PERIOCENTRUM
RESEARCH

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

Protocol /serial number: 2018063

Study Information:

Summary:

There is no literature that endorses or guarantees complete root coverage through any of the techniques described till the moment for the treatment of class III multiple gingival recessions, being effective treatments nevertheless in the resolution of Miller's class I or II. There is no randomized clinical trial comparing one technique against other in periodontal plastic surgery for root covering of class III multiple gingival recessions.

Study hypothesis: 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: 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; ceic.eeaa@euskadi.eus; 945 01 64 59; http://www.euskadi.eus/comite-etico-investigacion-clinica/), ref: PS2018063
Study design: Multicenter randomized controlled clinical trial.
Primary study design: Interventional
Secondary study design: Randomised controlled trial
Condition: 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

study hipothesis:
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.

The study was designed as a multi-center, randomized clinical trial on the treatment of multiple Miller Class III recession. Two different treatment modalities were assessed: tunneling technique with an autologous connective tissue graft (control group) was compared to an apical vestibular access flap with autologous connective tissue graft (test group) in terms of clinical outcomes , postoperative morbidity and professional perception. The procedures in the study were in accordance with the Declaration of Helsinki, as revised in 2013 and the study protocol was approved by the local ethics committee (CEIm-E 2018063). Informed consent was obtained from all participants included in the study.

primary outcome: The main objective of this study is to evaluate the clinical efficacy and the perception by the patient and the treatment professional of multiple type III recessions, using a tunnelled technique or an apical access technique.

secondary outcomes:
Average reduction in recession
Complete root coverage
Volume increase
Evaluate the time spent on both types of procedures
Patient satisfaction with the treatment received and its relationship with pre-surgical expectations (Visual Analogue Scale)
Assess analgesia intake
Aesthetic satisfaction by the clinical examiner

The intervention will we realized in a single session and the follow-up will be 12 months after the surgical procedure.

Eligibility

Participant inclusion criteria - Description:
- informed consent after detailed information
- adults at least 18 years of age
- patients with multiple recessions (≥2 teeth) class III Miller with shallow vestibulum depth and keratinized mucosa
- Non-molar teeth
- upper and lower jaw
- Healthy or periodontally treated patients

- systematically healthy or with fully controlled or stabilized diseases
- A medical report will be requested to confirm the stabilization of the specific disease
- general plaque control (FMPS) ≤ 25% (O'Leary et al 1972)
- Age group: Adult Participant inclusion criteria
- Gender: Both

Participant exclusion criteria:

- pregnant or breastfeeding patients
- uncontrolled periodontal disease
- patients treated with any medication that affects gingival conditions such as causing hyperplasia
- alcohol and/or drug abuse
- not signing informed consent
- molar area

Countries of recruitment: Spain

Trial participating centres:

ThinkingPerio Research - Periocentrum Bilbao
Alameda Urquijo street 2, 7th floor
Bilbao
48008
Spain

Sample size: A sample size of 30 patients was targeted for detecting a difference of 35% in Complete root coverage (number needed to treat = 3) at 12 months between the test and control group, using a multilevel logistic regression analysis adjusted for clustering (with an expected mean cluster size of 2.5 teeth/patient), with an 80% power and a critical level of significance of 0.05.

Patient recruitment: The patients will be recruited at the Ortiz-Vigón PerioCentrum Bilbao Clinic 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 vestibular depth and keratinized gingiva.

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, VAS patient questionnaire, professional satisfaction questionnaire, maintenance and completion of the study

52 weeks: intraoral photographs, intraoral radiographs, volumetric scan, VAS patient questionnaire, professional satisfaction questionnaire, maintenance and completion of the study

Randomization:

The randomization will be carried out prior to the procedure by the statistician 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.

inclusion criteria:

- informed consent after detailed information
- adults at least 18 years of age
- patients with multiple recessions (≥2 teeth) class III Miller with shallow vestibulum depth and keratinized mucosa
- Non-molar teeth
- upper and lower jaw
- Healthy or periodontally treated patients
- systematically healthy or with fully controlled or stabilized diseases
- A medical report will be requested to confirm the stabilization of the specific disease
- general plaque control (FMPS) ≤ 25% (O'Leary et al 1972)

exclusion criteria:

- pregnant or breastfeeding patients
- uncontrolled periodontal disease
- patients treated with any medication that affects gingival conditions such as causing hyperplasia
- alcohol and/or drug abuse
- not signing informed consent
- molar area

Revocation of participation:

Patients will be included in the clinical investigation for root covering as long as the inclusion criteria and none of the exclusion criteria are met. If 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 has passed away. If the patient wishes to withdraw from the clinical investigation, they have the right to do so at any time during the clinical investigation. The clinical research 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. A descriptive statistics will be made of the data obtained in both groups during the study. For analytical statistics, a Shapiro-Wilk normality test will be carried out for quantitative variables. Depending on the result, the Student's T test or the Mann-Whitney U test will be performed to determine the difference in means between the groups. To analyze intra-

group differences, 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 will be performed to analyze the differences between the groups and a McNemar test for intra-group differences. If convenient, a regression analysis will be carried out. The data obtained will be analyzed using the SPSS SPSS Statistics Desktop program, V21.00 (SPSS Inc., Chicago, IL, USA).

Main variable:

Average recession reduction: using a volumetric intraoral scanning

Secondary variables:

Complete root coverage: using a volumetric intraoral scanning
Time spent for each of the procedures
Patient satisfaction with the treatment received and its relationship with pre-surgical expectations
Treatment satisfaction with regard to pain, limitation of daily activity and taking medication

Declaration of Helsinki:

This study is carried out in accordance with CFR 21, part 50 of the directives of the Helsinki declaration (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.

Patient information and consent:

Before obtaining consent from the patient, all will receive exhaustive oral and written information about the development of the study. The patient must acknowledge if he meets any of the exclusion criteria because if so, he will be excluded from the study before or during the study if he is subsequently recognized.