Graftless Closed Sinus Tenting Using Dental Implants After Densah Burs Osteotomy Versus Conventional Osteotomy in Localized Sinus Pneumatization: a Randomized Clinical Trial

Thesis Protocol Submitted for Partial Fulfillment of the Requirements for Master's Degree In Oral & Maxillofacial Surgery
Faculty of Oral & Dental Medicine - Cairo University

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Supervisors' signature	Head of department's signature
1-Prof. Dr. Sameh Tarek	
2-Dr. Mohammed Omara	

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Evidence based committee (Reviewers)

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Research plan committee

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I. Administrative information:

1. Title:

Assessment of bone gain after closed sinus lifting using densa bur versus conventional technique in isolated sinus pneumatization: a

randomized clinical trial.

2. Protocol Registration:

This study will be registered at Clinicaltrials.gov by ID number NCT…….

3. Protocol version:

2019, Version: 1

4. Funding:

The trial is totally self-funded whether on a financial or a non-financial basis. Equipment units and some consumables are provided by Department of Oral and Maxillofacial surgery, Faculty of Dentistry Cairo University.

5. Roles and responsibilities:

1. Prof. Dr. Sameh Tarek

- Professor of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University.
- Main Supervisor.
- Responsible for auditing and main surgical supervision.

2. Dr. Mohammed Omara

- Lecturer of Oral and Maxillofacial Surgery- Cairo University.
- Assistant supervisor
- Responsible for randomization, allocation, outcome assessment, and supervising all surgical procedures.

3. Basma Mohammed Shaheen

- Researcher
- Responsible for recruitment and taking participant's consent, baseline data and outcome data collection, and performing clinical part of the trial.
- Thesis writing and final report of the research

Responsibilities:

Investigator: conducts the research and the operations needed.

Main supervisor: supervises the whole process of the research.

Assistant Supervisor: monitors the research progress (in details) and supervises the operations on patients.

II. Introduction:

Research question:

Will the use of densa bur lead to better bone gain around implant than conventional closed sinus lift in isolated pneumatized sinus?

Statement of the problem:

Isolated sinus pneumatization after single tooth extraction indicate sinus lifting for proper implant placement so the conventional way of using osteotomes to elevate the sinus is annoying to patient and also doesn't give the needed amount of bone around the implant.

Introducing new intervention of densa bur (reverse condensing oseodensification)helps increase bone gain around implant and decrease the patient discomfort

Rationale for conducting the research:

The formed bone around implant after using oseodensifying burs compared to control group of conventional osteotomes

Review of literature:

The rehabilitation of the edentulous posterior maxilla using osseointegrated implants is often challenging due alveolar bone resorption, low bone density and maxillary sinus pneumatization. Maxillary sinus lift is one of the most common surgical techniques used for increasing the available bone volume to place implants and restore function and esthetics transcrestal approach can be successfully adopted when residual bone height is at least 5 mm. Osteotome sinus floor elevation was 1st introduced by Summers (5,6)1994, and proved to be less invasive, more conservative, less time consuming, and reduces postoperative discomfort to the patient. Moreover, this technique was found to yield predictable results, with success rates of at least 95%.

Osseo densification is a new surgical technique of biomechanical bone preparation performed for dental implant placement where bone is compacted and auto grafted into open marrow spaces and osteotomy site walls in outwardly expanding directions. It was reported that Osseo densification increases the bone-implant contact, bone density, and primary stability. Moreover, The insertion torque peak is directly related to implant primary stability and host bone density. Furthermore, Ottoni et al. showed a reduction in failure rate of 20% in single-tooth implant restoration for every 9.8 N cm of torque increased.

The objective of this study was to evaluate crestal sinus elevation using oseodensification versus osteotomy clinically and radiographically in terms of marginal bone loss, primary and secondary stability and bone gain around the implant.

Explanation for choice of comparators:

The main disadvantage of use of osteotomes is patient discomfort and affected primary stability and bone gain in comparison to oseodensifycation.

7. Objectives:

The aim of study to compare the quantity of bone gained in use of densa bur (oseodensification) versus conventional closed sinus lift used as control group

Hypothesis:

Null hypothesis: this study is alternative hypothesis research based on that one technique will be more efficient and effective than the other. In our case, the bone gained after use of densa bur will be more and better quality than amount gained after use of osteotomes and this technique will be compared to the control group

Primary objective:

Evaluating amount of bone gain in both techniques

PICO

(P): isolated sinus pneumatization in extracted upper Molar (missing tooth sinus pneumatization)
I: densa bur in closed sinus lift (reverse cutting condensing bur)
C:conventional closed sinus lift (osteotomes in closed lifting)
O1: bone gain (increase bone volume) (apical bone fill) by x-ray subtraction
O2: primary stability (mechanical oseintegration) by ostell

8. Trial design:

- Randomized Controlled clinical trial.
- Parallel group study.
- Allocation Ratio 1: 1.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

Study is to be conducted in the Oral and Maxillofacial Department, Faculty of Dentistry, Cairo University.

10. Eligibility criteria:

Inclusion criteria:

No inflamed sinus

Min height 5-6 mm

Medical free

Patients who have given their consent for this trial.

Both genders males and females will be included.

Exclusion criteria:

- **Remaining ridges<5mm**

• Patients should not have taken drugs, especially bisphosphonates or drugs altering bone metabolism, within 2 months before the inclusion in the study.

- Subjected to irradiation in the head and neck area less than 1 year before implantation.

• Patients having history of allergy to any drugs.

• Patients who have a history of any concomitant major known medical problem and/or ongoing pharmacologic treatments

- Untreated periodontitis.
- Poor oral hygiene and motivation.
- Uncontrolled diabetes.
- Pregnant or nursing.
- Substance abuse.
- Psychiatric problems or unrealistic expectations.
- Severe bruxism or clenching.
- Immunosuppressed or immunocompromised.
- Treated or under treatment with intravenous amino-bisphosphonates.
- Active infection or severe inflammation in the area intended for implant placement.
- Unable to open mouth sufficiently to accommodate the surgical tooling.

- Patients participating in other studies, if the present protocol could not be properly followed.
- Referred only for implant placement or unable to attend a 5-year follow-up.

11. Interventions

All patients involved in this study will be divided in to two different groups, one group will receive densa bur sinus elevation and the second group is the control conventional sinus elevation

Clinical evaluation:

A through medical and dental history followed by clinical examination was carried out for all patients. Clinical measurements were taken to ensure patient adherence to our initial inclusion criteria prior to further investigations.

A pre-operative digital panoramic image and CBCT will be done to evaluate the height and the width of the intended sinus elevation

Intra operative procedures for both groups:

This clinical report describes two different groups Following the protocol of The Oxford Dental College Hospital, Bomannahalli.

In all groups :

Infiltration anesthesia or nerve block according the socket were administered using mepivacaine HCl (2%) with levonordefrin 1:20 000 (Scandonest 2%; Septodont, Saint- Maur-des-Fossés, France). Injection to control pain and bleeding for hemostasis. Scrubbing and draping of the patient was carried out in a standard fashion using betadine, traumatic extraction will then be done.

- **In first group: use of densa bur for closed sinus lift (oseodensification) and auto grafting**
- **in second groups : use of osteotomes in closed sinus lifting**
- **After 3 then 6 months post-operative CT scans will be done to evaluate the bone density, apical bone gain will be measured**

• in both group:

Follow up

Patients will be evaluated for primary stability at same day of operation and then radiographically after 3 then 6 months and weekly for first month for healing .

.

12. Outcomes:

TYPES OF OUTCOME	OUT COME	MEASURE DEVICE	MEASURE UNIT
PRIMARY 1RY	Bone gain	Cbct	Radiographic subtraction
2ry outcome	Primary stability	ostell	N cm torque

13.Participant timeline			Study period	
	Enrollment (T0)	Allocation	Intervention	Follow up
Study steps			Operation day	3 months after operation day (T1)
Enrollment: Eligability. screening Informed consent		- - -	----	
Pre-operative documentation	✓			
Allocation	- ---	✓	-----	
Generation sequence	✓	-------	----- -------	

Surgical exposure of the operated site	------	------	✓	
Intervention			✓	
Comparator	------	-------	✓	
Post-operative documentation				✓
Follow up for post-operative complications				✓

14. Sample size:

15. Recruitment:

- Patients' data will be enrolled in database of the Outpatient clinics of the Department of Oral & maxillofacial surgery, Faculty of Dentistry, Cairo University
- If there is a potential eligibility, the patient will be examined thoroughly as described before.
- Consecutive sampling is done through screening of patients. This will continue until the target population is achieved.
- Identifying and recruiting potential subjects is achieved through patient database

B) Assignment of interventions

16. Allocation:

16a. Randomization:

Dr. M.O. will carry out the randomization process using a software www.rand.org with a ratio of 1:1.

16b. Allocation concealment mechanism:

14 Cards will have sequential numbers one number for each card then these cards will be placed within opaque sealed envelopes. Then these envelops will be placed in a container (box), each participant will grasp one envelop the day of procedure. This step will be done by **Dr. M.O**.

16c. Implementation

Dr**. M.O.** is the person who will enroll the participants and assign the participants for intervention

17. Masking/blinding:

This trial is considered a randomized double blind clinical trial due to the following:

1. The participant will be blinded to the technique that will be used during the surgical operation.

2. The outcome assessor will be blinded

3. The operator (**DR.B.S.)** will not be blinded for both techniques during the surgical operation, as the two techniques are different. (**Dr. M.O.**).

The purpose of double blinding procedure is to reduce assessment bias and to increase accuracy and objectivity of clinical outcomes.

C) Data collection, management, and analysis:

18. Data collection methods

- **Primary Outcome:**
- The researcher (**DR.B.S)** and (**Dr. M.O.**) assistant supervisor. Will do the radiographic analysis.

Plans to promote participant retention and complete follow- up:

- **Participant Retention:**

A periodic regular follow up recalls will be planned every month for 3 months.

- **Participant Withdrawal*:***

The patient is allowed to drop at any time from the study Participant withdrawal will be recorded and the patient will be excluded from the study.
A percentage in the sample size is calculated to make up for any losses.
The investigator also may withdraw participants from the study under strict certain conditions and only if the proposed therapy were considered harmful to the patient.

19. Data management:

- Data forms and data entry

All these procedures will be done by **Prof.Dr. S.T.:**

- All data will be entered electronically.
- Patient files are to be stored in numerical order and stored in secure and accessible place.
- All data will be maintained in storage for 1 year after completion of the study.
- The electronic data and the scans of the patient will be backed up on a Drop box file for ensuring back up and ease of accessibility.

- Data Transmission and editing

The assessor data entry will be transmitted from the assessors to database officer in the blind separate datasheets who in return record them in participant chart before sending them to the statistician.

-Security and Back-up of data

All forms of the procedures related to study data will be kept in the project secure folder. Access to the study data will be restricted only to database officer. A complete back up of the primary database will be performed twice a month. Back-ups of periodic data analysis file will be kept.

20. Statistical methods:

Statistical analysis will be done later after approval of the board of Oral & Maxillofacial Surgery Department, Faculty of Dentistry – Cairo University.

D) Data monitoring:

21. Monitoring

The main supervisor Prof.Dr.S.M. Will be responsible for data monitoring. He will evaluate the outcome measures and any possible side effects that might affect the outcome.

22. Harms

Harm			
Intra-operative complications		Post-operative complications	
Harms	Avoidance&treatment	Harms	Avoidance&treatment
Bleeding	Care during implant placement	Infection	Antibiotic (Unasyn 1.5gm 1*2*7) (Flagyl 500mg vial 1*3*7) proper wound hygiene measures

23. Audit

Auditing of the study design will be done by Dr. **M.O.** the assistant supervisor

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IV. Ethics and dissemination

24. Research ethics approval

This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research - Faculty of Dentistry – Cairo University

25. Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Council of oral and maxillofacial surgery department.

26. Informed consent

Researcher **B.S** .will introduce and discuss the trial to patients who will be shown a video regarding the main aspects of the trial. Patients will then be able to have an informed discussion with the participating consultant. Researcher will obtain written consent from patients willing to participate in the trial. All consent forms will be translated into Arabic.

27. Confidentiality

- All study-related information such as photos, CBCT images, forms, charts will be stored in a password protected folder on the department database.
- The password will be available to the study team.
- But any personal information related to the patient's ID will be stored in and will acquire a coded ID with access only to the database officer.

28. Declaration of interest

The study is self-funded and there is no conflict of interest to declare.

29. Access to data

All the research team will have access to the data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information and the participant will be only identified by patient number.

30. Post-trial care

All patients will have the primary research contact number in case there is any emergency.

Follow up will continue until all patients are satisfied.

31. Dissemination policy

Study results will be published as partial fulfillment of the requirements for master's degree in Oral and maxillofacial surgery.

Topics suggested for presentation or publication will be circulated to the authors.

V. Appendices

32. Informed consent

Diagnostic chart

Patient No. ……..

Name: _____

Age: ____ Sex:

Weight:

Occupation:

Address:

Contact No.:

Medical history

……

……..

History of facial trauma with fractures of facial bones.

History of surgical operation in nasal region.

Facial asymmetry.

Clefts (lip and palate)

Any accompanying craniofacial syndromes.

Any diseases that compromise bone or soft tissue healing.

Medically compromised not fit for general anesthesia.

Dental history

……

Previous restorations

Previous extraction

Previous orthodontic treatment

Anterior open bite

Dental IQ

Motivation for treatment _____

Examining doctor

VI. References

1. CLINICAL AND RADIOGRAPHIC EVALUATION OF OSSEODENSIFICATION VERSUS OSTEOTOME FOR SINUS FLOOR ELEVATION IN PARTIALLY ATROPHIC MAXILLA: A PROSPECTIVE LONG TERM STUDY Shereen W Arafat* and Mohamed A Elbaz** https://edj.journals.ekb.eg/article_71261_ed987b0840ffacb78fc722592cb620ed.pdf

2. Primary Stability of Implant in Closed Sinus Lifting Cases Using Densa Bur Versus Osteotome https://clinicaltrials.gov/ct2/show/NCT03559777

3. Patient Perception and Radiographic Assessment of Sinus Lifting Procedure using Densa Bur versus Osteotome-mediated sinus lifting: A Randomized Clinical Thttps://adjc.journals.ekb.eg/article_165194_0f7e7df225cb83b2ace99f7d370d885c.pdf