

Data Analysis Plan – Project 0

**Hypothesis:** Increasing dosages of the active ingredient are correlated with improvements in attachment loss and pocket depth.

**Exposure:**  
Different levels of active ingredient. Levels are as follows: 1. No treatment (no gel) 2.placebo (gel) 3. Low Dose 4. Medium Dose 5. High Dose.

**Outcome:**  
Difference in attachment loss and pocket depth between baseline and 1-year measurements.

**Possible Covariates:**  
Sex (male, female), Race (African-American, Asian, Native American, White), age, smoking status (smoker, non-smoker) and the number of sites used in determining pocket depth and attachment loss.

**Analysis:**  
A univariate analysis between outcomes (change in attachment loss and pocket depth and exposure (dosage level) will be performed using general linear regression. Assumptions of linearity, homoscedasticity, and normality will be confirmed using diagnostic plots.

Relationship between possible covariates and outcomes will be analyzed. Particular attention will be paid to whether or not the number of sites used has an effect of the outcome. Covariates with a significant association with outcome will be considered for a multivariate model. P values <0.05 will be considered significant.

Since participants were randomly assigned, there should be no relationship between possible covariates and exposure. This will be confirmed using  $\chi^2$ /fisher’s exact for categorical variables (sex, race, smoking status) and ANOVA for continuous (age, sites).

Tables and Graphs:

Table 1. Characterstics of Study Participants by Treatment Group

	No gel (n = N(%))	Placebo (gel only) (n = N(%))	Low Dose (n = N(%))	Med Dose (n = N(%))	High Dose (n = N(%))
Female					
African American					
Asian					
Native American					
White					
Non-Smoker					
Age	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Sites					

Graphs – Boxplots of difference in attachment loss and pocket depth by treatment group.