The Anti-caries Efficacy of a Dentifrice Containing 1.5% Arginine and 1450 ppm Fluoride as Sodium Monofluorophosphate Assessed Using Quantitative Light-induced Fluorescence (QLF)

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Study objective
The objective of the study was to assess the ability of a new dentifrice containing 1.5% arginine, an insoluble calcium compound and fluoride to arrest or reverse naturally occurring buccal caries lesions in children measured using Quantitative Light-induced Fluorescence (QLF).

Trial conditions and methods

Products under investigation

Test dentifrice: 1.5% arginine and 1450 ppm fluoride as sodium monofluorophosphate (MFP) in a calcium base (Colgate-Palmolive Company, New York, NY)

Positive control dentifrice: 1450 ppm fluoride as sodium fluoride (NaF) in a silica base (Colgate-Palmolive Company, New York, NY)

Negative control dentifrice: Non-fluoride toothpaste in a calcium base (Colgate-Palmolive Company, New York, NY)

Study subjects

463 male and female subjects (children aged 9-13 years) from five schools in China with at least one visible white spot lesion on the buccal surface of one of the six upper anterior teeth.

Methods

In this double-blind, parallel-group study, 463 subjects with an established white spot lesion were given oral hygiene instructions and were randomly assigned to the test group, the positive control group or the negative control group (N=153-155 for each group). Following baseline examination, subjects were instructed to brush at least twice per day with their assigned toothpaste and toothbrush. On school days, subjects brushed in the afternoon under supervision for two minutes. Three to five images per subject were taken of the upper anterior teeth, using a QLF imaging system, so that clear views of any lesions could be captured. The camera and illuminator were mounted in a stabilizing unit. Together with video repositioning software, this enabled subjects to be accurately repositioned at each visit. Images were taken at baseline, and after three- and six- months use of the assigned product. The QLF software was used to determine lesion area, loss of fluorescence (ΔF), and lesion volume (ΔQ). The primary outcome was the mean subject ΔQ at the six-month examination. Comparisons between treatments were performed using a linear model controlling for baseline ΔQ value and number of lesions per subject and applying a Bonferroni adjustment to the pair wise comparisons. All statistical tests of hypotheses employed a level of significance of α=0.05.
Results
438 subjects completed the study. There were no statistically significant differences between the three study groups for any of the baseline measurements. For ΔQ, the baseline mean value for the three groups was 27.26. At three-months, mean ΔQ values were 18.00, 20.71, and 24.50 for the test, positive control and negative control, respectively, representing improvements from baseline of 34.0%, 24.0% and 10.1%. At six-months, mean ΔQ values were 13.46, 17.99, and 23.70 for the test, positive control and negative control, respectively, representing improvements from baseline of 50.6%, 34.0% and 13.1%. The difference between the test and positive control group was statistically significant (p=0.003), as were the differences between the negative control group and both the test and positive control groups (p≤0.001). The arginine-containing dentifrice demonstrated an improvement after only three months that was almost identical to that achieved by the conventional fluoride dentifrice after six months.

Mean ΔQ (representing lesion volume in mm².%) at baseline, three and six months with 95% confidence intervals

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Month 3</th>
<th>Month 6</th>
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<tbody>
<tr>
<td>1.5% Arginine/1450 MFP</td>
<td>88.9</td>
<td>78.9</td>
<td>47.2</td>
</tr>
<tr>
<td>1450 NaF/Silica</td>
<td>88.9</td>
<td>78.9</td>
<td>79.5</td>
</tr>
<tr>
<td>Non-fluoride in calcium base</td>
<td>90.9</td>
<td>80.7</td>
<td>44.0</td>
</tr>
</tbody>
</table>

Conclusion
A new dentifrice containing 1.5% arginine, an insoluble calcium compound, and 1450 ppm fluoride provides statistically significantly superior efficacy in arresting and reversing buccal caries lesions than a conventional 1450 ppm fluoride alone.