In-vivo and In-vitro Studies for Analysis of Mastication in Complete Denture Wearers with Resilient Denture Liners

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Abstract
Purpose: This study aimed to comprehensively evaluate mastication in individuals wearing dentures with permanent resilient liners. Materials and Methods: Of the 53 patients who were randomly allocated into two groups, 26 and 27 patients received mandibular complete dentures with an acrylic resilient liner (ARL) and conventional acrylic resin (CAR), respectively; 24 patients who had previously received mandibular complete dentures with a silicone resilient liner (SRL) served as a historical control. Mandibular movement during mastication was analyzed in 12, 10, and 10 age- and gender-matched subjects selected from the SRL, ARL, and CAR groups. Dynamic viscoelasticity and Shore A hardness tests were carried out to verify the relationship between the clinical trial findings and the mechanical properties of SRL, ARL, and CAR. Results: The masticatory performance of the SRL group was significantly higher than that of the ARL and CAR groups. Compared to the CAR and ARL groups, the SRL group showed longer occluding time in the initial, middle, and final phases. There were no significant differences in the maximum bite force among the three groups. The tanδ value of ARL was higher than those of SRL and CAR. The shear storage modulus G’ and shear loss modulus G” of CAR were higher than those of ARL and SRL. The hardness value of ARL was significantly greater than that of SRL. Conclusion: The prolonged occluding time due to the softness of resilient denture materials may improve the masticatory performance of complete denture wearers.

Keywords:
complete denture, resilient denture liner, mastication, dynamic viscoelasticity test, shore a hardness test

Introduction
The elderly population in Japan has been rapidly increasing (1), and this may lead to an increasing number of edentulous people who encounter difficulties in eating their daily meals due to atrophic mandibles. In general, the alveolar ridges in elderly people are often highly absorbed, and the oral mucosa that covers the ridge is occasionally thin with reduced resilience (2). Unfortunately, the inherent characteristics of the alveolar ridge mucosa that play a role in supporting complete dentures do not change in edentulous people. Currently, however, two treatment modalities can be employed to manage acquired chronic disorders in these edentulous patients with atrophic and thin mucosa without changing the inherent characteristics of their alveolar ridge mucosa. The first modality is treatment with implants, and the second is treatment with permanent resilient denture liners (RDLs). Despite the excellent advantages of implant treatment as compared to conventional complete dentures, implant treatment is not a viable solution for all edentulous patients due to medical, psychological, or economical constraints. On the other hand, treatments with permanent RDLs impose fewer restrictions on edentulous patients. Evidence regarding the advantages of implant denture treatment is available (3, 4), whereas that regarding the advantages of
RDLs is limited despite the introduction of RDLs in the clinical setting.

Based on these facts, Investigation was started on the manner in which an RDL is effective for complete denture treatments. Previously, Kimoto et al had carried out a randomized controlled trial that focused on the silicone type of permanent resilient liner (SRL) (5–8). This trial revealed that subjects wearing complete dentures with the SRL have greater masticatory performance as compared to those wearing dentures with conventional acrylic resin (CAR), and that the patients preferred complete dentures with the SRL to those with CAR. Following this, a new trial that focused on the acrylic type of permanent resilient liner (ARL) commenced in 2003. The outcome measures, namely, masticatory performance and jaw movement, were identical to those used in the previous study. Therefore, the author could comprehensively analyze the effects of RDLs, including those of typical RDL materials, on mastication.

In the current report, the author discusses the in-vivo findings of two clinical trials in order to present the clinical effects of RDLs on mastication in complete denture wearers by comparing the masticatory performances and jaw movements among the SRL, ARL, and CAR groups. Additionally, the author discusses an in-vitro study that was carried out in order to reveal the mechanical properties of the liners that influence the masticatory performances and jaw movements as well as to explain the clinical effects of RDLs on mastication on the basis of these mechanical properties. The identification of a mechanical property that can adequately explain the clinical effects of the liners on mastication would be valuable. This is because if this identified property can adequately explain the reason for the material-dependent variation in the occluding time, we can fabricate RDLs that will improve mastication in complete denture wearers.

The null hypothesis of this case was as follows: There are no differences in the masticatory performances, mandibular movement, and maximum bite force among the SRL, ARL, and CAR groups as well as in the mechanical property among the SRL, ARL, and CAR.

This study aimed to comprehensively evaluate the difference in clinical effectiveness between ARLs and SRLs applied to mandibular complete dentures by verifying the null hypothesis mentioned above.

**Materials and Methods**

**In-vivo study**

*Study population*

Study 1

Three subject groups were formed for the measurement of masticatory performance. Of the 53 subjects who were randomly allocated into two groups, 26 received mandibular complete dentures with ARLs (the ARL group; Physio Soft Rebase (PSR), Nissin, Kyoto) and 27 received mandibular complete dentures with CAR (the CAR group; Physio Resin (PR), Nissin, Kyoto). The historical controls were 24 patients who had received mandibular complete dentures with SRLs (the SRL group; Tokuyama Soft Relining MS (SL), Tokuyama, Tokyo, Japan) in the previous study (8). All maxillary complete dentures were fabricated using conventional heat-activated acrylic denture resin. Edentulous patients willing to undergo new complete denture treatments at the hospital affiliated to the Nihon University School of Dentistry at Matsudo, Chiba, Japan, were selected as study subjects. The exclusion criteria were as follows: (1) systemic or neurologic disease, (2) lack of an understanding of written or spoken Japanese, and (3) a lapse of less than 2 years since the final tooth extraction. Written informed consent was secured from all the subjects prior to their enrollment. The protocol of this study was reviewed and approved by the Human Ethics Committee at Nihon University School of Dentistry at Matsudo (Issue # EC01-001 and 02-036).

Study 2

A total of 10, 10, and 12 subjects were selected from the SRL, ARL, and CAR groups of study 1, respectively, for the analysis of their mandibular movement during mastication and maximum bite force mea-
measurements; these subjects were matched for gender and age.

**Treatment protocol**

Preliminary impressions were acquired using stock edentulous trays (DENTCRAFT StO-K TRAY, Yoshida, Tokyo, Japan) and irreversible hydrocolloid impression materials (Algiace Z, DENTSPLY-Sankin, Tokyo, Japan). Border molding was carried out using custom trays and a stick modeling compound (Peri Compound, GC, Tokyo, Japan). Next, wash impressions with a polyether impression material (Impregum™ F, 3M Espe, Germany) were obtained. Wax occlusal rims and a zinc oxide bite registration paste (Superbite Paste, Harry J. Bosworth, IL, USA) were used for jaw relation records. For the wax try-in, after verifying the vertical dimensions of the occlusion and centric relation records, the esthetics of the teeth arrangement was checked using a full-contour wax trial denture. The dentures were delivered after processing. Post-insertion appointments for adjustments were scheduled repeatedly until the patients were comfortable and free from tissue irritation.

**Laboratory protocol**

The CAR groups’ mandibular dentures and all groups’ maxillary complete dentures were fabricated only with PR. However, the ARL and SRL dentures were fabricated with PR and 2 mm thick PSR or SL, respectively. Conventional dough–stage heat-activated acrylic denture base resin was packed against the master cast and covered with a 2-mm thick spacer, according to the manufacturer’s instructions. After removing the spacer, the resilient lining material in the dough stage was inserted to replace the spacer. The flask was then packed and processed. The curing cycle for the prostheses was 90 min at 70°C, followed by 30 min at 100°C.

**Baseline measurements**

The data of the baseline characteristics of age, gender, edentulous period, and height of the alveolar ridge were collected by an assessor.

**Main outcome measurements**

**Masticatory performance**

Masticatory performance was measured using the sieving method under the following condition. The subjects were instructed to chew 3 g of peanuts 20 times on the preferred side. The chewed material was sieved using a 10–mesh screen, collected on filter paper, and dried (9).

**Mandibular movement**

The mandibular movement at the lower incisal point during chewing was recorded using the BioPak system (Bioresearch Inc., Milwaukee, WI, USA). The magnet was attached to the artificial mandibular central incisors of the complete denture by using an autopolymerizing acrylic resin. The long axis of the magnet was set parallel to the horizontal plane to permit sliding contact of the mandible in every direction. The sensor carrying the head frame of the BioPak system was centered for each subject according to the magnet’s location and oriented to the Frankfort horizontal plane.

The subjects sat comfortably with the Frankfort plane almost parallel to the ground. They were requested to chew peanuts (1 g) on the preferred side, and measurements were performed; this step was repeated three times (10). During chewing, the mandibular movements were recorded. Total chewing strokes were divided into three phase times; initial, middle, and final. From among these phase times, five consecutive stable strokes were selected to calculate the mean and standard deviation. The parameters for the mandibular movements, such as the opening phase time, closing phase time, occluding phase time, and complete time defined as the cycle time, were analyzed using the BioPak software program (Bioresearch Inc., Milwaukee, WI, USA).

**Maximum bite force measurements**

The system used for measuring the bite force comprised pressure-sensitive sheet and an analyzing computer (DENTAL PRESCALE and OCCLUZER FPD707, respectively, Fuji Photo Film Co., Tokyo, Japan). The subjects were instructed to bite the
pressure-sensitive sheet with maximum biting force in their intercuspal position. The computer analyzed the area and density of each impression from the digital image of the dental arch on the sheet. The measurements were repeated three times, and the mean and standard deviation were then calculated.

**In–vitro study**

*Preparation of specimens*

The silicone disk-shaped pattern for the dynamic viscoelasticity test and the square-shaped pattern for hardness measurement were invested in a conventional dental flask. The space created after the removal of the patterns was filled with the denture material of each type. CAR and ARL were cured at 70 °C for 90 min, followed by 100 °C for 30 min in the dental flask, while SRL was autopolymerized at room temperature for 20 min in the dental flask. All the specimens were polished until smooth by using emery paper (#600). The specimens were stored in distilled water at 25 °C for 10 days.

*Dynamic viscoelasticity test*

The dynamic viscoelasticity of five specimens (thickness, 1 mm; length, 4 mm; and width, 2 mm) of each material were measured using a viscoelastic spectrometer (Biomechanical Spectrometer DDV–VMF, Orientec Co., Tokyo, Japan) set at a frequency of 1 Hz based on the chewing cycle assessed using the data of jaw movements.

*Shore A hardness test*

The hardness of six specimens (thickness, 6 mm; length, 25 mm; and width, 25 mm) of each material was measured using a tester (Shore A Dukometer, Nishi Tokyo Seimitsu Co., Tokyo, Japan). While measuring, a probe is pressed against the surface of the specimen and held in position for a few seconds until a reading is obtained.

*Statistical analysis*

The participants’ baseline characteristics were compared among the CAR, ARL, and SRL groups by using one-way ANOVA and the \( \chi^2 \) test. The masticatory performance and maximum bite force were compared among the three groups by using one–way ANOVA and Bonferroni multiple comparison post-hoc tests. The values of the dynamic viscoelasticity test and the hardness test among these groups were also compared in the same way. Their mandibular movements were compared using repeated measure ANOVA and Bonferroni multiple comparison post-hoc tests. All statistical analyses were performed on a personal computer by using the statistical package Dr. SPSS II for Windows (SPSS, Chicago, IL, USA).

**Results**

*Subjects*

**Study 1**

Fig. 1 shows the participant flow. Of the 53 randomized subjects, 27 were allocated to the CAR group and 26 to the ARL group. Prior to the evaluation of the outcomes, 3 and 2 subjects from the CAR and ARL groups, respectively, withdrew from the trial. Table 1 shows the baseline characteristics of the 72 subjects, including those of the 24 subjects in the SRL group who served as historical controls. No significant differences were observed in any of the baseline characteristics among the ARL, SRL, and CAR groups (p>0.05, one–way ANOVA and \( \chi^2 \) test).

**Study 2**

Table 1 also shows the characteristics of the 32 age– and gender-matched subjects. No significant differences were observed in any of the baseline characteristics between the RDL and CAR groups (p>0.05, one–way ANOVA and \( \chi^2 \) test).

*Masticatory performance*

The SRL group showed significantly higher masticatory performance as compared to the ARL group (Fig. 2, p<0.01, one–way ANOVA and Bonferroni multiple comparison post-hoc tests). However, there was no significant difference in the masticatory performance between the ARL and CAR groups (Fig. 2, p>0.05, one–way ANOVA and Bonferroni multiple comparison post-hoc tests).
Fig. 1. Flowchart of the clinical trial. CAR: Conventional Acrylic Resin. ARL: Acrylic type of permanent Resilient Liner. SRL: Silicone type of permanent Resilient Liner

Table 1. Baseline characteristics of subjects

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th>Study 2</th>
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<tbody>
<tr>
<td></td>
<td>SRL (n=24)</td>
<td>ARL (n=24)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>69.9 (7.0)</td>
<td>73.5 (6.8)</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>12/12</td>
<td>13/11</td>
</tr>
<tr>
<td>Edentulous period (years)</td>
<td>12.1 (8.3)</td>
<td>15.3 (9.3)</td>
</tr>
<tr>
<td>Height of alveolar ridge (mm)</td>
<td>18.3 (4.4)</td>
<td>19.3 (6.2)</td>
</tr>
</tbody>
</table>

CAR: Conventional Acrylic Resin, ARL: Acrylic type of permanent Resilient Liner, SRL: Silicone type of permanent Resilient Liner.

There were no significant difference among SRL, ARL and CAR group (p>0.05)
Masticatory movement

The occluding phase time in the initial, middle, and final phases for the SRL group was significantly greater as compared to the ARL group. (Table 2, p<0.05, repeated measure ANOVA and Bonferroni multiple comparison post-hoc tests). However, there was no significant difference in the occluding phase time of the all phases between the ARL and CAR groups (Table 2, p>0.05, repeated measure ANOVA and Bonferroni multiple comparison post-hoc tests).

Maximum bite force

The maximum bite force was 246.2±117.1 (N) for the SRL group, 266.8±146.3 (N) for the ARL group, and 243±123.2 (N) for the CAR group. There were no significant differences in the maximum bite force among the three groups (p>0.05, one-way ANOVA and Bonferroni multiple comparison post-hoc tests).

Dynamic viscoelasticity test

The tanδ of ARL was higher than those of SRL and CAR. The shear storage modulus G’ and shear loss modulus G” of CAR were higher than the respective values of ARL and SRL (Fig. 3, p<0.01, one-way ANOVA and Bonferroni multiple comparison post-hoc tests). This implied that SRL is softer than ARL.

Shore A hardness test

The hardness value of ARL was significantly greater than that of SRL (Fig. 4, p<0.01, one-way ANOVA and Bonferroni multiple comparison post-hoc tests). This implied that SRL is softer than ARL.

Discussion

The aim of this study was to verify the effect of three complete denture treatments with the SRL, ARL, and CAR via two randomized clinical trials that focused on masticatory performances and jaw movements as outcome measures. In order to identify the parameter controlling masticatory performance, the mechanical properties of the RDLs were inves-
Shear storage modulus $G'$  

Shear loss modulus $G''$

Loss tangent $\tan \delta$

CAR: Conventional Acrylic Resin. ARL: Acrylic type of permanent Resilient Liner. SRL: Silicone type of permanent Resilient Liner. **represents significant difference ($p<0.01$)

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Fig. 4. Shore A Hardness. CAR: Conventional Acrylic Resin. ARL: Acrylic type of permanent Resilient Liner. SRL: Silicone type of permanent Resilient Liner. **represents significant difference ($p<0.01$)

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Bates et al. reported that complete denture wearers generally show improved masticatory performance with time due to acclimatization to new dentures (11). Further, the RCT study by So and Kimoto et al. that compared SRL and CAR also have indicated that the gradual adaptation after the delivery of dentures influences the improvement in masticatory performance (5-8). Thus, in the current study, the outcomes were measured at 2 months following the patients’ final adjustment in order to ensure a valid outcome. Although the result showed no difference in the maximum occlusal force among the three groups, the occluding time during the mandibular incisal movement was significantly prolonged in the SRL group as compared to that in the ARL and CAR groups.

The three groups (the SRL, ARL, and CAR) did not influence the maximum occlusal force. The feedback is controlled the mechanism that gums and mucosal recepters, are responded, due to the occulsive force exerted by the denture (12, 13), and it is not influenced by periodontal receptors (14). Kawano et al. reported that rotation in the lingual direction and displacement of the denture increases when the RDL denture that is extended to denture border, was loaded. As a result, the bone under the denture is subjected to increased stress intensity since the thickness of the RDL diminishes (15, 16). In the current study, dentures with SRL and ARL were fabricated by extending to denture border, as mentioned above. Consequently, the dentures with SRL and ARL are easily deformed, and this deformation increases the force against the alveolar ridge. Finally, this exces-
sive stress may stimulate mechanoreceptors on the alveolar ridge and may prevent subjects from biting with greater force. It is considered that CAR directly transmits occluding pressure against the mucosa, thus producing direct feedback.

SRL significantly increased the masticatory performance and prolonged occluding phase time. In general, humans can masticate foods most effectively when the clearance between the upper and lower molars is within 2 mm. This clearance is related to the extension in occluding time (17). It is also reported that clenching intensity increases at the intercuspal position (18). These findings suggest that the masticatory performance may strongly correlate with the occluding phase time.

The author considered that deformation of the lining materials may be the factor increasing the masticatory performance and prolonging the occluding phase time. In the dynamic viscoelasticity test, the $G'$, $G''$, and tan$\delta$ values of SRL were significantly lower than those of ARL; the low $G'$ and $G''$ values indicate low storage and loss of energy against dynamic stimulation. The low tan$\delta$ value indicates low viscous component and impact absorptivity. Thus, SRL is considered to be instantly deformed and hence shows the property of rubber elasticity. The Shore A test also reveals that SRL has deformation tendency.

Murata et al suggested that ideally, the RDLs should exhibit elastic behavior against the masticatory force in order to transmit the energy required for food comminution and should have a viscous component in order to distribute the force, absorb energy, and prevent force transmission to the denture-bearing tissue (19). Clinically, the obtained result can be considered to indicate that the high rubber elasticity of SRL effectively comminutes food.

The result of the dynamic viscoelasticity test revealed that ARL showed a higher tan$\delta$ value than SRL, indicating a high viscous component. A high tan$\delta$ value is considered to be indicative of an effective release of mucosal stimulation and pain. However, the masticatory values and occluding phase time of ARL are approximately that the same as those of CAR. This suggested that the high viscous component of ARL has limited influence on the masticatory value and occluding phase time.

In the current study, the clinical outcomes were measured at 2 months following the patients’ final adjustment. The viscoelasticity of the ARL dentures may change with time (20–22). Murata et al reported that the continual deterioration of ARL is caused by the leaching of the plasticizing agent into the saliva and water sorption from the saliva (23). This phenomenon resulted in the high tan$\delta$ value, which indicates an increase in the viscous component. In addition, it is difficult to maintain a constant thickness for ARL due to their higher creep behavior when compared to SRLs; these results in a lower stress distribution effect by the occlusal force derived from mastication (24). These above mentioned factors resulted in similar masticatory performances and occluding times in subjects with the ALR and CAR dentures; thus, there was no improvement in mastication between ALR and CAR denture wearers.

Wilson et al suggest the difficulty to propose the clinical success of RDLs from mechanical characters (25). Holt et al also suggest that the suitability of RDLs cannot be decided on the basis of a single parameter (26). The treatment effect of RDLs was influenced by various factors in clinical settings. However, the current study clarified that the elastic component is more important than the viscous component. Permanent resilient liners are considered as one of the parameters indicative of clinical significance.

Conclusion

The SRL group showed significantly high masticatory values and a prolonged occluding phase time. This indicates the association between the masticatory performance and occluding phase time. Further, dynamic viscoelasticity was considered as a parameter that could be used to assess the increase in masticatory performance and occluding phase time of RDLs.
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