

Comparing the effect of three different mechanical methods to clean implant surfaces to treat peri-implantitis

Submission date 15/07/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/08/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Peri-implantitis is an inflammation of the gums and bone around a dental implant that can lead to loss of bone. Peri-implantitis a common occurrence in clinical practice is and the frequency of this problem is increasing due to wide choices in dental implant options. Currently, there is no unified protocol that provides clear, specific steps and an effective method to treat peri-implantitis.

Who can participate?

Adult patients with peri-implantitis.

What does the study involve?

Participants will be allocated to receive one of three different mechanical methods to clean the implant surface (manual curettage, titanium brush, and diode laser) during the procedure, with an equal chance of receiving each. At 6 months after surgery, the participants will undergo clinical and radiological assessments to evaluate the effectiveness of each method.

What are the possible benefits and risks of participating?

The main benefit of this study is the possibility to receive a recommendation for, and treatment with, the most effective method to use in treating peri-implantitis. There is a risk of not achieving good results in some cases, however, due to the follow-up period of 6 months post-operation, the study team can manage these cases.

Where is the study run from?

Damascus University (Syria)

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

From May 2022 to April 2024

Who is funding the study?

Damascus University (Syria)

Who is the main contact?
Dr Kenan Saoud, kenan.saoud@outlook.com

Contact information

Type(s)
Scientific

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Study information

Scientific Title
A comparative study to evaluate the efficacy of three different methods of peri-implantitis surgical regenerative interventions

Study objectives
Do the three methods used in this research to treat implant surfaces have clinical and radiographical differences?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2022, Scientific Research Committee Faculty of Dentistry at Damascus University (MazzeH Highway, Damascus, Syria; +963113341864; manager@hcsr.gov.sy)

Study design
A comparative interventional randomized controlled study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Peri-implantitis

Interventions

First, cases will be diagnosed clinically and radiographically to ensure the matching of inclusion criteria.

After local anesthesia, a full thickness flap will be made in the implant site, and the affected areas around the implant will be determined. Participants will be randomised to receive one of the three selected mechanical methods (manual curettage, titanium brush, and diode laser). For all participants, this will then be followed by chemical agents EDTA 19% and local antibiotic, and covering implants surface with the bone graft then confirm a very tight closure.

The randomization of the sample will be done by giving a number for each acceptable case within the research and placing a letter numbering for the three research groups, a case number will be drawn with a corresponding of letters to determine the method of work for each case.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Microscopic topography of the implant surface formed after applying each method of mechanical treatments measured using scanning electronic microscope SEM at baseline and 6 months after the grafting process
2. Dimensions of the grafted alveolar ridge in the area of the implant at the transverse plane measured (clinically) using cone-beam computed tomography systems (CBCT) the day following the surgery and 6 months after the grafting process
3. Dimensions of the grafted alveolar ridge in the implantation area at the transverse and vertical levels measured using cone-beam computed tomography systems (CBCT) at baseline and 6 months after the grafting process
4. Gingival health measured using assessment of gingival indices, bleeding on probing (BOP), and peri-implant pocket depth (PPD) at baseline and 6 months after the grafting process

Key secondary outcome(s)

1. Effect on the keratinized gingiva measured using keratinized gingival width will be measured by a periodontal probe from a reference point at the buccal side of the implant (mid buccal surface of the gingival former) to the MGJ (muco-gingival junction) before the surgery and 6 months after the grafting process
2. Pain after surgery measured using a visual analogue score (VAS) at baseline, 24 h, 48 h, and one week after surgery at baseline and 6 months after the grafting process
3. Patient satisfaction with the surgical procedure measured using patient satisfaction questionnaire (PSQ-18) at 6 months after the grafting process

Completion date

15/04/2024

Eligibility

Key inclusion criteria

1. ≥ 1 implant with peri-implantitis with a peri-implant pocket depth ≥ 6 mm, bleeding on probing, and bone loss of $< 50\%$ of the implant's surface area

2. The surface of the affected dental implant is treated with acid etching and sandblasting (SLA) technique
3. The bone defect surrounding the implant is ≥ 2 walls and is estimated to be ≥ 3 mm of the implant length
4. Good oral health
5. No periodontitis on remaining teeth and no history of periodontitis leading to the loss of teeth
6. Presence of a gum strip adhered to the implant area of ≥ 2 mm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Implant movement
2. An excessive occlusal load on the implant
3. Being treated with drugs that cause bone metabolism disorder such as corticosteroids, oral contraceptives, hormonal and chemical treatments, or have undergone radiotherapy in the face area
4. Pregnancy or breastfeeding
5. Smoking (>10 units per day)
6. General systemic diseases (such as diabetes, cardiovascular disorders, leukemia, high arterial tension, coagulation disorders, and metabolic diseases)

Date of first enrolment

01/08/2022

Date of final enrolment

01/02/2023

Locations**Countries of recruitment**

Syria

Study participating centre

Faculty of Dentistry of Damascus University

Al-Mazzeah highway

Damascus

Syria

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Sponsor information

Organisation

Damascus University

ROR

<https://ror.org/03m098d13>

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available on request from Dr Kenan Saoud, kenan.saoud@outlook.com and in the publication related to it after the end of the research.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	In Arabic language		08/08/2022	No	Yes