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Guided biofilm therapy versus standard cleaning for the retreatment of deep gum pockets after periodontal therapy

Submission date 08/09/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/09/2026	**Overall study status** Ongoing	
Last Edited 09/09/2026	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
Efficacy of guided biofilm therapy vs. standard subgingival debridement during re-instrumentation in step 3 of treatment of moderate to advanced (stage II–IV) periodontitis: a randomized controlled trial

Study objectives
Compare clinical and microbiological outcomes of Guided Biofilm Therapy (GBT) vs. conventional SRP during repeated subgingival re-instrumentation (Step 3) in Stage II–IV periodontitis. H0: no between-group difference in patient-level pocket closure at 12 weeks, or in clinical /microbiological outcomes at 12 and 24 weeks. H1: GBT is superior to SRP for patient-level pocket closure at 12 weeks and selected secondary outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/02/2025, Ethics Committee for Scientific Research, "Victor Babeș" University of Medicine and Pharmacy Timișoara (Piața Eftimie Murgu, No. 2, Timisoara, 300041, Romania; +40 256 204 400; enache.alexandra@umft.ro), ref: 34/28.02.2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Moderate to advanced (Stage II–IV) periodontitis

Interventions
Test arm: GBT protocol — biofilm disclosure (EMS Biofilm Disclosure), supragingival air polishing (Airflow® Max), subgingival air polishing of pockets ≥4 mm (Perioflow®, Airflow®PLUS powder), residual calculus removal with minimally invasive piezoelectric instrumentation (EMS Piezon® PS / Piezon® P1 MAX) as needed; chlorhexidine 0.12% rinse twice daily for 2 weeks.
Control arm: SRP — piezoelectric ultrasonic instrumentation (EMS Piezon® PS) plus manual Gracey curettes under local anaesthesia; no air polishing; same chlorhexidine rinse regimen.
Both arms: single re-instrumentation session at baseline for non-responsive sites; a second protocolised re-instrumentation after the T1 (12-week) assessment, restricted to sites not meeting the endpoint, using the same allocated intervention.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Patient-level pocket closure measured using the proportion of sites per patient with probing pocket depth (PPD) ≤4 mm and no bleeding on probing (BOP), assessed by a calibrated examiner blinded to group allocation, at 12 weeks post-baseline (T1)

Key secondary outcome(s)
1. Clinical attachment level (CAL) measured using a periodontal probe at baseline, 12 and 24 weeks

2. Bleeding on probing (BOP) measured using a periodontal probe at baseline, 12 and 24 weeks

3. Gingival recession (REC) measured using a periodontal probe at baseline, 12 and 24 weeks

4. Patient-reported pain, discomfort, and treatment acceptability measured using a Visual analog scale (VAS) at an immediate time point post-procedure

5. Procedural efficiency measured using data collected on the total chairside time per treatment session at each treatment session

6. Subgingival periopathogen load (A. actinomycetemcomitans, P. gingivalis, P. intermedia, T. forsythia, T. denticola) measured using quantitative PCR at baseline and 24 weeks

Completion date
01/10/2027

Eligibility

Key inclusion criteria
1. Ages 18–75
2. Stage II–IV periodontitis

3. ≥15 teeth with PD 4–6 mm and positive BOP
4. Completed periodontal therapy Steps 1 and 2
5. Good systemic health and oral hygiene (API ≤35%, SBI ≤25%)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Heavy smokers (>10 cigarettes/day)
2. Pregnancy or lactation
3. Systemic conditions impairing healing (e.g. uncontrolled diabetes)
4. Allergy to erythritol or chlorhexidine
5. Unable to maintain adequate oral hygiene

Date of first enrolment
01/03/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
Romania

Sponsor information

Organisation
Victor Babeș University of Medicine and Pharmacy Timișoara

ROR
https://ror.org/00afdp487

Funder(s)

Funder type

Funder Name
Victor Babeș University of Medicine and Pharmacy Timișoara

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			09/09/2026	No	Yes
Participant information sheet	Clinical Study Information and Informed Consent		09/09/2026	No	Yes