ISRCTN10772194 https://doi.org/10.1186/ISRCTN10772194

Gum recession treatment with two different approaches

Submission date	Recruitment status	[_] Prospectively registered
18/01/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/01/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2024	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Gum disease is a very common condition where the gums become swollen, sore or infected. If untreated this can lead to receding gums (recession) that can expose the root of the tooth. This study aims to compare two treaments for recession (a tunneled technique or a buccal apical access flap).

Who can participate?
Adults over 18 years, with receding gums at multiple locations

What does the study involve?
Participants will be randomly allocated to receive one of the two treatments under investigation. Follow up will be for 1 year.

What are the possible benefits and risks of participating?
The benefit of participating should be that the patient will reduce their gingival recession and with this improvement, their sensibility and their aesthetic appearance will be improved, they will get a proper access to self-oral proper hygiene and they will reduce the risk of periodontal disease progression.
There is no attached risk from participating in the study. The risk is the same of surgical procedures as bruising, edema, redness, slight bleeding and reasonable pain or discomfort.

Where is the study run from?
ThinkingPerio Research (Spain)

When is the study starting and how long is it expected to run for?
August 2018 to August 2023

Who is funding the study?
Investigator initiated and funded

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

Contact information

Type(s)
Public

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

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
+34 944 15 89 02
alberto@ortizvigon.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

2018063

Study information

Scientific Title
Mucogingival treatment of class III gingival recessions with apical buccal access flap: randomized clinical trial

Acronym
ABA

Study objectives
Apical buccal access approach without modifying the critical area of interdental papilla allows better results of root coverage without compromising vascularization, while achieving an increase of keratinized mucosa and vestibulum depth. Tunnel approach, as control approach in the study, its a good option in terms of root coverage but its associated to reducing vestibulum depth. Furthermore, the apical buccal access approach is associated with lower patient morbidity and greater satisfaction due to the location of the incision, far from the area to be treated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/08/2018, 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; +34 945 01 64 59; ceic.eeaa@euskadi.eus), ref: PS2018063

Study design
Multicenter randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Miller Class III multiple gingival recessions

Interventions
The test group will be treated with apical buccal access approach and connective tissue graft

Control group will be treated with tunnel approach and connective tissue graft

The intervention will we realized in a single session and the follow-up will be 12 months after the surgical procedure. Randomization will be carried out by means of 5 blocks by a sequence generated by the computer.

Randomization:
The randomization will be carried out prior to the procedure by the statistician (EGT) but without the operator (AOV) knowing the technique that he will have to use until the moment of the first incision. Assignment to the test or control group is done using a block-based computer algorithm after the inclusion of the patient and prior to the surgical intervention. The randomization treatment assignment is disclosed at the time of the surgical procedure. Each patient included in the study has the same probabilities as the others of being assigned to the test or control group.

Surgical procedure:
On day 0 the first surgical procedure will be performed, which will include the following phases:
The stopwatch is activated to measure the intervention time
Local anesthesia
Depending on the randomization: incision to the bottom of the vestibule in a semilunar shape / preparation of the beds that will receive the graft by tunneling and connecting all the recessions through the tunnel without making incisions
Elevation of a full thickness flap to create a vascular bed for the graft
anesthetize the posterior palatal area (distal to the premolars) and take a graft that is the length and width of the treated area and is between 1-2mm thick
The stabilization of the grafts will be carried out by means of a dento-anchored suture to the contact points of the previously splinted teeth to be able to suture this way.
Photographic documentation before the incision, after preparation of the bed, after obtaining the graft and after suturing.
Record of the duration of surgery.
Recording the perception of the treatment by the patient with a visual analog scale
Post-surgical instructions

Post-surgical care:
After surgery, the patient will be offered the possibility of taking analgesics / anti-inflammatories (Enantyum 25 mg every 8 hours) and 0.12% chlorhexidine rinses (2 per day) for two weeks. Patients over 65 years of age and those who regularly take antiplatelet / anticoagulation medications will be offered to take a proton pump inhibitor (Omeprazole 20 mg once daily) for prophylaxis of gastrointestinal bleeding.
Patients will be instructed to carefully brush the intervened area for 4 weeks and two weeks after the surgical procedure, the sutures will be removed after taking photographic records, the perception of treatment by the patient and the amount of analgesics consumed and for how long.

Follow up:
2 weeks: intra-oral photographs, healing, adverse events, and VAS patient questionnaire along with suture removal
12 weeks: intra-oral photographs
24 weeks: intra-oral photographs, intra-oral radiographs, volumetric scan, measurements of recessions, amount of keratinized gingiva and vestibular depth. VAS patient questionnaire, professional satisfaction questionnaire, maintenance and completion of the study
52 weeks: intraoral photographs, intraoral radiographs, volumetric scan, measurements of recessions, amount of keratinized gingiva and vestibular depth. VAS patient questionnaire, professional satisfaction questionnaire, maintenance and completion of the study

Intervention Type
Procedure/Surgery

Primary outcome(s)
Recession reduction measured by a manual periodontal probe and intraoral scanning at baseline, 6 months and 12 month

Key secondary outcome(s))
1. Complete root coverage measured by a manual periodontal probe and intraoral scanning at baseline, 6 months and 12 months
2. Increased vestibule depth measured by a manual periodontal probe and intraoral scanning at baseline, 6 months and 12 months
3. Keratinized gum augmentation measured by a manual periodontal probe and intraoral scanning at baseline, 6 months and 12 months
4. Volume increase measured by a manual periodontal probe and intraoral scanning at baseline, 6 months and 12 months
5. Time spent on both types of procedures measured in minutes intrasurgically
6. Patient satisfaction with the treatment received and its relationship with pre-surgical expectations measured by a Visual Analogue Scale at baseline, 2weeks, 4weeks, 12weeks, 6months and 12 months
7. Analgesia intake measured taking into account the number of analgesic pills consumption by patient self-report at baseline, 6 months and 12 months
8. Aesthetic satisfaction by the clinical examiner measured by a blinded examiner at 6 and 12 months in order to evaluate the visual satisfaction with obtained outcome

Completion date
02/08/2023

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) class III Miller with shallow vestibulum depth and keratinized mucosa
4. Non-molar teeth
5. Upper and lower jaw
6. Healthy or periodontally treated patients
7. Systematically healthy or with fully controlled or stabilized diseases
8. A medical report will be requested to confirm the stabilization of the specific disease
9. General plaque control (FMPS) ≤25%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Pregnant or breastfeeding patients
2. Uncontrolled periodontal disease
3. Patients treated with any medication that affects gingival conditions such as causing hyperplasia
4. Alcohol and/or drug abuse
5. Not signing informed consent
6. Molar area

Date of first enrolment
01/09/2018

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
Spain

Study participating centre
ThinkingPerio Research
Periocentrum Bilbao
Alameda Urquijo street 2, 7th floor
Bilbao
Spain
48008

Sponsor information

Organisation
ThinkingPerio Research

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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		19/01/2021	04/02/2021	No	No