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

Submission date
02/10/2020

Recruitment status
No longer recruiting

Registration date
08/10/2020

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 burrs 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
17/10/2020

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

Age group
Adult

Sex
Both

Target number of participants
20

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

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Sponsor type
University/education

Website
https://www.egasmoniz.com.pt/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The aim is to publish the full protocol and consequently the results of the trial.

Intention to publish date
31/12/2023

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