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Original Research Article

Evaluation of success rate and marginal bone loss in dental implants subjected to early loading with a follow up of one year

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ABSTRACT

Background: Dental implants (also known as oral or endosseous implants are considered to be an important contribution to dentistry as they have revolutionized the way by which missing teeth are replaced with a high success rate. Implant success is evaluated by various implant health parameters along with patient satisfaction.
Aim & Objective: The aim of this study was to evaluate and compare the success rate and marginal bone loss in dental implants subjected to early loading versus conventional loading and also to find out the clinical viability of early loading in day-to-day practice, especially in the Armed Forces.
Material and Methods: This study was done with a split mouth design. Fifteen patients of either sex in the mean age of 22 to 52 years with bilateral missing first mandibular molar, fulfilling the inclusion criteria were selected and divided into two groups. In Group 1, subjected to early loading, (fifteen sites) the provisional prostheses were fabricated and cemented in occlusal contact with the opposing dentition within 8 weeks of implant placement. In Group 2 (fifteen sites) 15 implants were to be subjected to conventional loading after six months.
Results: Two implants were lost in group 1 and one implant in group 2 during the study. The difference in Periotest values of Group-1 and Group-2 was not significant (p value > 0.005). The Peri crestal bone level in both (early loading and conventional loading) groups were within the acceptable limits and difference between the groups was not significant (p value >0.005).
Conclusion: Based on the results of the study, it can be concluded that early loading is a viable treatment modality and can be routinely employed for rehabilitation of partially edentulous arches. Meticulous diagnosis and treatment planning, precise clinical and laboratory protocols are critical in long term success of prostheses.

1. Introduction

Dental implants have undoubtedly been one of the most significant scientific breakthroughs in dentistry over the past 25 years for overcoming the shortcomings of tooth supported fixed partial dentures and removable partial dentures.[1] Implant success is evaluated by various implant health parameters along with patient satisfaction and over the years it has been evaluated using the following parameters of pain, mobility, radiographic evaluation of crestal bone level, probing depth, peri implant diseases and adequate width of attached gingiva.[2] More recent articles have also stressed on the importance of successful prosthesis as one of the important criteria for success apart from implant survival.[3] But there is no single method which can actually determine a successful implant and therefore, generally a combination of methods are used.

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Primary implant stability and lack of micro movements are considered to be two of the main factors necessary for achieving predictable high success of osseointegrated dental implants.[4] To minimise the risk of implant failure, it has been recommended to keep the implants load-free during the healing period of 3 to 4months in mandible and 6 to 8 months in maxillae.[5] However, clinicians and researchers have questioned whether the conventional two-stage implant protocol with delayed loading, and its consequent lengthy treatment time from implant placement to final prosthesis, is an absolute requirement for successful osseointegration.[6] With the improvements in oral implantology resulting in improved prognosis and out-comes the concepts like immediate loading and early loading have been recommended.

In today's increasingly fast-paced, esthetically and functionally conscious society, patient's demand for fewer surgical interventions and short treatment time from implant placement to final restoration has increased steadily over the past decade. This change has led to the development of revised implant placement and loading protocols. Initiation of prosthetic rehabilitation immediately after implant placement can be either of functional or nonfunctional nature. In Immediate functional loading (IFL), the provisional prosthesis is delivered immediately (within 24h to 1week) after implant placement and is placed in occlusion with the opposing arch. In immediate non-functional loading (INFL), the provisional prosthesis is seated immediately after implant placement, but the prosthesis is not in occlusal contact with the opposing tooth.[7,8] Various studies have shown that the mechanical force generated by immediate functional loading may explain the favourable biologic response of bone and surrounding tissue.[9–11] However, in certain treatment modalities, loading implant indiscriminately and immediately is not safe because of potential unfavourable stress distribution and negative cellular response under high stress during early healing. The meta-analysis of two trials found insufficient evidence to determine whether there is a difference between immediate occlusal and non-occlusal loading, with regard to failure.[12,13]

The early loading protocol refers to the placement of provisional or permanent restoration, prior to the time of conventional loading, but after the time considered immediate loading.[14,15] A number of clinical studies have shown good clinical results with survival rates close to 100% in early loading situations of single implants.[16,17] and partial or full arch restorations, whether placed in maxilla or mandible and located in anterior or posterior locations. Moreover, results from prospective studies showed that marginal bone level was maintained with a mean marginal bone loss below 0.3 mm after three years of loading.[18] Early loading involves restoration of implants in or out of occlusion within a shorter time interval than conventional healing (normally after 6 weeks in the mandible and after the 8 weeks in the upper maxilla). Lazarra et al, Cochran et al and Testori et al reported a 98% to 100% short-term success rate for implants in the maxilla when adopting the early loading protocol. Mean bone loss in dental implants was minor in early loading compared with conventional loading. Marginal bone loss was evaluated from the radiography which was not greater than 1.5mm in the first year (osseointegration period) and 0.1mm during each successive year (follow-up period).[19]

In the current scenario, clinician often carries out the immediate loading protocol without understanding the science or evidence-based principles to support the clinical decisions. The question for researchers and clinicians is whether accelerated loading is possible without violating the important aspect of primary implant stability. There is an enormous lacuna in the literature regarding success of dental implants utilizing early loading protocol. Therefore, the present study was undertaken to comparatively evaluate the early loaded and conventionally loaded implants based on clinical and radiographic methods and also to find out the clinical viability of adopting the methodology in day-to-day practice, especially in the Armed Forces.

2. Materials and Methods

A total of 15 partially edentulous patients who needed bilateral replacement of missing first mandibular molar tooth of either sex and partially edentulous for at least one year prior to insertion of implants. The age of the patients ranged from 22 to 52 years. The patients were selected after a thorough screening, based on the following criteria:

2.1. Inclusion criteria

1. Absence of systemic disease.
2. Good oral hygiene.
3. Absence of chronic periodontal or periapical pathology.
4. Sufficient residual bone volume to receive implants of appropriate size.
5. Appropriate crown height space to maintain favorable crown: implant ratio.

2.2. Exclusion criteria

1. Insufficient bone volume
2. Missing upper first and second molar teeth without corresponding antagonists for occlusion
3. Poor oral hygiene
4. Chronic periodontal disease and periapical pathology
5. Presence of para-functional habits such as bruxism
6. Chronic smoker- smoking more than 20 cigarettes/day,
7. Patients under radiation therapy, chemotherapy, immunosuppressive drugs, corticosteroids

8. Presence of systemic medical conditions like liver pathology, blood dyscrasias, kidney disorders etc
9. Pregnancy
10. Inflammatory and autoimmune conditions of the oral cavity

The patients fulfilling the inclusion criteria were selected and divided into two groups:

1. Group 1 with Early Loading (fifteen sites) 15 implants were to be subjected to early loading i.e. the provisional prostheses were fabricated and cemented in occlusal contact with the opposing dentition within 8 weeks of implant placement.
2. Group 2 with Conventional Loading (fifteen sites) 15 implants were to be subjected to conventional loading after six months.

Every patient under this in-vivo study was subjected to early loading on one side of dental arch and other side subjected to conventional loading, thus eliminating any patient related bias.

2.3. Surgical procedures

Based on bone mapping, radiographic and clinical evaluation of existing bone the implant dimension was selected appropriately for every patient. Standard surgical protocol using the surgical template was followed for Group 1& 2 for the placement of implants (Figure 1). Two single stage implants (I2, AB Dental Devices Ltd, Ashdod, Israel) were placed in each patient in the mandibular molar region (A and B sites). A digital Orthopantomogram was done to verify the position and location of implants (Figure 2). After confirming the final positions, gingival former was attached to the implant so that there was no requirement of second stage surgery and loading protocols could be easily carried out (Figure 3). Patients were advised to continue the antibiotics and analgesics for three more days after the surgery. They were also instructed to maintain good oral hygiene by brushing and rinsing their mouth using 0.2% chlorhexidine gluconate mouthwash twice daily for two weeks**.**

2.4. Prosthodontic procedures

2.4.1. For group 1

Implants were loaded eight weeks after surgical placement for mandibular right segment. After confirming the implants were osseointegrated by clinical and radiological means, prosthodontic procedures were started. Impressions were made using open tray impression technique (Figure 4). The polyvinyl 'gingival mimic' was then put around the analogue at cameo surface of implant level impression and working model was poured in minimal expansion, high strength die stone. Impression of opposing arch was made in irreversible hydrocolloid impression material. Casts were then articulated on a semi adjustable articulator (Hanau model H2) using facebow transfer (Figure 5).

The shade selection for provisional prostheses was done prior to its fabrication on the articulated cast. Titanium abutments of appropriate size were selected and evaluated for sufficient interocclusal clearance on the articulated cast. Adjustments of the height of the abutments if any, were done by milling in lab with precaution to avoid any damage to the central screw. Heat cured provisional restoration was then fabricated in a conventional manner.

In Group 1 the provisional prosthesis was seated on the articulated cast and implant protected occlusal scheme was followed ensuring that no contacts between the prosthesis and opposing dentition during eccentric movements. The fabricated provisional prosthesis was luted (Figure 6) with non-eugenol temporary luting cement (TempoCemNE Germany) for ease of retrieval of the restorations. It was ensured that intraorally necessary occlusal correction was carried out as per protocols for Group 1, following Implant protected occlusion. Postoperative instructions regarding diet and oral hygiene maintenance were given to the patient. Interdental brushing methods and oral hygiene maintenance methods were taught to the patient. All patients were reviewed at baseline thereafter at 6months, 8months and 12months duration.

2.4.2. For group 2

After a period of 6 months, the provisional prostheses were fabricated for implants in the left mandibular segment following the same procedure explained for Group 1. Though definitive prosthesis can be given after six months of osseointegration, heat cure acrylic provisional were given for mandibular left segment for comparative evaluation. The effect of loading implants using the same materials needed to be evaluated. Laboratory protocols, cementation protocol and post-operative evaluation were the same as in Group 1. Definitive prostheses were made of metal ceramic after the period of evaluation for both groups using open tray impression technique and conventional lab protocols.

2.5. Evaluation of Implant health parameters

After implant placement the implant health parameters in Group 1 with early loading and Group 2 with conventional loading were evaluated as follows:

1. Assessment of implant stability by Periotest: at 6 months (6M), 8 months (8M) and 12 months (12M)
2. Assessment of Peri implant marginal bone level**:** at baseline (BL), 6 months (6M), 8 months (8M) and 12 months (12M).

2.6. Assessment of implant stability by periotest

The implant stability was measured with the help of Periotest at 6, 8 and 12 months for both the groups post implant insertion. The Periotest (Periotest S^{TM} Medizintechnik Gulden, Modautal, Germany) was used for measurement of implant stability and degree of osseointegration. During the measurement, the sleeve of the hand piece was kept at a distance of 0.5mm from the implant. The hand piece was held horizontally at right angles to the long axis of the implant and patient in an upright position (Figure 7a). Patient was instructed to keep his tongue and opposing teeth away from the evaluated implant/implant crown. The scale ranged from -08 to +50. The smaller values reflected greater stability. Values above 20 are irrelevant in Implantology. Multiple measurements were taken in the same direction of percussion and position of the patient and average values noted. Interpretations of the Periotest values were based on the manufacturer's instructions.

PT<0 Negative values are generally good; the implant is well osseointegrated.

PT 0 to +9 Clinical examination is necessary.

PT ≤ +10 The implant is not sufficiently osseointegrated.

2.7. Assessments of peri implant marginal bone level:

Peri implant marginal bone level was assessed via a dental X-ray machine, a radiovisiograph sensor, a patient positioning device and a 01 mm radiographic grid using long cone paralleling technique. The use of the patient positioning device ensured that a fixed source-film distance of 25 cm was followed for each assessment (Figure 7b). The device was attached to the tube head and the sensor was attached. The radiographic grid was attached to the sensor and became superimposed on the radiograph, thus facilitating measurements of bone loss (Figure 8). All measurements were made on both the mesial and distal aspects of the implants from the implant-abutment junction to the first contact of bone to implant. Mean bone loss was calculated for each patient based on these readings. Baseline measurements were made at the time of loading followed by measurements after 06, 08 and 12 months. If the bone was found to be flush with the implant-abutment junction, a value of zero was recorded.

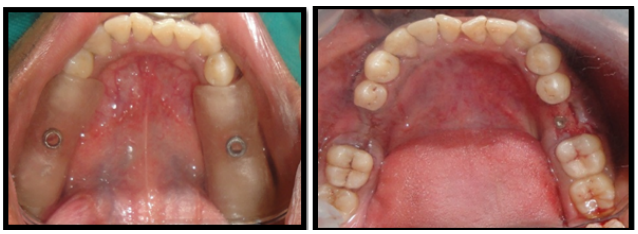

Figure 1: Surgical template at site of implant placement & implant placement done

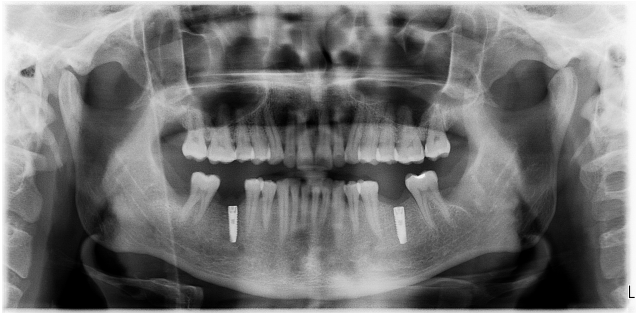

Figure 2: Digital orthopantogram after implant placement

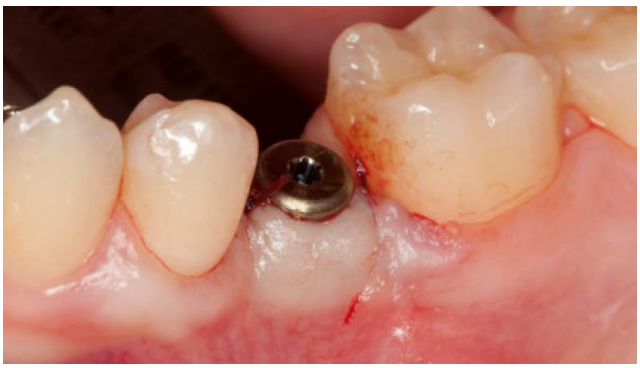

Figure 3: Gingival former in situ

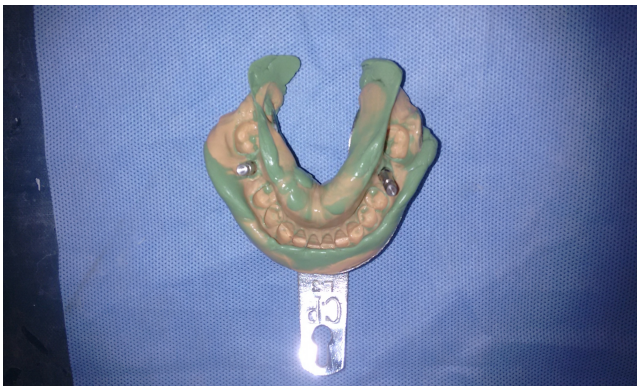

Figure 4: Open tray impression

3. Results

The statistical analysis of Periotest data obtained for Group 1 & Group 2 at 6 months,8 months and 12 months periods are presented in Table 1 **.** This table reflects mean, standard deviations and standard error mean at different periods (6M, 8M &12M). The mean and SD was calculated from the data of surviving implants only. Two cases in Group-1 and one case in Group -II showed peri-implantitis at the end of 06 months along with continued pain, discomfort and mobility. Clinically, these cases were considered 'failures'

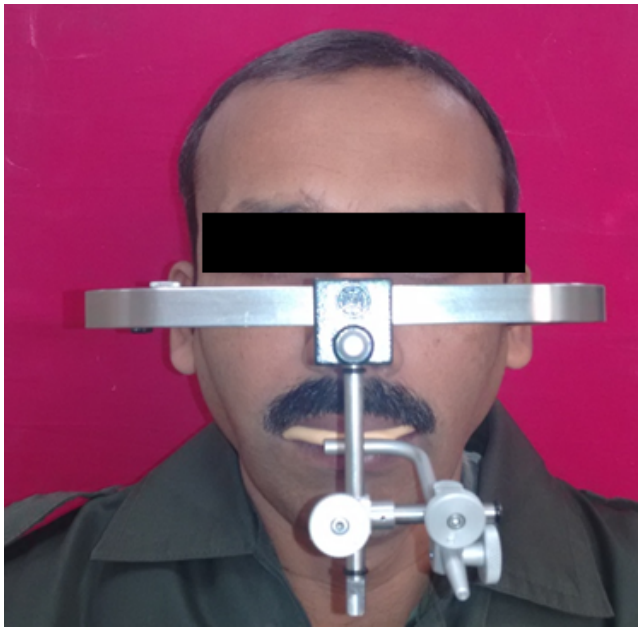

Figure 5: Face bow recording

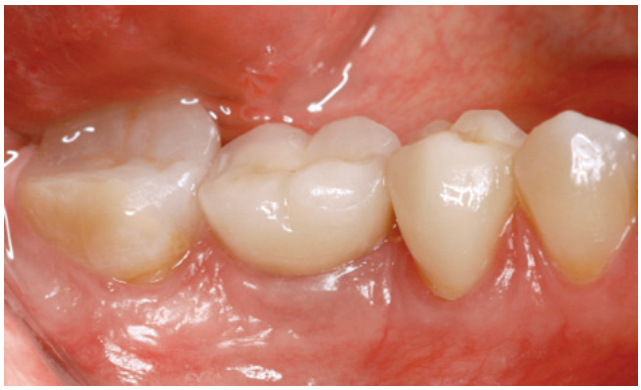

Figure 6: Acrylic provisional restoration wrt 46 with emergence profile

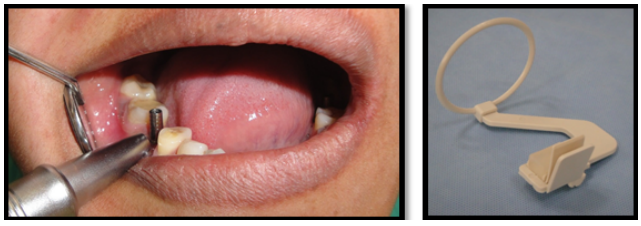

Figure 7: a: Periotest being used to check implant stability; **b:** Patient Positioning Device (Maquira Dental Products, Brazil)

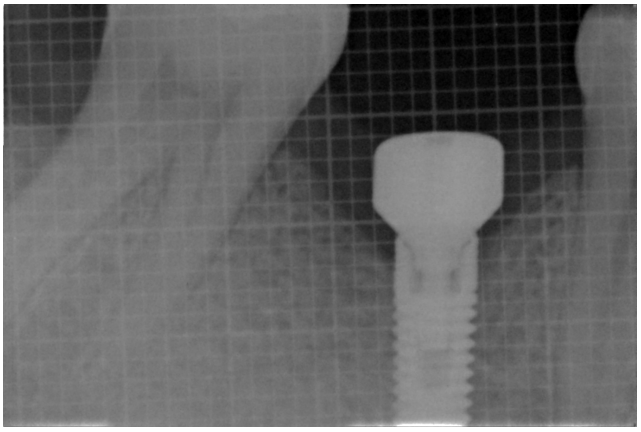

Figure 8: Measurement of bone loss on a radiovisiograph using a measuring grid (red lines demarcate distance between implant abutment junction and first bone-implant contact)

and the implants were removed surgically. Table 2 shows the independent sample t- test for comparison between Group 1 and Group 2. The t value and p value for 6M were -1.010 & 0.322, 8M were 1.176 & 0.251 and 12M were 1.771 & 0.089. Since $p > 0.005$ the values were not statistically significant.

The statistical analysis of data obtained for radiographic measurement of peri-crestal bone level on mesial and distal site of Group 1 & Group 2 at 6 months,8 months and 12 months periods are presented in Table 3 **.** All the values at the baseline measurement were 0 and constant for both the groups, therefore no mean, S.D could be calculated at the baseline. The Pericrestal bone level of the failed implants in the groups were not considered for calculation of mean and S.D. Table 4 shows the independent sample t- test for comparison between Group 1 and Group 2. Comparison between groups and within groups were not statistically significant, since $p > 0.005$.

In Group 1(Early loading), out of fifteen, two implants failed and in Group 2 (Conventional loading) out of fifteen, one implant failed. The overall success rates for Group 1 (Early loading) were 86.66% and for Group 2, (Conventional loading) 93.33% respectively.

4. Discussion

Loading protocols for dental implants have been a central focus of discussion in the field since the origin of osseointegration. Several consensus conferences have been held on the topic, and recommendations have been published based on the evidence available at the time, which has resulted in lots of confusion regarding concept of loading.[20–23]

The literature review regarding immediate loading and conventional loading had shown that it is a proven and established loading protocol.[24–26] But studies related to

Table 1: Statistical analysis of periotest value

	Group	N	Mean	Std. Deviation	Std. Error Mean
6 Month	1	13	-2.2308	.72501	.20108
	2	14	-1.9286	.82874	.22149
8 Month	1	13	-3.3077	.63043	.17485
	2	14	-3.6429	.84190	.22501
12 Month	1	13	-4.0000	.70711	.19612
	2	14	-4.5000	.75955	.20300

Table 2: Independent sample t-test for periotest

Month		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
6 Month	Equal variances assumed	-1.005	25	.325	-.30220	.30069	-.92148	.31708
	Equal variances not assumed	-1.010	24.921	.322	-.30220	.29915	-.91841	.31402
8 Month	Equal variances assumed	1.164	25	.256	.33516	.28806	-.25811	.92844
	Equal variances not assumed	1.176	23.971	.251	.33516	.28496	-.25299	.92332
12 Month	Equal variances assumed	1.767	25	.090	.50000	.28304	-.08293	1.08293
	Equal variances not assumed	1.771	24.999	.089	.50000	.28226	-.08132	1.08132

Table 3: Statistical analysis of pericrestal bone level

Months/Site	Groups	N	Mean	S.D	Std Error Mean
6M, Mesial	1	13	.2538	0.05189	0.01439
	2	14	.2286	0.04688	0.01253
6M, Distal	1	13	.2615	0.05064	0.01404
	2	14	.2429	0.05136	0.01373
8M, Mesial	1	13	.7462	0.07763	0.02153
	2	14	.7000	0.07845	0.02097
8M, Distal	1	13	.7462	0.6602	0.01831
	2	14	.7429	0.05136	0.01373
12M, Mesial	1	13	.8923	0.11875	0.03294
	2	14	.9000	0.12403	0.03315
12M, Distal	1	13	.8923	0.15525	0.04306
	2	14	.8929	0.09972	0.02665

Table 4: Independent sample t-test for pericrestal bone level

Month / Site		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
6M, MESIAL	Equal variances not assumed	1.325	24.23	.198	.02527	.01908	-.01409	.06464
6M, DISTAL	Equal variances not assumed	.951	24.90	.351	.01868	.01964	-.02177	.05913
8M, MESIAL	Equal variances not assumed	1.536	24.89	.137	.04615	.03005	-.01575	.10806
8M, DISTAL	Equal variances not assumed	.144	22.66	.887	.00330	.02288	-.04408	.05067
12M, MESIAL	Equal variances not assumed	-.165	24.97	.871	-.00769	.04673	-.10394	.08856
12M, DISTAL	Equal variances not assumed	-.011	20.21	.991	-.00055	.05064	-.10611	.10501

Table 5: Perio test values as per the manufacturer

Periotest Value Range	Interpretation
-8 to 0	Good osseointegration; the implant is well integrated and pressure can be applied to it
+1 to +9	A clinical examination is required: the application of pressure on the implant is generally not (yet) possible
+10 to +50	Osseointegration is insufficient and no pressure may be allowed to act on the implant

early loading are limited thus, there is lots of confusion among clinicians about the early loading protocol regarding timing of loading, occlusal scheme and type occlusal contacts.[27] In the present study, we have subjected early functional loading but with an implant protected occlusal scheme.

The idea behind the concept of keeping the temporary restoration in implant protected occlusion is to control the load on the prosthesis in order to allow undisturbed healing. The results of the present study showed that there was no statistically significant difference between the early loading and conventional loading concerning implant failures. The increase of load, applied to the prosthesis caused by the presence of the normal occlusal contact, seems to be unable to jeopardize or alter the healing process of the implant.[28] It has been suggested that it is not the absence of loading per se that is critical for osseointegration, but rather the absence of excessive micromotion at the interface. Micromotion consists of a relative movement between the implant surface and surrounding bone during functional loading and it is believed that, above a certain threshold, excessive interfacial micromotion early after the implantation interferes with local bone healing, predisposing to a fibrous tissue interface, preventing the fibrin clot from adhering to the implant surface during healing. In this study, the provisional restorations were made from heat cure polymerising acrylic resin. This method of fabrication will increase the longevity of provisional restoration and thus eliminating any need for change of provisional during the course of this study. The provisional restorations were replaced by PFM definitive restorations after completion of the study.

In this study the Periotest evaluation has been utilised because of its proven advantages and ready availability in our department. The Periotest S, which is utilized in this study, has a scale range from -8 to +50. The lower the Periotest value, the higher is the stability / damping effect of the test object (tooth or implant). Interpretations of the Periotest values were based on the manufacturer's instructions as mentioned in Table V. The mean Periotest values observed in this study were in general less negative in magnitude when compared to other studies.[29–32] Tawse Smith A et al in 2001[33] reported a mean Periotest value of -2.39 after 12 weeks and -3.84 after one year of implant placement. Behneke et al in 2002.[29] observed this value to be -3.9 at the time of loading and -4.8 after one year. Naert I et al in 2004.[30] reported a mean Periotest value of -3.5 at baseline and -5.2 after ten years. This difference in reported values may be due to the time of assessment of the Periotest values among different studies as well as the type of abutment being used. In all the preceding studies the Periotest values have been estimated after intervals of at least three to four months after loading.

Also, in this study the t value and p value for 6M were -1.010 & 0.322, 8M were 1.176 & 0.251 and 12M were 1.771 & 0.089 respectively. The absence of any statistically significant change in these values within the two groups over time is similar to the results obtained by Behneke et al,[29] Liao KY et al.[32] and Krennmair G et al.[31]Although, Tawse-Smith A et al.[33] and Naert I et al.[30] have reported significant differences in Periotest values over time, the period of assessment of both these studies is much longer and thus the results might not be comparable.

While interpreting these results, it needs to be kept in mind that all the values recorded for both the groups were less than 0 (which according to the manufacturer's instructions means that the implant is well osseointegrated). Also, the level of significance of this difference was relatively higher at six months post loading (p value was 0.322) than at eight months post loading (p value was 0.251). The level of significance was further lowered (p value was 0.089) at end of twelve months thus implying that the difference in Periotest values had reduced at the end of eight and twelve months respectively. It would hence be valuable to prolong the follow up period to investigate whether any difference remains in the Periotest values later between the two groups.

The most common method to assess the marginal bone loss is with a conventional periapical radiograph. The bone loss exhibited by the early loading group was 0.83 mm at the end of six months post loading and is in agreement with other studies that have investigated the immediate loading and early loading protocols.[32,34] Stricker A et al in 2004.[35] had observed a mean marginal bone loss of 0.71mm after one year of loading. Liao KY et al.[32] in their study had reported mean bone loss of 1.12mm after one year of loading. This is also similar to the results obtained in studies conducted on implants replacing one or more teeth.[36–38] Reddy MS et al in 2008.[38] had observed a mean marginal bone loss of about 0.7 mm after 12 months of loading. The mean marginal bone loss measured in studies by Tawse Smith A et al.[33] and Nkenke et al.[39] was 0.9and may indicate that the crestal bone levels had somewhat stabilized.

No statistically significant differences in the crestal bone loss measurements in the early loading group

were seen in our study when a comparison was made between baseline values and those measured thereafter. No significant differences were observed in this group between the measurements made at six, eight and twelve months after loading. This again seems to indicate that the bone levels had stabilized after witnessing a rapid decline during the first month after loading. The same was also seen in a study carried out by Tawse Smith A and Nkenke et al in the year 2001 & 2004 respectively.

The key to successful outcomes with early loading is the control of micro motion or the reduction or strain at the healing bone-implant interface. To minimize this strain, prostheses must be engineered to minimize both the magnitude and mechanical advantage of applied forces. The success of this prosthetic modality depends on controlling the amount of forces on implants and maximizing the bone-implant interface area. Other critical factors in these prosthetic modalities can be bone quality, implant design, diameter, and length. All of these factors have been linked to strain at the bone implant interface, which must be controlled to achieve predictable osseointegration and predictable success.

5. Conclusion

From this in vivo study it can be concluded that both early loading and conventional loading are viable treatment modalities that can be routinely employed for rehabilitation of partially edentulous arches with implant supported restorations after proper case selection, meticulous treatment planning and the precise technique. The present study was conducted at a single centre in a comparatively small cross-section of population and also the implants should be evaluated at least for a period of 5 years after loading to be termed as successful. So further long term, multicentric studies with more sample size are recommended in the Armed forces to substantiate these results.

6. Source of Funding

None.

7. Conflict of Interest

None.

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