Distal-extension removable partial dentures (RPDs) can be stabilized by posterior implants to support free-end saddles.\(^1\) Implant retainers for free-end RPDs improved the satisfaction and the masticatory function of patients.\(^1\)–\(^4\) Likewise, a reduced number of abutment teeth or unfavorable unilateral location may lead to insufficient retention of RPDs and overloading of the remaining teeth. Supplementary strategic implants for improved RPD retention and support have been shown to be a viable treatment option with high long-term survival rates of implants and prostheses.\(^5\)–\(^9\) Increasing the total number of abutments to five or six in the maxilla and to four in the mandible by placing strategic standard implants under an existing RPD improves not only the oral health–related quality of life,\(^10\) but it also has a substantial positive effect on masticatory performance.\(^11\)

### Stabilizing Removable Partial Dentures by Immediate or Delayed Loading of Mini-implants: Chewing Efficiency in a Randomized Controlled Clinical Trial

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**Purpose:** The aim of this investigation was to compare the chewing efficiency after immediate and delayed loading of mini-implants that served as supplementary support for removable partial dentures (RPDs).

**Materials and Methods:** In this four-center randomized trial, patients who had RPDs in arches with unfavorable tooth distributions, ie, no canine and at most two posterior teeth in one or both quadrants, received strategic mini-implants with ball abutments. The mini-implants in group A were loaded immediately either by housings with O-rings (insertion torque \(\geq 35\) Ncm) or by soft relining material (insertion torque \(< 35\) Ncm). In group B, the RPDs were only hollowed over the balls. After 4 months, the soft relined RPDs and all RPDs of group B received the housings. Masticatory efficiency was evaluated with a validated mixing ability test of two-colored chewing gum before surgery and 14 days, 4 months (before housing pickup), 4.5 months, and 12 months after surgery. The circular variance of hue was the measure of mixing.

**Results:** From 76 participants with 79 RPDs, 38 each were randomly allocated to group A or B. In group A, the housings in six participants were picked up immediately, and the remaining RPDs were primarily soft relined. There was a significant group difference only after 4 months. The mixing ability was better after immediate loading than after delayed loading \((P < .0001)\). In group B, the chewing efficiency was notably deteriorated after the RPDs were hollowed over the ball abutments. However, immediately after all housings were picked up, the chewing efficiency in both groups was substantially improved, and the variance of hue values after 1 year were very similar in the groups.

**Conclusion:** The chewing performance can be improved by inserting supplementary mini-implants under existing RPDs with unfavorable tooth support. This improvement occurred faster by immediate loading than by delayed loading. **Int J Oral Maxillofac Implants** 2020;35:178–186. doi: 10.11607/jomi.7707

**Keywords:** chewing function, dental, mini-implant, randomized controlled clinical trial, removable partial denture, strategic

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Masticatory function can be assessed subjectively by questionnaires, i.e., masticatory ability, and objectively by determining the particle size comminution of natural or artificial test foods. More recently, methods that employ color-changeable chewing gum or wax have gained popularity, as these methods are fairly simple, cheap, and applicable without specialized equipment. It was demonstrated that the results of this chewing test correlate well with the comminution technique, and it can therefore be used to assess masticatory function objectively.

Two-piece conventional implants (diameter > 3.5 mm) require sufficient bone volume. Augmentation procedures can enhance the alveolar ridge width. However, together with the costs of standard implants, they are expensive and an additional burden for the patient regarding surgical risks, postoperative pain, and treatment duration. One-piece mini-implants with diameters ≤ 2.9 mm were shown to be a viable treatment alternative for the stabilization of complete dentures. Most of the mini-implant studies used implants with diameters between 1.8 mm and 2.5 mm. The minimally invasive surgery approach by avoiding extended full-thickness flaps or augmentations in narrow alveolar ridges is advantageous for the elderly, especially in patients with general medical problems. In a recent randomized clinical trial, either one-piece implants with a narrow diameter of 3.0 mm or two-piece implants with a diameter of 3.75 mm were placed in the region of the first molar and immediately loaded to retain the saddles of mandibular Kennedy Class I RPDs. The 1-year implant survival rates were identical (93.3% in each group). After intervention, patient satisfaction substantially improved in both groups. Similar studies on mini-implants with ≤ 2.5 mm diameter as strategic abutments for the stabilization of existing RPDs are still lacking. Therefore, a 3-year randomized clinical trial was initiated for this treatment modality.

The primary outcome in this still-ongoing trial in one university clinic and three dental practices is the bone-level change around the implants.

The aim of this preliminary investigation was to compare the chewing efficiency with RPDs after immediate and delayed loading of mini-implants that served as supplementary support for the prostheses. An overall improvement independent from the loading principle was hypothesized; however, the improvement will occur faster in the immediate loading group than in the delayed loading group.

### MATERIALS AND METHODS

#### Treatment Groups

This trial is registered at the German register of clinical trials (Deutsches Register Klinischer Studien) under DRKS-ID: DRKS00007589 (www.germanctr.de) and was approved by the Ethics Committee of the University of Greifswald and by the responsible ethics committees of the dental practices. Written informed consent was obtained from each participant. The study design was reported in detail elsewhere. Briefly, arches with unfavorable tooth distribution to retain RPDs were included and classified. All included patients were either edentulous in one quadrant of the study arch (Class 0) or they had in one or both quadrants only incisors (Class 1), no canine and one posterior tooth (Class 2), or no canine and two posterior teeth (Class 3) (Fig 1). To attain two strategic abutments (teeth plus mini-implants) per quadrant in the mandible and three abutments per quadrant in the maxilla, 10- to 15-mm-long supplementary mini dental implants (MDI, formerly 3M ESPE and now Condent) with a diameter of 1.8, 2.1, or 2.4 mm were placed (Figs 1 and 2). The participants were randomly allocated once the RPD was hollowed out over the mini-implant ball abutments. The mini-implants were either loaded immediately (group A) or the recesses remained empty for 4 months (group B). In group A, immediate loading by the matrix housings with rubber O-rings was only performed if the insertion torque of all mini-implants was ≥ 35 Ncm; otherwise, the mini-implants were loaded by soft relining of the RPD in the implant area. After 4 months, the soft relined RPDs and all RPDs of group B received the housings. According to the power calculation for the primary outcome (bone-level change), a sample size of 26 in each group was planned for the whole 3-year study period, deducting possible losses to follow-up.
Examination Procedure

The participants were examined by the same trained dentist (A.A.) before mini-implant surgery (T₁) and 14 days (T₂), 4 months (before housing pickup, T₃), 4.5 months (T₄), and 12 months (T₅) after mini-implant placement. Masticatory efficiency was evaluated according to the two-colored chewing gum mixing ability test. A 43 × 12 × 3-mm strip of a commercially available two-layered (one violet and one green layer) chewing gum (Vivident Fruitswing Xylit Karpuz and Asai Üzümü, Perfetti Van Melle) was placed in the mouth. Each participant was asked to start chewing on one side, and the examiner counted silently up to 10 chewing cycles. Thereafter, the participant was asked to chew the gum on the other side for 10 cycles. Afterward, the gum bolus was obtained and dried with compressed air and put into a transparent plastic bag. An acrylate resin template was used to flatten the plastic-wrapped bolus to a 1-mm-thick wafer. The wafer was immediately scanned from both sides using a flatbed scanner at a resolution of 300 dots per inch (dpi) and saved as JPEGs (Fig 3). Each pair of images was analyzed as one file of a maximum size of 1,000 × 1,000 pixels using special software (ViewGum dHAL Software). The operator was blinded to the follow-up number and to the study groups. The pixels of the chewing gum area were transformed from RGB (red, green, blue) values to the HIS (hue, intensity, saturation) color space in the semi-automatically segmented image. Only the hue value of each pixel was used to gain a quantitative distribution of the hue mixture. The more pixels belonged to two well-separated groups of different hues, the poorer the chewing gum was mixed. The more pixels fused into an intermediate group between the original
groups, the better the mixing was. The circular variance of hue (VOH) was considered the measure of mixing. The higher the VOH value, the poorer the mixing ability of the two colored layers was, and thus, the chewing performance of the study participant.\textsuperscript{24} All chewing gum images were analyzed two times at an interval of 2 days.

**Statistical Analyses**

The reproducibility of the image analysis was estimated by the intraclass correlation coefficient (ICC). To estimate the treatment effect (immediate vs delayed loading), the linear regression was used. The treatment effect was adjusted for baseline values, age, sex, examination center, jaw, and jaw classification, and the covariance matrix was corrected for heteroscedasticity using Efron’s sandwich estimator for small sample sizes.\textsuperscript{25} Continuous variables (age, baseline values) were modeled by restricted cubic splines with three knots (Frank E. Harrell Jr.: rms: Regression Modeling Strategies; package version 5.1-2 of R’s version 3.5.1 R Core Team [2018]: R: A Language and Environment for Statistical Computing: R Foundation for Statistical Computing). For the special features of this tertiary outcome, the statistical analysis plan was adapted and finalized in several ways.\textsuperscript{21} First, the mixed model analysis over six joint time points was suspended, and it was preferred to analyze each time point separately because differences between groups were hypothesized after 4 months,\textsuperscript{21} but only temporarily for this outcome. Second, the model was switched from the ordinal logistic regression to the linear regression because the latter is easier to interpret and, contrary to what was expected, the assumptions hold except for slight deviations, which were relaxed using an appropriate sandwich estimator. Third, the adjusted treatment effect was prespecified for the ordinal logistic model\textsuperscript{21} because it is favorable in logistic models “in order to come as close as possible to the clinically most relevant subject-specific measure of treatment effect”\textsuperscript{26}; moreover, it was thought to improve precision by subtracting explained variation in linear models,\textsuperscript{27} which did not hold here. Note that adjusting for treatment centers and baseline values is generally recommended.\textsuperscript{28} However, the unadjusted treatment effect of interest, namely, after 4 months, is also presented because it yields unbiased treatment effects in linear models (but not in ordinal logistic models). Finally, this analysis did not adjust for smoking because this covariate was not expected to explain variance of chewing ability.\textsuperscript{21}

Change in chewing efficiency was tested using Stata’s Wilcoxon matched-pairs signed-rank test (Stata/MP software, release 14.2, Stata Corporation).

**RESULTS**

A total of 88 participants were enrolled (Fig 4). However, the therapy of some patients in one practice was delayed due to the illness of the dentist, and 12 patients had to be excluded. Ultimately, 76 participants (47 women) with 79 study arches (31 maxillae) were allocated. Table 1 shows other group-specific characteristics of the study participants before the intervention. The RPD retainers were either double crowns (n = 52), clasps (n = 10), combinations of double crowns and clasps (n = 15), or precision attachments (n = 2). The majority (> 90%) of the mandibular and maxillary RPDs had an open design at the teeth without any coverage of the surrounding soft tissue by the denture base. All RPDs were fabricated or optimized well with proper fit, occlusal harmony, and adequate vertical dimension by using custom-made trays for the impressions, relining of older RPDs, and occlusal adjustment. The patients were accustomed to the RPDs for at least 2 months after fabrication or optimization. The opposing arches showed either complete dentures (n = 10), RPDs (n = 49), fixed dental prostheses (n = 18), or a natural dentition (n = 2) with several numbers of remaining teeth. Figure 5 shows the distribution of the mini-implants on the tooth sites, and Table 2 shows the number of placed implants per arch.

In the study arches of group A, the housings in six participants were picked up immediately after implant placement (insertion torque ≥ 35 Ncm of all mini-implants). The remaining RPDs of 32 participants in group A were primarily soft relined, and the housings were picked up after 4 months just like the 39 RPDs in group B (Fig 4). After 4.5 months, one loss to follow-up in group A and two losses in group B occurred. Some participants (at T\textsubscript{1} and at T\textsubscript{2}, two each in both groups; at T\textsubscript{3}, three in group A and four in group B; at T\textsubscript{4}, one in group A) did not attend all the follow-up appointments. Additionally, five chewing gum specimens in group B (one each at T\textsubscript{1}, T\textsubscript{1}, T\textsubscript{4}, and two at T\textsubscript{2}) were not evaluable. The missing data were not imputed in the analysis.

The agreement between the repeated image analyses of the same specimen at the interval of 2 days yielded excellent values for the 287 gum specimens (ICC = 0.9998; 95% CI: 0.9997 to 0.9998).

Comparing the VOH values between groups at all follow-up times, one relevant effect of the loading time was observed 4 months after surgery at T\textsubscript{2} (Table 3). After adjustment for other variables (baseline values, sex, age, examination center, jaw, and jaw class), the color mixing ability of the chewing gum was better in group A (immediate loading) than in group B (delayed loading). The unadjusted difference between groups was 0.19 (95% CI: 0.12 to 0.26; P < .0001), and the difference
adjusted for centers and baseline values was 0.19 (95% CI: 0.11 to 0.27; \( P < .0001 \)).

Starting at 4 months after implant placement (T2), the chewing efficiency in group A was better at all follow-up times than before the intervention (Fig 6). Considering the two immediate loading approaches separately, a slight increase of the mixing ability after 2 weeks (T1) among the participants who received the housings immediately was detected, but there was a relevant decrease among the participants with soft relined RPDs (Fig 7).

In group B, there was a substantial deterioration in the mixing ability after 2 weeks (T1) that remained up to 4 months (T2) compared with the initial values (T–1). Shortly after the housing pickup at T3 (4.5 months after intervention), the mixing ability improved promptly up to VOH values after 1 year (T4), which were very similar to the values in group A (Fig 5).

**DISCUSSION**

As hypothesized, the chewing efficiency improved faster after immediate loading (group A) than after delayed loading of strategic mini-implants (group B). In group B, the masticatory function was notably
deteriorated after the RPDs were hollowed over the ball abutments. However, immediately after all housings were picked up, the chewing efficiency of the participants was substantially improved in both groups, and there were no differences between groups after 1 year.

Some issues in this study merit consideration. First, two different approaches were used in group A according to the manufacturer’s recommendation. The housings were only picked up immediately if the insertion torques of all implants were at least 35 Ncm; otherwise, the mini-implants were initially loaded by the soft relining material, and the housing pickup was done after 4 months. In a recent article on mini-implant mandibular overdentures, this principle was denoted as two-step loading. Immediate loading of mini-implants by the housings is a successful approach for mandibular overdentures, but it may lead to more implant failures and more bone resorption in maxillary overdentures. In a randomized study on four mandibular mini-implants, the overdentures of group 1 were hollowed over the ball abutments for 14 days and then soft relined for 2 months before the housings were picked up. In group 2, the mini-implants were immediately loaded by the housings. The mini-implants of group 1 had a higher survival rate than those of group 2. Thus, the present study chose the two-step immediate loading approach for the purpose of progressive bone loading in case of poorer bone quality and lower insertion torque, similar to a study on edentulous arches. In this retrospective study, the 4-year survival rates of mini-implants for overdenture stabilization showed only negligible differences between arches (94.3% in the maxilla and 95.7% in the mandible, respectively).

Whether this treatment method will be successful remains to be seen at the end of the analyses of all data when the study is completed.

Second, the mixing ability test of a two-colored chewing gum assesses only one aspect of the complex chewing behavior. The participants were asked to chew successively 10 cycles each on both sides. Individual compensation strategies may lead to better chewing efficiency up to swallowing, eg, preferred chewing sites or increases in chewing time or in cycles.

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**Table 1** Baseline Characteristics of the Study Participants by Group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Immediate loading</th>
<th>Delayed loading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Age (y)</td>
<td>66.4 (58.0–74.6)</td>
<td>65.4 (56.9–72.5)</td>
</tr>
<tr>
<td>Women</td>
<td>22 (58%)</td>
<td>25 (66%)</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>22 (58%)</td>
<td>14 (37%)</td>
</tr>
<tr>
<td>Ex</td>
<td>7 (18%)</td>
<td>15 (39%)</td>
</tr>
<tr>
<td>Current</td>
<td>8 (21%)</td>
<td>7 (18%)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (3%)</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 10 y</td>
<td>18 (47%)</td>
<td>16 (42%)</td>
</tr>
<tr>
<td>10 y</td>
<td>9 (24%)</td>
<td>17 (45%)</td>
</tr>
<tr>
<td>&gt; 10 y</td>
<td>10 (26%)</td>
<td>5 (13%)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Jaw level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>40</td>
<td>39</td>
</tr>
<tr>
<td>Age (y)</td>
<td>66.4 (57.0–74.8)</td>
<td>64.8 (56.9–72.5)</td>
</tr>
<tr>
<td>Women</td>
<td>23 (58%)</td>
<td>25 (64%)</td>
</tr>
<tr>
<td>Maxilla</td>
<td>15 (38%)</td>
<td>16 (41%)</td>
</tr>
</tbody>
</table>

**Jaw classification**

| Class 0 | 16 (40%) | 19 (49%) |
| Class 1 | 15 (38%) | 13 (33%) |
| Class 2 | 7 (18%)  | 5 (13%)  |
| Class 3 | 2 (5%)   | 2 (5%)   |

**Table 2** Number of Placed Mini-implants Per Arch

<table>
<thead>
<tr>
<th>Implant no. per arch</th>
<th>Maxilla</th>
<th>Mandible</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
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<td>3</td>
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<td>4</td>
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<td>19</td>
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<tr>
<td>5</td>
<td>7</td>
<td>23</td>
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</tr>
<tr>
<td>6</td>
<td>3</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>100</td>
<td>48</td>
</tr>
</tbody>
</table>
However, the chewing gum test including the software for quantification is a simple and precise method to evaluate chewing deficiencies.22,23 The test method is adequately validated,34 and its reliability was extensively approved.24

Third, although the RPDs of the study arches showed various retainers, the tooth and mini-implant distributions for the anchorage were comparable. The variety of opposing dentitions (complete dentures, RPDs, or fixed dental prostheses, no prostheses) was not considered since the power for statistical subgroup analyses was too weak. This variability in the occlusal scheme is a clear limitation.

The strengths of the study are the multicenter design with the involvement of a dental school and three dental offices. All examinations were performed by one trained dentist not involved in the treatment. Both the statistician and the operator who performed the colorimetric evaluation were blinded to the study groups.

To the best of the authors’ knowledge, this is the first prospective study evaluating mini-implants with a diameter of < 2.5 mm for this indication. In a recent randomized trial on immediately loaded implants for the distal support of free-end RPDs, one-piece implants with a diameter of 3.0 mm were compared.
with two-piece standard implants with a diameter of 3.75 mm. According to the definition, mini-implants should have a diameter of < 3 mm. Therefore, the implants used in the aforementioned trial should rather be assigned to the group of narrow-diameter implants.

Two weeks after surgery, participants with soft relined RPDs seemed to not be able to chew as efficiently as the six participants who received the housings immediately. After 4 months (just before housing pickup), participants with soft relined RPDs showed a remarkable improvement of chewing efficiency compared with the time before surgery. The housings can provide better retention and stability for the RPD than the soft relining material. The participants with soft relined RPDs obviously had a longer settling-in period than 2 weeks. It could even be that the improvement of the chewing efficiency in participants with soft relined RPDs occurred faster than after 4 months.

The decrease of chewing efficiency up to the housing pickup in group B was probably due to the reduced contact surface at the hollowed RPD site, and as a consequence, the RPD lost stability. The rapid increase of the chewing performance shortly after housing pickup impressively showed the effect of the supplementary support and retention due to the mini-implant housings.

In a few studies, similar improvements of the masticatory performance were demonstrated after the insertion of strategic standard-diameter implants. In previous studies, artificial (silicone cubes) and natural (peeled almonds, peanuts) test foods were used. Either the chewing cycles/time up to ready for swallowing were quantified or the number of chewing cycles was predefined. The test food was sieved, and the proportion between different particles sizes was assessed. The implants of two studies were placed in molar sites to provide distal support for free-end RPDs; ie, all anterior teeth including canines were present. In the third study, the distribution of the remaining teeth was similar to the present study, and the implants were placed both in the anterior and posterior areas including some molar implants. There were no differences in the particle size of the test food (almonds) before and after therapy. However, the number of chewing cycles and the chewing time until the participants were ready to swallow were markedly reduced. Additionally, questions with visual analog scales regarding the chewing ability of soft and hard foods confirmed the positive findings.

In the present study, most of the retainers on natural abutments were double crowns. The combination with implant-supported ball attachments is a simple and inexpensive solution since the housings can be easily incorporated under an existing RPD and compensate axial divergences between natural abutments and implants. The chewing ability would probably be better if supplementary implants provide the same rigid support by using double crowns. However, this would only be possible if two-piece standard implants are utilized, and beyond that, it would be a high-cost solution.

**CONCLUSIONS**

Within the limitations of this study, it can be concluded that the chewing function can be improved by inserting supplementary mini-implants under existing RPDs with unfavorable tooth support. This improvement occurred faster through immediate loading than by delayed loading of the implant ball attachments. Longer studies of this kind are needed.

**ACKNOWLEDGMENTS**

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