Allogeneic cortical lamina with apical buccal access for combined osseous & mucogingival defects around multiple adjacent teeth

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Key words:

Osseous dehiscence, gingival recession, apical buccal access, allogeneic cortical lamina

Title:

Allogeneic cortical lamina with apical buccal access for combined osseous & mucogingival defects around multiple adjacent teeth.

STUDY DESIGN:

A 52-week case series to evaluate the effectiveness of the vestibular apical access technique in treating gingival recessions to introduce a demineralized cortical sheet graft into the recipient bed and to assess complete root coverage, mean reduction in recession, gain of keratinized tissue and increase in vestibule depth.

Study hypothesis

The apical buccal access technique combined with a demineralized cortical lamina without modifying the critical zone of the interdental papillae allows adequate root coverage results without compromising vascularization, while achieving an increase in keratinized gingiva and depth. vestibule reducing post-surgical morbidity and intervention time.

Condition

Multiple vestibular gingival recessions with insufficient keratinized gingiva or vestibule depth for proper maintenance of the teeth. In addition, it must present a cortex less than 1mm on the CBCT.

Interventions . Surgical procedure:

Buccal apical access flap for the treatment of gingival recessions with Cortiflex® demineralized cortical lamina. DIZG Cortiflex® (allogeneic cortical lamina). In combination with DIZG Cortico-Cancellous Particulate (Cortico-Cancellous Bone 50:50 FDBA Particulate Allograft) for horizontal bone augmentation.

Primary outcome measure

Average recession reduction

Secondary outcome measures

- complete root coverage
- changes in keratinized mucosa
- changes in vestibulum depth
- average reduction of the recession

Participant 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, and may be in the upper and lower jaw.
patients who, in the three-dimensional x-ray, present a vestibular cortex less than 1mm thick
Healthy or periodontally treated patients
Systemically healthy or with completely controlled or stabilized diseases. A medical report will be requested that confirms the stabilization of the specific disease.
General plaque control (FMPS) ≤ 25% (O'Leary et al 1972)

Participant exclusion criteria

Pregnant or breastfeeding patients
Uncontrolled medical conditions
Uncontrolled periodontal disease
patients treated with any medication that affects gingival conditions such as causing hyperplasia
Alcohol and/or drug abuse

Do not sign informed consent
Despite having root recessions, it presents a cortex greater than 1mm in the 3D CBCT and therefore another type of technique is considered necessary.

STUDY OBJECTIVES:

Main goal:

- The main objective of this study is to evaluate the clinical effectiveness of the described technique for the treatment of multiple recessions.

Secondary objectives:

- The following objectives will be evaluated: Average recession reduction
- Complete root coverage
- Increased vestibule depth
- Increase in keratinized gingiva

TREATMENT:

All patients will be previously examined by a clinical examiner (ERC)
All patients will be operated on by the same operator (AOV)
The same operator will remove the sutures after 2 weeks
At 6 and 12 months, the clinical examiner will perform a thorough clinical, photographic and radiographic examination

The statistical part will be carried out by a statistician

Subject recruitment:

Patients will be recruited at Clínica Ortiz-Vigón PerioCentrum Bilbao. A preliminary evaluation will identify patients with multiple recessions with shallow vestibule depth and keratinized gingiva.

Materials & Methods:

Study population, design, and treatment procedure:

The project will be conducted as a prospective cohort study of 1-year duration in 1 clinical center. 15 systemically healthy patients with osseous dehiscences and gingival recessions in multiple adjacent teeth will be included.

Clinical assessments:
One calibrated examiner will perform the assessments. The following variables will be assessed at four sites around the implant: Plaque, probing pocket depth (PPD), bleeding on probing (BoP), probing attachment level (PAL) recession (REC). Keratinized mucosa (KM) will be measured in the buccal aspect of each included implant.

Data analysis:

The statistical analysis will consider all the data collected before, during and after the surgical intervention. A descriptive statistic of the data obtained in both groups will be carried out during the study. For the analytical statistics a Shapiro-Wilk normality test will be performed for the quantitative variables. The changes in the means obtained between the initial situation and 12 months of follow-up will be evaluated using a McNemar test. The patient is the unit of analysis. The data obtained will be analyzed through the SPSS SPSS Statistics Desktop program, V21.00 (SPSS Inc., Chicago, IL, USA)

Schedule of investigational events:

The flow chart and time schedule presented below illustrate the overall organization of the study including the sequence of examinations:

1. Ethical approval of protocol by local ethics committee

2. Study announcement and patient recruitment

3. Screening and identification of subjects.

4. Baseline clinical examination of patients selected for the study. Non-surgical periodontal treatment. Photographs, data collection of clinical parameters and measurements.

5. Radiographic examination, cone beam computed tomography and intraoral volumetric scanning will we recorded prior to surgery (within 2 weeks)

6. Surgical therapy. Assessment of PROM, photographs, periapical radiography, and surgery time will be recorded.

7. 2 weeks: suture removal. Assessment of PROM and photographs

8. 4 weeks: photographs

9. 12 weeks: photographs, professional supra-mucosal cleaning, and reinforcement of oral hygiene.

10. 24 weeks: photographs, periapical radiography, collection of possible complications and professional supra-mucosal cleaning and reinforcement of oral hygiene.

11. 48 weeks: photographs, periapical radiography, collection of possible complications, cone beam computed tomography, intraoral volumetric scanning and professional supra-mucosal cleaning and reinforcement of oral hygiene.

Ethical considerations and institutional review:

The protocol is being reviewed by the local Ethics Committee of Basque Country and the study will be registered at isrctn.com.
Each patient will receive oral and written information about study purpose and design, and they will have to sign a consent. Patients must understand that their participation in the study is voluntary, and they can leave it when they want. The study will be carried out following the recommendations of Helsinki declaration.

Facilities and expertise:

Study team:

Principal investigator:

Alberto Ortiz-Vigón (Department of Periodontology, Periocentrum Bilbao) has extensive experience in the field of periodontology, implant dentistry and peri-implantitis clinical research.

Study monitoring:

Erik Regidor (Department of Periodontology, Periocentrum Bilbao) has experience in monitoring randomized controlled clinical trials. He will attend all the study during the inclusion period as well as the follow-up period.

Clinical / practical work:

All investigators are trained researchers and specialists in periodontics.
All of them have an extended experience in periodontology, implant dentistry and surgical treatment of these type of clinical conditions.

Organization:

The study will be organized and monitored from Periocentrum Bilbao:

Principal Investigator: Dr. Alberto Ortiz-Vigón (Periocentrum Bilbao, Bilbao, Spain) Clinical Research Coordinator: Dr. Erik Regidor (Periocentrum Bilbao, Bilbao, Spain) Data managing: Dra. Ángela Redondo (Periocentrum Bilbao, Bilbao, Spain) Statistics: Idoia Ayllon (Periocentrum Bilbao, Bilbao, Spain)

Infrastructure

Periocentrum Bilbao has extended experience in periodontology and clinical research. Periocentrum Bilbao will be responsible of their data collection and when the study is finished, data analysis and interpretation will be made.
After data interpretation, manuscript will be prepared, and it will be submitted to a pre-reviewed journal.