A Comparison of the Efficacy of a Triclosan/Copolymer/Sodium Fluoride Dentifrice, a Stannous Fluoride/Sodium Hexametaphosphate/Zinc Lactate Dentifrice, and a Sodium Fluoride Dentifrice for the Control of Established Supragingival Plaque and Gingivitis: A Six-Week Clinical Study

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Abstract

- **Objective:** To compare the efficacy of a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride in controlling established gingivitis and supragingival plaque to that of a commercially available dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate, and a commercially available dentifrice containing 0.243% sodium fluoride.

- **Methods:** Following a baseline examination for gingivitis and supragingival plaque, qualifying adult male and female subjects from the Mississauga, Ontario, Canada area were randomized into three dentifrice groups. Subjects were instructed to brush their teeth twice daily (morning and evening) for one minute with their assigned dentifrice and a soft-bristled toothbrush. Examinations for gingivitis and supragingival plaque were repeated after six weeks of product use.

- **Results:** One-hundred eighty-two (182) subjects complied with the protocol and completed the study. Relative to the 0.243% sodium fluoride dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited statistically significant reductions in gingival index and supragingival plaque index scores of 26.5% and 29.4%, respectively, after six weeks of product use. Similarly, relative to the 0.243% sodium fluoride dentifrice group, the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group exhibited statistically significant reductions in gingival index and plaque index scores of 12.7% and 12.6%, respectively, after six weeks of product use. Further, relative to the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited statistically significant reductions in gingival index and plaque index scores of 15.8% and 19.2%, respectively.

- **Conclusion:** The overall results of this double-blind clinical study support the conclusion that a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride is efficacious for the control of established gingivitis and supragingival plaque, and that it provides a greater level of efficacy for the control of gingivitis and supragingival plaque than does a dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate.

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Introduction

Fluoride dentifrices have played a significant role in reducing dental caries, and many dentifrices on the market today deliver other oral health benefits, such as improvement in periodontal health. It is widely accepted that the control of plaque and gingivitis is the key to periodontal health. Controlling supragingival plaque starts with mechanical removal by tooth brushing. The American Dental Association defines the maintenance of good oral hygiene as tooth brushing for two minutes twice daily plus flossing once a day. However, it has been shown that self-performed tooth brushing and flossing is not always sufficient to maintain a healthy mouth. So manufacturers started looking at different chemothapeutic agents to incorporate into dentifrice formulations that would provide antiplaque and/or antigingivitis efficacy.

One such agent is triclosan, a phenolic antibacterial agent with low toxicity and a broad spectrum of activity, which has been shown to be effective against both gram positive and gram negative bacteria. Triclosan has been incorporated into a sodium fluoride dentifrice in combination with a polyvinylmethyl ether/maleic acid copolymer (PVM/MA copolymer) to ensure delivery and retention of the triclosan on oral hard and soft tissues. This dentifrice formulation (Colgate Total Toothpaste, Colgate-Palmolive Co., New York, NY, USA) has been clinically proven in numerous scientific publications to prevent and reduce plaque and reduce gingivitis in the adult population.
shown in long-term clinical studies to provide anticaries benefits, and has been clinically proven to prevent the progression of periodontitis. The Colgate Total Toothpaste is the only toothpaste approved by the US Food and Drug Administration for the prevention of plaque and gingivitis, and is accepted by the American Dental Association for the prevention of plaque and gingivitis.

Stannous fluoride dentifrices have been shown to reduce caries and improve plaque control and gingivitis. A stabilized stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice (Crest Pro-Health Toothpaste, Procter & Gamble Co., Cincinnati, OH, USA) has been reported to have a significant benefit on plaque control and gingival health, and to reduce further loss of attachment in patients with periodontitis.\(^\text{16,17}\) Stannous fluoride, like sodium fluoride, is a common ingredient found in dentifrices to reduce caries. Sodium hexametaphosphate has been reported in the literature to reduce calculus formation.\(^\text{18}\)

The objective of this six-week clinical study was to compare the antiplaque and antigingivitis efficacy of three commercially available dentifrices: a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride (Colgate Total) to a dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate (Crest Pro-Health). A fluoride dentifrice was included as a negative control (Crest Pro-Health Toothpaste, Procter & Gamble Co., Cincinnati, OH, USA). Gingivitis and plaque evaluations were conducted at baseline and after six weeks of product use.

**Materials and Methods**

This study employed a double-blind, randomized, three-treatment, parallel-group design. Adult male and female subjects from the Mississauga, Ontario, Canada area were enrolled into the study based upon the following criteria:

- Subjects had to be between 18 and 70 years of age, in good general health, and have signed an Informed Consent document.
- Subjects were required to be available for the six-week duration of the study.
- Subjects had to possess at least 20 uncrowned permanent natural teeth (excluding third molars).
- Subjects were required to present at baseline a mean gingival index score of at least 1.0 as determined by the use of the Loe and Silness Gingival Index,\(^\text{19,20}\) and a mean plaque index score of at least 1.5 as determined by the use of the Turesky modification of the Quigley-Hein Plaque Index.\(^\text{21,22}\)

Subjects were excluded from study participation if they:

- had partial removable dentures, orthodontic bands, or advanced periodontal disease (purulent exudate, tooth mobility, and/or extensive loss of periodontal attachment or alveolar bone).
- had tumor(s) of the soft or hard oral tissues, or five or more carious lesions requiring immediate restorative treatment.
- had a history of allergies to personal care/consumer products or their ingredients, or they could not refrain from eating or drinking due to medical conditions for periods of up to four hours.
- were pregnant or breast feeding women, or individuals who participated in any other clinical study or panel test within the last month of the start of the study.
- used antibiotics at any time during the one-month period prior to entering the study, were taking any prescription medication that might interfere with the study outcome, or received a dental prophylaxis during the two weeks prior to the study’s baseline examination.

Prospective subjects reported to the clinical facility having refrained from any oral hygiene procedures for twelve hours, and eating, drinking, and smoking for four hours prior to the visit. Subjects signed an informed consent form, and were screened by the dental examiner with respect to the inclusion/exclusion criteria. Subjects who met the inclusion/exclusion criteria received a baseline gingivitis and supragingival plaque examination and an oral soft and hard tissue assessment.

Qualifying subjects were randomized into three treatment groups which were balanced for baseline gingivitis and supragingival plaque scores. The three dentifrices tested in this study were as follows: 1) a commercially available dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride (Colgate Total Toothpaste); 2) a commercially available dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate (Crest Pro-Health Toothpaste); and 3) a commercially available dentifrice containing 0.243% sodium fluoride (Crest Cavity Protection Toothpaste).

Following treatment assignment, subjects were provided with a soft-bristled toothbrush and their assigned dentifrice. All dentifrices were over-wrapped in their original package to maintain the double-blind study design. Subjects were instructed to brush their teeth with their assigned dentifrice and toothbrush twice daily (morning and evening) for one minute, and to use only the dentifrice and toothbrush provided. Subjects were allowed to maintain routine oral hygiene procedures, such as flossing or using inter-dental stimulators. There were no restrictions regarding diet or smoking during the course of the study, although subjects were instructed to refrain from any oral hygiene procedures for twelve hours, and eating, drinking, and smoking for four hours prior to their six-week study examinations. Subjects returned to the clinical facility for gingivitis and supragingival plaque examinations after six weeks of product use. Additionally, at each examination, subjects received an evaluation of their oral soft tissue by the examining dentist, and were questioned for the occurrence of any adverse events.

**Clinical Scoring Procedures**

**Loe-Silness Gingival Index.** Gingivitis was scored according to the Loe-Silness Gingival Index. Each tooth was divided into six surfaces, three facial and three lingual, as follows: 1) mesio-facial; 2) mid-facial; 3) disto-facial; 4) mesio-lingual; 5) mid-lingual; and 6) disto-lingual. Third molars and those teeth with cervical restorations or prosthetic crowns were excluded from the scoring procedure. The gingiva adjacent to each tooth surface was scored as follows:

0 = Absence of inflammation.

1 = Mild inflammation—slight change in color and little change in texture.
2 = Moderate inflammation—moderate glazing, redness, edema,
and hypertrophy.
3 = Severe inflammation—marked redness and hypertrophy.

Tendency for spontaneous bleeding.

Subject-wise scores were determined by averaging the values
obtained over all scoreable surfaces in the mouth.

**Quigley-Hein Plaque Index.** Plaque was scored according to
the Turesky modification of the Quigley-Hein Plaque Index.
Each tooth was divided into six surfaces, three facial and three
lingual, as follows: 1) mesio-facial; 2) mid-facial; 3) disto-facial;
4) mesio-lingual; 5) mid-lingual; and 6) disto-lingual. Third molars
and those teeth with cervical restorations or prosthetic
crowns were excluded from the scoring procedure. Plaque was
disclosed and scored on each tooth surface according to the fol-
lowing criteria:

0 = No plaque.
1 = Separate flecks of plaque at the cervical margin.
2 = A thin, continuous band of plaque (up to 1 mm) at the cer-
vical margin.
3 = A band of plaque wider than 1 mm, but covering less
than 1/3 of the side of the crown of the tooth.
4 = Plaque covering at least 1/3, but less than 2/3 of the side
of the crown of the tooth.
5 = Plaque covering 2/3 or more of the side of the crown of
the tooth.

Subject-wise scores were determined by averaging the values
obtained over all scoreable surfaces in the mouth.

**Oral Soft and Hard Tissue Assessment.** The dental exam-
iner visually examined the oral cavity and peri-oral area using a
dental light and dental mirror prior to each plaque and gingivi-
tis examination. This examination included an evaluation of the
soft and hard palate, gingival mucosa, buccal mucosa, mucogingi-
vial fold areas, tongue, sublingual and submandibular areas,
salivary glands, and the tonsilar and pharyngeal areas.

**Adverse Events.** Adverse events were determined by verbal
indications from the subjects or by visual examination by the
dental examiner.

**Statistical Methods**

Statistical analyses were performed separately for the gingi-
ival index and plaque index scores. Comparisons of the treat-
ment groups with respect to baseline gingival index and plaque index
scores, as well as for age, were performed using analyses of
variance (ANOVA). Within-treatment comparisons of the gin-
gival index and plaque index scores obtained at the six-week ex-
aminations versus baseline were performed using paired t-tests.
Comparisons between treatment groups with respect to gender
were performed using chi-square tests. Comparisons of the treat-
mment groups with respect to baseline-adjusted gingival index
and plaque index scores at the six-week examinations were
performed using analyses of covariance (ANCOVA). Post-
ANCOVA pair-wise comparisons of the gingival and plaque in-
dex scores were performed using the Tukey test for multiple
comparisons. All statistical tests of hypotheses were two-sided,
and employed a level of significance of $\alpha = 0.05$.

**Results**

One-hundred and eighty-two (182) subjects complied with
the protocol and completed the six-week clinical study. A sum-
mary of the gender and age of the population who completed the
study is presented in Table I. The treatment groups did not dif-
fer significantly with respect to either of these characteristics.
Throughout the study, no adverse effects on the oral hard or soft
tissues were observed by the examiner or reported by the subjects
when questioned.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Treatment</th>
<th>n</th>
<th>Baseline Summary (Mean ± SD)$^4$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingivitis</td>
<td>0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride$^1$</td>
<td>61</td>
<td>$1.81 \pm 0.22$</td>
</tr>
<tr>
<td>Plaque</td>
<td>0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate$^2$</td>
<td>60</td>
<td>$1.88 \pm 0.26$</td>
</tr>
</tbody>
</table>

$^1$Colgate Total Toothpaste.
$^2$Crest Pro-Health Toothpaste.
$^3$Crest Cavity Protection Toothpaste.

**Baseline Data**

**Löe-Silness Gingival Index and Quigley-Hein Plaque Index.**
Table II presents a summary of the ginvial and plaque index
scores measured at baseline for subjects who completed the
study. The mean baseline gingival index scores were 1.81 for
the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium
fluoride dentifrice group, 1.82 for the 0.454% stannous fluoride/
sodium hexametaphosphate/zinc lactate dentifrice group, and

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Treatment</th>
<th>n</th>
<th>Baseline Summary (Mean ± SD)$^4$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingivitis</td>
<td>0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride$^1$</td>
<td>61</td>
<td>$2.73 \pm 0.27$</td>
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<tr>
<td>Plaque</td>
<td>0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate$^2$</td>
<td>61</td>
<td>$2.70 \pm 0.24$</td>
</tr>
</tbody>
</table>

$^1$Colgate Total Toothpaste.
$^2$Crest Pro-Health Toothpaste.
$^3$Crest Cavity Protection Toothpaste.
$^4$No statistically significant difference was indicated among the three dentifrice
groups at baseline.
1.88 for the 0.243% sodium fluoride dentifrice group. The mean baseline plaque index scores were 2.73 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 2.70 for the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, and 2.71 for the 0.243% sodium fluoride dentifrice group. No statistically significant differences were indicated among the dentifrice groups with respect to gingival or plaque index scores at baseline.

Six-Week Data

Löe-Silness Gingival Index. Table III presents a summary of the gingival index scores measured at the six-week examinations. The mean six-week gingival index scores were 1.33 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 1.58 for the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, and 1.81 for the 0.243% sodium fluoride dentifrice group.

Comparisons vs. Baseline. The mean percent reductions from baseline were 26.5% for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 13.2% for the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, and 3.7% for the 0.243% sodium fluoride dentifrice group. All reductions were statistically significant at the 95% confidence level.

Comparisons Among Dentifrice Groups. Relative to the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited a statistically significant 15.8% reduction in gingival index scores after six weeks of product use (p ≤ 0.05).

Relative to the 0.243% sodium fluoride dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited a statistically significant reduction in gingival index scores of 26.5%, while the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group exhibited a statistically significant 12.7% lower gingival index score, both after six weeks of product use (p ≤ 0.05).

Quigley-Hein Plaque Index. Table IV presents a summary of the plaque index scores measured at the six-week examinations. The mean six-week plaque index scores were 1.85 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 2.29 for the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, and 2.62 for the sodium fluoride dentifrice group.

Comparisons vs. Baseline. The mean percent reductions from baseline were 32.2% for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 15.2% for the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, and 3.3% for the 0.243% sodium fluoride dentifrice group. All reductions were statistically significant at the 95% confidence level.

Relative to 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited a statistically significant 19.2% reduction in plaque index scores after six weeks of product use (p ≤ 0.05).

Comparisons Among Dentifrice Groups. Relative to the 0.243% sodium fluoride dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited a statistically significant reduction in plaque index scores of 29.4%, while the 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate dentifrice group exhibited a statistically significant 12.6% lower gingival index score, both after six weeks of product use (p ≤ 0.05).

No adverse events were observed by the examining dentist nor noted by the subjects during the study.

Discussion

The maintenance of an effective level of plaque control is the cornerstone of any attempt to prevent and control periodontal disease, but most people fail to achieve a level of oral hygiene...
Table IV

Summary of the Six-Week Plaque Index Scores for Subjects Who Completed the Six-Week Clinical Study

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n</th>
<th>Six-Week Summary (Mean ± SD)</th>
<th>Within-Treatment Analysis Percent Reduction</th>
<th>Sig.</th>
<th>Between-Treatment Comparisons vs. Crest Pro-Health Percent Difference</th>
<th>Sig.</th>
<th>vs. Crest Cavity Protection Percent Difference</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride</td>
<td>61</td>
<td>1.85 ± 0.38</td>
<td>32.2%</td>
<td>p &lt; 0.05</td>
<td>19.2%</td>
<td>p &lt; 0.05</td>
<td>29.4%</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate</td>
<td>61</td>
<td>2.29 ± 0.46</td>
<td>15.2%</td>
<td>p &lt; 0.05</td>
<td>——</td>
<td>——</td>
<td>12.6%</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>0.243% sodium fluoride</td>
<td>60</td>
<td>2.62 ± 0.33</td>
<td>3.3%</td>
<td>p &lt; 0.05</td>
<td>——</td>
<td>——</td>
<td>——</td>
<td>——</td>
</tr>
</tbody>
</table>

1Colgate Total Toothpaste.
2Crest Pro-Health Toothpaste.
3Crest Cavity Protection Toothpaste.
4Percent reduction exhibited by the six-week mean relative to the baseline mean. A positive value indicates a lower plaque score at the six-week examination.
5Significance of paired t-test comparing the baseline and six-week plaque index scores.
6Difference between six-week means expressed as a percentage of the six-week mean for Crest Pro-Health Toothpaste. A positive value indicates a lower plaque score for Colgate Total Toothpaste than for Crest Pro-Health Toothpaste.
7Significance of post-ANOVA comparison of baseline-adjusted means.
8Difference between six-week means expressed as a percentage of the six-week mean for Crest Cavity Protection Toothpaste. The higher the percent difference the greater the plaque efficacy for the dentifrice.

commensurate with periodontal health.23,24 Periodontal diseases are initiated by plaque bacteria and, consequently, much research has focused on the possibility of enhancing oral hygiene by incorporating chemotherapeutic agents into dentifrice formulations.25 The effectiveness of a dentifrice formulation containing 0.3% triclosan and 2.0% copolymer in delivering a more effective level of plaque control and periodontal health has been demonstrated in numerous clinical trials and documented in narrative and systematic reviews.3-5,26,27 Dentifrices containing stabilized stannous fluoride have also been shown to improve plaque control and gingivitis in studies of six months’ duration.28-31

This double-blind, parallel, three-treatment clinical study provided a comparison of the plaque and gingivitis efficacy of a clinically documented, commercially available dentifrice formulation containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride (Colgate Total Toothpaste) to a commercially available dentifrice formulation containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate (Crest Pro-Health Toothpaste). The third dentifrice in the study was a commercially available dentifrice containing 0.243% sodium fluoride, used as a negative control (Crest Cavity Protection Toothpaste).

The results from the study indicated that after six weeks’ use of the dentifrices:

- All three dentifrice groups exhibited statistically significant reductions from baseline in gingival and plaque index scores.
- Both the Colgate Total dentifrice group and the Crest Pro-Health dentifrice group exhibited a statistically significantly lower gingival index score (26.5% and 12.7%, respectively) and plaque index score (29.4% and 12.6%, respectively) compared to the Crest Cavity Protection dentifrice group.
- The Colgate Total dentifrice group exhibited a statistically significant lower gingival index score (15.8%) and plaque index score (19.2%) compared to the Crest Pro-Health dentifrice group.

Conclusion

The results from this study confirm the results of many previous clinical studies that a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride is efficacious in reducing gingivitis and supragingival plaque.

The results from this research also show that a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride provides a greater level of efficacy than does a dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate.

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References


13. Correspondence on file, Colgate-Palmolive Company, New York, NY.


