Clinical Evaluation of Early Loaded and Unloaded Implants in Edentulous Mandible

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Abstract

Objectives The aim of this study is to compare and evaluate the clinical outcome of early loaded and unloaded implants in the interforaminal region of anterior mandible.

Materials and Methods Five completely edentulous patients aged between 45 and 65 years were selected satisfying certain criteria. Four implants were placed in 33, 43, 35 and 45 regions; implants in 33 and 43 regions were loaded by a Dolder bar supported overdenture at 7th day. The implants at 35 and 45 regions were connected to 33 and 43 regions, respectively after 4 months. The implants were divided into two groups. Group I consisted of early loaded implants (implants in the region of 33 and 43) and Group II consisted of delayed loaded implants (implants in the region of 35 and 45). The implants were evaluated for various clinical parameters at 2, 4 and 6 month intervals after initial placement.

Results There was significant increase in the bone to implant contact for unloaded implants as compared to early loaded at the end of 6 months of implant placement. There was increased marginal bone loss around early loaded implants as compared to unloaded implants at the end of 6 months. Clinical stability of early loaded implants was lower as compared to the unloaded implants at the end of 6 months. Survival rate for early loaded and unloaded

implants was 100% at the end of 6 months with all implants in function.

Conclusion Early loading of interforaminal mandibular implants demonstrated a highly acceptable clinical success at the end of 6 months. However, the bone density, marginal bone level and clinical stability were significantly lower for the early loaded implants as compared to unloaded implants.

Keywords Early loaded implants · Unloaded implants · CT scan · Periotest

Introduction

Predictable formation of a direct bone-to-implant interface is the major criteria in implant dentistry. The two-stage surgical protocol established by Branemark et al. [1] to accomplish osseointegration includes countersinking the implant below the crestal bone and maintaining a soft tissue covering over the implant for 3–6 months. During the last 15 years, various authors have reported that root form implants may osseointegrate, even though they extend above the bone and through the soft tissues during early bone remodeling [2]. This surgical approach has been called a one stage or non submerged implant procedure because it eliminates the second stage implant uncovering surgery and aids in immediate prosthetic rehabilitation of the patient.

Several studies have demonstrated that immediate loading of a complete mandibular overdenture supported by 4 implants connected with a bar results in implant survival rates that are comparable to those obtained following a delayed approach [3].

In this latter situation, González-García et al. [4] found an overall survival rate of 97.1% with no statistical

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differences between primary and secondary implant stability along the healing process in a conventional implant two-stage surgical procedure.

Experimental studies have shown that immediate loading of threaded implants does not necessarily lead to fibrous tissue healing. Instead, a bone-to-implant contact develops over a period of time, which is comparable with that of implants that are loaded conventionally. Implants retrieved from humans with adjacent bone have confirmed the experimental results, both in the mandible and maxilla. Bone to implant contact of up to 93% of the intra-bony part of the implant has been found and osseointegration of immediately loaded implants have been observed even in heavy smokers [5].

Accurate and detailed analysis of the jaw-bone is very much essential to make a decision regarding the patient selection, the implant surface type and the surgical technique to be used. As the mechanical behavior of the bone is a vital factor in attaining and maintaining osseointegration, several classification systems and procedure have been proposed for assessing the bone quality. These systems can also be used for predicting the prognosis of implant [6]. The jaw bone volume has been traditionally evaluated using intraoral and panoramic films besides computed tomography (CT) scans. Schwarz et al. [7] introduced the concept of CT for pre-operative assessment of dental implant candidates.

Stability is essential for optimal oral implant function. Osseointegration is a histological event that occurs gradually over a period of time which is essential for implant stability that must be verified at the moment the transmucosal abutments are connected to the endosseous fixtures and before fabricating the prosthesis for successful long term function [8].

The results of various clinical researches have encouraged a progressive shortening of this healing period of implants. As a result the concept of immediate loading of implants has been proposed. In particular, reliable results have been reported for implant-retained mandibular overdentures with immediate loading. There is paucity of prospective data on results of the immediate loading protocol. This study has been carried out to evaluate and compare the effectiveness of early and delayed loading protocol in implant retained mandibular overdentures.

Materials and Methods

This study was conducted in the referral and teaching hospital of Armed Forces, Army Dental Centre (R&R) Delhi Cantonment with the aim of rehabilitating the completely edentulous patients with early implant supported mandibular overdenture and a conventional maxillary denture. Four implants were placed in 33, 43, 35 and 45 regions; implants in 33 and 43 regions were loaded by a Dolder bar supported overdenture at 7th day. The implants

at 35 and 45 regions were connected to 33 and 43 regions, respectively after 4 months. The implants were divided into two groups. Group I consisted of early loaded implants (implants in the region of 33 and 43) and Group II consisted of delayed loaded implants (implants in the region of 35 and 45). The implants were evaluated for various clinical parameters at 2, 4 and 6 month intervals after initial placement.

Five completely edentulous patients aged between 45 and 65 years were selected satisfying the following criteria having good general health, healthy oral mucosa, no history of TMJ disorders, adequate interarch space, adequate bone quality and quantity, patients not requiring pre-prosthetic surgery, Angle's class I skeletal jaw relations, co-operative attitude and motivated patients. The study protocol was explained in detail to all patients and their consent for participating in the study was taken. Pre-surgical radiographic evaluation was carried out with panoramic radiograph. A surgical template was fabricated using clear autopolymerizing resin. Four holes were drilled on the template in the region of 33, 43, 35 and 45 regions. A 5 mm diameter metal ball was placed in each hole and panoramic radiograph was taken with the surgical template in the patient's mouth to check for the height of the bone. The metal balls were incorporated in the template mainly to calculate the amount of radiographic magnification that occurred. Blood and urine analysis was carried out for each patient pre-operatively to rule out any systemic disorders. Pre-operative CT scan was done to check for the bone density in the implant recipient sites. Conventional complete dentures were fabricated using a facebow transfer onto a semi adjustable articulator; semi anatomic teeth were used to achieve balanced occlusion.

All patients received oral antibiotics for 5 days starting 1 day prior to surgery. Patients were prescribed with capsule Augmentin 625 mg thrice daily for 5 days. The surgical instruments and the implant kit were sterilized in autoclave.

Biohorizon Maestro implants are packed in sterile vials. When the cap is removed from the inner vial, the implant and its two piece 3 in one abutment are exposed. This 3 in one abutment was used to place the implant with the help of a ratchet adapter. The implant was advanced into the prepared site until the platform was in flush with the crestal bone. The implants placed in 33, 43, 35 and 45 regions in all five patients had a dimension of 4 mm in diameter and 12 mm in length. The 0.50" hex driver was used to remove the 3 in one abutment screw, a hemostat was used to grasp the abutment during screw removal and the abutment was removed from 35 and 45 implants in all cases and the cover screw was placed (Figs. 1, 2, 3). Abutments from implants in the region of 33 and 43 were unscrewed but the abutments were not removed instead retained and used as

Fig. 1 Paralleling pins placed in the implant preparation site

Fig. 4 Abutments with external ball top screw in the region of 33 and 43

Fig. 2 Implants placed in the region of 33, 43, 35 and 45

Fig. 3 Post operative OPG

impression posts. An external ball top screw was inserted into the abutments to secure the abutments in place; the flap was sutured using nylon sutures. A custom tray was made and a closed tray impression was made using addition silicone impression material (Fig. 4). The external ball top screw was unscrewed and the abutments were removed, permucosal extensions were placed on the implants in 33 and 43 region. The abutment with the external ball top

Fig. 5 Polyvinyl siloxane impression with implant analog in place

screw and the implant analog were assembled and placed into the impression and the impression was poured in Type IV stone (Fig. 5). Custom castable abutments (hexed) and pre-fabricated bar were used for the fabrication of Dolder bar.

The implants in 33 and 43 regions were loaded with the Dolder bar on the 7th day in all cases (Fig. 6). The clip was attached to the denture (fabricated prior to surgery) using autopolymerizing resin and the denture was inserted (Figs. 7, 8, 9). 2 week post implant insertion occlusal adjustments were performed. No specific dietary guidelines were recommended to the patients.

After a delayed healing period of 3 and 1/2 months, a second stage surgery was performed in all patients in the region of 35 and 45, cover screws were removed and permucosal extensions were placed for 1 week (Fig. 10). After 1 week the Dolder bar in the region of 33 and 43 and the permucosal extensions on 35 and 45 were removed the

Fig. 6 Dolder bar connecting implants in the region of 33 and 43

Fig. 7 Mandibular complete denture with clip attached

Fig. 8 Complete denture insertion

3 in one abutment along with external ball top screw were assembled on all four implants and a closed tray impression was made using addition silicone impression material (Fig. 11). Dolder bar connecting all the four implants was fabricated and attached to the implants exactly at the end of

Fig. 9 Early loaded implant supported complete denture insertion

Fig. 10 Permucosal extensions placed in the region of 35 and 45 after 3 1/2 months

4th month (Fig. 12). The clip was attached to the existing denture using autopolymerizing resin and the denture was inserted (Figs. 13, 14). The clinical parameters were evaluated from the time of placement of the implants till 6 months.

Results

The results take into consideration the four quoted parameters: changes in bone density and marginal bone

Fig. 11 Abutments with external ball top screw in the region of 33, 43, 35 and 45

Fig. 12 Dolder bar connecting the implants

Fig. 13 Clips attached to the mandibular complete denture

level using computed tomography, clinical stability using Periotest and survival rate of early loaded and unloaded implants over a period of 6 months.

In this study CT scans were taken of the patients immediately after placement of the implants and at 2, 4 and 6 month interval to check for the bone density and marginal bone level for the immediate loaded and unloaded implants. Clinical stability was checked using Periotest

Fig. 14 Implant supported complete denture insertion

immediately after insertion of the denture and at 2, 4 and 6 month interval. Finally the survival rates for all the implants were noted at the end of 6 months. All the data obtained were tabulated and statistically analyzed as shown in Tables 1, 2, 3 and 4).

Discussion

Primary stability and postponement of loading of dental implants for approximately 3–6 months have been considered for years to allow osseointegration of dental implants. However, the necessity of waiting to load is not scientifically but rather clinically based. It is therefore justifiable to question whether this healing period is an absolute prerequisite for obtaining osseointegration, or if under circumstances this period can be shortened without jeopardizing osseointegration and long term results. It should be demonstrated whether any kind of motion transmitted to the implants during the early phases of integration can compromise the long-term results, or if there is a threshold below which micromotion may not compromise osseointegration.

Assessment of Bone Density Using Computed Tomography

There were no significant changes in the bone density for early loaded and unloaded implants at baseline, 2 and 4 months, however, significant changes were noted at the 6th month. At 4th and 6th month there was increase in the HU values for both early loaded and unloaded implants probably due to the bone formation and increase in the implant bone contact.

Table 1 Bone density (Hounsfield units-HU)

	Bone density			
	Base line	2 month	4 month	6 month
Group I, early loaded implants (33 and 43)	<i>N</i>	5	5	5
Minimum	1027.55	959.25	1059.55	1135.60
Maximum	1094.40	1071.05	1107.80	1182.90
Mean	1063.8300	1014.0100	1085.0500	1157.4500
Std dev	25.83824	40.02483	21.94359	22.45072
Group II, unloaded implants (35 and 45)	<i>N</i>	5	5	5
Minimum	1044.95	985.80	1075.40	1161.00
Maximum	1119.95	1083.20	1144.80	1261.75
Mean	1086.71	1030.58	1114.98	1204.62
Std dev	33.64891	36.98065	33.66531	38.04965

Table 2 Marginal bone level (mm)

	Marginal bone level			
	Base line	2 month	4 month	6 month
Group I, early loaded implants (33 and 43)	<i>N</i>	5	5	5
Minimum	0.05	0.65	1.2	1.6
Maximum	0.4	1.00	1.50	2.45
Mean	0.17	0.89	1.34	1.98
Std dev	0.13509	0.14748	0.11937	0.36159
Group II, unloaded implants (35 and 45)	<i>N</i>	5	5	5
Minimum	0.05	0.2	0.2	0.6
Maximum	0.2	0.45	0.55	0.75
Mean	0.11	0.29	0.43	0.68
Std dev	0.06519	0.10840	0.15248	0.05701

Table 3 Clinical stability (PTV)

	Clinical stability (PTV)			
	Base line	2 month	4 month	6 month
Group I, early loaded implants (33 and 43) (<i>N</i> = 5)	<i>N</i>	5	5	5
Minimum	−3.5	−1.5	−1.5	−2
Maximum	−2	0	0	0
Mean	−2.7	−0.6	−0.5	−1.1
Std dev	0.57009	0.54772	0.70711	1.02470
Group II, unloaded implants (35 and 45)	<i>N</i>	5	5	5
Minimum	−3.5	−2	−3.5	−4
Maximum	−2.5	−0.5	−1.5	−2
Mean	−3.1	−1.2	−2.5	−3
Std dev	0.54772	0.57009	0.79057	0.79057

Misch [9] noted that the bone density influences the amount of bone in contact with the implant surface not only at the first stage surgery, but also at the second stage

uncovery and early prosthetic loading. He also noted that bone loss phenomenon may be explained by evaluating the HU. The correlation of bone density, elastic modulus bone

Table 4 Assessment of survival rate

	Baseline (%)	2 month (%)	4 month (%)	6 month (%)
Early loaded implants (33 + 43)	100	100	100	100
Unloaded implants (35 + 45)	100	100	100	100

strength and bone implant contact percent when a load is applied on an implant are different for each bone density. Hence, it is very important to study the bone density prior to placement of the implants and also changes that occur after surgery.

Assessment of Marginal Bone Level Using Computed Tomography

There were no significant differences in the marginal bone level between the early loaded and unloaded implants on the CT at baseline. Statistical differences were noted at 2, 4 and 6 months.

Adell et al. [8] reported marginal bone loss in their 15 year study of osseointegrated implants in the edentulous mandible. The study indicated greater magnitude and occurrence of bone loss during the first year of prosthesis loading, averaging 1.2 mm with a range of 0–3 mm. The results of this study are similar in contrast to the study conducted by us.

Weber et al. [10] demonstrated that in one stage implants a large percentage of initial bone loss occurred during the first months, whereas in two-stage implants 40% of initial bone resorption was found after re-entry. The explanation of the findings was based on the bacterial colonization of one stage implants and the additional surgical trauma in two stage protocols.

This study compares and evaluates the mean marginal bone level on the mesial surface of early loaded and unloaded implants over a period of 6 months. Based on the results obtained it can be concluded that the mean marginal bone loss around early loaded implants was 1.8 mm and for unloaded implants was 0.6 mm over a period of 6 months. There were significant differences between the two groups.

Assessment of Clinical Stability Using Periotest

Implant stability, an indirect indication of osseointegration, is a measure of the clinical immobility of an implant. Periotest has been thoroughly studied and advocated as a reliable method to determine implant stability [11]. Schulte and Lukas [12] have described how the Periotest works in their article.

This study compared the PTVs for early loaded and unloaded implants over a period of 6 months. At baseline

and 2nd month there were no statistical significant differences between the two groups, however, significant differences were noted between the two groups at 4 and 6 months indicating better stability with the unloaded groups as compared to the early loaded implants.

Randow et al. [13] compared an experimental group (immediate loading fixed superstructures) with the traditional two stage concept. They found a decrease of Periotest values in immediate loaded groups with a mean of –2.6 and a mean of –3.9 for unloaded groups over a period of 18 months.

Assessment of Survival Rate

Finally the survival rate of early loaded and unloaded implants was assessed in this study over a period of 6 months. The survival rate of early loaded and unloaded implants was 100%. There was no failure of implants in both the groups although there was some amount of peri-implantitis around few of the early loaded implants in the first 2 months of loading. There were no other complaints reported by the patients over a period of 6 months. At the end of 6 months the soft tissues around the early loaded and unloaded implants were healthy in all five patients with the prosthesis in function.

Conclusion

Early loading of interforaminal mandibular implants demonstrated a highly acceptable clinical success at the end of 6 months. However, the bone density, marginal bone level and clinical stability were significantly lower for the early loaded implants as compared to unloaded implants. Further long term studies is necessary to evaluate bone density, marginal bone resorption, clinical stability and success rates in order to develop selection criteria for early implant loading.

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