

EFFICACY OF EARLY LOADED IMPLANTS: A CLINICO-RADIOGRAPHIC STUDY

Periodontology

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ABSTRACT

Background: The beginning of dental implants is evolving as avant-garde advancement and a tipping point to practice dentistry. Aim: The present study has discussed the performance of peri-implant soft and hard tissues in early loaded implants both clinically as well as radiographically.

Material and Methods: The sample of fifteen implant sites in patients above 17 years visiting the Out-Patients Department of Periodontology and Oral Implantology, Himachal Dental College, India has considered. Evolution of the performance is made based on the periodontal status and standardized radiographs on review, after 3rd, 6th, 12th and 24th weeks from the day of implant placement.

Results: The difference for means of modified sulcus bleeding index, probing depth and clinical attachment level from baseline has only found statistically significant at all the subsequent time intervals; in addition to that a significant change was observed in 6 weeks as compared with 12 and 24 weeks. Even though the radiographs of each implant site has shown no signs of peri-implant during first 3 months, but at all the subsequent time intervals significant difference was observed.

Conclusion: The study shows that the early loading of dental implants proved to be more expedient and effectual implant loading protocol for the patients.

KEYWORDS

Dental implants, Osseointegration, Early loading, Peri-implant tissues, Peri-implant zone

INTRODUCTION:

Oral rehabilitation of the edentulous patients with implant supported prosthesis has been developed to a viable and predictable treatment option.¹ To achieve long-term success, rigid fixation of the implants within the host bone site is required. This bone bonding ability has been termed as "osseointegration" by Brånemark et al(1977).¹ The process through which osseointegration is achieved depends on several factors, such as the biocompatibility of the metal, the design and surface conditions of the implant, the condition of the host bed, the surgical technique used and the loading conditions applied.² Traditionally, it was thought that the healing period of 3-6 months was critical for predictable osseointegration of dental implant. However, loading protocols became central focus of discussion in osseointegration.² In this connection, three prosthetic loading protocols have been described according to the time duration between surgical placement of the implant and its later restoration with prosthetic part: Immediate loading is an implant supported temporary or definitive restoration within 2 weeks of the implant insertion; early loading is implant supported restoration between 2 weeks and 3 months after implant placement, and Delayed loading is implant prosthesis after more than 3 months of implant placement.³

Most of the standard protocols in implant dentistry suggest a healing period of 3 months for mandible and 6 months for maxilla. However, the time required for the procedure, the need for additional surgical procedures, if any and especially the need for in definitive periods of temporization are obstacles that sometimes prevent the patients from implant treatments. To overcome these obstacles, loading implants within few weeks after implant placement would have been beneficial. Amongst all the loading protocols, early loaded implants have advantages because the patients can be rehabilitated with crowns with one stage surgery. The patient does not experience any discomfort due to function, esthetics or psychology associated with missing teeth especially in esthetic zone. It also provides a trans-mucosal extension that guides the healing of soft tissue and creates an esthetic emergence profile.⁴

The soft tissue connection to the transmucosal part is of crucial importance as it relates to the stability of the peri-implant tissues and prevention of peri-implant infection with subsequent destruction of peri-implant structures of implant.⁵ The peri-implant zone primarily comprises of crestal bone and healthy soft tissue and interface portion between the implant and mucosa. These two parameters are the prerequisite for the implant success. It is generally recognized that the epithelium lining the peri-implant sulcus is similar to the junctional epithelium adjacent to natural teeth. In contrast, connective tissue attachment to implant components is different from that observed for natural teeth. As the connective tissue interface is considered of paramount importance to support the epithelium and block its apical migration, this lack of mechanical resistance can potentially endanger the prognosis of dental implants.⁶

To achieve a good functional and esthetic result with implant restoration, it is important to consider the biological principles of soft and hard tissues around an implant.⁷

Hence, the present study deals with the evaluation of peri-implant soft and hard tissues around the early loaded implants clinically as well as radiographically.

MATERIAL AND METHODS:

STUDY DESIGN AND SAMPLE SIZE:

This was an observational study. As no hypothesis was planned to be tested, a formal sample size calculation was not performed. However, based on earlier studies^{31,32} and due to adverse geographical conditions only a total of fifteen implant sites was undertaken in the age group of 18 years and older comprising both male and female patients visiting the Out-Patients Department of Periodontology and Oral Implantology, Himachal Dental College, Sunder Nagar Himachal Pradesh(India). The screening procedure involved explanation of the details about the risks and benefits of participation in the study. Those who agreed voluntarily were required to sign a consent form prior to their inclusion in the study. The study protocol had been approved by the ethics committee of the Himachal Dental College.

As the sample size was only 15, and most of the parameters recorded were ordinal in nature, a non-parametric evaluation plan was adopted. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean±SD. The descriptive statistics we used mean and Standard deviation while the Wilcoxon signed rank test was applied to investigate the pre and post intervention difference. We also applied the Survival function and Kaplan Meir curve to estimate the survival of the subjects.

INCLUSION CRITERIA:

Patients aged 18 years and older, Willing to comply with all the study requirements, Absence of any relevant systemic conditions such as uncontrolled diabetes mellitus, osteoporosis, malignancies, irradiation and blood dyscrasias etc, Full mouth plaque scores of not more than 30%, Full mouth bleeding scores of not more than 30%, Need for implant placement in anterior or posterior area of mandible for fixed prosthetic rehabilitation with single tooth crown and availability of sufficient alveolar bone volume measuring more than 6.0 mm in width and 10.0 mm in height at the implant recipient site of mandible.

EXCLUSION CRITERIA:

Pregnant or lactating mothers, Untreated periodontal disease, Previously bone augmented implant recipient site, Presence of residual roots at the implant recipient site, Clinical signs of bruxism, Smokers and Indulgence in alcohol or drug abuse.

PRESURGICAL PROCEDURE:

After inclusion of the patient in this study, each individual underwent a

full diagnostic work up which included:

- All the patients included in the study were subjected to detailed medical and dental history. Periodontal assessment was done using Plaque Index (Loe and Sillness) and Sulcus Bleeding Index (Muhlemann and Son), besides measurement of Probing depth and Clinical attachment levels using UNC #12 probe to determine the diagnosis, prognosis as well as to help in treatment planning.
- Intra Oral Periapical and Orthopantomogram radiographs.
- Study casts and clinical photographs.
- Routine Blood Investigations - Hb, BT, CT, TLC, DLC, ELISA test for HIV, HbsAg for hepatitis and Fasting Blood Sugar.
- The length and diameter of the implant was calculated for each patient based on the intra oral examination, IOPA and OPG radiographic evaluation and diagnostic casts.
- Complete oral prophylaxis was done and oral hygiene instructions given to the patients.
- The patient was recalled for implant placement after one week.

SURGICAL PROCEDURE: (FIGURE 1-6)

The patient was scheduled for implant surgery after phase I therapy. Facial skin all around the oral cavity was scrubbed with Povidine Iodine solution and the patient was made to rinse with 0.2% Chlorhexidine Digluconate mouthrinse for one minute prior to the surgery. The patient was anesthetized using 2% Lidocaine with Adrenaline concentration of 1:80000. A crestal incision on the edentulous area with sulcular incision on adjacent teeth was extended using surgical blade #15 followed by vertical incisions at faciomesial/faciobuccal line angle. Buccal and lingual full-thickness mucoperiosteal flaps were elevated. Initially, a pilot drill and then series of drills were used precisely and incrementally to prepare the implant osteotomy site for the implant. A guide pin was placed in osteotomy site to confirm position and angulations for multiple implants.

The implant was placed into the prepared site with ratchet until resistance was met and seated into final position. Then gingival former was placed. The flap was trimmed so as to attach the knife edge border around the implant. The procedure was completed by repositioning and suturing the surgical flap with interrupted 4-0 silk sutures. One week after the placement of implant, the patient was recalled, sutures removed and oral hygiene instructions reinforced. The patient was recalled after another two weeks for removal of the gingival former and placement of abutment. The standard post-operative instructions were given for better soft tissue healing.

CLINICAL PARAMETERS ASSESSED: The periodontal status was evaluated at 3rd, 6th, 12th and 24th weeks according to the following indices from the day of implant placement.

Modified Plaque Index (mPII): Mombelliet. al (1987) modified the Loe and Sillness Plaque Index for use in such implant studies. Accordingly, the plaque adherent to four sites of the implant abutment at or below the crest of the peri-implant mucosa was scored on mesial, facial, distal and lingual surfaces as per the following criteria.

0: No detection of plaque

- 1: Plaque only recognized by running a probe across the smooth marginal surface of the implant.
- 2: Plaque can be seen by the naked eye.
- 3: Abundance of soft matter.

Modified Sulcus Bleeding Index (mBI):

Mombelliet. Al (1987) also modified the "Bleeding Index of Muhlemann and Son for assessment of bleeding on probing in such implant studies". Accordingly, the bleeding score was assessed on mesial, facial, distal and lingual surfaces as per the following criteria.

- 0: No bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant.
- 1: Isolated bleeding spots visible.
- 2: Blood forms a confluent red line on margin.
- 3: Heavy or profuse bleeding.

Probing depth (PD):

Probing depth (PD) was measured with the UNC-12 probe on mesial, facial, distal and lingual surfaces around the implant. The implant shoulder was used as a reference line for the location of the mucosal margin.

Clinical attachment level (CAL):

Clinical attachment level (CAL) was measured using UNC 12 probe on mesial, facial, distal and lingual surfaces around the implant (CAL = Probing depth + Distance between Implant shoulder and Mucosal margin).

Radiographic assessment: Figure (7 &8)

Standardized intraoral peri-apical radiograph with an attached x-ray grid was obtained for each implant site on 3rd, 6th, 12th and 24th weeks interval after placement of the implant. The x-ray unit with long cone paralleling device was used. The level of bone was measured on the mesial and distal aspect of each implant. The reference point was from implant shoulder to the crest of interproximal alveolar bone. To assess the changes in bone height, the distance between the implant shoulder and the first visible bone-implant contact (DIB) was determined by measuring the squares on radiograph and expressed in millimetres.

RESULTS (TABLES 1-5):

The present study comprised fifteen implant sites in patients with age group of 18 years and above of both sexes who visited the Department of Periodontology and Oral Implantology, Himachal dental college, Sundernagar.

The results presented here are on account of 12 implant sites in which assessment could be made during all the intervals as there was a dropout of 3 patients. Average scores of readings for a parameter at an interval were taken as the representative value of periodontal health for each implant site.

1. Modified Plaque Index:

Oral hygiene was well maintained in all patients. The mean modified plaque index remained stable during the observation period. The mean mPI was zero at 3, 6, 12 and 24 weeks (Table 1).

2. Modified Sulcus Bleeding Index:

At 3 weeks, mean modified sulcus bleeding index was 0.71 ± 0.44 . The mean sulcus bleeding index was 0.08 ± 0.12 at 6 weeks. By 12th and 24th week the mean modified sulcus bleeding index was zero. Thus, the difference from baseline was statistically significant at all the subsequent time intervals ($p < 0.05$) (Table 2).

Mean difference for modified sulcus bleeding index was statistically significant at 6 weeks when compared with 12 and 24 weeks. Statistically, no significant difference was observed between 12 and 24 weeks interval.

3. Probing depth:

At 3 weeks, mean probing depth was 1.40 ± 0.49 . The mean probing depth at 6 and 12 weeks was 0.67 ± 0.65 and 0.02 ± 0.07 respectively. At 24 weeks, mean probing depth was zero. Thus, the difference from baseline was statistically significant at all the subsequent time intervals ($p < 0.05$) (Table 3). Mean difference for probing depth was statistically significant at 6 weeks with when compared with 12 and 24 weeks. Statistically, no significant difference was observed between 12 and 24 weeks interval. The mean probing depth at 3 weeks was higher because the peri implant mucosa is more penetrable than around natural teeth¹². The reduction in mean pocket depth at 6, 12 and 24 weeks was observed²⁹.

4. Clinical Attachment Level:

At 3 weeks, mean clinical attachment level was 1.65 ± 0.74 . At 6, 12 and 24 weeks mean CAL was 1.10 ± 0.3 , 0.02 ± 0.07 and zero respectively. Thus, the difference from baseline was statistically significant at all the subsequent time intervals ($p < 0.05$) (Table 4).

Mean difference for clinical attachment level was statistically significant at 6 weeks compared with 12 and 24 weeks. Statistically, no significant difference was observed between 12 and 24 weeks interval.

5. Radiographic assessment:

The radiographs of each implant site revealed no signs of peri-implant radiolucency over the entire period of 6 months. At 3 weeks, mean bone loss was 0.88 ± 0.83 . The mean bone loss at 6, 12 and 24 weeks was 1.75 ± 0.84 , 1.88 ± 0.64 and 2.25 ± 0.62 respectively. Thus, the difference from baseline was statistically significant at all the subsequent time intervals ($p < 0.05$) (Table 5). Mean difference for radiographic bone loss was statistically non-significant at 6 weeks when compared with 12 and 24 weeks and at 12 with 24 weeks.

6. Survival rate:

Survival events were recorded upto 185th day after implantation. A total of 4 out of 15 implants failed. Thus overall survival rate was 73.3%. Survival functions at different time intervals ranged from 0.85 to 1.0. Overall cumulative survival function was 0.68 ± 0.14 . Median survival period for 185 days follow up was 182 days (Figure 6). Survival is related to the implant function at the time of checkup, whereas success additionally includes the probability for the implant to remain stable, as judged according to annual bone loss. In our study the cumulative survival rate was 73.3% (Table 6), 4 out of the 15 implants failed in the study. 2 implants failed at 3 weeks of implant placement, one at 6 weeks and one at 6 months. The failure of 2 implants at 3 weeks could be due to trauma i.e overheating during drilling or implant insertion.

DISCUSSION:

In the present study Uniti implants were used which have a unique cortico-cancellous design. Taking into consideration the sample size and economy we preferred using uniti system of implants.

Clinical outcome of various forms of surgical interventions are influenced by general level of oral hygiene. No plaque accumulation was observed on any of the implants during any follow up period. These results are in accordance with the studies^(8-10,24,27,31)

Analysis of the modified sulcus bleeding index was done at 3, 6, 12 and 24 weeks. The mean modified sulcus bleeding index reduced over time. **Luterbacher et al (2000)**¹¹ concluded that bleeding on probing has statistically higher diagnostic values for implants than for teeth. It was reported that higher scores of bleeding on probing were recorded from the healthy implant sites compared with the healthy natural dentition in the dog¹³. The peri-implant soft tissues revealed little tendency to bleed on probing at 6 weeks and were clinically healthy at 12 and 24 weeks⁸. This can again be explained by good oral hygiene of patients and was consistent with other studies. The absence of bleeding on probing is widely considered a useful clinical indicator of the absence of inflammation. On the contrary in his 5 year follow up study stated that bleeding on probing was found to increase till 6 months followed by decrease at 1st and 2nd year of implant placement.¹⁴ The bleeding on probing again increased at 3rd, 4th and 5th year of implant placement. The results are can be associated with the study by **Zhang et al (2016)**²⁵ and **Huynh-Ba Get al**²⁹.

Probing depth was used as the defining clinical parameter for determination of soft tissue maturity. The results are in accordance with the study by **Turkyilmaz I (2006)**¹⁵ which stated that decrease in probing depth over time was due to the shrinkage of gingiva after surgery as a natural result of healing. Another possible explanation for the stable probing depth between 4 and 12 weeks postoperatively could be due to soft tissue maturity which was established by the fourth postoperative week. Periodontal soft tissue maturation following full thickness flap elevation is histologically evident at 14 days for epithelium and at 30 days for connective tissue⁷

The mean clinical attachment loss at 6, 12 and 24 weeks did not increase. In accordance with the study by **Nishimura et al (1997)**¹² which stated that loss of attachment did not increase, rather it decreased a little, suggesting that the bone around implants was stable and showed gradual improvement. The reduction was due to implant surface to support subepithelial connective tissue attachment at the transmucosal part of the implant¹⁶.

In the present study the bone loss is less than 1.5 mm which is in accordance with the established criteria for the assessment of marginal bone level change in the first year that should be less than 1.5 mm and ongoing annual bone loss should be less than 0.2 mm¹⁷. This could be related to maturation of bone after implant placement and adaptation of bone to withstand functional forces. The bone loss at 3 and 6 weeks is in accordance with the study by **Cochran et al. 1996**¹⁸ which stated that the bone loss that occurs between the implant placement and loading could be related to surgical trauma and the compromise of the crestal bone vascular supply after the elevation of a mucoperiosteal flap and interruption of the vessels caused by osteotomy preparation.

The mean bone loss increased over the time from 3, 6, 12 and 24 weeks. The bone loss at 12 weeks was in accordance with the study by **Jung et al. 1996**¹⁹ which observed a bone loss to the level of the first thread with other systems like standard series, miniseries, and hex-lock implants

of the Steri-Oss system; and 3i standard implants. The bone loss could be explained by biomechanical adaptation of bone to occlusal loads. The bone loss at 24 weeks is in accordance to the study by **Adell et al. 1981**²⁰ who reported a bone loss of 1.2 mm using Branemark implants for the first year in the 15 year study. Chief cause for crestal bone loss after surgical procedure is a result of the alteration in the vascularization of the bone periosteum after flap reflection. Several experimental studies verified that avoiding flap reflection on the insertion of dental implants prevents the alteration of the vascularization resulting in less crestal bone resorption^{27,28}. The bone loss is also observed in traditional flap procedure with early loading of implants.²⁶

Survival is related to the implant function at the time of checkup, whereas success additionally includes the probability for the implant to remain stable, as judged according to annual bone loss. The results are in accordance with the study by **Bruyn H et al.** The third implant failed after 6 weeks of implant placement due to overloading²². One implant failed at 6 months due to unknown reasons. No prosthetic complications were noticed in 11 patients during the observation period and all of them had functioning prosthesis throughout the period of study²¹. However, 96.3 % of success rate of early loaded implants was observed in a study.^{23,30}

CONCLUSION:

The important factor in the successful early loaded implants during the first few weeks of implant insertion is the prevention of implant micro movement. Therefore additional long term studies with large sample size need to be done to further validate the treatment concept for early loading of dental implants in healed sites.

TABLES

Table 1: Modified Sulcus Bleeding Index at different follow up intervals during the study

SN	Time interval	n	Mean value	SD	Significance of change from baseline (Wilcoxon signed rank test)
1	3 weeks (Baseline)	12	1.4	0.49	
2	6 weeks	12	0.67	0.65	$z=2.887$; $p=0.004$
3	12 weeks	12	0.02	0.07	$z=3.114$; $p=0.002$
4	24 weeks	12	0	0	$z=3.140$; $p=0.002$

Table 2: Pocket Depth at different follow up intervals during the study

SN	Time interval	n	Mean value	SD	Significance of change from baseline (Wilcoxon signed rank test)
1	3 weeks	12	0.71	0.44	
2	6 weeks	12	0.08	0.12	$z=2.648$; $p=0.008$
3	12 weeks	12	0	0	$z=2.972$; $p=0.003$
4	24 weeks	12	0	0	$z=2.972$; $p=0.003$

Table 3: Clinical Attachment level at different follow up intervals during the study

SN	Time interval	n	Mean value	SD	Significance of change from baseline (Wilcoxon signed rank test)
1	3 weeks	12	1.65	0.74	
2	6 weeks	12	1.1	0.36	$z=2.014$; $p=0.014$
3	12 weeks	12	0.02	0.07	$z=3.114$; $p=0.002$
4	24 weeks	12	0	0	$z=3.114$; $p=0.002$

Table 4: Bone Level at different follow up intervals during the study

SN	Time interval	n	Mean value	SD	Significance of change from baseline (Wilcoxon signed rank test)
1	3 weeks	12	1.65	0.74	
2	6 weeks	12	1.1	0.36	$z=2.014$; $p=0.014$
3	12 weeks	12	0.02	0.07	$z=3.114$; $p=0.002$
4	24 weeks	12	0	0	$z=3.114$; $p=0.002$

Table 5: Survival Function at different follow up intervals

SN	FU Interval	No. entered	Survived	Failed	Survival Function	Cumulative survival function $\pm$ SE
1	3 weeks	15	13	2	0.87	0.87 ± 0.09

2	6 weeks	13	12	1	0.92	0.80±0.10
3	12 weeks	12	12	0	1	0.80±0.10
4	24 weeks	12	12	0	1	0.80±0.10
5	After 24 weeks	12	11	1	0.92	0.80±0.10
Total			11 (73.3%)	4 (26.7%)		

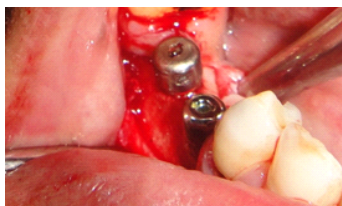
Median survival time = 182 days



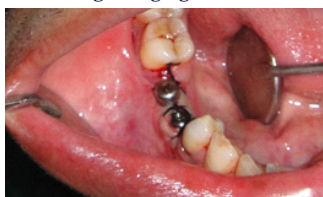
1. Pre-operative Edentulous site



2. Flap elevation



3. Fixture placement along with gingival former



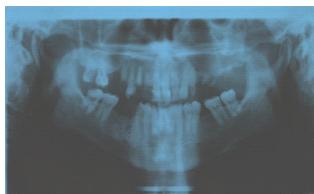
4. Suturing



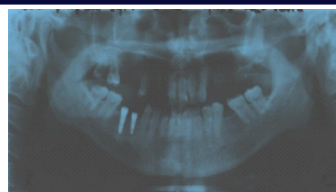
5. Abutment placement



6. Crown cementation



7. Pre-operative OPG



8. Post-operative OPG

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