"VICTOR BABEŞ" UNIVERSITY OF MEDICINE AND PHARMACY TIMIŞOARA

University Clinic of Periodontology

PATIENT INFORMATION SHEET

Study 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

Study Description

Purpose of the Study

You are invited to participate in a study that aims to evaluate the effect of temporary stabilization (through wire and composite splinting) of anterior mandibular teeth on the outcomes of periodontal surgical treatment. The study is designed for patients with advanced periodontitis (stage IV) who present with increased tooth mobility and require periodontal surgical treatment.

The study compares two situations: application of a temporary dental splint before periodontal surgical intervention and absence of this splint.

All participants will benefit from the following steps of periodontal disease treatment:

1. **Initial Visit:** Periodontal re-evaluation, professional teeth cleaning, and oral hygiene recommendations.
2. **(Only for some participants):** Application of a temporary dental splint before surgical intervention, depending on the group to which you have been allocated.
3. **Periodontal Surgical Intervention:** Performed according to medical indication, to treat persistent periodontal pockets.
4. **Follow-up Visits:** At 2 weeks, 2 months, 4 months, and 6 months after surgical intervention, for evaluation of healing and professional cleaning.

The estimated total duration of study participation is approximately **6-8 months**.

During the study, the following will be performed:

- Clinical evaluations of gingival status;
- Measurement of periodontal pocket depth and gingival bleeding;
- Assessment of tooth mobility;
- Standardized dental radiographs;

- Completion of questionnaires regarding comfort, function, and oral quality of life;
- Verification of dental splint integrity, when applicable.

Study participation

Participation in this study is voluntary. You may withdraw from participation at any time, without any consequence for your routine periodontal treatment.

Who can participate in the study?

Patients with advanced periodontitis (stage IV) who meet the following criteria can participate in this study:

- Present intact anterior mandibular teeth (between right and left canines);
- Have at least one tooth with increased mobility;
- Have completed previous stages of periodontal therapy and require surgical treatment;
- Do not present severe general conditions that may influence healing;
- Can comply with periodic follow-up visits;
- If they smoke, do not exceed 10 cigarettes per day and agree to maintain or reduce consumption during the study.

The study is not recommended for patients who have known allergies to the dental materials used or those who cannot comply with monitoring visits.

Possible benefits

- Temporary stabilization of mobile teeth;
- More favorable conditions for healing after periodontal surgical intervention;
- Improvement in masticatory comfort.

Possible inconveniences or minor risks

- **Temporary discomfort, pain, or inflammation associated with periodontal surgical intervention**—normal reactions for this type of treatment, for which you will receive clear instructions and be monitored;
- Temporary sensation of tension or discomfort after splint application;
- Possible plaque accumulation around the splinting wire, which can be controlled through careful hygiene;
- Partial debonding of composite material, which can be remedied during follow-up visits.

Is the treatment safe?

Yes. All procedures included in the study are part of standard periodontal disease treatment and do not involve experimental methods. Surgical intervention and dental splint application are routine procedures, performed by specialist physicians, and patients are monitored throughout the entire study duration.

Why is this study important?

Through your participation, you contribute to improving knowledge regarding temporary stabilization of mobile teeth before periodontal surgical treatment and to optimizing clinical protocols used in treating patients with advanced periodontal disease.

Confidentiality

Your personal data will be kept confidential and used exclusively for scientific purposes, without the possibility of identifying participants.

Questions and contact

For additional information, you may contact:

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