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A new technique for better healing of patients seeking oral rehabilitation with implants

Submission date
11/01/2023

Recruitment status
No longer recruiting

Registration date
05/05/2023

Overall study status
Completed

Last Edited
12/01/2023

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
Not infrequently, certain surgical procedures are required to contribute to successful bone regeneration in the mouth, increasing the level of bone and allowing a better chance for dental implants to be successfully placed. The aim of this study is to assess a new surgical technique with less damage for better healing of patients seeking oral rehabilitation with implants compared with a standard surgical technique.

Who can participate?
Patients aged 21 years and over with some missing teeth requiring surgery to reestablish a certain level of bone inside the mouth for dental implant placement

What does the study involve?
Patients will be randomly allocated to either the new oral surgical technique or the usual technique for bone regeneration of mouth locations that will receive dental implants.

What are the possible benefits and risks of participating?
The possible benefits are the preparation of a local oral site that will be better prepared to receive a dental implant, with the associated risks being those expected in oral surgeries: temporary symptoms and signs of pain, discomfort, swelling, and bleeding.

Where is the study run from?
Egas Moniz Dental Clinic (Portugal)

When is the study starting and how long is it expected to run for?
July 2022 to September 2025

Who is funding the study?
Egas Moniz School of Health and Sciences (Portugal)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CEEM-10-2022

Study information

Scientific Title

The modified cut-back incision technique to attain tension-free primary closure: a randomized controlled clinical trial

Acronym
mCASTing

Study objectives
This new technique, named modified-cutback advancement surgical technique (mCAST), has fewer complications compared to the periosteal releasing incision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2022, Egas Moniz Ethics Committee (Campus Universitário, Quinta da Granja Monte da Caparica 2829-511, Almada, Portugal; +351 (0)212946767, iuem@egasmoniz.edu.pt), ref: 1117/2022

Study design
Prospective randomized controlled multi-arm parallel-group double-blinded clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Partially edentulous patients requiring guided bone regeneration

Interventions
Each participant will be assigned in ascending order at the enrolment visit. Patients will be randomly assigned in a 1:1 ratio to either the test group (mCAST) or the control group (classic periosteal releasing incision) using an online randomization tool (https://www.randomizer.org/). Allocation concealment will be done with opaque envelopes, which will be opened by the surgeon immediately after the procedure. The sequence of envelopes will be done, a priori, by a non-involved researcher.

mCAST:
1. A crestal, slightly vestibular incision is performed in the area of augmentation
2. One or two vertical releasing incisions are performed, two teeth from the defect, in a wide manner, to make the base of the flap as wide as possible
3. A full-thickness flap is raised
4. After performing the augmentation procedure, cut-back incisions are performed at 60° towards the centre of the flap, thereby releasing the muscle tension. Depending on the amount of advancement necessary these cut-back incisions can be prolonged
5. Horizontal mattress sutures (dense polytetrafluoroethylene [d-PTFE]) are used to stabilize the flap
6. Suturing is started crestally and thereafter the releasing incisions are sutured starting apically

Intervention Type

Procedure/Surgery

Primary outcome(s)
Flap advancement measured in mm using a UNC 15 periodontal probe. The flap was extended with minimum tension while the probe was positioned perpendicular to the crest of the ridge and kept parallel to the flap direction The readings should be taken at the mesial, middle, and distal parts of the flap, for each part the advancement measured three times and an average of the three readings is recorded by a single examiner.

Key secondary outcome(s))
Postoperative pain is recorded using the Numerical Rating scale (NRS) and postoperative swelling is recorded using the Visual Analogue Scale (VAS). Both scores are recorded for 7days postoperatively and are collected from the patients on the suture removal visit.
Postoperative swelling is scored as follows:
1. None (no swelling)
2. Mild intraoral swelling confined to the surgical zone
3. Moderate intraoral swelling confined to the surgical zone
4. Intense (extraoral swelling spreading beyond the surgical zone)

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Systemically healthy
2.≥21years of age
3. Partially edentulous in the maxilla with 1-2 missing teeth
4. Insufficient ridge width (<5mm), no evidence of vertical loss
5. Adequate soft tissue phenotype (≥2mm and ≤4mm of thickness) and a minimum of 2mm of buccal keratinized tissue
6. Presence of proper inter-arch space for implant prosthesis placement
7. No clinical evidence of active periodontal disease or oral infections

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Sex
All

Key exclusion criteria

1. Systemic conditions that may interfere with the results (e.g., diabetes mellitus)
2. Local pathological defects
3. Unmotivated, uncooperative patients with poor oral hygiene
4. Habits that may jeopardize the implant longevity (e.g., smoking, alcoholism, or para-functional habits)
5. Bone-associated diseases or medication affecting bone metabolism (e.g., bisphosphonates)
6. History of radiation or chemotherapy
7. Inflammatory and autoimmune diseases
8. Shallow vestibular depth
9. History of oral surgery in the region of interest, which might have scared the periosteum

Date of first enrolment
23/01/2023

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
Portugal

Study participating centre
Egas Moniz Dental Clinic
Campus Universitário, Quinta da Granja
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Sponsor information

Organisation
Instituto Superior de Ciências da Saúde Egas Moniz

ROR
https://ror.org/01prbq409

Funder(s)

Funder type
University/education

Funder Name
Egas Moniz School of Health and Sciences

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a publicly available repository.
The name of the repository: Open Science Framework (OSF)
The type of data stored: Excel data
The process for requesting access: full access without request
Dates of availability: on a regular basis
Whether consent from participants was required and obtained: it will be accounted for
Comments on data anonymization: data will be anonymized
Any ethical or legal restrictions: none
Any additional comments: none

IPD sharing plan summary
Stored in publicly available repository