Protocol

The use of coronally advanced flap and subepithelial connective tissue graft with or without platelet rich fibrin in the treatment of Miller class I or II gingival recession: a randomized clinical trial

استخدام سديلة متقدمة كورونالي و تطعيم بالانسيج الضام مع أو بدون الصفائح الدموية الغنية الليفين في علاج ميلر الأول أو الثاني الركود اللثوي: تجربة سريرية عشوائية

Protocol

Submitted to the Faculty of Oral and Dental Medicine-Cairo University in partial fulfillment of requirements for Doctorate Degree in Periodontology

BY

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1. Title:

The use of coronally advanced flap and subepithelial connective tissue graft with or without platelet rich fibrin in the treatment of Miller class I or II gingival recession: a randomized clinical trial.

2. Trial registration:

NCT03199118

3.Protocol version

Protocol no 1., revised and approved by the Ethics Committee of Scientific Research - Faculty of Oral and Dental Medicine– Cairo University in **30/09/2017.**

4. Funding:

Self-funding.

5. Roles and responsibilities:

Supervisors and principle investigator:

 Main supervisor

Prof.Azza Ezzelarab

 Professor of Oral Medicine and Periodontology-Cairo University.

Role:

- Initiation and idea of the clinical trial.
- Randomization, sequence generation and allocation concealment of cases.
- Data monitoring

 Co-supervisor

Prof. Noha Ayman Ghallab

 Professor of Oral Medicine and Periodontology- Cairo University.

Role:

- Initiation and idea of the clinical trial.
- Measuring and recording the outcomes of the study: Recession width, recession depth, % of root coverage, probing depth, clinical attachment level, keratinized tissue biotype, root coverage esthetic score (RES), post-operative pain.
- Data collection

 Principle Investigator

Sarah Mohamed Ehab Elbanna

 Assistant lecturer in Oral Medicine and Periodontology department– Cairo University.

- Role:
- Surgical treatment.

M. Amira Mohamed

 Responsible for filing system in Oral Medicine and Periodontology department– Cairo University.

- Role:
- Data management

D. Role of steering committee

- Department of Oral Medicine and Periodontology, Faculty of Oral and Dental Medicine - Cairo University.

  It is responsible for ensuring that the research idea follows the research plan of the department .

- Evidence Based Committee, Faculty of Oral and Dental Medicine - Cairo University.

  It is responsible for:

  - Pico revision.
  - Protocol revision.
  - Reporting the methodology.
  - Sample size calculation and reporting of statistical methods.

- Ethical Committee, Faculty of Oral and Dental Medicine - Cairo University

It is responsible for:

- Ensuring that the trial does not violate privacy, ethical issues, or human rights.
- Supplying the main investigator with a template of informed consent.
- Approving the research, once it fulfills the required ethical criteria.

- Faculty and University board

It approves the protocol once it is approved by the previously mentioned boards and committees.

Introduction

6. Background and rationale

Gingival recession is a frequent, unwanted apical shift of the marginal tissue beyond the cemento-enamel junction (CEJ) and may cause faulty dimensions of keratinized tissue and aesthetic problems. The high concern in aesthetics and the resulting need to solve related problems such as hypersensitivity and root caries have preferred the advancement of many surgical plan that permit the coverage of exposed roots **(Roccuzzo *et al.*, 2002)**.

- **Statement of the problem:**

Gingival recession (GR) is a typical appearance in many populaces, and is considered as an early indication of periodontal sickness. A review showed that gingival subsidence is a typical condition with a pervasiveness of 68% for males contrasted with females who had 32% gingival recession **(Manchala et al.2012)**.

- **Rationale for carrying out the trial:**

Subepithelial connective tissue graft (SCTG) secured by a coronally advanced flap (CAF) is one of the substantial surgical alternatives and is utilized as often as possible because of its great consistency **(Wennstrom and Zucchelli, 1996; Paolantonio *et al.*, 2002; Tozum and Demiralp, 2003)**. However, uncertain complete root coverage (between 18.1 %and 86.7%) has been documented as well as confined regeneration of the lost attachment apparatus with a remedial through long junctional epithelium or adaptation of connective tissue to the root surface after the use of CAF+SCTG **(Cummings et al. 2005).**

One of the enhancers of periodontal tissue regeneration and promoters of early wound healing is found to be the Platelet rich fibrin (PRF) **(Tozüm et al. 2003).** There are only a few reports documenting the use of platelet rich plasma (PRP) in aesthetic periodontal surgery. **Petrungaro (2001)** published a case series in which PRP, SCTG and collagen membranes were used to cover gingival defect. The 2 months study resulted

in 3 mm root coverage. Accordingly, this study will assess the effect of PRF as an adjunct to CAF+SCTG on root coverage outcomes.

Introduction and review of literature

Gingival recession [GR] has been characterized as an apical move of the gingival edge over the CEJ and the unmasking of the root surface to the oral condition. **(Kassab et al.2003**). It is a familiar and unwanted condition that is commonly seen in dental clinics and affects population of all ages across the planet, represents the status of periodontal tissue and that's why it is not seen as a disease itself. Its existence is annoying for patients due to esthetic, mental and functionnal issues, e.g. dentine hypersensitivity, root caries and abrasion, cervical wear, tooth movement and dental erosion because of the exposure of the root surface to the oral environment **(Tugnait et al.2001). Armittage (1999)** has described forms of GR in the absence of periodontal disease which are known as developmental or acquired deformities and conditions.

The etiology of GR is multifactorial and is dependably the aftereffect of more than one component acting together, for example, anatomical [alveolar bone dehiscence, high muscle connection, occlusal injury, frenal pull, thin gingival biotype], inflammatory [destructive periodontal disorder, nearness of dental plaque and supra/subgingival calculus, inadequate teeth brushing], traumatic variables [vigorous oral cleanliness routine, oral piercing] and iatrogenic elements identified with reconstructive, conservative, orthodontic, periodontologic or prosthetic treatment **(Tugnait et al.2001; Kassab et al.2003; Dilsiz et al.2010**).

Normal periodontal tissue can be affected by GR **(Tugnait et al.2001)** and looks like a wedge shaped lesions on the buccal surface of the teeth, notably associated with malposed teeth and hard toothbrush use **(Khocht et al.1993)**, while in persons with bad oral hygiene it can be seen on any tooth surface **(Loe et al.1992)**. In majority of cases, root coverage methods not just aims to completely cover the denuded root and to enhance esthetics, but also to increase the width of the gingival tissue covering the recessions to enhance long term stability. **(Kennedy et al.1985).**

Free gingival grafts, grafts bringing together two modalities, pedicle grafts and guided tissue regeneration are among several treatment options for covering the exposed roots and to increase the width and thickness of the keratinized gingiva **(Bruno, 1994)**. Better esthetics, ease of plaque control and reduction of hypersensitivity are the main outcomes of these procedures. **(Michaelides and Wilson, 1994).**

CAF brought about the re-development of epithelial and connective tissue attachment with insignificant bone repair. Thereafter, many additionnal agents have been applied to improve healing and additionnaly reinforce clinical result. These include guided tissue regeneration (GTR) Bio-resorbable membrane **(Zucchelli *et al.*, 1998)**, enamel matrix proteins SCTG **(Berlucchi *et al.*, 2002)** recombinant growth factors, PRP and PRF **(Gonshor, 2002)**.One of the highly predictable surgical options is the CTG covered by a CAF **(Wennstrom and Zucchelli, 1996; Paolantonio *et al.*, 2002; Tozum and Demiralp, 2003)**. However, inconsistent complete root coverage (between 18.1 %and 86.7%) and limited regeneration of the missing attachment apparatus with a healing through long junctional epithelium or adaptation of connective tissue to the root surface after the use of CAF+SCTG **(Cummings et al.2005).**

According to **Marx *et al.* (1998)** who first reported applications and clinical benefits of PRP, it is "a volume of autologous plasma that has a platelet concentration above the baseline". Due to its good effect on wound healing acceleration, PRP has become a target of lots of researches. It is derived from concentrated platelets, allowing it to deliver a greater concentration of autologous growth factors including platelet derived growth factor, transforming growth factor-β, vascular endothelial growth factor, epithelial growth factors, insulin like growth factor. **(Okuda *et al.*, 2003).**

The use of PRF, a second-generation platelet concentrate, gives more advantages than the PRP. The main difference between PRF and commercially available PRP systems is that PRF does not need bovine thrombin or other exogenous activators in the preparation process. A gel-like substance is obtained after PRF preparation, containing high concentrations of non-activated, functional, intact platelets, contained within a fibrin matrix, that release, a relatively constant concentration of growth factors over a period of 7 days. Also a membrane can be produced by squeezing the gel-like matrix that can be

used as fibrin bandage acting as a matrix to fasten the healing of wound edges. Moreover its preparation is relatively easy, simple and fast. An economical autologous membrane is obtained in nearly 1 min and therefore the cost of a membrane and bone graft is avoided **(Thorat et al. 2011)** . Homeostasis and wound healing are stimulated by PRF and it has a supportive effect on the immune system, cell migration, and proliferation **(Dohan et al.2006)**

Numerous clinical and histological studies reveal that a specific platelet-concentrated therapeutic concept could be an encouraging medium for the enhancement of soft tissue healing and regeneration in periodontology and implantology **(Pini-Prato *et al.*, 1999).** Promising results have been recorded with the use of PRF in several periodontal surgical techniques, and healing of intrabony and furcation defects **(Sharma et al.2011)**. It may be thought that PRF can have a positive effect on the treatment outcomes of root coverage technique.

-Aim of the study

The aim of this randomized controlled clinical trial with a 6 months follow-up is to evaluate the effectiveness of CAF+SCTG+PRF in the treatment of Miller class I and II recession defects and to compare the outcomes to CAF+SCTG alone.

-PICOTS elements:

P (Patient/ Population): Patients with Miller's class I or II gingival recession.

I (Intervention): root coverage using CAF with SCTG and PRF.

C (Comparator /Control): root coverage using CAF with SCTG alone.

O (Outcome): recession depth

T: 6 months follow-up

S (Study design): Randomized controlled clinical Trial

Research question:

In patients with Miller class I or II gingival recession, does the use platelet rich fibrin in conjunction with CAF and SCTG reduce the recession depth if compared to CAF and SCTG alone?

7. Objectives of the study:

This research will be conducted in an attempt to achieve complete root coverage with physiologic probing depth and a harmonious view with the adjacent tissues using PRF in conjunction with CAF and SCTG.

Research hypothesis:

Null hypothesis: In patients with Miller class I and II gingival recession, there is no difference in root coverage outcomes following placement of PRF in conjunction with CAF and SCTG compared to CAF and SCTG alone.

The primary objective:

Recession depth which will be measured before the surgical procedure, then after 3 and 6 months.

The secondary objectives:

	Outcome name	Measuring Device	Measuring Unit
Primary1ry	Recession depth	William's graduated Periodontal probe	mm
Secondry2ry	Recession width	William's graduated Periodontal probe	mm
	Root coverage gain	William's graduated Periodontal probe	mm
	Probing depth	William's graduated Periodontal	mm

		probe	
	Clinical attachment level	William's graduated Periodontal probe	mm
	Gingival biotype	William's graduated Periodontal probe	mm
	Width of keratinized gingiva	William's graduated Periodontal probe	mm
	Patient satisfaction	Printed questionnaire Binary **(Zuhr et al.2014)**	Yes/No
	Root coverage esthetic score	Score **(Cairo et al. 2009)**	Categorical
	Post-Operative Pain	Numerical Rating Scale (NRS) **(Breivik et al. 2008)**	Numerical

8. Trial design:

 Parallel groups, Randomized Controlled Clinical Trial

Methods

9.Study setting:

 Study is to be conducted in the Oral Medicine and Periodontology department, Faculty of Oral and Dental Medicine – Cairo University, Egypt.

 Patients are to be selected from the outpatient clinic of the department of Oral Medicine and Periodontology-Cairo University:

- Dental units: Adec / knight
- Operator: PhD degree student in periodontology department
- Assistant: present

10.Eligibility criteria

i) Inclusion criteria: Patients eligible for the trial must comply with all of the following:

1) Patients 18 years and older

2) Buccal recession defects classified as either Miller class I or II gingival recession.

3) Clinical indication and/or patient request for recession coverage

4) Good oral hygiene

ii) Exclusion Criteria

1) Miller Class III and IV gingival recession.
2) Any systemic diseases or any medication.
3) Pregnancy.
4) Patients undergoing radiotherapy.
5) Handicapped and mentally retarded patients.
6) Current and former smokers as smoking is a contra-indication for plastic periodontal surgery (Khuller 2009).
7) Teeth with cervical restorations, abrasion.

11. Intervention:

11a- General operative procedures:

Preoperative evaluation

A periapical radiograph using paralleling technique will be performed for each patient. The patients will be randomly assigned into two groups;

Group A: patients receiving CAF with SCTG alone.

Group B: patients receiving PRF+CAF+SCTG.

Clinical examination:

Each patient will be examined intra-orally to check the conformity of the patient to the eligibility criteria mentioned before. If the patient meets the criteria, phase I therapy for

periodontal plastic procedures will be performed including thorough supragingival scaling and subgingival debridement. Maintenance of proper plaque control (both mechanical and chemical) by the patient will be also implemented.

Surgical procedures:

SCTG harvesting:

A measurement of the approximate length and width of the graft required will be taken. The graft will be harvested from the palate between the distal aspect of the canine and the midpalatal region of the first molar. Two parallel incisions will be performed in the palate using blade n.15, staying at least 2 mm away from the tooth margin. Pressure will be applied to the donor site with gauze soaked in saline after the graft will be taken. Silk sutures are used to simultaneously approximate both the flap margins and the entirely undermined donor area.

Surgical protocol:

The surgical area will be prepared and adequately anesthetized using 2% lignocaine HCL containing 1:80,000 epinephrine by giving block and infiltration anesthesia. After obtaining adequate anesthesia, two vertically divergent incisions (i.e. one mesial and one distal, immediately adjacent to the defect) extending beyond the MGJ will be made on the buccal aspect of the involved tooth. The sulcular incision will then be placed up to the end of the vertical incisions. Care will be taken to see that the papilla is intact. A trapezoidal flap will be elevated by a sharp dissection with no. 15 scalpel blade to raise a combined full-partial thickness flap to the level of the MGJ.

The flap will be extended well beyond the mucogingival junction so that it exhibits no tension when pulled coronally beyond the CEJ and should be extended at least 5 mm coronal to the most apical margin of the bony dehiscence. The intact papillae mesial and distal to the recession will be de-epithelized to provide a bleeding connective tissue bed for future the SCTG.

In the test group (group A), the root surface will be covered with the PRF membrane exceeding the margins of surrounding alveolar bone before placing SCTG, while in the control group (group B), SCTG will be placed over the recession defect

leaving the coronal margin of the graft at the level of the CEJ. In both groups, all graft material will be sutured to the periosteum using 5-0 resorbable suture. Finally the flaps will be positioned coronally to the CEJ without tension using 5-0 silk suture. Hemostasis will be achieved by applying gentle finger pressure for 4 minutes.

PRF preparation:

This procedure will be done only if the patient is allocated to group A where PRF will be placed and after the flap in the recession site has been prepared. Just before SCTG harvesting, blood will be taken from the anticubital region with a 24-gauge needle and injected into the 10-mL glass coated collection tube without anti-coagulant then immediately centrifuged at 2700 rpm for 12 minutes with a table centrifuge. The fibrin clot will be collected from the middle part of the tube and packed tightly in 2 sterile saline impregnated gauze in order to obtain a fibrin membrane.

A post-surgery protocol will be implemented emphasizing wound stability and infection control, including 0.12% chlorhexidine rinse twice per day. Gingival sutures will be removed 2 weeks post-surgery. Mechanical plaque control in the surgical area will be reinstituted at week 8 following surgery. Patients will be recalled for supragingival scaling and oral hygiene instructions on a monthly basis for the 6-month observation interval.

11.b: Criteria for Discontinuing or Modifying Intervention:

 There will be modification in the trial if any harm occurs to the patient.

 If patients shows any signs of progression of the disease, increased recession or periodontal abscess.

11-c: Strategies to improve adherence to intervention:

The patient will be followed up weekly the first month. The operator should explain the importance of follow up. Adherence to oral hygiene measures will be verified by showing the patient the amount of plaque on the periodontal probe and bleeding on probing using a mirror. The patient will receive 2 phone calls to remind him the follow up visit. Phone

number of a close person will be collected in case we cannot reach him on his phone. If the patient does not show up a home visit might be considered.

11-d: Concomitant care

The patients will receive postoperative instructions and oral hygiene guidelines that should be followed during the 6 month follow-up period. Patients will be recalled every 1 week for first month and then every month for supportive periodontal therapy till 6 months follow up.

Medications: Chlorohexidine 0.12% mouthwash 2 times/day for 1 week

Brofen 400 mg 3 times/day for 5 days

Soft tooth brush is to be used

12- Outcomes:

Dr Noha is responsible for measuring all the outcomes and collecting data.

	Outcome name	Measuring Device	Measuring Unit
Primary1ry	Recession depth	William's graduated Periodontal probe	Mm
Secondry2ry	Recession width	William's graduated Periodontal probe	Mm
	Root coverage gain	William's graduated Periodontal probe	Mm
	Probing depth	William's graduated Periodontal probe	Mm
	Clinical attachment level	William's graduated Periodontal probe	Mm
	Gingival biotype	William's graduated Periodontal probe	Mm
	Width of keratinized gingiva	William's graduated Periodontal probe	Mm
	Patient satisfaction	Printed questionnaire Binary **(Zuhr et al.2014)**	Yes/No
	Root coverage	Score	Categorical

	esthetic score	**(Cairo et al. 2009)**	
	Post-Operative Pain	Numerical Rating Scale (NRS) **(Breivik et al. 2008)**	Numerical

The probe is held parallel to the long axis of the tooth. The pressure applied with the probe tip should be between 10-20 grams. Blanching of the gingiva should be avoided.

- Recession depth: from the CEJ to the margin of the gingiva at the midbuccal point of the teeth.
- Recession width: measured horizontally between two borders of the recession
- % of root coverage: (preoperative vertical recession – postoperative vertical recession/preoperative vertical recession) x 100.
- Probing depth: measured from the gingival margin to the base of the pocket probe at the midbuccal point of the teeth.
- Clinical attachment loss: measured from the CEJ to the base of the sulcus at the midbuccal point of the teeth.
- Gingival biotype: under local anesthesia from 3 mm below the gingival margin trans-gingivally piercing tissues horizontally, perpendicular to the long axis of the tooth until it contacts bone.
- Width of keratinized gingiva: from the margin of the gingiva to the mucogingival junction at the midbuccal point of the teeth.
- Patient satisfaction: printed yes/ no questionnaire with 3 questions
- Root coverage esthetic score **(Cairo et al. 2009)**
- Post-Operative Pain**:** Numerical Rating Scale (NRS) with numbers from 0 to 10 (‘no pain’ to ‘worstpain imaginable’) for the first 2 weeks postoperatively. (Breivik et al. 2008)

13. Participant timeline

 After accepting to be enrolled in this study, all patients will receive proper oral hygiene instructions and will be motivated to stick to these instructions.

 After receiving the treatment, patients will be followed-up for 6 months.

Time point	T0	T1	T2	T3(weekly till T4)	T4(1 month)	T5 (3 months	T6(6 months)
Enrollment	X						
Eligibility screening	X						
Informed consent	X						
Initial phase (oral hygiene)		X					
Allocation			X				
Intervention			X				
Post-operative care				X	X		
		Assessment					
Radiograph	X			x	X	X	X
Recession depth		X				X	X
%of root coverage							X
Probing depth		X				X	X
Clinical attachment level		X				X	X
Gingival biotype		X				X	X
RES							X
Questionnaire					X		
Post-operative pain				X			

14 - Sample size

The aim of this study is to evaluate the use of coronally advanced flap and subepithelial connective tissue graft with or without platelet rich fibrin regarding Recession depth. In a previous study by **Keceli et al., 2015** the expected difference in Recession depth decrease from baseline between 2 groups is 0.45±0.38mm. Using power 80% and 5% significance level we will need to study 12 in each group to be able to reject the null hypothesis that the population means of the experimental and control groups are equal. This number is to be increased to 14 in each group to correct for non-parametric usage and increased again to 17 to compensate for possible losses during follow up. Sample size calculation was achieved using PS: Power and Sample Size Calculation software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA).

15- Recruitment strategy:

 Patients will be selected from the outpatient clinic of the Oral Medicine and Periodontology department, Faculty of Oral and Dental Medicine-Cairo University

 Screening of patients will continue until the target sample is achieved. (Consecutive sampling)

 Identifying and recruiting potential subjects will be achieved through patient database.

16-Allocation

Patients will be randomly allocated using computer generated randomization (www.randomizer.org) and will be performed by Dr Azza. The numbers will be allocated to each patient.

16a-Allocation concealement mechanism

 The two groups will be treated will be equally prepared for surgical procedure. Then the decision of which group will receive CAF+SCTG and which will receive CAF+SCTG combined with PRF will be selected according to the randomized numbers placed in opaque sealed envelopes. The number will be picked by participant.

16b-Implementation:

 All patients who give consent for participation and who fulfill the inclusion criteria will be randomized.

 Randomization will be performed by Dr Azza who is neither involved in the treatment nor in the outcome measuements.

17-Blinding

- Blinding of the participants and operator is not applicable because of the nature of the treatment.
- Outcome assessor will be blinded.
- The biostatistician will be blinded.

18-Data collection methods

18a-Data collection method:

The phone numbers and address of the patient included in the study will be recorded from them or extracted from the patient's file which will be available at Ms. Amira' s office , the one responsible for filing system in the Oral Medicine and Periodontology department The data will be collected by dr Noha, whether personal or numerical. They will be stored on excel sheets as an electronic copy and printed hardcopy sheets. The outcome data will be collected at 0, 3 and 6 months. Numerical data will be presented as mean and standard deviation

18b- Plans to promote participant retention and complete follow- up

 Telephone numbers of all patients included in the study will be recorded as a part of the written consent.

 All patients will be given a phone call at the time of the pre-determined follow up dates.and transportation fees may be offered.

19- Data management

 All data will be entered and saved electronically by Ms Amira All paper sheets that are concerned with the personal or outcome data will be stored in locked cabinet and in the computer at the Oral Medicine and Periodontology department.

The excel sheets of the patients data will be stored in the computer of the Oral Medicine and Periodontology Department- Faculty of Oral and Dental Medicine

 Patient files are to be stored in numerical order and stored in secured file. Data will be encrypted using a password.

 All data will be maintained in storage for 1 year after completion of the study.

20- Statistical method:

Data management and statistical analysis will be performed using Statistical Package for Social Sciences (SPSS) vs. 21. Numerical data will be summarized using means and standard deviations or medians and ranges. Data will be explored for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. Categorical data will be summarized as percentages. Comparisons between two groups and over time will be done by 2 way analysis of variance for repeated measures. If the time factor is not considerable, comparisons between the two groups for normally distributed numeric variables will be done using the Student's t-test while for non-normally distributed numeric variables will be done by Mann-Whitney test. A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

21-Data monitoring

-No formal data monitoring committee will be needed since it is a study with known minimal risks.

22-Harms

Any temporary or permanent adverse effect will be recorded and documented.

No Harms are expected.

23-Auditing

No auditing is to be done since no harms are expected.

24-Research ethics approval

-This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research -Faculty of Oral and Dental Medicine– Cairo University

25-Protocol amendments

Any modifications to the protocol which may have an impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Council of Periodontology Department.

26-Consent:

Researcher will introduce the trial to patients and provide full explanation of its aim and benefits in plain language. Patients will then be able to have an informed discussion with the researcher. Researcher will obtain written consent from patients willing to participate in the trial. All consent forms will be translated into Arabic.

27-Confidentiality

All study-related information will be stored securely. All participant information will be stored in locked file cabinets in areas with limited access. All reports, data collection, process, and administrative forms will be identified by a coded ID [identification] number only to maintain participant confidentiality. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems.

28- Declaration of interests

If there will be any conflict of interest it will be declared.

29-Access to data

The principal investigator and the supervisors will be given access to the data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

30-Ancillary and Post Trial Care

All patients will be followed up for one year after the clinical trial is over.

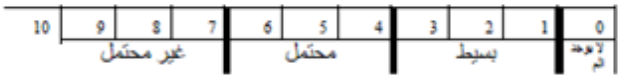
31-Dissemination policy

- Study results will be published as partial fulfillment of the requirements for Doctorate degree in Periodontology.
- Topics suggested for presentation or publication will be circulated to the authors.

(Keceli *et al.*, 2015)Appendix:

1. **Pain Scale**
   Filled in by the patient after being given instructions about charting by the dental operator.

مقياس الألم



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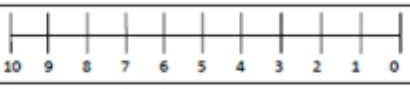
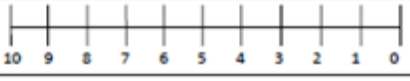
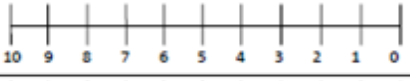
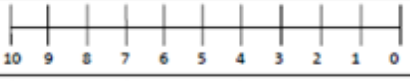
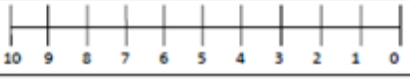
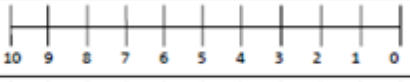
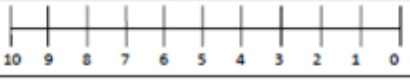
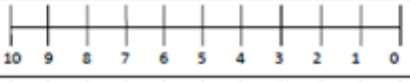
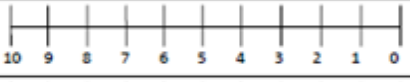
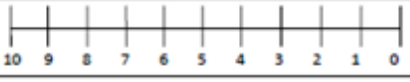
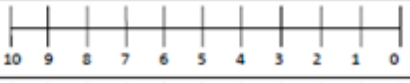
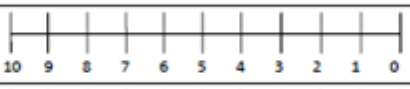
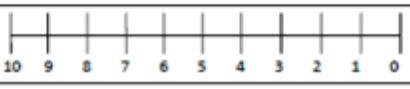
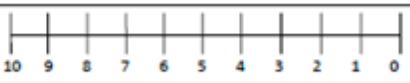
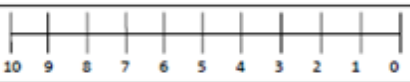
اليوم (0) يوم العمليه		
اليوم (1)		
اليوم (2)		
اليوم (3)		
اليوم (4)		
اليوم(5)		
اليوم (6)		
اليوم (7)		
اليوم (8)		
اليوم (9)		
اليوم (10)		
اليوم (11)		
اليوم (12)		
اليوم (13)		
اليوم (14)		

Filled in by the patient

مقياس رضا المريض بعد اجراء العملية

(1-7)

الاسم:

هل تود ان تجرى لك العملية مرة اخرى ؟

هل تنصح بها للاخرين ؟

الى اى مدى انت راض عن النتائج ؟

3. Root coverage esthetic score

The RES system evaluates five variables 6 months following surgery: gingival margin (GM), marginal tissue contour (MTC), soft tissue texture (STT), mucogingival junction (MGJ) alignment, and gingival color (GC). The clinical esthetic evaluation is performed without magnification. Zero, 3, or 6 points are used for the evaluation of the position of the gingival margin, whereas a score of 0 or 1 point is used for each of the other variables

- GM: -Zero points = failure of root coverage (gingival margin apical or equal to the baseline recession)

  -3 points = partial root coverage;

  -6 points = CRC.

- MTC: -Zero points = irregular gingival margin (does not follow the CEJ).
  -1point =proper marginal contour/ scalloped gingival margin (follows the CEJ).
- STT: - Zero points = scar formation and/or keloidlike appearance .

  -1 point = absence of scar or keloid formation.

- MGJ: - Zero points = MGJ not aligned with the MGJ of adjacent teeth.
  - 1 point = MGJ aligned with the MGJ of adjacent teeth.
- GC: -Zero points = color of tissue varies from gingival color at adjacent teeth.
  -1 point = normal color and integration with the adjacent soft tissues.

Thus, the ideal esthetic score is 10.

Zero points are assigned if the final position of the gingival margin is equal or apical to the previous recession depth (failure of root coverage procedure), irrespective of color, the presence of a scar, MTC, or MGJ. Zero points are also assigned when a partial or total loss of interproximal papilla (black triangle) occurred following the treatment.

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