Effect of intervention with silicone-based resilient denture liners on masticatory function of complete denture wearers

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I. Abstract

Introduction

The number of elderly adults in Japan is increasing and making it one of the oldest countries in the world. With the increasing incidence of tooth loss in the population, there is a growing demand for dentures. According to a survey on dental diseases conducted by the Ministry of Health, Labor and Welfare, the number of denture wearers increases with age.

As tooth loss progress, a complete denture is used for full edentulousness, their masticatory function is significantly lower than that of dentate individuals. The decline in masticatory function may have an impact on malnutrition. Therefore, to improve masticatory function in edentulous individuals are an essential issue.

One way to achieve a significant improvement in masticatory function is the application of a resilient denture liner to complete dentures. Several outcomes have reported the positive effects of resilient denture liner on masticatory function. However, those reports are limited to a few results, such as the sieving method using peanuts and maximum occlusal force. To the best of our knowledge, no test foods with physical properties other than peanuts or food intake in the daily diet have been used as an outcome in edentulous patients with silicone-based resilient denture liners (RD).

This study aimed to measure and compare masticatory performance and maximum occlusal force with gummy jelly, an objective evaluation by randomized controlled trial (Research I). The next objective of the study was to determine the effect of elastic denture liners on mandibular complete dentures on subjective masticatory function using patient-reported chewing ability (Research II).

Materials and methods (Research I / II)

Participants': The trial included edentulous patients who were willing to have a new set of complete dentures. Participants were randomly assigned to receive mandibular complete dentures with either a conventional denture base (CD group) or silicone-based resilient denture liner (RD group).

Outcome measurement: In Research I, masticatory performance (evaluated with gummy jelly) and the maximum occlusal force were measured at baseline, on final adjustment, and at three months after the final adjustment. Gummy jelly (GLUCOLUMN, GC, Tokyo, Japan) and the glucose-measuring

device (GLUCO SENSOR GS-II, GC, Tokyo, Japan) were used for the masticatory performance measurement. An electronic recording device (Occlusal Force-Meter GM10s, Nagano Keiki, Tokyo, Japan) was used to determine the maximum occlusal force between the upper and lower first molars. The measurement was performed thrice on both sides, and the mean value was used for the analysis. The outcomes were analyzed using two-way analysis of variance (two-way ANOVA), Bonferroni's multiple comparison test and a paired t-test. The statistical significance was set at $p < 0.05$. In Research II, the patient-reported chewing ability of six foods, soybean curd, fish sausage, soybean sprouts, cubic rice cracker, hard rice cracker, and dry squid, on a 100mm visual analog scale were measured and reported at baseline　the final adjustment and three months after the final adjustment. The outcomes were analyzed using Mann-Whitney U test ($p < 0.05$).

Results and discussion (Research I / II)

The masticatory performance was lower in the RD group than in the CD group at three months after the final adjustment; it increased significantly over time in the CD group, but not in the RD group. The maximum occlusal force in the RD group was significantly higher than that in the CD group at three months after the final adjustment; it increased significantly over time in the RD group, but not in the CD group.

Edentulous patients wearing mandibular complete denture with RD had a higher patient-reported chewing ability than those wearing a CD, but the fish sausage did not in the RD three months after the final adjustment. It also took three months for the patient-reported masticatory ability to improve for cubic rice crackers, hard rice crackers, and dry squid, and to show a difference between the RD and CD groups.

Conclusion

Silicone-based RD liners applied to mandibular complete dentures are effective in improving the maximum occlusal force but not the masticatory performance, as measured with gummy jelly. Although limited to some food types, mandibular complete dentures relined with silicone-based liners improved patient-reported chewing ability.

II. Introduction

Japan is one of the countries with the oldest population in the world. The statistical handbook of Japan (published by the Statistical Bureau, Ministry of Internal Affairs and Communications, in 2019) showed that the number of people aged 65 years or older was 35.88 million, constituting 28.4 % of the total population [1]. With the increasing incidence of tooth loss in the population, there is a growing demand for dentures. According to a survey on dental diseases conducted by the Ministry of Health, Labor and Welfare, the number of denture wearers increases with age [2].

As tooth loss progress, a complete denture is used for full edentulousness. However, their masticatory function is significantly lower than that of dentate individuals, and it is presumed that the average number of masticatory function is less than one-sixth of dentate individuals [3]. The decline in masticatory function is closely related to the nutritional status of the elderly in the previous report [4]; which is assumed that malnutrition may be caused by decreased masticatory function. Low nutrition may lead to frailty and sarcopenia in the long-term process [5], and in consequence, it may be related to the healthy life expectancy and quality of life of the elderly [6]. Therefore, to improve masticatory function in edentulous individuals are an essential issue.

One way to achieve a significant improvement in masticatory function is the application of a resilient denture liner to complete dentures [7]. The flexibility, resilience, and shock absorbency of resilient denture liners offer greater versatility for edentulous patients who are facing eating difficulties [8, 9]. Kimoto et al. demonstrated that silicone-based resilient liners improve masticatory performance, as measured by the sieving method using 3 g peanuts for 20 chewing cycles on the preferred chewing side [7]. Several outcomes have been used to evaluate the effectiveness of silicone-based resilient denture liners (RD), including masticatory performance[7, 10, 11], maximum occlusal force[7, 9, 10], muscle activity measured by electromyograms[7, 10, 12], satisfaction rating on chewing measured by 100-mm visual analog scale (VAS)[13], and Oral Health Impact Profile for Edentulous (OHIP-EDENT)[14].

Objective or subjective measures of treatment outcome are often used to assess masticatory function. One of the most widely recognized objective assessments is masticatory performance, which indicates the patient's ability to chew and crush certain types of food during chewing. Methods such as the

sieving method using peanuts [15], silicone [16], paraffin wax [17], color-changeable chewing gum [18], and gummy jelly [19] have been used to evaluate different masticatory processes (e.g., cutting, grinding, and mixing food). In recent years, gummy jelly has been widely used in clinical practice to measure the masticatory function of denture wearers. The other aspect of masticatory function is subjective assessment. A standardized questionnaire [20] is used for subjective assessment. In this way, the patient's perception of his or her oral condition is assessed with respect to the patient-reported chewing ability. Recent studies on the correlation between objective and subjective assessments have yielded different results [21]. Therefore, since masticatory function is closely related to the patient's daily diet, we thought it necessary to evaluate it comprehensively with as many multiple outcomes as the researcher could come up with. To the best of our knowledge, no test foods with physical properties other than peanuts or food intake in the daily diet have been used as an outcome in edentulous patients with silicone RD.

Thus, we conducted a randomized controlled trial to verify the effects of resilient denture liners applied mandibular complete dentures on masticatory function in complete denture wearers compared to a mandibular complete denture with a conventional denture base (CD), using the objective evaluation and subjective evaluation. The initial study to achieve the objective, we planned to measure and compare masticatory performance and maximum occlusal force with gummy jelly, an objective evaluation by randomized controlled trial. (Research I)

The next objective of the study was to determine the effect of elastic denture liners on mandibular complete dentures on subjective masticatory function using patient-reported chewing ability. (Research II)

III. Materials and Methods (Research I / II)

1. Participants'

1） Inclusion criteria

The participants had to be edentulous in both jaws and willing to have a new set of complete dentures.

2） Exclusion criteria

The participants with (1) diabetes mellitus, trigeminal neuralgia, or postherpetic neuralgia; (2) signs and symptoms of orofacial pain disorders; (3) wearing a pacemaker; (4) apparent cognitive

impairment; (5) a lack of understanding of written or spoken Japanese; or (6) a history of mandibular surgery [22] were excluded from the study.

2. Sample size calculation

The samples size was calculated based on the primary outcome, masticatory performance. A between-group difference of 30 mg/dL in the concentration of dissolved glucose was considered a clinically meaningful difference; 28 mg/dL was set as the standard deviation in both the RD and the CD group, based on previously reported data [23]. The calculated sample size required for achieving 80% power with an alpha level of 5% was 15 subjects per group.

3. Sampling, Randomization, allocation concealment and sequence generation

This study was a randomized controlled parallel clinical trial. The participants provided informed consent before the randomization. Participants were recruited consecutively between May 2017 and December 2019. A random permuted block method (block size: 4) was used to ensure that a certain proportion of patients received each treatment [24]. The six possible permutations were numbered as 1, 2, 3, 4, 5, and 6. Then, the allocation numbers were generated using the "RAND functions" in spreadsheet software (Excel, Microsoft Japan Co. Ltd, Tokyo, Japan), and were randomly assigned to either CD or RD. Blinding the participants was not feasible, since they were able to determine the type of denture.

4. Fabrication of intervention and control dentures

Both maxillary and mandibular complete dentures were fabricated by the conventional method. Alginate impression (Algiace-Z®, Dentsply-Sirona, Tokyo, Japan) and a stock tray (Mesh tray-Hayashi®, Dental Supply, Tokyo, Japan) were used for the preliminary impression. The final impression was taken using a custom tray, which was fabricated on the cast obtained from the preliminary impression. The tray was border-molded with impression compound (Peri Compound®, GC Corporation, Tokyo, Japan), followed by a wash impression with silicone impression material (EXADENTURE®, GC Corporation, Tokyo, Japan). After occlusal registration, the cast was mounted onto a semi-adjustable articulator (Hanau H2-Teledyne Water Pik®, Fort Collins, Colorado, USA)

using a facebow record. A fully bilateral balanced articulation occlusal scheme was arranged. Both groups used composite resin artificial teeth (Surpass®, GC, Tokyo, Japan).

After the try-in, occlusal adjustments were performed during maximum intercuspation and lateral excursive and protrusive movements; these were followed by the refinement of occluding surfaces using silicon carbide abrasive materials (Lapping paste®, GC Corporation, Tokyo, Japan). The RDs were invested in the denture flask. After the wax removal, a 2-mm-thick spacer was covered on the working cast. The heat-activated acrylic resin (Urban®, Shofu Dental Corporation, Tokyo, Japan) was packed, and after the final flask closure, polymerization was done at 90 minutes at 70°C, followed by 30 minutes at 100°C. After curing, the spacer was removed, and silicone-based permanent denture liner (Sofreliner MS®, Tokuyama Dental Corporation, Tokyo, Japan) was applied for the "reline". The CDs were polymerized with the same acrylic resin under the same conditions as the RDs.

5. Participants' characteristics

1） Participants' attributes

The participants were asked to provide details pertaining to their age, sex, edentulous period, number of previous dentures, and denture difficulty class at the beginning of the trial.

2） Mucosal thickness

Mucosal thickness under the right and left first molar artificial teeth on mandibular complete denture were measured by a single operator, using an ultrasonic measuring device (Krupp SDM®, Austenal Medizintechnik, Cologne, Germany). Slight pressure was applied to place the device probe perpendicular to and in contact with the measuring point. Each side measurement was performed thrice, and the mean value was calculated as a representative value. The mean of right and left representative values was used in the analysis as a mucosal thickness.

6. Outcomes

1） Masticatory performance

The masticatory performance was set as the primary outcome. The participants were asked to chew a cylindrically shaped (diameter, 15 mm; height, 8 mm) gummy jelly consisting of 40% maltose, 10% sorbitol, and 5% glucose (GLUCOLUMN®, GC, Tokyo, Japan) for 20 seconds on their habitual

chewing side. The subjects then held 10 mL of distilled water in their mouths, which they subsequently expectorated into a cup via a filter. The glucose concentration in the filtrate was measured by a glucose-measuring device (GLUCO SENSOR GS-II®, GC, Tokyo, Japan) to obtain the amount of glucose extraction, which was used as a quantitative parameter of the masticatory performance [25].

2） Maximum occlusal force

The maximum occlusal force was set as the secondary outcome. An electronic recording device (Occlusal Force-Meter GM10s®, Nagano Keiki, Tokyo, Japan) was used to determine the occlusal force between the upper and lower first molars. Normal mastication was performed; after placing food between the teeth, people tend to bite with a strong bite force to crush the food. We selected the occlusal Force-Meter GM10s because we intended to measure the bite force by simulating the mastication performed with a routine diet. The device was a digital force gauge with an 8.6-mm-thick bite element. Participants were instructed to bite down as hard as possible on the force gauge, but to stop clenching at the first sensation of discomfort. A pressure gauge displayed the bite force values in Newton on a digital screen [26]. The measurement was performed thrice on both sides, and the mean value was used for the analysis.

3） Patient-reported chewing ability with a 100 mm visual analog scale

The patient-reported chewing ability was set as the secondary outcome. The patient-reported chewing ability during the mastication of six foods, namely, soybean curd, fish sausage, soybean sprout, cubic rice cracker, hard rice cracker, and dry squid, were measured using the 100-mm VAS [27]. The six foods were selected based on Sato et al.'s study, which evaluated the chewing function of patients with complete denture [28]. The VAS data represented "very easy to chew" (100) at the extreme right and "very difficult to chew" (0) at the extreme left. Data was be recorded as continuous variables by measuring the distance at 1-mm intervals by using calipers, beginning at the extreme left.

7. Schedule for measuring outcomes

The outcomes were measured at baseline, on final completion of denture adjustment (final-adjustment), and at three months recall after final adjustment (three months after the final-adjustment).

If the participants in any of the allocated groups perceived pain when wearing the dentures and/or had difficulties requiring denture adjustment, the dentists treated the participants appropriately.

8. Data analysis

The intention-to-treat principle (ITT) was used for any missing data post-randomization. In Research I, the Kolmogorov-Smirnov test was performed to assess the normality of the outcome variables (i.e., masticatory performance and occlusal bite force). As the results indicated that these variables were normally distributed, parametric tests were used. The differences in the categorical variables between the two groups were analyzed using the chi-square test. The masticatory performance and maximum occlusal force were analyzed using a two-way analysis of variance (ANOVA) to compare the between-subjects factor (intervention [CD group and RD group]) and within-subjects factor (time course in the first 3 months after final adjustment). Bonferroni's multiple comparison test was used to analyze the difference in measurements between the two groups. The paired t-test was performed for an in-depth analysis of the time course in both groups. In Research Ⅱ, the Kolmogorov-Smirnov test assessed the normality of the outcome variables, that is, the patient-reported chewing abilities. As the results indicated that the data were not normally distributed, a non-parametric test, Mann–Whitney U test, was used to analyze the difference in measurements between the two groups. The analysis of the categorical variables between the two groups was carried out with a chi-square test. All statistical analyzes were performed using Statistical software (SPSS Statistics Package v21®, IBM, Armonk, New York, USA). The statistical significance was set at 5%.

IV. Results (Research I / II)

1. Participant flow

Recruitment of participants commenced in May 2017. As shown in Fig.1, 139 patients (aged 36–96) were consecutively sampled for this trial. Among them, 103 were excluded based on the inclusion and exclusion criteria. The remaining 36 individuals (aged 60–90) were included and randomly allocated into either the RD or CD group. Furthermore, two subjects in the RD group and seven subjects in the CD group dropped out and were accounted for in the intention-to-treat analysis. No excess harm was observed in the participants throughout the trial, and the follow-up rate was 75 %.

2. Participant characteristics

There were no significant differences between the participants' characteristics (Table 1).

3. Masticatory performance

The masticatory performance in the RD and CD groups at final adjustment and 3 months later are shown in Fig. 2.

1） Between-subject comparisons

Two-way ANOVA showed that the masticatory performance in the RD group was significantly different from that in the CD group (p = 0.013). The mean masticatory performance in the RD group following final adjustment (102.2 ± 39.9 mg/mL) was lower than that in the CD group (110.5 ± 26.7 mg/mL) by 7.5%, and the results of multiple comparisons with the Bonferroni method showed a no significant difference (p = 1.000). The mean masticatory performance in the RD group 3 months after the final adjustment (112.9 ± 27.4 mg/mL) was lower than that in the CD group (144.4 ± 24.4 mg/mL) by 21.8%, and the results of multiple comparisons with the Bonferroni method showed a significant difference (p = 0.016).

2） Within-subject comparisons

Two-way ANOVA showed that the masticatory performance increased significantly with the follow-up time (p = 0.002). In the RD group, the mean masticatory performance 3-months after the final adjustment was higher than the final adjustment by 10.5%. In the CD group, the mean masticatory performance at 3-months after the final adjustment was significantly different from that at the final adjustment by 30.7% (p = 0.001). The masticatory performance in the RD group showed a 10.5% increase and no significant change over time (p = 0.292).

4. Maximum occlusal force

The maximum occlusal force in the RD and CD groups at the final adjustment and 3-months after the final adjustment are shown in Fig. 3.

1） Between-subject comparison

Two-way ANOVA showed that the maximum occlusal force in the RD group was significantly different from that in the CD group ($p = 0.020$). The mean maximum occlusal force upon the final adjustment in the RD group (78.6 ± 39.7 N) was higher than that in the CD group (64.6 ± 27.3 N) by 21.7%, and the results of multiple comparisons with the Bonferroni method showed a no significant difference ($p = 1.000$). The mean maximum occlusal force 3-months after the final adjustment in the RD group (112.2 ± 60.2 N) was higher than that in the CD group (68.6 ± 13.8 N) by 63.6%, and the results of multiple comparisons with the Bonferroni method showed a significant difference ($p = 0.008$).

2） Within-subject comparison

Two-way ANOVA showed that the maximum occlusal force increased significantly with the follow-up time ($p = 0.002$). An interaction between intervention and time course was observed ($p = 0.012$), indicating that the change in maximum bite force differed over time, depending on the type of intervention (RD or CD). In the RD group, the maximum occlusal force at 3-months after the final adjustment was significantly different from that of the final adjustment by 42.7 % ($p = 0.002$). However, the maximum occlusal force in the CD group showed only a 6.2 % increase and no significant change over time ($p = 0.525$).

5. Patient-reported chewing ability with a 100 mm visual analog scale

Table 2 shows the median values and lower and upper quartile for the respective questions of the patient-reported chewing ability in each group at the final adjustment and three months later. At baseline, the patient-reported chewing ability showed no significant difference ($p > 0.05$) between the RD and CD in all foods. At the final adjustment, significant differences between the RD and CD groups were obtained only with the soybean curd ($p = 0.044$), fish sausage ($p = 0.033$), and soybean sprout ($p = 0.023$). At three months after the final adjustment, significant differences between the RD and CD groups was observed with the soybean curd ($p = 0.019$), soybean sprout ($p = 0.049$), cubic rice cracker ($p = 0.013$), hard rice cracker ($p = 0.020$), and dry squid ($p = 0.049$) were indicated.

V. Discussion

This research investigated the differences in masticatory function, performance (Research I) and patient-reported chewing ability (Research II) between silicone-based resilient denture lining and conventional complete dentures.

Research I demonstrated that silicone-based resilient denture liners improved the maximum occlusal force in patients wearing mandibular complete dentures than the conventional denture base resins but had no positive impact on masticatory performance. This result is different from the results of previous studies [7, 10, 11]. This discrepancy may occur from different masticatory assessment (e.g., cutting food, grinding food, softening of small particles, and mixing of particles with saliva) [29] and test foods (e.g., peanuts, silicone, paraffin wax, color-changeable chewing gum, and gummy jelly) [15-19].

The low masticatory performance in the RD group at three months after the final adjustment could be explained by the usage of gummy jelly, which is utilized for evaluating the degree of cutting food in the initial phase of chewing [30]. Kimoto et al. reported that complete dentures relined with silicone-based resilient denture liners had shown extension at initial and middle phases of the chewing cycle, which are used for cutting foods [7]; this may reflect a low efficiency in cutting food compared to conventional dentures. Additionally, gummy jelly is a food with high elasticity[31]; elastic materials are known to deform when stress is applied, with the strain disappearing upon stress removal, leading to complete product recovery to its original height and shape[32]. Generally, gummy jelly is also a hard material [33]. The elasticity and hardness of the gummy jelly would have led to increased difficulties in cutting foods in the initial phase of the masticatory process among participants, especially in the RD group.

Masticatory performance improved over time in the CD group. This was consistent with the report by Suzuki et al., who utilized gummy jelly to evaluate the masticatory ability of patients with conventional dentures [33]. While the improvement of masticatory performance with time in the RD group was 10.5%, this did not reach statistical significance. This was inconsistent with the findings of a previous report [7] and may be due to the different food samples used. It may be considered that patients wearing complete dentures with resilient denture liners may need more time to adjust to the

mastication of specific foods such as gummy jelly; this remains to be confirmed by studies with longer-term follow-up observation.

The RD group demonstrated a greater mean maximum occlusal force than the CD group at three months after the final adjustment. This finding was supported by Hayakawa et al., who reported that the maximum occlusal force increased after the insertion of a denture with silicone-based resilient denture liner [10]. Denture wearers have only one-sixth to one-fourth of the occlusal force and masticatory performance of a natural dentition [34-36]. Complete denture wearers attain the limit of their occlusal force earlier than individuals with natural dentition; this may be due to pressure from the denture base on the underlying mucosa and the reaching of the pain threshold. In other words, the degree of maximum occlusal force is dependent on the degree of mucosal tolerance to the stress under the denture base. In their simulation study, Yamamoto et al. reported that silicone-based resilient denture liners reduce the maximum stress on the artificial mucosa by almost 16.2% compared to the conventional denture base material used for the CD group in this study [37]. Furthermore, Furokawa et al. showed that edentulous patients wearing mandibular complete dentures with silicone-based resilient denture liners had an increased pain threshold [22]. Thus, the greater maximum occlusal force in the RD group compared to the CD group in the present study may have been attributed to not only the elasticity of the liner (which reduced the stress on the alveolar ridge mucosa), but also to the increased pain threshold (which made the alveolar ridge mucosa more resilient to stress).

The difference in the change of maximum occlusal force between the RD and CD groups was notable. The maximum occlusal force in the RD group improved by 42.7% with the time, while the CD group exhibited little change (6.2%). The maximum occlusal force was measured in the first molar region. As stated previously, the degree of maximum occlusal force dependent on the mucosal tolerance to the stress under the denture base immediately below the first molar region. Furthermore, mucosal anatomy is inherent and unchangeable in the short term. This may explain the lack of change in the maximum occlusal force among participants in the CD group over time. Nevertheless, this did not explain the results in the RD group. Following the final adjustment, a high maximum occlusal force would have been expected to be maintained 3 months later. However, the maximum occlusal force

was low at the final adjustment and increased to higher levels at 3 months after the final adjustment. This may have been explained by the participants' awareness of the effect of resilient denture liners on the mucosa beneath the denture base, and the following sequence of events: (1) in the initial period after the final adjustment, the participants remained skeptical about the shock-absorbing effect of the resilient denture liner; (2) the participants gradually became more aware of the effect of the resilient denture liner, and consequently changed their behaviors; (3) the participants' maximum occlusal force eventually increased 3 months after the final adjustment.

Research II revealed that edentulous patients wearing mandibular complete denture with RD had a higher patient-reported chewing ability than those without RD. There were three patterns of patient-reported chewing ability obtained from VAS for six foods in the RD compared to the CD group as follows: (1) higher at three months after the final adjustment, (2) higher at immediately after final adjustment, and (3) higher at the final adjustment, but with no difference at three months after the final adjustment.

The first pattern was observed in the cubic rice cracker, hard rice cracker, and dry squid. The patient-reported chewing ability obtained from the three foods in the RD group showed higher values than the CD group three months after the final adjustment. Considering three types of foods that were hard and difficult to eat, the reason for superiority in the RD group could be explained by its elasticity. It is well-known that these three foods are very hard to masticate for complete denture wearers [38]. Denture wearers have only one-sixth to one-fourth of the bite force of a natural dentition [3, 36] because they cannot bite more than the pain threshold of the alveolar ridge mucosa. However, in their simulated study, Yamamoto et al. reported that silicone-based RD reduces the maximum stress on the artificial mucosa by almost 16.2 % compared to the CD-based material used for the CD group in this study [37]. This cushioning effect of the RD contributed to the difference in the patient-reported chewing abilities between the RD and CD groups. Furthermore, Furokawa et al. showed that edentulous patients wearing mandibular complete dentures with silicone based RDs had an increased pain threshold[22]. Therefore, the greater patient-reported chewing ability in the RD group compared to the CD group in

the present study may have been attributed to the mixed effect of RD on the alveolar ridge: elasticity of the liner to reduce the stress on the alveolar ridge mucosa and to the increase pain threshold.

Immediately after the final adjustment, the patient-reported chewing ability on the three foods in the RD group was not higher than that in the CD group; that is, the patient-reported chewing ability on the three foods improved only in the RD not in the CD group. Kimoto et al. reported that edentulous patients wearing complete mandibular dentures with RD showed better masticatory performance than that with CD three months after the the denture adjustment; however, this did not show one month after the completion of denture adjustment [7]. Although there was a difference between the subjective and objective evaluations, the differences in the evaluation between the complete denture wearers in the CD and RD groups over time were almost the same. These differences in the patient-reported chewing ability over time might be explained by the fact that edentulous patients in the RD group gradually obtained the necessary skills for mastication by repeating a daily practice of food mastication. Furthermore, we instructed participants to consume soft foods after receiving their new dentures. Therefore, the early period after the new denture adjustment might have been insufficient for the adaptation period to the denture, and the participants could not fully use the viscoelastic properties of the RD.

The second pattern was observed in the soybean curd and soybean sprout. The RD group had a higher patient-reported chewing ability for the soybean curd and soybean sprout than that in the CD group immediately after the final adjustment. The pattern of patient-reported chewing ability from these two foods were inferred to different reasons. It was difficult to say that the reason for the differences between the RD and CD groups could be derived from the cushion effect of the RD on the alveolar ridge to relieve pain, given that soybean curd can easily be chewed, such that participants can squash the pudding with their tongue without pain. Koshino et al. classified the pudding into grade 1 difficulty, pertaining most easily chewed food [38]. The soybean curd is a kind of Japanese pudding. Thus, the results on the patient-reported chewing ability might be derived from participants' feeling of a denture, with or without an RD. Furokawa et al. reported that the psychological discomfort when wearing a denture was significantly lower in the RD group than in the CD group [22]. The emotional effect derived

from silicone-based RD would increase the patient-reported chewing ability on the soybean curd in the RD group and induce the difference of patient-reported chewing ability on the soybean curd between the RD and CD groups. In contrast, soybean sprout is harder than soybean curd; thus, an increased bite force might be necessary to break down the soybean sprout more, compressing the mandibular alveolar ride mucosa and, consequently, inducing pain. In the RD group, the cushioning effect of RD may have improved the patient-reported chewing ability on the soybean sprout.

The third pattern was observed in the fish sausage. Even though the difference was observed for the fish sausage immediately after the final adjustment, the difference was not observed three months after the final adjustment. The fish sausage is made by cooking fish meat with heat, and cooked fish meat increases elasticity. The elasticity of the RD itself and the elastic physical properties of the food may have influenced the patient-reported chewing ability.

The most surprising and unexpected result of Research I and II were that patients in the RD group showed a lower masticatory performance, as measured with gummy jelly, than those in the CD group. To the best of our knowledge, no previous study has reported inferior masticatory performance with silicone-based resilient denture liners compared to conventional denture base material. Prior evidence has suggested that silicone-based resilient denture liners provide either equal or better masticatory function than conventional denture base resins [7, 10, 11]. Also, in Research II, there was no difference between RD and CD groups in patient-reported chewing ability after 3 months for food with high elasticity (fish paste), even though RD was significantly higher in other foods. The results of Research I and II suggest that resilient denture liners may not be sufficiently effective with some foods with high elasticity.

The similarity of the baseline characteristics between the two groups showed the good randomization to contribute the high internal validity of data and the control of any bias to potentially modify the data. However, there were several limitations to this RCT. First, the current study was conducted at a single institution in Japan, which indicates low external validity. Second, it could not be completely blinded because the surgeons were able to recognize the differences between the groups by checking the completed dentures. In addition, a total of nine dropouts were observed, seven in the CD group

and two in the RD group; thus, a complete follow-up could not be performed. Furthermore, clinicians would have clinical questions such as how the chewing ability change with time of resilient liner deterioration and how the acrylic-based resilient denture liners not used in this study affect the chewing ability of patients with complete denture. Considering the limitations and clinical questions, further studies, including multiple research centers in Japan and larger sample sizes, are needed to confirm the results of this study.

VI. Conclusion

From research I and II, silicone-based RD liners applied to mandibular complete dentures effectively improved the maximum occlusal force and patient-reported chewing ability with some food compared to conventional dentures. However, RD liners showed a disadvantage in improving masticatory performance with food with high elasticity.

VII. References

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VIII. Tables and Figures

Table 1. Baseline participants characteristics.

Participants characteristics (n = 33)	CD (n = 17)	RD (n = 16)	*P*-value
Age (years)	73.2 (7.8)	77.7 (7.8)	0.09[a]
Sex (female/male)	8/10	8/10	1.00[b]
Edentulous period (months)	160.1 (96.1)	109.8 (92.5)	0.12[a]
No. of previous dentures			
Maxilla	2 (1.6)	1.9 (1.1)	0.81[a]
Mandible	2 (1.6)	1.9 (1.1)	0.81[a]
Classification of denture difficulty			
(Classes I, II, III, IV: number of participants)	(11,6,1,0)	(10,7,1,0)	0.94[b]
Mucosal thickess (mm)	1.8 (0.6)	2.1 (0.8)	0.29[a]
Masticatory performance (mg/dl)	95.6 (39.4)	79.3 (35.7)	0.20[a]
Maximum occulusal force (N)	54.8 (17.7)	60.8 (38.1)	0.55[a]

a: t-test, b: Chi-squared test

CD: Conventional denture base

RD: Resilient denture liner

Table 2. Median values (lower quartile, upper quartile) of the patient-reported chewing ability with a 100 mm visual analog scale in the RD group and CD group.

	Base line			Final-adjustmen			Three months after the final-adjustment		
	CD (n = 18)	RD (n = 18)	*P*-value	CD (n = 18)	RD (n = 18)	*P*-value	CD (n = 18)	RD (n = 18)	*P*-value
Soybean curd	93 (87.5-100)	92 (87.5-100)	0.744	93 (92.8-100)	100 (97-100)	0.044*	94 (94-100)	100 (99.5-100)	0.019*
Fish sausage	86 (77-100)	74 (50-100)	0.221	89 (89-100)	100 (92-100)	0.033*	93 (93-100)	100 (92.8-100)	0.146
Soybean sprout	70 (49.8-83.5)	79 (54.3-100)	0.179	90 (89-100)	100 (94.8-100)	0.023*	91.5 (91-100)	100 (94-100)	0.049*
Cubic rice cracker	67 (40-95.5)	62 (26.3-100)	0.774	82 (81.5-94)	98.5 (80.8-100)	0.123	83 (81-100)	100 (93.3-100)	0.013*
Hard rice cracker	58 (26.5-89.3)	60 (18.3-94.8)	0.634	77 (75.8-91.3)	97.5 (65.8-100)	0.191	81 (78.8-94.8)	100 (87-100)	0.020*
Dry squid	58 (17-89)	36 (0-59.8)	0.181	60 (46.3-85.5)	75 (23.5-100)	0.258	68 (68-89.5)	93.5 (75.5-100)	0.049*

Mann-Whitney U Test

CD: Conventional denture base

RD: Resilient denture liner

* Significant difference ($p < 0.05$)

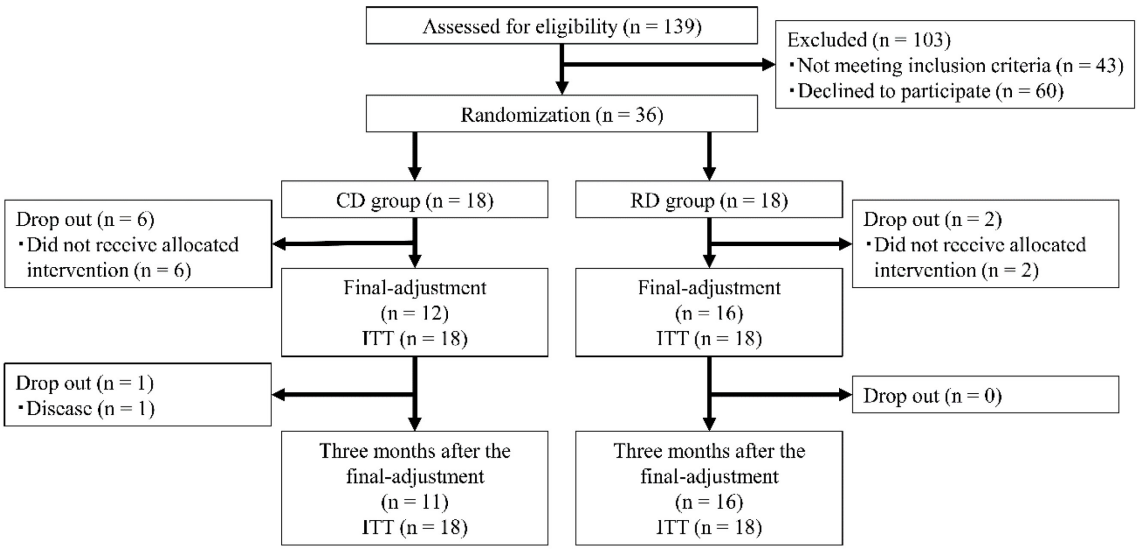

Fig. 1. Trial flowchart

The participants were consecutively recruited between May 2017 and December 2019.

The follow-up rate was 75%.

CD: conventional denture base

RD: resilient denture liner

ITT: intention to treat analysis

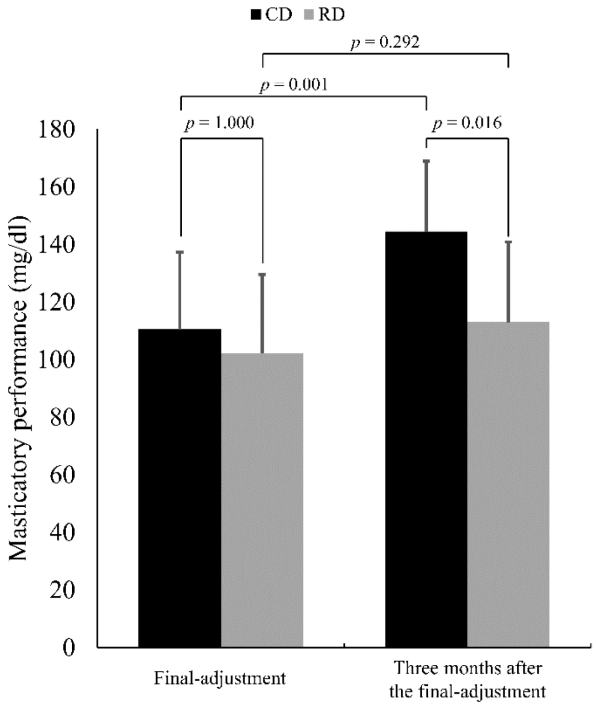

Fig. 2. Masticatory performance

The masticatory performance in the RD group was significantly lower than that in the CD group (two-way ANOVA: $p = 0.013$). There were no significant differences (multiple comparison test with Bonferroni: $p = 1.000$) between the two groups at the final adjustment. But the RD group was significantly lower than that in the CD group (multiple comparison test with Bonferroni: $p = 0.016$) at the 3 months after the final adjustment. The masticatory performance increased significantly and gradually (two-way ANOVA: $p = 0.006$). The mean masticatory performance 3 months after the final adjustment was significantly higher than the final adjustment in the CD group (paired t-test: $p = 0.001$), but the RD group did not show significant changes over time (paired t-test: $p = 0.292$).

CD: conventional denture base

RD: resilient denture liner

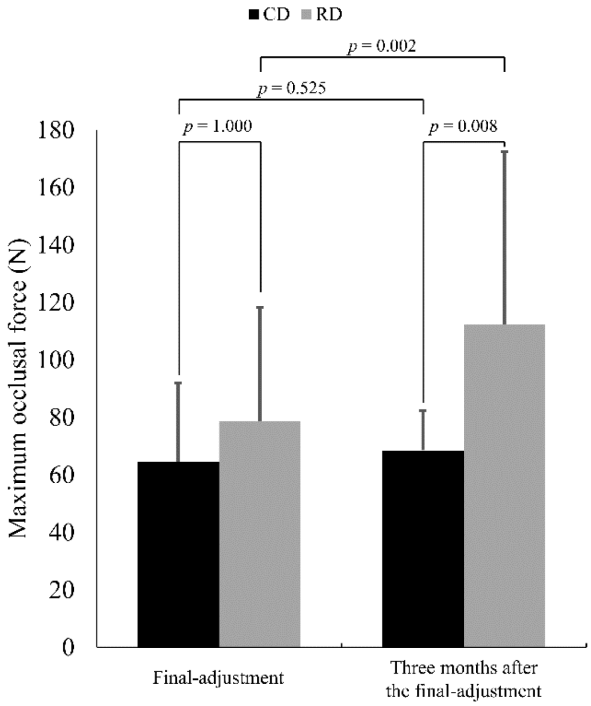

Fig. 3. Maximum occlusal force

The maximum occlusal force in the RD group was significantly higher than that in the CD group (two-way ANOVA: $p = 0.020$). There were no significant differences (multiple comparison test with Bonferroni: $p = 1.000$) between the two groups at the final adjustment. But the RD group was significantly higher than that in the CD group (multiple comparison test with Bonferroni: $p = 0.008$) at the 3 months after the final adjustment. The maximum occlusal force increased significantly with the follow-up time (two-way ANOVA: $p = 0.002$). The value in the RD group significantly and gradually increased over time (paired t-test: $p = 0.002$), while patients in the CD group did not show significant changes over time (paired t-test: $p = 0.525$).

CD: conventional denture base

RD: resilient denture liner