Randomized Controlled Trial Investigating the Effect of an Acrylic-Based Resilient Liner on Perceived Chewing Ability in Edentulous Patients Wearing Mandibular Complete Dentures

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Purpose: The aim of this study was to investigate the effect of an acrylic-based resilient liner (ARL) on perceived chewing ability in patients using mandibular complete dentures compared with that of patients using mandibular complete dentures with a conventional acrylic resin (CAR). ***Materials and Methods:*** This randomized controlled trial was conducted at two centers from April 2004 to July 2006. Seventy-four subjects were randomly allocated to either the ARL or CAR group using a random permuted block method after obtaining written informed consent. A valid questionnaire listing 35 foods was used to evaluate the subjects' perceived chewing ability of each item, assessed according to the following scale: 0 = cannot eat, 1 = can eat with difficulty, and 2 = can eat easily. If subjects did not eat the food because they disliked it or had not eaten it since first wearing dentures, they filled in a triangle or square, respectively. These figures were treated as a 0 during analysis. ***Results:*** No significant differences were observed between the ARL and CAR groups. The perceived chewing ability of subjects with new complete dentures was significantly higher than that of those with their old complete dentures. The duration of edentulism was positively associated with perceived chewing ability. ***Conclusions:*** An ARL applied to mandibular complete dentures has no significant impact on the perceived chewing ability of edentulous patients in comparison to a CAR. *Int J Prosthodont 2010;23:110–116.*

It has been suggested that the total number of edentulous patients wearing conventional complete dentures is projected to rise over the next 2 decades due to an increase in life expectancy,[1] which implies a greater number of edentulous patients seeking treatment. Although being treated with implants at an increasing rate, many edentulous patients cannot undergo such treatment because of physical or economic reasons. Such patients have no choice but to use conventional complete dentures. Reportedly, patients with an adequate mandibular ridge height report similar improvements whether they are treated with mandibular implant-retained overdentures or conventional complete dentures.[2] However, the latter are not always effective in edentulous patients because the atrophic and thin oral mucosa on the alveolar ridge in these patients cannot withstand the stress generated by the occlusal force. With an increasing incidence of complete edentulism, measures must be taken to alleviate such patients' difficulty in adaptation.

Edentulous patients who cannot be managed with conventional complete dentures may be helped by treatment with dentures containing resilient liners because of their stress distribution effect.[3] However, clinicians have not yet obtained sufficient evidence of the clinical effectiveness for resilient liners in complete denture wearers.

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A previously conducted study implementing a crossover randomized clinical trial of resilient liners suggested that application of permanent silicone-based resilient liners on mandibular dentures improves the masticatory performance of edentulous patients compared with conventional dentures,[4] and patients prefer mandibular dentures with permanent silicone-based resilient liners to conventional dentures.[5]

Impaired masticatory function may cause edentulous patients to avoid foods they find difficult to eat, or encourage them to modify food preparation to cope with masticatory inefficiencies. Although resilient liners help with the impaired mastication of complete denture wearers,[5] no evidence is available on how complete dentures with resilient liners affect food intake. Therefore, the purpose of this study was to conduct a randomized controlled trial, using a valid questionnaire on daily food intake, to determine how liners affect perceived chewing ability.

How an acrylic-based resilient liner (ARL) applied to mandibular complete dentures impacts the perceived chewing ability of patients in comparison to that of patients using mandibular complete dentures with a conventional acrylic resin liner (CAR) was investigated. The primary null hypothesis was that there is no difference in perceived chewing ability of complete denture wearers treated with an ARL or CAR at 2 months after the final adjustment.

Materials and Methods

Subjects

Edentulous subjects (n = 74) who were willing to undergo treatment with new complete dentures were recruited from Nihon University School of Dentistry at Matsudo Affiliated Hospital, Chiba, Japan, and Kanagawa Dental College Affiliated Hospital, Yokohama, Japan. Inclusion criteria were as follows: *(1)* duration of edentulism ranging from 0.3 to 34 years (mean: 13.1 ± 9.8 years), *(2)* men or women, *(3)* subjects aged 53 to 89 years (mean: 73.7 ± 7.7 years), *(4)* any category of residual ridge resorption according to classifications of the American College of Prosthodontists,[6] and *(5)* subjects having a history of adaptive or maladaptive prosthetic experience. Exclusion criteria consisted of subjects suffering from systemic or neurologic diseases or those with a lack of understanding of written or spoken Japanese.

Patients provided written informed consent prior to participation. The study protocol was reviewed and approved by the human ethics committees of Nihon University School of Dentistry at Matsudo and Kanagawa Dental College.

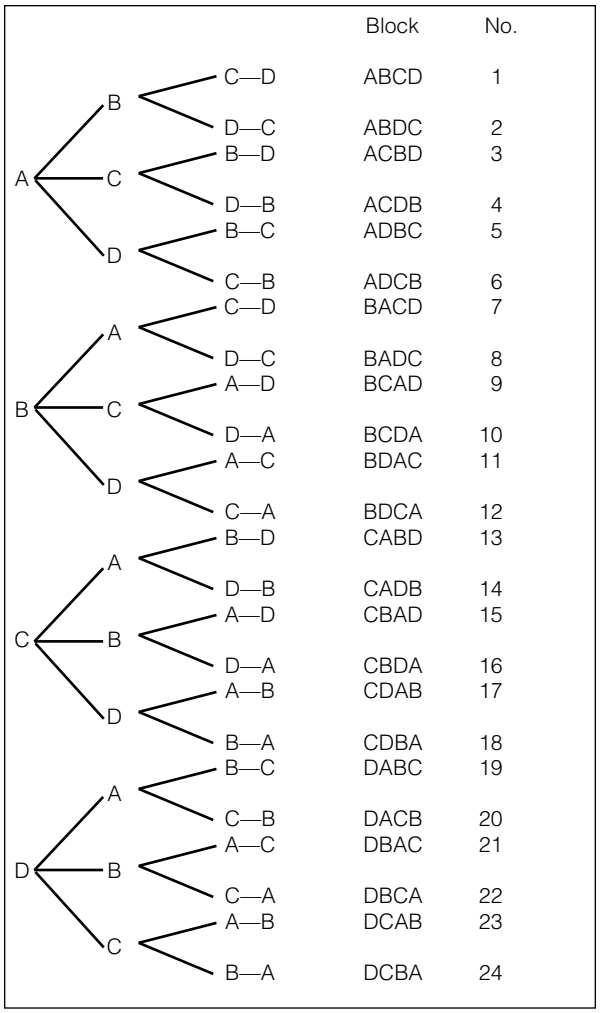

Fig 1 Allocation method of subjects. A, B, C, and D indicate the combinations of CAR and PD, CAR and NP, ARL and PD, and ARL and NP, respectively. Since there are 24 permutations for the 4 combinations, each block comprising A, B, C, and D is numbered from 1 to 24. This method ensures that the subjects were randomly allocated into either the CAR or ARL group, along with a parallel allocation into either the PD or NP group.

Randomization, Allocation, and Blinding

A randomized controlled trail was conducted at two hospitals from April 15, 2004 to July 20, 2006. Subjects were sampled consecutively. In a randomized controlled trial, to investigate the effects of dental prostheses on patients, the results obtained depend on interventions by the practitioner. Therefore, a permuted block method[7] was applied to randomize patients into either the ARL or CAR group, with a parallel allocation into either the prosthodontist (PD) or nonprosthodontist (NP) group (Fig 1). To ensure equal allocation to both sets of groups (ARL and CAR, PD and NP), blocks were

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Table 1 Demographics of Participants Enrolled in the Trial

Variables	CAR (n = 37)	ARL (n = 37)
Age (y)	73.3 ± 8.7	74.1 ± 6.8
Sex		
Male	17	20
Female	20	17
Type of practitioner		
Prosthodontist	19	19
Nonprosthodontist	18	18
Duration of edentulism (y)	12.1 ± 9.1	14.3 ± 10.5
Age of existing mandibular denture (y)	8.6 ± 7.8	8.1 ± 7.3
Height of alveolar ridge (mm)	17.6 ± 4.9	18.6 ± 6.4
Body mass index (kg/m^2)	21.5 ± 4.5	21.9 ± 3.3

ARL = acrylic-based resilient liner; CAR = conventional acrylic resin.

Table 2 Classification of Foods

Grade	Food
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 cucumber
3	Fried chicken, fried rice crackers, roasted chicken, apples, pickled eggplant, boiled beef, raw cabbage
4	Roasted pork, pickled scallion, pickled radish, rice cakes, peanuts, sliced raw cuttlefish, pork cutlett
5	Raw carrots, takuwan, jellyfish, vinegared octopus, raw trepang, raw abalone, dried cuttlefish

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

formed by the permutation of four combinations of denture base material and clinician (ARL with PD, ARL with NP, CAR with PD, and CAR with NP). As a result, 24 different blocks ($4 \times 3 \times 2 \times 1 = 24$) with different ordered combinations were obtained, and each was individually numbered from 1 to 24. Each computer-generated random-block table consisting of 24 numbers was prepared for both dental schools, and allocation was stratified by each hospital. However, the analyses reported here focus only on the allocation of denture base materials (ARL and CAR). According to the random-block table, one research assistant assigned subjects to their respective groups. Blinding of intervention based on type of practitioner was feasible, but that based on base material was deemed unfeasible because both the patients and clinicians were clearly aware of the type of material being used.

Measurement

Subject Attributes. An assessor collected patient attributes at baseline. These included sex, age, type of clinician, body mass index, duration of edentulism, age of existing denture, and height of alveolar ridge, measured according to the classification system of the American College of Prosthodontists[6] (Table 1). Body mass index was calculated by the following formula[8]:

$$\text{BMI} = \text{weight in kilograms}/(\text{height in meters})^2$$

Measurement Outcomes. The outcome to be measured was perceived chewing ability and was based on a valid questionnaire developed by Hirai et al.[9] The questionnaire listed 35 foods, and subjects assessed their personal perceived chewing ability of each item by the following scale: 0 = cannot eat, 1 = can eat with difficulty, and 2 = can eat easily. If subjects did not eat the item because they disliked the food or had not eaten it since first wearing dentures, they filled in a triangle or square, respectively. These figures were treated as a 0 for analysis. The food items were divided into five categories, each including rheologically similar-textured food items (Table 2). Grades 1 and 5 comprised the softest and hardest foods on the questionnaire, respectively. As the group number increased, so did the difficulty in chewing. Further, the mastication score was calculated by using the scores of each group as follows:

$$\text{Mastication score} = [[(\text{grade } 1 \times 1) + (\text{grade } 2 \times 1.14) + (\text{grade } 3 \times 1.30) + (\text{grade } 4 \times 1.52) + (\text{grade } 5 \times 3.00)] \times 100)/111.4$$

This score is a parameter used to comprehensively evaluate the perceived chewing ability according to individual values from each food category. Data were recorded 2 months after final denture adjustment because complete denture wearers fit with the ARL have not shown to become completely adapted to the masticatory process previous to this time point.[5]

Sample-Size Estimation and Power Analysis

This study was initially designed to evaluate patients' general satisfaction at 2 months after final adjustment. To determine the appropriate sample size, size estimation was performed by using the general satisfaction rating as the primary outcome. A between-group difference of 15 mm on the 100-mm visual analog scale rating of general satisfaction during the

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initial adjustment session was sought using a variance of 15.0 mm for the ARL group and 10.0 mm for the CAR group, based on data obtained from a previous study.[4] To fulfill the criteria of 80% power with a two-sided alpha level of 5%, 74 subjects were enrolled, taking into consideration potential dropouts. In this report, findings are presented on the secondary outcome, the perceived chewing ability. It was estimated that 31 edentulous subjects per treatment group would provide 84% power with a type I error of .05, for a clinically meaningful difference of 17 in mastication score with a variance of 22.4. The clinically meaningful difference in mastication score was defined as the value obtained by the condition in which one third of the items in the questionnaire improve individually by one point and the mastication score increases by 17 when old complete dentures are replaced with new ones.

Treatment Protocol

Stock edentulous trays (Dentcraft StO-K TRAY, Yoshida) and irreversible hydrocolloid impression materials (Algiace-Z, Dentsply-Sankin) were used to make preliminary impressions. Then, border-molding procedures were carried out using custom trays fabricated on study casts and a stick modeling compound (Peri Compound, GC). A polyether impression material (Impregum, 3M ESPE) was used to make final impressions.

The interarch relationship was recorded using occlusal rims and interocclusal registration paste (Superbite Paste, Harry J. Bosworth). During try-in, after verifying the vertical dimensions of the occlusal and centric relation records, when necessary, teeth were arranged esthetically on the full-contour wax trial denture. The patient's feedback and acceptance of the trial dentures were obtained. After processing, the dentures were inserted. Postinsertion appointments for adjustment were scheduled until the subjects were comfortable and free of tissue irritation. Using paste (PIP, Mizzy) and silicone (Fit Checker, GC) pressure-indicating materials, clinicians adjusted the dentures to relieve the area of irritation based on their diagnosis. Furthermore, if premature contacts were observed on the path of closure, occlusal adjustments were performed using articulating paper (GC). When deemed necessary, the dentures were remounted with semiadjustable articulators (Hanau H2, Teledyne Waterpik) for occlusal equilibration during the adjustment period.

Laboratory Protocol

Mandibular complete dentures with a CAR were fabricated using only conventional heat-activated acrylic resin (Physio Resin, Nissin). On the other hand, mandibular complete dentures with an ARL were fabricated using conventional heat-activated acrylic resin (Physio Resin, Nissin) and a 2-mm-thick permanent acrylic resin–based denture liner (Physio Soft Rebase, Nissin). As per manufacturer's instructions, conventional dough-stage heat-activated acrylic denture base resin was packed against the master cast covered with a 2-mm spacer. After removing the spacer, resilient lining material in a dough stage was inserted to replace the spacer. The resin was then compression-molded and processed. The curing cycle was 90 minutes at 70°C, followed by 30 minutes at 100°C.

Statistical Analysis

Comparison of the subjects' baseline characteristics between the ARL and CAR groups was performed using the Student *t* test. Proportions of baseline attributes (sex and type of clinician) were tested with the chi-square test. One-way repeated-measures analysis of variance (ANOVA) was used to test whether the type of denture base material (ARL or CAR) and replacement of the dentures (old with new) influenced the denture wearers' perceived chewing ability. Multiple regression analysis was applied to determine which sociodemographic, anatomical, and prosthetic variables were associated with each score. A *P* value below .05 was considered statistically significant.

All tests were two-tailed. All statistical analyses were performed on a personal computer with SPSS II for Windows (SPSS).

Results

Subjects

Seventy-four patients who had been consecutively sampled participated in this trial. The random permuted block within-strata method assigned 37 subjects each to the CAR and ARL groups. Table 1 shows the baseline characteristics of the subjects. No significant differences were observed in any of the characteristics of the baseline measurements between the CAR and ARL groups ($P \geq .05$, *t* and chi-square tests; Table 2). Figure 2 shows the subject flow. Of the 74 allocated subjects, 70 received new complete dentures and 62 were evaluated for perceived chewing ability.

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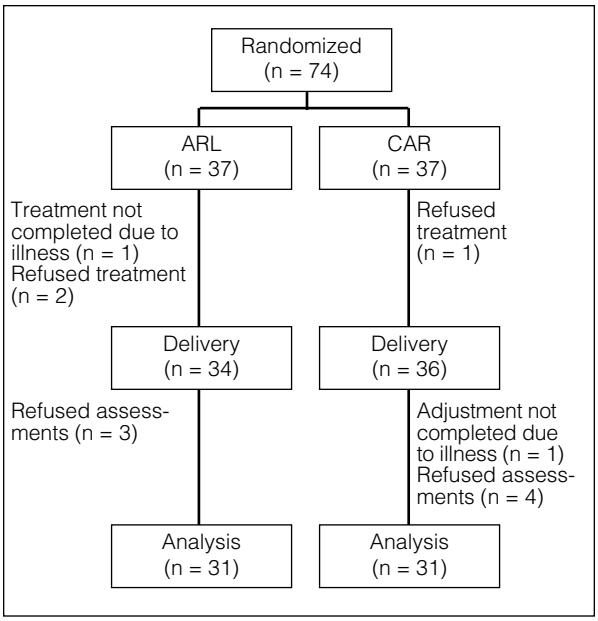

Fig 2 *(left)* Flow of subjects included in the study.

Table 3 Perceived Chewing Ability Pre- and Posttreatment

	ARL (n = 37)		CAR (n = 37)	
Grade	Pre	Post	Pre	Post
1	13.3 ± 1.1	13.3 ± 1.5	13.2 ± 1.8	13.1 ± 1.7
2	10.9 ± 3.7	12.5 ± 2.2	11.4 ± 3.4	12.4 ± 2.6
3	10.1 ± 3.1	12.1 ± 2.8	9.9 ± 3.4	11.2 ± 3.3
4	9.0 ± 3.5	11.5 ± 2.8	9.5 ± 3.5	10.9 ± 3.0
5	4.7 ± 3.6	5.4 ± 3.7	5.3 ± 3.6	5.3 ± 3.8
Mastication score	59.7 ± 19.6	63.3 ± 25.5	62.2 ± 20.3	62.7 ± 24.1

ARL = acrylic-based resilient liner; CAR = conventional acrylic resin; pre = pretreatment; post = posttreatment.

Table 4 Multiple Regression Analyses of Perceived Chewing Ability

	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5		Mastication score	
Predictors	β	*P*	β	*P*	β	*P*	β	*P*	β	*P*	β	*P*
Denture base material (CAR/ARL)	0.1	.85	0.3	.59	1.3	.11	0.9	.24	0.4	.73	−2.7	.67
Age (y)	−0.1	.39	−0.1	.23	−0.1	.38	−0.1	.39	−0.1	.13	−0.8	.09
Sex (male/female)	0.5	.28	1.1	.11	1.4	.14	0.1	.88	1.5	.25	4.4	.56
Type of practitioner (PD/NP)	0.3	.48	−0.3	.55	0.1	.89	0.3	.65	1.7	.10	−0.5	.93
Duration of edentulism (y)	0.1	.10	0.1	.08	0.1	.15	0.1	.01*	0.1	.11	1.3	.003*
Age of existing mandibular denture (y)	−0.1	.14	−0.1	.39	−0.1	.41	−0.1	.09	−0.1	.15	−0.5	.27
Height of alveolar ridge (mm)	−0.1	.11	−0.1	.44	−0.1	.20	−0.1	.82	−0.1	.27	−0.5	.42
Body mass index (kg/m^2)	0.1	.14	0.1	.18	0.2	.12	0.2	.23	0.1	.77	0.3	.81

*Statistically significant.
β = unstandardized regression coefficient; ARL = acrylic-based resilient liner; CAR = conventional acrylic resin; PD = prosthodontist; NP = nonprosthodontist.

Perceived Chewing Ability

Table 3 shows means and standard deviations of chewing ability scores at pre- and posttreatment for each denture base material (ARL or CAR). The 95% confidence intervals of treatment effects between the ARL and CAR groups at posttreatment were as follows: −1.0 to 0.5 for grade 1, −1.3 to 1.1 for grade 2, −2.5 to 0.5 for grade 3, −2.0 to 0.8 for grade 4, −2.0 to 1.8 for grade 5, and −12.5 to 11.4 for mastication score. One-way repeated-measures ANOVA revealed that the type of denture base material did not improve the perceived chewing ability based on scores obtained from grades 1, 2, 3, 4, and 5, as well as the mastication score. However, it did show that replacement of complete dentures (old with new) significantly improved the perceived chewing ability based on scores from grades 2 ($P = .023$), 3 ($P = .008$), and 4 ($P = .001$).

Furthermore, adjusting the sociodemographic variables of age, height of the alveolar ridge, duration of edentulism, period of wearing existing dentures, and type of clinician, the multiple regression analysis showed how the denture base material related to perceived chewing ability (Table 4). Similar to the results of the one-way repeated-measures ANOVA, it was found that the denture base material was not related to perceived chewing ability. However, another interesting finding was obtained: The duration of edentulism was associated with perceived chewing ability based on scores obtained from grade 4 ($P = .01$) and the mastication score ($P = .003$). As the duration of edentulism increased, the chewing ability increased.

Throughout the trial, the doctor in attendance did not report any adverse event, such as an allergic reaction to the denture materials.

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Discussion

This randomized controlled trial found that an ARL applied to mandibular complete dentures did not improve the patients' perceived chewing ability, but instead, the replacement of existing dentures with new ones significantly improved this ability. In addition, the duration of edentulism was found to be positively associated with perceived chewing ability.

Before starting this trial, it was expected that patients wearing complete dentures with an ARL would have an increased food intake compared to those with a CAR because comfort while chewing is reportedly more important for food intake than chewing ability,[10,11] and it has been confirmed that patients wearing complete dentures with an ARL are more comfortable while chewing.[12] The deviation from the expected result implies that perceived chewing ability determined by a food intake questionnaire is very complex. One study revealed that implant overdenture wearers have a similar food intake to conventional denture wearers.[13] Another report stated that prosthetic rehabilitation alone may not be sufficient to alter the diet of long-term edentulous patients.[14] Of course, the validity of the indexes used to evaluate the perceived chewing ability in this study has been confirmed by showing the association between them and masticatory performance, considered to be one of the standards to objectively evaluate masticatory ability.[9] Considering previous reports and results from this study comprehensively, the perceived chewing ability of complete denture wearers is not solely dependent on denture function.

Investigations to determine the perceived chewing ability for specific food categories revealed that denture replacement improved the perceived chewing ability for foods in grades 2, 3, and 4 but not for grades 1 (the category including the softest foods) or 5 (the category including the hardest foods). Contrary to the results of this study, one report stated that the replacement of old and ill-fitting dentures with new conventional complete dentures does not improve food intake.[15] Keeping in mind that food intake increases with an increase in perceived chewing ability, this inconsistent result is of interest. One explanation for the difference in results is the presence of diet counseling during delivery of new dentures. A report based on a randomized controlled trial suggested that tailored dietary counseling with denture replacement improves dietary behavior, and that dental clinics are an opportune setting for dietary counseling, which deserves further exploration since eating difficulties are the primary reason for seeking dental treatment.[16] Counseling of patients on denture delivery is mandatory for clinicians in Japan, with payment for counseling on use of newly inserted dentures covered by Japanese public social insurance. Therefore, clinicians are required to counsel on several occasions, including denture delivery. Dietary counseling by clinicians may be the reason for improvement in the perceived chewing ability.

Accordingly, clinicians should either work collaboratively with a nutritionist to achieve improved food intake for patients or gain knowledge on dietary intervention for denture wearers as a comprehensive health care provider. Findings from this study imply that it is very important for clinicians to advise new denture wearers to change their dietary habits and not to continue with past food habits and prejudices.

The duration of edentulism is related to alveolar ridge resorption.[17] Furthermore, advancing resorption of the edentulous alveolar ridge, particularly the mandibular ridge, is one of the most difficult problems facing the clinician because it results in excessive loss of denture-bearing tissue and limits denture function. However, this study found that the duration of edentulism is positively related to an increase in perceived chewing ability. This can be explained by the following concept: The long duration of edentulism suggests that patients have experience with complete dentures, and therefore know how to use and eat with their complete dentures. Generally, a certain amount of adaptation takes place since most individual skill sets improve with time. It seems that wearing complete dentures is no exception. The perceived chewing ability may increase as the duration of edentulism increases since the skills required to use complete dentures may also increase with time.

Perceived chewing ability determined by daily food intake is influenced by many factors, such as culture, lifestyle, and psychology. The questionnaire used in this study included some specific foods eaten only in Japan. Also, the sampling was limited to Japanese patients. Therefore, it may not be possible to apply the findings to other edentulous populations. To investigate the effect of resilient liners on perceived chewing ability globally, subjects from different environments should be included. Unfortunately, no published paper has been found on the perceived chewing ability of wearers of complete dentures with resilient liners. Therefore, further studies are needed to substantiate the evidence.

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Conclusions

The research design specifications of this study permit the following three conclusions:

1. An ARL applied to mandibular complete dentures does not significantly impact the perceived chewing ability of edentulous patients when compared to a CAR.
2. Replacement of old dentures with new ones significantly improves perceived chewing ability.
3. The duration of edentulism is positively associated with perceived chewing ability.

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