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## Triclosan copolymer/fluoride dentifrice with a new dimension of benefit: Relief from dentin hypersensitivity

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# Triclosan/copolymer/fluoride dentifrice with a new dimension of benefit: Relief from dentin hypersensitivity

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# A dentifrice with multiple benefits

Plaque and gingivitis control, reduction of caries, removal of stain, and sensitivity reduction are major issues in dentistry. Most dentifrices in the market have effects on some of these simultaneously, but until now none has offered a multi-benefit proven effect, all with one toothpaste technology**.**

This Special Issue of the *American Journal of Dentistry* presents the results of studies performed testing a new toothpaste technology containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and a specially-designed silica.

Dibart & Zhang introduce this special issue with an overview of the multi-tasking dentifrice.

In the second paper, Zaidel *et al* describe the mechanism of action of the dentifrice as an anti-hypersensitivity agent.

Chaknis *et al* report the results of a 6-month clinical study showing the efficacy of the new formulation reducing hypersensitivity.

The fourth paper, of Mankodi *et al*, shows the 6-month clinical results of the new dentifrice in effectively reducing supra-gingival plaque and gingivitis.

The final paper, by *Nathoo et al*, describes the beneficial effect of the dentifrice on the removal of extrinsic stains after a 6-week period.

I hope you will find these papers interesting and educational. The *Journal* thanks Colgate-Palmolive Company, the manufacturer of the 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and a specially-designed silica dentifrice, for sponsoring this Special Issue.

Franklin García-Godoy, DDS, MS
*Editor*

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# A multi-tasking dentifrice for the 21st century

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(*Am J Dent* 2011;24 Sp Is A: 3A-5A).

## Introduction

The toothbrush is a device designed to care for the health and cleanliness of the oral cavity. Toothpastes are products to be used with the toothbrush, that comprise ingredients to enhance the basic plaque removing functionality of the tooth-brush and provide additional benefits, *i.e.*, cavity reduction, breath freshening, removal of dental stain, overall oral cleanliness, and delivery of therapeutic agents.[1]

Dental caries is a plaque related disease, the result of which, if left untreated, is decay of the tooth and, ultimately, its loss. Prevention of dental caries is becoming increasingly a matter of social action and individual motivation – education in oral hygiene, dental visits, water fluoridation, brushing with a properly formulated fluoride dentifrice – appear to be the key elements of a successful preventive program. Although still very prevalent in developing and some developed countries, the decline in dental caries has been impressive over the last two decades or so and has been attributed, among other things, to the judicious use of fluoride and the increasing availability of fluoride dentifrices.[2]

Gingivitis is another plaque related disease, in this case, one that affects the gingiva and could possibly lead to a more serious form of gum disease (periodontitis). Plaque bacteria generate toxins that cause inflammation of the gingival tissues. Gingival inflammation is clinically recognized by the gingiva becoming red and puffy or bleeding when subjected to toothbrush or floss, as well as by bad breath. If left untreated, gingivitis could lead to periodontitis which may result in tooth mobility, abscess formation, and possible tooth loss.[3]

Dental stains can affect an individual's self confidence in our modern, highly esthetic driven society. Patients' desire for stain free teeth or whiter teeth cannot be underestimated by the dental professional or the dental product industry. Tooth staining can be of intrinsic or extrinsic origin. Extrinsic tooth staining occurs as the result of the binding of chromogenic components in certain foods, drinks, medications and tobacco products to the salivary pellicle on tooth surfaces.[4,5] Ingredients in dentifrices such as detergents, abrasive systems, cleaning compounds and enzymes may remove extrinsic tooth stains by loosening and removing stained debris and pellicle. The physical forces of brushing, combined with dentifrice ingredients, have been shown to enhance stain removal; thus, daily brushing with dentifrice represents a convenient method for the control of extrinsic tooth stain between professional dental cleanings.

Dentin hypersensitivity may be experienced after the dentin is exposed to the oral environment *via* gingival recession, periodontal treatment, or loss of the enamel *via* abrasion and/or erosion. With gingival recession, once the root is exposed and the cementum subsequently eroded, the exposed dentin is subjected to exterior stimuli. These stimuli are most commonly of a thermal, osmotic, electrical, chemical or dehydrating nature. The patient or sufferer then feels a pain that has been described as "short, sharp and that cannot be ascribed to any other form of dental defect or pathology".[6] This frequent clinical condition has long been a dilemma for both patients and dental practitioners; and with teeth being maintained longer, there is an increased demand placed upon the dentist to manage the sensitivity due to exposed dentin.

Many theories have been used to explain the mechanisms of dentin hypersensitivity. An early hypothesis was the dentinal receptor mechanism theory, which suggested that dentin hypersensitivity is caused by the direct stimulation of sensory nerve endings in dentin.[7] Today, this theory is not well accepted. Another theory was proposed by Rapp *et al*,[8] which suggested that odontoblasts act as receptor cells, mediating changes in the membrane potential of the odonto-blasts *via* synaptic junction with nerves. This could result in the sensation of pain from the nerve endings located in the pulpo-dentin border. This theory, like the previous one has some shortcomings and is not well accepted by the scientific community. The theory that is widely accepted to explain dentin hypersensitivity and related pain is the "hydrodynamic theory" as described by Brännström & Astron.[9] This hydro-dynamic theory proposes that the sensation is caused by the activation of mechanoreceptors in intratubular nerves or in the superficial pulp due to changes of the flow and/or volume of fluid within dentin tubules.[9,10]

The management of dentin hypersensitivity has classically consisted of using dentifrices containing potassium salts for nerve depolarization and disruption of neural response to pain stimuli, as the first line of action. This method has two shortcomings: (1) it does not address the cause of the problem (open dentin tubules); and (2) it does not provide rapid relief. Another approach, aimed at hypersensitivity relief, uses occlusion technology to plug or seal the tubules to prevent fluid movement within the dentin tubules and the subsequent pain response.[10,11] Occlusion technologies include oxalates, stannous and strontium precipitates, amorphous calcium phos-phate (ACP), bioactive glass and composite resins. These agents have been investigated for the treatment of hypersen-sitive teeth with various degrees of clinical efficiency (the evidence on strontium has been equivocal and stannous is slow to provide sensitivity relief).[1] Recently, the Colgate-Palmolive Company has developed a multi-benefit dentifrice with clinically-proven hypersensitivity benefits that combined fluoride, triclosan and co-polymer (polyvinylmethyl ether maleic acid) with specially-designed silica to occlude dentin tubules. This new dentifrice, which is part of the Colgate® Total® portfolio, provides relief of dentin hypersensitivity

along with several very useful consumer end benefits, as it also helps reduce caries, plaque and gingivitis, calculus, oral malodor and extrinsic stains.

**Reduction of dental caries**

About 40 years ago, few fluoride dentifrices were available in the mass market. Today, over 90% of the dentifrices sold in the United States contain fluoride as fluoride in various forms is the most popular active ingredient in toothpaste to prevent cavities. Sodium fluoride (NaF) is the most common source of fluoride but stannous fluoride ($SnF_2$) and sodium monofluorophosphate ($Na_2PO_3F$) are also used with numerous clinical trials having reported and established their anticaries efficacy.[12] This reduction in cavity rate, based solely on the use of a dentifrice containing 1000 ppm of fluoride in a compatible vehicle, was estimated to be as high as 30% when used in clinical trials and compared to non-fluoride toothpaste as a control.[1] In a survey of the current literature looking at 75 studies, Walsh *et al*[13] reported that the caries preventive effect of fluoride toothpaste increased significantly with higher fluoride concentrations compared to placebo (23% for 1000/1055/1100/1250 ppm and 36% for toothpastes with a concentration of 2400/2500/2800 ppm), but concentrations of 440/500/550 ppm and below showed no statistically significant effect when compared to placebo. The incremental benefits of higher fluoride concentrations in toothpastes were well recognized by Colgate-Palmolive. The new dentifrice described in this special issue with its concentration of sodium fluoride in the range 1000-1450 ppm meets local regulations and is an integral part of an anti-caries prevention program.

**Reduction of dentin hypersensitivity**

There are two ways to alleviate discomfort related to dentin hypersensitivity. The classical approach is to use potassium ions to depolarize and inactivate the nerves, blocking the sensation of pain. This approach does not provide immediate relief as it takes at least 2 weeks to produce noticeable clinical effects. The second approach is to use occlusion technology to plug or seal the tubules to prevent fluid movement within the dentin tubules and the subsequent pain response. Recently, the Colgate-Palmolive Company developed a dentifrice with specially-designed silica to occlude dentin tubules. The *in vitro* dentin occlusion efficacy and effects on dentin permeability of this new dentifrice were evaluated to gain insight into the mechanism of action of this novel technology for dentin hypersensitivity relief based on specially designed silica and copolymer system.[14] Acid-etched human dentin was evaluated with confocal laser scanning microscopy (CLSM) and scanning electron microscopy (SEM) after treatment with one of the following: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica (Test Dentifrice 1); (2) a dentifrice containing 0.3% triclosan and the same overall silica loading as Test Dentifrice 1 but without copolymer and the specially-designed silica (Placebo Dentifrice); (3) a commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate (Test Dentifrice 2); and (4) a commercially-available non-sensitive dentifrice containing 0.243% NaF in a silica base (Negative Control Dentifrice). The results showed that dentin specimens treated with Test Dentifrices 1 and 2 were significantly occluded compared to the Placebo Dentifrice and the Negative Control Dentifrice when visualized with CLSM. In addition, the level of occlusion remaining after challenge with an acid (*i.e.* cola) was highest for dentin treated with Test Dentifrice 1. The authors concluded that the triclosan/copolymer/specially-designed silica technology demonstrated the ability to provide dentin occlusion that can penetrate tubules, significantly reduce dentin permeability and remain after repeated acid challenge and exposure to simulated pulpal pressure.

In an 8-week randomized controlled clinical study, Chaknis *et al*[15] evaluated the dentin hypersensitivity efficacy reduction of three dentifrices on patients suffering from dentin hypersensitivity: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica (Test Dentifrice 1); (2) a commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate (Test Dentifrice 2); and (3) a commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base (Negative Control Dentifrice). One hundred-eighteen subjects were enrolled in this 8-week study. At all time points after the baseline examination, for both tactile and air blast sensitivity scores, the differences between Test Dentifrice 1 and the Negative Control Dentifrice were statistically significant ($P< 0.05$). The same held true for the differences between Test Dentifrice 1 and Test Dentifrice 2 ($P< 0.05$), with the new dentifrice with triclosan, PVM/MA copolymer, NaF, and specially-designed silica performing better than the commercially-available dentifrice containing 0.454% $Sn_2F$. The efficacy of the tested Colgate dentifrice lies in the significant dentin occlusion by the specially-designed silica system.[14] The superior clinically-observed reductions in hypersensitivity from Test Dentifrice 1 are believed to be due not only to efficient and tubule-penetrating occlusion, but also to the improved resistance of the specially-designed silica occlusion to dislodgement by pulpal pressure and resistance to acid challenge.[14]

**The control of established supra-gingival plaque and gingivitis**

A clinical study conducted by Mankodi *et al*[16] tested the ability of a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica (Test Dentifrice) to control the established dental plaque and gingivitis. One hundred fifteen subjects were enrolled in this 6-month study. After 6 months, the Test Dentifrice group exhibited statistically significant reductions from baseline with respect to Plaque Index, Plaque Severity Index, Gingival Index, and Gingivitis Severity Index scores. Moreover, compared to the Negative Control group using a dentifrice containing 0.243% NaF in a silica base, the Test Dentifrice group exhibited an 18.8% reduction in Plaque Index; a 50% reduction in Plaque Severity Index; a 19.6% reduction in Gingival Index; and a 60% reduction in Gingivitis Severity Index after 6 months, all of which were statistically significant. The authors concluded that a dentifrice containing 0.3%

triclosan, 2.0% PVM/MA copolymer, 0.243% NaF, and specially-designed silica provides a significant reduction in plaque and gingivitis when used over a period of 6 months.

### The removal of extrinsic enamel stains

In a single-center, double-blind, randomized clinical study,[17] the extrinsic stain removal efficacy of a new dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF, and specially-designed silica was tested against a clinically proven whitening dentifrice (containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% sodium fluoride in a high cleaning silica base) and a Negative Control Dentifrice (containing 0.243% NaF in a silica base). One hundred-seventeen subjects were enrolled in the 6-week study. Extrinsic stain area and stain intensity examinations were repeated at 3 and 6 weeks. The dentifrice containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF in specially-designed silica base demonstrated the same ability to improve stain scores at 3 weeks (39.8% and 40.7% respectively) and 6 weeks (58.8% and 61.8% respectively) as the clinically proven whitening dentifrice. There was no statistically significant difference between the clinical efficacy of the two products. The overall conclusion was that the new dentifrice containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF and specially-designed silica to occlude dentin tubules provided effective extrinsic stain removal performance when used twice daily over a period of 3 and 6 weeks.

## Conclusion

In this fast paced, esthetic/health conscious society, the development of a multiple benefit dentifrice for everyday use that can successfully alleviate dentin hypersensitivity in addition to protecting teeth against dental caries, and removing plaque and stains is a welcomed addition to our preventive armamentarium. This multi-tasking, cost efficient and easy to use product containing specially-designed silica should have its place, next to the toothbrush, in every household's bathroom vanity.

*Disclosure statement:* Dr. Dibart is a consultant for the Colgate-Palmolive Company. Dr. Zhang is a full-time employee of the Colgate-Palmolive Company.

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Special Issue Article

# Anti-hypersensitivity mechanism of action for a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica

**LYNETTE ZAIDEL**, PHD, **RAHUL PATEL**, BS, **SARITA MELLO**, PHD, **RODMAN HEU**, MS, **MICHAEL STRANICK**, PHD, **SUMAN CHOPRA**, PHD & **MICHAEL PRENCIPE**, PHD

**ABSTRACT: Purpose:** To evaluate the laboratory dentin occlusion efficacy and effects on dentin permeability of a new multi-benefit dentifrice in order to gain insight into the mechanism of action of a novel technology for dentin hypersensitivity relief based on a specially-designed silica and copolymer system. **Methods:** Acid-etched human dentin was evaluated with confocal laser scanning microscopy (CLSM) and scanning electron microscopy (SEM) after treatment with one of the following: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride with specially designed silica (Test Dentifrice 1); (2) a dentifrice containing 0.3% triclosan and the same overall silica loading as Test Dentifrice 1 but without copolymer and the specially-designed silica (Placebo Dentifrice); (3) a commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate (Test Dentifrice 2); and (4) a commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base (Negative Control Dentifrice). The composition of dentin treated with either Test Dentifrice 1 or Negative Control Dentifrice was analyzed using energy dispersive x-ray (EDX) and electron spectroscopy for chemical analysis (ESCA). To highlight dentin occluding efficacy of the specially-designed silica, dentin was treated with Test Dentifrice 1 formulated with fluorescently-tagged specially-designed silica and resulting occlusion followed with CLSM. The dentin occluding abilities of Test Dentifrices 1 and 2 were compared with the Negative Control dentifrice using CLSM after a 4-day cycling model consisting of twice daily dentifrice treatment and four acid challenges. Effects of treatment with Test Dentifrices 1 or 2 on dentin permeability and subsequent resistance of occluding deposits to acid dissolution and dislodgement by pulpal pressure were assessed using hydraulic conductance. **Results:** Dentin specimens treated with Test Dentifrices 1 and 2 were significantly occluded compared to Placebo Dentifrice and Negative Control Dentifrice when visualized with CLSM. The level of occlusion remaining after challenge with cola was highest for dentin treated with Test Dentifrice 1 in CLSM xz views. Test Dentifrice 1 produced dentin surface deposits and tubule plugs containing silicon in addition to calcium and phosphorus as indicated by ESCA and EDX. CLSM visualization of fluorescently-tagged material confirmed occlusion by the specially-designed silica which was localized at the dentin tubule openings. Imaging of dentin by CLSM after the 4-day cycling model revealed a significantly higher amount of occluded tubules for dentin treated with Test Dentifrice 1 compared to the Negative Control Dentifrice or Test Dentifrice 2. Etched dentin treated with the Test Dentifrice 1 was significantly less permeable compared to that treated with the Negative Control Dentifrice, exhibiting over 80% reduction in dentin permeability. The occlusion provided by the Test Dentifrice 1 was maintained and provided significantly better reduction in permeability after extended pulpal pressure and acid challenge compared to dentin treated with Test Dentifrice 2. (*Am J Dent* 2011;24 Sp Is A:6A-13A).

**CLINICAL SIGNIFICANCE:** The triclosan/copolymer/specially-designed silica technology demonstrated the ability to provide dentin occlusion that can penetrate tubules, significantly reduce dentin permeability and remain after repeated acid challenge and exposure to simulated pulpal pressure. The technology is amenable to mainstream dentifrice delivery and offers a unique and clinically efficacious alternative to conventional sensitivity relief toothpaste containing potassium and to multi-benefit products containing stannous fluoride.

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## Introduction

Dentin hypersensitivity is a common condition affecting up to 57% of adults with highest incidence at age 30 and above.[1,2] According to Brännström's hydrodynamic theory, tooth sensitivity results when dentin tubule openings become exposed and fluid movement occurs as a result of tactile, chemical, evaporative or osmotic stimuli.[3] The fluid movement triggers mechano-receptors of pulpal nerve fibers and is interpreted as pain. Exposure of dentin commonly results from wearing away of the tooth's protective surfaces (cementum and enamel) due to gum recession, acid exposure, and/or abrasion.[4]

Several over-the-counter dentifrices exist in the market for treatment of dentin hypersensitivity with varying degrees of efficacy and speed of relief. The classical approach to reduce tooth sensitivity uses potassium ions to depolarize and inactivate the nerves, blocking the sensation of pain. However, it typically takes at least 2 weeks to produce noticeable effects with potassium, in part due to the strong outward flow of dentin fluid through the exposed dentin tubules against which potassium ions must travel to build up to effective levels around the pulpal nerve fibers.[5] In addition, potassium can impart an undesirable salty taste and interfere with delivery of antimicrobial agents like triclosan.[6]

An alternative approach to hypersensitivity relief uses occlusion technology to plug or seal the tubules to prevent fluid

movement within the dentin tubules and the subsequent pain response.[2,7] Occlusion technologies include oxalates, stannous and strontium precipitates, amorphous calcium phosphate (ACP), arginine-calcium carbonate, bioactive glass and composite resins.[8] However, some occlusion agents, such as stannous salts or bioactive glass, along with the low water delivery systems required to maintain their efficacy, can sometimes result in compliance issues due to taste or mouth feel issues.

Ideally, any desensitizing dentifrice based upon occlusion technology would utilize a mainstream aqueous formulation to deliver efficacy, without compromising consumer appeal, compliance, or efficacy of other active ingredients. Recently, the Colgate-Palmolive Company developed a multi-benefit dentifrice with clinically-proven hypersensitivity benefits that combined triclosan and a polyvinylmethyl ether maleic acid (PVM/MA) copolymer with specially-designed silica to occlude dentin tubules.[9,10] In this paper, we describe laboratory studies which probe the effects on the dentin surface, permeability and acid resistance after treatment with the new triclosan/copolymer/NaF/specially-designed silica dentifrice and compared them to those of control dentifrices.

Surface analysis techniques including confocal laser scanning microscopy (CLSM), scanning electron microscopy (SEM), energy dispersive x-ray (EDX) and electron spectroscopy for chemical analysis (ESCA) allowed probing of occlusion deposits and the resistance of the deposits to acid challenge. The surface analysis studies were enhanced using fluorescently-tagged specially-designed silica in combination with CLSM analysis to determine specificity of the specially-designed silica for dentin tubules. In addition, the effect on dentin fluid flow was monitored using hydraulic conductance, including resistance to outward dentin fluid flow and acid dissolution, giving a better understanding of how the occlusion ability of the dentifrice formulation translates into the observed clinical hypersensitivity reduction.

## Materials and Methods

*Materials* - All test products were silica-based dentifrices and included: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride containing specially-designed silica (Test Dentifrice 1[a]); (2) a dentifrice containing 0.3% triclosan and the same overall silica loading as Test Dentifrice 1 but without copolymer and the specially-designed silica (Placebo Dentifrice[a]); (3) a commercially-available dentifrice containing 0.454% stannous fluoride with sodium hexametaphosphate and zinc lactate (Test Dentifrice 2[b]); and (4) a commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride (Negative Control Dentifrice[b]).

Buffer reagents were obtained from Sigma-Aldrich.[c] The phosphate buffered saline (PBS) solution was composed of 1.06 mM calcium chloride, 0.63 mM sodium phosphate monobasic, and 150 mM sodium chloride adjusted to pH 7 with sodium hydroxide. The artificial saliva (pH 7) was composed of 1.4 mM calcium chloride dihydrate, 2.6 mM sodium phosphate dibasic, 2.6 mM potassium phosphate monobasic, 0.2 mM magnesium chloride hexahydrate, 4.4 mM ammonium chloride, 15.5 mM potassium chloride, 6.4 mM sodium bicarbonate, 0.04 mM sodium citrate dihydrate, 6 mM glycine, 0.4 µM bovine serum albumin, 2.9 mM urea, 2.3 mM potassium thiocyanate and 1.25% Type II porcine mucin.

*Preparation of dentin disks for surface analysis and microscopy studies* - Dentin disks, 800 µm thick, were cut from the crown section of human molars in a parallel manner slightly below the enamel-dentin junction using a water-cooled, diamond bladed saw. The dentin disks were sanded using 600 grit wet paper and then polished using 1200 grit wet paper on a polishing wheel to create a uniform surface.

The tubules were opened by etching the dentin specimens in 6% citric acid for 1 minute. After etching, the specimens were rinsed with deionized (DI) water and then placed in a jar of DI water and sonicated for 10 minutes. The etched and sonicated specimens were stored in PBS.

*Treatment procedure for CLSM, SEM and ESCA studies* - The treatment method used for experiments with CLSM, SEM and ESCA consisted of brushing the occlusal surface of the etched dentin disks (n= 2 per product) with the undiluted dentifrice for 1 minute using a soft toothbrush wetted with PBS. Minimal brushing force (approximately 50-100 g pressure) was used to minimize any surface smearing effects from dentifrice abrasives. The treated disks were rinsed with DI water and incubated in PBS for at least 2 hours in between treatments. The treatment-incubation cycle was repeated for the desired number of treatments, typically 14, to simulate 1 week of twice daily usage. Acid challenge of the treated disks consisted of 1-minute soaking in a cola beverage after the 14 treatments were completed.

*Treatment procedure for 4-day cycling CLSM study* - Etched dentin disks were brushed on the occlusal side in duplicate with undiluted dentifrice at the beginning of the day and rinsed with DI water. After incubation in artificial saliva for at least 1 hour, disks were challenged four times with 1% citric acid (pH 3.8) for 2 minutes with at least 1 hour of artificial saliva incubation in between challenges. Prior to overnight incubation in artificial saliva, the disks were brushed again with dentifrice. This treatment and challenge procedure was followed for a total of 4 days, followed by CLSM analysis.

*Confocal laser scanning microscopy* - CLSM was used to view the dentin disk surfaces with a Leica TCS SP[d] confocal laser scanning microscope equipped with a spectral detection system. The 488 nm line from the argon laser along with a PLO APO x50 objective was used in all experiments. Images were generated from top view (xy) and side (xz) to visualize changes in dentin tubule occlusion. Baseline images of etched dentin disks were collected to ensure sufficient surface quality for imaging and confirm the presence of patent dentin tubules. The baseline images served as controls for comparison with treated and acid-challenged disk images.

*Dye binding experiments using confocal laser scanning microscopy in the reflectance-fluorescence mode* - A Leica TCS SP confocal laser scanning microscope was used with reflectance and fluorescence modes on two distinct acquisition channels to visualize dentin. The 488 nm laser was used to generate fluorescence images with a PLO APO x20 objective lens (0.7 na) and x4 digital zoom. The specially-designed silica was fluorescently-tagged using fluorescein isothiocyanate dye

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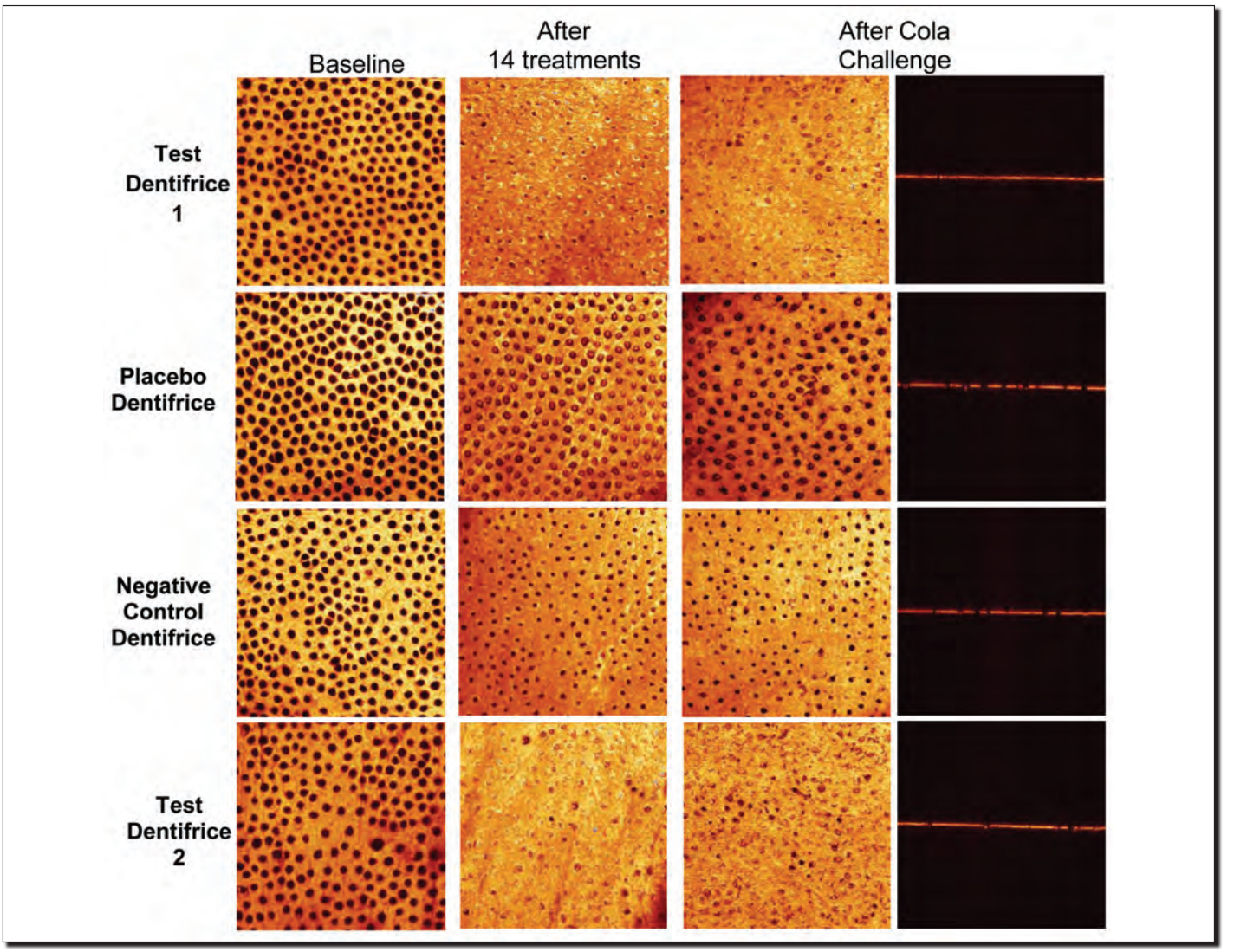


Fig. 1. Images acquired by CLSM of etched dentin surfaces before (left column) and after treatment (second column) with Test Dentifrice 1 (top row), Placebo Dentifrice (second row), Negative Control Dentifrice (third row), Test Dentifrice 2 (bottom row) and subsequent cola challenge (third column). The xz view of the cola-challenged dentin surface is shown in the far-right column.

(FITC) and formulated in the Test Dentifrice 1 in order to better visualize the dentin occlusion efficacy. Treatment consisted of a 10-brushing treatment regimen with fluorescent-labeled Test Dentifrice 1, followed by thorough rinsing with deionized water to remove any excess material deposited on the surface. A sequential acquisition routine was designed in order to capture reflectance and fluorescence images of the same focal area for higher experimental accuracy. Image colors were attributed arbitrarily, with the intensity scale of 255 pixels (z axis) relative to the fluorescence and reflectance intensities.

*Surface analysis by electron spectroscopy for chemical analysis, scanning electron microscopy and energy dispersive X-ray analysis* - The surface composition of etched dentin samples was determined using ESCA, both before and after treatment with the dentifrice products. In this way, each sample served as its own baseline for determining changes in composition resulting from dentifrice treatment. The ESCA experiments were carried out on a Physical Electronics[e] model 5800 spectrometer, utilizing monochromatic Al Kα x-rays. Two 800 µm diameter areas on each disk surface were analyzed to determine uniformity of surface composition. For all disks, the composition was reproducible for the two areas studied, suggesting a relatively uniform surface. ESCA survey scans were measured for each disk to determine the elements present on the surface, followed by high resolution scans for elemental quantification and chemical speciation.

SEM was used to obtain high resolution images of dentin treated with either Test Dentifrice 1 or Negative Control Dentifrice. The treated dentin samples were also freeze-fractured to observe occlusion as a function of depth and to characterize material coating the surface and penetrating the dentin tubules by EDX.

Dentin samples were examined using a LEO 1525[f] field emission SEM under low voltage conditions typically at 400 ± 20 volts. Samples were studied prior to treatment to ensure the dentin was in an open un-occluded state. The low voltage capabilities of the Field Emission SEM allowed each sample to serve as its own baseline. A minimum of six regions on each sample surface was studied. At each of these locations a series of images at progressively larger magnifications were taken over a range of x2,000 and x10,000. The images were stored on the hard drive of the SEM in TIF format and sized at 772 kB.

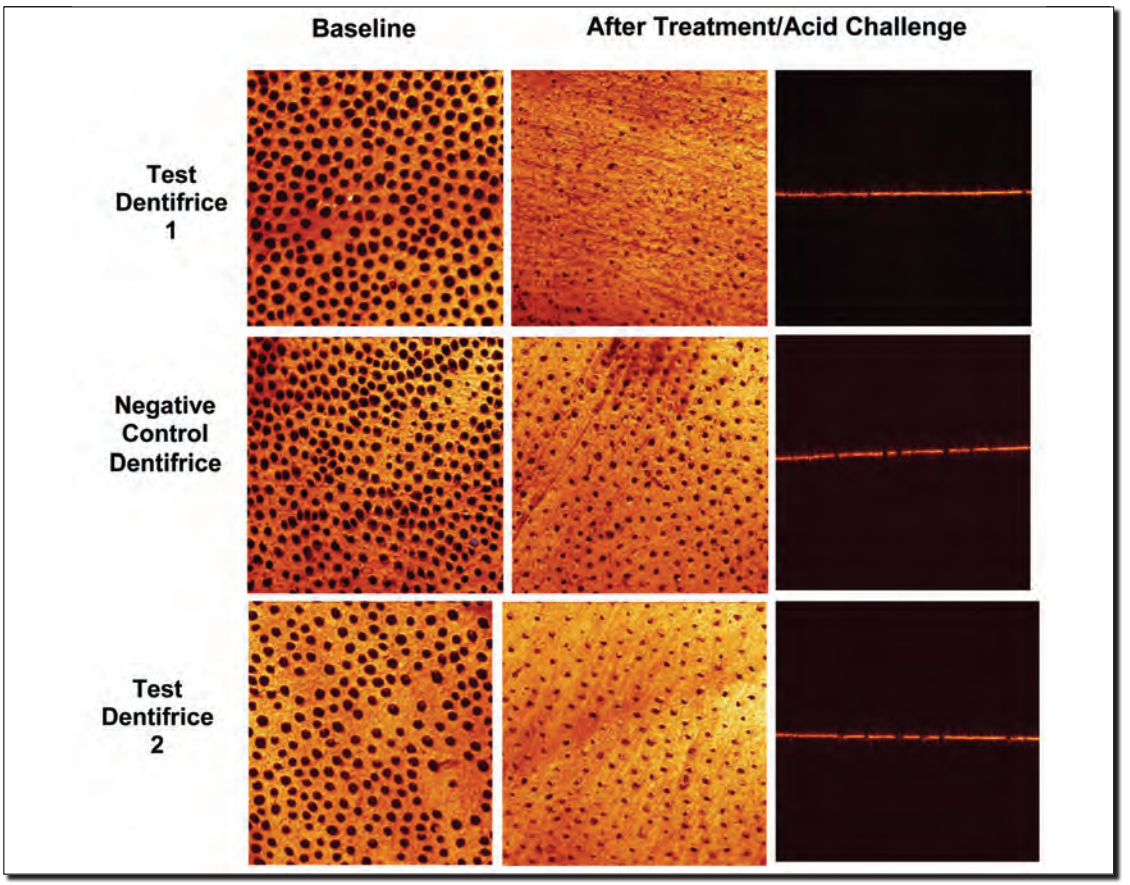


Fig. 2. Images acquired by CLSM of etched dentin surfaces before and after the 4-day cycling of acid challenge and treatment with Test Dentifrice 1 (top row), Negative Control Dentifrice (middle row) or Test Dentifrice 2 (bottom row). The xz view of the dentin surface is shown in the far-right column.

EDX analysis was performed on both the surface and the fracture face of the treated samples. The analysis was qualitative in nature. The analysis entailed multiple surveys of the surface as to ascertain the elemental composition. Once elemental composition was defined, elemental mapping was performed to locate the concentration sites of elements of interest such as Si. Following this, the sample was frozen in liquid nitrogen and fractured. The fractured sample was studied using the same procedure as on the surface where EDX surveys preceded elemental mapping.

*Hydraulic conductance* - Human molars were sectioned, mounted as dentin segments, etched and connected to a Flodec[g] device for hydraulic conductance measurements using the method of Pashley *et al*.[11] The hydraulic conductance of each segment after etching was measured at 70 cm water pressure. This measurement represented the baseline etched value. Segments were divided into two groups (n= 3 per group) such that average baseline values for each group were similar. Each segment was brushed for 1 minute using the same treatment and PBS incubation procedure previously described for the microscopy experiments. The segments were then rinsed with DI water, connected to the Flodec apparatus, and the conductance measured at 70 cm water pressure. This process was repeated for the indicated number of treatments. To determine the longevity and reactivity of the occlusive deposits, segments treated with either Test Dentifrice 1 or 2 were then incubated in PBS with agitation by a low-speed magnetic stir plate for 7 days followed by conductance measurements. To determine longevity under simulated pulpal pressure, segments were connected to pressure (20 cm water, 0.28 psi) with PBS incubation for 10 days and then acid challenged (6% citric acid pH2, 3 minutes, representing a strong acid challenge).

## Results

*Confocal laser scanning microscopy* - CLSM was used to compare dentin specimens treated with triclosan/copolymer/specially-designed silica dentifrice (Test Dentifrice 1), an 1100 ppm NaF dentifrice containing triclosan and the same overall silica loading as the triclosan/copolymer/specially-designed silica dentifrice but without copolymer and the specially-designed silica (Placebo Dentifrice), a commercially-available 1100 ppm NaF silica dentifrice (Negative Control Dentifrice), and a commercially-available multi-benefit 0.454% stannous fluoride/sodium hexametaphosphate/zinc lactate silica dentifrice (Test Dentifrice 2).

The results from the study showed that the dentin specimens treated with the triclosan/copolymer/specially-designed silica dentifrice were significantly occluded and resistant to cola challenge. CLSM images (Fig. 1) revealed significant surface coating and occluding deposits in the dentin tubules for disks treated with the Test Dentifrice 1 and Test Dentifrice 2. The Placebo and Negative Control Dentifrice-treated disks showed no significant surface coating and only slight deposition in the tubules with tubule openings still clearly defined. After cola challenge for 1 minute, the Test Dentifrice 1-treated disks showed retention of the coating/occlusion de-

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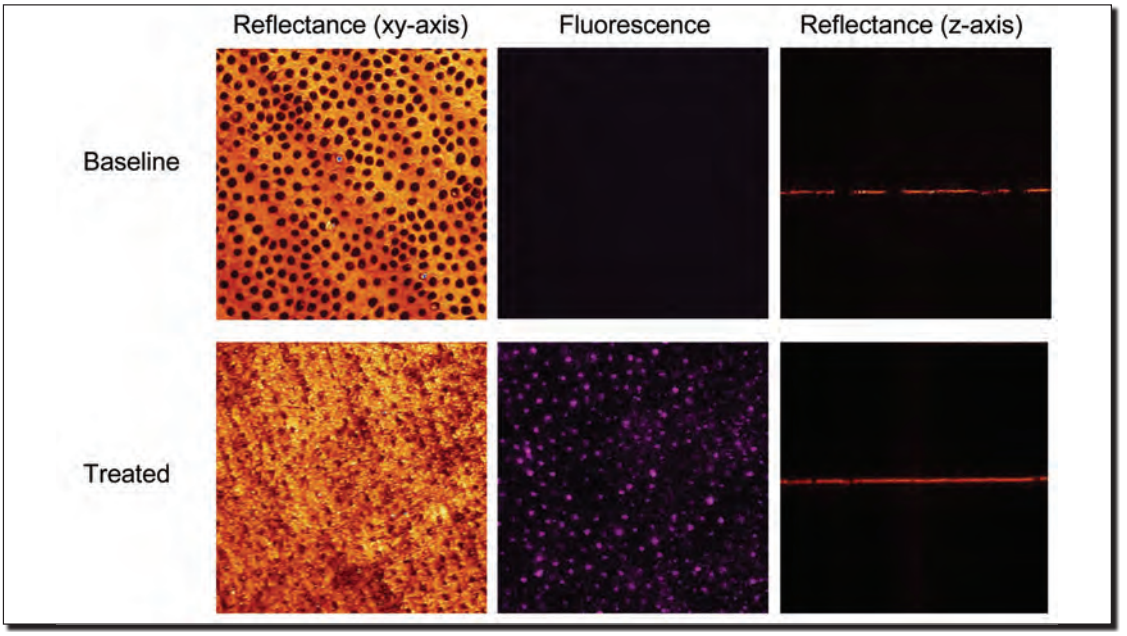


Fig. 3. Images acquired by CLSM in either reflectance or fluorescence (middle column) modes of etched dentin surfaces before (top row) and after treatment (bottom row) with Test Dentifrice 1 containing fluorescently-tagged specially-designed silica. The xz view of the dentin surface is shown in the far-right column.

Table. ESCA analysis of dentin samples before and after treatment with Negative Control Dentifrice or Test Dentifrice 1.

| Dentin | C | O | N | Ca | P | Na | F | Si |
|---|---|---|---|---|---|---|---|---|
| Before treatment | 62.24 (2.82) | 21.23 (1.25) | 14.55 (1.60) | 1.00 (0.51) | 0.78 (0.37) | - | - | 0.21 (0.05) |
| Negative Control treated | 42.30 (5.16) | 34.57 (4.63) | 9.28 (3.39) | 6.69 (2.85) | 4.79 (2.14) | 0.39 (0.10) | 0.40 (0.27) | 1.60 (1.65) |
| Test Dentifrice 1 treated | 38.71 (2.45) | 38.92 (2.19) | 6.24 (0.31) | 5.94 (0.99) | 4.08 (0.80) | 0.50 (0.10) | 0.44 (0.09) | 5.20 (2.13) |

posits, which was evident in the xz side-view as a solid, continuous line. In contrast, the cola-challenged, Placebo, Negative Control, and Test Dentifrice 2-treated disks showed a broken dashed line in the side view, indicating non-occluded tubule openings.

To further probe the acid resistance of dentifrice-treated dentin, a 4-day pH cycling model was used involving dentifrice treatment at the beginning and end of each day with four citric acid challenges and PBS incubation in between. This model was designed to mimic daily acid challenges introduced by acid beverages typically encountered in consumers' daily routine. Imaging of dentin by CLSM in xy and xz planes after the 4-day model revealed a significantly higher amount of occluded tubules for Test Dentifrice 1 *versus* Negative or Test Dentifrice 2-treated dentin (Fig. 2).

*Confocal laser scanning microscopy with fluorescently-tagged specially-designed silica* - CLSM was used to evaluate dentin treated with Test Dentifrice 1 containing FITC fluorescently-tagged specially-designed silica. As shown in Figure 3, untreated disks (baseline) showed open tubules when the image was taken in reflectance mode. No fluorescence was observed for untreated disks. A side view image emphasizes the open tubules as indicated by the broken line. After brushing with fluorescently-tagged Test Dentifrice 1, the dentin surface image showed occlusion of tubules on both reflectance and fluorescence modes, confirmed by the continuous line of the side view image. The fluorescent material was localized in the tubules, indicating occlusion by the specially-designed silica.

*ESCA, scanning electron microscopy, EDX* - ESCA was performed on dentin samples before and after treatment with either the Test Dentifrice 1 or Negative Control Dentifrice. The results are shown in the Table. The ESCA image of the etched dentin surface before treatment showed high levels of carbon (C), oxygen (O) and nitrogen (N) with lower levels of calcium (Ca) and phosphorus (P), consistent with a demineralized dentin surface composed of collagen proteins. After treatment, the reduction in carbon and nitrogen, and concurrent increase in calcium and phosphorous, for the Negative Control Dentifrice-treated dentin, suggest some mineralization of the surface, potentially from the calcium and phosphate salts in the PBS incubation solution. This trend was also seen with Test Dentifrice 1-treated dentin, however, the higher reduction in carbon and nitrogen and the presence of higher silicon content are indicative of a coating containing both silica and calcium phosphate covering the dentin surface.

Like the CLSM images, the high resolution SEM images also revealed significant dentin occlusion after treatment with Test Dentifrice 1 (Fig. 4). Elemental mapping by EDX of the Test Dentifrice 1-treated dentin indicated that the tubules were plugged with silicon-containing material as evidenced by a Si peak located at 1.74 keV (Fig. 5). The freeze-fracture SEM image (Fig. 6) and elemental mapping revealed sub-surface occlusion plugs over 8 µm-deep containing silicon, in addition to calcium and phosphorous. In contrast, dentin treated with Negative Control Dentifrice contained a large majority of open dentin tubules in SEM images (Fig. 4). Elemental mapping of a

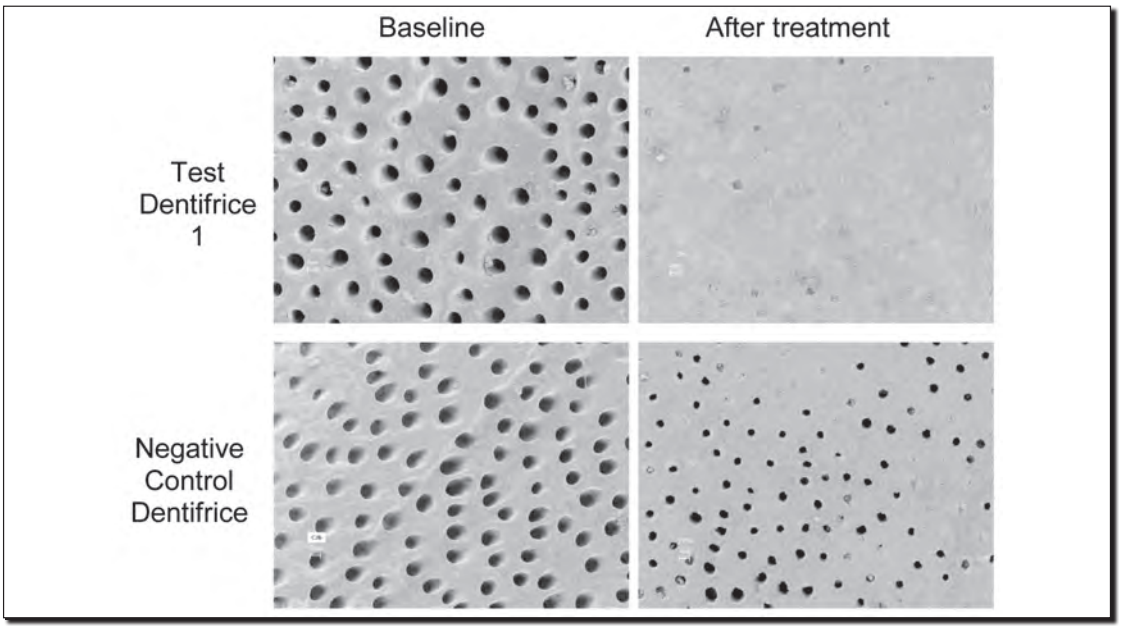


Fig. 4. SEM images (x5000 magnification) of etched dentin surfaces before and after treatment with either Test Dentifrice 1 (top row) or Negative Control Dentifrice (bottom row).

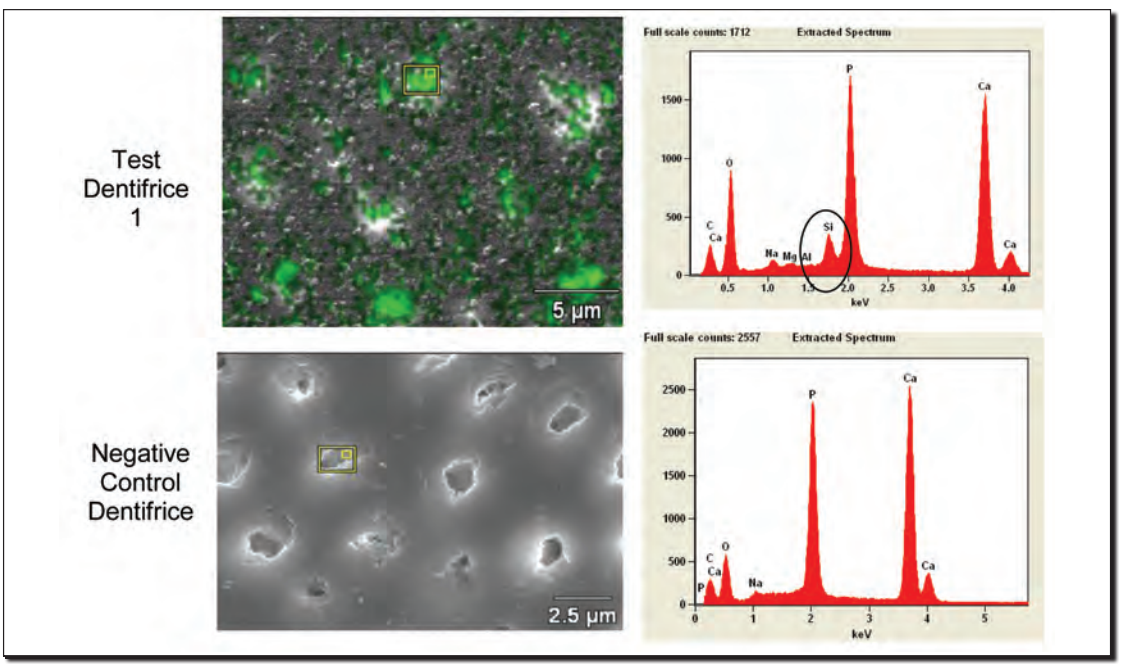


Fig. 5. SEM and EDX elemental mapping of etched dentin surfaces after treatment with either Test Dentifrice 1 (top row) or Negative Control Dentifrice (bottom row). Corresponding EDX spectra (right) were collected from the yellow-boxed areas indicated on the SEM images. The silicon EDX map indicated in green is overlaid on the SEM image for the Test Dentifrice 1. EDX spectra taken on the overall region and yellow-boxed areas seen in the Negative Control Dentifrice SEM image indicated that silicon was not detected above EDX detection limits for the Negative Control Dentifrice-treated dentin (< 30,000 ppm),

partially-occluded tubule from Negative Control Dentifrice-treated dentin (Fig. 5) revealed calcium and phosphorus, rather than silicon, suggesting the presence of marginal remineralization deposits formed by calcium and phosphate salts in the PBS incubation solution.

*Hydraulic conductance* - The effect of dentifrice treatment on dentin permeability was determined using hydraulic conductance. The first evaluation involved comparison of dentin treated with Test Dentifrice 1 or Negative Control Dentifrice. As shown in Fig. 7, dentin treated eight times with Test Dentifrice 1 showed over 80% reduction in dentin permeability, significantly higher than that observed for Negative Control Dentifrice-treated dentin.

The second conductance evaluation involved comparison of Test Dentifrices 1 and 2. After 14 treatments, Test Dentifrices 1 and 2 produced similar reductions in dentin permeability (Fig. 8). However, after pulpal pressure incubation for 10 days and subsequent citric acid challenge, only the Test Dentifrice 1-treated dentin retained the initial approximately 90% reduction in dentin permeability, which was significantly higher ($P < 0.05$) than Test Dentifrice 2-treated dentin.

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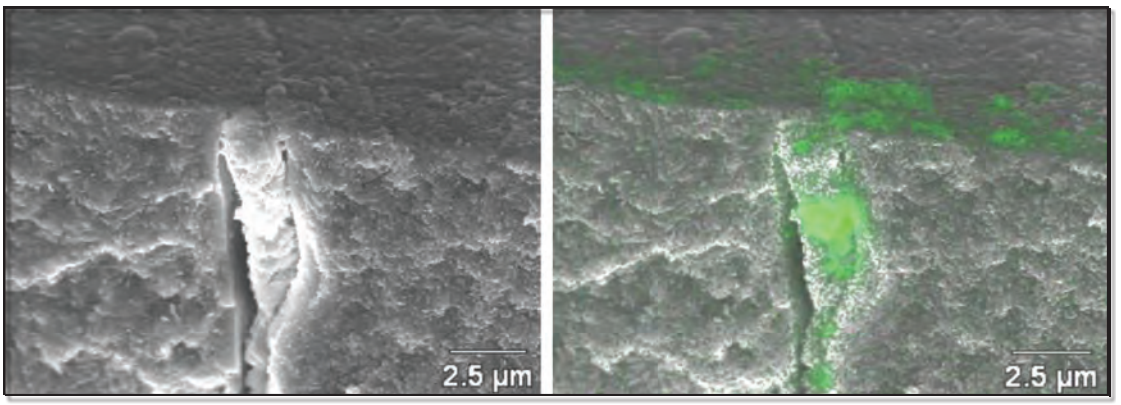


Fig. 6. SEM and EDX elemental mapping of cross-sectioned dentin after treatment with Test Dentifrice 1. The silicon EDX map indicated in green is overlaid on the SEM image (right).

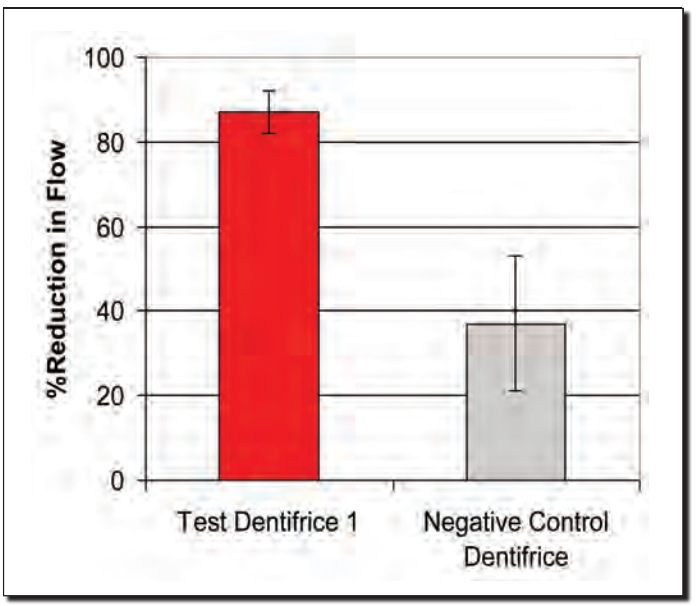


Fig. 7. Hydraulic conductance data of dentin treated eight times with either Test Dentifrice 1 or Negative Control Dentifrice. Reduction is relative to the baseline etched dentin.

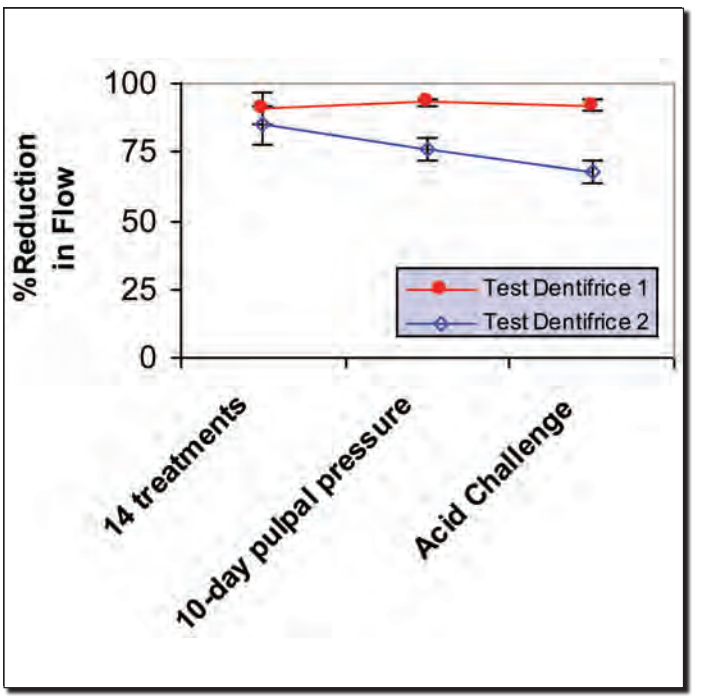


Fig. 8. Hydraulic conductance data of dentin treated with either Test Dentifrice 1 or 2 and subsequent exposure to simulated pulpal pressure and acid challenge. Reduction is relative to the baseline etched dentin.

## Discussion

Human hypersensitivity clinical studies confirmed that Test Dentifrice 1 provided statistically significant reductions in dentin hypersensitivity relative to Test Dentifrice 2 and Negative Control Dentifrice.[9,10] After 8 weeks, Test Dentifrice 1 provided 37.9% and 61.1% improvements in tactile sensitivity scores relative to Test Dentifrice 2 and Negative Control Dentifrice, respectively, and 27.2% and 34.0% relative reductions in air blast sensitivity respectively.[9]

The studies described in this paper were designed to gain more insight on how the triclosan/copolymer/specially-designed silica formulation provides relief of sensitivity. Previously-published laboratory studies[12,13] reported moderate reductions in dentin permeability from treatment of dentin with solutions or dentifrices containing polyvinylmethyl ether/maleic acid (PVM/MA) copolymers. The design of the specially-designed silica used in Test Dentifrice 1 focused on providing high purity particles of optimal surface area to maximize attraction to dentin surfaces along with specific diameters that would enable occlusion and penetration of dentin tubules. Thus, a key objective was determining whether the dentifrice formulation containing PVM/MA copolymer and the specially-designed silica would act together to provide a significant, acid-resistant occlusion when compared to both a standard silica abrasive dentifrice and a multi-benefit silica dentifrice containing stannous fluoride, sodium hexametaphosphate, and zinc lactate.

Surface analysis by CLSM and SEM clearly showed that the combination of PVM/MA copolymer with the specially-designed silica is highly effective in occluding patent dentin tubules, even after cola challenge. Conversely, no significant occlusion was observed with CLSM when dentifrices containing conventional abrasive silica without copolymer were applied to the dentin surface (Negative Control and Placebo Dentifrice). In addition, a 4-day treatment and acid challenge regimen revealed that the occlusion generated from the Test Dentifrice 1 was more tenacious and better able to survive multiple citric acid challenges compared to the Negative Control and Test Dentifrice 2.

EDX analysis confirmed tubule penetration of silicon-con-

taining material while CLSM fluorescent studies revealed specially-designed silica localized at occluded dentin tubule openings, indicating that specially-designed silica from the product entered the tubules and was sealed into the tubules, potentially aided by the PVM/MA copolymer.

A valuable complement to the qualitative imaging techniques is the hydraulic conductance method which provides quantitative data describing the ability of occluding deposits to slow outward dentin tubule fluid flow, a key factor attributed to reducing hypersensitivity. Hydraulic conductance experiments confirmed that the Test Dentifrice 1 occlusion deposits observed through surface microscopy techniques translated into a significant reduction in dentin permeability of over 80%. In addition, the occluded dentin was more resilient to pulpal pressure and citric acid challenge compared to the stannous fluoride/hexametaphosphate/zinc lactate Test Dentifrice 2. These findings may explain the hypersensitivity clinical results comparing these systems.[9] The higher tenacity of the occlusion deposits to pulpal pressure is likely due to the specially-designed silica in Test Dentifrice 1 which can penetrate tubules, as well as coat the surface. A separate study evaluating dentin occlusion efficacy of the stannous fluoride/hexametaphosphate/zinc lactate Test Dentifrice 2 revealed only a thin surface coating that could be seen by CLSM, but did not penetrate deep enough to be seen by SEM techniques.[14]

In summary, the technology described here offers a unique approach to provide clinically-documented hypersensitivity relief, in addition to the well-established anti-plaque and anti-gingivitis benefits of Colgate Total toothpaste. The studies reported here provide evidence of significant dentin occlusion by the copolymer/specially-designed silica system and provide a better understanding of its superior anti-hypersensitivity benefits observed in clinical studies comparing it to stannous fluoride/hexametaphosphate/zinc lactate and conventional silica dentifrices. The superior clinically-observed reductions in hypersensitivity from the Test Dentifrice 1 are believed to be due not only to efficient and tubule-penetrating occlusion, but also to the improved resistance of the specially-designed silica occlusion to dislodgement by pulpal pressure and resistance to acid challenge. These results stress the importance of including relevant challenges and measurement techniques in laboratory studies assessing dentin occlusion in order to more accurately predict clinically-relevant hypersensitivity efficacy.

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Special Issue Article

# Assessment of hypersensitivity reduction of a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica as compared to a dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate and zinc lactate and to a dentifrice containing 0.243% NaF on dentin hypersensitivity reduction: An 8-week study

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**ABSTRACT: Purpose:** To evaluate the 8-week dentin hypersensitivity efficacy of three toothpastes: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride and specially-designed silica (Test Dentifrice 1); (2) a commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate (Test Dentifrice 2); and (3) a commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base (Negative Control Dentifrice). **Methods:** For this 8-week randomized controlled clinical study, qualifying subjects had to have at least two hypersensitive teeth with a tactile hypersensitivity score (Yeaple Probe) between 10 and 50 grams of force, and air blast hypersensitivity score of 2 or 3 (Schiff Cold Air Sensitivity Scale). Subjects brushed twice daily for 1 minute, using the assigned toothpaste and toothbrush. Dentin hypersensitivity assessments, as well as examinations of oral hard and soft tissues, were conducted at the baseline examination and after 4 and 8 weeks of brushing. **Results:** 118 subjects complied with the protocol, and completed the 8-week study. At baseline, the mean tactile sensitivity scores for toothpastes (1), (2) and (3) were 13.6, 14.1 and 13.1; at 4 weeks 28.75, 20.13, and 20.00; and after 8 weeks 33.1, 24.0 and 20.5, respectively. The mean air blast scores for toothpastes (1), (2), and (3) at baseline were 2.5, 2.5, and 2.4; at 4 weeks 1.25, 1.50 and 1.85; and after 8 weeks 0.99, 1.36 and 1.5, respectively. At all time points after the baseline examination, for both tactile and air blast sensitivity scores, the differences between Test Dentifrice 1 and the Negative Control Dentifrice were statistically significant ($P < 0.05$). The differences between Test Dentifrice 1 and Test Dentifrice 2 were statistically significant ($P < 0.05$) at 4 and 8 weeks after baseline examination for tactile sensitivity scores and at 8 weeks after baseline examination for air blast sensitivity scores. (*Am J Dent* 2011;24 Sp Is A:14A-20A).

**CLINICAL SIGNIFICANCE:** The 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 and specially-designed silica provides significant improvements in dentin hypersensitivity relative to a toothpaste containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate and to a negative control toothpaste.

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## Introduction

Dentin hypersensitivity is commonly characterized by a sharp pain of short duration, which arises from exposed dentin in response to an external stimulus. The cause of the pain cannot be associated with any other type of dental problem. The pain trigger is usually a thermal, tactile, osmotic, or a dehydrating stimulus.[1] Dentin hypersensitivity is typically experienced when the root of the tooth has been exposed to the oral environment as a result of gingival recession. Gingival recession may occur naturally, however, poor oral hygiene habits such as excessive or improper tooth brushing may contribute to the process. In addition, surgical or non-surgical periodontal treatment may also result in gingival recession and exposure of the underlying dentin.

Dentin hypersensitivity usually occurs more frequently in the cervical area of the roots, where the cementum is very thin and dentin exposure initially occurs. Once the gingiva recedes, the overlying cementum is quickly lost, leaving exposed dentin open to the oral environment. The incidence of dentin hypersensitivity is increasing in the population[2] due to an increased longevity and improved maintenance of the dentition as people age, as well as the loss of enamel due to the increased consumption of acidic beverages by those in younger age groups. This increase will put greater demands on the dental profession to manage the sensitivity of cervically exposed dentin, as well as any secondary issues that may arise from the discomfort associated with dentin hypersensitivity. Unfortunately for many patients who suffer from dentin hypersensitivity, tooth brushing may be more difficult and can result in persistent and continued accumulation of dental plaque. This increase in dental plaque may lead to an increased incidence of caries, gingivitis, and more serious periodontal problems.[3]

Several theories have been proposed to explain the mechanism of dentin hypersensitivity, including the odontoblast transducer theory, the dentin receptor theory, and the hydrodynamic theory.[4,5] Scientific evidence supports the hydrodynamic theory (modified by Brännström[6] in 1963), which suggests that fluid movement within the dentin tubules

is the basis for the transmission of painful sensations. Non-noxious stimuli at the tooth surface cause fluid movement within the dentin tubules, affecting the pulpal mechano-receptors and resulting in the sensation of pain.

A number of agents have been proposed to help control dentin hypersensitivity and relieve discomfort. Products with these agents range from those that can be used by the patient at home to others that must be applied in the dental office by a dental professional. One approach is through the use of desensitizing dentifrices; specifically, toothpastes containing potassium salts. The other approach is to block or occlude the open dentin tubules in order to limit the displacement of fluids within them (decreased hydrodynamic flow), which will block neurotransmission and decrease the response to painful stimuli. One method by which the tubules can be occluded is through the deposition of fine particles on the surface of the dentin. These fine particles can comprise deposits of fine abrasives, such as silica, or precipitates of metal salts, such as stannous fluoride and calcium phosphate. An excellent review[2] provides a detailed discussion of the science and clinical evidence behind these and other dentin hypersensitivity treatments.

This 8-week clinical trial compared the dentin hypersensitivity reduction efficacy of a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, and 0.243% sodium fluoride with specially-designed silica (Test Dentifrice 1[a]) and of a commercially-available dentifrice containing 0.454% stannous fluoride, sodium hexametaphosphate, and zinc lactate in a silica base (Test Dentifrice 2[b]) to a commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base (Negative Control Dentifrice[b]).

## Materials and Methods

This clinical study was conducted at Concordia Clinical Research in Cedar Knolls, New Jersey, USA, and employed a double-blind, randomized, three-treatment, parallel-group design. Male and female subjects were enrolled into the study based upon the following criteria:

1. Subjects had to be between the ages of 18 and 70, in generally good health with no known allergies to the products being tested.

2. Subjects had to be available for the 8-week duration of the study, and to sign an informed consent form.

3. Subjects were required to possess a minimum of two hypersensitive teeth which were anterior to the molars and demonstrated cervical erosion/abrasion or gingival recession; and for which a tactile stimuli score of 10 to 50 grams of force (Yeaple probe) and an air blast stimuli score of 2 or 3 (Schiff Cold Air Sensitivity Scale) were present at the baseline examination.[7]

4. Subjects were excluded from the study if they had gross oral pathology, chronic disease, advanced periodontal disease or treatment for periodontal disease (including surgery) within the last 12 months, or hypersensitive teeth with contributing etiologies other than recognized clinically as being associated with dentin hypersensitivity, such as teeth with deep, defective or facial restorations; teeth used as abutments for fixed or removable partial dentures; teeth with full prosthetic crowns; teeth with suspected pulpitis; teeth with orthodontic bands; teeth with extensive caries or cracked enamel; teeth under abnormal occlusal forces; or teeth with mobility greater than one.

5. Subjects who began taking anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics within 1 month prior to the start of the study, or those who would have to begin taking them during the course of the study were excluded from participation in the study. Additionally, pregnant or lactating women, individuals currently participating in any other clinical study, or those who had used a desensitizing product within 3 months prior to the start of the study were also excluded.

6. Subjects with allergies to oral care products, personal care consumer products or their ingredients, or subjects with existing medical conditions, which precluded them from not eating and drinking for periods up to 4 hours, were excluded from participation in the study.

Prospective study subjects reported to the clinical facility having refrained from all oral hygiene procedures and chewing gum for 8 hours, and having refrained from eating and drinking for 4 hours prior to their examination. All prospective subjects who met the inclusion/exclusion criteria and signed an informed consent form received baseline tactile stimuli and air blast sensitivity evaluations, along with an oral soft and hard tissue assessment.

For each subject who qualified for participation in the study, two sensitive teeth that satisfied the enrollment criteria were identified for evaluation during the study. Qualifying subjects were randomly assigned to one of the three study treatments:

*Test Dentifrice 1* - A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer and 0.243% sodium fluoride with a specially-designed silica.

*Test Dentifrice 2* - A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.

*Negative Control Dentifrice* – A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.

Following study treatment assignment, subjects were provided with their assigned dentifrice and a soft-bristled toothbrush for home use. All of the dentifrice products were overwrapped and coded to mask the products' identity. Subjects were instructed to brush their teeth for 1 minute, twice daily (morning and evening) using only the dentifrice and toothbrush provided, and to refrain from any other oral hygiene procedures throughout the duration of the study. There were no restrictions regarding diet or smoking habits during the course of the study, except as indicated above.

After 4 weeks, and again after 8 weeks of product use, subjects returned to the clinical facility for tactile and air blast sensitivity evaluations of their baseline-designated study teeth and for oral soft and hard tissue assessments. All examinations were performed by the same dental examiner, using the same procedures as employed at baseline. Subjects were also

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Table 1. Summary of gender and age for subjects who completed the 8-week clinical study.

| | Number of subjects | | | Age | | Race | | | |
|---|---|---|---|---|---|---|---|---|---|
| Treatment | Male | Female | Total | Mean[4] | Range | Asian | African American | Caucasian | Hispanic |
| Test Dentifrice 1[1] | 5 | 35 | 40 | 52.1 | 18 - 70 | 1 | 0 | 39 | 0 |
| Test Dentifrice 2[2] | 6 | 33 | 39 | 47.1 | 21 - 63 | 1 | 0 | 38 | 0 |
| Negative Control Dentifrice[3] | 3 | 36 | 39 | 53.4 | 41 - 70 | 1 | 1 | 36 | 1 |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.
[3] A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.
[4] A statistically significant difference was indicated among the treatment groups at baseline with respect to age.

Table 2. Summary of the Baseline Tactile and Air Blast Sensitivity scores for subjects who completed the 8-week clinical study.

| Parameter & treatment | N | Baseline summary (Mean ± S.D.)[4] |
|---|---|---|
| **Tactile Sensitivity** | | |
| Test Dentifrice 1[1] | 40 | 13.63 ± 4.67 |
| Test Dentifrice 2[2] | 39 | 14.10 ± 7.42 |
| Negative Control Dentifrice[3] | 39 | 13.08 ± 6.45 |
| **Air Blast Sensitivity** | | |
| Test Dentifrice 1[1] | 40 | 2.50 ± 0.41 |
| Test Dentifrice 2[2] | 39 | 2.50 ± 0.40 |
| Negative Control Dentifrice[3] | 39 | 2.40 ± 0.45 |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.
[3] A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.
[4] No statistically significant difference was indicated among the three treatment groups at baseline with respect to either tactile sensitivity or air blast sensitivity.

interviewed with respect to the presence of adverse events and the use of concomitant medications.

### CLINICAL SCORING PROCEDURES

### Tactile sensitivity assessment[7]

Tactile sensitivity was assessed by use of the Model 200A Electronic Force Sensing Probe.[c] The application of this probe for dental sensitivity testing utilizing a #19 explorer tip at a pre-set force measured in grams was employed.

Teeth were evaluated for tactile sensitivity in the following manner:

1. The subject was instructed to respond at the point where he/she first experienced discomfort.
2. The explorer tip of the probe was applied to the buccal surface of each sensitive tooth at the CEJ.
3. The explorer tip was stroked perpendicular to the tooth beginning at a pre-set force of 10 g and increased by 10 g increments until the subject experienced discomfort, or until 50 g of force was applied.

Subject-wise scores were calculated by averaging the values measured on the two baseline-designated study teeth.

### Air blast sensitivity assessment[7]

Teeth were evaluated for air blast sensitivity in the following manner:

1. The sensitive tooth was isolated from the adjacent teeth (mesial and distal) by the placement of the examiner's fingers over the adjacent teeth.
2. Air was delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F (± 3°F). The air was directed at the exposed buccal surface of the sensitive tooth for 1 second from a distance of approximately 1 cm.
3. The Schiff Cold Air Sensitivity Scale was used to assess subject response to this stimulus. This scale is scored as follows:

0 = Subject does not respond to air stimulus;
1 = Subject responds to air stimulus but does not request discontinuation of stimulus;
2 = Subject responds to air stimulus and requests discontinuation or moves from stimulus;
3 = Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Subject-wise scores were calculated by averaging the values obtained from the two baseline-designated study teeth.

### 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. 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.

*Statistical methods* - Statistical analyses were performed separately for the tactile sensitivity assessments and the air blast sensitivity assessments. Comparisons of the treatment groups with respect to age, and with respect to baseline tactile sensitivity and air blast sensitivity scores were performed using ANOVA. Comparisons between the treatment groups with respect to gender were performed using chi-squared tests. Within-treatment comparisons of the baseline *versus* follow-up tactile sensitivity and air blast sensitivity scores were performed using paired *t*-tests. Comparisons of the treatment groups with respect to baseline-adjusted tactile sensitivity and air blast sensitivity scores at the follow-up examinations were performed using ANCOVA. All statistical tests of hypotheses were two sided, and employed a level of significance of $\alpha = 0.05$.

## Results

Of the 120 subjects who entered the study, 118 subjects (98.3%) complied with the protocol, and completed the 8-week examination. Subjects who did not complete the study did so for reasons unrelated to the use of the study treatments. A summary of the gender, age, and race of the study population who completed the 8-week examination is presented in Table 1.

Table 3. Summary of the 4-week Tactile Sensitivity scores for subjects who completed the 8-week clinical study.

| | | | Within treatment analysis | | Differences *vs.* other treatments: *vs* Test Dentifrice 2 | | *vs* Negative Control | |
|---|---|---|---|---|---|---|---|---|
| | N | 4-week summary (Mean ± SD) | Percent difference[4] | Sig.[5] | Percent difference[6] | Sig.[7] | Percent difference[8] | Sig.[7] |
| Test Dentifrice 1[1] | 40 | 28.75 ± 12.65 | 110.9% | P< 0.05 | 42.8% | P< 0.05 | 43.8% | P< 0.05 |
| Test Dentifrice 2[2] | 39 | 20.13 ± 11.61 | 42.8% | P< 0.05 | --- | --- | 0.7% | NS |
| Negative Control Dentifrice[3] | 39 | 20.00 ± 9.80 | 52.9% | P< 0.05 | --- | --- | --- | --- |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.
[3] A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.
[4] Percent difference exhibited by the 4-week mean relative to the baseline mean.
[5] Significance of paired *t*-test comparing the baseline and 4-week examinations.
[6] Between-treatment difference expressed as a percentage of the 4-week mean for Test Dentifrice 2. A positive value indicates an improvement in tactile sensitivity for Test Dentifrice 1 relative to Test Dentifrice 2.
[7] Significance of ANCOVA comparison of baseline-adjusted means. NS = P> 0.05.
[8] Between-treatment difference expressed as a percentage of the 4-week mean for the Negative Control Dentifrice. A positive value indicates an improvement in tactile sensitivity for Test Dentifrice 1 relative to the Negative Control Dentifrice.

Table 4. Summary of the 4-week Air Blast Sensitivity scores for subjects who completed the 8-week clinical study.

| | | | Within treatment analysis | | Reductions *vs.* other treatments: *vs* Test Dentifrice 2 | | *vs* Negative Control | |
|---|---|---|---|---|---|---|---|---|
| | N | 4-week Summary (Mean ± SD) | Percent reduction[4] | Sig.[5] | Percent reduction[6] | Sig.[7] | Percent reduction[8] | Sig.[7] |
| Test Dentifrice 1[1] | 40 | 1.25 ± 0.66 | 50.0% | P< 0.05 | 16.7% | NS | 32.4% | P< 0.05 |
| Test Dentifrice 2[2] | 39 | 1.50 ± 0.73 | 40.0% | P< 0.05 | --- | --- | 18.9% | P< 0.05 |
| Negative Control Dentifrice[3] | 39 | 1.85 ± 0.84 | 22.9% | P< 0.05 | --- | --- | --- | --- |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.
[3] A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.
[4] Percent reduction exhibited by the 4-week mean relative to the baseline mean.
[5] Significance of paired *t*-test comparing the baseline and 4-week examinations.
[6] Between-treatment reduction expressed as a percentage of the 4-week mean for Test Dentifrice 2. A positive value indicates a reduction in air blast sensitivity for Test Dentifrice 1 relative to Test Dentifrice 2.
[7] Significance of ANCOVA comparison of baseline-adjusted means. NS = P> 0.05.
[8] Between-treatment reduction expressed as a percentage of the 4-week mean for the Negative Control Dentifrice. A positive value indicates a reduction in air blast sensitivity for Test Dentifrice 1 relative to the Negative Control Dentifrice.

## BASELINE DATA

Table 2 presents a summary of the tactile and air blast sensitivity scores measured at the baseline examination. For tactile sensitivity, the mean baseline scores were 13.63 for the Test Dentifrice 1 group, 14.10 for the Test Dentifrice 2 group, and 13.08 for the Negative Control Dentifrice group. For air blast sensitivity, the mean baseline scores were 2.50 for the Test Dentifrice 1 group, 2.50 for the Test Dentifrice 2 group, and 2.40 for the Negative Control Dentifrice group. No statistically significant difference was indicated between the treatment groups with respect to either sensitivity score at baseline.

## 4-WEEK DATA

### Tactile sensitivity

Table 3 presents a summary of the tactile sensitivity scores measured after 4 weeks of product use.

*Comparisons versus baseline* - The mean 4-week tactile sensitivity scores were 28.75 for the Test Dentifrice 1 group, 20.13 for the Test Dentifrice 2 group, and 20.00 for the Negative Control Dentifrice group. The mean percent differences from baseline were 110.9% for the Test Dentifrice 1 group, 42.8% for the Test Dentifrice 2 group, and 52.9% for the Negative Control Dentifrice group, all of which were statistically significant.

*Comparison between treatment groups* - Relative to the Test Dentifrice 2 group, the Test Dentifrice 1 group exhibited a statistically significant (42.8%) improvement in tactile sensitivity after 4 weeks of product use. Relative to the Negative Control Dentifrice group, the Test Dentifrice 1 group exhibited a statistically significant (43.8%) improvement in tactile sensitivity at the 4-week examination; and the Test Dentifrice 2 group exhibited a 0.7% improvement in tactile sensitivity, which was not statistically significant.

### Air blast sensitivity

Table 4 presents a summary of the air blast sensitivity scores measured after 4 weeks of product use.

*Comparisons versus baseline* - The mean 4-week air blast sensitivity scores were 1.25 for the Test Dentifrice 1 group, 1.50 for the Test Dentifrice 2 group, and 1.85 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 50.0% for the Test Dentifrice 1 group, 40.0% for

Table 5. Summary of the 8-week Tactile Sensitivity scores for subjects who completed the 8-week clinical study.

| | | | Within treatment analysis | | Differences *vs.* other treatments | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | *vs* Test Dentifrice 2 | | *vs* Negative Control | |
| | N | 8-week summary (Mean ± SD) | Percent difference[4] | Sig.[5] | Percent difference[6] | Sig.[7] | Percent difference[8] | Sig.[7] |
| Test Dentifrice 1[1] | 40 | 33.05 ± 12.87 | 142.5% | P< 0.05 | 37.9% | P< 0.05 | 61.1% | P< 0.05 |
| Test Dentifrice 2[2] | 39 | 23.97 ± 12.73 | 70.0% | P< 0.05 | --- | --- | 16.9% | NS |
| Negative Control Dentifrice[3] | 39 | 20.51 ± 11.05 | 56.8% | P< 0.05 | --- | --- | --- | --- |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.
[3] A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.
[4] Percent difference exhibited by the 8-week mean relative to the baseline mean.
[5] Significance of paired *t*-test comparing the baseline and 8-week examinations.
[6] Between-treatment difference expressed as a percentage of the 8-week mean for Test Dentifrice 2. A positive value indicates an improvement in tactile sensitivity for Test Dentifrice 1 relative to Test Dentifrice 2.
[7] Significance of ANCOVA comparison of baseline-adjusted means. NS = P> 0.05.
[8] Between-treatment difference expressed as a percentage of the 8-week mean for the Negative Control Dentifrice. A positive value indicates an improvement in tactile sensitivity for Test Dentifrice 1 relative to the Negative Control Dentifrice.

Table 6. Summary of the 8-week Air Blast Sensitivity scores for subjects who completed the 8-week clinical study.

| | | | Within treatment analysis | | Reductions *vs.* other treatments | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | *vs* Test Dentifrice 2 | | *vs* Negative Control | |
| | N | 8-week summary (Mean ± SD) | Percent reduction[4] | Sig.[5] | Percent reduction[6] | Sig.[7] | Percent reduction[8] | Sig.[7] |
| Test Dentifrice 1[1] | 40 | 0.99 ± 0.56 | 60.4% | P< 0.05 | 27.2% | P< 0.05 | 34.0% | P< 0.05 |
| Test Dentifrice 2[2] | 39 | 1.36 ± 0.80 | 45.6% | P< 0.05 | --- | --- | 9.3% | NS |
| Negative Control Dentifrice[3] | 39 | 1.50 ± 0.85 | 37.5% | P< 0.05 | --- | --- | --- | --- |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate.
[3] A commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base.
[4] Percent reduction exhibited by the 8-week mean relative to the baseline mean.
[5] Significance of paired *t*-test comparing the baseline and 8-week examinations.
[6] Between-treatment reduction expressed as a percentage of the 8-week mean for Test Dentifrice 2. A positive value indicates a reduction in air blast sensitivity for Test Dentifrice 1 relative to Test Dentifrice 2.
[7] Significance of ANCOVA comparison of baseline-adjusted means. NS = P> 0.05.
[8] Between-treatment reduction expressed as a percentage of the 8-week mean for the Negative Control Dentifrice. A positive value indicates a reduction in air blast sensitivity for Test Dentifrice 1 relative to the Negative Control Dentifrice.

the Test Dentifrice 2 group, and 22.9% for the Negative Control Dentifrice group, all of which were statistically significant.

*Comparison between treatment groups* - Relative to the Test Dentifrice 2 group, the Test Dentifrice 1 group exhibited a 16.7% reduction in air blast sensitivity after 4 weeks of product use, which was not statistically significant. Relative to the Negative Control Dentifrice group, both the Test Dentifrice 1 group and the Test Dentifrice 2 group exhibited statistically significant reductions of 32.4% and 18.9%, respectively, in air blast sensitivity after 4 weeks of product use.

## 8-WEEK DATA

### Tactile sensitivity

Table 5 presents a summary of the tactile sensitivity scores measured after 8 weeks of product use.

*Comparisons versus baseline* - The mean 8-week tactile sensitivity scores were 33.05 for the Test Dentifrice 1 group, 23.97 for the Test Dentifrice 2 group, and 20.51 for the Negative Control Dentifrice group. The mean percent differences from baseline were 142.5% for the Test Dentifrice 1 group, 70.0% for the Test Dentifrice 2 group, and 56.8% for the Negative Control Dentifrice group, all of which were statistically significant.

*Comparison between treatment groups* - Relative to the Test Dentifrice 2 group, the Test Dentifrice 1 group exhibited a statistically significant improvement of 37.9% in tactile sensitivity after 8 weeks of product use. Relative to the Negative Control Dentifrice group, the Test Dentifrice 1 group exhibited a statistically significant 61.1% improvement in tactile sensitivity at the 8-week examination; and the Test Dentifrice 2 group exhibited a 16.9% improvement in tactile sensitivity, which was not statistically significant.

### Air blast sensitivity

Table 6 presents a summary of air blast sensitivity scores measured after 8 weeks of product use.

*Comparisons versus baseline* - The mean 8-week air blast sensitivity scores were 0.99 for the Test Dentifrice 1 group, 1.36 for the Test Dentifrice 2 group, and 1.50 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 60.4% for the Test Dentifrice 1 group, 45.6% for the Test Dentifrice 2 group, and 37.5% for the Negative

Control Dentifrice group, all of which were statistically significant.

*Comparison between treatment groups* - Relative to the Test Dentifrice 2 Group, the Test Dentifrice 1 Group exhibited a statistically significant 27.2% reduction in air blast sensitivity after 8 weeks of product use. Relative to the Negative Control Dentifrice Group, the Test Dentifrice 1 Group exhibited a statistically significant 34.0% reduction in air blast sensitivity at the 8-week examination; and the Test Dentifrice 2 exhibited a 9.3% reduction, which was not statistically significant.

**Oral soft and hard tissue assessments**

There were no abnormal oral hard or soft tissue findings reported during the study.

## Discussion

Dentin hypersensitivity is a relatively common problem seen in today's clinical practice. It is characterized by a sharp, transient pain in response to a sensory stimulus, which can impact the quality of life through its effects on eating, drinking, brushing teeth, and breathing.[8] Epidemiologic research[2] suggests that prevalence peaks between 30 and 40 years of age. As individuals retain their teeth for a longer period of time and as diets change, it is reasonable to expect that there will be a higher incidence of oral complaints related to dentin hypersensitivity, and with that an increase in requests for treatment. In addition, patients who have received periodontal therapy are four times more at risk for developing hypersensitivity than the general population.[9]

A number of professional and over-the-counter products have been developed to help alleviate the pain associated with dentin hypersensitivity. For example, potassium salts have been added to dentifrices as sensitivity reducing agents for many years. There is a body of clinical evidence[2] that demonstrates that potassium-based toothpastes are effective in reducing dentin hypersensitivity; however, some investigators have reported that potassium-based toothpastes are no more effective than regular fluoride toothpaste.[7,10,11]

Another approach has been to occlude dentin tubules, or at least reduce their diameter, with a technology that coats the dentin surface and fills the openings of the tubules.[2] Historically, this approach has primarily been used to manage sensitivity in the form of products applied by dental professionals using either a varnish or precipitates.[7] Such an approach reduces the movement of fluids in the dentin tubule, and results in the blockage of painful stimuli.

Dentifrices containing stannous fluoride have been used for caries prevention since the early 1960's. Stannous fluoride has also been shown to relieve dentin hypersensitivity.[12-14] In previous studies,[15,16] dentifrice formulations which contain stannous fluoride and sodium hexametaphosphate were shown to provide some reduction in dentin hypersensitivity when compared to a Negative Control sodium fluoride toothpaste at both 4- and 8-week time points. It is important to note that stannous fluoride containing toothpastes have historically been known to cause staining of teeth with extended use, and compliance issues due to the taste of the dentifrice.

The current study evaluated the dentin hypersensitivity efficacy of three toothpastes: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride and specially-designed silica (Test Dentifrice 1); (2) a commercially-available dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphate and zinc lactate (Test Dentifrice 2); and (3) a commercially-available non-sensitive dentifrice containing 0.243% sodium fluoride in a silica base (Negative Control Dentifrice). The results demonstrated that the triclosan/copolymer dentifrice with specially-designed silica, (Test Dentifrice 1) provided a significant reduction of dentin hypersensitivity when used over a period of 8 weeks and it provided significant improvements in dentin hypersensitivity relative to a commercially-available stannous fluoride with sodium hexametaphosphate and zinc lactate dentifrice in a silica base (Test Dentifrice 2) as well as a Negative Control Dentifrice containing sodium fluoride in a silica base when used over a period of 8 weeks.

It is important to note that patients with dentin hypersensitivity often have difficulty maintaining good plaque control in those areas with sensitivity. The use of a dentifrice which combines an anti-plaque/anti-gingivitis ingredient plus an anti-sensitivity ingredient would be very helpful to these patients. The Test Dentifrice 1 in this study (triclosan/copolymer/specially-designed silica) possesses these attributes. In several recent studies,[17-20] a similar dentifrice was shown to be superior to Test Dentifrice 2 for controlling plaque and gingivitis. These data, when taken together, demonstrate that a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride and specially-designed silica provides superior anti-plaque, anti-gingivitis and anti-hypersensitivity benefits *versus* a dentifrice containing 0.454% stannous fluoride in a silica base with sodium hexametaphosphaste and zinc lactate. Dental professionals should feel confident recommending this dentifrice to patients who have these dental problems for twice daily use during tooth brushing.

a. Colgate-Palmolive Co., New York, NY, USA.
b. Procter & Gamble Co., Cincinnati, OH, USA.
c. Yeaple Research, Pittsford, NY, USA.

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# Comparative investigation of a dentifrice containing triclosan/copolymer/sodium fluoride and specially-designed silica and a dentifrice containing 0.243% sodium fluoride in a silica base for the control of established supra-gingival plaque and gingivitis: A 6-month clinical study

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**ABSTRACT: Purpose:** To investigate the efficacy of a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica in controlling established dental plaque and gingivitis. **Methods:** Qualifying adult male and female subjects from the West Palm Beach, Florida area were randomly assigned into one of two treatment groups: (1) a dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica (Test Dentifrice); and (2) a dentifrice containing 0.243% sodium fluoride in a silica base (Negative Control Dentifrice). All subjects received an oral soft and hard tissue examination, baseline plaque and gingivitis were assessed, and subjects were dispensed their assigned dentifrice product along with a soft-bristled adult toothbrush for home use. Subjects were instructed to brush their teeth for 1 minute, twice daily (morning and evening), using only the dentifrice provided. Examinations for plaque and gingivitis, and oral soft and hard tissue assessments were repeated after 3 and 6 months of product use. **Results:** 115 subjects complied with the protocol, and completed the 6-month examination. After 6 months of product use, subjects assigned to the Test Dentifrice group exhibited statistically significant reductions from baseline with respect to Plaque Index, Plaque Severity Index, Gingival Index, and Gingivitis Severity Index scores; and subjects assigned to the Negative Control Dentifrice group exhibited statistically significant reductions from baseline with respect to Gingival Index scores only. Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited an 18.8% reduction in Plaque Index; a 50% reduction in Plaque Severity Index; a 19.6% reduction in Gingival Index; and a 60% reduction in Gingivitis Severity Index after 6 months, all of which were statistically significant. (*Am J Dent* 2011;24 Sp Is A:21A-27A).

**CLINICAL SIGNIFICANCE:** The 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, and specially-designed silica provides a significant reduction in plaque and gingivitis when used over a period of 6 months, and provides a greater level of efficacy for the control of plaque and gingivitis than does a negative control dentifrice containing 0.243% sodium fluoride in a silica base during this time period.

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## Introduction

Dental plaque, also known as dental biofilm, starts to form on teeth immediately after tooth brushing (either by a dental professional or through home care). It is well accepted that the dental biofilm is the cause of gingivitis.[1] The developing biofilm releases a variety of biologically active products that diffuse into the surrounding gingival tissue and initiate an inflammatory host response that results in the clinical manifestation of gingivitis.[2] If left untreated, gingivitis may progress to periodontitis, a more serious form of periodontal disease, characterized by the formation of periodontal pockets, loss of attachment, bone loss and eventually, perhaps, tooth loss. This advanced state of periodontal disease does not only impact oral health; recent studies have suggested that an association exists between periodontitis and systemic disease, such as cardiovascular disease and diabetes.[3]

It is critical for patients to control the formation of plaque and gingival inflammation. The most common method of supragingival plaque control is *via* tooth brushing with a fluoride-containing dentifrice.[4] The American Dental Association recommends brushing twice a day and flossing once a day as a regimen for good oral hygiene.[5] The challenge is that most patients do not brush with this frequency, use poor tooth brushing technique, do not brush for a long enough time, and also may not floss interproximally, leading to increased incidence of gingivitis.

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% PVM/MA copolymer) into a 0.243% sodium fluoride/silica dentifrice, which was clinically proven to reduce plaque and gingivitis in the adult population (Colgate® Total® Toothpaste[a]). Triclosan has a broad spectrum of activity, and is effective against both gram positive and gram negative bacteria.[6] Colgate Total Toothpaste also contains the copolymer PVM/MA, which when combined with the triclosan, ensures delivery and substantivity of the triclosan to hard and soft tissues.[6] Effective levels of triclosan are retained in the oral cavity 12 hours after brushing the teeth,

allowing prolonged control of oral bacteria that form the dental plaque and cause gingivitis. Numerous clinical studies have demonstrated that Colgate Total provides superior control of plaque and gingivitis *versus* regular fluoride toothpaste.[6-9]

The efficacy, mode of action and safety of a triclosan/ PVM/MA copolymer/sodium fluoride toothpaste has been thoroughly researched in the scientific literature.[6-9] Colgate Total Toothpaste is the first and only dentifrice to be given approval by the U.S. Food and Drug Administration under the New Drug Application process for the prevention of plaque and gingivitis, and it is the first dentifrice to be granted the full range of Seals of Acceptance from the American Dental Association for the prevention and reduction of tooth decay, gingivitis and plaque, bad breath, and tooth whitening. It also has well documented efficacy for inhibiting supra-gingival calculus formation.[7]

This 6-month clinical study compared head-to-head the anti-plaque and anti-gingivitis efficacy of a new dentifrice containing 0.3% triclosan/2.0% PVM/MA copolymer/ 0.243% sodium fluoride and specially-designed silica to a dentifrice containing 0.243% sodium fluoride in a silica base. Gingivitis and plaque evaluations were conducted at baseline and after 3 and 6 months of product use.

## Materials and Methods

This clinical study was conducted at Dental Products Testing in West Palm Beach, Florida, and employed a double-blind, randomized, two-treatment, parallel-group design. Male and female subjects were enrolled into the study based upon the following criteria:

(1) Subjects had to be between the ages of 18 and 70, in generally good health, and possess a minimum of 20 un-crowned permanent natural teeth (excluding third molars).

(2) Subjects needed to be available for the 6-month duration of the study, and to sign an informed consent form.

(3) Subjects were required to present a mean Löe-Silness Gingival Index score of at least 1.0, and a mean plaque index score of 1.5 or greater as determined by the use of the Turesky modification of the Quigley-Hein Plaque Index at the baseline examination.

(4) Subjects were excluded from the study if they had orthodontic bands, presence of partial removable dentures, tumor(s) of the soft or hard tissues of the oral cavity, advanced periodontal disease (purulent exudates, tooth mobility and/or extensive loss of periodontal attachment or alveolar bone), five or more carious lesions requiring immediate restorative treatment.

(5) Subjects with a history of allergy to personal care/consumer products or their ingredients, or with existing medical conditions which precluded them from not eating and drinking for periods up to 4 hours, or who were taking any prescription medication that might interfere with the study outcome were excluded from the study. Additionally, pregnant or lactating women were excluded from participation.

(6) Subjects were excluded if they had used antibiotics or participated in any other clinical study or test panel within 1 month prior to entry into the study, or if they had received a dental prophylaxis within 2 weeks prior to entry into the study.

Prospective study subjects reported to the clinical facility having refrained from all oral hygiene procedures for at least 12 hours, and having refrained from eating, drinking or smoking for 4 hours prior to their examination. All prospective subjects who met the inclusion/exclusion criteria, signed an informed consent form, and completed a medical history questionnaire received a baseline plaque and gingivitis examination, along with an oral soft and hard tissue assessment.

Qualifying subjects were stratified into two balanced groups based on their plaque and gingivitis scores, and were randomly assigned within strata to one of two study treatments. For the purpose of this report, the treatments are identified as follows:

*Test Dentifrice* - A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.[a]

*Negative Control Dentifrice* - A dentifrice containing 0.243% sodium fluoride in a silica base.[a]

Following study treatment assignment, subjects were provided with their assigned dentifrice and an adult, soft-bristled toothbrush for home use. Both of the dentifrice products were supplied in their original packaging and over-wrapped with a white label to mask the product's identity. Subjects were instructed to brush their teeth for 1 minute, twice daily (morning and evening) using only the dentifrice and toothbrush provided, and to refrain from any other oral hygiene procedures throughout the duration of the study. There were no restrictions regarding diet or smoking habits during the course of the study, except as indicated above.

After 3 months, and again after 6 months of product use, subjects returned to the clinical facility for plaque and gingivitis examinations, and oral soft and hard tissue assessments. All examinations were performed by the same dental examiner, using the same procedures as employed at baseline. At each examination, subjects were also interviewed with respect to any changes in medical history, the presence of adverse events, and the use of concomitant medications.

### CLINICAL SCORING PROCEDURES

*Plaque assessment* - Supra-gingival plaque on the facial and lingual surfaces of each tooth was scored according to the Turesky modification of the Quigley-Hein Plaque Index.[10,11] Each tooth was divided into six surfaces, three facially and three lingually, 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 following criteria:

0 = No plaque.
1 = Separate flecks of plaque at the cervical margin of the tooth.
2 = A thin, continuous band of plaque (up to 1 mm) at the cervical margin of the tooth.
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.

Whole-mouth mean scores were obtained by averaging the values obtained over all scoreable surfaces in the mouth.

Table 1. Summary of gender, age, and race for subjects who completed the 6-month clinical study.

| | Number of subjects | | | Age | | Race | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Treatment | Male | Female | Total | Mean[3] | Range | Asian | Black | Caucasian | Hispanic | Other |
| Test Dentifrice [1] | 17 | 40 | 57 | 38.9 | 20 – 60 | 5 | 7 | 38 | 7 | 0 |
| Negative Control Dentifrice [2] | 17 | 41 | 58 | 43.6 | 19 – 68 | 3 | 5 | 42 | 7 | 1 |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] A statistically significant difference was indicated between the two treatment groups at baseline with respect to age.

Table 2. Summary of the baseline Plaque Index and Plaque Severity Index scores for subjects who completed the 6-month clinical study.

| Parameter | Treatment | n | Baseline summary (Mean ± S.D.)[3] |
|---|---|---|---|
| Plaque Index | Test Dentifrice [1] | 57 | 2.46 ± 0.44 |
| | Negative Control Dentifrice [2] | 58 | 2.26 ± 0.46 |
| Plaque Severity | Test Dentifrice [1] | 57 | 0.37 ± 0.28 |
| | Negative Control Dentifrice [2] | 58 | 0.29 ± 0.26 |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] A statistically significant difference was indicated between the two treatment groups at baseline with respect to Plaque Index scores.

Table 3. Summary of the baseline Gingival Index and Gingivitis Severity Index scores for subjects who completed the 6-month clinical study.

| Parameter | Treatment | n | Baseline summary (Mean ± S.D.)[3] |
|---|---|---|---|
| Gingival Index | Test Dentifrice [1] | 57 | 1.10 ± 0.09 |
| | Negative Control Dentifrice [2] | 58 | 1.10 ± 0.09 |
| Gingivitis Severity | Test Dentifrice[1] | 57 | 0.12 ± 0.10 |
| | Negative Control Dentifrice [2] | 58 | 0.12 ± 0.09 |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] No statistically significant difference was indicated between the two treatment groups at baseline with respect to either the Gingival Index or Gingivitis Severity Index scores.

*Gingivitis assessment* - Gingivitis was scored according to the Löe-Silness Gingival Index.[1,12] Each tooth was divided into six surfaces, three facially and three lingually, 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, hypertrophy. Tendency to bleed upon probing.
3 = Severe inflammation: marked redness and hypertrophy. Tendency for spontaneous bleeding.

Whole-mouth mean scores were obtained by averaging the values obtained over all scoreable surfaces in the mouth.

*Plaque and Gingivitis Severity Indices* - In addition to the plaque and gingival indices discussed above, whole-mouth scores were also obtained with respect to the Plaque Severity Index and the Gingivitis Severity Index.[13,14] These indices measure the proportion of the segments in the mouth which have received high scores on the respective indices, specifically:

- The Plaque Severity Index indicates the proportion of segments in the mouth whose assigned modified Quigley-Hein Plaque Index scores were equal to 3, 4 or 5;
- The Gingivitis Severity Index indicates the proportion of segments in the mouth whose assigned modified Löe-Silness Gingival Index scores were equal to 2 or 3 (*i.e.*, bleeding sites).

*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. This examination/evaluation included an assessment of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sub-lingual and submandibular areas, salivary glands, and the tonsilar and pharyngeal areas of the mouth.

*Adverse events* - Adverse events were obtained from an interview with the subject and a dental examination by the investigator.

*Statistical methods* - Statistical analyses were performed separately for each of the four clinical indices used to score plaque and gingivitis in this study. Comparisons of the treatment groups with respect to baseline plaque and gingivitis scores, as well as for age, were performed using ANOVA.

Comparisons between the treatment groups with respect to gender and race were performed using chi-squared tests. Within-treatment comparisons of the plaque and gingivitis scores obtained at the follow-up examinations *versus* baseline were performed using paired *t*-tests. Comparisons of the treatment groups with respect to baseline-adjusted plaque and gingivitis scores at the follow-up examinations were performed using ANCOVA. Post-ANCOVA pairwise comparisons of the study treatments 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

Of the one hundred twenty-five (125) subjects enrolled in the study, 115 subjects (92.0%) complied with the protocol, and completed the 6-month examinations. Subjects who did not complete the study were discontinued for reasons unrelated to the use of the study treatments. A summary of the age, gender, and race of the study population who completed the 6-month examination is presented in Table 1. The treatment groups did not differ significantly with respect to gender or race. A statis-

Table 4. Summary of the 3-month Plaque Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 3-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 1.97 ± 0.33 | 19.9% | P< 0.05 | 9.2% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 2.17 ± 0.30 | 4.0% | P< 0.05 | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 3-month mean relative to the baseline mean. A positive value indicates a lower plaque score at the 3-month examination.
[4] Significance of paired *t*-test comparing the baseline and 3-month examinations.
[5] Between-treatment reduction expressed as a percentage of the 3-month mean for Negative Control Dentifrice. A positive value indicates a lower plaque score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

Table 5. Summary of the 3-month Plaque Severity Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 3-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 0.16 ± 0.14 | 56.8% | P< 0.05 | 36.0% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 0.25 ± 0.20 | 13.8% | P< 0.05 | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 3-month mean relative to the baseline mean. A positive value indicates a lower plaque severity score at the 3-month examination.
[4] Significance of paired *t*-test comparing the baseline and 3-month examinations.
[5] Between-treatment reduction expressed as a percentage of the 3-month mean for Negative Control Dentifrice. A positive value indicates a lower plaque severity score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

tically significant difference was indicated between the treatment groups with respect to age; however, this finding was judged by the investigator to be of no clinical relevance.

### BASELINE DATA

Table 2 presents a summary of the Plaque Index and Plaque Severity Index scores measured at the baseline examination for those subjects who completed the 6-month examinations. For the Plaque Index, the mean baseline scores were 2.46 for the Test Dentifrice group, and 2.26 for the Negative Control Dentifrice group. For the Plaque Severity Index, the mean baseline scores were 0.37 for the Test Dentifrice group, and 0.29 for the Negative Control Dentifrice group. A statistically significant difference was indicated between the treatment groups with respect to the mean baseline Plaque Index scores. (Analyses based on the Plaque Index scores from subsequent visits were adjusted for this difference through the use of ANCOVA).

Table 3 presents a summary of the Gingival Index and Gingivitis Severity Index scores measured at the baseline examination for those subjects who completed the 6-month examinations. For the Gingival Index, the mean baseline scores were 1.10 for the Test Dentifrice group, and 1.10 for the Negative Control Dentifrice group. For the Gingivitis Severity Index, the mean baseline scores were 0.12 for the Test Dentifrice group, and 0.12 for the Negative Control Dentifrice group. No statistically significant difference was indicated between the treatment groups with respect to the mean baseline scores for either gingival parameter.

### 3-MONTH DATA

#### Plaque Index

Table 4 presents a summary of the Plaque Index scores measured after 3 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 3-month Plaque Index scores were 1.97 for the Test Dentifrice group, and 2.17 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 19.9% for the Test Dentifrice group, and 4.0% for the Negative Control Dentifrice group, both of which were statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 9.2% reduction in Plaque Index scores after 3 months of product use.

#### Plaque Severity Index

Table 5 presents a summary of the Plaque Severity Index scores measured after 3 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 3-month Plaque Severity Index scores were 0.16 for the Test Dentifrice group, and 0.25 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 56.8% for the Test Dentifrice group, and 13.8% for the Negative Control Dentifrice group, both of which were statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group

Table 6. Summary of the 3-month Gingival Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 3-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 0.94 ± 0.09 | 14.5% | P< 0.05 | 11.3% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 1.06 ± 0.08 | 3.6% | P< 0.05 | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 3-month mean relative to the baseline mean. A positive value indicates a lower gingivitis score at the 3-month examination.
[4] Significance of paired *t*-test comparing the baseline and 3-month examinations.
[5] Between-treatment reduction expressed as a percentage of the 3-month mean for Negative Control Dentifrice. A positive value indicates a lower gingivitis score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

Table 7. Summary of the 3-month Gingivitis Severity Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 3-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 0.04 ± 0.05 | 66.7% | P< 0.05 | 55.6% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 0.09 ± 0.07 | 25.0% | P< 0.05 | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 3-month mean relative to the baseline mean. A positive value indicates a lower gingivitis severity score at the 3-month examination.
[4] Significance of paired *t*-test comparing the baseline and 3-month examinations.
[5] Between-treatment reduction expressed as a percentage of the 3-month mean for Negative Control Dentifrice. A positive value indicates a lower gingivitis severity score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

exhibited a statistically significant 36.0% reduction in Plaque Severity Index scores after 3 months of product use.

### Gingival Index

Table 6 presents a summary of the Gingival Index scores measured after 3 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 3-month Gingival Index scores were 0.94 for the Test Dentifrice group, and 1.06 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 14.5% for the Test Dentifrice group, and 3.6% for the Negative Control Dentifrice group, both of which were statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 11.3% reduction in Gingival Index scores after 3 months of product use.

### Gingivitis Severity Index

Table 7 presents a summary of the Gingivitis Severity Index scores measured after 3 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 3-month Gingivitis Severity Index scores were 0.04 for the Test Dentifrice group, and 0.09 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 66.7% for the Test Dentifrice group, and 25.0% for the Negative Control Dentifrice group, both of which were statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 55.6% reduction in Gingivitis Severity Index scores after 3 months of product use.

## 6-Month Data

### Plaque Index

Table 8 presents a summary of the Plaque Index scores measured after 6 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 6-month Plaque Index scores were 1.86 for the Test Dentifrice group, and 2.29 for the Negative Control Dentifrice group. The mean percent reduction from baseline was 24.4% for the Test Dentifrice group, which was statistically significant. The Negative Control Dentifrice group exhibited a 1.3% higher score relative to baseline, which was not statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 18.8% reduction in Plaque Index scores after 6 months of product use.

### Plaque Severity Index

Table 9 presents a summary of the Plaque Severity Index scores measured after 6 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 6-month Plaque Severity Index scores were 0.15 for the Test Dentifrice group, and 0.30 for the Negative Control Dentifrice group. The mean percent reduction from baseline was 59.5% for the Test Dentifrice group, which was statistically significant. The Negative Control Dentifrice group exhibited a 3.4% higher score relative

Table 8. Summary of the 6-month Plaque Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 6-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 1.86 ± 0.41 | 24.4% | P< 0.05 | 18.8% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 2.29 ± 0.39 | -1.3% | NS | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 6-month mean relative to the baseline mean. A positive value indicates a lower plaque score at the 6-month examination.
[4] Significance of paired *t*-test comparing the baseline and 6-month examinations. NS = P> 0.05.
[5] Between-treatment reduction expressed as a percentage of the 6-month mean for Negative Control Dentifrice. A positive value indicates a lower plaque score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

Table 9. Summary of the 6-month Plaque Severity Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 6-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 0.15 ± 0.16 | 59.5% | P< 0.05 | 50.0% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 0.30 ± 0.25 | -3.4% | NS | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 6-month mean relative to the baseline mean. A positive value indicates a lower Plaque Severity score at the 6-month examination.
[4] Significance of paired *t*-test comparing the baseline and 6-month examinations. NS = P> 0.05.
[5] Between-treatment reduction expressed as a percentage of the 6-month mean for Negative Control Dentifrice. A positive value indicates a lower Plaque Severity score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

to baseline, which was not statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 50.0% reduction in Plaque Severity Index scores after 6 months of product use.

**Gingival Index**

Table 10 presents a summary of the Gingival Index scores measured after 6 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 6-month Gingival Index scores were 0.86 for the Test Dentifrice group, and 1.07 for the Negative Control Dentifrice group. The mean percent reductions from baseline were 21.8% for the Test Dentifrice group, and 2.7% for the Negative Control Dentifrice group, both of which were statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 19.6% reduction in Gingival Index scores after 6 months of product use.

**Gingivitis Severity Index**

Table 11 presents a summary of the Gingivitis Severity Index scores measured after 6 months of product use for those subjects who completed the 6-month examinations.

*Comparisons versus baseline* - The mean 6-month Gingivitis Severity Index scores were 0.04 for the Test Dentifrice group, and 0.10 for the Negative Control Dentifrice group. The mean percent reduction from baseline was 66.7% for the Test Dentifrice group, which was statistically significant. The mean percent reduction from baseline was 16.7% for the Negative Control Dentifrice group, which was not statistically significant.

*Comparison between treatment groups* - Relative to the Negative Control Dentifrice group, the Test Dentifrice group exhibited a statistically significant 60.0% reduction in Gingivitis Severity Index scores after 6 months of product use.

**Oral soft and hard tissue assessments**

There were no abnormal oral hard or soft tissue findings reported during the study.

**Adverse events**

There were no adverse events reported during the study.

## Discussion

The control of supra-gingival plaque through mechanical cleaning is the most effective way a patient can maintain good gingival health.[15] However, it is well accepted by the profession that most patients do not spend the appropriate amount of time or use the correct technique in removing supra-gingival plaque during daily oral hygiene. Thus, the use of an anti-plaque and anti-gingivitis dentifrice is necessary for many patients.

It has been well established that a dentifrice containing 0.3% triclosan and a 2.0% PVM/MA copolymer provides superior anti-plaque and anti-gingivitis benefits *versus* a regular fluoride toothpaste.[8,9] In addition, recently published research demonstrates that a dentifrice containing 0.3% triclosan and a 2.0% PVM/MA copolymer provides superior anti-plaque and

Table 10. Summary of the 6-month Gingival Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 6-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 0.86 ± 0.11 | 21.8% | P< 0.05 | 19.6% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 1.07 ± 0.07 | 2.7% | P< 0.05 | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 6-month mean relative to the baseline mean. A positive value indicates a lower gingivitis score at the 6-month examination.
[4] Significance of paired *t*-test comparing the baseline and 6-month examinations.
[5] Between-treatment reduction expressed as a percentage of the 6-month mean for Negative Control Dentifrice. A positive value indicates a lower gingivitis score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

Table 11. Summary of the 6-month Gingivitis Severity Index scores for subjects who completed the 6-month clinical study.

| Treatment | n | 6-month summary (Mean ± S.D.) | Within-treatment analysis | | Between-treatment comparison | |
|---|---|---|---|---|---|---|
| | | | Percent reduction [3] | Sig.[4] | Percent reduction [5] | Sig.[6] |
| Test Dentifrice [1] | 57 | 0.04 ± 0.04 | 66.7% | P< 0.05 | 60.0% | P< 0.05 |
| Negative Control Dentifrice [2] | 58 | 0.10 ± 0.06 | 16.7% | NS | | |

[1] A dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride, and specially-designed silica.
[2] A dentifrice containing 0.243% sodium fluoride in a silica base.
[3] Percent reduction exhibited by the 6-month mean relative to the baseline mean. A positive value indicates a lower gingivitis severity score at the 6-month examination.
[4] Significance of paired *t*-test comparing the baseline and 6-month examinations. NS = P> 0.05.
[5] Between-treatment reduction expressed as a percentage of the 6-month mean for Negative Control Dentifrice. A positive value indicates a lower gingivitis severity score for Test Dentifrice than for Negative Control Dentifrice.
[6] Significance of post-ANCOVA comparison of baseline-adjusted means.

anti-gingivitis benefits *versus* a stannous fluoride/hexametaphosphate based dentifrice with purported anti-plaque and anti-gingivitis effects.[16-18]

The 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, and specially-designed silica provides a significant reduction in plaque and gingivitis when used over a period of 6 months *versus* a dentifrice containing 0.243% sodium fluoride in a silica base.

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Special Issue Article

# Extrinsic stain removal efficacy of a new dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica for sensitivity relief and whitening benefits as compared to a dentifrice containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF and to a negative control dentifrice containing 0.243% NaF: A 6-week study

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**ABSTRACT**: **Purpose:** This single-center, double-blind, randomized, parallel-group clinical study was designed to investigate the extrinsic stain removal efficacy of a new antisensitivity dentifrice containing 0.3% triclosan, 2% polyvinylmethyl ether/maleic acid copolymer (PVM/MA copolymer), 0.243% NaF and a new silica specially-designed to occlude dentin tubules, relative to a Positive Control dentifrice and a Negative Control dentifrice. **Methods:** 117 qualifying adults were stratified by baseline Lobene Stain Index scores and randomly assigned to brush twice daily using a soft-bristled toothbrush and one of three dentifrices: (1) the Test Dentifrice; (2) a previously clinically proven dentifrice variant containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF in a high cleaning silica base (Positive Control); and (3) a dentifrice containing 0.243% NaF in a silica base (Negative Control). Extrinsic stain area and stain intensity examinations were repeated after 3 and 6 weeks of product use. **Results:** Relative to the Negative Control group, the Test group and the Positive Control group exhibited statistically significant improvements in mean Lobene composite stain scores after 3 weeks of product use (39.8% and 40.7% respectively) and after 6 weeks of product use (58.8% and 61.8% respectively). There were no statistically significant differences observed between the stain removal performance of the Test Dentifrice and the Positive Control Dentifrice after 3 and 6 weeks of product use. (*Am J Dent* 2011;24 Sp Is A:28A-31A).

**CLINICAL SIGNIFICANCE:** The results of this double-blind clinical study support the conclusion that the tested new antisensitivity dentifrice containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF and specially-designed silica provides effective extrinsic stain removal performance when used twice daily over a period of 3 and 6 weeks.

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## Introduction

The absence of oral disease and dysfunction are no longer considered sole determinants of good oral health. According to oral health-related quality of life research, a positive sense of dentofacial self-confidence and the impact of oral conditions on social life are also important.[1] Perceptions of minor differences in dental esthetics have been found to significantly affect oral health-related quality of life.[2] Today's patients constantly remind their dental health provider to consider their desire to maintain or achieve "stain free" or "whiter" teeth when making oral care product recommendations.

Tooth staining can be of intrinsic or extrinsic origin. Intrinsic tooth stains are the result of the binding of undesirable pigments or chromogens into enamel or dentin.[3] The incorporation of these stains into these tooth structures occurs primarily during the tooth development process and its remediation relies mainly on vital or non-vital tooth bleaching procedures and/or on relatively invasive restorative treatment alternatives. Extrinsic tooth staining occurs as the result of the binding of chromogenic components in certain foods, drinks, medications and tobacco products to the salivary pellicle on tooth surfaces.[4,5] Ingredients in toothpastes such as detergents, abrasive systems, cleaning compounds and enzymes may remove extrinsic tooth stains by loosening and removing stained debris and pellicle. The physical forces of brushing, combined with dentifrice ingredients, have been shown to enhance stain removal;[1,6] thus, daily brushing with toothpaste represents a convenient method for the control of extrinsic tooth stain between professional dental cleanings.

The development of multicare toothpastes for everyday use has made product recommendations easier for dental health providers seeking to address all their patients' needs and desires regarding good health, social and psychological well being. Colgate® Total® dentifrice formulations, containing 0.3% triclosan and 2.0% polyvinylmethyl ether/maleic acid copolymer (PVM/MA copolymer) in combination with fluoride, provide multiple benefits such as extrinsic stain removal, and protection against plaque and gingivitis, caries, oral malodor, as well as the prevention of tartar accumulation.[7,8] A new Colgate Total dentifrice formulation containing a new silica specially-designed to occlude dentin tubules has been clinically proven to provide the additional benefit of significant dentin hypersensitivity relief.[9] The objective of this clinical study was to evaluate whether this new formulation provides the same gentle whitening efficacy that patients expect from twice daily brushing with other Colgate Total formulations. The clinical trial compared the extrinsic stain removal efficacy of this new dentifrice with 0.3% triclosan, 2% PVM/MA copolymer, 0.243% sodium fluoride (NaF) and specially-designed silica (Test Dentifrice) as compared to a toothpaste containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF in a high cleaning silica

Table 1. Summary of the age and gender for subjects who completed the 6-week clinical study.

| Treatment | Number of subjects | | | Age | |
|---|---|---|---|---|---|
| | Male | Female | Total | Mean | Range |
| Test Dentifrice [1] | 19 | 21 | 40 | 45.1 | 18 - 68 |
| Positive Control Dentifrice [2] | 11 | 28 | 39 | 37.9 | 28 - 65 |
| Negative Control Dentifrice [3] | 15 | 23 | 38 | 42.5 | 18 - 74 |

[1] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride and specially-designed silica.
[2] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride in a high-cleaning silica base.
[3] Dentifrice containing 0.243% sodium fluoride in a silica base.

Table 2. Summary of the baseline Lobene Composite Stain Index scores for subjects who completed the 6-week clinical study.

| Treatment | N | Baseline summary (Mean ± SD) [4] |
|---|---|---|
| Test Dentifrice [1] | 40 | 2.41 ± 0.91 |
| Positive Control Dentifrice [2] | 39 | 2.19 ± 0.77 |
| Negative Control Dentifrice [3] | 38 | 2.28 ± 0.72 |

[1] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride and specially-designed silica.
[2] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% sodium fluoride in a high-cleaning silica base.
[3] Dentifrice containing 0.243% sodium fluoride in a silica base.
[4] No statistically significant difference was indicated among the three treatment groups at baseline with respect to Lobene Composite Stain Index scores.

base (Positive Control Dentifrice); and a toothpaste containing 0.243% NaF in a silica base (Negative Control Dentifrice).

## Materials and Methods

*Subjects and study design* - The study population was comprised of subjects (age range 18–74 years) in good oral and general health. Prospective voluntary participants who indicated an interest in participation were scheduled for an oral examination by a dentist at the clinics of Oral Health Clinical Services LLC in Piscataway, New Jersey. The clinical protocol and informed consent were reviewed and approved by The Concordia Clinical Research Institutional Review Board in Cedar Knolls, New Jersey prior to the start of the study. Individuals who completed the informed consent process and met the selection criteria were enrolled. Inclusion criteria for the study consisted of subject's availability for the 6-week duration of the study and the presence of at least seven anterior teeth that were free of large restorations, intrinsic stain or dental prosthetic crowns which might interfere with the scoring of extrinsic stains. Subjects also needed to illustrate clinical evidence of a tendency to form extrinsic stain on anterior teeth by presenting at this visit a minimum mean Lobene Stain Index Area score of 0.5 and a minimum mean Lobene Stain Intensity Index score of 0.5.[10] Excluded from participation were individuals who had advanced periodontal disease, were taking prescription medications that might interfere with the study outcome, had received a dental prophylaxis during the 2 weeks prior to the study baseline examination, wore a removable partial denture or had orthodontic bands or brackets, were pregnant or lactating, or had participated in any other clinical study or panel test within 30 days prior to the start of the study.

This clinical study employed a three-arm, single-center, randomized, double-blind, parallel-group design. Subjects who met the inclusion/exclusion criteria received a baseline extrinsic tooth stain examination and oral soft tissue assessment. The study subjects were stratified on the basis of their baseline extrinsic stain scores and randomly assigned to participate in one of the three study groups.

*Dentifrices tested and study procedures* – The Test Dentifrice contained 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica to occlude dentin tubules.[a] The Positive Control Dentifrice contained 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF in a high cleaning silica base.[a] The Negative Control Dentifrice contained 0.243% NaF in a silica base.[b] All dentifrices were supplied in overwrapped tubes and assigned a unique code for randomized allocation to subjects. The subjects and the study examiner remained blinded to product assignment. While enrolled subjects were not instructed to alter their daily diet or other habits, they were instructed to discontinue the use of all other dentifrices, mouthwashes, gums, and other oral hygiene formulations for the duration of the study. All subjects were provided with their assigned dentifrice and a soft-bristled adult size toothbrush and were directed to brush twice daily for the 6-week duration of the study. Subjects were requested to return to the clinical facility for follow-up examinations at 3 and 6 weeks. All examinations were performed by the same dental examiner, using the same procedures as employed at baseline. Subjects were also interviewed with respect to the presence of adverse events and the use of concomitant medications.

*Clinical scoring procedures* - All clinical examinations were conducted under constant lighting conditions. Using the standard method described by Lobene,[10] each tooth was scored separately using four point area and intensity scales ranging from:

Stain area:

0 = No stain detected;
1 = Stain up to one-third of the region;
2 = Stain up to two-thirds of the region;
3 = Stain over more than two-thirds of the region.

Stain intensity:

0 = No stain;
1 = Light stain – yellow/tan;
2 = Moderate stain – medium brown;
3 = Heavy stain – dark brown/black.

A Lobene Composite Stain Index score comprising stain intensity and stain area scores was calculated for each "gingival

Table 3. Summary of the 3-week Lobene Composite Stain Index scores for subjects who completed the 6-week clinical study.

| | | | Within treatment analysis | | Between treatment comparison | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | *vs* Positive Control | | *vs* Negative Control | |
| Treatment | N | 3-week Summary (Mean ± SD) | Percent change[4] | Sig.[5] | Percent difference[6] | Sig.[7] | Percent difference[8] | Sig.[7] |
| Test Dentifrice[1] | 40 | 1.30 ± 0.75 | 46.1% | P< 0.05 | -1.6% | NS | 39.8% | P< 0.05 |
| Positive Control Dentifrice[2] | 39 | 1.28 ± 0.74 | 41.6% | P< 0.05 | --- | --- | 40.7% | P< 0.05 |
| Negative Control Dentifrice[3] | 38 | 2.16 ± 0.77 | 5.3% | P< 0.05 | --- | --- | --- | --- |

[1] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica.
[2] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF in a high-cleaning silica base.
[3] Dentifrice containing 0.243% NaF in a silica base.
[4] Percent change exhibited by the 3-week mean relative to the baseline mean. A positive value indicates a reduction in Lobene Composite Stain Index scores at the 3-week examination.
[5] Significance of paired *t*-test comparing the baseline and the 3-week examinations.
[6] Difference between the 3-week means expressed as a percentage of the 3-week mean for the Positive Control Dentifrice. A positive value indicates a reduction in Lobene Composite Stain Index scores in the row heading relative to the Positive Control Dentifrice.
[7] Difference between the 3-week means expressed as a percentage of the 3-week mean for the Negative Control Dentifrice. A positive value indicates a reduction in Lobene Composite Stain Index scores in the row heading relative to the Negative Control Dentifrice.
[8] Significance of ANCOVA comparison of baseline-adjusted means.

Table 4. Summary of the 6-week Lobene Composite Stain Index scores for subjects who completed the 6-week clinical study.

| | | | Within treatment analysis | | Between treatment comparison | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | *vs* Positive Control | | *vs* Negative Control | |
| Treatment | N | 6-week summary (Mean ± SD) | Percent change[4] | Sig.[5] | Percent difference[6] | Sig.[7] | Percent difference[8] | Sig.[7] |
| Test Dentifrice[1] | 40 | 0.82 ± 0.62 | 66.0% | P< 0.05 | -7.9% | NS | 58.8% | P< 0.05 |
| Positive Control Dentifrice[2] | 39 | 0.76 ± 0.52 | 65.3% | P< 0.05 | --- | --- | 61.8% | P< 0.05 |
| Negative Control Dentifrice[3] | 38 | 1.99 ± 0.76 | 12.7% | P< 0.05 | --- | --- | --- | --- |

[1] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF and specially-designed silica.
[2] Dentifrice containing 0.3% triclosan, 2.0% PVM/MA copolymer, 0.243% NaF in a high-cleaning silica base.
[3] Dentifrice containing 0.243% NaF in a silica base.
[4] Percent change exhibited by the 6-week mean relative to the baseline mean. A positive value indicates a reduction in Lobene Composite Stain Index scores at the 6-week examination.
[5] Significance of paired *t*-test comparing the baseline and the 6-week examinations.
[6] Difference between the 6-week means expressed as a percentage of the 6-week mean for the Positive Control Dentifrice. A positive value indicates a reduction in Lobene Composite Stain Index scores in the row heading relative to the Positive Control Dentifrice.
[7] Difference between the 6-week means expressed as a percentage of the 6-week mean for the Negative Control Dentifrice. A positive value indicates a reduction in Lobene Composite Stain Index scores in the row heading relative to the Negative Control Dentifrice.
[8] Significance of ANCOVA comparison of baseline-adjusted means.

region" and for each "body of tooth" surface evaluated for a total of 36 composite scores per subject. An average composite score was then calculated for each subject.

*Statistical methods* - Statistical analyses were performed for the Lobene Composite Stain Index scores. Comparisons of the treatment groups with respect to baseline Lobene Composite Stain Index scores were performed using an ANOVA. Comparisons among treatment groups with respect to gender were performed using a chi-square test and for age an ANOVA. Within-treatment comparisons of the baseline *versus* follow-up mean Lobene Composite Stain Index scores were performed using a paired *t*-test. Comparisons of the treatment groups with respect to baseline-adjusted Lobene Composite Stain Index scores at the follow-up examinations were performed using an ANCOVA. All statistical tests of hypotheses were two-sided, and employed a level of significance of $\alpha = 0.05$. Analyses were conducted using Minitab Statistical Software.[c]

## Results

One hundred and twenty subjects entered the clinical trial, of which 117 participants complied with the protocol, and completed the 6-week study. Although no adverse events were observed by the examiner or reported by the subjects, three subjects did not complete all the scheduled study visits for reasons unrelated to product use or participation in the study.

The composition of treatment groups did not differ significantly (P> 0.05) with respect to age and gender (Table 1). The mean Lobene Composite Stain Index scores measured at the baseline examination (Table 2) for those subjects who completed the clinical study were 2.41 for the Test group, 2.19 for the Positive Control group and 2.28 for the Negative Control group. No statistically significant difference (P> 0.05) was indicated among the treatment groups with respect to Lobene Composite Stain Index scores prior to dispensing study products.

Table 3 presents a summary of the mean Lobene Composite Stain Index scores measured after 3 weeks of product use. The mean 3-week Lobene composite stain index scores were 1.30 for the Test group, 1.28 for the Positive Control group and 2.16 for the Negative Control group. The percent changes from baseline were 46.1% for the Test group, 41.6% for the Positive Control group and 5.3% for the Negative Control group, all of which were statistically significant (P< 0.05). Relative to the

Negative Control group, the Test group and the Positive Control group both exhibited a statistically significant reduction (P< 0.05) in mean Lobene Composite Stain Index scores after 3 weeks of product use (39.8% and 40.7% respectively). Relative to the Positive Control group, the Test group did not exhibit a statistically significant reduction (P> 0.05) in mean Lobene composite stain index scores after 3 weeks of product use (-1.6%).

Table 4 presents a summary of the mean Lobene Composite Stain Index scores measured after 6 weeks of product use. The mean 6-week Lobene Composite Stain Index scores were 0.82 for the Test group, 0.76 for the Positive Control group and 1.99 for the Negative Control group. The percent changes from baseline were 66.0% for the Test group, 65.3% for the Positive Control group and 12.7% for the Negative Control group, all of which were statistically significant (P< 0.05). Relative to the Negative Control group, the Test group and the Positive Control group both exhibited statistically significant reductions (P< 0.05) in mean Lobene Composite Stain Index scores after 6 weeks of product use (58.8% and 61.8% respectively). Relative to the Positive Control group, the Test group did not exhibit a statistically significant reduction (P> 0.05) in mean Lobene Composite Stain Index score after 6 weeks of product use (-7.9%).

## Discussion

This clinical investigation examined the extrinsic stain removal efficacy of a new formulation proven to deliver superior dentin hypersensitivity relief.[9] The whitening efficacy evaluations were conducted using the Lobene Composite Stain Index, an assessment that provides numerical scores for extrinsic stains on the enamel and is widely reported in the literature.[11,12] Results from the 3- and 6-week evaluations were consistent. Statistical analyses comparing the Lobene Composite Stain Index scores at the two follow-up examinations indicate significant stain removal efficacy from twice daily brushing with the Test Dentifrice and the Positive Control Dentifrice, relative to the Negative Control. No statistically significant difference in stain removal efficacy was observed at any of the study time points between the Test and Positive Control Dentifrice formulations.

Different forms of silica are included in dentifrice formulations to perform different functions, which include thickening the toothpaste and providing mechanical cleaning action, without damaging any of the tissues in the mouth. In respect to the latter, high cleaning silicas provide enhanced stain removal, compared to more conventional silicas, to help whiten the teeth. The formulation of the Test Dentifrice contained a new silica specially-designed to occlude dentin tubules for the relief of dentin hypersensitivity, as well as to provide enhanced removal of surface stains. This formula has been proven in clinical studies to provide significant relief of dentin hypersensitivity compared to a commercially-available fluoride toothpaste control,[9,13] as well as to a commercially-available hypersensitivity toothpaste.[9] Further, laboratory studies[14] have shown that this new formula provides significant reductions in dentin permeability through robust occlusion of open and patent dentin tubules and this occlusion remained robust after applying pulpal pressure, and after acid challenge, consistent with the results on dentin hypersensitivity in the clinical studies. The results of the clinical study reported here demonstrate that the Test Dentifrice and the Positive Control Dentifrice delivered significant extrinsic stain removal efficacy as compared to the Negative Control, and there is no significant difference between the Test Dentifrice and the clinically proven effective whitening toothpaste control.

The Test Dentifrice provides the added new benefit of dentin hypersensitivity relief[9] to the previously proven multiple benefits of toothpaste formulations that contain 0.3% triclosan/2.0% PVM/MA/0.243% NaF.

The results of this double-blind clinical study demonstrate the extrinsic stain removal efficacy of twice daily brushing with a new antisensitivity formula containing 0.3% triclosan, 2% PVM/MA copolymer, 0.243% NaF and specially-designed silica to occlude dentin tubules.

a. Colgate-Palmolive Co., New York, NY, USA.
b. Procter & Gamble Co., Cincinnati, OH, USA.
c. Minitab, State College, PA, USA.

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