

# Refining bone structure for gum defects around teeth

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<b>Registration date</b> 28/11/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/03/2024	<b>Condition category</b> 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 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?  
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## Contact information

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Cohort study

**Study setting(s)**

Dental clinic

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**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 measure**

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

### **Secondary outcome measures**

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.

### **Overall study start date**

01/09/2019

### **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 ( $\geq 2$  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)  $\leq 25\%$  (O'Leary et al 1972)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

90 Years

**Sex**

Both

**Target number of participants**

15

**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**

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## Sponsor information

### Organisation

Arrow Development S.L.

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### Sponsor type

Research organisation

## Funder(s)

### Funder type

Industry

### Funder Name

Arrow Development SL

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

01/09/2025

### 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?
<a href="#">Protocol file</a>			24/11/2023	No	No