

STUDY PROTOCOL

Official Title:

**Graftless Periosteal Coverage versus Xenogenic Bone Graft beneath a
Collagen Membrane for Jumping Gap Management in Immediate
Mandibular Molar Implants:
A Randomized Controlled Clinical and Radiographic Trial**

ClinicalTrials.gov Identifier:

Pending assignment

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Version 1.0

- **Statement of the problem:**

Immediate or early implant placement inherently creates a horizontal gap, commonly referred to as the “**jumping gap**,” between the implant surface and the inner wall of the extraction socket. (1, 2) This gap requires management to prevent soft tissue ingrowth and maintain the buccal bone volume, which is critical for long-term aesthetic and functional success. (3, 4) The traditional and widely accepted management technique involves **particulate bone grafting** (e.g., xenograft or allograft) covered with a **resorbable collagen membrane**. (5)

However, spontaneous bone healing within peri-implant gaps has also been documented under favorable conditions, particularly when adequate defect stability and blood supply are maintained. (6, 7) The periosteum is a highly vascularized tissue containing **osteogenic progenitor cells and angiogenic factors**, suggesting potential regenerative capacity when utilized as a biological seal .(8)

A novel, **biomaterial-free approach** involves using **periosteal coverage**, where the periosteum, tissue rich in osteogenic and angiogenic cells, is coronally advanced to seal the gap. (9) However, there is currently **limited high-quality comparative evidence** evaluating whether this simplified biological approach (periosteal coverage) achieves comparable or superior horizontal bone fill and soft-tissue outcomes compared to the traditional bone graft and membrane technique in immediate posterior implants of the mandible.

▪ **Aim of the study:**

➤ **Primary Objective:**

To compare the regenerated bone volume & density at 4 months around implants treated with:

1. **Periosteal coverage only** (Study Group).
2. **Particulate bone grafting + collagen membrane** (Control Group).

➤ **Secondary Objectives**

1. To analyze **implant stability** (ISQ) changes over time.
2. To compare patient-reported outcomes (**pain, swelling**).
3. To compare the incidence of **postoperative complications** (membrane exposure, flap dehiscence, infection).

P.I.C.O. (Patient, Intervention, Comparison, Outcome)

- **P. (Patients):** Adults (18–60 years) requiring **immediate implant placement** at mandibular molar region with a buccal/horizontal gap ≥ 2 mm.
- **I. (Intervention):** **Periosteal coverage** only (no bone graft or membrane).
- **C. (Comparison):** **Particulate bone graft** (xenograft) + resorbable collagen membrane.
- **O. (Outcomes):** Bone volumetric and density analysis with comparison of **horizontal bone fill**, soft-tissue outcomes, implant stability (ISQ), and complications.

▪ **Subjects and Methods:**

➤ **Study Design, Setting, and Follow-up:**

This will be a **Prospective, parallel-arm, randomized controlled clinical trial** with a 1:1 allocation ratio. The primary outcome of volumetric and density bone analysis as well as the secondary aesthetic and stability outcomes will be assessed at 4 months. Informed consent will be obtained, and adverse events will be monitored and reported.

➤ **Study Population and Sample Size**

- **Inclusion Criteria:** Adults 18–60 years, indicated for single mandibular molar immediate implant placement, with an intraoperative jumping gap ≥ 2 mm, and adequate primary implant stability (≥ 30 Ncm).

- **Exclusion Criteria:** Uncontrolled systemic diseases (e.g., uncontrolled diabetes), smokers, acute infection at the site, immunosuppressive therapy, severe parafunction, or poor oral hygiene (PI > 25%).

- **Sample Size:**

The sample size was calculated using *GPower** software (version 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Germany) based on the primary outcome variable, which was defined as the mean marginal bone level change (mm) assessed radiographically at follow-up.

The calculation was performed for comparison between two independent groups: the graftless periosteal coverage group (Δ_1) and the xenogenic bone graft group (Δ_2). The effect size was expressed as Cohen's *d*, calculated as the absolute difference between group means divided by the pooled standard deviation ($d = |\Delta_1 - \Delta_2| / \sigma$).

Based on evidence from comparable dental implant studies, a clinically relevant mean difference of approximately 0.8 mm with an assumed standard deviation of 1.0 mm was considered, corresponding to a moderate effect size ($d = 0.8$). A two-tailed significance level (α) of 0.05 and a statistical power of 80% ($1 - \beta = 0.80$) were applied.

Under these assumptions, the required sample size was estimated to be 25 participants per group. To account for a potential dropout rate of 10%, the sample size was increased to 28 participants per group.

Accordingly, the final study population will consist of **56 participants, with equal allocation between the two study arms**. This methodology follows established principles for sample size determination in randomized controlled clinical trials.

This calculation method aligns with established biostatistical standards for clinical trials (Julious, 2009; Norman & Streiner, 2014; Rosner, 2015; Chow et al., 2008).

➤ **Interventions**

- **Group A (Test Group) — Periosteal Coverage:**

- Implant will be placed in the furcation area of single mandibular molar freshly extraction socket
- Periosteal Release Technique: A buccal full-thickness flap will be raised minimally, followed by a deep-to-shallow periosteal releasing incision.
- The periosteum will be coronally advanced to fully cover the implant shoulder and gap.
- The gap will be left to heal under the periosteal envelope (no graft, no membrane).

- Tension-free primary closure will be achieved.
- **Group B (Control Group) — Particulate Bone Graft + Collagen Membrane:**
 - Same extraction and implant placement protocol.
 - The gap will be filled with particulate xenograft.
 - The graft will be covered with a resorbable collagen membrane extending 2–3 mm beyond the defect.
 - Wound closure will be achieved.
 - Postoperative Care and Outcome Measures
- **Postoperative Care:**
 - Standardized regimen of antibiotics (Amoxicillin 500 mg TID × 5–7 days), analgesics (Ibuprofen 600 mg TID PRN), and CHX rinse (0.12% × 2 weeks). Sutures will be removed after 14 days.
- **Primary Outcome:**

Bone volumetric & density analysis 4 months post-operatively, measured via CBCT
- **Secondary Outcomes:**
 1. Implant Stability (ISQ will be measured at baseline and after 4 months)
 2. Patient-Reported Outcomes (VAS pain, swelling) assessed at 2nd, 7th and 14th day post-operatively.
 3. To compare the incidence of **postoperative complications** (membrane exposure, flap dehiscence, infection) assessed at 2nd, 7th and 14th day post-operative then once monthly for 4 months follow-up.

STUDY STATISTICAL ANALYSIS:

- Data analyzed using SPSS or R. Normality tested by Shapiro–Wilk test. Between-group comparisons performed using Independent t-test or Mann-Whitney U test. Repeated measures ANOVA will analyze longitudinal changes (ISQ, radiographic). Significance set at $p < 0.05$.

▪ **References:**

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