STUDY PROTOCOL

Pain Perception in Protection of the Palatal Donor Area After Harvesting a Free Gingival Graft Using Flowable Resin Versus a Self-Adhesive Dressing

English study-specific translation of Methodology II from the ethics-approved Spanish protocol

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Ethics Approval	Amendment approval issued 27 February 2026
Sponsor	Universidad Espíritu Santo (UEES)
Principal Investigator	Antonio Gabriel Lanata Flores
Study Site	UEES Dental Clinic, Samborondón, Guayas, Ecuador

Document status

This document is a faithful English, study-specific translation of the sections applicable to the palatal donor-site study (Methodology II) in the most recent Spanish protocol reviewed by the ethics committee. It was prepared solely to satisfy the English-language document-upload requirement of ClinicalTrials.gov. It does not replace, modify, or retrospectively amend the approved Spanish source protocol.

1. Source Document and Scope

The Spanish source document is titled “Clinical Behavior in the Regeneration of Soft and Hard Tissues of the Oral Cavity in Patients With Missing Teeth and Dental Defects Treated at the Universidad Espíritu Santo Dental Clinic From 2024 to 2029.” It is an umbrella research protocol containing four methodologies. This English document reproduces the general information and the complete study-specific content applicable to Methodology II, which evaluates two alternatives for protecting the palatal donor site after free gingival graft harvesting.

The source protocol was electronically signed on 19 February 2026 by the principal investigator and sponsor representative. The protocol amendment was approved by CEISH-ITSUP on 27 February 2026. The amendment concerned another methodology within the umbrella protocol and did not substantively alter Methodology II.

Translation convention

The approved design and wording have been preserved in meaning. Commercial names, concentrations, time points, eligibility criteria, planned sample size, and the planned split-mouth structure are retained as stated in the source. Where Methodology II did not specify a procedure—such as the random-sequence method, allocation concealment, masking, or a detailed statistical analysis—none has been added here.

2. General Study Information

Umbrella study type	Interventional research; randomized controlled trials without medicinal products or mobile devices
Planned umbrella duration	60 months: 1 May 2024 to 30 April 2029
Executing institution	Research Center, Universidad Espíritu Santo
Local coverage	Samborondón, Guayas, Ecuador
Study population	Adults requiring periodontal or peri-implant soft-tissue grafting

3. Background and Rationale

Autogenous soft-tissue grafts are widely used for root coverage, augmentation of soft tissues around dental implants and partially edentulous areas, papillary reconstruction, and correction of scars. Palatal mucosa and the maxillary tuberosity are suitable donor sites. The palate provides good visibility and access and may permit greater graft length and width than the tuberosity.

A free gingival graft is straightforward to design and harvest, but the palatal wound heals by secondary intention and may be associated with postoperative pain, bleeding, infection risk, and prolonged epithelialization. Accidental injury to a major palatal vessel or one of its collateral branches is an important cause of palatal bleeding. The source protocol notes that closure of the palatal defect may

require approximately two to four weeks and that pain is commonly greatest on the first postoperative day and decreases during the following two weeks.

Palatal healing depends on fibroblast proliferation, collagen synthesis, angiogenesis, wound contraction, revascularization, immune function, and epithelial-cell proliferation. Hemostatic agents, periodontal dressings, self-adhesive dressings, mechanical appliances, and platelet concentrates have been used to reduce bleeding, pain, and other postoperative morbidity.

Self-adhesive oral dressings based on hydrophilic polymers and hydroxyethyl cellulose can adhere to intraoral surfaces, absorb inflammatory exudate, and protect the wound. Their retention depends on the wound bed and oral conditions. Alternatively, adhesive restorative materials can form a tooth-supported flowable-resin barrier over the donor site. The barrier is intended to maintain the clot, support hemostasis, protect the denuded wound, and reduce morbidity. The source protocol identified limited comparative evidence for these two approaches.

4. Objectives

4.1 Umbrella objective

To assess the efficacy and feasibility of soft- and hard-tissue techniques in order to generate clinical knowledge that contributes to the advancement of dental practice.

4.2 Study-specific objective

To evaluate and compare techniques for covering palatal graft donor sites, with particular attention to morbidity, wound protection, healing, and postoperative pain.

5. Study Design and Planned Population

Methodology II was designed as an interventional comparative study of two alternative techniques for protecting the palatal donor site. All prospective participants were to receive information about the study, its procedures, and its interventions and were to provide informed consent before participating in study-related decisions and evaluations.

The planned sample was 30 patients with periodontal or peri-implant defects in at least two quadrants who required free gingival graft harvesting for periodontal or peri-implant surgery. The anticipated graft size was the palatal span corresponding to approximately three to four teeth, extending from the maxillary canine region to the maxillary first-molar region.

The source protocol planned two separate operative sessions in the same participant using a split-mouth structure. The two study groups were Group I, palatal protection using a self-adhesive periodontal dressing, and Group II, palatal protection using flowable resin. The source Methodology II did not separately describe the random-sequence generation method, allocation concealment, or masking.

6. Eligibility Criteria

6.1 Inclusion criteria

- Age greater than 18 years.
- Plaque-control score below 20%.
- Bleeding on probing below 10%.
- Need for two periodontal or peri-implant surgical procedures in the maxilla or mandible.
- No previous surgery at the palatal donor site.

6.2 Exclusion criteria

- Pregnancy or breastfeeding.
- Palatal lesions.
- Use of a prosthesis covering the palate.
- Periodontal disease.
- Current smoking.
- Systemic disease.

7. Surgical Procedures and Interventions

7.1 Common graft-harvesting procedure

Local anesthesia was to be administered using lidocaine with epinephrine 1:80,000. A free gingival graft was to be harvested with a No. 15C scalpel blade at a planned thickness of 2 mm and a length corresponding to three to four teeth, from the maxillary canine to the first-molar region. Hemostasis was to be obtained with gauze pressure and a local anesthetic containing vasoconstrictor. A hydrolyzed collagen hemostatic sponge (Hemospon) was to be placed over the palatal wound in both groups.

7.2 Group I — Self-adhesive periodontal dressing

The self-adhesive periodontal dressing was to be trimmed and adapted to the shape of the wound, extending 2–3 mm beyond the margins. X-shaped sutures were to maintain the material in position and stabilize the clot. The protocol described this as a modification of the manufacturer-recommended placement sequence, intended to prolong dressing retention and improve palatal protection.

7.3 Group II — Flowable resin

The initial graft-harvesting and hemostatic steps were to be the same as in Group I. The palatal enamel surfaces of the teeth adjacent to the wound were to be selectively etched with 35% phosphoric acid for 15 seconds, rinsed thoroughly, and treated with Single Bond Universal adhesive (3M). The source protocol specified placement of the hydrolyzed collagen sponge and X-shaped sutures to maintain and stabilize the clot. After hemostasis, flowable resin was to be applied beginning on the palatal tooth surfaces and extended to cover the full palatal wound.

Source-protocol fidelity

The reference to X-shaped sutures in the flowable-resin group is retained because it appears in the approved Spanish source protocol. The study as conducted is reported separately in the ClinicalTrials.gov results record and the post-completion statistical analysis plan; this translation does not rewrite the approved method to match later conduct.

8. Postoperative Follow-up and Outcomes

The protective materials and sutures were planned for removal on postoperative day 7. At that visit, palatal healing was to be assessed by evaluating granulation-tissue formation and re-epithelialization.

8.1 Outcomes identified in the source protocol

- Postoperative pain and patient morbidity associated with the palatal donor site.
- Maintenance and protection of the palatal wound and clot.
- Healing at the donor site, including granulation-tissue formation and re-epithelialization at postoperative day 7.

Methodology II did not specify a detailed pain-scale schedule, a formal outcome hierarchy, or a full statistical analysis method. Those details are therefore not added to this translation. Analysis of the completed study is described in the separately uploaded statistical analysis plan.

9. Ethical and Safety Considerations

Participants were to be informed about the study and provide informed consent. The source protocol identified infection as a potential risk and specified barrier methods, sterile instruments, and sterile gloves. A health professional and on-call physician were available in the UEES Clinic building should an infection occur, although infection was not expected.

Participant data were to be coded using limited identifying elements rather than full names. No biological samples were to be collected. Participants were not to receive financial compensation. They could withdraw without penalty or additional cost. The general source protocol stated a USD 15 facility-use charge, with no additional charge for participants who required financial accommodation.

The research team declared that the study would be conducted according to the terms approved by the Research Ethics Committee for Studies Involving Human Subjects and the Ecuadorian Ministry of Public Health and that a final report of study results would be submitted to the Ministry of Public Health.

10. Administrative Disclosure for Results Reporting

This section is an administrative disclosure prepared for ClinicalTrials.gov and is not part of the ethics-approved methodology. The approved source protocol planned 30 participants and a split-mouth, two-session design. The study was completed with 12 participants allocated to two independent parallel groups (6 per group). The completed study also used a tooth-supported resin barrier without sutures to

stabilize that barrier and followed pain for 14 days. These departures from the source protocol are disclosed in the ClinicalTrials.gov record, results tables, limitations, and the separately uploaded post-completion statistical analysis plan. They are not presented here as retroactive amendments.

11. References Cited in the Source Protocol

1. Meza-Mauricio J, Mourão ERST, Oliveira Marinho K, Vergara-Buenaventura A, Mendoza-Azpur G, Muniz FWMG, et al. Effect of collagen sponge and flowable resin composite on pain management after free gingival graft harvesting: A randomized controlled clinical trial. Eur J Oral Sci. 2023;131:e12935. doi:10.1111/eos.12935.
2. Zucchelli G, Tavelli L, McGuire MK, Rasperini G, Feinberg SE, Wang HL, Giannobile WV. Autogenous soft tissue grafting for periodontal and peri-implant plastic surgical reconstruction. J Periodontol. 2020;91(1):9–16. doi:10.1002/JPER.19-0350.
3. Zucchelli G, Mounssif I. Periodontal plastic surgery. Periodontol 2000. 2015;68(1):333–368. doi:10.1111/prd.12059.
4. Bitencourt FV, Cardoso De David S, Schutz JDS, Otto Kirst Neto A, Visioli F, Fiorini T. Minimizing patient morbidity after free gingival graft harvesting: A triple-blind randomized-controlled clinical trial. Clin Oral Implants Res. 2022;33(6):622–633. doi:10.1111/clr.13923.
5. Almeida VC, Pannuti CM, Ferreira MS, Lazarin RO, Romito GA, Jung RE, et al. Conventional versus flap-protected free gingival graft: A multicenter randomized clinical trial. Braz Oral Res. 2023;37:e001. doi:10.1590/1807-3107bor-2023.vol37.0001.

12. Source Approval and Signature Record

Source protocol date	19 February 2026
Principal Investigator	Antonio Gabriel Lanata Flores — electronically signed 19 February 2026
Sponsor representative	Patricia Estefania Ayala Aguirre — electronically signed in the source protocol
Ethics committee	CEISH-ITSUP
Ethics amendment approval	27 February 2026; research code 1715824376
Original language	Spanish

The signed Spanish source protocol and the ethics-committee approval letter remain the authoritative records. This English version is provided for public registry submission and should be read as a faithful translation of the study-specific approved content, not as a newly approved protocol version.