ABSTRACT

A total of 41 subjects were enrolled in the study and all but one was randomized. All 40 subjects who were randomized completed all four treatment periods and were included in the statistical analysis. There were 28 (70%) females and 12 (30%) males; and the subjects ranged in age from 20-69 years with an average age of 42.3 years.

The mean difference from baseline for all RMNPI endpoints for each brush were statistically significant (p<0.001). Specifically, the mean % reduction from baseline for the oscillation/rotation powerbrush with novel brushhead for Whole Mouth, Gingival Margin, and Interproximal RMNPI scores were 87.3%, 79.7%, and 92.2%, respectively. Similarly for the manual toothbrush, the mean % reductions were 68.8%, 54.9% and 80.5%, respectively.

For Whole Mouth RMNPI, Gingival Margin RMNPI, and Interproximal RMNPI, the oscillating-rotating powerbrush with novel brushhead removed statistically significantly more plaque (whole mouth, marginal and interproximal areas) compared to a manual toothbrush control. Both brushes were well tolerated.

MATERIALS AND METHODS

Study design
This was a replicated single use, 2 (two) treatment, examiner-blind, randomized, 4 (four) period crossover design. A total of 41 subjects were enrolled in the study.

Clinical examinations (4 periods)
The Rustogi Modification of the Navy Plaque Index (RMNPI) was used to measure the pre- and post-brushing plaque level by an experienced plaque examiner.

Product usage
The study involved a one week acclimation period where the subjects were given an Oral-B Professional Care 1000 toothbrush with previous Oral-B PrecisionClean brush head and Crest Cavity Protection (CCP) paste and brushing instructions (per manufacturer's usage instructions). They were instructed to use their acclimation products for 2 to 3 days and to switch back to their usual toothbrush product 48 hours prior to the start of Period 1. During the treatment periods subjects brushed with the power toothbrush (Oral-B Professional Care 1000 with newly designed PrecisionClean brush head) for 2 minutes per treatment and followed their manufacturer's instructions or as they normally do with the ADA manual toothbrush according to their randomization schedule.

Statistical analysis
The adjusted mean plaque removal scores (pre- minus post-brushing) for each treatment were analyzed for statistical significance from zero using a t-test (0.05 level of significance) on the adjusted treatment mean score differences from the mixed model analysis of covariance for a crossover design.

RESULTS

A total of 41 subjects were enrolled in the study and all but one was randomized. All 40 subjects who were randomized completed all four treatment periods and were included in the statistical analysis. There were 28 (70%) females and 12 (30%) males; and the subjects ranged in age from 20-69 years with an average age of 42.3 years.

The mean difference from baseline for all RMNPI endpoints for each brush were statistically significant (p<0.001). Specifically, the mean % reduction from baseline for the oscillation/rotation powerbrush with novel brushhead for Whole Mouth, Gingival Margin and Interproximal RMNPI scores were 87.3%, 79.7% and 92.2%, respectively. Similarly for the manual toothbrush, the mean % reductions were 68.8%, 54.9% and 80.5%, respectively.

For Whole Mouth RMNPI, Gingival Margin RMNPI, and Interproximal RMNPI, the oscillating-rotating powerbrush with novel brushhead removed statistically significantly more plaque (whole mouth, marginal and interproximal areas) compared to the manual toothbrush.

CONCLUSIONS

The rotating/oscillating Oral-B power toothbrush with novel brushhead was found to remove statistically significantly more plaque (whole mouth, marginal and interproximal areas) compared to a manual toothbrush control. Both brushes were well tolerated.

Table 1: Summary of the Pre- and Post Brushing Plaque Scores

<table>
<thead>
<tr>
<th>Subsite</th>
<th>Toothbrush</th>
<th>n</th>
<th>Mean ± SE % Reduction²</th>
<th>% Difference¹</th>
<th>Significance*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Mouth</td>
<td>Oscillating-Rotating Powerbrush¹</td>
<td>40</td>
<td>0.632 ± 0.054</td>
<td>97.7%</td>
<td>28.8%</td>
</tr>
<tr>
<td></td>
<td>ADA Manual Toothbrush</td>
<td>40</td>
<td>0.625 ± 0.054</td>
<td>68.8%</td>
<td>44.3%</td>
</tr>
<tr>
<td>Gingival Margin</td>
<td>Oscillating-Rotating Powerbrush¹</td>
<td>40</td>
<td>0.5 ± 0.0135</td>
<td>79.2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ADA Manual Toothbrush</td>
<td>40</td>
<td>0.504 ± 0.0135</td>
<td>54.9%</td>
<td>20.7%</td>
</tr>
<tr>
<td>Interproximal</td>
<td>Oscillating-Rotating Powerbrush¹</td>
<td>40</td>
<td>0.0 ± 0.0096</td>
<td>90.5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ADA Manual Toothbrush</td>
<td>40</td>
<td>0.085 ± 0.0096</td>
<td>40.5%</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 1: Percent Plaque Removal After Single Brushing

* Oral-B® Professional Care 1000 (220) rechargeable toothbrush (Procter & Gamble Company).
¹ Reduction between the pre- and post brushing plaque scores, expressed as a percentage of the pre-brushing score.
² Difference between pre- to post brushing reductions in plaque, expressed as a percentage of the reduction for the ADA Manual Toothbrush.
* Significance of treatment difference using a mixed model analysis of covariance for a crossover design with terms in the model for subject, treatment, period, and pre-brushing scores as the covariate.