American Association for Dental Research
March 19-22, 2014
Charlotte, North Carolina, USA

Schedule of Presentations
Research Supported by Procter & Gamble
### Thursday, March 20

<table>
<thead>
<tr>
<th>Abstract Number and Title</th>
<th>Presenter</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whitening Strip Safety and Effectiveness: Application Time and Duration Effects (Oral Presentation, Room 207BC)</td>
<td>R.W. Gerlach</td>
<td>8:00–9:30 am</td>
</tr>
<tr>
<td>Randomized Controlled Trial Comparing Marketed Whitening Products: Strips and Wraps</td>
<td>N. Gurich</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Randomized Clinical Trial Evaluating Flexible and Stretchable Tooth Whitening Strips</td>
<td>P.A. Sagel</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Placebo-Controlled Clinical Trial Evaluating High-Adhesion 10% H₂O₂ Whitening Strips</td>
<td>S. Nachnani</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Clinical Comparison of Flexible/Stretchable Whitening Strips and Laser Treatment</td>
<td>J.F. Simon</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Clinical Extrinsic Stain Prevention Efficacy of Two Dentifrices</td>
<td>L. Archila</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Comparative Response of Whitening Strips versus In-office Light-assisted Whitening</td>
<td>B. Magnuson</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Brush Head Retention of Powered Toothbrushes as Consumer Safety Measure</td>
<td>J. Amburgey</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>In-situ Erosion Study of a 0.454% Stannous Fluoride Dentifrice</td>
<td>T. He</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Comparison of Human and Bovine Dentin in RDA-EP Abrasivity Assessments</td>
<td>E. Schneiderman</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Breath and Plaque Prevention with Cetylpyridinium Chloride Rinses: Clinical Meta-Analysis</td>
<td>R. Cheng</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Meta-Analysis of Oral Safety with a 0.454% SnF₂ SHMP Dentifrice</td>
<td>G. Tzeghai</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Plaque Measured via Image Analysis Before and After Prophylaxis</td>
<td>N. Duque</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Reproducibility of Clinical and Self-Assessment of Air Sensitivity Response</td>
<td>E. Tzavaras</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Comparative Antimicrobial Efficacy of US Multibenefit Dentifrices In Vitro</td>
<td>E. Kincaid</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Dentinal Tubule Occlusion with Stannous Fluoride Dentifrices</td>
<td>M. Zsiska</td>
<td>3:30–4:45 pm</td>
</tr>
<tr>
<td>Comparative Antimicrobial Efficacy of Stannous Fluoride Dentifrices In Vitro</td>
<td>D.J. White</td>
<td>3:30–4:45 pm</td>
</tr>
</tbody>
</table>

### Friday, March 21

<table>
<thead>
<tr>
<th>Abstract Number and Title</th>
<th>Presenter</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Whitening Efficacy of 1-Hour Whitening Strip</td>
<td>S. Farrell</td>
<td>2:00–3:15 pm</td>
</tr>
</tbody>
</table>

*All posters will be presented in Exhibit Hall AB*
### Saturday, March 22

<table>
<thead>
<tr>
<th>ABSTRACT NUMBER AND TITLE</th>
<th>PRESENTER</th>
<th>TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1362 Antimicrobial Effects of Cetylpyridinium Chloride Mouthrinses (Oral Presentation, Room 213A)</td>
<td>Y.H. Zhang</td>
<td>8:00–9:30 am</td>
</tr>
<tr>
<td>1364 Gingivitis Imaging with L*(a)<em>b</em> Color for Dental Prophylaxis and Hygiene (Oral Presentation, Room 213A)</td>
<td>M.L. Barker</td>
<td>8:00–9:30 am</td>
</tr>
<tr>
<td>1366 Comparative Anti-gingivitis Efficacy of Oscillation-Rotation Electric Toothbrush vs. Manual Toothbrush (Oral Presentation, Room 213A)</td>
<td>M.A. Klukowska</td>
<td>8:00–9:30 am</td>
</tr>
<tr>
<td>1367 Abrasivity of Dentifrices Assessed by Contact and Non Contact Profilometry (Oral Presentation, Room 213A)</td>
<td>E.L. Colon</td>
<td>8:00–9:30 am</td>
</tr>
<tr>
<td>1518 Creating Artificial Carious Lesions: Depth as a Function of Saturation</td>
<td>A. Baig</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1519 Fluoride Retention Model: There is More Than Just Fluoride Uptake</td>
<td>K. Burkhardt</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1550 Randomized Controlled Trial of CPC Peroxide Rinse Effects on Plaque</td>
<td>M.J. Doyle</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1551 Clinical Trial of Early Effects of Combination Hygiene or Prophylaxis</td>
<td>C.E.E. Garcia-Godoy</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1553 Clinical Response to Two Stimuli by Subjects Reporting Tooth Sensitivity</td>
<td>M.L. Singh</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1555 Clinical Evaluation of Stannous Fluoride Dentifrice on Dentinal Hypersensitivity</td>
<td>S.D. Whalen</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1557 Demographic and Behavioral Effects on Stain Removal with Whitening Dentifrices</td>
<td>F.O. Ajayi</td>
<td>9:30–10:30 am</td>
</tr>
<tr>
<td>1560 Comparative Plaque Effects of Power Brush and Stannous Fluoride Paste</td>
<td>M.C. Miner</td>
<td>9:30–10:30 am</td>
</tr>
</tbody>
</table>

*All posters will be presented in Exhibit Hall AB

### Symposia Presentations by P&G Researchers

**Thursday, March 20**

<table>
<thead>
<tr>
<th>ABSTRACT NUMBER AND TITLE</th>
<th>PRESENTER</th>
<th>TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 Metabolomics of Oral Fluids (Room 217BC)</td>
<td>D.J. White</td>
<td>10:45 am–12:15 pm</td>
</tr>
</tbody>
</table>

**Friday, March 21**

<table>
<thead>
<tr>
<th>ABSTRACT NUMBER AND TITLE</th>
<th>PRESENTER</th>
<th>TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>763 Dental Research Opportunities in Industry (Room 213BC)</td>
<td>J. L. Winston</td>
<td>8:00–9:40 am</td>
</tr>
</tbody>
</table>

For more information, visit dentalcare.com
For additional FREE educational resources and tools, visit:

dentalcare.com

Over 150 FREE online CE courses on a variety of topics**
Customizable patient education in 20 languages
Case studies and other resources for students and faculty
and much more

**P&G is an ADA CERP Recognized Provider and an Approved PACE Program Provider by the Academy of General Dentistry.
Whitening Strip Safety and Effectiveness: Application Time and Duration Effects

Thursday, March 20, 2014: 8 a.m. - 9:30 a.m.
Location: 207BC (Charlotte Convention Center)

Presentation Type: Oral Session

R.W. Gerlach¹, M.K. Anastasia¹, F.A. Sagel¹, and I. Magnusson².¹Procter & Gamble Company, Mason, OH.²University of Florida, Gainesville, FL

Objective: A randomized clinical trial was conducted to evaluate application time and treatment duration effects on safety and effectiveness with high adhesiveness 10% hydrogen peroxide whitening strips.

Method: In this time ranging study, 90 adults who desired whitening were randomly assigned to one of three whitening strip groups, balancing for age and baseline tooth color. All subjects were dispensed high adhesiveness 10% hydrogen peroxide whitening strips plus a regular anti-cavity dentifrice and manual brush in blinded packaging for at-home unsupervised use. Treatments were identical except for dosage instructions, which specified once daily strip application on the maxillary arch for 30, 60 or 120 minutes (depending on group) for 14 days. Efficacy was measured objectively as L*a*b* color change from digital images after 3, 9, 11 & 15 days.

Result: Mean (SD) age was 37.4 (13.0) years, 62% were female, 7% used tobacco, and groups did not differ (p>0.42) on baseline values. After 2 strips use, each group exhibited significant (p<0.001) two-parameter whitening (ΔL* & ΔE*). The Day 3 adjusted ΔL means were -0.76, -1.23, and -1.87 in the 30, 60 and 120 minute groups, respectively. Whitening increased with continued use, and at Day 15, adjusted ΔL* means were -2.66, -3.53, and -4.12 in the 30, 60 and 120 minute groups, respectively. Groups differed significantly (p<0.05) for ΔL* at Days 3-15. The time response for ΔL* was generally similar to ΔE*. Minor and transient sensitivity on irritation were the most common adverse events, exhibiting a similar treatment response as color, except that safety findings did not generally increase after Day 9.

Conclusion: A randomized time-ranged clinical trial in a general population showed significant continuing time-dose responses for both tolerability and effectiveness, with the safety response evident through 8 strips, and the efficacy response evident through 14 strips.
Objective: This clinical study was conducted to evaluate oral safety and whitening efficacy of a 10% hydrogen-peroxide whitening strips (Crest® 3D White Whitestrips® Vivid) and the private-label whitening product (Equate 7-Day Dental Whitening System Advanced Whitening Wraps).

Methods: Seventy four adult volunteers with no prior history of tooth whitening were randomly assigned to either Crest® 3D White Whitestrips® Vivid used for 30 minutes once daily for ten consecutive days or Equate 7-Day Dental Whitening System Advanced Whitening Wraps used for 30 minutes once daily for seven consecutive days, according to manufacturers instructions. Efficacy was measured objectively as \( L^*a^*b^* \) color change using digital images of the maxillary anterior teeth at Baseline and Day 11.

Results: Seventy four healthy subjects with no prior history of tooth whitening and a mean age (SD) of 39.5 (12.7) completed the trial. At Day 11 visit, both groups demonstrated significant (p ≤ 0.0001) reduction in yellowness (\( \Delta b^* \)) and improvement in lightness (\( \Delta L^* \)) color parameters relative to Baseline. Crest® 3D White Whitestrips® Vivid showed significantly greater color improvement with the adjusted mean (SE) \( \Delta b^* \) of -1.87 (0.12) and -1.29 (0.12) for the whitening strips and wraps, respectively, and the adjusted mean (SE) \( \Delta L^* \) of 1.98 (0.14) and 1.53 (0.14) for the strips and wraps, respectively. Both products were well-tolerated.

Conclusion: This clinical research demonstrated superior whitening efficacy of Crest® 3D White Whitestrips® Vivid compared to Equate 7-Day Dental Whitening System Advanced Whitening Wraps after one kit.

MATERIALS AND METHODS

All products were allocated in blinded test kits with standard anti-cavity toothpaste and toothbrush. Tooth color (\( L^*a^*b^* \)) was measured objectively from standardized digital images of the maxillary anterior teeth. Analysis of covariance was used for color comparisons between treatments using baseline color and age as covariates. Safety was assessed from subject interview and oral examination.

Efficacy: Seventy four subjects completed the study. Mean age of subjects was 39.5, and 53% were female. At Day 11 visit, both groups demonstrated significant (p ≤ 0.0001) reduction in yellowness (\( \Delta b^* \)) and improvement in lightness (\( \Delta L^* \)) color parameters relative to Baseline. Crest 3D White Whitestrips® Vivid showed statistically significant decrease in yellowness (p ≤ 0.0009) and improvement in lightness (p = 0.026) relative to the Equate 7-Day Dental Whitening System Advanced Whitening Wraps.

TOOTH COLOR IMPROVEMENT AT DAY 11

<table>
<thead>
<tr>
<th>Product</th>
<th>Time Usage</th>
<th>n=37</th>
<th>Baseline</th>
<th>PD (Day 0)</th>
<th>Day 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strips</td>
<td>Strips – 30 minutes once a day – 10 days</td>
<td>37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wraps</td>
<td>Wraps – 30 minutes once a day – 7 days</td>
<td>37</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Safety: Mild transient tooth sensitivity was a most common adverse event in the study. No subject discontinued treatment due to an adverse event.

RESULTS

CONCLUSIONS

• This clinical research demonstrated superior whitening efficacy of Crest 3D White Whitestrips® Vivid compared to Equate 7-Day Dental Whitening System Advanced Whitening Wraps
• All test products were well-tolerated in the study, there were no adverse event-related drops.
Objective: This randomized, double-blind clinical trial compared the safety and effectiveness of flexible and stretchable 10% hydrogen peroxide whitening strips to a positive control.

Method: After informed consent and baseline, healthy adults with no tooth whitening history were randomly assigned flexible and stretchable 10% hydrogen peroxide strips or a marketed 10% hydrogen peroxide whitening strip (Crest® 3D White Whitestrips® Professional Effects) control. All strips were distributed in blinded foil pouches in a blinded test kit with a regular anticavity dentifrice and toothbrush, and instructions specifying 60 minutes QD application at-home for 14 days. Efficacy was measured objectively as $L^*a^*b^*$ color change using digital images of the maxillary anterior teeth at Baseline, Day 11, and Day 15.

Result: A total of 38 subjects with a mean (SD) age of 26.2 (9.6) years were randomized, 95% of whom completed the study. At Day 11, $\Delta b^*$ means (SD) were –2.7 (1.01) for the flexible and stretchable strip group and –2.7 (0.86) for the control. Continued use yielded additional whitening, with Day 15 $\Delta b^*$ means of –3.1 (0.92) and –3.1 (1.05) for the novel strip and control groups, respectively. Responses were similar for $\Delta L^*$, with both groups exhibiting highly significant ($p<0.0001$) whitening improvement beginning at Day 11. Adjusting for baseline, groups did not differ ($p>0.70$) on $\Delta b^*$ or $\Delta L^*$ at post-baseline timepoints. Both treatments were similarly well tolerated, with mild transient tooth sensitivity and oral irritation representing the most common adverse events.

Conclusion: In a double-blind clinical trial, use of novel, flexible and stretchable 10% hydrogen peroxide whitening strips provided significant whitening with a similar safety response to marketed whitening strip.

MATERIALS AND METHODS

A total of 38 subjects were randomized and received one of the following whitening treatment groups:

- flexible and stretchable 10% hydrogen peroxide strips used 60 minutes OD for 14 days (novel strip)
- marketed 10% hydrogen peroxide whitening strip used 60 minutes OD for 14 days (control strip)

The study population was limited to generally healthy adult volunteers with no prior bleaching history or current dentinal sensitivity. Efficacy and safety were evaluated at Baseline, Day 11, and Day 15. Tooth color ($L^*a^*b^*$) was measured objectively from standardized digital images of the maxillary anterior teeth. Analysis of covariance was used for color change comparisons between treatments using baseline color and age as covariates. Safety was assessed from clinical examination and subject report.

RESULTS

Efficacy Results: Mean age was 26.2 ranging from 19 to 56 years, and 61% of subjects were female. Groups were balanced ($p>0.3$) with respect to the Baseline tooth color and demographics. At both Day 11 and Day 15, both treatment groups provided statistically significant tooth color improvement relative to Baseline ($p<0.0001$).

Treatment Comparisons

<table>
<thead>
<tr>
<th>Treatment</th>
<th>$\Delta b^*$ (yellowness)</th>
<th>$\Delta L^*$ (lightness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 11 Control Strip</td>
<td>-2.75 (0.200)</td>
<td>2.08 (0.163)</td>
</tr>
<tr>
<td>Novel Strip</td>
<td>-2.66 (0.200)</td>
<td>2.03 (0.163)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.7538</td>
<td>0.8360</td>
</tr>
<tr>
<td>Day 15 Control Strip</td>
<td>-3.15 (0.193)</td>
<td>2.32 (0.138)</td>
</tr>
<tr>
<td>Novel Strip</td>
<td>-3.05 (0.193)</td>
<td>2.27 (0.138)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.7061</td>
<td>0.8090</td>
</tr>
</tbody>
</table>

Safety Outcomes

<table>
<thead>
<tr>
<th>Occurrence, % of subjects</th>
<th>Control Strip</th>
<th>Novel Strip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rep tooth sensitivity</td>
<td>30%</td>
<td>22%</td>
</tr>
<tr>
<td>Rep oral irritation</td>
<td>5%</td>
<td>11%</td>
</tr>
<tr>
<td>Observed oral irritation</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>AE drops</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

In a double-blind clinical trial, use of novel, flexible and stretchable 10% hydrogen peroxide whitening strips provided significant whitening with a similar safety response to marketed whitening strip.
Objective: A randomized, placebo-controlled clinical trial was conducted to assess the effectiveness and safety of high-adhesion 10% H₂O₂ tooth whitening strips.

Methods: Institutional review and informed consent were obtained, and subjects with no previous history of teeth whitening were randomly assigned to high-adhesion 10% H₂O₂ tooth whitening strips (Crest® 3D White Whitestrips® Professional Effects) or placebo strips without peroxide. Test strips plus a regular paste and brush were dispensed in blinded packaging with instructions for one hour daily use on maxillary teeth for ten consecutive days. Tooth color was measured at Baseline, Day 3 and Day 11 from intraoral digital images, and treatments were compared on two-parameter color improvement ($\Delta b^*$ and $\Delta L^*$). Safety was assessed by clinical examination and interview.

Results: Forty-one subjects with a mean age (SD) of 33.3 (14.26) completed the study. After two days of treatment (Day 3), subjects using 10% H₂O₂ strips demonstrated a statistically significant decrease in yellowness ($\Delta b^*$, $p \leq 0.0002$) and increase in lightness ($\Delta L^*$, $p<0.0001$) compared to placebo. At Day 11, the high adhesion 10% H₂O₂ group exhibited an incremental $-2.14 \Delta b^*$ and $2.29 \Delta L^*$ versus placebo, differing significantly ($p<0.0001$) from the control. Strip use was well-tolerated, 5 subjects (3 in the peroxide group 2 in the control) had minor oral irritation, and no subjects discontinued strip use due to adverse events.

Conclusion: A placebo-controlled clinical trial demonstrated that high-adhesion 10% H₂O₂ whitening strips were well-tolerated, and resulted in significant two-parameter tooth whitening after two days use.

RESULTS

Efficacy: Subjects ranged in age from 18 to 59 years with an average of 33 years. Fifty-four percent of the subjects were male. Treatment groups were balanced ($p > 0.60$) in demographic characteristics, behavioral parameters and baseline tooth color.

After 2 days of product use, the 10% peroxide strips demonstrated significant improvement of $\Delta b^*$ (yellowness) and $\Delta L^*$ (lightness) color parameters relative to both Baseline & placebo strips ($p \leq 0.0002$). The 10% peroxide group showed continual improvement through Day 11 with significant improvement relative to baseline placebo strips ($p<0.0001$).

Safety: Two subjects (10%) in the Placebo Strips group and three subjects (14%) in the Peroxide Strips group had mild oral irritation observed by the examiner. No subject in either group dropped from the study due to a treatment related adverse event.

CONCLUSIONS

A placebo-controlled clinical trial demonstrated that high-adhesion 10% H₂O₂ whitening strips were well-tolerated, and resulted in significant two-parameter tooth whitening after two days use.
Clinical Comparison of Flexible/Stretchable Whitening Strips and Laser Treatment.

Use of flexible/stretchable 10% hydrogen peroxide whitening strips for two weeks resulted in superior whitening response compared to an in-office laser-aided whitening system.

### ABSTRACT

**Objective:** A clinical trial was conducted to evaluate response of self-directed flexible/stretchable 10% hydrogen peroxide whitening strips relative to a professionally-administered, in-office laser-based whitening system.

**Methods:** Healthy adults with no previous history of vital tooth bleaching, who desired tooth whitening and provided informed consent were recruited. Enrolled subjects were randomly assigned (2:1) to either flexible/stretchable 10% hydrogen peroxide strips used 1-hour daily at-home for 14 days or a peroxide gel plus laser in-office treatment (LaserWhite20 and Epic™ 940µm Diode Laser System, Biolase, USA). Efficacy was measured objectively as L*a*b* color change from blinded digital images of the maxillary anterior teeth at Baseline and post-treatment Days 11 & 15, while safety was assessed from clinical examination and interview.

**Results:** Forty-one subjects ranged in age from 21 to 58 years old, and 76% were females. Relative to baseline, the flexible/stretchable 10% hydrogen peroxide whitening strips exhibited significant (p<0.01) improvement in both yellowness (£Δb*) and lightness (£ΔL*) at Day 11. Comparing treatments, the Day 15 adjusted Δb* and ΔL* means (SE) were –1.91 (0.16) and 2.19 (0.17) for the strip group and –0.64 (0.24) and 0.75 (0.27) for the gel+laser control, with groups differing significantly (p<0.0002) on color improvement. Mild transient tooth sensitivity and oral irritation were two most common adverse events, and these were observed and/or reported in both treatment groups.

**Conclusion:** Use of flexible/stretchable 10% hydrogen peroxide whitening strips for two weeks resulted in superior whitening response compared to an in-office laser-aided whitening system.

### MATERIALS AND METHODS

This was a randomized, two-treatment, parallel, examiner-blinded, clinical trial. Forty-two healthy adult volunteers with no history of prior bleaching and a Vita shade of A2 or darker were randomly assigned to one of the two treatment groups in a 2:1 ratio. Safety and efficacy measurements were taken at Baseline, Day 11, and Day 15. Whitening efficacy was measured via digital image analysis. Safety was assessed via subject interviews and oral exams.

### RESULTS

**Efficacy:** Mean age was 36 ranging from 21-58, and 76% of subjects were female. Groups were balanced (p > 0.5) with respect to the Baseline tooth color. At end-of-study (Day 15), both treatment groups provided statistically significant tooth color improvement relative to Baseline (p < 0.03). The strip group also demonstrated significantly greater yellowness (£Δb*) reduction and lightness (£ΔL*) improvement (p < 0.0002) relative to the gel+laser control at both visits.

**Safety:** Mild transient tooth sensitivity and oral irritation were two most common adverse events, and these were observed and/or reported in both treatment groups.

### CONCLUSIONS

Use of flexible/stretchable 10% hydrogen peroxide whitening strips for two weeks resulted in superior whitening response compared to an in-office laser-aided whitening system.

---

**Visit/Treatment** | **Adj. Mean Change from Baseline (SE)** | **2-sided p-value** | **Adj. Mean Change from Baseline (SE)** | **2-sided p-value**
---|---|---|---|---
**Day 11**
Gel+Laser Control | -0.736 (0.198) | 0.0002 | 0.249 (0.200) | <0.0001
Strip Group | -1.731 (0.142) | 1.582 (0.144) |
**Day 15**
Gel+Laser Control | -0.639 (0.240) | <0.0001 | 0.753 (0.267) | <0.0001
Strip Group | -1.907 (0.157) | 2.193 (0.174) |
Clinical Extrinsic Stain Prevention Efficacy of Two Dentifrices

T. HE1, M.L. BARKER1, M.K. ANASTASIA1, S. FARRELL1, G.TEREZHALMY2, and L. ARCHILA2
1Procter & Gamble Company, Mason, OH,
2University of Texas Health Science Center at San Antonio Dental School, San Antonio, TX,

ABSTRACT

Objective: To evaluate the extrinsic stain prevention efficacy of a pyrophosphate containing whitening dentifrice relative to a negative control.

Method: This was a 5-week treatment, parallel groups, double-blind, randomized and controlled clinical trial in which the whitening dentifrice (Crest 3 DWhite Luxe®) was compared with a negative control dentifrice (Colgate® Cavity Protection). The study model involved 2-week of stain induction followed by 5-week of treatment duration to assess the stain prevention efficacy. To induce stain, a sufficient number of subjects received a dental prophylaxis, and then began a brushing and tea rinsing regimen. Sixty healthy adults with sufficient stain accumulation enrolled into the treatment phase of the study. Following baseline examination, subjects received a dental prophylaxis and were randomly assigned to one of the two treatment groups. Subjects brushed twice daily and used tea rinsing three times a day for 5 weeks. Clinical examination by an experienced dental examiner using the Interproximal Modified Lobene (IML) stain index was conducted at BL, week 2 and 5. Analysis of covariance (ANCOVA) with treatment as a factor and Baseline Lobene score as the covariate was used to assess treatment differences. All comparisons were two-sided using a 5% level of significance.

Result: Baseline IML stain scores were balanced between the two treatment groups (p=0.57), with means of 2.89 and 2.96 for the pyrophosphate and the negative control dentifrices, respectively. At week 5, the adjusted mean IML score was 0.25 for the pyrophosphate group and 0.80 for the negative control group. The pyrophosphate containing dentifrice provided statistically significant extrinsic stain prevention efficacy after 5-week of product usage (p < 0.0001), representing 68.4% less stain accumulation relative to the negative control. All test products were well tolerated.

Conclusion: The research demonstrated the superior stain prevention efficacy of a pyrophosphate containing whitening dentifrice relative to a negative control dentifrice.

MATERIALS AND METHODS

Interproximal Modified Lobene Stain Index

The facial surfaces were divided into 4 regions as shown. Gingival & interproximal regions (mesial and distal) were defined as a band of about 2 mm wide.

RESULTS

Subjects ranged in age from 18 to 57 years with an average of 31 years. Ninety-two percent of the subjects were female. Treatment groups were balanced (p > 0.40) in demographic characteristics and baseline stain scores.

At Week 2, the Whitening dentifrice and the Negative Control exhibited adjusted means for overall surface stain of 0.06 and 0.10, respectively. The groups were not statistically different (p=0.18) at Week 2.

CONCLUSIONS

The research demonstrated the superior stain prevention efficacy of a pyrophosphate containing whitening dentifrice relative to a negative control dentifrice.
Comparative Response of Whitening Strips versus In-office Light-assisted Whitening

Thursday, March 20, 2014: 3:30 p.m. - 4:45 p.m.
Location: Exhibit Hall AB (Charlotte Convention Center)

Presentation Type: Poster Session

G. KUGEL1, R.D. PERRY2, B. MAGNUSON3, M. HANSONO3, M.K. ANASTASIA4, R.W. GERLACH2, and S. FARRELL2, 1Tufts University School of Dental Medicine, Boston, MA, 2Procter & Gamble Company, Mason, OH

Objective: The clinical study compared peroxide-based whitening with 10-day take-home whitening strips to an immediate in-office light-enhanced whitening treatment.

Methods: After institutional review and informed consent, 49 adults with no history of previous bleaching and a Vita shade of A2 or darker on maxillary anterior teeth were randomized (2:1) to at-home strips or in-office whitening treatments. The experimental group was daily 2-hour application of 10% hydrogen peroxide high-adhesion whitening strips (Cream® 3D White 2-Hour Express Whitestrips®) for at-home use over 10 days. The positive control was professional light-assisted application of a 25% hydrogen peroxide gel (Zoom® Advanced Power Chairside Whitening System) after soft tissue isolation following manufacturer’s recommendations. Efficacy was measured objectively as L* a* b* color change using digital images at Baseline and Day 11, and safety was assessed by intraoral examination and subject report.

Results: Mean (SD) age was 36.6 (11.8), 57% of subjects were female, and treatments were balanced (p>0.54) on starting tooth color. At Day 11, both groups exhibited significant (p < 0.001) color improvement from baseline. After adjusting for baseline and age, Day 11 L* a* b* means (SD) were -2.1 (0.14) for the strip group and -1.8 (0.20) for the in-office group. Groups did not differ (p > 0.22) on post-treatment L* a* b* whitening at Day 11. Tooth sensitivity and oral irritation were the most common adverse events, with the latter more common (38% of subjects) in the professional control.

Conclusion: Daily use of take-home whitening strips resulted in similar tooth whitening as a professional light-assisted whitening treatment.
Materials:

The high speed video investigation was carried out on an artificial jaw with an Oral-B Vitality electric toothbrush handle and a third party refill, which is no longer commercially available. Static pull testing was performed on Oral-B Precision Clean, Sunstar Gum and Panasonic EW-0981-W refills without a handle. A model and simulation studies were conducted on Oral-B Precision Clean refills only.

High speed video analysis:

To study the dynamics of the brush head detachment in detail the high speed video camera Phantom v12.1 by Vision Research was used at a frame rate of 500 frames-per-second with a resolution of 1280x960 pixel. The overall movement of the toothbrush can be observed and recorded on a standard video camera at 30 frames-per-second.

Static Pull Test:

Static pull testing, i.e. pulling off the brush head at various angular positions without brush head motion was carried out on a Zwick 2005 pull tester with a standard load cell. The refill was put in a groove of a base plate and fixed with a clamp positioned as close as possible to the brush head without restricting its motion. The pull speed started with 10mm/min up to a value of 0.5N pull force and was then increased to 50mm/min until the brush head came off. The maximum force during the pull process was recorded.

Modeling and Simulation:

Based on CAD data finite element models have been generated as a virtual substitute for real life tests, which is a very strong correlation to the laboratory data. The interactions between the different parts are defined as a small part. If dislodged, this part presents a potential choking hazard. Therefore, robust testing methods to assess retention forces are critical to ensure consumer safety during use of powered toothbrushes.

Objective:

Demonstrate that static brush head pull force in and of itself is the most appropriate test parameter to evaluate brush head retention.

Method:

Simulate in-use conditions in vitro using high speed video analysis to observe brush head movement when sufficient force is applied to result in brush head detachment.

Results:

High speed video analysis shows that when sufficient force is applied to the brush head it stops moving prior to detachment, which occurs at random oscillation angles. Static pull testing carried out at random oscillation angles on various commercially available brands from leading manufacturers, e.g. Oral-B, ranged from 92-132 N. Modeling and simulation was developed as a design tool to ensure the mechanical integrity before building molded samples with a very strong correlation to the laboratory data. These data demonstrate that movement of the brush head stops prior to its detachment. Furthermore, under no condition was the pull force < 90N. Therefore, pull force testing of the brush head while static is representative of brush head retention at the time of dislodgement. Additionally, the > 90N pull force requirement set forth in the European toy standard is appropriate for a minimum brush head retention threshold. Static pull force testing of powered brush heads is proposed as a method to aid brush head design to ensure safety of consumers during use.

EN 71-1:2011 Safety of toys: Part 1: Mechanical and physical properties

RESULTS

Conclusions:

The video analysis of the brush head detachment process demonstrates that the movement of the brush head stops prior to its dislodgement. Pull force testing of the brush head while static is representative of brush head movement at the time of dislodgement during consumer use. Testing of major refill types resulted in pull forces between 92N and 132N. As development tool Numerical Simulation with finite elements has proven to be a valid virtual substitute for real life tests, which can be used to restrict samples to promising candidates.

Furthermore, for all samples tested the pull force was > 90N. This investigation demonstrates that the > 90N pull force requirement set forth in the European toy standard is appropriate for a minimum brush head retention threshold. Static pull force testing of powered brush heads is proposed as a method to aid brush head design to ensure safety of consumers during use.

EN 71-1:2011 Safety of toys: Part 1: Mechanical and physical properties

Materials and methods:

1 EN 71-1:2011 Safety of toys: Part 1: Mechanical and physical properties

CONCLUSIONS

The video analysis of the brush head detachment process demonstrates that the movement of the brush head stops prior to its dislodgement. Pull force testing of the brush head while static is representative of brush head movement at the time of dislodgement during consumer use. Testing of major refill types resulted in pull forces between 92N and 132N. As development tool Numerical Simulation with finite elements has proven to be a valid virtual substitute for real life tests, which can be used to restrict samples to promising candidates.

Furthermore, for all samples tested the pull force was > 90N. This investigation demonstrates that the > 90N pull force requirement set forth in the European toy standard is appropriate for a minimum brush head retention threshold. Static pull force testing of powered brush heads is proposed as a method to aid brush head design to ensure safety of consumers during use.

EN 71-1:2011 Safety of toys: Part 1: Mechanical and physical properties
Objective: To compare the anti-erosion benefits of two marketed dentifrices in a 15 day in situ model.

Method: The present study utilized a single centre, double blind, randomized, two-treatment, and four-period crossover design. Thirty-seven subjects were enrolled and 33 completed the study. Each study period took place over a span of 15 days. Subjects were randomized to treatment sequences and received one of two marketed dentifrice products each period. Treatments included a 0.454% Stannous Fluoride dentifrice (Oral-B PRO EXPERT®) and a 0.3% Triclosan/sodium fluoride dentifrice (Colgate Total Advanced®). 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. Contact profilometry was used to measure surface changes of enamel samples at Baseline, days 10 and 15. Two measurements for each sample were recorded at each visit.

Result: No statistically significant treatment differences were observed at Baseline for the two dentifrice groups (p>0.44) with means of -0.015 and -0.024 for the Stannous Fluoride and the Triclosan dentifrices, respectively. At day 10 the Stannous Fluoride dentifrice demonstrated 66.8% lower enamel loss than the Triclosan dentifrice (p<0.0001) with means of 1.222µm and 3.676 µm, respectively, and at day 15, a 68.3% lower enamel loss (p<0.0001) with means of 1.595 µm and 5.027 µm, respectively. Both test products were well tolerated.

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

Materials and Methods

This was a single center, double-blind, randomized, supervised-usage, two-treatment, four-period crossover study. Subjects presented for 4 study periods and were randomized to treatment sequences and received one of two marketed dentifrice products each period. Each study period took place over a span of roughly 3 weeks and was comprised of 15 treatment days. Subjects were randomized to treatment sequences and received one of two marketed dentifrice products each period. Each study period took place over a span of roughly 3 weeks and was comprised of 15 treatment days. On Days 10 and 15 of the treatment periods, the enamel samples were measured for tissue loss using a calibrated contact surface profilometer. Since the Day 10 and 15 enamel loss distribution were right-skewed, the data were transformed using the natural log function to make the distribution bell-shaped before performing between-treatment analyses that assume normality. A general linear mixed model was used to compare treatments, and the final model included period and treatment as fixed effects and subject as a random effect.

Results

A total of 36 subjects were randomized to a test product sequence at study initiation, and 33 participants completed the trial through Treatment Period 4, Day 15. Subjects ranged in age from 23 to 65 years, averaging 44.8 years and 81% of the subjects were female.

Table: Enamel Protection at Day 10 and Day 15

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Original Scale in µm</th>
<th>Estimated Median (SE)</th>
<th>% Reduction vs. NaF/triclosan</th>
<th>2-sided P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SnF₂ dentifrice</td>
<td>1.22 (0.079)</td>
<td>67%</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>NaF/triclosan dentifrice</td>
<td>3.68 (0.239)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SnF₂ dentifrice</td>
<td>1.60 (0.104)</td>
<td>68%</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>NaF/triclosan dentifrice</td>
<td>5.03 (0.327)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a Estimated medians & standard errors (SE) were obtained by back-transforming the analysis from the natural log scale.
Comparison of Human and Bovine Dentin in RDA-EP Abrasivity Assessments
E. Colon, E. Schneiderman*, and DJ White
Procter & Gamble Company, Mason OH

ABSTRACT

Our laboratory has been developing a validated profilometry method (Radiative Dentin Abrasion – Equivalent Profilometry RDA-EP) for the assessment of dentifrice abrasivity which is equivalent to the standard RDA method (ISO 11609 Annex A). Initial validation of the method was developed with human dentin. Expansion of the method to the use of bovine substrates could increase accessibility of the technique. Objective: This study compared bovine to human root dentin substrates in dentifrice abrasivity assessments using optimized RDA-EP method.

MATERIALS AND METHODS

Three experimental dentinofices of low, medium and high abrasivity in the safe dentin abrasion range (RDA<250) were compared using human and bovine dentin-specimens (N=5/group). RDA was determined as specified in ISO 11609 Annex A. RDA-EP was determined using human and bovine dentin specimens (Vickers hardness 30-70, 0-10 microns leveling, window 3x3.5mm) with modified brushing methodology 4000 strokes, inclusion of RDA250, randomization of brushing stations, change of specimen orientation during brushing vs. ISO11609 Annex A. Pre-treatment dentin wear was analyzed by optical profilometry (Brucker Counter GT-K1) and contact profilometry (Taylor Hobson Talyform 50) using Talymap Gold 6.2 DigitalSurf.

RESULTS

Analysis of Human and Bovine dentin abrasion by bivariate fit showed RDA-EP values to be highly correlated. Optical Profilometry RMS 0.95; Stylus Profilometry RMS 0.89 (both analysis methods p<0.001).

CONCLUSIONS

Bovine substrates proved equivalent to human in comparative assessments of dentifrice abrasivity. The RDA-EP with bovine substrates would appear to be an adequate methodology for relative characterization of dentifrice abrasivity in vitro.
ABSTRACT

Objectives: An inclusive meta-analysis was conducted to evaluate the short-term post-prophylaxis effects of two cetylpyridinium chloride rinses on plaque and breath measured concurrently.

Methods: Subjects from two 4-day crossover clinical trials were included in the pooled analysis. In each study, general subjects with evidence of plaque accumulation received a dental prophylaxis and then were assigned two cetylpyridinium chloride (CPC) rinses for use over a 4-day period. Subjects received either a 0.07% CPC rinse (Crest ProHealth™) or 0.10% CPC rinse with 1.5% hydrogen peroxide (Crest ProHealth Clinical) in blinded rinse bottles, along with a regular anti-cavity paste and brush. Efficacy was measured at the end of each period as volatile sulfur compounds (VSC) in exhaled overnight breath measured via Halimeter, and disclosed plaque scored clinically using the Turesky-Modified Quigley-Hein Index (TMQHI). Treatment comparisons were made using analysis of covariance models with baseline as the covariate.

Results: The inclusive meta-analysis had 56 subjects, with mean (SD) age of 40.8 (8.0) years. Baseline means (SD) were 150.8 (89.1) for VSC and 1.93 (0.43) for TMQHI. For breath, Day 4 VSC means were 111.1 in the 0.07% CPC group and 60.5 in the 0.10% CPC + 1.5% H2O2 group, with treatments differing significantly (p<0.0001). For plaque, Day 4 TMQHI means were 1.01 in the 0.07% CPC group and 0.69 in the 0.10% CPC + 1.5% H2O2 group, with treatments differing significantly (p<0.0001).

Conclusion: An inclusive meta-analysis of breath and plaque responses showed significant 30%+ concurrent reductions in breath and plaque with a higher cetylpyridinium chloride plus hydrogen peroxide rinse when used after dental prophylaxis versus control.

MATERIALS AND METHODS

- Both studies were cross-over studies.
- Subjects with evidence of plaque accumulation received a dental prophylaxis after baseline plaque level was recorded. Subjects were then randomized to a treatment sequence that included two cetylpyridinium chloride (CPC) rinses for use over a 4-day period.
- Each period was preceded by a 7-10 day washout period and dental polishing.
- Subjects received either a 0.07% CPC rinse (Crest ProHealth™) or 0.10% CPC rinse with 1.5% hydrogen peroxide (Crest ProHealth Clinical) in blinded rinse bottles, along with a regular anti-cavity paste and brush.
- Efficacy was measured at the end of each period as volatile sulfur compounds (VSC) in exhaled overnight breath measured via Halimeter, and disclosed plaque scored clinically using the Turesky-Modified Quigley-Hein Index (TMQHI).
- Treatment comparisons were made using analysis of covariance models with baseline as the covariate.

RESULTS

- The meta-analysis had 56 subjects, with mean age of 40.8 years and standard deviation of 8 years.
- Baseline means were 150.8 for VSC and 1.93 for TMQHI.
- For plaque, Day 4 MQH means were 1.01 in the 0.07% CPC group and 0.69 in the 0.10% CPC + 1.5% H2O2 group, with treatments differing significantly (p<0.0001).
- For breath, Day 4 VSC means were 111.1 in the 0.07% CPC group and 60.5 in the 0.10% CPC + 1.5% H2O2 group, with treatments differing significantly (p<0.0001).

CONCLUSIONS

- An inclusive meta-analysis of breath and plaque responses showed significant 30%+ concurrent reductions in breath and plaque with a higher cetylpyridinium chloride plus hydrogen peroxide rinse when used after dental prophylaxis versus control.
- Both treatments were well-tolerated.
**Objective:** Evaluate the safety of a 0.454% stannous fluoride dentifrice with sodium hexametaphosphate (SnF₂ SHMP) under conditions of routine use from a diverse collection of clinical studies.

**Method:** Meta-analysis of data from 2664 healthy adult subjects who participated in 41 clinical studies. In each study, subjects were randomly assigned to the 0.454% stabilized SnF₂ SHMP dentifrice group for daily use over periods ranging from 2 weeks to 2 years depending on study design. In each study, oral safety was assessed via clinical examination or voluntary report. Adverse events (AE) were summarized both by subject and event occurrence and assessed for severity and causality.

**Result:** The study population exhibited considerable diversity in demographics, behaviors, and oral health. Of the 2664 subjects assigned the SnF₂ SHMP dentifrice, 50 subjects (1.9% of the population) had an AE, with a 95% confidence interval of (1.4%, 2.5%). Desquamation was the most frequent AE identified in 17 subjects (0.6% of the population), with a 95% confidence interval of (0.4%, 1.0%). Desquamation was mild in severity, and contributed minimally to dropout (0.08% of the population). Other findings were less common, and overall, only 8 subjects discontinued use due to a treatment-related AE.

**Conclusion:** This inclusive meta-analysis demonstrated that a 0.454% stannous fluoride dentifrice with sodium hexametaphosphate was generally well-tolerated over periods of up to 2 years daily use, with mild transient desquamation (<1%) representing the most common finding.

**MATERIALS AND METHODS**

Adverse Event data from 41 clinical trials totaling 2664 subjects were pooled into one dataset to conduct a meta-analysis of Oral Safety of stannous fluoride dentifrice. Oral safety was assessed by subject report or clinical examination. The data were analyzed and occurrence rates estimated with a 95% Clopper-Pearson confidence interval.

**RESULTS**

In summary, 50 out of 2664 subjects had generally mild AEs (52 AEs in total), with desquamation, gingival irritation and hyperesthesia being the most common, comparable to historic evidence on tartar control paste. The 41studies ranged from 2 weeks to 2 years in duration, were conducted at 17 locations across the globe, and measured 14 different endpoints.
Objective: This research used image analysis to evaluate the distribution of overnight and post-prophylaxis dental plaque.

Methods: After institutional review and informed consent, healthy adults were enrolled in a study to assess plaque accumulation overnight and immediately after prophylaxis. Subjects with overnight (unbrushed) plaque swished with a fluorescein rinse and expectorated, cheek retractors were inserted, and a single digital image was collected under standardized lighting conditions. Separately, air-dried calculus was assessed on 18 sites on 6 mandibular lingual surfaces (as presence or absence). Subjects received a routine whole mouth dental prophylaxis, immediately after which, fluorescein rinsing and imaging were repeated. Each digital image was analyzed blind to visit sequence to determine area (%) plaque coverage on the anterior facial tooth surfaces, and paired images were compared to assess between-visit differences.

Results: A total of 28 subjects had overnight and post-prophylaxis measurements, and all data were included in the analysis. Mean (SD) age was 38.2 (15.4) ranging from 23-73 years, 61% were female, and non-whites comprised 61% of study subjects. Overnight plaque coverage varied. Mean (SD) plaque area coverage was 16.9% (10.5), ranging from 2.6-39.6%. Calculus was identified at 62% of sites, ranging from 0-100% before prophylaxis. All subjects experienced plaque reductions with prophylaxis, with the minimum plaque area of 0.86% after prophylaxis. Overnight plaque was a significant effect in plaque removal by prophylaxis. Demographic factors and calculus presence/absence did not contribute to the prophylaxis plaque cleaning effect.

Conclusion: Use of image analysis demonstrates a high level of between-subject variability in natural plaque accumulation which impacts routine prophylaxis effectiveness.

Use of image analysis demonstrates a high level of between-subject variability in natural plaque accumulation which impacts routine prophylaxis effectiveness.
Reproducibility of Clinical and Self-Assessment of Air Sensitivity Response

Thursday, March 20, 2014: 3:30 p.m. - 4:45 p.m.
Location: Exhibit Hall AB (Charlotte Convention Center)

Presentation Type: Poster Session
Track: Clinician Track

A.S. Papas\(^1\), M.L. Singh\(^1\), E. Tzavaras\(^2\), P. Corrado\(^2\), J. Cimmino\(^2\), M.C. Miner\(^2\), M.L. Barker\(^2\), and R.W. Gerlach\(^2\), Tufts University School of Dental Medicine, Boston, MA; \(^2\)Tufts University, Boston, MA; \(^3\)Procter & Gamble Company, Mason, OH

Objective: This research evaluated the between-visit reproducibility of sensitivity response to air stimulation with two different measurement methods.

Method: Institutional review, informed consent and screening were conducted to identify subjects with evidence of gingival recession and moderate-to-severe dentinal hypersensitivity at one or two test sites. At each site, a trained examiner administered a 1-sec application of cool air (\(\sim 21^\circ\)C) using a dental syringe, immediately after which, clinical response was graded using a standard 4-point scale (Schiff) to categorize discomfort ranging from none-to-painful. After the clinical evaluation, subjects then self-rated sensitivity pain from none-to-worst using a standard 100-unit visual analog scale (VAS) on a laptop. This process was repeated at a second visit within 14 days with no other interventions, and neither the examiner nor the subject had access to the previous score. Intraclass correlations (ICC) were calculated using a 0-to-1 scale, where 0 represented no agreement and 1 represented perfect agreement.

Result: A total of 21 subjects attended both visits, and all data were included in the analysis. Age ranged from 32-74 years, with males comprising the majority (67%) of study subjects. There was considerable variation in both the clinical and self-assessments of air sensitivity. Visit 1 means (SD) were 2.36 (0.45) for Schiff and 70.78 (23.49) for VAS. Visit 2 means (SD) were 2.31 (0.46) for Schiff and 72.04 (24.82) for VAS. Clinical and self-assessment scores were well correlated across visits. The ICC for clinician-rated Schiff was 0.852 compared to the ICC for self-rated VAS was 0.727.

Conclusion: Self-assessment and clinician evaluation of dentinal hypersensitivity response to air were similarly reproducible for up to 2 weeks.


Comparative Antimicrobial Efficacy of US Multibenefit Dentifrices In Vitro

578

E KINCAID, M ZSISKA, and DJ WHITE

The Procter & Gamble Company, Mason, OH, USA

ABSTRACT

Laboratory testing is often used to predict clinical activity of multibenefit fluoridated dentifrices. To compare antimicrobial actions, the efficacy of formulations can be assessed in plaque growth or metabolism assays (e.g. J Clin Dent 6: 59-70, 1995).

Objectives: This study compared a group of commercially available multibenefit dentifrices toward reducing plaque metabolism in vitro.

Methods: Plaque biofilms were prepared on glass rods (N=4 test group) with whole saliva spiked with TSB as growth media. Following 3 days growth, plaque was treated a single time with 16.7% w/w dentifrice/water slurries for two minutes. Following rinsing plaque was immersed in glycolysis media containing 0.5% sucrose in TSB pH adjusted to 6.5. Plaque metabolism was followed at 37°C until indicator added to the negative control (Bromocresol Purple and Chlorophenol Red) responded assuring maximum dynamic range of the assay. Metabolic effects of dentifrice treatment were assessed as glycolysis inhibition by measuring medium pH post incubation. Four commercial dentifrices were tested: 1: Crest® Pro-Health (SnF2), II: Colgate® Total (MFP, Triclosan) III: Colgate® Total Zx Pro-Shield (MFP, Zinc citrate) IV: Crest® Regular cavity Protection (NaF, neg. control).

Results: pH decrease in medium (lesser decrease = less acid produced = more glycolysis inhibition) was analyzed by ANOVA and p-values for all treatment groups were calculated by Students t-test (a = b = c < p<0.05): I=1.28a; II=1.44b; III=1.51c; IV=1.92d.

Conclusions: Dentifrices containing antimicrobials showed efficacy in glycolysis inhibition in vitro. Under these conditions, the stannous fluoride containing dentifrices showed significantly higher efficacy than zinc citrate and triclosan containing MFP dentifrices in inhibiting plaque metabolism.

INTRODUCTION

Dental plaque is a complex multi-organism biofilm, initially formed on dental enamel by the attachment of planktonic bacteria and containing a large number of different species of anaerobe and aerobe bacteria. Acidogenic bacteria present in plaque biofilm lower the plaque pH when exposed to sucrose. The effect of treatments on the glycolysis as activity measured by pH can be used to assess the broad-spectrum anti-microbial effect of oral treatments. This in vitro plaque glycolysis model (IPGRM) is a technique in which plaque is grown from human saliva and treated with dentifrice slurries to determine antiglycolytic activity of treatments. The purpose of this technique is to provide a simple and quick method for determining if compounds have an influence on the metabolic pathways that plaque microorganisms utilize for the production of toxins that adversely affect tooth or gingival health.

MATERIALS AND METHODS

Design: In vitro biofilm assay conducted with n=4 replicates/assay. Test results were replicated with subsequent assay.

Biofilm Growth: Plaque biofilm growth was initiated by dipping polished glass rods overnight at 37°C into a medium consisting of pooled fresh human saliva (60% v/v) and trypticase soy broth (TSB, 40% v/v). To establish biofilm on the rods, on the morning of the second day the medium was exchanged to a sucrose-rich broth and biofilm was grown using growth medium (TSB 15 g, sucrose 50 g, and deionized (DI) water 467 ml) supplemented with freshly pooled saliva (33 g). After 5hrs the medium was changed again and biofilm was grown overnight in supplemented pooled saliva (10% (v/v) TSB and 1.25% (w/v) sucrose).

Treatment: Treatments included: I: Colgate Total (CT, MFP/triclosan) II: Colgate Total Zx Pro-Shield (CTP, MFP/Zinc citrate), and IIT: Crest Pro-Health (CPH, SnF2). Dentifrices were compared to a standard dentifrice as the negative control: Crest Cavity Protection, (CCP, NaF). The 2d-biofilms were treated with 16.7% dentifrice slurries (1:5) for 120 sec, then rinsed by dipping each glass rod twice for 10 sec into deionized water. Glycolysis: All treated rods were subsequently exposed to glycolysis media [0.03% TSB, 5% sucrose pH 6.5]. A few drops of Bromocresol Purple were added to one negative control tube, a few drops of Chlorophenol Red to a second negative control: Crest Cavity Protection, (CCP, NaF). The 2d-biofilms were treated with 16.7% dentifrice slurries for two minutes. Following rinsing plaque was immersed in glycolysis media containing 0.5% sucrose in TSB pH adjusted to 6.5. Plaque metabolism was followed at 37°C until indicator added to the negative control (Bromocresol Purple and Chlorophenol Red) responded assuring maximum dynamic range of the assay. Metabolic effects of dentifrice treatment were assessed as glycolysis inhibition by measuring medium pH post incubation. Four commercial dentifrices were tested: 1: Crest® Pro-Health (SnF2), II: Colgate® Total (MFP, Triclosan) III: Colgate® Total Zx Pro-Shield (MFP, Zinc citrate) IV: Crest® Regular cavity Protection (NaF, neg. control).

RESULTS

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Active pH</th>
<th>Final pH</th>
<th>∆pH</th>
<th>SD</th>
<th>Stat. Group*</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (Crest Pro-Health)</td>
<td>SnF2</td>
<td>5.28</td>
<td>1.28</td>
<td>0.08A</td>
<td></td>
</tr>
<tr>
<td>II (CT Advanced)</td>
<td>MFP/Triclosan</td>
<td>5.11</td>
<td>1.44</td>
<td>0.14B</td>
<td></td>
</tr>
<tr>
<td>III (CT Pro-Shield)</td>
<td>MFP / Zn Citrate</td>
<td>5.05</td>
<td>1.51</td>
<td>0.07B</td>
<td></td>
</tr>
<tr>
<td>IV (Crest Cavity, NC)</td>
<td>NaF</td>
<td>4.64</td>
<td>1.92</td>
<td>0.09C</td>
<td></td>
</tr>
</tbody>
</table>

* If two letters are different, the results are statistically different at p<0.05

Acid Production [pH] by Single Exposure Treatment (smaller is better)

CONCLUSIONS

All dentifrices containing antimicrobials showed efficacy in glycolysis inhibition in vitro. Under these conditions, the stannous fluoride containing dentifrice showed significantly higher efficacy than zinc citrate and triclosan containing MFP dentifrices in inhibiting plaque metabolism as assessed by glycolysis.

References:

Dentine tubule occlusion with Stannous Fluoride Dentifrices

M. Zsiska* and D.J. White
Procter & Gamble Company, Mason, OH

ABSTRACT

Dentifrices with proven clinical desensitization efficacy include formulations which form smear layers to block patent tubuli. SnF₂ provides a spectrum of useful clinical activities including control of dentinal hypersensitivity. The relative efficacy of SnF₂ formulations for providing desensitization may vary in rate of onset and duration of desensitization provided by tubule obturation (Zsiska et al., J Dent Res 2011; 90 (Spec Iss A): AADR/IADR 2634 and 2635).

Objectives: This study examined dentinal tubule occlusion effects of commercial stannous fluoride dentifrices and their mechanical and chemical durability in vitro.

Methods: Etched coronal dentin specimens prepared from extracted human third molars were randomized for tubule diameter and density and allocated to three dentifrice treatment groups (N=6) including I: Crest® Pro-Health (SnF₂) II: Sensodyne Repair & Protect (SnF₂) III Colgate Cavity Protection (MFP, neg. ctrl). Specimens were brushed with dentifrice for 5 brushing-cycles comprised of 2 minute paste applications followed by 1 hour saliva immersion. Post-brushing (PB) samples were gently agitated 16-hours in saliva to test smear layer physical durability (MC). Then specimens were challenged with citric acid pH3.5 for 1 minute to examine chemical durability (AC). Surfaces were imaged by light microscopy after 60 sec (PB1/2), 1 brushing cycle (PB1), 5 brushing cycles (PB5), mechanical (MC) and acid challenge (AC). Specimens were graded blind to treatment on a 6-point scale from 0: open tubuli to 5: no open tubuli, intact smear layer.

Results: PB1/2: I=1.64a II=0.80b III=0.13c PB1: I=2.25a II=1.54b III=0.31c PB5: I=3.95a II=2.53b III=0.73c MC: I=3.75a II=2.39b III=0.72c AC: I=3.55a II=2.20b III=0.78c (a≠b≠c p < 0.05 Students t comparison).

Conclusions: Stannous fluoride containing dentifrices differed substantially in onset of tubule occlusion and resistance to physical and chemical effects. These results point to clear differences in formulation efficiency in tubule occlusion in vitro.

MATERIALS AND METHODS

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Smearlayer Onset</th>
<th>Smearlayer Sustainability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>60 sec (1/2 cycle)</td>
<td>2min (1st cycle)</td>
</tr>
<tr>
<td>I (Crest Pro-Health SnF₂)</td>
<td>1.84 (0.24) A*</td>
<td>2.25 (0.25) A</td>
</tr>
<tr>
<td>II (Sensodyne Rep &amp; Protect SnF₂)</td>
<td>0.80 (0.09) B</td>
<td>1.54 (0.13) B</td>
</tr>
<tr>
<td>III (Colgate Cavity Protection MFP)</td>
<td>0.13 (0.07) C</td>
<td>0.31 (0.10) C</td>
</tr>
</tbody>
</table>

*Different letters denote statistical differences with p<0.05 (ANVOA, Student’s t-test)

RESULTS

<table>
<thead>
<tr>
<th>TUBA Occlusion Scores (TOS)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Score 0</th>
<th>Score 1</th>
<th>Score 2</th>
<th>Score 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open Tubule Coating</td>
<td>Treatment</td>
<td>Slabs</td>
<td>Score 1</td>
</tr>
<tr>
<td>Crest Pro-Health SnF₂</td>
<td>II (R&amp;P)</td>
<td>I (CPH)</td>
<td>Score 2</td>
</tr>
<tr>
<td>Sensodyne Rep &amp; Protect SnF₂</td>
<td>III (CCP)</td>
<td>II (R&amp;P)</td>
<td>Score 3</td>
</tr>
<tr>
<td>Colgate Cavity Protection MFP</td>
<td>I (CPH)</td>
<td>III (CCP)</td>
<td>Score 4</td>
</tr>
</tbody>
</table>

CONCLUSIONS

Stannous fluoride containing dentifrices differed substantially in onset of tubule occlusion and resistance to physical dispersion or acid solubilization of smear layers. These results point to clear differences in formulation efficiency in creation of robust smear layers potentially important for the control of dentinal hypersensitivity.
**ABSTRACT**

Stannous fluoride has proven to be a versatile and useful multidimensional active ingredient providing a spectrum of useful clinical activities including control of caries, plaque, bad breath and gingivitis and dentinal hypersensitivity. Despite its value, SnF2 remains a complex ingredient to formulate and requires skill in formulation of multibenefit dentifrices. The relative efficacy of SnF2 formulations varies according to formulations as does the range of benefits specific formulations may provide. **Objectives:** This study compared the antimicrobial activity of commercially available SnF2 dentifrices toward reducing plaque metabolism in vitro. **Methods:** To compare antimicrobial actions, the efficacy of formulations can be assessed in plaque growth or metabolism assays (e.g., J Clin Dent 6: 59-70, 1995). Plaque biofilms were prepared on glass rods (N=4/test group) with whole saliva spiked TSB as growth media. Following 3 days growth, plaque was treated a single time with 16.7% w/w dentifrice/water slurries for two minutes. Following rinsing plaque was immersed in glycolysis media containing 0.5 % sucrose in TSB pH adjusted to 6.5. Plaque metabolism was followed at 37°C until Bromocresol Purple/Chlorophenol Red (added to neg. ctrl) responded. Metabolic effects of dentifrice treatment were assessed by measuring medium pH post incubation. **Treatment Groups:** I: Crest® Regular Cavity Protection (NaF, neg. control); II: US Sensodyne Repair & Protect (SnF2) III: Crest Pro-Health (SnF2) IV: Crest Gumcare (positive control – SnF2).

**RESULTS:**

**Table:**

<table>
<thead>
<tr>
<th>Leg</th>
<th>Treatment</th>
<th>Final pH</th>
<th>Δ pH</th>
<th>Glycolysis Inhibition [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Crest Cavity Protection—NC</td>
<td>4.74</td>
<td>2.18</td>
<td>0.0 A</td>
</tr>
<tr>
<td>II</td>
<td>Sensodyne Repair &amp; Protect (US)</td>
<td>4.99</td>
<td>1.92</td>
<td>11.6 B</td>
</tr>
<tr>
<td>III</td>
<td>Crest Pro-Health</td>
<td>5.56</td>
<td>1.35</td>
<td>38.1 C</td>
</tr>
<tr>
<td>IV</td>
<td>Crest Gum Care—PC</td>
<td>5.63</td>
<td>1.28</td>
<td>41.1 C</td>
</tr>
</tbody>
</table>

*Different letters denote statistical differences with p<0.05 (ANOVA, Student’s t-test)

**CONCLUSIONS**

Stannous fluoride has been clinically proven to provide caries, sensitivity, erosion and antibacterial benefits when formulated in dentifrices. While Original Crest Gum Care (IV), Sensodyne Repair & Protect (II) and Crest Pro Health (III) all contain 0.454% Stannous Fluoride as their fluoride source, formulas showed significant differences in antibacterial efficacy as seen here. Stannous fluoride formulations may differ significantly in bioavailability for various clinical indications and this cannot be predicted by formulated dose alone.
ABSTRACT

Objective: This study evaluated safety and short-term whitening efficacy of a 1-hour whitening strip relative to a negative control.

Methods: This was a randomized, double-blinded, parallel design clinical study. Fifty-six adult volunteers with no history of prior bleaching, no existing tooth sensitivity and the Vita shade of A2 or darker on maxillary anterior teeth completed the study. Subjects were randomized to one of the two treatments: 1) 10% hydrogen peroxide high adhesion whitening strip (Crest 3D White 1-Hour Express) used with a regular cavity protection toothpaste and a flat trim manual brush and 2) a regular cavity protection toothpaste and a flat trim manual brush as a negative control. The strip was worn 1 hour daily for 4 days. Efficacy (digital image analysis) and safety (oral exams and subject interviews) were assessed at Baseline, Day 2 (day after treatment) and Day 5 (after 4 days of treatment).

Results: Mean age was 36 and 66% of subjects were female. At each study visit, the 1-hour strip group demonstrated significant (p < 0.02) improvement of b* and L* tooth color parameters relative to Baseline and the negative control. For the strip group, the Day 2 adjusted mean yellowness reduction (Δb*) was -0.54 and the adjusted mean lightness improvement (ΔL*) was 0.52. The benefit continued to increase through end-of-treatment (Day 5) with Day 5 adjusted mean Δb* and ΔL* values of -1.58 and 1.36, respectively. Both treatments were well-tolerated. Mild, transient tooth sensitivity and oral irritation were the two types of adverse events reported in the study. No subject discontinued treatment due to an adverse event.

Conclusion: The study demonstrated an immediate whitening effect from use of a single 10% hydrogen peroxide, 1-hour Whitening strip, and the benefit continued to improve through the course of the study.

MATERIALS AND METHODS

Fifty-six adult volunteers with no history of prior bleaching, no existing tooth sensitivity and the Vita shade of A2 or darker on maxillary anterior teeth completed the study. Subjects were randomized in approximately equal numbers and received one of the following treatments:

- Crest 3D White Whitestrips 1 Hour Express – 10% hydrogen peroxide high adhesion whitening strip worn 1 hour daily for 4 days.
- Negative control – cavity protection toothpaste + flat trim manual brush.

Efficacy and safety were evaluated at Baseline, Day 2 (day after first treatment), and Day 5 (after 4 days of treatment). Tooth color (L*a*b*) was measured objectively from standardized digital images of the maxillary anterior teeth. Analysis of covariance was used for color change comparisons between treatments using baseline color and age as covariates. Safety was assessed from oral exams and subject interviews.

RESULTS

Efficacy: Subjects ranged in age from 18-62 with an average of 36 years, and 66% were females. Groups were balanced with respect to baseline demographics and tooth color (p>0.2). At each study visit, the 1-hour strip group demonstrated significant (p < 0.02) improvement of b* and L* tooth color parameters relative to both the baseline and the negative control. For the strip group, the Day 2 adjusted mean yellowness reduction (Δb*) was -0.54 and the adjusted mean lightness improvement (ΔL*) was 0.52. The benefit continued to increase through end-of-treatment (Day 5) with Day 5 adjusted mean Δb* and ΔL* values of -1.58 and 1.36, respectively.

Safety: Transient tooth sensitivity and oral irritation were the two types of adverse events in the study. All adverse events were mild in severity. No subject discontinued treatment due to an AE.

<table>
<thead>
<tr>
<th>Adverse event by type</th>
<th>1-hour Whitening Strip, % subjects</th>
<th>Negative control, % subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported Tooth Sensitivity</td>
<td>7%</td>
<td>0%</td>
</tr>
<tr>
<td>Reported Oral Irritation</td>
<td>14%</td>
<td>0%</td>
</tr>
<tr>
<td>Observed Oral Irritation</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>AE Drops</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

The study demonstrated an immediate whitening effect from use of a single 10% hydrogen peroxide, 1-hour Whitening strip, and the benefit continued to improve through the course of the study.
Antimicrobial Effects of Cetylpyridinium Chloride Mouthrinses

Saturday, March 22, 2014: 8 a.m. - 9:30 a.m.
Location: 2134 (Charlotte Convention Center)

Presentation Type: Oral Session

Track: Clinic Track


1College of Dentistry, University of Tennessee Health Science Center, Memphis, TN, 2Procter & Gamble Company, Mason, OH

Plaque Glycolysis and Regrowth Method (PGRM) is a proven clinical assay for bioavailability, retention and proportional efficacy of mouthrinses containing the antimicrobial cetylpyridinium chloride (CPC) (J Clin Dent 6: 59, 1995; Food and Drug Administration 21 CFR Part 356 Vol 68: 103, May 29 2003). Objectives: This study compared the effectiveness of two CPC mouthrinses on PGRM efficacy.

Methods: The study employed a controlled, double-blind, randomized, two-treatment, four-period crossover design. 20 qualified adult PGRM subjects were supplied with commercially available CPC mouthrinses (Crest Pro-Health, Procter and Gamble Co.) for use throughout the trial. Test products included: 0.125% CPC antiseptic rinse (Colgate Total, Colgate-Palmolive - CT) and 0.07% CPC antiseptic rinse (Crest Pro-Health, Procter and Gamble - CPH). On treatment days, subjects visited the clinic in the morning prior to hygiene/dietary intervention, had supragingival baseline plaque samples collected from upper quadrants, followed by rinsing for 30 minutes with 20 mL of assigned treatment. Lower left and right quadrants plaque samples were collected 15 and 45 minutes after rinsing. Sampled plaques were vortexed, normalized for biomass and incubated under standard conditions to assess glycolysis (J Clin Dent 6: 59, 1995). pH of the plaque incubation suspensions was compared to starting pH and an Area Under Curve (AUC) aggregate analysis of glycolysis inhibition was used for treatment comparison. Results: ANCOVA adjusted measures: plaque metabolism pH: 15 min post rinse CPH 6.44 (±0.055) vs- CT 5.94 (±0.055) [p < 0.001, statistically significant (-)], 45 min post rinse: CPH 5.30 (±0.057) vs- CT 5.78 (±0.056) [p < 0.0001], AUC glycolysis: CPH 48.22 (1.95) vs- CT 29.10 (1.92) [p < 0.0001]. Conclusion: CPC bioavailability varied in commercial mouthrinses and activity was not proportional to supplied dose. CPH rinse with 700 ppm CPC provided 66% increase in glycolysis inhibition as compared to CT rinse containing 750 ppm CPC.
Gingivitis Imaging with L* a* b* Color for Dental Prophylaxis and Hygiene

Saturday, March 22, 2014: 8 a.m. - 9:30 a.m.
Location: 213A (Charlotte Convention Center)
Presentation Type: Oral Session

Track: Clinician Track
M.I. BARKER, M. RUBISH, M.C. MINER, and R.W. GERLACH, Procter & Gamble Company, Mason, OH

Objective: A clinical study was conducted to evaluate images of marginal gingival tissue combined with calibrated L* a* b* color to assess clinical gingivitis response of a dental prophylaxis followed by a 2 week hygiene period.

Method: After institutional review and informed consent, 59 healthy adults were enrolled with mild to moderate gingivitis and evidence of recession. After a baseline image, a dental prophylaxis was administered, and each subject was provided standard anti-cavity toothpaste with an Oral-B® Indicator toothbrush to use for 2 weeks, followed by another image. Gingival color response was measured with a non-invasive and objective method using high-resolution images of the anterior facial dentition with standard lighting. Red-green-blue (RGB) image pixels of marginal gingival color were converted to CIE L* a* b* values using color calibration with known standards. Images showing pixel level gingival color changes of the group and individual subjects were generated.

Result: At baseline before prophylaxis, the 1.5mm marginal gingival color had means (SD) of 60.1 (2.5) for L* lightness, 29.9 (1.7) for a* redness, and 11.1 (1.1) for b* yellowness. After prophylaxis and the 2 week hygiene period, significant (p<0.005) gingival color improvement was demonstrated with means (SD) of 1.9 (1.6) for ΔL*, -1.4 (1.2) for Δa*, and -0.3 (0.8) for Δb*. Measuring 0.33mm gingival margin near recession, Week 2 means (SD) showed significant (p<0.0001) color improvements of 2.2 (1.7) for ΔL*, -1.6 (1.3) for Δa*, and -0.6 (0.9) for Δb*. By color measure, correlations for 0.33mm vs. 1.5mm ranged from 0.93-0.97. L* correlated strongly (0.81-0.99) with each RGB channel, while Δa* improvements also correlated 0.52-0.60 with increased ΔG.

Conclusion: Using image analysis, significant a* redness reduction and increased L* lightness were observed on the gingival margin after dental prophylaxis followed by 2 weeks of standardized hygiene.
Comparative Anti-gingivitis Efficacy of Oscillation-Rotation Electric Toothbrush vs. Manual Toothbrush

Saturday, March 22, 2014: 8 a.m. - 9:30 a.m.
Location: 213A (Charlotte Convention Center)
Presentation Type: Oral Session

Track: Clinician Track

M.A. KLUKOWSKA1, N. SHARMA2, J.M. GRENDEL3, E. CONDE1, P. CUNNINGHAM1, and J. QAQISH1, 1Procter & Gamble Company, Mason, OH, 2Biosci Research Canada, Ltd, Mississauga, ON, Canada

Objectives: This clinical study was conducted to compare the effect of an oscillation-rotation power brush with experimental brushhead vs. manual brush on reduction of gingivitis over a 4-week period.

Method: This was a randomized, parallel, examiner-blind, 4-week clinical trial. The study population included 100 subjects with mild to moderate gingivitis. Subjects were randomly assigned one of two brush groups - oscillation-rotation (OR - Oral B® ProfessionalCare 1000™ handle with novel brushhead) or regular manual brush (ADA). Both groups used standard fluoridated toothpaste (Crest® Cavity Protection). Treatment was twice daily at-home. Gingivitis was evaluated at baseline and week 4 using the Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI). Statistical analyses were carried out using an analysis of covariance.

Result: The average baseline whole mouth MGI score was 2.050 for the OR and 2.048 for the manual group (not statistically different from each other, p=0.303). The average baseline number of bleeding sites was 14.6 for the OR and 14.8 for the manual group (also not statistically different from each other, p=0.576). Groups were balanced for age, gender, ethnicity, brush type user, and smoking status (p≥0.118). At Week 4 the oscillation-rotation power brush group showed a 15.2% reduction in gingivitis, and 70.7% reduction in number of bleeding sites, differing significantly (p<0.001) from baseline. The manual group had a 5.8% reduction in gingivitis and 46.3% in number of bleeding sites, differing significantly (p<0.001) from baseline. Between-group comparisons showed that OR brush with novel brushhead was significantly better for reduction of gingivitis (by 133.7%, p<0.001) and reduction of bleeding sites (by 51.3%, p<0.001) at Week 4 vs. the manual toothbrush.

Conclusion: The oscillation-rotation power brush with experimental brushhead provided significant improvements in gingivitis as compared to a manual toothbrush.
Abrasivity of Dentifrices Assessed by Contact and Non Contact Profilometry

Saturday, March 22, 2014: 8 a.m. - 9:30 a.m.
Location: 213A (Charlotte Convention Center)

Presentation Type: Oral Session

E. SCHNEIDERMAN1, L.I. COLON1, and D.J. WHITE5, 1Procter & Gamble Company, Mason, OH, 2Procter & Gamble Co., Mason, OH

Radioactive Dentin Abrasion (RDA) has been the gold standard for qualification of toothpastes for acceptable dentin wear. In RDA, irradiated human root dentin is abraded under standardized conditions of toothpaste treatment and wear is assessed by comparing scintillation counts between standards and test dentifrices. Profilometry can in principal be used to directly assess relative wear but robust validation of equivalent profilometry (RDA-EP) is lacking. Objectives: This study reports on the development of standardized validated conditions for RDA-EP in vitro and compares the relative dentin abrasivoy measured by RDA and RDA-EP using three dentifrices spanning the safe abrasivity range. Methods: Three dentifrices of variable abrasivity were compared to RDA100 and RDA250 internal standards (N=6/group). Radioactive RDA was determined as specified in ISO 11609 Annex A. RDA-EP was determined after optimization and validation of ISO method 11609 Annex B to increase reproducibility and accuracy by careful selection of human dentin specimens (Vickers hardness 30-70, 0-10 micron leveling, window 3x3.5mm) and brushing methodology (4000 strokes, inclusion of RDA250 upper limit by 2.5x brushing the internal RDA100 standard 10,000 strokes, randomization of brushing stations, change of specimen orientation during brushing). Dentin wear was analyzed by optical profilometry (Bruker Contour GT-K1) and contact profilometry (Taylor Hobson Talyform 500) using Talymap Gold 6.2 (DigitalSurf) software.

Results:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>RDA (a+b by Student Neuman-Keuls p&lt;0.05)</th>
<th>RDA-EP Contact / Optical Profilometry (a+b by Fisher's LSD p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RDA 100 standard</td>
<td>100cd</td>
<td>100d/100d</td>
</tr>
<tr>
<td>Low</td>
<td>71d</td>
<td>66e/62d</td>
</tr>
<tr>
<td>Med</td>
<td>118c</td>
<td>127c/127c</td>
</tr>
<tr>
<td>high</td>
<td>205b</td>
<td>166b/160b</td>
</tr>
<tr>
<td>RDA 250</td>
<td>241a</td>
<td>250a/250a</td>
</tr>
</tbody>
</table>

RDA-EP and radioactive RDA correlated with an RMS>0.9.

Conclusion: This standardized method permits assessment of dentifrice abrasivity using common V-8 brushing machines and available profilometry devices. The RDA-EP would appear a suitable replacement for RDA.
Objective: Artificial carious lesions formed using the method of White et al. (Caries Res. 1987) is used to investigate anticaries potential of fluoride dentifrices. This method creates lesions approximately 60–80µm deep. Since cavities develop at various depths, a study was conducted to determine the optimal parameters necessary to produce deeper lesions without compromising the surface of the tooth specimen. The objective of this study was to create lesions under varying degrees of saturation and duration, and to evaluate their ability to remineralize. Method: A modified Carbolpol demineralization solution with varying degrees of saturation with respect to HAP was used to create artificial carious lesions. Demin solutions contained either a) 25%, b) 43% or c) 50% saturated HAP @ pH 5.0. Twelve ground and polished human enamel specimens were placed in each demineralizing solution. Two specimens were removed from the solutions at the following time points 72hrs (3 days), 96hrs (4 days), 120hrs (5 days), 144hrs (6 days), 168hrs (7 days) and 192hrs (8 days). Further exposure to demineralization leads to remineralization of outer layers due to local increase in saturation.

Results: Lesion initiation and progression is directly related to both degree of saturation and duration of demineralization with lesion depth impacted more by duration of demineralization than degree of saturation. Conclusion: The demineralization solution containing 25% saturated HAP produced the most consistent lesions over an 8 day demineralization period, and just an extension of demineralization duration provides deeper lesions with no significant effect on surface integrity of enamel.

MATERIALS AND METHODS

Substrate: Human enamel core of 3mm diameter mounted on acrylic cylinder, followed by grinding and polishing.

Demineralizing solution: A Carbopol based demineralization solution was used to create different degrees of saturation with respect to hydroxyapatite in a 0.1M acetate buffer. All solutions are adjusted to pH 5.0.

1. 25% saturated with respect to HAP
2. 43% saturated with respect to HAP
3. 50% saturated with respect to HAP

Procedure:
• Twelve (12) ground and polished enamel specimens were placed in each demineralizing solution.
• Two (2) specimens from each group were removed from the demin and rinsed in deionized water at the following demin times: 72hrs (3 days), 96hrs (4 days), 120hrs (5 days), 144hrs (6 days), 168hrs (7 days) and 192hrs (8 days).
• Following the demineralization phase, all specimens were cut using a Taylor microtome to remove a 100µm section.
• The sections were X-rayed using standard procedures for Transverse Microradiographic (TMR) analysis.
• Data acquired from TMR analysis includes lesion depth (LD) and change in mineral density (∆Z), based on sound enamel normalized to 87% volume percent mineral.

RESULTS

Lesion Depth Increase as a Function of DS and Demineralization Duration

Lesion development at 25% DS

Lesion development at 50% DS

Lesion development at 43% DS

Lesion Progression Impacted Most by Duration of Demineralization

CONCLUSIONS

The demineralizing solution containing 25% saturated HAP produced the most consistent lesions over an 8 day demineralization period. Deeper lesions can be obtained by either decreasing degree of saturation or increasing duration of demineralization.
Objective: The ability of a dentifrice to fluoridate demineralized enamel is an important measure of a product’s potential anticaries efficacy. Enamel fluoride uptake is a widely used method to demonstrate performance of a dentifrice. While fluoride uptake measures the ability of fluoride to deposit on or into the enamel, it doesn’t indicate whether fluoride is incorporated into the enamel crystal lattice structure to form less soluble fluorapatite. The objective of this study was to evaluate the enamel fluoride retention ability of various fluoride salts, and to examine correlations between initial fluoride uptake and fluoride retained following demineralization of human enamel following 24-hour acid challenge using an in vitro fluoride retention model. Method: Demineralized human enamel specimens were prepared using standard procedures. Specimens were randomly placed in treatment groups and exposed to human saliva to form an initial pellicle layer. A 4-day cycling regime followed whereby dentifrice treatments (NaF, SnF2, and MFP) were interspersed with saliva and a demin challenge each day. Following the cycling procedure, fluoride uptake analysis was performed on each specimen using the fluoride biosorptive technique. All specimens were then exposed to fresh demineralization solution for 24 hours. Enamel biopsies were repeated to evaluate fluoride retained following acid exposure. Result: Data shows a fluoride dose response between initial fluoride uptake and fluoride retained following acid challenge. Different fluoride salts exhibited varying levels of fluoride uptake. The same rank ordering of fluoride salts was seen in retained fluoride values. Analysis of fluoride concentration after 24-hour acid challenge shows correlation with initial fluoride uptake values, indicating most of the fluoride is retained inside enamel and is part of the crystalline structure of dental mineral.

MATERIALS AND METHODS

Substrate Lesion Development: Human enamel core (3 mm diameter mounted on acrylic cylinder, ground and polished) are exposed to demineralization solution (0.1M lactic acid, 0.2% Carbopol, 50% saturated with respect to hydroxyapatite, pH 5.0) for 96 hours at 37°C to create sub-surface lesions about 60-80 micron deep.

Fluoride Uptake Analyses of Demineralized Enamel Chips –

Fluoride Uptake Analyses of Demineralized Enamel Chips –

Fluoride Uptake Analysis From Pre and Post Acid Challenge

Pre Acid Challenge:

After four days of cycling, enamel specimens are analyzed for fluoride uptake using the “microdrill biopsy” technique via extraction of a set quantity of enamel by milling and dissolving it in 0.5 M HClO4. The acid is buffered with TISAB II and the pH is adjusted with 0.5N NaOH. The fluoride content is measured using fluoride electrode and values are expressed in μg/cm² of analyzed surface. After fluoride uptake analysis, half of each sample surface that had been subjected to remineralization treatment is covered with nail polish. The portion which remains uncovered is then submitted to a new cycle of demineralization by acid treatment in a 0.2% Carbopol demineralization solution, for a period of 24 h at 37°C.

Post Acid Challenge:

Another microdrill biopsy using the technique described above is repeated to assess the fluoride content remaining following the final 24 hour acid treatment.

RESULTS

Effect of Acid Demineralization on F uptake

Correlation Between Pre and Post Acid F uptake

Fluoride Retained Post Acid Challenged

Fluoride Retention Model: There is More Than Just

Fluoride retention model.

CONCLUSIONS

• Fluoride dose response is maintained between initial fluoride uptake and fluoride retained following acid challenge.

• Different fluoride salts exhibited varying levels of fluoride uptake. The same rank ordering of fluoride salts was seen in retained fluoride values.

• Excellent correlations exist between pre- and post acid challenge of fluoride treated enamel, suggesting incorporation of fluoride in mineral

• Putting more fluoride into enamel does not necessarily mean greater incorporation into mineral

Analysis of fluoride concentration after 24-hour acid challenge shows correlation with initial fluoride uptake values, indicating most of the fluoride is retained inside enamel and is part of the crystalline structure of dental mineral.
Randomized Controlled Trial of CPC Peroxide Rinse Effects on Plaque

M.J. DOYLE*, R. CHENG, R.W. GERLACH
The Procter & Gamble Co., Mason, OH USA

ABSTRACT

Objectives: A randomized controlled clinical study was conducted to evaluate the effectiveness of a cetylpyridinium chloride rinse with peroxide on short-term plaque re-growth.

Methods: A 4-day crossover study evaluated, in part, the clinical effects of a 0.1% cetylpyridinium chloride (CPC) rinse containing 1.5% hydrogen peroxide on dental plaque in adults. After informed consent, enrolled subjects were provided a regular dentifrice and brush plus usage instructions for acclimation, and disclosed dental plaque was measured overnight. Subjects in this crossover study were randomly assigned to a treatment sequence that included: a 0.10% CPC + 1.5% H2O2 rinse (the experimental group), a 0.07% CPC rinse (Crest® Pro-Health), and a regular anti-cavity paste (Crest Cavity Protection) – the latter two of which served as positive and negative controls. Each period was preceded by a 7-10 day washout and dental polishing. Brushing was for 1 min BID, while rinsing was 30 sec BID. Whole mouth disclosed plaque was measured after each 4-day period by a treatment-blinded examiner using a standard 6-point clinical plaque index (TMQHI).

Results: A total of 30 adults (27-61 years of age) were enrolled. Post-treatment plaque scores were lowest in the experimental group and highest in the brushing only group. The Day 4 adjusted TMQHI means (SE) were 0.69 (0.058) in the 0.10% CPC + 1.5% H2O2 group, 0.95 (0.056) in the 0.07% CPC group, and 1.27 (0.057) in the brushing control. Both CPC rinse groups differed significantly (p<0.01) from the negative control, and the experimental rinse differed (p<0.01) from the positive control. Mild adverse events were observed with all products, but were directionally more common during experimental rinse use.

Conclusion: Over 4-days, use of a 0.1% cetylpyridinium chloride rinse with 1.5% hydrogen peroxide resulted in a significant 46% reduction in overnight whole mouth plaque relative to regular brushing.

MATERIALS AND METHODS

Subjects in this crossover study were randomly assigned to a treatment sequence that included:
- 0.10% CPC + 1.5% H2O2 rinse (experimental rinse)
- 0.07% CPC rinse (Crest® Pro-Health)
- a regular anti-cavity paste (brushing control)

• Each period was preceded by a 7-10 day washout and dental polishing.
• Brushing was for 1 min BID, while rinsing was 30 sec BID.
• Whole mouth disclosed plaque was measured after each 4-day period by a treatment-blinded examiner using a standard 6-point clinical plaque index (TMQHI).

RESULTS

Over 4-days, use of a 0.1% cetylpyridinium chloride rinse with 1.5% hydrogen peroxide resulted in a significant 46% reduction in overnight whole mouth plaque relative to regular brushing.
Objectives: A randomized, positively-controlled clinical trial was conducted to evaluate the early gingivitis effects of combination oral hygiene (brush, paste, rinse & floss) in a general population.

Methods: A total of 50 adults with mild-to-moderate gingival bleeding were randomly assigned to combination oral hygiene or a dental prophylaxis. The combination group received a flexible crisscross manual brush (Oral-B® Pro-Health Clinical Pro-flex), 0.454% stannous fluoride paste (Crest® Pro-Health Clinical Plaque Control), 0.1% cetylpyridinium chloride rinse (Crest® Pro-Health Clinical), and floss (Oral-B® Glide), while the control group received a dental prophylaxis, regular anticavity paste and standard manual brush. Test products were dispensed in blinded kits, usage was unsupervised at-home, and whole mouth gingivitis was measured by a treatment-blinded examiner to quantify change in bleeding sites after 7 days.

Results: The diverse general population had a mean (SD) age of 27.8 (8.3) years. At baseline, gingival bleeding was mild-to-moderate, with a mean (SD) 8.2 (5.1) sites, and an upper limit of 26 sites. A total of 48 subjects completed week 1 (24 per group). Relative to baseline, both the combination group and the prophylaxis control exhibited significant (p<0.0001) reductions in bleeding sites at 1-week. Comparing treatments, the adjusted bleeding site means (SE) were 2.4 (0.35) and 4.2 in the combination group and prophylaxis control, respectively. Groups differed significantly (p=0.0008) on bleeding sites after 1-week, favoring the combination group. There was one adverse event (oral irritation in the combination group), and all treatment was well-tolerated.

Conclusion: Use of combination daily oral hygiene regimen with an advanced manual brush, therapeutic paste and rinse plus floss resulted in a highly significant 43% greater incremental reduction in gingival bleeding than dental prophylaxis.

CONCLUSIONS

Use of combination daily oral hygiene regimen with an advanced manual brush, therapeutic paste and rinse plus floss resulted in a highly significant 43% greater incremental reduction in gingival bleeding than dental prophylaxis.
Clinical Response to Two Stimuli by Subjects Reporting Tooth Sensitivity

Saturday, March 22, 2014: 9:30 a.m. - 10:30 a.m.
Location: Exhibit Hall AB (Charlotte Convention Center)

Presentation Type: Poster Session

Track: Clinician Track

M.L. SINGH1, A.S. PAPAS2, M.L. BARKER2, and R.W. GERLACH2, 1Tufts University School of Dental Medicine, Boston, MA, 2Procter & Gamble Company, Mason, OH

Objective: This clinical study assessed two methods for sensitivity provocation in a general population.

Method: After institutional review and informed consent, 150 adult volunteers who reported natural tooth sensitivity were enrolled in a screening study to assess differential pain responses to two provocative stimuli (air and water). Oral hygiene was not standardized, except that subjects were instructed to avoid daily hygiene on the morning of evaluation. An interview and an oral examination were conducted to identify subjects with recession sites, which served as test sites for this study. Each test site was first stimulated with a 1-sec application of cool air (−21°C, 40-60 psi) using a dental syringe, after which, a single drop of refrigerated (−2°C) water from a 3 mL hypodermic syringe. Site response was measured immediately after each stimulus by a trained clinical examiner using a standard 4-point scale (Schiff) that categorized discomfort from none-to-painful.

Result: A total of 26 subjects (mean age of 46.1 years, 47% female) exhibited a sensitivity response at recession sites for air and/or water stimuli. Subjects averaged 3.73 (SE 0.23) sites with air response versus 2.21 (SE 0.25) for water, ranging from 0 to 16 for air and 0 to 13 for water. The total Schiff sum per subject averaged 5.52 (SE 0.72) for air and 3.14 (SE 0.34) for water, while mean Schiff scores per subject averaged 1.12 (SE 0.07) for air and 0.38 (0.07) water. Subject-level correlations between air and water stimuli were high for the number of sensitivity sites (r = 0.71) and total Schiff sum (r = 0.72). Mean Schiff level revealed an insignificant subject-level correlation.

Conclusion: In a general population without acclimation, use of two different stimuli (air and water) yielded consistent clinical sensitivity occurrence of teeth within-subjects and for total Schiff sum, while simple means yielded low subject-level consistency between stimuli.
Clinical Evaluation of Stannous Fluoride Dentifrice on Dentinal Hypersensitivity

Objective: To compare the dentinal hypersensitivity relief benefits of two marketed desensitizing dentifrices over an 8-week period.

Method: This study was a randomized, parallel group, controlled, 8-week clinical trial. Subjects reporting moderate dentinal hypersensitivity on 2 teeth (Schiff Index of 2 or 3 and Yeaple Probe 10g) were enrolled and randomized to one of the treatment dentifrices: a 0.454% stannous fluoride dentifrice (Oral-B® PRO EXPERT), or a marketed control dentifrice (Colgate® Total Advanced, UK). Subjects used the test product twice daily, 1 minute each time, for 8 weeks. Tactile Yeaple probe and thermal Schiff cold air assessments were performed at baseline, week 2, and week 8. Treatments were compared using ANOVA (Yeaple) or ANCOVA (Cold air) statistical analysis.

Result: One hundred subjects were randomized to treatment and 97 subjects completed the study with a mean age of 45.5 years. Treatment groups were balanced on Baseline mean Schiff air index (p=0.74) and Baseline Yeaple scores were 10.00 for all subjects. Relative to the control, the 0.454% stannous fluoride dentifrice demonstrated significantly superior sensitivity protection (p<0.0001) for mean Yeaple scores by 113.6% at week 2, and 183.8% at week 8. For Schiff cold air assessment, the 0.454% stannous fluoride dentifrice exhibited significantly superior sensitivity protection (p<0.0001) by 24.2% at week 2, and 67.7% at week 8. No adverse events were reported with either dentifrice.

Conclusion: The 0.454% stannous fluoride dentifrice provided superior rapid and long lasting dentinal hypersensitivity relief benefit when compared to the marketed desensitizing dentifrice control.

MATERIALS AND METHODS
This was a controlled, randomized, double blind, two-treatment, parallel group clinical trial. The target population was up to 100 healthy adult volunteers with at least two sensitive teeth demonstrating reproducible sensitivity to both thermal and tactile stimuli. Clinical examinations including tactile Yeaple probe and thermal Schiff cold air index were performed at baseline, week 2, and week 8. Sensitivity scores were averaged across both teeth for each subject and separately for each time point and sensitivity measure.

RESULTS
100 subjects were randomized to treatment and 97 subjects completed the study. Subjects ranged in age from 21 to 65 years with an average of 45.5 years. Seventy-nine percent (79%) of the subjects were female. Treatment groups were well balanced (p≥0.24) on age, ethnicity, and gender.

CONCLUSIONS
The 0.454% stannous fluoride dentifrice provided superior rapid and long lasting dentinal hypersensitivity relief benefit when compared to the marketed desensitizing dentifrice control.
Demographic and Behavioral Effects on Stain Removal with Whitening Dentifrices

F.O. AJAYI*, M.L. BARKER, A.R. BIESBROCK, R.W. GERLACH, T. HE
The Procter & Gamble Co., Mason, OH USA

ABSTRACT

Objectives: This meta-analysis was conducted to assess whether demographic parameters, behavioral factors or baseline stain levels impacted whitening dentifrice effectiveness in clinical trials with common study designs.

Methods: The pooled analysis was inclusive of all subjects in six clinical trials who were assigned a whitening dentifrice and had stain levels measured after 2-weeks usage. In each study, institutional review and informed consent were obtained, after which, adults with natural tooth stain were assigned one of 6 different marketed whitening dentifrices for at-home unsupervised use. At baseline, and again after 2 weeks treatment, extrinsic tooth stain area and intensity were measured by a treatment-blinded examiner using the Lobene index (LSI). Six different whitening dentifrices were included in the meta-analysis. The data were analyzed with a General Linear Mixed Model with baseline characteristics as fixed effects and study as a random effect.

Results: The meta-analysis consisted of 144 subjects with natural extrinsic tooth stain. Mean (SD) age was 44.3 (12.3) years, males comprised 51% of subjects, 24% used tobacco products, while 51% and 78% consumed tea or coffee, respectively. At baseline, subjects exhibited appreciable stain accumulation, as evidenced by an LSI mean (SD) of 1.6 (0.55). Subjects exhibited significant (p<0.0001) stain reduction after 2-weeks use of an assigned whitening dentifrice. In the pooled data, baseline stain was a significant effect in the model (p<0.0001). Behavioral factors, such as coffee or tea consumption or smoking, and demographic factors such as age or gender, were not significant effects.

Conclusion: Meta-analysis of data from clinical trials that evaluated effectiveness of whitening dentifrice for natural stain removal demonstrated that starting stain level, but not demographics or behavioral factors, affected response.

MATERIALS AND METHODS

Baseline and Week 2 data from six clinical trials totaling 144 subjects with extrinsic tooth stain were pooled into one dataset to conduct a meta analysis of stain removal with commonly used whitening dentifrices from major brands. Extrinsic tooth stain area and intensity were measured by a treatment-blinded examiner using the Lobene index (LSI). Six different whitening dentifrices were included in the meta-analysis. The data were analyzed with a general linear mixed model with baseline characteristics as fixed effects and study as a random effect.

RESULTS

144 subjects were included in this meta-analysis. Subjects ranged in age from 19 to 68 years with a mean (SD) of 44.3 (12.3) years, and 49% of the subjects were female. At baseline, subjects exhibited an LSI mean (SD) of 1.58 (0.55).

Demographics Summary

<table>
<thead>
<tr>
<th>Gender (M/F)</th>
<th>Coffee (Yes/No)</th>
<th>Tea (Yes/No)</th>
<th>Smoke (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>51</td>
<td>49</td>
<td>78</td>
</tr>
</tbody>
</table>

Natural Extrinsic Stain

Week 2 Change from Baseline

Baseline

Demographic and Behavioral Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Category</th>
<th>Change from Baseline Estimate (SE)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Slope</td>
<td>-0.92 (0.05)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Age</td>
<td>Slope</td>
<td>0.003 (0.002)</td>
<td>0.1690</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>-1.18 (0.09)</td>
<td>0.0980</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>-1.26 (0.09)</td>
<td></td>
</tr>
<tr>
<td>Smoke</td>
<td>Yes</td>
<td>-1.17 (0.10)</td>
<td>0.6337</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>-1.26 (0.09)</td>
<td></td>
</tr>
<tr>
<td>Coffee</td>
<td>Yes</td>
<td>-1.20 (0.09)</td>
<td>0.6407</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>-1.23 (0.10)</td>
<td></td>
</tr>
<tr>
<td>Tea</td>
<td>Yes</td>
<td>-1.23 (0.09)</td>
<td>0.1379</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>-1.21 (0.10)</td>
<td></td>
</tr>
</tbody>
</table>

*For every one unit increase in baseline stain, there was an additional 0.92 reduction in stain at Week 2.

CONCLUSIONS

Meta-analysis of data from clinical trials that evaluated effectiveness of whitening dentifrice for natural stain removal demonstrated that starting stain level, but not demographics or behavioral factors, affected response.
Initial Comparative Plaque Effects of Power Brush and SnF2 Paste

R.W. GERLACH1, M. MINER*, M.L. BARKER1, I. MAGNUSSON2
1The Procter & Gamble Co., Mason, OH USA, 2University of Florida, Gainesville, FL USA

ABSTRACT

Objectives: A randomized controlled trial compared use of a power brush and therapeutic dentifrice on overnight plaque accumulation and plaque removal.

Methods: Healthy adults with overnight plaque were randomly assigned to a combination paste-brush group or regular brushing control. Subjects received either the combination treatment with 0.454% stannous fluoride sodium hexametaphosphate dentifrice (Crest® Pro-Health) and power brush (Oral-B® ProfessionalCare Series 500 with the Oral-B Precision Clean® brush head, or a regular anticavity paste and manual brush. Use was at-home and unsupervised, and response was measured with image analysis of fluorescein-disclosed plaque area (%) after 1-week at prebrush (overnight) and postbrush time points.

Results: Study subjects had a mean (SD) age of 38.8 (15.5), with 42 subjects evaluated after 1 week use. At baseline, groups were balanced (p > 0.51) on baseline plaque, with overall mean (SD) prebrush and postbrush plaque area% of 11.4 (6.5) and 5.6 (4.3), respectively. Only the power brush + therapeutic paste combination exhibited significant (p<0.01) improvements from baseline for both prebrush and postbrush plaque. Relative to the control, the combination group exhibited 47% and 46% reductions in adjusted mean prebrush and postbrush plaque after 1 week use. Treatments differed significantly (p<0.004) for overnight and post-brushing plaque, favoring the combination group. Treatments were generally well-tolerated.

Conclusion: Use of a combination stannous fluoride dentifrice and rotation-oscillation power brush yielded an average 47% reduction in overnight or postbrush plaque relative to the regular brushing control.

MATERIALS AND METHODS

This was a randomized, controlled, single-blind, 2-treatment parallel group study. The study population consisted of 50 healthy adult volunteers with plaque. Following an acclimation period subjects were randomized to 1) Crest® Pro-Health toothpaste, Oral-B® ProfessionalCare Series 500 powered toothbrush with the Oral-B Precision Clean® brush head, or 2) regular brushing with a standard anti-cavity toothpaste and manual toothbrush. Use was at-home and unsupervised, and response was measured with image analysis of fluorescein-disclosed plaque area (%) after 1-week at prebrush (overnight) and postbrush time points.

RESULTS

Fifty subjects signed an informed consent, were randomized and received treatment. Forty-two subjects were evaluated after 1 week use. Subjects ranged in age from 19 to 79 years with an average of 39 years, and 76% of the subjects were female. Treatment groups were well balanced (p≥0.569) on age, ethnicity and gender.

Case Study: Subject from the Combination Group was a 32-year-old Caucasian Female. She had 18.6% Overnight Pre-Brush Plaque Area and 8.9% Post-Brush Plaque Area at Baseline. After using the combination of products for 1 week, she had 7.1% Overnight Pre-Brush Plaque Area and 2.3% Post-Brush Plaque Area at the Week 1 visit.

CONCLUSIONS

Use of a combination stannous fluoride dentifrice and rotation-oscillation power brush yielded an average 47% reduction in overnight or postbrush plaque relative to the regular brushing control.