Project 0 Report

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# **Introduction** The goal of this project is to determine whether a new gel aimed at treating gum disease improves dental measurements after 1 year of use. Subjects were randomized to one of 5 groups, which included both a control group and placebo gel treatment group. The other three groups had differing levels of the active ingredient in the gel treatment: low, medium, or high. 26 subjects were originally randomized to these groups, resulting in a total of 130 subjects measured at baseline. At baseline and at the 1 year follow-up visit, each subject's gum attachment and gum pocket depth were measured at a number of sites, and these measurements were averaged to create an average attachment and average pocket depth score for each subject at each time point. The primary research question was whether the treatment results in lower average pocket depths and attachments after one year. # **Methods** Originally, there were 130 subjects included in the subject who were randomized to 5 treatment groups. Since 27 subjects were missing pocket depth and attachment measurements at 1 year, they were excluded from the analysis, including the descriptive analyses. Variables were created to quantify the differences in pocket depth and attachment measurements between the baseline and 1 year follow-up time points, and these were used as the primary outcomes for the analyses. For each of the two clinical outcomes, the difference between the baseline and 1 year follow-up measurements were modeled in multiple linear regressions as a function of the baseline values for the respective measurement and the treatment group to best answer the primary research question. Additional covariates were not included in the models, since the trial was randomized, but the summaries of these demographic variables are included in Table 1. All analyses were performed in R version 3.4.0. # **Results** The demographics of the 103 patients are shown in Table 1, including their measurements for both outcomes at the baseline and 1 year time points. *Table 1.* This table describes the demographics of the 103 individuals who remained in the study for the entire year; the 27 individuals with missing outcomes were excluded as they were excluded from the analysis.

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|  | Placebo | Control | Low Dose | Medium Dose | High Dose |
| Sex (n (%)) | NA | NA | NA | NA | NA |
| Male | 10 ( 0.43 ) | 7 ( 0.3 ) | 9 ( 0.43 ) | 7 ( 0.35 ) | 3 ( 0.19 ) |
| Female | 13 ( 0.57 ) | 16 ( 0.7 ) | 12 ( 0.57 ) | 13 ( 0.65 ) | 13 ( 0.81 ) |
| Race (n (%)) | NA | NA | NA | NA | NA |
| Native American | 0 ( 0 ) | 1 ( 0.04 ) | 1 ( 0.05 ) | 0 ( 0 ) | 1 ( 0.06 ) |
| African American | 1 ( 0.04 ) | 1 ( 0.04 ) | 3 ( 0.14 ) | 0 ( 0 ) | 1 ( 0.06 ) |
| Asian | 1 ( 0.04 ) | 1 ( 0.04 ) | 0 ( 0 ) | 1 ( 0.05 ) | 0 ( 0 ) |
| White | 21 ( 0.91 ) | 20 ( 0.87 ) | 17 ( 0.81 ) | 19 ( 0.95 ) | 14 ( 0.88 ) |
| Age (mean (sd)) | 50.15 ( 9.95 ) | 50.15 ( 9.95 ) | 50.15 ( 9.95 ) | 50.15 ( 9.95 ) | 50.15 ( 9.95 ) |
| Smoker (n (%)) | NA | NA | NA | NA | NA |
| No | 13 ( 0.57 ) | 16 ( 0.7 ) | 15 ( 0.71 ) | 12 ( 0.6 ) | 11 ( 0.69 ) |
| Yes | 10 ( 0.43 ) | 7 ( 0.3 ) | 6 ( 0.29 ) | 9 ( 0.45 ) | 5 ( 0.31 ) |
| Sites measured (mean (sd)) | 159.65 ( 10.66 ) | 153.91 ( 11.24 ) | 161.71 ( 8.16 ) | 153.5 ( 17.12 ) | 158.25 ( 8.73 ) |
| Attachment at baseline (mean (sd)) | 1.83 ( 0.66 ) | 2.55 ( 0.65 ) | 2.1 ( 1.09 ) | 2.24 ( 0.67 ) | 2.31 ( 1.01 ) |
| Attachment at 1 year (mean (sd)) | 1.74 ( 0.54 ) | 2.33 ( 0.55 ) | 2.08 ( 1.06 ) | 2.24 ( 0.65 ) | 2.15 ( 0.92 ) |
| Pocket depth at baseline (mean (sd)) | 3.1 ( 0.39 ) | 3.29 ( 0.49 ) | 3.22 ( 0.64 ) | 3.05 ( 0.42 ) | 3.18 ( 0.28 ) |
| Pocket depth at 1 year (mean (sd)) | 2.75 ( 0.48 ) | 2.95 ( 0.46 ) | 3.02 ( 0.58 ) | 2.84 ( 0.47 ) | 2.8 ( 0.42 ) |
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| *Outcome 1: Gum attachment* |  |  |  |  |  |
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| First, the yearly difference in gum att | achment--the baseli | ne attachment subtr | acted from the att | achment at 1 year- | -was compared among the five treatment groups. |
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| *Figure 1.* This graph displays the yea | rly difference in a | ttachment among the | control, placebo, | and three levels | of treatment groups. |
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| [](Project\_0\_Report\_Code\_files/figure- | docx/unnamed-chunk- | 2-1.png) |  |  |  |
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| The results of the multiple linear regr | ession for this out | come are shown belo | w in Table 2. |  |  |
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| *Table 2.* This table displays the beta | estimates, 95% con | fidence intervals, | and p-values for t | he treatment group | s and baseline attachment measurement covariates in this multiple linear regression model. |
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|  | Estimate | 95% Confidence Interval | p-value |
| Intercept (Control) | 0.107 | (-0.075 , 0.289) | 0.253 |
| Placebo | 0.042 | (-0.107 , 0.191) | 0.582 |
| Low Dose | 0.146 | (-0.003 , 0.295) | 0.057 |
| Medium Dose | 0.176 | (0.027 , 0.325) | 0.023 |
| High Dose | 0.027 | (-0.132 , 0.186) | 0.742 |
| Baseline Attachment | -0.129 | (-0.188 , -0.07) | <0.001 |
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| There were only two si | gnificant p | redictors of the differenc | e in gum attachment: medium concentration of the active ingredient compared to the control group (p = 0.023) and baseline attachment (p < 0.001). However, the medium concentration in the gel did not reduce gum attachment measurements; compared to the control group, those in the medium concentration group had differences in gum attachment that were 0.176 points higher, when controlling for baseline values. |
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| Therefore, although th | ere was an | overall decrease in whole- | mouth average gum attachment of -0.099451, this difference was only significantly explained by baseline gum attachment values. For every one point increase in baseline gum attachment, there was a decrease of 0.129 points in the yearly difference in gum attachment. |
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| \*Outcome 2: Gum pocket | depth\* |  |  |
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| Second, the yearly dif | ference in | pocket depth--the baseline | pocket depth subtracted from the pocket depth at 1 year--was compared among the five treatment groups. |
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| *Figure 2.* This graph | displays t | he yearly difference in po | cket depth among the control, placebo, and three levels of treatment groups. |
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| [](Project\_0\_Report\_C | ode\_files/f | igure-docx/unnamed-chunk-4 | -1.png) |
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| The results of the mul | tiple linea | r regression for this outc | ome are shown below in Table 3. |
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| *Table 3.* This table | displays th | e beta estimates, 95% conf | idence intervals, and p-values for the treatment groups and baseline pocket depth covariates in this multiple linear regression model. |
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|  | Estimate | 95% Confidence Interval | p-value |
| Intercept (Control) | 0.033 | (-0.343 , 0.409) | 0.862 |
| Placebo | -0.033 | (-0.184 , 0.118) | 0.670 |
| Low Dose | 0.125 | (-0.028 , 0.278) | 0.113 |
| Medium Dose | 0.108 | (-0.049 , 0.265) | 0.179 |
| High Dose | -0.056 | (-0.221 , 0.109) | 0.506 |
| Baseline Pocket Depth | -0.113 | (-0.223 , -0.003) | 0.046 |
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| There was an overall dec | rease in po | cket depth of -0.2943543, | which was only significantly explained by baseline pocket depth (p = 0.046). For every 1 point increase in baseline pocket depth, there was a -0.113 decrease in yearly difference in pocket depth. |
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| *Conclusions* |  |  |  |
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| Based on the results of | the two mod | els, treatment does not ha | ve a signifcant effect on producing lower average pocket depth and attachment loss at one year. |
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| This study is potentiall | y limited b | y the 27 individuals who h | ad missing outcomes. Based on a brief analysis of these 27 individuals, there were no patterns to clearly explain their missingness. However, the greatest number of individuals were missing from the high concentration of active ingredient group, so there is less information available to be able to fully analyze the effect of the high concentrations of the active ingredient in the gel. |