Clinical Study Comparing the Efficacy of Two Denture Adhesives in Complete Denture Patients

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Purpose: The aim of this study was to compare the efficacy of two denture adhesives in edentulous patients wearing complete maxillary and mandibular dentures. ***Materials and Methods:*** Twenty-four edentulous patients were treated with complete dentures following a standardized protocol. Resistance to dislodgement of both dentures was measured in simulated functional movements by means of a gnathometer and a dynamometer. These outcome measurements were assessed first without the adhesive and then after two successive 2-week periods of using a randomly assigned denture adhesive in a crossover experimental design. The adhesives used were a standard one (Kukident Classic) and a new adhesive with a similar formulation but different physical characteristics (Kukident Pro). ***Results:*** Twenty-four patients (mean age: 58 years) participated in this study. Gnathometer results demonstrated significant differences between the nonadhesive group and both the experimental adhesive ($P = .008$) and the control adhesive groups ($P = .021$). Differences between both adhesive groups were not significant ($P = .161$). Dynamometer results showed highly significant differences between the maxillary and mandibular dentures in both the nonadhesive group and the two adhesive groups ($P \leq .0001$). Similarly, highly significant differences were found when any of the adhesive groups were compared with the nonadhesive group ($P = .0001$). The patient subjective evaluation was very favorable for both adhesives. ***Conclusions:*** This study confirms the predicted and expected improvement in the stability and retention of well-fitting complete dentures with the adjunctive use of adhesives. The observed and recorded improvements with the new adhesive as compared to the traditional one were not statistically significant. *Int J Prosthodont 2009;22:361–367.*

Denture adhesives are widely used by patients wearing removable prostheses, as confirmed by their reported sales in several industrialized countries.[1,2] However, clinicians seem ambivalent about the routine prescription of such an adjunct for improved denture retention and stability, even when prostheses are well made and perceived as fitting well.[3–7]

Adhesives are generally composed of rubber, pectins, methylcellulose, hydroxyl-methylcellulose, carboxyl-methylcellulose, sodium-cellulose, and synthetic polymers that improve the denture support both by mechanical and physicochemical mechanisms. Additional compounds in their composition may include antimicrobial agents, additives, colorings, and preservatives. They have been marketed in different vehicles such as powders, pastes, creams, strips, as well as so-called adhesive cushions.[8] Their mechanism of action is usually to increase the contact between the tissues and the denture and form a retentive force between the oral mucosa and the denture via an intermediary film composed of a combination of the adhesive, saliva, and other oral fluids.[9]

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Numerous publications describe the use of a range of sophisticated methods to test the retentive contribution of adhesives to denture stability.[10–15] The majority demonstrate significant improvements with maxillary dentures,[10,12,15] but mandibular ones lack comparable information. Moreover, the latter concern should also be assessed in the context of the far more profound impact of advanced residual ridge reduction in long-standing mandibular edentulism. Also, the published studies usually fail to consider the possible dissolution of the adhesive material following the intake of fluids, mainly hot beverages.

Recently, Özcan et al[16] and Psillakis et al[17] reported on the use of disposable gnathometers to quantitatively assess the masticatory force needed to dislodge a denture. They too demonstrated a significant benefit of using denture adhesives in improving the retention and stability of the tested prostheses. There are, however, few studies comparing different denture adhesives in different clinical situations, such as when bimaxillary dentures are used. The main purpose of this clinical investigation was to compare the efficacy of two denture adhesives in denture-wearing completely edentulous patients under specific testing situations. A secondary objective evaluated patient-mediated outcomes associated with complete denture use, such as perceived degrees of retention and satisfaction and ease of cleaning.

Materials and Methods

Patients

Twenty-six patients were selected from those seeking prosthodontic treatment at the Department of Prosthodontics in the Faculty of Odontology from the Complutense University of Madrid. Inclusion criteria were as follows: *(1)* fully edentulous in both arches for at least 1 year prior to the study's initiation, *(2)* no previous history of using denture adhesives, *(3)* demonstrating good acceptance of complete denture treatment following a standard period of adaptation and adjustment, *(4)* absence of systemic health problems that would preclude attendance for the scheduled clinical study appointments, *(5)* confirmed absence of a history of allergic sensitivity to any of the adhesive materials' components, and *(6)* full compliance with the study's protocol and objectives as per approval by an ethical committee–approved informed consent.

Treatments

Before the start of the study, each patient had a new pair of complete dentures manufactured following the standard protocol employed in the Department of Prosthodontics. This protocol includes the making of anatomic impressions without applying pressure to the soft tissues using standard edentulous trays and alginate material. The craniofacial transfer registrations were taken with a facebow and transferred to a semi-adjustable articulator (Stratos 300, Ivoclar Vivadent) with an individualized adjustment. The base of the prosthesis was designed using post-dam seals and made of acrylic of a standard composition (SR Ivocap High Impact, Ivoclar Vivadent) and with physical properties in accordance with the ISO 1567.[18]

The teeth used had a basic composition of four-layered polymethyl methacrylate (SR Orthotyp PE for posterior teeth and SR Vivadent PE for anterior teeth, Ivoclar Vivadent). They were mounted using a bilateral balanced occlusal scheme.

Once manufactured, the dentures were tested on the patients for proper accuracy and adjustment. Patients were asked to wear them for 4 weeks to allow the dentures to get adjusted and to reach a good fit. After this period and once the presence of any lesion or wound in the mucosa was ruled out, the patients entered the experimental part of the study.

Study Materials

The control adhesive (Kukident, Procter and Gamble) was a marketed adhesive in the form of a cream and composed by PVM/MA copolymers, liquid paraffin, sodium cellulose, petrol, colorings, preservatives, and aromatic particles.

The experimental adhesive (Kukident Pro, Procter and Gamble), also in the form of a cream, shares a similar basic formulation with the control adhesive, although with changes in the preservatives and excipients that change its physical properties, mainly its consistency and behavior when wet.

Outcome Variables

Two main quantitative outcome variables were used to test the retention and stability of the denture: a gnathometer and a dynamometer.

A gnathometer (Procter and Gamble) is an instrument used to measure the occlusal force required to dislodge a well-fit complete denture when a patient chews (Fig 1). The instrument is interposed between the maxillary and mandibular dentures and the patient is asked to bite slowly until one of the dentures is dislodged. This point is then registered on a scale from 0 to 10. The measures were repeated three times, allowing the repositioning of the denture by the patient between measurements and enough time until he or she felt comfortable. In each instance, the gnathometer was positioned in two locations, one at the level of

Fig 1 *(left)* The gnathometer.

Fig 2 *(right)* The dynamometer.

the incisors and the other between the first molars. The mean value between both measurements was used for the analysis.

A dynamometer (Correx) is a calibrated instrument that measures the necessary force to dislodge the denture when traction is applied (Fig 2). This instrument consists of a gauge and a rod that is inserted under the prosthesis. Then, pressure is applied to dislodge it. The instrument measures quantitatively (in cN) the force needed to dislodge the prosthesis from the patient's residual crest. Two registrations were made, first in the anterior-frenum area and then in the lateral-posterior area. The mean value between both measurements was used for the analysis.

The patient-centered outcomes were recorded by means of a questionnaire that the patient filled out at the end of each test period. This questionnaire assessed the subjective patient evaluation of the following variables in a five-category scale (excellent, good, normal, poor, or very poor): denture retention, flavor and consistency of the prosthesis, ease of cleaning and removal of adhesive remnants from the denture, ease of removal of adhesive remnants from the mouth, and the patient's wish to use the adhesive again.

Experimental Design

A crossover, randomized double-blind clinical trial with a 2-week clearance period was adopted. After a 4-week adaptation period for the new dentures, patients underwent a baseline-recording visit. In this visit they were asked to wear their dentures without the adhesive and initial gnathometer and dynamometer values were registered. They were then randomly assigned to use one of the tested adhesives by means of a computer-generated randomization list. They were then instructed in the use of the adhesive and were asked to use it during the following 2 weeks. In brief, the patient was instructed to apply the adhesive cream along the residual crest axis in both dentures, after they were cleaned and dried.

At the 2-week evaluation visit, the same outcome measurements were registered and the patients returned their completed questionnaires. After this visit, patients were instructed to continue using their denture during the next 2 weeks but without any adhesive (clearance period). After this period, the patients were again asked to use a newly assigned adhesive for another 2-week period, and similar baseline and 2-week evaluations were carried out.

The quantitative outcome variables (gnathometer and dynamometer) were always registered at two time periods, first at the beginning of the session and again 2 hours after the patient had drank a hot beverage.

Data Analysis

The sample size utilized was calculated from the expected effect of the adhesive Kukident Classic (control)[16] on the gnathometer for 80% power, using a specific software (Sample Power 2.0, SPSS).

The quantitative data from the gnathometer and dynamometer were expressed in means ± SD. After checking for normality using the Kolmogorov-Smirnov test, results from experimental and control groups after the use of the adhesives were compared with nonparametric tests (Wilcoxon matched-pairs test).

The impact of drinking hot beverages on the adhesive results was analyzed using the Student *t* test for paired samples. The impact of residual crest resorption, the location of the prosthesis, and gender were analyzed using repeated-measures analysis of variance (ANOVA).

The qualitative data from the questionnaires were expressed in percentages. Differences between the groups for the different answer categories were tested for significance using chi-square analysis.

Table 1 Gnathometer Values

Group*	Mean ± SD	Median	95% CI
Nonadhesive	0.93 ± 0.44	0.75	0.75–1.12
Control adhesive	1.39 ± 0.98	1.12	0.98–1.80
Experimental adhesive	1.58 ± 0.99	1.50	0.16–2.00

*P = .008 between nonadhesive and experimental groups. P = .021 between nonadhesive and control groups. P = .161 between experimental and control groups.

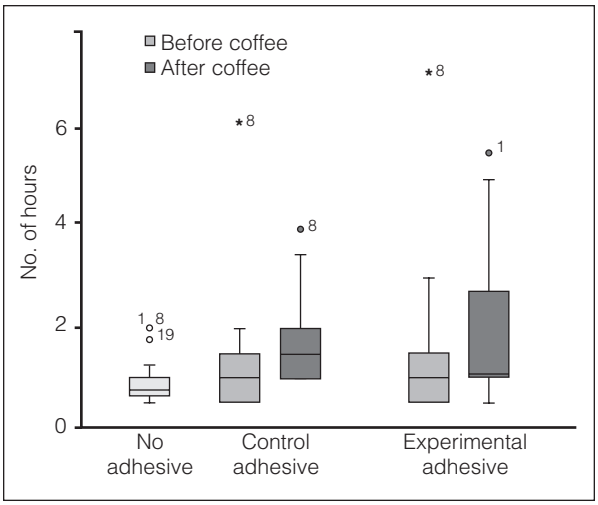

Fig 3 Boxplot of the effect of drinking a hot beverage after the application of the adhesives with the gnathometer. Numbers denote specific cases; dots stand for outlier values and asterisks for extreme values.

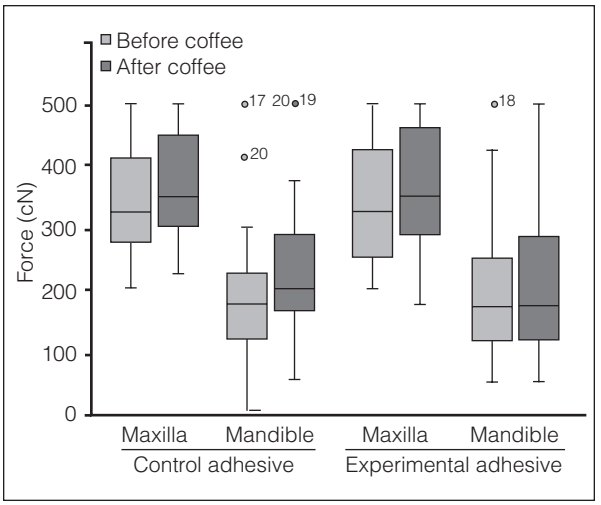

Fig 4 Boxplot of the effect of drinking a hot beverage after the application of the adhesives with the dynamometer. Numbers denote specific cases; dots stand for outlier values.

A significance level was established at 5% and the software program SPSS for Windows 14.0 (SPSS) was used for all data analyses

Results

Two of the 26 patients did not participate in the experimental part of the study as a result of one's death and another's moving to a new address that could not be located. Both patients wore the new dentures but did not enter the experimental part of the study and their data were not included in the analysis. The remaining patients (n = 24) attended all visits. These patients ranged in age from 45 to 82 years, with a mean age of 58 years. They were classified according to the topography of the residual bone crest into two main groups: normal ridges (62.5%) and resorbed or expulsive ridges (37.5%).

Table 1 shows the results obtained with the gnathometer. Without the use of any adhesive, the dentures were dislodged at a mean of 0.93 units (SD = 0.44). With the use of the control adhesive (Kukident Classic) the occlusal force needed was 1.39 units (SD = 0.98), and with the use of the experimental adhesive (Kukident Pro), it was 1.58 units (SD = 0.99). The group comparisons using the Wilcoxon test demonstrated significant differences between the nonadhesive group versus both the experimental (P = .008) and the test adhesive groups (P = .021). Differences between the two adhesive groups were not significant (P = .161).

The effect of drinking a hot beverage after the application of the adhesives was assessed in the two adhesive groups. The results are shown in Fig 3. The Wilcoxon test demonstrated significant differences before and after drinking for the control adhesive group, evidenced by a significant increase (P = .026). In the experimental group, there were also higher values after the hot drink. However, these differences were not statistically significant (P = .073).

The effect of drinking a hot beverage after the application of the adhesives was also assessed with the dynamometer. The results are shown in Fig 4. Similar to its effect on occusal forces (gnathometer), the traction force needed to dislodge the prosthesis was also higher for both adhesive groups after the drinking period. However, these differences were not statistically significant in either the maxillary or mandibular dentures.

Table 2 Dynamometer Values (cN)

Group*	Mean ± SD	Median	95% CI
Maxillary			
Nonadhesive	257.95 ± 90.60	237.37	219.60–296.20
Control adhesive	351.66 ± 80.10	334.37	317.84–385.49
Experimental adhesive	352.13 ± 85.62	343.75	315.97–388.29
Mandibular			
Nonadhesive	54.36 ± 63.68	25.00	27.42–81.25
Control adhesive	208.80 ± 107.11	187.50	163.57–254.03
Experimental adhesive	202.81 ± 111.74	181.25	155.62–249.99

*P = .0001 between maxillary and mandibular dentures in the nonadhesive group. P = .0001 between maxillary and mandibular dentures in both adhesive groups. P = .0001 between the nonadhesive and both adhesive groups.

Table 2 shows the results of the forces needed to dislodge the dentures measured with the dynamometer and expressed in cN. In the nonadhesive group, highly significant differences were found between the maxillary and mandibular dentures (P = .0001). Both adhesive groups showed highly significant differences when the maxillary denture was compared with the mandibular (P = .0001), and highly significant differences were found when any of the adhesive groups were compared with the nonadhesive group (P = .0001).

The repeated-measures ANOVA with an intrasubject factor (maxillary versus mandibular denture) and an intersubject factor (adhesive control versus experimental) did not demonstrate significant differences when the two adhesives were compared (P = .834).

The results from this outcome variable were also analyzed after stratification according to the topography of the residual crest. No significant differences were found between the normal and resorbed alveolar crests when the two adhesives were compared (P = .592). Similarly, when the results were stratified according to the patient's gender, differences between both adhesives were not statistically significant (P = .230).

The results of the patient-centered outcomes based on the answers to the questionnaire are shown in Table 3. When the different answers were compared according to the adhesive used, no significant differences were found except for question 6 (Would you ever use this adhesive if you had to purchase it?). For this question, the Wilcoxon test demonstrated significant differences in favor of the experimental adhesive (z = –2,271, P = .023). In general, the patients were very satisfied with the use of both adhesives. When they were asked their appraisal of the retention provided, the results were either good or very good for 87% of the patients in the test group and exactly the same (87%) in the experimental group. Regarding the flavor and odor of the adhesive, most patients found it normal or pleasant (95% in the experimental group; 85% in the control group). Also, patients found the elimination of adhesive remnants easy or very easy when cleaning the prosthesis or when removing them from the mouth. The majority of patients in both groups would use the adhesive again even if they had to purchase it. The answer to this question showed a clear, more positive response in the patients belonging to the experimental group when compared with the control (83% versus 58%, respectively).

Discussion

Wearing complete dentures without adjunctive retentive aids has frequently caused a high degree of dissatisfaction in denture wearers, especially in the mandible. This is because of the limited dimensions of mandibular prostheses and a high degree of interaction of the complex oral and tongue musculature.[8] In the maxilla, the presence of a nonmobile keratinized mucosa, the absence of significant muscle pull, and a wide contact surface provide a reasonable degree of support, stability, and retention of the prosthesis, in spite of the force of gravity. The dynamometer results reported in this study when dentures were used without an adhesive confirm these general observations. In the maxilla, the mean value of resistance to denture dislodgement was 258 cN (SD = 90); in the mandible, it was 54 cN (SD = 53). In summary, the resistance of vertical dislodging was five times higher in the maxilla than in the mandible.

Several studies have reported that prosthesis retention and stability can be improved with the use of denture adhesives. The studies showed a significant improvement when adhesives were used,[9,17,19–21] although most of the studies used maxillary prostheses for evaluation.[5,10,12] However, it must be emphasized that the force dislodgment tests were often simulated. Furthermore, the population groups studied cannot be regarded as a representative of a larger spectrum of edentulous denture-wearing experiences with an equally large spectrum of different patient-mediated perceptions.

Table 3 Results from the Patients' Questionnaire (%)

Retention of the prosthesis with the assigned adhesive	NA	Very bad	Bad	Normal	Good	Very good
Control	–	–	–	12.5	66.7	20.8
Experimental	4.2	–	–	8.3	50	37.5

Flavor and consistency of the assigned adhesive	NA	Very unpleasant	Unpleasant	Indifferent	Pleasant	Very pleasant
Control	–	–	12.5	50.0	33.3	4.2
Experimental	4.2	–	–	70.8	25	–

Odor of the assigned adhesive	NA	Very unpleasant	Unpleasant	Indifferent	Pleasant	Very pleasant
Control	4.2	–	4.2	54.2	37.5	–
Experimental	4.2	–	–	75.0	20.8	–

Cleanliness and removal of remnants	NA	Very difficult	Difficult	Normal	Easy	Very easy
Control	–	4.2	8.3	20.8	37.5	29.2
Experimental	4.2	–	–	20.8	50.0	25.0

Ease of removal of remnants from the mouth	NA	Very difficult	Difficult	Normal	Easy	Very easy
Control	–	–	12.5	25.0	50.0	12.5
Experimental	4.2	–	4.3	30.4	39.1	26.1

Future usage even if had of purchase	NA	Never	Occasionally	Always
Control	4.2	12.5	29.2	58.3
Experimental	4.2	4.2	8.3	83.3

NA = not answered.

In this investigation, two quantitative outcome variables were combined. First, the gnathometer was used to assess movements of dislocation when both arches bit simultaneously. These movements may be considered to be rather similar to some of the movements made during chewing. The dynamometer assessed the individual denture dislodgement when a vertical traction force was applied. These forces may be presumed to simulate those made by the patient during talking, laughing, gesticulating, and other everyday activities. In this manner, the combination of both outcome measurements permits the test of a wide variety of movements that may influence the stability of a complete denture in use. However, the authors hasten to acknowledge that the sum of all the forces tested do not add up to the frequency, duration, and magnitude of routine functional or parafunctional forces.

The authors also sought to evaluate patient-perceived outcomes, since clinical experience confirms that patient perceptions of clinical outcomes do not automatically match clinician-perceived or even measured ones. Indeed, numerous experienced clinicians regard the patient-determined psychologic benefit of denture adhesives as superior to what can be measured by scientific or quantitative means.[20]

The gnathometer results obtained in this investigation clearly show that the use of both adhesives significantly improved the denture stability and retention capacity by the patient. However, the mean values obtained were inferior to what has been reported by other authors using the same measurement device.[16,17] These authors have reported mean values of 4.60, compared to the mean of 1.58 obtained in this study. Nevertheless, the percentage of improvement with the use of the adhesive when compared with the use of dentures without adhesive was similar (70% improvement reported in both studies). The discrepancies in the absolute values may be due to the different measurement techniques utilized in this investigation, since in this study bite movements were measured at two locations, anteriorly and posteriorly, and then averaged, while in other studies only anterior bite movements were evaluated. Moreover, in the referred studies, the patients were only edentulous in the maxilla; in this investigation, they were fully edentulous, which increased the risk of dislodgment when using the gnathometer.

It has also been reported that the retentive capacity of denture adhesives is lost over time, mostly during the period when hot beverages are consumed.[4] In fact, Fløystrand et al[13] reported a correlation between the dissolution of denture adhesive and the subsequent loss of bond strength. However, other authors have reported that adhesives are efficient during periods of up to 8 hours,[16,20] and they even improve their efficacy with time. This effect may be due to the absorption of fluids by the adhesive, which increases its volume and

thus its contact surface between the mucosa and the prosthesis.[22] Our study supports this mechanism, since the intake of hot beverages increased the retention in both adhesive groups.

The dynamometer results reflected the significant efficacy of both adhesives in increasing the resistance of the prosthesis to dislodgment when a traction force was applied. This significant outcome was obtained for both the maxillary and mandibular dentures. Both adhesives attained mean retention values of approximately 300 cN, similar to some of the attachment mechanisms available on the market for improving denture retention.[23]

In the management of complete denture patients,[8] the psychologic aspects of treatment are of paramount importance, and equally as important as the accurate technical construction of the prosthesis. All patients completed a structured questionnaire after regular use of their dentures with the assigned adhesive. No preference was shown and the patients were mostly indifferent to their odor or flavor. Most of the patients also found the adhesives easy or very easy to use, with only 4% reporting difficulties in eliminating the remnants of the adhesive. The retention of the denture with the use of the adhesive was either good or very good according to 87% of patients. The patients did not show any preference for the type of adhesive, although a higher percentage of them stated that they would use the experimental adhesive (Kukident Pro) again even if they had to purchase it.

Conclusion

Within the limitations of the study's design (ie, size, power, diversity, time-dependence considerations) together with the selection of a specific patient population group, it was found that denture adhesives improve the stability and retention of the complete denture–wearing experience. The two tested adhesives were both efficacious but without statistically significant differences.

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