Immediate versus Conventionally Loaded Single Implant in the Posterior Mandible: A Randomized Clinical Trial

Gorrela Harsha*, Basava Sankar, Arthi Sirivore, S. Haritha, T. Srujana, K. Saidhep

Department of Oral and Maxillofacial Surgery, MNR Dental College and Hospital, Hyderabad, Telangana, India.

Abstract

Background: The aim of this study was to compare the clinical outcome of immediately loaded implants to that of conventionally (delayed) loaded implants for the restoration of mandibular first molar with stability as the primary objective and bleeding on probing, probing depth, implant mobility, marginal bone loss, and peri-implant radiolucency as the secondary objectives. **Materials and Methods:** The study included twenty patients who were in need of replacement of missing mandibular first molar. Ten patients received single tooth implants, immediately loaded (test group) within 2 days of placement, and the remaining ten patients received single tooth implants which were loaded conventionally (control group) after 3 months of placement. Clinical and radiographical evaluation was done for all the implants until 6 months after loading. **Results:** The post-surgical healing was uneventful for all patients. Primary stability of implants loaded through either way was not significantly different either at three (71.60 ± 2.16 vs. 72.35 ± 2.40, $P = 0.47$) or 6 months (73.80 ± 2.91 vs. 74.15 ± 2.72, $P = 0.78$) after loading. There was no bleeding on probing and the probing depths remained well within the normal range after 6 months of loading in both groups (1.20 ± 0.44 vs. 1.80 ± 0.42, $t = -2.26$, $P = 0.02$) implant mobility was absent in all cases with minimal marginal bone loss (for mesial side – 0.10 ± 0.21 vs. 0.15 ± 0.24, $t = -0.37$, $P = 0.70$ and for distal side – 0.15 ± 0.24 vs. 0.15 ± 0.33, $t = -0.26$, $P = 0.79$) and without peri-implant radiolucency. **Conclusion:** The single tooth restoration of mandibular first molars with immediate loading can be used as a successful alternative to the conventional loading technique. However, as these results were obtained with a small sample size and shorter follow-up time, long-term studies with larger samples are recommended for a good predictability and external validity.

Keywords: ISQ, Dental implant, Immediate loading, Delayed loading.

Introduction

Ever since rehabilitation of edentulous patients began, removable and fixed partial or complete dentures remained the traditional methods of treatment for quite some time. Certain limitations such as compromised retention and stability associated with such modalities affected the patients' functional abilities in addition to posing a challenging psychological impact. Discovery of implants was a major break-through that outweighed all the previous approaches of replacing missing teeth, through its superior design and placement technique.

The concept and necessity of "osseointegration" in implant placement were pioneered by Branemark *et al*. in 1952 through his experiment on fusing a titanium cylinder into the thigh bone of a rabbit.[1] According to the conventional Branemark protocol, a healing period of 3–6 months was required for the implants to be loaded, after fixture placement.[2] Since the malaise from edentulousness during this lengthy healing period was overwhelming to the patients, the idea of immediate loading was put forward.[3-5]

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The first successful attempt of placing a Vitallium implant in bone immediately after a dental extraction was exhibited by Strock. The results of the first clinical trial on immediately loaded implants that went on for 10 years revealed quite higher failure rates for immediately loaded as compared to conventionally loaded implants.[6] But a deeper understanding of the healing cascade and subsequent design modifications contributed to higher survival rates.

The micro-motion induced fibrous tissue, formed around the surface of immediately loaded implants was initially believed to have caused its failure. However, it was later reported that low frequency micro-motion was in fact necessary to stimulate

Address for correspondence: Dr. Gorrela Harsha, Department of Oral and Maxillofacial Surgery, MNR Dental College and Hospital, Hyderabad, Telangana, India. Email: drgharshaomfs@gmail.com

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bone growth.[7] Many studies have shown immediate loading to be an equally good and viable option as conventionally loaded implants with similar survival rates.[8-11]

The importance, implants have gained in oral rehabilitation mandate the reduction of their failure rate. Primary stability (implant stability at the time of fixture placement) has been propounded to play a crucial role for a successful osseointegration,[12,13] measured through a variety of methods like perio-test ultrasonic method, the resonance frequency method, push through and pull through, and radiographic assessment.[14] There is a paucity of literature in the Indian context on comparison of outcome of immediately and conventionally loaded implants, based on implant stability.

Given the above, we aimed to compare the clinical outcome of immediately loaded to that of conventionally loaded implants placed for the restoration of mandibular first molar, with primary emphasis on "implant stability" measured using resonance frequency method. Our secondary objectives were to compare parameters of bleeding on probing, probing depth, implant mobility, marginal bone loss, and peri-implant radiolucency between the two approaches.

Materials and Methods

The present parallel design clinical trial with an allocation ratio of 1:1 was conducted at the Department of Oral and Maxillofacial Surgery, MNR Dental College and Hospital, Sangareddy, and included twenty patients in need of replacement of missing mandibular posterior tooth, randomly divided into two groups consisting of ten patients each. The random sequence generation was based on a table of random numbers. Group A consisted of patients who received immediately loaded implants in the mandibular posterior region along with abutment on the same day and acrylic crown was placed within 48 h. The second group consisted of patients that received conventionally loaded implants on which cover screw was placed and loaded after 3 months. Allocation concealment to the surgeon and patients was not possible as they were aware of the timing of implant loading.

Primary outcome assessed was implant stability quotient (ISQ) and secondary outcome was bleeding on probing, probing depth, implant mobility, marginal bone loss, and peri-implant radiolucency. All the outcome were assessed by a single person within the team and were blinded to the allocation thus making this a single blinded study. Radiographs were assessed by two examiners, the inter-examiner agreement of which was calculated using kappa statistics. The criteria for inclusion into the study were – history of extraction of mandibular posterior tooth for not less than 3 months before planning for implants, with the corresponding edentulous space having sufficient bone quality and quantity; reluctance to have a removable and fixed partial denture; and insufficient periodontal support on natural abutments for a conventional fixed partial denture. Whereas those having a systemic condition that would make it risky for a minor oral surgery procedure; had received a radiation therapy in the head and neck region; having the habit of tobacco and alcohol abuse; possessing psychological problems and a habit of bruxism were excluded.

Pre-operative evaluation

A thorough history accompanied by radiographs, clinical evaluation, and routine blood investigations was obtained. Diagnostic casts were used to evaluate the intra-arch relationship, while the bone architecture assessment and precise estimation of the bone height above the mandibular canal so as to plan for the implant length, were done using intra oral periapical (IOPA) radiographs and OPG. The implant width was selected based on the alveolar ridge width that was determined through ridge mapping with a bone calipers. All the patients underwent an initial oral prophylaxis followed by oral hygiene instructions, to clear out the debris and make the oral environment favorable for wound healing.

Surgical procedure

The entire treatment protocol in both the groups was performed by the same team of surgeons to attain standardization with respect to all the procedures and prevent bias. Before the surgery, the patients were instructed to rinse with 0.12% chlorhexidine mouth wash and a subperiosteal lignocaine injection (2% with 1:80,000) was infiltrated in both the groups. Tissue removal from the alveolar crest was done through a biopsy punch in the immediately loaded group whereas a crestal incision followed by complete mucoperiosteal flap reflection was given in the conventionally loaded patients. The implant bed was prepared with a standard pilot drill under copious saline irrigation. After a confirmed check with the angulation using a paralleling tool, standard osteotomy drills with the help of a physio dispenser were used for sequential drilling. Pre-selected longest and widest implants were threaded into the prepared site up to crestal level using ratchet and insertion tool. For immediate loading implants, abutments were placed on the day of implant placement and left in place undisturbed until prosthetic procedure. All implants showed good primary stability. The implant mount was removed with the help of hex tool, followed by cover screw placement and the mucoperiosteal flap was closed with 4.0 silk in the conventionally loaded group.

Adin (Touareg-s) implants, 10–13 mm in length, and 4.2–5 mm in diameter were placed at the level of crestal bone after which soft-tissue edges were sutured in the delayed loading implants Antibiotics (Tab. Amoxclav 625mg BID for 5 days) and anti-inflammatory medication (tab aceclofenac sodium + paracetamol+ serratiopeptidase bd for 3 days) were prescribed for all patients. Suture removal was done 7 days later, followed by patients review on a regular basis in which marginal bone levels and peri-implant radiolucency were assessed making use of IOPA radiographs and RVG. Bleeding on probing and probing depth was assessed in both the groups, with a standard William's periodontal probe, in the 1st, 3rd and 6th months postoperatively after loading.

Parameters assessed

Ostells ISQ apparatus was used to measure implant stability (Figure 1), on the day, 3 and 6 months after implant placement that displays results in terms of ISQ ranging from 0 to 100 and works on the principle of resonance frequency (6–9 KHZ) analysis After the implant was placed in posterior mandible (Figure 2), abutment was attached (Figure 3), to which smart peg was attached and implant stability was measured using Ostell ISQ apparatus immediately after placement of implant (Figure 4). The ease in handling, accuracy and non-invasiveness expedite the usage of this device. An increasing ISQ trend indicates transition from initial mechanical stability to secondary biological stability. The ease in handling, accuracy, and non-invasiveness expedite the usage of this device. An increasing ISQ trend indicates transition from initial mechanical stability to secondary biological stability. There is a probe whose tip is attached to the device and touched to the smart peg to receive the resonance frequencies, while holding the device in a perpendicular direction to the implant. A smart peg assembly is selected from a range of sizes available with Ostell ISQ apparatus. Implant Stability was measured using Ostell ISQ values at 3, (Figure 5) and 6 months (Figures 6 and 7) and increase in implant stabilityISQ values were noted.

As rigid fixation is usually the first clinical criterion evaluated for a dental implant, clinical implant mobility scale by Misch[15] was used to check mobility and the values were noted as present or absent at the time, 1st and 6th months after placement. Bleeding on probing that reflects the degree of peri-implant mucositis and the possibility of progression in to peri-implantitis was noted as present or absent. Radiographic bone loss and increased pocket depth have been correlated with sulcular bleeding.

Peri-implant radiolucency around implant at subsequent visits was observed and recorded as either 0 for absence or 1 for presence of radiolucency at any implant to bone contact site. A probing device that allowed simultaneous monitoring of probing force and probe penetration with standardized insertion pathway was used to measure probing depth. Marginal bone loss in each implant was assessed by periapical radiographs examination. The accepted criteria for implant success include 1–1.5 mm of bone loss during the 1st year after loading and <0.2 mm thereafter.

Statistical analysis

All the descriptive statistics were tabulated in Microsoft Excel and statistical analysis was executed using Statistical Package for the Social Sciences version 24 (IBM SPSS statistics for windows, version 24.0 Armonk NY: IBM Corp). Intragroup comparison of ISQ values at different intervals was done using "Repeated Measures ANOVA" and intergroup comparisons using *t*-test. Mann–Whitney U-tests were used for between group comparisons of bleeding on probing and t test for probing depths and marginal bone loss. Significance (*P*-value) was set at ≤0.05 for all the tests. Kappa statistics were calculated for inter examiner variation with respect to radiographic evaluation.

Results

The present trial was conducted for a period of 15 months, from March 2018 to June 2019 that included males and females in 2:3 ratio with eight males and 12 females. The mean age of the patients in the immediate group was 27.7 ± 5.38 years and 23.1 ± 3.45 in the delayed group (Table 1). The mean length of the implants was 12.25 and 11.65 and mean diameter 4.65 and 4.65 in the immediate and delayed groups, respectively, with no significant differences between the two groups (Table 2).

The two groups did not significantly differ with respect to implant stability either immediately or in the 3rd and 6th months. The ISQ values, at baseline, 3 and 6 months of placement, were 73.75 ± 1.83; 71.60 ± 2.16 and 73.80 ± 2.91, respectively, for the immediately loaded implants. For the conventionally loaded implants, the values were 72.90 ± 2.77; 72.35 ± 2.40 and 74.15 ± 2.72 at the time, after 3 and 6 months of placement, respectively (Tables 1 and 2).

Implant mobility was absent in all the patients from both the groups at all the 3 time intervals. After 1 month of placement, marginal bone loss on the mesial and distal sides, respectively, was 1.1 ± 0.56 and 1.2 ± 0.41 for immediately loaded implants; and 0.95 ± 0.49 and 0.82 ± 0.33 for delayed loaded implants. Whereas 6 months later, the amount of bone loss on the mesial

Table 1: Mean age of study subjects in the two groups

Groups	Mean age	SD Age
Immediate Implant	27.70	5.38
Delayed Implant	23.10	3.45
Total	25.40	4.99

Table 2: Comparison of diameter and length in immediate and delayed loaded implants by unpaired t test

Variables	Groups	Mean	SD	t-Value	P-Value
Diameter (in mm)	Immediate Implant	4.6800	0.3373	-1.6630	0.0963
	Delayed Implant	4.6800	0.4541		
Diameter (in mm)	Immediate Implant	12.2500	1.2748	-1.2095	0.2265
	Delayed Implant	11.6500	1.1559		

Figure 1: Left to right. (a) Ostell ISQ apparatus, (b) implant surgical kit, (c) Adin implant, (d) pre-operative OPG of the patient

Figure 2: Implant placement

Figure 3: Abutment placement

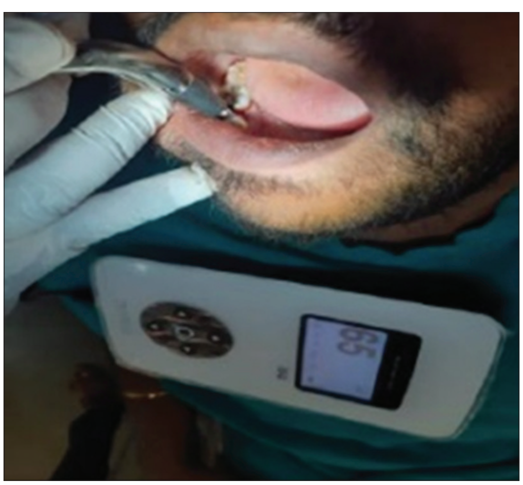

Figure 4: ISQ values immediately after placement

and distal sides reduced significantly in both the groups (Table 3). None of the twenty implants showed peri-implant radiolucency during 6 months of follow-up after loading them (Table 4).

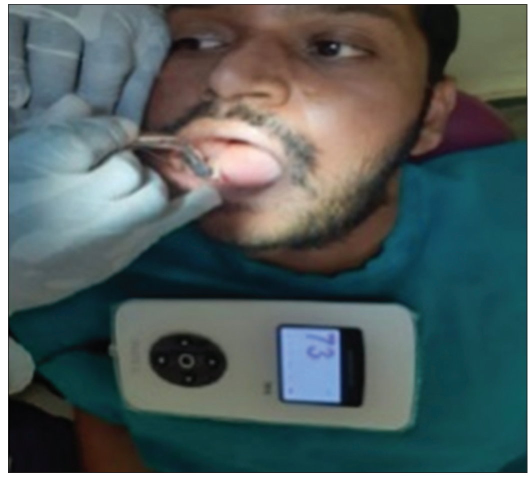

Figure 5: ISQ values after 3 months

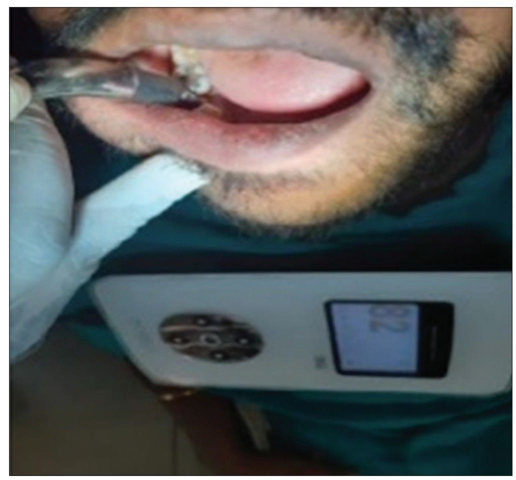

Figure 6: ISQ values after 6 months

Figure 7: Post-operative RVG after implant placement

Bleeding on probing was present in one patient each from both the groups because of prosthesis loosening that subsided after crown re-cementation. After 6 months it was not noted in any of them (Table 5). Probing depth values for all twenty patients after 1 and 6 months of loading were within the normal range (1–3 mm). In immediate loading group, the mean value of probing depth was 1.8 ± 0.63 and 1.2 ± 0.42 after 1 and 6 months of loading, respectively, whereas in the delayed loading group, the probing depth values after 1 month of loading were 1.8 ± 0.42 and remained the same even after 6 months of loading (Table 6).

No statistically significant difference in the marginal bone loss was observed between the two groups at one (for mesial side – 1.1 ± 0.56 vs. 0.95 ± 0.49, t = –0.34, P = 0.73 and for distal side – 1.15 ± 0.41 vs. 0.82 ± 0.33, t = –1.73, P = 0.08) or 6 months (for mesial side – 0.10 ± 0.21 vs. 0.15 ± 0.24, t = –0.37, P = 0.70 and for distal side – 0.15 ± 0.24 vs. 0.15 ± 0.33, t = –0.26, P = 0.79) of follow-up (Tables 7 and 8).

Table 3.1: Comparison of ISQ scores at different time intervals in both the groups analysed using repeated measures ANOVA

Group	Time interval	N	Mean ISQ	Standard Deviation	F statistic	p value
Immediate	Baseline	10	73.75	1.83	48.33	0.00*
	3 months	10	71.60	2.16		
	6 months	10	73.80	2.91		
Delayed	Baseline	10	72.90	2.77	6.28	0.02*
	3 months	10	72.35	2.40		
	6 months	10	74.15	2.72		

* p value significant at <0.05

Table 3.2: Between group comparison of ISQ scores at different time intervals analysed using unpaired t test

Time intervals	Groups	N	Mean	Std. Deviation	T value	P value
ISQ IMMEDIATE	GROUP A	10	73.75	1.83	0.81	0.428 NS
	GROUP B	10	72.90	2.77		
ISQ 3 MONTHS	GROUP A	10	71.60	2.16	-0.73	0.472 NS
	GROUP B	10	72.35	2.40		
ISQ 6 MONTHS	GROUP A	10	73.80	2.91	-0.27	0.784 NS
	GROUP B	10	74.15	2.72		

Table 4: Implant mobility of Immediate and Delayed implants according to clinical implant mobility scale at various intervals

Intervals	Immediate implants		Delayed implants	
	Absent	Present	Absent	Present
At the time of implant placement	10.00	0.00	10.00	0.00
After 1st month of crown cementation	10.00	0.00	10.00	0.00
After 6th month crown cementation	10.00	0.00	10.00	0.00

Table 5: Comparison of peri-implant radiolucency of Immediate and Delayed implant at various stages

Intervals	Immediateimplants		Delayed implants	
	Absent	Present	Absent	Present
At the time of implant placement	10.00	0.00	10.00	0.00
After 1st month of crown cementation	10.00	0.00	10.00	0.00
After 6th month crown cementation	10.00	0.00	10.00	0.00

Discussion

Partial or complete edentulousness, that caused remarkable anguish to the patient's decades ago, can now be relieved

Table 6: Comparison of Bleeding on probing in immediate and delayed implants after 1st month and after 6th month of crown cementation, using Mann-Whitney U test

Crown Cementation	Groups	Mean	SD	U-Value	P-Value
After 1st Month	Immediate Implant	0.20	0.42	50.0000	1.0000
	Delayed Implant	0.20	0.42		
After 6th Month	Immediate Implant	0.00	0.00	34.0000	1.0000
	Delayed Implant	0.00	0.00		

Table 7: Comparison of Probing depth in immediate and conventional implants after 1st month and after 6th month of crown cementation by unpaired t test

Crown Cementation	Groups	Mean	SD	t-Value	P-Value
After 1st month	Immediate Implant	1.80	0.63	0.0756	0.9397
	Delayed Implant	1.80	0.42		
After 6th month	Immediate Implant	1.20	0.47	-2.2678	0.0233*
	Delayed Implant	1.80	0.42		

*p<0.05

Table 8.1: Comparison of Bone loss in mm (After 1 month of crown cementation) in Immediate and Delayed implants at mesial and distal sides by unpaired t test

Side	Groups	Mean	SD	t-Value	P-Value
Mesial	Immediate Implant	1.1000	0.5676	-0.3402	0.7337
	Delayed Implant	0.9500	0.4972		
Distal	Immediate Implant	1.1500	0.4116	-1.7386	0.0821
	Delayed Implant	0.8250	0.3344		

Table 8.2: Comparison of Bone loss in mm (After 6th month of crown cementation) in Immediate and Delayed implant at mesial and distal sides by unpaired t test

Side	Groups	Mean	SD	t-Value	P-Value
Mesial	Immediate Implant	0.1000	0.2108	-0.3780	0.7055
	Delayed Implant	0.1500	0.2415		
Distal	Immediate Implant	0.1500	0.2415	-0.2646	0.7913
	Delayed Implant	0.1500	0.3375		

with the best treatment modalities. From rehabilitating cases that require a distal extension RPD to replacing the entire arch, implants are an excellent choice for restorations quite analogous to the natural teeth, garnering patients' greatest satisfaction. Molars being the first to erupt and having a longer exposure to the oral cavity are generally the most frequently lost teeth. Failure to replace them would jeopardize the entire stomatognathic system, ranging from occlusal derangement to severe TMJ pathologies, thereby making it imperative for a timely and uneventful placement of implants. As implant stability momentously amounts to its success, it would be worthwhile to compare the primary stability of immediately and delayed loaded implants along with a few other parameters. Besides, implant stability also depends on the size, to neutralize which, similar sized implants were used in both the groups. No significant differences in the length and diameter of implants used in the two groups were observed.

In the present study, Ostell (smartpeg™; Integration diagnostics AB) device was used to measure primary stability in terms of ISQ that revealed high (>70) stability for all the implants. Comparisons made immediately, 3 and 6 months after placement revealed no significant difference between immediately and delayed loaded techniques. Furthermore, the ISQ values immediately, at 3 and 6 months of placement were 73.75 ± 1.83; 71.60 ± 2.16 and 73.80 ± 2.91, respectively, for the immediately loaded implants. For the conventionally loaded implants, the values were 72.90 ± 2.77; 72.35 ± 2.40 and 74.15 ± 2.72 at the time, after 3 and 6 months of placement, respectively. There was a significant difference between the baseline and 3 months ISQ scores and also between 3 and 6 months for the immediately loaded implants; and the ISQ scores for the conventionally loaded implants different significantly only between 3 and 6 months.

The previous studies reveal that the ISQ values tend to decrease in the first 3 months, start increasing thereafter and become stable around 9–12 months.[16] The initial fall in the values was linked to the changes within the bone-implant interface and the properties of the surrounding bone in connection to the time taken for bone formation and maturation.[17] The succeeding rise in the values was due to the complete integration of the implants within an year, leading to enhanced stability.[18] At none of the time points in the present study, was there a statistically significant difference in the ISQ values between the immediately and conventionally loaded implants comparable to the results of Bischof *et al*.[19] and Nedir *et al*.[20] investigating dental implant primary stability and suggested that an ISQ of ≥54 in immediately loaded implants will reliably promote osseointegration. In accordance to this, all the implants had ISQ ≥54, measured at different time points, thus leading to stable implants with a good survival rate (100%).

Mobility is the primary determining factor for implant health and rigid fixation is usually the first clinical criterion evaluated for a dental implant. All the implants in our study showed 100% survival rate with no reported mobility in any of the groups. Lorenzoni *et al*.[21] and Chidagam *et al*.[11] also reported zero mobility for all implants.

Peri-implant radiolucency around implants was recorded on a Dentascan. Degigi *et al*.[22] suggested using radiographic measurements and probing depth together form a comprehensive assessment of implant success. Our study showed absolutely no peri-implant radiolucency in either of the groups both at 1 and 6 months after placement in support of Schnitman PA[23] also failed to see any radiolucency around immediately loaded implants with fixed prosthesis in their 10 years follow-up period.

As bleeding on probing generally precedes inflammation, it would be a valid indicator of the health of peri-implant tissues.[24] Bleeding on probing was present in one patient from both groups after 1 month of loading because of loosening of prosthesis which subsided after re-cementation of crown. However, after 3 and 6 months of crown cementation, none of the patients from both groups showed bleeding on probing, identical to the results of Salvi *et al*.[25] that observed bleeding only in 9.7% and 8.3% of the immediate and conventional groups, respectively. Chidagam *et al*.[11] also demonstrated bleeding from a single implant in each of the groups that subsided in the due course of 6 months.

Probing is an appropriate method of assessing the potential deleterious changes around the implant and should be performed once every 3–4 months up to 1 year after delivery of an implant. The values obtained for all the twenty implants either at 1 or 6 months were within the acceptable limits of 1–3 mm. There was a statistically significant reduction in the mean probing depth in the immediately loaded implants from the 1st to the 6th months (1.8–1.2 mm), while it was the same in the conventionally loaded implants even at the end of 6 months (1.8 mm). Schincaglia *et al*. hypothesized that the significantly lesser probing depth in the immediately loaded implants was due to osteo deposition induced by mechanical strain.[26] When the two groups were compared at 1 month, no significant difference was found in the probing depths, but there was a statistically significant lesser probing depth in the test group than the control group at 6 months. Heydenrijk *et al*.[27] found in his study, that the mean probing depth decreased in immediate loading group after 6 months of crown placement to 3.3 mm from 3.6 mm at 1 month. However, no change was seen in delayed loading group which remained 3.7 mm. At both stages,marginal bone loss has long been regarded as one key factor contributing to implant failure. According to the literature, both biological and biomechanical factors may be related to marginal bone loss during healing. Host related factors include plaque control, smoking wound healing capacity. Marginal bone loss in each implant was assessed by periapical radiographs examination. No statistically significant difference in the marginal bone loss was observed between the two groups at 1 or 6 months of follow-up, either on the mesial or distal sides of the implants. Engelhardt *et al*.,[28] Esposito *et al*.,[29] and Sandaa *et al*.[30] also in their different systematic reviews divulged insignificant differences in the marginal bone loss values of different loading techniques, namely, immediate and delayed.

Despite our study adding valuable inputs to the literature on comparison between immediately and conventionally loaded implants, sample size was a major limitation. Future studies with larger samples are recommended to improve the validity and generalizability of the results. The clinical outcome of implants loaded through either of the approaches was favorable. The stability of immediately loaded implants in our study was as good as conventionally loaded ones with no significantly detectable differences between them and the post-surgical healing period uneventful for all patients.

Conclusion

The study demonstrated that immediately loaded implants were as good as conventionally loaded not only in terms of stability but also other parameters that assessed implant health and could be used as an alternative choice.

Conflicts of Interest

The authors declare that they have no potential conflict of interests regarding this article.

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