Statistical Report

Protocol Title:

Clinical Efficacy and Safety Evaluation of OraCare Health Rinse in Adults on Plaque and Gingivitis in a Six-Week Model

Protocol:

ProBreathMD: PBMD-2023-001

FINAL

November 27, 2023

<p style="text-align:center">Table of Contents</p>

Executive Summary

Study Objectives

The objective of this 6-week, randomized, examiner-blind clinical trial is to evaluate the safety and efficacy of Test OraCare Health Rinse compared to tooth brushing alone for the reduction of gingivitis and plaque when used unsupervised, twice daily at home.

The efficacy endpoints are:

Mean change in MGI at Weeks 2 and 6 for:

- Whole Mouth
- Interproximal (mesial and distal)

Change in mean number of healthy sites (MGI=0,1) from Baseline (MGI=2,3,4) at Week 2 and Week 6

Mean change in EBI scores at Weeks 2 and 6 for:

- Whole Mouth
- Interproximal (mesial and distal)

Mean change in number of bleeding sites (EBI=1 or 2) from Baseline to "0" bleeding sites at Weeks 2 and 6 for:

- Whole Mouth
- Interproximal (mesial and distal)

Mean change in LSPI scores at Weeks 2 and 6 for:

- Whole Mouth
- Gumline
- Interproximal (mesial and distal)

Mean change in BOP and scores and Periodontal Pocket Depth (PPD) at Week 6 for:

- Whole Mouth
- Interproximal (mesial and distal)

All efficacy variable results will be discussed in this Executive Summary.

Subjects were enrolled into one of two treatment groups. The treatment groups are:

- Control Group: Twice daily brushing with an ADA reference manual soft toothbrush plus ADA accepted dentifrice

- Test Group: Marketed OraCare Rinse following twice daily brushing with an ADA reference manual soft toothbrush plus ADA accepted dentifrice

Assessments were done at baseline, a 2-Week assessment, and a 6-Week assessment. For the purpose of labelling and identifying the two (2) groups, the text 'Control' will be used for the Control Group, and 'Test' will be used for the Test Group. The term 'Plaque' may be used to describe the Turesky Modification of the Quigley-Hein Plaque Index as further modified by Lobene and Soparkar (LSPI).

Demographic and Baseline Data

Sixty-five (65) subjects were randomized and sixty (63) completed the study. The demographic data will be presented for the enrolled subjects. The gender breakdown was 47 females and 18 males. The mean age was 48.8 years with the minimum age being 20 years and the maximum being 74 years. Demographic characteristics were comparable among the treatments at baseline. Full demographic summary data are given in Appendix Table 1.

Study Results

The 6-Week results of the Modified Gingival Index (MGI), the Expanded Bleeding Index (EBI), and the Turesky Modification of the Quigley-Hein Plaque Index as further modified by Lobene and Soparkar (LSPI) showed that the Test group improved during the study ($p < 0.001$). The active treatment was statistically superior to the Control in biofilm reduction ($p < 0.001$, all LSPI endpoints) and resulted in better gingival health ($p < 0.001$, all MGI and EBI endpoints, except mean number of healthy bleeding sites at 2-weeks, $p = 0.044$). This superiority in efficacy

occurred at both the 2-Week evaluation and the 6-Week evaluation. Also, Bleeding on Probing (BOP) and Periodontal Pocket Depth (PPD) at Week 6 for the active treatment showed statistically significant less bleeding on probing ($p<0.001$), and pocket depth improvement ($p<0.001$) in the 6-Week Study. Also, the active rinse was statistically superior to the Control group for BOP ($p<0.001$) and PDD ($p<0.001$).

Executive Summary Figure 1 below shows the 6-Week MGI improvements. The active treatment was about 6-times more effective in MGI improvement during the 6-week study (as well as 5-times more effective at 2-weeks) for whole mouth and interproximal sites compared to the Control group ($p<0.001$; for whole mouth, and interproximal sites, see Appendix Table 10).

Executive Summary Figure 1: MGI Improvement: Baseline to Week 6
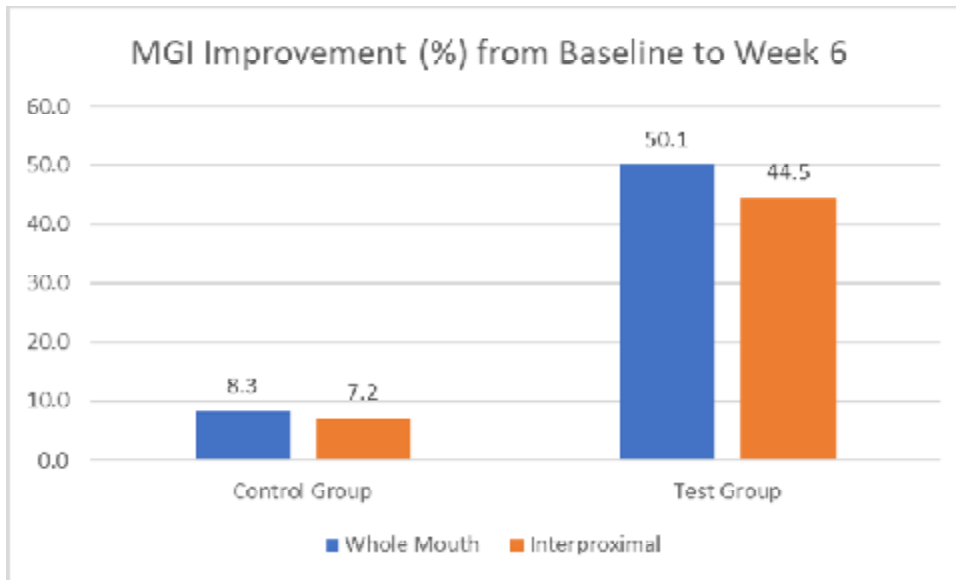
Results for the change in the number of MGI healthy sites followed the pattern seen for the MGI data. The change in healthy site for the active rinse was about 22 (adjusted for missing sites) (p<0.001), whereas, the Control group added less than 1 healthy site during the study. The superiority in change to healthy sites for the Test group was statistically significant (p<0.001) compared to the Control.

As seen in Executive Summary Figure 2 below the active treatment showed positive improvements for Expanded Bleeding Index (EBI) and was far superior to the Control Group (p<0.001; for whole mouth, and interproximal sites, see Appendix Table 11).

Executive Summary Figure 2: Expanded Bleeding Index Improvement: Baseline to Week 6
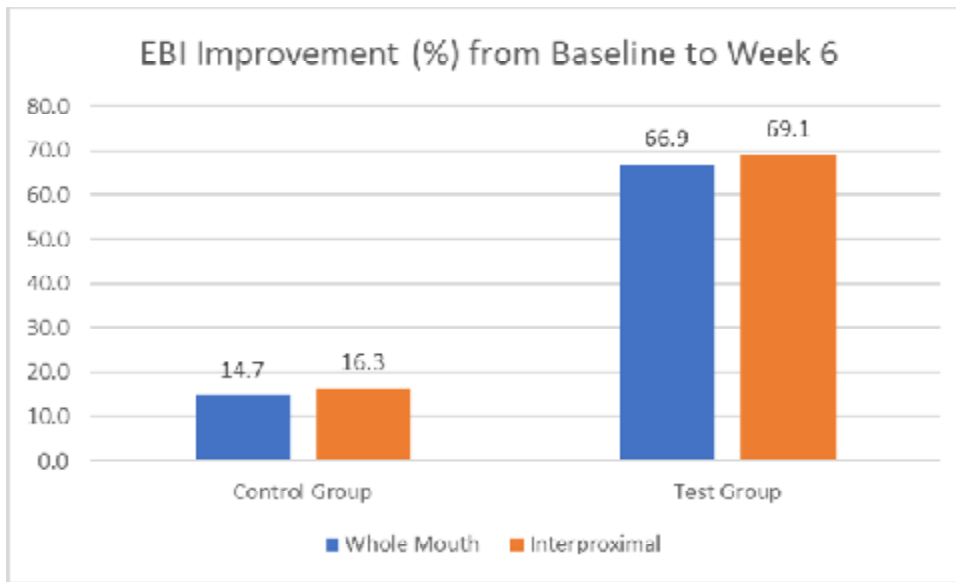
Change to healthy bleeding sites increased by about 50% (adjusted for missing sites) (p<0.001) for the active treatment (about 31 sites), whereas, the Control group added approximately 21 healthy sites during the 6-week study (see Appendix Table 4 and Table 5). The superiority in change to healthy sites was statistically significant (p<0.001) at Week 6 compared to the Control (Appendix Table 15).

Executive Summary Figure 3: Plaque (LSPI) Improvement: Baseline to Week 6

Plaque Improvement from Baseline to Week 6

(Control Group values: Whole mouth, -0.2; Gumline, 0.5; Interproximal, -1.9)

As seen in Executive Summary Figure 3 above the active treatments showed positive improvements for biofilm reduction and was far superior to the Control Group ($p<0.001$; for whole mou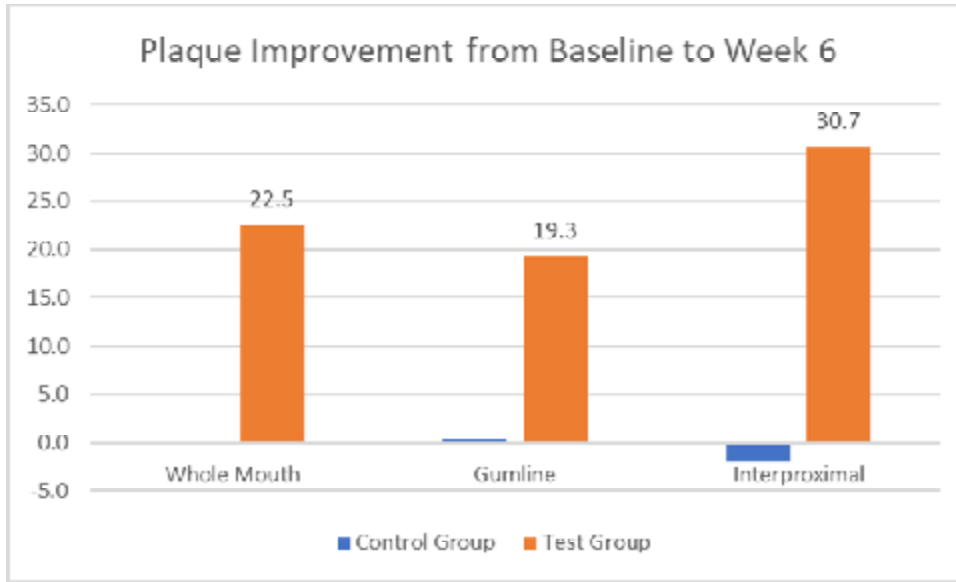th, gumline and interproximal sites, see Appendix Table 16). In fact, the Control group did not show any change in plaque during the 6-week study (see Appendix Table 6).

Summary

- The active treatment provided very positive outcomes towards gingival health over the 6-week study with about 6-times the improvement seen for the Control group.

- The active treatment increased about 22 healthy MGI sites compared to less than 1 site for the Control group.

- The active treatment provided very positive outcomes towards plaque biofilm removal over the 6-week study with a 22% improvement in whole mouth compared to no improvement for the Control group.

- The active treatment showed in excess of 35-times improvement in the Periodontal Pocket Depth compared to the Control group.

7

- The active treatment rinse showed superiority for every endpoint evaluated in comparison to the Control group.

Statistical Report

The body of this report will include sections and results that have not been discussed in detail in the Executive Summary. For the study synopsis, inclusion and exclusion criteria, analysis endpoints, and statistical analysis methods see the Executive Summary and / or the Protocol.

Study Design

See the Protocol and Study Report.

Statistical Analysis

See the Protocol and Study Report

Data Displays

Computer-generated tables adhere to the following specifications. Unless otherwise specified, the estimated mean for a set of values should be printed to two more decimal place than the raw (observed) data and rounded appropriately. Standard errors should be printed to three more additional decimal places than the raw (observed) data and rounded appropriately. For example, for plaque (i.e., data in integer values) data presentations will follow the following example given below.

Parameter	Data Presentation in Output
Raw data (e.g., plaque data)	X
Mean	X.XX
Standard Deviation (Standard Error)	X.XXX
Min - Max	X.XX – X.XX

The p value will be printed in tables rounded to three (3) decimal places and formatted as '0.xxx'. P values less than 0.001 will be formatted in the tables as 'p<0.001'. All fractional numeric values are printed with a zero to the left of the decimal point (e.g., 0.8). A percentage of less than one hundred is printed to a least two decimal places. Summaries are provided in

9

Executive Summary Tables, and Appendix Tables in this report. Improvement summaries and comparisons will be provided in tables. Tables providing summary statistics (e.g., mean, standard deviation, and comparisons of treatment change) will appear in the Appendix.

Results

Safety

No safety issues arose during the conduct of the study. Examination of the oral cavity at baseline, Week 2 and Week 6 assessments indicated normal findings for: perioral area / lips; buccal, labial, and sublingual mucosa, gingiva free/attached, tongue, palate hard/soft, uvula, oropharynx, and other soft / hard tissue. There were no adverse events during the conduct of the study.

Modified Gingival Index

All endpoints for the Test group improved over the study (p<0.001; see Appendix Table 2 to Table 3) and the improvements were greatly superior to the Control (p<0.001, see Appendix Tables 10 to 12).

The change (% improvement) in MGI and EBI and change in the number of healthy sites for MGI are given in Table 1 below. MGI improvements at Week 6 for whole mouth and interproximal sites were about 6-times the improvement seen in the Control group.

10

Table 1: Change (% improvement) in MGI and EBI and Change (Number) of Healthy Sites

	MGI Whole Mouth	MGI Interproximal	Healthy MGI [1]	EBI Whole Mouth	EBI Interproximal	Healthy EBI [2]
Control						
2-Week	6.1%	4.6%		20.1%	16.0%	23.3
6-Week	8.3%	7.2%	0.07	14.7%	16.3%	21.0
Test						
2-Week	33.0%	27.9%		60.0%	61.7%	28.8
6-Week	50.1%	44.5%	20.6	66.9%	67.9%	30.7
1 Change in mean number of healthy gingival sites adjusted for missing sites. 2 Change in mean number of healthy bleeding sites adjusted for missing sites						

Expanded Bleeding Index

All endpoints for the active treatment Test improved over the study (p<0.001; see Appendix Table 4 and Table 5) and the improvements were greatly superior to the Control (p<0.001; except mean number of healthy bleeding sites at 2-weeks, p=0.010). Improvements were about 4.5-times greater for the active treatment compared to the Control group at Week 6.

The change in the number of healthy sites for EBI are given in Table 1 above. EBI improvements to healthy sites at Week 6 for whole mouth interproximal sites and were about 50% greater than the improvement seen in the Control group (about 31 compared to about 21). These differences are statistically significant (p<0.001). The 2-week improvement was also significantly better for the Test group compared to the Control group (p=0.044).

Plaque (LSPI)

Plaque results given in Table 2 below.

Table 2: Mean change (%) in Plaque (LSPI), BOP and PPD

Table 2							
	LSPI Whole Mouth	LSPI Gumline	LSPI Proximal	BOP Whole Mouth	BOP Proximal	PPD Whole Mouth	PPD Proximal
Control							
2-Week	-0.1%	-0.4%	0.7%				
6-Week	-0.2%	0.5%	-1.9%	-7.1%	-12.6%	0.2%	0.4%
Test							
2-Week	23.7%	19.8%	33.4%				
6-Week	22.5%	19.3%	30.7%	66.7%	66.2%	8.9%	7.4%

Plaque did not statistically change from Baseline for the Control group (p>0.504; Appendix Table 6). Week 6 plaque improvements for the active treatment was very positive, whole mouth biofilm improvement for the Test group was 22.5%.

Plaque (whole mouth, interproximal, and gumline) for the Test group improved over the study (p<0.001; see Appendix Table 6 and Table 7) and the improvements were superior to the Control (p<0.001, see Appendix Tables 16 and Table 17).

Bleeding on Probing

Table 2 above shows that the Control group regressed in BOP during the study, while the active treatment had major gains in BOP (66.7%) whole mouth improvement for the Test group). All BOP assessments for the active treatment improved over the study (p<0.001, see Appendix Table 8) and the improvements were greatly superior to the Control (p<0.001, see Appendix Tables 18).

Periodontal Pocket Depth

Table 2 above provided summary data for PDD. The Test group showed a 35-times improvement in the PDD compared to the Control group.

All PPD assessments for the active treatment improved over the study (p<0.001; see Appendix Table 9) and the improvements were statistically superior to the Control group (p<0.001, see Appendix Tables 19).

Conclusion
- The active treatment provided very positive outcomes towards gingival health over the 6-week study with about 6-times the improvement seen for the Control group.
- The active treatment increased about 22 healthy MGI sites compared to less than 1 site for the Control group.
- The active treatment provided very positive outcomes towards plaque biofilm removal over the 6-week study with a 22.5% improvement in whole mouth compared to no improvement for the Control group.
- The active treatment showed in excess of 35-times improvement in the Periodontal Pocket Depth compared to the Control group.

- The active treatment rinse showed superiority for every endpoint evaluated in comparison to the Control group.

Appendix

Table 1

Demographics

	Control (N=33)	Test (N=32)	Total (N=65)	P value[1]
Age (years)				0.537
N	33	32	65	
Mean	47.8	49.9	48.8	
Standard Deviation	13.91	15.24	15.51	
Standard Error	2.42	2.69	1.80	
Minimum	20.0	20.0	20.0	
Maximum	74.0	73.0	74.0	
Gender				0.408
Male	11 (33.3%)	7 (21.9%)	18 (27.7%)	
Female	22 (66.7%)	25 (78.1%)	47 (72.3%)	
Race				0.850
American Indian Alaskan Native	1 (3.0%)	0 (0.0%)	1 (1.5%)	
Black African American	2 (6.1%)	1 (3.1%)	3 (4.6%)	
White	28 (84.8%)	30 (93.8%)	58 (89.2%)	
Asian	1 (3.0%)	0 (0.0%)	1 (1.5%)	
Other	1 (3.0%)	1 (3.1%)	2 (3.1%)	
Ethnicity				1.000
Hispanic / Latino	1 (3.0%)	0 (0.0%)	1 (1.5%)	
Non-Hispanic / Latino	32 (97.0%)	32 (100.0%)	64 (98.5%)	

Legend for Appendix Table 1

1 P-value for age from a three-treatment ANOVA, the other p-values from a Fisher's Exact Test.

16

Appendix Table 2

MGI Summary Statistics: Week 6

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	32	2.61	2.52	2.69	0.286	0.050	2.68	2.05	3.00		
Post Whole	32	2.39	2.30	2.49	0.309	0.055	2.40	1.93	2.95		
Whole	32	0.22	0.16	0.27	0.190	0.034	0.18	-0.04	0.73	6.4	<0.001
Pre Proximal	32	2.72	2.64	2.80	0.273	0.048	2.83	2.15	3.00		
Post Proximal	32	2.53	2.44	2.62	0.300	0.053	2.55	2.05	3.00		
Proximal	32	0.20	0.14	0.25	0.176	0.031	0.16	-0.02	0.68	6.3	<0.001
MGI Healthy	32	0.07	-0.05	0.18	0.381	0.067	0.00	0.00	2.15	1.0	0.325

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	2.63	2.56	2.70	0.232	0.042	2.66	2.09	3.00		
Post Whole	31	1.31	1.21	1.42	0.343	0.062	1.31	0.78	2.09		
Whole	31	1.32	1.24	1.40	0.264	0.047	1.31	0.66	1.79	27.8	<0.001
Pre Proximal	31	2.75	2.68	2.82	0.229	0.041	2.76	2.20	3.00		
Post Proximal	31	1.53	1.43	1.63	0.335	0.060	1.50	1.01	2.25		
Proximal	31	1.22	1.15	1.30	0.252	0.045	1.19	0.67	1.69	27.0	<0.001
MGI Healthy	31	22.16	17.96	26.35	13.76	2.471	22.00	0.00	45.23	9.0	<0.001

17

Appendix Table 2 (continued)

MGI Summary Statistics: Week 6

Legend for Appendix Table 2

Pre Variable = Baseline score
Post Variable = Week 6 score
MGI Healthy = Change in mean number of healthy gingival sites adjusted for missing sites

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

18

Appendix Table 3

MGI Summary Statistics: Week 2

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	33	2.62	2.54	2.71	0.289	0.050	2.70	2.05	3.00		
Post Whole	33	2.46	2.37	2.55	0.291	0.051	2.47	1.91	3.00		
Whole	33	0.16	0.12	0.21	0.151	0.026	0.15	-0.15	0.53	6.1	<0.001
Pre Proximal	33	2.73	2.65	2.81	0.273	0.048	2.83	2.15	3.00		
Post Proximal	33	2.60	2.53	2.68	0.252	0.044	2.64	2.11	3.00		
Proximal	33	0.13	0.09	0.16	0.130	0.023	0.11	-0.09	0.43	5.6	<0.001
MGI Healthy	33	0.00	0.00	0.00	0.000	0.000	0.00	0.00	0.00		

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	2.63	2.56	2.70	0.232	0.042	2.66	2.09	3.00	63.2	
Post Whole	31	1.76	1.66	1.87	0.354	0.064	1.80	1.05	2.44	27.7	
Whole	31	0.87	0.80	0.94	0.240	0.043	0.87	0.46	1.38	20.2	<0.001
Pre Proximal	31	2.75	2.68	2.82	0.229	0.041	2.76	2.20	3.00	66.8	
Post Proximal	31	1.98	1.88	2.09	0.350	0.063	2.01	1.34	2.69	31.5	
Proximal	31	0.77	0.70	0.84	0.242	0.043	0.73	0.29	1.33	17.7	<0.001
MGI Healthy	31	6.64	4.06	9.23	8.476	1.522	3.50	0.00	32.00	4.4	<0.001

Appendix Table 3 (continued)

MGI Summary Statistics: Week 2

Legend for Appendix Table 3

Pre Variable = Baseline score
Post Variable = Week 2 score
MGI Healthy = Change in mean number of healthy gingival sites adjusted for missing sites

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Appendix Table 4

EBI Summary Statistics: Week 6

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	32	0.30	0.25	0.35	0.178	0.031	0.25	0.13	0.85		
Post Whole	32	0.26	0.22	0.29	0.118	0.021	0.25	0.11	0.58		
Whole	32	0.04	0.01	0.07	0.100	0.018	0.02	-0.09	0.41	2.5	0.018
Pre Proximal	32	0.29	0.24	0.35	0.189	0.033	0.24	0.09	0.83		
Post Proximal	32	0.25	0.21	0.28	0.115	0.020	0.23	0.08	0.51		
Proximal	32	0.05	0.01	0.08	0.112	0.020	0.04	-0.08	0.47	2.4	0.021
EBI Healthy	32	21.02	18.29	23.74	9.091	1.607	19.03	9.33	52.64	13.1	<0.001

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	0.30	0.24	0.36	0.193	0.035	0.23	0.13	0.99		
Post Whole	31	0.10	0.07	0.12	0.082	0.015	0.07	0.01	0.40		
Whole	31	0.20	0.16	0.24	0.128	0.023	0.17	0.07	0.59	8.7	<0.001
Pre Proximal	31	0.29	0.22	0.35	0.209	0.038	0.22	0.10	1.03		
Post Proximal	31	0.09	0.07	0.11	0.074	0.013	0.06	0.00	0.33		
Proximal	31	0.20	0.15	0.25	0.154	0.028	0.15	0.04	0.69	7.2	<0.001
EBI Healthy	31	30.73	26.89	34.58	12.620	2.267	28.00	14.00	71.08	13.6	<0.001

Appendix Table 4 (continued)

EBI Summary Statistics: Week 6

Legend for Appendix Table 4

Pre Variable = Baseline score
Post Variable = Week 6 score (Table 4) / Week 2 score (Table 5)
EBI Healthy = Change to healthy bleeding sites adjusted for missing sites

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Appendix Table 5

EBI Summary Statistics: Week 2

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	33	0.31	0.26	0.36	0.183	0.032	0.25	0.13	0.85		
Post Whole	33	0.25	0.22	0.28	0.112	0.020	0.22	0.11	0.65		
Whole	33	0.06	0.03	0.10	0.111	0.019	0.06	-0.10	0.37	3.2	0.003
Pre Proximal	33	0.30	0.24	0.36	0.189	0.033	0.24	0.09	0.83		
Post Proximal	33	0.25	0.22	0.29	0.120	0.021	0.22	0.10	0.66		
Proximal	33	0.05	0.01	0.08	0.122	0.021	0.03	-0.13	0.38	2.3	0.030
EBI Healthy	33	23.34	20.17	26.51	10.740	1.870	22.40	6.00	56.00	12.5	<0.001

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	0.30	0.24	0.36	0.193	0.035	0.23	0.13	0.99		
Post Whole	31	0.12	0.09	0.15	0.106	0.019	0.09	0.02	0.49		
Whole	31	0.18	0.14	0.21	0.114	0.020	0.15	-0.03	0.49	8.8	<0.001
Pre Proximal	31	0.29	0.22	0.35	0.209	0.038	0.22	0.10	1.03		
Post Proximal	31	0.11	0.08	0.14	0.108	0.019	0.08	0.00	0.51		
Proximal	31	0.18	0.14	0.22	0.125	0.023	0.15	-0.04	0.52	7.9	<0.001
EBI Healthy	31	28.81	25.59	32.03	10.564	1.897	25.00	15.00	56.00	15.2	<0.001

Appendix Table 5 (continued)
EBI Summary Statistics: Week 2

Legend for Appendix Table 5

Pre Variable = Baseline score
Post Variable = Week 2 score
EBI Healthy = Change to healthy bleeding sites adjusted for missing sites

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Sponsor Protocol #PBMD-2023-001   Statistical Report: Test vs Control
                                                             Final 27Nov23

Appendix Table 6

Plaque (LSPI) Summary Statistics: Week 6

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	32	2.90	2.75	3.04	0.481	0.085	2.95	1.98	3.91		
Post Whole	32	2.90	2.78	3.02	0.403	0.071	2.88	2.30	3.93		
Whole	32	-0.01	-0.08	0.07	0.262	0.046	-0.04	-0.38	0.53	0.1	0.905
Pre Proximal	32	3.12	3.00	3.24	0.397	0.070	3.16	2.36	4.04		
Post Proximal	32	3.10	3.00	3.21	0.353	0.062	3.04	2.57	4.06		
Proximal	32	0.02	-0.05	0.08	0.221	0.039	-0.01	-0.32	0.44	0.4	0.701
Pre Gumline	32	2.45	2.25	2.66	0.684	0.121	2.63	1.21	3.69		
Post Gumline	32	2.50	2.33	2.66	0.542	0.096	2.43	1.57	3.67		
Gumline	32	-0.05	-0.16	0.07	0.393	0.069	-0.09	-0.71	0.80	0.7	0.504

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	2.98	2.84	3.11	0.442	0.079	3.04	2.10	3.88		
Post Whole	31	2.31	2.18	2.44	0.435	0.078	2.30	1.54	2.96		
Whole	31	0.67	0.57	0.77	0.326	0.059	0.70	0.18	1.34	11.5	<0.001
Pre Proximal	31	3.21	3.09	3.32	0.382	0.069	3.26	2.29	3.97		
Post Proximal	31	2.59	2.46	2.71	0.412	0.074	2.53	1.82	3.19		
Proximal	31	0.62	0.53	0.71	0.300	0.054	0.63	0.19	1.34	11.5	<0.001
Pre Gumline	31	2.52	2.34	2.71	0.597	0.107	2.54	1.48	3.70	23.5	
Post Gumline	31	1.75	1.59	1.91	0.530	0.095	1.74	0.98	2.64	18.4	
Gumline	31	0.78	0.64	0.91	0.454	0.081	0.77	0.13	1.95	9.5	<0.001

Plaque (LSPI) Summary Statistics: Week 6

Legend for Appendix Table 6

Pre Variable = Baseline score
Post Variable = Week 6 score

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Appendix Table 7

Plaque (LSPI) Summary Statistics: Week 2

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	33	2.90	2.76	3.04	0.473	0.082	2.96	1.98	3.91		
Post Whole	33	2.90	2.78	3.02	0.403	0.070	2.92	2.05	3.73		
Whole	33	0.00	-0.08	0.08	0.274	0.048	-0.04	-0.55	0.75	0.1	0.946
Pre Proximal	33	3.12	3.00	3.23	0.391	0.068	3.16	2.36	4.04		
Post Proximal	33	3.13	3.03	3.23	0.338	0.059	3.14	2.44	3.83		
Proximal	33	-0.01	-0.07	0.05	0.202	0.035	-0.01	-0.50	0.50	0.4	0.695
Pre Gumline	33	2.46	2.26	2.66	0.675	0.118	2.68	1.21	3.69		
Post Gumline	33	2.44	2.27	2.61	0.568	0.099	2.46	1.27	3.54		
Gumline	33	0.02	-0.11	0.15	0.450	0.078	0.02	-0.96	1.24	0.2	0.820

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	2.98	2.84	3.11	0.442	0.079	3.04	2.10	3.88		
Post Whole	31	2.27	2.14	2.40	0.426	0.076	2.28	1.39	3.22		
Whole	31	0.70	0.58	0.83	0.416	0.075	0.66	-0.03	1.61	9.4	<0.001
Pre Proximal	31	3.21	3.09	3.32	0.382	0.069	3.26	2.29	3.97		
Post Proximal	31	2.57	2.44	2.70	0.420	0.075	2.61	1.73	3.42		
Proximal	31	0.64	0.52	0.75	0.374	0.067	0.57	0.06	1.51	9.5	<0.001
Pre Gumline	31	2.52	2.34	2.71	0.597	0.107	2.54	1.48	3.70		
Post Gumline	31	1.68	1.53	1.83	0.486	0.087	1.63	0.70	2.81		
Gumline	31	0.84	0.68	1.01	0.548	0.098	0.77	-0.23	2.07	8.6	<0.001

Appendix Table 7 (continued)

Plaque (LSPI) Summary Statistics: Week 2

Legend for Appendix Table 7

Pre Variable = Baseline score
Post Variable = Week 2 score

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Appendix Table 8

Bleeding on Probing (BOP) Summary Statistics: Week 6

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	32	0.04	0.03	0.05	0.045	0.008	0.02	0.00	0.17		
Post Whole	32	0.04	0.03	0.05	0.038	0.007	0.04	0.00	0.15		
Whole	32	0.00	-0.01	0.00	0.023	0.004	0.00	-0.07	0.06	0.7	0.476
Pre Proximal	32	0.04	0.03	0.06	0.053	0.009	0.03	0.00	0.21		
Post Proximal	32	0.05	0.04	0.06	0.044	0.008	0.04	0.00	0.18		
Proximal	32	-0.01	-0.01	0.00	0.027	0.005	0.00	-0.08	0.04	1.2	0.252

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	31	0.06	0.04	0.08	0.077	0.014	0.04	0.00	0.43	4.3	<0.001
Post Whole	31	0.02	0.01	0.03	0.026	0.005	0.01	0.00	0.11	4.2	<0.001
Whole	31	0.04	0.02	0.06	0.057	0.010	0.02	-0.01	0.31	3.9	<0.001
Pre Proximal	31	0.06	0.03	0.08	0.080	0.014	0.04	0.00	0.44	4.0	<0.001
Post Proximal	31	0.02	0.01	0.03	0.026	0.005	0.00	0.00	0.08	4.2	<0.001
Proximal	31	0.04	0.02	0.06	0.064	0.012	0.02	-0.01	0.35	3.3	0.002

Legend for Appendix Table 8

Pre Variable = Baseline score
Post Variable = Week 6 score

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Appendix Table 9

Periodontal Pocket Depth (PPD) Summary Statistics: Week 6

Control

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	32	2.22	2.16	2.29	0.224	0.040	2.24	1.78	2.83	56.1	
Post Whole	32	2.22	2.15	2.28	0.216	0.038	2.22	1.79	2.81	58.0	
Whole	32	0.01	-0.02	0.03	0.070	0.012	0.00	-0.14	0.26	0.4	0.675
Pre Proximal	32	2.44	2.37	2.51	0.224	0.040	2.44	1.94	3.04	61.6	
Post Proximal	32	2.43	2.37	2.49	0.211	0.037	2.44	1.94	3.02	65.2	
Proximal	32	0.01	-0.01	0.03	0.071	0.013	0.01	-0.15	0.19	0.7	0.485

Test

Variable	n	mean	lclm	uclm	std	stderr	median	min	max	t	probt
Pre Whole	28	2.34	2.26	2.41	0.231	0.044	2.31	1.94	2.86		
Post Whole	28	2.17	2.09	2.24	0.232	0.044	2.09	1.86	2.71		
Whole	28	0.17	0.13	0.21	0.126	0.024	0.13	-0.01	0.46	7.2	<0.001
Pre Proximal	28	2.56	2.48	2.64	0.243	0.046	2.53	2.11	3.11		
Post Proximal	28	2.41	2.33	2.48	0.245	0.046	2.32	2.10	2.96		
Proximal	28	0.15	0.12	0.19	0.109	0.021	0.13	0.00	0.39	7.4	<0.001

Legend for Appendix Table 9

Pre Variable = Baseline score
Post Variable = Week 6 score

LCLM = lower limit of the confidence interval
UCLM = upper limit of the confidence limit
Std   = standard deviation
Stderr   = standard error
Median = median value
Max   = maximum value
T   = T-statistic for test of means
ProbT   = Probability value for the T-statistic

Appendix Table 10

ANCOVA Results for MGI: Week 6

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	1.10	0.058	<0.001	0.98	1.22

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	1.02	0.055	<0.001	0.92	1.14

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 11

ANCOVA Results for MGI: Week 2

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.71	0.050	<0.001	0.61	0.82

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.64	0.048	<0.001	0.55	0.74

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 12

Change in Mean Number of MGI Healthy Sites: Week 6 & Week 2

Variable	Change in Mean Number of MGI Healthy Sites: Week 6				
ANOVA Overall p-value	<0.001				
Comparison	Mean Difference	Mean Difference Stderr	P-value	Mean Difference Lower CI	Mean Difference Upper CI
Test vs Control	22.09	2.433	<0.001	17.23	29.96

Variable	Change in Mean Number of MGI Healthy Sites: Week 2				
ANOVA Overall p-value	<0.001				
Comparison	Mean Difference	Mean Difference Stderr	P-value	Mean Difference Lower CI	Mean Difference Upper CI
Test vs Control	6.64	1.474	<0.001	3.69	9.59

LSMean Difference = Mean difference of the treatment means

P-value = P-value of the test of the Mean difference

Mean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 13

ANCOVA Results for EBI: Week 6

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.16	0.016	<0.001	0.13	0.19

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.15	0.015	<0.001	0.12	0.19

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 14

ANCOVA Results for EBI: Week 2

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.12	0.014	<0.001	0.09	0.15

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.14	0.016	<0.001	0.10	0.17

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 15

Change in Mean Number to Healthy Bleeding (EBI) Sites: Week 6 & Week 2

Variable	Change in Mean Number of Healthy Bleeding (EBI) Sites: Week 6				
ANOVA Overall p-value	<0.001				
Comparison	Mean Difference	Mean Difference Stderr	P-value	Mean Difference Lower CI	Mean Difference Upper CI
Test vs Control	9.72	2.754	<0.001	4.19	15.24

Variable	Change in Mean Number of Healthy Bleeding (EBI) Sites: Week 2				
ANOVA Overall p-value	0.044				
Comparison	Mean Difference	Mean Difference Stderr	P-value	Mean Difference Lower CI	Mean Difference Upper CI
Test vs Control	5.47	2.665	0.044	0.15	10.80

Mean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the Mean difference

Mean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 16

ANCOVA Results for Plaque (LSPI): Week 6

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.65	0.067	<0.001	0.52	0.79

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.58	0.063	<0.001	0.46	0.71

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 16 (continued)

ANCOVA Results for Plaque (LSPI): Week 6

Variable	Gumline				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.79	0.089	<0.001	0.62	0.97

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 17

ANCOVA Results for Plaque (LSPI): Week 2

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.68	0.077	<0.001	0.52	0.83

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.62	0.069	<0.001	0.48	0.76

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 17 (continued)

ANCOVA Results for Plaque (LSPI): Week 2

Variable	Gumline				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	P-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.79	0.102	<0.001	0.59	1.00

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 18

ANCOVA Results for Bleeding on Probing (BOP): Week 6

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	Adjusted p-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.03	0.005	<0.001	0.02	0.04

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	Adjusted p-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.03	0.006	<0.001	0.02	0.04

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Appendix Table 19

ANCOVA Results for Periodontal Pocket Depth (PPD): Week 6

Variable	Whole Mouth				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	Adjusted p-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.19	0.027	<0.001	0.14	0.24

Variable	Interproximal				
ANCOVA Overall p-value	<0.001				
Comparison	LSMean Difference	LSMean Difference Stderr	Adjusted p-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Test vs Control	0.17	0.031	<0.001	0.11	0.23

LSMean Difference = Mean difference of the covariate adjusted treatment means

P-value = P-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

END OF DOCUMENT