STUDY PROTOCOL

COVER PAGE

Official Title: Periosteal Sutures for Fixation of Composite Bone Graft Substitutes in Guided Bone Regeneration: A Randomized Controlled Clinical Trial

NCT Number: NCT[TO BE ASSIGNED]

Document Type: Study Protocol

Version/Identifier: Version 1.0

Document Date: 29-Dec-2025

Sponsor: SigmaGraft Biomaterials

Study Site: Periodontics Clinic / Dental Unit, Hospital San Camilo

Ethics Approval: Scientific Ethics Committee of Servicio de Salud Aconcagua (CEC-SSA 19/2021)

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Title

Periosteal Sutures for Fixation of Composite Bone Graft Substitutes in Guided Bone Regeneration: A Randomized Controlled Clinical Trial

Background and Rationale

Guided bone regeneration (GBR) performed simultaneously with implant placement is a common approach to augment deficient alveolar ridges in the anterior maxilla. Predictable outcomes depend on maintaining a stable regenerative compartment and achieving tension-free primary closure. Stabilization of the graft and membrane is considered critical to limit micromotion during early healing. Titanium fixation devices (tacks) are frequently used for this purpose but require additional hardware and procedural steps. Periosteal mattress sutures have been proposed as a hardware-free alternative to stabilize the graft and membrane through periosteal anchorage.

Objectives

Primary Objective

To compare postoperative buccal bone dimensions following horizontal GBR in the anterior maxilla using periosteal mattress sutures versus titanium tacks for graft/membrane stabilization.

Secondary Objective

To compare an integrated metric of buccal bone contour (reconstructed buccal bone area) derived from CBCT measurements across the evaluated region.

Study Design

This is a pilot, parallel-arm, randomized controlled clinical trial with two intervention groups:

Periosteal mattress sutures for graft/membrane stabilization

Titanium tacks for graft/membrane stabilization

All participants undergo implant placement in healed ridges with simultaneous horizontal GBR. The only difference between groups is the stabilization method.

Study Setting

Participants are recruited consecutively from the Periodontics Clinic / Dental Unit of Hospital San Camilo, where patients seeking implant therapy in the anterior maxilla are screened for eligibility.

Participant Eligibility

Inclusion Criteria

Patients seeking implant therapy in the anterior maxilla

Clinical indication for simultaneous guided bone regeneration (GBR) at the time of implant placement

Implant placement in a healed ridge (not an immediate post-extraction site)

Ability and willingness to provide written informed consent

Exclusion Criteria

Uncontrolled diabetes

Ongoing bisphosphonate therapy

Recruitment and Informed Consent

Potential participants are screened by the clinical team. A trained investigator not involved in surgical treatment provides verbal and written information, obtains written informed consent in the presence of an authorized witness, and confirms participation is voluntary and can be discontinued at any time.

Randomization and Allocation

Participants are randomly allocated to one of the two stabilization approaches.

Randomization method: [Specify method used, e.g., computer-generated random sequence]

Allocation concealment: [Specify method used, e.g., sealed opaque envelopes]

Blinding (Masking)

Because the stabilization method differs, blinding of the surgeon is not feasible. Clinical data collection and radiographic measurements are performed by calibrated personnel not involved in the surgical procedures.

Interventions

Common Procedures in Both Arms

Implant placement in healed ridges following standard surgical protocols

Horizontal buccal augmentation using a xenogeneic composite collagenated bovine block graft substitute

Coverage with a resorbable collagen membrane

Flap advancement and tension-free primary closure

Standard postoperative care and follow-up

Arm A: Periosteal Mattress Sutures

The graft and membrane are stabilized using a periosteal mattress suture technique, employing vertically oriented periosteal sutures for lateral immobilization and a

supplemental horizontal mattress suture between flap edges to prevent apical displacement.

Arm B: Titanium Tacks

The graft and membrane are stabilized using titanium fixation tacks to provide rigid immobilization.

Schedule of Assessments and Follow-up

Baseline (after consent)

Full clinical examination

CBCT at an external radiology facility

Digital impressions

Surgery (Day 0)

Implant placement with simultaneous GBR according to allocated stabilization method

Postoperative Follow-up

Day 7: soft tissue healing assessment; suture management as indicated

Day 14: soft tissue healing assessment; suture removal as indicated

Approximately 4 weeks: additional evaluation consistent with institutional implant patient protocol

6 months: CBCT and digital impressions for quantitative and qualitative evaluation of regenerated tissues

Outcome Measures

Primary Outcome

Mean buccal bone thickness (mm) at 6 months, measured on CBCT at 1 mm, 3 mm, and 6 mm apical to the implant platform (linear distance from implant surface to the outer buccal bone contour). The primary endpoint is the mean of the three measurements.

Secondary Outcome

Reconstructed buccal bone area between 1 mm and 6 mm, calculated from the CBCT-derived thickness measurements to represent an integrated buccal bone envelope metric.

Radiographic Acquisition and Measurement Procedures

At 6 months, CBCT is obtained using a standardized acquisition protocol. For each implant, measurements are made at 1 mm, 3 mm, and 6 mm apical to the implant platform. Cross-sectional views are oriented to obtain a true buccolingual slice perpendicular to the implant long axis. Measurements are performed by a calibrated examiner using radiographic analysis software with known spatial resolution.

Safety Considerations

CBCT involves ionizing radiation. Two CBCT scans are performed as part of baseline and 6-month assessments. Dose-reduction measures are implemented, including use of CBCT (instead of conventional CT) and protective lead apron. Clinical follow-up captures healing outcomes and any complications.

Data Management and Confidentiality

Participant information is stored securely with restricted access. Data used for analysis are de-identified whenever possible. Only authorized study personnel have access to identifiable information.

Ethical Considerations

The study is conducted under approval of the Scientific Ethics Committee of Servicio de Salud Aconcagua (CEC-SSA 19/2021) and in accordance with applicable national regulations. Written informed consent is obtained prior to study participation.

Protocol Deviations and Amendments

Any protocol deviations are documented. Amendments, if required, will be reviewed and approved by the ethics committee prior to implementation, unless immediate changes are needed to protect participant safety.

Dissemination

Study findings may be presented at scientific meetings and submitted for publication in peer-reviewed journals. No identifying participant information will be disclosed.