A Clinical Investigation of the Efficacy of Three Commercially Available Dentifrices for Controlling Established Gingivitis and Supragingival Plaque

Surendra Singh, DDS
UMDNJ, New Jersey Dental School
Newark, NJ, USA
and
Oral Health Clinical Services
Piscataway, NJ, USA

Patricia Chaknis, BS William DeVizio, DMD
Margaret Petrone, JD Fotinos S. Panagakos, DMD, PhD
Colgate-Palmolive Technology Center
Piscataway, NJ, USA

Howard M. Proskin, PhD
Howard M. Proskin & Associates, Inc.
Rochester, NY, USA

Abstract

Objective: To assess the efficacy of a dentifrice containing 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride for controlling established gingivitis and supragingival plaque relative to that of a dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate, and a dentifrice containing 0.243% sodium fluoride as a negative control.

Methods: Following a baseline examination for gingivitis and supragingival plaque, qualifying adult male and female subjects from the Piscataway, NJ, USA 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 and seventy-one (171) subjects complied with the protocol and completed the study. Relative to the group using the dentifrice with 0.243% sodium fluoride alone, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride group exhibited statistically significant reductions in gingival index and supragingival plaque index scores of 25.3% and 33.0%, respectively, after six weeks of product use. Similarly, relative to the group using the 0.243% sodium fluoride dentifrice, the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group exhibited statistically significant reductions in gingival index and plaque index scores of 8.1% and 14.1% after six weeks of product use. Further, relative to the 0.454% stannous fluoride, sodium hexametaphosphate, and 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 18.7% and 22%, 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/0.243% sodium fluoride is efficacious for the control of established gingivitis and supragingival plaque as compared to a regular fluoride dentifrice, 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

It is well accepted that bacterial plaque (biofilm) is the forerunner to gingivitis,1 and that gingivitis is widespread in the general population.1-3 If left untreated, gingivitis can lead to periodontitis, a more serious form of periodontal disease. Periodontal disease, along with dental caries, is a common oral condition in adults today.4 Based upon survey data, it has been suggested that over 75% of today’s adult population is affected by the occurrence of gingivitis.5 The use of fluoridated toothpastes and mouthrinses, and water fluoridation have resulted in a decline in dental caries. However, gingivitis and periodontitis have not followed a similar pattern of decline. Over 750 species of bacteria can be found in the oral cavity, and specific groups of bacteria among these are the precursors to periodontal disease, including gingivitis and periodontitis.6,7

Even with effective tooth cleaning, bacteria colonize the tooth surface, most notably around the gingival margin and interden- tal spaces.8 The developing biofilm (plaque) releases a variety of biologically active products that diffuse into the gingival epithelium to initiate the host response that eventually results in gingivitis. Left untreated, periodontal pockets may form, bone could resorb, and the tooth might be lost.

Having a disease-free oral cavity is now more important than ever. Over the last ten years, epidemiologic and clinical studies
have been conducted to understand the relationship between oral and systemic health. It is now believed that oral inflammation associated with periodontitis may contribute to systemic inflammation which has been associated with systemic diseases, most notably coronary heart disease, peripheral arterial disease, ischemic stroke, and diabetes. Therefore, it is vitally important to control the formation of plaque and gingival inflammation.

The most common method of supragingival plaque control is by tooth brushing, which is the mechanical removal of plaque. The American Dental Association recommends brushing twice a day and flossing once a day as a regimen for good oral hygiene. The problem is that most people do not brush that often or brush long enough to achieve sufficient plaque removal, or do not brush properly in order to receive optimum results.

Dental professionals worldwide agree that self-performed plaque control is not adequate to achieve gingival health. In fact, it has been reported in one study that 94% of subjects said they brushed and flossed every day, and yet all subjects had visible plaque on more than 90% of tooth surfaces.

In the early 1990s, a dentifrice was introduced into the marketplace which incorporated a chemotherapeutic agent with anti-plaque activity (0.3% triclosan) and a copolymer of polyvinylmethyl ether and maleic acid (2.0% PVM/MA copolymer) into a 0.243% sodium fluoride dentifrice, which was clinically proven to reduce plaque and gingivitis in an adult population (Colgate Total® Toothpaste, Colgate-Palmolive Co., New York, NY, USA). Triclosan is a bisphenolic antibacterial agent which has low toxicity and a broad spectrum of activity, being effective against both gram positive and gram negative bacteria. Colgate Total Toothpaste also contains the copolymer PVM/MA which when combined with triclosan, ensures delivery and retention of the triclosan on hard and soft tissues. Effective levels of triclosan are retained in the oral cavity 12 hours after brushing the teeth, allowing prolonged control of oral bacteria that cause plaque, gingivitis, tartar, and bad breath. It has been shown in long-term clinical studies to provide anticaries benefits, and has been clinically shown to reduce the recurrence of periodontal disease.

The combination of 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride has been clinically proven, in over seventy clinical studies, to provide oral health benefits. The efficacy, mode of action, and safety of a triclosan/PVM/MA copolymer/sodium fluoride toothpaste has been thoroughly researched in over 200 articles in the scientific literature. 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.

More recently, a dentifrice was introduced into the marketplace claiming antigingivitis efficacy. The dentifrice contains 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate. Stannous fluoride, like sodium fluoride, is an active ingredient found in dentifrices to reduce caries. There have been reports in the literature which show that stannous fluoride is effective in reducing gingivitis, but it has also been shown to cause surface staining of the teeth. Sodium hexametaphos-
Qualifying subjects were randomized into one of 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/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, Procter & Gamble Company, Cincinnati, OH, USA); and 3) a commercially available dentifrice containing 0.243% sodium fluoride (Crest® Cavity Protection Toothpaste, Procter & Gamble Company, Cincinnati, OH, USA).

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. 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

Löe-Silness Gingival Index. Gingivitis was scored according to the Löe-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 = No plaque.
1 = Separate flecks of plaque at the cervical margin.
2 = A thin, continuous band of plaque (up to 1 mm) at the cervical 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 examiner visually examined the oral cavity and peri-oral area using a dental light and dental mirror prior to each plaque and gingivitis examination. This examination included an evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival 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 of the dental examiner.

Statistical Methods

Statistical analyses were performed separately for the gingival index and plaque index scores. Comparisons of the treatment 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 gingival index and plaque index scores obtained at the six-week examinations 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 treatment 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 indices scores were performed using the Tukey test for multiple comparisons. All statistical tests of hypothesis were two-sided and employed a level of significance of \( \alpha = 0.05 \).

Results

One-hundred seventy-one (171) subjects complied with the protocol and completed the six-week clinical study. A summary of the gender and age of the population who completed the study is presented in Table I. The treatment groups did not differ 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.

Baseline Data

Löe-Silness Gingival Index and Quigley-Hein Plaque Index. Table II presents a summary of the gingival and plaque index scores measured at baseline for subjects who completed the study. The mean baseline gingival index scores were 1.13 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium
fluoride dentifrice group, 1.09 for the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group, and 1.11 for the 0.243% sodium fluoride dentifrice group. The mean baseline plaque index scores were 2.34 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 2.27 for the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group, and 2.22 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 0.74 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 0.91 for the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group, and 0.99 for the 0.243% sodium fluoride dentifrice group. No statistically significant differences were indicated among the dentifrice groups with respect to gingival index scores at baseline.

Comparisons vs. Baseline. The mean percent reductions from baseline were 34.5% for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 16.5% for the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group, and 10.8% 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, and zinc lactate dentifrice group, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited a statistically significant 18.7% reduction in gingival index scores.
after six weeks of product use ($p \leq 0.05$). 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 25.3%, while the 0.454% stannous fluoride with sodium hexametaphosphate and zinc lactate dentifrice group exhibited a statistically significant 8.1% lower gingival index score, both after six weeks of product use ($p \leq 0.05$).

**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 1.38 for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 1.77 for the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group, and 2.06 for the 0.243% sodium fluoride dentifrice group.

**Comparisons vs. Baseline.** The mean percent reductions from baseline were 41% for the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group, 22% for the 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate dentifrice group, and 7.2% 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 baseline, the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice group exhibited a statistically significant 22% reduction in plaque index scores after six weeks of product use ($p \leq 0.05$).

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 22% reduction in plaque index scores after six weeks of product use ($p \leq 0.05$).

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

**Discussion**

There are many dentifrices on the market today that claim to provide multiple benefits to the consumer. Some dentifrices provide caries and tartar protection, other dentifrices provide caries and sensitivity protection, while others provide caries, plaque, and gingivitis protection.

Colgate Total Toothpaste was first marketed in the early 1990s. Since the inception of the original 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride dentifrice, several product variants have been introduced into the marketplace. These variants all maintained the same combination of active ingredients. The efficacy, mode of action, and safety of a triclosan/PVM/MA copolymer/sodium fluoride dentifrice have been researched and confirmed in over 200 articles in the literature.

Recently, a dentifrice claiming multiple benefits was introduced into the marketplace. Its active ingredient for both caries and plaque/gingivitis benefits is 0.454% stannous fluoride, with sodium hexametaphosphate and zinc lactate. There has been some ambiguity in the literature with regard to antibacterial and antimicrobial-based benefits, such as plaque and gingivitis reductions, that are ascribed to stannous fluoride. This variability may be primarily related to the inherent instability of stannous fluoride in the aqueous medium of dentifrices. In addition, it has been widely reported that prolonged use of stannous fluoride products causes dental staining.

This examiner-blind, three-treatment clinical study provided a comparison of the plaque and gingivitis efficacy of Colgate Total Toothpaste to Crest Pro-Health dentifrice, and Crest Cavity Protection toothpaste as a negative control. The results from the study indicated that after six weeks:

- all three dentifrice groups exhibited statistically significant reductions from baseline in gingival and plaque index scores;

**Table IV**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n</th>
<th>Six-Week Summary (Mean ± SD)</th>
<th>Within-Treatment Analysis</th>
<th>Between-Treatment Comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride</td>
<td>57</td>
<td>1.38 ± 0.38</td>
<td>41.0% $p &lt; 0.05$</td>
<td>22.0% $p &lt; 0.05$ 33.0% $p &lt; 0.05$</td>
</tr>
<tr>
<td>0.243% sodium fluoride</td>
<td>58</td>
<td>1.77 ± 0.46</td>
<td>22.0% $p &lt; 0.05$</td>
<td>—</td>
</tr>
<tr>
<td>0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate</td>
<td>56</td>
<td>2.06 ± 0.39</td>
<td>7.2% $p &lt; 0.05$</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-ANCOVA 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.
• both the Colgate Total Toothpaste group and the Crest Pro-Health dentifrice group exhibited a statistically significantly lower gingival index score (25.3% and 8.1%, respectively) and plaque index score (33% and 14.1%, respectively), compared to the Crest Cavity Protection toothpaste group.
• the Colgate Total Toothpaste group exhibited a statistically significantly lower gingival index score (18.7%) and statistically significantly lower plaque index score (22%) compared to the Crest Pro-Health dentifrice group.

Conclusion
The results from this study confirm the results of 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, utilizing a head-to-head comparison of two commercially available dentifrices, also show that the dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride provides a greater level of antiplaque and antgingivitis efficacy than does a dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate.

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For further correspondence with the authors of this paper, contact Patricia Chaknis—pat_chaknis@colpal.com.

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