

Comparison of two surgical techniques (osseodensification versus lateral window) for maxillary sinus augmentation

Submission date 02/10/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/12/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dental implants are an excellent treatment option for edentulous patients (missing teeth) with high success rates. Historically, the posterior maxilla (the bone that forms the upper jaw) has been associated with a higher rate of implant failure. In addition to the low bone density, a frequent limitation for implant placement in the posterior maxilla is the reduced residual bone height associated with maxillary sinus pneumatization (increase in sinus volume).

In these extreme cases, there are two possible surgical approaches to elevate the sinus mucosa: the classical lateral window approach or the crestal approach. The lateral window technique was initially developed in the 1970s and is still widely used today. It is a very predictable technique but it is associated with higher patient morbidity (illness). This approach requires a wide surgical flap with vertical releasing incisions, contrary to the crestal approach. This more extensive surgical approach can result in increased pain, face swelling and ecchymosis (discoloration of the skin). In addition, during the preparation of the lateral window, there may be disruption of blood vessels. The potential risk of infection is also higher compared to the crestal approach.

Later, in 1994, a new technique for maxillary sinus elevation through the crestal approach using osteotomes (surgical dental instruments) was suggested. This crestal approach is less surgically invasive, though the repeated impact of a hammer for the progression of osteotome is very traumatic with potential unintentional displacement, fracture or side effects such as benign paroxysmal positional vertigo (mild to intense dizziness).

In 2015, a new concept of implant site preparation termed osseodensification was described. This technique recommends the use of burs specially designed to rotate in a non-cutting mode, counterclockwise at 800 to 1200 rpm, for bone densification through compaction autografting. The burs are dual-action and can also be used in cutting mode (clockwise direction). Through this technique, it is possible to expand the bony crest, creating a layer of compacted bone along the implant bed walls. Since it "pushes" the bone instead of removing it, osseodensification has the capacity to prepare the implant site while elevating the sinus membrane with lower morbidity than the classical technique.

In 2018, a study showed osseodensification allowed sinus elevation in cases with residual bone height as low as 2 mm, without the disadvantages inherent to the lateral window technique and the osteotome technique. The main advantages of osseodensification compared to osteotomes

are: it is substantially less traumatic for the patient (since it is not necessary to use a hammer to penetrate the cortical of the maxillary sinus); it allows greater increases in height and it can also be used with high predictability in cases with oblique sinus floor. In addition, osseodensification has the inherent advantage of all the crestal approach techniques – the preservation of the buccal bone wall.

The aim of this study is to compare the osseodensification technique with the classical lateral window technique for maxillary sinus elevation in cases with residual bone height less than 5 mm.

Who can participate?

Patients aged 22 or older with at least one tooth missing in the posterior maxilla and reduced residual bone height

What does the study involve?

Patients will be randomly allocated to surgery with osseodensification or the lateral window technique. With the exception of the surgical technique used, all other treatment will be similar for both groups. Patients will be followed up for 6 months after surgery and until the implants are loaded with the final restoration. Pain perception is measured during the first week after surgery.

What are the possible benefits and risks of participating?

The risks of participating in the study are the risks inherent to the surgical procedure itself, which patients would need in any case.

Where is the study run from?

Egas Moniz University Dental Clinic (Portugal)

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

October 2020 to August 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

João Gaspar

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

EM01901

Study information

Scientific Title

Maxillary sinus elevation through the crestal approach with osseodensification versus the lateral window technique

Acronym

DENSINUS

Study objectives

In maxillary sinus elevation through the crestal approach, osseodensification provides a lower pain perception and quality of life impact than the lateral window technique.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/02/2020, Egas Moniz Ethics Committee, Cooperative de Ensino Superior Egas Moniz (Comissão de Ética Egas Moniz, Campus Universitário, Quinta da Granja, Monte de Caparica, 2829-511, Caparica, Portugal; +351 (0)212 946 768; iuem@egasmoniz.edu.pt), ref: 859

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Reduced bone height in the posterior maxilla (1-4 mm)

Interventions

Participants will be randomized to test or control treatment (osseodensification versus the lateral window technique) based on computer-generated random codes. The allocation will be hidden from the surgeon by opaque envelopes to be opened right before the surgical procedure. With the exception of the surgical technique used, all methodology will be similar for both groups. Patients will be followed up for 6 months after surgery and until the implants are loaded with the final restoration.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Pain perception measured using the Visual Analogue Scale during the first week after surgery

Key secondary outcome(s)

1. Implant insertion torque measured by manual torque wrench immediately after implant placement
2. Implant Stability Quotient (ISQ) obtained using resonance frequency analysis (RFA) measured by specific device Osstell® immediately after implant placement
3. Quality of life measured using the Oral Health Impact Profile 14 translated in Portuguese during the first week after surgery
4. Implant osseointegration success rate measured using clinical examination at 6 months after surgery
5. Patient registration of analgesic medication usage during the first week after surgery

Completion date

31/08/2022

Eligibility**Key inclusion criteria**

1. Adults aged 22 or older
2. Systemically healthy, without active periodontal disease (gingivitis or periodontitis) or peri-implant disease (mucositis or periimplantitis) in implants already present
3. Non-smokers
4. Absence of tooth in the posterior maxillary and reduced bone height (1-4 mm of residual bone), with the need for maxillary sinus elevation for implant rehabilitation
5. Minimum crestal bone width of 6 mm
6. No temporomandibular dysfunction
7. Remaining teeth in sound condition
8. Appropriate interocclusal space for implant rehabilitation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Pregnancy
2. Smokers
3. History of alcoholism or drug abuse during the past 5 years
4. Hypertension or uncontrolled diabetes
5. Pathology of the maxillary sinus
6. Temporomandibular pathology
7. Patients with malignant tumors
8. Patients taking steroids daily or taking bisphosphonates
9. Patients with a history of chemotherapy or radiation therapy in the last 24 months

Date of first enrolment

01/11/2020

Date of final enrolment

01/04/2021

Locations**Countries of recruitment**

Portugal

Study participating centre

Egas Moniz - Cooperativa de Ensino Superior, CRL

Campus Universitário, Quinta da Granja

Monte de Caparica

Almada

Portugal

2829-511 Caparica

Sponsor information**Organisation**

Egas Moniz Cooperativa de Ensino Superior - CRL

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data will be stored in the Egas Moniz University repository named Repositório Egas Moniz (<http://comum.rcaap.pt/handle/10400.26/4758>).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/11/2023	05/12/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes