

Statistical Analysis Plan

Title of Research: The Use of MI Varnish for the Prevention and Reduction of White Spot Lesions in Orthodontic Treatment

WIRB Protocol #: 20120677

Principal Investigator: Dr. Chung How Kau, BDS, MScD, PhD.

Document Date: January 1, 2018

Results and Statistics

The results will be evaluated in the following manner:

- (1) Difference in prevention of white spot formation between the control and the study groups using the EDI scores
- (2) Standard statistical methods were employed to analyze all data.

Data Collection and Database Management

Data collection, database management, and data analyses were performed by sponsor personnel or its designee. Only the sponsor, or its appropriate designee, had access to individual-level patient data collected as part of this study, regardless of whether the patient provided informed consent and HIPAA authorization. All individual level patient data had identification information removed.

Data Analysis

All measured variables and derived parameters will be tabulated by descriptive statistics.

For categorical variables summary tables will be provided giving sample size, absolute and relative frequency and 95% CI (Confidence Interval) for proportions.

For continuous variables summary tables will be provided giving sample size, arithmetic mean, standard deviation, median, minimum and maximum and 95% CI (Confidence Interval) for means of variables.

All tests will be two-tailed, and a p value of 5% or less will be considered statistically significant.

All statistical analyses will be performed and data appendices will be created using the SAS® system Version 9.1.3 or higher.

The effects of noncompliance, dropouts, and covariates on treatment will be assessed to determine the impact on the general applicability of results from this study.

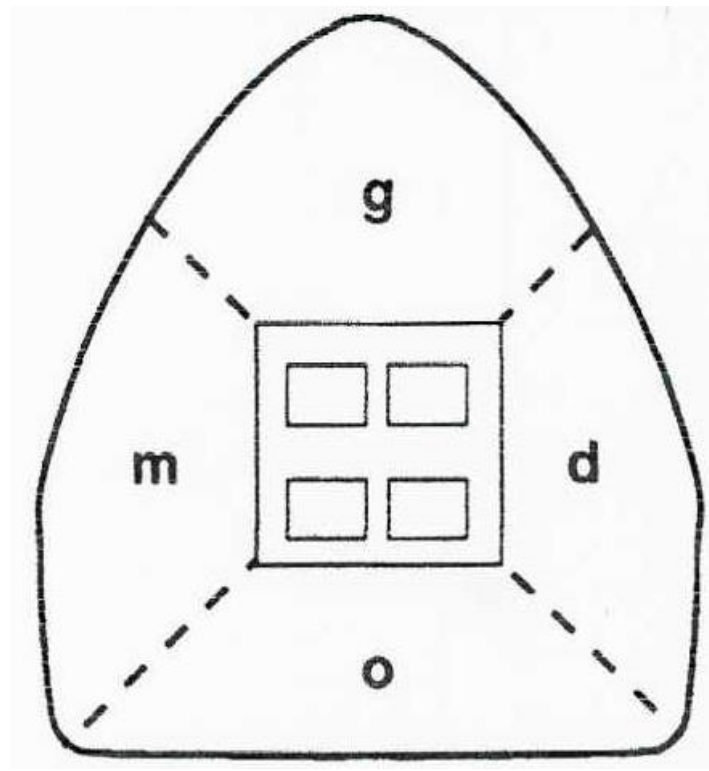


Figure 1. Enamel Decalcification Index. Facial surface of each tooth was divided into four areas. A score was allocated for each area of each tooth: 0=No decalcification to 3=Decalcifications covering 100% of the area.