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How low-level laser therapy helps dental implants stay stable in different bone types

Submission date
17/03/2025

Recruitment status
No longer recruiting

Registration date
19/03/2025

Overall study status
Completed

Last Edited
04/12/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to evaluate the effectiveness of laser biomodulation in enhancing the osseointegration and stability of dental implants. This research aims to improve the outcomes of dental implant procedures, potentially offering better long term success rates for patients and shortening the loading time.

Who can participate?
Patients aged 18-60 years old who are medically fit with sufficient bone volume and require bilateral maxillary dental implants.

What does the study involve?
Participants in this study will undergo the standard dental implant procedure with the application of laser every 2 weeks for 2 months. The procedure will be performed by a qualified dental professional, and follow-up visits will be scheduled to monitor the osseointegration and stability of the implant. During these visits, they may undergo radiographic imaging and other assessments as required.

What are the possible benefits and risks of participating?
Participants may benefit from improved implant outcomes. However, these benefits are not guaranteed. The risks involved in this study are similar to those associated with standard dental implant procedures, including but not limited to infection, implant failure, and discomfort. In addition, the use of laser is expected to enhance implant stability and osseointegration, potentially reducing the risk of implant failure.

Where is the study run from?
The study will be conducted at the postgraduate clinics of the College of Dentistry, University of Sulaimani.

When is the study starting and how long is it expected to run for?
December 2024 to December 2025

Who is funding 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

Protocol serial number
Research ID (702), College of Dentistry/ University of Sulaimani

Study information

Scientific Title
Effect of low-level laser therapy on stability of dental implants in D3 and D4 bone quality: a split-mouth randomized controlled clinical trial

Study objectives
Regarding secondary implant stability after 2 months, there is no significant difference between using laser therapy on the implant area and following standard procedures for dental implants in D3 and D4 bone quality in the upper jaw.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 16/12/2024, The Ethics Committee of the College of Dentistry (University of Sulaimani, As Sulaymaniyah, 46001, Iraq; +964 770 452 2890; dentistry.ethics@univsul.edu.iq), ref: COD-EC-24 -0057

Study design
Split-mouth randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Effect of low-level laser therapy on stability of dental implants in D3 and D4 bone quality

Interventions
Sample and sample size
Forty implants in patients aged 18-60 years old, requesting dental implants with bilateral D3 and D4 maxillary bone after taking informed consent for participation in this study will be included in this study. Then patients will be randomly recruited and the maxillary arches will be randomly assigned to two groups (20 implants for each group). For the randomization when a patient is recruited before any radiographic or clinical assessment randomly we assign one side of the Jaw to be study group and the other side as the control. This commenced with the upper right side being the control in the first case, the left side being the control in the next case and so on.

First group: Standard implant site preparation. (Control group one side of the maxilla for each test group).
Second group: Standard implant site preparation and Laser photobiomodulation.
Exclusion Criteria: Patients with systemic disease that affects bone metabolism and healing, smokers and bone height less than 10 mm will be excluded.

- Cone-beam computed tomography (CBCT) radiological assessment is going to be done for each patient to determine the volume of bone and density using the Hounsfield unit (HU).
- Surgical guide and flapless approach will be used for placement of the implants and for the precise localization of the implant for the next visits.
- PSK line two piece Oxy dental implants, diameter of 4.0 mm and 4.5 mm and length of 10.0 mm and 11.5 mm will be placed in at least 10 patients.
- Delayed implant placement and delayed loading protocols will be employed in this study.
- Low Level Diode laser will be used for laser group and the first session will be applied on the first day of implant placement and will continue over 2 months at intervals of every 2 weeks.
- Lasing Parameters: Wavelength (940nm) at a 2mm distance, continuous wave with 0.3 W output power at four different locations (Buccal, Palatal, Mesial and Distal) for 20 seconds each at minimum 10 J/cm2.
- Resonance Frequency Analysis (RFA) using Osstell® device will be used to record the ISQ at time of implant placement and after 2 months.
The Osstell ISQ Scale will be used to define the stability of the implant.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Implant stability quotient (ISQ) value measured using Resonance Frequency Analysis with an Osstell® device at time of implant placement and after 2 months

Key secondary outcome(s))
Marginal bone loss measured using cone-beam computed tomography (CBCT) radiological assessment in the initial healing period

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Medically fit patients requesting bilateral dental implants with D3 and D4 maxillary bone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with systemic diseases and/or on medications that affect bone metabolism and healing
2. Smokers
3. Bone height less than 10 mm

Date of first enrolment
01/12/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Iraq

Study participating centre
College of Dentistry, University of Sulaimani
City campus, Eskan, Zanko Street, Sulaimania
As sulaymaniyah
Iraq
46001

Sponsor information

Organisation
University of Sulaimani

ROR
https://ror.org/00saanr69

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

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			19/03/2025	No	Yes