile Portable Water Flosser;*
- *I can use the water flosser to get to the harder to reach area of my mouth better than string floss;*
- *Gums are healthier than using string floss;*
- *Does not damage gums;*
- *Helps break down plaque build up;*
- *Delivers cleaner and brighter teeth without damaging gums;*
- *Clinically shown to be gentle on sensitive teeth and gums;*
- *Safe and effective;*
- *Easy to use;*
- *Reduction of plaque;*



- *91.4% of consumers stated that their gums feel cleaner than flossing with string floss;*
- *94.3% of consumers stated that their gums look healthier than flossing with strong floss;*
- *Found to clean better than traditional string for 91.4% of consumer;*
- *For sensitive teeth;*
- *For sensitive gum;*