Research

A randomized controlled trial for evaluation of bone density changes around immediate functionally and nonfunctionally loaded implants using three-dimensional cone-beam computed tomography

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Abstract

Aim: The aim of this study was to compare and assess bone density changes around immediate functionally and nonfunctionally loaded implants.

Settings and design: *In vivo* comparative study

Materials and Methods: Sixty participants selected based on the predetermined inclusion and exclusion criteria received single tooth implants in mandible under two implant loading protocols: Immediate functionally loaded (IFL) and immediate nonfunctionally loaded (INFL). Randomization was done by computer-aided simple randomization procedure. Self-tapering, aggressive SLA implants were placed in the single tooth edentulous sites of mandible in both the groups. Three-dimensional cone-beam computed tomography (3D CBCT) was taken at baseline, 3 and 6 months postimplant placement. Quantitative analysis of the bone density was performed using 3D CBCT in three areas around the implants at crestal, middle, and apical regions of implants.

Statistical Analysis Used: Quantitative data were summarized as mean $\pm$ standard deviation. Statistical analyses were performed using the SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA) by unpaired *t*-test.

Results: Bone density changes after implant placement in IFL group from baseline to 3 months were; crestal region (314.18 $\pm$ 71.69), middle (278.23 $\pm$ 70.17), apical (274.70 $\pm$ 59.79) and changes from 3 to 6 months were; crestal (−105.55 $\pm$ 39.60), middle (−114.80 $\pm$ 41.46), apical (−141.88 $\pm$ 69.58). Bone density changes after implant placement in INFL group from baseline to 3 months were crestal region (199.42 $\pm$ 47.97), middle (56.91 $\pm$ 10.39), apical (200.98 $\pm$ 67.43) and changes from 3 to 6 months were; crestal (−194.38 $\pm$ 75.30), middle (−204.40 $\pm$ 63.75), apical (−191.28 $\pm$ 62.33).

Conclusions: It was concluded that INFL implant group showed better bone density when compared to IFL implant group.

Keywords: Bone density, dental implant, immediate loading, stability

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INTRODUCTION

Prolonged healing durations of 3–6 months serves as the basis of success associated with conventional loading (CL) or delayed loading protocols. The rationale is to keep the implant in an uninterrupted environment during the healing period.[1] The concept of immediate loading came into existence mostly due to the increased treatment time and prolonged period of edentulousness associated with the CL protocol. In addition, reduced bone density has been observed around the delayed loaded implant after the 3–6 months period due to the lack of functional stimulation during the healing period. These studies concluded that mechanical bone stimulation serves as one of the key factors in the regulation of bone remodeling.[2-5]

Immediate and early loading of dental implants as a technique is gaining popularity gradually owing to drastically reduced treatment periods and minimal discomfort attributed to the periods of edentulism. Copious histological and histomorphometric studies have shown that the osseointegration with immediately loaded implants is comparable to that with delayed loaded implants. Piattelli *et al.* in their study reported that, as the bone is loaded post the initial healing period, the peri-implant bone changes from a fine trabecular pattern to coarser and denser trabecular pattern, especially in the crestal half of implant interface.[6] This ossification process around implants, improves the support for the final prosthesis. However, literature pertaining to assessment of alterations in mineral bone density around implants and the comparison between different loading protocols are scarce.

Immediate loading protocols are dependent on a high primary stability which in turn is affected by a multitude of factors such as the quality and density of the available bone, as well as, the design, shape and surface characteristics of the implant. As concluded by various studies, immediate loading of dental implants can be accomplished successfully.[7] Furthermore, there might not exist a significant difference in parameters such as marginal bone levels with different loading protocols. Marginal bone levels are determined by implant surface modifications, design, implant position, surgical technique employed, and implant-abutment configuration.

In the long-term, greater resistance to occlusal forces can be achieved with an increased bone density around the implants, more so when considering the immediately loaded implants. However, there is a scarce reporting of literature concerning the quantitative assessment of bone mineral density (BMD) changes around implants, especially immediately loaded implants. Various tools can be utilized for such an assessment. One of the valid and widely used methods of assessing BMD at various skeletal sites is dual energy x-ray absorptiometry (DEXA).[8,9] However, cross-sectional imaging isn't an option extended with DEXA. Consequently, its applicability for implant placement is low. Other conventional imaging modalities being 2 dimensional, such as digital panorams, radiovisiography, cephalometric and tomographic images don't offer the possibility of accurate measurements of bone width and height. Hence, alternate computing tools, such as three-dimensional cone beam computed tomography (CBCT) and computerized axial tomography (CT) have been utilized to measure BMD in the oral cavity.[10]

The present study was conceptualized to determine whether there exists a difference in the quantitative radiographic bone density changes around implant as measured using CBCT scans, under the demanding conditions of immediate functional and nonfunctional loading. The null hypothesis was that no difference would be found in the alveolar bone density between immediate functionally and immediate nonfunctionally loaded (IFL and INFL) implants.

MATERIALS AND METHODS

Source of data

This prospective study progressed over the course of 2½ years in Department of Prosthodontics, Crown and Bridges, Faculty of Dental Sciences, King George's Medical University, Lucknow, U.P. and ethical clearance was obtained (Reference Code: 84th ECM IIA/P11).

Sample size

Sample size was calculated using the following formula:

$n = 17\ \sigma^2/\Delta^2 + 1$

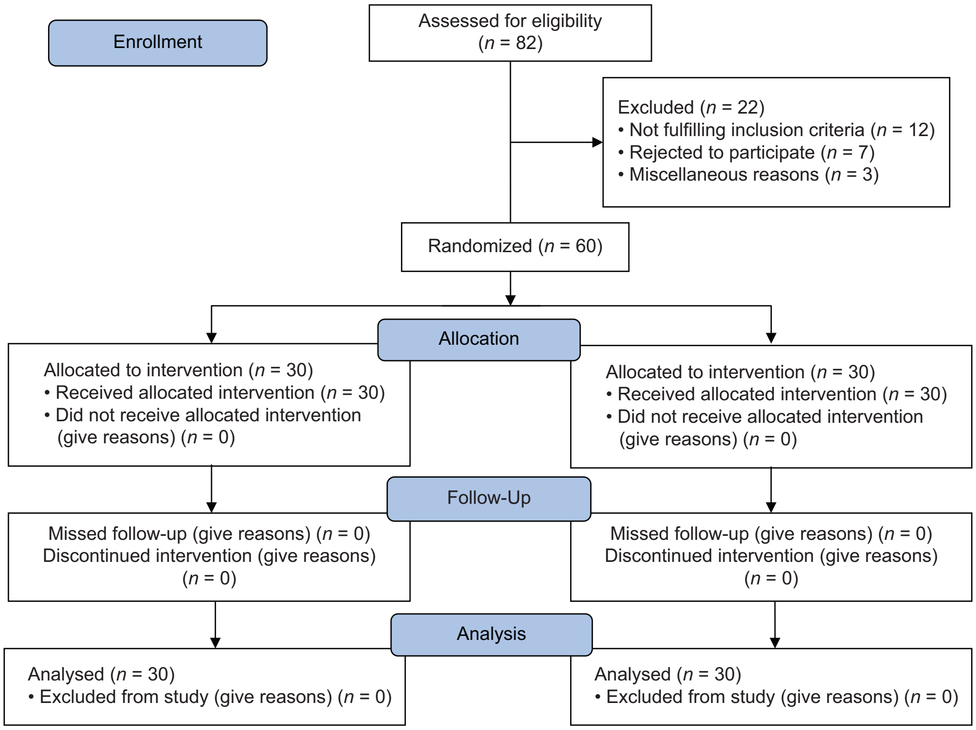
n = Sample size

σ = Standard deviation (SD)

Δ = Difference in effect of two interventions.

Study design

This was a randomized, prospective, longitudinal and *in vivo* comparative study. Eighty-two subjects were assessed for eligibility, out of which sixty subjects were enrolled for the study fulfilling the following inclusion and exclusion criteria [Flow Chart 1]:



Flow Chart 1: CONSORT 2010 flow chart

Inclusion criteria

1. Edentulous area in the posterior mandible with a single tooth missing
2. Healthy patient with no systemic conditions, good oral hygiene and consenting to participate
3. Subjects aged >18 years
4. Subjects with bone volume of more than 10.0 mm in height and 7.0 mm in width as evidenced on a preoperative CBCT scan
5. Subjects having implant stability quotient (ISQ) value of stability more than 60 during implant surgery.

Exclusion criteria

1. Systemic conditions which are contra-indications to the surgery, such as uncontrolled diabetes, presence of immunosuppressed state, history of head and neck cancer, patients on anticoagulants, and patients on oral/intravenous aminobisphosphonates
2. Patients needing regenerative bone techniques prior to implant insertion
3. Patients with diseases pertaining to oral cavity
4. Missing antagonistic teeth in the opposite maxillary arch.

The patients fulfilling study criteria were randomly divided by computer aided simple randomization into two groups, each consisting of thirty patients:

- Group I - Self-tapering SLA implants subjected to IFL was control group
- Group II - Self-tapering SLA implants subjected to INFL was test group.

Clinical procedure

Meticulous clinical and radiographic analysis was carried out for the preoperative evaluation of each subject. Bone anatomy was evaluated prior to implant placement using CBCT (CS9300 carestream, Atlanta, GA). Height and thickness of the bone was evaluated using the resultant DICOM files and implant dimensions were decided accordingly for each subject. The self-tapering, aggressive SLA implants of Tag Dental, Noga Medical, Israel were planned to be used in the present study as they have good initial stability and short healing period.

Following routine surgical protocol, prophylactic dose of antibiotic was given to the patients 1 h prior to surgery, followed by anesthetizing locally using articaine with adrenaline (1:100,000). A mid-crestal incision along with two lateral releasing incisions was given in fully healed single edentulous sites and a full-thickness flap was raised. Sequential osteotomy following manufacturer's recommendations was done. Equi-crestal placement of implants followed by torquing using a manual wrench (35 Ncm) was done to achieve primary implant stability. ISQ values were recorded using RFA (Osstell, Integration Diagnostics, Göteborg, Sweden) using a transducer placed on the fixtures. Stimulation of the elements using a sinusoidal wave causes vibration of the beam. RFA values are recorded as ISQ on a scale from 1 to 100. Implants could only be loaded immediately (within 48 h after implant placement) by means of a single provisional resin crown when their mean ISQ recorded was equal to or more than 60. A prefabricated titanium abutment was prepared and screwed on the implant followed by placement of a provisional resin crown (Protemp, 3M) on the abutment. Occlusion was carefully evaluated using articulating paper (40 μ) (Arti-Check micro-thin, Bausch, Nashua, USA). As these tear resistant papers are coated with blue ink on one side and red on the other, the same paper can be used to evaluate centric as well as eccentric contacts by alternating the two colors. In the IFL group (n = 30), only light static contacts during maximum intercuspation as compared to adjacent natural teeth were established wherein during centric contact adjacent natural teeth had heavier contacts as compared to the centric primary contact on the implant crown [Figures 1-4], and any undue overloading was avoided. In the INFL group (n = 30), no contacts during maximum intercuspation or during eccentric movements were left [Figures 5-8]. Hence, in INFL group there wasn't any contact between the rehabilitated implant crown and the antagonist tooth at all times, making the implant loaded nonfunctionally. Postprovisionalisation, oral hygiene maintenance instructions, anti-inflammatory drugs (ibroprofen 500 mg BD for 5 days) and antibiotic (amoxicillin 500 mg TDS for 5 days) were prescribed. All subject were recalled after 1 week for evaluation of surgical site and removal of sutures. The provisional crowns were left in place for a period of 6 months and subsequently replaced by PFM crown. At 3 months appointment, a fresh CBCT was recorded for each patient, in both groups, which was repeated again at 6 months appointment. Detailed radiographic evaluation was done at baseline, 3 months and 6 months. Thereafter, quantitative analysis of bone density was performed in both the groups using CBCT in three areas i.e., crestal, middle and apical region of implants.

Assessment of bone density

DICOM files obtained using software (CS 3D imaging) were used for bone density assessment of each subject.

Figure 1: Preoperative photograph of immediate functionally loaded group

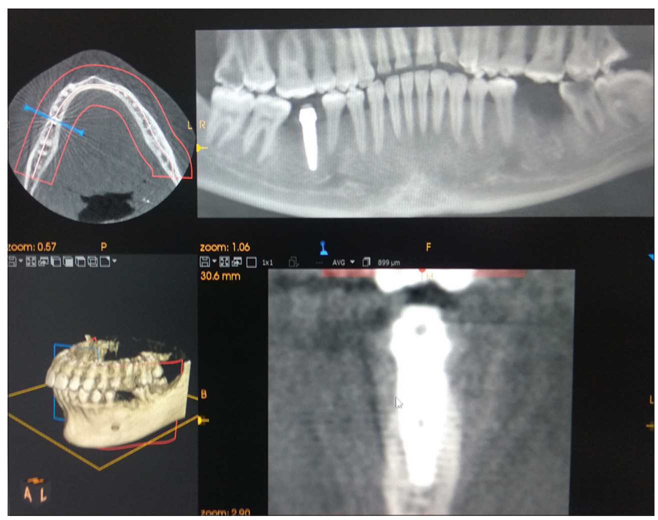


Figure 2: Preoperative assessment of bone by cone beam computed tomography

Figure 3: Clinical photograph with abutment

Figure 4: Clinical photograph with Prosthesis

Figure 5: Preoperative photograph of immediate nonfunctionally loaded group

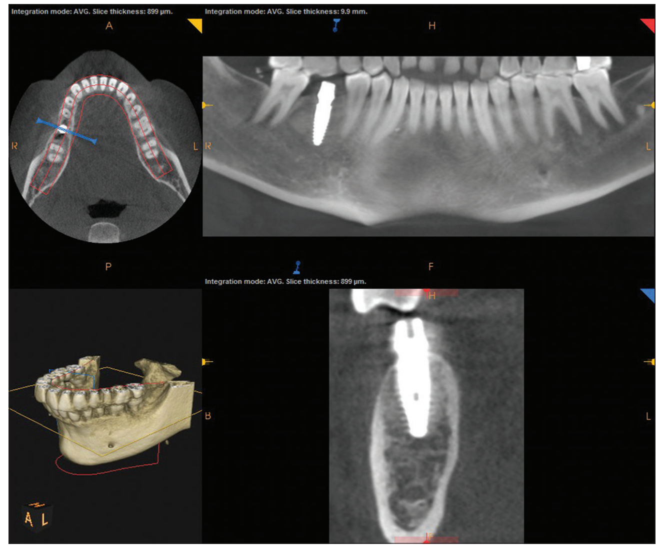


Figure 6: Preoperative assessment of bone by cone beam computed tomography

Figure 7: Clinical photograph with abutment

Figure 8: Clinical photograph with prosthesis

By moving the pointer from one region to another on the monitor, this software automatically provide the changes in the values in numbers. The values of the bone around each implant were measured in three areas around the implants at crestal, middle and apical region of implants.

Statistical analysis

The results were analyzed using descriptive statistics and making comparisons among various groups. Quantitative data was summarized as mean ± SD. Statistical analysis was done using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA) using unpaired *t*-test.

RESULTS

Implants in both groups were placed from January 2018 to January 2020. All data were recorded till July 2020. Baseline characteristics of two groups were statistically similar like gender, age, implant lengths and implant diameter and it did not affect the outcome of the present study.

Intragroup bone density measurements revealed that INFL group showed lesser bone density changes when compared to IFL group at the three levels i.e., crest, middle and apical, at the predetermined time intervals [Table 1].

Intergroup comparison of bone density changes at the crestal region showed significant differences at baseline to 3 months ($P < 0.001$) and 3–6 months ($P < 0.001$) [Table 2].

In the middle region the significant differences were found between both group from baseline to 3 months ($P < 0.001$) and 3–6 months ($P < 0.001$) [Table 3].

In the apical region significant differences were found between both group from baseline to 3 months ($P < 0.001$) and 3–6 months ($P < 0.005$) [Table 4].

Overall the significant differences were found between IFL and INFL group in bone density changes from baseline to 3 months ($P < 0.001$), 3 months to 6 months ($P < 0.001$)

with INFL group showing lesser bone density changes when compared to IFL group [Table 5].

DISCUSSION

In implant dentistry, starting from preoperative evaluation and examination to the actual surgical procedure to be followed and finally the prosthetic planning, including the loading protocol, the precise time of loading as well as the maintenance of the implant in the long run, is all dependent on the bone density.[11] The results of the present study stated that bone density was better maintained in INFL group when compared to IFL group. Therefore null hypothesis of the study was rejected. Bone density changes occurring during the course of this study were analyzed using 3D CBCT. Problems of projection geometry, superimpositions and total absence of the third dimension of bone depth, makes 2-D imaging not 100% accurate and reliable.[12,13] Hence, to improve the accuracy of bone density assessment, 3D CBCT was used in the present study.

Prosthetic restoration of an implant can be done either using conventional loaded protocol or immediate or early loaded protocol. Romanos *et al*. showed that following immediate loading of threaded implants, a bone-to-implant contact is established similar to that of conventionally loaded implants.[14-16] Also, immediate loading protocol reduces the overall treatment time as well as the cost, along with reducing the surgical exposures by eliminating second stage surgery. Hence, immediate loading approach has emerged as a more superior protocol with wide patient acceptance. Immediate prosthetic rehabilitation following implant placement can be accomplished either functionally or nonfunctionally.[17]

In the present study, subjects were divided into two groups on the basis of loading. Bone density was assessed at crestal, middle and apical region of the implant for both groups at periodic intervals of 0, 3 and 6 months postimplant placement and immediate rehabilitation. The CBCT measure of bone of implant in the both IFL group and INFL group showed decreased mean bone density at 3 months compared to baseline; however the mean bone density increased from 3 months to 6 months. The decrease in bone density at 3 months postimplant placement, in both groups, can be explained by formation of initial weaker and less mineralized woven bone after implant osteotomy. Thereafter, an increase in mean bone density values noted with both groups from 3 months to 6 months illustrates the conversion of less mineralized woven bone to highly mineralized and organized lamellar bone.[18] In the present study, significant bone changes have been observed at the apex after implant placement in both IFL and INFL groups. On intergroup comparison, the bone density in the apex region was found to be significantly reduced in IFL group compared to INFL group. This could be attributed due to the stress created by the immediate functional loading of the implant in IFL group used in the

Table 1: Mean bone density in the crestal, middle and apical region after implant placement in immediate functionally loaded and immediate nonfunctionally loaded group at predetermined time intervals

Timeline	Crestal	Middle	Apical
	IFL Group		
Baseline	1541.20±406.17	1438.05±400.29	1242.82±376.82
3 months	1227.02±422.10	1159.82±417.01	968.12±368.69
6 months	1421.40±389.97	1364.22±386.59	1159.40±362.85
	INFL Group		
Baseline	1507.00±427.00	1433.17±426.52	1237.62±406.83
3 months	1307.58±438.74	1239.22±433.36	1036.63±400.43
6 months	1413.13±427.48	1354.02±430.12	1178.52±407.17

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded

Table 2: Intergroup comparison of overall bone changes in the crestal region after implant placement between immediate functionally loaded and immediate nonfunctionally loaded group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	314.18±71.69	199.42±47.97	7.29	<0.001
3-6	−105.55±39.60	−194.38±75.30	5.72	<0.001

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

Table 3: Intergroup comparison of overall bone changes in the middle region after implant placement between immediate functionally loaded and immediate nonfunctionally loaded group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	278.23±70.17	56.91±10.39	5.11	<0.001
3-6	−114.80±41.46	−204.40±63.75	6.45	<0.001

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

Table 4: Intergroup comparison of overall bone changes in the apical region after implant placement between immediate functionally loaded and immediate nonfunctionally loaded group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	274.70±59.79	200.98±67.43	4.48	<0.001
3-6	−141.88±69.58	−191.28±62.33	2.90	<0.005

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

Table 5: Intergroup comparison of overall bone changes after implant placement between immediate functionally loaded and immediate nonfunctionally loaded test group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	289.04±69.03	198.12±57.41	9.61	<0.001
3-6	−120.74±53.75	−196.69±66.85	8.40	<0.001

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation present study.[19] Bone density changes in the apex postimplant placement is consistent with the study by Tavitian *et al*.[20] INFL group also showed lesser bone density changes in the middle region as compared to the IFL group at all times. Also, the crestal bone density changes was found to be significantly higher in the IFL group compared to INFL group. Stress concentration usually is highest at the crestal bone-implant interface.[21,22] The higher bone density changes at the crest in IFL group compared to INFL group can be attributed to increased crestal bone loss along with higher crestal bone demineralization seen with IFL implants.[23]Along with that, lateral forces exerted on IFL group may also be an attribute to the higher bone density changes as compared to INFL group where no contacts were present in the prosthesis.[24] Overall intergroup comparison of the IFL and INFL at all regions, showed significant differences in bone density changes from baseline to 3 months ($P < 0.001$) and 3 months to 6 months ($P < 0.001$) with IFL group showing greater bone density changes as compared to INFL group from baseline to 3 months (289.04 ± 69.03 and 198.12 ± 57.41 respectively) and 3 months to 6 months (-120.74 ± 53.75 and -196.69 ± 66.85 respectively). Immediately provisionalised implants have varying degrees of micromotion depending on their loading protocol; functionally or nonfunctionally. Lesser degree of change in bone density from baseline in INFL group compared to IFL group can be attributed to comparatively smaller micromotion in INFL implants than IFL implants.[25,26]

Limitation

- The sample size of both groups was small and study lack more reliable split mouth design
- Long term, multi-centric studies with larger sample sizes and a longer follow up period are suggested for future research
- The result of study should not be extrapolated for all type of implants.

CONCLUSIONS

Within the limitation of the present study, we concluded that INFL implant group showed lesser bone density changes when compared to IFL implant group and it was statistically significant. INFL implant improves the bone density of the patients. Bone density is one of the important factors affecting the overall success of treatment. Hence, quantification analysis of bone density is essential.

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Conflicts of interest

There are no conflicts of interest.

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