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Can temporary tooth splinting improve healing after gum surgery in patients with severe gum disease?

Submission date
13/02/2026

Recruitment status
Not yet recruiting

Registration date
17/02/2026

Overall study status
Ongoing

Last Edited
01/06/2026

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Severe gum disease (Stage IV periodontitis) can lead to major loss of bone around the teeth. In some patients, the lower front teeth become loose and uncomfortable, especially during chewing. Even after thorough cleaning below the gums, surgery is sometimes still needed to treat deep pockets that remain.
When teeth are already loose, their movement during healing may influence how well the surgical treatment works. One possible way to improve stability is to temporarily join the lower front teeth together with a thin metal wire bonded to the inner surfaces. This type of splint is commonly used in clinical practice to reduce mobility and improve comfort, but there is limited evidence about whether placing it before surgery improves healing results.
The main goal is to see whether splinting increases the number of treated sites that heal to shallow pocket depths without bleeding.

Who can participate?
Adult patients with advanced gum disease who require surgery in the lower front teeth and have at least one mobile tooth.

What does the study involve?
In this study, participants will be randomly assigned to one of two groups. One group will receive a temporary splint one week before surgery. The other group will undergo the same surgery without splinting. All patients will receive identical surgical care and follow-up.
Participants will be monitored for six months. We will also assess changes in gum measurements, tooth mobility, patient comfort, and, in the splinted group, how well the splint performs.

What are the possible benefits and risks of participating?
The findings may help determine whether temporary stabilization before surgery improves outcomes in patients with advanced periodontal disease.

Risks not provided at time of registration

Where is the study run from?
University Clinic of Periodontology, “Victor Babeș” University of Medicine and Pharmacy, Romania.

When is the study starting and how long is it expected to run for?
February 2027 to March 2028.

Who is funding the study?
University Clinic of Periodontology, “Victor Babeș” University of Medicine and Pharmacy, Romania.

Who is the main contact?
Dr Alla Belova, alla.belova@umft.ro

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Effect of temporary composite-bonded wire splinting on the proportion of sites reaching therapeutic endpoints after surgical Step 3 of periodontal therapy in advanced (stage IV) periodontitis patients: a randomized controlled trial

Acronym
SPLINT-PERIO

Study objectives

To evaluate whether temporary lingual composite-bonded eight-strand braided wire splinting of the intact mandibular anterior teeth (3.3–4.3) with hypermobility due to advanced periodontitis, placed prior to surgical Step 3 of periodontal therapy, increases the proportion of sites that reach therapeutic endpoints (PD ≤ 4 mm and no BOP) at 24 weeks post-operatively, compared with no splinting. Secondary aims include evaluating changes in probing depth, bleeding on probing and changes in clinical attachment, reductions in post-operative mobility, and patient-reported outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/02/2026, The Ethical Committee of Scientific Research of “Victor Babeș” University of Medicine and Pharmacy, Timișoara (Str. Ciresului nr. 1A, Timisoara, 300610, Romania; +407256466001; enache.alexandra@umft.ro), ref: 09/02.08.2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Historical

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Treatment of Stage IV periodontitis in adults with hypermobile mandibular anterior teeth undergoing Step 3 periodontal surgery.

Interventions
Test Group Protocol
Participants in the test group will undergo seven scheduled visits throughout the study period. At Visit 1 (baseline), conducted after completion of the Step 2 periodontal treatment, a comprehensive periodontal evaluation will be performed. During this visit, participants will receive oral hygiene instructions (OHI), undergo professional mechanical plaque removal (PMPR), and complete patient-reported outcome measures (PROMs).
One week prior to the scheduled surgery (Visit 1a), participants in the test group will receive lingual splint placement according to their randomization assignment, allowing for patient adaptation to the splint before the surgical intervention.

Visit 3 will consist of PROMs collection, followed, during the same appointment, by periodontal surgery as clinically indicated. The surgical procedures will be performed according to standard protocols, with the pre-placed lingual splint remaining in situ to provide stabilization during the healing phase.
Post-operative follow-up will begin at Visit 4, scheduled 2 weeks after surgery, during which sutures will be removed, gentle ultrasonic supragingival debridement will be performed, antiseptic irrigations will be administered, and splint integrity will be verified.
Subsequent follow-up visits will occur at 8 weeks (Visit 5), 16 weeks (Visit 6), and 24 weeks (Visit 7) post-surgery. Each of these visits will include periodontal re-evaluation, collection of PROMs, PMPR, and splint integrity checks. The final visit (Visit 7) will additionally involve splint removal and assessment for potential replacement of the temporary splint with a permanent one, determined by the clinical outcomes observed during re-evaluation.

Control Group Protocol
Patients in the control group will be evaluated according to the six-visit schedule. Visit 1 (baseline) will be identical to the test group, including a comprehensive periodontal evaluation after Step 2 treatment completion, OHI, PMPR, and PROMs collection.
In the control group, periodontal surgery (Step 3) will be performed at Visit 2 without prior splint placement, representing the standard treatment approach.
Post-operative care in the control group will mirror the test group timeline at corresponding time points. Visit 4 (2 weeks post-surgery) will include suture removal, gentle ultrasonic supragingival debridement, and antiseptic irrigations, but without splint-related assessments. Follow-up visits at 8 weeks (Visit 5), 16 weeks (Visit 6), and 24 weeks (Visit 7) post-surgery each will comprise periodontal re-evaluation, PROMs collection, and PMPR.

Probing depth (PD) and bleeding on probing (BOP) will be assessed at six sites per tooth (mesiobuccal, mid-buccal, distobuccal, mesiolingual, mid-lingual, distolingual) in teeth 3.3–4.3 using a UNC-15 periodontal probe (Hu-Friedy, Chicago, IL, USA) with standardized probing force (~0.25 N). Bleeding is recorded if present within 10 seconds after probing. The percentage of sites achieving PD ≤4 mm and absence of BOP at 24 weeks post-operatively will be calculated per patient.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. A probing depth (PD) ≤ 4 mm and absence of bleeding on probing (BOP) measured using a UNC-15 periodontal probe (Hu-Friedy, Chicago, IL, USA) with standardized probing force (~0.25 N) at 24 weeks post-operatively

Key secondary outcome(s)
1. Change in probing depth (PD) at six sites per tooth in teeth 3.3–4.3 measured using a UNC-15 periodontal probe. at baseline, 8 weeks, 16 weeks, and 24 weeks post-operatively

2. Change in clinical attachment level (CAL) at six sites per tooth in teeth 3.3–4.3 measured using a UNC-15 periodontal probe at baseline, 8 weeks, 16 weeks, and 24 weeks post-operatively

3. Bleeding on probing (BOP) measured using a UNC-15 periodontal probe at baseline, 8 weeks, 16 weeks, and 24 weeks post-operatively

4. Tooth mobility (objective measurement) measured using Periotest values obtained from vestibular approach with three measurements per tooth averaged (teeth 3.3–4.3) at baseline and 24 weeks post-operatively

5. Tooth mobility (clinical grading) measured using Miller mobility index (grades 0–III) assessed clinically using reciprocal instrument pressure at baseline and 24 weeks post-operatively

6. Oral health-related quality of life measured using the Oral Health Impact Profile (OHIP-14) questionnaire at baseline, pre-surgery, 2 weeks, 8 weeks, 16 weeks, and 24 weeks post-operatively

7. Splint integrity and failure rate measured using clinical assessment of splint integrity categorized as intact, composite chipping, partial debonding, complete debonding, or wire fracture; number of repairs and time to first failure recorded, at 2 weeks, 8 weeks, 16 weeks, and 24 weeks post-operatively

Completion date
03/03/2028

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Diagnosis of Stage IV periodontitis, according to the 2018 classification, all grades
3. Intact mandibular anterior region (teeth 3.3–4.3)
4. Presence of at least one tooth in the 3.3–4.3 region with a mobility degree of II or III (Miller's classification)
5. Patients who underwent step 2 of periodontal therapy and are scheduled for surgical step 3 for not having reached the therapeutic endpoints in the intact mandibular anterior region (teeth 3.3–4.3)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Inadequate oral hygiene following Step 2 of therapy (Full-mouth plaque score > 25%)
2. Systemic diseases or medical conditions known to affect periodontal healing
3. Presence of infrabony defects deeper than 4mm in 3.3 – 4.3 region; such defects, treatable by regenerative approaches, would preclude the patients to comply with the scheduled follow-up visits of the experiment
4. Smoking >10 cigarettes/day
5. Allergy to latex and any known sensitivity to the dental materials employed

Date of first enrolment
24/02/2027

Date of final enrolment
31/12/2027

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?
Other files	Romanian		13/02/2026	No	No
Other files			17/02/2026	No	No
Participant information sheet	Romanian		13/02/2026	No	Yes
Participant information sheet			17/02/2026	No	Yes
Protocol file	English		13/02/2026	No	No