Two-Step Immediate Loading of Mandibular Overdentures Retained by Mini-implants: A Prospective Clinical Study

Jin-Hong Park, DDS, MSc1/Sang-Wan Shin, DDS, MPH, PhD, MSc2/Jeong-Yol Lee, DMD, MSc, PhD1

Purpose: This study aimed to evaluate treatment outcomes of mandibular overdentures retained by two different mini-implant systems with ball attachments under a two-step immediate loading protocol. Materials and Methods: This clinical trial investigated treatment outcomes of mandibular mini-implant overdentures in 45 edentulous patients. MDI implants (3M ESPE) and SlimLine implants (Dentium) were randomly selected for placement in the anterior mandible in each group (MDI = 21; SlimLine = 24) with a flapless surgical approach. The side of the tissue in the region of the complete mandibular denture where mini-implants were placed was immediately relined with soft reliner (COE-SOFT). The female components were attached on the dentures 2 months after implant placement. Clinical and radiographic data were collected during follow-up. Statistical analyses were performed using SPSS software version 22.0 (α = .05). Results: A total of 177 mini-implants were inserted in the anterior mandibles of 45 totally edentulous patients. There were five implant failures (97.2% success rate) and no significant differences between the two implant groups. Most mini-implants showed stable initial Periotest values (a mean ± standard deviation of 1.03 ± 3.65 mm) and a mean marginal bone loss of 0.50 ± 0.75 mm at 12 months. Multiple regression analysis revealed that implants ≤ 2.4 mm in diameter had higher Periotest values than those ≥ 2.8 mm. Initial Periotest values significantly influenced implant failure (P < .05). Conclusion: There were no significant differences in treatment outcomes between patients treated with MDI or SlimLine implants. Mini-implants with wider diameters showed higher initial stability than those with narrow diameters, which may influence implant survival. Int J Prosthodont 2018;31:446–450. doi: 10.11607/ijp.5776

Mandibular implant–retained overdentures incorporating mini-diameter implants (MDIs) offer several advantages for the management of fully edentulous patients, such as less invasive surgical intervention (with flapless surgery or immediate loading), low initial cost, and good results for edentulous patients with medically compromised health and/or restricted alveolar bone.1–4

The establishment of primary implant stability is positively correlated with implant osseointegration and long-term success5; however, high primary stability is often difficult to obtain in a clinical setting, especially for MDIs because of their reduced diameters. In addition, minimal implant micromovement is necessary to achieve successful osseointegration,6,7 but MDIs can produce micromovements of over 200 microns during function.8 This may lead to increased stress on the alveolar bone after implant placement. Therefore, this 1-year prospective study aimed to assess the use of mandibular mini-implant overdentures (MMIO) under a two-step immediate loading protocol and their ability to reduce stress during the healing period.

Materials and Methods

Study Sample

This study was designed as a comparative prospective cohort analysis of two mini-implant systems (MDI, 3MTM ESPE; SlimLine, Dentium). Based on the inclusion and exclusion criteria (Table 1), 48 completely edentulous patients (24 men and 24 women) with a mean age ± standard deviation (SD) of 70.8 ± 7.8 years were selected from among outpatients treated at the implant clinic of Korea University Guro Hospital Dental Center between April 2014 and December 2015. The patients were randomly distributed into two groups: the MDI group and the SlimLine group. All participating patients provided written informed consent after being informed of the nature of the procedure, possible complications, and potential treatment alternatives. Patients were kept under observation for 12 months. Statistical analyses were performed using SPSS software version 22.0 (α = .05)
consent and were informed about the purpose of this study in both oral and written form. The study protocol was approved by the Ethics Committee of Korea University Guro Hospital (MD12031).

**Surgical and Prosthetic Procedures**

Each patient’s existing dentures were assessed based on maintenance, support, and stability. Modification or fabrication of new dentures for both arches was conducted if the dentures were compromised. The dentures were duplicated to produce radiographic and surgical stents. Panoramic radiographs and cone beam computed tomography (CBCT) data were evaluated to determine the amount of residual bone and the location of implant placement. Treatment plans for all patients included an implant-retained mandibular overdenture with four MDIs placed anteriorly in the mandible. All implants were placed under local anesthesia according to the manufacturer’s recommendations with a flapless surgical approach. The side of the tissue in the region of the mandibular complete denture where mini-implants were placed was immediately relined with COE-SOFT (Coe). The female components were attached to the dentures at 2 months after implant placement (Fig 1).

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<th>Inclusion criteria</th>
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<td>Completely edentulous or complete denture wearer in the maxilla and mandible</td>
<td>Pregnancy</td>
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<td>Complete denture wearer with adequate occlusal plane, occlusal relationship, and lack of severe attrition of the artificial teeth</td>
<td>Recent history of myocardial infarction</td>
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<td>Absence of prolonged disorders, such as temporomandibular joint disorders and soft tissue lesions</td>
<td>Uncontrolled systemic disease</td>
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<td>Well-motivated adult younger than 85 years</td>
<td>Bleeding disorders</td>
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<td>Available residual alveolar ridge in the lower anterior region with a minimum height of 10 mm and sufficient bucco-lingual width</td>
<td>Present or suspected mental illness</td>
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<td>Hypersensitivity to implant materials</td>
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<td>Participation may affect clinical trial results (research director’s discretion)</td>
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<td>Expected surgical complications</td>
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Table 1  Inclusion and Exclusion Criteria

Fig 1  Clinical case of a mandibular mini-implant-retained overdenture. (a) Intraoral photo before surgery. (b) Intraoral photo after implant placement. (c) Intraoral photo after 1 year follow-up. (d) Mandibular complete denture. (e) Mandibular complete denture relined with soft reliner after implant placement. (f) Final prosthesis on mandible. (g) Panoramic view before surgery. (h) Panoramic view after 1 year of loading.
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Clinical and Radiographic Evaluations

Clinical and radiographic parameters were assessed at the time of surgery (T0) and 2 months (T2), 6 months (T6), and 12 months (T12) after implant placement.

Implant survival was assessed according to the Albrektsson and Zarb criteria. An implant that soundly maintained its function until final observation was considered to have survived, and removal of the implant was defined as failure. Implant stability was evaluated by insertion torque value (ITV) and mean initial Periotest value (PTV; Periotest M, Medizintechnik Gulden Modautal). PTVs were recorded after three repeated measurements at the follow-up visits T0, T2, and T12.

Standardized intraoral periapical radiographs were taken using a long-cone paralleling radiographic method at T0, T6, and T12. Marginal bone levels were measured on both mesial and distal sides of the implant. Marginal bone loss (MBL) was measured by subtracting the bone level at the time of surgery (T0) from that at the subsequent follow-up, and the overall mean MBL was computed as an average for both the mesial and distal sides of the implant.

Statistical Analyses

Fisher exact test and t test were used to evaluate the distribution of patients between the two groups. Cumulative survival rate (CSR) was analyzed by the Kaplan-Meier method, and the relationships between potential risk factors and CSR were assessed using the multiple Cox proportional hazard model. Normal distributions of data (implant stability, MBL) were tested using Kolmogorov-Smirnov tests. The PTV and MBL data were analyzed using repeated analysis of variance (ANOVA) followed by Tukey test. Multiple linear regression analysis was employed to assess the relationships between multiple variables (group, position, diameter, and length of implant) and iPTV or T12 MBL. All statistical analyses were performed using IBM SPSS software version 20.0 (α = .05).

Results

Three out of 48 patients dropped out; therefore, a total of 45 patients received 177 implants (MDI group = 21 patients, SlimLine group = 24 patients, Table 2). In most patients, four mini-implants were placed; however, two patients received three and two 3M EPSE mini-implants due to poor bone quality. The length and diameter of the implants used are shown in Table 3.

Cumulative Survival of Mini-implants

Based on Kaplan-Meier survival analysis, the CSR of mini-implants was 97.2% (MDI = 95.1%; SlimLine = 99.0%) (Fig 2). During the observation period, 5 out of
the 177 implants failed (3 of 45 patients). Potential risk factors associated with implant failure that were preliminarily assessed included group (MDI vs SlimLine), position of implant (mesial vs distal), diameter of implant (≤ 2.4 vs ≥ 2.8 mm), length of implant (10 vs ≥ 12 mm), and iPTV. As a result, group, position, and iPTV were included in the multiple Cox proportional regression analysis (P < .20). Finally, it was observed that iPTV was significantly associated with implant failure (P = .001). For each 1-unit increase in iPTV, the hazard ratio for implant failure increased by 1.221 (Table 4).

### Peri-implant Tissue Condition

#### Implant Stability

The mean implant ITV was 26.4 ± 11.3 Ncm. The mean PTVs were 1.03 ± 3.65, 1.97 ± 3.19, and 1.47 ± 3.28 at T₀, T₂, and T₁₂, respectively. During the observation period, implants ≤ 2.4 mm in diameter had higher PTVs than implants 2.8 mm in diameter during the observation period (P = .001). T₀ = at surgery; T₂ = 2 months after implant placement; T₁₂ = 12 months after implant placement.

#### Marginal Bone Loss

The mean MBL was 0.50 ± 0.75 mm at T₁₂ (MDI = 0.60 ± 0.82 mm, SlimLine = 0.43 ± 0.67 mm) (Fig 4). The mean MBL was not associated with group or with position, diameter, or length of implant based on multiple linear regression analysis (Table 6, P > .05).

### Discussion

In this prospective clinical study of mandibular implant overdentures that assessed two different mini-implant systems with ball attachments, a total of 177 implants were placed in 45 patients. There were no significant differences in treatment outcomes between MDI or SlimLine implants. A total of five implants in three patients (three, one, and one implant, respectively) failed during the 1-year follow-up period. The patient who had three implant failures received two additional regular-size implants for overdentures and then dropped out of the study. The two patients in whom only one implant failed were able to maintain the overdentures with three mini-implants without additional implant placement.
The main advantages of MMIO treatment include minimally invasive surgery and immediate loading due to the small amount of bone required for implant placement.1,11 However, immediate loading of implants requires caution during treatment. According to previous studies, high initial fixation of implants is suggested to have an ITV of 30 (5) Ncm or more, PTV from –7 to –1, and an ISQ value of 60 to 75 for immediate loading.12,13 Although MDIs have relatively low initial fixation—with an ITV of 15 Ncm or more14 and PTV from –8 to +915—it is difficult to obtain stable primary stability for MDIs due to their reduced diameters. In addition, D4 type bone is frequent in the mandibular anterior region.16 Therefore, a countermeasure against relatively low initial fixation is needed for one-body MDIs. According to a previous study, early loading showed potential as a viable alternative treatment option,17 but the initial stability of MDIs remains unclear. In the present study, all MDIs were relieved until 2 months after implant placement to reduce exposure to excessive stress during the initial healing period. A total of 12 out of 117 MDIs were placed with an ITV lower than 15 Ncm, while five implants had an iPTV of 10 or more. Only one of the 12 implants with low initial fixation failed, and the remaining implants were well maintained during the observation period.

Narrower diameter implants (< 3.3 mm) have been reported to have lower survival rates compared to wider implants.18 Implant diameter is a secondary critical factor for long-term survival of dental implants, alongside surgical protocol, primary stability, and oral hygiene maintenance visits.19 In this study, iPTV was associated with implant failure, while wider diameter implants had higher initial fixation than narrower implants. Therefore, although flapless surgery is used for MDIs, it remains necessary to select the maximum implant diameter allowed by the residual bone.20

Although MMIOs showed favorable results after a 1-year follow-up period, long-term follow-up is needed to further assess implant predictability.

Conclusions

Within the limitations of this study, MMIOs showed predictable results regardless of which mini-implant system was used during a short-term follow-up period. Wider diameter mini-implants showed higher initial stability. Higher initial stability of mini-implants may lead to better implant survival.

Acknowledgments

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References