

Effect of photofunctionalization of dental implants on implants stability at an early stage of healing

Submission date 17/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/01/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/01/2025	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

Despite the high success rate of treatment with dental implants, the long healing period, especially in poor-quality bone, remains one of the most important limitations of its use. Therefore, efforts continue to reduce this time by improving the surface characteristics of the implant using various physical and chemical methods. UV photofunctionalization is defined as one of the methods of modifying the surface of titanium after UV treatment, including changes in physicochemical properties and improvement of biological features.

Who can participate?

Patients aged 18 years old and over with bilateral edentulous area in the maxilla

What are the possible benefits and risks of participating?

The possible benefits of using photofunctionalization of dental implant surfaces are to gain more implant stability in the early stage of the healing and accelerate osseointegration. However, the possible risks of participating may be related to the stress on the implants which may happen during measuring the implant stability using a dental device.

Where is the study run from?

Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University

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

December 2021 to December 2024

Who is the funding of the study?

Investigator initiated and funded

Who is the main contact?

Dr Mohammad Kattaa, Mohammed.katta96@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil Known

ClinicalTrials.gov (NCT)

Nil Known

Protocol serial number

Nil Known

Study information

Scientific Title

Effect the photofunctionalization on early osseointegration and Implant Stability of titanium dental implants in the maxillary

Study objectives

The null hypothesis was that no significant difference exists between the UV-treated and non-treated implants in terms of implant stability in the maxilla

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 02/02/2024, Damascus University (Oral and Maxillofacial Surgery Department, Faculty of Dental Medicine, Damascus University, Damascus, 4671, Syria; +96 11 33923011; verification. dicr@damascusuniversity.edu.sy), ref: DN-020624-237

Study design

Double-blind randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Improving the stability of the dental implants in the poor quality bone

Interventions

This study is a randomized controlled trial, including 2 groups of implants which will be placed in the same patients - the control group will receive conventional commercial implants, and the experimental group will receive UV-irradiated implants. Implants will be randomized into 2 groups using <http://www.randomizer.org/>.

The follow-up for each patient is 3 months with 4 visits for each patient :

1. 2 weeks postoperative
2. 4 weeks postoperative
3. 8 weeks postoperative
4. 12 weeks postoperative

Intervention Type

Procedure/Surgery

Primary outcome(s)

Implant stability measured using the Mega ISQ Implant Stability Meter at 5 endpoints: (T0) immediately after surgery, (T1) 2 weeks, (T2) 4 weeks, (T3) 8 weeks, and (T4) 12 weeks

Key secondary outcome(s)

Insertion torque measured using a Torque Ratchet immediately after surgery for all implants

Completion date

19/12/2024

Eligibility

Key inclusion criteria

1. Patients with sufficient residual bone for conventional implant placement
2. Patients with bilateral Edentulous area in the maxilla
3. Patients displaying compliance with oral healthcare instructions and necessary visits

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

13

Key exclusion criteria

1. Patients having undergone radiotherapy or with diseases such as osteoporosis that are a contraindication to implant placement
2. Patients with inadequate bone height and width available for implant placement and requiring horizontal or vertical bone augmentation
3. Medically compromised patients with systemic conditions that can impede implant stability and influence the treatment outcome

Date of first enrolment

01/02/2023

Date of final enrolment

01/02/2024

Locations

Countries of recruitment

Syria

Study participating centre

Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University
Mazzeh Highway
Damascus
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Sponsor information**Organisation**

Damascus University

ROR

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

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date