Clinical Evaluation of a Modified Technique for Free Gingival Graft Stabilization Using Titanium Fixation Tacs Around Implants Versus Conventional Suturing Technique: A Randomized Controlled Clinical Trial

التقييم السريري لتقنية معدلة لتثبيت الطعوم اللثوية باستخدام أدوات التثبيت التيتانيوم حول الغرسات مقابل تقنية الخياطة التقليدية : تجربة سريرية عشوائية

Protocol Submitted to:
Faculty of Dentistry, Cairo University in partial fulfillment of the requirements for Master's Degree in Implantology - Periodontology

By

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B.Sc. in Oral and Dental Medicine, Cairo University, 2019

Code:

Supervisors' signature

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Head of department's signature

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Evidence based committee (Reviewers)		
Name	**Signature**	**Date**
1.		24.9.2024
2.		24.9.2024
Research plan committee		
Name	**Signature**	**Date**
1.		24.9.2024
2.		24-9-2024

I. Administrative information:

1. Title:

Clinical Evaluation of a Modified Technique for Free Gingival Graft Stabilization Using Ti Fixation Tacs Around Implants Versus Conventional Suturing Technique: A Randomized Controlled Clinical Trial.

2. Protocol Registration:

The trial will be registered on Clinicaltrials.gov

3. Protocol version:

Date and version identifier.

4. Funding:

The trial is totally self-funded whether on a financial or a non-financial basis. Equipment units and some consumables are provided by Department of Oral Medicine, Periodontology, and Oral Diagnosis, Faculty of Dentistry, Cairo University.

5. Roles and responsibilities:

Main supervisor: Prof. Dr. Amr Zahran

- Initiation of the study.
- Generation of random sequence numbers and implementation of randomization.
- Supervision of surgical procedures.
- Revision of protocol and final thesis.

Co-supervisor: Dr. Manar El Zanaty

- Randomization, blinding and data interpretation.
- Treatment supervision during the study.
- Final thesis manuscript revision.

Main investigator: Mohamed Atef Kamal

- Recruitment and allocation of patients.
- Preparation and follow-up of patients.
- Surgical treatment of patients.
- Preparation of protocol and thesis.

Trial sponsor: Faculty of Dentistry, Cairo University.

Committees:

- Research plan committee
- Oral Medicine and Periodontology department council
- Evidence based dentistry committee
- Ethics committee
- Faculty Council

II. Introduction:

6. Background and rationale:

Research question:

In patients with inadequate keratinized gingiva undergoing soft tissue augmentation by free gingival graft , will graft stabilization using Titanium fixation tacs affect the amount of keratinized tissue gain compared to graft stabilization using sutures ?

Statement of the problem:

The presence of adequate Keratinized tissue (KT) is imperative to both teeth and dental implants. It enhances proper oral hygiene and periodontal health, also it masks the metallic hue of the housed dental implants (Thoma et al., 2018). Being autogenous, easy to harvest and with a predictable surgical outcome concerning increasing the expanse of the attached gingiva, the free gingival graft (FGG) became the gold standard for the build-up of the KT (Dragan et al., 2017).

However, assured graft stability remains crucial for its success. The mucosal graft must be constantly fixed throughout the initial healing phase, as even minor mobility would contribute to compromised vascularization, impaired healing, and failed integration with the underlying periosteum (Lim et al., 2018). Furthermore, less than optimal preservation of graft nutrition frequently yields significant graft shrinkage. A suitable graft thickness, an atraumatic surgical method, and quick and intimate stabilization are essential to guard against dehydration and vascular damage with excessive graft shrinkage (Dragan et al., 2017).

Although graft suturing represents the traditional aim of stabilization, each suture is supposed to induce a localized hematoma between the graft and the underlying periosteum, this hinder the plasmatic circulation of the recipient bed and induce micro separations along the underside of the graft during the initial stage of healing, which adversely affects the stabilization of the blood clot and compromise the graft nutrition (Shaikh et al., 2021).

Various techniques tried to replace the routine suturing of the FCG; cyanoacrylate to decrease the rate of shrinkage(Gümüş & Buduneli, 2014), surgical mini-screws for stabilizing apically positioned flaps rather than being conventionally sutured(Moayer et al., 2018), stent to support the graft instead of sutures(Korkis et al., 2019), and using bone tacks into an acellular dermal matrix to augment a keratinized mucosa around root-form dental implants (Shi et al., 2020).

Rationale for conducting the research:

Free gingival graft obtained from the palate, usually replaces missing or lost keratinized tissue. Although it represents the gold standard, its success relies on providing intimate and atraumatic stabilization, as maintaining the plasmatic circulation is crucial for graft healing and perfusion, considering that judging the success of FGG is based on the extent of the postoperative healing contraction and the quality of graft adherence to the underlying periosteum (Minsk L, 2002).

Suturing can be time consuming and sometimes fail to achieve a positive result (Shi et al., 2020). Also it was reported that for every one-minute increase of the gingival augmentation procedure time, there is a 4% likely increase for pain and a 3% for swelling (Griffin et al., 2006).

However, by using fixation tacs the surgical time can be significantly reduced and the procedure can be less technique sensitive (Shi et al., 2020).

Review of literature:

Dental implants are a practical solution for replacing missing teeth, having a reported survival rate of 95% or higher over 5–10 years (Albrektsson et al., 2017).

Dental implants are immune to dental caries but not to peri-implant diseases. Peri-implant mucositis affects only the mucosa surrounding implants, but peri-implantitis is a more serious inflammatory lesion in the mucosa around implants that is accompanied by loss of supporting bone (Albrektsson et al., 2019).

Crestal bone loss in the first year of implant function is usually exempt from pathological diagnoses since this bone loss is considered normal remodelling in response to unavoidable bone injury during implant surgery (Albrektsson et al., 2017). However, continuous crestal bone loss after the first year of function may indicate peri-implantitis.

In order to achieve long-term success in implant therapy, it is essential to maintain healthy peri-implant tissues. Plaque accumulation adjacent to dental implants results in the development of peri-implant mucositis (Renvert & Polyzois, 2015). Such persistent inflammation may result in crestal bone loss around implants (Ferreira et al., 2006).

As the function of keratinized gingiva (KG) around teeth is thought to be a physical barrier between the oral environment and the underlying connective tissues (Brito et al., 2014), a lack of keratinized mucosa (KM) has been investigated as a risk indicator for peri-implant disease. Experimental studies in animal models have revealed more crestal bone loss and attachment loss in implants exhibiting a lack of KM in the presence of plaque-induced inflammation than in implants with healthy KM (Warrer et al., 1995).

Other studies have recommended augmentation of KM around implants because a lack of KM around implants was associated with increased plaque accumulation, mucosal inflammation and recession (Oh et al., 2020).

Explanation for choice of comparators:

Patients with less than 2mm width of keratinized gingiva around dental implants augmented by free gingival graft and stabilized by conventional suturing technique, since conventional suturing is a fundamental surgical principle for free gingival graft stabilization

Hypothesis:

There is no significant difference in increasing the width of keratinized gingiva following stabilization of the FGG by Ti fixation tacs versus sutures.

7. Objectives:

The aim of this randomized, controlled, parallel-grouped, clinical trial is to evaluate the width of keratinized gingiva after FGG stabilized by Ti fixation tacs compared to traditional suturing.

8. Trial design:

The current study will be designed as : Parallel groups, Randomized Controlled Clinical Trial, Two arms, Superiority Trial with 1:1 Allocation .

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

This study will be carried out on patients enrolled from the Outpatient Clinic of Oral Medicine and Periodontology department, Faculty of Dentistry, Cairo University.

10. Eligibility criteria:

Inclusion criteria

- Systemically healthy individuals of age ≥ 18 to 40 years with absence of active periodontal disease.
- Having inadequate width of keratinized gingiva (< 2 mm).
- No systemic disease according to Modified Cornell Medical Index health questionnaire
- Non-smoker.
- Full mouth plaque index (PI) and full-mouth bleeding on probing (BOP) score of ≤ 15%.
- No malocclusion, crowding, fillings, missing or supernumerary mandibular anterior teeth.
- No blood-borne conditions.

Exclusion criteria

- Active orthodontic treatment.
- Previous periodontal surgery.
- Systemic disease.
- Use of blood thinners.
- Use of any drugs that might lead to gingival enlargement.
- Mucogingival stress, bruxism.
- Pregnancy or lactation.

- Pregnancy or lactation.

11. Interventions

1- Preoperative evaluation:

Evaluation of the patient's general condition of the oral cavity, to make sure it complies with the criteria required to be enrolled in the study in terms of oral hygiene, pathological conditions. Once the study subject is deemed eligible for inclusion, the patient will be informed of the procedure and an informed consent will be signed.

A set of intraoral pictures will be taken before the initiation of any surgical procedure to fully document the case.

2- Surgical procedures:

1- Local anaesthesia to both donor and recipient sites (Articaine HCl 4% + Epinephrine 1:100,000) will be administered by infiltration to achieve the necessary anaesthesia.

2- Recipient site preparation:

A) Partial-thickness mucosal flap will be done using a 15c surgical blade. Two oblique vertical extensions mesially and distally will be done. Then a blunt dissection of the epithelium, connective tissue, and muscle fibers using a periosteal elevator leaving the periosteum firmly attached to the underlying bone.

B) The flap will be rolled and sutured apically to the underlying periosteum with 5-0 monofilaments sutures (Prolene)

C) A saline-moistened gauze was then placed over the recipient site until harvesting the FGG.

3- Donor site preparation:

A) The Free gingival graft will be harvested from the position of the palatal root of the first molar and the distal line angle of the Canine. As this area provides the thickest mucosal graft, and two mms apical to the gingival margin to maximumly 12 mm apart, which represent the average safe distance that would guard against the injury of the neurovascular bundle

B) A graft template will be formulated and adapted.

C) After gentle blade demarcation of the boundaries of the graft template, the palatal mucosa will be sculptured to a thickness of 1.5 mm, which approximately corresponds to the length of the blade bevel, keeping the blade parallel to the epithelial surface during the mucosal separation.

4- Graft stabilization:

A) After the recipient site is copiously irrigated and cleaned from mobile and fatty tissues, the graft is horizontally placed into the most favoured position, with its underside facing the underlying periosteum.

In group (1) (test)

The free gingival grafts will be stabilized with titanium tacks of 4.5 mm length. The graft will be stretched by fixing one tack at its distal end, then another tack at its mesial one, followed by the other tacks as required

In group 2 (control)

The free gingival grafts will be stabilized with conventional suturing with 6-0 monofilaments sutures (Prolene) performing simple interrupted sutures and periosteal stabilizing sutures.

3- Postoperative instructions and follow up:

Administration of:

1- Antibiotics (Amoxicillin 875mg /clavulanic acid 125mg twice daily for 5 days) to prevent any chance of infection.

2- Anti-inflammatory drugs (NSAIDS; Ibuprofen 600mg two times daily for 5 days) to avoid any chance of edema or pain or swelling.

3- Antiseptic mouth rinse (0.12% Chlorhexidine oral rinse) will be prescribed for 60 seconds two times a day for 14 days.

Patient self-care instructions:

1- Application of an ice pack to the treated area for the first 24 hours then application of hot fomentations.

2- Avoid any brushing or trauma to the surgical site for one week.

3- Avoid smoking

The patient will be instructed to follow up for the next 6 months

12. Outcomes:

PICO

Population: Patients with less than 2mm width of keratinized gingiva around implants at the second stage of implant placement in non-esthetic area.

Intervention: Free gingival graft stabilized by Titanium fixation tacs

Control: Free gingival graft stabilized by sutures.

Outcome: Width of keratinized gingiva

Time: 6-month follow up

	Outcome	Measuring Device	Measuring Unit
Primary outcomes	Width of keratinized gingiva	William's graduated Periodontal probe	Millimeters (mm)
Secondary outcomes	Gingival thickness	Endodontic finger spreader with a rubber stopper	Millimeters (mm)
	Graft dimension (surface area)	Image J software & William's graduated Periodontal probe	Square Millimeters (mm2)
	Post operative pain	Visual analog scale (VAS)	Numerical (0-10)
	Surgery time	-	Minutes

Width of keratinized gingiva will be measured in millimeters using William's graduated Periodontal probe from the free gingival margin till the mucogingival junction (Basegmez et al., 2013)

Gingival thickness will be measured in millimeters using Endodontic finger spreader with rubber stopper inserted perpendicular to the bone , 2 mm apical to gingival margin (Silva et al., 2010).

Graft dimension (surface area) will be measured using William's graduated Periodontal probe by measuring the length (mesio-distal distance) and width (apico-coronal distance) (Barbosa et al., 2009)

Aided by a Java-based analysis software; the Image J software (Image J, National Institutes of Health, Bethesda, Maryland, USA), which can calculate area and pixel value statistics of user-defined selections, with an analysis and processing function available at any magnification factor. Known implant crown length, implant healing collar length or a probe visible in the photograph will be used to set the scale of each image.(Oh et al., 2020)

Post operative pain will be measured using Visual Analog Scale (VAS) scales (0-10) : pain scores (ranging from 0 to 10, where 0 indicated no pain, 1 indicated minimal pain, and 10 signified severe pain) will be recorded after one week (Thoma et al., 2023)

Surgery time will be measured in seconds focusing on the graft fixation step (Thoma et al., 2023)

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	**T_0**	**T_1** 1week (baseline)	**T_2** after 2 weeks from T_1	**T_3** 3-months after last session	**T_4** 6-months after last session
Enrollment	X				
Eligibility screen	X				
Informed consent	X				
Initial phase (Oral hygiene measures)	X				
Allocation		X			
Intervention		X			
Tacs removal / suture removal			X		
Measurements					
Width of keratinized gingiva		X		X	X
Gingival thickness		X		X	X
Graft dimension (surface area)		X		X	X
Post operative pain			X		
Surgery time		X			

14. Sample size:

We are planning a study of a continuous response variable from independent control and experimental subjects with 1 control per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 0.4. If the true difference in the experimental and control means is 0.5, we will need to study 11 experimental subjects and 11 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this and experimental subjects with 1 control(s) per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 0.4. If the true difference in the experimental and control means is 0.5, we will need to study 11 experimental subjects and 11 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

15. Recruitment:

- The main investigator will be responsible for recruitment of patients.
- Patients will be selected from the outpatient clinic of the Oral Medicine and Periodontology Department, Faculty of Dentistry - Cairo University.
- Screening of patients will continue until the target sample is achieved.
- Identifying and recruiting potential subjects will be achieved through patient database.

B) Assignment of interventions

16. Allocation:

16a. Randomization:

The site with inadequate keratinized gingiva to be augmented will be randomly allocated to the intervention groups using computer generated random numbers that will be performed by main supervisor. The patients will be allocated in a ratio of 1:1.

16b. Allocation concealment mechanism:

Each site with inadequate keratinized gingiva will be randomly allocated to either intervention group or control group. The allocation sequence will be concealed in opaque sealed envelopes, which will be identified with the initials of the patient's name. For each patient, the envelope will be opened immediately before the intervention. Patients will be blinded during the intervention and follow-up sessions.

The initials of the patient's name will be picked by the main supervisor.

16c. Implementation

The main supervisor will be responsible for generation of allocation sequence and will assign the participants to either intervention or control groups. The main investigator will be responsible for patient enrollment.

17. Masking/blinding:

- The patients will be blinded
- The operator will be blinded

C) Data collection, management, and analysis:

18. Data collection methods

All the date of the patients included in the study will be recorded from them or extracted from the patient's file.

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

All patients will receive a phone call at the time of the predetermined follow up dates.

19. Data management:

• All data will be entered and saved electronically.
• 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 after completion of the study for 5 years.

20. Statistical methods:

Numerical data will be explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Data will be represented as mean, standard deviation, standard error and 95% Confidence Interval (CI) values. For parametric data; repeated measures ANOVA will be used to compare between the groups as well as to study the changes by time within each group. For nonparametric data; Mann-Whitney U test will be used to compare between the two groups. Friedman's test will be used to study the changes by time within each group. Wilcoxon signed-rank test with Bonferroni's adjustment will be used for pair-wise comparisons when Friedman's test is significant. Qualitative data will be presented as frequencies and percentages. Chi-square test or Fisher's Exact test (when applicable) will be used to compare between the groups. The effect size of the intervention will be estimated by calculating risk ratios, Absolute Risk, Relative Risk and Number Needed to Treat with 95% CIs for binary outcomes and mean differences with 95% CIs for continuous outcomes. Inter-observer reliability (agreement) will be measured using Cronbach's alpha reliability coefficient and Intra-Class Correlation Coefficient. The significance level is set at $P \leq 0.05$. Statistical analysis will be performed with IBM SPSS Statistics Version 20 for Windows.

D) Data monitoring:

21. 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.

- In case of any harm, bone graft will be removed.
- Post-operative bleeding will be managed immediately by checking the wound to control bleeding according to the cause. Post-operative pain will be managed by the use of non-steroidal anti-inflammatory drugs.

23. Audit

- Auditing of the study design will be done by the evidence-based committee – Faculty of Oral and Dental Medicine – Cairo University.

IV. Ethics and dissemination

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

26. Informed 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 have been 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 laboratory specimens, 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 interest

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

29. Access to data

The principal investigator and the supervisors will have 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. Post-trial care

All patients will be followed up for six months after the clinical trial is over.

31. Dissemination policy

Study results will be published as partial fulfilment of the requirements for Master's degree in implantology- Periodontology.

Topics suggested for presentation or publication will be circulated to the authors.

V. Appendices

32. Informed 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 have been translated into Arabic.

33. Biological specimens

Not applicable in this study

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