Effect of an Acrylic Resin–Based Resilient Liner Applied to Mandibular Complete Dentures on Satisfaction Ratings Among Edentulous Patients

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> Purpose: The aim of this study was to investigate whether an acrylic resin-based resilient liner (ARL) could improve the satisfaction ratings of complete denture wearers. The null hypothesis was that no difference exists between the satisfaction ratings of conventional acrylic resin denture (CARD) wearers and those of ARL denture (ARLD) wearers. Materials and Methods: From April 2004 to July 2006, a randomized controlled trial was conducted at two centers, including 74 edentulous patients. Of these, 37 patients were each randomly allocated to the ARLD and CARD groups. All of the patients rated their satisfaction with dentures, including general satisfaction and satisfaction with chewing ability, speaking, cleaning, stability, retention, comfort, and esthetics. These satisfaction ratings were measured by a 100-mm visual analog scale. Perceived chewing ability of different foods, divided into five grades, was measured using a questionnaire. The mastication index (MI) was calculated for each grade. Results: General satisfaction, satisfaction with chewing, and satisfaction with speaking were significantly higher in the ARLD than in the CARD group (P = .049, .025, and .049, respectively). The chewing satisfaction with maxillary dentures in the ARLD group was significantly higher than that of the CARD group (P = .02). No significant difference existed between the MI of the ARLD (69.2 ± 17.0) and CARD groups (66.7 ± 18.7). Conclusions: Within its limitations, this study showed that the ARL improves a complete denture wearer's satisfaction ratings. Int J Prosthodont 2014;27:561-566. doi: 10.11607/ijp.3935

With the increase in the number of edentulous patients,¹ dentists frequently encounter cases of edentulous patients with intractable pain on atrophic mandibles induced by their complete dentures. The inherent characteristics of the mucosa cannot be changed. Therefore, the acquired chronic disorder of these edentulous patients with atrophic and thin mucosa can be treated with implants^{2,3} or permanent

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resilient denture liners.⁴⁻⁷ However, treatment using implants is not a viable solution for most edentulous patients due to medical, psychological, or financial constraints; treatment with permanent resilient denture liners is more feasible for edentulous patients.

The results of a crossover randomized clinical trial of the resilient liner suggested that edentulous patients prefer mandibular complete dentures with silicone-based resilient liners to mandibular conventional dentures, although no difference was found between the satisfaction ratings for mandibular complete dentures with a silicone-based resilient denture liner and those for mandibular conventional dentures.⁴ However, to the authors' knowledge, no study has reported a complete denture wearer's satisfaction ratings for mandibular complete denture suite denture wearer's satisfaction ratings for mandibular complete dentures with an acrylic resin–based resilient liner (ARL), although it has been revealed that the ARL has clinical effects to reduce pain on the mandibular alveolar ridge and improve chewing ability of complete denture wearers.^{5–7}

The purpose of this study was to investigate whether the ARL can improve the satisfaction ratings of complete denture wearers. The null hypothesis was that no difference exists between the satisfaction ratings of conventional acrylic resin denture (CARD) wearers and those of ARL denture (ARLD) wearers.

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Table 1 Baseline Characteristics

Characteristic	CARD (n = 37)	ARLD (n = 37)
Age (y)	73.3 ± 8.7	74.1 ± 6.8
Sex (male/female)	17/20	20/17
Edentulous period (y)	11.8 ± 9.2	14.1 ± 10.5
Age of maxillary existing dentures (y)	7.6 ± 8.5	8.1 ± 7.3
Age of mandibular existing dentures (y)	7.0 ± 7.9	6.2 ± 6.6
No. of previous maxillary dentures	2.0 ± 1.5	2.2 ± 1.6
No. of previous mandibular dentures	2.1 ± 1.5	2.2 ± 1.7
Height of alveolar ridge (mm)	17.6 ± 4.9	18.6 ± 6.4

CARD = conventional acrylic resin denture; ARLD = acrylic resinbased resilient liner denture.

Materials and Methods

Study Design and Participants

For this randomized controlled clinical trial, edentulous patients were recruited between April 15, 2004, and July 20, 2006, from Nihon University School of Dentistry at Matsudo Affiliated Hospital and Kanagawa Dental College Affiliated Hospital. The recruited patients were randomized into either the CARD or ARLD group according to prepared random number tables. One computer-generated random number table each was prepared for Nihon University School of Dentistry at Matsudo Affiliated Hospital and Kanagawa Dental College Affiliated Hospital.

The participants were recruited regardless of their sex, age, adaptive, or maladaptive experience while wearing mandibular hard dentures, and the height of the alveolar ridge, which was measured on a panoramic radiograph and classified according to the system of the American College of Prosthodontists.⁸ Patients were not included in the study if they met either of the following exclusion criteria: (1) lack of physical strength to participate in the trial due to systemic disease and/or aging and (2) lack of understanding of written or spoken Japanese. Each patient received oral and written information regarding the study.

Sample Size Calculation

The appropriate sample size was estimated by using the general satisfaction rating as the primary outcome for this trial. Based on the results of a previous study,⁴ the authors sought a between-group difference of 10 mm on the 100-mm visual analog scale (VAS) rating of general satisfaction during the initial adjustment session, using a variance of 15 mm for ARLD

Table 2Foods in Each Grade

Grade	Foods
1	Pudding, bananas, boiled cabbage, boiled carrots, boiled taro, sliced raw tuna, boiled onion
2	Strawberries, ham, boiled chicken, boiled fishpaste patty, konnyaku, boiled kombu (tsukudani kombu), raw cabbage
3	Fried chicken, fried rice cracker, roasted chicken, apples, pickled eggplant, boiled beef, raw cabbage
4	Roasted pork, pickled scallion, pickled radish, rice cake, peanuts, sliced raw cuttlefish, pork cutlet
5	Raw carrots, takuwan, jellyfish, vinegared octopus, raw trepang, raw abalone, dried cuttlefish
1	

Taro = Japanese taro potato; konnyaku = a paste made from starch of the devil's tongue plant; kombu = tangleweed; takuwan = deeply pickled radish; trepang = sea cucumber.

wearers and 10 mm for CARD wearers. To fulfill the criteria of 80% power with a two-sided alpha level of 5% and to factor in potential participant dropouts, 74 people were enrolled in this study.

Measurement Outcomes

Baseline characteristics. The assessors noted the baseline characteristics of the patients, such as sex, age, edentulous period, age of existing denture, number of previous dentures, and height of the alveolar ridge (Table 1). Based on the classification of complete edentulism according to the American College of Prosthodontists, to minimize any variations while measuring using radiographic techniques, the heights of the alveolar ridges of the mandibles were measured on the radiograph at the least-vertical-height portion of the mandibles.⁸

Denture satisfaction ratings. The denture satisfaction ratings were measured by a 100-mm VAS. The general satisfaction and satisfaction with respect to denture functions such as chewing ability, speaking, cleaning, stability, retention, comfort, and esthetics were measured. The left-side anchor on the VAS of satisfaction ratings was "Not at all satisfied," and the right-side anchor was "Extremely satisfied."

Perceived chewing ability of foods. The valid questionnaire developed by Hirai et al⁹ was used to measure the perceived chewing ability. Each of the 35 foods listed in the questionnaire (Table 2) was evaluated by the participants as per the following criteria: 0 = cannot eat, 1 = can eat with difficulty, and 2 = can eat easily. If a participant refused to eat a listed food item, the food item was scored as 0. The 35 food items are graded between 1 and 5, in the order of their increasing hardness. Food items belonging to the same grade have a similar rheological texture.

Schedule for measurement of outcomes. The outcomes were measured 2 months after the completion of the denture adjustments. Based on the patients' complaints after denture delivery, the dentists decided when denture adjustment was completed.

Construction of Complete Dentures

Mandibular complete dentures for the CARD group were constructed using only conventional heatactivated acrylic resin (Physio Resin, Nissin Dental Products); those for the ARLD group were constructed using conventional heat-activated acrylic resin and a constructed 2-mm-thick permanent ARL (Physio Soft Rebase, Nissin Dental Products). Participants of both groups wore conventional maxillary complete dentures using conventional heat-activated acrylic resin. The Physio Soft Rebase consisted of polyethyl methacrylate powder, non-phthalate plasticizer liquid, and methacrylate ester derivatives. Shore A hardness was approximately 35. Maxillary complete dentures also were fabricated using heat-activated acrylic denture resin. According to the manufacturer's instructions, conventional dough-stage heat-activated acrylic denture-base resin was packed against the master cast, which was covered with a 2-mm spacer. After removing the spacer, the resilient lining material in the dough stage was inserted to replace the spacer. The resin was then compression-molded and processed. The curing cycle was as follows: 90 min at 70°C followed by 30 minutes at 100°C.

Statistical Analysis

The baseline characteristics of the participants in the CARD and ARLD groups were compared by the *t* test and chi-square test. The *t* test was used to compare the satisfaction ratings and perceived chewing ability between the CARD and ARLD groups. Multiple regression analysis was performed to analyze the association between general satisfaction and the other seven satisfaction ratings regarding denture functions such as chewing, speaking, cleaning, stability, retention, comfort, and esthetic items. P < .05 was considered to indicate statistical significance.

Results

Number of Participants and Baseline Characteristics

Seventy-four consecutive patients were randomized for this trial. Of the 74 participants, 37 participants were each assigned to the CARD and ARLD groups. A total of 62 participants completed the trial (Fig 1).



Fig 1 Flowchart showing the course of the participants in the study. The follow-up rates of the participants in the CARD and ARLD groups are 81.1% and 86.5%, respectively.

After receiving the dentures, 5 participants dropped out of the CARD group, whereas no participants chose to drop out in the ARLD group. No significant differences were observed in any of the baseline characteristics between the CARD and ARLD groups (P > .05, Student *t* test and chi-square test; see Table 1).

Denture Satisfaction Ratings

The general satisfaction, satisfaction with chewing, and satisfaction with speaking with mandibular dentures in the ARLD group were significantly higher than those in the CARD group (P = .049, .025, and .049, respectively; Fig 2). Chewing satisfaction with maxillary dentures in the ARLD group was significantly higher than in the CARD group (P = .02; Fig 3).

Multiple regression analysis showed that the general satisfaction rating was significantly associated with chewing satisfaction (P = .045) and satisfaction with comfort (P = .002). Any troubles with the dentures themselves, such as fracture, were not observed in either group at measurement time.

Perceived Chewing Ability

The mastication index (MI) of the CARD group (66.7 \pm 18.7) was not significantly different from that of the ARLD group (69.2 \pm 17.0). No significant difference in chewing foods between the CARD and ARLD groups was observed in grades 1, 2, 3, 4, and 5 (*P* > .05; see Fig 4).





16 14 12 10 Score 8. 6 4 2 0 Grade 1 Grade 2 Grade 3 Grade 4 Grade 5 CARD ARLD

Fig 2 Satisfaction ratings of mandibular complete dentures provided by the participants. The general satisfaction, satisfaction with speaking, and satisfaction with chewing were significantly different between the CARD and ARLD groups. CARD = conventional acrylic resin denture; ARLD = acrylic resinbased resilient liner denture. *Represents statistical significance (P < .05).

Fig 3 Satisfaction ratings of maxillary complete dentures provided by the participants. The satisfaction with chewing was significantly different between the CARD and ARLD groups. CARD = conventional acrylic resin denture; ARLD = acrylic resin-based resilient liner denture. *Represents statistical significance (P < .05).

Fig 4 Perceived chewing ability of the participants. CARD = conventional acrylic resin denture; ARLD = acrylic resin-based resilient liner denture. There was no significant difference between the CARD and ARLD groups.

Discussion

In this study, the patient satisfaction with an ARLD was compared to that with a CARD. The results of this randomized controlled clinical trial indicated that the ARL can improve the satisfaction ratings of complete denture wearers. The strength of evidence derived from any clinical trial depends on how the biases are controlled. In this study, the baseline characteristics of the two groups were homogenous, suggesting that the randomization was appropriately performed and that the results of this trial are valid. To the authors' knowledge, this is the first randomized controlled clinical trial to examine the effects of an ARL on the satisfaction ratings of a complete denture wearer.

The satisfaction rating of chewing in the ARLD group was significantly higher than that in the CARD group. What caused the differences in chewing satisfaction between the CARD and ARLD groups? In view of the fact that this study was designed as a randomized controlled clinical trial without any bias, the only difference between the groups was whether the resilient liner was applied to the mandibular dentures. Therefore, it is reasonable to assume that the mechanical property of the ARL contributed to the improvement in chewing satisfaction. Murata et al reported that viscoelastic properties such as a shear storage modulus and loss tangent lead to the most marked improvement in masticatory function.¹⁰ In addition, it is well known that the ARL facilitates wider dispersion of force and increases absorption of the impact force,11-13 resulting in improved mastication induced by an extended occluding phase.⁴ Furthermore, it has been reported that the mechanoreceptors in the denture-supporting mucosa might play an important role in controlling sensory feedback regarding masticatory function in complete denture wearers.¹⁴ These reports partially explain the improved chewing satisfaction in the ARLD group since the ARL facilitates mastication by reducing irritation of the mucosa.

Furthermore, not only was the satisfaction rating of chewing for mandibular dentures in the ARLD group higher than that for mandibular dentures in the CARD group but the satisfaction rating of chewing with maxillary dentures in the ARLD group was also higher than that for maxillary dentures in the CARD group. Although the maxillary dentures were not fabricated using ARL, the chewing satisfaction with maxillary dentures in the ARLD group was significantly higher than in the CARD group. This may be partially due to the fact that complete denture wearers originally evaluated chewing as one unit, independent of maxillary or mandibular complete dentures. The increased functional ability of mandibular dentures, induced by the resilient liner, might affect the maxillary denture satisfaction rating of chewing even though the resilient liner was not applied to maxillary dentures.

Although the chewing satisfaction rating in the ARLD group was significantly increased, the MI score in the ARLD group was not significantly higher than that of the CARD group. In general, the MI score is influenced by the number of food items consumed by an individual during his or her daily meal, whereas the chewing satisfaction rating is influenced by the manner in which a food item is consumed. Therefore, the number of food items consumed does not necessarily influence chewing satisfaction. In addition, it has been reported that complete denture wearers with poor-quality, old dentures retain their previously established poor dietary habits even after they receive functionally adequate new dentures.¹⁵ We believe that this may contribute to the MI scores obtained in this study.

The speaking satisfaction rating among the ARLD wearers was higher than that among the CARD wearers. In general, speaking is a daily activity that is necessary to communicate with others and be social; it is not just limited to complete denture wearers.¹⁶ If complete denture wearers experienced irritation or pain in their mouth, they would hesitate to speak, resulting in decreased satisfaction rating of not only speaking but also general satisfaction. It is conceivable that speaking is significantly affected by resilient liners that can influence chewing, causing improved satisfaction in ARLD wearers than in CARD wearers.

The general satisfaction rating with mandibular dentures in the ARLD group was significantly higher than that with mandibular dentures in the CARD group. According to the multiple regression analysis performed in this study, the general satisfaction rating was significantly related to the satisfaction ratings of chewing and comfort. The effect of ARLD on chewing has already been described. Considering that mastication affects oral health-related quality of life,17,18 it is conceivable that the general satisfaction rating was affected by the chewing rating. In addition, the general satisfaction rating also was affected by the satisfaction rating of comfort, although no statistical difference in the comfort rating existed between the ARLD and CARD groups. The results of this study showed that a larger sample size would have resulted in a statistically significant difference in comfort ratings between the groups. Although further large sample studies are warranted, this study shows that the application of an ARL to a mandibular complete denture generally improves the satisfaction of edentulous complete denture wearers.

The chemical properties of the ARLs, the plasticizers of which eluted into the saliva, cause gradual loss of the initial softness of the denture base.^{19,20} Since this study scheduled measurement of outcomes at 2 months after the completion of the denture adjustments, readers have to recognize that the satisfaction ratings of complete denture wearers may change with the gradual loss of the initial softness of the denture base. Further research in this field is needed.

Conclusions

Within the limitations of the current study, the ARL improved the satisfaction ratings of complete denture wearers.

Acknowledgments

This study has been conducted in accordance with the Declaration of Helsinki. Each subject received oral and written information regarding the study and provided informed consent. The study protocol was reviewed and approved by the Human Ethics Committees of Nihon University School of Dentistry at Matsudo (EC 02-036) and Kanagawa Dental College (no. 19). This study was supported by a Grant-in-Aid for Scientific Research (C19592262) from the Ministry of Education, Culture, Sports, Science and Technology, Japan. The authors reported no conflicts of interest related to this study.

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