Study protocol

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

Aim of the study

The aim of this pilot randomized clinical study is to evaluate whether temporary lingual composite-bonded eight-strand braided wire splinting placed prior to surgical Step 3 periodontal therapy increases the **proportion of sites reaching therapeutic endpoints** (PD ≤ 4 mm and no BOP) at 24 weeks post-operatively in the mandibular inter-canine region (teeth 3.3–4.3), compared with no splinting.

Secondary aims include evaluating changes in PD, CAL, BOP/bleeding scores, gingival recession, tooth mobility (clinical and objective), and patient-reported outcomes.

Materials and methods

Study design:

This study is designed as a randomized controlled clinical trial with two parallel groups (pre-surgical splinting vs. no splinting) and a 6-month follow-up period. Adult patients diagnosed with Stage IV periodontitis, presenting intact mandibular anterior dentition (teeth 3.3–4.3) and indication for surgical Step 3 therapy after completion of Step 2, will be randomly allocated in a 1:1 ratio into two parallel groups:

- a test group, in which a temporary lingual composite-bonded braided stainless-steel wire splint is placed on the mandibular anterior teeth one week prior to periodontal surgery;
- a control group, in which no splinting is performed prior to surgery.

Randomization will be performed using a computer-generated sequence with allocation concealment ensured by sealed opaque envelopes. The decision regarding the type of surgical procedure (Modified Widman Flap or Apically Positioned Flap) is made based on clinical indication before randomization.

The treatment workflow will include scheduled visits:

Visit 1 (Baseline; after completion of Step 2):

Comprehensive periodontal re-evaluation of the mandibular anterior region (3.3–4.3), oral hygiene instructions (OHI), professional mechanical plaque removal (PMPR), and PROMs collection.

Test group only

Visit 1a (1-week pre-surgery):

Placement of temporary lingual composite-bonded braided wire splint.

Both groups:

Visit 2 (Surgery; Step 3):

PROMs collection followed by periodontal surgery in the 3.3–4.3 region as clinically indicated (Modified Widman Flap or Apically Positioned Flap). The surgical approach will be determined **before randomization**.

Post-operative follow-up:

Visit 4 (2 weeks post-surgery): suture removal, gentle supragingival debridement/irrigations, reinforcement of OHI; splint integrity check (test group).
Visit 5 (8 weeks post-surgery): periodontal re-evaluation, PMPR, PROMs; splint integrity check (test group).
Visit 6 (16 weeks post-surgery): periodontal re-evaluation, PMPR, PROMs; splint integrity check (test group).
Visit 7 (24 weeks post-surgery): final periodontal re-evaluation, PMPR, PROMs; splint removal (test group) and decision regarding permanent stabilization as per clinical indication.

Study Population:

Patients will be recruited from the University Clinic of Periodontology, “Victor Babeș” University of Medicine and Pharmacy, Timișoara, Romania, and screened according to predefined criteria. All participants will provide written informed consent prior to enrollment.

Inclusion criteria:

- Age ≥ 18 years;
- Patients with no diseases with influence on periodontitis
- Diagnosis of Stage IV periodontitis, according to the 2018 classification, all grades;
- Intact mandibular anterior region (teeth 3.3–4.3);
- Presence of at least one tooth in the 3.3–4.3 region with a mobility degree of II or III (Miller’s classification);
- 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).

Exclusion criteria:

- Presence of any systemic diseases or conditions known to affect the periodontium;
- Inadequate oral hygiene following Step 2 of therapy (Full-mouth plaque score > 25%);
- 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;
- Smoking > cigarettes/day;
- Allergy to latex and any known sensitivity to the dental materials employed.

5. Data Collection

At baseline and follow-up visits, the following data will be collected (focused on teeth 3.3–4.3, aligned with the model protocol structure):

A. Clinical parameters: PD and CAL (6 sites/tooth), BOP/bleeding score, plaque score for experimental teeth, gingival recession (as applicable).

B. Mobility assessment: Miller mobility grading (baseline and 24 weeks) and objective mobility measurements using Periotest® (according to manufacturer protocol; repeated readings averaged).

C. Radiographic assessment: Standardized periapical radiographs of 3.3–4.3 at baseline (pre-surgical) and at 6 months' post-surgery.

D. Patient-reported outcomes (PROMs): OHIP-14 at baseline and follow-up visits; splint-specific VAS items administered in the splinted group during post-surgical follow-ups.

E. Splint evaluation (test group): Integrity status at each follow-up visit (intact / chipping /partial debond / complete debond / wire fracture) and maintenance interventions recorded.

Outcomes

Primary outcome:

- **Proportion of sites** in the 3.3–4.3 segment reaching therapeutic endpoints (PD ≤ 4 mm and no BOP) at 24 weeks post-operatively, calculated at patient level.

Secondary outcomes:

- Changes in PD, CAL, BOP/bleeding scores, gingival recession
- Changes in tooth mobility (Periotest values; Miller index)
- PROMs (OHIP-14 and splint-specific VAS)
- Splint integrity, maintenance burden, and failures (test group)

Sample size calculation

Sample size was calculated for the primary outcome of proportion of sites achieving probing depth ≤4mm AND no bleeding on probing at 24 weeks. Based on direct evidence showing 45.9% success in deep pockets (≥6mm) after 6 months of non-surgical treatment (Ferrarotti

et al., 2023), and accounting for the additional benefit of resective surgery (27-30% improvement) over non-surgical (Sanz-Sánchez et al., 2020), we estimated a 60% success rate in the control group. With an expected 30-35% relative improvement from pre-surgical splinting, and assuming a standard deviation of 20%, 38-44 patients (19-22 per group) provides 80% power to detect this difference relative improvement at $\alpha=0.05$ (two-sided) and 10% dropout.

Statistical analysis

Descriptive statistics will include percentages for binary and nominal categorical variables, medians and interquartile ranges for ordinal variables, and means and standard deviations for continuous variables. Descriptive statistics will be calculated for the outcome variables and for other variables of interest, both at the level at which the variables were measured (site, tooth, or patient) and at the level at which the variables will be analysed, if different from the measurement level. Descriptive statistics will be calculated overall and separately for each randomization group (splint versus no splint).

All statistical analyses will be performed using statistical models that consider the level at which the outcome variable is analysed (tooth or patient) and the data type of the outcome variables (binary, nominal, ordinal, or continuous).

For analyses performed at the patient level, logistic regression models will be used for binary outcomes, multinomial logistic regression models for nominal outcomes, ordinal logistic regression models for ordinal outcomes, and linear regression models for continuous outcomes. The models will include the randomization group (splint versus no splint) as the independent variable of interest and, where appropriate, a priori identified covariates of interest. Estimates of the effects of interest will be reported together with corresponding 95% confidence intervals.

For analyses performed at the tooth level, mixed-effects logistic regression models will be used for binary outcomes, mixed multinomial logistic regression models for nominal outcomes, mixed-effects ordinal logistic regression models for ordinal outcomes, and mixed-effects linear regression models for continuous outcomes. These models will include a random effect for patient to account for clustering of teeth within the same individual, and as fixed effects the randomization group (splint versus no splint) and, where appropriate, a priori identified covariates of interest. Estimates of the effects of interest will be reported together with corresponding 95% confidence intervals.