

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

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

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

17/09/2016

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

Age group

Adult

Sex

Both

Target number of participants

10

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

Sponsor details

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Sponsor type

University/education

Website

<http://www.mans.edu.eg/en/>

ROR

<https://ror.org/01k8vtd75>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The study protocol is available but not yet published.

Intention to publish date

08/09/2022

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?
Results article		30/12/2022	09/11/2023	Yes	No