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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

Registration date
09/10/2021

Overall study status
Completed

Last Edited
09/11/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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
https://ror.org/01k8vtd75

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?
Results article		30/12/2022	09/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes