**Research Protocol**

**Protocol Title:**

# Early Stability of Short Implants with Shallow Threads in the Posterior Mandible: A Controlled Clinical Pilot Study.

**Date: August - 19- 2025**


**Principal Investigator**

Mohammad Abdulwahab Abdullah Al-Jonaid

**Thesis Supervisor:**

Dr. Ali Hussain Al-Hudaied

(Associate Professor of Oral and Maxillofacial Surgery)

University of Science and Technology,

**Yemen.**

## 1. Background and Rationale

Patients with severely resorbed posterior mandibles face a significant challenge.While short implants (SHI, ≤8mm) offer a less invasive alternative to complex bone augmentation, they are associated with a higher risk of early failure, often linked to compromised stability during the critical healing phase known as the "stability dip." This dip, a period of osteoclast-mediated resorption, creates micromotion that can disrupt osseointegration. The role of implant macrodesign, specifically shallow threads, and bone density in modulating this early stability trajectory remains unclear. This study aims to prospectively compare the early stability dynamics of short (7mm) versus standard (11mm) shallow-threaded implants to provide evidence for their use as a viable graft-less solution.

## 2. Study Objectives and Hypotheses

**· Primary Objective:**

To compare the early stability dynamics (primary stability, stability dip, and onset of secondary stability) of 7 mm short implants (SHI) versus 11 mm standard implants (SDI), both with an identical shallow-threaded macrodesign, in the non-augmented posterior mandible over 4 weeks.

**· Secondary Objective:**

To assess the effect of bone density (D2 vs. D3) on these stability parameters.

**Hypotheses**:

· $H_o1$: No significant difference in primary stability (ITV, ISQ-T0) exists between SHI and SDI.

· $H_o2$: No significant relationship exists between baseline ISQ and the stability dip magnitude/duration for either implant type.

· $H_o3$: Bone density has no differential effect on stability parameters between SHI and SDI.

## 3. Study Design

A prospective, controlled, non-randomized clinical pilot study employing ≥ 80% split-mouth design where anatomically feasible. Implant allocation follows clinical necessity principles:

· Short Implant (SHI; 7 mm): Sites with 8–10 mm bone height above the inferior alveolar canal.

· Standard Implant (SDI; 11 mm): Sites with >10 mm bone height. Randomization is precluded on ethical grounds, as placing an SHI in a site suitable for an SDI violates the standard of care.

## 4. Participant Selection

**· Inclusion Criteria:**

· Aged 18–65 years.

· Posterior mandibular partial edentulism requiring implant placement.

· Native bone height of 8–13 mm above the inferior alveolar canal.

· Bone width ≥5.5 mm.

· Bone density classified as D2 (850–1250 HU) or D3 (350–850 HU) via pre-operative CBCT.

· Plaque Index ≤1.

· ASA physical status I or II.

· Provides written informed consent.

· **Exclusion Criteria:**

· Absolute surgical contraindications.

· Uncontrolled diabetes (HbA1c >7%) or immunosuppression.

· History of head/neck radiation or bisphosphonate therapy.

· Active periodontitis (PPD >5 mm) or bone pathology.

· Smoking >10 cigarettes/day.

· Parafunctional habits.

· Previous bone grafting at the intended implant site.

## 5. Sample Size

The sample will consist of Ten participants receiving 20 implants (10 SHI, 10 SDI). This is a pilot feasibility sample, determined by strict eligibility criteria and a post-hoc power analysis indicating 80% power to detect a clinically significant difference in ISQ dip (ΔISQ ≥5) with an alpha of 0.05.

## 6. Materials and Methods

**· Implant System:**

A tiologic TWINFIT implants (DENTAURUM GmbH). Both SHI (7mm) and SDI (11mm) share an identical design:

- 4.2mm diameter
- 5-degree taper
- Shallow threads (0.35-0.45mm),
- Sandblasted, acid-etched (SLA) surface.

**· Key Equipment:**

· CBCT Machine (Vatech EZ-3D) for pre-surgical planning and bone density assessment.

· Surgical motor (W&H Implantmed) with a 20:1 reduction handpiece.

· Calibrated torque wrench.

· Resonance Frequency Analysis (RFA) device (Penguin RFA) with type 4 SmartPegs.

**7. Study Procedures**

**· Pre-Operative Phase:**

1. Screening against inclusion/exclusion criteria.

2. Clinical examination and plaque index recording.

3. CBCT scan with Hounsfield Unit (HU) calibration using a hydroxyapatite phantom to determine bone density (D2/D3).

4. Obtaining written informed consent.

· **Surgical Protocol:**

1. Premedication: Ibuprofen 400 mg.

2. Asepsis with povidone-iodine (perioral) and chlorhexidine (intraoral).

3. Local anesthesia (2% lidocaine with 1:80,000 epinephrine).

4. Crestal incision and full-thickness flap elevation.

5. Osteotomy performed with an under-preparation protocol.

6. Implant placement with slow manual seating. Insertion Torque Value (ITV) is recorded during the final 90° rotation.

7. SmartPeg attachment and baseline Implant Stability Quotient (ISQ) measurement using RFA (T0).

8. Closure with sutures.

· **Post-Operative Care:**

· Analgesics (Diclofenac) and antibiotics (Amoxicillin/Clavulanate).

· Instructions for soft diet and chlorhexidine mouth rinses.

**· Follow-up and Stability Monitoring:**

· Participants will return for ISQ measurements at the end of weeks 1, 2, 3, and 4 (T1, T2, T3, T4).

· At each visit, quadruple RFA measurements (buccal, lingual, mesial, distal) will be taken, and the mean ISQ value calculated.

## 8. Outcome Measures

**· Primary Stability:**

· Insertion Torque Value (ITV) in Ncm.

· Baseline ISQ value (T0).

**· Stability Dip Characteristics:**

· Dip Magnitude (ΔISQ-min): Difference between ISQ at T0 and the lowest ISQ value (ISQ-min) recorded between T1-T4.

· Time of Dip (T-min): The week (T1-T4) at which the lowest ISQ value occurred.

· **Secondary Stability Onset**: The first timepoint where ISQ values consistently increase by ≥2 units from the ISQ-min.

· **Effect Modifier:** Bone density (D2 vs. D3) as a primary covariate.

**9. Data Management and Statistical Analysis**

· **Data Collection:**

De-identified data will be recorded on standardized Case Report Forms (CRFs) and stored in a password-protected electronic database (Excel).

· **Statistical Analysis:**

Will be performed using SPSS Statistics (v28). Analysis will include:

· Descriptive statistics for all variables.

· Paired t-tests (for bilateral cases) and independent samples t-tests (for full dataset) to compare primary stability ($H_o1$).

· Pearson/Spearman correlation to assess the relationship between baseline ISQ and dip magnitude ($H_o2$).

· Linear Mixed Models (LMM) to analyze longitudinal ISQ trajectories.

· Two-Way ANOVA to test the interaction effect of Implant Type and Bone Density on dip magnitude ($H_o3$).

· A p-value of <0.05 will be considered statistically significant, with Bonferroni correction for multiple comparisons.

## 10. Ethical Considerations

**· Approval:**

This study has been approved by the University of Science and Technology Institutional Review Board. (IRB Approval No: **1447/0062/UREC/UST**).

**· Informed Consent:**

Written informed consent will be obtained from all participants after a detailed explanation of the study procedures, potential risks, and benefits.

**· Confidentiality:**

All participant data will be de-identified and stored securely. Access will be limited to the research team.

**· Risk Management:**

The study follows the ALARA principle for radiation. All surgical procedures will adhere to standard clinical protocols to minimize risks. An adverse event reporting plan is in place.

**11. Dissemination Plan**

The results of this study will be presented in the candidate's Master's thesis and submitted for publication in a peer-reviewed international journal in the field of oral implantology.Findings may also be presented at relevant scientific conferences.

**INFORMED CONSENT FORM**

**”Early Stability of Shallow-Threaded Short vs. Standard Implants in Posterior Mandible: A Controlled Pilot Trial”**

**Principal Investigator: Mohammad Abdulwahab Al-Jonaid**

**University of Science and Technology, Sana’a, Yemen**

**Supervisor: Dr. Ali Al-Hudaied**

## 1. Study Purpose

You are invited to participate in a research study comparing two dental implant designs. The goal is to evaluate early stability patterns of short (7mm) versus standard (11mm) implants with shallow threads in the lower jaw.

## 2. Procedures

If you agree, you will:

- Undergo a dental exam and 3D scan (CBCT).

- Receive implant (length determined by your bone anatomy).

- Attend 5 visits over 4 weeks for stability measurements (painless RFA tests).

- Follow post-operative care instructions.

## 3. Risks and Discomforts

Potential risks include:

- Mild pain/swelling after surgery (managed with medication).

- Rare: Infection, nerve injury, or implant failure (<5% based on literature).

## 4. Benefits

- Free implant/implants placement and follow-up care.

- Contribution to scientific knowledge about minimally invasive implant options.

## 5. Confidentiality

Your data will be:

- Stored under a code (no names).

- Accessible only to the research team.

- Published only in aggregated form.

**6. Voluntary Participation**

You may:

- Withdraw anytime without penalty.

- Ask questions before/during the study.

- Receive alternative treatments if you decline.

**7. Costs & Compensation**

- No cost for study procedures.

- Compensation for travel expenses (if applicable).

**8. Contact Information**

For questions, contact:

**- Researcher: Mohammad Abdulwahab Al-Jonaid [711726732/ mohjon6@gmail.com]**

**- Supervisor: Dr. Ali Al-Hudaied**

**(@gmail.com)**

**- Ethics Committee: [UST]**

**Participant's Declaration**

**I confirm that:**

- I have read this form (or it was read to me).

- I understand the purpose, procedures, and risks.

- I voluntarily agree to participate.

- I will receive a copy of this form.

**Participant's Name:** _____

**Signature**: _____ **Date**: ___/___/___

**Investigator's Name**: _____

**Signature**: _____ **Date**: ___/___/___

Republic Of Yemen
UNIVERSITY OF SCIENCE & TECHNOLOGY
Faculty of Medicine & Health Sciences
Research Ethics Committee

الجمهورية اليمنية
جامعة العلوم والتكنولوجيا
كلية الطب والعلوم الصحية
لجنة أخلاقيات البحث العلمي

# Research Ethics Committee approval form
# استمارة للحصول على موافقة لجنة أخلاقيات البحث العلمي

## University Research Ethics Committee Decision

In accordance with the Research Ethics Committee (UREC) practice at the University of Science and Technology (UST), and the Declaration of Helsinki and World Health Organization guidelines, the UREC reviewed the research proposal submitted and found that it has fulfilled guarantees and safeguards for research ethics and it complies with the policy of the committee.

The required documents have been submitted according to the committee guidelines.

العنوان الكامل للدراسة باللغة العربية:
الاستقرار المبكر لغرسات الأسنان القصيرة ذات الشغرات الضحلة في الفك السفلي الجهة الخلفية: دراسة سريرية تجريبية محكمة

**Title of study:**
Early Stability of Short Dental Implants with Shallow Threads in The Posterior Mandible: A Controlled Clinical Pilot Study

**Investigator(s):**
Mohammad Abdulwahab Al-Jonaid

**Decision:** Accepted

**Study ID:** 1447/0062/UREC/UST

**Date**: 19-8-2025

**UREC Chairperson**

**Dr. Essam Al-Safadi**

**UREC- stamp**