2017 Dental Research Presentations

IADR/AADR/CADR General Session, March 22 – 25, 2017
(San Francisco, CA, USA)

Schedule of Presentations
Research Supported by P&G Oral Health
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Objective:
Chemotherapeutic antimicrobial toothpastes play an important role in the control of dental plaque and treatment and prevention of gingivitis. Objectives: This clinical study was conducted to compare the effect of a stannous fluoride dentifrice vs. triclosan containing dentifrice on reduction of plaque over a 4-week period.

Method:
This was a randomized, parallel, double-blind, 4-week clinical trial. The study population included 120 subjects with evidence of plaque. Subjects were randomized to one of two treatment groups: experimental 0.454% stannous fluoride dentifrice (SnF2) or triclosan dentifrice (Colgate Total (CT)). Both groups used a regular manual brush (ADA soft toothbrush). Treatment was twice daily at-home. Plaque was evaluated at baseline and after 4 weeks of product use using Rustogi Modification of the Navy Plaque Index (RMNPI). Statistical analyses utilized analysis of covariance.

Results:
118 subjects completed the study. Average age was 41.6 years ranging from 18 to 71 and 25% were male. The baseline whole mouth plaque level was 0.619 and groups were not statistically different (p=0.17) for plaque, or demographic characteristics (p>0.1). At Week 4 both groups demonstrated statistically significant (p<0.0001) reductions in plaque level vs. baseline, with SnF2 group being statistically better (p<0.0001) than the CT group for the whole mouth (23.1%) and interproximal (43.5%) RMNPI Plaque Index. Both treatments were well tolerated.

Conclusion:
The stannous fluoride dentifrice provided significant reductions in plaque as compared to the triclosan containing dentifrice.

Objective:
To evaluate the protective effects of a highly bio-available 0.454% stannous fluoride dentifrice on acid challenged enamel specimen relative to a marketed dentifrice in a 10 day in situ model.

Method:
The present study utilized a double blind, randomised, two-treatment, controlled, and four period crossover design. Thirty-six healthy adults were enrolled. Subjects were randomized to a treatment sequence. Each study period took place over a span of 10 days. Contact profilometry was used to measure the surface change of tooth enamel. Treatments included a highly bio-available 0.454% Stannous Fluoride dentifrice (1100ppm fluoride) and a marketed control 0.3% Tricolsan containing dentifrice (Colgate Total®, 1100ppm fluoride). Subjects wore an intra-oral appliance retaining 2 polished human enamel samples for 6 hours/day, swishing with the assigned dentifrice slurry twice a day and swishing with 250ml of orange juice for 10 minutes four times/ day. Two measurements for each sample were recorded at baseline and day 10.

Results:
Thirty-one subjects completed the study. Mean age of the subjects was 40.5 years old. At day 10 the stannous fluoride dentifrice demonstrated a 93% lower enamel loss than the conventional dentifrice (p<0.001) with means of 0.097 µm and 1.495 µm, respectively. All products were well tolerated.

Conclusion:
The in situ clinical study demonstrated superior anti-erosion efficacy of the 0.454% stannous fluoride dentifrice relative to the marketed 0.3% Triclosan containing dentifrice against an erosive challenge to human enamel.

Superior Long-Term Dental Plaque Reduction of a Rechargeable Oscillation-Rotation Toothbrush

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Abstract

Objective:
This clinical study was conducted to evaluate the dental plaque removal efficacy of an oscillating-rotating rechargeable power brush with a CrossAction brush head compared to a manual toothbrush.

Method:
This study was a randomized, examiner-blind, 8-week parallel design, which examined plaque removal of two toothbrushes: ADA manual brush (ADA) or Oral-B Professional Care 1000 (OBPC) with CrossAction brush head. One hundred subjects with evidence of dental plaque were randomized to one of the treatments. Plaque was scored before toothbrushing using the Turesky-Modified Quigley-and-Hein Plaque Index (TMQHPI) at Baseline and Week-8 visits. Both groups used standard fluoridated toothpaste (Crest Cavity Protection). Toothbrushing was performed following manufacturer’s usage instructions (OBPC), or as subjects would normally do (ADA). Statistical analyses were carried out using an analysis of covariance.

Results:
Baseline whole mouth plaque scores were 2.596 and 2.696 for the power brush and manual toothbrush treatments, respectively, and were not statistically different (p=0.239). Baseline interproximal plaque values were 2.885 for OBPC and 2.993 for ADA (p=0.174). Week-8 whole mouth pre-brush scores were 2.167 (OBPC) and 2.628 (ADA) and interproximal values were 2.472 (OBPC) vs 2.919 (ADA). OBPC significantly reduced plaque both for whole-mouth as well as for interproximal sites in the course of this study (p<0.001). Between treatment comparisons showed that the power brush provided statistically significantly higher plaque reduction than the ADA brush (p<0.001).

Materials and Methods

Study Design: Eight-week, 2-treatment, examiner-blind, randomized, parallel study.

Treatments: Electric rechargeable oscillation-rotation toothbrush (Test OBPC - Oral-B® Professional Care 1000 with Cross Action brush head) or regular manual toothbrush (Control - ADA), both using standard fluoridated toothpaste (Crest Cavity Protection).

Clinical Endpoint: Baseline and Week-8 Whole Mouth and Interproximal Turesky-modified Quigley-Hein Plaque Index (TMQHPI).

Subjects: 100 healthy subjects with a mean age of 43.9 years (range 18-76) were enrolled into this study and 69% were female.

Product Use: Subjects brushed their teeth using assigned products, either the manual brush as they normally would or the electric toothbrush according to the manufacturer’s usage instructions. Prior to scheduled visits subjects refrained for 3-6 h from any oral hygiene.

Statistical Analysis: A mixed model Analysis of Covariance was used to analyze the plaque reduction for product differences. Baseline scores were included as the covariate. Treatment comparisons were two-sided tests carried out at the 5% significance level.

Conclusions
The oscillating-rotating rechargeable power brush with CrossAction brush head removed statistically significantly more plaque as compared to a manual toothbrush control over an 8-week period. Both brushes were well tolerated.
Clinical Anti-Gingivitis Efficacy of a 0.454% SnF₂ Dentifrice

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Abstract

Objective:
The present clinical trial compared the gingivitis reduction efficacy of a 0.454% stannous fluoride dentifrice relative to a negative control dentifrice and dental prophylaxis after 3 months use.

Method:
This randomized, controlled, double-blind, parallel-group study enrolled healthy adult volunteers assigned randomly to one of the three treatment groups: an experimental 0.454% stannous fluoride dentifrice (n=51), a negative control dentifrice (Colgate Cavity Protection®, n=49), and dental prophylaxis with regular brushing (Crest Cavity Protection®, n=20). Subjects brushed with the assigned dentifrice twice daily, one minute each time, using a soft manual toothbrush for 3 months. A qualified dental examiner conducted gingivitis evaluation using Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) at Baseline, Week 6, and Month 3. Treatment groups were compared using analysis of covariance methods. All comparisons were 2-sided with the significance level of 5%.

Results:
Mean age was 41.6 years, and groups were balanced (p≥0.70) on demographics and baseline gingivitis scores. The positive control group was statistically (p≤0.04) significantly better than the negative control at all visits in all efficacy endpoints, demonstrating that the clinical model had sufficient sensitivity to detect treatment differences relative to the negative control. The SnF₂ dentifrice demonstrated statistically significant lower MGI scores (p<0.0001), number of bleeding sites (p≤0.0002), and GBI scores (p≤0.002) at week 6 and Month 3 relative to the negative control dentifrice.

Conclusion:
This randomized controlled clinical trial demonstrated the anti-gingivitis efficacy for a 0.454% stannous fluoride dentifrice relative to a negative control dentifrice in a 3-month gingivitis clinical trial.

Materials and Methods

Design: Randomized, double-blind, 2-treatment, parallel design study; 3 months duration

Treatments:
• 1) Negative control – Colgate Cavity Protection (0.76% NaMFP);
• 2) Test product – Experimental 0.454% SnF₂;
• 3) Positive control – oral prophylaxis + regular brushing (0.243% NaF)

Product use: Brushed twice daily, morning and night for 1 minute

Measures: Modified Gingival Index (MGI), Gingival Bleeding Index (GBI)

Population: Healthy adult volunteers with existing gingivitis

Statistical analysis: Analysis of covariance (ANCOVA) with baseline as covariate. Statistical comparisons were two-sided with a significance level of 0.05

Results

A total of 116 subjects (mean age of 41 years, 63% female) were enrolled and completed the study. Groups were well balanced on demographics and baseline gingivitis scores (p≥0.70). The test dentifrice demonstrated statistically significant lower MGI scores (p<0.003) and number of bleeding sites derived from GBI (p<0.0001), at week 6 and week 12 relative to the negative control. Model sensitivity to detect treatment differences was demonstrated with the positive control providing significant difference relative to the negative control (p<0.0001).

Conclusions

This randomized controlled clinical trial demonstrated the anti-gingivitis efficacy for a 0.454% stannous fluoride dentifrice relative to a negative control dentifrice in a 3-month gingivitis clinical trial. There were no adverse events reported during the study.
The Oral Malodor Reduction Efficacy of a 0.454% SnF2 Dentifrice

T. He, M. Anastasia, R. Eusebio, S. D. Whalen
Oral Health Care, Procter & Gamble Company, Mason, Ohio, USA

Abstract

Objective:
To compare the oral malodor reduction efficacy of a 0.454% stannous fluoride dentifrice relative to a positive and a negative control dentifrices using Halimeter as the measurement.

Method:
This was a controlled, randomized, double-blind, 3-treatment, 4-period cross-over study. Twenty-eight subjects who met study entrance criteria were enrolled into the study. Following an acclimation period, subjects were randomly assigned to a treatment sequence comprising three treatments: experimental 0.454% stannous fluoride dentifrice, positive control Crest Pro-Health dentifrice (0.454% Stannous Fluoride), negative control Crest Cavity Protection dentifrice (0.243% Sodium Fluoride). Volatile sulfur compound (VSC) levels were measured using a Halimeter during each treatment period at four time points: Baseline prior to treatment, overnight 24 and 48 hours post-baseline, and daytime 51 hours post-baseline. VSC levels were analyzed using analysis of variance (ANOVA) for crossover studies. Statistical comparisons were two-sided, with a significance level of 0.05.

Results:
A total of 23 subjects completed study. The adjusted mean VSC levels were significantly lower for the experimental SnF2 dentifrice at overnight 24 hour, 48 hour, and daytime 51 hour (p≤0.0099) as compared to negative control. The Experimental SnF2 paste had lower VSC scores at overnight 24 hour (p<0.03) and 48 hour (p=0.05), and no statistically differences at 51 hour (p=0.25) as compared to the positive control.

Conclusion:
This present study demonstrated the oral malodor reduction efficacy of the stannous fluoride dentifrices. All test dentifrices were well tolerated.

Materials and Methods

This randomized, double-blind, controlled clinical study evaluated the anti-malodor efficacy of an experimental 0.454% SnF2 dentifrice relative to a positive and a negative control. Subjects used the assigned test product twice daily. Oral malodor was measured using a calibrated halimeter at baseline and 3 time points post baseline (24, 48, and 51 hours).

VSC scores measured by the Halimeter was analyzed using analysis of variance (ANOVA) for crossover studies. Treatment comparisons were two-sided at the 5% significance level .
Gingivitis Reduction Efficacy of StannousContaining Sodium Fluoride Dentifrices

J Zhao1, T He2*, JL Chang3, Y He3, N Ji3
1Peking Union Medical College Hospital, 2P&G Mason Business Center, USA; 3P&G Beijing Innovation Center, China

Abstract

Objective:
To assess the gingivitis reduction effect of two stannous containing sodium fluoride dentifrices.

Method:
This was a randomized, controlled, double-blind, twotreatment parallel group clinical study. Eighty-three generally healthy adults with existing mild gingivitis and self reported sub-optimal oral health were enrolled into the study. Oral tissue safety and gingivitis examination using the Mazza modification of the Papillary Bleeding Index were conducted at Baseline and Week 2. After the baseline examination, Subjects were randomized to one of the two treatment groups based on gingivitis level, smoking status, age, and gender. Treatment included an experimental stannous containing sodium fluoride dentifrice (6100ppm stannous, 1450ppm sodium fluoride) and a marketed stannous containing sodium fluoride dentifrice (Crest® Pro-Health, 6100ppm stannous, 1450ppm sodium fluoride). Subjects used the test products twice daily, 2 minutes each time. Statistical comparisons were two-sided, with a significance level of 0.05.

Results:
A total of eighty-three (83) subjects completed study; the two groups were well balanced on age and gender (p>0.78). Baseline means were balanced between the two groups (p>0.34). At Week 2, both groups provided statistically significant (p<0.0001) gingivitis reduction relative to baseline, for the whole mouth Mazza mean and number of bleeding sites. There was no significant (p=0.96) difference between the two dentifrices in both gingivitis index and bleeding site. No treatment related adverse events were reported or observed in the study.

Conclusion:
Both stannous containing sodium fluoride dentifrices demonstrated significant gingivitis reduction efficacy in subject population with self reported sub-optimal oral health. Test products were well tolerated.

Materials and Methods

This randomized, controlled, double-blind, and parallel group clinical study enrolled eighty-three adult subjects with mild gingivitis and self reported sub-optimal oral health. Oral tissue safety and gingivitis examination using the Mazza modification of the Papillary Bleeding Index were conducted at Baseline and Week 2. Subjects used an experimental or a marketed stannous containing sodium fluoride dentifrice over the course of the study.

“Sub-optimal health” is a deep rooted consumer belief in Asian culture. It is the physical state between health and disease, i.e. symptoms such as fatigue exist but there is no detectable illness. Sub-optimal oral health is defined as a transition state from “health” to “disease” that includes preventable and reversible early stage common oral conditions, including:
- Early stage caries lesions, i.e. demineralization, white spot lesions
- Early stage reversible mild gingivitis, at the non-persistent sites
- Transient dentinal hypersensitivity

Materials and Methods

J Zhao1, T He2*, JL Chang3, Y He3, N Ji3
1Peking Union Medical College Hospital, 2P&G Mason Business Center, USA; 3P&G Beijing Innovation Center, China

Results

Conclusions

Both stannous containing sodium fluoride dentifrices demonstrated significant gingivitis reduction efficacy in subject population with mild gingivitis and self reported sub-optimal oral health. Establishing sub-optimal oral health concept can help promote early reversal of preventable common oral problems which is an important step toward oral and whole body wellness.
Uptake of Stannous Fluoride into Oral Plaque and Antibacterial Efficacy

1) Procter & Gamble Company, Mason, OH, USA 2) College of Dentistry, University of Tennessee, Memphis, TN, USA

Abstract

Objective:
Stannous Fluoride is an effective antimicrobial providing reductions in both plaque and gingivitis. Bioavailability of SnF2 to the oral plaque biofilm requires both penetration and retention of stannous fluoride within dental plaque. This study evaluated the efficacy of SnF2 dentifrices on inhibiting oral plaque biofilm growth and acid production, and compared reactivity to delivery of tin into oral plaque biofilm.

Method:
In this study 20 qualified PGRM panelists were treated with SnF2-dentifrices in a double blind, four-treatment and eight-period longitudinal design. Panelists were supplied with acclimation NaF dentifrice (Crest Cavity Protection, Procter and Gamble) for use throughout the trial. Test products included 0.454 % SnF2 dentifrices: I. Experimental SnF2 formula, II. Crest Pro Health Advanced, III. Crest Pro Health Clean Mint, and IV. Sensodyne Repair & Protect. After collecting overnight baseline plaque samples, panelists swished with dentifrice slurry (1:2) for 1 minute. Post-treatment plaque samples were collected after 30 minutes. Plaque samples were vortexed, normalized for biomass and analyzed for glycolysis inhibition (increase in pH) and tin content using the Plaque Glycolysis and Regrowth Method (PGRM) (J Clin Dent 6:59, 1995; FDA 21CFR Part 356 Vol. 68:103, May 29, 2003), and inductively coupled plasma mass spectrometry.

Results:

pH decrease I=0.59a; II=0.47b; III=0.36c; IV=0.26d; tin content I= 183.7a; II=116.6b; III=67.1c; IV=68.8c.

Conclusion:
Higher Sn-uptake into plaque biofilm was generally correlated with antimicrobial efficacy (p<0.0001). However Sn uptake alone was not sufficient to explain the efficacy differences among several treatments, which suggests that tin uptake and retention is not the only factor affecting bioavailability.


Materials and Methods

Study Design: Randomized double-blind four-treatment, eight-period longitudinal study with n=20 subjects.

Treatments: All subjects used each treatment twice on subsequent visits. Visits were separated by at least one day to avoid carry-over effects.

Results

Conclusions
The uptake of Stannous Fluoride into oral plaque biofilm was strongly associated with antimicrobial efficacy. However, differences in efficacy cannot be explained by tin uptake alone and are likely associated with bioavailability of stannous to dental plaque. Formulation of dentifrices with superior efficacy requires both understanding of tin uptake and stannous bioavailability.
Prevention of Oral Health Problems (Periodontal Inflammation as a Public Health Problem)

DJ White

Objective:

Method:

Results:

Conclusion:
Abstract

Objective:
The mechanism of stain control by whitening dentifrices can be due to abrasive action and chemical stain removal or prevention of stain uptake. Dentreifices often exhibit a combination of these mechanisms and contain abrasives and surface active chelants like phosphates. This study has the objective to evaluate cleaning performance of North American dentifrices with different surface-active and abrasive components. The contribution of abrasive action can be evaluated in laboratory testing by determining the Pellicle Cleaning Ratio (PCR, J Dent Res 1982, 61, 1236-1239). The contribution of chelants can be assessed using the hydroxyapatite powder stain removal (PSRM) and prevention (PSPM) models (J Clin Dent 2002, 13(1) 19-24). This in vitro study compared stain removal and prevention of four different dentifrices containing different surface active chelant systems.

Method:
Treatment dentifrices included: I Crest 3D White Brilliance (NaF, Hexametaphosphate, SLS); II Crest Pro Health (SnF2, Hexametaphosphate, SLS); III Sensodyne True White (NaF, Pentasodium Triphosphate, Betaine); IV US Crest Cavity Protection (NaF, SLS, negative control). Evaluations include: A) PCR (n=8) stained bovine enamel chips; B) PSRM (n=3); Tea-stained Hydroxyapatite powder (HAP) is treated with supernatant from 25% w/w dentifrice slurry for 60 sec, washed with water, tea-stained, filtered and the filter disk air-dried. Color change from baseline in PCR, PSRM and PSPM was determined by measuring L*a*b* using a color calibrated imaging system. PCR-values were calculated in the usual manner using calcium pyrophosphate at 800 brush strokes as reference. PSRM and PSPM outcomes were reported as overall color change (∆E).

Conclusions:
Hexametaphosphate-containing dentifrices significantly showed superior efficacy in cleaning, such as PCR, stain prevention and removal.

Materials and Methods

PCR: The Pellicle Cleaning Ratio test is a laboratory method to assess the overall cleaning of dentifrices (Stookey et al., J Dent Research, 1982, 61: 1236-1239, 1982). The test assesses the combined action of chemical and abrasive cleaning on extrinsic stain removal on tooth surfaces. Stookey-stained bovine enamel specimen were obtained from Therametrics Inc. Specimens with 25 < L* < 40 color values were stratified to N=8 per treatment group. The blocks were brushed for a total of 800 strokes in a V8 brushing system at 150g load using Sodium Pyrophosphate (20w/w% in 0.5%Carboxymethylcellulose, 10% Glycerol) with imaging after 800 strokes.

PSRM: The Powder Stain Removal Model (PSRM) is a variant, where as opposed to the PSPM above, the hydroxyapatite powder (HAP) is pre-stained with tea followed by treatment with dentifrice supernatant or rinse. Treatment of tea-stained HAP with oral care actives, either in rinse or dentifrice form, results in different levels of stain removal depending upon the ability of the actives to disrupt the binding of these chromogens onto HAP surface. Tea-stained Hydroxyapatite powder (HAP) is treated with supernatant from 25% w/w dentifrice slurry for 60 sec, washed with water, suspended, filtered and the filter disk air-dried. The magnitude of stain removal can then be calculated by color measurement.

Color measurement: Color change from baseline in PCR, PSRM and PSPM was determined by measuring L*a*b* using a color calibrated imaging system. PCR-values were calculated in the usual manner using calcium pyrophosphate at 800 brush strokes as reference. PSRM and PSPM outcomes were reported as overall color change (∆E).

Results

Conclusions
Hexametaphosphate-containing dentifrices showed superior stain control benefits. Laboratory testing is able to differentiate between the three mechanisms aiding in stain control - abrasive stain removal, chemical stain removal and chemical stain prevention.

References:
Stain: Control; J Dent Res (AADR/IADR) 2016; 96 (Spec Iss A) # 469
PCR: J Dent Res 1982, 61, 1236-1239
PSRM/PSPM: J Clin Dent 2002; 13(1) 19-24

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Materials and Methods

PSRM: The Powder Stain Removal Model (PSRM) is a variant, where as opposed to the PSPM above, the hydroxyapatite powder (HAP) is pre-stained with tea followed by treatment with dentifrice supernatant or rinse. Treatment of tea-stained HAP with oral care actives, either in rinse or dentifrice form, results in different levels of stain removal depending upon the ability of the actives to disrupt the binding of these chromogens onto HAP surface. Tea-stained Hydroxyapatite powder (HAP) is treated with supernatant from 25% w/w dentifrice slurry for 60 sec, washed with water, suspended, filtered and the filter disk air-dried. The magnitude of stain removal can then be calculated by color measurement.

Color measurement: Color change from baseline in PCR, PSRM and PSPM was determined by measuring L*a*b* using a color calibrated imaging system. PCR-values were calculated in the usual manner using calcium pyrophosphate at 800 brush strokes as reference. PSRM and PSPM outcomes were reported as overall color change (∆E).

Results

Conclusions
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PCR: J Dent Res 1982, 61, 1236-1239
PSRM/PSPM: J Clin Dent 2002; 13(1) 19-24

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Efficacy of a Battery Manual Toothbrush removing Dental Stain

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Abstract

Objective:
To evaluate and compare dental stain removal efficacy of a battery toothbrush.

Method:
This was a randomized, controlled, two treatment, parallel group, single-blind, one-week study involving forty healthy adults with visible dental stain on the facial surfaces of the anterior teeth. Subjects were randomized to one of the following treatments: Oral-B Pulsar battery toothbrush (Pulsar) or a positive control marketed whitening manual toothbrush (control) and received instructions to brush their teeth for one minute twice a day for 1 week using a standard dentifrice. Safety and efficacy assessments were conducted at the Baseline visit and after 1 week of product use, by an experienced examiner. Brush safety was evaluated by oral examination of hard and soft tissues; and dental stain was scored using the Modified Lobene Stain Index and the Interproximal Modified Lobene Stain Index. The data was analyzed using non-parametric analysis of covariance.

Results:
For the composite scores of the Modified Lobene Stain Index, the baseline values were 2.94 for Pulsar and 3.43 for the positive control (p=0.072). After 1 week the reductions from baseline were 0.96 for Pulsar and 0.91 for the control with statistical significance for both brushes (p<0.001). For the Interproximal Modified Lobene Stain Index, the baseline scores in the gingival and interproximal regions were 3.24 and 3.24 for Pulsar and 3.82 and 3.57 for the control. After 1 week of use the reduction from baseline were 0.81 and 1.17 for Pulsar and 0.84 and 1.22 for the control with statistical significance for both brushes (p<0.001). The comparison between the groups did not show differences between the manual brushes in both indices (p>0.05).

Conclusion:
The Oral B Pulsar battery toothbrush and the positive control marketed whitening toothbrush removed statistically significantly dental stain after one week of use and both have similar efficacy. Both brushes were well tolerated.

Materials and Methods

R GOYAL1, J QAQISH1, RA CCAHUANA-VASQUEZ2*, JM GRENDER3, E CONDE3, PA CUNNINGHAM3
(1 All Sum Research Center Ltd., Mississauga, ON, Canada; 2 Procter & Gamble Service GmbH, Kronberg, Germany; 3Procter & Gamble Co, Mason, OH, USA)

Materials and Methods

Results

Table 1. Baseline demographic characteristics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>PULSAR (N=21)</th>
<th>POSITIVE CONTROL (N=15)</th>
<th>OVERALL (N=40)</th>
<th>IP VIMAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>28.9 (22.6)</td>
<td>30.4 (25.7)</td>
<td>29.6 (24.3)</td>
<td>0.616</td>
</tr>
<tr>
<td>Male</td>
<td>16 (76.2%)</td>
<td>11 (73.3%)</td>
<td>15 (75%)</td>
<td>0.753</td>
</tr>
<tr>
<td>Female</td>
<td>5 (23.8%)</td>
<td>4 (26.7%)</td>
<td>5 (25%)</td>
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</tr>
</tbody>
</table>

Table 2. Modified Lobene/Dental Stain Index Results

<table>
<thead>
<tr>
<th>GROUP</th>
<th>BASELINE</th>
<th>VALUE 1</th>
<th>p-value</th>
<th>C-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSITIVE CONTROL</td>
<td>3.43 (.178)</td>
<td>2.53 (1.231)</td>
<td>&lt;0.001</td>
<td>0.08</td>
</tr>
<tr>
<td>PULSAR</td>
<td>2.54 (0.653)</td>
<td>1.98 (0.419)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Interproximal Modified Lobene Dental Stain Index Results

<table>
<thead>
<tr>
<th>GROUP</th>
<th>BASELINE</th>
<th>VALUE 1</th>
<th>p-value</th>
<th>C-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSITIVE CONTROL</td>
<td>3.92 (1.763)</td>
<td>2.67 (1.730)</td>
<td>&lt;0.001</td>
<td>0.620</td>
</tr>
<tr>
<td>PULSAR</td>
<td>3.24 (0.785)</td>
<td>2.43 (1.077)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

The Oral B Pulsar battery toothbrush and the positive control marketed whitening toothbrush removed statistically significant dental stain after one week of use and both have similar efficacy. Both brushes were well tolerated.
In-Office Research of Stain Removal Efficacy of Stannous Fluoride Dentifrice

M. Meza, N. Parmell
Oral Health Care, Procter & Gamble Company, Mason, Ohio, USA

Abstract

Objective:
An in-office trial compared use of three dentifrices on cleaning/stain removal, while also obtaining subjects’ assessment of the perceived occurrence of tooth staining.

Method:
At each office, subjects were assigned to one of three dentifrices: an experimental 0.454% SnF2 dentifrice, 0.454% stannous fluoride sodium hexametaphosphate dentifrice (Crest® Pro-Health Clinical Gum Protection) or Colgate Total and manual brush. Use was at-home and unsupervised, tooth discoloration was observed by each dental professional, and subjects’ perception of discoloration was assessed at Baseline, Month 3 and Month 6.

Results:
230 subjects participated in the study from 28 dental offices. After 6 months product use, there was no difference in negative recommendations by dental professionals between the 3 treatments. There were more positive recommendations of an experimental 0.454% SnF2 dentifrice (64%) relative to Colgate Total (57%) and Crest® Pro-Health Clinical Gum Protection (61%). There was no statistical difference in percent of dental professional observed tooth discoloration between an experimental 0.454% SnF2 dentifrice (43%) and Colgate Total (42%), and both had less observed stain than Crest® Pro-Health Clinical Gum Protection (51%). Furthermore, the percent of subjects who indicated they experienced stain using an experimental 0.454% SnF2 dentifrice is comparable to the commercial benchmark, 7.9% and 7.8% respectively. All treatments were generally well-tolerated.

Conclusion:
Use of experimental 0.454% stannous fluoride dentifrice exhibits similar amounts of dental professional observed stain relative to Colgate Total, and comparable professional recommendation.

Materials and Methods

A three-leg, blind extended use study among US patients by dental professionals in dispersed offices. Each dental professional placed 9 patients in their practice (3 patients per product) with one of three toothpaste products for use over 6 months. Patients completed a baseline assessment of their oral health and evaluated the product after using it for 3 and 6 months in place of their usual product. The dental professionals evaluated each patient at baseline during a routine prophylaxis visit and after 3 and 6 months of product usage. Tooth discoloration was observed by both dental professionals and patients. 230 subjects were assigned to one of three products: 1) an experimental 0.454% SnF2 dentifrice, 2) Crest® Pro-Health Clinical Gum Protection or 3) Colgate Total Clean Mint. Products were compared using Fisher’s Exact Test.

Results

Use of experimental 0.454% stannous fluoride dentifrice exhibits similar amounts of dental professional observed stain relative to Colgate Total, and comparable professional recommendation.
Comparative Esthetic Responses of Whitening Dentifrices with Dentinal Hypersensitivity

Sushma Nachnani,* Steve Lee, Jill Underwood, Robert Gerlach

Objective:
A randomized positively-controlled clinical trial was conducted to evaluate the safety and effectiveness of two-step (therapeutic + whitening) oral hygiene on esthetic responses in subjects with dentinal hypersensitivity.

Method:
The study targeted adult volunteers with air-based dentinal hypersensitivity plus suboptimal hygiene as evidenced by malodor and/or stain. Institutional review and informed consent were obtained, and subjects were assigned a regular anticavity dentifrice and manual brush for acclimation. After 1-week, baseline measurements were collected, and subjects were randomly assigned to one of two whitening dentifrices. Groups were 1) two-step oral hygiene with a 0.454% SnF2 toothpaste followed by a 3% H2O2 gel (Crest® Pro-Health [HD]™ Procter & Gamble Co.) or 2) 5%KNO3 w/ NaF (Sensodyne® Extra Whitening, GlaxoSmithKline), the latter of which served as the positive experimental control. Test products were dispensed in blinded test kits with a regular manual brush (Oral-B® Indicator). After 2-weeks, esthetic responses were independently assessed blind to treatment using a 9-point hedonic scale for malodor and a 4-point (Lobene) index for stain area and intensity.

Results:
The study population (N=57) exhibited considerable diversity in age (18-65 years), gender and ethnicity. Baseline means (SD) were 8.5 (0.53) for malodor, and 0.5 (0.31) for composite Lobene stain, with groups balanced on baseline malodor, stain and demographics. All subjects completing the study and were included in the analyses. Relative to baseline, both groups exhibited significant (p<0.001) reductions in malodor and stain. Between-group comparisons favored the two-step oral hygiene group, which exhibited 20-60+% improvements relative to the control for odor, composite stain, stain area and stain intensity. Both whitening products were well-tolerated.

Conclusion:
While both treatments were effective, use of a two-step oral hygiene routine of a stannous fluoride dentifrice plus hydrogen peroxide gel yielded improvements in overall esthetic response for adults with dentinal hypersensitivity and suboptimal hygiene.

1-Month Randomized Controlled Trial Comparing Brush Effects on Sensitivity Response

Chad Anderson,* Gerard Kugel, Marco Ferrari, Robert Gerlach

Objective:
A randomized controlled trial was conducted to compare power and manual brushing effects on a professional + at-home sensitivity regimen.

Method:
In this practice-based research, institutional review was obtained, adults with a history of dentinal hypersensitivity were screened, and test sites with air sensitivity were selected. After baseline measurements, a professional treatment with oxalate acid potassium salt solution (Super Seal® Dental Desensitizing Liner, Phoenix Dental) was administered. Balancing for baseline, subjects were then randomly assigned to a rotation-oscillation power brush (Oral-B® Professional Care 4000, Procter & Gamble) or manual crisscross brush control. Test products were dispensed in blinded test kits with a 0.454% stannous fluoride dentifrice for at-home use. Sensitivity was measured after stimulation with a 1-sec application of cool air from a dental air syringe. Two measurements were collected: clinical sensitivity was measured using a standard 4-point scale (Schiff), while self-assessment used a 100 point pain-ranking scale (VAS) collected via a tablet.

Results:
A total of 24 adults were enrolled (12 per group), ages ranged from 21-67 years, most (92%) subjects were female, and 23 completed the 1-month recall. Baseline sensitivity means (SD) were 2.4 (0.72) for Schiff Air, and 57.9 (17.0) for VAS. Both groups exhibited significant (p<0.05) durable reductions in sensitivity (Schiff and/or VAS) with treatment. Overall, the power brush group exhibited greater sensitivity reductions, and groups differed (p=0.006) for VAS sensitivity. Each treatment was well-tolerated, and there were no “for cause” dropouts.

Conclusion:
In practice-based research, use of a rotation-oscillation power brush improved dentinal hypersensitivity responses to professional plus at-home care over a 30 day period.

Objective:
Practice-based research was conducted to assess decision-making, oral tolerability and effectiveness of topical oxalate use and home care to treat dentinal hypersensitivity.

Method:
After institutional review, a multicenter practice-based study was conducted among adults with evidence of dentinal hypersensitivity. After training, practitioners at 4 US sites recruited and enrolled individuals with dentinal hypersensitivity in the clinical study, and selected one of two specific professional + at-home treatments. Subjects received either 1) professional paint-on application of 3% oxalate acid potassium salt solution (Super Seal® Dental Desensitizing Liner, Phoenix Dental) plus 0.454% stannous fluoride (Crest® Sensi Repair & Prevent, Procter & Gamble) for at-home use or 2) professional 10-minute application of a 1.5% oxalate gel strip (Crest Sensi-Stop™ Strips, Procter & Gamble) plus 5 additional oxalate strips for subsequent at-home use. After professional treatment, an oral examination was conducted to assess tolerability. Each subject received the selected follow-up product (paste or strip) for at-home use, and a post-treatment examination and/or interview was scheduled 2-8 weeks after treatment.

Results:
A total of 105 subjects were enrolled, 104 received treatment and 100 were evaluated after at-home use. Mean age was 43.6 years, ranging from 19-74, and 73% were female. Strips were more commonly selected for in-office use (55% vs 45%), with coverage, ease-of-use and patient preference as factors in treatment selection. Favorable experiential responses were reported by 84% and 68% of the strip and paint-on users, respectively. Week 2-8 post-treatment responses were generally similar, with significant ($p<0.05$) reductions in sensitivity for both groups. There was one adverse event (sloughing) reported by one subject in the paint-on plus paste group.

Conclusion:
In practice-based research, strip or paint-on oxalates plus at-home care resulted in significant immediate and durable reductions in reported dentinal hypersensitivity for periods of up to 8 weeks.

Objective:
A pooled analysis of clinical trials outcomes from one study site was conducted to assess relationships/merits of two different provocative methods (tactile and air) to assess dentinal hypersensitivity responses following treatment.

Method:
The inclusive analysis used subject-level sensitivity responses from 3 randomized controlled trials at a single clinical site. In each study, subjects with dentinal hypersensitivity were randomly assigned to specific anti-sensitivity treatments (1.5% oxalate gel strips, 0.454% stannous fluoride dentifrice plus 3% H2O2 gel, or 5% KNO3 plus NaF dentifrice) or a negative control, depending on design. Stimulated sensitivity was graded before/after treatment by a single clinical examiner using standard methods. First, controlled (Yeaple) probing was conducted to measure pressure tolerability (in gm), after which, a 1-sec application of cool air (~21°C, 40-60 psi) was used to measure air sensitivity on a 4-point scale (Schiff). End-of-treatment responses for all subjects and groups were pooled and regression analysis was used to assess relationships between tactile and air responses.

Results:
A total of 219 subjects with 251 test sites participated in the research. The population exhibited considerable diversity in age (18-70 years), gender (61% female) and ethnicity. Treatment assignments – oxalates (74 subjects) stannous fluoride (35), potassium nitrate (75) and negative control (35) – yielded varying sensitivity responses. Overall, 55% of teeth showed reductions in both tactile and air sensitivity, 20% showed improvements in one of two endpoints, while 25% showed no improvement. Combining the 4 treatment groups, mean (SD) changes were 11.63 (12.57) gm for tactile tolerability and 0.97 (0.88) for air tolerability. Tactile and air responses were well-correlated (r=0.60).

Conclusion:
A pooled analysis of clinical trials involving showed that, while clinical measurement of dentinal hypersensitivity yielded different responses to tactile or air stimulation, outcomes were generally well-correlated.

A Clinical Study to Evaluate Cleaning Efficacy of Dentifrices in a 4-Day Plaque Model

M. KLUKOWSKA1; E. CONDE1; R. EUSEBIO1; M. GABBARD1
(1 The Procter & Gamble Co., Mason, OH)

Abstract

Objective:
To evaluate the cleaning efficacy of an experimental dentifrice relative to a negative control.

Method:
This was a controlled, double-blind, randomized, 2-treatment, 4-period cross-over design, 4-day partial brushing plaque study. Test dentifrice products included an experimental toothpaste (0.243% Sodium fluoride with 0.788% Zinc citrate) and Crest® Cavity Protection (0.243% Sodium fluoride). Prior to the treatment phase each subject had a dental prophylaxis and underwent an acclimation period using the negative control. Each treatment period consisted of 4 days and was separated by a washout period of 1 week. Treatments consisted of a baseline visit plaque evaluation using the Turesky Modification of Quigley Hein Index, followed by teeth polishing. Subjects were then randomly assigned to a treatment sequence and used their assigned products twice daily for 4 days. Subjects brushed their lingual surfaces for 30 seconds and immediately swished with slurry of the assigned dentifrice for one minute. After that, they were asked to expectorate and repeat the brushing and swishing one more time. On Day 4 post treatment, subjects returned for a final plaque exam. The treatments and washout periods were repeated until all four treatment periods were completed. A general linear mixed model was used to analyze plaque scores with baseline used as a covariate. Statistical comparisons were two-sided with a significance level of 0.05.

Results:
Of 32 subjects randomized to treatment, 26 completed the study with evaluable data for analysis. Treatments were balanced for baseline whole mouth, buccal, and lingual plaque measurements (p>0.3). The experimental dentifrice demonstrated significantly superior cleaning vs. the negative control with respect to whole mouth (by 12%, p<0.0001), buccal surfaces (by 12%, p<0.0001) and lingual surfaces (by 12%, p<0.0001).

Conclusion:
This study demonstrated greater cleaning efficacy of the experimental dentifrice relative to the negative control.

Materials and Methods

Study Design: double-blind, randomized (in sequence), 2-treatment, 4-period cross-over design, 4-day partial brushing plaque study.

Treatments: Experimental dentifrice (0.243% Sodium fluoride with 0.788% Zinc citrate) or Crest Cavity Protection Dentifrice, both using ADA reference manual toothbrush.

Clinical Endpoint: Baseline and Day 4 Whole Mouth Turesky-modified Quigley-Hein Plaque Index (TQHPI).

Subjects: 30 healthy subjects with a mean age of 47.1 years (range 31-61) were enrolled into this study and 57% were male.

Product Usage: Subjects were asked to only brush their lingual surfaces with their assigned dentifrice for 30 seconds twice daily (first day treatment product usage was supervised by clinic staff). Without expectoration, subjects were instructed to swish with the slurry left in their mouth for 60 seconds. After that, they were asked to spit out the slurry and repeat the brushing and swishing one more time. Subjects were asked not to eat or drink anything for 30 minutes following use of the test products.

Statistical Analysis: A general linear mixed model was used to analyze plaque scores with baseline used as a covariate and treatment as fixed effects. Treatment comparisons were two-sided tests carried out at the 5% significance level.

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Conclusions

This study demonstrated greater cleaning efficacy of the experimental dentifrice relative to the negative control.
Analysis of Caries-Like Lesions by Microhardness and Brightfield Optical Images

Samuel St. John,* Jennifer Kennedy

Objective:
Analysis of artificial caries-like lesions is fundamental to the development of new caries therapies. Unfortunately, quantitative microradiography and microhardness measurements require specialized equipment, are slow and laborious. We here present a method to analyze caries-like lesions quickly and effectively with less specialized equipment. Objective: To compare the mineral content of lesions determined from analysis of microscope images of lesion cross sections (MLA) with that determined by cross-section microhardness profiles (CSMH).

Method:
Caries-like lesions were made with a variety of mineral contents over three weeks in a protocol similar to that used by Stookey et al. 2011 with a demineralization buffer pH of 4.3. A variety of treatments were compared comprising different fluoride sources (NaF, SnF2), fluoride concentrations (100 – 5000 ppm), and chelants (sodium acid pyrophosphate, sodium hexametaphosphate, and zinc citrate). Following treatment, lesions were cross-sectioned and indented using a method described by Featherstone et al. 1983. Microscope images were obtained under reflected brightfield illumination at 5x magnification. Images were changed to greyscale and adjusted so the pixel lightness range was 0 – 250. A region of the image (100x250 pixels) next to the indents was converted to vol% mineral by interpolating the lightness value (0 vol% mineral = 0 pixel lightness, 87 vol% mineral = 255 pixel lightness). Pixel length was calibrated using the indents. Lesion profiles were integrated to obtain the vol% mineral-micrometer and compared for each treatment leg. Five studies were compared comprising 34 treatment legs and 340 lesions.

Results:
In individual studies, the correlation between MLA and CSMH by treatment leg was high (Pearson's correlation coefficient, r² > 0.9 in all cases). Between study correlation was low (r² = 0.41). The correlation between studies for results scaled to controls rose markedly (r² = 0.87).

Conclusion:
We conclude that either technique can be used to determine the mineral content of caries-like lesions.

Prevention of Caries by SnF2 in a Microbial Caries Model

Anif Baig*, S. Flannagan†, E. Schneiderman*, S. St. John*, M. Fontana†, C. González-Cabezas†
* The Procter & Gamble Company, Mason, OH, USA, †University of Michigan, School of Dentistry, Ann Arbor, Michigan, USA

Abstract

Objective:
Stannous fluoride (SnF2) containing toothpaste has shown to have anticaries and antigingivitis effects. Its antimicrobial impact on the caries process is not well-understood. The purpose of this study was to determine the caries prevention potential of SnF2-based dentifrice when compared to NaF- and SMFP-based dentifrices using a microbial artificial-mouth caries model.

Method:
Four groups of 16 human enamel specimens were inoculated with Streptococcus mutans and exposed for seven days to circulating Trypticase Soy Broth+5% sucrose for 30 minutes, 3x/day, and to a mineral wash solution for the rest of the day. Developing biofilms were exposed (2x/day) to one of the following dentifrice slurries containing: 1100 ppm NaF, 1100 ppm SMFP, 1100 ppm SnF2, or 0 ppm F (placebo). Spent fluid from vessels was monitored daily for pH. At the end of the study, biofilms were sonicated and lesion volume was analyzed by cross-sectional microhardness (CSMH). Specimens were then stained with a fluorescent dye to determine lesion depth (LD) using confocal microscopy.

Results:
SnF2 treated specimens had significantly less biofilm than SMFP or Placebo treated specimens (p<0.05), and numerically lower than NaF treated specimens. Lesion depth was significantly different among all groups (p<0.01): placebo had the deepest lesions (65±3.5µm), followed by the NaF group (42±7.1µm) and the SMFP group (32.1±5.2 µm); and the SnF2 group showing the shallowest lesions (24.5±5.7µm). Caries lesions showed that the total amount of mineral loss (delta AUC sound – AUC lesion) was the least with the SnF2 treated group (477±234) and the largest with the placebo group (1271±194), with no significant difference between NaF and SMFP (804±196; 758±237).

Conclusion:
Results from this study suggest that the antimicrobial activity observed from the SnF2-containing dentifrice treatments could explain its greater caries prevention potential in this microbial artificial-mouth caries model.

Materials and Methods

Study Design: A glass vessel housing human enamel specimens under sterile conditions is used as an artificial mouth with provision for in-flow and out-flow of liquids from the vessel. Each vessel contains 16 defect free sectioned, ground and polished specimens (3 x 3 mm) and is used for one treatment group (16 specimens / group). The lateral sides of each specimen and about 10-20% of surface were covered with an acid-resistant varnish, allowing only 80-90% of the enamel surface exposed. All groups are exposed to the same environmental conditions for seven days and differs only in the daily treatment with dentifrices. Each group received two daily 2-minute treatments with the 1:2 slurry of four different dentifrices; Placebo, 1100 NaF, 1100 SMFP and an experimental 1100 SnF2 toothpaste.

Results

Conclusions

The microbial artificial-mouth caries model enables evaluation of anticaries performance of materials that work through mechanism beyond fluoride’s remineralization and demin inhibition only, and the antimicrobial activity observed from the SnF2 dentifrice could explain its greater caries prevention potential.
Extrinsic Stain Removal Efficacy Of a 0.454% Stannous Fluoride Dentifrice

Lynn Friesen, Tao He, Rachelle Eusebio

Objective:
The objective of this study was to assess the extrinsic stain removal benefit delivered by a Stannous Fluoride dentifrice (SnF2) and a positive control dentifrice over a two-week period.

Method:
This study utilized a randomized, two-week, double-blind, parallel group design. A total of 50 generally healthy adults with visible extrinsic tooth stain were enrolled in the study. At Baseline, an Interproximal Modified Lobene (IML) examination was performed on the facial surfaces of the twelve anterior teeth. The two teeth with the highest IML composite scores were selected as the test teeth. Subjects were stratified on stain scores of the two test teeth, and gender, and randomized to one of two treatment groups: experimental 0.454% Stannous Fluoride dentifrice or Colgate Total Whitening â dentifrice. Then, subjects were instructed to use the test product following the on-package brushing instructions at home over the two week study duration. Tooth color was reassessed at Week Two. The Baseline to post-treatment average change in stain score was tested using paired t-tests. Analysis of covariance (ANCOVA) with treatment as a factor and Baseline Lobene score as the covariate was used to assess treatment differences post-treatment. All comparisons were two-sided using a 5% level of significance.

Results:
Fifty subjects were randomized, received treatment and completed the study. The treatment groups were well balanced at Baseline for stain values (p>0.18) and with respect to baseline demographic characteristics (p>0.08). Both groups showed statistically significant reductions in IML stain scores at Week Two (p < 0.0001) relative to Baseline. The experimental SnF2 group demonstrated significantly less IML stain overall and for interproximal surfaces than the positive control group (p<0.0012).

Conclusion:
The study demonstrated the statistically significant extrinsic stain removal efficacy for the 0.454% stannous fluoride dentifrice relative to Baseline and the positive control.

Periodontal Inflamed Surface Area Changes in Women with Pregnancy Gingivitis

Maria Geisinger,* Mengyi Shi, Nicolaas Geurs, Maninder Kaur, Robert Gerlach, Julie Grender, Michael Reddy

Objective:
Pregnancy gingivitis has been shown to develop in up to 70% of pregnant women and gingival inflammation to increase throughout gestation. Previous studies have demonstrated that an intensive oral hygiene regimen was able to decrease clinical signs of gingival inflammation in pregnant women.

Method:
Pregnant women between 8-24 weeks of gestational age with at least 30 bleeding sites were included. Subjects were randomized to receive either an intensive oral hygiene regimen (OHR) or control oral hygiene instructions (OHC). Calibrated examiners measured whole mouth gingivitis scores using a standard 4-point clinical index (Loe-Silness GI) and probing depth (PD) were measured at six sites per tooth at baseline and at 8 weeks. Periodontal inflamed surface area (PISA) was calculated using PD and bleeding sites (LSC ≥ 2) and a published PISA calculator based upon mean periodontal epithelial surface area (PESA) for each tooth type. OHR and OHC groups were compared using a paired t-test.

Results:
306 women between 18-44 years of age recruited at UAB Center for Women’s Health Research were treated with either OHC or OHR at between 8-24 weeks of pregnancy. Mean PISA at baseline was 584.9 and 562.3 for OHC and OHR, respectively (p=0.2362). Mean PISA at 8 weeks was 420.7 and 409.0 for OHC and OHR, respectively (p=0.698). The change in PISA over the study period [ΔPISA(SD)] for OHC and OHR was 164.22(306.404) and 153.35(256.982), respectively (p=0.738).

Conclusion:
As clinical inflammation and LSGI have been known to increase throughout pregnancy, the increase in PISA in both groups may be expected. The lack of significant difference between the PISA values for OHC and OHR groups may indicate that any focus on oral hygiene during pregnancy may mitigate increases in PISA during pregnancy in women with pregnancy gingivitis and these results may differ from previous results due to the early gestational age at which the participants were enrolled.

Objective:
This clinical trial compared whitening efficacy of whitening strips with light system to in-office treatment.

Method:
After institutional review and informed consent, 58 adults with no history of previous bleaching and a Vita shade of A2 or darker on maxillary anterior teeth were randomized to either whitening strips (10% H2O2) with Light or Opalescence® Boost (40% H2O2) groups in a 2 to 1 ratio. Subjects in Strip+Light group were instructed to use whitening strip on their maxillary anterior teeth for a total of 60 minutes once a day for 10 days. During the last 5 minutes of each wear, subjects applied the light device to their anterior teeth. Subjects in the in-office treatment group received two 20-minute chairside treatments. Efficacy was measured objectively as L*a*b* color change using digital images at Baseline and at Day 11, and safety was evaluated by examination and subject interview.

Results:
Mean (SD) age was 41.7 (11.7), and treatments were balanced based on the initial tooth color (p>0.55). At end of treatment, both groups exhibited significant (p < 0.001) color improvement from baseline. The Strip+Light group provided significantly greater (p<0.0001) reductions in yellowness (Δb∗) and improvements in lightness (ΔL∗) relative to the in-office group with adjusted means of -2.635 and -0.844 for Δb∗, and 1.959 and 0.909 for ΔL*, respectively.

Conclusion:
Whitening strips with light delivered superior to in-office treatment whitening efficacy.

Clinical Trial to Evaluate Efficacy of Whitening Dentifrice

Nataliya Gurich,* Mary Kay Anastasia, Jimmy Qaqish, C. Ram Goyal

Objective:
A clinical trial was conducted to assess the safety and effectiveness of whitening toothpaste relative to a negative control on extrinsic tooth stain.

Method:
This randomized controlled trial evaluated extrinsic tooth stain over a four-week period. After institutional review and informed consent, adult volunteers with natural extrinsic tooth stain were randomly assigned to either 1) twice daily use of a 0.243% sodium fluoride whitening dentifrice with an Oral-B Indicator soft manual toothbrush or 2) Colgate® Cavity Protection Toothpaste (0.76% Sodium Monofluorophosphate) with an Oral-B Indicator soft manual toothbrush. Stain was assessed for intensity, area of coverage and composite scores on facial and lingual surfaces of anterior teeth using the Lobene Stain Index after two and four weeks of product use. Safety was assessed from clinical examination and interview. Analysis of covariance was used to compare the treatment difference between the two groups. The statistical comparisons were two sided using a 5% level of significance.

Results:
Mean (SD) age of the 110 evaluable subjects was 47.6 (11.52) years, with groups balanced on area, intensity and composite stain (p>0.22). Both dentifrices showed significant (<0.0001) stain reductions relative to Baseline at Weeks 2 and 4. At Week 2, the Whitening Dentifrice group demonstrated a significantly lower composite stain score relative to the negative control group by 20% (p<0.0001) with adjusted means of 1.448 and 1.808, respectively. At Week 4, the Whitening Dentifrice group demonstrated a significantly lower composite stain score relative to the negative control group by 48% (p<0.0001) with adjusted means of 0.941 and 1.797, respectively. Both products were well-tolerated.

Conclusion:
In a negatively-controlled study, whitening dentifrice significantly reduced extrinsic tooth stain with continuing improvement at each tested time-point.

**Short-term Stain Removal with Whitening Dentifrice Relative to Prophylaxis**

Tracie Hill,* Nataliya Gurich, Mary Kay Anastasia, Hasani Gillispie

**Objective:**
This randomized, controlled clinical study evaluated extrinsic stain removal efficacy of a whitening dentifrice relative to a positive control after 1 week of use.

**Method:**
After institutional review and informed consent, 50 healthy volunteers with visible stains on the facial surfaces of anterior teeth were enrolled into the study. Subjects were randomly assigned to dental prophylaxis or a sodium hexametaphosphate-containing dentifrice. Efficacy was measured via Interproximal Modified Lobene (IML) index at Baseline and after 3, 5 and 7 days of use. Safety was assessed from clinical examination and interview. Comparisons to baseline used paired difference t-tests (two-sided, 5% significance).

**Results:**
Mean (SD) age of subjects was 36.4 (11.65), and 82% were female. At Day 3 both the Whitening Dentifrice group and the Dental Prophylaxis group demonstrated statistically significant reductions (p<0.0001) from Baseline in IML stain scores with a mean change of 4.39 and 4.29, respectively. At Day 5 and Day 7, the Whitening Dentifrice group and the Dental Prophylaxis group were not significantly different from each other (p>0.3) in IML stain overall or for interproximal surfaces. Both treatments were well tolerated.

**Conclusion:**
This clinical study demonstrated statistically significant stain removal efficacy of the SHMP-containing whitening dentifrice throughout one week of use.

Objective:
This clinical trial assessed the safety and efficacy of a light device used in conjunction with whitening strips relative to whitening strips alone.

Method:
After institutional review and informed consent, 41 adults with no history of previous bleaching and a Vita shade of A2 or darker on maxillary anterior teeth, were randomized to either a Strip Alone or a Strip + Light group for 10 once a day treatments. Both groups were instructed to apply a whitening strip on their maxillary anterior teeth for a total of 60 minutes. Subjects in the Strip + Light group were instructed to apply light device to the anterior teeth during the last 5 minutes of strip wear. Efficacy was measured objectively as L*a*b* color change using digital images at Baseline and Day 4, 8 and 11, and safety was assessed by intraoral examination and subject interview.

Results:
Mean (SD) age was 37.4 (6.42), and treatments were balanced (p>0.6) on starting tooth color. Beginning as early as Day 4 and continuing through Day 11, both groups demonstrated statistically significant (p < 0.009) reduction in yellowness (Δb*) and increase in lightness (ΔL*) relative to baseline. The Strip + Light group demonstrated statistically significant yellowness improvement (Δb*) relative to the Strip group at each time-point (p < 0.02) with adjusted means after three, seven and ten treatments of -1.59 and -0.97, -2.50 and -1.85, -3.49 and -2.51, respectively. Both treatments were well tolerated, and no subjects dropped out of the study due to the adverse event.

Conclusion:
Light-enhanced strip treatment resulted in more efficacious color tooth improvement than strip alone.

Factors Associated With Carious Lesions in a Medicated Population

Mabi Singh,* Athena Papas, Sarah Pagni, Matthew Finkelman

Objective:
Cariel caries is a multifactorial disease. The objective of this study was to investigate the factors associated with progression of carious lesions in a population who were on prescription medications.

Method:
Six hundred forty six subjects were recalled in 9-12 months and reexamined for incipient and frank carious lesions on the coronal and root surfaces. Inclusion criteria for the study were the use of xerogenic medication, salivary flow below 0.2 ml/min, being 40 – 80 years old, and having at least 10 teeth. Medication(s) were self-reported. Oral hygiene care, frequency of dental visits, income and smoking status were recorded. Statistical analysis was conducted via Spearman’s rho and the Mann-Whitney U test.

Results:
The mean age was 65.0 (SD = 9.91) years and 58% were females. The mean number of teeth was 23.2(2.4), and mean number of medications taken 3.5(2.4). Variables exhibiting significant Spearman correlation with total incipient and cavitated carious lesions were the number of teeth present (Spearman rho = -.087, p=.027), flossing (Spearman rho =-.114, p=.005), age (Spearman rho = -.114, p = .004), and income (Spearman rho =-.100, p=.013). Sex (p =.007) and psychiatric medication (p < .001) were also significantly associated with total carious lesions (Mann-Whitney U test), with males and subjects on psychiatric medication(s) exhibiting more total carious lesions. Number of medications, blood pressure medications, frequency of brushing, medication to control pain, smoking status and frequency of dental visits did not show statistically significant association with total carious lesions.

Conclusion:
Although development of carious lesions involves multiple factors, income, oral hygiene behavior, especially flossing and xerogenic medications may be associated with incipient and frank carious lesions. Larger studies need to be conducted with more stratification of the medication groups to determine the causal effect.

Relationship of Gingivitis Severity and Response to a Paste/Gel Sequence

Pejmon Amini, Alborz Amini,* Melanie Miner, Robert Gerlach

Objective:
An integrated analysis was conducted to assess factors affecting the effectiveness of a daily 2-step dentifrice and gel system to treat established gingival bleeding.

Method:
IRB and informed consent were obtained, and adults with gingivitis were recruited for two randomized controlled trials. These RCTs, which were conducted at a single clinical site with a single clinical examiner, had one group randomly assigned to daily oral hygiene with a 2-step system. These subjects used a 0.454% stannous fluoride dentifrice and 3% H2O2 gel (Crest® Pro-Health® [HD]™ Procter & Gamble), which was dispensed blind to treatment in a kit with a regular soft brush and instructions for twice-daily at-home use. Gingival bleeding was measured clinically at baseline and end-of-treatment by a single treatment-blinded examiner using the Gingival Bleeding Index (GBI) to quantify number of bleeding sites (BS). The inclusive analysis used regression analysis to assess relationships between baseline severity and response.

Results:
The analysis had a diverse population (N=65) assigned to the paste/gel sequence (age 18–64 years, 57% female). At baseline, the BS mean was 49.7, ranging from less than 20 BS to more than 130. After use of the paste/gel sequence, mean BS was 23.4 at end-of-treatment, which represented a significant (p<0.0001) 53% reduction in gingival bleeding. The overwhelming majority (98%) of subjects showed improvement from baseline. Baseline severity and response were highly positively correlated (r=0.90). Use of the stannous fluoride plus hydrogen peroxide sequence was well-tolerated, and adverse events were generally unremarkable.

Conclusion:
Integrated analysis of two randomized controlled trials showed greater than 50% reductions in gingival bleeding following short-term use of a two-step 0.454% SnF2 then 3.0% H2O2 paste and gel sequence, with responses positively correlated with baseline severity.

Objective:
This parallel, randomized, controlled, examiner-blind clinical trial compared the safety and effectiveness of combination oral hygiene (electric brush, sequential stannous fluoride plus hydrogen peroxide paste, floss) or dental prophylaxis on clinical gingivitis.

Method:
52 adults were evaluated for gingivitis, and enrolled subjects were randomly assigned to one of two interventions: combination hygiene (CH) or professional care plus routine hygiene (PC). Gingivitis was measured by Loe-Silness Gingivitis Index. Test products were dispensed in blinded kits. The CH group received 0.454% SnF2 toothpaste plus 3% H2O2 gel sequence (Crest® ProHealth [HD]) together with an electric brush with Bluetooth connectivity (Oral-B® ProfessionalCare SmartSeries 5000 with Bluetooth/Oral-B CrossAction® brush head) and floss (Oral-B® Glide® Pro-Health Clinical Protection floss), while the PC group received a thorough dental prophylaxis plus a regular anticavity paste and manual brush. Daily treatment was unsupervised at-home, and subjects were evaluated biweekly over 6-weeks to assess change in gingivitis bleeding sites.

Results:
The CH group had significant (p<0.01) increasing improvement in gingivitis bleeding beginning at Week 2 and continuing through Week 6, resulting in 84% of subjects with no bleeding at Week 6, while the PC group exhibited significant (p<0.01) bleeding reductions at Week 2 that declined thereafter, resulting in 0% of subjects with no bleeding at Week 6. In the CH group adjusted bleeding site means were 3.1, 1.1 & 0.2 at Weeks 2, 4 & 6, respectively, while in contrast, PC showed biweekly adjusted bleeding site means of 6.9, 7.5 & 9.9. Groups differed significantly (p=0.0001) beginning at Week 2 and continuing throughout the study. Both treatments were well-tolerated.

Conclusion:
Use of a combination daily oral hygiene regimen involving an electric brush, floss plus a therapeutic paste resulted in significant (p<0.01) improvements in gingivitis and bleeding relative to dental prophylaxis and routine hygiene.

Anti-Plaque Effects of a SnF₂ Dentifrice Relative to Marketed Controls

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Abstract

Objective:
This clinical study evaluated the anti-plaque efficacy of an experimental 0.454% stannous fluoride dentifrice relative to marketed positive and negative controls using a 4-day plaque model.

Method:
This was a controlled, double-blind, randomized, 3-treatment, 3-period, cross-over 4-day partial brushing plaque study. A total of 36 subjects were randomly assigned to a treatment sequence and in each period tested one of three test products: an experimental 0.454% stannous fluoride dentifrice, a 0.454% stannous fluoride dentifrice (Crest Pro-Health®), and a negative control (Colgate Cavity Protection®). Subjects received a dental prophylaxis prior to study initiation. Each study period took place over a span of 4 days. Treatment periods were separated by a washout period of at least 7 days. In each treatment period, baseline visit involved a plaque examination using the Turesky modification of Quigley Hein plaque index (TMQHPI) followed by a dental polishing. Subjects then used the product assigned in their sequences twice daily for 4 days. Subjects brushed their lingual surfaces for 30 seconds. After expectoration, each brushing was immediately followed by swishing with the dentifrice slurry for 60 seconds. Clinical examinations were conducted 4 days post treatment. Plaque scores were analyzed using a general linear model. Statistical comparisons relative to the experimental dentifrice were two-sided using a 5% level of significance.

Results:
Both the 0.454% stannous fluoride dentifrices provided statistically significant plaque benefit when compared to the negative control (p<0.0001). The experimental stannous fluoride dentifrice did not differ significantly relative to the Crest Pro-Health® dentifrice with respect to whole mouth plaque reduction (p=0.75).

Conclusion:
This research demonstrated the effectiveness of the 0.454% stannous fluoride dentifrices in the control of dental plaque. All test products were well tolerated.

Materials and Methods

This randomized, double-blind, controlled clinical study evaluated the anti-plaque efficacy of an experimental 0.454% SnF₂ dentifrice relative to a positive and a negative control.
Anti-calculus Efficacy of a SnF2 Dentifrice in a Three-month Clinical Study

Jeffrey Milleman,* Tao He, Mary Kay Anastasia

Objective:
The objective of the study was to assess the calculus prevention benefit of an experimental 0.454% Stannous Fluoride (SnF2) dentifrice relative to a negative control dentifrice.

Method:
This was a 3-month, parallel-group, double-blind, randomized and controlled clinical trial in which the 0.454% experimental SnF2 dentifrice was compared to a negative control dentifrice (Colgate Cavity Protection®). Subjects received a dental prophylaxis and then entered a 2-month run-in phase. At the end of the 2 months, subjects received Volpe Manhold Index (V-MI) calculus examination. Qualified subjects who formed a minimum of 9mm of calculus on the lingual surfaces of the six mandibular anterior teeth were re-prophied and randomly assigned to one of the two treatments. Subjects brushed with their assigned product twice daily using a standard manual toothbrush, one minute each time, over the 3-month duration. Safety and efficacy measurements were taken via OST and V-MI exams at Baseline, Week 6 and Month 3. Treatment groups were compared using the analysis of covariance method. All statistical tests were two-sided with a 5% level of significance.

Results:
Of the 80 subjects who were randomized to treatment, 78 completed the study. Treatment groups were balanced with demographic variables and Baseline calculus scores (p>0.2). The calculus score for the SnF2 dentifrice group was significantly lower than that of the control group (p=0.05 at Week 6, p<0.01 at Month 3). Both test products were well tolerated.

Conclusion:
The research demonstrated superior anti-calculus efficacy of the SnF2 dentifrice relative to the negative control dentifrice in this 3-month clinical trial.

Concurrent Sensitivity and Gingivitis Effects of SnF2/H2O2 Hygiene: Inclusive Meta-Analysis

Robert Gerlach,* Paul Sagel

Objective:
An inclusive meta-analysis compared health effects of sequential stannous fluoride plus hydrogen peroxide oral hygiene to a positive control in adults with dentinal hypersensitivity and moderate-to-severe gingivitis.

Method:
All subject-level sensitivity and gingivitis data from 4 randomized controlled trials were analyzed. In each trial, subjects with dentinal hypersensitivity were randomly assigned to one of two whitening groups: 0.454% SnF2 toothpaste plus 3% H2O2 gel sequence (Crest® ProHealth [HD]) or 5% KNO3 plus NaF dentifrice (Sensodyne® Extra Whitening), which served as the positive control. Test products were over-labeled and dispensed blinded to treatment for at-home use. Safety and effectiveness measures were collected at baseline and end-of-treatment (1 or 2 weeks). Sensitivity was measured after direct test site stimulation using evaporative (1-sec cool air) and/or tactile (10-50 gm) techniques, and quantified using a 4-point scale (Schiff), force in gm (Yeaple), and a 9-point comfort/discomfort scale. Whole mouth gingivitis was measured clinically with a 4-point (LSGI) gingivitis or 3-point bleeding (GBI) index to quantify number of bleeding sites.

Results:
A total of 241 subjects (119 & 122 in sequence & control) were included in the meta-analysis. The diverse population, 18-68 years & 60% female, had concurrent air sensitivity plus a mean (SD) 69.7 (25.1) bleeding sites. Relative to baseline, both groups exhibited significant (p<0.0001) reductions in sensitivity across stimuli and methods, with groups differing on Schiff air, tactile probing force and discomfort (p<0.05) favoring the sequence. End-of-treatment bleeding site means (SE) were 23.0 (1.5) and 57.4 (1.4) in the sequence and control groups, respectively, and like sensitivity, groups differed significantly (p<0.001). Adverse events were uncommon and did not contribute to dropout.

Conclusion:
A novel stannous fluoride plus hydrogen peroxide hygiene sequence had concurrent sensitivity and gingivitis benefits, including ~20-60% improvements in health in head-to-head testing versus the potassium nitrate control.

CPC Uptake into Oral Plaque Biofilm Correlates to Antibacterial Efficacy

Yanhui Zhang,* Franklin Garcia-Godoy, Colette Stewart, Qian Zheng, Rachelle Eusebio, Deepa Khambe, Malgorzata Klukowska, Donald White, Marianne Zsiska

Objective:
The efficacy of antimicrobials on plaque biofilm reduction relies on the uptake and retention of the antimicrobial into the plaque biofilm. Cetylpyridinium chloride (CPC) mouthrinses reduce plaque and gingivitis effectively. This study aims to evaluate the efficacy of CPC rinses on acid reduction and compare the efficacy to the delivery of CPC into oral plaque biofilm.

Method:
In this study 20 qualified PGRM panelists were treated with CPC-containing mouthrinses in a single-blind, two-treatment, and four-period longitudinal design. NaF dentifrice (Crest Cavity Protection, Procter and Gamble) were used as acclimation product throughout the trial. Tested products: I. 0.750% CPC anti-gingivitis rinse (Colgate Total, Colgate Palmolive, CT) and II. 0.070% CPC antigingivitis rinse (Crest Pro Health, Procter and Gamble, CPH). On treatment days, subjects visited the clinic prior to hygiene/breakfast, had baseline plaque sampled and rinsed with 20mL assigned treatment for 30 seconds. Plaque samples were again collected 30 minutes after rinsing. Plaque samples were vortexed, normalized for biomass and analyzed for glycolysis inhibition using the Plaque Glycolysis and Regrowth Method (PGRM) (J Clin Dent 6:59, 1995; FDA 21CFR Part 356 Vol. 68:103, May 29, 2003) and CPC-content using tandem mass spectrometric (LC/MS/MS) detection methods.

Results:
Glycolysis inhibition I. CT: a= 0.39, II. CPH: b = 0.69; Biofilm uptake (ng CPC/mL biofilm dispersion) I. CT: c=1187.64, II. CPH: d = 1803.99 (a≠b, c≠d, p<0.05 Student’s test).

Conclusion:
CPC-uptake into plaque biofilm correlates with antimicrobial efficacy (p<0.0001) suggests that uptake of antimicrobial into the biofilm matrix contributes to antimicrobial response. The 700ppm CPC rinse (CPH) is significantly superior to the 750 ppm CPC rinse (CT) due to the bioavailability of CPC.

Abstract

Dentifrices today are formulated with multiple ingredient combinations broadening fluoride decay preventive benefits to other important patient needs including for example gingival health. Innovation in these multibenefit dentifrices requires maintenance of core anticaries benefits. Confirmation of this is accomplished through profile laboratory testing.

Objective:
The pH cycling caries lesion progression model developed by Featherstone et al. has been validated as a screening method to confirm anticaries performance of fluoridated dentifrices (Caries Res 1987;21:502-512). This study evaluated the anticaries performance of three newly formulated Crest Pro Health stannous fluoride dentifrices containing a modified chelation stabilization system in comparison to USP standard control dentifrices in vitro.

Method:
Testing followed the protocol described in Am J Dent 2011;24:322-328. Crowns of human molars (5 groups, 10 teeth/group) were subjected to 14 days of alternating demineralization (6hr, pH 4.4, Ca/P/acetate) and remineralization (17 hr, pH 7, Ca/P) with dentifrice treatment (1:3 slurry in DDW) 2x daily for 1 minute each (before and after the demin period). Dentifrices (silica abrasive/1100 ppm F as SnF2) tested included: A: SnF2 I; B: SnF2 II; C: SnF2 III; D: USP reference standard SnF2; E: USP ref standard 1/10 dilution negative control. Following pH cycling enamel crowns were cross sectioned and evaluated by cross sectioned microhardness and mineral loss calculated as $\Delta Z \times \Delta m$.

Results:
Mean (SD) $\Delta Z$ values measured: A:270(495)a; B:512(245)a; C:648(587)a; D:198(256)a; E:2653(756)b with a<b (p<0.05) Tukeys multiple comparison t test.

Conclusion:
The anticaries efficacy of a newly formulated Crest Pro Health multibenefit SnF2 dentifrices match that of USP clinical standard and superior to low dose negative control. The test dentifrices passed the half rule establishing equivalence.

Results

![Graph showing pH Cycling Caries Lesion Progression Model]

Conclusions

The anticaries efficacy of newly formulated Crest Pro Health multibenefit SnF2 dentifrices match that of USP clinical standard and are superior to low dose negative control. The test dentifrices passed the half rule establishing equivalence.
Abstract

Objective:
This meta-analysis was conducted to evaluate oral safety of an experimental 0.454% SnF2 dentifrice relative to a positive control.

Method:
Data from 10 clinical studies with 412 healthy adult subjects were included in the analysis. Of those, 4 were parallel studies 5 or 6 weeks in duration (long-term) and 6 were crossover studies with each period < 1 week (short-term). In each parallel study, subjects were randomized to either the experimental 0.454% SnF2 test dentifrice or a marketed 0.454% SnF2 positive control dentifrice. In the crossover studies, subjects were randomized to the order they received the treatments. Oral soft and hard tissue safety was assessed via clinical examination or voluntary reports. Proportion of subjects with adverse events (AE) was summarized by study and treatment. Treatments were compared using generalized linear mixed model.

Results:
Study population exhibited diversity in demographics, behaviors, and oral health. Of the 298 subjects that tested the test dentifrice, 32 (10.7%) had ≥ 1 AE. Of the 273 subjects that tested the positive control, 65 (23.8%) had ≥ 1 AE. Desquamation was the most frequent AE. In the long-term studies, the percent of subjects with ≥ 1 desquamation was 2% [95% CI of (0%, 7%)] in the test group and 18% [95% CI of (11%, 26%)] in the control group. In the short-term studies, the percent of subjects with ≥ 1 desquamation was 4% [95% CI of (2%, 8%)] in the test group and 13% [95% CI of (8%, 19%)] in the control group. The test group had significantly (p≤0.0014) lower occurrence of desquamation than the positive control. Other findings were less common, and no subject discontinued use due to a treatment-related AE.

Conclusion:
This meta-analysis demonstrated that an experimental 0.454% SnF2 dentifrice was generally well-tolerated with mild transient desquamation representing the most common finding.

Materials and Methods

10 Clinical Studies were included that tested both the experimental 0.454% SnF2 dentifrice and a marketed 0.454% SnF2 positive control dentifrice
- Four long term (> 1 week) parallel studies.
- Six short term (< 1 week) crossover studies.

- Included examiner-observed and subject-reported desquamation events;
- The proportion of subjects with at least one desquamation adverse event was calculated along with 95% CI for each treatment;
- Generalized linear mixed model was used to calculate the odds ratio and test for differences between the treatment groups.

Conclusions

This meta-analysis demonstrated that an experimental 0.454% SnF2 dentifrice was generally well-tolerated with mild transient desquamation representing the most common finding.
Objective:
This meta-analysis was conducted to evaluate the safety of an experimental 0.454% SnF₂ dentifrice relative to a negative control.

Method:
Seven randomized, controlled clinical trials were included in the analysis. One hundred-eighty subjects participated in two 12-week, long-term, parallel clinical studies, and 156 subjects participated in five short-term crossover studies with treatment periods < 1 week in duration. In each parallel study, subjects were randomized to either the experimental 0.454% SnF₂ dentifrice (test group) or a 0.76% Na monofluorophosphate dentifrice (Colgate® Cavity Protection, negative control) for daily use. In each crossover study, subjects were randomized to a sequence in which they received both products. Oral tissue safety was assessed via clinical examination or voluntary reports. Proportion of subjects with adverse events (AEs) was summarized by study and treatment. Treatments were compared using generalized linear mixed model.

Results:
Subjects age ranged from 18 to 84 years, and diverse ethnicity was represented. Of the 243 subjects that tested the test dentifrice, 10 subjects (4.1%) had ≥ 1 AE. Of the 235 subjects that tested the negative control, 6 subjects (2.6%) had ≥ 1 AE. Desquamation was the most frequent AE. In the short-term studies, the percent of subjects with ≥ 1 desquamation was 5% [95% CI of (2%, 9%)] in the test group and 4% [95% CI of (2%, 9%)] in the negative control. The two treatments did not differ significantly from each other with respect to occurrence of desquamation (p = 0.5429). No AEs were reported or observed in the long-term studies. All AEs were mild in nature, and no subjects discontinued use due to a treatment-related AE.

Conclusion:
In this meta-analysis of clinical trials up to 12 weeks in duration, the oral tissue safety profile of the experimental 0.454% SnF₂ dentifrice was comparable to that of a regular cavity protection dentifrice.
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