Alveolar Ridge Preservation Using Cortical Lamina Versus Xenograft and Collagen Membrane: A Randomized Clinical Study

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Study Protocol

Project Summary

This randomized controlled clinical study aims to evaluate the efficacy of alveolar ridge preservation (ARP) using a cortical lamina compared to a xenograft with a collagen membrane. Alveolar bone resorption following tooth extraction represents a major clinical challenge, affecting both functional and aesthetic outcomes. The study will involve 40 patients requiring tooth extraction in the premolar, canine, or incisor regions. Participants will be randomized into two groups: test (cortical lamina placement) and control (xenograft plus collagen membrane). Cone Beam CT (CBCT) scans and digital impressions will be performed before extraction and after 6 months to assess dimensional and volumetric changes. Histologic samples will be collected at implant installation. The primary outcomes are horizontal and vertical dimensional changes and volumetric differences. Secondary outcomes include histologic parameters of new bone formation. Statistical analyses will be performed with significance set at $p < 0.05$. This study is expected to contribute evidence-based data to support the use of cortical lamina as an effective ARP technique.

General Information
Protocol title: Alveolar Ridge Preservation Using Cortical Lamina Versus Xenograft and Collagen Membrane: A Randomized Clinical Study
Protocol identifying number: ISRCTN (pending confirmation)
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Study sites: Departement Oral Surgery, Faculty of Dentistry, University of Medical Science of La Habana, 10400 La Habana, Cuba
Collaborating investigators: Franco Bengazi, Tomaso Mainetti, Karol Alí Apaza Alccayhuaman
Laboratories involved: Histology Lab at University of Medical Science of La Habana , Cuba and, ARDEC Academ, Riccione/Rimini, Italy

Rationale & Background Information

Tooth extraction triggers significant alveolar bone resorption, particularly affecting the buccal plate. This leads to ridge width and height reduction, complicating implant placement. Current ARP techniques, including xenografts, allografts, and membranes, reduce resorption but do not fully prevent volume loss. A novel technique proposes the placement of a cortical lamina between the buccal bone and mucoperiosteal flap to inhibit periosteal activity and preserve ridge dimensions. Preliminary reports indicate promising results, but controlled clinical evidence is lacking. This study will provide quantitative and histologic evaluation of this approach compared to a standard xenograft and membrane technique.

Study Goals and Objectives

Primary Objective: To compare horizontal and vertical ridge dimensional changes between cortical lamina and xenograft groups.

Secondary Objectives: To evaluate histological new bone formation and residual graft content after six months of healing.

Study Design

Type of study: Prospective, parallel-arm, randomized controlled trial.

Number of participants: 40 (20 per group).

Duration: 6-month healing phase followed by implant placement.

Randomization: Computer-generated random allocation sequence.

Blinding: Single-blind (examiner).

Methodology

After tooth extraction, a full-thickness flap will be elevated. In the test group, a cortical lamina will be placed between the buccal bone and flap. In the control group, the socket will be filled with a xenograft and covered by a collagen membrane. Wounds will be sutured for non-submerged (test) or submerged (control) healing. CBCT scans and impressions will be obtained before extraction and at 6 months. Biopsies will be collected during implant site preparation for histologic evaluation.

Safety Considerations and Follow-up

Patient safety will be ensured through adherence to surgical asepsis, postoperative monitoring, and informed consent. Any adverse events will be documented and managed according to clinical standards. Follow-up visits will occur at 2 weeks, 1 month, 3 months, and 6 months.

Data Management and Statistical Analysis

Data will be anonymized and stored securely. Normality will be tested using the Shapiro–Wilk test. Depending on distribution, comparisons will be made using ANOVA or Kruskal–Wallis tests with post-hoc analyses. Statistical significance will be set at $p < 0.05$.

Quality Assurance

The study will follow Good Clinical Practice (GCP) guidelines and the CONSORT statement. Calibration of examiners and standardized surgical protocols will ensure methodological consistency.

Expected Outcomes

The cortical lamina technique is expected to yield superior preservation of ridge dimensions and new bone formation compared to xenograft with collagen membrane, potentially simplifying future implant placement.

Dissemination of Results and Publication Policy

Results will be published in peer-reviewed journals and presented at international conferences. Authorship will follow ICMJE criteria, and participants will receive summarized study outcomes.

Duration and Timeline

Month 1–2: Patient recruitment and baseline assessments.
Month 2–3: Surgeries and interventions.
Month 4–8: Follow-up and data collection.
Month 9: Data analysis and reporting.

Problems Anticipated

Potential issues include patient dropout, infection, or minor wound dehiscence. To mitigate, over-recruitment and standardized postoperative care are planned.

Project Management and Ethics

Principal Investigator: Prof. Daniele Botticelli, MD, PhD.
Ethical approval: University of Medical Science of Havana Ethics Committee.
The study complies with the Declaration of Helsinki and Good Clinical Practice. Written informed consent will be obtained.

Budget, Support, and Collaborations

Funding source: ARDEC Academy, Rimini, Italy.
Collaborations: University of Medical Science of Havana.