

Preliminary Analysis

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This is the preliminary analysis report for the Project 0 Dental Data. This study is interested in the effect of a gel treatment on gum health as measured by attachment loss and pocket depth. Measurements for both outcomes were taken at a wide variety of sites and averaged to determine a whole mouth value. Measurements were collected a baseline before treatment began and after one-year of treatment. The study participants were randomly assigned to one of five-treatment groups - no-treatment (no-gel), gel only (no-active ingredient/placebo), low dose, medium dose, high dose. The characteristics of each group are shown in Table 1. To confirm random assignment, categorical variables were tested using χ^2 and Fisher's Exact and continuous variables were tested using ANOVA. p-values are shown in Table 1.

Table 1: Characteristics of Study Participants by Treatment Group

	No Treatment (n=23)	Placebo (n=22)	Low (n=21)	Medium (n=19)	High (n=16)	p- value
Sex	N(%)	N(%)	N(%)	N(%)	N(%)	0.45
Female	16(70)	12(55)	12(57)	13(68)	13(81)	
Smoker						0.71
Yes	7(30)	10(45)	6(29)	8(42)	5(31)	
Race						0.77
White	20(87)	20(91)	17(81)	18(95)	14(88)	
	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	
Age	51(10)	47(9)	51(10)	49(10)	53(11)	0.40
No of Sites	154(11)	161(10)	162(8)	156(15)	158(9)	0.10
Baseline Attachment	3(1)	2(1)	2(1)	2(1)	2(1)	0.02
Baseline Pocket Depth	3(0)	3(0)	3(1)	3(0)	3(0)	0.44

	Estimate	Std. Error	t value	Pr(> t)
trtgroupFactoredPlacebo	-0.6448	0.2237	-2.883	0.004859
trtgroupFactoredLow	-0.2443	0.2264	-1.079	0.2831
trtgroupFactoredMedium	-0.06021	0.2325	-0.259	0.7962
trtgroupFactoredHigh	-0.1776	0.2441	-0.7273	0.4688
(Intercept)	2.326	0.1564	14.88	1.16e-26

Table 3: Results of linear regression model of difference in mean attachment loss at 1-year by treatment group The only potential co-variate with a significant relationship to the exposure was attachment loss at baseline. This would also be expected to effect outcome and was therefore adjusted for in the final model. The overall p-value for the univariate model comparing mean attachment loss at 1-year was 0.0484. For the univariate model comparing mean pocket depth at 1 -year was 0.3556. As you can see from table 2, pairwise t-test show the significant difference in attachment loss at 1-year from the no treatment group is the placebo group.

Observations	Residual Std. Error	R^2	Adjusted R^2
101	0.75	0.09394	0.05619

Additionally, because attachment loss at baseline was significantly different across treatment groups, a linear regression adjusted for baseline measurements was also performed.

	Estimate	Std. Error	t value	Pr(> t)
trtgroupFactoredPlacebo	0.05679	0.07831	0.7252	0.4701
trtgroupFactoredLow	0.1487	0.07637	1.947	0.05451
trtgroupFactoredMedium	0.1829	0.07758	2.358	0.02043
trtgroupFactoredHigh	0.02802	0.08129	0.3447	0.7311
Project0_no_missing[, 8]	0.8768	0.03143	27.9	1.497e-47
(Intercept)	0.09219	0.09541	0.9663	0.3363

Table 5: Results of linear regression model of difference in mean attachment loss at 1-year by treatment group adjusted for baseline measurement When adjusting for baseline attachment, there was a significant difference between the medium treatment and no treatment (Table 3).

Observations	Residual Std. Error	R^2	Adjusted R^2
101	0.2487	0.9014	0.8962