STATISTICAL ANALYSIS PLAN

Flowable Resin Composite Versus a Self-Adhesive Oral Dressing for Palatal Donor-Site Protection After Free Gingival Graft Harvesting: A Pilot Randomized Clinical Trial

ClinicalTrials.gov Identifier: NCT06593275
Unique Protocol ID: 2024-ODONT-002B
Sponsor: Universidad de Especialidades Espiritu Santo
Principal Investigator: Antonio Lanata Flores
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Transparency statement. This SAP was finalized after study completion to document the statistical methods used for results reporting. It was not approved by the ethics committee before participant enrollment and must not be interpreted as a prospectively finalized SAP.

Prepared for submission with summary results to ClinicalTrials.gov

1. Purpose and Document Status

This Statistical Analysis Plan (SAP) defines the analysis populations, outcome definitions, statistical methods, and reporting conventions for NCT06593275. Its purpose is to support transparent reporting of the completed pilot randomized trial.

Post-completion status. The SAP was assembled after completion of participant follow-up from the archived ethics protocol materials, the final specialty thesis, and the ClinicalTrials.gov results record. No committee-approved SAP that fully reflected the conducted parallel-group study was available. Consequently, all analyses described here are exploratory and no claim of prospective statistical prespecification is made.

Source hierarchy. Participant-level source data and contemporaneous study records take precedence over this document. The ClinicalTrials.gov results tables provide the public summary, while the final thesis provides the documented descriptive and inferential analyses.

2. Study Overview

Item	Specification
Design	Single-center, two-arm, parallel-group pilot randomized clinical trial
Setting	Postgraduate Dental Clinic, Universidad de Especialidades Espiritu Santo, Samborondon, Ecuador
Allocation	1:1 to flowable resin composite or self-adhesive oral dressing
Unit of allocation and analysis	Individual participant and one palatal donor site
Planned enrollment	30 participants in the ethics protocol and initial registry record
Actual enrollment	12 participants; 6 per treatment arm
Follow-up	From surgery through postoperative day 14
Recruitment status	Terminated when the predefined recruitment period ended before the planned sample was reached

3. Objectives and Outcomes

3.1 Primary objective and outcome

The primary objective was to compare postoperative palatal donor-site pain following protection with a flowable resin composite barrier versus a self-adhesive oral dressing. Pain was self-reported once daily on postoperative days 1 through 14 using an 11-point Numerical Rating Scale (NRS) from 0 (no pain) to 10 (maximum pain); higher scores indicate greater pain.

Although early study documents used the term visual analogue scale, the administered electronic form used discrete integer response options from 0 to 10 and is therefore reported as an NRS.

3.2 Secondary outcomes

Outcome	Definition	Unit/time point
Free gingival graft-harvesting time	Elapsed time required to harvest the graft	Seconds; intraoperative day 0
Protective-material application time	Elapsed time required to prepare and place the assigned protective material	Seconds; intraoperative day 0
Intraoral retention time	Days from surgery until complete detachment of the assigned protective material	Days; through day 14

3.3 Baseline, procedural, and safety variables

Baseline variables were age and sex. Procedural comparability variables were graft length, width, and thickness in millimeters. Safety reporting included all-cause mortality, serious adverse events, and other adverse events through postoperative day 14.

4. Analysis Populations

Population	Definition	Primary use
Full analysis set	All randomized participants who received the assigned intervention and contributed at least one post-baseline pain assessment	Primary and secondary effectiveness summaries
Per-protocol set	Participants completing the assigned intervention and 14-day follow-up without a major protocol deviation affecting outcome interpretation	Supportive analysis if different from the full analysis set
Safety set	All randomized participants who received either protective intervention	Adverse-event summaries

All 12 randomized participants completed follow-up; therefore, the full analysis, per-protocol, and safety populations contained the same six participants per arm.

5. Data Handling and Derived Variables

Treatment coding. Flowable resin composite is the active comparator and self-adhesive oral dressing is the experimental intervention.

Pain data. Each daily NRS response is analyzed as a numeric score from 0 to 10. No composite score or area-under-the-curve measure was defined in the source report.

Timing variables. Graft-harvesting and application times are retained in seconds. Retention time is retained in days.

Range and consistency checks. Values outside the permitted NRS range or impossible time values are queried against source records. Treatment assignment, denominators, and day labels are checked before analysis.

6. General Statistical Principles

Analytical framework. The study is an exploratory pilot trial. Estimates, observed patterns, and uncertainty are emphasized over definitive claims of efficacy.

Descriptive statistics. Continuous variables are summarized by treatment arm using the mean and standard deviation. Categorical variables are summarized using counts and percentages.

Statistical testing. Tests are two-sided with a nominal significance level of 0.05. Exact p values are reported where available. No adjustment for multiple comparisons is applied; inferential results are exploratory.

Missing data. No imputation is performed. Daily pain summaries use the available observations for the corresponding day, with the denominator displayed. The number and reason for missing observations are reported if present.

Outliers. No observation is excluded solely because it is statistically extreme. Exclusion requires a documented data error or a prespecified population rule.

Precision. Means are generally reported to two decimal places and standard deviations to three decimal places, while retaining additional precision when needed to reproduce the archived results tables.

7. Statistical Analyses

7.1 Participant flow and baseline characteristics

Participant disposition is summarized by arm as started, completed, and not completed. Age is compared using an independent-samples Student t test. Sex is compared using the Pearson chi-square test, with Fisher exact testing preferred if expected cell counts are too small. Graft length, width, and thickness are compared using independent-samples t tests.

7.2 Primary outcome: daily postoperative pain

Daily NRS scores are presented by treatment arm for each postoperative day as mean and standard deviation, with the number analyzed. The principal comparison is the descriptive between-arm pattern over the 14-day follow-up.

Within each treatment arm, change across postoperative days 1 through 14 is evaluated using the Friedman test for repeated nonparametric measurements. The Friedman chi-square statistic, degrees of freedom, and p value are reported.

Because only six participants were analyzed per arm, no between-arm test of daily pain is treated as confirmatory. If exploratory between-arm testing is performed for an individual day, the Mann-Whitney U test may be used and must be clearly labeled exploratory; no multiplicity adjustment is applied. Conclusions must not be based solely on isolated daily p values.

7.3 Secondary outcomes

Graft-harvesting time, protective-material application time, and intraoral retention time are summarized by arm as mean and standard deviation. Between-arm comparisons use an independent-samples Student t test, consistent with the archived study report. The mean difference, 95% confidence interval when available, t statistic, degrees of freedom, and p value are reported.

7.4 Safety outcomes

For each treatment arm, the number at risk and the number and percentage affected are reported for all-cause mortality, serious adverse events, and other adverse events from surgery through postoperative day 14. No inferential safety comparison is planned.

8. Sensitivity, Subgroup, and Multiplicity Considerations

No subgroup analysis is planned because of the small sample. If the full analysis and per-protocol populations differ, the primary descriptive pain table may be repeated in the per-protocol population as a sensitivity analysis. No formal multiplicity correction is applied, and all inferential analyses are interpreted as exploratory.

9. Protocol and Analysis Deviations

The ethics protocol available for this project was an umbrella protocol and described a target of 30 participants and a split-mouth/two-procedure approach for the palatal sub-study. The conducted study used two independent parallel groups with 12 participants in total. No ethics-approved amendment aligning those design details was available when this SAP was prepared.

Early protocol materials referred to a visual analogue scale, whereas the administered electronic pain instrument used discrete integer choices from 0 through 10; results are therefore described as an 11-point Numerical Rating Scale.

Recruitment stopped when the predefined recruitment period ended, before the planned sample size was achieved. The reduced sample limits precision, statistical power, and generalizability.

This SAP was finalized after study completion. Any statistical method not demonstrably documented in the archived study report is identified as optional or exploratory rather than prespecified.

10. Planned Reporting Tables

Table	Content	Primary statistics
1	Participant flow and baseline characteristics	n (%), mean (SD), exploratory baseline p values
2	Daily palatal donor-site pain, postoperative days 1-14	n, mean (SD) by arm; Friedman test within arm
3	Graft dimensions and intraoperative timing variables	n, mean (SD), between-arm t tests
4	Intraoral retention time	n, mean (SD), mean difference and exploratory p value
5	Adverse events	Affected/at risk, percentage by arm

11. Document Basis

This SAP was prepared from: (1) the ethics protocol materials for the umbrella oral soft- and hard-tissue regeneration project, including the palatal protection methodology; (2) the final specialty thesis by Christian Gustavo Garcia Erazo; and (3) the NCT06593275 registration and summary-results record.

12. Approval for Results Reporting

This signature section documents review of the final post-completion SAP and does not indicate prospective ethics approval.

Principal Investigator	Antonio Lanata Flores
Signature	ANTONIO GABRIEL LANATA FLORES Digitally signed by ANTONIO GABRIEL LANATA FLORES
Date	26 July 2026

Statistical reviewer, if applicable	