Abstract

Objective: The purpose of this study was to examine the effects of various product combinations involving brush, paste, rinse, and floss on the prevention of plaque regrowth and gingivitis.

Methodology: In this randomized, parallel-group, examiner-blind, eight-week study, 179 subjects with gingivitis had a dental prophylaxis and were randomly assigned to one of six product combinations: 1) Colgate® Wave manual toothbrush + Colgate® Total® dentifrice (0.3% triclosan/copolymer dentifrice; 2) Wave + Total + Listerine® (essential oils rinse); 3) Oral-B® CrossAction® manual toothbrush + Crest® Pro-Health™ dentifrice (0.454% stannous fluoride/sodium hexametaphosphate); 4) CrossAction + Pro-Health dentifrice + Crest® Pro-Health™ rinse (0.07% cetylpyridinium chloride rinse); 5) Oral-B® ProfessionalCare® Series 8000 power toothbrush + Pro-Health dentifrice; or 6) ProfessionalCare power brush + Pro-Health dentifrice + Oral-B® Hummingbird® power flosser. Subjects used their test products for the duration of the study. Whole mouth plaque, gingivitis, and product-related adverse events were assessed. Treatments were compared at a 0.05 level of significance.

Results: One-hundred and seventy-four subjects completed the study and were included in the data analysis. At Week 8, the overnight adjusted whole mouth overnight plaque scores were statistically significantly lower in all other groups relative to the Wave + Total group (p ≤ 0.030). Plaque scores were also statistically significantly lower (~ 20%) in both groups where a therapeutic rinse was added to a manual brush and therapeutic paste relative to scores for the brush plus paste without a rinse (p ≤ 0.034). All groups showed a reduction in gingivitis at Week 4, and mean scores remained stable or increased slightly at Week 8. The power toothbrush groups were directionally better at preventing gingivitis relapse than the manual groups at Weeks 4 and 8.

Conclusion: Reductions in overnight plaque were seen when therapeutic rinses were added to manual brush plus therapeutic dentifrice regimens above that observed with manual brush and therapeutic dentifrice alone.

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Introduction

Removal of dental plaque is recognized as advantageous in the maintenance of gingival health and prevention of periodontal disease.1-3 Mechanical plaque removal using a toothbrush twice daily, together with daily interdental cleaning, has long been recommended as an effective oral hygiene regimen. Despite this recognition, optimal oral hygiene is often not achieved, as evidenced by the prevalence of plaque-induced gingivitis in the general population.4 Various behavioral and physical factors, such as manual dexterity and motivation, have been implicated in suboptimal personal plaque control.5

Numerous technologies have been clinically evaluated with respect to impact on oral hygiene and plaque control. Two approaches have largely dominated clinical research—evaluation of mechanical or chemotherapeutic mechanisms for plaque control. Improved mechanical plaque removal may be achieved through the use of improved toothbrushes and/or flossing.6,7 One example involves the use of rotation/oscillation toothbrushes, which in systematic review is recognized to result in greater plaque removal and less gingivitis than conventional manual toothbrushes.8 Chemotherapeutic plaque control may be readily achieved via antimicrobial dentifrices or rinses. There is a considerable body of clinical research on dentifrices with triclosan/copolymer9,10 or stannous fluoride,11,12 and rinses with chlorhexidine,13,14 essential oils,15,16 or cetylpyridinium chloride17,18 showing significant longer-term plaque reductions relative to various controls.

These approaches for plaque control may be used alone or in combination with various oral hygiene products. While the effectiveness of these individual toothpastes, rinses, and toothbrushes has been well established, there is less evidence on the clinical response (efficacy or safety) associated with various combinations. This eight-week pilot study aimed to evaluate various home care regimens, involving combinations of toothbrushes, dentifrices, rinses, and an interdental aid, on plaque build-up and gingivitis. Six combinations were selected for this pilot, all of which were based on the use of popular therapeutic dentifrices (triclosan/copolymer or stannous fluoride). Recognizing the thousands of possible combinations of marketed oral hygiene products used adjunctively, this pilot specifically focused on the possible contribution of popular therapeutic rinses or powered floss to oral health when these agents were used adjunctively with leading antimicrobial dentifrices.
**Materials and Methods**

This was a randomized, parallel group, examiner-blind, eight-week study. The protocol was approved by an institutional review board before study initiation, and written informed consent was obtained from each subject before study entry. Eligibility was limited to healthy subjects between 18 and 70 years of age, with at least 15 Löe-Silness bleeding sites at screening, who reported brushing at least twice daily. Subjects with less than 16 natural teeth, orthodontic appliances, removable partial dentures, or extensive dental treatment needs were excluded. Others were excluded due to pre-medication needs for dental care, history of antibiotic usage two weeks prior to study initiation, pregnancy, or nursing.

The test products were different combinations of manual or powered toothbrushes, dentifrices, rinses, and floss. A complete factorial analysis would have required 24 test groups, which was not feasible for a pilot study, so six combinations were selected that included some of the most popular therapeutic dentifrices and rinses, along with manual brushes or a powered brush and powered floss. Specific test products included:

- Two manual toothbrushes: Colgate® Wave (Colgate-Palmolive Company, New York, NY, USA) and Oral-B® CrossAction® (Procter & Gamble Company, Cincinnati, OH, USA);
- Two dentifrices: Colgate® Total® with 0.3% triclosan/copolymer (Colgate-Palmolive, New York, NY, USA) and Crest® Pro-Health™ with 0.454% stannous fluoride/sodium hexametaphosphate (Procter & Gamble Company, Cincinnati, OH, USA);
- Two oral rinses: Listerine® with essential oils (Johnson & Johnson, New Brunswick, NJ, USA) and alcohol-free Crest® Pro-Health Rinse™ with 0.07% cetylpyridinium chloride (Procter & Gamble Company, Cincinnati, OH, USA); and
- Two power devices (toothbrush or floss): Oral-B® ProfessionalCare® Series oscillating/rotating power toothbrush (Procter & Gamble Company, Cincinnati, OH, USA) and Oral-B® Hummingbird® power flosser (Procter & Gamble Company, Cincinnati, OH USA).

For blinding, all test products were distributed in blinded kit boxes, instructions were provided remotely from examination, and all clinical assessments (efficacy and safety) were conducted by examiners who were blinded as to treatment assignment. Subjects received written (test kit) and verbal (supervised) instructions on product usage, including twice daily use of assigned brushes/pastes, and/or rinses and floss (in order). Subjects brushed for two minutes with a full ribbon of paste. Rinsing was conducted after brushing twice daily for 30 seconds with 20 mL of rinse, followed by expectoration. Product usage was supervised at the Baseline and Week 4 visits. All other usage was unsupervised at home following manufacturer’s instructions. After completing the assigned oral hygiene, study subjects were instructed to not eat or drink for 30 minutes. There were two baseline visits, one each for gingivitis and plaque measurement. Subjects were instructed to refrain from tooth brushing (12 hours), eating, drinking, and smoking (all for four hours) prior to baseline measurements. Eligibility was determined after plaque assessment, after which a dental prophylaxis was administered. Eligible subjects were stratified based on gender and the number of baseline bleeding sites (≤ 40 or ≥ 41), and randomly assigned to one of six test regimens (Table I). Plaque and gingivitis measures were collected again after four and eight weeks of treatment. Any product-related adverse events were recorded at each visit.

### Table I

<table>
<thead>
<tr>
<th>Group</th>
<th>Toothbrush</th>
<th>Therapeutic Dentifrice</th>
<th>Adjunct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wave+Total</td>
<td>Colgate Wave</td>
<td>Colgate Total</td>
<td></td>
</tr>
<tr>
<td>Wave+Total +Listerine</td>
<td>Colgate Wave</td>
<td>Colgate Total</td>
<td>Listerine Rinse</td>
</tr>
<tr>
<td>CrossAction +ProHealth</td>
<td>Oral-B CrossAction</td>
<td>Crest Pro-Health</td>
<td></td>
</tr>
<tr>
<td>CrossAction+ProHealth+ProHealth Rinse</td>
<td>Oral-B CrossAction</td>
<td>Crest Pro-Health</td>
<td>Crest Pro-Health Rinse</td>
</tr>
<tr>
<td>ProfCare+ProHealth</td>
<td>Oral-B ProfessionalCare</td>
<td>Crest Pro-Health</td>
<td></td>
</tr>
<tr>
<td>ProfCare+ProHealth+Hummingbird</td>
<td>Oral-B ProfessionalCare</td>
<td>Crest Pro-Health</td>
<td>Oral-B Hummingbird</td>
</tr>
</tbody>
</table>

Whole mouth plaque was measured by the Rustogi Modification of the Navy Plaque Index on both buccal and lingual surfaces of all teeth using a score of 0 = absent or 1 = present. The total number of tooth areas with plaque present was divided by the total number of tooth areas scored to calculate the mean score for each subject. Gingivitis was assessed using the Löe & Silness Gingival Index (GI) on six surfaces (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual) using a 0–3 scale, where 0 = no inflammation and 3 = severe inflammation. A whole mouth GI score was determined by summing the scores for individual sites and dividing by the number of scorable sites examined. Third molars were not graded for plaque or gingivitis. At baseline and Week 8, a comprehensive oral examination was conducted blind to treatment assignment to ascertain any adverse events, and possible causality.

Analysis variables were whole mouth mean plaque and gingivitis scores. Analysis of variance (ANOVA) was used to compare baseline plaque and gingivitis scores. An analysis of covariance (ANCOVA) was performed on four-week and eight-week data with baseline scores as covariates. In the study protocol, three primary pairwise group comparisons were specified to evaluate the effect of adding either of two therapeutic rinses to a daily tooth brushing regimen and to evaluate the effect of adding a powered flossing aid to a daily regimen involving a powered toothbrush. For completeness, the remaining pairwise treatment group comparisons were also calculated and reported. Each statistical test was conducted using a significance level of $\alpha = 0.05$.

### Results

There were 179 subjects enrolled, with 174 completing the eight-week study. The population ranged in age from 18–69 years, with females accounting for 69% of participants. Analysis of variance showed the six treatment groups did not differ significantly ($p > 0.1$) on baseline mean whole mouth plaque or gingivitis scores. No subject discontinued treatment due to product-related adverse events.
Compared to baseline, all six regimens had reductions in plaque levels from baseline to four and eight weeks (Figure 1). At four weeks, reductions of 10% to 20% occurred in unadjusted mean plaque scores relative to the overall average baseline. At eight weeks, plaque reductions reached 35% to 58% of baseline group means.

Treatments differed significantly \( (p = 0.001) \) on adjusted mean whole mouth plaque scores at Week 8 (Table II). Between-group comparisons showed whole mouth plaque scores were statistically significantly lower for each of the treatment groups versus the Wave+Total group \( (p \leq 0.030) \). The Week 8 adjusted mean plaque score for CrossAction+ProHealth+ProHealth Rinse was also statistically significantly lower than the corresponding scores for CrossAction+ProHealth \( (p = 0.034) \) and ProfCare+ProHealth+Hummingbird \( (p = 0.036) \). In both cases, where a therapeutic rinse was added to a manual toothbrush plus therapeutic dentifrice regimen, the addition of the rinse resulted in statistically significant incremental reductions in plaque scores of approximately 20% of the manual toothbrush plus dentifrice scores. The addition of a powered flosser to the power toothbrush plus therapeutic dentifrice regimen (ProfCare+Pro+Health) did not result in a statistically significant reduction in plaque \( (p > 0.10) \).

All groups exhibited reductions in gingivitis at the first (Week 4) post-prophylaxis visit (Figure 2). At eight weeks, mean gingivitis scores were stable or increased slightly. Relative to the pre-prophylaxis baseline, all groups continued to exhibit 38% to 60% reductions in gingivitis at Week 8.

**Figure 1.** Mean plaque scores and standard errors by regimen and time: Baseline (solid bars), 4-week means (striped bars) and 8-week (shaded bars).

**Table II**

Whole Tooth Plaque Scores at Baseline (Mean ± SE) and at Weeks 4 and 8 (Adjusted Mean ± SE)

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Baseline Mean ± SE</th>
<th>Week 4 Adjusted Means* ± SE</th>
<th>Week 8 Adjusted Means † ± SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wave+Total</td>
<td>30</td>
<td>0.393 ± 0.008</td>
<td>0.354 ± 0.012</td>
<td>0.256 ± 0.014</td>
</tr>
<tr>
<td>Wave+Total+Listerine</td>
<td>29</td>
<td>0.390 ± 0.006</td>
<td>0.315 ± 0.012</td>
<td>0.206 ± 0.014</td>
</tr>
<tr>
<td>CrossAction+ProHealth</td>
<td>30</td>
<td>0.399 ± 0.007</td>
<td>0.327 ± 0.012</td>
<td>0.214 ± 0.014</td>
</tr>
<tr>
<td>CrossAction+ProHealth+ProHealth Rinse</td>
<td>28</td>
<td>0.413 ± 0.014</td>
<td>0.330 ± 0.012</td>
<td>0.172 ± 0.014</td>
</tr>
<tr>
<td>ProfCare+ProHealth</td>
<td>29</td>
<td>0.393 ± 0.010</td>
<td>0.322 ± 0.012</td>
<td>0.190 ± 0.014</td>
</tr>
<tr>
<td>ProfCare+ProHealth+Hummingbird</td>
<td>28</td>
<td>0.386 ± 0.008</td>
<td>0.324 ± 0.012</td>
<td>0.214 ± 0.014</td>
</tr>
</tbody>
</table>

*ANOVA baseline treatment group comparison p-value = 0.387.
*ANCOVA 4 weeks treatment group comparison p-value = 0.265.
Sample sizes at 4 weeks were 29, 29, 29, 26, 29 and 28.
†ANCOVA 8 weeks treatment group comparison p-value = 0.001.
Paired treatment comparisons:
Wave+Total versus Wave+Total+Listerine; \( p = 0.099 \)
Wave+Total versus CrossAction+ProHealth; \( p = 0.025 \)
Wave+Total versus CrossAction+ProHealth+ProHealth Rinse; \( p < 0.001 \)
Wave+Total versus ProfCare+ProHealth; \( p = 0.007 \)
Wave+Total versus ProfCare+ProHealth+Hummingbird; \( p = 0.036 \)
CrossAction+ProHealth versus CrossAction+ProHealth+ProHealth Rinse; \( p = 0.034 \)
ProfCare+ProHealth+Hummingbird versus CrossAction+ProHealth+ProHealth Rinse; \( p = 0.036 \).

**Figure 2.** Mean gingivitis scores and standard errors for all treatment regimens: Baseline mean (solid bars), 4-week adjusted means (striped bars) and 8-week adjusted means (shaded bars).

**Table III**

Gingivitis Scores at Baseline (Man ± SE) and at Weeks 4 and 8 (Adjusted Mean ± SE)

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Baseline Mean ± SE</th>
<th>Week 4 Adjusted Means* ± SE</th>
<th>Week 8 Adjusted Means † ± SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wave+Total</td>
<td>30</td>
<td>0.453 ± 0.057</td>
<td>0.165 ± 0.022</td>
<td>0.211 ± 0.023</td>
</tr>
<tr>
<td>Wave+Total+Listerine</td>
<td>29</td>
<td>0.408 ± 0.045</td>
<td>0.181 ± 0.022</td>
<td>0.244 ± 0.024</td>
</tr>
<tr>
<td>CrossAction+ProHealth</td>
<td>30</td>
<td>0.360 ± 0.040</td>
<td>0.217 ± 0.022</td>
<td>0.222 ± 0.023</td>
</tr>
<tr>
<td>CrossAction+ProHealth+ProHealth Rinse</td>
<td>28</td>
<td>0.382 ± 0.042</td>
<td>0.178 ± 0.023</td>
<td>0.225 ± 0.024</td>
</tr>
<tr>
<td>ProfCare+ProHealth</td>
<td>29</td>
<td>0.390 ± 0.036</td>
<td>0.142 ± 0.022</td>
<td>0.157 ± 0.024</td>
</tr>
<tr>
<td>ProfCare+ProHealth+Hummingbird</td>
<td>28</td>
<td>0.374 ± 0.037</td>
<td>0.159 ± 0.022</td>
<td>0.158 ± 0.024</td>
</tr>
</tbody>
</table>

*ANOVA baseline treatment group comparison p-value = 0.718
*ANCOVA 4 weeks treatment group comparison p-value = 0.248.
Sample sizes at 4 weeks were 29, 29, 29, 26, 29 and 28.
†ANCOVA 8 weeks treatment group comparison p-value = 0.040.
Paired treatment comparisons:
Wave+Total+Listerine versus ProfCare+ProHealth; \( p = 0.010 \)
Wave+Total+Listerine versus ProfCare+ProHealth+Hummingbird; \( p = 0.012 \)
CrossAction+ProHealth versus ProfCare+ProHealth; \( p = 0.048 \)
CrossAction+ProHealth versus ProfCare+ProHealth+Hummingbird; \( p = 0.056 \)
CrossAction+ProHealth+ProHealth Rinse versus ProfCare+ProHealth; \( p = 0.044 \)
CrossAction+ProHealth+ProHealth Rinse versus ProfCare+ProHealth+Hummingbird; \( p = 0.052a \).
The power toothbrush groups were directionally better at preventing gingivitis relapse than the manual toothbrush groups at Weeks 4 and 8 (Table III). At Week 8, analysis of covariance showed statistically significant group differences in adjusted means for gingivitis scores ($p = 0.040$), with several statistically significant differences for the powered toothbrush groups versus the manual toothbrush groups.

**Discussion**

Improved plaque control versus conventional brushing may be achieved through various chemotherapeutics and mechanical approaches. The popularity of chemotherapeutic approaches, in specific, has increased following the introduction of antimicrobial dentifrices and rinses.$^{21,22}$While clinical evidence often may come from single product studies, oral hygiene often involves a combination of products (e.g., power brush and chemotherapeutic pastes). This pilot clinical study was conducted to evaluate various combinations, with specific reference to incremental clinical effects with antimicrobial toothpastes.

There were two prominent outcomes. First, use of an antimicrobial rinse yielded incremental plaque control when paired with an antimicrobial dentifrice. When a therapeutic rinse was added to a manual toothbrush plus therapeutic dentifrice regimen, use of the rinse contributed statistically significant incremental reductions in plaque scores of approximately 20%. This was evident for an essential oils rinse used with triclosan/copolymer dentifrice, and for a cetylpyridinium chloride rinse used with stannous fluoride dentifrice, and as such, was not manufacturer/brand specific. Second, power brushing with a therapeutic dentifrice contributed to significant reductions in gingivitis versus manual brushing regimens. Use of a powered brush and therapeutic paste yielded 25-35% reductions in gingivitis versus manual brushing, regardless of whether a power flosser was used in this regimen. These effects have been described in the literature and confirm the effectiveness of oscillating/rotating power brushes.$^8$

Interestingly, the highest overall plaque score at eight weeks was a manual brush plus therapeutic paste (Wave+Total), while the lowest was a different manual toothbrush used with an antimicrobial paste and rinse (CrossAction+ProHealth+ProHealth Rinse). We speculate that combining therapeutic rinsing with an antimicrobial paste represents one of the easiest routes to yield incremental plaque control. Because rinsing is relatively simple to execute, use of therapeutic rinses may be a particularly accessible approach for improved oral hygiene relative to more complex techniques. We note, however, that the highest Week 8 gingivitis scores were in one manual brush, paste and rinse combination (Wave+Total+Listerine), and not significantly different from the rinse + paste alone (Wave+Total). As such, it is unclear what magnitude of effects can be realized with various therapeutic rinse and paste combinations. With group sizes of approximately 30, this research may not have had sufficient power to detect the presence or absence of gingivitis effects for certain combinations after only eight weeks of usage.

Multivariable research is always complex. This pilot, for example, only tested six of the 24 possible combinations in this research (one brush and one paste with or without one “other” treatment). Other combinations were possible and may have yielded different results. Nonetheless, this research may provide important evidence on daily oral care regimens. One focus of this pilot study was the examination of the effects of two prominent therapeutic dentifrices (triclosan copolymer and stannous fluoride), and respectively marketed manual brushes, used with or without popular, comarketed therapeutic rinses. As such, that aspect of the research evaluated a single variable—the incremental contribution of a therapeutic rinse. The positive findings, which transcended manufacturer (test products were distributed by three different manufacturers) may provide important evidence on the merits of concomitant use of therapeutic rinses and dentifrices as part of daily oral hygiene.

**Conclusion**

Adjuvant use of therapeutic rinses resulted in an approximately 20% incremental reduction in plaque regrowth compared to manual brushing with therapeutic dentifrices.

**Acknowledgments:** This study was supported by The Procter & Gamble Company. For further correspondence with the author(s) of this paper, contact Dr. Aaron Biesbrock—biesbrock.ar@pg.com.

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