Abstract

An Evaluation of the Effectiveness of an Experimental Oral Therapy Paste (Revitin™ with NuPath® Bioactives) on Oral Soft Tissue Health

C. H. Pameijer (1), N. Grande (2), G. Plotino (2). A. Butti(2), A. Lerda(3), V. Pasquali(3) 1Professor Emeritus University of Connecticut; Hartford, CT; 2School of Dentistry, Catholic University of Rome, Italy. 3 Private Practice, Rome, Italy

Background
Emerging science has linked the breakdown in oral health to a degenerating oral biofilm where the ecology of the microbial community taken as a collective, rather than as specific putative species, seems to be the best model for understanding the dynamics and thus for designing effective treatment. Standard detergent-based toothpastes attempt to eliminate the oral biofilm which precludes any valuable function that a healthy biofilm might perform in maintaining oral health. An experimental oral therapy paste designed to shift a degenerative oral biofilm towards an ecology compatible with oral health, has been proposed. An initial pilot study in humans showed a 25% reduction in gingival inflammation after 7 days of use ($p<0.05$). This study seeks to evaluate the effects of this paste (R), on plaque index (PI), gingival index (GI), and bleeding index (BI) as compared to a standard detergent-based toothpaste (Crest® Whitening Expressions) as control (C).

Method
This was a single blind, split mouth, single cross-over study, one month duration on 10 patients (n=10). Predetermined parameters were established and data and photos collected.
Base-line data was collected in two random opposing quadrants that were scaled, following which the subjects were placed on the control paste for one week. A second set of data was collected on the other two opposing quadrants, which were also scaled, following which the subjects were placed on the experimental paste for one and two weeks. Scores for PI, GI, and BI were collected and analyzed for statistical significance using a Kraskal-Wallis non-parametric analysis.

Results (C)=Control; (R)=Revitin
PI data: For maxillary arches: 22.82 +/- 7.26 (C); 11.47 +/- 6.20 (R) $p<.001$; 49.7% improvement
For mandibular arches: 29.97 +/- 8.54 (C); 17.32 +/- 10.33 $p<.001$; 42.2% improvement
BI data: For maxillary arches: 7.65 +/- 2.06 (C); 2.45 +/- 1.70 (R) $p<.001$; 67.8% improvement
For mandibular arches: 7.38+/- 2.82 (C); 1.71 +/- 1.27 (R) $p<.001$; 76.8% improvement
GI data: For maxillary arches: 20.74+/- 3.88 (C); 11.31+/- 6.03 (R) $p<.001$; 45.5% improvement
For mandibular arches: 21.67+/-3.92 (C); 13.27 +/- 5.43 (R) $p<.001$; 38.8% improvement
Statistical analysis demonstrated all parameters to be significant ($p<0.01$).

Conclusions
This study confirms the findings of the pilot study and does so with a higher degree of statistical certainty ($p<.001$). The experimental oral therapy paste showed statistically and clinically significant improvements over the control paste for PI, BI and GI of, respectively, 46%, 72.5%, and 42% after fourteen days of use. These results indicate that a biofilm balancing approach to oral health care as taken by the experimental paste appears to more effectively restore oral soft tissue health than traditional detergent based products. Further research, using larger sample sizes and more sophisticated experimental designs will show whether a biofilm balancing approach to oral health care will sustain improved oral health over the long term.