

Role of Colgate Total toothpaste in helping control plaque and gingivitis

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ABSTRACT: Purpose: To assess the anti-plaque and anti-gingivitis effects of a dentifrice containing 0.3% triclosan, 2% copolymer and 0.243% (1,100 ppm) sodium fluoride in subjects with moderate plaque-induced gingivitis. **Methods:** This was a single center, monadic study. Subjects had at least 20 teeth remaining in the functional dentition, excluding third molars. Following a baseline examination for plaque, gingival inflammation and bleeding, 75 qualified healthy adult males and females, ages 18-70 were selected to participate in the study. Dental prophylaxis was performed and subjects were provided with two tubes of toothpaste (Colgate Total) and a soft-bristle toothbrush (Colgate Wave Toothbrush). The subjects were instructed to brush twice daily using a modified Bass brushing technique. At the end of the 6- to 8-week period subjects returned for collection of clinical and subjective data. **Results:** 75 subjects completed the study. Both clinical and subjective reductions were significant. The results showed statistically significant reductions in plaque index, gingival inflammation and bleeding on probing. The overall conclusion was that Colgate Total was a comprehensive dentifrice that produced a significant reduction in gingivitis, plaque, and bleeding. (*Am J Dent* 2014;27:167-170).

CLINICAL SIGNIFICANCE: The results of this monadic clinical study support the conclusion that a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride is effective in reducing plaque and gingivitis when used over a period of 6 weeks.

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Introduction

Plaque-induced gingivitis is the most common form of the periodontal diseases and affects a significant portion of the population.¹ It is defined as inflammation of the gingiva in the absence of clinical attachment loss.¹ Gingivitis may be characterized by the presence of any of the following clinical signs: redness and edema of the gingival tissue, bleeding upon provocation, changes in contour and consistency, presence of calculus and/or plaque, and no radiographic evidence of crestal bone loss.¹

The therapeutic goal is to establish gingival health through the elimination of the etiologic factors; e.g., plaque, calculus, and other plaque-retentive factors.¹ Contributing systemic risk factors may affect treatment and therapeutic outcomes for plaque-induced gingivitis. These may include diabetes, smoking, and certain periodontal bacteria, aging, gender, genetic predisposition, systemic diseases and conditions (immunosuppression), stress, nutrition, pregnancy, substance abuse, HIV infection, and medications.¹

Supragingival plaque control is crucial for the prevention of gingivitis and periodontitis.² Recent studies have indicated that professionally supervised, self-performed plaque control exercised over extended periods of time may be an important measure in the treatment of sites with moderately advanced periodontitis.³ To enhance the effect of daily mechanical tooth cleaning, antimicrobial substances have been incorporated in dentifrice preparations.^{2,3}

Dentifrices containing the antibacterial agent triclosan have been reported to retard the build-up of human dental plaque.⁴ As with most oral hygiene measures employing a chemical means of plaque control, the intraoral retention of substantivity of the active agent is considered to be one of the important factors affecting its antiplaque efficacy.⁴ It is generally appreciated by researchers in the field that the concentration of the anti-

microbial must be above the minimal inhibitory concentration to exert a bacteriostatic effect and that maintenance of this concentration can prolong or improve the therapeutic effect.⁴

Triclosan (2, 4, 4'-trichloro-2'-hydroxydiphenyl ether) is a nonionic antibacterial agent with demonstrated in vitro activity against both gram-positive and gram-negative bacteria.⁵ This compound does not cause disturbance of the oral microbial ecology, has no adverse side-effects, as is often associated with many antimicrobial agents, and is compatible with the anionic components of fluoride dentifrices.^{5,6} Furthermore, the addition of triclosan to oral care products has been shown to reduce dental plaque, gingivitis and calculus.⁶ However, to obtain these benefits it has been necessary to increase triclosan efficacy by developing a delivery system which prolongs its residence time in the oral cavity.⁶ A copolymer of polyvinylmethyl ether (PVM) and maleic acid (MA) has been found to be well-suited for this purpose, since it retained triclosan on the soft and hard surfaces of the oral cavity over a prolonged period of time.⁶

This technology was evaluated in numerous human clinical studies using a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride in a silica base.⁶ This formulation has been found to be more effective in reducing dental plaque, gingivitis and calculus than regular fluoride dentifrices.⁶ Mateu et al⁷ conducted a double-blind clinical study of 94 individuals and concluded that the triclosan/copolymer dentifrice is efficacious for the control of established supragingival plaque and gingivitis. In another study, Cullinan et al⁸ studied the long-term use of triclosan/copolymer dentifrice on the progression of periodontal disease in a general adult population. The study design was a double-blind, controlled clinical trial of 504 volunteers. After examination and being matched for disease status, plaque index, age and gender, participants were assigned to either a control or test group. Participants were re-examined after 6, 12, 24, 36, 48 and

60 months. The results revealed that there was significant reduction of probing depths greater than or equal to 3.5 mm with the group using the triclosan/copolymer dentifrice over the course of the study when compared with the control group. The authors concluded that in a normal adult population, unsupervised use of a triclosan/copolymer dentifrice is effective in slowing the progression of periodontal disease.⁸ Because of the bactericidal effectiveness of triclosan and incorporation of a copolymer to keep the triclosan actively protecting teeth and gingiva up to 12 hours between brushings, Colgate Total^a and is approved by the ADA and FDA to prevent plaque and gingivitis.

This monadic trial was conducted to allow dental hygiene students to assess the anti-plaque and anti-gingivitis effects of 0.3% triclosan/copolymer dentifrice in human subjects with moderate plaque-associated gingivitis used over a 6- to 8-week period. In addition to clinical assessment, subjective assessment by the students was performed.

Materials and Methods

A total of 75 subjects with mild-to-moderate plaque-associated gingivitis were enrolled in this single-center trial, utilizing a monadic design with one arm:

Arm A – Commercially available dentifrice (Colgate Total) containing 0.3% triclosan, 2.0% copolymer and 0.243% (1,100 PPM) sodium fluoride used twice daily over 6 weeks.

The study was conducted at Hostos Community College Dental Hygiene Patient Care Facility, South Bronx, New York, USA. The study was reviewed and approved by the CUNY IRB (CW-09-002HCC).

Adult male and female subjects were enrolled in the study based on the following criteria:

Inclusion criteria:

1. Subjects had to be between 18 and 70 years of age.
2. Subjects had to be able and willing to follow study procedures and instructions.
3. Subjects were required to sign an informed consent form.
4. Subjects were required to have generalized, moderate plaque-associated gingivitis as determined by the investigator or designee during the baseline examination.
5. Subjects were required to be present with at least 20 teeth in the functional dentition, excluding third molars.

Exclusion criteria:

Subjects were excluded from the study for any of the following reasons:

1. Subjects who had chronically used (i.e., 2 weeks or more) Colgate Total (triclosan/copolymer) dentifrice within 6 months prior to enrollment.
2. Subjects with gross oral pathology, including widespread caries or chronic neglect, extensive restoration, pre-existing gross plaque and calculus, or soft or hard tissue tumor of the oral cavity.
3. Subjects with periodontitis as indicated by periodontal pocketing > 5 mm at screening.
4. Subjects with a history of early onset periodontitis or acute necrotizing ulcerative gingivitis.
5. Subjects with concomitant endodontic or periodontal therapy other than prophylaxis within 6 months prior to enrollment.
6. Subjects with orthodontic appliances or removable partial dentures.
7. Subjects chronically treated (i.e., 2 weeks or more) with any medication known to affect inflammation or periodontal status or

(e.g., aspirin, nonsteroidal anti-inflammatory drugs, steroids, statins, phenytoin, calcium antagonists, cyclosporin and coumadin) within 1 month of the screening examination. All other medications for chronic medical conditions should have been initiated at least 3 months prior to enrollment.

8. Subjects who had been treated with antibiotics for medical or dental reasons within 3 months prior to enrollment.
9. Subjects with clinically significant or unstable organic disease; subjects with compromised healing potential such as those with diabetes mellitus or connective tissue disorders; subjects with heart murmurs, histories of rheumatic fever, valvular disease or prosthetic joint replacement necessitating antibiotic prophylaxis.
10. Female subjects who reported being pregnant or lactating.
11. Subjects with active infectious diseases such as hepatitis, human immunodeficiency virus or tuberculosis.
12. Subjects diagnosed with human immunodeficiency virus (HIV) or subjects that are immunocompromised as determined by the Investigator.

Visit 1 (Baseline visit) - All prospective study subjects who met the inclusion/exclusion criteria received a baseline screening at Visit 1 to determine eligibility for study enrollment. The following procedures were performed during this visit in the order cited:

1. Study personnel obtained a signed written informed consent from the patient.
2. Study personnel obtained medical history and demographics (e.g., gender, age, and ethnicity) related to the patient.
3. Study personnel recorded any concurrent medications and the date of the initiating dose.
4. The examining clinician performed a screening periodontal probing examination using a UNC-15 probe. The examining clinician measured probing depth (PD) and percent bleeding on probing (%BOP) for all existing teeth (excluding third molars) at six sites per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual).
5. The examining clinician performed an oral soft tissue examination.
6. The dental examiner clinically measured the Plaque Index, Gingival Index, percent bleeding on probing, at six sites per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual) and calculated a PI, GI and percent bleeding for the entire mouth. Data was recorded using PI and GI forms.
7. Data collected was recorded using the Baseline Visit Form.
8. The clinician performed a dental prophylaxis on the subject.
9. Study personnel dispensed pre-weighed dentifrice to eligible subjects (two 221 g tubes per subject). The patient was instructed to administer the randomized dentifrice twice daily via the modified Bass brushing technique.

Subjects were provided with one soft bristled toothbrush (Colgate Wave Toothbrush^a) at Baseline and were instructed to cover the entire length of the bristle section of the toothbrush with the dentifrice. The subjects used a combination of sulcular brushing (i.e. bristles positioned in the gingival sulcus and angled 45° to the tooth apex), small circular, vibratory motions and a rolling stroke (i.e. sweeping coronally). Subjects applied the study dentifrice to the entire dentition and gingiva using these methods. Upon completion, subjects expectorated any excess dentifrice. Subjects rinsed with water following dentifrice use.

There were no restrictions with regard to drinking or eating following dentifrice use. During the trial, no specific interdental cleaning method was advocated (e.g., dental floss or tooth picks). Subjects continued using their habitual interdental cleaning practices in addition to the randomized dentifrices.

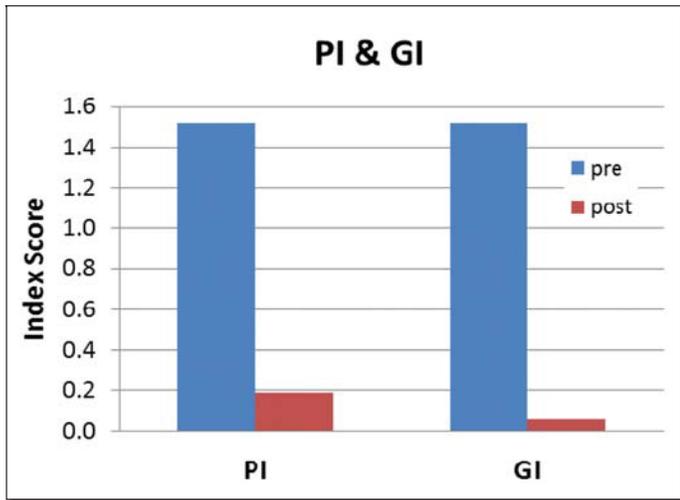


Fig. 1. Reductions in the gingival index and plaque index decreased from 1.5 to 0.02 and from 1.5 to 0.01, respectively.

Visit 2 (6- to 8-week visit) - Visit 2 occurred at week 7 (± 7 days). The following procedures were performed in the order cited:

1. The examining clinician performed an oral soft tissue examination.
2. The examiner clinically measured the Plaque Index, Gingival Index and percent bleeding on probing for all existing teeth (excluding third molars) at six sites per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual), and calculated a PI, GI and percent bleeding for the entire mouth.
3. Data collected was recorded using the Week 6-8 Visit Form. The clinician and patient completed all subjective questions on the form.

Clinical periodontal assessments - At the initial/baseline visit, probing depth (PD) and bleeding on probing (%BOP) were measured to determine subject eligibility. At Visit 2 (6-8 weeks) supragingival plaque (Plaque Index) and gingival inflammation (Gingival index), probing depth, and bleeding on probing were assessed.

All clinical periodontal assessments were performed using a manual University of North Carolina (UNC-15) periodontal probe at six periodontal sites per tooth (i.e., mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual).

Plaque Index (PI) - Relative amount of supragingival plaque recorded on an ordinal scale of 0-3 as follows:

- 0 = No plaque in the gingival area.
- 1 = A film of plaque adhering to the free gingival margin and the adjacent tooth. The plaque may be recognized only by running a probe across the tooth surface.
- 2 = Moderate accumulation of soft deposits within the gingival pocket and on the gingival margin and/or adjacent tooth surface, which can be seen by the naked eye.
- 3 = Abundance of soft matter within the gingival pocket and/or on the gingival margin and the adjacent tooth surface.

Gingival Index (GI) - Degree of gingival inflammation recorded on an ordinal scale of 0-3 as follows:

- 0 = Normal gingiva.
- 1 = Mild inflammation (slight change in color, slight edema); no bleeding on palpation (i.e. sulcular sweep).
- 2 = Moderate inflammation (redness, edema, glazing); bleeding on palpation (i.e., sulcular sweep).
- 3 = Severe inflammation (i.e., marked redness, edema); ulceration, tendency to spontaneous bleeding.

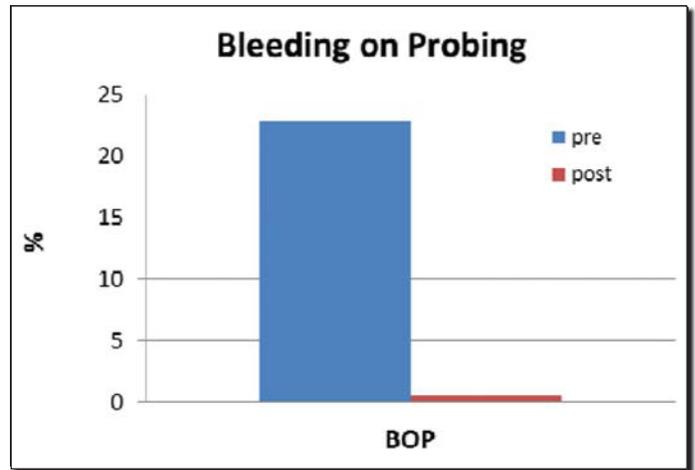


Fig. 2. Significant reductions for the percent bleeding on probing for the entire mouth were shown.

Pocket depth (PD) - PD was measured from the free gingival margin to the base of the pocket and was recorded in whole millimeters. If a PD reading fell between two millimeter readings, the rule was to round down and the lower of the two readings were recorded.

Bleeding on probing (BOP) - Presence or absence of bleeding to manual probing was recorded as a dichotomous variable as follows:

- 0 = No bleeding within 10 seconds after probing.
- 1 = Bleeding within 10 seconds after probing.

Subjective assessments - The examining clinician subjectively evaluated the patient's oral condition (gingival inflammation, bleeding on probing, spontaneous bleeding, plaque, caries, white spot lesions, calculus, halitosis, stain) on a scale from 1 (none) to 5 (severe).

Results

The study encountered recruitment challenges due to many subjects already using Colgate Total as a daily oral regimen. Nonetheless, 75 subjects met the inclusion/exclusion criteria and entered this single center, monadic study to assess the anti-plaque and anti-gingivitis effects of 0.3% triclosan/copolymer (Colgate Total) dentifrice in subjects with moderate plaque-induced gingivitis over a 6-8 week period. At the end of the 6-week interval, 75 subjects completed the study and returned to Hostos Community College Dental Hygiene Patient Care facility. The examining clinician performed an oral soft tissue examination, and clinically measured the Plaque Index, Gingival Index, and percent Bleeding on Probing (%BOP) for all existing teeth (excluding third molars) at six sites per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual), and calculated the PI, GI and %BOP for the entire mouth.

The dental examiners noted decreased visual signs of gingival inflammation and lower plaque scores. Reductions in the gingival index and plaque index decreased from 1.5 to 0.2 and from 1.5 to 0.05, respectively (Fig. 1). Significant reductions in the percent bleeding decreased from 22.8 to 0.6 for the entire mouth (Fig. 2).

In addition to the clinical data collected, subjective data was also collected in a questionnaire form from dental examiners. Overall the examiners' feedback of the dentifrice was over-

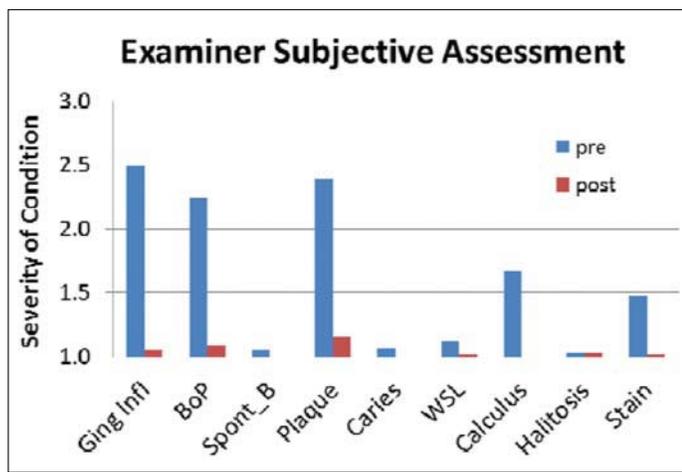


Fig 3. Favorable subjective assessment by the examining hygienists for the use of Colgate Total toothpaste. Ging Infl: Gingival Inflammation; BoP: Bleeding on Probing; Spont_B: Spontaneous Bleeding; WSL: White Spot Lesions (Scale from 1/none – 5/severe).

whelmingly favorable (Fig. 3). All examiners reported that they would recommend this dentifrice to their patients and that after seeing the results obtained with the use of Colgate Total, recommending a dentifrice with fluoride alone for daily use is not enough to maintain proper oral hygiene.

Discussion

Colgate Total toothpaste was originally designed and optimized for maximum delivery and retention of triclosan onto oral surfaces. This was achieved by utilizing a special copolymer to increase the substantivity of triclosan to both the hard and soft tissue of the oral cavity. This technology reduces the loss of triclosan from oral surfaces which normally would occur during salivary flow.⁶

Many human clinical trials have confirmed that the triclosan/copolymer system resulted in beneficial improvements with significant reductions in the parameters associated with both plaque accumulation and gingivitis.^{5,6,9} Therefore, the potential clinical use of Colgate Total was as an antiplaque, antigingivitis, and anticalculus dentifrice.⁹ The results also show that a reduction in supragingival plaque formation is an important means of controlling gingivitis and that the two entities are closely related.¹⁰ Studies further concluded that the triclosan dentifrice may have an effect on gingivitis above and beyond what can be accomplished by plaque reduction alone.^{2,3} Therefore, the recommendation of an antigingivitis dentifrice can contribute to the improved health of gingival tissue. Triclosan is the primary agent that has shown efficacy in reducing gingival inflammation. Furthermore, triclosan combined with a copolymer of polyvinyl methoxyethylene and maleic acid (PVM/MA) increase the substantivity. Moreover, the use of dentifrice containing triclosan has demonstrated significant reductions in supragingival biofilm formation, reduction in gingival inflammation in vivo, and inhibition of inflammatory mediators in vitro including interleukin-1 β and prostaglandin E₂.^{3,11,12}

The results of this single-center clinical study demonstrated that the use of a commercially available dentifrice containing

0.3% triclosan, 2.0% copolymer and 0.243% (1100 ppm) sodium fluoride (Colgate Total) when used twice daily over a 6-week period provided statistically significant and clinically beneficial effect on plaque-induced gingivitis. Overall both clinical and subjective reductions were significant. The results showed statistically significant reductions in plaque index, gingival inflammation and bleeding on probing. Specifically, reductions in plaque ranged from 1.5 to 0.2; gingivitis reductions ranged from 1.5 to 0.05 and reductions for bleeding on probing ranged from 22.8% to 0.6%.

The overall conclusion was that Colgate Total was a comprehensive dentifrice that produces a significant reduction in gingivitis, plaque, and bleeding. From an educational point of view this study can be tied into the curriculum in many ways. Student's participation in the study enforced the importance of administering proper dental hygiene care and patient specific oral hygiene instructions. Students also stated that they developed an improved understanding of product efficacy. For future studies, schools should connect this study with a particular dental hygiene course.

a. Colgate-Palmolive, New York, NY, USA.

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