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Original article

Multivariate analysis reveals oral health-related quality of life of complete denture wearers with denture adhesives: a multicenter randomized controlled trial

Yoshihiko Ito^{a, b*}, Guang Hong^{a, c}, Akito Tsuboi^{a, d}, Yasuhiko Kawai^{a, e}, Hisatomo Kondo^{a, f}, Taro Nomura^{a, f}, Suguru Kimoto^{a, c}, Atsuko Gunji^{a, c}, Asako Suzuki^{a, g}, Gaku Ohwada^{a, h}, Shunsuke Minakuchi^{a, h}, Yusuke Sato^{a, h}, Tetsuya Suzuki^{a, i}, Katsuhiko Kimoto^{a, j}, Noriyuki Hoshi^{a, j}, Makiko Saita^{a, j}, Yoshikazu Yoneyama^{a, k}, Yohei Sato^{a, k}, Masakazu Morokuma^{a, l}, Joji Okazaki^{a, m}, Takeshi Maeda^{a, m}, Kenichiro Nakai^{a, m}, Tetsuo Ichikawa^{a, n}, Kan Nagao^{a, n}, Keiko Fujimoto^{a, n}, Hiroshi Murata^{a, o}, Tadafumi Kurogi^{a, o}, Kazuma Takase^{a, o}, Masahiro Nishimura^{a, p}, Yasuhiro Nishi^{a, p}, Mamoru Murakami^{a, q}, Toshio Hosoi^{a, r}, Taizo Hamada^{a, s}

^a The Japan Denture Care Society, Japan

^b Division of Aging and Geriatric Dentistry, Tohoku University Graduate School of Dentistry, Sendai, Japan

^c Division for Globalization Initiative, Liaison Center for Innovative Dentistry, Tohoku University Graduate School of Dentistry, Sendai, Japan

^d Division of Community Oral Health Science, Department of Community Medical Supports, Tohoku Medical Megabank Organization, Tohoku University, Sendai, Japan

^e Department of Removable Prosthodontics, Nihon University School of Dentistry at Matsudo, Chiba, Japan

^f Department of Prosthodontics and Oral Implantology, School of Dentistry, Iwate Medical University, Morioka, Japan

^g Department of Removable Prosthodontics, Nihon University Graduate School of Dentistry at Matsudo, Chiba, Japan

^h Gerodontology and Oral Rehabilitation, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, Tokyo, Japan

ⁱ Section of Oral Prosthetic Engineering, Tokyo Medical and Dental University, Tokyo, Japan

^j Division of Prosthodontics & Oral Rehabilitation Department of Oral Function and Restoration Graduate School of Dentistry Kanagawa Dental University, Kanagawa, Japan

^k Department of Removable Prosthodontics, Tsurumi University School of Dental Medicine, Kanagawa, Japan

^l Morokuma Dental Clinic, Nagasaki, Japan

^m Department of Removable Prosthodontics and Occlusion Osaka Dental University, Osaka, Japan

ⁿ Department of Prosthodontics and Oral Rehabilitation, Graduate School of Biomedical Sciences, Tokushima University, Tokushima, Japan

^o Department of Prosthetic Dentistry, Graduate School of Biomedical Sciences, Nagasaki University, Nagasaki, Japan

^p Department of Oral and Maxillofacial Prosthodontics, Field of Oral and Maxillofacial Rehabilitation, Course for Advanced Therapeutic, Kagoshima University Graduate School of Medical and Dental Sciences, Kagoshima, Japan

^q Denture Prosthodontic Restoration, Advanced Dentistry Center, Kagoshima University Medical and Dental Hospital, Kagoshima, Japan

^r Tsurumi University School of Dental Medicine, Kanagawa, Japan

^s Hiroshima University, Hiroshima, Japan

Abstract

Purpose: To investigate the difference in improvement of oral health-related quality of life (OHR-QoL) depending on the oral and denture conditions of a complete denture wearer when using a cream or powder type denture adhesive in a 10-center parallel randomized clinical trial.

Methods: Two hundred edentulous subjects who wore complete dentures were allocated to each of the three groups according to denture adhesive type: cream, powder, and control (saline solution). The materials were applied to the mucosal surface of the dentures for 4 days, and baseline data and data after the intervention were collected. OHR-QoL was assessed using the Japanese version of the modified Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT-J) scale for outcome. Multivariate analysis was used to investigate improvements in OHR-QoL according to participant characteristics among complete denture wearers using these materials.

Results: OHIP-EDENT-J scores were significantly decreased in all groups after the intervention ($p < 0.05$); however, there were no statistically significant differences among the groups. Multiple logistic regression analysis revealed a significant association between the vertical height of the maxillary and mandibular alveolar ridge and OHIP-EDENT-J scores in the cream-type denture adhesive group. In contrast, there were no significant association between participant characteristics and OHIP-EDENT-J scores in the powder-type adhesive and control groups.

Conclusions: The use of denture adhesives could improve OHR-QoL for complete denture wearers. The cream-type denture adhesives may be expected to improve OHR-QoL in patients with poor residual ridge conditions compared with patients with good residual ridge conditions.

Keywords: Multivariate analysis, OHR-QoL, Complete denture, Denture adhesive

1. Introduction

Denture adhesives have been developed as a useful adjunct to improve denture retention, stability, and function, including bite force, chewing ability, food occlusion, patient satisfaction, and oral health-related quality of life (OHR-QoL) [1, 2, 3]. Many clinical studies have been performed to clarify the effectiveness of denture adhesives [4]. To date, most investigators agree that denture adhesives improve denture retention and stability [5, 6, 7, 8, 9, 10, 11, 12, 13] and OHR-QoL [14, 15]. These studies have usually used a case-control design and could not assess denture adhesive efficacy with their covariates.

A randomized, crossover, double-blind clinical trial demonstrated that denture adhesives significantly improved the satisfaction of complete denture wearers due to better retention, stability, and less accumulation of food particles between the denture and the mucosa compared with nonuse of complete denture adhesives [16], and that masticatory efficacy was higher with the use of denture adhesive than without [17].

Using multivariate analysis, the present study aimed to determine improvements in OHR-QoL among complete denture wearers who used denture adhesives (cream or powder type) according to participant characteristics (i.e., oral condition[s], denture condition[s]). The null hypothesis was that for any participant characteristic, the application of either type of denture adhesive (cream type or powder type) or control would not produce differences in OHR-QoL, and would not result in differences in the improvement of OHR-QoL between baseline and 4 days after application of the adhesive.

The present trial is also known as the Denture Adhesive Guideline (DAG) project [18]. The aim of the trial was to verify the efficacy of denture adhesives in formulating guidelines for the use of denture adhesives in patients with complete dentures.

2. Materials and methods

2.1. Study setting and trial design

The full protocol for this study is available online in an open access format [18]. The trial was registered with the US Clinical Trials (Registry NCT01712802) on October 17, 2012. A diagram illustrating the study flow is shown in Fig. 1. The present randomized controlled trial (RCT) was performed at the following 10 institutions, and was approved by the relevant ethics board at each research center (names of all bodies and approval numbers): Iwate Medical University (Ethics Committee of School of Dentistry, Iwate Medical University, Morioka, Iwate, Japan; No. 1192); Tohoku University (Ethics Committee of Tohoku University Graduate School of Dentistry, Sendai, Miyagi, Japan; No. 25-4); Tokyo Medical and Dental University (Ethics Committee of the Faculty of Dentistry, Tokyo Medical and Dental University, Tokyo, Japan; No. 960); Nihon University School of Dentistry at Matsudo (Ethics Review Committee of Nihon University School of Dentistry at Matsudo, Japan; No. 15-12-020-1); Tsurumi University (Research Ethics Committee of Tsurumi University School of Dental Medicine, Yokohama, Kanagawa, Japan; No. 1115); Kanagawa Dental University (Kanagawa Dental University Committee for Research Screening, Yokosuka, Kanagawa, Japan; No. 223); Osaka Dental University (Osaka Dental University Dental Ethics Committee, Osaka, Japan; No. 110780); Tokushima University (Ethics Committee of Tokushima University Hospital, Tokushima, Japan; No. 1697);

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

2.2. Participants

2.2.1. Inclusion and exclusion criteria

Participants included edentulous individuals who visited the study-associated facilities for new fabrication, adjustment, or recall of complete dentures. The protocol did not limit the inclusion of participants based on chief complaint(s), such as pain, looseness, speech, and esthetics, among others.

Individuals ≥ 90 years of age, those with any serious systemic illnesses that made participation in the study difficult, those unable to understand and/or respond to the questionnaires used in the study, individuals who wore metal-based complete dentures, used denture adhesives regularly, had maxillofacial defects covered by prosthetics, used a tissue conditioner, and/or had severe oral dryness (dryness score ≤ 20), were excluded from the study.

2.2.2. Sample size calculation

The total sample size for the three groups was 300. All individuals provided written informed consent before participation. A between-group difference of 29 mm on visual analog scale (VAS) ratings for general satisfaction was considered to be a meaningful difference. Using variances of 20 mm in the intervention groups and 23 mm in the control group, which were based on previously reported data [19, 20], 100 subjects per group, including a projected dropout rate of 10%, was required to achieve 80% power with an alpha level of 5%.

2.2.3. Randomization, allocation concealment, and sequence generation

A randomized, controlled, parallel clinical trial was conducted at the above-mentioned 10 centers. Participants were randomly assigned to one of the following three groups and were instructed to apply either a denture adhesive or a control solution to both their maxillary and mandibular dentures: cream-type denture adhesive (Cream), powder-type denture adhesive (Powder), and saline (Control) (Fig. 1). Balanced allocation of participants to each group was achieved using the following method. Three-hundred random allocation numbers with no over- or underlap were generated using the “RAND” and “RANK” functions in a spreadsheet program (Excel, Microsoft Japan Co. Ltd., Tokyo, Japan). The first to 300th numbers were ordered randomly. As per the assignment, 300 envelopes containing a card stamped with the group name were prepared. The 300 envelopes were divided 30-by-30 for the 10 centers in sequence. The coordinator at each facility opened an envelope for each subject who was recruited and allocated the subject according to the card in the envelope. The allocation information was managed by the coordinator such that the evaluator was blinded. This method enabled equal and random allocation of 300 numbers to the three groups. Once the 300 participants were completely allocated, the number of participants in each of the three groups was equalized. Blinding the participants to the intervention was not feasible because the participants were able to determine the type of denture adhesive they used.

2.3. Intervention

The intervention in this trial was the use of one of the following denture adhesives or control solution on maxillary and mandibular complete dentures for four consecutive days: participants in the Cream group were asked to use a cream-type denture adhesive (Poligrip S, GlaxoSmithKline, Tokyo, Japan); those in the Powder group used a powder-type denture adhesive (Poligrip Powder, GlaxoSmithKline, Tokyo, Japan), and subjects in the Control group used saline solution

* Corresponding author at: Division of Aging and Geriatric Dentistry, Tohoku University Graduate School of Dentistry, 4-1 Seiryō-machi, Aoba-ku, Sendai 980-8575, Japan.

E-mail address: yoshihiko.ito.b7@tohoku.ac.jp (Y. Ito).

Fig. 1. Diagram illustrating trial and participant flow.

(isotonic sodium chloride solution 20 mL CMX; Chemix Inc., Yokohama, Japan) instead of a denture adhesive.

As mentioned, the coordinator instructed participants how to use the denture adhesive or control solution. Before applying the cream-type denture adhesive, subjects were instructed to clean, rinse, and dry their dentures. The tube containing the cream-type adhesive was gently squeezed to place the cream in small strips or a series of dots on the denture surface. Finally, the dentures were pressed firmly in place and held briefly. Individuals in the Cream were instructed to apply the denture adhesive once per day before eating breakfast.

Before applying the powder-type denture adhesive, subjects were instructed to clean, rinse, and leave their dentures wet. The bottle containing the powder was gently squeezed or tapped to dispense the powder onto the entire denture surface. Excess powder was shaken off, and the denture was pressed into place and held briefly. Those in the Powder were instructed to apply the denture adhesive before eating breakfast and dinner.

The procedures for applying saline solution for control (distributed as eight bottles, with one bottle to be used per application) were as follows. Before applying the solution, dentures were cleaned, rinsed, and left wet. The bottle containing the saline solution was gently squeezed to dispense the liquid onto the entire denture surface; the denture was then pressed into place and held briefly. Those in the Control were instructed to apply the denture adhesive before eating breakfast, lunch, and dinner.

All participants were permitted to use additional denture adhesives whenever they wanted. Compliance with the intervention with regard to using the denture adhesives and control were checked by weighing the remaining denture adhesive and counting the remaining number of saline solution bottles.

2.4. Trial schedule

Day 0

The dentists at each center asked eligible complete denture wearers

to meet with the coordinator, who interviewed the participants and explained the trial. Written informed consent was obtained from each candidate. Once the candidate provided informed consent to the coordinator, an evaluator performed eligibility screening to check whether any of the exclusion criteria were applied. The coordinator then randomly allocated qualified candidates to one of the three trial groups using the above-mentioned envelope method. The participants were asked to visit the center twice during the study period.

Day 1

The evaluators performed baseline measurements. The coordinator described, along with the manufacturer's instructions, how to use the denture adhesive to each participant. Each participant was also instructed to remove any remaining denture adhesive immediately before applying the new denture adhesive or before sleeping at night. The participants began applying the denture adhesive before dinner on day 1, and then to eat dinner with the denture adhesive or saline solution applied.

Days 2 and 3

The participants did not visit the hospital on these days. However, they continued to use the denture adhesive or saline solution three times per day.

Day 4

Participants visited the hospital after eating breakfast with the denture adhesive or saline solution applied. The appointment was scheduled so that the participants consumed a total of eight meals over the four-day period with the adhesive or saline solution applied: three breakfasts, two lunches, and three dinners. The final measurements were performed at the hospital. Each participant returned the remaining denture adhesive or saline solution to the evaluator to verify compliance during the trial. If the participants experienced pain when wearing their dentures, and/or experienced difficulty with their existing dentures and required denture adjustment or repair during the trial, the

dentists appropriately treated the participants in all of the allocated groups. Group allocation information was managed solely by the coordinator, and this information was not communicated to the evaluator. After the final measurement in each center, the collected data were sent to a third-party organization for conversion to digital data, and blinded digital data were sent for analysis to the respective coordinator.

2.5. Study outcomes

The present study evaluated participant OHR-QoL using the modified Japanese version of the Oral Health Impact Profile for edentulous patients (OHIP-EDENT-J) scale comprising 19 items. The OHIP-EDENT-J has demonstrated good reliability and validity [21] and is distributed among the following seven subscales: functional limitations, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Participants were asked to rate the frequency with which they believed they encountered these items on a 5-point Likert scale, as follows: never (score = 0), hardly ever (score = 1), occasionally (score = 2), fairly often (score = 3), and very often (score = 4). The score sum ranged from 0 to 76.

2.6. Participant characteristics as covariates

At baseline, participant characteristics were evaluated using an assessment sheet authorized by the Japan Prosthodontic Society [22]. This study included 10 institutions broadly located in Japan with few opportunities for examination training and agreement to the examination protocol; hence, every examiner was not sufficiently calibrated. To compensate for this insufficient calibration, specialists certified by the Japanese Prosthodontic Society (JPS), who had sufficient clinical experience and understood the examination protocol for edentulous patients recommended by the JPS, were used as examiners in each institute. Participant data regarding alveolar ridge morphology, vertical height and ruggedness, complete denture fitness, and occlusal condition were assessed. Specifically:

Vertical height of alveolar ridge was evaluated at the part of the first molar.

Maxillary: high (10 mm<), middle (6–10 mm), low (0–6 mm), almost none (<0 mm)

Mandibular: high (5 mm<), middle (3–5 mm), low (0–3 mm), almost none (<0 mm)

Ruggedness of the alveolar ridge was evaluated by the presence or absence of bone prominences and undercuts of the ridge: none, little, moderate, and much.

Complete denture fitness was rated on a four-point scale by silicone type fitness test material: fits evenly, partially unfitted, widely unfitted, no fit at all.

Occlusal condition was evaluated by stability and whether or not both sides were separated open in tapping and eccentric positions.

Participant characteristics, such as age, sex, and history of complete denture wearing, were also collected as covariates.

2.7. Statistical analysis

All statistical analyses were performed using JMP® Pro version 13.1.0 (SAS, USA); differences with $p < 0.05$ were considered to be statistically significant, excluding participants with missing data.

The Kruskal-Wallis test and the chi-squared test, adjusted by Bonferroni correction ($p < 0.0167$), were used to compare participant characteristics. The Wilcoxon signed-rank test was used to perform within-group comparisons of pre- and post-intervention measurements. Regression analysis was performed using the above covariates as predictors. For each intervention group, subgroup analysis was performed between the different subpopulations defined by the baseline

characteristics of each participant to investigate whether the impact of the intervention was different across these patient characteristics.

3. Results

3.1. Participant flow and characteristics

Subject recruitment commenced in September 2013 and concluded in October 2016. A total of 200 participants from 10 institutions were registered for the present study. Recruitment of subjects was, therefore, terminated earlier than the pre-implementation study plan that projected 300 subjects.

A diagram illustrating the pre-implant and trial flow is presented in Fig. 1. The 200 subjects enrolled in the study were randomly allocated to one of the three groups: Cream ($n = 64$), Powder ($n = 69$), and Control ($n = 67$). Fifty-three subjects were excluded due to drop out (16 participants) or missing data (37 participants). The details of the missing data are shown in Table 1. Some subjects had data missing in multiple data, and there was no bias in the distribution of missing data. The final analysis target was 147 participants: Cream ($N = 50$), Powder ($N = 46$), and Control ($N = 51$). Participant characteristics at baseline among the three groups were generally comparable (Table 2). Participants were divided according to the median value of each item, except for history, which was divided according to > 10 -year categories, and for occlusal condition, which was divided by whether the intercuspal position was stable bilaterally and the eccentric position was stable.

There were no significant differences in participant characteristics among the three groups, confirming that randomization was adequately performed.

3.2. Pre- and post-intervention OHIP-EDENT-J scores

The mean OHIP-EDENT-J scores of the Cream, Powder, and Control at baseline were 15.8 ± 10.8 , 19.2 ± 13.1 , and 19.2 ± 13.7 , respectively (Fig. 2). No significant differences among the groups were found pre- or post-intervention (pre-intervention, $P = 0.41$; post-intervention, $P = 0.36$; Cream, 10.6 ± 9.1 ; Powder, 14.1 ± 11.9 ; Control, 14.2 ± 12.6 ; Kruskal–Wallis test). However, all groups demonstrated a significant decrease in OHIP-EDENT-J scores after the intervention ($P < 0.05$ [Wilcoxon signed-rank test]).

3.3. Relationship between denture or oral conditions and OHIP-EDENT-J scores in subgroup analyses

The relationship between denture or oral condition and OHIP-EDENT-J scores in each group according to Wilcoxon rank sum or chi-squared tests are summarized in Table 3. From the distribution of the scores change, participants with a score change of minus one or less before and after the intervention were defined as decreasing group, and those with zero (in the third quartile) or more as increasing group.

In the Cream, the number of participants with low/high vertical height of the maxillary alveolar ridge was 27/10 among those in whom scores decreased and 5/8 among those in whom scores increased. The number of subjects with mandibular alveolar ridge was 27/10 among those in whom scores decreased and 6/7 in those in whom score increased. A significant association was found between vertical height of the maxillary alveolar ridge and score ($P = 0.04$). Although it was not significant in the mandible, a similar tendency was observed ($P = 0.08$). However, there were no significant associations between score and other characteristics.

In the Powder and Control groups, there was no significant association between score and any characteristic. Furthermore, no significant differences were found in the change of OHIP-EDENT-J scores between the allocation groups when comparing only participants with poor maxillary or mandibular alveolar ridge conditions.

Table 1. The details of the missing data.

	Group			total
	Cream No=10	Powder No=15	Control No=12	
Age	0	0	1	1
Complete denture history	0	2	4	6
Occlusal condition	4	6	3	13
Complete denture fitness				
Maxillary	3	7	4	14
Mandibular	5	10	6	21
Vertical height of alveolar ridge				
Maxillary	3	5	3	11
Mandibular	3	5	3	11
Ruggedness of alveolar ridge				
Maxillary	3	6	4	13
Mandibular	3	6	3	12
OHIP-EDENT-J score				
Day1	5	3	5	13
Day4	7	12	6	25
total	36	62	42	140

Table 2. Baseline comparison of groups according to participant characteristics (all subjects included).

	Group			p-Value
	Cream (N=50)	Powder (N=46)	Control (N=51)	
Age (S.D.)	76.0(8.2)	75.8(8.4)	74.1(7.81)	0.30a
Sex (male / female)	27/23	19/27	24/27	0.46b
Complete denture history (<10 years / 10 years≤)	15/35	15/31	21/30	0.47b
Occlusal condition (unstable / stable)	17/33	12/34	14/37	0.65b
Complete denture fitness (poor / well)				
Maxillary	24/26	15/31	21/30	0.31b
Mandibular	30/20	18/28	19/32	0.04b
Vertical height of alveolar ridge (low / high)				
Maxillary	32/18	17/19	28/23	0.65b
Mandibular	33/17	26/20	26/25	0.30b
Ruggedness of alveolar ridge (much / none)				
Maxillary	22/28	17/29	19/32	0.72b
Mandibular	29/21	21/25	21/30	0.22b

a:Kruskal-wallis test

b:Chi-squared test Bonferroni correction

(Maxillary: $P = 0.14$; Cream: -8.2 ± 1.6 , Powder: -3.9 ± 1.7 , Control: -4.4 ± 1.7 , Mandibular: $P = 0.38$; Cream: -5.8 ± 1.6 , Powder: -3.3 ± 1.8 , Control: -6.0 ± 1.8 , respectively [Kruskal-Wallis test]).

Multiple logistic regression analysis, including all covariates, was performed in each intervention group, with the results summarized in Table 4. In the Cream, there was a significant association between vertical height of the maxillary and mandibular alveolar ridge and OHIP-EDENT-J scores. Participants with a low vertical height of the alveolar ridge demonstrated a significant decrease in OHIP-EDENT-J scores compared to those with a high vertical height of the alveolar ridge (maxillary, odds ratio [OR] 7.73 [95% confidence interval (CI) 1.47–40.58]; mandibular, OR 5.23 [95% CI 1.04–26.21]). However, there were no significant associations between the other characteristics. On the other hand, there were no significant associations between any characteristics and OHIP-EDENT-J scores in the Powder and Control

: $p < 0.01$ (Wilcoxon signed-rank test) Fig. 2.** Changes Japanese version of the modified Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT-J) scores after application of denture adhesives.

groups.

4. Discussion

In this study, participant characteristics at baseline were comparable among the three groups, and randomization was adequately performed. The evaluators were adequately blinded by not being informed about participant assignments because separate assigning coordinators managed information at each facility. Thus, high internal validity was obtained using well-performed randomization in our study. Furthermore, this study was conducted by ten research centers from almost all regions of Japan, and the participants recruited did not have regional differences. Every participant used their complete dentures daily, with no significant problems. Age and sex were not restricted as inclusion criteria. Most systemic diseases were also not excluded in this study, except for several conditions that would interfere with the conduct of denture use assessment, such as severe xerostomia and mild cognitive impairment. Therefore, the results from our study can be extrapolated to general complete denture users in Japan.

Individual satisfaction with dentures is mainly dependent on denture stability and mastication ability [23]. Previous studies have used different methods to evaluate participant satisfaction with dentures, with the VAS being the most common method. Several investigators have described the utility of the VAS for the evaluation of satisfaction in denture wearers [24, 25, 26, 27, 28, 29]. Munoz et al. [25] reported that participant confidence, comfort, and satisfaction with dentures, evaluated using a seven-point visual scale, were improved using a cream-type denture adhesive. Koronis et al. [26] reported that the use of a cushion-type denture adhesive improved the satisfaction of participants according to a specially designed questionnaire for denture wearers. However, even in our research, each participant often seemed to have different meanings for the question of denture satisfaction/use and responded with fluctuation in VAS score over time. These observations suggest that it may not be appropriate to use VAS scores to compare the degree of satisfaction among participants, and other assessment tools must be used. Additionally, nuances in the same question may change if the language or expression of the question is different. Therefore, it may not be appropriate to compare the degree of satisfaction among participants.

The OHIP-EDENT-J has been validated and is reliable, as is the VAS, with virtually no differences caused by how questions are expressed. Therefore, the OHIP-EDENT-J was used to evaluate and

Table 3. The relationship between decrease/increase in Japanese version of the modified Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT-J) scores and participant characteristics in each group.

Change of OHIP-EDENT-J score	Cream			Powder			Control		
	Decrease	Increase	p-Value	Decrease	Increase	p-Value	Decrease	Increase	p-Value
Age (S.D.)	75.7(8.6)	77.0(7.0)	0.76a	75.8(8.1)	75.8(9.3)	0.66a	74.8(7.8)	72.6(7.8)	0.21a
Sex (male / female)	20/17	7/6	0.99b	15/17	4/10	0.25b	15/20	9/7	0.37b
Complete denture history (<10 years / 10 years≤)	13/24	2/11	0.18b	12/20	3/11	0.28b	14/21	7/9	0.80b
Occlusal condition (unstable / stable)	13/24	4/9	0.78b	9/23	3/11	0.63b	9/26	5/11	0.68b
Complete denture fitness (poor / well)									
Maxillary	18/19	6/7	0.88b	10/22	5/9	0.77b	15/20	6/10	0.72b
Mandibular	21/16	9/4	0.43b	12/20	6/8	0.73b	11/24	8/8	0.20b
Vertical height of alveolar ridge (low / high)									
Maxillary	27/10	5/8	0.04*b	19/13	8/6	0.89b	19/16	9/7	0.90b
Mandibular	27/10	6/7	0.08b	17/15	9/5	0.48b	18/17	8/8	0.92b
Ruggedness of alveolar ridge (much / none)									
Maxillary	16/21	6/7	0.86b	12/20	5/9	0.91b	13/22	6/10	0.98b
Mandibular	21/16	8/5	0.76b	13/19	8/6	0.30b	13/22	8/8	0.39b

a:Wilcoxon rank sum test

b:Chi-squared test

Table 4. Odds ratios describing the relationship between decrease/increase in Japanese version of the modified Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT-J) scores and participant characteristics in each group according to multiple logistic regression analysis.

	Cream					Powder					Control				
	B	S.E.	Odds ratios	95% CI	p-Value	B	S.E.	Odds ratios	95% CI	p-Value	B	S.E.	Odds ratios	95% CI	p-Value
Maxillary															
Age	0.00	0.05			0.95	0.01	0.05			0.86	0.04	0.05			0.42
Sex	0.24	0.38	1.60	0.36-7.19	0.54	0.61	0.44	3.42	0.62-19.01	0.16	-0.27	0.31	0.59	0.17-2.02	0.40
Complete denture history	0.91	0.54	6.17	0.73-52.11	0.09	0.51	0.49	2.75	0.40-18.66	0.30	-0.08	0.32	0.85	0.24-3.02	0.81
Occlusal condition	0.10	0.46	1.23	0.20-7.50	0.82	0.37	0.53	2.11	0.26-16.97	0.48	-0.17	0.39	0.71	0.15-3.29	0.66
Complete denture fitness	-0.36	0.44	0.49	0.09-2.76	0.42	-0.32	0.48	0.53	0.08-3.47	0.51	0.14	0.36	1.32	0.33-5.35	0.69
Vertical height of alveolar ridge	1.02	0.42	7.73	1.47-40.58	0.02*	0.45	0.47	2.44	0.39-15.16	0.34	0.01	0.32	1.01	0.28-3.62	0.98
Ruggedness of alveolar ridge	-0.41	0.39	0.44	0.09-2.05	0.29	0.08	0.38	1.18	0.26-5.29	0.83	0.14	0.37	1.33	0.31-5.65	0.70
Mandibular															
Age	-0.01	0.05			0.83	0.02	0.05			0.62	0.06	0.05			0.24
Sex	0.17	0.37	1.39	0.32-6.04	0.66	0.38	0.36	2.14	0.52-8.84	0.29	-0.38	0.34	0.46	0.12-1.75	0.26
Complete denture history	0.77	0.51	4.65	0.64-34.02	0.13	0.41	0.49	2.28	0.34-15.55	0.40	-0.14	0.40	0.75	0.16-3.60	0.72
Occlusal condition	0.12	0.42	1.27	0.24-6.70	0.78	0.41	0.45	2.29	0.39-13.48	0.36	0.13	0.38	1.31	0.29-5.86	0.73
Complete denture fitness	-0.70	0.46	0.25	0.04-1.46	0.12	-0.19	0.37	0.69	0.16-2.94	0.61	-0.82	0.46	0.20	0.03-1.21	0.08
Vertical height of alveolar ridge	0.83	0.41	5.23	1.04-26.21	0.04*	-0.05	0.39	0.91	0.20-4.10	0.90	0.24	0.42	1.61	0.31-8.40	0.57
Ruggedness of alveolar ridge	-0.25	0.39	0.60	0.13-2.81	0.52	-0.44	0.36	0.41	0.10-1.70	0.22	-0.27	0.37	0.58	0.14-2.44	0.46

Multiple logistic regression analysis

Categorization:

Sex (male:1 / female:0), Complete denture history (<10 years:1 / 10 years≤:0), Occlusal condition (unstable:1 / stable:0)

Complete denture fitness (poor:1 / well:0), Vertical height of alveolar ridge (low:1, high:0), Ruggedness of alveolar ridge (much:1, none:0)

compare participant OHR-QoL in the present study. OHIP-EDENT-J scores decreased significantly after the intervention in all groups. This means that denture adhesives improved the OHR-QoL of complete denture wearers. Polyzois et al. [30] reported that using denture adhesives improved patient OHR-QoL according to the OHIP scale, and were more effective in patients with a poor alveolar ridge or ill-fitting denture. The present study also demonstrated that denture adhesives improve patient OHR-QoL. A systematic review investigating the effect of denture adhesives by Papadiochou et al. [31] concluded that improved patient satisfaction with dentures was attributed to improvement in retention, stability, and mastication

ability. The results of this study may be attributed to increased satisfaction by improving stability and chewing ability due to the viscosity of denture adhesives and other factors reported in previous studies.

The results of multiple logistic regression analysis considered the condition of the alveolar ridge and dentures, and there was a significant association between vertical height of the alveolar ridge and OHIP-EDENT-J scores only in the Cream. Kulak et al. [11] and Polyzois et al. [30] reported that the use of cream-type denture adhesives improved denture satisfaction or OHR-QoL. They suggested that the degree of absorption of the alveolar ridge may affect satisfaction or OHR-QoL.

Goncalves et al. [32] reported that mastication ability for dentures was improved by using cream-type or tape-type denture adhesives, and was more effective in patients with a resorbed alveolar ridge. The study by Kronis et al. [26], who investigated a cushion-type denture adhesive, also suggested the same possibility. In studies involving patients with well-fitting dentures, Shamsolketabi et al. [33] and Torres-Sanchez et al. [16] reported that participant satisfaction with dentures with cream-type adhesives is not affected by the condition of the alveolar ridge. The present study also included individuals with ill-fitting dentures, in whom the condition of the alveolar ridge was poor. Therefore, in such cases, stability was improved by sufficiently filling the space between the denture and the alveolar ridge due to the thicker consistency of the cream-type denture adhesive. As for the Cream, it is possible that the OHIP-EDENT-J scores were reduced in those with poor alveolar ridge condition. In contrast, there was no difference in the degree of improvement of OHR-QoL according to the condition of the alveolar ridge in those in the Powder. Cream is closer to a solid consistency than powder, which may result in greater sealing properties. It was suggested that cream-type denture adhesives may be more effective in improving patients' OHR-QoL in whom retention and stability of complete dentures are compromised by poor residual ridge conditions than in those with good residual ridge conditions.

The present study had some limitations, the first of which was the intervention period of 4 days, given that the use of denture adhesives is generally recommended as a supplementary and temporary application. The intervention period in this study was likely not long enough to evaluate the effectiveness of denture adhesives. Further intervention studies are necessary to examine the factors influencing prognosis prediction with regard to the regular use of denture adhesives. We also acknowledge a possible limitation in the blinding method of the participants. The control sample was provided to participants as a bottle of saline solution, which has completely different physical properties and appearance from familiar commercially available denture adhesives. Although some participants doubted the effect of the control solution before intervention, OHR-QoL with dentures improved after the intervention in Control. Saline solution may have been effective in moistening the mouth, similar to saliva, and a possible placebo effect may have occurred. Even in the two denture adhesive groups (Cream and Powder), a placebo effect due to the recognition that denture adhesive was being used could occur, possibly resulting in some reduction in OHIP-EDENT-J scores.

5. Conclusion

The findings of the present study revealed that using denture adhesives could improve OHR-QoL in complete denture wearers. In particular, cream-type denture adhesives may be expected to improve OHR-QoL in patients with poor retention and stability of complete dentures due to poor residual ridge conditions compared to patients with good residual ridge conditions. This suggests that selection of a suitable denture adhesive based on a patient's oral condition(s) might be important.

Competing Interests

The authors declare that there are no conflicts of interest.

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