Clinical Trial Findings Summary

FORSYTH INSTITUTE

A randomized trial evaluating the efficacy of **ECO Balance** on gingival inflammation, oral malodor and teeth whitening

STATISTICALLY SIGNIFICANT IMPROVEMENTS
in all soft tissue measurements (PD, BOP, GI, PI)

16X MORE EFFECTIVE*
than brushing and flossing when used with the GLO device

8X MORE EFFECTIVE*
than brushing and flossing alone when used daily on top of toothpaste for brushing

Gum disease affects 75% of adults in the United States[1]

**at reducing gingival bleeding*

[1]Kim, J. & Amar, S. (2006).Periodontal disease and systemic conditions: A bidirectional relationship. Odontology, 94(1); 10-21.

Trial Design

A 60-day randomized, parallel design study conducted on medically healthy participants with gingivitis and/or moderate periodontitis (age range: 18-55).

GROUP ONE
ECO Balance in GLO Device (1x daily)

GROUP TWO
ECO Balance on top of toothpaste (2x daily)

GROUP THREE
Brushing with toothpaste (2x daily) and split mouth flossing

Results

SOFT TISSUE ENDPOINTS

Bleeding on Probing (BOP)
Decreased by 32% for Group 1 and 16% for Group 2, displaying statistically significant improvements. BOP increased in non-flossing control

Probing Depth (PD)
Statistically significant reduction of .5mm, on average, using ECO Balance. Control group differences were not statistically significant.

Gingival Index (GI)
There were statistically significant differences in tissues color, quality and inflammation when using ECO Balance. Control group differences were not statistically significant.

Plaque Index (PI)
Statistically significant differences in reductions of plaque. Control group differences were not statistically significant.

AESTHETIC ENDPOINTS

Whitening
Using ECO Balance with GLO Device, teeth lightened from 1-4 shades (avg=1) after 6 week treatment, with statistical significance. Participants saw an average of 1-2 shades lighter after 4 days.

Breath Freshening
Participants using ECO Balance had greater reductions in volatile sulfur compounds than control group.

BIOLOGICAL ENDPOINTS

Microbial Profile
Using ECO Balance, there were statistically significant reductions in perio-pathogenic bacteria, which are related to a high risk of atherosclerosis.*

Inflammatory Markers
Statistically significant reductions in several inflammatory cytokines when using ECO Balance.

GLO Science™ Professional

Background

A randomized clinical trial was performed to test the efficacy of a cetylpridium chloride-based post foaming gel containing hydrogen peroxide, sodium bicarbonate and xylitol, on gingivitis, oral malodor and tooth whitening following a 6-week treatment and a 2-week post-treatment rebound.

Methods

A total of 39 healthy participants with existing gingivitis and/or mild periodontitis were included in the study and randomly assigned to either one of two treatment groups (Group 1: formulation + GLO Device; Group 2: formulation + toothbrush) or a split-mouth control group (Group 3a: brushing; Group 3b: brushing & flossing). Clinical measures (BOP, GI, PI & PD) were chosen to reflect gingival health, tooth whiteness and breath quality. Participants returned for a treatment follow up visit at Day 42, which then the study products use was discontinued, and the participants returned for final measurements at Day 60 to assess rebound. Within-treatment statistical analysis of clinical parameters from baseline to treatment and rebound endpoints were conducted. Microbial samples taken at baseline and follow up were analyzed by DNA-DNA hybridization techniques to determine changes in subgingival flora profile. Participants' gingival crevicular fluids were analyzed for proinflammatory proteins (i.e., cytokines & chemokines).

Results

Bleeding on probing, gingival index, plaque index, probing depth, oral malodor and tooth shade were significantly reduced in both treatment groups (Group 1 & Group 2) at 6-weeks compared to baseline ($p<0.05$). The reductions in BOP, GI and PI for Group 1 were significantly greater than brushing & flossing ($pBOP=0.007$; $pGI=0.036$ $pPI=0.035$). Participants in Group 1 experienced sixteen-times greater reduction in bleeding and plaque than brushing & flossing. Participants using the formulation saw significant reductions of periopathogens and proinflammatory proteins greater than control, in addition to reduced malodor and whiter teeth.

Conclusion

The results indicate that the foaming gel formulation significantly reduces gingivitis, freshens breath and whitens teeth, greater than the current standard home care of brushing & flossing.