Original Research Paper

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Clinical Efficacy of Two Denture Adhesives Among Complete Denture Patients: A Cross-over Randomized Clinical Trial

Abstract:

Aims and objectives: The clinical efficacy of different forms of denture adhesives have been inconsistent among studies with unclear differences among them. The aim of this study is to evaluate the masticatory efficiency and satisfaction of complete denture wearers without and with the use of two different forms of commercially available denture adhesives.

Material and Methods: 30 edentulous participants with new complete dentures placed one month before the commencement of the study were included in this cross-over randomized clinical trial (CTRI/2021/07/035238) which compared a powder adhesive and a cream adhesive along with no adhesive use. The objective assessment used the Edlund and Lamm index for masticatory efficiency and the subjective assessment followed a specially designed questionnaire. Both assessments were carried out on days 0,7 and 21. One-way ANOVA was used to compare the objective data and the questionnaire responses were obtained as percentages.

Results: The one-way ANOVA test for difference between the groups was statistically insignificant for all layers (P>.05). The questionnaire responses revealed that 53.3% of the participants preferred the use of cream adhesive over powder adhesive.

Conclusions: No significant difference in the masticatory efficiency was noted between the two denture adhesives and without adhesive use. Patient satisfaction was greater with adhesive use showing a predilection towards cream adhesive due to its longer duration of action and improved chewing ability

Key-words: Denture adhesive, mastication, complete dentures, prosthesis retention, patient satisfaction.

Introduction:

Tooth loss is a common problem in developing countries and although various fixed implant-supported prosthetic options are available, most of the completely edentulous population particularly the geriatric, cannot afford them and are ultimately provided with complete dentures.[1]

Complete denture service despite its history of good patient satisfaction,[1,2] can still lead to problems for some patients as a result of inadequate retention and stability.[3] These problems can arise despite good denture construction principles and techniques due to compromised residual ridges.[3,4] In such cases, denture adhesives have been shown to improve denture retention and patient satisfaction.[4,5]

Denture adhesives are soluble or insoluble substances that have some component that swells on interaction with water or saliva to enhance the contact between the denture and the underlying tissues.[6,7] These are frequently utilized with the mandibular denture and its use with the maxillary denture is associated with younger individuals for psychological support.[8] The use of denture adhesives has also been shown to have a positive correlation with the oral health-related quality of life (OHR-QoL).[9] However, knowledge among practitioners and patients with regard to denture adhesives is found to be lacking in some places.[10]

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Although enhanced masticatory function can be expected subsequent to the improved retention provided by these materials, previous studies show conflicting results.[5,11-15] The efficiency of different forms of dentures adhesives which include powders, creams, wafers, and strips have been inconsistent among studies.[11-13] The methodologies to study masticatory performance are diverse including particle breakdown, concentration assessment and colorimetric evaluation methods wherein the more commonly used sieve method provides easy assessment in a clinical set-up.[16] In addition, there are few good quality randomized controlled trails on the subject warranting the need for further evidence.[17] Trials that combine both subjective and objective assessment of the use of denture adhesives are also limited.[3,13,18]

This study was designed with the purpose of evaluating two different forms of denture adhesives, denture adhesive PA - a powder (Fixon Powder, ICPA Health Products Ltd.), denture adhesive CA - a cream (Polident, Glaxo Smith Kline) and the absence of denture adhesive - WA. The objective assessment used the Edlund and Lamm index,[19] and subjective assessment followed a specially designed questionnaire to provide a more comprehensive report of clinical application.

The null hypothesis tested was that there would be no difference in the masticatory efficiency and satisfaction of complete denture wearers without and with the use two different forms of commercially available denture adhesives.

Materials and Methods:

The present study was designed as a cross-over randomized clinical trial and was carried out at the Department of Prosthodontics, with the approval of the Institutional ethics committee (Ref.No.IEC/OMC/2021/M.No.(06)/Acad-64). The study protocol was registered with the clinical trials registry – India prospectively (CTRI/2021/07/035238). The sample size was estimated using G*Power statistical power analysis program to 20 per group based on a previous study with $\alpha = 0.05$ and power set at 0.95.[14] The final sample size was kept at 30 edentulous participants per group to compensate for any loss to follow-up during the period of study.

Inclusion criteria was composed of adults (age-21 to 90 years) with completely edentulous maxilla and mandible with satisfactory denture bearing area according to the scoring method of Kapur KK,[11] new dentures placed 1 month before but not more than 1 year before the study,[14] and the dentures meeting the clinically good dentures criteria of Kapur KK.[11] Exclusion criteria involved the presence of any active oral pathology, presence of uncontrolled systemic disease, any physical or mental disability. Additionally, participants with known allergy to any of the components of the adhesives used were excluded.

Participants were selected according to the inclusion criteria after complete oral examination by an experienced prosthodontist. The participants were explained in detail about the study and informed consent was obtained from those willing to take part. Complete dentures meeting the good dentures criteria were fabricated for all the participants,[14] required adjustments were made, and they were allowed to adapt to their dentures for at least one month.[18,20] The 30 edentulous participants were allocated to their respective denture adhesive group by simple random sampling using the lottery method with an allocation ratio of 1:1. The flow diagram of participants and grouping is depicted according to the CONSORT statementin Figure 1.

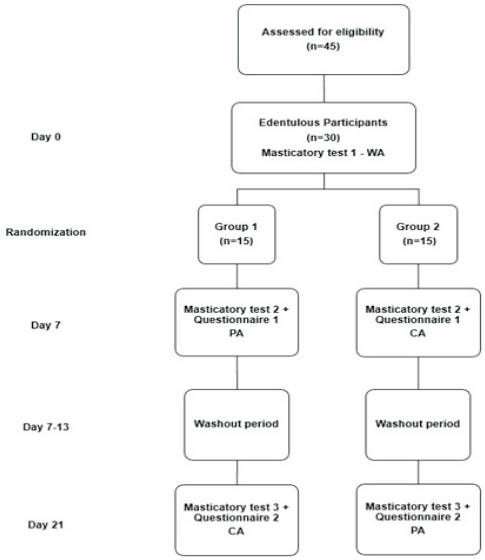

Figure 1. Study flow diagram. WA: Without adhesive, PA: Powder adhesive, CA: Cream adhesive.

Masticatory test was carried out at baseline for the edentulous participants without the use of denture adhesive (WA, n=30). The edentulous participants after group allocation (PA, n=15 or CA, n=15), were instructed in the use of their assigned adhesives. Denture adhesive CA was applied as small strips in three regions, one incisor region and two molar/premolar ridge regions in the mandible and one in the midline of the palate and two in the molar/premolar ridge regions of the maxilla [Figure 2a], while denture adhesive PA was sprinkled over the impression surface of both the dentures before seating into place [Figure 2b].[6] The participants could not

be blinded because of the visible form of the adhesives. After one week of usage, the second masticatory test and questionnaire with nine questions was administered [Table 1]. Participants were then advised to stop using any adhesive with their dentures for the next week to enable a wash out period. After this the groups were interchanged for the cross-over and similarly instructed in the usage of the new adhesive assigned for one week. The cross-over enabled both adhesives to be tested in all 30 patients, effectively bringing the sample size to 30 per adhesive. The final masticatory test and questionnaire were administered on day 21. This had an additional question about which adhesive was perceived to be better.

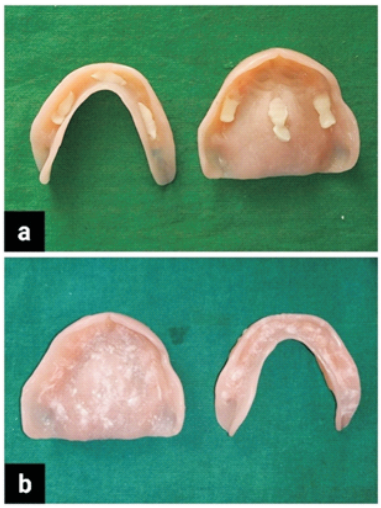

Figure 2. a) Application of cream adhesive; b) Application of powder adhesive

Table 1: Questions for both adhesives

1. How satisfied are you with the retention of your lower denture after applying the denture adhesive?		
a) Not satisfied	b) Fairly satisfied	c) Very satisfied
2. How satisfied are you with the retention of your upper denture after applying the denture adhesive?		
a) Not satisfied	b) Fairly satisfied	c) Very satisfied
3. Did usage of the denture adhesive improve the retention of your lower denture?		
a) No	b) Cannot tell	c) Yes
4. Did usage of the denture adhesive improve the retention of your upper denture?		
a) No	b) Cannot tell	c) Yes
5. How long did the denture adhesive have an effect on the retention of your lower denture?		
a) < 4 hours	b) 4 – 12 hours	c) > 12 hours
6. How long did the denture adhesive have an effect on the retention of your upper denture?		
a) < 4 hours	b) 4 – 12 hours	c) > 12 hours
7. How was your ability to chew after the application of the denture adhesive?		
a) Much worse	b) No difference	c) Much better
8. How was it to apply the denture adhesive to your denture?		
a) Difficult	b) Manageable	c) Easy
9. How was it to remove the denture adhesive from your denture?		
a) Difficult	b) Manageable	c) Easy
10. Which denture adhesive do you think was better? (Part of second questionnaire)		
a) Powder adhesive	b) Cream adhesive	

The masticatory efficiency was assessed by the Edlund and Lamm method using a layered sieve container [Figure 3a].[19] A prefabricated stainless-steel mold [Figure 3b] was used to make irreversible hydrocolloid tablets (Zelgan, Dentsply) of 5 mm thickness, 20 mm diameter, and weight 2.1 g [Figure 3c].[14,19] Participants were given the tablet and advised to chew for 20 masticatory strokes.[12,14,19] The masticated material was rinsed with 50 ml of water and collected into a plastic container [Figure 3d]. This process was evaluated and carried out by two investigators. The separation of the masticated particles was carried out in the sieve container by one investigator who was blinded to the adhesive used. The container had three layers: layer 1 with sieve of 2.4 mm aperture, layer 2 with sieve of 1.2 mm aperture, and a final collecting base forming layer 3 [Figure 3a].[14] This assembly was placed on to a dental vibrator at 50 Hz for 120 seconds for particle separation.[19] After separation of the particles [Figure 3e], the content from each layer was collected separately, dried and weighed on a digital weighing scale. The quantitative values obtained and subjective responses were entered in an excel sheet. Data analysis was performed by a statistician who was blinded to the groups, using a specialized software (IBM SPSS Statistics v20; IBM Corp). One-way ANOVA was used to compare the mean and standard deviation values between the three groups (PA, CA, WA). The questionnaire responses were subjected to descriptive statistics and obtained as percentages

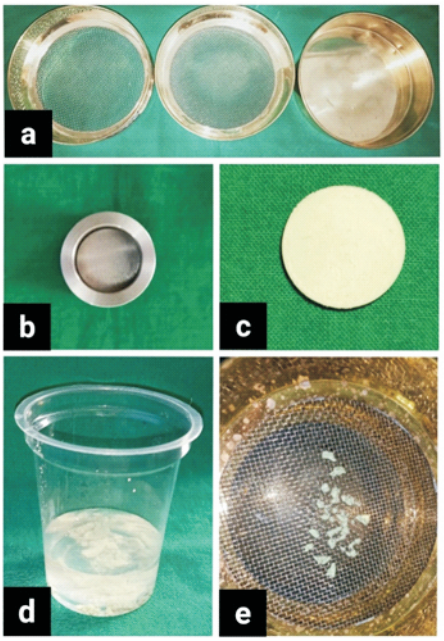

Figure 3. a) Sieve container with three layers; b) Prefabricated stainless-steel mold; c) Irreversible hydrocolloid tablet; d) Collected masticated material; e) Masticated material separated in the top layer

Results:

Thirty edentulous participants (21 male and 9 female) of average age 57 years took part in this study. The results obtained are tabulated in Table 2. The mean and standard deviation (SD) of the quantitative data have been summarized and P< .05 was deemed statistically significant.

Table 2. Intergroup comparison of volume of remnant material at all layers

Variable		Mean	SD	SE	95% Confidence Interval		F statistic	P value
					Lower	Upper		
Layer 1	WA	1.306	0.279	0.051	1.202	1.410	0.35	0.69
	PA	1.232	0.368	0.067	1.095	1.369		
	CA	1.266	0.362	0.066	1.131	1.401		
Layer 2	WA	0.365	0.184	0.034	0.297	0.434	0.34	0.70
	PA	0.405	0.225	0.041	0.321	0.489		
	CA	0.400	0.198	0.036	0.327	0.474		
Layer 3	WA	0.390	0.218	0.040	0.309	0.472	0.06	0.93
	PA	0.413	0.287	0.052	0.306	0.520		
	CA	0.398	0.223	0.041	0.315	0.481		

WA: Without adhesive, PA: Powder adhesive, CA: Cream adhesive, SD: Standard deviation, SE: Standard error, **F statistic:** ANOVA test statistic,**P value:** Probability value (Statistically significant difference if P<.05).

The average value of remnant material weight in all the layers for the participants revealed that it was highest in layer 1 for all three groups. There was a slight improvement in masticatory efficiency after use of either adhesive PA and CA as follows: mean weight of crushed material in layer 1, CA (1.26 ±0.36g), PA (1.23 ±0.36g) compared to WA (1.30 ±0.27g); layer 2, PA (0.40 ±0.22g), CA (0.40 ±0.19g) compared to WA (0.36 ±0.18g); and layer 3, PA (0.41 ±0.28g), CA (0.39 ±0.22g) compared to WA (0.39 ±0.21g). The 1-way ANOVA test for difference between the groups was statistically insignificant for all layers (P>.05).

The graphical representation of the questionnaire responses in percentages are depicted in Figure 4. 90% of the those who used PA felt that the retention of their lower dentures had improved and 73.3% were fairly satisfied with it. In case of CA, all the participants felt an improvement in the retention of their lower dentures with 53.3% being very satisfied. With respect to the retention of the upper denture, 90% after PA use and 100% after CA use noticed an improvement. Most of the participants were fairly satisfied (53.3%) after PA use and very satisfied (60%) after CA use with the retention of their upper dentures. With regard to the duration of retentive effect on the lower denture, after usage of PA, half of them found it to be less than four hours while the remaining said that it was between four to twelve hours. For the upper denture, the retentive duration of PA was found to be between four to twelve hours by most (60%) participants. After CA use, a majority of the participants felt that the duration of retentive effect on lower (83.3%) and upper (86.7%) dentures was between four to twelve hours with only few of them (10%) finding it to be greater than twelve hours for both dentures. Majority of participants (PA- 66.7% and CA- 80%) felt that their ability to chew was much better after adhesive use. Application of PA was easy according to 80% of the participants, while removal of the same was easy for 70% of them. The application of CA however, was either manageable (53.3%) or easy (40%) for most participants. Almost half of the participants found the removal of CA from their dentures to be only manageable (46.7%). Lastly, 53.3% of the participants preferred the use of CA over PA.

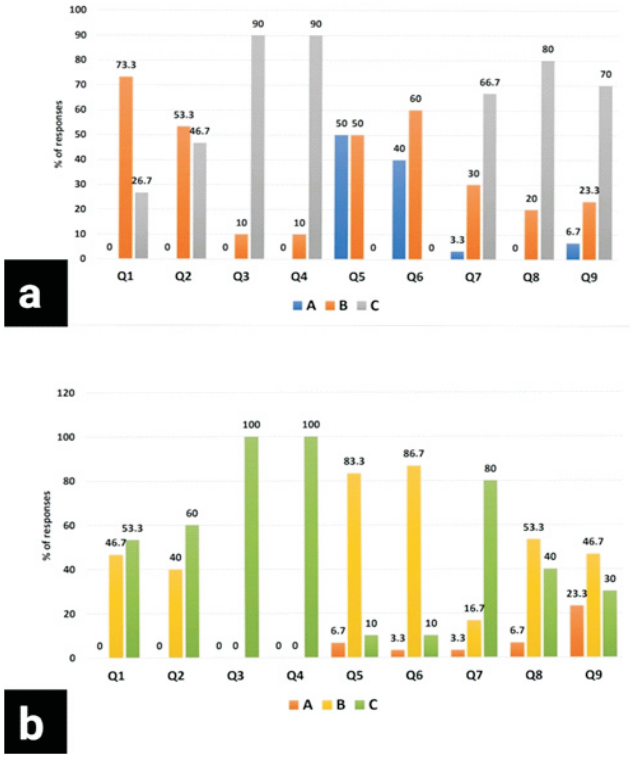

Figure 4. a) Responses to Questionnaire – Adhesive PA (in %); b) Responses to Questionnaire – Adhesive CA (in %)

Discussion:

The results of this study show that there is no quantitative difference in the masticatory efficiency of complete denture wearers following the use of denture adhesives, while the

subjective responses suggest an improved satisfaction among them. Hence the null hypothesis was partially accepted.

Despite the several new methodologies available for assessment of masticatory efficiency, the sieve method due to its practicality continues to be the gold standard.[16] This study used a food substitute similar to a previous study to reduce the bias due to composition, taste, shape and consistency of food stuff.[14,19] The usage of a similar methodology also enables comparison with previous studies.[14] Another strength of this study is the addition of a subjective analysis which provides a correlation between clinical evaluation and daily function which may not always suggest the same results.[2]

The adhesives tested included a powder with carboxymethyl cellulose as the active ingredient and a cream with polyvinyl methyl ether/maleic acid copolymer along with carboxymethyl cellulose. Both forms of adhesives have been shown to increase the retention and stability of dentures by their inherent physical and chemical properties.[3,6,12,14] This was further proven in this work by the subjective responses elicited from the participants. However, the main results of this study showed no improvement in masticatory efficiency following the use of either powder or cream adhesive which is contrary to previous research.[5,12-14] KapurKK had obtained similar results with both hard and soft food stuff.[11] The inter group comparison between the two forms of adhesives also proved insignificant comparable to previous work.[11,12] Masticatory efficiency of complete denture wearers is dependent on several factors which include the state of denture bearing tissues,[5] mindset of the patient, previous history of denture use, period of edentulousness, control of the oral and peri-oral musculature, and denture adaptation.[2] The enhanced retention and stability offered by the denture adhesives in this study as confirmed by the questionnaire responses, did not improve the objective outcomes as they are not lone standing factors in determining masticatory efficiency. Hence, denture adhesives may not necessarily improve the chewing efficiency in patients who use them.

Overall, the subjective assessment revealed that the participants were more satisfied with their dentures after denture adhesive use, with a preference of cream adhesive due to their prolonged period of action and better chewing ability compared to powder adhesive. The longer duration of action could be due to the presence of long-acting salts as the active ingredient.[6] Other subjective research has also shown similar results for cream adhesives.[3,9,13,15] Ease of use is a criterion that determines the preference for any given material especially among the older people who may be limited in their motor skills and abilities. In general, the powder adhesive was easy to apply and remove. Similar to previous research, the cream adhesive while improving retention due to its sticky nature was accompanied by the drawback of being difficult to remove from the dentures.[11] This maybe associated with poor oral hygiene,[7] and needs to be improved upon in newer formulations. The limitations of this trial include selection of newly edentulous participants as well as participants with prior denture experience, lack of participant blinding, and a short intervention period. Longer intervention periods may lead to different results as the patients may become habituated to the regular use of adhesives with their denture in terms of application, seating and chewing of different food substances. Fujimori et al had shown that the effect of these adhesives might be more relevant in poor denture bearing tissues.[5]

Another study had shown that the cream adhesive could be suggested in cases with poor residual ridge conditions.[9]

According toOhwada et al, while denture adhesives did not improve the perceived masticatory ability in patients with regard to soft foods, they may have a significant effect in cases of harder foods.[15] In a study that evaluated masticatory function for both natural food and artificial substitute, similar results were obtained for both by providing faster and effective chewing cycles.[13] Proper standardization of methodology in future trials which include test foods and testing period would enable direct comparison of results.

The lack of consensus and adequate knowledge regarding denture adhesive use could be rectified by proper dissemination of information among practitioners and patients. Education on appropriate application of adhesives along with maintenance of dentures and oral health can improve treatment outcomes in complete denture service. While the choice of adhesive can be made on a case-to-case basis, cream adhesives may be employed in situations where there is a need for improved retention and longer duration of action. Although the objective improvement in masticatory efficiency remains inconclusive, the subjective improvement

in satisfaction among patients may be reason enough to prescribe denture adhesives on a patient specific basis.

Conclusion:

Following conclusions were drawn based upon the results obtained and within the limitations of the study:

1. There is no significant difference in the masticatory efficiency following use of the two denture adhesives and among them.
2. When subjectively assessed, participants were more satisfied when denture adhesives were used, with a predilection towards cream adhesive due to its longer duration of action and improved chewing ability.

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