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Influence of tissue graft substitute in the treatment of gingival recessions

Submission date 12/08/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/08/2024	**Overall study status** Ongoing	
Last Edited 02/10/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
The treatment of multiple adjacent gingival recessions in teeth with interproximal attachment loss is probably one of the most challenging situations in the field of periodontal plastic surgery. Furthermore, usually, this clinical condition is combined with reduction of keratinized tissue and vestibulum depth. Several surgical approaches have been proposed to treat these recessions with heterogeneous results. Recently, scientific literature has reported that an apical buccal access flap combined with an autologous connective tissue graft could be a successful surgical design. Nevertheless, the quantity of connective tissue grafts for multiple adjacent gingival recessions is high and the use of different substitutes as acellular dermal matrixes is associated with lower patient morbidity. The study aims to evaluate the clinical effects and patient perceptions of the use of an acellular dermal matrix combined with apical buccal access flap in terms of complete root coverage, reduction of the recession or percentage of coverage and changes in volumetric terms, keratinized tissue width and thickness and patient perception and reported measurements.

Who can participate?
Adult patients presenting multiple adjacent gingival recessions with interproximal attachment loss

What does the study involve?
In this study, participants are randomly assigned to different treatment groups to test whether a new treatment works better than the current one or a placebo. The study follows the participants over time to see how they respond and has a follow-up of 12 months. Participants will be treated with an apical buccal flap and acellular dermal matrix (test) or autologous connective tissue graft (control).

What are the possible benefits and risks of participating?
Benefits
1. Advancement of Medical Knowledge:
Participation in this study will contribute to the growing knowledge regarding the efficacy and safety of different techniques for treating gingival recessions. This can lead to improved treatment protocols and better patient outcomes in the future.

2. Access to Innovative Treatments:
Participants may receive a novel treatment with a soft tissue substitute that could offer benefits such as reduced morbidity, less postoperative discomfort, and quicker recovery times compared to traditional connective tissue grafts.

3. Close Monitoring and Care:
Being part of a clinical study often entails regular and comprehensive follow-up care. Participants will benefit from detailed monitoring of their oral health, which may result in earlier detection and management of any potential complications.

4. Improvement of Aesthetic and Functional Outcomes:
Participants may experience improved aesthetic and functional outcomes, including enhanced gingival contour and coverage, as well as potential reductions in tooth sensitivity.

Risks
1. Uncertain Outcomes:
The nature of the soft tissue substitute means that its long-term effectiveness and safety are not fully established. Participants may face a higher risk of graft failure, insufficient root coverage, or other unforeseen complications.

2. Surgical Risks:
As with any surgical procedure, there are inherent risks including bleeding, pain, swelling, and infection. These risks are present in both the experimental and control groups, though they may vary in severity depending on the treatment received.

3. Postoperative Discomfort:
The soft tissue substitute, while potentially less invasive, may still result in postoperative discomfort. Participants undergoing the connective tissue graft may experience more significant discomfort due to the harvesting of tissue from the palate.

4. Study-Specific Protocol Risks:
Adherence to study protocols may require participants to follow strict postoperative care instructions, attend multiple follow-up visits, and undergo additional assessments, which could be time-consuming and burdensome.

Where is the study run from?
Clínica Ortiz-Vigón Periocentrum Research Bilbao

When is the study starting and how long is it expected to run for?
January 2023 to December 2027

Who is funding the study?
Arrow Research Development SL

Who is the main contact?
Mr Aitor Rilo, aitor@ortizvigon.com

Contact information

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Scientific

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Study information

Scientific Title
Treatment of multiple adjacent gingival recessions with interproximal attachment loss with an acellular dermal matrix and apical buccal access. Randomized clinical trial

Study objectives
The use of an acellular dermal matrix in the treatment of multiple adjacent gingival recessions in teeth with attachment loss reduces the patient morbidity, and surgical intervention time and offers non-inferior clinical outcomes in terms of complete coverage of the recession, percentage of coverage or reduction of the recession, increase of keratinized tissue thickness and width and volumetric changes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/07/2023, 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, Vitoria-Gasteiz, 01010, Spain; +34 945 01 64 59; ceic.eeaa@euskadi.eus), ref: PS2023042

Primary study design
Interventional

Study design
Prospective randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple adjacent gingival recessions with interproximal attachment loss

Interventions
The study will be a prospective randomized clinical trial with a follow-up of 12 months. Patients presenting multiple adjacent gingival recessions with interproximal attachment loss (RT3 from Cairo et al 2011 Classification) will be treated with an apical buccal flap and acellular dermal matrix (test) or autologous connective tissue graft] (control) randomly. The randomization and treatment allocation to the experimental and control groups will be performed using sealed envelopes.

- Control group: treatment of gingival recessions with apical buccal access flap/ approach and autologous connective tissue graft].
- Test group: treatment of gingival recessions with apical buccal access flap/approach and acellular dermal matrix

Intervention Type
Procedure/Surgery

Primary outcome(s)
Complete coverage of the recession measured using a periodontal probe, intra-oral scanning file (STL) and digital software overlapping different files at 6 and 12 months

Key secondary outcome(s)
1. Esthetic score measured using using numeric values from 0 to 10 at 6 months and 1 year
2. Patient-reported postoperative pain measured using a VAS scale at 2 weeks
3. Patient satisfaction measured using a VAS scale at 1 year
4. Keratinized tissue width (KTW) gain measured in mm using a manual periodontal probe at 6 months and 1 year
5. Keratinized tissue thickness (KTT) measured in mm using an intra-oral scanning file (STL) and digital software at 6 months and 1 year
6. Professional-reported esthetics measured by a blinded examiner using numeric values from 1 to 5 at 6 months and 1 year

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Patients ≥ 18 years old
2. Periodontally and systemically healthy
3. Patients presenting multiple (at least 2) adjacent gingival recessions with interproximal a9achment loss - RT3 gingival recessions from Cairo et al 2011 Classification, including gingival recessions in upper and lower maxilla from premolar to premolar area.
4. Full mouth plaque score and full mouth bleeding score ≤ 20% (measured at four sites per tooth)
5. The patient must be able to perform food oral hygiene

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Contraindications for periodontal surgery or systemically unhealthy
2. Patients pregnant or attempting to get pregnant
3. Uncontrolled periodontal disease
4. Gingival recessions in the molar area
5. Single gingival recession

Date of first enrolment
28/08/2024

Date of final enrolment
21/03/2027

Locations

Countries of recruitment
Spain

Study participating centre
Clínica Ortiz-Vigón Periocentrum Research Bilbao
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Sponsor information

Organisation
Arrow Research Development SL

Funder(s)

Funder type
Industry

Funder Name
Arrow Research 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 Mr Aitor Rilo, aitor@ortizvigon.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			19/11/2024	No	No