Scientific Project Request (for Botiss Mucoderm®)

1. Project Title

Clinical comparison of coronally-advanced flap plus Xenogeneic Porcine-derived acellular dermal Matrix (**Botiss Mucoderm®**) and subepithelial connective tissue graft in the treatment of single tooth recessions.

2. Principal Investigator Information

First Name: **Suleiman**. Last Name: **Dayoub**.

DDS, MSc, PhD.

Name of University/Hospital/Clinic: **Damascus University - Faculty of Dentistry**.

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3. Co-Investigators

Co-investigators:

First Name: **Mohammad** last name: **Al abed**

DDS, MSc student in Periodontics, Periodontology Department, Faculty of Dentistry, Damascus University.

The role: as a surgeon.

4. Contact Country

Countries: Syria

5. Study Center Set-Up

☒ Monocenter

☐ Multicenter

6. Project Description

Primary Objective(only one primary objective):

Recession coverage and soft tissue thickening for isolated recession.

Secondary Objective (one or more secondary objectives):

Comparing between two surgical methods (CAF+ Botiss Mucoderm® and CAF + SCTG).

Study Groups:

Fifteen subjects (range of age 18 to 45 years) with complain of gingival recessions Will be selected.

Thirty defects will be randomly divided into two groups by flip of a coin: control group (will be treated with CAF +SCTG) and test group (will be treated with CAF+ XDM) The patients will be selected on a consecutive basis among patients consulting the department of Periodontology, School of Dentistry, Damascus University.

Group 1 (Control): **CAF** + **SCTG**

Group 2 (Test): **CAF** + **Botiss Mucoderm®**

7. Hypotheses

Null hypothsis H_o:

Significance level $\alpha = 0.05$ (critical value 95%)

1. There is no significant difference exists in the means of the parmetric variables (RD, KW..) between the CAF+XDM group and the CAF+SCTG group in paired samples.
2. There is no significant difference exists in the means of the parmetric variables (RD, KW..) between the CAF+XDM group and the CAF+SCTG group in intergroup independent samples.
3. And there are no significant differences in ordinal and nominal variables between the two groups in paired samples and independent ones.

Alternative hypoyhesis (H1):

The main hypothesis suggests There are significant differences exists between the two groups, where the CAF+XDM will result in superior result outcomes than CAF+SCTG regarding the primary outcome (implant coverage) after 3 months.

SPSS statistical programe will be used, Significance level $\alpha = 0.05$ (critical value 95%) and the following tests will be used:

- Kolmogorov-Samirnov test will be used to define the probability distributions, in Normal distribution of the parametric samples (RD, KW..) we will use (Independent samples t-test and Paired sample t-test). In non-normal distribution (Mann-whitney U test for independent samples and Wilcoxon's signed rank test for paired samples) will be used.

In ordinal variables Wilcoxon's signed rank test for paired samples will be used as well.

And for the nominal variables Chi-squared test for independent samples and paired samples McNemar test will be used.

To determine the association between VAS and other outcomes Spearman's correlation coefficient will be calculated.

8. Primary Outcome

Root coverage by measuring the Recession (REC) and the thickness of Keratinized Tissue (KT).

9. Secondary Outcome

Secondary Endpoints:

1. **change in visible plaque index.**
2. **Recession width (RW).**
3. **width of keratinized tissue (KT).**
4. **thickness of gingival tissue (GT).**
5. **probing depth (PD).**
6. **clinical attachment level (CAL).**
7. **healin index.**
8. **Pain index (PI).**
9. **Patient aesthetics Perceptions.**

10. Project Characteristics

- [ ] in vitro study
- [ ] Pre-clinical study
- [x] Clinical study (cohorts)
- [ ] Case series
- [ ] Cohort
- [ ] Randomized study
- [x] Split mouth
- [ ] Controlled study
- [ ] Non-blinded study
- [x] Single-blinded study
- [ ] Double-blinded study
- [x] Prospective
- [ ] Retrospective
- [ ] Other:

11. Study Assessments and Timelines

1. **Recession depth (REC):** the distance between cementoenamel junction(CEJ) and gingival margin at temporary or final crown.

   Time line: 1) at baseline, 2) at 2 weeks postoperative, 3) at 1 month postoperative, 4) and at 3 months postoperative.

2. **change in visible plaque index:**

1- Score 0 - No plaque

2- Score 1 - Separate flecks of plaque at the cervical margin of the tooth

3- Score 2 - A thin continuous band of plaque at the cervical margin of the tooth

4- Score 3 - A band of plaque wider then 1mm covering less than 1/3rd of the crown of the tooth

5- Score 4 - Plaque covering at least 1/3rd but less than 2/3rd of the crown of the tooth

6- Score 5 - Plaque covering 2/3rd or more of the crown of the tooth

   Time line: 1) baseline, 2) at 2 weeks postoperative, 3) 1 month and 4) 3 month postoperative.

3. **Recession width (RW):** 1 mm incisal to free gingival margin.

   Time line: 1) at baseline, 2) at 2 weeks postoperative, 3) at 1 month postoperative, 4) and at 3 months postoperative.

4. **width of keratinized tissue (KT):** from the free gingival margin to the mucogingival junction

   Time line:1) baseline, 2) 2 weeks postoperative, 3) 1 month postoperative and 4) 3 months postoperative.

5. **thickness of gingival tissue (GT):** with an injection needle and a silicon marker, 3 mm below the gingival margin.

   Time line: 1) base line, and 2) 3 months postoperative.

6. **probing depth (PD):** distance between the gingival margin and the bottom of the pocket measured at the mid-buccal aspect of the tooth.

   Time line: 1) at baseline, 2) and 3 months postoperative.

7. **clinical attachment level (CAL):** distance between the CEJ and the bottom of the pocket measured at the mid-buccal aspect of the tooth.

   Time line: 1)baseline, 2) at 3 months postoperative.

8. **healin index:**

1- score 1 = uneventful healing with no gingival edema, erythema, suppuration, patient discomfort, or flap dehiscence

2- score 2 = uneventful healing with slight gingival edema, erythema, patient discomfort, or flap dehiscence, but no suppuration

3- score 3 = poor wound healing with significant gingival edema, erythema, patient discomfort, flap dehiscence, or any suppuration

Time line: 1) at two weeks following surgery and (2) at one month following surgery.

9. **Pain index (PI):**

Using Visual Analogue scale (VAS) (2001 Crichton), Patients will be asked to select among 100 scores (0 indicating no pain at all , 50 indicating average pain, and 100 indicating very painful).

Time line: 1) at 2 hours, 2) 24 hours, 3) 48 hours,4) 72 hours following surgery and 5) at 1-week after surgery.

10. **Patient aesthetics Perceptions:**

Using Visual Analogue Scale (VAS) Patients will be asked to select among 100 scores (0 indicating very bad, 50 indicating average, and 100 indicating excellent results).

Time line: at three months post-surgery.

Methods:

The two intervention groups consisted of coronally advanced flaps with autologous connective tissue graft (standard of care control) and a porcine-derrived acellular dermal matrix (Botiss Mucoderm® ,Botiss gmbh, Berlin, Germany).

Pre-Surgical Preparation:

As part of the screening phase for inclusion, all patients will have a full mouth periodontal examination with registration of probing pocket depths (PD) and full-mouth bleeding scores(FMBS), Once the selected patients agreed to participate in the study, they will be provided with customized oral hygiene instructions, including control of traumatic tooth brushing techniques as well as a dental prophylaxis and polishing.

Surgical phase:

I. Local anesthesia anesthetize the recipient site.

II. Tooth surface preparation.

III. sulcular incision will be made at the recession site and extend horizontally into the adjacent interdental regions.

IV. Bilateral vertical releasing incisions, connected to the horizontal incision, will be extended out into the lining mucosa.

V. A full-thickness flap will be elevated until the mucogingival junction

VI. a periosteal release will be made to eliminate tension and advance the flap coronally.

VII. de-epithelializing The facial aspects of the interdental papillae.

VIII. Applying XDM (Botiss Mucoderm®) onto the surface.

IX. The mucoperiosteal flap coronally advanced to the level of the CEJ and suture to the de-epithelialized papillae.

Post-surgicalprotocol:

The surgical protocol in the control group will be identical with test group protocol with these exceptions:

- A partial thickness flap will be elevated instead of full thickness flap.
- A SCTG harvested from the palate will be used to cover the exposed denuded implant surface in lieu of placement of XDM in the test group.
- As in the test group the mucosal flap will passively coronally advanced to the level of the CEJ.
- Verbal and written postoperative instructions will be given to each patient.

appropriate medication and analgesics will be prescribed according to individual need.

Each patient will be asked to avoid brushing and use 0.12% chlorhexidine digluconatemouthrinse, twice a day for 30 seconds, for the first two weeks postoperatively.

Subjects will be instructed to avoid trauma to the treated area.

Follow-up visits will be in week $1,2,4,6$ and 12 post operative

the sutures will be removed in the first 2 visits and all the clinical measurements will be recorded at the follow-up visit.

12. Planned Number of Patients

Planned patient number: 15 Patients / 30 Sites (split-mouth)

13. Products Used

Products used in the project: Botiss Mucoderm® 15×20

Project Start

Plannedstart of the project: 2\8\2021

14. Project End

Estimated end of the project: 1\1\2023

15. Output

Planned output: scientific publication.

16. Therapeutic Area

- ☐ Extraction Socket Management
- ☒ Soft Tissue Management
- ☐ Major Bone Augmentation
- ☐ Minor Bone Augmentation
- ☐ Sinus Floor Augmentation
- ☐ Periimplantitis
- ☐ Periodontal Defects