Early versus Delayed Loading of Mandibular Implant-Supported Overdentures: 5-Year Results

Ilser Turkyilmaz, DDS, PhD;* Tolga F. Tözüm, DDS, PhD;† Celal Tumer, DDS, PhD‡

ABSTRACT

Background and purpose: Because of poor retention of complete removable dentures for edentulous patients, implant-supported mandibular overdentures have lately become a popular alternative for them. The aims of this prospective study were to evaluate treatment outcomes of mandibular overdentures supported by two unsplinted early-loaded implants and compare these results with those for delayed-loaded implants.

Materials and methods: A total of 26 edentulous patients were treated with two unsplinted implants supporting a mandibular overdenture. All implants were placed in the canine regions of each mandible according to the one-stage surgical protocol. There were two groups: test group, in which the overdenture was connected 1 week after surgery, and control group, in which the overdenture was connected 3 months after surgery. Standardized clinical and radiographic parameters were recorded at surgery, and after 3, 6, 12, and 18 months, and 2, 3, 4, and 5 years.

Results: No implants were lost, and 0.93 ± 0.3 mm marginal bone resorption was noted for all implants after 5 years. Clinical implant stability measurements, clinical peri-implant parameters, and marginal bone resorptions showed no statistically significant differences between the two groups over 5 years.

Conclusion: The results of this prospective clinical study suggest that there is no significant difference in the clinical and radiographic state of patients treated with implant supported mandibular overdentures loaded either 1 week or 3 months after surgery.

KEY WORDS: early loading, implant, mandible, overdentures, RFA, stability

INTRODUCTION

Removable complete dentures have been a traditional and common way to restore edentulous patients for years. However, the progressive bone resorption of the edentulous alveolar ridge is the main concern when rehabilitation of the edentulous mandible using a removable complete denture is considered.[1] Removable complete dentures are not sufficient to reestablish the oral function in relation to either chewing efficiency or bite force.[1,2] Masticatory performance of people wearing complete dentures is less than 20% of the masticatory performance of those with natural dentition.[3] Problems with the mandibular denture declared by patients are more likely than with the maxillary denture. The common reasons for dissatisfaction are pain, sore spots, poor denture stability, and eating difficulties.[4] Functional loss results from the lack of support and stability but is also affected by reduced salivary flow, decreased tongue motor control, reduced bite force, and diminished oral sensory function.[5,6]

In 2002, an international symposium at McGill University concluded that a conventional denture was no longer the most appropriate option for restoring the edentulous mandible and that the two-implant–retained overdenture should become the first choice for prosthodontic treatment.[7] Several researchers have demonstrated that this treatment modality can be successful

*Assistant professor, Department of Prosthodontics, Dental School, University of Texas Health Science Center at San Antonio, Texas, USA; †associate professor, Department of Periodontology, Faculty of Dentistry, Hacettepe University, Ankara, Turkey; ‡professor, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Hacettepe University, Ankara, Turkey

Reprint requests: Dr. Ilser Turkyilmaz, Department of Prosthodontics, Dental School, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, MSC 7912, San Antonio, TX 78229-3900, USA; e-mail: turkyilmaz@uthscsa.edu

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and that adequate denture satisfaction related to improved retention can be achieved.[8,9] It is also manifest that the success rate of dental implants is high with this treatment modality.[10,11]

Three types of loading protocols have also been stated in the consensus report[12] as follows: (1) immediate loading, wherein the prosthesis is attached to the implants the same day the implants are inserted; (2) early loading, wherein the prosthesis is attached at a second procedure, earlier than the conventional healing period of 3 to 6 months, and whose time of loading should be in days/weeks; and (3) delayed loading, wherein the prosthesis is attached at a second procedure after a conventional healing period of 3 to 6 months.

One-stage implant treatment, by the use of either nonsubmerged implants[13] or modified two-stage submerged treatment using a one-stage surgical protocol[14,15], has recently become more popular. The placement of implants in a one-stage procedure has some advantages: only one surgical intervention is needed, treatment time is shorter, costs are lower, and clinical monitoring of the implants is possible during the osseointegration period.

Earlier animal[16,17] and human studies[18] showed that rough-surfaced implants can osseointegrate faster than machined-surfaced titanium implants. Ivanoff and colleagues[18] placed TiUnite and machined Brånemark System micro-implants (Nobel Biocare AB, Göteborg, Sweden) in human jawbone (9 maxilla, 11 mandibles) and reported that bone–implant contact was higher for the TiUnite surface. Recent improvements of the implant surfaces (i.e., thermal oxidation, plasma spraying, grit blasting, acid etching) and the implant designs (parallel-wall implants, tapered implants) have encouraged researchers that immediate/early loading protocols are possible.[16–19]

Dental literature included studies about immediate or early loading protocols for splinted implants supporting mandibular overdentures.[20,21] However, only few studies including long- or short-term outcomes of early-/immediate loading of unsplinted implants supporting mandibular overdentures are available in the dental literature.[22,23] The purpose of this prospective clinical trial was to compare the clinical performance of early-and delayed-loaded dental implants supporting mandibular overdentures and present 5-year outcomes of these implants.

MATERIALS AND METHODS

Twenty-six edentulous patients having persistent problems with their conventional mandibular complete dentures were included in this study in 2003. Ethical approval was obtained from the Ethics Committee of Hacettepe University, Ankara, Turkey. All implants were placed (C.D.), and all dentures were delivered by the first author (I.T.) in the Dental School, Hacettepe University. The two authors (I.T. and T.T.) followed up these patients for 2 years in the same university. Then, the same two authors followed up these patients up to 5 years in either the same university or private practice. Inclusion criteria were age of 50 to 76 years, adequate bone volume in the anterior mandible to place 3.75×15-mm implants, and consistent complaint about their existing dentures. Exclusion criteria were uncontrolled systemic disease likely to compromise implant surgery, previously bone grafting, and fresh extraction sockets in the anterior part of the mandible. Panoramic radiograph (Planmeca OY, Helsinki, Finland) and computerized tomography (Siemens AR-SP 40, Munich, Germany) were used for preoperative evaluation of the mandible for each patient.

Surgical and Prosthodontic Procedures

Each patient signed an informed consent form before implant surgery. The surgical protocol for implant placement was the same for both groups. After local anesthesia was administered, an intraoral crestal incision was performed in the canine region of each mandible. Mucoperiosteal flaps were elevated both buccally and lingually to expose the bone. When the alveolar crest was too thin (knife edge) to place the implant, the alveolar crest was adjusted by using a bur under irrigation with a sterile saline to obtain a flat, bony base. The surgical procedure for implant placement followed the standard procedures suggested by the manufacturer. Two implants (3.75×15 mm, TiUnite, MK III) were placed in the canine regions of the mandible of each patient.

Patients Were Randomly Allocated into Two Groups by Flipping a Coin. Group T (test group): Ball abutments (3 mm, Nobel Biocare AB) were seated on the implants immediately after the implant placement. Baseline resonance frequency (RF) measurements were made at implant level before the mucoperiosteal flaps allowing ball abutments were sutured. The patients were

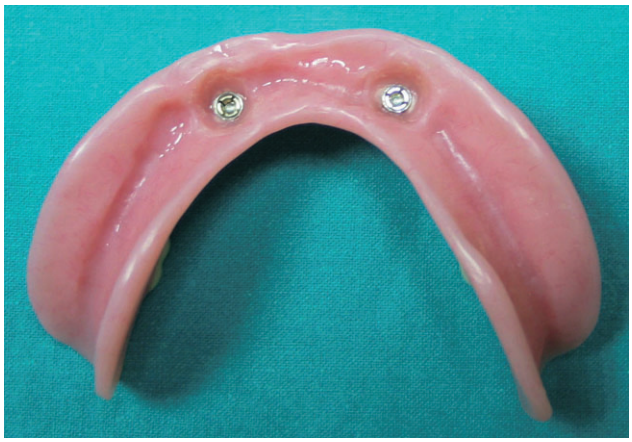

Figure 1 The implant-supported mandibular overdenture with gold caps.

prescribed a soft diet for the first week. The following standardized steps were performed to fabricate new prostheses on day 5 after surgery: Initially, study casts were made after making preliminary impressions by using irreversible hydrocolloid (Cavex, CA37, Haarlem, the Netherlands). The final impressions were made with a custom-made acrylic resin tray by using silicone impression material (Coltex® Medium, Coltene/Whaledent AG, Altstatten, Switzerland). The ball abutment replicas were placed into the impression and the definitive cast was poured (Moldano, Bayern, Leverrusen, Germany). Wax occlusion rims were attached to the maxillary and mandibular base plates, and final maxillomandibular jaw relation was determined. After the maxillary and mandibular casts were mounted, tooth arrangement (Major Dent, Moncalieri, Italy) was accomplished, and esthetics, phonetics, and occlusion were checked. If needed, modifications were made at this time. The restorations were returned to the laboratory for final processing by using heat-polymerized acrylic resin (Meliodent, Heraeus Kulzer Ltd., Newbury, Germany) on the sixth day after surgery. The maxillary complete denture and implant-supported mandibular overdenture with respective gold caps were delivered to the patients 1 week after implant placement (Figure 1). All dentures were made by the same dental technician for standardization.

Group C (control group): Healing abutments were seated on the implants after the implant placement. New maxillary and mandibular complete dentures were delivered 1 week after the implant placement. However, particular care was taken to ensure sufficient room between healing abutments and complete denture. Thus, the mandibular complete denture did not contact the healing abutments. Three months after implant placement, the healing abutments were replaced with ball abutments (3 mm, Nobel Biocare AB). A reline impression was made, and mandibular complete denture was converted to implant-supported mandibular overdenture.

Follow-Up

Radiographic Evaluation. For the marginal bone resorption to be determined, standardized intraoral radiographs of the implants were obtained with a paralleling technique described by Payne and colleagues[24] at implant placement after 6, 12, and 18 months and 2, 3, 4, and 5 years. Particular care was given to see the thread of each implant sharply. All radiographs were scanned to digital files, and marginal bone changes were measured in a computer by using an image analysis software by one examiner using the implant/abutment junction as a reference.[24] The distance between two threads of the implant, which is 0.6 mm for the implants used, was considered for the calibration of the measurements.

Implant Stability Evaluation. Resonance frequency analysis (RFA) measurements (Osstell, Integration Diagnostics AB, Göteborg, Sweden) were performed at implant surgery and after 3, 6, 12, and 18 months and 2, 3, 4, and 5 years. At these follow-up visits, the ball/healing abutments were removed from the patient and implant-level RFA measurements were taken with a transducer (Figure 2). The measurements were given in implant stability quotient (ISQ) units ranging from 0 to 100.

Peri-implant Evaluation. The following four peri-implant parameters for each implant were recorded at

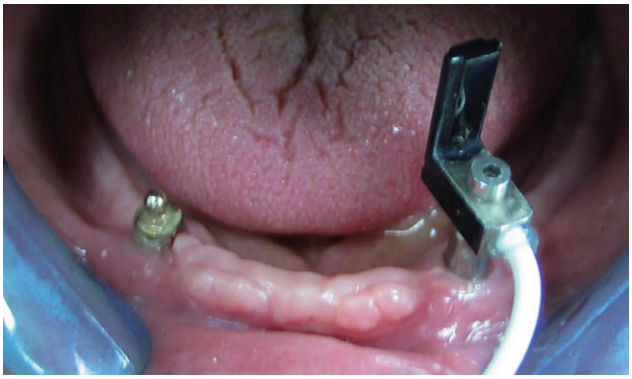

Figure 2 Clinically implant-level resonance frequency analysis measurement.

TABLE 1 Average Values (mm ± SD) of Marginal Bone Levels

Groups	Surgery	Month 6	Month 12	Month 18	Year 2	Year 3	Year 4	Year 5
Group T	0.7 ± 0.3	0.85 ± 0.3	0.97 ± 0.3	1 ± 0.3	1.13 ± 0.3	1.25 ± 0.2	1.44 ± 0.2	1.61 ± 0.3
Group C	0.63 ± 0.2	0.82 ± 0.2	0.91 ± 0.3	0.95 ± 0.3	1.11 ± 0.3	1.26 ± 0.3	1.42 ± 0.3	1.57 ± 0.2

follow-up visits of 1, 6, 12, and 18 months and 2, 3, 4, and 5 years after the implant surgery.

- Peri-implant plaque index (PI). Plaque adherent to all abutments, at sites, at or below the crest of the peri-implant mucosa was quantitated by using the PI of Löe and Sillness[25], as modified by Mombelli and colleagues.[26]
- Peri-implant probing depth (PD). The probing pocket depth was measured at four sites (mid-mesial, mid-distal, mid-buccal, mid-lingual) per implant by using a standardized Michigan O-periodontal probe with Williams markings. Special care was given to strict parallelism between the probe and the long axis of the healing abutment or ball abutment.
- Peri-implant bleeding index (BI). This is measured by applying the principles of previous overdenture studies and the sulcus BI of Muhleman and Son[27] as modified by Mombelli and colleagues.[26]
- Gingival index (GI). This is measured with Löe and Sillness method at four sites (mid-mesial, mid-distal, mid-buccal, mid-lingual) per implant.[25]

Then, the average of that four values was determined for each implant. Thus, each implant had one PI, PD, BI, and GI values.

Statistical Analysis

SPSS statistical software (SPSS Inc., Chicago, IL, USA) was used for all statistical analysis. The distribution of data was nonparametric, which was determined by the Kolmogorov–Smirnov test. Mann-Whitney *U* test was used to compare the marginal bone loss, implant stability, and peri-implant (PI, PD, BI, GI) values and between the two groups. *p* Value of <0.05 was considered statistically significant.

RESULTS

Twenty-six patients (14 females, 12 males), whose ages were 50 to 76 years (mean age: 63 years) were included in this study. The mean age of the patients in groups T and C were 62.3 ± 8 and 63.2 ± 7, respectively. Postoperative recovery was uneventful for all patients. All patients completed the 5-year follow-up period.

Radiographic Parameters

No implants were lost, and the mean marginal bone loss for all implants was 0.93 ± 0.3 mm after 5 years, giving a success rate of 100%. The mean marginal bone resorptions were 0.91 ± 0.3 and 0.94 ± 0.2 mm for groups T and C, respectively (Table 1), indicating no statistically significant difference over 5 years ($p > 0.05$).

Implant Stability Parameters

The mean ISQ values were 74.9 ± 3.8 and 75 ± 4.5 for groups T and C at surgery, and corresponding values were 74.8 ± 2.5 and 74.1 ± 3.1 at 5-year visit, meaning, no statistical significance ($p > 0.05$). Also, no significant differences were observed between the two groups at other follow-up visits ($p > 0.05$) (Figure 3).

Peri-implant Parameters

Table 2 included an overview of all peri-implant parameters during the follow-up period. The mean PI, PD, BI, and GI values indicated no statistically significant differences between the two groups during 5 years ($p > 0.05$). The mean PI, PD, BI, and GI values for each group had

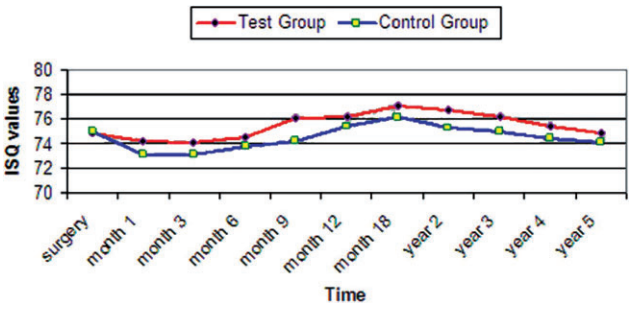

Figure 3 The average implant stability quotient (ISQ) values for each group during 5 years. No significant differences were noted between the two groups ($p > 0.05$) at any time.

TABLE 2 Average Values (±SD) of Peri-implant Parameters with Time

Parameters	Month 1	Month 6	Month 12	Month 18	Year 2	Year 3	Year 4	Year 5
PI								
Group T	1.1 ± 0.9	0.85 ± 0.9	0.8 ± 1	0.62 ± 0.6	0.89 ± 0.7	0.95 ± 0.5	1.07 ± 0.6	1.22 ± 0.4
Group C	1.13 ± 0.9	0.46 ± 0.6	0.54 ± 0.7	0.5 ± 0.5	0.76 ± 0.6	0.85 ± 0.4	1.03 ± 0.5	1.17 ± 0.5
PD								
Group T	2.46 ± 0.5	1.63 ± 0.6	1.28 ± 0.6	1.22 ± 0.6	1.48 ± 0.4	1.61 ± 0.5	1.75 ± 0.3	1.84 ± 0.4
Group C	2.32 ± 0.6	1.39 ± 0.5	1.02 ± 0.6	0.92 ± 0.6	1.23 ± 0.6	1.39 ± 0.5	1.71 ± 0.4	1.83 ± 0.4
BI								
Group T	0.95 ± 0.9	0,65 ± 0.7	0,35 ± 0.5	0.23 ± 0.5	0.5 ± 0.5	0.69 ± 0.4	0.88 ± 0.3	1.03 ± 0.3
Group C	0.79 ± 0.6	0,59 ± 0.6	0,26 ± 0.5	0.21 ± 0.4	0.44 ± 0.4	0.6 ± 0.4	0.81 ± 0.4	0.95 ± 0.4
GI								
Group T	1.05 ± 0.4	0.98 ± 0.5	0.79 ± 0.4	0.75 ± 0.4	0.92 ± 0.3	1.03 ± 0.3	1.22 ± 0.3	1.38 ± 0.3
Group C	0.94 ± 0.8	0.89 ± 0.5	0.75 ± 0.4	0.61 ± 0.5	0.86 ± 0.6	0.96 ± 0.4	1.27 ± 0.4	1.4 ± 0.3

a tendency to decrease during 18 months, and these values increased from month 18 to year 5. However, the amount of this decrease and increase was not statistically significant between the two groups, as $p > 0.05$.

DISCUSSION

For edentulous elderly people with limited physical and economic resources, it may not be easy to have advanced and expensive oral treatment. If optimal treatment can be provided in a short period of time with single-stage surgery, it would be an advantage for these edentulous patients. The implant success rate (100%) in both groups indicate that the mandibular overdenture supported by two unsplinted implants is a promising treatment modality, and the results of this study are consistent with other implant overdenture studies.[28,29]

Payne and colleagues[28] evaluated the success rates of two types of roughened surface implants, with early 2-week functional loading of paired mandibular interforaminal implants with overdentures. Two implants were placed in the anterior mandible of 24 patients by using one-stage standardized surgical procedures. Previously constructed conventional mandibular dentures were temporarily relined and worn by the participants for the first 2 weeks; participants had a soft diet. Two weeks after implant surgery and following some mucosal healing, the mandibular dentures had the tissue conditioner removed and the appropriate matrices included for an unsplinted prosthodontic design. No implants were lost. There were no significant differences in marginal bone loss (0.28 mm), peri-implant parameters, or prosthodontic maintenance between the groups over the study period. Marzola and colleagues[29] evaluated clinically and radiographically the performance of two implants immediately loaded supporting a ball attachment-retained mandibular overdenture. Seventeen edentulous patients were included in that study. Each patient received two implants placed after a minimal flap elevation. After implant placement, a mandibular complete denture was connected to the implants by using ball abutments. Patients were followed-up for 1 year. After 12 months of loading, no implant failure was reported, and the survival rate was 100%. Average marginal bone loss was 0.7 mm. They concluded that the immediate loading of two implants by means of a ball abutment–retained mandibular complete denture may be a predictable treatment option.

The mean marginal bone resorption was 0.93 ± 0.3 mm for all patients in this study after 5 years. Visser and colleagues[30] reported 1.6 mm marginal bone resorption for implants supporting mandibular overdentures after 5 years, while Naert and colleagues[31] reported 0.55 mm marginal bone resorption for unsplinted implants supporting mandibular overdentures after 5 years. These differences might have resulted from patient-related factors such as quality of mandibular bone and chewing force, and the type of the implants and abutments used. In this study, the patients were edentulous and wearing removable complete maxillary dentures, which resulted in limited forces on the mandibular implants.

All implants were placed in the canine regions of the mandible in this study. The bone density in the anterior mandible is higher than in the other regions in the

mouth, which was previously determined by Turkyilmaz and colleagues[32] They determined the relationship between bone density, insertion torque, and implant stability at implant placement. One-hundred eight patients were treated with 230 implants. A computerized tomography machine was used for preoperative evaluation of the jawbone. The maximum insertion torque values were recorded with the OsseoCare™ equipment (Nobel Biocare AB). Implant stability measurements were performed with the Osstell machine. There were 80 anterior mandibular sites, 50 posterior mandibular sites, 45 anterior maxillary sites, and 55 posterior maxillary sites. The bone density values varied from 271 to 1231 Hounsfield Units (HU). The mean bone density values were 928 ± 220, 669 ± 194, 732 ± 163, and 459 ± 108 HU for the anterior mandible, posterior mandible, anterior maxilla, posterior maxilla, respectively. They also found statistically significant correlations between bone density and insertion torque values; bone density and ISQ values; and insertion torque and ISQ values.

This high bone density results in high primary stability in this study, which is known as one of the important determinant of success.[33] Payne and colleagues[28] reported that average primary stability of about 75 ISQ units for 24 Southern implants whose designs are similar to Brånemark implants. The result of the present study agrees with their results. The ISQ values decreased slightly in the first 3 months, and increased from month 3 to month 18, which is consistent with the data reported by Friberg and colleagues[34] They also reported some marginal bone loss for 61 Brånemark implants during the first months, which could explain the decrease, because RFA measurements are affected by the distance from the RFA transducer to the first bone contact.[35] This decrease could be explained by the marginal bone loss. However, it seems that bone remodeling affected implant stability positively over time and therefore counteracted the effect of marginal bone loss.

No significant differences in peri-implant soft tissue parameters (PI, PD, BI, GI) were observed between test and control groups during five years, and these outcomes are consistent with earlier studies.[31,36,37] The mean PI values increased for both groups from month 18 to month 24. This indicates that the patients in group T have a good ball abutment cleaning sensitivity until month 18 because PI values decreased from baseline to month 18. The mean PI values of group C were lower than those of group T. It has been considered that this difference might have resulted from the using period of ball abutments as they were seated on the implants in the control group at the 3-month visit. The mean PD values were limited because the excess amount of peri-implant mucosa was removed by cervicular incision immediately after the implant placement. This limited amount of cervical gingiva around the ball/healing abutments allowed easier implant-level RF measurements. The mean PD values decreased particularly from month 1 to 6. It has been considered that this decrease might have resulted from the shrinkage of gingiva after surgery as a natural result of healing.

CONCLUSION

Under the guidelines of this study, it has been suggested that, when compared with a 3-month traditional healing period, 1 week of early-loading protocol for two 15-mm-long unsplinted implants supporting a mandibular overdenture may be a safe treatment modality for an edentulous mandible.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare. [Correction added after online publication 24 May 2010: Conflict of Interest Statement added.]

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