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Testing a new type of dental implant for people with severe bone loss in the upper back jaw

Submission date 07/06/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/06/2025	**Overall study status** Completed	
Last Edited 11/06/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
This study is exploring a new way to help people who have lost a lot of bone in the back part of their upper jaw. Normally, these patients would need a complex surgery called a sinus lift before getting dental implants. This study is testing a different approach using special implants called pterygoid and compressive implants, which can be placed right away without the need for that surgery. The researchers want to see how successful this method is after one year, how much pain it causes, and whether it affects the health of the gums.

Who can participate?
People can take part in the study if they have at least 4 mm of bone width in the premolar area of their upper jaw, and if a specific part of their sinus is located in front of the second premolar.

What does the study involve?
Participants will receive dental implants under local anesthesia. The dentist will make a small cut in the gum, place the implants in the premolar and pterygoid areas, and then stitch the area closed. The implants must be placed with a certain amount of pressure to be included in the study. The researchers will follow up with participants for one year to check how well the implants are working, how much pain they experience, and how their gums respond.

What are the possible benefits and risks of participating?
The main benefit is that participants may receive a full set of upper teeth without needing more invasive surgery. However, as with any dental procedure, there are risks such as pain, swelling, or implant failure. The study will monitor these closely.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
September 2022 to September 2025.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Mazen Zenati, mazenzenati@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of Immediate Loading Using Multi Units compressive and pterygoid one piece implants with severe posterior maxillary atrophy

Study objectives
1. Pterygoid implants will be sufficient and successful.
2. Pterygoid implants will serve as an alternative to external sinus lifts.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/04/2025, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, 00258, Syria; +963 1133923192; ap.srd@damascusuniversity.edu.sy), ref: DN-150425-H25

Study design
Interventional with one group (before-and-after study) no control group one-center study and single-blinded (statistician)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe bone deficiency in the posterior region of the maxilla

Interventions
The participants will be treated under local anesthesia by using lidocaine with epinephrine 1: 80,000. An incision will be made along the crest, and a full-thickness flap will be elevated. Implants will be placed in the premolars and pterygoid regions.
Pterygoid and premolar implants should attain an insertion torque of at least 45 Ncm to be included in the study. Suture the incision using 4/0 nylon sutures with a reversed cutting needle.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Insertion torque using ratchet (at baseline)
2. Pain levels using VAS (daily in the first 7 days)
3. Plaque Score and Gingival Index using Periodontal probe (after 7 days, 3 months, 6 months, 9 months, and 12 months)

Key secondary outcome(s))
Implant success after one year using a periodontal probe

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Presence of bone width 4 mm in premolar area.
2. Inferior corner of the anterior wall of the sinus positioned anterior to the second premolar.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

70 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Patients with bruxism and/or clenching.
2. Presence of systemic uncontrolled diseases that could represent a general contraindication to put implants.
3. Ongoing maxillary radiation therapy.
4. Active chemotherapy.

Date of first enrolment
01/01/2023

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Fayez Mansour st, Almazzah
Damascus
Syria
11259

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be publish in the results of the study.

IPD sharing plan summary
Published as a supplement to the results publication