

Effect of denture adhesives on masticatory performance: Multicenter randomized controlled trial

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Abstract

Purpose: The purpose of this study is to investigate the effects of denture adhesives on masticatory performance via a 10-center, parallel, randomized, controlled trial of complete denture wearers in Japan.

Methods: The trial was conducted between September 2013 and October 2016. The inclusion criteria were complete edentulism, willingness to undergo new complete denture treatment, and willingness to return for recall treatment. The exclusion criteria were age 90 years or older, presence of severe systemic illness, inability to understand the questionnaires, wearing metal base complete dentures, denture adhesive user, wearing prosthetics for maxillofacial defects, wearing complete dentures with tissue conditioners, and severe xerostomia. Randomization of the powder-type denture adhesive (powder), cream-type denture adhesive (cream), and control (saline) groups was performed using a sealed envelope system. Masticatory performance was measured using color-changeable chewing gum. Intervention blinding was not feasible.

Results: Sixty-seven control, 69 powder, and 64 cream participants are analyzed using the intention-to-treat principle. The participants in all groups show significantly improved masticatory performance at post-intervention (paired *t*-test with Bonferroni correction $P < 0.0001$). However, no significant difference in masticatory performance is detected among the three groups (one-way analysis of variance). A significant negative correlation between pre- and post-changes in masticatory performance and intraoral condition scores is observed (Pearson's correlation coefficient, $P < 0.0001$).

Conclusions: Although denture adhesives improved the masticatory performance of complete denture wearers, their clinical effects are comparable to those of saline solution. The use of denture adhesives is more effective in complete denture wearers with unsatisfactory intraoral conditions.

Keywords: Complete denture, Denture adhesive, Masticatory performance, Multicenter study, Randomized controlled clinical trial

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1. Introduction

Since their introduction in the dental market in 1913, denture adhesives have been widely used by denture wearers for over 100 years[1]. Because denture adhesives are useful adjuncts that improve both denture retention and stability[2], the American Dental Association categorized denture adhesives as medical products in 1935. Previous randomized controlled trials (RCTs) demonstrated that denture adhesives contributed to improved retention and stability as well as reduced the accumulation of food particles, thus resulting in significantly greater satisfaction[3] and masticatory efficacy[4] among complete denture wearers.

In Japan, the market for denture adhesives continues to expand and was estimated at 12 billion yen in 2008[5]. The use of denture adhesives has become relevant in an aging society, with many older individuals unable to attend dental clinics to obtain professional care, such as for the adjustment of dentures with low retention and stability. This implies that patients in Japan use denture adhesives as an alternative to denture treatment. Because every country has a specific food culture[6,7] that may affect the masticatory performance of complete denture wearers, the effect of denture adhesives on masticatory performance must be verified in each country. However, RCTs for testing the effects of denture adhesives among Japanese complete denture wearers have not been conducted.

The aim of this study is to investigate the effects of denture adhesives on masticatory performance via a 10-center, parallel, randomized, controlled trial of complete denture wearers in Japan. We hypothesize that the use of two types of denture adhesives (cream and powder) will not result in any difference in masticatory performance after 4 days of application, compared with before application, or compared with a saline control.

2. Materials and Methods

2.1. Trial organization

The trial was organized by the Japan Denture Care Society. YK, the principal investigator, prepared the study protocol, which was used at 10 centers, including Iwate Medical University, Tohoku University, Tokyo Medical and Dental University, Nihon University School of Dentistry at Matsudo, Tsurumi University, Kanagawa Dental College, Osaka Dental College, University of Tokushima, Nagasaki University, and Kagoshima University. SK and AG, the chief coordinators, communicated regularly with the coordinators of each center. Each center comprised its own coordinator and an evaluator. The coordinators managed the schedules of the participants and evaluators as well as ensured randomization (see below). The raters measured the results of the study, received training on the method to measure and perform the measurements, and recorded the data. Dentists who provided denture care to the participants were not allowed to evaluate the study. Subsequently, the recorded data were sent to a third party for entry. Blinded digital data were returned to the chief coordinator for analysis. This study was registered with the National Clinical Trials Registry (NCT01712802) on October 17, 2012.

2.2. Participants and ethical approval

Participants were recruited from 10 centers between September 2013 and October 2016. The inclusion criteria were as follows: (1) completely edentulous, (2) willing to undergo new complete

denture treatment, and (3) willing to return for recall treatment. The exclusion criteria were as follows: (1) age 90 years or older, (2) presence of severe systemic illness that would hinder participation in the study, (3) inability to understand and respond to the questionnaires, (4) wearing complete dentures with a metal base, (5) regular use of denture adhesive, (6) wearing prosthetics due to maxillofacial defects, (7) wearing complete dentures with tissue conditioners, and (8) severe xerostomia (dryness score ≤ 20). The study was conducted in accordance with the principles of the Declaration of Helsinki. Each participant received oral and written information regarding the study and provided informed consent. The study protocol was approved by the Health and Hygiene Ethics Committees of Iwate Medical University (Ethics Committee #1192, Iwate Medical University School of Dentistry), Tohoku University (Ethics Committee #25-4, Tohoku University Graduate School of Dentistry), Tokyo Medical and Dental University (Ethics Committee #960, Tokyo Medical and Dental University School of Dentistry), Nihon University, Matsudo School of Dentistry (Ethics Review Committee #15-12-020-1, Nihon University, Matsudo School of Dentistry), Tsurumi University (Tsurumi University School of Dentistry Research Ethics Committee #1115), Kanagawa Dental College (Kanagawa Dental College Research Review Committee #223), Osaka Dental College (ODU Dental Ethics Committee #110780), University of Tokushima (Tokushima University Hospital Ethics Committee #1697), Nagasaki University (Nagasaki University Hospital Ethics Committee #1362430-2) (Nagasaki University Hospital Ethics Committee #1362430-2), and Kagoshima University (Kagoshima University Hospital Clinical Research Ethics Committee #25-17).

2.3. Sample size calculation

Based on previous reports[8,9], we predicted that general satisfaction assessed based on a visual analog scale (VAS) in the intervention and control groups would be 75 and 46 mm, respectively. Thus, a 29-mm mean difference in the VAS assessment of overall satisfaction between the intervention and control groups was considered a clinically important difference. Based on previously reported data[8,9], using variances of 20 and 23 mm in the intervention and control groups, respectively, 100 participants were required in each group to obtain 80% power at an alpha level of 5%, assuming a dropout rate of 10%.

2.4. Randomization and allocation confidentiality

A randomized controlled parallel clinical trial was conducted at the 10 centers listed in Section 1. The participants were randomly allocated to one of the following three groups based on the intervention adopted: cream-type denture adhesive (cream), powder-type denture adhesive (powder), and saline solution control (control) using sealed envelope system. Intervention blinding was not feasible because the participants were aware of the type of denture adhesive used. However, the raters were blinded to the group assignments.

2.5. Intervention

The participants were instructed to adhere to the instructions prescribed for the use of both maxillary and mandibular dentures (Fig. 1) for four consecutive days. We selected cream and powder-based formulations of denture adhesives because they are typically used for research purposes. The denture adhesive cream comprised methoxyethylene/maleic anhydride copolymer petrolatum, sodium carboxymethyl cellulose, liquid paraffin, and propyl parahydroxy-

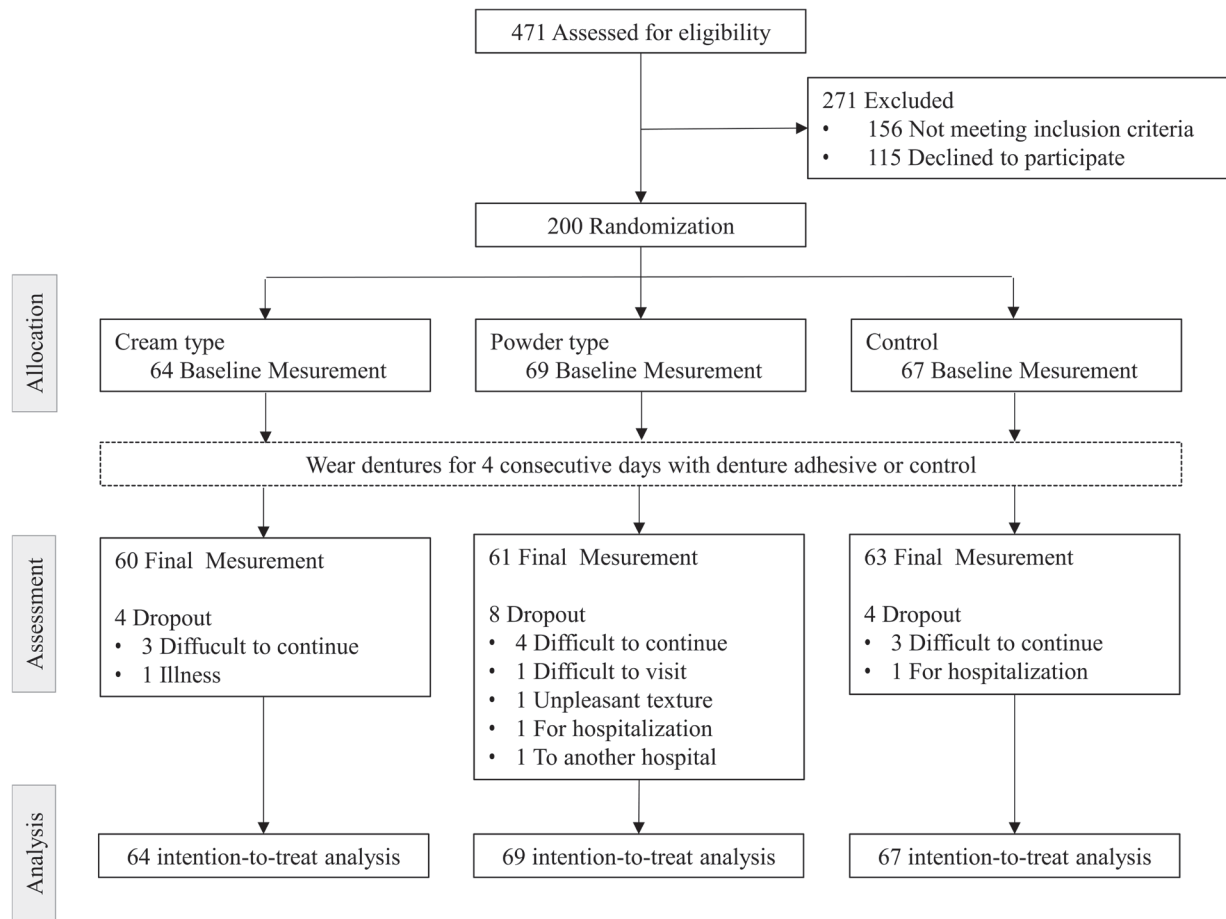


Fig. 1. Trial flowchart. Follow-up rate of 92% (184/200)

benzoate (Polygrip S; GlaxoSmithKline, Tokyo, Japan). The denture adhesive powder comprised methoxyethylene/maleic anhydride copolymer and sodium carboxymethyl cellulose (polygrip powder; GlaxoSmithKline, Tokyo, Japan). The control was a saline solution (isotonic [0.9%] sodium chloride solution, 20 mL CMX; Chemix Inc., Yokohama, Japan).

2.6. Schedule of trial

A summary of the schedules from days 0 to 4 is presented **Table 1**.

2.6.1. Day 0

The dentists at each center requested eligible denture wearers to meet the coordinator. The coordinator met the participants and explained the study. Written informed consent was obtained from all the participants. Subsequently, the evaluator conducted an eligibility review to determine whether the participants satisfied the inclusion and exclusion criteria. Next, the coordinator randomly assigned eligible candidates to one among three study groups. The participants were instructed to return to the center twice during the study period.

2.6.2. Day 1

On day 1, the evaluator performed baseline measurements, as

shown in **Table 2**. The study coordinators explained to the participants regarding the use of the denture adhesives or control solution based on the manufacturer's instructions. The procedure for applying the powder was as follows: (1) The dentures were cleaned, rinsed, and maintained in wet state before the powder was applied. (2) The powder was dispersed on the supporting areas of the denture by lightly gripping or tapping the bottle. (3) Any excess powder was shaken off, and the denture was fitted via a brief push. (4) The powder-type denture adhesive was applied before breakfast and dinner. (5) The denture adhesives were used when necessary. (6) The remaining denture adhesive was removed immediately before each new application of denture adhesive or before bedtime. (7) The denture adhesive was applied before dinner on day 1. Meanwhile, the cream adhesive was applied as follows: (1) The dentures were cleaned, rinsed, and dried before the cream was applied. (2) The cream tube was squeezed gently and the cream was applied to the supporting areas of the denture in small strips or dots. (3) The dentures were fitted via a brief push. (4) The cream type denture adhesive was applied once a day before breakfast. (5) The denture adhesives was used when necessary. (6) The remaining denture adhesive was removed immediately before each new application of denture adhesive or before bedtime. (7) The denture adhesive was applied before dinner on day 1. The procedure for applying the control saline was as follows (eight bottles were supplied to each participant, and one bottle was supplied for each use): (1) Before application, the dentures were cleaned, rinsed, and maintained in wet state. (2) The bottle was lightly squeezed and the

Table 1. Schedule of trial

Trial Schedule	Day 0	Day 1	Day 2	Day 3	Day 4
Eligibility screen	○				
Explanation of trial and Informed consent	○				
Instructions to denture adhesive		○			
Random assignment	○				
Baseline measurement		○			
Final measurement					○
Hospital visit	○				○
Breakfast using dentures with denture adhesive			○	○	○
Lunch using dentures with denture adhesive			○	○	
Dinner using dentures with denture adhesive		○	○	○	

○: The activity is scheduled on this day

Table 2. Participant characteristics

Participant characteristics	Control (n=67)	Powder (n=69)	Cream (n=64)	P-value
Age (years)	74.8 (7.5)	76.4 (8.2)	75.2 (8.4)	0.48 ^a
Sex (female/male)	38 / 29	34 / 35	33 / 31	0.67 ^b
Edentulous period (months)	176.6 (168.3)	198.6 (163.4)	177.4 (159.7)	0.68 ^a
Period wearing existing denture (months)				
Maxillary denture	70.3 (140.1)	72.3 (146.4)	93.0 (198.8)	0.69 ^a
Mandibular denture	76.1 (146.8)	73.8 (108.1)	82.2 (162.5)	0.76 ^a
Masticatory performance	32.1 (13.0)	31.3 (13.0)	33.4 (14.2)	0.67 ^a
Intraoral condition score	74.0 (11.9)	72.5 (11.7)	74.3 (12.1)	0.90 ^a

^a: Analysis of variance; ^b: Chi-squared test. There is no significant difference in participant characteristics between Control, Powder, and Cream.

solution was applied across the supporting areas of the denture. (3) The denture was pressed and held in place for a short time. (4) Saline was administered before breakfast, lunch, and dinner. (5) Saline was used when necessary. (6) Saline was applied before dinner on day 1.

2.6.3. Days 2 and 3

No hospital visits were made on days 2 or 3. Denture adhesives were applied using the same method as that used on day 1.

2.6.4. Day 4

The final measurement was performed on day 4. The participants used the denture adhesive from before dinner on day 1 to before breakfast on day 4, using the application method described above. On day 4, the participants visited the hospital for the final measurement, and the denture adhesive was maintained on the denture. Thus, the participants used denture adhesives before eight meals in total: three dinners (days 1, 2, and 3), three breakfasts (days 2, 3, and 4), and two lunches (days 2 and 3). The evaluator weighed the remaining amount of denture adhesive and determined the remaining amount of saline solution to verify the participant's compliance with the use of the denture adhesive. If the participants in any of the groups experience pain or encounter any problems with the existing denture, then the dentist will provide the appropriate treatment.

2.7. Outcomes

2.7.1. Masticatory performance

Color-changing chewing gum (masticatory performance-evalu-

ating gum; XYLITOL Lotte Co., Ltd., Tokyo, Japan) and a colorimeter (CR-13; Konica Minolta Sensing, Tokyo, Japan) were used to evaluate chewing ability. The measurements were performed as described in previous reports[10,11], and the participants were instructed to chew the gum 100 times at a rhythm of once per second (set by a metronome) based on their preferred side, i.e., without instructions regarding the side on which they should chew. The gum was removed immediately after chewing. The gum was compressed and flattened to a thickness of 1.5 mm between two glass plates and then placed on a polyethylene film. The gum color was measured using a polyethylene film using a colorimeter.

The CIE-L*a*b* color system was used to evaluate the color changes. One color is represented as a point plotted in the color space on three axes: L*, a*, and b*. The L*-axis represents the brightness of a color. The a*-axis represents the position between red and green, with positive and negative values representing reddish and greenish colors, respectively. The b*-axis represents the position between blue and yellow, with positive and negative values indicating yellowness and blueness, respectively. Using a colorimeter, we measured the color at five locations: the center between the left and right edges, and approximately 3-mm above, below, left, and right of this point. The L*, a*, and b* values of these five points were averaged for the analysis. From each mean value of L*, a*, and b*, the difference between two colors in the CIE-L*a*b* color space (ΔE) was calculated for 60 strokes using the following equation:

$$\Delta E = \left[(L^* - 72.3)^2 + (a^* - 14.9)^2 + (b^* - 33.0)^2 \right]^{1/2}$$

The L^* , a^* , and b^* values before chewing were 72.3, 14.9, and 33.9, respectively. ΔE was used to evaluate masticatory performance.

2.7.2. Participant characteristics as covariates

A questionnaire issued by the Japan Prosthodontic Society was used to obtain baseline data pertaining to characteristics related to the oral condition of the participants, including the morphology of the residual ridge, condition of the oral mucosa, relationship between the maxilla and mandible, abnormal habits, quantity and quality of saliva, and frenum attachment[12]. The participants' intraoral condition-associated characteristics were quantified, and the associated difficulty level in complete denture treatment was defined for each edentulous patient. The mean total intraoral condition score was 100. Low scores implied difficult-to-treat cases, whereas high scores reflected easy-to-treat cases. As covariates, the participants' characteristics (age, sex, edentulous period, and age of existing complete denture) were obtained.

2.8. Data analyses

First, we analyzed the normality of distribution of ΔE values using the Kolmogorov-Smirnov test and discovered that the data were normally distributed. Thus, parametric tests were performed for data analysis.

The characteristics of the participants were compared among the three groups using the one-way analysis of variance (ANOVA). Differences in the proportions of categorical variables among the three groups were analyzed using the chi-squared test.

The between-group masticatory performance post-intervention among the control, powder, and cream groups was tested using the one-way ANOVA. Within-group comparisons of the pre- and post-intervention measurements were performed for each group using a paired t -test with Bonferroni correction.

The association between masticatory performance and intraoral condition scores was analyzed using Pearson's correlation coefficients. Finally, a linear regression equation was derived from the data.

We used the intention-to-treat (ITT) principle to account for missing data after randomization. All statistical analyses were performed using the IBM SPSS Statistics Package v21 (IBM, Armonk, NY, USA), and statistical significance was set at $P < 0.05$.

3. Results

3.1. Participant flow

The participant recruitment commenced in September 2013 and ended in October 2016. A total of 471 patients (aged 43–95 years) were sampled consecutively for the trial (Fig. 1). Based on the selection criteria, 271 patients were excluded. The remaining 200 patients were randomized into cream, powder, and control groups. Finally, 64 participants in the cream group (4 dropouts), 69 in the powder group (8 dropouts), and 67 in the control group (4 dropouts) participated in the ITT analyses. The overall follow-up duration was 92%.

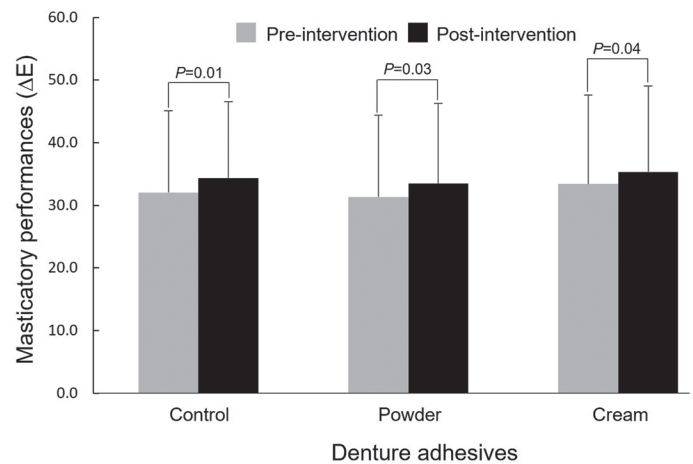


Fig. 2. Masticatory performance. The between-subject analysis, using an analysis of variance, showed no significant differences in masticatory performance among the control, powder, and cream groups. The within-subject analysis, by means of the Bonferroni-corrected t -test, revealed significantly different masticatory performances from pre- to post-intervention in the control ($P = 0.01$), powder ($P = 0.03$), and cream ($P = 0.04$) groups.

3.2. Participants' characteristics

No significant differences were indicated in the characteristics of the participants between the groups (Table 2), indicating appropriate randomization.

3.3. Masticatory performance

The pre-post comparisons of the masticatory performance of each group are shown in Figure 2. For the control, powder, and cream groups at baseline, the ΔE values were 32.1 ± 13.0 , 31.3 ± 13.0 , and 33.4 ± 14.2 , respectively, and at post-intervention, they were 34.4 ± 12.2 , 33.5 ± 12.8 , and 35.3 ± 13.7 , respectively. Within group analyses showed significant differences in masticatory performance between pre- and post-intervention in the control ($P = 0.01$), powder ($P = 0.03$), and cream ($P = 0.04$) groups. Between-group analyses revealed no significant differences in masticatory performance among the control, powder, and cream groups.

Figure 3 shows the association between the pre- and post-changes in masticatory performance and intraoral condition scores. The Pearson correlation coefficient (r) was -0.249 . A significant negative correlation between pre- and post-changes of masticatory performance and intraoral condition scores was observed ($P < 0.0001$). A linear regression equation ($y = -0.1598x + 13.895$) was calculated from the data.

4. Discussion

The 10-center, parallel, randomized, controlled trial, which was performed to investigate the effect of denture adhesive on masticatory performance, showed that the masticatory performance of complete denture wearers improved after they used denture adhesive; the effect of denture adhesive was comparable to that of saline solution used as a control. Participants with worse intraoral condition showed better masticatory performance than those with better denture adhesives.

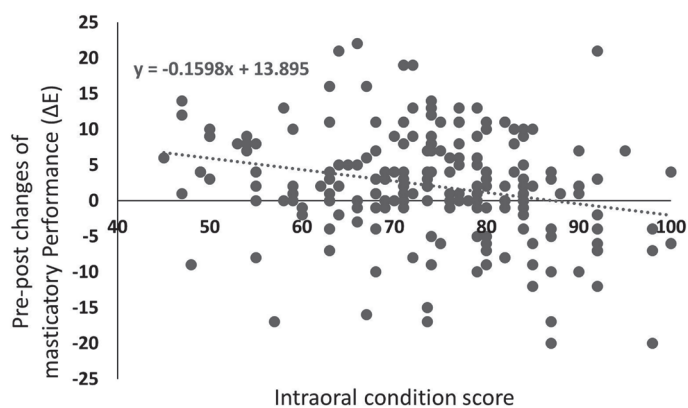


Fig. 3. Association between masticatory performance and intraoral condition. A significant negative correlation was observed between masticatory performance and the intraoral condition score ($P < 0.001$).

This study revealed that the clinical effect of denture adhesive on masticatory performance was comparable to that of saline solution used as a control. However, the effects of denture adhesive on the masticatory performance remain controversial. Berg reported that the use of denture adhesive improved the chewing ability of complete denture wearers[13]. In a crossover randomized clinical trial, De Oliveira *et al.* reported that using denture adhesive with new dentures improved the masticatory performance of complete denture wearers; however, no significant differences were indicated between cream- and powder-type adhesives[14]. Fujimori *et al.* reported that the masticatory performance of complete denture wearers with weak denture-bearing tissues, but not those with good denture-bearing tissues, improved via the use of denture adhesive[15]. The different results of the studies above indicate that the effect of denture adhesive on masticatory performance might vary depending on the study protocol. Most studies measured masticatory performance immediately after the application of denture adhesive. However, in our protocol, the participants did not apply denture adhesive to their dentures prior to the measurement of their masticatory performance. Some studies suggested the application of denture adhesive every 3 h to maintain the desired retention in denture wearers[16–18]. Considering the above, the dissolution of denture adhesive from dentures might have nullified the effect of denture adhesive on masticatory performance.

This study showed a significant negative correlation between masticatory performance changes based on pre-intervention to post-intervention and intraoral condition scores. Considering that the mean intraoral condition scores of the cream, powder, and control groups were 74.3 ± 12.1 , 72.5 ± 11.7 , and 74.0 ± 11.9 , respectively, the intraoral condition of most participants was satisfactory. However, different results may have been obtained if we targeted participants with unsatisfactory intraoral conditions. Thus, RCTs targeting complete denture wearers with poor intraoral condition scores and/or new dentures should be conducted. The result of the current study conveys the clinical significance of participants with worse intraoral conditions achieving desirable masticatory performance from the use of denture adhesives.

Regardless of whether denture adhesive or saline solution was used, masticatory performance improved significantly. Gonçalves *et al.* reported that the retention force derived from denture adhesives

improved chewing ability[19]. Meanwhile, saline solution is unlikely to enhance the retention force. However, the use of denture adhesive provides psychological support and promotes confidence in patients who are not willing to use prostheses[2]. Complete denture wearers gradually acquire the skills required for mastication by repeating the daily practice of food mastication[20]. With indirect psychological support derived from the placebo effect, patients using a saline solution can improve their skills in using complete dentures, which will improve their masticatory performance. In this study, we hypothesize that the benefit of denture adhesive is derived from psychological support via the placebo effect. However, to verify this hypothesis, both active (saline) and passive control (nothing used) should have been considered. Further studies are warranted to clarify whether the psychological support received by patients presents a placebo effect that might improve denture management by denture wearers.

For this study, a wide range of complete denture wearers were recruited, among which some participants did not experience unsatisfactory denture retention and/or stability. Furthermore, the intraoral conditions of most participants were favorable. Some limitations are presented in this study, and the results pertaining to masticatory ability may not necessarily be applicable to a population encountering unsatisfactory denture retention/stability and intraoral conditions.

5. Conclusions

Although denture adhesives improve the masticatory performance of complete denture wearers, their clinical effect is comparable to that of saline solution. The use of denture adhesives is more effective in complete denture wearers with unsatisfactory intraoral conditions.

Acknowledgments

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Conflict of interest

The authors have no conflicts of interest to declare.

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