HMUD,2425177

Optimizing Alveolar Ridge Expansion:

A Clinical Comparison of Magneto-Dynamic Ridge Splitting and Versah Osseodensification Techniques

1st May 2025

1.Introduction

Adequate alveolar bone is primary requirement for successful dental implant therapy. However, many patients present with narrow alveolar ridges that necessitate surgical intervention (like bone augmentation procedures) to create sufficient horizontal bone width for implant placement. Conventional techniques such as the use of osteotomes and traditional drilling and tools often result in uncontrolled bone removal, thermal damage, and unpredictable fractures of bone, which can compromise implant stability and long-term success rate [1]. Consequently, minimally invasive approaches have been explored to overcome these limitations and enhance clinical outcomes.

One innovative method is magneto-dynamic ridge splitting using the Magnetic Mallet. This technique uses controlled electromagnetic impulses to achieve precise lateral expansion and alveolar bone compaction. Clinical reports and systematic reviews have demonstrated that the Magnetic Mallet can facilitate ridge splitting with minimal trauma, reduced marginal bone loss, and improved primary implant stability [1, 2, 3]. The impulse-driven mechanism not only preserves the cortical bone but also induces bone condensation, thereby creating an optimal environment for immediate placement of dental implants.

In parallel, the concept of osseodensification has emerged as a promising alternative for ridge expansion. Osseodensification utilizes specially designed drills such as Densah burs; that operate in an inoffensive, densifying mode. Rather than removing bone, this technique compacts and autografts the existing bone into the osteotomy walls, resulting in increased bone density and enhanced bone-to-implant contact. Studies have reported that osseodensification leads to significant improvements in insertion torque and implant primary stability, making it particularly beneficial in cases of poor bone quantity or quality [4, 5, 6].

Despite their individual merits, up to our knowledge there is no research directly comparing the magneto-dynamic ridge splitting technique with the Versah osseodensification protocol. This research proposal aims to fill that gap by conducting a prospective clinical trial that evaluates both techniques in terms of alveolar bone expansion, implant stability, and patient-centered outcomes. By rigorously comparing these two novel approaches, the study intends to determine which method offers superior bone preservation and clinical predictability,

ultimately guiding clinicians toward more effective and minimally invasive ridge expansion strategies.

2.Study Objectives

- **Primary Objective:**
  Compare the effectiveness of the magneto-dynamic ridge splitting technique versus Versah drills in preserving alveolar bone dimensions and achieving optimal primary implant stability.
- **Secondary Objectives:**
  - Assess changes in buccolingual ridge width using CBCT imaging at baseline, and at 4 months post-surgery.

3. Hypotheses

- **Null Hypothesis (H_o):**
  There is no significant difference in alveolar bone preservation or implant stability between the magneto-dynamic technique and the Versah osseodensification drills.
- **Alternative Hypothesis (H_1):**
  The magneto-dynamic ridge splitting technique will result in greater alveolar bone preservation, enhanced implant stability, and reduced patient morbidity compared to the Versah osseodensification protocol.

4. Materials and Methods

- **Study Design:**
  A prospective, single-center, randomized controlled clinical trial.
- **Participants:**
  A calculated sample of patients (n = X, based on power analysis) requiring ridge expansion for implant placement. Inclusion criteria will include patients with narrow alveolar ridges (e.g., 4–6 mm width) and adequate bone quality as assessed by CBCT. Exclusion criteria will include systemic conditions contraindicating oral implant surgery.
- 20 cases will be collected (40 implants) 20 dental implants for each group.

- **Interventions:**
    - **Group A:** Ridge splitting performed using the Magnetic Mallet with osteotomes to achieve controlled expamtion.
    - **Group B:** Ridge expansion using Versah drills in osseodensification.

- **Outcome Measures:**
    - **Primary Outcomes:**
        - Change in alveolar ridge dimensions (measured via CBCT) immediately post-surgery and at 4 months follow-up.
        - Implant Stability Quotient (ISQ) measurements taken at implant placement and during second stage surgery using **Osstell ISQ**.
    - **Secondary Outcomes:**
        - **Soft Tissue Analysis:**

          Utilize intraoral scans to assess soft tissue thickness and volumetric changes preoperatively and during follow-up. This will help us understand the impact of each technique on peri-implant soft tissue health and aesthetics.

- **Surgical Procedure:**

1. Preoperative CBCT imaging.

2. In Group A, perform ridge splitting using the Magnetic Mallet's calibrated impulses for controlled bone condensation (Meta Ergonomica, Turbigo, Milano, Italy).

3. In Group B, follow the Versah protocol to gradually expand the ridge using osseodensification drills (Densah™ burs), as outlined in the protocol (6) .

4. Implant placement will be performed immediately after ridge expansion, with standardized implant systems in both groups; ROOTT Implant System (TRATE AG, Swiss).

- **Data Collection:**
  -Clinical measurements

  -CBCT images,

  -ISQ values will be collected and recorded in a structured database. Ostell mentor device (Integration Diagnostics AB, Sävedalen, Sweden) uses RFA to measure implant mobility

and stiffness, yielding the results as implant stability quotients (ISQs), which range between 1 (lowest stability) and 100 (highest).[7]

-Utilize intraoral scans to assess soft tissue thickness and volumetric changes preoperatively and during follow-up using Medit i700 (Medit, South Korea, software version 1.12.0).

5. Statistical Analysis

- Data will be analyzed using paired t-tests or ANOVA for continuous variables (ridge dimensions and ISQ values).
- A p-value < 0.05 will be considered statistically significant.
- Sample size calculations will be based on expected differences in ridge expansion outcomes and implant stability derived from preliminary data and the literature.

6. Ethical Considerations

- The study will adhere to the principles of the Declaration of Helsinki.
- Ethical Approval will be obtained before commencing patient recruitment.
- Informed consent will be secured from all participants, clearly explaining the novel nature of the techniques and any associated risks.

7. Timeline and Budget

- **Timeline:**
    - Months 1: Ethical approval and research registration.
    - Months 2-7: Surgical procedures and immediate follow-up evaluations.
    - Months 8-10: Data collection and analysis.
    - Months 10-12: Manuscript preparation and submission to a high-impact journal.
- **Budget:**
    - Estimated costs include CBCT imaging, surgical instruments (Magnetic Mallet, Versah drills), implant components, data management, and personnel costs. Funding sources may include institutional grants or industry partnerships.

8. Expected Outcomes and Impact

- It is anticipated that the magneto-dynamic technique will demonstrate superior bone preservation and improved implant stability compared to the Versah drill method, potentially translating to reduced post-operative pain and faster healing.
- These findings could establish a new standard in ridge expansion procedures and contribute significantly to the implantology literature, making the study attractive for publication in a high-impact journal.

9. Conclusion

This research proposal outlines a study designed to directly compare two innovative ridge expansion techniques. The novel approach of using magneto-dynamic impulses for ridge splitting may offer significant advantages over traditional osseodensification drills. Successful outcomes could lead to improved clinical protocols, enhanced patient outcomes, and further innovation in minimally invasive implant surgery.

References

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Patient Informed Consent Form

Study Title: Optimizing Alveolar Ridge Expansion: A Clinical Comparison of Magneto Dynamic Ridge Splitting and Versah Osseodensification Techniques

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Purpose of the Study:

You are invited to participate in a clinical research study that aims to compare two surgical techniques for ridge expansion prior to dental implant placement. This research will help determine which method offers better results in terms of bone preservation and implant stability.

Procedures:

If you agree to participate, you will undergo one of two types of ridge expansion surgeries (either using the Magnetic Mallet or Versah drills) followed by implant placement. CBCT scans and intraoral scans will be taken before and after the procedure to assess the outcomes.

Potential Risks and Benefits:

As with any oral surgery, there may be minor discomfort, swelling, or bleeding. These techniques are minimally invasive and have shown good outcomes in previous studies. Your participation may benefit you by improving your oral health and contribute to advancing dental implant research.

Confidentiality:

All your information will be kept confidential. Only the study team will have access to your data.

Voluntary Participation:

Your participation is completely voluntary. You may withdraw from the study at any time without any penalty or effect on your treatment.

Consent Statement:

I have read and understood the information above. I consent to participate in this study.

Patient's Name: Signature: Date:

Investigator's Signature: Date: