

Maxillary sinus augmentation using different osseodensification protocols: a retrospective study with 3-year follow-up

Submission date 24/09/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/10/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/10/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The rehabilitation of atrophic jaws may require sinus floor elevation procedures before or simultaneously with implant placement. Several surgical procedures have been documented for maxillary sinus elevation to overcome this bone resorption, and more recently, conservative and minimally invasive protocols using the osseodensification (OD) technique have been described. This study aims to determine the relationship between Insertion torque (IT) and resonance frequency analysis (RFA) on the day of implant placement. And how the ISQ varied over 36 months of follow-up.

Who can participate?

Patients at least 18 years old with healed edentulous sites in the posterior maxilla with residual bone height between 2 and 8 mm to facilitate the placement of implants requiring sinus grafting procedures

What does the study involve?

The study involves the use of a novel osseous technique in the rehabilitation of atrophic maxillae.

What are the possible benefits and risks of participating?

The use of osseodensification technique differs from other maxillary sinus elevation techniques, which use subtractive instrumentation method to perform the implant bed to the desired diameter, increasing the risk of perforation of the maxillary sinus membrane.

Where is the study run from?

Cooperativa de Ensino Superior Politécnico e Universitário (Portugal)

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

February 2019 to February 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Sinus floor elevation using osseodensification protocols I, II and III: a retrospective study with 36 months follow-up

Study objectives

To determine the relationship between insertion torque (IT) and resonance frequency analysis (RFA) on the day of implant placement, and how the implant stability quotient (ISQ) varied over 36 months of follow-up.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 05/02/2019, Ethics Committee of the University Institute of Health Sciences (Rua Central de Gandra, Gandra, 4585-116, Portugal; +351 (0)224 157 100; sec.ce@cespu.pt), ref: 02/CE-IUCS/2019

Study design

Retrospective observational study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Dental implant stability

Interventions

The participants provided their informed consent after being thoroughly enlightened about the goal and methods of the study both orally and in writing.

A meticulous clinical examination, an assessment of oral hygiene, and a detailed analysis of the patients' medical and dental histories comprised the initial evaluation of each patient.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Insertion torque (IT) measured using a manual torque wrench (Straumann®, Basel, Switzerland) and resonance frequency analysis (RFA) on the day of implant placement

Key secondary outcome(s)

The implant stability quotient (ISQ) value was recorded as the average of buccal, lingual, mesial, and distal measurements using Osstell® IDX (Osstell, W&H, Gothenburg, Sweden) immediately after implant placement (T1); 1 year after implant placement (T2); 2 years of follow-up (T3); 3 years of follow-up (T4)

Completion date

15/02/2022

Eligibility**Key inclusion criteria**

1. At least 18 years old
2. Healed edentulous sites in the posterior maxilla with residual bone height between 2 and 8 mm to facilitate the placement of implants requiring sinus grafting procedures after prior analysis with Cone Beam computer Tomography (CBCT, New Tom® Go 3D, CEFLA S.C., Imola (BO) Italy)

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

105

Key exclusion criteria

1. Irradiated patients
2. Impaired immune systems
3. Smoking, drug abuse or alcoholism
4. Diabetes
5. Heart disease
6. Bleeding disorders
7. Sinus pathology
8. Previous bone augmentation
9. Past or current usage of steroids or bisphosphonates

Date of first enrolment

06/02/2019

Date of final enrolment

06/02/2022

Locations

Countries of recruitment

Portugal

Study participating centre

University Institute of Health Sciences - IUCS

Rua Central de Gandra

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Sponsor information

Organisation

Cooperativa de Ensino Superior Politécnico e Universitário

ROR

<https://ror.org/00w7bj245>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study are stored in a non-publicly available repository (<https://repositorio.cespu.pt/>)

IPD sharing plan summary

Stored in non-publicly available repository