



**CARIES INHIBITORY EFFECT OF
FLUORIDE CO-CRYSTALLIZED SUCROSE
- ESTABLISHING A FIELD TRIAL -**

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There is growing evidence that dental caries prevalence is increasing to epidemic proportions in many developing countries. Increasing economic growth, and the resultant ready access to information and products from developed countries, often results in a greater tendency for increase^d reliance in the diet on fast, refined foods, and reduction in the more natural traditional eating patterns. There is a great deal of evidence to show that this move to increased volume and frequency of refined carbohydrate consumption leads in most instances to a rapid increase in dental caries prevalence. Unfortunately, in developing countries, such changes are not followed by improvements in dental health services and education.

However, caries has been largely controlled in most developed countries, not by provision of treatment, but by the use of relatively simple public health preventive methods, in particular the widespread use of systemic and topical fluorides. Furthermore, this high level of reduction in caries prevalence has been achieved while the volume and frequency of refined carbohydrate consumption has remained relatively unchanged. Yet many of the methods that have been used to deliver fluoride ion to the population are not suitable for use in developing countries.

For example, in Indonesia, water fluoridation is not feasible because of the widely dispersed population, the wide use of well water,

and the very hot climate compared with most developed countries. Although tooth pastes are available in urban markets, they are not widely used by the population because of cost. Also dental health is not a high priority for many people.

Yet, the experience in developed countries leads to the conclusion that the widespread delivery of the fluoride ion in low dose to the population, would be the most cost and benefit effective method of controlling caries progression. Those methods which appear most suitable to achieve this in developing countries are the use of salt or sugar as fluoride vehicles. There is little information on the level of distribution and the utilization of salt in Indonesia, and this might be quite variable because of the wide diversity of cultural sub-groups who make up the population. Sugar would seem to be a most practical vehicle, its use being a major cause of caries development. However it has not been used on a population basis as yet, and there remains some concerns as to the economical, ethical and even political aspects of its use in such a way (Bratthall and Barnes. 1995). Yet, it has been proven very effective in the one human study so far conducted (Luoma et al, 1979), and in numerous animal studies (Mundorff, et. al., 1988, Bowen and Pearson, 1992; Luoma, et. al., 1972).

Considering the urgency of dealing with the rapid increase in caries prevalence in parts of Indonesia, the objective in this project was to design and implement a field trial, to test the effectiveness of a 10 ppm fluoride co-crystallized sugar in inhibiting caries. If successful, such a trial may assist in the conducting of more widespread trials in other developing countries, and provide support for the introduction of this method as a potentially inexpensive, though effective public health preventive method.

The primary requirement of such a trial is the safety aspect and a year was spent in :

1. conducting laboratory studies to determine that concentration of fluoride ion which would be most effective in caries inhibition, yet be clearly safe in terms of toxicity and in terms of providing minimal risk of fluorosis in young children.
2. determining the method of its combination with sugar to provide a homogenous product concentration and ready availability to the oral hard tissues.
3. selecting potential test populations, and determining their dietary patterns, background fluoride intake levels and ensuring that strict control could be maintained on sugar consumption.

The clinical trial was carried out in Medan, Indonesia in which subjects were children, 7-19 years of age, of mixed gender, living in two orphanages and a "pesantren" (a kind of boarding school) over a duration of 18 months period. The children were divided into a control group who had ordinary sugar and a test group who consumed a 10 ppm fluoride co-crystallized sucrose. Each child consumed approximately 60 gms sugar per day incorporating in the daily menu.

Data for DMFS scores were obtained, using a double blind clinical evaluation format, before and after 18 months utilization of fluoride co-crystallized sucrose. Analysis of Variance with significance level $p < 0.05$ were used to analyse the changes in the DMFS scores and their increments over the duration of the trial. Caries progression data calculated from the progress of the D, M and F components and the initiation/reversal of initial carious lesions, were also analyzed.

Analysis of Variance with significance level $p < 0.05$ revealed that significant increases in DMFS scores were found in the control and test groups, though the caries increment was significantly higher in the control group. Caries progression rates were significantly higher in the

control group. Development of initial carious lesions was found in the control group, while a slight reversal of such lesions was detected in the test group.

To assist in safety control, urine analyses of fluoride ion levels were carried out before the study and at six monthly intervals in sample individuals in both groups. A significant increase in urinary fluoride level was detected in the test group after a one-year period, while there was a tendency for a decrease in urinary fluoride concentration in the control group.

A further test carried out was to investigate whether 10 ppm co-crystallized sugar resulted in remineralization of previously artificially demineralized carious lesions in sterilized enamel slabs, bonded to the buccal surfaces of maxillary first molars of randomly selected subjects in both groups over a three week period. Previous *in vitro* tests, using an artificial remineralizing solution with 10 ppm fluoride in sugar had resulted in a substantial level of remineralization over 28 days. However the result of the *in vivo* experiment revealed an insignificant level of remineralization had resulted from the use of a 10 ppm fluoride co-crystallized sucrose.

Overall, the presence of 10 ppm fluoride co-crystallized with sucrose resulted in a significant difference in caries development between control and test groups. This result looks very promising, even though it needs to be viewed with caution, due largely to the short duration over which it was achieved. Further field trials are needed, involving larger number of subjects over longer periods of time.

As the present study was carried out in a closely confined and controlled population of subjects, it would be preferable for studies involving local population groups, e.g. in a village, to be carried out. However, all such applications must consider very carefully all sources

of fluoride ion available and ensure safety in the overall levels of fluoride utilization.