Comparison of the Short-Term Antiplaque/Antibacterial Efficacy of Two Commercial Dentifrices

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Abstract

• **Objective:** The objective of these three clinical trials was to compare the impact of two commercial products, Colgate® Total® and Crest® Pro-Health®, on the formation of dental plaque over a 24-hour period of time. The studies utilized the Modified Gingival Margin Plaque Index (MGMPI), a validated and reliable clinical method for assessing the efficacy of products in reducing plaque build-up.

• **Methods:** Colgate Total and Crest Pro-Health were the test products for all three clinical trials. Colgate® Great Regular Flavor (CR) was used as the universal washout product. Colgate Total, as the only toothpaste approved by the FDA under an NDA for antiplaque, antigingivitis, and anticaries benefits, contains 0.3% triclosan/2.0% PVM/MA copolymer for antigingivitis and antiplaque, as well as 0.243% sodium fluoride (NaF) for anticaries. Crest Pro-Health contains 0.454% stannous fluoride (SnF₂) as both a monographed anticaries agent and a monographed antigingivitis agent, along with sodium hexametaphosphate and zinc lactate. Twenty-five healthy subjects meeting all study criteria were included into each of the double-blind studies. Product assignment was randomized and a crossover design was implemented. Informed consent was obtained from all subjects prior to commencement of each of the studies. The studies followed published MGMPI procedures, which require subjects to receive a dental scaling/prophylaxis followed by a one-week washout period prior to use of test products. A baseline MGMPI score was calculated following use of the test products in the dental clinic. Subjects refrained from all oral hygiene for 24 hours following use of each test product, and returned to the clinic for a 24-hour MGMPI score. Following a washout period, subjects repeated the procedure with the other test product as per the crossover design. The differences (delta) between baseline plaque scores and 24-hour plaque scores were independently calculated for each study, and the delta values were compared for the two test products in each of the studies.

• **Results:** In all three clinical trials, Colgate Total significantly reduced plaque regrowth over a 24-hour time period (p ≤ 0.05) compared to Crest Pro-Health. Existing differences were determined via a paired t-test, which confirmed that Colgate Total was statistically significantly different from Crest Pro-Health.

• **Conclusion:** These *in vivo* data support the antiplaque benefit of the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice. Additionally, the results support that Colgate Total provides superior efficacy in inhibiting the formation of dental plaque compared to Crest Pro-Health.

**Introduction**

Plaque removal by way of a daily home care regimen has long been understood by the dental professional and consumers to be an important element of oral health. The use of a dentifrice in one form or another dates back to ancient Greek and Roman civilizations, commencing with powder formulations containing a myriad of interesting ingredients. Dental plaque contributes to several concerns, both cosmetic and pathologic in nature. For instance, dental plaque contributes to caries, periodontal disease, and halitosis. Emerging evidence strongly suggests the oral inflammation caused by the bacteria living in the dental plaque may contribute to various systemic diseases, including, but not limited to diabetes, cardiovascular disease, low birth weight, preterm babies, and osteoporosis.

Worldwide, many techniques and products designed to achieve improved oral health exist; toothbrushes, rinses, floss, and dentifrices, to name a few, are available for consumers to purchase. Numerous clinical studies have been conducted examining the efficacy of examples of each of the above-mentioned products with variable results. Many limitations exist in plaque removal with a conventional brush and paste, including but not limited to manual dexterity, dental anatomy, and personal habits.

Adjunctive products and procedures, as well as clinically proven chemotherapeutic products, have been suggested to improve the outcome, including improving the design of the toothbrush for improved mechanical removal, and improving the dentifrice to deliver an agent to retard plaque regrowth. One example was the development of the only FDA-approved and ADA-accepted dentifrice with anticaries, antiplaque, and antigingivitis benefits, containing 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride in a silica base (Colgate® Total®, Colgate-Palmolive Co., New York, NY, USA). Numerous clinical studies have been conducted worldwide documenting the efficacy of this product for anticaries, antiplaque, and antigingivitis effects. Among four published carries clinical studies, a 36-month controlled, double-blind study found Colgate Total (CT) to significantly reduce the formation of cavities compared to a control dentifrice containing fluoride alone. In several six- or seven-month double-blind studies, CT significantly reduced plaque accumulation and gingivitis when used twice daily, compared to a dentifrice containing sodium fluoride.
Several short- and long-term, double-blind, randomized clinical trials, evaluating both antiplaque and antigingivitis efficacy of CT, were conducted. The duration of the studies ranged from one week to six months. CT was tested versus a placebo dentifrice. Plaque was scored using the widely accepted modified Quigley-Hein Plaque Index. The gingivitis scoring method used to assess gingivitis was the Löe-Silness Gingival Scoring Index. CT was found to consistently deliver a superior anti-plaque and antigingivitis benefit over the placebo dentifrice. The unique nature of CT is found in the combination of the active ingredient, triclosan, in conjunction with the copolymer. Triclosan is a longstanding ingredient in consumer products, used safely and effectively for over 30 years. Triclosan has a rare and useful dual function. It serves as an antibacterial agent, as well as an anti-inflammatory agent. The copolymer ensures the delivery and retention of the triclosan, allowing for bioavailability in the oral cavity for 12 hours. This 12-hour bioavailability is instrumental for delivering the antiplaque and antigingivitis efficacy of CT. A plaque viability study, published by Amornchat, et al., in Thailand, documented the retention of triclosan in dental plaque and its sustained antibacterial effects 12 hours after a single brushing with CT, confirming the long-lasting antiplaque-bacteria benefit.

Inflammation is the natural physiologic process to combat infection. Acute inflammation, if kept under control, aids in promoting initial tissue repair. Chronic inflammation, however, may lead to tissue destruction. Gingivitis, inflammation of the gingival tissue, if left untreated may become chronic and progress into the more destructive stages of periodontitis. CT has been shown to be effective in treating gingivitis, the result of both the anti-bacterial effect and the anti-inflammatory effect of the triclosan found in the dentifrice. In laboratory studies, Modeer, et al., demonstrated that as IL-1β was increased from 50 pg/ml to 200 pg/ml, the presence of triclosan at 1 μg/ml prevented a significant increase of prostaglandin E2 (PGE2) production.

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The aim of this clinical research was to test, in three separate clinical studies, the ability of Colgate Total and Crest Pro-Health to prevent plaque formation, in vivo, over 24 hours.

**Materials and Methods**

Three products were used in the clinical studies: Colgate Total with 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride in a silica base; Crest Pro-Health with 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate; and Colgate® Great Regular Flavor (Colgate-Palmolive Company, New York, NY, USA) as a washout product with 0.76% sodium monofluorophosphate. All toothbrushes were adult soft toothbrushes manufactured by the Colgate-Palmolive Company.

Three clinical studies were conducted utilizing the published Modified Gingival Margin Plaque Index (MGMPI). Each of the three studies used the same 25 healthy human subjects meeting the following criteria. All subjects ranged in age from 18–65, and were required to have a minimum of 15 healthy (uncrowned) teeth, excluding third molars. All subjects needed to provide written informed consent, and be willing to discontinue oral hygiene for 24 hours. Subjects with any known allergy to personal care or consumer products with ingredients relevant in any way to the test products (including tin) were excluded. Additional exclusion criteria included any conditions requiring pre-medication for dental visits, advanced periodontal disease, extensive untreated dental caries, and diseases of the hard or soft palate. Subjects wearing orthodontic appliances, or presenting with abnormal salivary flow, or taking drugs affecting salivary flow were also excluded. The use of antibiotics for one month prior to or during the study was also an exclusion criterion. Subjects taking over-the-counter medications (other than basic analgesics) and subjects participating in other clinical studies were excluded. Subjects currently pregnant or breastfeeding, as well as subjects suffering from immunocompromised states were excluded.

All three studies were conducted with the same clinical procedure. Subjects willing to sign the informed consent and meeting all inclusion and exclusion criteria were treated in the dental clinic. Dental scaling and prophylaxis were performed to completely remove dental plaque and dental calculus. Subjects were given washout products, Colgate Great Regular Flavor toothpaste and a Colgate soft manual toothbrush, with the instructions to use only these products and to brush twice daily for the washout period. Subjects returned to the dental clinic approximately one week after the commencement of the washout period. Study treatments were assigned via a randomized, incomplete block design using an alternating pattern starting with the first panelist enrolled. In the clinic, they brushed for one minute with a full ribbon of Colgate Great Regular Flavor. This brushing was
followed by a one-minute brushing, again with a full ribbon of the assigned test product. All products were blinded to both the subject and the examiner by way of an over-wrap. Following these brushing procedures, subjects were free to rinse with water and were then instructed to rinse with approximately 10 ml of a red commercial disclosing solution for 30 seconds. The dental examiner obtained the baseline MGMPI plaque score. Subjects were then instructed to refrain from all oral hygiene for 24 hours. Twenty-four hours later, the subjects returned to the dental clinic, rinsed with the disclosing solution, and the dental examiner obtained the final MGMPI plaque score.

The above procedure was repeated in accordance with the crossover design, so that both products could be tested by each individual in each of the clinical studies. One subject in study #1 did not complete the study due to antibiotic use at the start of the study. The need for the antibiotics was determined to be unrelated to the clinical study.

For each subject and each product, the baseline MGMPI plaque score was subtracted from the final MGMPI plaque score, rendering a delta value for the change in plaque score according to a previously published formula. This delta reflects the amount of plaque that developed over the 24-hour period. Measurements were obtained using the patented Xu-Barnes probe.

### Statistical Analysis

Change in the MGMPI plaque score in a 24-hour post-treatment (no brushing) period was calculated for each subject for each treatment cell. A paired t-test, using the subject and treatment as factors, was used to detect if significant differences between products exist. A difference between treatments is considered to be significant if a 95% confidence level (p < 0.05) is achieved.

### Results

All three studies provided results demonstrating CT provided a significant (p ≤ 0.05) antiplaque effect compared to CPH when using the products in a randomized manner (Figure 1 and Table I).

![Figure 1](image)

**Figure 1.** The average mean MGMPI scores depicted for three clinical studies demonstrating a single use of CT resulted in significantly less dental plaque formation as compared to a single use of CPH post-brushing over a 24-hour time period.

### Table I

<table>
<thead>
<tr>
<th>Study</th>
<th>CT Mean ± SD</th>
<th>CPH Mean ± SD</th>
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</thead>
<tbody>
<tr>
<td>Study #1</td>
<td>14.14 ± 8.02</td>
<td>22.05 ± 12.42</td>
</tr>
<tr>
<td>Study #2</td>
<td>12.95 ± 7.18</td>
<td>25.35 ± 10.08</td>
</tr>
<tr>
<td>Study #3</td>
<td>9.65 ± 8.30</td>
<td>27.09 ± 11.95</td>
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</table>

*Test products are statistically different (p < 0.05 at 95% confidence level).

### Discussion

Many oral care products exist in the marketplace today. Consumers increasingly demonstrate their understanding of the value of high quality oral care products, and the importance of good oral hygiene. Various efficacy claims, such as antiplaque, antigingivitis, whitening, and antitartar, are often made. In an evidence-based domain, such claims need to be documented. Whenever possible, the most rigorous level of testing, the double-blind randomized clinical trial, is desirable.

Many plaque assessment methods have been published, and have been used to assess product efficacy with great success. Two commonly used methods for short-term studies are the Quigley-Hein Plaque Index (QHPI), used in the four-day plaque regrowth model, and the Modified Gingival Margin Plaque Index (MGMPI), used in the 24-hour plaque regrowth model. The two methods have been published extensively, and a 2005 paper compared the four-day methodology with the MGMPI. Following the review of several clinical studies, the paper found both methods predicted the long-term (six-month) antiplaque efficacy of commercial products in a similar fashion. A 2008 paper reviewed 29 clinical studies utilizing the MGMPI methodology. All studies tested two commercial products, the therapeutic dentifrice containing 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride in a silica base versus a regular fluoride dentifrice. Twenty-four of the 28 studies predicted the superiority of the therapeutic dentifrice over the regular fluoride dentifrice. The four studies, failing to show superiority, were determined to be underpowered when reviewing the sample size of each.

The three clinical studies presented in this paper were sufficiently powered to be able to detect differences between two products, should those differences exist. Additionally, the design of a double-blind, randomized clinical trial satisfies the rigorous expectations for evidence-based documentation. The same subjects and the same examiner were recruited for all three studies, reducing unnecessary variability.

To summarize the findings, in all three trials CT significantly reduced plaque regrowth over 24 hours compared to CPH. Existing differences were determined via a two-way ANOVA. The t-test confirmed that CT was statistically significantly different from CPH.

### Conclusion

Colgate Total inhibited the formation of dental plaque over 24 hours versus Crest Pro-Health in a statistically significant fashion. These *in vivo* data provide compelling results to support the antiplaque benefit of the 0.3% triclosan/2.0% PVM/MA copolymer/0.243% sodium fluoride dentifrice. Additionally, the results
support that Colgate Total provides superior efficacy in inhibiting the formation of dental plaque compared to Crest Pro-Health.

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References