

# Topical iodine and fluoride varnish combined is more effective than fluoride varnish alone for protecting erupting first permanent molars: a retrospective cohort study

Ohnmar K. Tut, BDS<sup>1</sup>; Peter M. Milgrom, DDS<sup>2</sup>

1 Ministry of Health, Republic of the Marshall Islands

2 University of Washington

## Keywords

retrospective cohort study; oral health; fluoride; fluoride varnish; PVP-iodine; children; dental caries.

## Correspondence

Dr. Peter M. Milgrom, University of Washington, Box 357475, Seattle, WA 98195-7475.  
Tel.: 206-685-4183; Fax: 206-685-4258;  
e-mail: dfrc@u.washington.edu. Ohnmar K. Tut is with the Ministry of Health, Republic of the Marshall Islands. Peter M. Milgrom is with the University of Washington.

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## Abstract

**Objective:** This communication examines the combined effect of topical polyvinylpyrrolidone (PVP)-iodine plus fluoride varnish in the prevention of tooth decay in erupting first permanent molars in an ongoing public health program.

**Methods:** The evaluation employed a retrospective cohort design with two groups of children 60-83 months. Cohort 1 (2004-05) received three times per school year topical fluoride varnish, and Cohort 2 (2008-09) received topical application of 10 percent PVP-iodine followed at each visit with topical fluoride varnish. The children were examined clinically at the beginning and end of the school year.

**Results:** The proportion of children with caries-free first permanent molars in Cohort 2 (PVP-iodine plus fluoride varnish) was 0.883 and was greater than that in Cohort 1 (varnish), which was 0.785 (Chi-square = 1.000E1, df 1,  $P < 0.002$ ).

**Conclusions:** This evaluation of an ongoing dental public health program adds evidence that topical antiseptics applied at the same time as fluoride varnish are more effective than varnish alone. Randomized trials are needed.

## Introduction

There are several studies of the utility of antiseptic agents to inhibit caries in older individuals (1,2). With regard to children, some are strong advocates for combining fluorides with various antimicrobials, especially for children with limited access to curative care, because topical fluorides do not provide complete protection against tooth decay (3,4). The in vitro and in vivo iodine antiseptic literature on dental caries of three decades ago was promising, but most human studies were very small (5,6). There has been a recent series of pilot and small-scale clinical studies of utility of polyvinylpyrrolidone (PVP)-iodine in young

children, some with established active early childhood caries (ECC), with strongly encouraging data (7-10).

## Methods

### Design

The study employed a retrospective cohort design with two groups of children who were 60-83 months at the end of the study.

### Setting

The outcomes evaluation was conducted on Majuro atoll in the Republic of the Marshall Islands (RMI). The Ministry of Health was a participant in the Pacific Islands Early Childhood Caries Prevention Project sponsored by the Office of Head Start. The RMI government has converted Head Start centers into kindergartens. RMI is also a grantee of the Targeted State Maternal and Child Oral Health Service Systems program. The University of Washington Institutional Review Board approved the evaluation.

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## Cohorts

The test cohort attended kindergarten in 2008-09 and included 428 children with a mean age of 70.7 months [standard deviation (SD) = 5.3] at the final clinical examination. The comparison cohort of 186 children attended kindergarten in 2004-05 and had a mean age of 71.0 months (SD = 4.3) at the final examination. There was no difference in the age of the children between the two cohorts. The children were drawn from the same group of schools but fewer schools were included in the initial cohort. Boys and girls were equally distributed in both cohorts. The socioeconomic characteristics of the schools in the two cohorts are quite similar. Parents gave their permission for the children to be part of the program. Special educational materials designed for populations with low health literacy were used to inform parents.

## Treatments

Every child within a particular school received the same intervention. All children within the cohort received the same treatment and all children in all the schools participated. The test cohort received combined treatment with PVP-iodine and fluoride varnish and the comparison cohort received only fluoride varnish.

### PVP-iodine

PVP-iodine (1 percent active iodine, Allegiance Health Corporation, McGaw Park, IL, USA), approved by the Food and Drug Administration for topical use in the mouth, was applied at 3-month intervals during the school year. The 3-month period was chosen because it corresponded with the usual application of fluoride varnish in this setting. The children were seated in a portable dental chair or placed on a mat on the classroom floor with the child's head in the lap of the assistant and the mother assisting. Clinically, the teeth were dried with gauze and then painted with about 0.2-mL PVP-iodine. The exact amount applied clinically was not standardized. After application, the teeth can then be dried again and coated with fluoride varnish at the same visit.

### Fluoride varnish

Varnish (Cavity Shield, OMNII Oral Pharmaceuticals, West Palm Beach, FL, USA) was applied at the same 3-month intervals during the school year as the PVP-iodine. The teeth were wiped with cotton gauze and the varnish applied with a disposable brush. The parent was asked not to allow the child to eat or brush his or her teeth for 1 hour.

## Fluoridated toothpaste

The children in both cohorts were given toothbrushes (Colgate-Palmolive, Looney Tunes 3-8 years, New York, NY, USA) and fluoridated toothpaste (Dinosaur Fluoride toothpaste, Sheffield Laboratories, New London, CT, USA) as part of the RMI dental public health program. At the beginning of the year, the children received instruction in toothbrushing by a preventive assistant and then they were supervised in brushing by teachers. Each child had his or her own toothbrush. Teachers were instructed to place pea-sized amount of toothpaste on each child's brush. Children also were given toothbrushes and paste for home brushing. There were no differences in the approach used over time or between schools.

## Clinical examinations and measures

Children were examined clinically by a single trained examiner at the beginning and end of the school year (September/May). Caries prevalence is very high in this population and progresses rapidly (11,12). The primary clinical evaluation outcome of the study was the number of decayed first permanent molars (D) defined as a cavitated tooth. A single dentist examiner (OKT) was trained to the World Health Organization (WHO) diagnostic protocol, and examined the teeth visually using a disposable dental mirror and artificial light. Compared with a gold standard examiner (PM), the examiner demonstrated excellent reliability for caries diagnosis (inter-rater correlation coefficient of 1.00 and 0.96 at two different points in time). The deciduous teeth were also examined.

## Statistical analysis

De-identified data were provided for the analysis. The data were cleaned and entered into SPSS Version 16 (SPSS Inc., Chicago, IL, USA) for Mac. To assess the outcome in the permanent molars, the D component of the WHO assessment scheme was dichotomized as either cavitated or caries-free and the differences between the cohorts evaluated contingency table analysis. Potential differences between the cohorts (age at examination and deft) were examined using *t*-tests. Paired *t*-tests were used to evaluate whether deft increased within each cohort.

## Results

### Participation

All of the children were examined at both time points in both cohorts. All of the children in Cohort 1 (fluoride alone)

received all three treatments and 100 percent of children in Cohort 2 (PVP-iodine plus fluoride) received all the treatments.

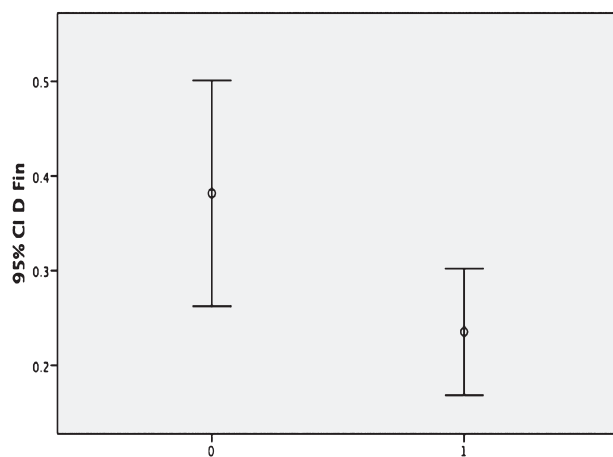
### Initial caries level

At the beginning of the study, the mean dft was 8.9 (SD = 4.6) teeth for the test cohort and 9.4 (SD = 5.1) teeth for the comparison cohort and they were not different ( $t = 1.1$ ,  $P = 0.27$ ). On average, the children had less than one erupted molar at the start of the school year and there was no difference between the two cohorts ( $t = 0.54$ ,  $P = 0.59$ ).

### Analysis by cohort

The proportion of children with caries-free first permanent molars in Cohort 2 (PVP-iodine plus fluoride varnish) was 0.883 and was greater than that in Cohort 1 (varnish), which was 0.785 (Chi-square = 1.000E1, df 1,  $P < 0.002$ ). The odds of being caries-free were 2.1 (95% confidence interval 1.3, 3.3). Figure 1 illustrates the difference in mean D teeth by cohort. The mean increase in D teeth was 0.12 (SD = 0.44) in Cohort 2 and 0.29 (SD = 0.69) in Cohort 1 ( $t = 3.1$ ,  $P = 0.002$ ). Adjustment for initial dft did not change the result.

Mean dft at follow-up did not differ between the cohorts (mean 10.1, SD = 4.6,  $P > 0.05$ ). Both groups had dft increase significantly. Mean dft for Cohort 2 (PVP-iodine plus fluoride varnish) increased from 8.93 (SD = 4.65) to 10.10 teeth ( $t = 13.96$ ,  $P = 0.000$ ), and mean dft for Cohort 1 (varnish) increased from 9.40 (SD = 5.06) to 10.08 (SD = 4.58) teeth ( $t = 3.21$ ,  $P = 0.002$ ).



**Figure 1** Mean and 95% confidence interval for D teeth at the final examination after one school year in a retrospective cohort study. Group 0 (2004-05 school year) in the figure received fluoride varnish only. Group 1 (2008-09 school year) in the figure received a combination treatment of topical PVP-iodine followed by fluoride varnish three times per year.

### Adverse effects

None of the children in either cohort experienced any adverse effects secondary to PVP-iodine treatment. There was no staining of the teeth in the PVP-iodine plus fluoride cohort. None of the children complained about the taste of the PVP-iodine. There were also no adverse effects unrelated to the treatments.

### Discussion

The results are consistent with earlier pilot studies in younger children suggesting that combination treatment with anti-septics and fluoride varnish are more effective than fluoride treatments alone. The children in the combined treatment were twice as likely to be caries-free in the permanent molars than children in the fluoride alone cohort. Antimicrobials are likely to be most effective when permanent teeth are first erupting and the occlusal surfaces are not yet colonized. In contrast, the PVP-iodine did not appear to protect the already infected and extensively damaged primary dentition.

The results of this evaluation are important because much tooth decay in permanent molars occurs before the teeth are fully erupted and can be sealed (13,14).

### Limitations

The evaluation used a quasi-experimental design. The public health program participants were neither assigned randomly to treatment conditions nor was there control for cohort (time) effects. The examiner was not blind to the treatments the children received. The examinations were a routine part of an ongoing dental public health program conducted by the RMI government.

While the results should be interpreted with caution, the findings are impressive and argue persuasively for randomized clinical trials of combination treatment in children at high risk for tooth decay. Such studies need to follow the children for a longer time and should be focused on children with erupting teeth. Xylitol, with specific activity against *Streptococcus mutans*, is also a candidate for combination treatment in addition to PVP-iodine (12,15). A recent review of prevention technology since the Surgeon General's report made the same call (16).

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