10.5005/JP-Journals-10012-1076
ORIGINAL RESEARCH

Implant-retained Mandibular Overdentures: A Comparative Study of Immediate Loading *vs* Delayed Loading after One Year

Shojaedin Shayegh, Hassan Semyari, Alireza Forouzandeh Shahraki, Mohammad Reza Hakimaneh

ABSTRACT

Purpose: The aim of this study was to compare the clinical and radiographical outcomes of two loading protocols of mandibular overdentures supported by two unsplinted implants.

Materials and methods: Twenty completely edentulous patients were included in the study. Patients were categorized in two groups each containing 10 patients. In group A, patients received at least two implants in symphysis areas inserted after a minimal flap reflection, and 2 months after implant placement, a mandibular complete denture was connected to the implants using ball attachments. In second group, prosthesis was loaded immediately after placing the implants in symphysis areas without any flap reflection. Patients were examined at 1, 12, 24 and 48 weeks after loading. At postoperative visits, occlusion was checked and the need for any prosthesis maintenance was recorded. Mobility of the implants, radiolucency around the implant and amount of crestal bone loss was checked and measured for both groups during the checkup sessions. Also any prosthetic problems were recorded.

Results: After 12 months of loading, in both group no implant failure was reported and the survival rate was 100% in immediate and delay loading groups. Average of bone resorption in control group at the end of study was 0.84 ± 0.05 mm and in the test group was 0.84 ± 0.03 mm. In all patients after every 6 months the plastic O-rings were changed due to frictional wearing. In test group, in three patients the mandibular denture fractured, while, in control group it happened in two patients. In the test group, two patients experienced unbearable pain, while, in the control group seven patients experienced unbearable pain and they needed analgesics. None of the patients in test group experienced edema, swelling and discomfort after surgery due to flapless surgery, while in the control group four patients experienced edema and swelling after surgery.

Conclusion: The results of this study suggest that immediate loading of two implants supporting mandibular overdenture has outcomes comparable with conventional loading protocols. This clinical approach offers good stability and comfort while keeping high implant success rate.

Keywords: Dental implant, Free-standing attachments, Immediate loading, Delay loading, Overdenture, Retentive ball anchors.

How to cite this article: Shayegh S, Semyari H, Shahraki AF, Hakimaneh MR. Implant-retained Mandibular Overdentures: A Comparative Study of Immediate Loading *vs* Delayed Loading after One Year. Int J Oral Implantol Clin Res 2012;3(3):105-110.

Source of support: Nil

Conflict of interest: None declared

INTRODUCTION

Edentulism is a disability affecting millions of individuals worldwide. Edentulism remains prevalent in some elderly communities with more than 50% of the population.[1] Tooth loss of multiple etiologies, particularly caries and periodontal disease, that leads to early edentulism is associated with residual ridge resorption and affiliated problems of removable denture use. Beyond the physiological consequences of continued resorption of the mandible, altered facial form, and diminished masticatory function, edentulism has been reproducibly associated with reduced quality of life.[2] Treatment of edentulism using removable dentures has additional, negative consequences. The progressive bone resorption of the edentulous ridge is the main concern when rehabilitation of the edentulous mandible using a complete denture is considered.[3] Complete dentures are not sufficient for re-establishing the oral function either in relation to chewing efficiency.[4] The psychological aspects of edentulism include social embarrassment from denture use, measured reduction in quality of life and low self-esteem.[5]

In the 1960s, the advent of osseointegrated implants helped to resolve many of the problems with retention and stability of complete dentures.[6] The successful prosthetic outcome of implant-retained overdentures (IOD) had such a high impact on the academic and clinical community that in recent 2-day meeting at McGill University in Montreal, implant authorities suggested that the prosthetic rehabilitation with conventional denture of a patient with a completely edentulous mandible should no longer be the treatment of choice. Instead, the placement of two implants and fabrication of an IOD should be the option to consider first.[7,8]

Since, the first publication by Branemark et al[9] and Schroeder et al,[10] one of the most important paradigms, both for submerged and nonsubmerged implants, for adequate osseointegration of dental implants has occurred, with a waiting period varying approximately from 3 to 6 months.[11] During this critical healing phase, patients are asked not to wear the removable prostheses for at least 2 to 4 weeks after the surgery.[12] Then, a series of time-consuming appointments for soft relining are necessary to maintain the complete denture stable and clean without jeopardizing the implants' healing.[13]

In the case of patients with edentulous atrophic mandibles, this can create discomfort owing to the instability of the provisional denture, which frequently occurs because of reduction of sulci and superficial insertion of muscles, such as mentalis, genioglossal and mylohyoid muscles. In recent years an increasing interest toward a shortening of times between implant placement and implant loading has developed.[11] A literature review of experimental research indicated that early loading itself was not a contraindication to successful osseointegration; the latter was dependent on maintenance of a load that prevented extensive micromotion at the bone-implant interface. This micromotion was determined experimentally to be between 50 and 150 μm.[14]

During the 20 years, placement of a bar-retained 4-implant overdenture in the front region of the mandible has become the treatment of choice in overdenture prosthetic.[15] However, because the success rate of implantation in the anterior mandible is now very high, use of only two or three implants for overdenture retention has proved successful.[16,17] When cost is considered, two-implant ball-retained mandibular overdentures have demonstrable advantages compared to implant-supported complete dentures or two-implant or four-implant bar-retained options.[18] According to the studies about prevalence of edentulism in Iran, 32% of adults (above 35 years old) are edentulous.[19] Accessing difficulties to developed laboratories for most of dentists, wide range of edentulous patients across the country and high costs have made the use of overdenture retained by bar difficult.

The present study aimed to compare clinical and radiographical outcomes of dental implants with RBM surface (DIO, Busan, Korea) immediately loaded with delay loaded by means of complete denture retained by two ball attachments. The null hypothesis was that there would be no differences in outcomes between immediate and delayed loaded mandibular two-implant supported overdentures with respect to clinical and radiographical indexes.

MATERIALS AND METHODS

The research protocol was approved by Institutional Review Board of School of Dentistry of the Shahed University, and patients were selected among the patients population of Department of Prosthodontics. Twenty adults were included in this study. Patients were divided into two groups, control and test group. Every group consists of 10 patients. In control group, patients received their IOD with delay loading protocol and in test group patients received their IOD immediately after implants placements with flapless procedure. After signing the informed consent, the patients were consecutively included in the study, provided that they fulfilled the following inclusion criteria:

- Completely edentulous in both arches and not older than 80 years of age
- Wore complete dentures in both arches for at least 3 months
- Sufficient amount of bone volume for placement of implants with minimum dimensions of 4 × 10 mm in the mandibular symphisis region. Dimension and quality of bone evaluated by using panoramic radiography and cone-beam computed tomography that must be DII or DIII (according to Zarb and Lekholm classification)
- Healed bone sites, at least 6 months postextraction
- No need for bone augmentation
- Sufficient implant primary stability: Insertion torque (IT) ≥ 20 Ncm
- No medical contraindication for implant therapy
- Absence of active infections, neoplastic lesions, history of radiotherapy or chemotherapy in jaws within last 12 months, alcohol or drug abuse, temporomandibular joint disorder and facial pain
- Agreement for participating in the study.

Those who were selected for the study were contacted and scheduled for an initial screening. During this session and for evaluation of alveolar ridge condition, pathology or impacted teeth, panoramic radiographs were made for all subjects. Also clinical examination was performed and the following information was collected: Subject's chief complaint, previous dental and medical history, width and anatomy of mandibular alveolar ridge and jaw relationship.

Prosthetic Procedures

New maxillary and mandibular complete dentures were made for all patients, in the Department of Prosthodontics, Faculty of Dentistry, Shahed University, Tehran, Iran. Follow-up sessions were scheduled for all patients after denture delivery and necessary adjustments was performed. When patients were comfortable with their new dentures, the implant surgery appointment was scheduled.

Surgical Procedures

Before implant surgery, prophylaxy was performed for both groups with 2 gm amoxicillin 1 hour before surgery and 0.2% chlorhexidine solution rinse, 5 minutes before operation.

For the patients in test group, surgery was performed under local anesthesia (2% lidocaine/adrenaline, Astra Zeneca) and flapless. Position of implants was becoming distinct by using a sharp burr and the implant osteotomy

was performed according to the protocol suggested by the manufacturer. After performing osteotomies, DIO System IFI implant (DIO, Busan, Korea) was inserted. All the implants were 4 mm diameter and 10 mm long. The final insertion torque was determined by the surgeon and confirmed to allow for excellent primary implant stability without damaging the adjacent bone by excessive torque.

After placement of implants, a resonance frequency analysis device (Osstell, Integration Diagnostics) was used to check the implant stability quotient (ISQ). After measuring of the initial stability, the implant was provided with a proper ball attachment, which was tightened with 30 Ncm of torque. Immediately after surgery, the mandibular denture was modified by creating enough room for the housing of the attachment in the intaglio surface and checked with a pressure-indicating silicone media (GC, Tokyo, Japan). Once the appropriate passive relief of the denture was completed and the occlusion was carefully checked, the attachment was picked up intraorally with cold-curing resin (GC Reline, Alsip, IL, USA). In order to be assured of correct position of ball abutments and housings, an intraoral radiography was taken using paralleling technique. Occlusion was then rechecked and eventually adjusted as well as the adaptation on the residual ridges and the patients received postoperative instructions. Subjects were instructed to rinse 0.2% chlorhexidine gluconate for 1 minute twice a day and prescribed 500 µg amoxicillin every 6 hours for 7 days. No limitations to chewing function were given and the patients were instructed not to remove the prosthesis for 1 week.

For the patients in the control group, after a local anesthesia and a full thickness flap, the implant osteotomy was performed and 4 mm diameter implants with 10 mm length were inserted under the same protocol used in test group. The flap was sutured after tightening the cover screws, postoperative instructions were given and the patients were released. The subjects were recalled 1 week later for removing the sutures and after relieving the implants' positions in prosthesis, dentures were given to them. After 2 months postoperatively dentures were modified to accept the housings and delivered to the patients.

Evaluation Phase

A follow-up check was performed 7 days after surgery to evaluate healing, check denture fit and occlusion and make any necessary adjustments. Periapical radiography by parallel technique by using film holder was taken at the baseline and 1, 12, 24 and 48 weeks after loading. All images were taken by expert technician under supervision of oral and maxillofacial radiologist. All periapical radiographs were scanned by a film scanner (Microtek, Hsinchu, Taiwan) and bone resorption in mesial and distal of each implant was evaluated by image analysis software (Adobe Photoshop) and a mean value was calculated for each implant. The implant platform was used as the reference point, and measurements of the bone were made at the nearest thread. The distance between the threads was 0.6 mm. All radiographic measurements were performed by an experienced radiologist. Measurements were repeated, and no differences between the readings were recorded. At each follow-up appointment, the success of each implant was evaluated according to the criteria proposed by Smith and Zarb[20] and modified as follows. The implant was considered a failure when there was peri-implant radiolucency noted on the radiographs, visible mobility, ongoing pathologic process, pain, suppuration or discomfort. For evaluation of peri-implant sulcus depths in mesial, distal, buccal and lingual plastic probe was used and a mean value was calculated for each implant. As a reason of evaluation and any problem prevention, all patients were recalled once in a month. The number and nature of any unplanned visits was also recorded. All prosthetic procedures and follow-up studies were performed by a dentist under supervision of an experienced prosthodontist. Statistical analysis of raw data was performed with repeated analysis of variance (ANOVA) test and SPSS 16 software.

RESULTS

In this study, 20 patients with initial inclusion criteria that were referred to the prosthetic department of the Shahed University were selected. These 20 patients were divided in two groups. In control group, the overdenture was applied 2 months after surgery and in test group, implants were loaded immediately or maximum 24 hours after surgery. In control group, due to some disease, one of patients excluded from the study and in test group one of the patients, because of changing of residence, gave up treatment and another patient excluded from the study due to occurrence of accident and mandibular fracture. Totally, eight patients in test group (six men and two women with mean age of 60 years) and nine patients in control group (five men and four women with mean age of 62 years) participated in this study. After implants placement and loading implant success factors including assessment of bone resorption, peri-implant radiolucency noted on the radiographs, peri-implant sulcus depths, visible mobility, ongoing pathologic process, pain, suppuration or discomfort were evaluated.

The peri-implant bone resorption and sulcus depth in groups, in first, 12, 24 and 48 weeks after loading, were recorded at each recall visit (Tables 1 and 2). Analysis of

Table 1: Peri-implant bone resorption and sulcus depth in test group

Experimental group	*Intervals (weeks)*	*Bone resorption (mm)*	*Sulcus depth (mm)*
Test group	0-1	0.09 ± 0.01	2.97 ± 0.40
	1-12	0.31 ± 0.03	2.92 ± 0.42
	12-24	0.59 ± 0.04	2.75 ± 0.37
	24-48	0.84 ± 0.03	2.42 ± 0.28

Table 2: Peri-implant bone resorption and sulcus depth in control group

Experimental group	*Intervals (weeks)*	*Bone resorption (mm)*	*Sulcus depth (mm)*
Control group	0-1	0.20 ± 0.02	3.30 ± 0.48
	1-12	0.38 ± 0.07	3.04 ± 0.71
	12-24	0.61 ± 0.07	2.82 ± 0.40
	24-48	0.84 ± 0.05	2.37 ± 0.29

raw data demonstrated significant differences between marginal bone changes during 1 year of study in two groups ($p < 0.001$). However, at the end of 1 year evaluation marginal bone changes between two groups were similar. In the case of sulcus depth evaluation, no statistically significant differences were founded between the two groups ($p = 0.418$).

There was not any pathological and noted radiolucency in radiographical evaluation in both groups. Clinical mobility was evaluated in both groups, none of implants became mobile. The resonance frequency analysis was performed at the end of 1 year of study and revealed ISQ values above 60 for all 34 implants, with a mean value of 72.3 (range, 63-80) for test group. For the control group, mean value of ISQ at the end of 1 year of study was revealed 74.4 (range, 66-84). In this study, in test group, implant placement was performed without flap reflection, and only two patients have experienced unbearable pain and needed analgesics, while, in control group the implant placement was accompanied with flap reflection and periosteum elevation, seven patients have experienced unbearable pain and needed analgesic drugs. Clinical evaluation of surgical sites in test group during 2 or 3 days after surgery showed that there was not any edema or swelling around implants, while in control group, peri-implant edema was observed in four patients.

None of patients experienced pain and there was not any sign of infection in them during the period of study. Totally, during 1 year study no implant was failed in both groups and the cumulative survival rate were 100% for both groups.

Clinical complications and need for extra maintenance was recorded, as reported in Table 3. The major problem was wearing the plastic O-ring that caused changing them after every 6 months in both groups. The other prosthetic problem was fracture of mandibular denture of three patients in test group and two patients in control group, from metal housing place. In the test group, in two cases, and in the control group, in one case the denture fractured twice; therefore, they were repaired the second time with a complete laboratory reline by adding a metal framework inside the prostheses to increase fracture resistance.

Table 3: Maintenance needs among subjects (n = 20) during the first year

Procedure	*Control group (n = 10)*	*Test group (n = 10)*
Screw loosening of ball attachments	2	2
Fractured denture teeth	0	0
Fractured prostheses	3	5
Fractured opposing denture	0	1
Chairside reline	2	2
Laboratory reline	1	2
Detachment of matrix	0	0
Repositioning and/or replacement of matrix	0	0

DISCUSSION

In the present study, we tried to evaluate outcomes of immediate loading of mandibular two-implant overdenture and compare it with delayed loading concept. The 100% survival rate of dental implants observed in the present study for the test group is comparable to previous reports relative to ball-retained overdentures.[21-27] Compared to the traditional delayed loading approach as described by Branemark et al,[9] immediate loading protocols significantly reduced treatment time for the patient. One surgical session can be avoided using the one-stage approach, and the definitive prosthesis is inserted the same day as implant insertion, allowing the patients to return to their usual routines life and work much sooner.

In this study, analysis of raw data demonstrated significant differences between marginal bone changes during 1 year of study in two groups. However, at the end of 1 year evaluation marginal bone changes between two groups were similar. These changes can be raising from

different factors, that it seem, the most important factor is method of surgery: Surgery without flap elevation in test group in comparison with surgery with full thickness flap and periosteum elevation in control group. The mean value of bone loss in both groups, at the end of 1 year, was within the value reported in the literature and was consistent with a previous report on implant-supporting bar-retained overdenture loaded immediately.[28-30] In a study with an immediate loading protocol on two nonsplinted implants, 40% of the patients could not wear the denture because of postoperative swelling, causing pain and mucosal irritation,[31] whereas in this study, immediate loading of the dentures were performed by using the flapless surgery which reduced pain, swelling and patients discomfort and reduced need for analgesics. However, when deciding whether to place dental implants without raising a flap, several considerations have to be kept in mind. The operator is working blind, and bone perforations may be more likely to occur. The flapless implant insertion requires a certain degree of clinical experience, and anatomical requirements (e.g. sufficient bone quantity) must be fulfilled.[32]

Implant primary stability at the time of surgical placement is one of the most important clinical parameters to avoid excessive micromovement when immediate loading is attempted.[33] In this study, patients in which implants were placed in their mandible with 45 Ncm torque and higher went to test group and others went to control group.

In another study that evaluated immediate loading of dental implants supporting ball attachment implant overdentures showed a survival rate of 96.5%.[34] However, in this study, the housing for attachments in the mandibular dentures were filled with impression material and the retaining mechanism was not connected immediately to the ball attachments to reduce potentially negative forces on the implants. Conversely, in the present investigation in the test group, the prosthesis was delivered immediately after surgery, with fully functional connection of the attachment mechanism of the ball attachments.

In the other study that evaluated immediate loading of dental implants supporting ball attachment implant overdentures showed a success rate of 94%.[35] However in this study, the patients were placed on a liquid diet for the first 4 weeks after surgery and then a soft diet was recommended for the remainder of the implant healing phase (4-6 months) and to minimize unnecessary loading to the implants, the patients was instructed to remove the overdenture no more than one time per day for cleaning within the first 4 weeks after implant placement. Conversely, in the present investigation in the immediate loading group, no limitations to chewing function were given to the patients, and to minimize unnecessary loading to the implants, the patients were instructed not to remove the prosthesis for 1 week.

The peri-implant sulcus depth in both groups during the investigation decreased, and no significant differences between the changes of peri-implant sulcus depth in both group were found ($p = 0.418$). During this investigation, all patients were recalled for further evaluation monthly and during these appointments hygiene control points were reminded them and fortunately, no sign of inflammation and soft tissue hypertrophy was observed. The hypothesis that there should be no difference between immediate and delayed loaded mandibular two-implant supported overdentures with respect to clinical and radiographical indexes was thus supported by the present study.

CONCLUSION

Preliminary results from this study, despite the limitations due to the small number of patients and the short observation time, seem to demonstrate that survival and success rates of immediately loaded implants are consistent with delayed loading, so it can recommended as a predictable method of treatment. Nevertheless, further investigations on a wider patient population are certainly needed to confirm this finding.

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ABOUT THE AUTHORS

Shojaedin Shayegh

Associate Professor, Department of Prosthodontics, Dentistry Faculty Shahed University of Medical Science, Iran

Hassan Semyari

Associate Professor, Department of Periodontics, Dentistry Faculty Shahed University of Medical Science, Iran

Alireza Forouzandeh Shahraki

General Dentist, Shahed University of Medical Science, Iran

Mohammad Reza Hakimaneh (Corresponding Author)

Assistant Professor, Department of Prosthodontics, Dentistry Faculty Shahed University of Medical Science, Iran, e-mail: rezahakimane@shahed.ac.ir