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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/01/2025	**Overall study status** Completed	
Last Edited 20/01/2025	**Condition category** Oral Health	

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?
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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
Syria
4671

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes