PERIOCENTRUM
RESEARCH

Title: Treatment of gingival recessions by means of apical buccal access flap and connective tissue graft: case series.

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

Analyzed approach: Technique described as vestibular apical access for the treatment of class III recessions as an option when performing mucogingival surgery techniques or periodontal plastic surgery.

Multicentre study:

1. Clínica Ortiz-Vigón Periocentrum Research Bilbao - Alberto Ortiz Vigón , Erik Regidor
2. PerioCentrum Research Madrid, Fabio Vignoletti

Type of alterations: type III multiple vestibular gingival recessions (recession of the gingival margin with loss of attachment / destruction of periodontal tissues) with insufficient keratinized gingiva or depth of the vestibule for the correct maintenance of the teeth.

Principal investigator: Alberto Ortiz-Vigón & Fabio Vignoletti

Co-Investigators: Erik Regidor Correa

Director and promoter of the study: Alberto Ortiz-Vigón

Operator: Alberto Ortiz-Vigón (Bilbao) & Fabio Vignoletti (Madrid)

Clinical Examiner: Erik Regidor

Clinical Study Duration: 52 weeks

Start of the study: After the approval of the ethics committee

LEGAL CONSIDERATIONS:

This study will be carried out in accordance with Spanish legislation regarding the development of clinical studies in humans. The start of this study is based on a research protocol developed by Arrow Development SL and carried out at the Ortiz-Vigón Clinic and PerioCentrum Reina Mercedes.

STUDY DESIGN:

Prospective, bicentric, 12-month case series. The objective of the study is to evaluate the clinical efficacy of a mucogingival surgery technique described for the treatment of resurfacing gingival recessions around teeth.

HYPOTHESIS:

The apical access technique without modifying the critical area of the interdental papillae allows to improve root coverage results without compromising vascularization, obtaining greater root coverage and an increase in keratinized gingiva.

JUSTIFICATION:

There is no literature that supports or guarantees complete root coverage using any of the techniques described to date for the treatment of multiple type III recessions. The justification for carrying out this technique is that the series of cases and the purposes of cases carried out to date show a successful achievement of complete root coverage and percentage of root coverage, increasing the vestibular keratinized gingiva and without compromising the depth of the vestibule and even increasing it compared to what could happen with the tunneling technique

TECHNIQUE INFORMATION:

The vestibular apical access technique is a modification of the original technique described in 1963 by Edlan-Mecjhar. The original technique describes two vertical incisions and a horizontal incision at the bottom of the vestibule through which a full-thickness flap is raised to pull it coronally and cover the recessions.
The first modification was in 1979 described by Schmid et al. in which a partial-thickness semilunar incision was made at the bottom of the vestibule.

Already in 2006, Remolina et al described an elliptical incision in the depth of the vestibule with partial thickness, performed an apical displacement of the periosteum, intra-sulcular incision in the tooth area and added a connective tissue graft from apical for the first time.
Recently, in 2014, Bethaz et al., through a series of cases, described a partial-thickness horizontal incision in the vestibule depth, performed a full-thickness flap in the vestibule depth and towards coronal and intracrevicular incision and detach papillae to advance them coronally. at tooth level. In addition, like the previous authors, they also add a connective tissue graft.
This new modification called vestibular apical access technique that is to be investigated through this research protocol is carried out through the following steps chronologically:
Semilunar incision at the bottom of the vestibule, practically in the labial musculature
Take off and lift the flap to full thickness to eliminate tension and achieve passivity in the flap
Mobilize the coronal part that is intended to cover existing recessions
Obtain a connective tissue graft from the palate using minimally invasive techniques
Introduce the graft through the apical incision made at the beginning
suturing to the recipient bed and anchoring at the contact points to pull as much as possible towards the coronal in order to achieve the greatest possible root coverage.

Main goal:

The main objective of this study is to evaluate the clinical efficacy of treating multiple type III recessions by apical access with a connective tissue graft.

Secondary objectives:

The following objectives will be evaluated:
Average reduction of the recession
Complete root coverage
Increased vestibule depth
Keratinized gingiva augmentation

TREATMENT:

All patients will be previously examined by a clinical examiner (ERC)
All patients will be operated by the same operator (AOV in Bilbao and FV in Madrid)
The same operator will remove the sutures at 2 weeks
Patients will be reviewed at 3, 6 and 12 months to fill in the data of the clinical variables analyzed
The statistical part will be performed by a statistician

Subject Recruitment:

Patients will be recruited at Clínica Ortiz-Vigón PerioCentrum Bilbao and PerioCentrum Research Madrid, Spain. A preliminary evaluation will identify patients with multiple class III recessions (recession that reaches or exceeds the mucogingival line and there is interproximal attachment loss), with shallow vestibule depth and keratinized gingiva.

Inclusion criteria:

Patients who meet the following inclusion criteria will be included:

Informed consent after detailed information

Adults at least 18 years of age

Patients with multiple recessions (≥2 teeth) type III with shallow vestibule depth and keratinized gingiva that do not include molars, which may be in the upper and lower jaws.

Healthy or periodontally treated patients

Systemically healthy or with fully controlled or stabilized diseases. A medical report will be requested confirming the stabilization of the specific disease.

General plaque control (FMPS) ≤ 25% (O´Leary et al 1972)

Exclusion criteria:

Pregnant or lactating patients

Uncontrolled medical conditions

Uncontrolled periodontal disease

patients treated with any drug that affects gingival conditions such as causing hyperplasia

Alcohol and/or drug abuse

Not signing informed consent

PRE-SURGICAL EVALUATION:

In the month prior to surgery, the following procedures will be recorded:

Patient medical history, dental history, and clinical and radiographic evaluation

Photographs of the area to be intervened: vestibular, occlusal, profile

Measurement of extension / length of the recessions that are going to be included in the study

Vestibule depth measurement

Measurement of the amount of keratinized gingiva

Intra-oral X-ray of the area to be operated on

Pre-procedure volumetry by intra-oral scanner

Patient survey about pre-treatment recessions

Pre-surgical maintenance prior to all procedures

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
semilunar deep vestibular incision
Elevation of a full-thickness flap to create a vascular bed for the graft
anesthetize posterior palatal area (distal to premolars) and take a graft that is the length and width of the treated area and between 1-2mm thick
The stabilization of the grafts will be carried out by means of a dental-anchored suture to the contact points of the previously splinted teeth in order to be able to suture in this way.
Photographic documentation before the incision, after bed preparation, after obtaining the graft and after suturing.
Post-surgical instructions

Post-surgical medication:

After surgery, the patient will be offered the possibility of taking analgesics/anti-inflammatories (Enantyum 25 mg every 8 hours) and 0.12% chlorhexidine mouthwashes (twice a day) for two weeks. Patients over 65 years of age and those who regularly take antiplatelet/anticoagulant medications will be offered to take a proton pump inhibitor (Omeprazole 20 mg once a day) 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 patient's perception of the treatment and the amount of analgesics consumed and for how long.

Follow-up visits:

2 weeks: intra-oral photographs and suture removal
12 weeks: intra-oral photographs

24 weeks: intra-oral photographs, intra-oral radiographs, measurements of recessions, amount of keratinized gingiva and vestibule depth, and periodontal maintenance

52 weeks: intraoral photographs, intraoral radiographs, measurements of recessions, amount of keratinized gingiva and vestibule depth, periodontal maintenance and study completion

Interrupt Criteria:

A patient will be discontinued from the study if:
A medical condition or situation occurs such that continuing to participate in the study would not be in the best interest of the patient
Patient meets any of the exclusion criteria (either newly developed or previously unrecognized)
The patient does not comply with the study protocol.
In addition, patients are free to stop participating in the study at any time they request it without the need for justification on their part.

Revocation of participation:

Patients will be included in the clinical investigation for root coverage as long as the inclusion criteria and none of the exclusion criteria are met. In the event that a patient is withdrawn from follow-up after grafting, the reason for withdrawal must be clearly indicated. These patients will be included in the final analysis of the clinical investigation. Reasons for withdrawal include, but are not limited to: missed visits, patient wishes to withdraw, adverse events, and patient is deceased. If the patient wishes to withdraw from clinical research, they have the right to do so at any time during the clinical research. A clinical investigation patient who has been withdrawn will not be replaced by a new patient.

Statistics:

The statistical analysis will take into account all the data collected before, during and after the surgical intervention. For analytical statistics, a Shapiro-Wilk normality test will be performed for quantitative variables. Depending on the result, the Student's T test or the Mann-Whitney U test

will be performed. To analyze the differences between the patients, a Student's T test will be used for paired samples in the quantitative variables or a Wilcoxon test if the distribution is not normal. For categorical variables, the Chi-Square test and a McNemar test for differences between patients will be performed. If appropriate, a regression analysis will be performed. The data obtained will be analyzed using the SPSS SPSS Statistics Desktop, V21.00 program (SPSS Inc., Chicago, IL, USA).

Main variable:

Mean recession reduction: using a CP15 millimeter probe

Secondary variables:

Complete root coverage: using a CP15 millimeter probe
Mean recession reduction: using a CP15 millimeter probe
Keratinized gingiva augmentation: using a CP15 millimeter probe
Increased vestibular depth: It will be measured from the gingival margin to the point of the deepest concavity of the vestibular apical mucosal fold. using a CP15 millimeter probe

RESULTS:

The data obtained will be evaluated to examine each of the variables and be able to establish the efficacy of the procedure with the apical access technique and a connective tissue graft for root coverage. The only participation in the study is the completion of the statistics section.

ETHICAL REQUIREMENTS:

Declaration of Helsinki:

This study is carried out in accordance with CFR 21, part 50 of the Helsinki declaration guidelines (Appendix 1 of the declaration adopted at the 18th World Medical Assembly in Tokyo 1975 and revised in Seoul in 2008). The latest version of the Declaration of Helsinki is included in the protocol as an appendix.

The study complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of April 27, 2016 regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data and Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights that repeals Organic Law 15/1999, of December 5, on the protection of personal data. Personal data will be processed by ALBERTO ORTIZ-VIGÓN. No data will be transferred to third parties, except legal obligation. The patient will be informed that they have the right of access, rectification, deletion of their data, and the limitation or opposition to their treatment. A private database will be created to which only ALBERTO ORTIZ-VIGÓN will have access. It will be completely confidential and he will be responsible for confidentiality, security and maintenance.

Patient information and consent:

Prior to obtaining consent from the patient, all will receive exhaustive oral and written information about the development of the study. The patient must recognize if he meets any of the exclusion criteria because if so, he will be excluded from the study before or during it if he recognizes it later.

PROTOCOL REVIEW:

The study will not start until the approval of the protocol, the information for the patient and the informed consent report, by each regional ethics committee.