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

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| **Submission date**<br>17/01/2025 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>20/01/2025 | **Overall study status**<br>Completed | |
| **Last Edited**<br>20/01/2025 | **Condition category**<br>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?
Dr Mohammad Kattaa, Mohammed.katta96@gmail.com

## Contact information

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Public, Scientific, Principal investigator

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# Additional identifiers

# 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

### Primary study design
Interventional

### Study design
Double-blind randomized controlled clinical trial

### 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