Journal of Dental Sciences 17 (2022) 70–77

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.e-jds.com

Original Article

Patient-reported outcomes with immediate-loaded two-implant-supported mandibular overdentures: Results of a 5-year prospective study

Yuriko Komagamine [a], Manabu Kanazawa [a*], Daisuke Sato [b,c], Maiko Iwaki [d], Anna Miyayasu [a], Shunsuke Minakuchi [a]

[a] *Gerodontology and Oral Rehabilitation, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, Tokyo, Japan*
[b] *Department of Implant Dentistry, School of Dentistry, Showa University, Tokyo, Japan*
[c] *Oral Implantology and Regenerative Dental Medicine, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, Tokyo, Japan*
[d] *Oral Diagnosis and General Dentistry, University Hospital of Dentistry, Tokyo Medical and Dental University, Tokyo, Japan*

Received 7 March 2021; Final revision received 13 April 2021
Available online 17 June 2021

KEYWORDS
Immediate loading;
Overdenture;
Unsplinted attachment systems;
Ball anchors;
Patient-reported outcomes

Abstract *Background/purpose:* Few studies have comprehensively assessed long-term patient-reported outcomes for overdentures supported by two immediate implants. The purpose of the study was to evaluate patient-reported outcomes of immediately loaded two-implant-supported overdentures retained by ball attachments over a 5-year evaluation period.
Material and methods: Nineteen participants with edentulous mandibles were provided with immediately loaded two-unsplinted-implant-supported overdentures retained by ball attachments. The participants completed the Japanese version of the Oral Health Impact Profile (OHIP)-EDENT-19 and the Patient's Denture Assessment (PDA). Additionally, patient satisfaction was measured by a 100-mm visual analog scale (VAS). Measurements were performed at baseline, and at 1 and 5 years following implant surgery.
Results: Seventeen participants and 14 participants were evaluated at the 1-year and 5-year assessment, respectively. Considering the OHIP-EDENT-19, there was a significant decrease in the total ($p = 0.046$), "functional limitation" ($p = 0.021$), and "physical disability" ($p = 0.034$) scores at 1 year and the total ($p = 0.045$) and "physical disability" ($p = 0.024$) scores at 5 years following surgery, compared to the baseline scores. Considering the PDA, there was a significant increase in the "function" ($p = 0.038$) and "lower denture" ($p = 0.003$) scores at 1 year and the

* Corresponding author. Gerodontology and Oral Rehabilitation, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo, 113-8549, Japan. Fax: +81 3 5803 4645.
E-mail address: m.kanazawa.gerd@tmd.ac.jp (M. Kanazawa).

https://doi.org/10.1016/j.jds.2021.04.011

"function" ($p = 0.032$), "lower denture" ($p = 0.008$), and "esthetic and speech" ($p = 0.043$) scores at 5 years following surgery, compared to the baseline scores. Patient satisfaction at 1 year following surgery was significantly greater than that at baseline ($p = 0.005$).
Conclusion: Immediately loaded two-unsplinted-implant-supported overdentures retained by ball attachments improved the oral health-related quality of life and self-assessment of dentures by the patients up to 5 years following implant surgery.

Introduction

In Japan, complete dentures remain the first-line treatment for tooth replacement in elderly edentulous individuals, although implant-supported overdentures are a well-established treatment modality with a confirmed long-term prognosis. Implant-supported overdentures may become an advantageous treatment option for tooth replacement in edentulous arches in the future because of their cost-effectiveness.

With the immediate loading protocol, the prosthesis is attached on the day of implant placement; this is in contrast to conventional loading, in which the prosthesis is attached following a 3–6-month healing period.[1] Indeed, the use of an immediate loading protocol in implant-supported overdenture treatment has some advantages, such as the reduced number of surgical procedures and time to restoration of function, as well as the elimination of the need to use unstable existing dentures during the healing period. However, there is scarce evidence on the efficacy of immediate-loaded versus conventional-loaded two-unsplinted-implant-supported overdentures.

There are several studies on the laboratory-based outcomes with immediate-loaded two-unsplinted-implant-supported overdentures, such as the implant survival rate and peri-implant bone loss.[2–18] In contrast, few studies have evaluated patient-reported outcomes, especially over a period of several years. Emami et al. reported significant improvements in the Oral Health Impact Profile-Edentulous (OHIP-EDENT) scores and the scores of questionnaire items assessing the satisfaction among patients with immediate-loaded mandibular two-implant-supported overdentures retained by locator attachments, 2 years following loading.[8] Kronstrom et al. reported a significant improvement in the total score of the OHIP-EDENT-19 among patients with immediate-loaded mandibular one- or two-implant-supported overdentures retained by ball attachments for 5 years following implant surgery.[14] Patient-reported outcomes are the most important metric for treatment success or failure, in addition to laboratory-based outcomes. Combined patient-reported and laboratory-based outcome assessment is essential for comprehensive evaluation of treatment outcomes involving implant-supported overdentures.[19]

The Patient's Denture Assessment (PDA) is a questionnaire that has been developed for the assessment of the patients' perception of the impact of denture treatment. The PDA comprises 22 items that capture both positive and negative denture-related effects; these items are categorized into the following six subscales: "function," "lower denture," "upper denture," "expectation," "esthetics and speech," and "importance." Its validity and reliability have been confirmed by prior studies.[20–22] While the PDA assesses the impact of denture treatment on patient perception, consciousness, and subjective feelings regarding the dentures, the OHIP assesses the functional, social, and psychological effects of oral disease conditions associated with prosthodontic treatment.

To date, no studies have comprehensively assessed long-term patient-reported outcomes by evaluating not only the changes in patient satisfaction and oral health-related quality of life ([OHRQoL] using OHIP), but also patient perception of the impact of denture treatment (using PDA), following the provision of overdentures supported by two immediate implants retained by ball attachments. Therefore, the purpose of this study was to evaluate patient-reported outcomes of immediate-loaded two-unsplinted-implant-supported overdentures over a 5-year evaluation period by comparing those obtained prior to the provision of implant-supported overdentures with those obtained at 1 year and 5 years following implant loading. The null hypothesis stated that there would be no difference in patient-reported outcomes at 1 and 5 years following implant loading compared to the baseline.

Materials and methods

Study design and population

This study utilized a pretest-posttest design. The study protocol was approved by the Ethics Committee of the Faculty of Dentistry at Tokyo Medical and Dental University (approval no. 441) and was registered in the University Hospital Medical Information Network Center (UMIN-CTR Clinical Trial, registration no.: UMIN000032836). All participants provided written informed consent prior to participation.

Participants were recruited at the Prosthodontics clinic of Tokyo Medical and Dental University Hospital, Faculty of Dentistry, from Month 2009 to Month 2011. Participants had to meet the following inclusion criteria:

(1) A completely edentulous mandible, with no restrictions on the status of the opposing maxillary dentition,
(2) Adequate bone volume in the anterior mandible for placement of two implants with a minimum dimension of 4.0×10.0 mm,

(3) No need for bone augmentation,
(4) Willingness to wait at least 4 months for healing after extraction,
(5) Good oral hygiene, and
(6) Possession of an adequate understanding of written and spoken Japanese to respond to our questionnaire.

The following were the exclusion criteria:

(1) Uncontrolled systemic disease that might compromise the implant surgery,
(2) History of chemotherapy or radiotherapy to the head and neck region,
(3) History of smoking (heavy smokers),
(4) History of bisphosphonate administration, and
(5) Current infectious disease.

Surgical procedure

The surgical and prosthetic procedures followed the protocol described in a previous study.[23] Panoramic radiographs were utilized for preoperative clinical assessment of each mandible. Participants received a new mandibular complete denture or had their existing mandibular complete denture relined to improve the fit prior to implant placement. The treatment protocol also included computed tomography scanning, preoperative planning, manufacturing 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 mandibular interforaminal area of each participant according to the manufacturer's protocol for a flapless surgical procedure. The same implantologist, who was associated with Tokyo Medical and Dental University Hospital, Faculty of Dentistry, placed all the implants.

Prosthodontic procedure

On the same day as implant insertion, two ball attachments (Nobel Biocare) were positioned and connected to each implant using a torque of at least 35 Ncm; this was followed by the incorporation of a gold cap (Nobel Biocare) into the intaglio surface of the denture intraorally using autopolymerizing acrylic resin (Unifast III, GC, Tokyo, Japan). The participants were instructed to wear their dentures for 24 h to minimize postoperative swelling and to prevent the dentures from being maladapted. They were instructed not to remove their denture during the first week, except for denture cleaning and oral hygiene procedures conducted by the operator. The participants removed their dentures and brushed the implants three times a day. The new implant-supported overdentures were fabricated 6 months following the operation. All participants received prosthetic treatment during the study period by a single prosthodontist who was associated with the Tokyo Medical and Dental University Hospital, Faculty of Dentistry.

Postoperative antibiotics (750 mg amoxicillin per day, for 7 days) and analgesics (60 mg loxoprofen) were prescribed to all the participants. The participants were instructed to rinse with 0.2% benzethonium chloride solution three times per day for 2 weeks, and to start brushing the individual implant attachments 1 week after the surgery. No food restrictions were placed.

Outcomes

The outcome measurements described below were performed for all the participants before implant placement (baseline) and at 1 and 5 years following implant placement. All outcomes were assessed by two dentists who were not involved in the treatment provision.

OHIP-EDENT-19

OHRQoL was measured using the Japanese version of the OHIP-EDENT-19 (Table 1), which is composed of 19 question items and the same seven conceptual subdomains as the English version: "functional limitation", "pain", "psychological discomfort", "physical disability", "psychological disability", "social disability", and "handicap."[24] The Japanese version of the OHIP-EDENT-19 has been validated.

For each question item, participants were asked how frequently they had experienced a given event in the last month. Responses were ascertained on a scale of 0—4 (0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, and 4 = very often). OHRQoL impairment was characterized by the OHIP-EDENT-19 summary score, which is the sum of all 19 question item frequencies. The OHIP-EDENT-19 summary score could thus range from 0 to 76, with higher scores indicating a greater degree of OHRQoL impairment.

PDA

The PDA comprises 22 question items encompassing the following six subscales: "function," "lower denture," "upper denture," "expectation," "esthetics and speech," and "importance."[20—22] Table 2 presents the 22 question items of the PDA, which were translated from Japanese into English for this article. The reliability and validity of the Japanese version of the PDA have been confirmed.[19] In the questionnaire, each item was measured using a 100-mm visual analog scale (VAS), which consisted of a horizontal 100-mm line anchored by words representing the worst situation at the extreme left of the scale and words representing the best situation at the extreme right. All participants were instructed to complete the five subscale scores of the PDA, except for "upper denture." The five subscale scores, with the exception of "upper denture," were calculated by summing the values for the question items corresponding to each subscale.

Patient satisfaction

Patient satisfaction was measured using a 100-mm VAS. Patients rated their general satisfaction with their dentures on a VAS with the anchor words "completely dissatisfied" and "completely satisfied"; each word was converted to a score on a scale of 0 and 100 mm.

Statistical analysis

Steel's test was conducted to compare patient satisfaction, OHIP-EDENT-19 total and subdomain scores, and PDA

Table 1 Question items in the Japanese version of Oral Health Impact Profile-Edentulous.

Subdomain	Questionnaire items
Functional limitation	Q1. Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?
	Q2. Have you had food catching in your teeth or dentures?
	Q3. Have you felt that your dentures have not been fitting properly?
Physical pain	Q4. Have you had painful aching in your mouth?
	Q5. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?
	Q6. Have you had sore spots in your mouth?
	Q7. Have you felt dry in your mouth?
Psychological discomfort	Q8. Have you been worried by dental problems?
	Q9. Have you been self conscious because of problems with your teeth, mouth or dentures?
Physical disability	Q10. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?
	Q11. Have you been unable to eat well with your dentures because of problems with them?
	Q12. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
Psychological disability	Q13. Have you been upset because of problems with your teeth, mouth or dentures?
	Q14. Have your been a bit embarrassed because of problems with your teeth, mouth or dentures?
Social disability	Q15. Have you avoided going out because of problems with your teeth, mouth or dentures?
	Q16. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?
	Q17. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
Handicap	Q18. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?
	Q19. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

subscale scores between the baseline and 1 year post-surgery, and between the baseline and 5 years post-surgery. All statistical analyses were performed using the statistical software program JMP ver. 13 (SAS Institute, NC, USA). Statistical significance for all tests was set at $p < 0.05$.

Table 2 Question items in the Patient's Denture Assessment.

Subscale	Questionnaire items
Function	Q1. How much pain do you feel?
	Q2. How easy is it to swallow foods and liquids?
	Q3. How pleasant is it to eat food?
	Q4. How tired does your jaw feel?
Esthetics and Speech	Q5. How concerned are you about being stared at by others?
	Q6. How difficult is it to engage in a conversation with others?
	Q7. How concerned are you about the appearance of your mouth?
	Q8. How often do your dentures click when chewing?
Lower denture	Q9. How often are food particles stuck in your lower denture?
	Q10. How stable is your lower denture?
	Q11. How well does your lower denture fit your gum?
	Q12. How uncomfortable is your lower denture?
Expectation	Q13. Do you think your new dentures will meet your expectations?
	Q14. Do you think that there will be any problems with your new dentures?
	Q15. Do you think your new dentures will suit you?
Upper denture	Q16. How often are food particles stuck in your upper denture?
	Q17. How well does your upper denture fit your gums?
	Q18. How often does your upper denture fall off?
Importance	Q19. Do you think your dentures are a part of your body?
	Q20. How important are your dentures to you?
	Q21. How easy is it to take care of your dentures?
	Q22. Do you feel at ease when wearing your dentures?

Results

Of the 23 enrolled participants, 19 (9 males and 10 females; mean age, 69.8 years) were provided with immediate-loaded two-unsplinted-implant-supported overdentures retained by ball attachments. These 19 participants were followed up for 5 years following loading. Two participants were excluded at the 6-month assessment. One participant reported removing the denture for a 48-h period. This was contrary to the instructions of not removing their dentures during the first week. As the gingiva around the implants had swollen, the denture could not be re-inserted into the original and correct position; therefore, gingival plastic surgery was subsequently performed. The second excluded participant had lost a single implant, and was a smoker with

diabetes. Two participants were excluded at the 2-year evaluation; one participant was lost to follow-up and the other participant had been diagnosed with a mental disease. One participant was excluded at the 3-year evaluation due to loss of the lower denture. Thus, 17 participants were evaluated at the 1-year assessment, while a total of 14 participants were evaluated at the 5-year assessment. In terms of the prosthetic status of the opposing maxillary arch, 12 participants had complete dentures and six had removable partial dentures. One patient had a completely dentate maxillary arch. At least seven maxillary teeth were missing in each of the patients with a removable partial denture. All participants had experience of having at least one mandibular complete denture previously.

Compared with the baseline, there was a significant decrease in the total, "functional limitation," and "physical disability" scores of the OHIP-EDENT-19 at 1 year post-surgery. Furthermore, there was a significant decrease in the total and "physical disability" scores of the OHIP-EDENT-19 at 5 years post-surgery (Table 3). On the other hand, there was a significant increase in the "function" and "lower denture" subscale scores of the PDA at 1 year post-surgery, and in the "function," "lower denture," and "esthetic and speech" scores at 5- year post-surgery, compared with the baseline (Table 4). In addition, there was a significant increase in patients' satisfaction at 1 year ($p = 0.005$), but not at 5 years post-surgery (Table 5).

Discussion

In the present study, we assessed the long-term changes in the total and subdomain scores of the OHIP-EDENT-19, as well as the PDA and patient satisfaction scores, 1-year and 5-years following the provision of immediate-loaded two-unsplinted-implant-supported overdentures. Since significant improvements were observed in the total OHIP and PDA scores (including some subdomain and subscale scores), as well as patient satisfaction scores at 1 and 5 years following implant placement, the null hypothesis was rejected. The results suggested that the immediate loading of two unsplinted implants could provide sufficient stability and retention of lower dentures, leading to improvements in OHRQoL and patient perception of the impacts of denture treatment on longer-term function.

In this study, the "lower denture" subscale scores of the PDA, which consisted of four question items related to the retention and stability of lower dentures, showed significant improvement at both 1 and 5 years following surgery compared with the baseline. In a previous study, the "lower denture" subscale was identified as the greatest significant independent variable among the six PDA subscales for positive change in the OHIP-EDENT-19 total score at approximately 2 months following new conventional denture replacement among complete denture wearers.[21] Therefore, the increase in retention and stability of lower dentures after conversion to two-unsplinted-implant-supported overdentures in the present study may have contributed to not only short-term improvement of OHRQoL but also long-term improvement up to at least 5 years.

The "physical disability" scores of the OHIP-EDENT-19 and the "function" scores of the PDA showed significant improvements at both evaluations compared with the baseline. In addition, the "functional limitation" subdomain scores of the OHIP-EDENT-19 showed significant improvements only at 1-year post-surgery. The question items of the "physical disability" and "functional limitation" subdomains of the OHIP-EDENT-19 and the "function"

Table 3 Difference in the OHIP-EDENT-J scores between baseline and the 1-year and 5-year evaluations[a].

	Baseline (T0)	1 year (T1)	*p*-value Δ (T0—T1)	5 years (T2)	*p*-value Δ (T0—T2)
Total score	25 [16.5, 30]	17 [8, 21]	0.046*	11.5 [8, 24.5]	0.045*
Functional limitation	6 [5, 7]	4 [3, 5]	0.021*	4 [3, 5.8]	0.087
Physical pain	5 [3, 6.5]	3 [3, 5]	0.431	3.5 [1.3, 4]	0.107
Psychological discomfort	3 [2.5, 4]	2 [1, 4]	0.208	1 [1, 3]	0.058
Physical disability	4 [3, 6]	3 [2, 4]	0.034*	2 [1, 3.8]	0.024*
Psychological disability	2 [0.5, 2]	1 [0, 2]	0.341	1 [0, 2]	0.572
Social disability	2 [0, 3]	0 [0, 3]	0.368	0 [0, 2.5]	0.423
Handicap	2 [0, 2]	0 [0, 2]	0.281	1 [0, 2]	1.000

*P-value < 0.05. OHIP-EDENT-J, Japanese version of the Oral Health Impact Profile (OHIP)-EDENT.
[a] Data are presented as median [first quartile, third quartile].

Table 4 Difference in the PDA scores between baseline and the 1-year and 5-year evaluations.[a]

	Baseline (T0)	1 year (T1)	*p*-value* Δ(T0—T1)	5 years (T2)	*p*-value* Δ(T0—T2)
Function	297 [252, 352.5]	350 [330.5, 381]	0.038*	375 [331.3, 386]	0.032*
Lower denture	225 [156.5, 280]	322 [277, 355]	0.003*	328.5 [276.3, 380.5]	0.008*
Expectation	273 [249, 283]	285 [251, 290]	0.583	279 [265, 289.8]	0.520
Esthetic and Speech	240 [183.5, 354.5]	348 [290, 376]	0.120	376.5 [354.5, 386.5]	0.043*
Importance	340 [306.5, 371.5]	342 [306, 380]	0.844	373 [338.3, 388]	0.180

*p-value < 0.05. PDA, Patient's Denture Assessment.
[a] Data are presented as median [first quartile, third quartile].

Table 5 Difference in the patient satisfaction scores between baseline and the 1-year and 5-year evaluations[a].

	Baseline (T0)	1 year (T1)	*p*-value* Δ(T0–T1)	5 years (T2)	*p*-value* Δ(T0–T2)
Patient satisfaction	60 [50, 90]	90 [85, 98]	0.005*	86.5 [72.8, 97]	0.051

*p-value < 0.05.
[a] Data are presented as median [first quartile, third quartile].

subdomain of the PDA are mainly related to eating. As lower retention and stability of the mandibular denture in combination with the maxillary denture potentially leads to denture instability during chewing,[25] the sole improvement of the mandibular denture stability may still be sufficient to contribute to an improvement in eating. These three variables showed significant and equivalent improvements at both 1- and/or 5-year evaluations of the OHIP-EDENT-19, similar to the "lower denture" subscale of the PDA.

On the other hand, the "esthetic and speech" subdomain scores of the PDA, which consisted of four question items related to conversation and appearance, only showed significant improvements at the 5-year evaluation. In a previous study, the "esthetic and speech" subscale was identified as a significant independent variable for positive change in the total score of the OHIP-EDENT-19.[20] Speech is a complex skill requiring prolonged adaptation,[26,27] whereas appearance does not require a long adaptation period. In another study, there was a significant improvement in speech 6 months following new complete denture replacement.[28] Hence, the adaptation period for speech seems to be more than 6 months, although differences in language and pronunciation are considered to influence the adaptation period. While longer evaluation periods of 1 and 5 years were utilized in the present study, significant improvements in the "esthetic and speech" subscale scores of the PDA were only observed at the 5-year evaluation; this may have reflected the extended period of time required for speech adaptation.

In the present study, there were significant improvements in the OHIP-EDENT-19 total, "functional limitation," and "physical disability" scores at the 1-year evaluation, and the total and "physical disability" scores at the 5-year evaluation; the number of subdomains exhibiting significant improvements was lower compared with previous studies. Yunus et al. evaluated the OHIP-EDENT-19 total and subdomain scores among patients with conventionally loaded mandibular two-implant-supported overdentures retained by telescopic attachments 1 year following loading. They reported significant improvements in the total OHIP-EDENT-19 score, as well as five out of seven subdomains; these included the "functional limitation," "physical pain," "physical disability," "psychological disability," and "social disability" subdomains.[29] In another study, Emami et al. evaluated the total and subdomain scores of the OHIP-EDENT-19 among patients with immediately loaded mandibular two-implant-supported overdentures retained by locator attachments 2 years after loading; significant improvements in the total score and all subdomain scores were observed.[7] On the other hand, conventional denture and implant treatment has been shown to have little influence on the improvement of the "psychological discomfort," "handicap," and "social disability" subdomains, which consist of question items related to depression, social interaction avoidance, and difficulties with relationships and life satisfaction.[30] Moreover, the OHIP provides greater weightage to more severe and less common outcomes among older people compared to the Geriatric/General Oral Health Assessment Index, which places greater weightage on common outcomes. This accounts for a higher prevalence of zero scores in the OHIP, resulting in a floor effect.[31] In contrast to previous studies, the participants in the present study were provided with new conventional dentures before implant surgery, or had their existing mandibular complete dentures relined; hence, they may have been less likely to ascribe severe behavioral and psychological impacts to their complete dentures at baseline.

In the present study, the total score of the OHIP-EDENT showed significant improvements compared with the baseline at both the 1-year and 5-year evaluations. Kronstrom et al. evaluated the total score of the OHIP-EDENT-19 among patients with immediately loaded mandibular one- or two-implant-supported overdentures retained by ball attachments for 5 years following implant surgery in a randomized controlled study. They reported that the total score of the OHIP was significantly improved with both one- and two-implant-supported overdentures at 1, 3, and 5 years following implant surgery,[12–14] supporting the results of the present study. These findings suggest that immediate-loaded two-unsplinted-implant-supported overdentures may provide sustained improvements in OHRQoL over the long-term.

Patient satisfaction significantly improved only at the 1-year evaluation. This was consistent with the results of previous studies that found the general satisfaction of patients with immediate-loaded two-unsplinted-implant-supported overdentures retained by locator attachments to be significantly improved at 1 and 2 years following implant surgery.[8] Nevertheless, a high level of patient satisfaction was not sustained at the 5-year evaluation in the present study. Such a decrease may have been expected, as similar findings have been reported with conventional complete dentures over a 5-year period. Although different attachment systems may influence patient-reported outcomes, a previous study reported no significant differences among three different attachment systems.[32]

As the technical quality of conventional dentures may affect the OHRQoL,[33] all the denture treatment in the present study was performed by the same dentist, and the dentures were fabricated by the same dental technician. In addition, since men showed significantly better OHIP scores than women in a previous study,[14] sex could be one of the factors that affect the OHRQoL. Therefore, the ratio of men to women in the present study was distributed in a ratio of one-to-one.

The present study had certain limitations. First, the sample size was small and we did not compare the results

to a control group because of the pre-post design; therefore, the results admittedly need to be interpreted with caution. A randomized controlled study with a larger sample size is warranted to elucidate more fully the long-term effects of immediate-loaded mandibular one- or two-implant-supported overdentures on patient-reported outcomes. Second, several participants wore maxillary removable partial dentures while the majority of the participants wore maxillary complete dentures, which seemed to have influenced the results. Although a prior study has reported a lack of differences in the OHIP-49 total and subdomain scores, between complete denture wearers and removable partial denture wearers,[34] future studies should be performed in participants with both edentulous maxilla and mandible. Third, since all the participants in the present study were recruited in a university hospital setting, the participants' personalities, as well as mucosal and osseous tissue conditions, may not have been representative of the general population.

Within the limitations of the study, immediately loaded two-unsplinted-implant-supported overdentures retained by ball attachments could improve the oral health-related quality of life and self-assessment of dentures mainly regarding function by the patients up to 5 years following implant surgery.

Declaration of competing interest

The authors have no relevant financial or non-financial interests to disclose.

Acknowledgments

This research was supported by a Grant-in-Aid for Scientific Research (grant number 21791880).

References

1. Turkyilmaz I, Tozum TF, Fuhrmann DM, Tumer C. Seven-year follow-up results of TiUnite implants supporting mandibular overdentures: early versus delayed loading. *Clin Implant Dent Relat Res* 2012;14. e83—90.
2. Marzola R, Scotti R, Fazi G, Schincaglia GP. Immediate loading of two implants supporting a ball attachment-retained mandibular overdenture: a prospective clinical study. *Clin Implant Dent Relat Res* 2007;9:136—43.
3. Liao KY, Kan JY, Rungcharassaeng K, Lozada JL, Herford AS, Goodacre CJ. Immediate loading of two freestanding implants retaining a mandibular overdenture: 1-year pilot prospective study. *Int J Oral Maxillofac Implants* 2010;25:784—90.
4. da Silva RJ, Issa JP, Semprini M, et al. Clinical feasibility of mandibular implant overdenture retainers submitted to immediate load. *Gerodontology* 2011;28:227—32.
5. Roe P, Kan JY, Rungcharassaeng K, Lozada JL. Immediate loading of unsplinted implants in the anterior mandible for overdentures: 3-year results. *Int J Oral Maxillofac Implants* 2011;26:1296—302.
6. Roe P, Kan JY, Rungcharassaeng K, et al. Immediate loading of unsplinted implants in the anterior mandible for overdentures: a case series. *Int J Oral Maxillofac Implants* 2010;25:1028—35.
7. Menassa M, de Grandmont P, Audy N, Durand R, Rompré P, Emami E. Patients' expectations, satisfaction, and quality of life with immediate loading protocol. *Clin Oral Implants Res* 2016;27:83—9.
8. Emami E, Cerutti-Kopplin D, Menassa M, et al. Does immediate loading affect clinical and patient-centered outcomes of mandibular 2-unsplinted-implant overdenture? A 2-year within-case analysis. *J Dent* 2016;50:30—6.
9. Elsyad MA, Al-Mahdy YF, Fouad MM. Marginal bone loss adjacent to conventional and immediate loaded two implants supporting a ball-retained mandibular overdenture: a 3-year randomized clinical trial. *Clin Oral Implants Res* 2012;23:496—503.
10. Elsyad MA, Elsaih EA, Khairallah AS. Marginal bone resorption around immediate and delayed loaded implants supporting a locator-retained mandibular overdenture. A 1-year randomised controlled trial. *J Oral Rehabil* 2014;41:608—18.
11. Elsyad MA, Mahanna FF, Elshahat MA, Elshoukouki AH. Locators versus magnetic attachment effect on peri-implant tissue health of immediate loaded two implants retaining a mandibular overdenture: a 1-year randomised trial. *J Oral Rehabil* 2016;43:297—305.
12. Kronstrom M, Davis B, Loney R, Gerrow J, Hollender L. A prospective randomized study on the immediate loading of mandibular overdentures supported by one or two implants: a 12-month follow-up report. *Int J Oral Maxillofac Implants* 2010;25:181—8.
13. Kronstrom M, Davis B, Loney R, Gerrow J, Hollender L. A prospective randomized study on the immediate loading of mandibular overdentures supported by one or two implants; a 3 year follow-up report. *Clin Implant Dent Relat Res* 2014;16:323—9.
14. Kronstrom M, Davis B, Loney R, Gerrow J, Hollender L. Satisfaction and clinical outcomes among patients with immediately loaded mandibular overdentures supported by one or two dental implants: results of a 5-year prospective randomized clinical trial. *Int J Oral Maxillofac Implants* 2017;32:128—36.
15. Omura Y, Kanazawa M, Sato D, Kasugai S, Minakuchi S. Comparison of patient-reported outcomes between immediately and conventionally loaded mandibular two-implant overdentures: a preliminary study. *J Prosthodont Res* 2016;60:185—92.
16. Schincaglia GP, Rubin S, Thacker S, Dhingra A, Trombelli L, Ioannidou E. Marginal bone response around immediate- and delayed-loading implants supporting a locator-retained mandibular overdenture: a randomized controlled study. *Int J Oral Maxillofac Implants* 2016;31:448—58.
17. van Kampen FM, van der Bilt A, Cune MS, Fontijn-Tekamp FA, Bosman F. Masticatory function with implant-supported overdentures. *J Dent Res* 2004;83:708—11.
18. Cardoso RG, Melo LA, Barbosa GA, et al. Impact of mandibular conventional denture and overdenture on quality of life and masticatory efficiency. *Braz Oral Res* 2016;30:e102.
19. Cheng T, Sun G, Huo J, He X, Wang Y, Ren YF. Patient satisfaction and masticatory efficiency of single implant-retained mandibular overdentures using the stud and magnetic attachments. *J Dent* 2012;40:1018—23.
20. Komagamine Y, Kanazawa M, Kaiba Y, Sato Y, Minakuchi S. Reliability and validity of a questionnaire for self-assessment of complete dentures. *BMC Oral Health* 2014;14:45.
21. Komagamine Y, Kanazawa M, Kaiba Y, Sato Y, Minakuchi S, Sasaki Y. Association between self-assessment of complete dentures and oral health-related quality of life. *J Oral Rehabil* 2012;39:847—57.
22. Komagamine Y, Kanazawa M, Sasaki Y, Sato Y, Minakuchi S. Prognoses of new complete dentures from the patient's denture assessment of existing dentures. *Clin Oral Investig* 2017;21:1495—501.
23. Sato D, Kanazawa M, Kim YK, et al. Immediate loading of two freestanding implants placed by computer-guided flapless

surgery supporting a mandibular overdenture with magnetic attachments. *J Prosthodont Res* 2016;60:54—62.
24. Sato Y, Kaiba Y, Yamaga E, Minakuchi S. Reliability and validity of a Japanese version of the oral health impact profile for edentulous subjects. *Gerodontology* 2012;29:e1033—7.
25. van der Bilt A. Assessment of mastication with implications for oralrehabilitation: a review. *J Oral Rehabil* 2011;38:754—80.
26. Shigli K, Hebbal M. Assessment of changes in oral health-related quality of life among patients with complete denture before and 1 month post-insertion using Geriatric Oral Health Assessment Index. *Gerodontology* 2010;27:167—73.
27. Ellis JS, Pelekis ND, Thomason JM. Conventional rehabilitation of edentulous patients: the impact on oral health-related quality of life and patient satisfaction. *J Prosthodont* 2007;16:37—42.
28. Awad MA, Lund JP, Shapiro SH, et al. Oral health status and treatment satisfaction with mandibular implant overdentures and conventional dentures: a randomized clinical trial in a senior population. *Int J Prosthodont* 2003;16:390—6.
29. Yunus N, Saub R, Taiyeb Ali TB, Salleh NM, Baig MR. Patient-based and clinical outcomes of implant telescopic attachment-retained mandibular overdentures: a 1-year longitudinal prospective study. *Int J Oral Maxillofac Implants* 2014;29:1149—56.
30. Awad M, Al-Shamrany M, Locker D, Allen F, Feine J. Effect of reducing the number of items of the Oral Health Impact Profile on responsiveness, validity and reliability in edentulous populations. *Community Dent Oral Epidemiol* 2008;36:12—20.
31. Ikebe K, Hazeyama T, Enoki K, et al. Comparison of GOHAI and OHIP-14 measures in relation to objective values of oral function in elderly Japanese. *Community Dent Oral Epidemiol* 2012;40:406—14.
32. Kim HY, Lee JY, Shin SW, Bryant SR. Attachment systems for mandibular implant overdentures: a systematic review. *J Adv Prosthodont* 2012;4:197—203.
33. John MT, Slade GD, Szentpétery A, Setz JM. Oral health-related quality of life in patients treated with fixed, removable, and complete dentures 1 month and 6 to 12 months after treatment. *Int J Prosthodont* 2004;17:503—11.
34. Bae KH, Kim C, Paik DI, Kim JB. A comparison of oral health related quality of life between complete and partial removable denture-wearing older adults in Korea. *J Oral Rehabil* 2006;33:317—22.