Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Postoperative 660 nm Low-Level Laser Therapy on the Radiographic Crestal Bone Loss of Fresh Socket Implants

Protocol summary

Study aim

This study investigated the effect of postoperative 660 nm Low-Level Laser Therapy (LLLT) on the radiographic crestal bone loss of fresh socket implants.

Design

This study is a double blind clinical trial with two arm parallel groups. Thirty patients were randomly divided into two groups: laser (intervention) and no-laser groups (control). Random allocation list was generated using randomization software . Each patient could just provide an area for implant treatment.

Settings and conduct

This study was performed in Department of Maxillofacial Surgery of Islamic Azad University of Isfahan. Immediately after tooth extraction, the implant was inserted into the the tooth socket area in terms of the standard protocol. LLLT was immediately started after surgery, and was repeated for three times per week for 2 weeks. The operator was not blinded. All other contributors to the study were blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Individuals referred to the Department of Oral and Maxillofacial Surgery, were treated with tooth extraction and implant placement, without inflammation or gingivitis, Healthy adults who are at least 18 years old, Sufficient bone density to receive the implant, Having at least 6 mm bucco-lingual ridge width at the site of implant placement. Exclusion criteria Pregnancy or lactation, using anticoagulants, systemic glucocorticoid therapies, acute oral infection, untreated or uncontrolled periodontal disease.

Intervention groups

660 nm LLLT was applied in this study along implants longitudinal axis to the member of laser group(intervention group). To implants in the no-laser group(control group), the laser did not shine.

Main outcome variables

Bone quantification at the implant site was assessed using periapical intraoral radiograph and computerized software immediately after the surgery and also by passing 4 months from that.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191019045159N1**
Registration date: **2019-12-04, 1398/09/13**
Registration timing: **retrospective**

Last update: **2019-12-04, 1398/09/13**
Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Alireza Sighari Deljavan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3535 4123

Email address

alireza_sigharydeljavan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-10-07, 1398/07/15

Trial completion date
2019-10-07, 1398/07/15

Scientific title
Effect of Postoperative 660 nm Low-Level Laser Therapy on the Radiographic Crestal Bone Loss of Fresh Socket Implants

Public title
Effect of Low-Level Laser Therapy on Bone Loss around Dental Implants

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals referred to the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Islamic Azad University, Isfahan, Iran, were treated with tooth extraction and implant placement. patients without inflammation or gingivitis. Healthy adults who are at least 18 years old. Sufficient bone density to receive the implant without the need for bone augmentation. no history of tooth extraction within selected 6 months. Having at least 6 mm bucco-lingual ridge width at the site of implant placement for inserting an implant at least 4 mm in diameter in ideal position.

Exclusion criteria:
pregnancy or lactation systemic diseases affecting osseointegration using anticoagulants systemic glucocorticoid therapies history of radiotherapy in craniofacial region in the last 12 months smoking more than 10 cigarettes per day mouth cancer history of seizures Acute oral infection Untreated or uncontrolled periodontal disease

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Thirty patients were randomly divided into two groups: laser (intervention) and no-laser groups (control). Random allocation list was generated using randomization software (RandList version 1.2; DatIng GmbH, Tübingen, Deutschland). Each patient could just provide an area for implant treatment.

Blinding (investigator's opinion)
Double blinded

Blinding description
The stages of the study were described for each patient and the volunteers who completed the study completed the written informed consent form and entered the study. We placed the laser on the patient's surgical area in control group ,but no laser emission is received to them to avoid bias during the study. The amount of bone resorption was calculated by a radiologist using the software to identify the smallest pixel identifiable from the bone. The person who calculated the amount of bone resorption by software from the patient's graphs was blinded regarding group assignment. The data analyzer also did not know whether the patients were in the intervention or control group and the data were given to him as groups one and two.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University of Isfahan

Street address
Jey st

City
Isfahan

Province
Isfehan

Postal code
5157679445

Approval date
2018-09-12, 1397/06/21

Ethics committee reference number
IR.IAU.KHUISF.REC.1397.072

Health conditions studied

1

Description of health condition studied
Crestal Bone Loss

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Crestal Bone Loss

Timepoint
immediately after the surgery and also by passing 4 months from that.

Method of measurement
Bone quantification at the implant site was assessed

using periapical intraoral radiograph and computerized software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After selection of the patients based on eligibility criteria, local anesthesia was performed by injecting 2% lidocaine (with adrenaline 1/80000). After cutting the crestal and removing the mucoperiosteal flap and extracting the tooth without trauma, preparation of bone -level implant recipient was done under cooling with physiological serum solution, in terms of the manufacturer's protocol (Dio, Seoul, Korea). For all implants, a speed of 15rpm with a torque of 35-40 Ncm was used. Diameter of the implants was chosen so that, at least 1 mm of bone remained on both buccal and palatal sides after implant placement. For vertical positioning, the implant should also be positioned in the same level of buccal bone crest. After implantation, the implant was implanted with the surrounding mucosa and the area was sutured, and the sutures were removed by passing 7 days from surgery. After the surgery, all the patients received amoxicillin (1.5 g) or clindamycin (1.8 g) daily for 3 days as well as non-steroidal anti-inflammatory drug for pain relief and mouthwash. The patients were also received advice regarding oral hygiene. No temporary dentures were placed during the 4-month follow-up.A low-level 660 nm diode laser illuminated to surrounding tissues of the implant along its longitudinal axis was applied in this study. Low-Level Laser Treatment (LLLT) was started immediately after the surgery and was repeated three times per week for 2 weeks. Total radiation dose per treatment for each implant unit was 6.26 J / cm^2. Output power was checked before working with the power meter.

Category

Prevention

2

Description

Control group: After selection of the patients based on eligibility criteria, local anesthesia was performed by injecting 2% lidocaine (with adrenaline 1/80000). After cutting the crestal and removing the mucoperiosteal flap and extracting the tooth without trauma, preparation of bone -level implant recipient was done under cooling with physiological serum solution, in terms of the manufacturer's protocol (Dio, Seoul, Korea). For all implants, a speed of 15rpm with a torque of 35-40 Ncm was used. Diameter of the implants was chosen so that, at least 1 mm of bone remained on both buccal and palatal sides after implant placement. For vertical positioning, the implant should also be positioned in the same level of buccal bone crest. After implantation, the implant was implanted with the surrounding mucosa and the area was sutured, and the sutures were removed by passing 7 days from surgery. After the surgery, all the patients received amoxicillin (1.5 g) or clindamycin (1.8 g) daily for 3 days as well as non-steroidal anti-inflammatory drug for pain relief and mouthwash. To implants in the control group, the laser did not shine. We placed the laser on the patient's surgical area in control group ,but no laser emission is received to them to avoid bias during the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Oral and Maxillofacial Surgery Department of Islamic Azad University of Isfahan

Full name of responsible person
Alireza Sighari Deljavan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Hasan Momeni

Street address
Faculty of Dentistry, Islamic Azad University, Jay Street, Isfahan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Vice chancellor for research of Islamic Azad University of Isfahan

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Alireza Sighari Deljavan

Position
Postgraduate Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Position
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Latest degree
A Level or less

Other areas of specialty/work
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Position
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Latest degree
A Level or less

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after unidentifiable people

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
Data will be available to researchers working in academia and in the industry as well.

Under which criteria data/document could be used

All the scientific analyzes that are required to advance science and industry are permitted on the data of this study.

From where data/document is obtainable

For any information you can send an email to this email address: Alireza_sigharydeljavan@yahoo.com

What processes are involved for a request to access data/document

For recieving these documents you can send your Individual specifications and desired request to this email address: Alireza_sigharydeljavan@yahoo.com

Comments