Anticaries Efficacy of a Sodium Monofluorophosphate Dentifrice Containing Xylitol in a Dicalcium Phosphate Dihydrate Base: A 30-month caries clinical study in Costa Rica.

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Purpose

To compare the long-term caries increment associated with the use of two dentifrices:

- A test dentifrice containing 0.836% sodium monofluorophosphate (1100 ppm F) in a dicalcium phosphate dihydrate base plus 10% xylitol

- A positive control dentifrice containing 0.836% sodium monofluorophosphate (1100 ppm F) in a dicalcium phosphate dihydrate base
**Introduction**

*In vitro* investigations of xylitol have focused on its inhibition of demineralization, and on its favorable effects on such caries-related parameters as bacterial incubation curves, pH, rate, extent, and type of acid production, insoluble polysaccharide synthesis, and calcium/phosphorous dissolution, and on other parameters either alone or in comparison with other sugar alcohols and carbohydrates.

Studies have indicated a potentially additive effect of fluoride (F) and xylitol on such parameters as post-demineralization enamel integrity and decreased lactate production by *S. mutans* in presence of glucose (Sintes *et al*).

A long-term effect was suggested by the analysis of a subset of children who had participated in a xylitol field study, in which subjects who were available for a 5-year follow-up exam suggested that caries increments may have continued to decline during the (5-year) post-study period in initially 11-12 year-old children who had xylitol chewing gum during their participation in the study (Isokangas et al).

Clinical caries studies on the effect of xylitol-containing dentifrices have been reported. Sintes et al provided a direct comparison of the caries increments associated with the use of a fluoride dentifrice formulated with, and without xylitol.
Study population-

3,394 school children aged 7-12 years selected to participate in 30-month, double blind clinical caries study at 28 public schools in the central plateau of Costa Rica including San José, Cartago, Alajuela and Heredia.

This area possesses a naturally occurring drinking water fluoride (F) concentration of less than 0.1 ppm.

A salt fluoridation program was established in 1987 with a recommended dose of 200 ppm (Salas et al).
Sample-

Subjects were stratified into two balanced groups within the participating schools on the basis of age and sex. A minimum required baseline caries risk for each child was set to at least one decayed/filled surface (DFS).

Treatment regimen-

This clinical study included two dentifrices:

- A test dentifrice containing 0.836% sodium monofluorophosphate (1100 ppm F) in a dicalcium phosphate dihydrate base plus 10% xylitol.

- A positive control dentifrice containing 0.836% sodium monofluorophosphate (1100 ppm F) in a dicalcium phosphate dihydrate base (with no added xylitol).
**Materials and Methods**

**Clinical examinations**-

- Two calibrated examiners.
- Kappa Statistic for Inter and Intra examiner reproducibility was greater than 0.9.

**Diagnostic Criteria**-

- National Institute of Dental Research (NIDR)

A DFS score was determined for each participant and then a mean DFS score was calculated for each dentifrice group.

From the post-baseline examinations, the mean incremental DFS score was calculated for each dentifrice group.
Materials and Methods

**Statistical Analysis**-

The comparison of the treatment groups with respect to baseline caries prevalence, and with respect to the caries increments between the baseline and the 12- and 30-month exams was made using ANOVA.

All statistical tests of hypotheses were two-tailed, and employed a level of significance of $\alpha = 0.05$. 
Conclusion

The results of this 30-month clinical study supports the conclusion that a test dentifrice containing 0.836% (1100 ppm F) sodium monofluorophosphate in a dicalcium phosphate dihydrate base with 10% xylitol provides superior clinical anticaries efficacy than a positive control dentifrice containing 0.836% (1100 ppm F) sodium monofluorophosphate in a dicalcium phosphate dihydrate base without xylitol. Therefore, this clinical study reinforces the anticaries benefits of adding xylitol to dentifrices.
Results

- 2,539 subjects were available for the 30-month exam.

Table 1. Summary of mean baseline and incremental DFS and DFT scores for subjects examined at each of the subsequent study visits

<table>
<thead>
<tr>
<th>Visit</th>
<th>Dentifrice</th>
<th>n</th>
<th>Baseline $\text{DFS}^3_{\text{SD}}$</th>
<th>Baseline $\text{DFT}^4_{\text{SD}}$</th>
<th>Incremental $\text{DFS}^3_{\text{SD}}$</th>
<th>Incremental $\text{DFT}^4_{\text{SD}}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
<td>Test dentifrice$^1$</td>
<td>1482</td>
<td>3.80±2.30</td>
<td>2.49±1.20</td>
<td>0.49±1.40</td>
<td>0.19±0.79</td>
</tr>
<tr>
<td></td>
<td>Positive control dentifrice$^2$</td>
<td>1442</td>
<td>3.79±2.29</td>
<td>2.50±1.19</td>
<td>0.61±1.49</td>
<td>0.29±0.90</td>
</tr>
<tr>
<td>30 months</td>
<td>Test dentifrice$^1$</td>
<td>1280</td>
<td>3.69±2.20</td>
<td>2.41±1.20</td>
<td>1.30±1.89</td>
<td>0.69±1.10</td>
</tr>
<tr>
<td></td>
<td>Positive control dentifrice$^2$</td>
<td>1259</td>
<td>3.70±2.19</td>
<td>2.40±119</td>
<td>1.51±2.00</td>
<td>0.81±1.21</td>
</tr>
</tbody>
</table>
Table 2. Results of statistical analyses investigating the comparative anticaries efficacy of the study dentifrices over the 30-month study period

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean incremental caries scores</th>
<th>% Reduction&lt;sup&gt;5&lt;/sup&gt;</th>
<th>P-value&lt;sup&gt;6&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test dentifrice&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Positive control dentifrice&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>DFS&lt;sup&gt;3&lt;/sup&gt;</td>
<td>1.30</td>
<td>1.51</td>
<td>13.9</td>
</tr>
<tr>
<td>DFT&lt;sup&gt;4&lt;/sup&gt;</td>
<td>0.69</td>
<td>0.81</td>
<td>14.8</td>
</tr>
</tbody>
</table>
Conclusion

A test dentrifice containing 0.836% (1100 ppm F) sodium monofluorophosphate in a dicalcium phosphate dihydrate base with 10% xylitol provides superior clinical anticaries efficacy than a positive control dentrifice containing 0.836% (1100 ppm F) sodium monofluorophosphate in a dicalcium phosphate dihydrate base without xylitol.