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 anti-sensitivity 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 1s A:28A-31A).

Clinical significance: The results of this double-blind clinical study support the conclusion that the tested new anti-sensitivity 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.

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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of subjects</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Test Dentifrice 1</td>
<td>19</td>
<td>21</td>
</tr>
<tr>
<td>Positive Control Dentifrice 2</td>
<td>11</td>
<td>28</td>
</tr>
<tr>
<td>Negative Control Dentifrice 3</td>
<td>15</td>
<td>23</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>Baseline summary (Mean ± SD) a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Dentifrice 1</td>
<td>40</td>
<td>2.41 ± 0.91</td>
</tr>
<tr>
<td>Positive Control Dentifrice 2</td>
<td>39</td>
<td>2.19 ± 0.77</td>
</tr>
<tr>
<td>Negative Control Dentifrice 3</td>
<td>38</td>
<td>2.28 ± 0.72</td>
</tr>
</tbody>
</table>

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.

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 prosthesis 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.a 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, b 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
Lobene Composite Stain Index scores were performed using a

Treatment N (Mean ± SD) change 4 Sig. 5 difference 6 Sig. 7 difference 8 Sig.

Positive Control Dentifrice 2 39 0.76 ± 0.52 65.3% P< 0.05 --- --- 61.8% P< 0.05

level of significance of

statistical tests of hypotheses were two-sided, and employed a

follow-up examinations were performed using an ANCOVA. All

datable groups with respect to baseline Lobene Composite

Compos- stom index scores were measured after 3 weeks of product use.

Table 3 presents a summary of the mean Lobene Composite Stain Index scores prior to dispensing study products.

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

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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 α = 0.05. Analyses were conducted using Minitab Statistical Software.

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
toothpaste. Further, laboratory studies have shown that this new formula provides significant reductions in dentin permeability compared to more conventional silicas, to help whiten the teeth. Different forms of silica are included in dentifrice formulations, which include thickening the toothpaste and providing mechanical cleaning action, without damaging any of the tissues in the mouth.

**Discussion**

This clinical investigation examined the extrinsic stain removal efficacy of a new formulation proven to deliver superior dentin hypersensitivity relief. 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. 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 contains 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, as well as to a commercially-available hypersensitivity toothpaste. Further, laboratory studies 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 pulp 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 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.

**References**

9. Chaknis P, Panagakos FS, DeVizio W, Sowinski J, Petrone D, Proskin H. 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. Am J Dent 2011;24 (Sp Is A):14A-20A.