**GEL EFFECTIVENESS FOR THE TREATMENT OF GUM DEPRECIATION: REDUCTION IN ATTACHMENT LOSS AND POCKET DEPTH**

**INTRODUCTION**

A new gel treatment with varying levels of active component was tested using 130 participants for reduction in attachment loss and pocket depth measurements. The original dataset contained nine variables and 130 observations (with a maximum of 28 missing values; or 21.5%). The varying treatment levels included a control group, placebo group, and then low/medium/and high concentration groups of the active component in the gel. Pocket depth and attachment loss measurements were calculated using an average of different “site” measurements. The hypotheses for this investigation include:

1. There is a difference in treatment groups for the effectiveness of the gel to reduce attachment loss; the null is indicative of no difference between treatment groups.
2. There is a difference in treatment groups for the effectiveness of the gel to reduce pocket depth measurement; the null is indicative of no difference between treatment groups.

Effectiveness of the gel is measured by two different time points: attachment loss and pocket depth at baseline, and then both after one year. Treatment using the gel is assumed to have been put on by each participant twice daily. This study was a randomized trial design with participants being assigned to one of the five treatment groups: and each of the 130 observations representing a different participant.

**METHODS**

While the original data included nine variables, variables for both attachment loss and pocket depth measurements were created to model the difference from baseline to one year. In addition, treatment group was dummy coded to identify differences between treatment level (groups) in analysis. Data points for attachment loss at baseline against attachment loss change was plotted to ensure there weren’t any violations of independence, linearity, homoscedasticity, little multicollinearity, or multivariate normality. The same was done for pocket depth.

Missing values were similar across all variables ranging from 27-28, representative of 22% (maximum) of the entire sample population.

Descriptive statistics were gathered on the data to include the mean, standard deviation and frequency for continuous variables; and the frequency and percent for categorical variables (regardless of their involvement in the final model). Results from the descriptive analysis can be referenced in Table 1.

Independent associations for each covariate against both pocket depth difference and attachment loss difference were run to determine significance. It’s important to note that attachment loss at baseline and pocket depth measurement at baseline were included as covariates in independent associations and the final models; as that those starting at significant losses in attachment or pocket depth may see more of an effect than those within “normal” range values.

While demographic variables were collected, they were not important for the investigator in this study and thus the choice was made to only include them in the final model if the independent association proved to be significant. Additionally, confounding was not seen to be a factor in this study due to the nature of the trial being randomized. Thus, only including sex as a covariate in the final model for pocket depth was due to it being significant in independent associations with pocket depth difference.

After determining independent significance for each of the covariates, two final linear regression models were developed. The final linear regression model for pocket depth difference only included pocket depth at baseline as a covariate, as well as treatment group. A linear regression model for attachment loss difference included attachment loss at baseline, treatment group, and sex as it was significant in independent associations with pocket depth difference. A secondary model for attachment loss difference was run without sex as a covariate to view the impact on the model; due to the increase in F-value and significance within the model, this was chosen to be representative of the final model.

**RESULTS**

Descriptive statistics including frequency, percent, mean and standard deviation for select covariates can be seen in table one. The mean age was 49.94 ± (10.03) which represents a generally older population of adults enrolled into the study. Pocket depth and attachment loss overall only saw about 0.3/0.4mm change from baseline to one year. Additionally, while covariates were only selected for their statistical significance with each outcome for the final model; it is important to note the larger population of white participants over other races. While the treatment groups are assigned evenly with equal participants in each, for analysis purposes: the control group was used as the reference group.

While independent associations for each covariate were run to determine statistical significance only: sex (for attachment loss difference outcome, p=0.05), and attachment loss at baseline (p= 0.0017) were significant covariates for the attachment loss difference outcome.

Table 2 outlines results from the final model for the outcome as attachment loss difference from baseline to year one. The only significant difference between treatment groups is seen in the “medium” gel treatment group, with a p-value of 0.04 and confidence interval from (0, 0.16). The intercept in this model is 0.02 (SE 0.05), with the control as the reference group. Aside from the medium treatment group being significantly associated with the outcome, it can also be seen that attachment loss at baseline is significantly associated with attachment loss difference from baseline to year one. The intercept for this term is -0.04 (SE 0.02), and can be interpreted as: for every one millimeter increase in attachment loss difference, attachment loss at baseline is expected to drop by 0.04 mm. This is important in interpreting where a patient started out from, and how much they may benefit from using a gel treatment.

Table 3 outlines the output from the final model for pocket depth difference and the included covariates. There were not any significant differences between treatment groups and the outcome, nor a significant association between pocket depth baseline and the outcome.

**CONCLUSIONS**

While only the “Medium” treatment group was significantly associated with the difference in attachment loss from baseline to year one: it’s unclear if this is due to participant commitment to gel treatment regimen, or those levels of gel treatment made an actual difference in reducing attachment loss. Another speculation is that the concentration of the active component in the gel is only effective to a point, and that the high level concentration has leveled off effectiveness as compared to the medium gel treatment group. Adding more time points for comparison, or reporting on attitudes towards other tooth health measures may be better indicative of this relationship and the gel treatment effectiveness. It’s also important to note that prior literature has stated that gel treatments for gum restoration are not as effective outside of the pediatric population. With the mean age in this study being 49, it may not be as effective as it could be on a younger population in reducing attachment loss or pocket depth. Gathering more data points, and other relevant explanatory variables could benefit future studies in further testing of these gel treatments.

**REPRODUCIBLE RESEARCH**

The dataset provided by the investigator was imported into SAS using the following code:

**PROC** **IMPORT** OUT= WORK.dental

DATAFILE= "C:\Users\Kayla\Desktop\dental.csv"

DBMS=CSV REPLACE;

GETNAMES=YES;

DATAROW=**2**;

**RUN**;

The code for the final models can be seen here with additional code on GITHUB:

/\*Final model for PDDIFF\*/

**PROC** **REG** DATA = WORK.dentalclean;

model PDDIFF = PLACEBO LOW MEDIUM HIGH PDBASE / clb;

**run**;

/\*Final model for ATTACHDIFFf\*/

**PROC** **REG** DATA = DENTALCLEAN;

MODEL ATTACHDIFF = SEX PLACEBO LOW MEDIUM HIGH ATTACHBASE / clb;

**RUN**;

/\*Final model for ATTACHDIFF without SEX\*/

**PROC** **REG** DATA = DENTALCLEAN;

MODEL ATTACHDIFF = PLACEBO LOW MEDIUM HIGH ATTACHBASE / clb;

**RUN**;

A link to the GITHUB repository where you can view full code can be found here: https://github.com/BIOS6623-UCD/bios6623-kbell28k/tree/master/Project0/Code