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International Association for Dental Research

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Placebo-Controlled Clinical Trial of 0.07% CPC Rinse on Induced Gingivitis

J.J. WITT1, R.D. GIBB1, A.D. LOGUE1, R.W. GERLACH1, and L. ARCHILA2, 1The Procter and Gamble Company, Mason, OH, USA, 2University of Texas - San Antonio / Health Science Ctr, USA

Objective: A placebo-controlled clinical trial was conducted to evaluate use of a 0.07% cetylpyridinium chloride rinse on induced (experimental) gingivitis. Methods: After 21-days of supervised oral hygiene and prophylaxis, 57 healthy adults were randomized to one of two groups: 0.07% cetylpyridinium chloride rinse (Crest® Pro-Health™ Night) or placebo. Normal oral hygiene was suspended for 21-days of gingivitis induction, during which, subjects rinsed twice daily for 30-seconds with 20 mL of the assigned rinse. After completion of the 21-day gingivitis induction phase, a prophylaxis was administered and oral hygiene restored, and subjects were monitored through resolution. Clinical response was measured using the modified Papillary Bleeding Index at Day -21, 0 and 21. Results: Mean (SD) age was 30.2 (10.2), and 74% of subjects were female. All completed the 21-day induced gingivitis period and were included in the analysis. Relative to pretreatment, both groups experienced significant (p<0.001) improvement during the initial hygiene phase, as evidenced by 40%+ reductions in mean PBI. Compared to baseline (post-hygiene Day 0), the placebo group was the only one to exhibit a significant increase in PBI (p=0.006). The 0.07% CPC did not differ (p>0.37) from baseline PBI after 21 days without oral hygiene. At Day 21, adjusted mean (SE) PBI was 1.02 (0.05) in the 0.07% CPC group compared to 1.24 (0.05) in placebo, with groups differing significantly (p=0.005). Conclusion: In a 21-day induced gingivitis study, twice daily use of a 0.07% cetylpyridinium chloride rinse prevented significant gingivitis onset relative to baseline and reduced gingivitis relative to placebo control.

The Oral-Malodor Reduction Efficacy of a 0.454% Stannous Fluoride Dentifrice

Y. ZHANG1, X. CHEN2, X. FENG2, L. SUN1, X. LI1, and T. HE1, 1The Procter and Gamble Co., Mason, OH, USA & Beijing, China, 2Shanghai Jiao Tong University, Shanghai, China

Objective: To compare the oral malodor protection efficacy of a 0.454% stannous fluoride dentifrice versus a negative control (0.243% sodium fluoride) using Halimeter as the measurement. Methods: This is a 4 treatment, 5 periods, examiner-blinded, cross-over and randomized study design. Healthy subjects who met the entrance criteria were enrolled into the study. After baseline halimeter measurement, subjects were randomly assigned to one of the four treatments (SnF2 dentifrice groups, with or without tongue brushing; negative control dentifrice groups, with or without tongue brushing) based on baseline halimeter scores, age, and gender. Test products were used three times a day. Breath measurement was taken 24 hours after baseline the next day morning, followed by a product treatment. Final breath measurement was taken four hours post-treatment that was 28 hours after baseline. Results: Thirty-three subjects were enrolled and completed the study. The adjusted mean volatile sulfur compound (VSC) levels were significantly lower in the SnF2 groups than the NaF groups, at both 24 (p<0.01) and 28 (p<0.001) hours post baseline time points. Tongue brushing did not provide additional statistically significant breath benefits when compared to toothbrushing alone. Both dentifrices were well tolerated. Conclusions: The present study demonstrated the safety and effectiveness of the 0.454% stannous fluoride dentifrice in malodor control relative to a negative control.
ABSTRACT

Objective: A randomized, examiner-blind clinical trial was conducted to evaluate the 7-day clinical effectiveness and tolerability of two self-directed, hydrogen peroxide whitening systems.

Methods: 30 healthy adults without hypersensitivity were randomized to one of two marketed whitening systems. Subjects received either a full supply of Aquafresh® White Trays™ (TRAY) or one-half supply of Crest® Whitestrips® Classic (½STRIP) for the 7-day study. Subjects were provided with labeled usage instructions, and both arches were treated at-home and unsupervised. Clinical response was measured from digital images (CIELAB), examination and interview at baseline and end-of-treatment using standard methods.

Results: Mean age was 44 years, with 67% female. Groups were balanced (p > 0.42) on pertinent demographic and behavioral parameters and starting L*a*b* tooth color. Relative to baseline, both the TRAY and ½STRIP group experienced significant (p < 0.004) reduction in yellowness (Δb∗) and increased brightness (ΔL*). On the maxillary arch, adjusted mean Δb∗ (SE) was –1.1 (0.15) for each group, while adjusted mean ΔL* (SE) was 1.0 (0.20) for each group. For the mandibular arch, adjusted mean Δb∗ (SE) was –0.6 (0.16) for the TRAY group and –1.0 (0.16) for the ½STRIP group, while adjusted mean ΔL* (SE) was 0.7 (0.16) for the TRAY group and 1.0 (0.16) for the ½STRIP group. Groups did not differ significantly with respect to tooth color (Table 3).

RESULTS

In Table 1, the mean age was 44 years, with 67% female. Groups were well balanced (p > 0.42) for demographics and starting L*a*b* tooth color.

Table 1: Demographic and Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>½STRIP</th>
<th>TRAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Age: Mean (Std Dev)</td>
<td>43.1 (10.52)</td>
<td>43.8 (8.12)</td>
</tr>
<tr>
<td>Number of Females (%)</td>
<td>11 (73%)</td>
<td>9 (60%)</td>
</tr>
</tbody>
</table>

Table 2: Safety Results

<table>
<thead>
<tr>
<th></th>
<th>½STRIP</th>
<th>TRAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported Tooth sensitivity</td>
<td>13%</td>
<td>27%</td>
</tr>
<tr>
<td>Reported Oral Irritation</td>
<td>33%</td>
<td>40%</td>
</tr>
<tr>
<td>Treatment -Related AE Dropouts</td>
<td>0%</td>
<td>7%</td>
</tr>
</tbody>
</table>

CONCLUSION

In head-to-head testing, use of one-half of a standard box of 6% hydrogen peroxide whitening strips yielded similar whitening with fewer adverse events compared to a 7-day at-home, hydrogen peroxide tray system.
Objectives: This research compared a 32-site partial mouth plaque grading to the conventional 168-site whole mouth method.

Methods: A trained plaque examiner assessed whole mouth plaque levels from 100 healthy dentate adults with medication-induced xerostomia. Whole mouth disclosed plaque was assessed using a 6-point categorical scale (MQH), the Turesky modification of the Quigley Hein index. Partial mouth grading scores collected from the facial anterior sites (visible sites) were compared to whole mouth (all sites) scores. Intra-class correlations (ICC) and 95% lower confidence bounds (LCB) were calculated using a 0-to-1 scale, where 0 represented no agreement and 1 represented perfect agreement.

Results: The study population ranged in age from 20-86 years, and exhibited considerable diversity with respect to gender and ethnicity. All data were included in the analysis. There was considerable variation in individual MQH plaque, with subject mean scores ranging from 1.6 – 4.3 for all sites, compared to 1.4 – 4.8 for visible sites. Mean (SD) MQH plaque scores were 3.26 (0.56) at all sites and 3.20 (0.64) at visible sites, and did not differ significantly. Subject MQH scores (all versus visible) were highly correlated at the subject-level, with Pearson correlation coefficient of \( r = 0.751 \) (p<0.001). The ICC was 0.743, with a 95% LCB of 0.659.

Conclusion: Data from a large cross-sectional study showed that visible plaque, i.e., plaque formed on the facial surfaces of the anterior teeth, provides an efficient, (requiring only 32 graded sites versus 168 whole mouth) and reliable, (intraclass correlation = 0.743, estimate of whole mouth plaque.

ABSTRACT

OBJECTIVE

Objective: This research compared a 32-site partial mouth plaque grading to the conventional 168-site whole mouth method.

METHODS

Methods: A trained plaque examiner assessed whole mouth plaque levels from 100 healthy dentate adults with medication-induced xerostomia. Whole mouth disclosed plaque was assessed using a 6-point categorical scale (MQH), the Turesky modification of the Quigley Hein index. Partial mouth grading scores collected from the facial anterior sites (visible sites) were compared to whole mouth (all sites) scores. Intra-class correlations (ICC) and 95% lower confidence bounds (LCB) were calculated using a 0-to-1 scale, where 0 represented no agreement and 1 represented perfect agreement.

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RCT Comparing Natural Stain Removal of Two Whitening Dentifrices

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1P&G (Technical Centres Ltd.), Rusham Park, Egham, UK; 2P&G, Mason, OH, USA; 3University of Texas Health Science Center at San Antonio, TX, USA

ABSTRACT

Objectives: A randomized controlled clinical trial was conducted to evaluate the clinical effectiveness of two whitening dentifrices on natural tooth stain removal.

Methods: 30 generally healthy adults with visible extrinsic facial stain on 6 anterior teeth were randomly assigned to a standard manual toothbrush and one of two whitening dentifrices. Subjects received either an experimental anti-cavity whitening dentifrice or a marketed control (Crest® Vivid White) for unsupervised twice daily brushing.

Stain area and intensity were measured using a standard index (Lobene) at baseline and after 14 days treatment.

Results: Mean (SD) age was 45.4 (13.0) years, with females comprising 67% of the study population. One subject in the control was lost to follow-up. All other subjects completed the 14-day study and were included in the analysis. The population presented with appreciable stain at baseline, with composite stain mean (SD) of 2.27 (0.37) and 2.35 (0.82) in the experimental and control groups respectively. Groups were balanced on pertinent demographic and behavioral parameters and baseline stain (p=0.43). Both groups exhibited significant (p < 0.0001) stain reduction relative to baseline at day 14. At the end of treatment, median composite stain removal was 84% in the experimental group and 83% in the control group.

Conclusion: In a randomized controlled clinical trial, 14 days use of an experimental anti-cavity whitening dentifrice removed appreciable natural extrinsic tooth stain.

MATERIALS AND METHODS

This was a parallel group, examiner-blinded clinical trial measuring extrinsic stain removal. A total of 30 generally healthy volunteers, between the ages of 23 and 68 years of age, exhibiting a mean modified Lobene score of ≥ 1.0 on the facial surfaces of at least 6 anterior teeth were enrolled and completed the trial. Subjects were stratified according to baseline Lobene composite scores and gender. Within strata, subjects were randomized to one of the two treatment groups.

Fourteen subjects were assigned to the Experimental dentifrice treatment and sixteen were assigned to Crest Vivid White (previously established as providing stain removal benefit not significantly different from Sonicare Advance 4100 toothbrush with Crest Cavity Protection dentifrice). All subjects were told to discontinue the use of all other oral hygiene products, and asked to brush twice daily with the assigned treatments for two minutes each in front of a mirror.

Efficacy was measured using the modified Lobene Index, and safety was assessed from clinical examination and subjects’ reports at the Baseline and Day 14 visits. For Lobene stain scores, comparisons to baseline for each treatment group were performed using paired-difference t-tests. Analysis of covariance was used for between group comparisons of the modified Lobene score using Baseline scores as a covariate. All statistical comparisons were two-sided with a 5% significance level.

RESULTS

Efficacy:

Each treatment group exhibited statistically significant (p < 0.001) Lobene area, intensity, and composite stain reduction from baseline. Median % reductions of the composite score were 84% for the experimental dentifrice group and 83% for the Crest Vivid White group.

Adjusted means and standard errors for Lobene Composite whole tooth stain removal were –1.85 ± 0.072 and –1.89 ± 0.069, for the experimental dentifrice and Crest Vivid White, respectively. The adjusted means were not statistically different(p > 0.69) at Day 14 from each other.

Safety: The examiner observed one subject in the Experimental Dentifrice group with two adverse events (mouth ulcerations). No subjects discontinued product use due to a treatment-related adverse event.

CONCLUSION

In a randomized controlled clinical trial, 14 days use of an experimental anti-cavity whitening dentifrice removed appreciable natural extrinsic tooth stain.
Vital tooth bleaching is administered in a variety of forms including trays, strips and paint on high concentration treatments. The concentrations and conditions of bleaching vary considerably between these treatment forms. **Objective:** This study applied an accelerated exposure model to evaluate tooth surface reactivity of a novel bleaching gel containing hydrogen peroxide and sodium pyrophosphate. **Methods:** Bovine molars were cross sectioned and blocks were mounted in Durabase acrylic with final polishing on gamma alumina. Blocks were pre-measured for surface microhardness (Buehler - Vickers diamond 200 g load) and surface roughness (Taylor Hobson stylus profilometer). Specimens were allocated to one of 4 treatment groups (N=4): non treated control (stored humid at 37°C); and three groups which were exposed to treatments in 4 – 2 hour cycling blocks with pooled saliva immersion in between: toothpaste treated control (25 % Crest® Regular flavor paste/water slurry placed on surface fresh for 4 consecutive 30 min. periods); Crest Whitestrips® Daily Multicare™ strips – applied directly on the enamel surface for 4 consecutive 30 min. periods; experimental H2O2 + pyrophosphate bleaching strip applied directly on the tooth surface for 4 consecutive 30 min. periods; Post treatment (8 hour exposure) teeth were compared for final surface microhardness and also surface roughness. **Results:** Treatment groups showed nsd in hardness or roughness at baseline. Post treatment VHN: NonTreat=320±17a; PasteOnly=320±1a; DayStrip=287±2b; H2O2/PyroStrip=309±5ab. Post treatment surface roughness: NonTreat=0.076±0.031a; PasteOnly=0.074±0.040a; DayStrip=0.117±0.013a; H2O2/PyroStrip=0.098±0.009a. a ≠ b p<0.05 Students. **Conclusions:** An accelerated exposure model permitted the rapid assessment of bleach strip reactivity with enamel surfaces. Bleaches proven passive to dental enamel in chronic (realistic) cycling (Daystrip at 2 years use) produced a good dynamic range for test comparisons (small hardness decrease and roughness increase). A H2O2/PyroStrip was found to be equivalent to standard day-strip in effects on surface hardness and roughness in vitro.

**INTRODUCTION**

Forms of OTC bleaching from Crest® Whitestrips™ include shorter duration daily use products such as Crest Whitestrips® Daily Multicare™. The hard tissue safety of both regular Whitestrips and daily Whitestrips has been established in chronic testing regimens simulating clinical exposures and including both surface and subsurface histomorphological measures. The assessment of bleach safety may at this point be qualified with more simplified surface focused acute treatment regimens using clinically established standards as controls.

**PURPOSE**

Characterize the response of human enamel following a period of laboratory bleaching treatments using an experimental bleaching strip containing H2O2 tooth whitener combined with sodium pyrophosphate in an acute testing protocol.
Vital tooth bleaching is administered in a variety of forms including trays, strips and paint on high concentration treatments. The concentrations and conditions of bleaching vary considerably between these application forms. **Objective:** This study compared physical and micromorphological surface changes associated with exposure of human dentin specimens to a cycle of chronic bleaching with hydrogen peroxide bleaching strips designed for daily application in vitro. **Methods:** Extracted human canines were used to prepare root dentin blocks in Durabase acrylic with final polishing 12 µm grit aluminum oxide for a smear layer. Blocks were pre-measured for surface microhardness (Vickers 200 g). Bleach-cycled teeth were bleached with 6.0 % hydrogen peroxide bleaching strips (Crest Whitestrips® Daily Multicare™) 4x/day for a total of 720 treatment cycles. The bleached group also received bid daily treatment with Crest Regular dentifrice as a 25 % slurry for 5 minutes per day which was followed by a brief surface brushing under tap water. A cycled-control group received dentifrice treatments only while a third group was saved as a non treated control. Following 720 exposures teeth were compared for final surface microhardness and also surface roughness measured with Taylor Hobson stylus profilometer. **Results:** VHN measurements for dentin at T=720 treatments: Bleach = 57±4ab; Cycle/Control = 56±2b; Untreated = 60±4a (a ≠ b p<0.05 Students t). Surface roughness T=720: Bleach = 0.041±0.004a; Cycle/Control = 0.048±0.006b; Untreated = 0.055±0.023 (a ≠ b p<0.05 Students t). Profilometry did not reveal any smear layer etching. **Conclusions:** Dentin surface microhardness and roughness were not significantly changed following simulation of 2 years daily bleaching as compared to non-bleach cycled and untreated specimens. The cycling protocol resulted in slight smoothing of dentin surfaces as compared to non-cycled and non-treated controls – likely due to smear layer polishing from paste abrasives.
ABSTRACT

Objective: A clinical study was conducted to evaluate day time and overnight oral malodor reduction benefit of a 0.454% SnF₂ therapeutic dentifrice with short-term and long-term use.

Methods: The study was a randomized, double-blinded, two-treatment, 3-period cross-over clinical trial. After completing an acclimation period, 45 subjects with existing oral malodor were randomly assigned to a cross-over treatment sequence consisting of 0.454% SnF₂ Crest® Pro-Health™ dentifrice (SnF₂ dentifrice) and Crest® Cavity Protection dentifrice (control). For each treatment period, subjects brushed with the assigned product twice a day for 7 days. Oral malodor was assessed on a 9-point hedonic scale at Baseline, Day 2 - overnight, Day 2 – daytime (4 hours post morning brushing), Day 8 - overnight, Day 8 - daytime (4 hours post morning brushing). Treatment periods were separated by wash-out periods during which subjects brushed with the control dentifrice.

Results: Subjects had a mean age of 39 years, 58% of the subjects were female and the mean Baseline hedonic score was 7.4. Relative to a control dentifrice, use of the SnF₂ were significant reductions in short-term and long-term daytime and overnight oral malodor effects of 0.454% SnF₂ therapeutic dentifrice, respectively. The mean daytime hedonic scores ranged from 3.3 to 9.0. Hedonic values did not differ significantly between treatments at Baseline with means (SE) of 7.25 (0.17) and 7.56 (0.17) for the SnF₂ and control dentifrice, respectively. Forty-five subjects with existing oral malodor completed a 7-day acclimation phase during which they brushed twice daily with a regular dentifrice (Crest Cavity Protection). At the beginning of the treatment phase subjects were randomly assigned to a 3-period cross-over treatment sequence consisting of 0.454% SnF₂ therapeutic dentifrice and a control dentifrice. Subjects were instructed to brush with the assigned product 1 minute, twice a day for 7 days. Each treatment period consisted of the Baseline, Day 2 - overnight, Day 2 – daytime (4 hours post morning brushing), Day 8 - overnight, Day 8 – daytime (4 hours post morning brushing) breath evaluations. Subjects were instructed to abstain from oral hygiene, eating, and drinking prior to the overnight breath assessments at Baseline, Day 2 and Day 8. Oral malodor was evaluated on a 9-point hedonic scale, product safety was assessed via subject interviews and oral soft tissue examinations. Treatment groups were compared at each visit using a general linear mixed model, and all comparisons were two-sided with a 5% significance level. The carryover effect was not statistically significant for each visit.

Conclusion: The use of the 0.454% SnF₂ dentifrice resulted in significant reduction in short-term and long-term daytime and overnight malodor relative to a control dentifrice.

MATERIALS AND METHODS

Methods: This was a randomized, double-blinded, two-treatment, cross-over clinical trial that consisted of the acclimation phase and three treatment periods separated by wash-out periods (Figure 1).

RESULTS

Table 1. Mean (SE) overnight hedonic scores

<table>
<thead>
<tr>
<th></th>
<th>Day 2</th>
<th>Day 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>SnF₂ dentifrice</td>
<td>2.78 (0.28)</td>
<td>3.15 (0.29)</td>
</tr>
<tr>
<td>Control dentifrice</td>
<td>4.34 (0.29)</td>
<td>5.13 (0.30)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt; 0.001</td>
<td>&lt; 0.002</td>
</tr>
</tbody>
</table>

Table 2. Mean (SE) daytime hedonic scores

<table>
<thead>
<tr>
<th></th>
<th>Day 2</th>
<th>Day 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>SnF₂ dentifrice</td>
<td>2.44 (0.23)</td>
<td>2.41 (0.29)</td>
</tr>
<tr>
<td>Control dentifrice</td>
<td>3.38 (0.24)</td>
<td>4.12 (0.29)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt; 0.002</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Both products were well-tolerated.

PURPOSE

Objective: To evaluate short-term and long-term daytime and overnight oral malodor effects of 0.454% SnF₂ therapeutic dentifrice relative to a control.

CONCLUSION

The use of the 0.454% SnF₂ dentifrice resulted in significant reduction in short-term and long-term daytime and overnight malodor relative to a control dentifrice.
ABSTRACT

Objective: The objective of the study was to evaluate the anti-gingivitis effect of a rechargeable power toothbrush relative to a manual toothbrush using a gingivitis treatment model.

Methods: This was a randomized, single blind, single center, two-leg, three-month controlled clinical study. One hundred and forty three healthy adult subjects with gingivitis were enrolled into the study. Baseline visit involved clinical examination using Mazza gingival index, an inflammation and bleeding combined index. Subjects were then randomly assigned to one of the two treatment groups: a rechargeable power toothbrush that features an oscillating/rotating/pulsating action (Oral-B ProfessionalCare® 7000) and a manual toothbrush (Lion Dentor Systema®). The power toothbrush was used following manufacturer’s usage instruction (2 minutes, twice daily). Subjects used the manual toothbrush as they would normally do (1 minute, twice daily). All subjects used the same regular anti-cavity toothpaste. Clinical gingivitis examination was repeated at month 1, 2, and 3 post baseline visit. ANCOVA was used to compare the change of Mazza GI score from baseline between two groups with baseline as covariate. All comparisons were conducted at two-sided 95% confidence level.

Results: Baseline gingivitis scores were balanced between the two treatment groups. The power toothbrush provided statistically significantly greater gingivitis reduction relative to the manual toothbrush as early as month 1 (p<0.01). Similar treatment difference in favor of the power toothbrush was observed at month 2 (p<0.01) and month 3 (p<0.01).

Conclusion: The research demonstrated the superior anti-gingivitis effect for the power versus the manual toothbrush. Both treatment groups were well tolerated in the study.

INTRODUCTION

Regular use of toothbrush is effective in removing plaque and prevent the onset of periodontal diseases. The most recent Cochrane review suggested that only the rotating/oscillating toothbrush consistently provided superior clinical plaque and gingivitis benefits when compared to manual toothbrushes. The present study was designed to assess the anti-gingivitis effect of a rechargeable power toothbrush relative to a manual toothbrush using a gingivitis treatment model.

MATERIALS AND METHODS

Study Design: This is a controlled, parallel group, 3-month gingivitis treatment study. Institution review and informed consent were obtained prior to study initiation. A total of 143 healthy adult subjects with gingivitis were randomly assigned to the treatments.

Clinical examinations (BL, Month 1, 2, and 3):
Mazza Gingival Index - Inflammation and bleeding combined index

Product usage:
Twice daily home use following manufacturer’s usage instruction (2min/each time – power brush)
All subjects used the same regular anti-cavity toothpaste

Statistical analysis:
Analysis of covariance (ANCOVA) with treatment as a factor and baseline MGI score as the covariate was used to assess treatment differences. The comparisons were two sided at 0.05 significance level.

RESULTS

1. Demographics:
Age, gender, and smoking were well balanced between the two groups.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>BASELINE MEAN (SD)</th>
<th>ADJUSTED MEAN CHANGE FROM BASELINE (SE)</th>
<th>TREATMENT DIFFERENCE</th>
<th>TWO-SIDED P-VALUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASELINE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POWER BRUSH</td>
<td>63</td>
<td>1.79 (0.32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MANUAL BRUSH</td>
<td>59</td>
<td>1.78 (0.30)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MONTH1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POWER BRUSH</td>
<td>56</td>
<td>1.80 (0.32)</td>
<td>-0.35 (0.03)</td>
<td>-0.11</td>
<td>0.0009</td>
</tr>
<tr>
<td>MANUAL BRUSH</td>
<td>57</td>
<td>1.80 (0.29)</td>
<td>-0.24 (0.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MONTH2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POWER BRUSH</td>
<td>61</td>
<td>1.79 (0.32)</td>
<td>-0.42 (0.03)</td>
<td>-0.15</td>
<td>0.0003</td>
</tr>
<tr>
<td>MANUAL BRUSH</td>
<td>53</td>
<td>1.79 (0.31)</td>
<td>-0.27 (0.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MONTH3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POWER BRUSH</td>
<td>57</td>
<td>1.81 (0.31)</td>
<td>-0.48 (0.03)</td>
<td>-0.12</td>
<td>0.0010</td>
</tr>
<tr>
<td>MANUAL BRUSH</td>
<td>55</td>
<td>1.80 (0.29)</td>
<td>-0.36 (0.03)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Treatment Comparisons
- BL gingivitis scores were balanced between the groups.
- The power toothbrush provided superior anti-gingivitis benefit compared to the manual toothbrush at all visits.
- Analysis of covariance – adjusting for baseline gingivitis scores were well balanced between the two groups.

CONCLUSION

The rotating/oscillating Oral-B power toothbrush is more effective than a manual toothbrush with respect to improving gingival health.

Both toothbrushes are safe to use.
**0176 Changes in Transcriptome Profile During Experimental Gingivitis Induction and Resolution**


**Objective:** We conducted a 28 day experimental gingivitis model using stents to explore the changes in gingival gene expression profiles. **Methods:** At baseline (Day-0) 15 healthy subjects were given two posterior sextant acrylic stents to be worn during tooth brushing to promote plaque overgrowth during the 28 day gingivitis induction period. Patients were followed weekly and at Day-28, stents were discontinued, subjects received prophylaxis and oral hygiene was re-established. Interproximal tissue biopsies were collected at Day-0, Day-28 and at resolution Day-35 for mRNA extraction and transcriptome analyses by Affymetrix array (U133 Plus 2.0, ~54500 probe sets). Exploratory analyses were performed (p<0.05) on 40 arrays to examine time-dependent changes as well as gene-symptom associations. **Results:** We found a significant change in gene expression of 4108 genes comparing Day-0 to Day-28, which was greater than the chance alone expected finding of 2731 probe sets at Ą=0.05. At Day 28, 88 genes were up-regulated by >1.5-fold and 27 by>2.0 fold. Several gene pathways demonstrated significant changes during induction that were reversed by treatment by Day-35. These include pathways associated with inflammation, oxidative stress, T-cell activation and wound repair that involved most cellular compartments including epithelial cells, vascular cells, fibroblasts and immunocytes. Pathway analyses consistently indicate the temporal modulation of chemokines especially CCL4, 5 and CxCL2, 3, 8, 10, 11, as well as increases in Interleukin-1-alpha and beta. Neutrophil recruitment and activation appeared to dominate over TLR-4/LPS activation processes. The TLR-7 receptor was the major Toll-like receptor that was upregulated. The neutrophil neurogenic inflammatory protein prokineticin-2 was upregulated 4.6 fold at p=0.006. **Conclusion:** In experimental gingivitis the gene expression profile suggests a dominant chemokine and neutrophil-mediated response that may include bacterial nucleic acid activation of neurogenic pathways, rather than LPS-TLR-4/2 processes. Supported by Procter and Gamble and RR-00046.

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**0288 Clinical Study Evaluating 0.454% Stannous Fluoride Dentifrice on Established Gingivitis**

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**Objective:** A double-blind, randomized controlled 3-month clinical trial was conducted to evaluate the effects of a 0.454% stannous fluoride sodium hexametaphosphate dentifrice on established gingivitis. **Methods:** Adults with mild gingivitis were randomized to a therapeutic dentifrice with 0.454% stannous fluoride sodium hexametaphosphate dentifrice (Crest® ProHealth™) or a negative dentifrice control (Crest® Cavity Protection). No prophylaxis was administered in this treatment study, subjects were simply dispensed assigned test products, and instructed on at-home unsupervised brushing. Efficacy was measured at baseline and Month 3 via a whole mouth clinical gingivitis index (Loe-Silness), while safety was assessed from examination and interview. **Results:** A total of 70 subjects (35 per group) were evaluated at Month 3. That population averaged 31 years of age, mean (SD) gingivitis scores were 0.27 (0.13), and groups were balanced with respect to demographics and gingivitis scores. At Month 3, the 0.454% stannous fluoride group had experienced a 54% reduction in gingivitis, and a 56% reduction in bleeding, differing significantly (p<0.001) from baseline on each endpoint. Between-group comparisons showed a 24% reduction in bleeding and a 23% reduction in gingivitis, with the 0.454% stannous fluoride dentifrice differing significantly (p<0.001) from baseline on each endpoint. Between-group comparisons showed a 24% reduction in bleeding and a 23% reduction in gingivitis, with the 0.454% stannous fluoride dentifrice differing significantly from the negative control. Adverse events were limited to mild oral irritation (both groups), with no early “for cause” dropouts. **Conclusion:** In a general population, 3-month use of 0.454% stannous fluoride sodium hexametaphosphate dentifrice for the treatment of gingivitis resulted in 23-24% reductions in gingivitis and bleeding relative to a regular dentifrice control.
0541
Dietary and Other Caries Risk Factors Associated with Psychiatric Medications

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Objectives: The purpose of this study is to evaluate caries increments in a psychiatric subgroup of participants taking known xerogenic medications and to examine the associated dietary and other risk factors. Methods: A single calibrated examiner determined caries at the baseline visit and at a 9 month follow-up visit on 684 Boston-area volunteers aged 40-80 taking a xerogenic medication with demonstrated salivary hypofunction. The psychiatric subgroup (n= 173) had a mean unstimulated salivary flow = 0.056ml/min, a mean age of 60, 65% female, 89.6% Caucasian, 59% under $35,000 and mean of 24 teeth. Caries increments were determined by changes from sound to carious, sound to filled, and filled to recurrent. Reversals were subtracted as decrements. A modified Block food frequency questionnaire was administered. Results: The mean annualized increment was 0.947± 2.910. Using a stepwise logistic regression model that controlled for baseline caries, consumption of sugar (p ≤ 0.038), smoking (p ≤ 0.009) and psychiatric medications use (p ≤ 0.003), were all significantly associated with caries incidence. Number of teeth, flossing, brushing, dental visits and income were also included in the model and found not to be significant. The types of the sugar consumed by volunteers on psychiatric medications and other medications were compared using an 2-tailed independent t-test. The total sugar intake of the psychiatric patients was significantly higher (p ≤. 020). These participants also consumed significantly more liquid sugar (p≤.024) and solid sugar (p≤.025). Semi-solid sugars, sticky sugar, slowly-dissolving sugar consumption was not found to be significantly different. Conclusion: Elderly volunteers taking psychiatric medications are at increased risk for developing dental caries despite good hygiene habits and regular dental visits. Their increased risk for caries may be explained partially by an increased consumption of sugar to soothe dry mouth and increased smoking. Longer longitudinal studies are necessary to establish a relationship. (Funded by Procter and Gamble)

1020
Clinical Comparison of Dissolving and Non-dissolving Marketed Whitening Strips

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Objective: This randomized, examiner-blinded, parallel design clinical trial compared efficacy of two marketed whitening strips. Methods: 55 subjects were randomly assigned to one of two whitening treatments: Listerine Whitening® Quick Dissolving Strips worn twice a day until completely dissolved for 14 days (dissolving strips) or Crest® Whitestrips® Premium Plus containing 10% hydrogen peroxide and worn 30 min twice a day for 10 days (non-dissolving strips). Whitening efficacy was measured objectively from CIELAB digital measurements at Baseline, Day 8, Day 11 and Day 15, and product safety was assessed via subject interviews and oral examination conducted at each visit. Whitening response was compared at each visit and at the end-of-treatment (Day 15 for the dissolving strips vs. Day 11 for the non-dissolving strips) using the analysis of covariance method. Results: The study participants ranged in age from 19 to 71, and 64% of subjects were female. The two groups were well-balanced with respect to the Baseline tooth color. At each study visit, the non-dissolving strip group demonstrated significantly greater tooth color improvement (p < 0.0006) relative to the dissolving strip group. At the end-of-treatment, use of dissolving strips resulted in adjusted means of -1.35 for ∆b* and 0.95 for ∆L*, while the use of non-dissolving strips resulted in adjusted means of -2.12 for ∆b* and 1.72 for ∆L* with treatment differences being highly significant (p < 0.0005). In addition, the non-dissolving strip group demonstrated significantly greater (p < 0.02) tooth color improvement (both ∆b* and ∆L*) at Day 8 compared to the dissolving strip group at day 15. No adverse events were reported in any of the treatment groups. Conclusion: Use of the 10% hydrogen peroxide non-dissolving strips resulted in significantly greater tooth whitening relative to that of the dissolving whitening strips.
1021 Relative Efficacy of Two Marketed Hydrogen Peroxide Whitening Strips

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Objective: Efficacy of two marketed hydrogen peroxide whitening strip regimens was compared in this randomized, examiner-blinded clinical trial. Methods: A total of 57 healthy adult volunteers were randomized to one of the two treatments: Listerine Whitening® Quick Dissolving Strips (LWQD strip) or 6% hydrogen peroxide Crest® Whitestrips® (control strips). Both products were used twice daily for 14 days per manufacturer’s instructions: LWQD were worn until completely dissolved and the control strips were worn for 30 min per application. Efficacy was measured objectively as L*a*b* color change using digital images of the maxillary anterior teeth at Baseline, Day 8, and Day 15. Results: The average age of study participants was 42.1 and 63% were females. At Day 8, adjusted mean (SE) $\Delta b^*$ was -0.82 (0.12) for the LWQD strip and -1.32 (0.12) for the control strip while adjusted mean (SE) $\Delta L^*$ was 0.97 (0.14) and 1.75 (0.14) for the LWQD and the control strips, respectively. At the end-of-treatment at Day 15, adjusted mean (SE) $\Delta b^*$ was -1.50 (0.17) for the LWQD strip and -2.03 (0.16) for the control strip. For $\Delta L^*$, end-of-treatment, adjusted means (SE) were 1.33 (0.20) for the LWQD strip compared to 2.06 (0.18) for the control strip. Groups differed significantly for both $\Delta b^*$ and $\Delta L^*$ at the end-of-treatment (p < 0.03) and at Day 8 (p < 0.005) favoring the control strip. No product-related adverse events were reported. Conclusion: Use of the 6% hydrogen peroxide control strip provided superior whitening versus a dissolving hydrogen peroxide whitening strip.

1022 Clinical Evaluation of Dissolving Whitening Strips and a Marked Control

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Objective: This randomized, parallel, single-blinded clinical research was conducted to evaluate the efficacy and safety of new dissolving whitening strips relative to a positive control. Methods: Seventy subjects were enrolled in the study and randomly assigned to one of the two treatments: Listerine Whitening® Quick Dissolving Strips worn twice daily until dissolved for 14 days (14-day strips) or 10% H$_2$O$_2$ Crest® Whitestrips® Premium Plus worn 30 min twice daily for 10 days (10-day control strips). Digital images of maxillary teeth were taken at Baseline, Days 11 and 15. Efficacy was assessed as L*a*b* color change using digital images of the maxillary anterior teeth at each visit. Results: Subjects ranged from 18 to 83 years of age, 71% were females. Both groups were balanced with respect to Baseline tooth color (p > 0.7). Both strip groups demonstrated significant (p < 0.0001) color improvement for yellowness ($\Delta b^*$) and lightness/brightness ($\Delta L^*$) relative to Baseline. At each visit, use of the 10-day control strip resulted in significantly (p < 0.02) greater improvement of $\Delta b^*$ and $\Delta L^*$ compared to that of the 14-day strips. The end-of-treatment comparisons (Day 11 for the 10-day control strips vs. Day 15 for the 14-day strips) also showed significantly (p < 0.0005) greater whitening by the 10-day strips. The end-of-treatment adjusted $\Delta b^*$ means ± standard errors were -1.49 ± 0.14 and -2.21 ± 0.14 for the 14-day and the 10-day strips, respectively. The adjusted $\Delta L^*$ means ± standard errors were 1.12 ± 0.14 and 1.96 ± 0.14 for the 14-day and the 10-day regimen, respectively. Both products were well-tolerated. Conclusion: Use of the 10% H$_2$O$_2$ marketed control whitening strips resulted in a greater tooth color improvement compared to that of the new dissolving whitening strips.
Tooth whitening treatments in the United States include OTC strips. **Objectives:** This study compared subsurface and surface ultrastructure of human enamel and dentin exposed to a cycle of chronic bleaching with hydrogen peroxide bleaching strips (designed for daily application) in vitro. **Methods:** Enamel and dentin blocks were sectioned from extracted teeth and mounted in Durabase acrylic with 12 µm alumina polish (for a smear layer) on dentin and gamma alumina (0.30 µm alumina) on enamel. Teeth were bleached with 6.0 % hydrogen peroxide bleaching strips 4x/day for a total of 720 treatment cycles with Crest Whitestrips® Daily MulticareTM bleaching strips. Bleach and a non-bleach control groups received bid cycled treatment with Crest® Regular dentifrice as a 25% paste/water slurry for 5 minutes/day and between treatments specimens were stored in pooled human saliva. A third group of specimens was saved as a non-treated control. Following cycling, specimens from all three groups were selected for surface analysis or cross sectioned with a diamond saw for transverse evaluation of tooth ultrastructural changes. CLSM measures were carried out using a Leica TCS SP2 confocal laser scanning microscope with a He/Ne laser in reflection mode. **Results:** CLSM technique provides non-destructive in-depth imaging by recording series of consecutive images in tissues, which enables three dimensional visualizations of bleached dentin and enamel. CLSM observations revealed no etching or wear processes on enamel or dentin surfaces undergoing bleach treatments. Subsurface ultrastructure visualized below surfaces and on sectioned specimens revealed normal enamel prismatic and dentin tubular ultrastructure. **Conclusions:** The treatment regimen simulated over two years exposure to day-strips bleaching. CLSM analysis including histomorphological assessments of surface and subsurface enamel and dentin show that chronic bleaching with a day-strip did not influence tooth structure.
1401 Comparative Clinical Trial with a Paste, Power Brush & Rinse

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Objectives: A clinical study was conducted to evaluate the combination use of a therapeutic dentifrice and rinse plus power brush on plaque accumulation. Methods: Healthy adults with evidence of overnight plaque accumulation were randomly assigned to a combination paste-rinse-brush group or control. Subjects received either the combination treatment with 0.454% stannous fluoride sodium hexametaphosphate dentifrice (Crest Pro-Health Night), a rotating-oscillating powered brush (Oral-B Vitality Precision Clean), and 0.07% cetylpyridinium chloride rinse Crest Pro-Health Night), or a regular brush + paste control, with use at-home and unsupervised. Digital plaque image analysis was used to objectively measure fluorescein-disclosed prebrush (overnight) and postbrush plaque area on the anterior facial tooth surfaces after two and four weeks. Results: 37 subjects with a mean (SD) age of 36.1 (12.8) were enrolled, and 36 were analyzed at each post-baseline visit. Groups were balanced (p > 0.45) on baseline plaque, with mean (SD) prebrush scores ranging from 15.6-16.2%. Relative to the control, the combination group exhibited 71% and 67% reductions in overnight plaque at Week 2 and 4, respectively, and 59% reduction in post-brushing plaque scores. Treatments differed significantly (p<0.0005) throughout the study for overnight and post-brushing plaque, favoring the combination group. Treatments were generally well-tolerated, with one subject experiencing mild oral irritation in the combination group. Conclusion: Use of the combination stannous fluoride dentifrice, power brush and rinse yielded an average 69% reduction in overnight plaque relative to the control.

1513 Changes in Oral Health Status in Volunteers on Psychiatric Medications

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Objectives: The purpose of this study is to compare changes in oral health status over a 9 month period in a group taking psychiatric medications (P) to a group (NP) taking known xerogenic medications and to examine the associated risk factors. Methods: Calibrated examiners recorded dental caries and periodontal status at baseline and at a 9 month follow-up visit on 653 Boston area volunteers, aged 40-80, who were taking at least one xerogenic or psychiatric medication, with demonstrated salivary hypofunction. Periodontal and caries increments, dental care, oral hygiene habits and smoking were factored in. A binary logistic regression model was used for statistical analysis. Results: The P group (n=173) had a mean unstimulated salivary flow of 0.056ml/min, a mean age of 60, 65% female, 89.6% Caucasian, 59% under $35,000 and mean of 24 teeth, whereas the NP group(n=480) had a mean unstimulated salivary flow of 0.067ml/min, mean number of 23 teeth, was 55% female, 86% Caucasian with a mean age of 67, 54% under $35,000 and a significantly higher SS (1.62 vs. 1.37 (p ≤ 0.007) and less perceived dryness (p ≤ 0.0001). The NP had a significantly higher increase in attachment loss (NP 1.76± 0.696 vs. P 1.59±0.674 (p ≤ 0.043) and recession (NP 0.519±0.389 vs. P 0.400 ± 0.323, ≤ 0.006) than the P group. The mean annualized caries increment for the P group was 0.947±2.910 vs. NP 0.4472±1.385 (p ≤ 0.009). The number of medications was higher in the P group 4.5 vs. 3.1 (p ≤ 0.0001). The number of teeth at baseline was higher in the P group, 24 vs. 23 (p ≤ 0.010) in the NP group, yet the increment in missing surfaces was significantly higher (p ≤ 0.006). Conclusion: People taking psychiatric medications are at significantly higher risk for developing dental caries and losing teeth, despite acceptable oral hygiene habits and regular dental visits. The use of multiple psychiatric medications may induce even greater deleterious effects on teeth. Longitudinal studies are needed to confirm the effects of xerogenic medications. (Funded by Procter and Gamble)
**2048**

**Daily Repeatability of Post-Brushing Disclosed Plaque Measurement**

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**Objective:** This research evaluated after-brushing disclosed plaque measurement reproducibility. **Methods:** After training, a plaque examiner assessed plaque levels from 50 healthy dentate adults over a two-day period. On Day 1, subjects presented with overnight plaque, and then brushed for 30-seconds using a regular anticavity dentifrice and manual brush. Whole mouth disclosed plaque was assessed using a 6-point categorical scale (MQH), the Turesky modification of the Quigley Hein index. This process was repeated on Day 2. Intra-class correlations (ICC) and 95% lower confidence bounds (LCB) were calculated using a 0-to-1 scale, where 0 represented no agreement and 1 represented perfect agreement. **Results:** All 50 subjects attended both visits, and all data were included in the analysis. Age ranged from 18-71 years, with females comprising the majority (68%) of study subjects. There was considerable variation in postbrush MQH plaque. Day 1 scores ranged from 1.0-3.94, while Day 2 ranged from 0.64-3.50. MQH means (SD) were 2.19 (0.59) and 2.03 (0.70) at Day 1 and Day 2, respectively. Postbrush MQH scores were well correlated (0.791) across visits (p<0.0001). The ICC was 0.761, with a 95% LCB of 0.631. **Conclusion:** Use of a standard whole mouth plaque index yielded highly reproducible 30-second post-brushing disclosed plaque scores.

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**2049**

**Clinical Effectiveness of Timed Morning Brushing on MQH Plaque**

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**Objectives:** This research was conducted to assess the effects of timed morning brushing on the removal of overnight disclosed plaque. **Methods:** A total of 88 generally healthy adults were enrolled in the study. After evening brushing, subjects were instructed to abstain from further oral hygiene until the next day evaluation. Disclosed plaque accumulation was assessed on a 6-point categorical scale using the Modified Quigley Hein (MQH) method. Subjects were provided a regular anticavity dentifrice (Crest® Cavity Protection) and standard manual toothbrush, and brushed under supervision for 30 seconds, after which, MQH plaque was assessed. Prebrush and postbrush plaque scores were compared using a paired difference t-test. **Results:** Mean (SD) age was 34.7 (13.3) years. 70% of participants were female. The population exhibited a considerable range in overnight MQH plaque, with scores ranging from 0.6-4.0. Mean (SD) prebrush MQH plaque was 1.95 (0.62). With one exception, individual MQH scores were lower after brushing, ranging from 0.6 - 2.8. Mean (SD) postbrush MQH plaque was 1.4 (0.4), differing significantly (p<0.0001) from prebrush scores. Treatment was well-tolerated. **Conclusion:** Timed, 30-second morning brushing with a manual toothbrush and regular toothpaste reduced mean overnight MQH plaque scores by approximately 28%.
Use of Digital Plaque Image Analysis for Morning Brushing Effectiveness

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Objectives: Digital plaque image analysis was used to instrumentally assess the effectiveness of morning brushing on overnight plaque accumulation. Methods: After IRB approval and informed consent, 37 generally healthy adults abstained from eating, drinking, tooth brushing or other oral hygiene overnight prior to morning (AM) evaluation. Subjects rinsed with 5 mL of a 1240 ppm fluorescein rinse and expectorated. Immediately thereafter, cheek retractors were inserted, and a single digital image was collected under standardized lighting conditions. Subjects were provided a regular anticavity dentifrice (Crest® Cavity Protection) and standard manual toothbrush for routine whole mouth oral hygiene, after which, rinsing and imaging were repeated. Image analysis was used to objectively measure fluorescein-disclosed prebrush (overnight) and postbrush plaque area on the anterior facial tooth surfaces. Prebrush and postbrush plaque areas were compared using a paired differences t-test. Results: The study population ranged from 19-62 years of age, with females comprising 76% of participants. Prior to brushing, overnight plaque ranged from 4.3-37.9% of tooth surfaces. Mean (SD) overnight plaque area was 15.9% (8.6). All subjects removed some plaque with brushing, with postbrushing area ranging from 2.2-22.0%. Mean (SD) postbrushing area was 7.9 (4.9), differing significantly (p<0.0001) from prebrush area. Most (57%) left more than 50% of plaque after brushing, and none removed all plaque. Conclusion: Morning brushing with a manual toothbrush and regular toothpaste is only partially effective, with digital plaque image analysis demonstrating approximately 50% of overnight anterior facial dental plaque remaining after brushing.

1H NMR-Based Metabonomic Analysis of Human Saliva

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Objectives: Here, we have focused on saliva and explored this technique's ability to predict the oral health status (OHS) of humans and probe the therapeutic efficacies (TEs) of oral health care products (OHCPs). Methods: A panel of 40 volunteers were placed on a standardised oral hygiene regimen (NaF-containing toothpaste [1]) for a 5-week period to establish baseline salivary metabolite concentrations. This panel was then divided into 2 x 20 volunteer intervention treatment legs: the first of these received dentifrice [2] (utilised during weeks 6-8), whilst the second was maintained on dentifrice [1] for the same period (participants were blinded with regard to product identities). The panel then returned to product [1] for weeks 9 and 10. 5 daily a.m. ‘wake-up’ saliva specimens were collected during each week, and oral soft tissue examinations were performed during weeks 5 and 10. NMR spectra were acquired on a 400 MHz spectrometer, and multivariate analysis of NMR data was conducted by a supervised pattern recognition technique. Results: Multivariate analysis of data acquired revealed that the 1H NMR profiles of saliva specimens provided a valuable means of predicting the OHS scores of participants (correlation between observed and predicted values, r = 0.8144): propionate, n-butyrate and trimethylamine concentrations were key determinants of OHS. Moreover, the technique could clearly distinguish between the TEs of the products tested, and also detect deviations from the study protocol. Conclusions: 1H NMR-based metabonomic analysis of human saliva provides a powerful index of OHS and serves as a cost-effective and reliable means of evaluating the TEs of OHCPs in clinical trials. [1] and [2]: Crest Decay Prevention and Crest Pro-Health toothpastes respectively, The Procter and Gamble Company, USA.
Extracellular Polymeric Substance (EPS), excreted by biofilm bacteria, constitutes the glue that holds a biofilm together and moreover protects biofilm organisms against antimicrobial attacks. Interference in EPS production would therefore be a valuable tool in preventing dental plaque formation. **Objectives:** The aim of this study is to assess effects of a stannous fluoride dentifrice on EPS production in vivo. **Methods:** Eight volunteers carried out standard oral hygiene with Crest® Regular dentifrice to establish a treatment and washout baseline (2 weeks) and then continued hygiene using Crest® Pro-Health™ (stannous fluoride - hexametaphosphate) dentifrice. After one week application, the entire dentition was sampled for plaque after refraining from all oral hygiene during 24h. Plaque was dispersed by sonication and immediately analyzed after BacLight live/dead staining and EPS was quantified using a phenol-sulfuric acid reaction according to Dubois. **Results:** During use of a standard dentifrice, the amount of EPS produced per mouth (430±248µg/mouth) as well as per biofilm bacterium (156±85x10⁻⁹µg/bacterium) was significantly (p<0.01, Student t-test) higher than during the use of a stannous fluoride containing dentifrice (163±56µg/mouth and 67±30x10⁻⁹µg/bacterium, respectively). **Conclusions:** Stannous fluoride dentifrice is effective in reducing bacterial EPS production in dental plaque.

**Objective:** A pilot clinical trial was conducted to evaluate the clinical response of 0.454% stannous fluoride dentifrice used during routine crown and bridge treatment. **Methods:** After informed consent, healthy adults undergoing crown and bridge treatment at the dental school were randomized to a therapeutic dentifrice or normal oral hygiene, which served as the untreated control. Test products were distributed blind to treatment at the preparation visit, with subjects receiving either 0.454% stannous fluoride sodium hexametaphosphate (Crest® Pro-Health™) or control. Subjects were instructed to brush normally (unsupervised) at least twice daily. Gingivitis and bleeding were measured at the preparation, impression and cementation visits using a standard clinical index (Loe-Silness). Treatments were compared using non-parametric ANCOVA. **Results:** 33 subjects with common gingivitis evaluators at all time points were included the analysis. Groups were balanced (p>0.33) on gingivitis and bleeding at baseline. At both the impression and cementation visits, the stannous fluoride dentifrice group had lower observed gingivitis and bleeding scores than control. In the crown preparation region, median gingivitis scores were 0.00 in the stannous fluoride group compared to 0.26 in the control, resulting significantly lower gingivitis (p<0.01) and bleeding (p<0.05) with the therapeutic dentifrice at the impression visit. Outcomes were directionally similar at cementation, with median gingivitis scores of 0.11 in the stannous fluoride group and 0.33 in control. Treatment was generally well-tolerated. **Conclusion:** This pilot study supports use of 0.454% stannous fluoride dentifrice to reduce gingivitis and bleeding during crown and bridge treatment.
**Oral Malodor Reduction with 3-week Use of 0.454% SnF₂ Dentifrice**

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**Objective:** This clinical study evaluated the effects of the 3-week use of a 0.454% SnF₂ therapeutic dentifrice on oral malodor. **Methods:** The study was a randomized, double-blinded, two-treatment, parallel design clinical trial. After completing an acclimation period, 71 subjects with existing oral malodor were randomized to one of the two treatments: 0.454% SnF₂ Crest® Pro-Health™ dentifrice (SnF₂ dentifrice) or Crest® Cavity Protection dentifrice (control). Subjects brushed with the assigned product twice a day for 3 weeks. Oral malodor was assessed on a 9-point hedonic scale at Baseline, Week 1 and Week 3. **Results:** The mean age of study participants was 37.8 and 59% were female. The baseline mean hedonic score was 8.19. At Week 1, the mean hedonic scores (SE) were 3.40 (0.18) and 6.62 (0.18) for the SnF₂ dentifrice and the control dentifrice, respectively. At Week 3, the mean hedonic scores (SE) were 1.55 (0.18) and 5.28 (0.18) for the SnF₂ dentifrice and the control dentifrice, respectively. Relative to the control, the use of the SnF₂ dentifrice resulted in significantly (p < 0.0001) greater reduction in oral malodor at both visits. Both treatments were well-tolerated. **Conclusion:** Three-week use of the 0.454% SnF₂ dentifrice resulted in sustained significant improvement in oral malodor relative to a control dentifrice.

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**1H NMR Investigations of Diurnal Metabolic Variations in Human Saliva**

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High-resolution 1H nuclear magnetic resonance (NMR) analysis serves as a powerful means of probing the metabolic status of human saliva. **Objectives:** Since the excretion of selected metabolites in this biofluid serve as ‘markers’ of microbial activity and soft-tissue inflammation, we employed this technique to track diurnal modifications in the salivary composition of a group of subjects using a pre-allocated dentifrice. **Methods:** Non-medically-compromised subjects (n = 10) were provided with a NaF-containing toothpaste [1] and were permitted to brush as usual (2 x daily) for 2 weeks in order to establish ‘baseline’ salivary metabolic data. During weeks 3 and 4, each subject supplied saliva specimens at 5 daily time-points (0, 30, 120, 360 and 600 min. post-brushing) on 3 separate days. The time 0 (pre-brush) sample was collected immediately following a.m. ‘wake-up’ and prior to performance of oral activities. 1H NMR measurements were made on a Bruker Avance AX-600 spectrometer. Statistical analysis of salivary concentration data was conducted by ANOVA. **Results:** Significant time-dependent trends were observed in the concentrations of selected salivary biomolecules: i.e. lactate and acetate serving as markers of caries, propionate, n- and iso-butyrates as indicators of periodontal disease, and malodorous di- and trimethylamines associated with halitosis. Indeed, all of these metabolites had elevated salivary levels in the a.m. pre-brushing samples (p << 0.05) and, with the exception of lactate, significantly lower and relatively constant concentrations at each subsequent diurnal time-point (plots of lactate level versus time-point revealed diurnal ‘spikes’). **Conclusions:** Multicomponent 1H NMR analysis of salivary biomolecules provides much valuable information regarding the diurnal variation of metabolic markers of oral disease activity. Results acquired revealed that overnight periods represent a significant challenge to oral health (despite previous night-time hygeine measures), and therefore products specifically designed for long-term, overnight action may provide unique oral healthcare advantages. [1] Crest Decay Prevention toothpaste, The Procter and Gamble Company, USA.
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