

The effectiveness of a novel osseous densification approach on implants' primary and secondary stability: a clinical trial

Submission date 24/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/04/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/06/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Primary stability in dental implants is crucial for successful bone integration, and factors like the surgical procedure and bone density play key roles in achieving it. The size of the hole drilled, the design of the implant, and the amount of pressure on the bone all affect how stable the implant is.

Insertion torque and the patient's bone density also impact how well the implant stabilizes. Higher insertion torque leads to better stability compared to lower values. Where the jawbone is less dense there may be less contact between the bone and the implant, which can reduce stability. Ensuring there's enough bone during implant preparation is crucial for long-term stability. Secondary stability, which develops over time as the bone remodels around the implant, is also important. A new drilling method called osseodensification increases bone density around the implant, improves primary stability, reduces implant movement during integration and allows for immediate loading in some cases. The aim of this study is to evaluate the effectiveness of osseodensification in low-density bone.

Who can participate?

Patients over the age of 18 years who require at least two dental implants in the upper jaw

What does the study involve?

In order to compare osseodensification and conventional drilling, implants were placed side by side with both techniques and assessed at three different times: at implant placement, 6 months after implant placement, and 1-year follow-up.

What are the possible benefits and risks of participating?

Osseodensification helps increase bone density and boosts the initial stability of the implant. This is important for reducing movements of the implant during integration in low-density bone. Another benefit is that it reduces the size of the holes made during drilling when the drills are taken out.

Where is the study run from?

University Institute of Health Sciences - IUCS Portugal in CESPU - Famalicão clinical unit (Portugal)

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

January 2019 to December 2023

Who is funding the study?

Infante da Camara Dental Institute (Portugal)

Who is the main contact?

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Additional identifiers

Study information

Scientific Title

The effectiveness of osseodensification drilling versus conventional surgical technique on implant stability: a clinical trial

Acronym

Osseodensification

Study objectives

The aim of this study is to evaluate osseodensification effectiveness in low-density bone and assess insertion torque and resonance frequency analysis at three different times:

1. On the day of implant placement (T1)
2. 6 months after implant placement (T2)
3. 1-year follow-up (T3)

Osseodensification provides less invasive surgeries with a lower pain perception and less post-operative morbidity.

Ethics approval required

Ethics approval required

Ethics approval(s)

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

Study design

Clinical trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Dental implant stability in low density bone

Interventions

Osseodensification and conventional drilling in dental implant surgery in type IV bone.

All patients underwent a preliminary assessment that included a careful analysis of their medical and dental histories and a detailed clinical examination. Patients were thoroughly informed, by means of oral and written explanations, about the purpose and procedures of the study, and informed consent was obtained from all participants.

In order to perform a comparison between osseodensification and subtractive conventional drilling, implants were placed side by side with both techniques to establish a comparison in

resonance frequency analysis (RFA) and torque values matched for age, gender and smoking habit.

Insertion torque (IT) and resonance frequency analysis were carried out at three different times: i) surgical phase of implant placement (T1); ii) 6 months after implant placement (T2); iii) 1-year follow-up (T3).

Intervention Type

Procedure/Surgery

Primary outcome(s)

Insertion torque was measured at T1 using a manual torque wrench (Straumann®) and the implant stability quotient (ISQ) was registered as the average of the buccal, lingual, mesial and distal readings using the Osstell® ISQ device (Osstell, W&H, Gothenburg, Sweden)

Key secondary outcome(s)

ISQ measured using the Osstell® ISQ device at 6 months and 1 year after surgery

Completion date

16/12/2023

Eligibility

Key inclusion criteria

1. At least 18 years old
2. Have healed edentulous sites on the posterior maxillae region with at least 3 months postextraction period
3. Need to receive at least two dental implants
4. Have sufficient residual bone volume for implant placement without the need for bone augmentation where the minimum ridge height and width should be ≥ 8 and ≥ 6 mm, respectively

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

Key exclusion criteria

1. Alcoholism
2. Smoking
3. Drug abuse
4. Diabetes
5. Heart disease
6. Bleeding disorders
7. Weakened immune systems
8. Radiation exposure
9. Past or ongoing use of steroids or bisphosphonates
10. Previous bone regenerative or augmentation procedures

Date of first enrolment

06/02/2019

Date of final enrolment

10/03/2019

Locations

Countries of recruitment

Portugal

Study participating centre

University Institute of Health Sciences - IUCS

Rua Central de Gandra

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4585-116

Sponsor information

Organisation

Infante da Camara Dental Institute

Funder(s)

Funder type

Research organisation

Funder Name

Infante da Camara Dental Institute

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/05/2024	19/06/2024	Yes	No