ISRCTN17397796 https://doi.org/10.1186/ISRCTN17397796

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

Registration date
06/10/2025

Overall study status
Completed

Last Edited
06/10/2025

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
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?
Prof. Marco Câmara, marco.camara@iucs.cespu.pt

Contact information

Type(s)
Public, Scientific

Contact name
Prof Rosana Costa

ORCID ID
https://orcid.org/0000-0003-2462-4734

Contact details
Rua Central de Gandra
Gandra
Portugal
4585-116
+351 (0)914240555
rosana.costa@iucs.cespu.pt

Type(s)
Principal investigator

Contact name
Prof Marco Camara

ORCID ID
https://orcid.org/0000-0002-9551-5407

Contact details
Rua Central de Gandra
Gandra
Portugal
4585-116
+351 (0)914112775
marco.camara@iucs.cespu.pt

Additional identifiers

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

Primary study design
Observational

Study design
Retrospective observational study

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
Gandra
Portugal
4585-116

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