Comparative Assessment of Primary Implant Stability by Osseodensification Using Densah Burs vs Conventional Drilling Methods.

A Thesis Protocol

Submitted for partial fulfillment of the requirements of the

Master Degree in dental science

In

Oral and Maxillofacial Surgery

Research code:**HE 11**

Submitted By

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Faculty of Dentistry

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Thesis Research Protocol”

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Degree: ☒ **M.D.Sc.** ☐ **D.D.Sc** ☐ **PH.D.**

Department: Oral and maxillofacial surgery

Thesis Title in English: Comparative Assessment of Primary Implant Stability by Osseodensification Using Densah Burs vs Conventional Drilling Methods.

1. Abstract

Introduction: Conventional drilling removes bone, which may reduce stability. Osseodensification, using Densah burs, preserves and compacts bone, improving primary stability without the need for bone grafting—especially useful in areas with low bone density. **Aim :**to assess the mechanical advantages offered by osseodensification in terms of initial implant fixation, as well as its potential to enhance bone density around the implant site. **Methodology:** Study Design :Twenty implants will be placed and divided into two groups .Group 1: 10 implants placed using osseodensification technique with Densah burs .Group 2: 10 implants placed using conventional drilling technique .Primary Stability Measurement :Primary stability of each implant will be measured using the OSTELL device to record the implant stability.

2. Introduction and Background

Dental implantology has become a cornerstone in modern restorative dentistry, providing effective solutions for patients with missing teeth. Over recent decades, significant technological advancements have been made in implant design, surface treatments, and surgical protocols, all contributing to improved success rates and patient satisfaction **(Albrektsson et al., 1986; Javed & Romanos, 2022)**. Despite these advancements, achieving optimal primary stability remains a critical determinant for the success of dental implants, especially in cases involving compromised bone quality or density**.**

Primary stability refers to the mechanical engagement between the implant and surrounding bone at the time of placement. It is vital for ensuring proper osseointegration, preventing micro-movements that can lead to implant failure **(Rossi et al., 2023)**. Bone density is among the most important factors affecting primary stability; low-density bone, commonly found in the posterior maxilla and atrophic jaws, poses challenges due to its softer structure and reduced ability to anchor the implant firmly **(Javed & Romanos, 2022).**

Traditional drilling techniques create an osteotomy by cutting and removing bone to fit the implant. While effective, this subtractive approach may compromise the bone's natural architecture, reduce bone volume, and decrease initial implant stability. Additionally, in regions with poor bone quality, adjunctive procedures such as bone grafting or sinus augmentation are often necessary, increasing treatment complexity, duration, and patient morbidity **(Almutairi et al., 2022**).

To address these challenges, osseodensification was introduced as a novel surgical technique. Unlike conventional drilling, osseodensification uses specially designed Densah burs that rotate counterclockwise at high speed to compact and preserve bone during osteotomy preparation **(Huwais & Meyer, 2017)**. This method conserves bone volume, increases bone density around the implant site, and enhances primary stability without the need for additional grafting procedures.

Several studies have reported promising outcomes for osseodensification. Clinical and preclinical research shows increased insertion torque values, improved implant stability quotient (ISQ), and better preservation of marginal bone levels **(Khairnar et al., 2024; Saleh et al., 2024)**. These benefits may translate into higher success rates, faster healing times, and reduced patient discomfort. Moreover, osseodensification may allow immediate or early loading protocols even in low-density bone scenarios, which can significantly improve patient outcomes and satisfaction.

However, despite the growing body of evidence, there remains a lack of robust clinical trials comparing osseodensification directly to conventional drilling techniques across different bone qualities and patient populations. Most available studies focus on biomechanical aspects or animal models, limiting the applicability of their findings to routine clinical practice. Furthermore, long-term follow-up data assessing implant survival and bone remodeling patterns after osseodensification are scarce **(Rossi et al., 2023; Saleh et al., 2024)**.

This study aims to fill this gap by conducting a controlled clinical trial to compare the primary stability and early radiographic outcomes of implants placed using osseodensification versus conventional drilling. By providing direct clinical evidence, the research hopes to offer valuable insights into the potential mechanical and biological advantages of osseodensification, guiding clinicians toward evidence-based implant placement protocols that optimize success in patients with varying bone conditions.

Despite the promising results of osseodensification in improving primary stability, there is still a knowledge gap regarding how it compares to conventional drilling techniques in clinical practice. Specifically, the long-term outcomes, effectiveness, and benefits of osseodensification, compared to traditional methods, remain unclear. This research seeks to fill this gap by directly comparing the primary stability of implants placed using osseodensification with those placed using conventional drilling methods.

3. Research Question (RQ):

What is the effect of using densah bur on the primary stability compared to conventional drilling methods ?

4. Research Hypothesis, Aim, Objectives & Expected Outcomesss

a. Hypothesis

Null Hypothesis (H0) :
There is no significant difference in primary implant stability between implants placed using osseodensification with Densah burs and those placed using conventional drilling techniques.

Alternative Hypothesis (H1) :
There is significant difference in primary implant stability between implants placed using osseodensification with Densah burs and those placed using conventional drilling techniques.

b. Aim

to assess the mechanical advantages and the potential of enhancment bone density around the implant site upon osseodensification using Desah burs.

c. Objectives

Clinical parameters :

-measure and compare the implant stability in implants placed by osseodensification and conventional drilling using the OSTELL device .

-monitor postoperative pain by VAS through visual inspection and palpation .

-monitor postoperative edema by assess edema rating postoperatively.

-inflammation assessment score clinically at the implant site.

Radiographic parameters :

-measure and compare changes in bone density around the implant sites using digital periapical radiographs Radiographic Assessment Using CliniView and ImageJ Software .

- measure any peri-implant radiolucency or signs of bone loss associated with each drilling technique by using digital periapical radiographs.

d. Expected Outcomes

Osseodensification using Densah burs may provide superior primary stability and better osseointegration outcomes compared to conventional drilling techniques.

5. Research Design and Methods

I. Material, Subjects, and Methods

I-Materials:

Item	Composition	Trade name
Surgical Lancet No.15	Carbon steel	Newdolhi ,India
Local anesthesia	Articaine with epinephrine (1:100,000)	Alexandercaine, Alexandria governorate, Egypt

Dental implants	Titanium	SGS , Turkey
Densah Burs Kit	Titanium	

II-Methods:

a) The Study and its Design:

Randomized controlled clinical study, randomization will be done using www.randomizer.org.

This study will follow a comparative clinical design to evaluate the primary stability and osseointegration of dental implants placed using osseodensification with Densah burs versus conventional drilling techniques. The primary focus will be on comparing the effectiveness of osseodensification in enhancing implant primary stability.

b) Study Setting:

This study will be carried out on patients selected from those who were referred to the department of oral and maxillofacial surgery Faculty of Dentistry, Suez Canal University.

c) Study Population and Sample:

Study Population: The population will consist of patients who require dental implants as assessed via pre-operative radiographic analysis.

- Inclusion Criteria:(Misch CE; 2020)

- Both gender
- Patients aged 18-65 years.
- Patients requiring dental implants in areas with varying bone quality.
- No systemic diseases that interfere with bone healing or implant success (e.g., uncontrolled diabetes or osteoporosis).

- Exclusion Criteria: (Lin et al., 2019, Mandelli et al., 2019)

- Patient with systemic disease affection bone metabolism
- Large periapical radiographic changes related to the tooth to be Extracted, in the form of abscess, granuloma, or cyst.
- Teeth need trans-alveolar extraction.
- Patients with contraindication to surgical treatment.
- Patients suffering from a psychological disorder.
- Patients with uncontrolled medical conditions

d) Surgical procedures:

All procedures will be conducted in a clinical setting under strict aseptic conditions , Patients will be assigned to two groups (10 implants each)**:**

Group 1 (Osseodensification Group)**:**

Osteotomies will be prepared using Densah burs in a counterclockwise direction with saline irrigation**.**

Group 2 (Conventional Drilling Group)**:**

Standard sequential drilling will be performed using conventional burs in a clockwise direction**.**

1. Preoperative Preparation**:**

   Patients will rinse with 0.12% chlorhexidine for 1 minute**.**

   Local anesthesia (articaine 4% with epinephrine 1:100,000) will be administered**.**

   A mid-crestal incision will be made to expose the alveolar ridge**.**

2. Implant Insertion:

   • The titanium dental implant will be inserted into the prepared site using either a hand ratchet or implant motor at controlled torque (typically 30–45 Ncm).

   • Primary stability will be assessed using resonance frequency analysis (e.g., OSSTELL ISQ).

   • A healing abutment or cover screw will be placed depending on whether a one-stage or two-stage protocol is selected.

   • Flap will be repositioned and sutured using 4-0 or 5-0 non-

resorbable or resorbable sutures using interrupted or horizontal mattress technique.

3. Postoperative Instructions and Medications:
   - The patient will be instructed to maintain strict oral hygiene and avoid brushing near the surgical site for 7 days.
   - Chlorhexidine mouth rinse 0.12% twice daily for 10 days will be prescribed.
   - Analgesics (e.g., ibuprofen 600 mg every 8 hours as needed) and antibiotics (e.g., amoxicillin/clavulanic acid 1 g twice daily for 5 days) will be administered.
4. Follow-up:
   - Sutures will be removed after 7–10 days in the two-stage protocol.
   - Healing will be monitored clinically and radiographically.
   - Osseointegration will be reassessed after 3 months, and if satisfactory, prosthetic loading will be initiated.

5. : Patient follow-up and recall:

Post-operative medication and instruction:

Medications prescribed will be: Antibiotic, Anti-inflammatory and Analgesics for pain relief. Instructions will be told and written for the patient as present in the logbook of the Oral and Maxillofacial department, Suez Canal University.

Follow-up intervals for clinical outcomes:

Immediate post-operative to assess implant stability

3Months - 6 Months, to assess the following clinical parameters:

F1- Postoperative pain :(Misch CE; 2020)

This will be assessed using a 10-point Visual Analogue Scale (VAS) in the 1st week postoperatively. (0-1= None, 2-4=Mild-Moderate, 8-10= Severe)

F2- Postoperative edema :(Misch CE; 2020)

Swelling rating assessed one week post-operative as follows:

1 =none (no visible swelling), 2 = mild (intraoral swelling in the surgical zone), 3 = moderate (extraoral swelling in the surgical zone), and 4 = severe (extraoral swelling extending beyond the surgical zone and visible hematoma and ecchymosis)

- 1 = None (no visible swelling)

- 2 = Mild (intraoral swelling in the surgical zone)

- 3 = Moderate (extraoral swelling in the surgical zone)

- 4 = Severe (extraoral swelling extending beyond the surgical zone with visible hematoma and ecchymosis).

F3-Inflammation Assessment Score: **(Misch CE; 2020)**

Inflammation at the implant site will be scored clinically as follows:

- Score 0: No redness, swelling, or bleeding

- Score 1: Mild redness and slight swelling, no bleeding

- Score 2: Moderate redness, swelling, and bleeding on probing

- Score 3: Severe inflammation with spontaneous bleeding and/or suppuration

F4- Implant stability (Meredith, 1998; Ostman et al., 2006).

Implant stability will be measured by Osstell device.

a- immediately following implant placement

b- 3 months - 6 months postoperatively

The radiographic evaluation:

Radiographic Assessment Using CliniView and ImageJ Software (Mangano, C., et al. (2016)

Digital periapical radiographs will be taken at baseline and at the 3-month follow-up using the paralleling technique to ensure image standardization.

Radiographs will first be viewed using CliniView software for basic enhancement and verification of image quality.

To assess peri-implant bone density, radiographs will be exported in TIFF format and analyzed using ImageJ software (NIH, USA). The following steps will be performed:

-Calibration of the image using a known reference (e.g., implant length in mm).
-A region of interest (ROI) will be selected around the implant site (mesial and distal).
-The mean gray value within the ROI will be recorded, representing the bone density in that area.
-Measurements will be repeated by two independent examiners to ensure accuracy and consistency.

Changes in gray value readings over time will be used to evaluate the effect of osseodensification vs. conventional drilling on bone density around the implant site.

6. Statistical plan

a- Sample size calculation

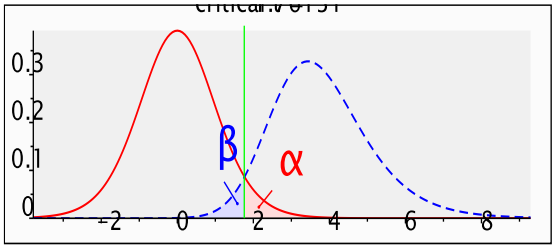
Sample size calculation was performed using G*Power version 3.1.9.2

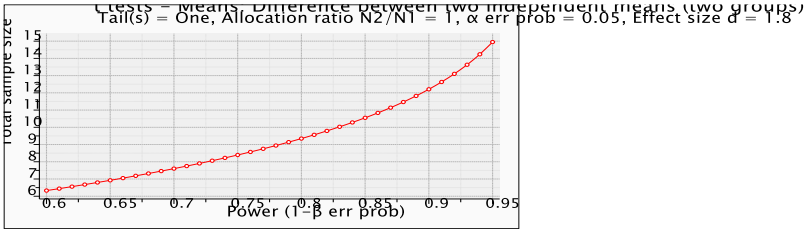
Faul *et al,* (2007).

The effect size conventions (d) were **1.80** (large) based on previous studies (Kar **et al., 2020**) using alpha (α) level of 0.05 and Beta (β) level

of 0.05, i.e., power = 80%; the estimated sample size (n) as a minimum should be **20 samples** (dental implants) and will be divided equally 10 patients in each group:

Groups	Descriptive	No.of samples
Group 1		**10**
Group 2		**10**
Total sample size		**20**





Fig, power for sample size distribution

b-Statistical analysis:

All collected data will be calculated, tabulated, and statistically analyzed using suitable statistical tests as follows.

a. **A normality test** will be done to check normal distribution for data by Shapiro-Wilk test.
b. **Descriptive statistics** will be calculated in the form of Mean ± Standard deviation (SD), range (Max- Min). Qualitative data will be presented as frequencies (n) and percentages (%).
c. **T- test or Mann-Whitney test (*According to the types of data*)**
   Independent Student's T-test or Mann-Whitney will be performed for the mean differences between the two groups for normally distributed and not normally distributed respectively.
d. Chi square will be used for qualitative data analysis.
e. Statistical analysis will be performed using the computer program SPSS software for windows version 26.0 (Statistical Package for Social Science, Armonk, NY: IBM Corp)
f. $P<0.05$ is considered significant.

7. Ethics consideration:

The present research will be conducted after the approval of the Research Ethics Committee (REC) of the Faculty of Dentistry, Suez Canal University. It will be conducted on 20 patients who meet the inclusion criteria specified in the study. Ethical considerations regarding patient well-being, safety, and confidentiality will be undertaken by the researcher. An informed written consent will be signed by all subjects/patients before commencing the study. The consent will explain the clinical examinations, procedures, potential risks, benefits, and the follow-up required for participation in the study.

8. Time Plan

Include Grant Chart as following example:

Starting: After approval of ethical committee and faculty council

Ending: after 12 months

Activity/Month	1	2	3	4	5	6	7	8	9	10	11	12
Patient selection/Surgery	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐
Collecting data and Statistical Analysis	☐	☐	☐	☒	☒	☒	☒	☒	☒	☐	☐	☐
Writing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒

9.Research Estimated Budget in Egyptian Pound

Supplementary				Publications	**Total**
1	Implant	Radiographic Examination	Others		
2	Implants and surgical additive materials	Preoperative CBCT and, Postoperative periapical digital X-Ray	Local anesthesia, Saline		
total	40000	6000	2000	2000	50000

Sponsored by the researcher himself

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1) **11. Appendices** (Consent form)

Suez Canal University

Faculty of Dentistry

Research Ethics Committee (REC)

Investigator Application Form

1- Name of researcher: Mohamed Ahmed Abdalmawgoud Abdallah

2- Name of Department: Oral and Maxillofacial Surgery

3- Adress of researcher:

Menia-ElQamh-Sharkia,Egypt

a- Email: mohamedgoda1050@gmail.com
b- Phone number +201100100349
c- Fax number: none

4- Name (s) of Co-investigator (s):

Prof. Dr, Mohamed Ahmed Elsholkamy
Dr. Mohamed Nageh Gad El Hak

5- Grade of protocol:

*M.D.Sc. (√) *Ph.D. () *Doctorate degree (D.D.Sc.) ( ) *Other( )

*Domestic ( ) *Multi-Centre within Egypt( ) *International( )

6- Title of the research: Comparative Assessment of Primary Implant Stability by Osseodensification Using Densah Burs vs Conventional Drilling Methods.

7-Type of the research:

*Drug trial ( ) *Surgical technique (√) *Investigative technique ( )

*Devise study ( ) *Survey study ( )*Blood sampling ( )

*Review of old records ( )

8-Subjects of research:

* Children (< 18 years): ( ) *Adults (>18 years) (√)

* Vulnerable groups (no)

9- Request is being made to waive (give-up) informed consent:Yes: ()No:(√)

10- The research is for the good of society: Yes: (√) No: ( )

11-Study design:

a-Phase type I: ( ) II: ( ) III: ( )

b-Randomization: Yes: (√) No: ( )

c-Placebo: Yes: ( ) No: (√)

d-Genetic sampling: Yes: ( ) No: (√)

e-Other: Yes: ( ) No: (√)

12-Facilities for the research are available: Yes: (√) No: ( )

13- List the risks of the study:

Postoperative edema, Postoperative infection, Failure of implant.

14- Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained? Yes: (√) No: ( )

15- Privacy and confidentiality of subjects are assured Yes: (√) No: ( )

16- The subject of the research could quit at any time without penalty or loss of any benefits to which they would otherwise be entitled Yes: (√) No: ( )

Signature of the principal investigator: Date: