University of California, Irvine
School of Medicine – Beckman Laser Institute and Medical Clinic

Study Report – PWS-OEH-0921

A fourteen-day clinical study in 30 subjects to determine the effect on halitosis of OE Clean & Fresh Breath[R] mouthwash

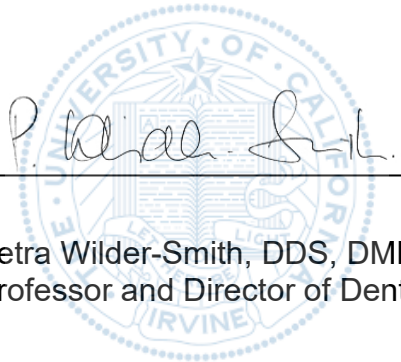
Study Goal:

To determine the effect on halitosis of rinsing twice-daily during 14 days with OE Clean & Fresh Breath[R] mouthwash.

Study Overview:

Thirty subjects with moderate to severe halitosis as determined using a standard halimeter as well as organoleptic evaluation by 2 blinded investigators were recruited. Baseline measurements were recorded 3x from each subject using the halimeter, and once each by two individual pre-standardized clinicians to obtain mean baseline halitosis values. Subjects then continued with their regular oral hygiene measures. Additionally, they used the allocated test mouthwash for 14 days, rinsing for 2 minutes twice daily with the OE Clean & Fresh Breath[R] mouthwash. On Day 14, three halimeter measurements and 1 organoleptic measurement by each of 2 blinded investigators were repeated. Statistical analysis of the data determined that twice-daily use of OE Clean & Fresh Breath[R] mouthwash over 14 days resulted in a significant reduction in halitosis score, with the digital score improving by almost 50%, and the organoleptic score by more than 60%.

Submitted by:



Petra Wilder-Smith, DDS, DMD, PhD
Professor and Director of Dentistry

Date Submitted

9.28.2021

1. PURPOSE

Goal of this single center, in vivo, blinded study was to determine the effect in individuals with moderate to severe halitosis of rinsing twice-daily during 14 days with OE Clean & Fresh Breath^{R} mouthwash. Halitosis was determined using 2 approaches: (1) a digital halimeter and (2) organoleptic measurements by 2 pre-standardized, blinded investigators.

2. MATERIALS AND METHODS

2.1. Subjects

30 subjects with a baseline mean digital halitosis score of >150 and a mean baseline organoleptic score of $\geq$ 2 were recruited and provided written, informed consent.

Subjects additionally met the following inclusion and exclusion criteria:

Inclusion Criteria

1. Male or non-pregnant female, 18 years of age and above.
2. Minimum of 25 teeth present.
3. Willing and able to provide written informed consent.
4. Willing and able to comply with study visits as described in the protocol.
5. Available for follow up on the telephone.

Exclusion Criteria

1. Unable or unwilling to sign the informed consent form.
2. Participation in any other clinical study within the last 30 days prior to enrollment into this study.
3. Subjects who must receive dental treatment during the study duration.
4. History of significant adverse effects following use of oral hygiene products such as toothpastes and mouth rinses.
5. Allergy to personal care/consumer products or their ingredients.
6. Diagnosed with Sjögren's disease, or immune deficiency diseases (i.e., HIV or AIDS, poorly controlled diabetes), or anti TNF-alpha medication for rheumatoid arthritis, systemic antibiotics in the last 3 months, anti-inflammatory drugs, or immune suppressants.

7. Presence of any condition, abnormality, or situation at Baseline that in the opinion of the Principal Investigator may affect the patient's ability to comply with study requirements

2.2. Protocol

This study was performed in full compliance with University of California Irvine IRB protocol 1997-1972, and all clinical procedures were conducted in accordance with the Helsinki Declaration of 1975, as updated in 2013. No significant changes were made in the study design after commencement of the study. The rolling recruitment through advertisements was initiated in August 2021 and all the study visits were completed by two examiners by end of September 2021.

Subjects maintained their regular dietary and oral hygiene routines throughout the study duration. They were provided masked bottles of mouth rinse for the study duration. These bottles contained OE Clean & Fresh Breath^{R} mouthwash. Subjects rinsed twice daily for 2 minutes with the allocated mouthwash for 2 weeks, shaking the bottle for 1 minute before each use. Subjects were told that their allocated bottle of mouthwash may contain an active or an inactive mouth rinse.

Testing was undertaken on Day 0 of the study, and again on Day 14. All appointments were scheduled in the morning before eating and hygiene procedures, to standardize oral conditions. Prior to halimeter (Halimeter Plus, Interscan Corp, Simi Valley, CA 93063) measurements, patients were asked to keep their mouths closed for 3 min while breathing through the nose. After 3 minutes, a disposable suction tip was mounted on the handpiece of the halimeter and inserted into the subject's mouth. Subjects were asked to exhale briefly through the suction tip for 30 s. The procedure was repeated thrice for each subject, and each time, the peak value was recorded by the halimeter. Standard organoleptic testing was performed by 2 separate, blinded, pre-standardized clinicians at a distance of 10cm from the oral cavity, and semi-quantitative severity grades were assigned as follows:

0: no oral malodour

1: mild oral malodour

2: moderate oral malodour

3: strong oral malodour.

Clinicians were told that each subject was allocated a masked bottle of mouthwash that may have contained an active or an inactive mouthwash.

2.3. Test Mouthwash

1. *Test formulation*: Luminex Oral Essentials Clean & Fresh Breath^{R} (Beverly Hills, CA 90210)

2.4. Endpoints and Data Analysis

Statistical analysis was performed using an unpaired T-test to compare mouthwash effect on halimeter and organoleptic measurements, and Pearson correlation coefficients to evaluate agreement between halimeter and organoleptic scores.

3. RESULTS

All subjects completed the study in full compliance with the protocol. No adverse events were reported or observed.

Raw data are presented in the Appendix under Table A.1

Halimeter Mean Baseline Score (S.D.) (n= 15)	Halimeter Mean Endpoint Score (S.D.) (n= 15)	Halimeter Mean Score Difference (%)	Organoleptic Mean Baseline Score (S.D.) (n= 15)	Organoleptic Mean Endpoint Score (S.D.) (n= 15)	Organoleptic Mean Score Difference (%)
210.3 (24.2)	108.3 (28)	-102.0 (-48.5%)	2.55 (0.46)	0.92 (0.37)	-1.55 (-60.8%)

Table 1: Mean Halimeter and Organoleptic Scores over Time

Halimeter scores ($p<0.0001$) and organoleptic scores ($p<0.0001$) were significantly improved at study endpoint vs study baseline.

The Pearson corelation coefficient (R) between halimeter and organoleptic score measured 0.861 (sig; $p<0.0001$) at study baseline, and 0.772 (sig; $p<0.0001$) at study endpoint.

4. CONCLUSION

After 2 weeks of twice-daily use of OE Clean & Fresh BreathR mouthwash, thirty subjects showed significant reduction in halitosis score, with the digital halitosis score improving by almost 50%, and the organoleptic score by more than 60%. There was very good corelation between halimeter and organoleptic halitosis scores.

APPENDIX

Table A.1: Halimeter measurements (3 at baseline and 3 at endpoint) and organoleptic scores (2 investigators at each timepoint) for each subject

(T0 – baseline; TF – final; Hal-halimeter; Org1- organoleptic score, first investigator; Org2 - organoleptic score, second investigator)

ID	T0 Hal 1	T0 Hal 2	T0 Hal 3	T0 Org 1	T0 Org 2	TF Hal 1	TF Hal 2	TF Hal 3	TF Org 1	TF Org 2
1	184	169	217	2	2	82	59	71	1	0
2	242	258	221	3	3	87	99	111	1	1
3	194	227	173	2	2	69	93	86	1	1
4	183	169	241	2	2	62	43	69	0	0
5	240	221	206	3	2	107	121	92	1	1
6	249	230	217	3	3	121	146	134	1	2
7	238	227	250	3	3	113	126	133	1	1
8	239	216	232	3	3	94	97	74	1	1
9	210	179	188	2	2	46	82	55	0	0
10	184	193	217	3	2	87	79	101	1	1
11	226	200	189	2	3	105	103	89	1	1
12	194	191	168	2	2	105	131	94	1	1
13	168	147	182	2	3	134	97	111	1	1
14	232	217	245	3	3	156	130	128	2	1
15	218	237	249	3	3	94	121	131	1	1
16	198	157	173	2	2	86	72	94	0	1
17	246	230	221	3	3	109	133	142	1	1
18	200	244	206	3	3	124	96	115	1	1
19	234	246	218	3	3	125	132	149	1	1
20	163	168	182	2	2	73	94	113	1	1
21	213	186	206	2	2	117	85	79	1	1
22	202	217	179	2	2	146	132	119	1	1
23	246	239	225	3	3	123	99	139	1	1
24	147	175	189	2	2	72	70	86	0	0
25	230	249	218	3	3	143	128	117	1	1

26	244	221	199	3	3	94	132	120	1	1
27	197	244	230	2	3	94	99	109	1	1
28	218	239	244	3	3	111	117	138	1	1
29	236	215	239	3	3	220	193	186	2	1
30	172	150	197	2	2	130	124	99	1	1