

Statistical Analysis Plan

Guided Biofilm Therapy versus Conventional Prophylaxis with Ultrasonic Scaling and Bristle-Brush Polishing for Extrinsic Tooth Stain Management: A Randomized Split-Mouth Clinical Trial

Official Title

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This document is prepared for public posting on ClinicalTrials.gov. It contains no names or identifiers of research participants.

1. Purpose and Scope

This Statistical Analysis Plan (SAP) defines the statistical analyses for the completed randomized split-mouth trial registered as NCT07799558. The SAP corresponds to the prespecified primary endpoint and secondary outcomes described in the ethics-approved protocol and explains the analysis populations, derived variables, statistical tests, multiplicity control, and reporting conventions.

2. Trial Overview

The study included 34 participants, each contributing one GBT-treated and one BBP-treated half-mouth. Sixty individuals were screened, 26 were excluded before enrollment, and all 34 included participants completed the 1- and 2-month follow-up visits. The randomized sequences were GBT right/BBP left and BBP right/GBT left, with 17 participants in each sequence.

Analysis domain	Definition
Primary endpoint	Participant-level half-mouth ΔE^*ab difference, GBT minus BBP, from T0 to T2
Secondary colour endpoints	GBT versus BBP ΔE^*ab from T0 to T1 and T1 to T2
Categorical colour endpoints	Tooth-level categories using $\Delta E^*ab < 1.2$, $1.2-2.7$, and > 2.7
Patient-reported endpoint	VAS discomfort after each half-mouth procedure
Procedural endpoint	Half-mouth procedure time in minutes
Association endpoint	Spearman correlation between procedure time and VAS within each protocol

3. Analysis Populations

The full analysis population consisted of all 34 randomized participants who completed both follow-up visits. Because there were no post-enrollment losses or missing T1/T2 visits, the full analysis population and the per-protocol population were identical. Each participant was analyzed according to the randomized treatment assigned to the corresponding half-mouth.

4. Data Preparation and Derived Variables

For each tooth and time point, the three SpectroShade readings were averaged. The eight evaluated teeth within each half-mouth were then averaged to produce a participant-level half-mouth value for L^* , a^* , b^* , and each ΔE^*ab interval. ΔE^*ab was calculated as the Euclidean CIELAB distance: $[(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. Values were derived separately for T0-T1, T1-T2, and T0-T2.

Tooth-level colour-change categories were defined as below the 50:50 perceptibility threshold (< 1.2), perceptible but within the acceptability range ($1.2-2.7$), and above the acceptability threshold (> 2.7). VAS was recorded on a 0-10 scale. Procedure time was converted to minutes.

5. Descriptive Analysis

Continuous variables were summarized using mean, standard deviation, median, minimum, and maximum, as appropriate. Categorical variables were summarized using counts and percentages. Participant characteristics and treatment sequence allocation were reported descriptively. No inferential comparison of baseline demographic characteristics was planned because treatment was assigned within participants.

6. Distributional Assessment

Normality of continuous variables was assessed using the Shapiro-Wilk and Kolmogorov-Smirnov tests, Q-Q plots, and skewness and kurtosis values. The choice between parametric and non-parametric analyses was based on the distribution and measurement characteristics of each endpoint.

7. Primary Analysis

The primary comparison was the within-participant paired difference in half-mouth ΔE^*ab from T0 to T2 between GBT and BBP. A paired-samples t-test was used. The treatment effect was reported as the mean paired difference (GBT minus BBP) with a two-sided 95% confidence interval and Cohen's d_z . Statistical significance was assessed at $p < 0.05$.

8. Secondary Analyses

The T0-T1 and T1-T2 half-mouth ΔE^*ab comparisons were analyzed using paired-samples t-tests. Holm adjustment was applied across the secondary ΔE^*ab interval comparisons. The direction of the treatment effect was consistently expressed as GBT minus BBP.

Tooth-level colour categories were compared using ordinal generalized estimating equations with robust standard errors to account for clustering of multiple teeth within each participant. Wald χ^2 statistics and Holm-adjusted p-values were reported for the three principal intervals.

VAS discomfort and procedure time were compared between GBT and BBP using the Wilcoxon signed-rank test. Results were summarized using medians, ranges, paired median differences with interquartile ranges, test statistics, p-values, and matched-pairs rank-biserial correlation effect sizes. Negative differences indicate lower values with GBT.

The association between procedure time and VAS was evaluated separately within the GBT and BBP protocols using Spearman rank correlation coefficients with two-sided p-values.

9. Supplementary and Sensitivity Analyses

Supplementary analyses included right-versus-left comparisons of continuous colour outcomes, side-specific GBT-versus-BBP comparisons, time-VAS correlations, and categorical side-specific analyses. Paired tests were used when observations were naturally paired; Welch independent-samples tests were used where side-specific comparisons required independent group variances. Holm adjustment was used for multiple GBT-versus-BBP comparisons within each side.

The split-mouth design was the prespecified primary framework. No imputation was required because all 34 participants completed all scheduled assessments. No interim analysis, stopping rule, subgroup analysis, or covariate-adjusted primary model was planned.

10. Missing Data and Protocol Deviations

A participant was considered evaluable only if both half-mouths had the relevant measurement at the specified time point. In the completed dataset, no participant missed the T1 or T2 visit and no post-enrollment exclusion occurred. If a future reproducibility analysis encounters missing tooth-level readings, the participant-level half-mouth mean will be calculated from available valid evaluated teeth only when the prespecified measurement set remains interpretable; otherwise the endpoint will be reported as missing without single-value imputation.

The study was retrospectively registered. This status is disclosed in the trial record and manuscript. The primary and secondary endpoints were defined in the ethics-approved protocol before enrollment, and the present SAP documents the analysis approach used for the reported results.

11. Statistical Software and Reporting

Analyses were performed using Python 3.11 (Python Software Foundation) with SciPy 1.11 and statsmodels 0.14. All tests were two-sided. Continuous estimates are reported with appropriate measures of precision, including 95% confidence intervals for the primary paired treatment effect. P-values are reported to three decimals where applicable; values below 0.001 are reported as <0.001.

12. Data Availability

The associated dataset is available in the Zenodo repository at <https://doi.org/10.5281/zenodo.22916438>. The publicly posted SAP contains no names or direct identifiers of research participants.