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Beckman Laser Institute

1002 Health Sciences Road East
Irvine, CA 92612-1475
(949) 824-6996
(949) 824-4713 Fax

Final Report:

A Clinical Study to Identify the Effects of

Lumineux Oral Essentials Clean and Fresh Mouthwash®

on

Inflammatory Markers in Gingival Crevicular Fluid

Petra Wilder-Smith, DDS, PhD

Professor, Director of Dentistry

University of California, Irvine

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Petra Wilder-Smith 12.5.19

GOAL

The goal of this study was to determine the effect of Lumineux Oral Essentials Clean and Fresh Mouthwash® vs. a placebo on crevicular fluid markers of inflammation.

MATERIAL AND METHODS

This prospective, randomized, controlled, double-blind study was conducted in 50 subjects.

Study Overview

Eligibility was determined by baseline measurements performed before study begin. Once eligibility was determined, 50 subjects were enrolled. Subjects were randomly assigned (randomizer.com) in a 1:1 ratio to treatment with either the test mouthwash (Lumineux Oral Essentials Clean and Fresh Mouthwash®, Los Angeles CA 90026) or a control rinse containing water and flavoring only.

Subjects were instructed to rinse with one capful of their allocated mouthwash for 60 seconds after breakfast and again before bedtime. No eating or drinking was allowed for 30 mins after rinsing. Subjects were instructed to continue with their usual oral hygiene regimen. They used the study materials for 30 days and returned used mouth rinse containers at each visit. Each returned container was weighed to measure compliance.

Subjects were evaluated at Baseline (Day 0) and Day 30.

Sample collection

The two to four sites that had the most severe inflammation as determined by visual examination and periodontal probing were selected in each patient. Standard gingival crevicular fluid (GCF) collection techniques were used. First, sites were isolated with cotton rolls and gently air dried. Fluid samples were collected sequentially with 3 sterile Periopaper strips (Oraflow Inc., Planview, NT, USA) that were inserted into the gingival crevice until mild resistance was felt and then left in place for 30 seconds. After GCF collection, all 3 strips from the same site were promptly placed in one single, empty 1.5 ml Eppendorf vial and immediately frozen at −80°C until use [1]. Samples were transported in dry ice to a commercial biomarker assay laboratory (Westcoast Biosciences, Irvine, CA, USA) where they were processed by a blinded technician using the standard Luminex assay method (Luminex Corporation, Austin, TX, USA) [1].

Evaluation Criteria

Markers of inflammation were identified from crevicular fluid on Day 0 and Day 30.

The gingival index (G.I.) was recorded by a blinded, pre-standardized periodontist on Day 0 and Day 30.

Crevicular Fluid markers: IL-1β, TNF-α, Day 30 vs baseline

Clinical Indices: Gingival Index (G.I.): scale 0-3, Day 30 vs baseline

50 Subjects were enrolled in this study

Inclusion/Exclusion Criteria

Inclusion Criteria

1. Male or female Subjects 30 years or older
2. Able to provide written informed consent

3. Gingival index > 1.5

4. Able to attend all study visits

5. Available for follow up on the telephone.

6. Minimum of 20 teeth

Exclusion Criteria

1. Participation in any other clinical study within the last 30 days

2. Need for dental treatment during study.

3. History of significant adverse effects following use of oral hygiene products such as toothpastes and mouth rinses; allergy to personal care/consumer products or their ingredients.

4. Presence of any condition, abnormality or situation at Baseline that in the opinion of the Principal Investigator may preclude the volunteer's ability to comply with study requirements, including completion of the study or the quality of the data.

5. Sjögren's disease

6. Immune deficiency diseases, i.e. HIV AIDS

7. Pregnant females

8. Poorly controlled diabetes

9. Anti TNF Alpha medication for rheumatoid arthritis

10. Systemic antibiotics in the last 3 months

11. Anti-inflammatory drugs

12. Immune suppressants

Primary Outcomes IL-1β, TNF-α, in crevicular fluid; Day 30 vs baseline

Secondary Outcomes GI; Day 30 vs baseline

Treatments

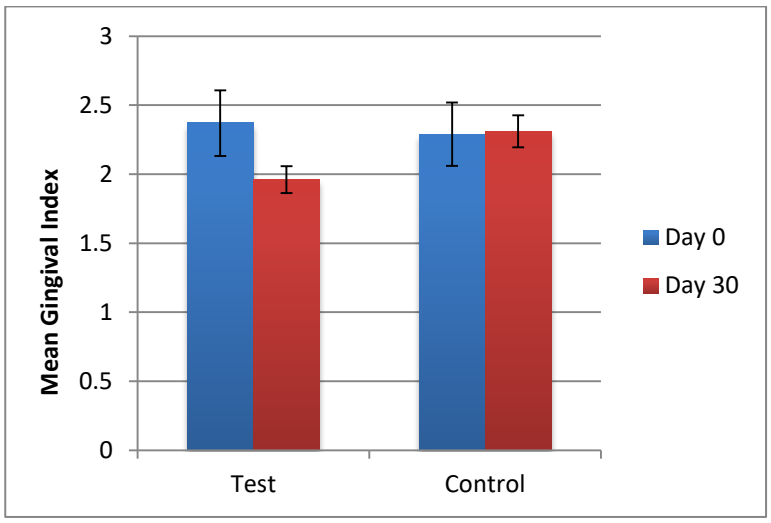
1. Lumineux Oral Essentials Clean and Fresh Mouthwash® ((Lumineux Oral Essentials, Los Angeles CA 90026).

Ingredients: Organic aloe barbadensis (aloe vera) leaf juice, xylitol*, purified water (aqua), dead sea salt (maris sal), gaultheria procumbens (wintergreen) leaf oil, mentha viridis (spearmint) leaf oil, organic mentha piperita (peppermint) leaf oil, ocimum basilicum (basil) oil, eugenia caryophyllus (clove) flower.

2. Water with added color and flavoring to achieve similar appearance and taste as (1).

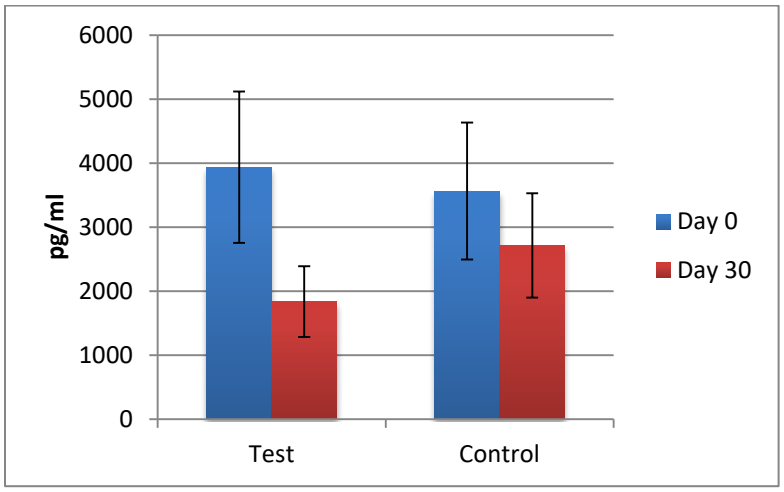
RESULTS

1. Gingival Index



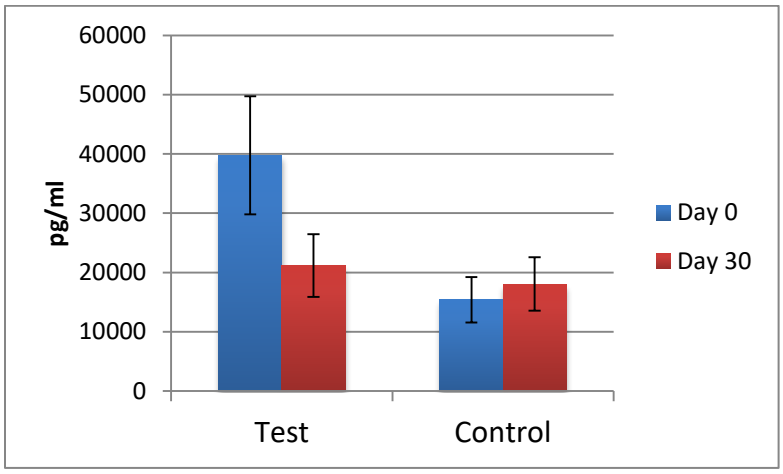
After 30 days, the Gingival Index was reduced by 0.41 (SD 0.25) in the test group, whereas it increased by 0.02 (SD 0.27) in the control group. In the test group the difference in G.I. between Day 30 and Day 0 was significant at p=0.037. In the control group, G. I. did not change significantly (p>0.1).

2. Crevicular Fluid TNF-α



After 30 days, the crevicular fluid TNF-α was reduced by 2,100.7pg/ml (53.8%) (SD 814) in the test group, whereas it was reduced by 850pg/ml (23.9%) (SD 784) in the control group. In the test group, the difference in TNF- α concentrations between Day 30 and Day 0 was significant at p=0.028. In the control group there was no significant change (p>0.1).

3. Crevicular Fluid IL-1β



After 30 days, the crevicular fluid IL-1β was reduced by 18,582.3 pg/ml (47%) (SD 8,156) in the test group, whereas it increased by 2,680pg/ml (15%) (SD 4,763) in the control group. In the test group, the difference in IL-1β concentrations between Day 30 and Day 0 was significant at p=0.045. In the control group there was no significant change (p>0.1).

CONCLUSION

In subjects with moderate-to-severe gingival inflammation, a test mouthwash used twice daily for 30 days significantly reduced Crevicular Fluid IL-1β and TNF-α as well as G.I.

REFERENCES

1. Moscicki AB, Yao TJ, Russell JS, Farhat S, Scott M, Magpantay L, Halec G, Shiboski CH, Ryder MI; Pediatric HIV/AIDS Cohort Study. Biomarkers of oral inflammation in perinatally HIV-infected and perinatally HIV-exposed, uninfected youth. J Clin Periodontol. 2019 Aug 6. doi: 10.1111/jcpe.13179. [Epub ahead of print] PubMed PMID: 31385616.