Cairo University
Faculty of Dentistry
Research Ethics Committee

جامعه القاهرة
كلية طب الأسنان
لجنه أخلاقيات البحث العلمي

Human Subjects Application Form

Kindly fulfill the following:

Research title:

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.

Full name of the researcher(s): *Mohamed Atef Kamal Ibrahim*

Affiliation of the researcher(s): *Faculty of Oral and Dental Medicine, Cairo University*

Category of study: ***Master*** ***[✓]*** ***PHD/D*** ***[ ]*** ***Others*** ***[ ]***

Type of study design*: Randomized Controlled Clinical Trial.*

Objective of the research:

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?

Steps of the research in short including the following:

- ***The inclusion and exclusion criteria for patient selection.***

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.*

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11 Elsaraya Street , Manial , Cairo, Egypt
Tel.(002) (02) 23642705/ 23642483/ Ext 543
Fax(002) (02) 23646375

11شارع السرايا – المنيل - القاهرة
ت 23642705 - 23642483 - داخلـــى (543)
فاكس 23646375

Email: rec@dentistry.cu.edu.eg

- *Use of blood thinners.*
- *Use of any drugs that might lead to gingival enlargement.*
- *Mucogingival stress, bruxism.*
- *Pregnancy or lactation.*

- ***Mention the source of the patients enrolled in the research.***

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

- ***Mention the settings with the place where the research will be conducted.***

Clinic of Oral Medicine and Periodontology department, Faculty of Dentistry, Cairo University

- ***In case of patient below the age of 21 years old, a verbal assent from the participant and a written informed consent form will be signed from his/her parents/ guardian is required.***

- ***Description of the methodology.***

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*

- ***Sample size calculation.***

The currents sample size was measured using SPSS power software with a 1:1 allocation for using Width of keratinized gingiva as the primary outcome and minimal clinically significant difference, based on expert opinion. The calculations were based on the expert opinion and data extracted from (Basegmez, C. et al., 2013)

- *The 1ry outcome: Width of the keratinized gingiva*
- *Entry 1: Standard deviation of the control group: 0.4*
- *Entry 2: Minimal clinically significant difference: 0.5*
- *Alpha level of significance: 0.05*
- *Power of the study: 0.8*

- *Statistical test used: t-test*
- *The calculated sample size: 11 per group, 22 in total.*
- *Increased sample by 20% for anticipated missing data: 13 per group , 26 in total*

- ***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.
- ***Number of visits & follow up period.***

5 visits in total , 6 months follow up period

T0: Enrollment , Eligibility screen ,Informed consent, Initial phase (Oral hygiene measures)

T1: Allocation, Intervention, Measurements (after 1 week from T0)

T2: Post operative pain evaluation (after 1 week from T1)

T3: Tacs removal /suture removal (after 1 week from T2)

T4: 3 months follow up

T5: 6 months follow up

Direct benefit of the research to the human volunteer: *Augmentation of the inadequate keratinized tissues around dental implants*

The scientific interest and the desired public benefit of the research:

A comparison between two techniques for free gingival graft fixation in cases with inadequate keratinized gingiva around dental implants , and the clinical significance of the outcomes.

Side effects and the degree of risk and expected to occur and how to deal with them:

-Pain and swelling are expected and will be dealt by Patient self-care instructions, Medication administration and follow up.

-bacterial infection will be dealt by prophylactic antibiotics and oral mouth wash

-bleeding will be dealt by local hemostatic agents (ligation if blood vessel injury)

Patient's full knowledge of the research steps: Reading [✓] Oral explanation [✓] Other [ ]

1. **I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.**
2. **The researcher has informed me of the possible therapeutic alternatives for this research.**
3. **The researcher has informed me of all the possible risks of this research and how to deal with it.**
4. **I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.**
5. **I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions for my health.**
6. **I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher if I enter any other research throughout the period of this research.**
7. **I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.**

After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons anytime.

The researcher in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).

Signature:

Date:

هذا البحث تمت موافقة اللجنه عليه برقم
