

## Effects of a Novel Mouthwash on Plaque Presence and Gingival Health

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Received date: October 05, 2017; Accepted date: October 14, 2017; Published date: October 21, 2017

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### Abstract

**Background:** The specific aim of this study was to evaluate the effects of a new mouthwash on plaque and gingival health.

**Methods:** An in vivo prospective, randomized, controlled, double-blinded study design was used. Ten subjects who had received professional prophylaxis 4-6 weeks prior to study begin abstained from oral hygiene on the lower anterior teeth for 3 days. Baseline measurements including gingival index (GI), plaque index (PI) and bleeding Index (mSBI) were recorded before and afterwards. Participants were randomized with regard to sequence of twice daily 1 min use of a test mouthwash (Oral Essentials® Clean & Fresh Mouthwash), a control mouthwash (Peridex™) and no mouthwash while abstaining from brushing the lower anterior teeth. GI, PI and mSBI were recorded before and after each 3-day long arm, with a one week wash out period in between. The effects of each mouthwash on clinical indices were compared using a 2-sided t-test.

**Results:** Test and control mouthwashes produced similar levels of plaque reduction and gingival inflammation ( $p>0.05$ ) that were significantly better than use of no mouthwash ( $p<0.05$ ).

**Conclusions:** A test mouthwash achieved similar effects with regard to plaque control and gingival health as a widely used chlorhexidine mouthwash.

**Keywords:** Plaque; Gingival inflammation; Oral hygiene; Mouthwash

### Introduction

Periodontal disease affects not only oral health. Recent research has identified potential linkage with systemic conditions such as cardiovascular disease [1-8], diabetes [8], adverse pregnancy outcomes [9], rheumatic arthritis [10], aspiration pneumonia [11] and Chronic Obstructive Airways Disease [11]. It is also being investigated as a potential etiological factor in colorectal cancer [12], oral squamous cell carcinoma [9], pancreatic cancer [13] and breast cancer [14].

Because mechanical plaque removal is arduous, repetitive and time-consuming, adjuncts such as mouthwashes are welcomed by most individuals [15]. However, studies report widely varying levels of effectiveness with regard to plaque removal, and reported side-effects include altered taste and discoloration [16]. Thus, great interest exists in exploring new formulations and mechanisms for improving plaque control.

The goal of this study was to identify the ability of a test mouthwash (Oral Essentials®, Beverly Hills, CA) to reduce plaque presence and improve gingival health. Its effects were compared against those of a control mouthwash (Peridex™) and the use of no mouthwash at all. Study hypothesis: a test mouthwash will remove plaque and support gingival health equally well as an existing OTC mouthwash [17-21].

### Materials and Methods

#### Study design

This was a prospective, randomized, controlled, double-blinded study. All participants provided written informed consent prior to study initiation.

**Subjects:** Seven female and 3 male subjects were recruited and enrolled in his pilot study. Their ages ranged from 22-38 years old (mean age of 31 years).

#### Inclusion criteria:

- Mild to moderate gingival inflammation (Löe and Silness Gingival Index  $\geq 2$ ) [22]
- All pocket depths  $\leq 5$  mm
- Healthy hard and soft tissues based on visual clinical exam
- Professional dental cleaning 4-6 weeks prior to enrollment

#### Exclusion criteria:

- Any known allergies to personal care, food or cosmetic consumer products
- Any medical condition which requires pre-medication prior to dental procedures,
- Diminished immune function
- Reported poor wound healing,
- Use of antibiotics within the last 3 months.
- Hepatitis, HIV, ulcer forming diseases, abscesses, granulomas, or severe gingivitis or periodontitis

- Tobacco use
- Pregnant
- Lactating

### Clinical protocol

Ten subjects who had received professional prophylaxis within 4-6 weeks of study begin abstained from oral hygiene on the lower anterior teeth for 3 days. Plaque levels (Turesky Modification of Quigley-Hein Index [23] (PI), gingival inflammation (Löe and Silness Gingival Index [22] (GI), and sulcus bleeding (mSBI) [24] were recorded before and after cessation of oral hygiene measures (please see below for details). Next, participants were randomized with regard to sequence of twice daily 1 min use of a test mouthwash, a control mouthwash and no mouthwash while abstaining from brushing the lower anterior teeth. GI, PI and mSBI were recorded before and after each 3-day long arm. During the one week wash out period between each study arm, subjects brushed with Crest<sup>®</sup> Pro-Health<sup>™</sup> toothpaste (Procter and Gamble, Cincinnati, OH) using a new Oral B<sup>®</sup> Pro-Flex<sup>™</sup> toothbrush (Procter and Gamble, Cincinnati, OH) for each washout period of the study. Use of any other oral hygiene measures was not permitted, included chewing gum. At each visit this information was repeated to the subjects and a written information sheet was also sent home with them after each visit.

One independent study manager uniquely had access to the key for the sample codes. Otherwise, all investigators and subjects were blinded with regard to the mouthwash allocation. At each visit, subjects were questioned about any potential adverse effects of any products. 24-hour telephone contact information was provided to all subjects in case of any emergencies.

### Indices

Plaque was scored on a scale of 0 to 5 according to the Turesky modification of the Quigley-Hein Plaque Index [23]. Gingival health was evaluated using the Löe-Silness Gingival Index (0-3) [22] and the Sulcus Bleeding Index [24].

### Data analysis

In order to evaluate the data, the difference between endpoint and baseline value for each parameter was determined for each subject. Using a 2-sided T-test and standard statistical approach for crossover studies [25], the clinical indices at study end were compared between (a) test and control mouthwash and (b) test mouthwash vs no mouthwash.

### Results

At study outset and after 3 days of abstaining from oral hygiene, the clinical indices did not differ significantly between all subjects (Figures 1-3). None of the data showed any evidence of a significant carryover effect from the first arm to the second ( $p > 0.186$ ). For all of the clinical indices measured, the test mouthwash effects did not differ significantly from those of the control mouthwash ( $p > 0.164$ ). Both mouthwashes removed plaque and maintained gingival health more effectively than when no mouthwash was used ( $p < 0.05$ ).

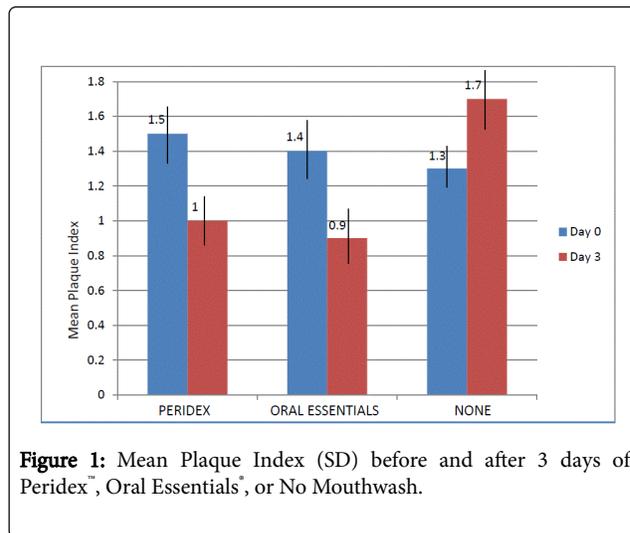


Figure 1: Mean Plaque Index (SD) before and after 3 days of Peridex<sup>™</sup>, Oral Essentials<sup>®</sup>, or No Mouthwash.

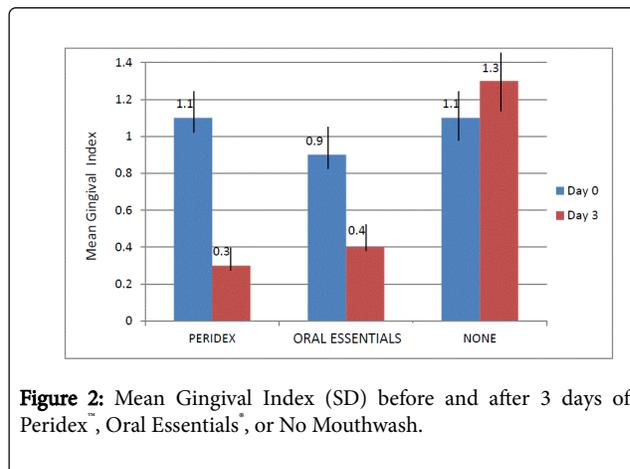


Figure 2: Mean Gingival Index (SD) before and after 3 days of Peridex<sup>™</sup>, Oral Essentials<sup>®</sup>, or No Mouthwash.

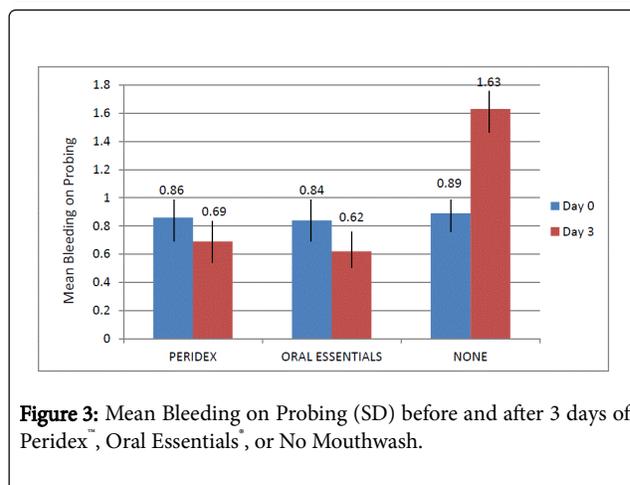


Figure 3: Mean Bleeding on Probing (SD) before and after 3 days of Peridex<sup>™</sup>, Oral Essentials<sup>®</sup>, or No Mouthwash.

### Discussion

Goal of this in vivo study was to compare the level of plaque control and clinical gingivitis after the use of a test mouthwash vs a control

mouthwash and use of no mouthwash at all. A professional prophylaxis was performed 4-6 weeks prior to enrollment to remove calculus and allow for gingival healing.

The crossover study design that was used in this research is valid where there are minimal carry over effects [26,27]. Our data confirm that this was indeed the case in this study. In order to further overcome any potential effects of the sequential crossover design of this study, the sequence of mouthwash usage was randomized so that 3 subjects used the test mouthwash first, 3 subjects used the control mouthwash first, and 4 subjects used no mouthwash at all first [28]. Overall, during the 8-week study period, oral health improved in both groups using the mouthwash [29-35].

Three-day use of the test or the control mouthwash reduced plaque presence and gingival inflammation to a very similar degree. Plaque indices were reduced by approximately 30% after 3-day use of either mouthwash, whereas plaque levels increased by approx. 25% when no mouthwash was used. Gingival indices and BOP were significantly reduced after use of either mouthwash, whereas they increased significantly in the absence of a mouthwash regimen [36-48].

Mechanical plaque control has limited effectiveness in ensuring oral health. For this reason there exists considerable interest in alternative or adjunct approaches to existing mechanical oral hygiene techniques. For example, chlorhexidine provides for excellent short-term plaque control and concomitant improvement in gingival health. However, its use is limited due to some of its side effects that include tooth staining and taste alterations after longer usage [49]. Moreover, unlike the test product, chlorhexidine has been shown *ex vivo* to have a cytotoxic effect on cells [50]. Because of the pressing need for additional options, a wide range of active components is under investigation as possible alternatives to chlorhexidine. The novel plaque-control mouthwash formulation used in this study may provide a useful adjunct for plaque control means of overcoming the shortcomings of existing mechanical and chemical methods of plaque control.

## Conclusion

In this clinical pilot study, a test mouthwash demonstrated comparable levels of plaque control and reduction in gingival inflammation over 3 days to a commonly used chlorhexidine-based mouthwash. Further studies in greater numbers of subjects are required to evaluate the effectiveness of the test mouthwash over longer periods and to identify ideal usage regimens.

## Conflict of Interest Statement

No conflict of interest

## Author Contributions Statement

### Angel Emmanuel Rodriguez

Concept/Design, data collection, drafting article, final approval.

### Janet Ajdaharian

Concept/Design, data collection, drafting article.

## Acknowledgement

This research was supported by Oral Essentials<sup>®</sup> Inc.

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