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Research Protocol

Dentistry Section

Efficacy of Three Different Photobiomodulation Therapies on Primary and Secondary Implant Stability in D3 and D4 Bone Type- A Research Protocol for Randomised Controlled Trial

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ABSTRACT

Introduction: Osseointegration is considered one of the most important deciding factors to check for implant stability, which decides successful outcome of the implant. Photobiomodulation has been used to improve the implant stability by enhancing osseointegration. Photobiomodulation (PBM) or Low-level Laser Therapy (LLLT) causes an enhanced effect in the bone implant contact.

Need for the Study: There are no definitive therapies/protocol of LLLT in cases of bone density of D3 and D4. Also, there are no studies in literature which compares the different laser settings so that a standardised setting can be established. Therefore, there is a need to generate evidence, whether reducing the number of appointments and reducing the amount of energy given in D3 and D4 (compromised) bone can help achieve early loading in patients.

Aim: To evaluate and compare the effect of three different photobiomodulation therapies on primary and secondary implant stability in D3 and D4 bone type in comparison to control group to achieve early loading.

Materials and Methods: This randomised controlled, double-blinded trial allocated 108 patients having D3 or D4 bone, according to Misch classification into six groups. Three different PBM therapy which is either therapy A, B or C (placebo) will be used. The implant stability will be measured by Ostell meter in Implant Stability Quotients (ISQ) scale, immediately after surgery, after three weeks, after 12 weeks and after six months of surgery. The bone density will be measured before surgery and three months after surgery.

Expected Outcome: At the end of the study, an evidence will be generated, whether reducing the number of appointments and reducing the amount of energy given in D3 and D4 (compromised) bone can help achieve early loading in patients. Patients treated using PBM therapy, either protocol A or protocol B may show enhanced implant stability.

Keywords: Compromised bone, Early loading, Low level laser therapy, Osseointegration

INTRODUCTION

Exemplary aesthetics, high success rates and functional characteristics has made the field of dental implants very popular, amongst patients with dentition defects. However, risk of failure in implants is still seen in many patients due to lack of osseointegration. A number of factors can influence osseointegration. Various factors like physical, chemical, and biological promotes the process of osseointegration, from which one of the factor is 'Photobiomodulation therapy (PBMT)'[1]. "Photobiomodulation (PBM) is a non invasive treatment that uses light irradiation of low intensity so that the effects are a response to light and not to heat" [2]. LLLT or rather called PBM therapy has become popular recently, with its applications in field of dentistry and medicine continuously growing [3].

Lasers at various wavelengths that are popularly used for PBM are visible (660 nm), near infrared (810 nm and 940 nm), and less often, midinfrared (1,040 nm, 2,940 nm, 9,400 nm, or 10,400 nm). Broad light sources and Light Emitting Diode (LED) are also becoming famous due to enhanced effect, good quality and control that is offered by the latest devices [4]. Experimental study have described that PBM invigorates the proliferation and differentiation of osteoblasts and also it increases the bonding to titanium implant [5].

There is a study that documented that after implant laser irradiation, there was seen an enhanced effect in the stability of implant and the Bone-Implant Contact (BIC). LLLT laser which has a lesser density of energy invigorates the "mitochondrial and cellular membrane photoreceptors" to synthesise Adenosine Tri-Phosphate (ATP), which will further cause an enhancement of cell proliferation rate [6]. The stability of implant can be checked using various methods like reverse torque test, shear torque test, percussion test, radiographic analysis, periotest insertion torque test, and resonance frequency analysis [7]. Radiographic analysis by Cone Beam Computed Tomography (CBCT) can also help in the evaluation of bone density which can be significantly corresponded with other stability parameters of implant. Therefore, it is possible to predict the initial stability of an implant using CBCT before the placement of an implant [8]. Due to high diversity in the methodology related to duration, dosage and energy used in LLLT for which deriving conclusion as to what should be the optimum/ideal range for duration, energy and dosage is not clear. Hence, PBM therapies need to be standardised using laser parameters and RCT with longer follow-up periods, proper sample size calculation, randomisation and blinding method should be conducted to reduce risk of bias. Thus, in the present study, a comparison will be done between three different photobiomodulation therapies on primary and secondary implant stability in D3 and D4 bone type in comparison to control group to achieve early loading. Hence, the present ptotocol is planned with following objectives:

- To evaluate the primary and secondary implant stability in D3 and D4 type bone after Photobiomodulation following Low Level Laser Therapy (LLLT) A, LLLT B and therapy C (placebo).
- To compare the primary and secondary implant stability in D3 and D4 type bone amongst all six experimental groups.
- To assess and compare the effect of therapy A and B as compared to C (control) on implant loading time in D3 and D4 bone type.

MATERIALS AND METHODS

This randomised controlled, double-blinded trial shall be performed at the Department of Prosthodontics and Crown and Bridge, Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India. for a period of 3 years. The study began in February 2022 and is going on as per the planned protocol.

Ethical clearance has been obtained from the university with the reference number DMIMS(DU)/IEC/2021/628. The study is registered under registration number CTRI/2022/04/042033.

Inclusion criteria: Patients in whom requisite volume of bone for placement of implant is required in such manner that the patient doesn't have the need for augmentation of bone, patients with missing teeth and those indicated for implant therapy for replacement of same having D3 and D4 type bone quality (150 to 850 HU) will be included as cases in the study after taking written informed consent. Healthy men and women patients of age 20-50 years, who have undergone hygienist treatment before clinical trial and have good oral hygiene index will be included as controls in the study.

Exclusion criteria: Those patients with D1, D2 and D5 bone, or having chronic debilitating diseases like scleroderma, rheumatoid arthritis, immunocompromised patients or those with systemic disease (osteoporosis) or with present or past history of deleterious habits (smoking/tobacco/alcohol), patients with uncontrolled periodontal disease or who had undergone radiotherapy/ bisphosphonate medication, or patients who will report of taking drugs interfering with wound healing and not willing to participate in the study or report for follow-ups, will be excluded from the study participants.

Sample size calculation: The minimum sample size for each group is 18 according to formula:

k=n2/n1=1

where n 1=sample size for group #1,

n 2=sample size for group #2, K=ratio of sample size for group #2 to group #1.

A total of 108 patients reporting to the study centre for implant placement and have D3 or D4 bone type according to Misch classification [9] will be considered for the present study.

The experimental groups to be studied shall be as follows [Table/Fig-1].

GROUP 1-Low Level Laser Therapy (LLLT) A in D3 bone

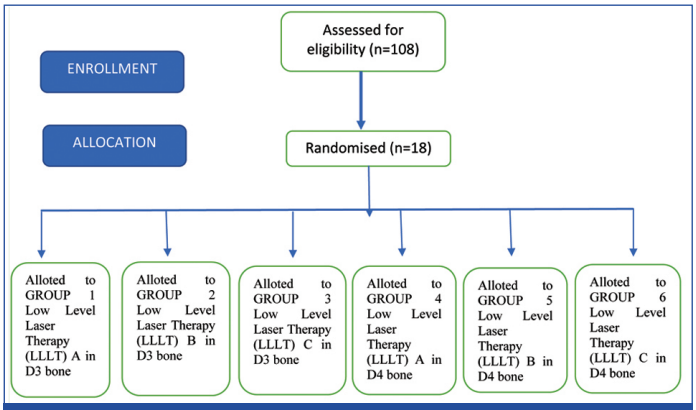
GROUP 2-Low Level Laser Therapy B in D3 bone

GROUP 3-Low Level Laser Therapy C in D3 bone

GROUP 4-Low Level Laser Therapy A in D4 bone

GROUP 5-Low Level Laser Therapy B in D4 bone

GROUP 6-Low Level Laser Therapy C in D4 bone



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flowchart.

Study Procedure

Laser parameters will be as follows: "Biolase Epic X dental diode laser at a wavelength of 940 nm" for all three protocols [Table/Fig-2]. In the systematic review by Chen Y et al., [1], the studies which showed a desirable implant stability enhancement were considered, as there was no comparison done between the different laser parameters.

LLLT specifications	Protocol A	Protocol B	Protocol C (placebo group which will follow either Protocol A or B but with the laser handpiece in kept in off mode)
Output Power	100 mW	100 mW	NA
Spot area	0.5 cm^2	0.5 cm^2	NA
Average power density (irradiance)	200 W/cm^2 Or 20 mW/cm^2	200 W/cm^2 Or 20 mW/cm^2	NA
Fluence	8 J/cm^2	8 J/cm^2	NA
Mode	Continuous	Continuous	NA
Site	Buccal and palatal site, in contact with mucosa	Buccal and palatal site, in contact with mucosa	Buccal and palatal site in contact with mucosa
Time	40 seconds at each side	40 seconds at each side	40 seconds at each side
Energy	4 J each side	4 J each side	NA
Sessions	7 (surgery day, at 2, 4, 6, 8, 10, and 12 days postoperatively)	5 (surgery day, 3, 7, 10, and 14 days postoperatively	Either A or B
Final dose	**54 J**	**40 J**	**NA**

[Table/Fig-2]: Laser parameters for different protocols.
LLLT: Low level laser therapy

All surgical procedures and irradiation procedure will be performed by the same surgeon. The patient irradiation will be performed on randomly selected patients assigned to one of the experimental group following the laid out inclusion and exclusion criteria. The randomisation will be done using computer generated randomisation. The patient shall be blinded about the treatment intervention. Along with the patient, the evaluator will be blinded and he will check the implant stability and bone density changes. The study sequence is described below in a step-wise manner.

Following patient selection and group allocation, the bone density (grey values) of implant site shall be measured using CBCT at three different locations viz. apical, middle and cervical before implant surgery for all the patients. After implant placement, the experimental groups shall receive treatment as per designed PBM therapy which is either Therapy A, B or C which is randomly allocated. The implant stability will be measured by Ostell meter in ISQ scale, immediately after surgery, after three weeks, after 12 weeks and after six months of surgery. The bone density will be measured using Hounsfield units before surgery and three months after surgery. The measurements will be done five times and mean results will be evaluated. There will be measurement of bone density (grayscale value) at three levels; cervical, middle, and apical part of each implant. The measurement will be done by CBCT software (Romexis).

The grading for Hounsfield Units (HU) will be as follows: [9]

D1: >1250 HU

D2: 850-1250 HU

D3: 350-850 HU

D4: 150-350 HU

D5: <150 HU

EXPECTED OUTCOME

At the end of the study, an evidence will be generated whether reducing the number of appointments and reducing the amount of energy given in D3 and D4 (compromised) bone can help achieve early loading in patients. Patients treated using PBM therapy either protocol A or protocol B are expected to show enhanced implant stability.

DISCUSSION

Low Level Laser Therapy (LLLT) or Photobiomodulation (PBM) is an innovational method that can be used to accelerate the healing of bone and also enhance the initial stability of implant. A monochromatic light with a low energy density is applied which will cause non thermal photochemistry effects on cellular level [10]. A study conducted by Matys J et al., documented an increase in the stability of implants and the Bone-Implant Contact (BIC) factor, after implant laser irradiation [6]. The 635 nm diode laser was used in 40 implants placed in 24 patients with D2 bone. It had two groups control group and patients undergoing LLLT and the study evaluated the implant stability and bone density after LLLT. They reach the conclusion that LLLT enhanced secondary implant stability after four weeks and increased bone density value after 12 weeks at the middle and apical level [6].

Gokmenoglu C et al., conducted a study in 15 partially edentulous patients divided in two groups LED and control with type 2 or type 3 bone (Lekholm and Zarb). The effect of LED PBM was checked on osseointegration by measuring ISQ values and evaluating Interleukin (IL)-1b, Tumour Growth Factor (TGF)-b, Prostaglandin E2 (PGE2), and Nitric Oxide (NO) levels in the Peri-Implant Crevicular Fluid (PICF) during a three-month period. They reached a conclusion that, LED application to surgical area showed a positive effect on the osseointegration process, and implant stability could be maintained [11].

Gholami L et al., conducted a literature review for in-vivo (animal or clinical) articles, until April 2019, wherein only studies with low irradiation doses without any thermal effects used only for their photobiomodulatory purposes were included and positive effects of application of LLLT on most of studies were reported [3]. Chen Y et al., conducted, a systematic review and reached a conclusion that the present studies conducted were not able to provide enough evidence which will show the positive effects of PBM therapy on implants in patients. Hence, an increased number of high-quality clinical Randomised Controlled Trials (RCTs) are required to verify the data and to draw convincing conclusions [1].

CONCLUSION(S)

Photobiomodulation can be achieved using low levels of laser irradiation and seems to be a promising technique due to its positive effects and biomodulatory interaction with cells and living tissue. It was first used in medicine and physiotherapy, but recently, it is also finding its way into routine dental practice. The present study will help to know the effects of photobiomodulation on osseointegration, which will enhance the primary and secondary stability of dental implants.

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