Twelve-Month Short-Term Marginal Bone Remodeling at Monolithic Zirconia Full-Arch Prostheses in the Maxilla and Mandible: A Clinical Study

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STUDY PROTOCOL

1. Background and Rationale

Monolithic zirconia full-arch implant-supported prostheses have gained widespread clinical use due to their high mechanical strength, esthetic longevity, and lower chipping risk compared to veneered restorations. Despite increasing adoption, limited evidence exists regarding whether marginal bone remodeling differs between maxillary and mandibular zirconia rehabilitations and whether mandibular morphology or arch geometry influence early remodeling outcomes.

Mandibular deformation during function ("mandibular flexure") and anatomical variations such as U-shaped vs V-shaped mandibular arches may contribute to differences in bone response. This study evaluates early remodeling patterns under strictly standardized surgical and prosthetic conditions to determine whether mandibular anatomy plays a measurable role.

2. Study Objectives

Primary Objective

To compare 12-month marginal bone remodeling (MBL) between maxillary and mandibular full-arch monolithic zirconia implant-supported prostheses.

Secondary Objectives

- To evaluate whether mandibular morphology (U-shaped vs V-shaped) affects early marginal bone remodeling.
- To assess associations between arch geometry (inter-implant distance, cantilever length) and MBL.
- To evaluate 12-month implant and prosthetic survival rates.
- To assess patient-reported outcomes (OHIP-14 and VAS satisfaction).
- To document biological and mechanical complications.

3. Study Design

This is a prospective observational cohort study with a 12-month follow-up period.
All patients receive standard-of-care implant placement and monolithic zirconia full-arch prosthetic rehabilitation. No experimental intervention is assigned.

Study Groups

- **Group 1:** Maxillary full-arch rehabilitations
- **Group 2:** Mandibular full-arch rehabilitations
    - Sub-analysis: U-shaped vs V-shaped mandibles

Observation Period

Baseline (prosthesis delivery) → 12 months.

Sample Size

49 rehabilitated arches in 40 edentulous patients.
Power >85% to detect a 0.2 mm difference in MBL (SD 0.30 mm).

4. Study Population

Inclusion Criteria

- Age ≥ 50 years
- Edentulous maxilla and/or mandible
- Adequate bone volume for 6–8 implant placement
- Non-smokers or light smokers (<10 cigarettes/day)
- Able to provide informed consent

Exclusion Criteria

- Bruxism
- Bisphosphonate therapy
- Uncontrolled systemic diseases
- Contraindications to implant surgery
- Active oral infection or poor hygiene

5. Surgical and Prosthetic Procedures

- Guided placement of 6–8 NobelParallel TiUltra implants per arch.
- Immediate loading with a PMMA provisional prosthesis within 48 hours.
- Delivery of the definitive monolithic zirconia prosthesis at 3 months using a full digital workflow.
- Standardized radiographs and follow-up examinations.

6. Assessments

6.1 Radiographic Assessment

- Standardized periapical radiographs using paralleling technique and fixed exposure settings.
- Image calibration based on implant thread pitch.
- Two calibrated examiners (ICC=0.94) measure MBL; discrepancies >0.1 mm resolved by consensus.

6.2 Mandibular Morphology Classification

- CBCT-based classification using validated criteria (intercanine/intermolar ratio and anterior arch angle).
- U-shaped vs V-shaped categorization.

6.3 Geometric Measurements

- Inter-implant distance (distal implants).
- Cantilever length (distal extension).
  Measurements obtained from final CAD designs.

6.4 Clinical Outcomes

- Implant survival
- Prosthetic survival
- Mechanical complications (e.g., chipping, screw loosening, framework fracture)
- Biological complications

6.5 Patient-Reported Outcomes

- OHIP-14
- VAS satisfaction (0–10)

7. Outcome Measures

Primary Outcome

Marginal Bone Loss (mm)
Change in peri-implant marginal bone level measured from baseline to 12 months.
Higher values = greater bone loss (worse outcome).

Secondary Outcomes

1. **Implant and Prosthetic Survival Rate**
   Percentage surviving without removal or failure. Higher % = better outcome.

2. **Patient-Reported Outcomes**

- OHIP-14 (0–56; higher = worse)
- VAS satisfaction (0–10; higher = better)

3. **Mechanical and Biological Complications**
   Presence/absence and type of event.

8. Statistical Analysis Plan

- Normality: Shapiro–Wilk test
- Between-group comparisons: Two-way ANOVA
- Morphology subgroups: One-way ANOVA with Bonferroni
- Paired comparisons (bimaxillary patients): Paired t-test
- Correlations: Pearson (separately for each arch)
- Significance level: $\alpha = 0.05$

Secondary analyses are exploratory.

9. Ethical Considerations

- Approved by UIC Ethics Committee (REST-ECL-2020-02).
- Conducted in accordance with the Declaration of Helsinki.
- All participants provided informed consent.
- Data stored securely and pseudo-anonymized.

10. Data Management

- Coded, de-identified datasets stored on secure servers.
- Access limited to authorized researchers.
- Data retained for 15 years.

11. Study Timeline

- Start Date: December 2024

- Primary Completion Date: December 2025
- Study Completion Date: December 2025

12. Dissemination Plan

Results will be submitted for peer-reviewed publication and presented at scientific conferences. No identifying participant information will be released.