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Apical access for treatment of peri-implantitis

Submission date 12/11/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/11/2023	**Overall study status** Ongoing	
Last Edited 14/11/2023	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Periimplantitis is a pathological condition that occurs in the tissues surrounding dental implants. It is characterized by inflammation of the peri-implant connective tissue and loss of progressive support bone. The use of membranes has shown superior results to using bone grafts alone in terms go bone gain around implants prior to or simultaneous to their placement. Nonetheless, around implants with infectious diseases, the use of membranes has been associated with a higher risk of membrane and bone graft particle exposure after wound dehiscence or separation of the wound edges, due to a failure of proper wound healing during the healing period. Apical buccal access flap has been described as a surgical procedure with a low rate of complications such as soft tissue dehiscence and exposure of membrane and/or bone substitute particles. The overall objective of this study is to evaluate the clinical effects of an apical buccal access flap combined with a xenogeneic bone graft and a resorbable collagen membrane in the surgical reconstructive therapy of peri-implantitis.

Who can participate?
Patients with implants ≥ 1 year in function and diagnosed with advanced peri-implantitis at ≥ 1 implant

What does the study involve?
The study involves a new surgical design for the treatment of peri-implantitis-related intra-bony defects due to peri-implantitis progression. The hypothesis is that this new surgical design will improve patient perception and will reduce the appearance of complications such as soft tissue dehiscences, and exposure of membranes and bone particles.

What are the possible benefits and risks of participating?
The benefit of participating will be that the participant's peri-implant disease will be treated and arrested. There is no additional risk of participating.

Where is the study run from?
Clínica Ortiz-Vigón dental office (Spain)

When is the study starting and how long is it expected to run for?
May 2023 to December 2025

Who is funding the study?
Arrow Development SL (Spain)

Who is the main contact?
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Public, Scientific, Principal Investigator

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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
Apical buccal access flap for the reconstructive therapy of peri-implantitis-associated intra-bony defects- prospective cohort study

Study objectives
The use of apical buccal access flap (surgical design) combined with a xenograft and resorbable collagen membrane offers an additional benefit in the reconstructive surgical therapy of peri-implant related bony defects in terms of bone gain and reduction of complications, increasing patient satisfaction.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/09/2023, Basque Country Local Ethics Committee (Donostia-San Sebastián, 1, Vitoria, 01010, Spain; +34 945 01 80 00; ceic.eeaa@euskadi.eus), ref: PS2023043

Study design
Prospective cohort study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Dental clinic

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
Advanced peri-implantitis

Interventions

The project will be conducted as a prospective cohort study of 1-year duration in 1 clinical center. 20 systemically healthy patients with implants ≥ 1 year in function and diagnosed with advanced peri-implantitis at ≥ 1 implant will be enrolled.

Surgical procedures will be performed one month after non-surgical periodontal treatment. On the same day of surgical therapy, an antibiotic will be administered for 7 days (amoxicillin 500mg / 7 days / 8 hours). The first apical buccal access flap will be performed. The implant surface will be decontaminated with Labrida® Chitosan Brush and an intra-bony component of the defect will be filled with a xenogeneic bone graft. Finally, a resorbable collagen membrane will be used to cover all the bone grafts and primary wound closure will be obtained with suture. Sutures will be removed 2 weeks after surgical therapy. Clinical examinations will be performed at 4, 12, 24 and 48 weeks after surgical therapy. Maintenance therapy will be realized at 12, 24 and 48 weeks after therapy.

Intervention Type
Procedure/Surgery

Primary outcome measure
Treatment success will be defined as the absence of bleeding on probing (BoP)/pus, probing pocket depth (PPD) ≤5 mm and ≤1 mm recession measured using a periodontal manual probe CP 15 Hu-Friedy at 4, 12, 24 and 48 weeks after surgical therapy

Secondary outcome measures
Clinical assessments:
One calibrated examiner will perform the assessments. The following variables will be assessed at four sites around the implant: Plaque, probing pocket depth (PPD), bleeding on probing (BoP), probing attachment level (PAL) recession (REC). Keratinized mucosa (KM) will be measured in the buccal aspect of each included implant measured using a periodontal manual probe CP 15 Hu-Friedy at baseline, 24 and 48 weeks

Surgical assessments:
1. Defect configuration will be measured by one calibrated examiner in each clinical center to understand how much impact it has on clinical outcomes measured using a periodontal manual probe CP 15 Hu-Friedy at intra-surgically:
2. Osseous defect-related measures / Recording of osseous defect characteristics:
2.1. Defect width (measured in mesial, distal, buccal, and palatal/lingual aspects)
2.2. Distance from implant neck to depth of the osseous defect (measured in mesial, distal, buccal, and palatal/lingual aspects)
2.3. Distance from osseous ridge to depth of the osseous defect (measured in mesial, distal, buccal, and palatal/lingual aspects)

Radiographic assessments:
Radiographic marginal bone level in mesial and distal aspects measured in mm with Image-J® digital software using intra-oral radiographs obtained before surgery (baseline) and at 6- and 12-month re-examinations. Analysis of radiographs will be performed by a specialist. The examiner will be blinded to treatment procedures. The assessment will include defect fill in both follow-up visits.

Volumetric changes:
Linear changes measured using Implant-Studio® digital software at 1, 3 and 5 mm from the mucosal peri-implant margin. Intra-oral scanning will be obtained before surgery (baseline) at 6

months and 12 months of re-examination. Analysis of STL archives will be performed by a specialist. The examiner will be blinded to treatment procedures. The assessment will include volumetric changes after matching the baseline intra-oral scanning, 6 months of intra-oral scanning and 12 months of intra-oral scanning.

Overall study start date
01/05/2023

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years old
2. Peri-implant bone defect ≥ 3mm assessed radiographically
3. PPD ≥ 5mm combined with bleeding on probing or suppuration
4. Intra-surgically, the bone defect must have at least an intraosseous component of 3mm and a width of no more than 4mm implants ≥ 1 year in function

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Treated for peri-implantitis during the previous 6 months
2. Intake of systemic or local antibiotics during the previous 6 months
3. Pregnant patients
4. Systemically unhealthy patients
5. Patients allergic to collagen

Date of first enrolment
01/12/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Spain

Study participating centre
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Sponsor information

Organisation
Arrow Development S.L.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Arrow Development SL

Results and Publications

Publication and dissemination plan

When we reach the total number of patients treated we will follow them for 12months. After we will prepare the manuscript and publish it by the firsts months of 2026 in a high impact journal

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Erik Regidor, erik@ortizvigon.com when the study is finished and during the manuscript submission.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			14/11/2023	No	No