

# Effects of denture adhesives on denture retention and occlusal forces in complete denture wearers: A multicenter, randomized controlled trial

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# Abstract

**Purpose:** This study aimed to determine the effects of denture adhesives on denture retention and occlusal force in complete denture wearers in a multicenter, randomized, parallel-group controlled trial.

**Methods:** Two hundred edentulous patients wearing complete dentures were allocated to three groups: powder-type denture adhesive, cream-type denture adhesive, and control (saline solution). Denture adhesives and saline solution were applied to the dentures for 4 days. The retentive force of the dentures and occlusal force were measured using a force transducer occlusal force meter at baseline and after 4 days of intervention. In addition to between-group comparisons, subgroup analyses of denture retention and occlusal force were performed based on the level of difficulty of the edentulism treatment. The levels were ranked as I (easy), II, III, and IV (difficult).

**Results:** Cream-type denture adhesives significantly improved the retentive force of the dentures (P<0.01) and occlusal force (P<0.05), with no significant differences between baseline and post-intervention forces in the powder-type denture adhesive and control groups. In within-group comparisons, cream-type denture adhesives improved both the retentive and occlusal forces at Level II (P<0.05), and powder-type denture adhesives improved the occlusal force at Level II (P<0.01). **Conclusions:** Application of cream-type denture adhesives effectively improves the denture retention and occlusal force in complete denture wearers with a moderate degree of difficulty during edentulism treatment.

Keywords: Denture adhesive, Complete denture, Denture retention, Occlusal force, Multicenter randomized controlled trial

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# 1. Introduction

In recent years, the number of older adults has increased worldwide, especially in Japan, which has become a super-aging society. Accordingly, the number of patients using dentures has increased with the increase in the number of older persons worldwide[1]. Furthermore, in many denture wearers, severe resorption of the residual ridge[2] and dry mouth[3] lead to poor retention and stability of dentures. The application of denture adhesives is effective for such denture wearers in improving denture retention and stability when sufficient retention and stability are not obtained, even though the contact between the denture intaglio surface and the basal seat mucosa is sufficient[4].

Denture adhesives are classified into glue and liner types[5]. A glue-type denture adhesive is applied in cream, powder, sheet, or tape form. Water-soluble polymers, such as sodium carboxymethyl cellulose (CMC-Na), poly(methyl vinyl ether-maleic anhydride) (PVM-MA), or sodium polyacrylate, which are included in the glue-type materials, absorb saliva and provide adhesion, thus improving the retention and stability of dentures[6]. A liner type (cushion form) denture adhesive consists of a non-aqueous paste of polyvinyl acetate and ethyl alcohol, and it improves the retention and stability by filling the gap between the denture intaglio surface of ill-fitting dentures and the basal seat mucosa<sup>[7]</sup>. Generally, the use of both powder- and cream-type denture adhesives, rather than the liner type, is recommended for clinical cases, because both powder- and cream-type denture adhesives produce a thin layer of denture adhesive while minimally changing the occlusal relationship after application[8].

The clinical efficacy of cream-type denture adhesives has been evaluated based on the retention and stability of dentures[9–12], masticatory performance[13–15], bite force[11,16,17], and oral healthrelated quality of life[18–20]. Some non-randomized controlled trials (N-RCTs) of the clinical issues related to denture adhesives have been conducted[21–23]. However, a randomized controlled trial (RCT) is generally preferred over a N-RCT because of bias and objective evaluation. In RCTs of denture adhesives, both crossover[15] and parallel groups[13,14] trials have been conducted. The influence of the first procedure on the results obtained by the second procedure and the interaction between the two procedures were generally lower in a parallel-group trial than in a crossover group trial. Furthermore, multi-institutional joint research has the advantage of recruiting many cases and avoiding bias in the conditions of cases compared to a single-center study.

Although many clinical studies on the effects of denture adhesives have been reported, there have been no multicenter, randomized, parallel-group controlled trials with a sufficient number of participants. Therefore, as part of the Denture Adhesive Guideline (DAG) project, our research group comprising 10 centers[24] decided to verify the clinical efficacy of denture adhesives to establish the guidelines for the use of denture adhesives by complete denture wearers and for instructions by dentists or dental hygienists using the data obtained in the trial above. Denture adhesives are widely used; however, there is a possibility that the users apply denture adhesives improperly because the materials are not under the control of dentists. The content of the user's misuse may be application to cases that are inappropriate in terms of the oral condition, in addition to the amount and frequency of use. Our previous studies demonstrated an improvement in satisfaction[25], oral health-related quality of life[26], and efficacy for patients with oral dryness[27] through the application of denture adhesives in complete denture wearers. Furthermore, it is also necessary to determine the relationship between the degree of difficulty of edentulism treatment, including the morphological level of the residual ridge, denture retention, and occlusal force of dentures to establish guidelines for the use of denture adhesives.



Fig. 1. Trial flowchart

In this study, the effects of the application of denture adhesives to complete dentures on denture retention and occlusal force of dentures and the relationship between the effect and degree of difficulty of edentulism treatment were evaluated using the data obtained in the DAG project, which was a multicenter, randomized, parallel-group controlled trial[27]. It was hypothesized that the application of cream- and powder-type denture adhesives improves denture retention and occlusal force in complete denture wearers, and that the effect of denture adhesives increases as the difficulty of edentulism treatment increases.

# 2. Materials and Methods

#### 2.1. Study design and trial schedule

The full protocol of this study has been reported and is available online in an open-access format[24]. This trial was registered in the US Clinical Trials Registry (NCT01712802) on October 17, 2012. The protocol has also been described in our previous studies[25–27].

A flowchart of the study[25-27] is shown in Figure 1. The randomized, parallel-group controlled trial was performed at the following 10 centers and was approved by the relevant ethics board at each center (name and approval number of each center): lwate Medical University (Ethics Committee of School of Dentistry, Iwate Medical University, No. 1192); Tohoku University (Ethics Committee of Tohoku University Graduate School of Dentistry, No. 25-4); Tokyo Medical and Dental University (Ethics Committee of the Faculty of Dentistry, Tokyo Medical and Dental University, No. 960); Nihon University School of Dentistry at Matsudo (Ethics Review Committee of Nihon University School of Dentistry at Matsudo, No. 15-12-020-1); Tsurumi University (Research Ethics Committee of Tsurumi University School of Dental Medicine, No. 1115); Kanagawa Dental University (Kanagawa Dental University Committee for Research Screening, No. 223); Osaka Dental University (Osaka Dental University Dental Ethics Committee, No. 110780); Tokushima University (Ethics Committee of Tokushima University Hospital, No. 1697); Nagasaki University (Clinical Research Ethics Committee in Nagasaki University Hospital, No.

Material	Туре	Manufacturer	Composition*
Poligrip Powder	Powder	Earth Chemical Co., Ltd., Tokyo, Japan / GlaxoSmithKline K.K., Tokyo, Japan	Methoxyethylene / maleic anhydride copolymer, sodium carboxymethyl cellulose
Poligrip S	Cream	Earth Chemical Co., Ltd., Tokyo, Japan / GlaxoSmithKline K.K., Tokyo, Japan	Methoxyethylene / maleic anhydride copolymer, petrolatum, sodium carboxymethyl cellulose, light liquid paraffin, propyl parahydroxybenzoate, aroma chemical, No. 3 aluminium lake

Table 1. Denture adhesives used

\*Composition as given by manufacturers

1362430-2); and Kagoshima University (Clinical Study Ethics Committee of Kagoshima University Hospital, No. 25-17).

#### 2.2. Participants

The participants were edentulous patients who visited the above 10 centers for new fabrication, adjustment, and regular dental examinations of the complete dentures[24–27]. The protocol did not limit participation due to chief complaints such as masticatory pain, speech, appearance, instability, and lack of retention. The exclusion criteria were as follows: i) age  $\geq$  90 years; ii) serious systemic disease that may make it difficult to participate in this study; iii) inability to understand the questionnaires used in this study; iv) wear metal plate dentures; v) regularly use denture adhesives; vi) wear a maxillofacial prosthesis; vii) wear dentures lined with tissue conditioners; and viii) have severe dry mouth (dryness score  $\leq$  20). Informed consent was obtained from each participant prior to the start of the study.

#### 2.3. Sample size, randomization, and blinding

The total sample size was 300, divided into three groups (100 patients per group), as described below (2.4. Intervention). Three hundred patients, including a projected dropout rate of 10%, were deemed necessary to achieve 80% power with an alpha level of 5%[24–27]. Three hundred random allocation cards were created using Excel's RAND and RANK functions (Microsoft Japan Co. Ltd., Tokyo, Japan). Group names were printed on the cards, and 30 cards were distributed to each of the 10 centers. The coordinator at each center allocated participants according to the group name on the card. The coordinator managed the allocation of information to hide the information from the evaluator.

## 2.4. Intervention

The intervention was the application of powder-type denture adhesives, cream-type denture adhesives (**Table 1**), or control (saline solution) on maxillary and mandibular complete dentures for four consecutive days[24–27]. A saline solution (isotonic sodium chloride solution, 20 mL CMX; Chemix Inc., Yokohama, Japan) was used as the control. The participants were divided into three groups: powder-type denture adhesive, cream-type denture adhesive, and control groups. The coordinators taught the participants the methods of application of the denture adhesives and saline solution as follows. Instructions on how to apply the denture adhesives were also provided to each participant.

In the powder-type denture adhesive group, dentures were cleaned, rinsed, and left wet. Subsequently, an appropriate amount of powder was sprinkled onto the intaglio surfaces of the dentures, and the excess powder that was not dissolved in water was shaken off. Participants pressed the dentures firmly and held them briefly. They were instructed to apply the denture adhesive before eating breakfast and dinner.

In the cream-type denture adhesive group, dentures were cleaned, rinsed, and dried. An appropriate amount of cream was then placed on the intaglio surfaces of the dentures. Subsequently, approximately 0.5 to 3.0 cm of cream was placed in 2 to 3 places onto the intaglio surfaces of the dentures. Participants pressed the dentures firmly and held them briefly. They were instructed to apply the denture adhesive once a day before eating breakfast.

In the control group, dentures were cleaned, rinsed, and left wet. Subsequently, 20 mL of saline solution was poured onto the intaglio surfaces of the dentures by squeezing the bottle to keep the surface wet. Participants pressed the dentures firmly and held them briefly. They were instructed to apply the saline solution before every meal.

The participants applied denture adhesives and saline solution as stated above according to the manufacturer's instructions. They were also instructed to remove the remaining materials before sleeping at night and apply new materials in the morning. Participants were permitted to apply additional denture adhesives and saline solutions whenever they wished. Compliance with the intervention concerning the application of denture adhesives and saline solution was confirmed by measuring the weight of the remaining denture adhesives and counting the remaining number of bottles of saline solution at the end of the 4-day intervention period.

## 2.5. Trial schedule

Figure 1 shows the flowchart of this study[25-27].

## Day 0

The attending dentists at each center asked the complete denture wearers to listen to an explanation of this trial from a coordinator. After the coordinator obtained written informed consent from the candidates, an evaluator conducted eligibility screening to check whether the candidates met any of the exclusion criteria. The coordinator then allocated the candidates to one of the above three groups (powder-type denture adhesive, cream-type denture adhesive, and control groups) using envelopes that contained a card stamped with the group name.

## Day 1

The evaluators conducted baseline measurements[24]. The coordinator explained to the participants how to use the denture adhesives and saline solution, as described above. The participants applied the denture adhesives or saline solution before dinner on day 1 and then ate dinner.

## Days 2 and 3

The participants did not visit the hospital on days two and three. They continued to apply denture adhesives or saline solution corresponding to the group to which they had been allocated.

### Day 4

The participants were scheduled to have eight meals, specifically three breakfasts, two lunches, and three dinners, with dentures lined with denture adhesive or saline solution. The participants visited each hospital after eating breakfast with the application of these materials, and the final measurements were performed. Compliance during the trial was confirmed by measuring the quantity of residual denture adhesives and saline solution, as noted above.

The attending dentists adjusted the existing dentures if the participants complained of problems, such as masticatory pain during the trial. Information concerning group allocation was managed solely by the coordinators at each center and not by the evaluators. The collected data were sent to a third-party organization for conversion to digital data. Blinded digital data were sent back to the chief coordinator at each center for analysis.

## 2.6. Outcomes

#### 2.6.1. Retentive force (resistance to dislodgement)

The retentive force (resistance to dislodgement) of the dentures was determined using a force transducer occlusal force meter (GM10; Nagano Keiki, Tokyo, Japan), according to our previous report[24] (**Fig. 2**). This device consists of a digital hydraulic pressure gauge and vinyl biting element covered with a plastic sheath. The values displayed on the device are in Newtons. The pressure sensor at the tip of the device was placed on the incisal artificial teeth of the mandibular dentures and the evaluators instructed the participants to continually bite it. The evaluators continued to view the display values until the maxillary and/or mandibular dentures were dislodged. The value of the retentive force (resistance to dislodgement) is defined as the maximum voluntary occlusal force exerted during the bite in the incisal region before dislodgement of the maxillary and/or mandibular dentures. Each measurement was repeated three times.

#### 2.6.2. Occlusal force

The maximum voluntary occlusal force[16,28] was also determined bilaterally in the first molar region using the abovementioned force transducer occlusal force meter (**Fig. 2**). Each measurement was repeated thrice.

#### 2.6.3. Data analysis and statistical analysis

The participants were classified based on the degree of difficulty of edentulism treatment, and the analysis was performed using a series of data obtained from the DAG project[24–27]. The participants were classified into four subgroups using a data sheet for intraoral condition-associated characteristics of edentulous patients authorized by the Japan Prosthodontic Society[29] to evaluate the relationship between outcomes and the degree of difficulty in the treatment of edentulous patients. This examination consisted of five items: 1) shape of the residual ridge, such as height, width, and unevenness (maximum score: 30); 2) condition of the basal seat mucosa,





Fig. 2. Force transducer occlusal force meter (a), resistance to dislodgement of denture (b), and measurements of occlusal force (c)

such as tissue displacement and inflammation (maximum score: 20); 3) ridge relationship (maximum 30 scores); 4) abnormal habit, vomiting reflex, and so on (maximum score: 10); and 5) others concerning frenulum and saliva (maximum score: 10). Each item was evaluated on several levels and scored. These scores were then summed. The difficulty level of edentulous patients was defined using the total scores as follows: Level I, 55–70; Level II, 40–54; Level III, 25–39; and Level IV, 24 or less. The maximum value for the dataset was 100.

An intention-to-treat (ITT) analysis was performed, and missing values due to dropouts were compensated for by substituting the median or mean values obtained from other participants. The Kruskal-Wallis test and chi-squared test were used to compare the participants' characteristics. Between-group comparisons were performed using the Kruskal-Wallis test, and the pre- and postintervention values were compared using the Wilcoxon signed-rank test. Within-group comparisons of the pre- and post-intervention measurements were performed using the Wilcoxon signed-rank test. The level of significance for all tests was set at P < 0.05.

# 3. Results

#### 3.1. Participants' information and allocation status

Participants in this trial were recruited from September 2013 to October 2016[25–27]. A total of 471 edentulous patients (age range:43–95 years) participated in this study; 271 were excluded according to the inclusion and exclusion criteria, resulting in the selection of 200 participants who were allocated randomly into three groups (control, 67; powder-type denture adhesive, 69; and cream-type denture adhesive, 64). The participants, including the dropouts in each group, were included in the ITT analysis (**Fig. 1**).

No significant differences were found in any of the participants' characteristics and the values of retentive force (resistance to dislodgement) of the dentures and occlusal force at baseline among the three groups, confirming the proper randomization of the participants (**Table 2**)[27].

#### 3.2. Degree of difficulty of edentulism treatment of the participants

**Table 3** shows the distribution of the degree of difficulty of edentulism treatment obtained using the classification method

#### Table 2. Comparison of the three groups by participants' characteristics and outcomes at baseline[23]

	Group			
	Control	Powder-type denture adhesive	Cream-type denture adhesive	P-Value
	(n = 67)	(n = 69)	(n = 64)	
Age (y: median [IQR])	76.0 [71.0-80.0]	77.0 [72.0-81.0]	77.0 [69.3-81.0]	0.58ª
Sex (M/F)	29/38	35/34	31/33	0.67 <sup>b</sup>
Edentulous period (month: median [IQR])	120.0 [48.0-240.0]	180.0 [84.0-288.0]	120.0 [72.0-234.0]	0.48 <sup>a</sup>
Period of current-use (month: median [IQR])				
Maxillary denture	27.0 [12.0-72.0]	24.0 [12.0-108.0]	27.0 [18.0-60.0]	0.85 <sup>a</sup>
Mandibular denture	24.0 [12.0-60.0]	24.0 [12.0-42.0]	24.0 [13.5-60.0]	0.39 <sup>a</sup>
Resistance to dislodgement (N: median [IQR])	15.7 [0.0-34.7]	16.7 [0.0-29.2]	12.8 [0.0-24.7]	0.20 <sup>a</sup>
Occlusal bite force (N: median)	53.5 [25.3-81.7]	49.0 [29.3-65.1]	38.4 [20.4-68.3]	0.27 <sup>a</sup>

IQR: interquartile range, a: Kruskal-Wallis test, b: Chi-squared test

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Subgroup	Group			
	Control	Powder-type denture adhesive	Cream-type denture adhesive	Total
Level I	22	20	20	62
Level II	37	37	36	110
Level III	8	12	8	28
Level IV	0	0	0	0
Total	67	69	64	200

\*Classification authorized by the Japan Prosthodontic Society[27]

authorized by the Japan Prosthodontic Society[29]. The degree of treatment difficulty of the participants was as follows: Level I, 62 participants (31.0%); Level II, 110 participants (55.0%); Level III, 28 participants (14.0%); Level IV, 0 participants (0%).

#### 3.3. Retentive force (resistance to dislodgement)

The amount used per application of the denture adhesives and saline solution was calculated from the remaining amount, and each evaluator confirmed that an unsuitable amount was not applied. Consequently, compliance with the intervention was also confirmed.

**Figure 3** shows the retentive force (resistance to dislodgement) at baseline and post-intervention in each group. Significant differences in retentive force were not found among the control, powder- and cream-type denture adhesive groups at both baseline and post-intervention. The retentive force of the cream-type denture adhesive group was significantly higher post-intervention than at baseline (P < 0.05). Significant differences were not found between the baseline and post-intervention in the control and powder-type denture adhesive group.

**Figure 4** shows the subgroup analyses of the relationships between the retentive force at baseline and post-intervention, and the level of difficulty of edentulism treatment in each group. The median values of the retentive force were higher post-intervention than at baseline at all the levels in each group. However, the retentive force of only Level II participants in the cream-type denture adhesive group was higher post-intervention than that at baseline (P < 0.05). No significant differences were found between baseline and post-intervention at any level in each group, except for Level II in the

cream-type denture adhesive group.

#### 3.4. Occlusal force

**Figure 5** shows the occlusal forces at baseline and post-intervention in each group. According to between-group analyses, there were no significant differences in occlusal force among the control, powder-type denture adhesive and cream-type denture adhesive groups at both baseline and post-intervention. Within-group analyses demonstrated that the occlusal force of the cream-type denture adhesive group was significantly higher post-intervention than that at baseline (P < 0.05). No significant differences were found between the baseline and post-intervention in the control and powder-type denture adhesive groups.

**Figure 6** shows the subgroup analyses of the relationships between the occlusal force at baseline and post-intervention, and the level of difficulty of edentulism treatment in each group. The occlusal force of Level II participants in both the powder- and cream-type denture adhesive groups was significantly higher post-intervention than at baseline (P < 0.05). No significant differences were found between baseline and post-intervention for Level I and Level III participants in both the powder- and cream-type denture adhesive groups, although the median values of Level I and Level III participants in the cream-type denture adhesive group were higher post-intervention than at baseline. No significant differences were observed in the control group.

# 4. Discussion

The present findings partially confirm our hypotheses that



Fig. 3. Resistance to dislodgement at baseline and post-intervention in the three groups. o: outliers, +: extremes. \*\* P<0.01



**Fig. 4.** Resistance to dislodgement at baseline and post-intervention at each level of difficulty of edentulism treatment in the three groups. o: outliers, +: extremes. \* P<0.05

the application of cream-type denture adhesives increases both the retentive force of complete dentures and the occlusal force of complete denture wearers, and that the application of powder-type denture adhesives increases the occlusal force. The powder-type denture adhesives did not improve denture retention. Furthermore, the hypothesis that the effect of denture adhesives is greater with an increase in the difficulty of edentulism treatment was rejected.

Generally, denture retention increases with a larger denture intaglio surface, better fit between the denture and basal seat mucosa, higher hydrophilicity of the denture base material, and higher viscosity and larger amount of saliva[6,30]. Glue-type denture adhesives such as powder-type and cream-type that have a high viscosity compensate for the lack and properties of saliva, resulting in stronger adhesion strength both to the denture base materials and basal seat mucosa, and higher resistance to dislodgement of dentures, thereby providing denture retention and stability[8]. The clinical efficacy of denture adhesives, such as masticatory function and satisfaction of denture wearers, depends highly on their viscosity and persistence of initial properties, in addition to their biocompatibility, pH level, manipulation, and washability.

Glue-type denture adhesives provide adhesion after absorption



**Fig. 5.** Occlusal forces at baseline and post-intervention in the three groups o: outliers; +: extreme.  $+^4$ : four extremes of 200 N or more,  $+^3$ : three extremes of 200 N or more. \* P<0.05



**Fig. 6.** Occlusal forces at baseline and post-intervention at each level of difficulty of edentulism treatment in the three groups. o: outliers, +: extremes. \*\* P<0.01, \* P<0.05

of saliva and require some amount of saliva. Furthermore, excessively dry conditions may lead to difficulty in removing the denture adhesive remnants from the mouth. Thus, individuals with severe dry mouth (dryness score  $\leq 20$ ) were excluded from the study[16,31]. The effectiveness of denture adhesives in patients with oral dryness has already been evaluated by our research group, and it has been reported that denture adhesives improve masticatory function in such patients[27]. In addition, candidates aged  $\geq 90$  years were also excluded because the denture adhesives are applied under self-management and most of these patients will face difficulty to ensure compliance with the intervention.

A study evaluated the effects of different types of denture adhesives on the incisal bite force of complete denture wearers until dislodgement of the maxillary denture, that is, denture retention[22]. The study demonstrated that the incisal bite force until the dislodgement of the maxillary denture was significantly improved by the application of all types of denture adhesives compared with no application of denture adhesives. The effectiveness tended to be greater for cream-type denture adhesives than for powder-type adhesives, followed by adhesive strips. Another study demonstrated that a significant increase in masticatory performance was observed after using both powder- and cream-type denture adhesives when compared with no application of denture adhesives, and no significant differences were found between the powder- and cream-type denture adhesives[15]. The present study's results are partially inconsistent with those of the abovementioned studies.

In this study, cream-type denture adhesives improved the retentive force (i.e., resistance to dislodgement) of dentures; however, powder-type denture adhesives did not. When the user applies a powder-type denture adhesive, the powder is sprinkled onto the intaglio surfaces of the dentures. It is difficult to effectively maintain high and constant adhesion strength between the intaglio surfaces of the dentures and the basal seat mucosa because the viscosity of powder-type denture adhesives changes depending on the amount and ratio of powder-to-water added. A lower powder-to-water ratio decreased the viscosity of the materials. A wide range of amounts of powder sprinkled and water adhered would exist among the patients. The amount applied varies with the time of application, even in the same patient. Thus, the effect of the powder-type materials varied widely among patients. The difficulty of manipulation and the resulting instability of viscosity would affect the retentive force of dentures. In contrast to powder-type materials, cream-type denture adhesives exhibit high and constant viscosities. Furthermore, watersoluble polymers in powder-type materials, such as sodium carboxymethyl cellulose (CMC-Na) and poly(methyl vinyl ether-maleic anhydride) (PVM-MA), dissolve easily in the mouth because of the low viscosity of the water used as the base. In contrast, cream-type denture adhesives consist of petrolatum and liquid paraffin, which are ointment bases, in addition to CMC-Na and PVM-MA[8]. Thus, the viscosity of cream-type materials is higher than that of powder-type materials. Moreover, the initial properties, such as viscosity, would last longer than powder-type materials during the application because the high viscosity of the ointment bases would prevent the leachability of water-soluble polymers in the mouth. Thus, the application of cream-type denture adhesives is likely to increase denture retention more than powder-type materials.

Previous studies[11,15,16,22] evaluated the incisal bite force until dislodgement of maxillary dentures. However, little information is available on the maximum voluntary occlusal force in the molar regions, which may be one of the parameters of masticatory function in denture wearers. In this study, the occlusal force of denture wearers tended to improve with cream-type denture adhesives when compared with powder-type denture adhesives and saline solution, although the powder-type materials increased the occlusal force of the participants with a Level II degree of difficulty in edentulism treatment. Denture adhesives reduce pain in the basal seat mucosa during mastication by absorbing the masticatory force through the thin layer and reducing the friction caused by denture instability[32]. Cream-type denture adhesives, which have higher viscosity than powder-type materials, work more effectively in absorbing force and reducing friction than powder-type materials.

The efficacy of denture adhesives for denture retention and occlusal force was greater in denture wearers with a Level II difficulty in edentulism treatment. However, improvements in denture retention and occlusal force were not found in Levels I and III. Even if denture adhesives are not applied to Level I edentulous patients, sufficient denture retention would be obtained, because these edentulous patients have a sufficiently high and wide residual ridge, elastic basal seat mucosa, and normal ridge relationship compared with other levels. Conversely, Level III patients have relatively severe residual ridge resorption, inelastic mucosa, and incorrect ridge relationship compared with Levels I and II. The denture adhesives did not tend to improve the denture retention of Level III patients, probably because the adhesive strength of denture adhesives to the basal seat mucosa and denture base resin would not be sufficient to improve the retention for severe residual ridge resorption. Furthermore, the occlusal force of the patients with severe disorder of the ridge relationship did not improve because of the insufficient adhesive strength of the materials and instability of dentures. Level III patients have lower scores for conditions of mucosa, ridge relationship, and especially residual ridge than Level II patients. More denture adhesives or materials with higher adhesion strength may be necessary in difficult cases.

Currently, powder- and cream-type denture adhesives are mainly used by denture wearers. Although further studies are necessary, cream-type denture adhesives should be used by edentulous patients who complain of instability and lack denture retention. Furthermore, the application to Level II patients would be recommended compared with Levels I and III from the perspective of the difficulty of edentulism treatment. Dentists or dental hygienists should correctly instruct the use of denture adhesives, such as the sort, amount, and number of uses per day.

This study had several limitations. One purpose of this study was to evaluate the relationship between the difficulty of edentulism treatment and denture retention and occlusal forces. However, no patients exhibited a Level IV degree of difficulty with edentulism treatment. In addition, the number of patients with Level I and III degrees of difficulty was smaller than that of patients with a Level II degree. Although cream-type denture adhesives tended to produce higher retentive and occlusal forces at Levels I and III, no significant differences were observed. However, increasing the number of patients at these levels may have led to significant differences. Further research is necessary, especially involving edentulous patients who have difficulty with edentulism treatment and other characteristics such as severe residual ridge resorption and malocclusion. In this study, the retentive force and occlusal force were measured with the application of denture adhesives or control (saline solution) at each hospital after eating breakfast. The remaining amount of denture adhesive at the intaglio surfaces of dentures might have differed among the patients during the measurement because the start time of measurement after the application of denture adhesives varied among the patients. It would be necessary to standardize the time until measurement after the application of denture adhesives and saline solution in future studies. Furthermore, the portion where the materials were applied to the denture and the additional daily application desired by the participants could not be monitored, although the evaluators could identify any doubt about the amount used from the perspective of determining compliance with the intervention. It is necessary to solve the abovementioned problems for a rigorous evaluation.

To our knowledge, this was the first study to analyze the relationship between the effect of denture adhesive application and the degree of difficulty in edentulism treatment. From the perspective of denture retention and occlusal forces of complete dentures, cream-type denture adhesives can be recommended for edentulous patients experiencing moderate difficulty in edentulism treatment.

# 5. Conclusions

The application of cream-type denture adhesives would effectively improve denture retention and occlusal force in complete denture wearers with a moderate degree of difficulty in edentulism treatment.

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# **Conflict of interest statement**

The authors declare no conflicts of interest related to this article.

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