

Treatment of gum recession around tooth implants

Submission date 16/07/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/12/2024	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

Gum recession is the process in which the tissue that surrounds the teeth pulls away from a tooth, exposing more of the tooth or the tooth's root. This can cause damage to supporting bone. To repair the damage and prevent further dental problems, a gum tissue graft may be needed.

During the procedure, tissue from the roof of your mouth (palate) is removed and then stitched to the gum tissue surrounding the exposed root. An alternative to using your own tissue, NovoMatrix is an acellular dermal matrix consisting of tissue-engineered porcine material. The aim of this clinical trial is to evaluate the outcomes from performing a graft using the patient's own tissue or NovoMatrix material.

Who can participate?

Adults over 18 years, with receding gums causing bleeding.

What does the study involve?

Participants will be randomly allocated to receive treatment to restore the gum using either the patient's own tissue or using NovoMatrix.

What are the possible benefits and risks of participating?

The main benefit is that patients will see their soft tissue wounds around implants covered. There is no additional risk of participating, these types of surgical interventions are part of daily routine.

Where is the study run from?

Periocentrum Bilbao (Spain)

When is the study starting and how long is it expected to run for?

June 2021 to June 2024

Who is funding the study?

Oral Reconstruction Foundation (Switzerland)

Arrow Development (Spain)

Who is the main contact?

Dr Erik Regidor Correa, erik@ortizvigon.com

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Contact information

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Scientific

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Additional identifiers

Protocol serial number

PS2019001

Study information

Scientific Title

Coverage of buccal soft tissue dehiscences around implants with an acellular dermal matrix and apical buccal access. Randomized clinical trial

Study objectives

The use of acellular dermal matrix in the treatment of buccal soft tissue dehiscences reduces the patient morbidity, surgical intervention time and offers non inferior clinical outcomes

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/03/2021, Ethical Committee of the Basque Country (CEIm de Euskadi [Comité de Ética de la Investigación Clínica con medicamentos] Farmaziako Zuzendaritza / Dirección de Farmacia. Osasun saila / Departamento de Salud. Eusko Jaurlaritza / Gobierno Vasco C/ Donostia-San Sebastián, 1 – 01010 Vitoria-Gasteiz, Spain; +34 945 01 64 59; ceic.eeaa@euskadi.eus), ref: PS2019001

Study design

Prospective randomized clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Buccal soft tissue dehiscences (recessions) around dental implants

Interventions

Surgical intervention: Control group: treatment of buccal soft tissue dehiscences with apical buccal access approach and autologous connective tissue graft. Test group: treatment of buccal soft tissue dehiscences with apical buccal access flap and NovoMatrix.

Randomization: Before the surgical intervention. Each subject will randomly assigned with the assistance of computer software to one of the following groups:

Control group: treatment of buccal soft tissue dehiscences with apical buccal access approach and autologous connective tissue graft.

Test group: treatment of buccal soft tissue dehiscences with apical buccal access approach and NovoMatrix.

Postoperative care: Subjects will receive detailed written and verbal post-operative instruction. Subjects will be instructed to avoid mechanical disturbance of the surgical site for the first week. Oral hygiene instructions included 0.12 chlorhexidine mouth rinses after 24hours and no direct brushing of the surgical site for one week . All subjects will prescribe oral antibiotics.

Azithromycin 250mg 1 per day for 3 days will be the medication of choice. An anti-inflammatory (Enantyum 25mg every 8 hours for 3-5 days) will be prescribed to all subjects.

Follow up visits: 2 weeks (photo and patient questionnaire), 4 weeks (photo and patient questionnaire), 12 weeks (photo and patient questionnaire), 6 months (photo, periapical X-ray, patient questionnaire and intraoral scan for volumetric changes, professional questionnaire), 12

months (photo, periapical X-ray, patient questionnaire and intraoral scan for volumetric changes, professional questionnaire).

Intervention Type

Procedure/Surgery

Primary outcome(s)

The primary outcome will be mean mid-facial recession coverage (mRC) measured as a percentage. Time frame: 6 months and 1 year with an intraoral scanning file (STL) and digital software

Key secondary outcome(s)

1. Esthetic score [Time Frame: 6 months and 1 year] measured using esthetic score measured using numeric values from 0 to 10
2. Patient-reported esthetics [Time Frame: 6 months and 1 year] measured using patient-reported esthetics measured using numeric values from 1 to 5
3. Patient-reported post-operative pain [Time Frame: 2 weeks] measured using patient-reported post-operative pain, based on VAS scale, measured as numbers from 0 to 10.
4. Keratinized tissue (KT) gain [Time Frame: 6 months and 1 year] measured using KT gain measured in mm with a manual periodontal probe
5. Keratinized tissue thickness (KTT) [Time Frame: 6 months and 1 year] measured using KTT gain measured in mm an intraoral scanning file (STL) and digital software
6. Professional-reported esthetics [Time Frame: 6 months and 1 year] measured using blinded examiner reported esthetics measured using numeric values from 1 to 5

Completion date

10/06/2024

Eligibility

Key inclusion criteria

1. Age ≥ 18 years
2. Periodontally and systemically healthy
3. Full-mouth plaque score and full-mouth bleeding score $\leq 20\%$ (measured at four sites per tooth)
4. Correct implant 3-dimensional position or buccal position ≤ 1 mm
5. Buccal soft tissue dehiscence ≤ 4 mm
6. Only osseointegrated implants
7. The patient must be able to perform good oral hygiene

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

28

Key exclusion criteria

1. Contraindications for periodontal surgery
2. Patients pregnant or attempting to get pregnant
3. Malpositioned implant
4. Soft tissue dehiscence (STD) >4 mm
5. Existing of peri-implantitis
6. Severe bone loss (≥ 4 mm)
7. Moderate-severe interproximal bone loss (implant fixture level to the alveolar bone >3 mm)
8. Moderate-severe papilla height loss (Nordland and Tarnow implant papillae index >1)
9. Previous mucogingival surgery around the implant within the past six months or implant placement at the surgical site less than six months prior
10. Smoking more than 10 cigarettes a day

Date of first enrolment

01/08/2021

Date of final enrolment

01/08/2023

Locations

Countries of recruitment

Spain

Study participating centre

Periocentrum Bilbao

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Sponsor information

Organisation

Oral Reconstruction Foundation

ROR

<https://ror.org/0178qr782>

Organisation

Arrow Development

Organisation

ThinkingPerio Research

Funder(s)

Funder type

Research organisation

Funder Name

Oral Reconstruction Foundation

Funder Name

Arrow Development

Funder Name

ThinkingPerio Research

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			20/07/2021	No	No