ISRCTN75484225 https://doi.org/10.1186/ISRCTN75484225

Treatment of gum recession around tooth implants

Submission date	Recruitment status	[X] Prospectively registered
16/07/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/07/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/12/2024	Oral Health	[_] 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
Dr Alberto Ortiz-Vigón Carnicero, alberto@ortizvigon.com

Contact information

Type(s)
Scientific

Contact name
Dr Erik Regidor Correa

ORCID ID
https://orcid.org/0000-0003-3338-6379

Contact details
Alameda Urquijo nº 2 - 7ª planta
Bilbao
Spain
48008
+34 944158902
erik@ortizvigon.com

Type(s)
Scientific

Contact name
Dr Alberto Ortiz-Vigón Carnicero

ORCID ID
https://orcid.org/0000-0002-1863-5907

Contact details
Alameda Urquijo nº 2 - 7ª planta
Bilbao
Spain
48008
+34 944158902
alberto@ortizvigon.com

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

Primary study design
Interventional

Study design
Prospective randomized clinical trial

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 clorhexidine 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 ≤ 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 (≥4mm)
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
Alameda Urquijo nº 2 - 7ª planta
Bilbao
Spain
48008

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