

# Comparing the effect of two different grafts, one derived from the palate and the other from the patient's blood, on the improvement of gum tissue thickness around dental implants

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| <b>Submission date</b><br>27/09/2021   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>09/10/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>09/11/2023       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Several esthetic (cosmetic) complications are associated with insufficient gingival (gum) tissue around dental implants. The aim of this study is to compare the effect of two different grafts, one derived from the palate and the other from the patient's blood, on the improvement of gum tissue thickness around dental implants.

### Who can participate?

Patients aged 21 years old or above with two missing teeth with thin gingival (gum) tissue

### What does the study involve?

During dental implant placement for each participant one site is treated with a graft derived from the palate and the other with a graft from the patient's blood.

### What are the possible benefits and risks of participating?

Participants may benefit from having their missing teeth replaced with esthetically enhanced, implant-supported restorations. The risks include implant failure.

### Where is the study run from?

Mansoura University (Egypt)

### When is the study starting and how long is it expected to run for?

September 2016 to September 2020

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Islam Ateia

islammr7@gmail.com

## Contact information

### Type(s)

Public

### Contact name

Dr Islam Ateia

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## Additional identifiers

### Protocol serial number

2019-112

## Study information

### Scientific Title

Comparison of platelet-rich fibrin and sub-epithelial connective tissue graft in managing thin gingival biotype surrounding acid-etched titanium implants

### Study objectives

Platelet-rich fibrin (PRF) could be an effective alternative to sub-epithelial connective tissue graft (SCTG) in the augmentation of the peri-implant soft tissue thickness

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 17/09/2016, Mansoura University Ethics board (Faculty of Dentistry, Mansoura University, Mansoura, Egypt 35516; +20 (0)1004763722; melewa@mans.edu.eg), ref: not applicable

### Study design

Randomized controlled split-mouth study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Peri-implant soft tissue repair

### **Interventions**

The present study was a split-mouth controlled clinical trial.

For each study participant, one site was treated with SCTG while the other was treated with PRF membrane during dental implant placement.

Treatment outcomes included the assessment of the facial gingival thickness using cone-beam computed tomography (CBCT) at the baseline (T0) and 6 months postoperatively (T1), and the Pink esthetic score (PES) at T1 and 3 months later after prosthesis placement (T2).

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Change in peri-implant soft tissue thickness measured using cone-beam computed tomography (CBCT) at the baseline (T0) and 6 months postoperatively (T1)

### **Key secondary outcome(s)**

Esthetic improvement measured using the Pink esthetic score (PES) at T1 and 3 months later after prosthesis placement (T2)

### **Completion date**

08/09/2020

## **Eligibility**

### **Key inclusion criteria**

1. Bilateral missing teeth in the maxillary anterior and premolar area
2. Facial thin gingival phenotype facially (i.e. 1.5 mm) as evaluated using cone-beam computed tomography (CBCT) (Claffey and Shanley 1986)
3. Bilateral edentulous sites dimension of at least 5.5mm bucco-lingually, 5.5mm mesio-distally, and with a minimal bone height of 8 mm
4. Teeth adjacent to the selected edentulous site must be free of periodontal disease involvement
5. Adjacent teeth permit occlusal guidance
6. An opposing dentition to the edentulous area with teeth, implants or fixed prosthesis

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

10

**Key exclusion criteria**

1. Untreated rampant caries and/or uncontrolled periodontal disease
2. Insufficient inter-occlusal distance for implant placement and restoration
3. Smokers
4. Systemic diseases contraindicating the dental implant placement like osteoporosis and uncontrolled diabetes mellitus
5. History of radiation in the head and neck region
6. Pregnancy
7. Uncooperative patient

**Date of first enrolment**

04/04/2017

**Date of final enrolment**

01/02/2020

**Locations****Countries of recruitment**

Egypt

**Study participating centre**

**Mansoura University**

Mansoura

Egypt

35516

**Sponsor information****Organisation**

Mansoura University

ROR

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Islam Ateia (islammr7@gmail.com) through direct e-mail sharing, including patient raw data sheets (without names or contact details), participant consents, and stats sheets. Data will be available at the end of the study and will be stored for a lifetime.

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 30/12/2022   | 09/11/2023 | Yes            | No              |