STATISTICAL ANALYSIS PLAN (SAP)

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STATISTICAL ANALYSIS PLAN

Overview

This SAP describes the statistical procedures for comparing radiographic buccal bone outcomes between two independent groups in a pilot randomized controlled clinical trial: periosteal mattress sutures versus titanium tacks for graft/membrane stabilization during horizontal guided bone regeneration with simultaneous implant placement in the anterior maxilla.

Analysis Populations

Primary analysis set: participants/implants with evaluable 6-month CBCT measurements at all specified reference levels.

Handling of missing data: cases without evaluable CBCT measurements due to loss to follow-up or non-interpretable imaging (e.g., artifacts) will be excluded from the

corresponding radiographic endpoint analyses. Reasons for missingness will be documented.

Endpoints

Primary Endpoint

Mean buccal bone thickness (mm) at 6 months.

For each implant, buccal bone thickness is measured at 1 mm, 3 mm, and 6 mm apical to the implant platform. The mean of these three values is calculated and used as the primary endpoint.

Secondary Endpoints

Buccal bone thickness (mm) at each individual level (1 mm, 3 mm, 6 mm) at 6 months.

Reconstructed buccal bone area between 1 mm and 6 mm at 6 months, computed from thickness measurements using a geometric approach based on two trapezoidal regions across the 1–3 mm and 3–6 mm segments.

Descriptive Statistics

For each group and each endpoint, continuous variables will be summarized as:

Sample size (n)

Mean and standard deviation

Median and interquartile range

Minimum and maximum (optional)

Assumption Checking (Normality)

Normality of each endpoint within each group will be assessed using the Shapiro–Wilk test.

Inferential Comparisons (Between-Group)

For each endpoint (1 mm, 3 mm, 6 mm thickness; mean thickness; reconstructed area):

If both groups meet normality assumptions: compare groups using an independent-samples t-test with Welch's correction.

If normality is not met in either group: compare groups using the Mann–Whitney U test.

All tests will be two-tailed with a significance threshold of $p < 0.05$.

Multiplicity

Because this is a pilot study, analyses are primarily exploratory. The primary endpoint is mean buccal bone thickness. Secondary endpoints will be interpreted descriptively and inferentially without formal multiplicity adjustment unless otherwise specified.

Software

Statistical analyses may be conducted using Python (version 3.11 or later) or equivalent validated statistical software. Data handling may be performed using common scientific computing libraries; final outputs will be archived with analysis scripts and an analysis log.

Reporting

Results will be reported by group with appropriate summary statistics and effect estimates. Graphical summaries of distributions may be included to support interpretation. Any deviations from this SAP will be documented and justified in the final report.