

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

Submission date 11/01/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/05/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/01/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

João Botelho, jbotelho@egasmoniz.edu.pt

Contact information

Type(s)

Scientific

Contact name

Prof João Botelho

ORCID ID

<http://orcid.org/0000-0002-1019-8263>

Contact details

Campus Universitário

Quinta da Granja

Monte da Caparica

Almada

Portugal

2829-511

+351 (0)212946840

jbotelho@egasmoniz.edu.pt

Type(s)

Principal Investigator

Contact name

Prof Andy Temmerman

Contact details

Oude Markt 13, 3000

Leuven

Belgium

3000

+32 (0)16 32 40 10

andy.temmerman@kuleuven.be

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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 7 days 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)

Overall study start date

01/07/2022

Completion date

01/09/2025

Eligibility

Key inclusion criteria

1. Systemically healthy
2. ≥21 years 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

Age group

Adult

Lower age limit

21 Years

Sex

Both

Target number of participants

40

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

Monte da Caparica

Almada

Portugal

2829-511

Sponsor information

Organisation

Instituto Superior de Ciências da Saúde Egas Moniz

Sponsor details

Campus Universitário

Quinta da Granja

Monte da Caparica

Almada

Portugal

2829-511

+351 (0)212946806

jmendes@egasmoniz.edu.pt

Sponsor type

University/education

Website

<https://legacy.egasmoniz.com.pt/pt-pt.aspx>

ROR

<https://ror.org/01prbq409>

Funder(s)**Funder type**

University/education

Funder Name

Egas Moniz School of Health and Sciences

Results and Publications**Publication and dissemination plan**

The researchers intend to publish the results and associated data in a high-impact peer-reviewed journal

Intention to publish date

01/12/2025

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