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Comparing dental implant placement with or without bone graft materials in maxillary sinus elevation

Submission date
14/11/2025

Recruitment status
No longer recruiting

Registration date
17/11/2025

Overall study status
Completed

Last Edited
17/11/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Some patients do not have enough bone in the back part of the upper jaw to support dental implants. A common solution is a surgical procedure called maxillary sinus floor elevation, which gently lifts the sinus membrane to create space for new bone. Traditionally, this space is filled with bone graft materials. However, recent studies suggest that implants might heal well even without adding grafts. This study aims to compare two approaches: sinus floor elevation with grafting material and without grafting material, to understand whether the graft is truly necessary for successful healing and implant stability.

Who can participate?
Adults aged 21 years or older who need dental implants in the back part of the upper jaw and have 6 mm or less of remaining bone height. Participants must have healthy maxillary sinuses and must be able to achieve good initial implant stability.
People with uncontrolled medical conditions, sinus diseases, heavy smoking, past chemotherapy or radiotherapy, or previous bone regeneration in the area cannot take part.

What does the study involve?
Participants will be randomly assigned to one of two groups:
- Control group: sinus lifted and space filled with a collagenated bone graft.
- Test group: sinus lifted but no graft is added.
All patients will receive dental implants during the same surgery. Clinical checks and X-rays (including CBCT scans) will be taken before surgery, shortly after, at 6 months, and then at 1 and 3 years to monitor healing, bone formation, and implant stability.
After six months, the implants will be restored with crowns or bridges.
Participants will receive high-quality surgical treatment and close clinical follow-up.

What are the possible benefits and risks of participating?
There may or may not be a direct benefit for each participant, but the findings could improve future dental implant care.
Risks are the same as for standard sinus lift surgery, including swelling, bruising, temporary

discomfort, or sinus complications. These are usually mild and manageable with medication and proper follow-up.

Where is the study run from?
The University of Medical Sciences of Havana, Faculty of Dentistry, Cuba.

When is the study starting and how long is it expected to run for?
April 2024 to September 2024

Who is funding the study?
The ARDEC Academy, Italy.

Who is the main contact?
Dr. Daniele Botticelli, daniele.botticelli@ardec.it

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Maxillary sinus floor elevation: implant placement with and without grafting materials. a randomized controlled clinical trial

Acronym
GRAFT-FREE

Study objectives
Primary aim
To compare the clinical and radiographic outcomes of maxillary sinus floor elevation performed with and without the use of grafting materials when dental implants are placed simultaneously.

Study question
Does sinus floor elevation without grafting material result in clinical and radiographic outcomes comparable to those achieved when grafting material is used?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/04/2024, University of Medical Science of Havana Ethics Committee (Calle 146 # 3102, Playa, La Habana, La Habana, 3102, Cuba; +53 53852670; joaquinurbizo@infomed.sld.cu), ref: 2024/03

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Atrophic maxilla

Interventions
Participants will be randomly allocated into two parallel groups using sealed opaque envelopes prepared by an investigator not involved in surgery.

Test group: Sinus floor elevation without grafting material
Participants in this group will undergo lateral window maxillary sinus floor elevation. After lifting the sinus membrane, no grafting material will be placed in the elevated space.
Dental implants will be inserted simultaneously, ensuring a 3–4 mm apical protrusion into the elevated sinus cavity. Healing abutments will be placed for submerged healing. Standard postoperative medication will be prescribed, and sutures will be removed after approximately two weeks.

Control group: Sinus floor elevation with collagenated xenograft
Participants in this group will undergo the same lateral window sinus elevation procedure. After membrane elevation, the space will be filled with a collagenated xenograft.
Implants of the same type and dimensions will be placed simultaneously, also protruding 3–4

mm beyond the sinus floor. A cortical lamina will be positioned over the access window in both groups. Healing abutments will be placed, and postoperative care will follow the same protocol.
Common procedures for both groups
Local anaesthesia will be administered.
A bony window of approximately 8 mm × 10 mm will be prepared and displaced inwards along with the elevated sinus membrane.
Implants will be placed following manufacturer instructions.
A submerged healing period of six months will be allowed before prosthetic restoration with crowns or bridges.
Follow-up CBCT scans will be taken at baseline, 7–10 days postoperatively, 6 months, and 1 and 3 years.
Clinical examinations, including plaque index, bleeding on probing, and probing depth, will be performed at follow-up visits.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Amount of new bone formation in the elevated sinus area measured using linear and/or volumetric measurements of new hard tissue around the implant (mesial, buccal, distal, and palatal aspects) assessed on CBCT scans at baseline, 6 months, 1 year, and 3 years after surgery

Key secondary outcome(s)
1. Implant survival measured using the presence or absence of implant loss, assessed clinically and radiographically according to standard implant survival criteria at at prosthesis delivery, 1 year, and 3 years after loading

2. Implant stability measured using clinical assessment of implant mobility and signs of failure during follow-up visits at prosthesis delivery, 1 year, and 3 years after loading

3. Changes in sinus membrane height and elevated space measured using measurement (in mm) of sinus membrane height and morphology of the elevated space on CBCT scans at 7–10 days, 6 months, 1 year, and 3 years after surgery

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Adults aged 21 years or older
2. Patients requiring oral rehabilitation with implants placed in conjunction with maxillary sinus floor elevation
3. Residual bone height ≤ 6 mm
4. Clinically and radiographically healthy maxillary sinuses
5. Ability to obtain adequate primary implant stability in the residual alveolar bone

Healthy volunteers allowed
Yes

Age group

Mixed

Lower age limit
21 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Presence of any uncontrolled systemic disease
2. Current or past chemotherapy or radiotherapy
3. Smoking >10 cigarettes per day
4. Previous bone regeneration procedures in the area of interest
5. History or presence of maxillary sinus pathology, including:
5.1. Chronic or recurrent sinusitis
5.2. Mucosal cysts or polyps affecting the surgical area
5.3. Ostium obstruction
5.4. Previous sinus surgery
5.5. Sinonasal tumors or structural abnormalities
6. Acute upper respiratory infections at the time of surgery
7. Severe nasal septum deviation compromising sinus ventilation
8. Allergy or contraindication to local anesthetics, antibiotics, or medications required for the procedure
9. Pregnancy or breastfeeding
10. Insufficient oral hygiene or poor compliance expected with follow-up
11. Bruxism or parafunctional habits judged potentially detrimental to implant stability

Date of first enrolment
29/04/2024

Date of final enrolment
04/07/2024

Locations

Countries of recruitment
Cuba

Sponsor information

Organisation
Ardec Academy

Funder(s)

Funder type

Funder Name
Ardec Academy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available