CHAPTER 3

A pilot study on mandibular overdentures retained by mini dental implants: marginal bone level changes and patient-based ratings of clinical outcome

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ABSTRACT

Purpose: The aim of this study was to investigate the effect of immediately loaded mini dental implants (MDIs) used to support mandibular overdentures on the peri-implant bone level as well as patients’ related levels of satisfaction and quality of life.

Materials and methods: Four MDIs were placed in the interforaminal region of 10 completely edentulous patients, and the implants were loaded immediately (same day) with an overdenture. Radiographic assessment of the bone loss during a period of 18 months was performed by measuring the bone level changes at the mesial and distal aspects of each implant on panoramic radiographs. At the end of this period, patients’ satisfaction level on the visual analogue scale (VAS) and oral health-related quality of life was assessed by means of questionnaires.

Results: A mean bone loss of 1.04 mm on the mesial and distal sides was recorded during the 18-month period after loading of the implants. The score for general satisfaction level was 95.67 ± 5.68. Similarly high VAS scores were given by the patients in all other specific items on patient satisfaction. The total score for the Oral Health Impact Profile-20 (OHIP-20) was 34.07 ± 13.90, which was comparable to that recorded in other studies.

Conclusions: The short-term radiographic peri-implant bone level changes of MDIs immediately loaded with overdentures in the edentulous mandible were within the physiologic limits. The patients expressed a high level of satisfaction and oral health-related quality of life with this treatment modality.
INTRODUCTION

Implant-retained overdentures are an established treatment option to improve oral health-related quality of life (OHRQoL) in edentulous patients. The most common protocol used is the implant-retained overdenture treatment, which includes placement of two implants in the anterior region of the mandible. The McGill and the York consensus have stated that there is overwhelming evidence that a mandibular two-implant-supported overdenture is a viable option for rehabilitation of the edentulous mandible and should be regarded as the standard of care for this group of patients.

Up until about 1995, it was suggested that an osseointegration phase of 3 to 6 months for dental implants was required to achieve predictable treatment outcomes. Publications in the experimental and clinical literature showed, however, that successful osseointegration of implants exposed to early or immediate loading can be achieved.

Immediate loading with mandibular overdentures is a protocol in which implants are connected to the prosthesis within one week after implant placement. For the edentulous mandible, the literature supports immediate loading of microroughened implants with overdentures. The proposed advantages for protocols with shorter healing times prior to implant loading are a reduction in the number of surgical and prosthetic procedures, associated clinical time, healing periods, and treatment costs. Recent studies on the immediate loading of two implants with an overdenture also show promising results. However, a limitation of the immediate loading treatment protocol has been the diameter of the implants. An alternative to standard implants in the edentulous mandible is the use of mini dental implants (MDIs). Recent studies on implants with a reduced diameter of 1.8 and 2.1 mm immediately loaded used to support overdentures in the edentulous mandible show success rates of these implants varying between 86% and 95% after 5 years.

The benefits of providing an implant overdenture on mini implants include the fact that the treatment is cheaper and simpler (the prosthetic part requires fewer appointments and shorter treatment times). The narrow diameter of the MDIs allows, in some cases, a simplified insertion technique involving placement without raising a flap. The alternative treatment is a bone augmentation procedure followed by the insertion of regular-sized implants. The limitations and unpredictability of these techniques with a relative high risk of implant loss have been reported in the literature. Long-term clinical evaluation of the implants used to support mandibular overdentures includes, among other parameters, changes in the marginal bone levels around implants. Changes that are beyond the normal limits can result in loss of bone anchorage of the implant. Bone loss of less than 1.5 mm for the first year after loading and no more than 0.2 mm of additional bone loss per year thereafter is generally accepted as within the physiologic limits. The evaluation of marginal bone level changes over time is possible by comparing radiographs taken at different intervals. Clinical and radiographic outcomes of immediately loaded MDIs used for long-term stabilization of overdentures as an alternative to standard-sized implant overdentures have already been published in the literature.
the advantage of eliminating the need for uncomfortable intraoral film holders. Intraoral
devices are usually painful for the edentulous patient, particularly when the clinical height
of the residual ridge is limited.24

Beyond clinical findings, patients’ perception of how implant treatment contributes to
their quality of life and overall satisfaction are also relevant. It is important for assessing
a treatment modality to have an indication of its impact on a patient’s satisfaction
and quality of life. For this purpose, general satisfaction ratings on a visual analog
scale (VAS) as well as the Oral Health Impact Profile (OHIP) questionnaires have been
extensively used.

Recently, a denture-specific short version of the OHIP has been developed (OHIP-20).
This questionnaire consists of seven domains: functional limitations, physical pain,
psychologic discomfort, physical disability, psychologic disability, social disability and
handicap. It has been illustrated that the OHIP-20 form possesses good psychometric
properties, and that it is very useful for clinical trial of oral prostheses.25,26

The aim of this study was to present the radiographic results and patients’ satisfaction
levels of a treatment concept with four mini dental implants loaded immediately
after placement (the same day) utilized to retain a mandibular overdenture in
edentulous patients.

MATERIALS AND METHODS

The study population consisted of 10 completely edentulous patients who had complaints
about the stability and retention of their mandibular dentures. They were treated in an
implant referral practice and in the implant clinic of the Academic Center for Dentistry
Amsterdam (ACTA) in 2012 as a pilot study. The study was conducted in accordance
with the Helsinki Declaration of 1975, as revised in 2000, and the patients provided an
informed consent to participate in the study. The main goal of this study was to test
the procedure and the feasibility of the application of MDIs in the edentulous mandible.
As such, it was carried out as a pilot study prior to a larger clinical trial (METc VUmc
registration number 2013/208).

Inclusion criteria dictated that the patient be completely edentulous for at least 6 months,
have a maladaptive mandibular denture, and have adequate bone for an implant length
of at least 10 mm and diameter of at least 1.8 mm. The exclusion criteria included: (1)
patients who received radiotherapy to the head or neck region for malignancies; (2)
patients on long-term steroids, immunosuppressants, or bisphosphonates; (3) smokers;
(4) patients with physical and mental disabilities that interfere with the maintenance of
implants; (5) systemic diseases precluding implant surgery.

In cases where satisfying dentures with respect to occlusion, esthetics, vertical dimension
in occlusion, denture base extension, and fit were present, the existing ones were used.
Otherwise, a new set of dentures was fabricated prior to implant treatment. For the included patients, a panoramic radiograph was made in which the proper implant length was selected after detection of magnification errors.

**Surgical procedures**

After a midcrestal incision, a mucoperiosteal flap was raised both on the labial and lingual aspects. If the width of the alveolar ridge was inadequate, vertical ridge reduction was performed. A pilot drill was used to make an initial opening to an average depth of one-third to one-half the threaded length of the implant. Each implant was inserted into the initial opening by rotating it clockwise while exerting downward pressure (self-tapping insertion technique). The implant was further advanced with the torque wrench to a minimum of 35 Ncm to allow immediate loading. Each patient received four MDIs (3M ESPE MDI) in the interforaminal mandibular region. The diameter of the implants was either 1.8 mm or 2.1 mm, and their length varied from 10 to 15 mm.

**Prosthetic procedures**

To modify the existing prosthesis to an implant-retained overdenture, an indirect restorative protocol was applied. Immediately after surgery the existing mandibular denture was hollowed out. The existing denture was utilized as an impression tray, and an impression was made using the close tray impression technique. For this purpose, the O-Ball impression copings were inserted directly onto each O-Ball MDI implant. To pick up the impression copings and record each implant’s position accurately, a polyether impression material was used (3M ESPE Impregum). The denture was modified in the laboratory by embedding the metal housings and removable O-ring attachments in the denture base. The denture was placed in immediate functional loading the same day of implant placement. The patients were instructed not to remove their mandibular overdentures during the first week except for oral hygiene. All patients received appropriate postoperative instructions, and regular follow-up appointments were scheduled.

**Radiographic outcome**

To illustrate the changes in the bone level around the inserted implants, digital panoramic radiographs (Planmeca, exposure settings of 18 seconds, 65kV and 6mA) were obtained at implant placement and at the 18-month follow-up examination. The immediate postoperative radiograph was used as a baseline reference. Image analysis software ((Image J, version 1.37, National Institute of Health [NIH]) was used to measure the distance between the upper part of the polished transgingival collar of the implant shoulder and the most apical level of the bone deemed to be in contact with the implant surface. The measurements were calibrated using the known length of the implants as reference. The vertical bone level, the location of the upper part of the polished transgingival collar of the implant, the first crestal bone-to-implant contact, and the apical border of the implant were identified as reference points at the mesial and distal aspects of each implant. The given dimensions for each implant were used as reference lengths to compensate for the magnification. The distance in millimetres from the polished transgingival collar of the implant to the first crestal bone-to-implant contact was measured at each side (Figure 1).
Two observers were asked to evaluate the digital images. To assess the intraobserver variability, each of the two observers performed all measurements twice with a 1-week interval. The observers were asked to measure the distance between the reference points and the marginal bone level at the mesial and distal aspects of each implant.

![Figure 1. Measurements of bone level on panoramic radiographs](image)

**Questionnaires**

Self-administered questionnaires were given to the patients 18 months after delivery of the implant overdentures. To measure the OHRQoL, the OHIP with 20 items (OHIP-20) was used. The items of this version were scored on a six-point scale, ranging from 1 (never) to 6 (all the time), with higher scores thus indicating a lower level of OHRQoL. The total score was computed for the OHIP-20 when there were no more than four missing values per patient. The scores for the seven dimensions-functional limitations, physical pain, psychologic discomfort, physical disability, psychologic disability, social disability and handicap-were computed when a maximum of one item had a missing value. The missing data points were replaced by the mean of that patient for each scale.

In addition, each subject was asked to rate, on a 100-mm VAS, their level of general satisfaction, as well as the comfort and stability of their overdentures, and the ability to chew, clean and speak. The VAS questionnaires carried the anchor words “not satisfied at all” (0 mm) or “completely satisfied” (100 mm). The mean values and SD of patients’ satisfaction in general and in specific aspects was calculated. Socio-demographic information (sex, age, educational level) and details about the current situation (such as years of being edentulous, time that the existing denture was made) were also gathered.
Statistical analysis
Statistical analysis was performed using IBM Statistics (v23.0, SPSS). To determine the intraobserver and interobserver reliability of the bone level measurements, intraclass correlation coefficients were computed for baseline and 18 months separately. In the following analysis, marginal bone level (mesial and distal) was calculated as the mean of the four repeated measurements of the four MDIs. Paired t tests were used to compare the mesial with the distal site and baseline with 18 months. A significance level of 5% was used. The results of the OHIP and VAS scales are presented as descriptive statistics only.

RESULTS
The study population consisted of completely edentulous patients who desired implants in the mandibular arch for better prosthesis stabilization. Two of the patients were not available for the 18-month recall appointment, as one of them had passed away and the other was unable to attend. Data were acquired from 8 patients (6 men and 2 women) with a mean age of 70.6 years (range: 58 to 79 years). The mean age of wearing a complete mandibular denture for the first time was 47.5 years (range: 28 to 67 years). All patients received four MDIs in the anterior mandible that were immediately loaded with an implant-retained overdenture. Insertion torque of at least 35 Ncm was recorded at implant placement.

In relation to the marginal bone level measurements, the intraobserver and interobserver reliability appeared to be excellent. For both the measurements at baseline and 18 months, all intraclass correlation coefficients were 0.99. In Table 1, the mean marginal bone level at both side is presented for baseline and after 18 months. The paired t tests indicated that there was no statistically significant difference between the mesial and distal sites at baseline and after 18 months (p = .377 and p = .907). The marginal bone level increased between baseline and 18 months for the mesial (p = .008) and the distal sites (p = .004). A bar chart with the means and the SDs for mesial and distal sites is shown in Figure 2.

Only one patient had two missing items with regard to the OHIP items. The OHIP-20 mean scores and SDs of the six men and two women are shown in Table 2. The mean scores and their SD of the satisfaction level of the patients are shown in Table 3.

| Table 1. Marginal bone level in mm at baseline and after 18 months and the results of the paired t-Test of the difference (n=8) |
|------------------|------------------|------------------|------------------|------------------|
|                   | Baseline Mean ± SD | 18 months Mean ± SD | Difference Mean ± SD | 95% CI          | p               |
| Mesial            | 3.17 ± 0.60       | 4.21 ± 0.74       | 1.05 ± 0.81       | 0.37-1.72       | 0.008           |
| Distal            | 3.20 ± 0.56       | 4.23 ± 0.76       | 1.02 ± 0.70       | 0.44-1.61       | 0.004           |
| p                 | 0.377             | 0.907             |                  |                  |                 |
Figure 2. Bar chart of bone level changes at the mesial and distal sites (means and SDs).

Table 2. OHIP-20 scales

<table>
<thead>
<tr>
<th>Descriptive Statistics</th>
<th>n</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean ± SDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>OHIP_total</td>
<td>8</td>
<td>22.00</td>
<td>61.00</td>
<td>34.06 ± 13.90</td>
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<tr>
<td>OHIP_functional_limitation</td>
<td>8</td>
<td>5.00</td>
<td>13.00</td>
<td>8.12 ± 3.09</td>
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<td>OHIP_physical_pain</td>
<td>8</td>
<td>4.00</td>
<td>15.00</td>
<td>7.87 ± 3.94</td>
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<tr>
<td>OHIP_psychological_discomfort</td>
<td>8</td>
<td>2.00</td>
<td>9.00</td>
<td>3.62 ± 2.44</td>
</tr>
<tr>
<td>OHIP_physical_disability</td>
<td>8</td>
<td>4.00</td>
<td>13.00</td>
<td>6.00 ± 3.02</td>
</tr>
<tr>
<td>OHIP_psychological_disability</td>
<td>8</td>
<td>2.00</td>
<td>7.00</td>
<td>2.75 ± 1.75</td>
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<tr>
<td>OHIP_social_disability</td>
<td>8</td>
<td>3.00</td>
<td>4.00</td>
<td>3.12 ± 0.35</td>
</tr>
<tr>
<td>OHIP_handicap</td>
<td>8</td>
<td>2.00</td>
<td>5.00</td>
<td>2.50 ± 1.06</td>
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</tbody>
</table>
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Table 3. VAS scales

<table>
<thead>
<tr>
<th>Descriptive Statistics</th>
<th>n</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean ± SDs</th>
</tr>
</thead>
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<tr>
<td>Ease of cleaning VAS 0-100</td>
<td>6</td>
<td>51.00</td>
<td>100.00</td>
<td>82.33± 23.20</td>
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<tr>
<td>General satisfaction VAS 0-100</td>
<td>6</td>
<td>87.00</td>
<td>100.00</td>
<td>95.67 ± 5.68</td>
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<td>Ability to speak VAS 0-100</td>
<td>6</td>
<td>1.00</td>
<td>12.00</td>
<td>94.50 ± 4.18</td>
</tr>
<tr>
<td>Comfort VAS 0-100</td>
<td>6</td>
<td>86.00</td>
<td>100.00</td>
<td>93.33 ± 6.05</td>
</tr>
<tr>
<td>Esthetics VAS 0-100</td>
<td>6</td>
<td>31.00</td>
<td>100.00</td>
<td>82.83 ± 26.76</td>
</tr>
<tr>
<td>Stability VAS 0-100</td>
<td>6</td>
<td>49.00</td>
<td>99.00</td>
<td>82.33 ± 19.01</td>
</tr>
</tbody>
</table>

**Ability to chew (AC)**

| (AC) general VAS 0-100                  | 6  | 72.00   | 100.00  | 89.33 ± 9.33 |
| (AC) bread VAS 0-100                   | 6  | 82.00   | 100.00  | 93.33 ± 7.65 |
| (AC) cheese VAS 0-100                  | 6  | 54.00   | 93.00   | 73.67 ± 15.69|
| (AC) carrot VAS 0-100                   | 6  | 1.00    | 99.00   | 64.50 ± 35.10|
| (AC) sausage VAS 0-100                  | 6  | 53.00   | 98.00   | 80.67 ± 18.03|
| (AC) meet VAS 0-100                    | 6  | 51.00   | 100.00  | 82.50 ± 20.40|
| (AC) apple VAS 0-100                   | 6  | 50.00   | 98.00   | 81.00 ± 16.90|
| (AC) lettuce VAS 0-100                 | 6  | 88.00   | 100.00  | 95.17 ± 5.52 |

**Functie (F)**

| (F) general VAS 0-100                   | 6  | 51.00   | 100.00  | 87.83 ± 18.92|
| (F) bread VAS 0-100                    | 6  | 46.00   | 100.00  | 85.66 ± 21.84|
| (F) cheese VAS 0-100                   | 6  | 40.00   | 100.00  | 84.00 ± 24.49|
| (F) carrot VAS 0-100                    | 5  | 37.00   | 100.00  | 78.00 ± 26.44|
| (F) sausage VAS 0-100                   | 6  | 36.00   | 100.00  | 81.16 ± 24.80|
| (F) meet VAS 0-100                     | 6  | 36.00   | 100.00  | 85.16 ± 24.76|
| (F) apple VAS 0-100                    | 6  | 67.00   | 100.00  | 86.66 ± 16.00|
| (F) lettuce VAS 0-100                  | 5  | 56.00   | 100.00  | 84.60 ± 17.78|

| Condition of the mouth general VAS 0-100| 6  | 51.00   | 99.00   | 74.83 ± 19.32|
| Condition of the mouth effect on general health VAS 0-100 | 6  | 50.00   | 100.00  | 76.83 ± 21.45|

**DISCUSSION**

MDIs have the potential to be an adequate cost-effective alternative for denture stabilization in the edentulous mandible, especially in patients with narrow mandibular ridges where an augmentation procedure would have otherwise been necessary. The present study reported a survival rate of 100% for the MDIs used to retain the mandibular overdentures. Similarly high survival rates of MDIs supporting mandibular overdentures were shown in other studies as well. 22,27,28

Radiographic assessment of the peri-implant bone level was performed by means of panoramic radiographs taken at the time of implant placement and 18 months later. The radiographic bone level changes in this study were within the expected range reported in the literature. In a study where a similar methodology was used to measure marginal bone loss around immediately loaded implants of conventional size in edentulous patients with
an implant-retained overdenture, the authors reported a mean radiographic bone loss of 0.67 mm 2 years after treatment.\textsuperscript{29} Radiographic results of immediate loading of two interforaminal implants with a bar-connected overdenture in the edentulous mandible were presented by Stricker et al.\textsuperscript{12} Panoramic radiographs of the patients demonstrated that marginal bone resorption after 24 months averaged 0.79 mm. This method of evaluating the bone level around implants in the long term was also used by Heckmann et al.\textsuperscript{30} The objective of the study was to investigate soft- and hard tissue conditions of mandibular two-implant telescopic overdentures after a period of 10 years. According to the authors, the severely resorbed alveolar process and the presence of a high floor of the mouth in the patients investigated made it difficult to apply any other radiographic technique apart from panoramic radiographs. The same problems were encountered in this study, meaning that the next best alternative was chosen.

**OHIP**

The impact of certain dental events on the OHRQoL may be measured via an OHIP. The use of health status measures to evaluate the impact of clinical interventions on OHRQoL has been suggested by several authors.\textsuperscript{31-33} The OHIP-20 form has been used for subjects who had complaints wearing conventional complete dentures. These patients often expressed a negative impact on quality of life parameters. It has been demonstrated that the OHIP in its short 20-item version possesses good psychometric properties, and that it is very useful for clinical trials of oral prostheses.\textsuperscript{25} Because, in the present study, a baseline reference was not available, it was not possible to compare the satisfaction level and oral health status before and after treatment. However, the mean values of the OHIP domains recorded in the present study were compared with the values obtained in other studies of similar design. In particular, the results presented by Heydecke et al.\textsuperscript{25} were used as a reference point. In this randomized clinical trial, the impact of implant overdentures on a wide range of possible oral health problems that might influence the quality of life was described. Among other parameters, the authors reported the measurement of treatment differences 6 months after insertion of mandibular implant overdentures using the organ-specific OHIP-20 questionnaire. In one of the groups, the patients received implant overdentures supported by ball attachments, and the oral health status (OHIP-20) was measured before treatment and 6 months afterward. The results indicated a significant improvement on all OHIP-20 score scales. A comparison was made between these OHIP scores and the ones obtained in the present study. The individual values for functional limitation, physical pain, psychologic discomfort, physical disability, psychologic disability, social disability and handicap as well as the total scores were similar. Therefore, the comparison of the ratings can lead to the conclusion that the patients’ OHRQoL has reached a high level with the modification of their mandibular prostheses to implant-retained overdentures. Other studies have also shown that replacement complete dentures stabilised by implants in the mandible resulted in a significant improvement in the OHRQoL.\textsuperscript{34} The difference, however, is that in the present study, an immediate loading protocol was used. The impact on OHRQoL following treatment with implants using an immediate loading protocol was reported by
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Attard et al. A profound improvement was observed through the OHIP questionnaire when the mandibular overdentures were converted to an implant overdenture. The global OHIP scores recorded in the present study were comparable to those obtained in the aforementioned study after insertion of the implant overdentures, and in any case, significantly lower (lower scores imply better quality of life) than the scores recorded by Attard et al for new conventional dentures. Interestingly, no significant change was observed when the OHIP scores soon after implant placement were compared with those obtained at the 1-year recall, implying that the improvement in quality of life was maintained after 1 year of function.

Satisfaction

Although a prospective evaluation of patient satisfaction was not available, the patients reported high ratings in absolute numbers in perceived ability to chew and speak as well as high satisfaction ratings for stability and comfort. These values can be compared with posttreatment ratings obtained in other studies. In particular, ratings of posttreatment satisfaction with MDIs were compared with those presented by Rachid et al. The authors investigated the effectiveness of mandibular overdentures supported by two implants and ball attachments in a multinational study. Patients wearing implant overdentures mentioned significantly higher ratings of satisfaction than patients who selected and received conventional dentures. The patients rated their satisfaction with the mandibular prostheses on 100-mm VAS questionnaires at 6 months posttreatment. The evaluation of patient satisfaction was made using a validated questionnaire that has been found to be sensitive in the edentulous population. In the present study, the ratings recorded for the satisfaction in general as well for specific aspects of satisfaction, such as the ability to clean, speak, and chew, and the levels of comfort and stability were in the region of 85 to 95 on the 1-100 VAS and similar to those recorded in the study of Rashid et al. These values are also comparable to those recorded by Thomason et al, where high satisfaction scores were given by the patients for most variables 6 months after provision of implant overdentures in the mandible. The ratings recorded in the present study showed that patients’ general satisfaction scores were high and positive, and the responses to specific attributes of their prostheses were also similarly high and positive. This observation is in accordance with the findings of another study where it was shown that patients’ ratings on different aspects of their dentures are highly and positively correlated with their general satisfaction. It seems, therefore, that implant treatment has a positive effect on patient satisfaction level, regardless of the time of loading of the implants retaining a mandibular overdenture.

The present study had several limitations. First, a control group was not included. That means that the marginal bone level changes could not be compared directly with those of delayed loading protocols or immediate loading protocols that have utilized different type of attachment mechanisms. However, these parameters are well documented in the literature. Moreover, a small number of patients were treated, and the evaluation period was rather short.
The radiographic method used in this study to assess peri-implant bone loss was an orthopantomogram. The reason for this was that some of the patients presented with significant crestal ridge resorption resulting in superficial insertion of the muscles in the floor of the mouth. This would have made the use of intraoral radiographs uncomfortable for the patients. Although this method of bone level evaluation around dental implants has been criticized by some authors concerning its reliability, many publications have used panoramic radiograph as a mean of measuring bone loss around implants in edentulous patients treated with implant overdentures. Nevertheless, it has been argued that the measurements obtained are not consistent and reliable because of inherent magnification errors and lack of standardization. Even if, however, intraoral radiographs appear to be more accurate, it should be noted that it is difficult to obtain extremely standardized radiographs with only one degree of angulation error in the interforaminal region.

CONCLUSIONS

Results after an 18-month evaluation of implant-retained overdentures on four MDIs show that factors such as bone loss and patient satisfaction are comparable to those in studies where two- and four-implant-retained overdentures were used. Thus, it may be concluded that at least in the short term, implant-retained overdentures on four MDIs may provide a viable treatment option.

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