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:
Attachment loss and pocket depth at 1-year measurements.

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

Analysis:
A univariate analysis between outcomes (attachment loss and pocket depth at 1-year) 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 and baseline measurements 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 χ^2/fisher's exact for categorical variables (sex, race, smoking status) and ANOVA for continuous (age, sites, baseline).

Tables and Graphs:
Table 1. Characterstics of Study Participants by Treatment Group

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

Analysis that have significant overall F statistics will be considered for inclusion in tables.