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Refining bone structure for gum defects around teeth

Submission date	Recruitment status	[_] Prospectively registered
23/11/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/11/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2024	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Gum problems in the back of your mouth can come with issues like not enough protective gum tissue, shallow spaces between your teeth and cheeks, and unusual tissue connections. When all these oral issues happen at once, fixing them and getting good results for covering exposed tooth roots becomes more challenging. So, it's crucial to carefully choose the right surgical method.

While methods like moving existing tissue and creating a tunnel are well-supported by science, a different technique called apical buccal access (ABA) might have some unique benefits. Adding a special kind of biomaterial called allogeneic cortical lamina to the ABA technique could be a promising solution for combined bone and gum problems.

Our main goal in this study is to check how well this approach works for treating multiple gum recessions.

Who can participate?
Adults over 18 years, with several recessions in the gums near the cheek, and not enough tough gum tissue or depth between the teeth and cheek to keep things healthy. Also, when we look at a special type of X-ray called CBCT, the outer layer of the bone (cortex) is less than 1mm thick.

What does the study involve?
The study does not involve anything else than the treatment of the osseous-mucogingival defect and the routine follow up visits that we perform with or without participating in the study.

What are the possible benefits and risks of participating?
The benefit is that the osseous-mucogingival defect around their teeth will be treated and there is no risk of participating in the study

Where is the study run from?
CLINICA ORTIZ-VIGON (Spain)

When is the study starting and how long is it expected to run for?
September 2019 to September 2025

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

Who is the main contact?
Dr Alberto Ortiz-Vigón, alberto@ortizvigon.com
Dr Erik Regidor, erik@ortizvigon.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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 662025988
erik@ortizvigon.com

Type(s)
Public, Scientific

Contact name
Dr Alberto Ortiz-Vigón

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PS2019009

Study information

Scientific Title
Allogeneic cortical lamina with apical buccal access for combined osseous & mucogingival defects around multiple adjacent teeth

Study objectives
The apical buccal access technique combined with a demineralized cortical lamina without modifying the critical zone of the interdental papillae allows adequate root coverage results without compromising vascularization, while achieving an increase in keratinized gingiva and depth, vestibule reducing post-surgical morbidity and intervention time.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/05/2019, Basque Country local ethics committee (Donostia-San Sebastián, 1, Vitoria, 01010, Spain; +34 945 019 303; ceic.eeaa@euskadi.eus), ref: PS2019009

Study design
Prospective cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple vestibular gingival recessions with insufficient keratinized gingiva or vestibule depth for proper maintenance of the teeth. In addition, it must present a cortex less than 1mm on the CBCT.

Interventions
First patients coming to periodontal maintenance will be examined. Patients with combined osseous-mucogingival defects around multiple adjacent teeth will be identified in a preliminary exam. In this visit, clinical and radiographic variables will be recorded. Then, the surgical procedure will be performed with allogeneic bone lamina and apical buccal access surgical design. Sutures at 2 weeks will be removed. Follow up visits will be at 3, 6 and 12 months. Periodontal maintenance therapy will be conducted at 6 and 12 months and during these visits, clinical and radiographic variables will be recorded. After 12 months of follow up the study will be finished.

Surgical procedure:
Buccal apical access flap for the treatment of gingival recessions with Cortiflex® demineralized cortical lamina. DIZG Cortiflex® (allogeneic cortical lamina). In combination with DIZG Cortico-Cancellous Particulate (Cortico-Cancellous Bone 50:50 FDBA Particulate Allograft) for horizontal bone augmentation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Average recession reduction measured with manual periodontal probe (Hu-Friedy CP15) at baseline, 6 and 12 months. Furthermore, intraoral scan will be recorded.

Key secondary outcome(s))
1. Complete root coverage measured with manual periodontal probe (Hu-Friedy CP15) at baseline, 6 and 12 months. Furthermore, intraoral scan will be recorded.
2.. Changes in keratinized mucosa measured with manual periodontal probe (Hu-Friedy CP15) at baseline, 6 and 12 months. Furthermore, intraoral scan will be recorded.
3. Changes in vestibulum depth measured with manual periodontal probe (Hu-Friedy CP15) at baseline, 6 and 12 months. Furthermore, intraoral scan will be recorded.
4. Average reduction of the recession measured with manual periodontal probe (Hu-Friedy CP15) at baseline, 6 and 12 months. Furthermore, intraoral scan will be recorded.

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Informed consent after detailed information
2. Adults at least 18 years of age
3. Patients with multiple recessions (≥2 teeth) type III with shallow vestibule depth and keratinized gingiva that do not include molars, and may be in the upper and lower jaw.
4. Patients who, in the three-dimensional x-ray, present a vestibular cortex less than 1mm thick
5. Healthy or periodontally treated patients
6. Systemically healthy or with completely controlled or stabilized diseases. A medical report will be requested that confirms the stabilization of the specific disease.
7. General plaque control (FMPS) ≤ 25% (O'Leary et al 1972)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
90 years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Pregnant or breastfeeding patients
2. Uncontrolled medical conditions
3. Uncontrolled periodontal disease
4. Patients treated with any medication that affects gingival conditions such as causing hyperplasia
5. Alcohol and/or drug abuse
6. Do not sign informed consent
7. Despite having root recessions, it presents a cortex greater than 1mm in the 3D CBCT and therefore another type of technique is considered necessary.

Date of first enrolment
01/09/2019

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
Spain

Study participating centre
Clínica Ortiz-Vigón
C/ alameda urquijo 2 7º floor
Bilbao
Spain
48008

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
Not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			24/11/2023	No	No