Clinical and Radiographic Evaluation of Delayed Implant Placement Following Socket Preservation with Injectable Alloplastic Bone Graft : A Randomized Controlled Study .

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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Dentist at The Egyptian ministry of health ,2021

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"Thesis Research Protocol"

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1. Abstract

Introduction: Tooth extraction leads to alveolar ridge resorption which can compromise future implant placement. Socket preservation using alloplastic bone grafts may help maintain ridge dimensions and allow for predictable delayed implant placement. Injectable alloplastic bone substitutes have gained attention due to their ease of handling and osteoconductive properties. **Aim**: To evaluate the clinical and radiographic outcomes of delayed implant placement after socket preservation using injectable alloplastic bone graft. **Methodology**: Twenty Implants will be placed in 20 patients that have previously extracted a lower posterior tooth, . Group (1) : patients without socket preservation after extraction . Group (2): patients with socket preservation after extraction . Clinical outcomes including soft tissue healing, implant stability, and postoperative complications will be assessed. Radiographic evaluation using CBCT will be made before implant placement, and after 6 months to measure changes in ridge width and height.

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2. Introduction and Background

Tooth extraction is often associated with significant remodeling of the alveolar ridge. This natural biological process results in resorption of the alveolar bone, with the greatest volume of bone loss occurring within the first 3–6 months following extraction .Studies have shown that horizontal bone loss can reach up to 50% in width and 60% in height during this period **(Van der Weijden et al., 2009).**

This resorptive process is not only a physiological consequence of tooth loss but also a critical challenge for the prosthetically-driven placement of dental implants .Alveolar ridge preservation (ARP) techniques have been developed to mitigate this bone loss by preserving the ridge volume immediately following extraction .ARP commonly involves the placement of bone graft materials into the extraction socket, often with or without a barrier membrane, to support new bone formation and maintain soft tissue contours **(Avila-Ortiz et al., 2014).**

Multiple types of bone grafts have been introduced for this purpose, including autografts, allografts, xenografts, and alloplastic materials, each with distinct biological and handling properties .Alloplastic grafts, which are synthetic in nature, offer several advantages such as biocompatibility, lack of disease transmission risk, and ease of manipulation. Among these, injectable alloplastic bone substitutes have gained increasing popularity due to their moldability, minimally invasive application, and ability to conform precisely to the defect morphology **(Mangano et al., 2013).**

These materials generally consist of calcium phosphate or sulfate compounds and function primarily through osteoconduction, providing a scaffold for bone in-growth **(Jensen et al., 2006).**

Their injectable nature allows for easy delivery into the socket without the need for extensive surgical manipulation, thus reducing chair time and improving patient comfort .While immediate implant placement is sometimes employed in ideal conditions (i.e., intact bony walls, absence

of infection), it is not always feasible or advisable. Clinical situations involving thin biotypes, bone deficiencies, or aesthetic demands often necessitate a delayed implant placement protocol to allow for adequate tissue healing and graft maturation **(Chen & Buser, 2009).**

In such scenarios, prior socket preservation may significantly influence the quality and quantity of bone available at the time of implant placement.

Several clinical trials and systematic reviews have demonstrated the effectiveness of socket preservation procedures in reducing post-extraction dimensional changes and enhancing the conditions for implant placement **(Mardas et al., 2015; Vignoletti et al., 2012).**

However, the specific role of injectable alloplastic materials in socket preservation—particularly in terms of long-term clinical and radiographic outcomes—remains underexplored. Additionally, there is limited evidence regarding the bone quality they produce in healed sites and their influence on primary implant stability .Cone beam computed tomography (CBCT) has become the gold standard for evaluating dimensional bone changes due to its high accuracy and low radiation dose. It allows for detailed 3D assessment of bone volume, ridge width, height, and density **(Bornstein et al., 2014).**

Upon search of literature , up-to knowledge there are insufficient studies assessing delayed implant placement following socket preservation with injectable bone graft ,hence , the aim of the present study .

3. Research Q (RQ):

In patients that require delayed implant in posterior mandible , what is the effect of delayed implant placement following socket preservation with Injectable bone graft ? Clinically regarding implant stability , soft tissue healing and postoperative pain. As well as radiographically regarding horizontal and vertical dimensional changes in the alveolar ridge?

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4. Research Hypothesis, Aim, Objectives & Expected Outcomes

a. Hypothesis

Null Hypothesis (H_0):

There is no significant difference in the effect of delayed implant placement following socket preservation in comparison to implant placement without socket preservation.

Alternative Hypothesis (H_1):

There is a significant difference in the behavior of delayed implant placement following socket preservation in comparison to implant placement without socket preservation .

b. Aim

To evaluate the clinical and radiographic outcomes of delayed implant placement after socket preservation using injectable alloplastic bone graft.

c. Objectives

Clinical parameters:

1)Measure implant stability at the time of placement and after osseointegration using OSTELL .(immediately after implant placement and 6 month after implant placement)

2)Assess soft tissue healing and wound dehiscence by visual inspection (one week after the surgery)

3)Monitor postoperative pain by VAS and swelling through visual inspection and palpation .(Day 1, Day 3 ,and Day 7 postoperatively)

4)Record any complications (infection, graft exposure, etc.) by visual inspection .(afte one week)

Radiographic parameters :

1)Measure horizontal and vertical dimensional changes in the alveolar

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ridge after 6 months using CBCT.
2)Evaluate the radiographic bone density at the grafted site (after 6 months)

d. Expected Outcomes

Socket preservation using injectable alloplastic bone graft may reduce alveolar ridge resorption, enhance bone quality at the implant site, and facilitate optimal implant placement.

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5. Research Design and Methods

1- Materials :

item	Type	Manufacturer
Dental implant	Titanium	SGS Turkey
Local anesthetic	Articaine 4% with epinephrine 1:100,000	Alexadricaine
Sutures	4-0 or 5-0 resorbable/non-resorbable sutures	Asset suture

2- Methods

A –Study Design:

Controlled clinical study , randomization has been done for the patients before extraction and socket preservation using http//www.randomizer.org

B – Study Settings :

Outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Suez Canal University.

C-Study population :

20 patients requiring delayed implant placement in posterior mandibular region , the patients will be divided into 2 equal groups (n = 10 per group).

1-Patient selection and eligibility criteria

Inclusion criteria: (Lin et al., 2019, Mandelli et al., 2019)

- Patient aged between 40 and 60 years
- General good health.
- Volunteer subjects have to voluntarily sign an informed consent.
- Patient Indicated for single implant placement in lower posterior area.

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Inclusion criteria for patients in group I

- Patient with a previously extracted lower posterior tooth and the socket was preserved with injectable bone graft .

Exclusion criteria: (Lin et al., 2019, Mandelli et al., 2019)

- Patient with systemic disease affection bone metabolism .
- Patients with contraindication to surgical treatment.
- Patients with uncontrolled medical conditions.

2-Patient Grouping :

Group I (Test Group):
Including 10 patients with extracted mandibular posterior tooth who undergone socket preservation with Injectable alloplastic bone graft.

Group II (Control Group):
Including 10 patient with extracted mandibular posterior tooth and left for natural healing.

D -Methodology

Pre-operative assessment.

Clinical assessment will also include evaluation of soft tissue quality, keratinized gingiva, and occlusal considerations to ensure proper implant planning (Bornstein et al., 2014).

Radiographic assessment

Before implant placement, patients will undergo radiographic evaluation, including cone-beam computed tomography (CBCT) to assess alveolar ridge dimensions, bone density, and anatomical structures such inferior alveolar nerve. At 4 months post-extraction, prior to implant placement (baseline)

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CBCT Equipment Specifications:

- Device: Scanora 3D by Soredex (Tuusula, Finland)

Specifications

- Imaging type: CBCT with optional high-resolution 2D panoramic
- Fields of View (FOV): 60 × 60 mm, 75 × 100 mm, 75 × 145 mm, optional XL up to 130 × 145 mm
- Voxel size: 0.4 mm
- Scan time: 8–30 sec (effective exposure 2–7.5 sec)
- X-ray tube: 60–90 kV, 1.0–8.0 mA, fixed anode
- Focal spot: 0.5 mm (IEC 60336)
- Detector: Flat panel (CBCT), CCD (panoramic)
- Features: AutoSwitch between CBCT and panoramic
- Dimensions: 1973 × 1600 × 1400 mm

Patients will be scanned in a seated upright position with a rigid head support to minimize motion artifacts.

Surgical Protocol:

The dental implant placement will be performed under strict aseptic conditions and following standard surgical protocol for delayed implantation. The procedure will take place approximately 4 months following tooth extraction and socket preservation for patient in both groups. (Peitsinis et al., 2025; ITI, 2018)

1. **Preoperative Preparation** (Esposito et al., 2023) :
   - Patient will rinse with 0.12% chlorhexidine gluconate mouthwash for 1 minute.
   - Extraoral skin will be disinfected with povidone-iodine.

   - Local anesthesia will be administered using 4% Articaine with 1:100,000 epinephrine via infiltration or nerve block as needed.

2. **Surgical Access(Misch, 2021):**
   - A mid-crestal incision will be made in the edentulous ridge using a scalpel blade no.15.
   - Two small vertical releasing incisions may be added to ensure

adequate access, depending on tissue quality.

- A full-thickness mucoperiosteal flap will be reflected to expose the underlying alveolar bone.

3. Osteotomy Preparation(Misch, 2021):
Standard clinical guidelines will guide the implant position (based on CBCT).

- A round bur will be used to mark the implant site. (Misch, 2021)
- Sequential drills of increasing diameter (pilot drill, twist drills) will be used at low speed (800–1200 rpm) under copious sterile saline irrigation to prepare the osteotomy to the desired depth and diameter according to the implant system used.

- Direction indicators or paralleling pins may be inserted intermittently to verify angulation and position.

4. Implant Insertion(Misch, 2021):
- 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 .

- Flap will be repositioned and sutured using 4-0 or 5-0 non-resorbable or resorbable sutures using interrupted or horizontal mattress technique. (Misch, 2021)

5.**Postoperative Instructions and Medications(Esposito et al., 2023)**
- 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.

6. **Follow-up (ITI, 2018):**
   - Sutures will be removed after 7–10 days. (Misch, 2021)
   - Healing will be monitored clinically and radiographically.

   - Osseointegration will be reassessed after 3 months, and if satisfactory, prosthetic loading will be initiated.
   - Abutment will be placed and impression will be taken to get the final restoration loading.

Post-operative Assessment

A-Clinical Evaluations

1-Implant Stability will be assessed using a non-invasive method based on resonance frequency analysis (RFA) utilizing the Osstell ISQ® device. This technique provides a quantitative measure of the implant's mechanical stability in bone and is highly predictive of osseointegration success (Meredith, 1998; Ostman et al., 2006).

After implant insertion, a smart peg compatible with the implant system will be attached to the implant fixture using the manufacturer's torque recommendation (approximately 4–6 Ncm). The Osstell probe will then be positioned near the peg without contact to transmit magnetic pulses.

Measurements will be taken in two directions (buccolingual and mesiodistal), and the mean Implant Stability Quotient (ISQ) will be calculated. The ISQ scale ranges from 1 to 100, with values above 65 generally indicating high primary stability suitable for early or immediate loading (Sennerby & Meredith, 2008).

Stability will be measured at the time of implant placement and again after a healing period of 6 months to assess secondary (biological) stability.

2-Postoperative pain will be evaluated using the Visual Analog Scale (VAS), a widely accepted and validated method for measuring subjective pain perception in clinical dental studies. The VAS is a 10-centimeter horizontal line with endpoints defined as "0" (no pain) and "10" (worst

imaginable pain). Patients will be instructed to mark the line at the point that best represents their pain intensity at predefined intervals: Day 1, Day 3, and Day 7 postoperatively. (Alghamdi et al., 2023).

3-Soft Tissue Healing: Careful examination of the surgical site to assess epithelialization, and detection of any wound dehiscence or delayed soft tissue healing one week after surgery (Buser et al., 2017).

4. Complication Monitoring: Recording of any complications such as infection, graft exposure, hematoma, suture dehiscence, or early implant mobility. These events will be documented systematically for subsequent analysis (Esposito et al., 2013).

B-Radiographic Assessment

Radiographic evaluation will be performed using Cone Beam Computed Tomography (CBCT) to assess dimensional and qualitative changes in the alveolar ridge at different stages of the study. CBCT provides high-resolution three-dimensional imaging and has become the gold standard for quantitative bone analysis in implant dentistry (Gonzalez-Garcia et al., 2023). All images will be evaluated using dedicated on demand for consistent calibration.

Scans will be taken at the following time points:

- 6 months post-implantation to assess bone remodeling around the implant

Parameters to be assessed include (Alssum et al., 2025; Gong et al., 2024):

1) Marginal bone level changes.
2) Vertical ridge height (buccal and lingual/palatal aspects)
3) Bone density around the implant (in Hounsfield Units)
4) Buccal plate thickness.

6. Statistical plan

a) **Sample size calculation**:

will be two-tailed (Chan Y, 2003).

Sample size calculation :

The sample size for this study was calculated according to **Chan, 2003** and used the following equation: (**Chan Y, 2003**)

$$N = \frac{(\mathrm{Z}\alpha)^2 * (S)^2}{(d)^2}$$

N = Total sample size,

Zα= Is Standard normal variate and its equal to 1.96 at P< 0.05,

SD = Standard deviation of variable,

d = Absolute error or precision

Zα	SD	D
1.96	4.6	2

$$N = \frac{(1.96)^2 * (4.6)^2}{(2)^2} = 20.3 \approx 20\ implants$$

The total sample size calculations revealed that the sample size should be 20 samples

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will be divided equally as follows:

Groups	Descriptive	Samples
Group A	Implants in Sockets preserved with IBS	10
Group B	Implants in Empty socket	10

This sample size is in agreement with previous study that test in similar subject

(Mandelli et al., 2019)

Statistical analysis:

Data will be coded and entered using the statistical package SPSS version 22. Data will be summarized using mean and standard deviation. Data will be explored for normality using the Kolmogorov-Smirnov test. Comparisons between both groups for normally distributed data will be done using a t-test. P value less than or equal to 0.05 will be considered statistically 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 twenty 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. explain the clinical examinations, procedures, potential risks, benefits, and the follow-up required for participation in the study.

8. Time Plan

Starting After approval of the Ethical Committee and faculty council**. Ending**: 12 Months

Include Grant Chart as following example:

Activity/Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Ethical Approval &Preparation	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Patient Selection & Consent	☐	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Implant Placement	☐	☐	☐	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Final Evaluations (Clinical&CBCT)	☐	☐	☐	☐	☐	☒	☒	☒	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Statistical Analysis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Writing & Submission.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. Research Estimated Budget in Egyptian Pound

Supplementary					Publications	Total
Radiographs	drugs/ Lab chemicals	Lab-investigations Software	Material	Others (mention)		
CBCT	Antibiotics, analgesics, anti-inflammatory Drugs	Implant systems 20 implant	Lancet#15, Suture silk , Local anesthesia, Saline			
10000	1500	48000	2000		2000	63500

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11. Appendices

(Questionnaire / Consent form)

Faculty of Dentistry Research
Ethics Committee (REC)

Investigator Application Form

1- Name of researcher: **Ahmed Rawhy Mounir Saleh**

2- Name of Department: **Oral and Maxillofacial Surgery**

3- Address of researcher: Ibrahimia sharqia.

a- Email: ahmedrawhi96@gmail.com

b- Phone number: 01022552382

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

Prof. Dr. **Mohamed Ahmed Elsholkamy**

Dr. **MohamedNageh 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 Clinical and Radiographic Evaluation of Delayed Implant Placement Following Socket Preservation with Injectable Alloplastic Bone Graft.

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) : (✓)

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:

1. Infection at the surgical site.
2. Pain or swelling during the healing phase.
3. Graft failure or insufficient bone regeneration.
4. Allergic reaction or sensitivity to the graft material (rare).
5. Implant failure due to poor osseointegration (in rare cases).

14-List the potential benefits, if any, to the subjects:

1. Preservation of bone volume after tooth extraction, reducing the risk of future bone loss.
2. Improved implant stability due to better bone quality.
3. More predictable implant placement with proper bone dimensions.
4. Enhanced aesthetic outcomes, especially in visible areas.
5. Minimally invasive handling of the graft material (injectable).
6. Reduced need for additional bone grafting procedures later.
7. Better healing of soft tissues due to ridge preservation.

15-Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained? Yes: (✓)

No: ( )

16-Privacy and confidentiality of subjects are assured Yes: (✓) No: ( )

17-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: ( )

18- All surgeries will done under supervision of professors

Signature of the principal investigator: Date:

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