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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

Registration date
02/04/2024

Overall study status
Completed

Last Edited
19/06/2024

Condition category
Oral Health

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See study outputs table

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 measure
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)

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

Overall study start date
15/01/2019

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
120

Total final enrolment
90

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
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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Research organisation

Funder Name
Infante da Camara Dental Institute

Results and Publications

Publication and dissemination plan
Finalised the data collection of 278 implants in 90 patients in T1, T2 and T3, now in statistical analysis.

Intention to publish date
08/06/2024

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