Immediate Loading of Mandibular Overdentures Retained by Two Mini-Implants: A Case Series Preliminary Report

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Purpose: This preliminary case series report sought to evaluate the efficacy of an immediate loading protocol for mandibular overdentures retained by two mini-implants with the outcome measures patient satisfaction, masticatory cycles, and masticatory efficiency at 1 year. Materials and Methods: A convenience sample of 11 patients was recruited, and the clinical protocol consisted of immediately loading two mini-implants (10 mm long and 2.4 mm or 2.9 mm in diameter) via a mandibular overdenture connection with Locator attachments. Each patient completed a satisfaction questionnaire and underwent masticatory cycle recordings and masticatory efficiency tests. Implant-related evaluations were carried out by assessing probing depth (PD), Plaque Index (PI), bleeding on probing (BOP), mobility, and pain. All tests and evaluations were carried out six times: before implant surgery (T₀), just before implant surgery with patient under anesthesia (T₁), following implant insertion with patient still under anesthesia (T₂), and at 3 months (T₃), 6 months (T₆), and 1 year (T₁₂) after implant insertion. Results: Implant survival rate was 95%, and statistically significant increases (P < .05) in masticatory cycle patterns, masticatory efficiency, comfort, stability, and phonetics were also recorded. Conclusion: The employed treatment protocol suggests promise as a viable treatment option that in the short term provides improved prosthesis stability, comfort, and function while decreasing surgical invasiveness. Long-term follow-up outcomes in larger patient sample studies will be required to confirm and validate the merits of this preliminary report. Int J Prosthodont 2018;31:558–564. doi: 10.11607/ijp.5589

The prevalence of edentulism and its contribution to compromising patients’ quality of life (QoL) are predicted to increase in association with an aging global population¹. Complete denture therapy can improve esthetics, phonetics, and comfort, but masticatory function is often compromised, especially in a time-dependent context. Reports suggest² that between 10% and 18% of denture wearers are dissatisfied with this type of treatment and complain of esthetic problems with their maxillary dentures and of pain and instability with their mandibular ones. The introduction of Brånemark’s osseointegration technique offered compelling promise for a breakthrough in managing edentulism. Osseointegration’s implant-supported overdenture approach was quickly embraced by the profession as a less expensive, less surgically invasive, and more reliable way to fulfill patients’ functional denture-wearing expectations. Numerous publications endorse this treatment initiative’s successful outcomes, with robust reports of high success rates for comfort, masticatory efficiency, and improved QoL.³,⁴ Mini dental implants (characterized by a diameter of less than 3 mm) were initially adopted as provisional retention for overdentures during the osseointegration time of conventional implants. In 2001, the US Food and Drug Administration (FDA) approved the use of mini-implants for long-term prosthetic rehabilitations. The advantages of adopting mini-implants, especially for elderly patients, for retention of overdentures include decreased costs and clinical time, a minimally invasive surgical procedure, and an implant design that allows for an immediate loading protocol. However, there is a lack of reliable clinical data analyzing functional parameters and patient satisfaction when using mini-implants. This preliminary report describes the outcomes—patient satisfaction, masticatory cycles, and masticatory efficiency—of a clinical protocol of two immediately loaded mini-implants used as retention for an overdenture following 1 year of functional use.
Materials and Methods

The present protocol was designed as a case series study. Patients included in the study were recruited from among those rehabilitated with a complete denture between January 2014 and March 2015 at the Prosthodontics Department of Turin Dental School according to the following inclusion criteria: maxillary and mandibular edentulism; absence of local or systemic contraindications to implant rehabilitation; adequately made complete dentures; and willingness to join the study.

Masticatory cycle recordings were analyzed in collaboration with the Department of Mechanical and Aerospace Engineering of Politecnico di Torino. The protocol was drafted in accordance with the Directive on Good Clinical Practice (GCP) of the European Union and the Helsinki Declaration. In July 2014, the study protocol and informed consent forms were approved by an institutional review board and ethics committee (Comitato etico interaziendale A.O.U Città della Salute e della Scienza di Torino - A.O. Mauriziano- A.S.L. TO1, protocol number 0077357).

Research Protocol

The research protocol consisted of the following examinations: patient satisfaction questionnaire; masticatory cycle recordings; masticatory efficiency test; and clinical implant evaluation. The examinations were carried out six times according to a specific time sequence: before implant surgery (T0), just before implant surgery (T1), following implant insertion with patient still under anesthesia (T2), and at 3 months (T3), 6 months (T6), and 1 year (T12) after implant insertion (Table 1).

Table 1 Description of the Protocol Stages

<table>
<thead>
<tr>
<th></th>
<th>VAS scores</th>
<th>Masticatory cycles and masticatory efficiency test</th>
<th>Implant survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>X</td>
<td></td>
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<tr>
<td>T3</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>T6</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>T12</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*X* indicates that the measure was assessed at the follow-up point. T0 = first visit; T1 = before surgery, under anesthesia; T2 = after implant loading, under anesthesia; T3 = 3 months postsurgery; T6 = 6 months postsurgery; T12 = 12 months postsurgery.

Patients were asked to fill in a satisfaction form regarding the level of comfort during function, painfulness, the stability of the prosthesis, and the amount of time spent wearing the prosthesis (Table 2). There were seven questions that patients had to answer using a visual analog scale (VAS) from 0 to 10.5,6

Masticatory Cycle Recordings. Patients’ masticatory cycle patterns on the sagittal and frontal planes were evaluated using a kinesiograph (K7 Evaluation system, Myotronics-Noromed) and specific cube-shaped jellies of 2 cm per side prepared according to Gunne’s modified protocol.7 Use of a kinesiograph allows the recording of mandibular dynamics tracking the position of a magnet applied on the inferior incisors. The magnet motion is detected by a helmet fixed on the patient’s head thanks to changes in the field strength caused by the magnet movement. The kinesiograph is then connected to a computer provided with a dedicated software to visualize the masticatory cycle pattern directly. During each trial, patients performed 10 masticatory cycles chewing 2 jellies, and the test was repeated twice.

Masticatory Efficiency Test. To objectify the level of food comminution, a masticatory test based on the ability to break up a test food was performed following the protocol proposed by Olthoff8 and modified by the Utrecht School.9 The test food consisted of small cubes (5 to 6 mm per side) of an ordinary impression silicone (Optosil Comfort putty/Xantopren, Kulzer) prepared using a special metal grid. Each subject was invited to masticate 17 cubes, equivalent to 3 cm³ of material, for a total of 60 chewing cycles, which may be considered to be within the recommended range of cycles required to comminute Optosil cubes homogeneously. The masticated food collected from the patient’s oral cavity was sieved under a stream of water at constant pressure by means of four sieves whose pore diameters were progressively smaller (8 mm, 5.6 mm, 4 mm, 2.3 mm); afterwards, the sieved food was collected, dried, and weighed.

Clinical Implant Evaluation. According to the indices suggested by the Consensus Report of the Sixth
Immediate Loading of Mandibular Overdentures Retained by Two Mini-Implants

European Workshop of Periodontology\textsuperscript{10} in diagnosing and preventing peri-implant disease, the following parameters were analyzed: probing depth (PD), Plaque Index (PI), bleeding on probing (BOP), mobility, and pain. These evaluations were carried out during follow-up at T\textsubscript{3}, T\textsubscript{6}, and T\textsubscript{12}.

Clinical Protocol

Every patient underwent presurgical radiographic examinations (panoramic x-ray and cone beam computed tomography [CBCT]) prior to implant placement. Smokers were encouraged to quit smoking at the time they joined the protocol, and all patients underwent oral hygiene reinforcement throughout the follow-up stages.

The clinical protocol called for the insertion of two mini-implants to be connected to the mandibular overdenture with Locator attachments. LODI implants (Locator Overdenture Implant system, Zest Dental Solutions) were used. All surgical interventions were performed by the same operator. After performing anesthesia with mepivacaine 20 mg/mL and epinephrine 1:100,000, a total thickness flap with median release incision was elevated. Implants were 10 mm long, and diameter (2.4 mm or 2.9 mm) depended on bone ridge thickness. The implant site was underprepared and the diameter of the final dedicated drill was 2.1 mm to give mini-implants a high primary stability. All implants were placed with a 50-Ncm insertion torque. Afterwards, 2.5- or 4.0-mm diameter Locator attachments were connected with an insertion torque of 30 Ncm, and resorbable 4-0 sutures (Vicryl, Ethicon) were given. Based on the high primary stability and the tissue-friendly morphology of the Locator attachments, immediate loading could be performed, as specifically expected by the LODI implant protocol.

Low-retention Locator laboratory matrices (Locator Overdenture Implant System, Zest Dental Solutions) were embedded in the overdenture with a direct method. The prosthetist was delivered immediately after surgery, and T\textsubscript{2} tests were performed while patients were still under the effect of the anesthesia. After 3 months, Locator laboratory matrices were substituted with higher-retention ones. The diameter of the Locator attachments remained unvaried regardless of the implant diameter.

Statistical Analyses

Given the limited sample size available, a statistical compromise power analysis was performed (GPower 3.1) for \( \alpha \) and \( \beta \) values estimation as a rational compromise between the demands for a low \( \alpha \) risk and a large power level given a fixed sample size, a fixed effect size, and an error ratio of \( \beta/\alpha \). Analysis of variance (ANOVA) with repeated measures within factors was chosen as a statistical test, setting one group for the patient factor, four measurements for patient satisfaction questionnaire (T\textsubscript{0}, T\textsubscript{3}, T\textsubscript{6}, T\textsubscript{12}), and six measurements in each other test (T\textsubscript{0}, T\textsubscript{1}, T\textsubscript{2}, T\textsubscript{3}, T\textsubscript{6}, T\textsubscript{12}) for the time factor. The effect size was 0.25, considering a medium effect size for time of measure using Cohen’s criteria. The error ratio \( \beta/\alpha \) was set to 1, considering Type I and Type II errors equally serious, and sample size was set to 120 for average mandibular opening and maximum mandibular opening parameters (2 replications for each test) and to 60 for masticatory efficiency tests and satisfaction questionnaire (1 replication for each test). The nonsphericity correction \( \epsilon \) (Geisser-Greenhouse’s epsilon) was computed from experimental data in GraphPad Prism 7.0 for each tested parameter obtained:

- Masticatory cycle recordings: \( \epsilon = 0.39 \) (average mandibular opening) and \( \epsilon = 0.34 \) (maximum mandibular opening)
- Masticatory efficiency test: \( \epsilon = 0.51 \) (sieve 2), \( \epsilon = 0.42 \) (sieve 3), \( \epsilon = 0.53 \) (sieve 4), and \( \epsilon = 0.48 \) (final sieve)
- Patient satisfaction questionnaire: \( \epsilon = 0.44 \) (hours/day), \( \epsilon = 0.70 \) (cheek biting), \( \epsilon = 0.62 \) (masticatory efficiency), \( \epsilon = 0.44 \) (pain), \( \epsilon = 0.54 \) (comfort), \( \epsilon = 0.46 \) (stability), and \( \epsilon = 0.47 \) (phonetics)

The power values (the probability of correctly rejecting a false null hypothesis, 1-\( \beta \)) of each test performed were: 69.7% for average mandibular opening and 68.5% for maximum mandibular opening; 62.9% for sieve 2, 61.7% for sieve 3, 63.2% for sieve 4, and 62.6% for final sieve; and for the patient satisfaction questionnaire, 64.1% for hours/day, 67.8% for cheek biting, 66.8% for masticatory efficiency, 64.1% for pain, 65.6% for comfort, 64.4% for stability, and 64.6% for phonetics.

To test the null hypothesis (a mandibular overdenture retained by two mini-implants with immediate loading does not generate an improvement in masticatory efficiency/patient satisfaction), a repeated measures one-way ANOVA (GraphPad Prism 7.0) was carried out not assuming equal variability of differences and therefore including the Geisser-Greenhouse correction factor. Confidence level was set to 95% in each ANOVA analysis performed. Moreover, paired \( t \) tests for T\textsubscript{0} vs T\textsubscript{3} and T\textsubscript{0} vs T\textsubscript{12} for patient satisfaction results were performed to analyze immediate improvement after implant loading and the improvement after 1 year, with a confidence level set to 95%.

Results

A total of 11 patients (8 women, 3 men) aged between 54 and 85 years (mean ± standard deviation [SD])
age = 68 ± 9.8 years) fulfilled the inclusion criteria and were recruited for the study. Overall, 22 implants were inserted between November 2014 and July 2015. One implant was lost in a male patient affected by type 2 diabetes mellitus, which was under medical control at the time of the surgery. Due to the clinical situation, this patient could only undergo the clinical implant evaluation and not evaluations for masticatory cycles, masticatory efficiency, and patient satisfaction; therefore, the results consider only 10 patients regarding the three latter measures.

**Patient Satisfaction**

The differences between T₀ and T₃ and between T₀ and T₁₂ were taken into account to analyze the improvement that occurred 3 months after implant placement and 1 year after implant placement, respectively.

At T₁₂, the VAS scores of satisfaction tests revealed statistically significant increases in masticatory efficiency perceived by all patients: Six patients reported improved comfort, three did not report any variations, and one reported diminished comfort with the implant-retained prosthesis. Pain decreased in eight patients, while the other two did not have pain with the old or the new prosthesis. Eight patients claimed improved prosthetic stability, while for two patients it remained unvaried. Two patients reported decreased cheek biting with the new prosthesis, while eight did not bite their cheeks with the old or the new prosthesis. For six patients, the number of hours spent wearing the prosthesis increased, while for the other four it remained unvaried. Eight patients improved their speaking ability, while the other two did not report any variation. These improvements emerged in the postoperative period at T₃ and remained stable at T₁₂ (Fig 1).

**Masticatory Cycle Recordings**

The mean mandibular opening, defined as the mean of all the mean mandibular openings of every cycle, was recorded (Table 3). The maximum mandibular opening, defined as the mean of all the maximum mandibular openings of every cycle, was also recorded (Table 4).

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**Table 3** Analysis of Mean Mandibular Opening Values (mm)

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Mean ± standard deviation</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>T₀</td>
<td>9.5</td>
<td>15.3 ± 3.60</td>
<td>21.1</td>
</tr>
<tr>
<td>T₁</td>
<td>11.7</td>
<td>17.4 ± 5.90</td>
<td>29.1</td>
</tr>
<tr>
<td>T₂</td>
<td>11.1</td>
<td>17.4 ± 6.20</td>
<td>33.5</td>
</tr>
<tr>
<td>T₃</td>
<td>12.4</td>
<td>18.6 ± 5.60</td>
<td>33.8</td>
</tr>
<tr>
<td>T₆</td>
<td>13.1</td>
<td>19.7 ± 4.60</td>
<td>32.9</td>
</tr>
<tr>
<td>T₁₂</td>
<td>14.8</td>
<td>22.8 ± 8.10</td>
<td>46.9</td>
</tr>
</tbody>
</table>

T₀ = first visit; T₁ = before surgery, under anesthesia; T₂ = after implant loading, under anesthesia; T₃ = 3 months postsurgery; T₆ = 6 months postsurgery; T₁₂ = 12 months postsurgery.

**Table 4** Analysis of Maximum Mandibular Opening Values (mm)

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Mean ± standard deviation</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>T₀</td>
<td>13.8</td>
<td>20.4 ± 4.90</td>
<td>32.8</td>
</tr>
<tr>
<td>T₁</td>
<td>14.0</td>
<td>21.9 ± 6.20</td>
<td>35.2</td>
</tr>
<tr>
<td>T₂</td>
<td>14.4</td>
<td>23.6 ± 6.90</td>
<td>41.7</td>
</tr>
<tr>
<td>T₃</td>
<td>14.7</td>
<td>22.9 ± 6.20</td>
<td>38.3</td>
</tr>
<tr>
<td>T₆</td>
<td>17.0</td>
<td>25.2 ± 6.10</td>
<td>32.6</td>
</tr>
<tr>
<td>T₁₂</td>
<td>20.2</td>
<td>29.2 ± 10.10</td>
<td>59.5</td>
</tr>
</tbody>
</table>

T₀ = first visit; T₁ = before surgery, under anesthesia; T₂ = after implant loading, under anesthesia; T₃ = 3 months postsurgery; T₆ = 6 months postsurgery; T₁₂ = 12 months postsurgery.

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Fig 1 Comparison of visual analog scale (VAS) scores on patient satisfaction questionnaire measured at T₀, T₃, and T₁₂. *P ≤ .05.
opening, defined as the widest cycle performed by the patients during each series of cycles, was also recorded (Table 4).

ANOVA revealed that both patient and time factors were statistically significant \((P < .05)\), as well as their interactions for all parameters.

### Masticatory Efficiency Test

The first sieve was not relevant in any cases and was not inserted in the analysis of the results. The mean values of the other sieve measurements are reported in Table 5 and Fig 2.

According to ANOVA, all single factors analyzed were statistically significant \((P < .05)\), except for the third and fourth sieves.

All patients made the worst performance at \(T_1\), showing a medium decrease (87.8%) in efficiency of the final sieved food product. All patients improved their masticatory performance from \(T_1\) to \(T_2\), as demonstrated by the 485.2% increase in efficiency between \(T_1\) and \(T_2\). The final sieve showed a medium decrease (42.5%) in efficiency at \(T_2\) compared to \(T_0\).

Eight patients presented a medium improvement (24.8%) in masticatory efficiency in the final sieved product from \(T_0\) to \(T_{12}\). The other two patients showed a decrease, comprised in the SD.

### Clinical Implant Evaluation

No surgical or postsurgical complications occurred. PI (Fig 3), BOP (Fig 4), and PD (Fig 5) were recorded at \(T_3\), \(T_6\), and \(T_{12}\).

Plaque accumulation around 13 implants at \(T_3\) and \(T_6\) was present; after 1 year, the index was positive for 8 implants. BOP was recorded at three implant sites at \(T_3\), five sites at \(T_6\), and two sites at \(T_{12}\). At \(T_3\), 14 implants showed 1 mm of PD, 5 implants 2 mm, and 2 implants 3 mm. At \(T_6\), 14 implants showed 1 mm of PD, 5 implants 2 mm, and 2 implants 3 mm. At \(T_{12}\), 16 implants showed 1 mm of PD, 3 implants 2 mm, and 2 implants 3 mm.

One implant was lost at the 1-year follow-up, while none of the remaining 21 implants showed signs of mobility and no patient reported pain on percussion. Implant survival at 12 months was 95%.

### Discussion

The primary outcome of the present study was to evaluate the survival of two immediately loaded mini-implants used to retain a mandibular overdenture at a follow-up of 1 year. Clinical evaluation at the prescribed time showed an implant survival rate of 95%, which is comparable to results in similar studies.\(^{11,12}\)

PI, PD, BOP, mobility, and pain were regularly assessed throughout the follow-up stages in order to promptly diagnose and monitor possible signs of peri-implant disease, although evidence for a robust correlation is still unclear. A number of possible risk factors\(^{10}\) (eg, diabetes mellitus, poor oral hygiene, and smoking) were identified and brought to the patients’ attention. Although there is limited evidence\(^{13}\) that diabetes mellitus with poor metabolic control may be associated with adverse peri-implant changes, the patient whose diabetes mellitus was under...
medical control at the time of surgery lost one implant by the 1-year follow-up. All patients were encouraged to quit smoking and were taught appropriate oral hygiene protocols. It is presumed that these measures resulted in a reduction of PI, PD, and BOP indices at the 1-year follow-up.

Thanks to its repeatability, low invasiveness, and easy visualization format, the kinesiograph proved to be a useful instrument to perform the analysis of masticatory cycles and to evaluate movement changes occurring before and after implant anchorage. The analysis of masticatory cycles showed a medium increase of the patients’ opening range at the 1-year follow up, in accordance with similar studies. In the present protocol, the masticatory cycles recorded after implant anchorage were drop shaped and more similar to those of a dentate patient compared to the cycles recorded with the complete denture prior to implant placement. This outcome supports the hypotheses that the increased stability of the implant-retained prosthesis is determinant in increasing masticatory cycle pattern and width and that the neuromuscular system undergoes a progressive adaptation to the new rehabilitation, in accordance with similar studies. In the present protocol, a masticatory test based on the ability to break up a test food was performed. Among the several techniques developed, the Olthoff protocol was adopted based on the fact that it was repeatable, more precise, and easy to perform. A progressive and significant improvement in terms of masticatory efficiency was shown at the 1-year follow up in 80% of the patients, thus confirming the results reported by other studies. The most relevant data were drawn by the comparison between T1 and T2, which showed an increase in masticatory efficiency of 485.2%; indeed, at T1 and T2, patients were under the effect of the anesthesia in a such a way that the outcome obtained depended only on the implant-related prosthetic stability and not on other factors.

The analysis of the VAS scores highlighted significant improvements perceived by the patients following the implant anchorage, also in accordance with similar studies. However, it is important to assert that patients wearing a complete denture seem to be much more influenced by their psychosocial situation than by the effectiveness of their prosthetic rehabilitation. In the current study, some of the answers to the questionnaire appeared to be influenced by patients’ occasionally unrealistic expectations.

Conclusions

There are clear limitations to this short-term clinical study, especially given the fact that a time-dependent radiographic evaluation could not be undertaken. Nonetheless, the outcomes of the present study suggest that immediate loading of two mini-implants to support an overdenture is a viable treatment option for edentulous patients. This appears to be the result of enhanced prosthetic stability, comfort, and function, plus a minimally surgically invasive intervention. The employed masticatory cycle recordings and efficiency tests also appeared to provide a reliable assessment of the changes associated with provision of

Fig 3  Comparison of Plaque Index (PI) values measured at T3, T6, and T12.

Fig 4  Comparison of probing depth (PD) values measured at T3, T6, and T12.

Fig 5  Comparison of bleeding on probing (BOP) values measured at T3, T6, and T12.
implant support and retention. Furthermore, patient satisfaction questionnaires provided a useful assessment of patient responses to treatment in terms of prosthetic adaptation.

Long-term follow up studies involving a larger patient cohort will be required to confirm and validate data from this preliminary report.

Acknowledgments

The authors report no conflicts of interest related to this study.

References


Literature Abstract

Restorative Treatment in Patients with Amelogenesis Imperfecta: A Review

The aim of this review was to summarize the contemporary scientific evidence available regarding restorative dental treatment in patients with Amelogenesis imperfecta (AI). An electronic literature search was conducted using the search term “Amelogenesis imperfecta” in the PubMed/MEDLINE database as well as Google Scholar. Prospective and retrospective clinical studies that investigated the outcome of direct and/or indirect dental restorative treatment in patients with AI, that were published in English, and that had an observation time of at least 1 year were included in this review. The articles identified were screened and analyzed by two reviewers according to inclusion and exclusion criteria in three review rounds. Six prospective or retrospective clinical studies analyzing longevity and complications associated with dental restorative treatment in patients with AI met the inclusion criteria. Extracted data suggested that in patients with AI, indirect restorations feature superior predictability and longevity to direct restorations. As endodontic complications were infrequently observed and periodontal parameters regularly improved with the insertion of indirect restorations, dental treatment in patients with AI should focus on indirect restorations as soon as possible. While adhesive bonding techniques to enamel surfaces in patients with AI merely feature limited predictability and longevity and as the available data are scarce, further laboratory and clinical studies should be performed to investigate the performance of minimally invasive indirect restorations bonded to enamel in patients with AI.