

## ABSTRACT

Calibration of caries examiners for clinical studies is a difficult proposition given the slow nature of the disease. Assessment of repeatability is often readily achieved, but that does not necessarily translate into examiner sensitivity to detect caries progression. This novel examiner calibration study design was a longitudinal, 12-month exercise conducted to assess the proficiency of seven examiners to detect caries progression in the permanent teeth of children between the ages of 9 and 12, as well as their repeatability. This study was conducted in Connersville, IN, where the public water supply was not fluoridated. A total of 228 children were enrolled in this study. At baseline, caries examinations were performed by each of the seven examiners using a visual-tactile examination method performed with the aid of an artificial light, mouth mirror, compressed air, and a dental explorer employing a modified Radike criteria. Importantly, white spot demineralization was not scored as caries. In addition, a subset of 15 subjects was examined twice by each examiner at baseline as a repeatability exercise. At year 1, 198 subjects were examined by six of the examiners, as the seventh examiner was only available to examine a subset of 91 subjects. All six of the examiners examining the entire returning cohort observed a statistically significant ( $p < 0.05$ ) positive caries increment over the one-year study period as compared to baseline, with DMFS increments ranging from  $0.37 \pm 0.13$  to  $1.59 \pm 0.13$  surfaces. With respect to repeatability, all seven examiners had kappa scores  $> 0.70$  for baseline DMFS, while kappa scores for DMFS increment ranged from 0.46 to 0.94. **This 12-month model has promise for assessing both repeatability of examiner scores and examiner sensitivity to caries progression.**

## INTRODUCTION

Longitudinal study designs are based on the ability to detect change in disease status during a prescribed time frame. As such, two critical factors for differentiating the efficacy of products in longitudinal studies are progression/regression of disease in the population being observed and examiner sensitivity with respect to detecting that change.

These basic tenets are operative in the conduct of caries clinical trials, where historically changes in disease have been monitored by a clinical examiner employing a visual-tactile examination that was often supplemented with radiographic examination. This study was designed to assess multiple examiners with respect to their ability to detect caries progression over a 1-year period.

## OBJECTIVE

1. To test the proficiency of examiners in assessing dental caries progression using the standard visual-tactile criteria.
2. To assess examiner repeatability.

## MATERIALS AND METHODS

### Study Design

This study was a longitudinal, single site, examiner blind comparison of caries in children ages 9 to 12 with evaluations at baseline and 12 months. In addition, examiner repeatability was assessed at both time points. Six examiners in addition to a standard examiner were included. Visual-Tactile caries examinations were conducted at baseline and 12 months. Five surfaces per posterior tooth and four surfaces per anterior tooth were scored. Subjects were given a caries examination by each of the 7 examiners according to a predetermined order (Examiner 1, Examiner 2, etc.). This order of examiners was kept constant throughout the study. In addition, examiner repeatability was assessed for a subset of 16 subjects at both visits. These subjects were chosen to represent a range of DMFS scores. The dental examinations were performed using conventional portable equipment, fiber optic lighted mirrors and a #23 dental explorer.

### Subjects

The study population was limited to generally healthy children age 9, 10, 11 and 12 years of age at the study start, who reside in the sub-optimal (0.2 ppm) fluoride community of Connersville, Indiana. Subjects were instructed to continue their normal oral hygiene routine using their own dentifrice ad lib for the duration of the study.

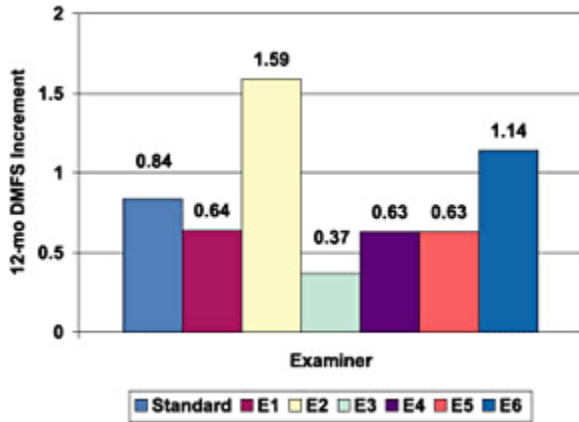
### Statistics

Baseline DMFS scores for the standard examiner were compared with the remaining examiners using analysis of variance. One-year DMFS increment scores for the standard examiner were compared with the remaining examiners using analysis of covariance, with baseline DMFS score as the covariate. Examiner reproducibility was evaluated by computing weighted kappa statistics, separately for each examiner, for the subset of subjects examined in the reproducibility phase of the study. Separate kappa calculations were performed for the baseline DMFS scores and 12-month DMFS increment scores.

## RESULTS

Two hundred and twenty-eight subjects were examined at the baseline visit by a standard examiner and 6 other participating examiners. At the 12-month examination period, 198 subjects were examined by 6 of the 7 original examiners. Examiners 2 and 3 had significantly ( $p < 0.05$ ) different DMFS increments than the standard examiner. One examiner was available only to examine 91 subjects. A subset of 16 subjects was examined twice by each of the 7 examiners at baseline and twice by 6 of the examiners at 1 year as repeatability exercises.

12-Month Adjusted Mean DMFS Increment for 7 Examiners



**CONCLUSION**

All six of the examiners examining the entire returning cohort observed a statistically significant ( $p < 0.05$ ) positive caries increment over the one year study period as compared to baseline, with adjusted mean DMFS increments ( $\pm$  SEM) ranging from  $0.37 \pm 0.13$  to  $1.59 \pm 0.13$  surfaces. With respect to repeatability, all seven examiners had kappa scores  $> 0.70$  for baseline DMFS, while kappa scores for DMFS increment ranged from 0.46 to 0.94. This model has promise for assessing both repeatability of examiner scores and examiner sensitivity to caries progression over a 12 month period.

Weighted Kappa at Baseline vs. at 12-Month Increment for 6 Examiners

