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ABSTRACT: The aim of this PROTEITH[®] study was to verify the efficacy of a plant protein dentifrice on the reduction of plaque and gingivitis. Eleven volunteers with established gingivitis were randomly assigned to this test group involving a plant-based complete protein dentifrice without fluoride.

Subjects were instructed to use PROTEITH[®] while plaque and gingivitis assessments were captured as a baseline measurement. A certified dentist examined all patients' gum pocket sizes in this study. The subjects' frontal and lingual gum pockets were reduced by an average of 19%, from an unhealthy level of 3.2mm to a healthy level of 2.6mm.

In addition, significant reductions in plaque levels and gingivitis in this group were visually observed during the post-intervention examinations after the use of PROTEITH[®]. No adverse reactions were reported nor observed with the use of the PROTEITH[®] product.

In contrast, a control group of patients who did not receive the PROTEITH® treatment had no change in their gum pockets, with a baseline average of 3.04 mm and a post-study average of 3.03 mm.

This study concluded that the PROTEITH® dentifrice is effective in reducing gum tissue pockets associated with plaque and periodontal disease for patients who have gingivitis.

DESCRIPTORS: Gingivitis; Plant preparations

INTRODUCTION

MATERIALS AND METHODS

Patients for this study were observed at the West End Family Dental Clinic in Louisville, Kentucky during their routine dental visits. They were included in the data analysis if they were over 18 years old, had previous gum pocket issues and were willing to use PROTEITH® toothpowder. The study used a longitudinal experimental design, where participants' gum tissue pocket sizes were measured at baseline and after at least one period of intervention. The baseline condition measured typical facial and lingual pocket sizes for individuals. Participants notified their dentist that they were exclusively using PROTEITH®. Their pocket sizes were measured again during their next dental visit.

Statistical analysis was performed using Microsoft Excel and R Script in Microsoft Power Bl. Pocket sizes were collected and recorded during both the baseline and the intervention phases. In some cases, participants' pocket sizes were recorded again after an additional intervention phase. Pocket sizes were recorded for both facial and lingual categories to assess if there were any differences.

Averages were calculated for each participant's gum pocket sizes at each phase to observe any change between baseline and intervention measures as well as between facial and lingual pockets. Standard deviation was calculated to show variability between the experimental variables. These conditions were compared by means of the patient's t-test, and associations between experimental conditions and facial and lingual categories were verified by means of the chi-square test. All statistical tests employed a level of significance of $\alpha = 0.05$.

RESULTS

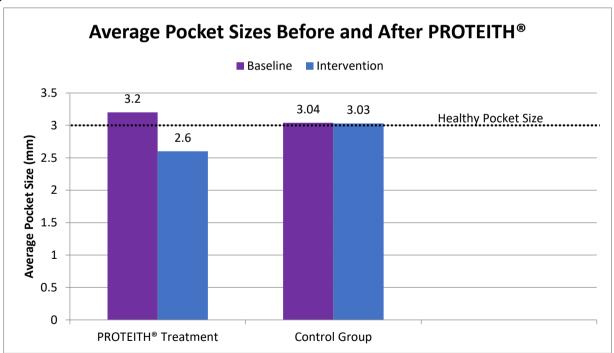
Eleven patients' gum tissue progress was recorded between a baseline and intervention condition (ie, the exclusive use of PROTEITH® plant protein toothpowder). Average patient baseline-to-intervention duration was 9.7 months and ranged up to 14 months. None of the patients returned to a baseline condition after completing their intervention.

Patients' pocket sizes ranged between 2.3mm and 4.8mm during baseline. After the first intervention phase, the test group showed a 16% reduction in pocket size (to 2.7mm average) for facial surfaces while recording 19% reduction in pocket sizes (to 2.6mm average) for lingual surfaces (Figure 1).

Demographics data was not collected for these patients and no analysis was conducted to discern any differences between demographic groups.

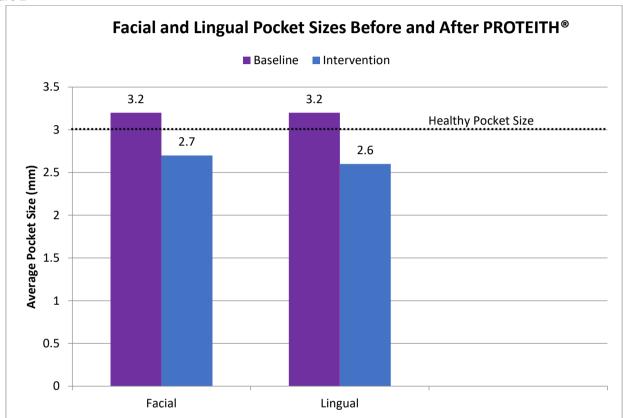
A control group of 16 patients had their gum pockets measured during the same time period and the average pocket size were reduced by by only 0.01 mm, or -0.14%, going from 3.04mm to 3.03mm, which is statistically insignificant.

Figure 1



For both facial and lingual surfaces, there was a significant reduction in pocket size between baseline and intervention phases. While the difference between the facial and lingual groups was not statistically significant, the results between baseline and intervention phases were demonstrably different. (Figure 2)

Figure 2



A t-test analysis was conducted to show if there was a statistically significant difference between the baseline and intervention conditions: the intervention proved statistically significant with 95% confidence (p-value=0.000895, alpha=0.05) (Table 1 and Table 2).

TABLE 1 - Mean, median and comparison between experimental conditions at facial and lingual aspects.

Herbal toothpowder Mean ± SD 3.2 ± 0.7 2.6 ± 0.2		
	0.000005004*	
N = 11 Median 3.3 2.9	0.000895294*	

^{*}Significant at the 5% level

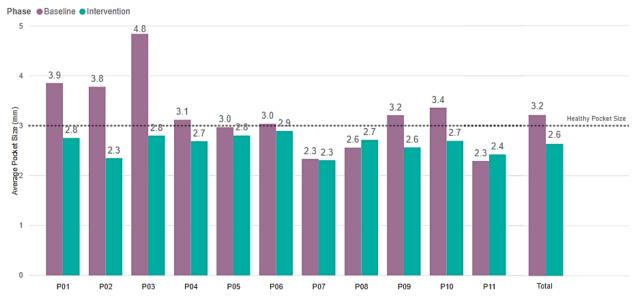
Table 2 - t-Test: Two-Sample Assuming Unequal Variances

	Before	After
	<i>PROTEITH®</i>	<i>PROTEITH®</i>
Mean	3.213462411	2.635575026
Variance	0.548431818	0.053255623
Observations	22	22
Hypothesized Mean Difference	0	
df	25	
t Stat	3.494371553	
P(T<=t) one-tail	0.000895294	
t Critical one-tail	1.708140761	
P(T<=t) two-tail	0.001790588	
t Critical two-tail	2.059538553	

In all cases except two (Patient P08, with baseline average=2.6mm, intervention average=2.7mm; and Patient P11, with baseline average=2.3mm, intervention average=2.4mm), patients obtained positive results from taking part in the intervention phase as compared to their baseline (Figure 3). In these two cases, the 0.1mm increase in gum pocket averages reflects statistically unchanged levels.

In the other nine cases, patients had smaller average pocket sizes after intervention as compared to baseline, and several were significantly reduced. No adverse reactions to the PROTEITH® treatment were observed by the clinician or reported by any patients during or after the trial.

Figure 3
Average Pocket Sizes Before and After PROTEITH®



DISCUSSION

Currently, chemical-free toothpowders are relatively scarce in the oral hygiene market. The PROTEITH® product is completely natural and contains plant-based proteins, vitamins and minerals. Users have reported it to be effective at cleaning and whitening teeth their as well as improving their overall dental health, which is consistent with the observations from this study.

This is the first study performed on the PROTEITH® product to empirically measure as well as visually observe its effectiveness on dental health by a trained dental professional, specifically focusing on the improvement of gum disease and gingivitis. The results proved to be outstanding, with nearly all subjects showing moderate to significant improvements over time and none displaying statistically measurable deterioration.

In all cases, patients reduced or maintained their gum pocket sizes to below 3mm average, commonly accepted as a healthy size.

While the duration of the intervention phases varied by weeks (Mean = 41, Standard Deviation = 18, Max = 59, Min = 15), the maximum length of time to observe results was a little over a year of use before noting effective results. In some cases (patients P02 and P03), whose intervention phases lasted 20 and 15 weeks, respectively, pocket sizes were reduced by 39% and 42%, respectively, to healthy levels.

Additionally, six participants had changes from unhealthy pocket sizes (P01 = 3.9mm, P02 = 3.8mm, P03 = 4.8mm, P04 = 3.1mm, P09 = 3.2mm, P10 = 3.4mm) to healthy pocket sizes (P01 = 2.8mm, P02 = 2.3mm, P03 = 2.8mm, P04 = 2.7mm, P09 = 2.6mm, P10 = 2.7mm) once the intervention was complete.

These study results demonstrate the specific and unique effectiveness of PROTEITH® protein toothpowder on oral health. Similar clinical results have not been reported with other all-natural toothpowders.

CONCLUSION

The authors conclude that the PROTEITH® dentifrice was able to consistently and significantly reduce to healthy levels both frontal and lingual gum tissue pockets that had deteriorated due to plaque and gingivitis. Patients who did not use PROTEITH® did not achieve any improvement in their gum pockets.

Although not quantified, we also observed patients in this study achieve additional benefits from exclusive use of PROTEITH® throughout the duration of the study, including healed mouth sores, improved breath, reduced tooth sensitivity and removal of teeth stains.