

Apical access for treatment of peri-implantitis

Submission date 12/11/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/12/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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 of 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?
1. Erik Regidor, erik@ortizvigon.com
2. Alberto Ortiz-Vigón, alberto@ortizvigon.com

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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.eaaa@euskadi.eus), ref: PS2023043

Study design

Prospective cohort study

Primary study design

Interventional

Study type(s)

Treatment

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 1 month after non-surgical periodontal treatment. On the same day of surgical therapy, an antibiotic will be administered for 7 days (amoxicillin 500 mg / 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(s)

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

Key secondary outcome(s)

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.

Completion date

01/12/2025

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years old
2. Peri-implant bone defect ≥ 3 mm assessed radiographically

3. PPD \geq 5 mm combined with bleeding on probing or suppuration
4. Intra-surgically, the bone defect must have at least an intraosseous component of 3 mm and a width of no more than 4mm implants \geq 1 year in function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Total final enrolment

15

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**Clinica Ortiz-Vigon**

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Sponsor information

Organisation

Arrow Development S.L.

Funder(s)

Funder type

Industry

Funder Name

Arrow Development SL

Results and Publications

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