J Med Dent Sci 2021; 68: 9–16

Original Article

A preliminary comparison of marginal bone-level changes, survival rates, and prosthodontic maintenances between immediately and conventionally loaded two-implant overdentures with magnetic attachments

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Abstract

Purpose: This study compared marginal bone-level changes, survival rates, and prosthodontic maintenance between immediately and conventionally loaded mandibular two-implant overdentures (2-IODs) retained by magnetic attachments, over a 60-month period from implant insertion.
Materials and Methods: 19 mandibular edentulous participants were randomly allocated to either an immediate-loading or a conventional-loading group. Two implants were placed in each participant via flapless surgery. The implants in the immediate-loading and conventional-loading groups were loaded with magnetic attachments on the same day as implant placement and 3 months after surgery, respectively. The marginal bone-level changes were measured at 2 weeks, and at 6, 12, 24, 36, 48, and 60 months after implant placement, using standardized periapical radiographs.
Results: The mean radiographic marginal bone-level change was –1.42 mm and –1.39 mm for the immediate-loading and conventional-loading groups, respectively at 60 months, and there was no significant difference between two groups. The cumulative survival rate was 100% and 89% for immediate and conventional loading, respectively, and there was no significant difference between two groups.
Conclusions: Within the limitations of this study, the immediate-loading 2-IODs tended to require frequent maintenance and both immediately and conventionally loaded 2-IODs resulted in acceptable marginal bone-level changes.

Key Words: clinical research, edentulous mandible, marginal bone-level changes, immediate loading, overdenture

Introduction

The McGill Consensus statement of 2002 concluded that a two-implant-retained overdenture (2-IOD) is the standard treatment for the edentulous mandible.[1] Implant overdentures not only enhance stability, retention, and patient satisfaction, but also patient sociability.[2] Traditionally, for osseointegration of implants, a healing period of 3 to 6 months has been recommended, and functional loading should be avoided during this time.[3] However, the long healing period might impose an intolerable situation esthetically, functionally, psychologically, as well as socially, on some patients, particularly those who are completely edentulous.[4] Thus, an immediate-loading protocol was developed to improve patients' satisfaction and quality of life, by shortening the rehabilitation time and promoting faster recovery of oral function.[5-8]

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Received October 19; Accepted December 9, 2020;
Released January, 2021

Measurement of the marginal bone-level changes around implants is commonly regarded as one of the most important criteria in determining implant success.[9, 10] The radiographs used to measure marginal bone-level changes should be standard periapical films with specified reference points and angulations.[9] Elsyad *et al.* reported that, in a randomized controlled trial (RCT) of immediate loading of mandibular 2-IODs, with a 1-year observation period, using locator attachments, marginal bone-level changes over 1 year were significantly greater in the immediate-loading group than those in the conventional-loading group.[6] In contrast, Schincaglia *et al.* reported significantly less marginal bone-level changes with immediate loading than those with conventional loading 2-IODs at one year, in an RCT of immediate loading of 2-IODs using locator attachments.[11] Nevertheless, there have been no long-term RCTs comparing immediate loading and conventional loading of 2-IODs with magnetic attachments.

The aims of this randomized controlled study were to compare the marginal bone-level changes around implants, accumulated survival rates, and prosthodontic maintenances of immediately and conventionally loaded mandibular 2-IODs retained by magnetic attachments for mandibular edentulous patients during a 60-month post-surgical follow-up period.

Materials and Methods

Trial Design

The study was performed from 2012 to 2018. This study was a randomized, unblinded, parallel-group trial that compared marginal bone-level changes of immediately loaded with those of conventionally loaded mandibular 2-IODs retained by magnetic attachments (Clinical trial registration: UMIN000009889). Detailed descriptions of the protocols in this study have been reported previously.[12]

Participants

Participants were recruited by telephone from patients who had previously visited the Dental Hospital of Tokyo Medical and Dental University. All participants were provided with oral and written information about the clinical study and gave written informed consent. The Ethical Review Committee of the Faculty of Dentistry, Tokyo Medical and Dental University, approved the study protocol (Registration number 693).

The inclusion criteria were as follows: a completely edentulous mandible with any opposing maxillary occlusion status, adequate bone volume for the placement of two implants with minimum dimensions of 4.0 × 10.0 mm in the anterior mandible, no requirement for bone augmentation, commitment to undergo at least 4 months of healing after extraction, and commitment to practice good oral hygiene.

The exclusion criteria were as follows: presence of uncontrolled systemic disease that could compromise implant surgery, a history of chemotherapy or radiotherapy in the head and neck region, smoking >20 cigarettes a day, and a history of bisphosphonate use.

Sample size estimation

The primary outcome of the study was the patient-reported outcome. [12] Because there were no previous reports regarding comparisons of patient-reported outcomes between immediately and conventionally loaded mandibular 2-IODs with magnet attachments, a sample size of 10 participants per group was chosen for this preliminary study.

Randomization and blinding

The participants were randomly assigned to an immediate-loading group ("immediate group") or a conventional-loading group ("conventional group"). Randomized treatment allocation was performed using the minimization method, which is a dynamic allocation method. the groups were assigned in order so that the mean values between two groups were balanced, considering age, sex, and ACP classification, respectively. New complete mandibular dentures, fabricated at the hospital, were provided to all participants. Due to the nature of the treatment, blinding was not possible for both participants and clinicians.

Surgical and prosthetic procedures

The surgical and prosthetic procedures used in this study followed the protocols described in a previous report.[13] New mandibular dentures were given to all participants, and they were treated in accordance with the described protocol, including computed tomography scans, preoperative planning, fabrication of surgical guides, and implant placement procedures. Two implants (Nobel Speedy Groovy RP, 4 × 10–18 mm, Nobel Biocare, Gothenburg, Sweden) were inserted in the inter-foraminal area through a flapless surgical procedure, by the same experienced implantologist.

In the immediate group, concurrent with implant insertion, keepers (Magfit, Aichi Steel Co, Aichi, Japan) were connected to each implant. Magnet assemblies (Magfit) were then incorporated into the intaglio surface of the dentures intra-orally, by using autopolymerizing acrylic

Figure 1: Acquisition of radiographs using the paralleling technique.
The film holder was indexed on the magnetic attachment to allow for reproducible film positioning.

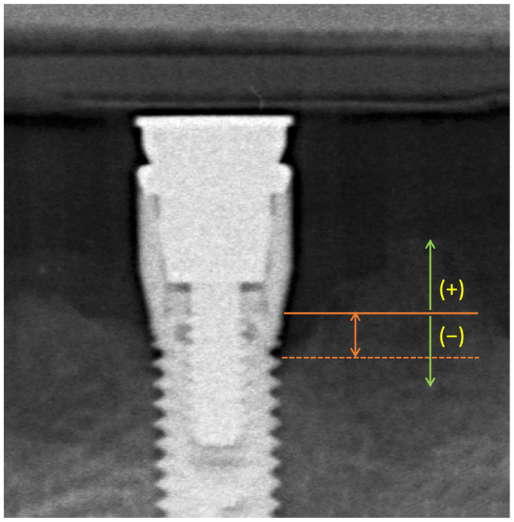

Figure 2: Peri-implant marginal bone-level assessments.
The marginal bone-levels on the mesial and distal sides of the implant and from the implant platform to the most coronal bone level are measured.

resin (Unifast Ⅲ, GC Corp, Bunkyo, Japan). In the conventional group, concurrent with implant insertion, two healing abutments were connected. Three months after implant surgery, the healing abutments were replaced with keepers and magnetic assemblies in the same way as for the immediate group.

Outcomes

Marginal bone-level change

Dental radiographs were obtained by intraoral digital radiography using standard periapical films. Marginal bone-level changes were measured on standardized periapical radiographs. At 2 weeks after the surgery and at the 6-, 12-, 24-, 36-, 48-, and 60-month follow-up visits, standardized periapical radiographs were obtained using the paralleling technique with a customized film holder. The film holder (Uni-Grip, Dentsply Sirona, York, PA, USA) was indexed on the magnet attachment (Magfit) to allow for reproducible film positioning (Figure 1). The reference point was the implant platform. The distance between the reference point and the most coronal bone level in contact with the implant surface was measured on the right and left sides of each implant, using i-View-2D, Version 1.8 with Image analysis software (Morita, Osaka, Japan). The first coronal bone-to-implant contact at surgery was defined as baseline, and it was measured within 2 weeks after the surgery. Marginal bone-level changes were measured as the difference between the baseline value and each assessment time-value (Figure 2). A single examiner, who did not participate in the treatment and blinded to group assignment, conducted the radiographic analysis. The measurements were performed twice with an interval of 3 months. Intraclass Correlation Coefficients (ICC) estimates and their 95% confident intervals were calculated based on a single-measurement, absolute-agreement, 2-way mixed-effects model. ICC resulted in 0.92 [95% confidence interval: 0.91, 0.94]. The averages of the first and second measurement results were used as marginal bone-level change data. The mean value of both sides of two implants for each participant at each time point was used in the analysis as the patient level.

Implant survival rate

With reference to past criteria,[14] Implants still functional at follow-up were considered for calculation of survival and cumulative survival rates until 60 months after the surgery. The cumulative survival rate was calculated using Kaplan-Meier analysis.

Prosthodontic maintenance and complications

The reasons for additional maintenance visits, including reincorporation of the magnet, abutment loosening/detachment, denture fracture, denture relining, occlusal plane reconstruction, new denture fabrication because of tooth wear, and abutment change, were also recorded for a 60-month period from the surgery.

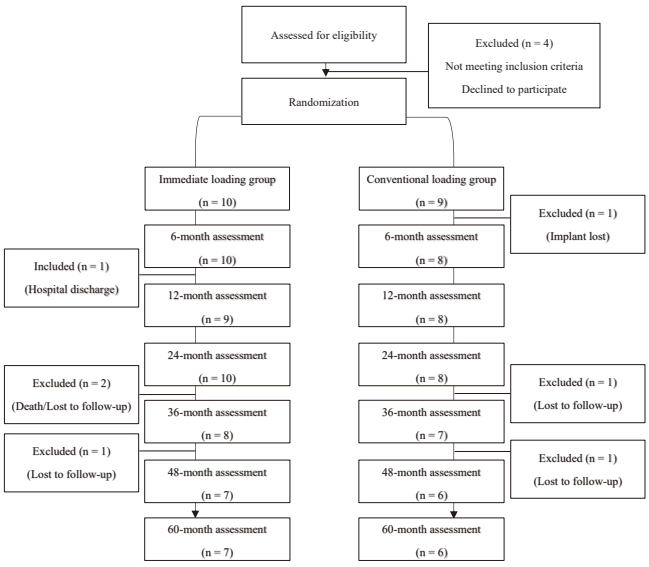

Figure 3: Study flowchart

Table 1:Baseline characteristics of participants in both groups

Characteristics	Total (n = 19)	Immediate group (n = 10)	Conventional group (n = 9)	P
Age, mean (SD), (year)	68.4 (9.9)	69.2 (10.6)	66.6 (9.1)	0.57*
Gender (male/female)	9/10	6/4	3/6	0.37†
ACP classification (n)				1.00†
I	4	2	2	
II	5	3	2	
III	7	4	3	
IV	3	1	2	
Maxillary occlusion status (dentulous/edentulous)	5/14	3/7	2/7	

*Based on non-paired t-test.
†Based on Fisher's exact test
There were no statistically significant differences between the two groups.
ACP: American College of Prosthodontists

Statistical analysis

Unpaired t-tests and Fisher's exact tests were used to compare the baseline characteristics of participants between the two groups. The Shapiro-Wilk test was used to assess the normality of response variable data distribution. As the data of marginal bone level changes data were normally distributed, the two way analysis of variance (ANOVA) test was used for analysis with the difference of two groups and assessment time points as factors. The main effects were loading protocol and assessment time period with the interaction included. To compare the survival rate between the two groups, a log-rank test was performed to determine the 60-month accumulated survival rate. All statistical analyses were performed using statistical software (version 16.0; SPSS Inc., Chicago, IL, USA). A p-value of <0.05 was considered to indicate statistical significance.

Results

Figure 3 shows the flow of participants in this study. Initially, 23 participants with an edentulous mandibular arch were enrolled in the study. Four patients who did not meet the inclusion criteria, including one with poor general health, one with uncontrolled diabetes, and two who subsequently withdrew from participation, were excluded. Therefore, 19 participants (9 males and 10 females), with an average age of 68.4 years, were definitively enrolled in this study. Table 1 shows the baseline characteristics of the participants. There were no significant differences in age, sex, or American College of Prosthodontists classification between the two groups. In the immediate group, one participant each did not attend the 12-month, 36-month, and 48-month assessments due to some general health problems, and one participant died before the 36-month assessment. In the conventional group, one participant lost bilateral implants a month after the surgery, and one participant each at the 36-month and 48-month assessments could not be evaluated due to general health problems. Thirteen participants (7 participants in the immediate group and 6 participants in the conventional group) were analyzed in 60-month assessment.

Table 2 shows the marginal bone-level change results. The mean and standard deviation of marginal bone-level changes at 12-month were −1.11 mm and 0.68 mm for the immediate group and −0.73 mm and 0.82 mm for the conventional group, respectively. The marginal bone-level change increased in each group during the observation period. The mean and standard deviation of marginal bone-level changes at 60-month were −1.42 mm and 0.65 mm for the immediate group and −1.39 mm and 0.66 mm for the conventional group. Table 3 showed the summary of two-way ANOVA of marginal bone level changes. According to the 2-way ANOVA, only assessment time period significantly affected the marginal bone level changes ($p=.004$). Loading protocol had no significant effect on the marginal bone level changes, and no significant interaction was found between loading protocol and assessment time period.

Table 2: Marginal bone-level changes in both groups from 6 to 60 months after surgery

	Mean Standard deviation					
Assessment period	6 months	12 months	24 months	36 months	48 months	60 months
Immediate group	-0.86 0.69	-1.11 0.68	-1.11 0.69	-1.24 0.70	-139 0.70	-1.42 0.65
Conventional group	-0.66 0.78	-0.73 0.82	-0.87 0.57	-1.05 0.63	-1.25 0.71	-1.39 0.66

Table 3: Summery of ANOVA of marginal bone level changes

Test	Effect	df	F	P
Marginal bone level changes	Loading Protocol	1	0.131	0.724
	Assessment time period	1.717	7.942	0.004
	Loading Protocol ×Assessment time period	1.717	0.673	0.500

Table 4: Prosthodontic maintenance and complications during the 5-year follow-up period

Prosthodontic events	Immediate	Conventional
Reincorporation of magnet	25	7
Abutment Loosening/detaching	10/2	6/2
Denture fracture	12	4
Denture relining	2	2
New denture fabrication because of tooth wear	2	0
Occlusal plane reconstruction	1	0
Abutment change	1	0
All events in 5 years	55	21
1–12 months	33	15
12–24 months	5	0
24–36 months	7	3
36–48 months	2	1
48–60 months	8	2

One patient in the conventional group withdrew because of implant failure at 1 month after placement. The remaining implants did not show any abnormalities that indicated implant failure during the 60-month period. Therefore, the 60-month accumulated survival rates were 100% and 89% for the immediate group and the conventional group, respectively, and there was no significant difference between two groups ($p = .131$).

Table 4 presents the number of prosthodontic maintenance interventions. The number of prosthodontic maintenance interventions up to the 12-month follow-up in both groups was greater than that after the 24-month follow-up, and the overall frequency of the prosthodontic maintenance tended to be greater in the immediate group than that in the conventional group. The most common maintenance procedure was replacement of the magnet.

Discussion

In this study, we compared marginal bone-level changes, survival rates, and prosthodontic maintenance between immediately and conventionally loaded mandibular two-implant overdentures retained by magnetic attachments, over a 60-month period from implant insertion. There were no significant differences in marginal bone-level change between the immediate group and the conventional group.

In this study, the mean and standard deviation of marginal bone-level changes at 12-month were –1.11 mm and 0.68 mm for the immediate group and –0.73 mm and 0.82 mm for the conventional group, respectively, while the mean and standard deviation of marginal bone-level changes at 60-month were –1.42 mm and 0.65 for the immediate group and –1.39 mm and 0.66 mm for the

conventional group, respectively. Rungcharassaeng *et al.* reported that under an immediately loaded IOD, maximum bone resorption occurred in the initial phase, but stabilized after 6 months.[15] The increased bone resorption in the early period may be due to bone responses after immediate loading from the prosthesis, and is attributed to healing and reorganization combined with functional stresses.[16] As proposed by Albrektsson *et al.* and others, marginal bone-level change of less than 1.5 mm during the first year,[17, 18] followed by a maximum of 0.2 mm annually thereafter, are requirements for implant success.[17] Similarly, in a previous study of immediate loading of 2-IOD using magnetic attachments, Elsyad *et al.* reported a marginal bone-level change of 0.68 ± 0.09 mm during 1 year.[19] Furthermore, Pae *et al.* reported that the 1-year marginal bone-level change was −1.51 ± 0.74 mm.[20] Thus, our results were comparable to those of earlier studies.[19, 20] Therefore, the marginal bone-level changes found in this study were considered reasonable and clinically acceptable.

In this study, no significant differences in marginal bone-level changes were observed between the immediate group and conventional group. This result was similar to the findings of Lohari *et al.*, who compared immediately loaded 2-IOD with conventionally loaded 2-IOD with a ball attachment.[21] In contrast, previous studies have reported that there were no significant differences in marginal bone-level changes between magnet, ball, and bar attachments in 2-IOD.[22, 23]

With regard to retention mechanisms, the magnetic attachment has unlimited lateral movement and superior force transfer characteristics.[24] In addition, the magnetic attachment exhibits less strain during overdenture dislodgement and under loading at molar regions than bar and ball attachment systems.[25] In our study, implants in the immediate group may not have been exposed to excessive stress during the healing period after implant insertions, which may explain why no significant difference in marginal bone-level change was observed between the immediate group and the conventional group.

In the 60-month accumulated survival rates of this study there was no significant difference between the immediate group and the conventional group. The results of survival rates in the immediate group were in agreement with other studies of 2-IOD with magnetic attachments.[19] A recent meta-analysis found no statistically significant difference in implant failure or marginal bone-level changes between immediate and conventional loading of implants supporting mandibular overdentures, although the sample size of the included studies was small, and hence, the results should be interpreted with caution.[26] The results of this study were thus consistent with previous studies, and the survival rate was not poor in either group.

In our study, the number of prosthodontic maintenance interventions up to 12 months in both groups was greater than that after 24 months, and the overall frequency of the prosthodontic maintenances tended to be greater in the immediate group than that in the conventional group. Most studies reported that implant prosthodontic maintenance was mostly required during the first 12 months and was related to alterations in the contour and repair of abutments or attachments.[27, 28] In addition, the finding that the number of the prosthodontic maintenance interventions in the immediate group was greater than that in the conventional group was in accord with the results of an earlier study.[29] The most frequent prosthodontic maintenance required in our study was replacement of the magnetic attachment. It is difficult to control bleeding during the surgery, and thus it is possible that moisture-proofing was inadequate; however, this is important for incorporation of the magnet into the denture, as moisture can inhibit adhesion of the resin, and result in detachment. The second most common prosthodontic maintenance intervention involved correction of abutment screw loosening. In our study, the abutment systems were external connections. A systematic review has shown that abutments with external connections loosen more frequently than those with internal connections.[30] Thus, the use of external connections may have resulted in the high number of abutment screw loosening events in this study.

This study had several limitations. First was the relatively small sample size, which resulted in the low statistical significance. Post-hoc analysis showed that the statistical power for detecting a difference in marginal changes in bone levels between immediately loaded and conventionally loaded 2-IODs was 0.23, and that a sample size of 82 was required to achieve a statistical power of 0.8. The reason why the null hypothesis could not be rejected in this study might be due to the small statistical power of the test, care must be taken in the interpretation of the results of this study. In future studies, RCTs with larger sample sizes to reduce type 2 errors should be considered. In addition, because of the small number of sample sizes, care must be taken when interpreting the statistically significant differences in Table 1. Second, the participants' maxillary occlusion status was inconsistent, although most of them were edentulous. Although the presence of opposing teeth is not a risk factor for the success of mandibular implant overdentures,[31] variation

in maxillary dentition might affect inconsistent load to the lower denture. Future RCTs that include only edentulous participants are necessary to clarify this aspect. Third, standardized periapical radiographs have some limitations. In this study, marginal bone-level change was assessed using periapical radiographs. This method is indicated for determining changes in marginal bone-levels over time. [10, 32] Nevertheless, periodontal radiographs provide a two-dimensional image of the three-dimensional structure; so, only the mesial and distal surfaces can be measured, not the buccal or lingual surfaces.[32] In addition, because of anatomical difficulties in correct placement of customized film holders, standardized periapical radiographs are not useful in all cases involving implant placement in the edentulous mandible.[33] Elysad *et al.* and Lohari *et al.* used computed tomography to measure marginal bone-level changes.[34, 21] With this method, bone resorption can be measured on not only the mesial and distal surfaces but also the buccal and lingual surfaces, although the limitation of this technique includes increased radiation exposure and costs.[34] Therefore, further studies using computed tomography are required to assess peri-implant bone loss and validate our results.

Conclusions

Despite the limitations of this study, no significant differences in bone resorption and survival rate up to 5 years were observed between the immediately loaded and conventionally loaded mandibular 2-IODs retained by magnetic attachments, and the results of both groups were clinically acceptable. The number of prosthodontic maintenance interventions required up to the first year in both groups was greater than that after the second year, and the immediate-loading 2-IODs tended to require frequent maintenance.

Conflict of interest

All the authors declare that they have no conflicts of interest.

Acknowledgments

This work was supported by the Japan Society for the Promotion of Science KAKENHI Grant Number 25462986. The authors gratefully acknowledge Drs. Masatoshi Negoro, Yoko Uehara, Sai Tun Naing, and Katheng Awutsadaporn for their assistance with prosthetic treatment and data collection.

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