#### **Original Article**

### Evaluation of crestal bone loss and stability of immediate functional loading versus immediate non-functional loading of single-mandibular posterior implants: A pilot randomized controlled clinical trial

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#### ABSTRACT

**Background:** The aim of this study is to evaluate and compare the crestal bone loss and stability of single mandibular posterior dental implants placed in immediate functional loading (IFL) and immediate nonfunctional loading (INFL) during 6 months after placement.

**Materials and Methods:** Forty single piece root form titanium implants were placed in 20 patients using IFL and INFL techniques. The change in the level of crestal bone was measured on standardized digital periapical radiographs using SOPRO imaging software and stability of implants using resonance frequency analyser taken at the baseline, 1, 3, and 6 months. The measurements were statistically analyzed using the independent and paired *t*-test (P < 0.05, statistically significant).

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Address for correspondence: Dr. Sruthima NVS Gottumukkala, Department of Periodontics, Vishnu School of Dentistry, Bhimavaram, Andhra Pradesh, India. E-mail: drsruthima@ vahoo.co.in **Results:** The mean change in the crestal bone level from baseline to 6 months was significant in both techniques. The implant stability quotient (ISQ) values at first and third months were lower than those at the baseline for both the groups. However, the ISQ values at the sixth month were similar to baseline for both the groups. The crestal bone changes and the ISQ values when compared between the groups showed no statistically significant difference.

**Conclusion:** IFL of dental implants have equivalent results and success rate as that of immediately provisionalized implants within the limitations of this study.

Key Words: Crestal bone loss, dental implants, immediate loading, implant stability, resonance frequency analysis

#### **INTRODUCTION**

Implant dentistry has had drastic changes in the last few decades. The principles, hypothesis, and method of treatment have changed considerably. In recent times, treatment of edentulism with implant therapy has undergone a sea of changes in its various phases. Included among these are single stage and immediate loading implants placed with the flapless surgical

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approach.<sup>[1]</sup> Immediate occlusal loading refers to full functional occlusal loading of an implant within 2 weeks of placement.<sup>[2]</sup> Nonfunctional immediate restoration refers to implant prostheses placed within 2 weeks of implant placement with no direct functional occlusal loading.<sup>[2]</sup> Thus, fewer surgeries are necessary, and the risk of morbidity is lower. The patient will be able to obtain an acceptable esthetic result during the entire treatment period, and functional rehabilitation is improved.

The concept of functional loading is against the hypothesis that functional loads on to the implants during the initial healing period may cause failure due to fibrous ankylosis.<sup>[3]</sup> It was also felt that micromovement on to the implants will disturb the osseointegration of implants.<sup>[4]</sup> However, research has shown that immediate loading has given the same results as

delayed loading.<sup>[5,6]</sup> Despite its frequent use, minimal data are available on the long-term clinical success rate of immediate functional loading (IFL) and immediate non-functional loading (INFL) of implants. Recent studies have shown that nonfunctional immediate loading can yield predictable results.<sup>[7,8]</sup> However, there are very few studies supporting functional loading, especially in posterior mandible.<sup>[9]</sup>

Numerous factors, such as the surgical, host related, occlusal factors, and implant design and characteristics, play a role in the success of implant placement. Of the factors related to the surgical technique, the establishment of primary stability has been described as the single most important variable for success of immediately loaded implants.<sup>[10-12]</sup> The transmission of micromotion to an implant body after placement can result in the crestal bone loss and failure of osseointegration. It has been shown that micromotion must be limited to <100 nm to achieve implant-to-bone contact.<sup>[13]</sup>

In view of the above considerations, the aim of this study was formulated to compare the changes in the crestal bone levels and implant stability following implant prosthesis placement with IFL and INFL techniques.

#### MATERIALS AND METHODS

The study followed a double-blinded, randomization pattern using the fair coin tossing method after obtaining ethical clearance from the institutional review board. Twenty patients aged 25-45 years, with the need for single bilateral implant placement in the mandibular posterior region [Figure 1], sufficient alveolar bone volume at the implant site (i.e., >5.5 mm width labiolingually and >12 mm height), with type I-III bone quality and ASA Classification P1 (normal, healthy patient) were included in the study from August 2007 to November 2008. Patients with insufficient bone quantity, severe intermaxillary skeletal discrepancy, severe clenching habit, bruxism or other parafunctional habits, and patients who had already received or lost implants in the potential implantation site, drugs or alcohol abusers, smokers, pregnant or lactating women, patients who had undergone radiotherapy for malignancies of the head and neck region, patients undergoing chemotherapy, patients with systemic disorders including diabetes, hypertension, bleeding disorders, metabolic bone disorders, liver disease and renal diseases, immunocompromised patients including those infected with

HIV were excluded from the study. The study used a split mouth design wherein contralateral sites with single missing mandibular molars were randomly assigned to either of the groups, i.e., IFL and INFL groups using a fair coin tossing method.

Blood analyses were done for each patient to assess the health status. Diagnostic impressions — two of the concerned arch (mandibular arch in this study) and one of the opposing arch — were made in irreversible hydrocolloid (Aquasil Soft putty/Regular set, DENTSPLY DE TREY GmbH, Germany) using perforated stock impression trays. The impressions were poured in the type III dental stone. The interocclusal relationship was registered using modelling wax reinforced with zinc-oxide eugenol impression paste. This record was used to mount one set of casts on a mean value articulator. A diagnostic wax-up was done on the mounted cast. The site of implant placement was marked on the diagnostic cast in relation to the central fossa of the waxed-up tooth.

Bone mapping was carried out to assess the soft tissue thickness, measure the bone width, and evaluate the ridge contour. The area was anesthetized by local infiltration using 2% lignocaine with adrenaline. Bone meter was selected as an aid for bone mapping. Panoramic radiographs and digital periapical radiographs were used to assess the available bone dimensions. The magnification error was corrected by taking the radiographs with known dimensions of orthodontic wires. The site for flapless placement of fixture was selected based on the following criteria:<sup>[12]</sup>

- a. Bone width of at least 4.5 mm must be available without undercuts of more than 15°.
- b. Keratinized tissue of at least 5 mm must be present.

A surgical stent was fabricated on the diagnostic waxup using clear autopolymerizing acrylic resin (DPI-RR



**Figure 1:** Preoperative panoramic radiograph showing bilateral missing single posterior teeth

Cold Cure, DPI, India) to locate the site of implant placement intraorally during surgery. Single-stage, single-piece threaded titanium root form endosseous implants (varying from 8 to 11.5 mm in length and 4.2 and 5 mm in diameter) were selected based on the available dimensions. Implants (Adin dental implants, Afula) were carefully placed in the prepared sites [Figure 2] using the routine protocol with all the surgical precautions to avoid implant complications. Primary stability was checked with oblique pressure applied on the abutment using fingertips. A digital radiograph was obtained to confirm the complete placement of the implants and to check its parallelism with adjacent teeth [Figure 3].

Immediately after surgery, impressions were made using irreversible hydrocolloid and temporary restorations were fabricated using autopolymerizing acrylic resin (DPI-RR Cold Cure, DPI, India). The restorations were trimmed, polished, and were tried in patient mouth. Occlusal contacts were adjusted



Figure 2: Bilateral single mandibular posterior implants in place — intraorally

in the patient's mouth. Implants for the different loading protocols were selected randomly. For the non-functional group, the restorations were given in infraocclusion both in centric and eccentric relations [Figure 4]. For the functional group, restorations were given with centric occlusal contacts [Figure 5] without any eccentric occlusal contacts. The final impression was made in polyvinylsiloxane using the double mix technique with a stock tray. Both casts were mounted on the articulator using a wax interocclusal record reinforced with zinc-oxide eugenol paste. The restorations were fabricated in metal-ceramic and the occlusion followed was implant protective occlusion, i.e., light contact in centric and eccentric positions under normal biting force and uniform contact with adjacent teeth in centric and eccentric positions under heavy biting force. The provisional and definitive restorations were cemented using IRM zinc-oxide cement [Figure 6]. Postoperatively, the patients were advised to continue routine oral hygiene procedures. Patients were advised to eat soft diet and to avoid placing hard food in the area of provisional crown for 6 weeks. Patients were seen at regular 2-week intervals after the surgical procedure for the first month and

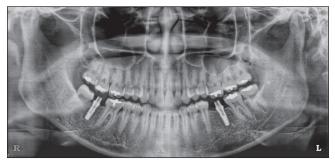




Figure 4: Nonfunctional restoration in infraocclusion both in centric and eccentric relations

Figure 3: Panoramic radiograph showing single mandibular posterior implants in parallelism to the adjacent natural teeth



Figure 5: Functional restoration with centric occlusal contacts

followed by monthly visits for 6 months. Occlusion was verified at every appointment.

After the implants were placed, a series of digital radiographs were obtained at 0, 1, 3, and 6 months duration to study the changes in the amount of crestal bone level. The distance from the finish line of the abutment to the crest of the bone where it contacted the implant was measured both mesially and distally [Figure 7]. The finish line of the abutment portion was taken as the reference point in this study. The distance from the finish line to the apex of the implant was also measured, which was then used to divide the known original length of the implant from the finish line to the apex to calculate the magnification factor. The magnification factor was then multiplied to the measured distance on mesial and distal sides of implant to derive the original distance.

Implant stability quotient (ISQ) values were measured with an Osstell® (Integration Diagnostics AB, Gothenburg, Sweden) [Figure 8]. The abutment of the implant was modified to allow smart peg attachment. The transducer was maintained perpendicular to the implant. Subsequently, ISQ values were registered in the distance.

#### **Statistical analyses**

The measurement values were subjected to statistical analysis using the independent *t*-test and paired *t*-test for any significant difference between the two parameters (P < 0.05, statistically significant). Mean and standard deviations were estimated from the samples for each study group. Mean values were compared between the groups by the independent *t*-test. The paired *t*-test was used to compare the mean values between different time points in each study group.

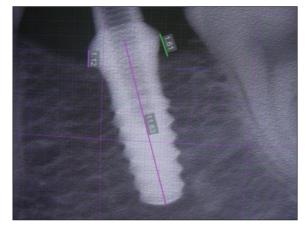
#### RESULTS

Twenty patients, i.e., 13 females and 7 males, participated in the study in the age range of 25-45 years and with requirement for placement of bilateral mandibular posterior implants. In addition, 16 molars and 4 premolars in the IFL group and 14 molars and 6 premolars in the INFL group were replaced using endosseous two-piece implants.

The results of the study showed that there was no statistically significant difference in the ISQ values [Table 1 and Figure 9] and the crestal bone height evaluated on the mesial [Table 2 and Figure 10] and distal sides [Table 3 and Figure 11] at the baseline,



Figure 6: Provisional restorations cemented



**Figure 7:** Radiographic measurement of crestal bone loss on mesial and distal surfaces of implants



Figure 8: Measurement of ISQ values with the Ostell apparatus

1 month, 3, and 6 months after implant placement between the IFL and INFL groups. Table 4 shows that the mean ISQ values measured on day 1, when compared to ISQ values of the first month and third month were significantly lower in both the groups. The ISQ values of day 1 compared to the ISQ values of the sixth month was not significantly different. ISQ values recorded on the first month and third month were significantly lower when compared with ISQ values of the sixth month.

Tables 5 and 6 show that in both the IFL and INFL groups on mesial and distal surfaces, the mean change in the crestal bone height from 1, 3, and 6 months was statistically significant. This represents that there was significant amount of bone loss from the first month to third month and sixth month in both the IFL and INFL groups.

#### DISCUSSION

The objectives of this randomized prospective clinical study were to evaluate the effects of immediate loading of single tooth mandibular posterior implants

# Table 1: Comparison of mean ISQ values forimmediate functional loading and immediatenonfunctional loading implants

Variable	IFL Mean ± SD	IFNL Mean ± SD	P Value
Baseline	55±3.87	55.8±1.64	0.68
1 month	46.6±3.57	48.8±1.64	0.25
3 months	49.8±3.27	51.8±1.78	0.27
6 months	54.6±4.03	55.2±1.48	0.76

## Table 2: Comparison of mean alveolar bone loss between IFL and INFL methods on mesial side

Variable	IFL Mean ± SD	INFL Mean ± SD	P Value
First month	0.084±0.011	0.082±0.008	0.76
Third month	0.144±0.018	0.166±0.015	0.07
Sixth month	0.226±0.024	0.226±0.024	1.00

\*P < 0.05; statistically significant

## Table 3: Comparisons of mean alveolar bone lossbetween IFL and INFL methods on distal side

Variable	IFL Mean ± SD	INFL Mean ± SD	P value
First month	0.068±0.008	0.072±0.010	0.53
Third month	0.146±0.011	0.148±0.008	0.76
Sixth month	0.206±0.011	0.214±0.016	0.40

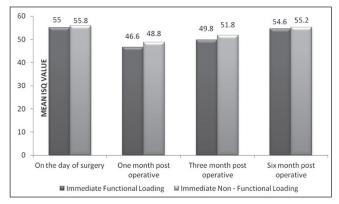


Figure 9: Comparison of mean ISQ values for the IFL and INFL techniques at different time intervals

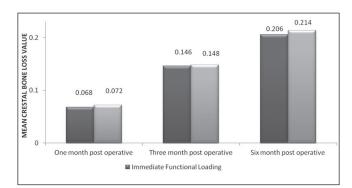


Figure 10: Comparison of mean crestal bone loss values for the IFL and INFL techniques on mesial sides at different time intervals

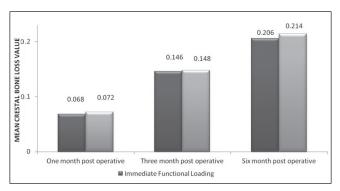


Figure 11: Comparison of mean crestal bone loss values for the IFL and INFL techniques on distal sides at different time intervals

#### Table 4: Comparisons of mean ISQ values between different time-points for IFL and INFL groups

Time points	IFL group		INFL group	
	Change mean ± SD	P value	Change mean ± SD	P value
Baseline, First month	8.4	<0.001*	7.0	<0.001
Baseline, 3 months	5.2	<0.001*	4.0	<0.001
Baseline, 6 months	0.4	0.688	0.6	0.468
1-3 months	-3.2	0.001*	-3.0	0.001
1-6 months	-8.0	0.001*	-6.4	0.001
3-6 months	-4.8	0.006	-3.4	0.008

\*P < 0.05; statistically significant

Time interval	Mesial surface	Mesial surface		
	Change mean ± SD	P value	Change mean ± SD	P value
1-3 months	-0.06±0.007	<0.001*	-0.07±0.004	<0.001*
1-6 months	-0.14±0.013	<0.001*	-0.13±0.008	<0.001*
3-6 months	-0.08±0.008	<0.001*	-0.06±0.007	<0.001*

Table 5: Comparisons of mean alveolar bone loss between different time-points for the IFL group on mesial and distal sides

\*P < 0.05; statistically significant

 Table 6: Comparisons of mean alveolar bone loss between different time-points for the INFL group on mesial and distal sides

Time interval	Mesial surface		Distal surface	
	Change mean ± SD	P value	Change mean ± SD	P value
1-3 months	-0.08±0.008	<0.001*	-0.07±0.005	<0.001*
1-6 months	-0.14±0.016	<0.001*	-0.14±0.008	<0.001*
3-6 months	-0.06±0.010	<0.001*	-0.06±0.008	<0.001*

\*P < 0.05; statistically significant

on the ISQ values, on crestal bone height (evaluated radiographically) around implants and implant survival.

Implant stability is directly related to the health of the bone surrounding it. The evaluation of the crestal bone height in the vicinity of the placed implant radiographically does help the implantologist to determine the prognosis of the treatment. The literature does establish the relationships between:

- a. Quality of bone at the implant site and crestal bone loss denser the bone, the less the crestal bone loss observed.<sup>[14,15]</sup>
- b. Stress exerted on the implant after placement and crestal bone loss.<sup>[16,17]</sup>
- c. Force factors such as bruxism, clenching, cantilevers including crown height also influence the crestal bone loss.<sup>[16]</sup>

Excessive stress placed on implant immediately does cause more bone loss because the crestal height comes to fall in the pathological overload zone. Hence, occlusal overload will influence the crestal bone loss.

Zhou *et al.*<sup>[18]</sup> found that the Resonance Frequency Analysis(RFA)value increased with the boneto-implant contact during the healing phase and correlated with the histomorphometric data. It is concluded, therefore, that RFA may be a reliable biomechanical technique that can monitor the osseointergration and helps to identify the nature of osseointegration.

In this study, there was no statistical significance in mean ISQ values between the IFL and INFL groups by evaluating 6-month implant stability with RFA using the Osstell device. This is in accordance with the study conducted by Lindheboom *et al.*<sup>[19]</sup> However, the two groups have shown a decrease in the ISQ values from the day of surgery to the first month. This is attributed to the bone remodelling that occurs around implants during this phase. However, the ISQ value has increased from the first month and has almost reached to the original values by the end of sixth month. This increase in ISQ values is due to osseointergration of implants to the adjacent bone.

Both IFL and INFL implants showed similar radiographic results in our study. Mean bone loss was not statistically significant between the two groups. There was no significant difference in the crestal bone loss between the IFL and INFL groups. This is in accordance with the study conducted by Lindheboom et al.<sup>[19]</sup> However, in each group, there was statistically significant amount of bone loss from the first month to third and sixth months although this had no clinical significance. This increase in the amount of bone loss is due to the bone remodelling and this rate of bone loss decreases as the time progresses. The amount of bone loss was lower than that found in the study of Norton,<sup>[20]</sup> in which he describes a mean bone loss of 0.40 mm after a period of 15.7 to 27 months. However, in that study, only immediate temporization and not immediate functional loading were studied.

There was no loss of implants in either IFL or INFL groups. However, due to the small sample size in our study, no definite conclusions on implant survival can be drawn.

In this study, there were no lateral forces on the implants due to the lack of eccentric contacts. The presence of centric contacts in the IFL group will transmit axial stresses on to the implants. The lack of any significant crestal bone loss between the IFL and INFL groups can be due to the absence of nonaxial forces in either group. The lack of significant difference in ISQ values can be due to the presence of forces within the physiologic range.

The idea behind the concept of keeping temporary restoration out of occlusion was to control the load on the single tooth unit to allow undisturbed healing. The role of tongue pressure and periosteal musculature may be an under estimated factor in immediately provisionalized, but nonloaded implants. Moreover, occlusion might not be the only determinant of implant success because there was no statistical significant difference between IFL implants and INFL group.

#### CONCLUSION

Within the limits of this study, the preliminary data indicate that immediate loading of implants under functional occlusal loading have good stability and an equivalent success rate as compared to nonfunctional loading under the absence of eccentric forces. Thus, it owes an improvement in the masticatory function and a better patient acceptance. However, further studies under the presence of eccentric forces need to be evaluated.

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