Official title: Efficacy of two sonic toothbrushes in reducing extrinsic tooth stain: An 8-week randomized clinical trial

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Study Protocol and Statistical Analysis Plan

Study Design

This randomized, investigator-blinded, parallel-group clinical trial compared three toothbrush interventions. The study protocol was approved by the Institutional Review Board of Guanghua School of Stomatology, Sun Yat-sen University (Guangzhou, China). The eight-week study was conducted in full accordance with the ethical principles outlined in the World Medical Association Declaration of Helsinki. The trial was registered at ClinicalTrials.gov under the identifier NCT05202093, first submitted on Jan 07, 2022.It was conducted at the Guanghua School of Stomatology, Sun Yat-sen University, from March to July 2022.

Sample size calculation

Based on data from a previous clinical study evaluating the tooth stain removal efficacy of a whitening product, the sample size for the present trial was calculated. Assuming a standard deviation of 0.5 for Lobene stain area scores, a sample size of 40 participants per group was determined to be necessary at baseline. This calculation was designed to detect a 20% difference between groups with 80% statistical power at a significance level of $\alpha = 0.05$, while also accounting for a 10% attrition rate.

Study population

Adults residing in Guangzhou were invited to participate in the study. Prior to enrollment, the study details were thoroughly explained to all potential participants to ensure a full understanding of the purpose and procedures. Written informed consent was obtained from each individual. Participants were subsequently enrolled based on the inclusion and exclusion criteria. The inclusion criteria were: 1) aged 18-70 years; 2) good general health; 3) ability to attend all scheduled visits over the 8-week study period; 4) possession of more than 20 natural permanent teeth, excluding third molars, which are free of crowns or extensive restorative materials; 5) at least 12 anterior teeth suitable for scoring (i.e., free of crowns, veneers, large restorations, trauma, or non-vital pulp); 6) a whole-mouth mean Lobene stain composite score greater than 1. Exclusion criteria included: 1) severe oral or systemic diseases; 2) advanced periodontal diseases; 3) pregnancy or lactation; 4) dental fluorosis or tetracycline

staining; 5) orthodontic appliances or partial removable dentures; 6) participation in other clinical trials; 7) professional prophylaxis within 3 months or tooth whitening within 6 months; and 8) known allergy to study products.

Randomization

Eligible patients were assigned computer-generated random numbers in ascending order as they were enrolled in the study by an external dentist. They were then randomly allocated to one of three groups. The external dentist responsible for randomization maintained exclusive access to the group allocation information throughout the trial. All other study personnel remained blinded to the randomization information during the study.

Intervention

Patients in test group 1 were given the Oclean Digital Visual toothbrush (2.16 N·cm torque), patients in test group 2 received the Oclean Sonic Electric toothbrush (1.96 N·cm torque), and patients in the control group were provided with the Oral-B Classic 40 soft regular manual toothbrush.

Patients received their assigned toothbrushes along with the same toothpaste. The distribution of the study products occurred at a separate location. One study member was responsible for distributing the study products, while all other study members remained unaware of group assignments throughout the study.

Patients were instructed to brush their teeth twice daily (once in the morning and once in the evening) for one minute each session, using only the provided products, while maintaining their usual diet and oral hygiene habits.

Clinical assessments

Clinical examinations were conducted at baseline, 4 weeks, and 8 weeks by a single investigator who was unaware of the type of toothbrush used by each patient. The examinations included assessments of tooth stain as well as evaluations of both soft and hard oral tissues. Tooth stain was assessed on the buccal surfaces of six maxillary anterior teeth and on both the buccal and lingual surfaces of six mandibular anterior teeth using the Lobene Stain Index[30]. Each tooth surface was divided into two regions: the gingival region and the body region. The Lobene Stain Index quantifies

both the area and intensity of extrinsic tooth stain. The stain intensity was scored on a scale from 0 to 3, with the following criteria: 0 = no stain; 1 = light stain (yellow to light brown or gray); 2 = moderate stain (medium brown); and 3 = heavy stain (dark brown to black). Stain area was also scored on a scale from 0 to 3, based on the proportion of the tooth surface covered by stain, using these criteria: 0 = no stain detected; 1 = stain covering up to one-third of the region; 2 = stain covering more than one-third to two-thirds of the region; and 3 = stain covering more than two-thirds of the region. The composite score was calculated as the product of the stain area and intensity scores. The mean Lobene stain area, intensity, and composite scores were determined by summing the scores from all assessed regions of the tooth surfaces and dividing by the total number of regions evaluated.

A comprehensive examination of the oral soft and hard tissues was conducted to identify any abnormalities. The assessment included the soft and hard palate, oral mucosa, tongue, sublingual and submandibular regions, salivary glands, and the pharyngeal and laryngeal areas.

At each follow-up, an investigator asked patients about any adverse events during product use, including brushing discomfort, allergic reactions, and changes in oral soft tissues. General health changes related to the product were also monitored throughout the study.

After each examination session, the collected data were securely stored by a designated study facilitator. Other study personnel had no access to participant data during the study.

Statistical analysis

Statistical analyses were performed to assess differences among the three groups. Chi-square test and one-way analysis of variance (ANOVA) were utilized to compare the differences among treatment groups on gender, age and baseline Lobene stain scores. Analysis of covariance (ANCOVA), adjusted for baseline Lobene stain score as a covariate, was applied to compare inter-group differences in stain area, intensity, and composite scores at 4 and 8 weeks. Within each group, paired t-tests were used to

assess changes in Lobene stain scores between baseline and each follow-up time point (4 and 8 weeks). All tests were two-sided, with a significance threshold set at $\alpha=0.05$.