PROJECT TITLE:

Coverage of buccal soft tissue dehiscences around implants with an acellular dermal matrix and apical buccal access. Randomized clinical trial.

PRINCIPAL INVESTIGATOR:

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Summary:

Buccal soft tissue dehiscences around dental implant is termed by the presence of a mucosal cleft that exposes the implant shoulder, prosthetic abutment or implant surface that may jeopardize the appearance of peri-implant tissues and esthetic outcome. Several surgical approaches have been proposed to treat buccal soft tissue dehiscences with heterogeneous results. Apical buccal access flap combined with autologous connective tissue graft has demonstrated to be successful surgical design in treating gingival recessions around teeth. Nevertheless acellular dermal matrix is associated with lower patient morbidity. The aim of this randomized clinical trial is to evaluate the clinical efficacy of an acelullar dermal matrix called Novomatrix® in terms of coverage of buccal soft tissue dehiscences around implant and patient perception and reported measurements.

Relevance of the project:

There is no enough evidence in the treatment of buccal soft tissue dehiscences around implants and the scientific literature in this field reports heterogeneous outcomes in terms of clinical outcomes. There is no evidence reporting patient reported outcomes in the treatment of this type of clinical condition that jeopardizes the esthetic outcome of implant therapy. The hypothesis of this study is that the use of acellular dermal matrix in the treatment of buccal soft tissue dehiscences reduces the patient morbidity, surgical intervention time and offers non inferior clinical outcomes. Furthermore, Intraoral scan, digital tools and software will be used to measure height, thickness and volumetric changes in order to improve the quality of data acquisition in clinical research.

Aim and Purpose:

the aim of this clinical trial is to evaluate the clinical efficacy of a surgical intervention for the treatment of buccal soft tissue dehiscences around implants combining an apical buccal access flap with the use of either an acellular dermal matrix or a connective tissue graft in terms of dehiscence coverage and patient reported outcome measures.

Project design:

The study will be a prospective randomized clinical trial with a follow-up of 12months. Patients with buccal soft tissue dehiscences around implants will be treated with apical buccal access flap and acellular dermal matrix (test) or autologous connective tissue graft (control) will be used randomly. The randomization and treatment allocation to the experimental and control groups will be performed using sealed envelopes.

Hypothesis:

The use of acellular dermal matrix in the treatment of buccal soft tissue dehiscences reduces the patient morbidity, surgical intervention time and offers non inferior clinical outcomes

Material and method

1. Pre-screening: the clinical component of this trial will be conducted in Periocentrum Bilbao clinic
2. Clinical Screening: a complete medical and dental history will be obtained. Patients will be informe of the study purpose. Consent will be obtained by both written and verbal explanations of the potential risks and benefits of participating, along with other possible treatment options. Ample time will be designated for questions and answers, if needed. Pre-surgical records: photo, periapical x-ray, CBCT and intraoral scan (STL).

3. Inclusion criteria:

- Age ≥ 18 years
- Periodontally and systemically healthy
- Full-mouth plaque score and full-mouth bleeding score ≤ 20% (measured at four sites per tooth)
- Correct implant 3-dimensional position or buccal position ≤ 1 mm
- Buccal soft tissue dehiscence ≤ 4 mm
- Only osseointegrated implants
- The patient must be able to perform good oral hygiene

4. Exclusion criteria:

- Contraindications for periodontal surgery
- Patients pregnant or attempting to get pregnant
- Malpositioned implant
- Soft tissue dehiscence (STD) > 4 mm
- Existing of peri-implantitis
- Severe bone loss (≥4mm)
- Moderate-severe interproximal bone loss (implant fixture level to the alveolar bone > 3 mm)
- Moderate-severe papilla height loss (Nordland and Tarnow implant papillae index >1)
- Previous mucogingival surgery around the implant within the past six months or implant placement at the surgical site less than six months prior
- Smoking more than 10 cigarettes a day

5. Randomization: Before the surgical intervention. Each subject will randomly assigned with the assistance of computer software to one of the following groups: Control group: treatment of buccal soft tissue dehiscences with apical buccal access approach and autologous connective tissue graft. Test group: treatment of buccal soft tissue dehiscences with apical buccal access approach and NovoMatrix.

6. Baseline Measurements: a periodontal probe will be used to record gingival and plaque indices, probing pocket depth, amount of keratinized mucosa. An intraoral scan will be used to assess the volumetric changes (height and thickness) and changes in recession or buccal soft tissue dehiscence around implants

7. Surgical intervention: Control group: treatment of buccal soft tissue dehiscences with apical buccal access approach and autologous connective tissue graft. Test group: treatment of buccal soft tissue dehiscences with apical buccal access flap and NovoMatrix.

8. Postoperative care: Subjects will receive detailed written and verbal post-operative instruction. Subjects will be instructed to avoid mechanical disturbance of the surgical site for the first week. Oral hygiene instructions included 0.12 clorhexidine mouth rinses after 24hours and no direct brushing of the surgical site for one week . All subjects will prescribe oral antibiotics. Azithromycin 250mg 1 per day for 3 days will be the medication of choice. An anti-inflammatory (Enantyum 25mg every 8 hours for 3-5 days) will be prescribed to all subjects.

9. Follow up visits: 2 weeks (photo and patient questionnaire), 4 weeks (photo and patient questionnaire), 12 weeks (photo and patient questionnaire), 6 months (photo, periapical X-ray, patient questionnaire and intraoral scan for volumetric changes, professional questionnaire), 12 months (photo, periapical X-ray, patient questionnaire and intraoral scan for volumetric changes, professional questionnaire).

Primary endpoint: The primary outcome will be mean mid-facial recession coverage (mRC) measured as a percentage. Time frame: 6 months and 1 year with an intraoral scanning file (STL) and digital software

Secondary endpoints:

1. Esthetic score [Time Frame: 6 months and 1 year]Esthetic score measured using numeric values from 0 to 10
2. Patient-reported esthetics [Time Frame: 6 months and 1 year]Patient-reported esthetics measured using numeric values from 1 to 5
3. Patient-reported post-operative pain [Time Frame: 2 weeks]Patient-reported post-operative pain, based on VAS scale, measured as numbers from 0 to 10.
4. Keratinized tissue (KT) gain [Time Frame: 6 months and 1 year]KT gain measured in mm with a manual periodontal probe
5. Keratinized tissue thickness (KTT) [Time Frame: 6 months and 1 year]KTT gain measured in mm an intraoral scanning file (STL) and digital software
6. Professional-reported esthetics [Time Frame: 6 months and 1 year]Blinded examiner reported esthetics measured using numeric values from 1 to 5

Indication: Buccal soft tissue dehiscences around implants

Sample size calculation: Calculated number: 28

Rationale: A power calculation revealed that a sample size of minimum of 11 patients per group are necessary to detect a difference in recession depth of 0.8mm between test and control sites, using a paired t test with 80% power and 0.05 level of significance. Therefore, a total amount of 28 patients will be included, 14 per group.

Statistical method:

The statistical analysis will take into account 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