

Study Protocol

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

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

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NCT07799558

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Sponsor and study site

Atatürk University Faculty of Dentistry, Department of Periodontology
Erzurum, Türkiye

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

1. Administrative Information

1.1 Study identification

This document describes the randomized split-mouth clinical trial registered as NCT07799558. The trial was retrospectively registered at ClinicalTrials.gov. The protocol was approved by the Atatürk University Faculty of Medicine Clinical Research Ethics Committee (decision no. 926; 27 November 2025).

1.2 Responsible institution

Atatürk University Faculty of Dentistry, Department of Periodontology, Erzurum, Türkiye. The study was conducted at the Department of Periodontology between December 2025 and June 2026, with follow-up completed at 2 months.

1.3 Protocol status

This is the protocol document for the completed study. The study was conducted in accordance with this protocol and the Declaration of Helsinki. Written informed consent was obtained before enrollment.

2. Background and Rationale

Extrinsic tooth staining is a common esthetic concern associated with chromogenic deposits on the acquired pellicle, dental biofilm, and tooth surface. Professional prophylaxis aims to remove these deposits while limiting unnecessary abrasion and maintaining a surface that is less susceptible to renewed biofilm and stain accumulation. Guided Biofilm Therapy (GBT) is a biofilm-oriented protocol that uses disclosing of biofilm, low-abrasive erythritol air polishing, and ultrasonic instrumentation for supragingival hard deposits. Conventional prophylaxis in this study consisted of supragingival ultrasonic scaling followed by bristle-brush polishing with prophylaxis paste.

The clinical effect of these complete protocols on post-treatment tooth-colour stability, patient discomfort, and procedure time is not fully established. A split-mouth design permits direct within-participant comparison while reducing the influence of interindividual differences in tooth colour, diet, salivary exposure, and staining susceptibility.

3. Objectives and Hypotheses

Primary objective. To compare the change in tooth colour from immediately after treatment (T0) to 2 months (T2) between GBT and conventional ultrasonic scaling followed by bristle-brush polishing with prophylaxis paste (BBP).

Secondary objectives. To compare colour change during T0-T1 and T1-T2, the distribution of tooth-level colour changes relative to perceptibility and acceptability thresholds, patient-reported discomfort, and procedure time.

Primary hypothesis. There is no difference between GBT and BBP in ΔE^*ab from T0 to T2.

4. Study Design

This was a single-centre, randomized, controlled, outcome-assessor-blinded, split-mouth clinical trial. Each participant contributed a right and a left half-mouth. Both interventions were performed during the same clinical session, with the right half-mouth treated first and the left half-mouth treated second. Each participant therefore served as their own control.

Design feature	Specification
Participants screened	60
Included and randomized	34
Completed and analyzed	34; no post-enrollment losses
Treatment allocation	17 GBT right/BBP left; 17 BBP right/GBT left
Evaluated teeth	Maxillary and mandibular central incisors, lateral incisors, canines, and first premolars; vestibular surfaces
Follow-up	T0 immediately after treatment, T1 at 1 month, T2 at 2 months

5. Participants

5.1 Screening and eligibility

Sixty individuals presenting with extrinsic tooth staining were screened. Twenty-six were excluded because they did not meet the predefined eligibility criteria. Thirty-four participants were included, randomized, completed follow-up, and were analyzed.

5.2 Inclusion criteria

- Age 18 years or older.
- Systemically healthy.
- Written informed consent.
- At least moderate bilateral extrinsic staining on the evaluated teeth, defined as a Lobene Stain Index intensity score of at least 2.
- Right-handed toothbrushing.
- No periodontal treatment within the preceding 6 months.

5.3 Exclusion criteria

- Periodontitis; smoking; antibiotic use within the preceding 3 months; acute periodontal disease; or allergy to erythritol polishing powder.
- Restorations, caries, excessive wear, or structural defects affecting colour measurement on evaluated teeth.
- Active orthodontic treatment, developmental or structural dental anomalies affecting enamel or susceptibility to staining, or severe crowding preventing standardized measurements.

Baseline periodontal status was assessed using plaque index, gingival index, bleeding on probing, probing depth, and radiographic examination. Diagnosis followed the 2017 World Workshop classification. Participants with periodontitis were excluded; participants with gingivitis remained eligible. These assessments were used for eligibility screening and were not analyzed as study outcomes.

6. Interventions

6.1 Common clinical procedures

The vestibular surfaces of the maxillary and mandibular central incisors, lateral incisors, canines, and first premolars on both sides were treated. Second premolars and posterior teeth were not evaluated. All clinical procedures were performed by one investigator. Supragingival ultrasonic instrumentation with a PIEZON® system (EMS, Nyon, Switzerland) equipped with a PIEZON® PS instrument was performed on both half-mouths in all 34 participants.

6.2 Guided Biofilm Therapy

Biofilm was disclosed using EMS Biofilm Discloser. The disclosed, biofilm-positive areas and extrinsic staining were removed using low-abrasive erythritol powder with particles of approximately 14-25 µm (AIRFLOW® PLUS Powder, EMS, Nyon, Switzerland) delivered by an AIRFLOW® Prophylaxis Master. The supragingival AIRFLOW handpiece was positioned approximately 5 mm from the tooth surface at an angle of 30°-60°, directed toward the middle third using short, controlled circular movements and away from gingival tissues. Supragingival PIEZON® instrumentation was then performed on all GBT-treated half-mouths. Surfaces were reassessed and additional cleaning was performed when required.

6.3 Conventional bristle-brush polishing

Supragingival PIEZON® instrumentation was performed first. Extrinsic staining was then removed using a polishing brush (Ardadent, Ankara, Türkiye) and Detartrine® prophylaxis paste (Septodont, Saint-Maur-des-Fossés, France; relative dentin abrasivity 143.63 ± 23.86) with a low-speed micromotor (W&H, Bürmoos, Austria) at 2500-3000 rpm. Light pressure and short, controlled, intermittent movements parallel to the tooth surface were used. Water cooling was provided when necessary. Surfaces were reassessed and additional polishing was performed when required.

7. Outcomes and Measurements

7.1 Tooth-colour outcome

Tooth colour was measured using SpectroShade™ MICRO (MHT Optic Research AG, Milan, Italy) according to the CIELAB system. The device was calibrated before each measurement session. Measurements were obtained from the middle third of the vestibular surface under standardized illumination, with the device positioned perpendicular to the surface. The same anatomical region was reproduced at follow-up using tooth morphology and the corresponding SpectroShade image. Three readings were obtained with repositioning between readings, and their mean was used for each tooth. Eight evaluated teeth were averaged to obtain a participant-level half-mouth value.

Measurements were obtained immediately after treatment (T0), at 1 month (T1), and at 2 months (T2). Colour change was calculated as $\Delta E^*_{ab} = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$ for T0-T1, T1-T2, and T0-T2. The primary endpoint was T0-T2 ΔE^*_{ab} . The 50:50 perceptibility threshold was 1.2 and the acceptability threshold was 2.7.

7.2 Patient-reported discomfort

Immediately after each half-mouth procedure, participants rated overall discomfort on a 10-cm horizontal visual analog scale from 0 (no discomfort) to 10 (unbearable discomfort). The first-side VAS was recorded before the second-side procedure began. The second-side VAS was recorded immediately after the second procedure.

7.3 Procedure time

Procedure time was recorded separately for each half-mouth using a digital stopwatch. Timing began with the first clinical step of the assigned protocol and ended after final surface inspection. Patient preparation, isolation, oral-hygiene instruction, and post-treatment recommendations were excluded.

8. Randomization and Masking

A computer-generated block-randomization list with block size four allocated participants equally to two treatment sequences: GBT right/BBP left or BBP right/GBT left. Allocation was concealed in opaque, sealed, sequentially numbered envelopes opened after enrollment. The colour assessor was blinded to treatment allocation. The operator and participants could not be blinded because the interventions were visibly different. Statistical analyses used coded group labels.

9. Sample Size

G*Power 3.1.9.7 was used for a two-sided paired-samples t-test with $\alpha=0.05$ and 80% power. The effect-size assumption was based on ΔE^*ab values reported by Sigwart et al. (2025), with a paired-measure correlation of 0.50 and Cohen's d_z of 0.496. The minimum required sample size was 34 participants.

10. Ethical and Regulatory Considerations

The study was approved by the Atatürk University Faculty of Medicine Clinical Research Ethics Committee (decision no. 926; 27 November 2025) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from every participant before enrollment. The trial was retrospectively registered at ClinicalTrials.gov under NCT07799558. No participant names or direct identifiers are included in this document.

11. Data Management and Dissemination

Data were recorded using coded participant identifiers. The analysis dataset contained no participant names. Study findings are reported in aggregate, and the associated dataset is available in the Zenodo repository at <https://doi.org/10.5281/zenodo.22916438>. Results will be disseminated through the ClinicalTrials.gov record and scientific publication.