Clinical, Radiographic and Histologic Assessment of the Efficacy of Bioactive Glass as a Novel Grafting Material in Maxillary Sinus Floor Augmentation: 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-12**

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“Thesis Research Protocol”

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Thesis Title in English: **Clinical, Radiographic and Histologic Assessment of the Efficacy of Using Bioactive Glass as a Novel Bone Grafting Material in Augmentation of the Maxillary Sinus: A Randomized Controlled Clinical Trial**

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1. Abstract:

Introduction: Maxillary sinus augmentation is considered a reliable procedure to increase bone volume in the posterior maxilla prior to dental implant placement. The choice of bone grafting material is critical to the success of this procedure. While xenografts have been widely used due to their biocompatibility and osteoconductivity, bioactive glass bone grafts have recently emerged as a promising alternative due to their ability to stimulate bone regeneration and enhance osteointegration. The novel bioactive glass material (Unigraft®) is designed to be biocompatible, biodegradable, and osteostimulative, making it a potentially valuable substitute to conventional grafts. The current research is significant as it addresses the need to explore alternative grafting materials with enhanced biological properties for predictable clinical outcomes.

Aim: This study aims to evaluate the clinical, radiographic, and histologic performance of bioactive glass bone graft material (Unigraft®) in maxillary sinus augmentation.

Methodology: A total of 20 patients requiring maxillary sinus augmentation in the posterior maxilla will be selected according to specific inclusion and exclusion criteria. Patients will be randomly allocated into two groups of 10 patients each. Group 1:(study group) 10 patients will receive a bioactive glass bone graft material (Unigraft®), while group 2 (control group) 10 patients will receive xenograft. Clinical evaluation will include assessment of postoperative healing, soft tissue response, and any complications. Radiographic assessment will be performed using cone beam computed tomography (CBCT) preoperatively, postoperatively and after 6 months to measure bone height gain and bone density. Histologic evaluation will be conducted by harvesting core biopsies from the augmented sinus area at the time of dental implant placement, to assess new bone formation and graft integration.

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2. Introduction and Background

Sinus augmentation has become a common surgical procedure to allow dental implant placement in the posterior maxilla with severely resorbed alveolar ridge. Loss of posterior maxillary teeth leads to maxillary sinus pneumatization and progressive alveolar bone resorption, resulting in limited bone height, which hinders implant placement. Thus, sinus floor elevation techniques have evolved as predictable procedures to manage such cases. **(Temmerman et al., 2021**).

Rehabilitation of the atrophic posterior maxilla with dental implants remains a clinical challenge due to insufficient vertical bone height and poor bone quality. The main causes are alveolar bone resorption following tooth loss and the physiological pneumatization of the maxillary sinus, both of which compromise the available bone for implant anchorage. **(Al-Moraissi et al., 2023).**

To overcome these anatomical limitations, sinus floor elevation procedures have been developed to augment the vertical bone height in the posterior maxilla. Among these, the lateral window approach has shown high predictability, particularly in cases where the residual bone height is less than 4 mm. This technique allows direct access to the sinus membrane and facilitates placement of bone graft materials beneath the elevated Schneiderian membrane.
(Tan et al., 2022).

Various grafting materials have been used to support new bone formation in the elevated sinus cavity, including autografts, allografts, xenografts, and alloplasts. While autogenous bone has been considered the gold standard due to its osteogenic potential, it is associated with donor site morbidity and limited volume availability. As a result, alternative graft materials have gained popularity in recent years. **(Starch-Jensen and Aludden, 2021).**

Xenografts, derived from animal sources such as bovine bone, are commonly used due to their osteoconductive properties and structural similarity to human bone. Despite their clinical success, their slow resorption rate and lack of bioactivity may limit their ability to stimulate bone regeneration efficiently. **(Kwon et al., 2021).**

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Recently, bioactive glass has emerged as a promising alloplastic material due to its unique properties. It is a synthetic, biocompatible, and biodegradable graft that actively participates in the bone healing process by releasing ions that stimulate osteogenesis and angiogenesis. Additionally, it has demonstrated antimicrobial effects, making it favorable in grafting procedures.
(Zhao et al., 2023).

In clinical studies, bioactive glass has shown favorable outcomes in sinus lift procedures, with comparable or even superior results to traditional grafts like xenografts. Its ability to form a strong bond with host bone and promote new bone formation has been documented in both in vivo and clinical settings. **(Elshazly et al., 2022).**

Bioactive glass has been shown to promote bone formation and vascularization, making it a viable alternative to xenografts **(Goutam et al, 2022)**.

Bioactive glass also demonstrates antimicrobial properties, contributing to reduced infection risk in grafted sites **(Zhao et al, 2015)**.

Additionally, it is bioresorbable and remodels over time into native bone, addressing one of the limitations associated with the persistence of xenograft particles in the grafted area **(El-Rashidy et al, 2017)**.

Although studies have investigated bioactive glass in sinus augmentation procedures, a gap remains in the literature regarding its effectiveness compared to xenografts specifically in SA4 cases where the challenges are greater due to severe bone loss **(Yucesoy et al, 2022)**.

The regenerative effect of bioactive glass is attributed to its ionic dissolution products, such as calcium, phosphate, and silica, which stimulate osteoblastic differentiation and enhance bone matrix synthesis **(Schumacher et al., 2021)**.

Moreover, bioactive glass exhibits antimicrobial activity against common oral pathogens, reducing the risk of postoperative infections **(Zhu et al., 2021)**.

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In SA 4 maxillary defects, where achieving rapid bone regeneration is essential, bioactive glass offers accelerated bone integration and infection control, making it a valuable alternative to traditional grafts **(Westhauser et al., 2021)**.

However, limited data is available comparing the clinical performance of bioactive glass to xenograft in severely atrophic maxillae classified as SA4, where the bone height is extremely reduced. Therefore, it remains essential to further investigate the effectiveness of bioactive glass in such challenging cases to validate its potential as a reliable graft material in sinus augmentation. **(Kim et al., 2023).**

Given the increasing clinical application of bioactive glass and the limitations of current grafting options, further research is needed to directly compare its effectiveness with xenografts in cases of severe bone loss. Such investigations will help determine whether bioactive glass can be considered a predictable and efficient alternative for sinus augmentation in SA4 patients. **(Rossi et al., 2023).**

Bioactive glass exerts its regenerative effect through a well-documented ionic exchange process, where the material interacts with body fluids to form a hydroxycarbonate apatite (HCA) layer, closely resembling the mineral phase of natural bone. This surface layer facilitates the attachment, proliferation, and differentiation of osteoblasts, thereby promoting new bone formation. In addition, the release of silicon, calcium, and phosphate ions has been shown to upregulate genes related to osteogenesis and angiogenesis. **(Baino et al., 2020).**

One of the advantages of bioactive glass over xenografts is its ability to be completely resorbed and replaced by vital bone over time. This contrasts with xenografts, which may remain partially unresorbed in the grafted area for years, potentially limiting the amount of functional bone available for implant integration. Furthermore, bioactive glass can be customized in terms of particle size, porosity, and degradation rate, which enhances its clinical versatility. **(Day et al., 2022).**

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In addition to its osteostimulatory capacity, bioactive glass has demonstrated intrinsic antibacterial properties, especially against oral pathogens such as *Streptococcus mutans* and *Porphyromonas gingivalis*. This characteristic may help reduce postoperative infection rates, particularly in sinus augmentation procedures where microbial contamination from the sinus cavity is a concern. **(Zhang et al., 2021).**

The selection of graft material becomes even more critical in SA4 cases, where the initial stability of implants is almost non-existent, and graft performance determines the success of subsequent implant placement. An ideal graft in such cases must not only support osteoconduction but also enhance bone formation in a relatively short time to allow for timely implant placement. **(Esposito et al., 2023).**

From a surgical perspective, the use of bioactive glass may also offer handling benefits. Its particulate nature allows easy packing and adaptation to the sinus floor, and its radiopacity permits post-operative radiographic assessment. Additionally, its synthetic origin eliminates the risks associated with disease transmission and immunogenic reactions observed with animal-derived grafts. **(Rahman et al., 2021).**

Therefore, a well-designed randomized clinical study comparing bioactive glass to xenograft in SA4-classified maxillary sinuses would provide valuable insight into the clinical performance of this novel material. Such a study could help establish whether bioactive glass is a suitable, or even superior, alternative to conventional xenografts in managing extreme atrophy cases requiring sinus augmentation. **(Kim et al., 2023).**

Histologic assessment remains the gold standard for evaluating bone regeneration following sinus augmentation procedures, as it provides direct evidence of new bone formation, graft resorption, and tissue integration. Unlike radiographic analysis, which offers only a general view of mineralization, histological evaluation allows quantification of vital bone, residual graft, and connective tissue within the augmented area. **(Troiano et al., 2021).**

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Studies comparing xenografts and bioactive glass in histologic sections have revealed distinct differences in tissue response. Xenografts typically show good osteoconduction but tend to remain partially unresorbed for extended periods, often being encapsulated by fibrous tissue. In contrast, bioactive glass is more readily resorbed and replaced by vital bone, with minimal fibrous tissue interposition. **(Cervino et al., 2020).**

Histomorphometric analysis of grafted sinuses using bioactive glass has shown significantly higher percentages of new bone formation compared to xenograft in some trials, particularly after a healing period of 6 to 8 months. This is attributed to the bioactive nature of the material and its capacity to stimulate early vascular invasion and osteoblast differentiation. **(El-Rashidy et al., 2022).**

One of the critical parameters assessed histologically is the quality of the bone–graft interface. In xenograft samples, residual particles are often seen loosely embedded or separated from the new bone by a connective tissue layer. In contrast, bioactive glass particles frequently demonstrate direct contact with newly formed bone, suggesting better osteointegration. **(Jung et al., 2023).**

In addition to evaluating bone formation, histology provides insight into the inflammatory response elicited by different grafts. Bioactive glass has consistently demonstrated a mild or absent inflammatory response, supporting its high biocompatibility. Xenografts, although generally safe, may occasionally provoke mild chronic inflammation, especially if deproteinization is incomplete. **(Bechara et al., 2021).**

Up to the best of our knowledge, there is no enough studies that evaluate the efficacy of bioactive glass in maxillary sinus agumentation, thus this study will be carried out to evaluate the clinical, radiographic, and histologic performance of bioactive glass bone graft material (Unigraft®) in maxillary sinus augmentation.

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3. Research Question (RQ):

In patients with severely atrophied edentulous posterior maxillary ridges requiring maxillary sinus augmentation, what is the effect of using bioactive glass bone graft compared to xenograft in terms of bone formation, graft resorption, histological healing, and overall clinical outcomes?"

4. Research Hypothesis, Aim, Objectives & Expected Outcomesss

a. Hypothesis

Null Hypothesis: There is no significant difference in clinical, radiographic, or histological outcomes between sinus augmentation using bioactive glass bone graft and xenograft in SA 4 posterior maxilla cases.

Alternative Hypothesis: There is significant difference in clinical, radiographic, or histological outcomes between sinus augmentation using bioactive glass bone graft and xenograft in SA 4 posterior maxilla cases.

b. Aim

to evaluate the clinical, radiographic, and histologic performance of bioactive glass bone graft material (Unigraft®) in maxillary sinus augmentationx`.

c. Objectives:

•Clinical Evaluation: Assess intra-operative ease of application, post-operative pain (using Visual Analogue Scale), and edema.

•Radiographic Evaluation: Measure bone height and density changes using CBCT at immediate post-operative and 6-month follow-up intervals.

•Histological Evaluation: To assess bone formation, residual graft particles, and bone maturation in biopsy samples at implant placement.

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d. Expected Outcomes

It is expected that bioactive glass bone graft may result in easier intra-operative handling, faster bone regeneration, superior bone quality, and fewer post-operative complications compared to xenograft. Additionally, bioactive glass may promote quicker angiogenesis and faster graft remodeling, especially in challenging SA 4 cases where residual bone height is critically low.

5. Research Design and Methods

I-Materials:

The following materials will be used in the study:

Item	Composition	Trade name
Local anesthesia	Articaine 4% with epinephrine (1:100,000)	Artpharma, Cairo governorate, Egypt
Surgical Lancet No.15	Carbon steel	Newdolhi, India
Sutures (Vicryl)	Polyglactin 910	Egysorb Vicryl, Cairo governorate, Egypt

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Bioactive Glass Bone Graft (Unigraft)	45% Silicon Dioxide (SiO_2) 24.5% Sodium Oxide (Na_2O) 24.5% Calcium Oxide (CaO) 6%PhosphorusPentoxid(P_2O_5)	Unigraft, Biomed, USA
Xenograft	Deproteinized bovine bone (natural hydroxyapatite)	Bio-Oss, Switzerland
Collagen Membrane	Purified collagen membrane	Unimatrix, Germany
Irrigation Solution	Sterile saline solution	Normal Saline
Misc. Surgical instruments	Needle holders, scissors, elevators, forceps, etc.	Standard OMFS kit
Bone trephine bur	Stainless steel, cylindrical bur for Bone biopsy	Hu-Friedy, USA
Formalin 10% neutral buffered	10% formaldehyde in phosphate buffer	Sigma-Aldrich, USA
Hematoxylin&Eosin staining kit	Hematoxylin + Eosin Y stains for General tissue structure	Sigma-Aldrich, USA
Light microscope	Binocular microscope with high-resolution optics	Olympus, Japan

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II-Methods:

a) **study design:** Randomized controlled clinical study, randomization
   a. done using random group generator (random.org).

b) **study setting:** The study will be conducted in the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Suez Canal University.

c) **Study population and samples:** Participants enrolled in this study will be selected from a group of patients seeking implant supported dental restorations in an atrophic posterior maxilla requiring staged augmentation.

d) **Patient selection:** 20 edentulous sites indicated for an implant supported restoration in severely atrophic posterior maxilla. Patients could be partially edentulous receiving a single implant restoration or fully edentulous receiving an implant supported overdenture.

Patient will be selected based on eligibility criteria:

Inclusion criteria: (**Testori et al., 2024**)
- Adult male/female patients above the age of 18.
- Patients with one or more teeth requiring implant supported dental restoration in atrophic maxilla.
- Alveolar bone height less than 5 mm at the defective site.
- Good oral hygiene.
- Patient's consensual agreement to be enrolled in the study.

Exclusion criteria: (**Wimalarathna., 2021**).
- Medically compromised patients with conditions contraindicating surgery (eg. uncontrolled diabetics, bisphosphonate intake, radio or chemotherapy).
- Patients with active infection at or related to the site of surgery (eg. acute sinusitis).
- Heavy smokers.
-Patients not indicated for an implant supported restoration at the time of enrollment (eg. active/untreated periodontal disease).
(Patients developing any medical condition that interferes with the outcomes after enrolment in the study will be excluded).

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e) Clinical examination and radiographic evaluation:
- Thorough clinical examination of the oral cavity, mucosal thickness, inter-arch distance as well as dental history taking and whether previous complications occurred with local anesthesia and compliance to given treatments and instructions.
- Each patient will have a CBCT for evaluation and measurement of bone height at the defected site requiring restoration. This will dictate the exact location of the osteotomy and the desired height and width of augmentation as well as help in planning for implant placement. CBCTs will be done using the following exposure parameters for standardization: 6x8 cm field of view, 90 KV, 10 mA, an exposure time of 6.1 seconds and a voxel size of 0.2 mm.

f) Random allocation: Patients will be randomly allocated in the two groups of the study.

g) Surgical Procedure:

Local Anesthesia

•The surgical field will be anesthetized using Articaine 4% with epinephrine (1:100,000).

•Adequate anesthesia of the posterior maxilla is essential to ensure patient comfort and optimal working conditions.

Incision and Flap Reflection

•A trapezoidal mucoperiosteal flap is designed with a crestal incision extending over the edentulous area, accompanied by two releasing incisions (mesially and distally).

•A periosteal elevator is used to carefully reflect the flap, exposing the lateral wall of the maxillary sinus.

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Lateral Window Preparation

•A round diamond bur (or piezoelectric handpiece) is used to outline and create the lateral antrostomy (window) in the lateral wall of the maxillary sinus.

•Care is taken to preserve a “trap door” of bone if desired, which may be repositioned later to help support the elevated membrane and graft.

•The bony window is thinned until a bluish hue of the sinus membrane is visible.

Sinus Membrane Elevation

•The Schneiderian membrane is gently elevated from the sinus floor and the medial wall using specialized sinus curettes or piezo tips.

•Any perforations in the membrane, if minor, may be repaired using a collagen membrane or fibrin sealant.

•The membrane is carefully freed mesially, distally, and superiorly to create adequate space for the graft material.

Graft Placement

•Group A (Bioactive glass Group): Bioactive glass (Unigraft®) graft material is introduced into the elevated sinus cavity.

•Group B (Xenograft Group): A bovine-derived xenograft (Bio-Oss) is used to fill the space under the elevated membrane.

•In both groups, a collagen membrane (Unimatrix) may be placed over the lateral window to contain the graft and stabilize the area, if indicated.

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Closure

•The flap is repositioned and sutured to achieve primary closure using resorbable or non-resorbable sutures (e.g., Vicryl 3-0).

•Sutures are typically removed after 7–10 days, depending on the healing progress and the type of suture used.

Postoperative Care

1.Medications:

•Antibiotics (e.g., Amoxicillin 500 mg every 8 hours for 5–7 days)

•Analgesics (e.g., Ibuprofen or Paracetamol) and anti-inflammatory drugs, if required.

•Nasal decongestants or saline nasal spray may be prescribed to keep the sinus ostium clear.

2.Instructions:

•Patients are advised to avoid blowing their nose or creating negative pressure in the sinus for at least 2 weeks.

•Gentle rinsing with chlorhexidine mouthwash is recommended to maintain oral hygiene.

•Soft diet is advised for the first few days.

3.Follow-up Appointments:

•The patient is scheduled for suture removal and follow-up examinations to assess healing.

•A radiographic evaluation (e.g., CBCT) may be performed after 6 months to evaluate bone height gain.

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i) Clinical examination and assessment:

Post operative edema and pain will be assessed during the post-operative follow up phase using edema scale and VAS pain scores respectively.

- Signs of inflammation, tissue reaction or local irritation will be assessed and recorded.

j) Radiographic examination and assessment:

- CBCT will be obtained preoperatively, postoperatively and after 6 months to evaluate the formed bone in terms of height and density.

- CBCT images will be compared for evaluation and calculation of the change in the graft material and at the surgical site after augmentation using OnDemand3D ®App software (Cybermed, Seoul, Korea).

K) Histologic Assessment:

At the time of implant placement (6 months post-sinus lift), bone core biopsies will be harvested from the grafted sinus area using a trephine bur under sterile conditions. The samples will be fixed in 10% buffered formalin, decalcified, embedded in paraffin, sectioned, and stained with Hematoxylin and Eosin (H&E) stain.
The histologic evaluation will include:

- Assessment of new bone formation.
- Presence of residual graft material.
- Inflammatory response or foreign body reaction.

The goal of the histologic assessment is to determine the quality and quantity of the newly formed bone, compare the integration and resorption rates of both graft materials, and evaluate tissue compatibility. This process will help correlate histological findings with the clinical and radiographic outcomes, providing a comprehensive evaluation of the grafting materials. The histologic analysis will be performed following the standard protocols approved and commonly used in public universities and research centers in Egypt, ensuring reproducibility and consistency.

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6. Statistical plan

a) Sample size calculation:

To evaluate the difference between the two proposed groups;

group I: study group and group II: control group. A **Paired T Test** is proposed. A minimum total sample size of 18 samples will be sufficient to detect the effect size of 1.2 mm change in bone height and a power (1-β=0.80) of 80% at a significance probability level of $p<0.05$ partial eta squared of 0.14 based on previous study. (**Silva et al, 2020**)

According to sample size calculations, each group would be represented by a minimum of 9 samples and a total sample size 18 samples will be selected for the study as shown in figure 1. The actual size attained will be augmented by around 10 - 20% to assure that would make up for any missing data and margin of error. A total of 20 samples will be selected for the study (Table 1). The sample size was calculated according to G*Power software version 3.1.9.6. **(Cohen, 1988, Faul et al., 2007, Knapp, Herschel. 2017)**.

Where;

f: is the effect size; α= 0.05; β= 0.20; Power= 1- β = 0.80

$$f = \frac{\sigma_\mu}{\sigma}$$

$$\sigma_\mu^2 = \frac{\sum_{i=1}^{k} n_j (\mu_i - \mu)^2}{N}$$

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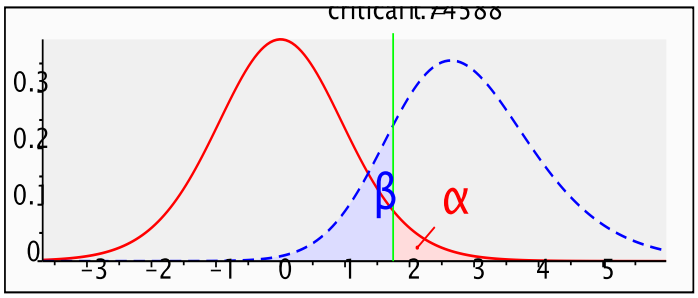

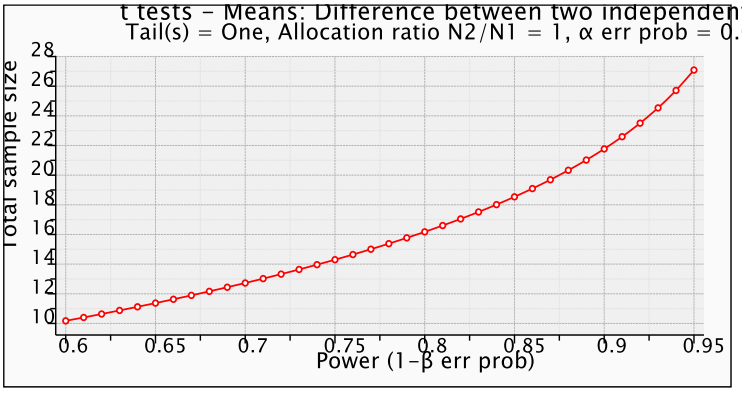

Figure 1. Sample size calculations

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Table 2: Variables of the study

Variable	Symbol	Donates	Number of samples
G	G1	Group 1: Bioactive glass (study group)	10
	G2	Group 2: Xenograft (control group)	10
Total Sample Size			20

b) Statistical analysis

All data will be subjected to statistical analysis. The statistical analysis will be performed using SPSS version X software (IBM SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA). Data will be presented as the mean ± SD. The one-sample Kolmogorov–Smirnov test will be used to examine the normality of data distribution. Repeated measures analysis of variance (ANOVA) will be used to compare variables within each study group, and a post hoc test will be performed if the ANOVA is significant. The paired samples t-test will be used to compare each pair of studied variables within each study group. The independent samples t-test will be used to compare variables between the two groups studied. For all tests, the result will be considered statistically significant if the P-value is equal to or less than 0.05.

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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 samples of patients' ethical considerations regarding patient well-being and confidentiality will be undertaken by the researcher and an informed written consent will be signed by the subjects/ patients before commencing the study explaining all clinical examinations, procedures and follow up.

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	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒

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9.Research Estimated Budget in Egyptian Pound

CBCT	Materials	Others Miscellaneous	Statistics	Publications	Total
1800/case	Bioactive glass (Unigraft®) 42,000	500 disposables /case	5000	20,000	147,300
28,800	Xenograft: 43,500	8000			
	85,500				

Sponsored by the researcher himself.

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11. Appendices

-1-

Suez Canal University

Faculty of Dentistry

Research Ethics Committee (REC)

Investigator Application Form

1-Name of researcher: **Mostafa Anwar Ahmed Elfeky.**
2-Name of Department: **Oral and maxillofacial surgery.**

3-Adress of researcher: **Behira,Egypt**

a- Email : **mostafa_elfeky@dent.suez.edu.eg**
b- Phone number **+20 1000543404**
c- Fax number: **none**

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

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, Radiographic and Histologic Assessment of the Efficacy of Using Bioactive Glass as a Novel Bone Grafting Material in Augmentation of the Maxillary Sinus: A Randomized Controlled Clinical Trial

7-Type of the research:
*Drug trial ( ) *Surgical technique (√) *Investigative technique (√)

*Devise study ( ) *Survey study ( )*Blood sampling ( )
*Review of old records ( )

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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: pain, edema, wound infection, sinusitis, temporary epistaxis.

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:

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Suez Canal University

Faculty of Dentistry

Research Ethics Committee

Informed Consent Form for Participation in a Medical Research Study

.....:(Gender) ..... (Participant's Name)

..... : Date of Birth:.....:(Age)

1- Study Title:
Clinical, Radiographic and Histologic Assessment of the Efficacy of Bioactive Glass as a Novel Grafting Material in Maxillary Sinus Floor Augmentation: A Randomized Controlled Study

2- Background and Purpose of the Study:

this study compares bioactive glass and xenograft in sinus lift procedures in terms of new bone formation and bone height gain

3- Study Procedures in Detail:
This study is limited to individuals seeking fixed dental prostheses supported by implants in the posterior maxilla (molars/premolars), where bone height is insufficient for implant placement.

The study will evaluate two techniques using either synthetic or xenogenic bone graft materials to augment the posterior maxilla through maxillary sinus lift as a preliminary stage before implant placement.

Participants must meet specific inclusion criteria and must not have general or localized health conditions that contraindicate the surgical procedure.

Study Location: Oral and Maxillofacial Surgery Clinics, Faculty of Dentistry, Suez Canal University, Ismailia- Egypt.

Study Duration: 6 months.

Number of Participants: 20 sites with atrophic bone due to maxillary sinus pneumatization.

Study Steps:

- After volunteering and meeting the eligibility criteria, you will be randomly assigned to one of the two groups:

Group 1 (n=10): Patients with deficient posterior maxillary bone height will undergo sinus lift using bioactive glass. Clinical, radiographic, and histologic assessments will be conducted to evaluate new bone formation and graft integration.

Group 2 (n=10): Patients with similar conditions will undergo sinus lift using xenograft to compare its effectiveness with the bioactive glass in terms of bone formation and success rate.

All participants will undergo CBCT imaging before inclusion, after the first surgery, and at the end of the study period.

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4- Expected Benefits of the Study:

This procedure may increase bone height in the posterior maxilla to allow implant-supported prostheses. Long-term benefits may include enhanced retention of fixed or removable prostheses using dental implants to replace more missing teeth in the upper jaw.

5- Possible Risks:

Risks may include complications associated with surgical procedures such as pain, swelling, wound infection, sinusitis, or temporary nasal bleeding.

6- Compensation for Risks:

If insufficient bone is formed for implant placement at the end of the study, the issue will be addressed during the second surgical stage by adding more graft material or modifying the implant procedure.

7- Available Alternatives if You Decline Participation:

Conventional fixed or removable dental prostheses.

8- Confidentiality of Your Information:

Your data will be kept strictly confidential and accessed only by the principal investigator. Upon study completion, you will be informed of the overall results and any findings relevant to your health status.

9- Your Right to Withdraw:

You may withdraw from the study at any time without giving reasons and without facing any negative consequences.

10- Use of Biological Samples (if applicable):

Any samples taken during this study will not be used for any other research.

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11- For Any Inquiries, You May Contact:

- Principal Investigator: Dr. Mostafa Anwar Ahmed El-Feky.
- Phone**:** +201000543404.
- Co-Investigator: Dr. Mohamed Nageh.
- Phone**:** +201226182970
- Ethics Committee Coordinator: Miss. Doaa Adel.
- Phone: +201277901960

I acknowledge that I have read, understood, and agreed to the procedures described in this research.

Participant's Name: .....
Signature: .....
Fingerprint: .....
Date: .....

Note: The volunteer has the right to receive a copy of this consent form.

This Study Is:

☑ A Master's Thesis
☐ A PhD Thesis
☑ Non-funded Research

Approved by the Research Ethics Committee on: 19 JUNE 2025

Committee Chairperson: .....
Committee Stamp

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