International Journal of Dentistry and Oral Science (IJDOS)
ISSN: 2377-8075

Evaluation of Plaque Removal Efficacy of a Novel Dye-Containing Toothpaste: A Clinical Trial

Research Article

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Abstract

Background: Dental plaque contributes to caries and periodontal disease, therefore efficient plaque removal promotes oral health. We hypothesize that individuals brushing with toothpaste containing plaque-indicating dye will demonstrate higher plaque removal efficacy than those using conventional toothpaste. This study tested plaque removal efficacy between a novel FDA-registered toothpaste with plaque-indicating dye and a control toothpaste without indicating dye.
Methods: Thirty-one adult participants enrolled in the study were randomized and divided into two groups. Control group participants brushed with control toothpaste for two visits. Experimental group participants brushed with control toothpaste for their first visit and brushed with experimental toothpaste (*PlaqueHD*™, TJA Health LLC, Joliet, Illinois) for their second visit. Participants brushed according to the manufacturer's instructions. Prior to all visits, participants discontinued oral hygiene for 12-16 hours. After brushing, participants rinsed with fluorescein solution and intraoral photographs were taken using an ultraviolet digital camera. The presence of plaque on tooth surfaces was visualized by plaque-bound fluorescein and quantified. Images from both visits were compared using custom software to calculate percentage-change of remaining plaque. Statistics (SPSS version 22.0) were performed to compare plaque reduction between groups.
Results: Participants using the experimental toothpaste demonstrated significantly less plaque remaining between visits (51.3% reduction, p=0.015) than participants using only the placebo toothpaste (8.3% reduction, p=0.189).
Conclusions: Mechanical plaque removal by brushing with toothpaste containing plaque-indicating dye significantly reduced plaque compared to brushing with toothpaste without dye. This innovative dentifrice may improve oral hygiene and reduce plaque-related damages to teeth and oral tissues.

Keywords: Plaque Removal; DPIA; Plaque Disclosing; Oral Disease; Dentifrice.

Abbreviations: DPIA = Digital Plaque Imaging Analysis; FDA = Food and Drug Administration; NHANES = National Health and Nutrition Examination Survey; OPRS = Office for the Protection of Research Subjects; OTC = Over-the-counter; SD = Standard Deviation; UIC = University of Illinois at Chicago; UV = Ultraviolet.

Introduction

Ineffective dental plaque removal has been shown to cause demineralization, caries, gingivitis, and periodontitis [1, 2]. This results in physical and cosmetic damage to both oral soft and hard tissues in the form of bleeding and swollen gums, white spot lesions, enamel discoloration, the need for restorations, and potentially tooth loss. Prevalence of tooth decay and periodontal disease is high despite many patients' claims of following recommended oral hygiene guidelines. In fact, according to the 1999-2004 National Health and Nutrition Examination Survey (NHANES), the prevalence of caries in adults is 92% and periodontal disease is 8.52% [3].

Poor oral hygiene skill and lack of dental knowledge negatively impact plaque removal efficacy and the ability to accurately evaluate one's oral status. Increasing education and technique instruction is one way to address the problem, but another valid option is

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Received: December 12, 2015
Accepted: January 12, 2016
Published: January 13, 2016

Citation: Stevens K et al., (2016) Evaluation of Plaque Removal Efficacy of a Novel Dye-Containing Toothpaste: A Clinical Trial. *Int J Dentistry Oral Sci.* 03(1), 185-189.
doi: http://dx.doi.org/10.19070/2377-8075-1600039

to improve oral hygiene products to enhance plaque removal efficiency. This is especially important in populations of underrepresented minorities, low socioeconomic status, and the elderly that traditionally have less access to regular professional oral care [4]. Adding a visible dye to toothpaste to disclose remaining plaque after toothbrushing has the potential to enhance patients' awareness and encourage them to be more thorough when performing oral hygiene.

Plaque determination and analysis have been traditionally performed in dental clinics using various manual indices such as those developed by Ramfjord, Silness and Loe, Turesky, and Elliott [5]. However, according to Pretty et al., "traditional plaque indices are problematic due to their integral nature and their failure to detect small, but potentially clinically relevant changes in plaque area" [6]. These procedures are also time consuming, more subjective, and more invasive to patients. The digital plaque imaging analysis (DPIA) method utilizes photography and computer software to accelerate data collection, operator consistency, reproducibility of results, the ability to store data for later use and analysis [7-9]. Patient comfort is also an important factor. Dental plaque can be stained with a disclosing agent, e.g. fluorescein disodium salt (FD&C No. 8), a well-documented method for intraoral plaque disclosure [7-9]. Long wave UV light (405nm), commonly used in medical, scientific, and law enforcement applications, has been used to excite the fluorescein on plaque, gingiva, and enamel with significant photographic color separation for quantitative analysis [7]. Its efficacy, safety, and reliability have been tested extensively [9-12].

The objective of this study was to compare the efficacy of plaque removal between a fluoridated toothpaste with plaque-indicating dye versus an equivalent toothpaste with no dye using the DPIA method. The dye in the experimental toothpaste is a Food and Drug Administration (FDA) registered organic food colorant which adheres to plaque and stains it green to provide visual indication of the location of plaque. We determined whether the presence of a visual indicating dye, coupled with instructions on how to use the toothpaste containing it, would cause a difference in plaque removal efficacy. Our ultimate goal was to increase awareness of existing plaque deposits and to improve plaque removal efficiency during homecare. We hypothesized that brushing with a toothpaste containing plaque-indicating dye, along with proper instruction, results in higher plaque removal efficacy than using a traditional toothpaste without the dye.

Materials and Methods

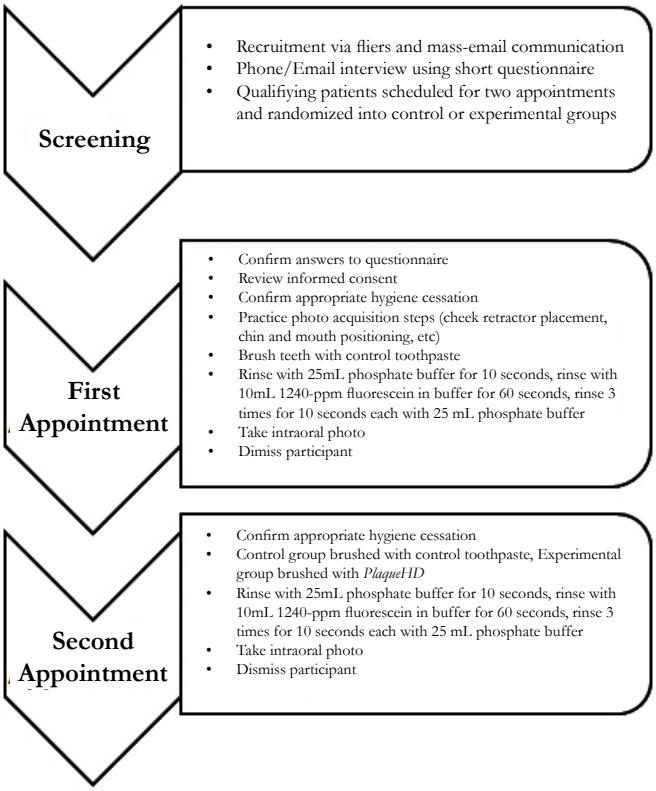
Design and Treatment Protocol

Preliminary studies were performed to establish optimal methodology and study protocol for accurate and reproducible data collection for the proposed study.

Thirty-nine participants were initially recruited in this randomized, controlled clinical study. Participants were recruited using a classified ad or with flyers posted around the university and nearby hospital system. The study protocol was approved by the University of Illinois at Chicago (UIC) Institutional Review Board. The screening questionnaire was administered to interested participants in person or via phone. See Figure 1 for protocol flowchart.

Inclusion Criteria: Participants must be 18 years of age or older, in good general health (self-assessment), and must have all 12 anterior teeth present (canine to canine).

Figure 1. Representation of patient recruitment/screening, followed by steps taken during data collection appointments.



Exclusion Criteria: Participants should not be pregnant or nursing, not be a dental student or faculty or staff member, not have taken antibiotics within two weeks prior to testing, not have dry mouth symptoms or significant food allergies, not have dental restorations or caries (canine to canine in both arches), and not have had anterior dental work or prophylaxis performed within 30 days prior to testing.

Qualified participants were randomly assigned to one of the two groups based on a computer generated order – control and experimental. They were required to make two visits to the UIC College of Dentistry over the course of 7-10 days. Participants in the control group only used the control toothpaste during visits, whereas participants in the experimental group used the control toothpaste at one visit and the experimental toothpaste (*PlaqueHD*™) at the second visit. *PlaqueHD*™ is an FDA-registered toothpaste which contains an FDA-registered Annato (*Bixo orellana*) seed extract dye, plus FD&C Blue No. 1, which gives the toothpaste a green color that adheres to intraoral plaque. Both fluoridated toothpastes had similar chemical compositions, apart from the presence of a plaque-indicating dye in the experimental toothpaste.

Participants were instructed to refrain from brushing, flossing, or using other oral hygiene aids and chewing gum the evening prior and morning of the visit. At the first visit, informed consent was administered to confirm that participants understood the risks and benefits and had an opportunity to ask questions. Participants were then asked to brush their teeth with the control (no dye) toothpaste using a provided manual toothbrush (Henry Schein Inc., Melville, NY) for one minute in front of a mirror. They were then asked to complete the following procedure for plaque disclosing: rinse for 10 seconds with 25 mL of phosphate buffer, rinse for 1 minute with 5.0 mL of 1240-ppm fluorescein (FD&C yellow No.8) in phosphate buffer, rinse 3 times for 10 seconds with 25 mL of phosphate buffer [7]. The phosphate buffer consisted of 3.62g monosodium phosphate and 0.349g disodium phosphate in 2L of water at a pH of 5.5. Participants expectorated the solution after each rinse.

After rinsing, a digital frontal intraoral image of the participant's upper and lower teeth was captured. Images were taken using a Canon Rebel Xi camera (Canon, Melville, NY) with a Tamron 90mm fixed focal lens (Tamron, Commack, NY) and a mounted black-light emitting flash (Digi-Slave L-Ring Ultra II UV, SR Electronics, Dallas, TX). Images were oriented to be as perpendicular to the incisors as possible, and centered on the maxillary midline such that the anterior teeth were in focus. Participants were asked to hold cheek retractors during image capture to increase the visibility of their teeth and gingiva. Image capture took place in a dark room and all images were then saved to a desktop computer.

At the second visit, participants in the control group brushed with the control toothpaste again while the treatment group brushed with the experimental toothpaste (*PlaqueHD*™). The brushing, disclosing, and photographic procedures were identical to those that took place during the first appointment. Specific brushing instructions were given prior to brushing and rinsing for the experimental toothpaste, i.e. "brush for one minute and concentrate on removing any green stains."

Data Analysis and Statistics

Using computer software, the twelve anterior teeth in each digital photo were masked by the investigator to define the area of analysis. The investigator was blinded to which group each photograph belonged to. The ratio of (plaque pixels)/(plaque + teeth pixels) x 100% was calculated to give an overall patient plaque coverage score. Statistical analysis assessed results of the plaque reduction [7].

Using IBM SPSS Statistics for Windows, Version 22.0 Armonk, NY: IBM Corp., statistics were performed to test the mean of plaque reduction in the control and experimental groups. Parametric Student paired samples *t*-test and independent *t*-test were performed. Data normality was tested with Shapiro-Wilk Normality tests. Subsequent non-parametric tests were performed as needed.

Results

Preliminary data from a different set of participants (n=35), obtained without giving specific hygiene instructions, showed no mean significant differences in plaque reduction between the control and experimental toothpaste ($p>0.05$, data not shown).

Thirty-nine subjects were initially recruited and divided into control (20 subjects) and experimental (19 subjects) groups. Six subjects dropped out due to scheduling conflicts leaving 16 subjects in the control group and 17 in the experimental group. All remaining thirty-three participants (ages 18-64) completed the two visits; no complaints or adverse effects after using the toothpastes were reported.

The results showed there was no statistically significant mean differences between the control group and experimental group at the baseline initial appointment when using the control dentifrice, $t(31) = (0.737)$, p-value=0.466. There were also no statistically significant differences in mean plaque reduction between the first and second visits for the control group [$t(15) = (-1.377)$, p-value=0.189, Table 1].

The data showed statistically significant mean plaque reduction between the initial baseline appointment and the second appointment for the experimental group using *PlaqueHD*™, [$t(16) = (2.718)$, p-value=0.015, Table 2]. The data in Figure 2 show that participants using the experimental toothpaste had more than four times as much plaque elimination than those using the control toothpaste (8.3% mean change versus 51.3% mean change), with the mean change in the control group not deemed of statistically significant value (p=0.189).

The data also showed a statistically significant mean difference between the control group and the experimental group after the second appointment, $t(31) = (2.241)$, p-value=0.032).

The data analysis is reported using parametric data from Student paired samples *t*-test and independent *t*-test. The Shapiro-Wilk Normality test results indicated that the raw data were not distributed on a normal curve, therefore corresponding non-parametric tests were run, as well. Similar results were found with parametric and non-parametric tests, so parametric data were reported.

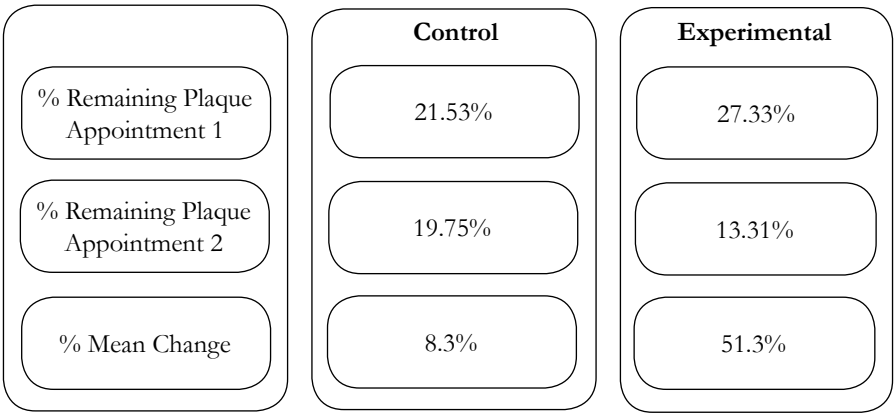
Table 1. Comparison of Mean Plaque Coverage (%) of The Control Group between Appointments.

Appointment	N	Mean, SD	Mean Diff	95% CI		p-value
				Lower	Upper	
1	16	21.53 ± 23.34	1.78	0.97	4.52	0.189
2	16	19.75 ± 22.76				

Table 2. Comparison of Mean Plaque Coverage (%) of The Experimental Group between Appointments.

Appointment	N	Mean, SD	Mean Diff	95% CI		p-value
				Lower	Upper	
1	17	27.33 ± 28.62	14.02	3.09	24.96	0.015
2	17	13.31 ± 17.56				

Figure 2. Comparison of percentage plaque remaining, as well as a mean change, at both visits.



Discussion

It has been shown that self-performed mechanical plaque removal in adults may frequently be ineffective [13] and that by providing a means to assess individual's oral hygiene habits at home can significantly improve plaque removal efficacy [14]. It seems obvious, therefore, that by simplifying oral hygiene awareness, patients are likely to have improved homecare.

Patients and providers have long been aware of various plaque indicating products, but their use outside of dental offices is typically limited. For example, plaque disclosing tablets and solutions are commonly used in dental offices, but over-the-counter (OTC) oral hygiene products that incorporate a plaque-indicating dye in toothpaste have not been commercially available for direct-to-consumer use.

Toothpaste combined with a plaque-disclosing agent is also more likely to work for patients than using multiple products concurrently to achieve the same result. One might speculate that this type of toothpaste may reinforce improved hygiene habits by showing patients where they are deficient in removing plaque. Choo et al explained that without such reinforcement, patients are likely to revert back to old, possibly ineffectual, habits. This is especially important in children, where establishing an easy, visual method of performing good oral hygiene is important for a lifetime of reduced oral disease [15]. In a review by Renz et al, several studies were cited demonstrating that, for adults, effective plaque removal is based not only on the ability to remove plaque but an understanding of how to do so [16]. By combining proper oral hygiene instructions and a toothpaste that discloses remaining plaque, adults should be more effective at removing dental plaque.

In our preliminary study, performed with different subjects, there was no significant difference between a control toothpaste and *PlaqueHD*™ when no oral hygiene instructions were given. These findings demonstrated that no inherent plaque-removing ability exists for *PlaqueHD*™ compared to the control toothpaste, and they confirm the importance of proper use instructions with such a product. The current study showed that participants given instructions on how to use a plaque-disclosing toothpaste demonstrated a significant improvement in plaque removal efficacy. Our results demonstrate that when subjects used the control toothpaste at both visits, there was no significant difference in plaque on their teeth – this is because they had no signal to perform hygiene any differently than they normally did and maintained their same oral-hygiene habits. Those participants using *PlaqueHD*™, after being given instructions, were able to demonstrate significantly better mechanical plaque removal because they were able to visualize remaining plaque and remove it. The long-term use of such a product is therefore likely to promote better hygiene habits, and possibly reduce oral diseases.

Further studies with increased subject sample size are warranted. Studies focused on patients with fixed orthodontic appliances would also be beneficial because these patients are typically at higher risk for plaque-mediated disease [8].

Conclusion

This study demonstrates that brushing with a toothpaste with plaque-indicating dye, combined with proper use instructions, significantly increases plaque removal efficacy.

Acknowledgements

We would like to thank TJA Health, LLC, for their donation of single-dose samples of *PlaqueHD*™ and fluoridated generic control toothpaste for use in this study. The authors declare that they have no conflicting or financial interests.

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