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Investigating a tissue grafting technique for treatment of gum recession associated with loose teeth

Submission date 19/11/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 11/04/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/08/2022	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
When gums (gingiva) recede, the roots of the teeth are exposed and the teeth can become loose. Gum recession can be treated by surgically moving (grafting) tissue from the mouth to cover the exposed part of the tooth root. There are several techniques of gingival grafting. This study aims to investigate a technique called apical access, which takes tissue from the roof of the mouth (palate).

Who can participate?
Adults who are otherwise healthy, who have gum recession of several adjacent teeth with the teeth becoming loose and who don't have gum disease or have gum disease that has been treated successfully.

What does the study involve?
Dental patients who have noticed discomfort when brushing their teeth, who have experienced progression of gum recession and who have difficulties in accessing the teeth to keep them clean will be offered apical access grafting. All participants in the study will receive the same treatment. Their teeth and gums will be examined and the recession measured before treatment and at 6 and 12 months after treatment.

What are the possible benefits and risks of participating?
The benefit of participating in the study is the reduction of their gingival recessions. Patients receive the same treatment if they do not participate in the study. There is no additional risk for participating in the study compared with receiving the surgery to correct their gum problems outside of the study.

Where is the study run from?
Periocentrum Bilbao (Spain)

When is the study starting and how long is it expected to run for?
January 2016 to December 2017

Who is funding the study?
Periocentrum Research (Spain)

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
001

Study information

Scientific Title
Periapical tunnel access for mucogingival root coverage: a case series

Study objectives
Periapical tunnel access for mucogingival root coverage is associated with lower patient morbidity, adequate root coverage and keratinized tissue gain and a greater vestibulum depth gain

Ethics approval required
Old ethics approval format

Ethics approval(s)

This study does not require ethics approval because it is a routine and habitual technique in those cases in which we have a reduced vestibulum depth associated with low keratinized tissue and gingival recessions

Study design
Observational descriptive case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Multiple gingival recessions type III or Cairo RT2 with a narrow keratinized tissue and a shallow vestibulum

Interventions
Patient receive oral hygiene instructions for at least 2 months before surgery.
As a baseline measurement, a periodontal probe is used to record the length of recession, keratinized tissue and vestibular depth. Intraoral photographs and radiography are also taken.
All surgeries are performed by the same experienced periodontist (Alberto Ortiz-Vigon). An initial semilunar incision is made in the alveolar mucosa. The incision is extended one tooth on either side of the recessions. The flap is elevated with a periostotome to advance it coronally without tension. A connective tissue graft is harvested from the posterior palate by means of a single-incision technique and according to the mesio-distal length of the recessions. The donor site is sutured with a cross-mattress suture. This connective tissue graft is positioned under the flap and the flap is repositioned slightly coronal to the cement-enamel junction, with suspended sutures around the contact points. The apical area is sutured by means of sutures anchored to the periosteum.
Subjects receive detailed written and verbal post-operative instruction. Subjects are instructed to avoid mechanical disturbance of the surgical site for the first week. Oral hygiene instructions include 0.12% chlorhexidine mouth rinses after 24 h and no direct brushing of the surgical site for 4 weeks. No antibiotics are prescribed. An anti-inflammatory (Enantyum 25 mg every 8 h for 3-5 days) is prescribed to all subjects.
Subjects return to the clinic after 2, 4, 26 and 52 weeks. Sutures are removed 2 weeks postoperatively. Photographs will be taken after 2, 26 and 52 weeks. At 52 weeks clinical measurements are repeated with a periodontal probe.

Intervention Type
Procedure/Surgery

Primary outcome measure
Recession reduction, assessed by the difference between cement enamel junction and gingival margin in baseline and 1 year follow-up. The recession is measured from the cemento- enamel junction (CEJ) to the most apical point of the gingival margin.

Secondary outcome measures
1. Complete root coverage measured at 6 months and 12 months after surgical procedure with a CP15 periodontal probe
2. Vestibular depth (the distance between the coronal margin of the attached gingiva and the greatest concavity of the mucobuccal fold below) measured at 6 months and 12 months after surgical procedure with a CP15 periodontal probe
3. Keratinized tissue increase (measuring one point in each tooth) measured at 6 months and 12 months after surgical procedure with a CP15 periodontal probe

Overall study start date
05/01/2016

Completion date
21/12/2017

Eligibility

Key inclusion criteria
1. Presence of at least 2 adjacent recession class III
2. Periodontal pocket depth <5 mm
3. No bleeding on probing
4. Bone loss >2 mm
5. <2 mm keratinized tissue
6. No intra-bony defects >2 mm
7. Aged over 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
Recession class I or II

Date of first enrolment

01/03/2016

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Spain

Study participating centre
PerioCentrum Research
Alameda Urquijo Street n2 7ºfloor
Bilbao
Spain
48008

Sponsor information

Organisation
Periocentrum Research Bilbao

Sponsor details
Alameda Urquijo Street n2 7ºfloor
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Periocentrum Research Bilbao

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			24/08/2022	No	No