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A Clinical Study to Evaluate Denture Adhesive Use in Well-Fitting Dentures

Carlos A. Munoz, DDS, MS,[1] Linda Gendreau, DDS, MS,[2] Gilbert Shanga, PhD,[2] Tabetha Magnuszewski, RDH,[1] Patricia Fernandez, RDH, BS,[2] & John Durocher, BA[2]

[1]University at Buffalo School of Dental Medicine (SUNY), Buffalo, NY
[2]GlaxoSmithKline Consumer Healthcare, Parsippany, NJ

Keywords
Dentures; denture adhesive; retention; stability; Kapur Index; incisal bite force; mastication; food under dentures.

Correspondence
John Durocher, GlaxoSmithKline Consumer Healthcare, 1500 Littleton Rd., Parsippany, NJ 07054. E-mail: John.P.Durocher@gsk.com

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Abstract

Purpose: The objective of this study was the assessment of retention and stability and functional benefits of denture adhesive applied to well-fitting and well-made dentures.
Materials and Methods: This was a randomized, crossover study to compare two marketed denture adhesives (test cream, Super Poligrip® Free, and test strip, Super Poligrip® Comfort Seal Strips) and an unmarketed cream adhesive (GlaxoSmith Kline Consumer Healthcare) with no adhesive as the negative control. Thirty-six subjects completed the study. One hour after the application of denture adhesive, retention and stability were measured using the Kapur Index and maxillary incisal bite force. Two hours after application, functional tests were used to assess denture movement and peanut particle migration under the denture. Subjects also rated confidence, comfort, satisfaction with dentures, and denture wobble in conjunction with the functional tests.
Results: Denture adhesives significantly ($p < 0.05$) improved retention and stability of well-fitting dentures. Subjects experienced significantly ($p < 0.05$) fewer dislodgements while eating an apple after adhesive was applied to dentures. Significant ($p < 0.05$) increases in subjective ratings of confidence and comfort as well as decreases in denture wobble were associated with the use of adhesive. There was significant ($p < 0.05$) improvement in satisfaction ratings for cream adhesives. A single application of each denture adhesive was well tolerated.
Conclusion: The results of this study provide evidence that use of Super Poligrip® denture adhesives can enhance aspects of performance of complete well-fitting dentures as well as provide increased comfort, confidence, and satisfaction with dentures.

Denture adhesives are commercially available products used by many denture wearers as an over-the-counter approach to improve denture retention and stability. Denture adhesives are formulated with a mixture of short- and long-acting synthetic polymers that hydrate and increase in volume to fill voids between the denture and mucosal tissues. In addition, the increased viscosity of hydrated adhesive helps to optimize interfacial forces that aid in denture retention. The long-acting polymers improve cohesive forces within the adhesive through molecular cross-linking, increasing the strength of the adhesive film and extending resistance to washout from under the denture.[1]

The dental literature reflects the clinical indications for use of denture adhesives in well-made dentures.[1-3] These include instances when anatomic structures are compromised by ridge shape, tissue resiliency, and border attachment locations that do not favor adequate stability and retention. The use of adhesive may be appropriate when medical conditions such as stroke impair neuromuscular control and adversely affect a patient's ability to develop the adaptive muscle behaviors necessary for control of denture movement in function and rest. A denture adhesive may also act as a cushion for denture-bearing mucosa that may be thinned by age or susceptible to irritation from the lack of lubrication from poor quality or quantity of saliva. Denture adhesive may provide another benefit to patients by reducing the amount of food particles collecting under the denture. Finally, denture adhesives may also be indicated when well-made complete dentures do not satisfy a patient's perceived retention and stability expectations. Modern denture adhesives are available in different forms such as creams, strips, and powders to fulfill a range of consumer needs.

A number of recognized objective methods have been used to demonstrate the effectiveness of denture adhesive.[4] These include the Kapur Index[5] and bite force[6] to measure denture retention and stability, denture dislodgement[7] to measure denture movement in function, and masticatory performance,[5] an indicator of chewing efficiency. Other methods reported in the literature include biomechanical methods such as electromyography and kinesiography[8] to study retention and stability. In addition to objective measures, patient-based and quality-of-life outcomes have confirmed denture wearers can perceive changes in denture performance with the use of adhesive and report increased comfort, confidence, and satisfaction with their dentures as a result.[9]

The aim of the present investigation was to use recognized test methods to evaluate the effect of three denture adhesives on the retention, stability, and movement in function of well-fitting and well-made dentures. In addition, a large population-based consumer research survey among 8262 Canadian denture wearers was sponsored by GlaxoSmithKline and conducted by the Chapman Group in May 2004. It was found that among the 2986 respondents, the most common experience reported was the perceived presence of food particles under the denture during mastication (25% reported regularly and 90% reported occasionally).

While in 1980, Tarbet et al[7] reported that subjects perceived fewer food particles under their dentures with adhesive use, it was also an aim of the present study to explore the development of a quantitative test of adhesive as a barrier to help prevent food entrapment under dentures. In addition to objective measures, subjective ratings of perceived comfort, confidence, and satisfaction, as well as the perceived degree of denture movement, were recorded whenever a functional test was used. The results of oral soft tissue examinations and spontaneous reports of adverse experiences were recorded as safety assessments after short-term exposure to the denture adhesive products.

Materials and methods

Patient population

Eligible subjects were aged 18 years or older with well-fitting and well-made full upper and lower dentures. They must also have been willing to comply with all study procedures. Patients with immediate dentures or overdentures were not included. Denture fit was assessed by a single examiner using the Kapur criteria (Olshan modification)[10] displayed in Table 1, which also presents the criteria used to identify well-made dentures.

Study design

This was a single-center, randomized, clinical evaluator blinded, crossover clinical study. The study was reviewed and approved by the Institutional Review Board at the University at Buffalo School of Dental Medicine (SUNY), and informed consent was obtained from each patient prior to implementation of the study procedures.

Patients and dentures were screened for inclusion and enrolled on visit 1. A baseline oral soft tissue evaluation was also made at that visit.

Table 1 Evaluation criteria for well-fitting and well-made dentures

Kapur Index	
Retention	Stability
5: Excellent—excellent resistance to vertical pull and lateral force	4: Excellent—no rocking on supporting structures under pressure
4: Very good—very good resistance to vertical pull and lateral force	3: Good—very slight rocking under pressure
3: Good—moderate resistance to vertical pull and lateral force	2: Fair—sufficient stability; demonstrates slight rocking under pressure
2: Fair—moderate resistance to vertical pull and little or no resistance to lateral force	1: Poor—some stability, demonstrates moderate rocking under pressure
1: Poor—slight resistance to vertical pull and little or no resistance to lateral force	0: No stability—extreme rocking under pressure
0: No retention—denture displaces itself.	

Well-fitting dentures were defined as having a Kapur Index Sum Score ≥ 6. Sum score = sum of retention and stability scores for maxillary + mandibular dentures.

Well-made dentures were defined as having adequate vertical dimension, freeway space, horizontal occlusal relationships, and border extension and acceptable porosity, tissue surfaces, polished surfaces, color, and thickness.

In total, four efficacy tests were performed using the methods described below. On each test day either the Kapur Index, bite force, and peanut particle migration (visits 2, 4, 6, and 8) or denture dislodgement (visits 3, 5, 7, and 9) were measured. Three denture adhesives were evaluated by all patients, and all patients also completed the tests with no adhesive in their dentures. The days and order in which adhesives were used was based on a predetermined randomization scheme prepared by the Biostatistics and Data Management Department at GlaxoSmithKline Consumer Healthcare. An oral soft tissue evaluation was also made at the final visit.

Test methods

Efficacy

Kapur Index: The Kapur Index is based on a scale that categorizes criteria commonly used in clinical practice to evaluate retention and stability of dentures. In 1992, Olshan et al[10] modified the standard Kapur Scale by expanding the upper ranges to elevate its sensitivity for discriminating retention and stability. In the present study, maxillary and mandibular dentures were checked clinically by a single, experienced examiner for denture base fit and occlusal relationships and scored using the criteria in Table 1. The dentures were then removed, and the maxillary and mandibular denture-bearing tissues were scored. On the days when adhesive was to be tested, the index was taken 1 hour after placement of the adhesive.

Bite force: Bite force indicates denture retention by measuring the tipping force required to dislodge the upper

denture.[11] One examiner, experienced with the use of the bite force method, performed the measurements in the present study. Patients were instructed on the procedure for taking bite force measurements, and any patient not willing or able to successfully complete the tasks required was terminated prior to randomization. In the present study, patients were asked to bite on a strain gauge transducer fitted to the incisors of the maxillary denture to ensure reproducibility. The maximum force exerted before the denture dislodged or at 40 lbs, whichever occurred first, was recorded. When indicated, readings were taken 1 hour after the application of denture adhesive.

Denture dislodgement: Tarbet et al[7] presented a method of counting denture dislodgements during normal eating of a standardized portion of food. Patients in the present study were presented with a whole apple and asked to (1) take a bite, (2) chew completely, and (3) swallow and then record the number of dislodgements that occurred during these three steps. Subjects repeated these steps until the apple was consumed. The number of bites needed to consume the apple, the number of dislodgments, and the number of bites to first dislodgement were recorded. If an adhesive was applied to the denture as per the randomization schedule, the test was initiated 2 hours after application of the adhesive.

Peanut particle migration: In the present study, a quantitative method based on consumption of peanuts, a brittle food used in studies of masticatory efficiency,[5] was used. The weight of peanut particles retrieved from under dentures when no adhesive was used was compared to when adhesive was used. The following is a brief summary of the method.

Each subject was asked to chew and swallow 32 g of non-salted dry-roasted peanuts. Peanut particles were removed from the external surfaces of the maxillary and mandibular dentures. Patients removed their dentures, and a staff member removed any residual adhesive and peanut particles from the hard palate of each participant's mouth and the ridge area under the lower denture using gauze. Maxillary and mandibular dentures and the corresponding gauze were placed in separate beakers and sonicated to loosen any adhering peanut particles. The solution in each beaker was strained through a mesh sieve until only peanut particles remained on the sieve. The collected particles were air-dried overnight and then transferred from the screen to a preweighed aluminum weighing pan and dried in an oven. The weight of the retrieved peanuts was then determined. On days when adhesive was to be tested, the peanuts were chewed 2 hours after the application of denture adhesive.

Comfort, confidence, satisfaction, and denture wobble: Each time patients ate an apple or peanuts, they were asked to rate their level of comfort, confidence, satisfaction with dentures, and perception of denture wobble. A separate question and seven-point visual scale ranging from 0 (none) to 6 (strongest possible) was used for each of the four measures (comfort, confidence, satisfaction, denture wobble).

Safety

Adverse events: In this study, an adverse event was considered to be any medical occurrence that occurred following administration of a product for testing purposes and which did not necessarily have a causal relationship with the product. In addition to capturing spontaneous reports of all adverse events, an examination of the oral soft tissues was made at baseline and again after all other study procedures had been completed. The examination included the labial mucosa (including lips), buccal mucosa, tongue, gingival mucosa, sublingual area, hard and soft palates, mucogingival folds, submandibular area, salivary glands, and tonsilar and pharyngeal areas. Observations were made of any erythema, desquamation and ulcerations, and other relevant clinical observations. Any abnormal findings at the final examination that had not been noted at baseline were recorded as adverse events.

Table 2 Demographic characteristics

Characteristic	Randomized patients (N = 37)
Gender N (%)	
Male	19(51.4%)
Female	18(48.6%)
Mean age (SD) of patients, years	70.65(11.0)
Race N (%)	
Caucasian	32(86.5)
Black	5(13.5)
Mean (SD) age of dentures, years	6.4(8.8)
How long wearing dentures? Mean (SD), years	23(20.7)

SD = standard deviation.

Products tested

One major manufacturer, GlaxoSmithKline Consumer Healthcare, offers a line of adhesives that includes the complete range of product forms. Therefore, products from this manufacturer were included in the study.

- Test cream: Super Poligrip® Free [Polyvinylmethyl ether/maleic acid (PVM/MA) sodium-calcium mixed partial salt], GlaxoSmithKline Consumer Healthcare
- Unmarketed cream adhesive (PVM/MA sodium-magnesium-zinc mixed partial salt), GlaxoSmithKline Consumer Healthcare
- Test strip: Super Poligrip® Comfort Seal Strips [(Polyethylene glycol (PEG-90), microcrystalline wax, polybutene, cellulose gum), GlaxoSmithKline Consumer Healthcare

To ensure that the clinical evaluator remained blinded, one staff member, not involved with the efficacy measurements, applied the test products to the patients' dentures. All test products used in this study were applied in amounts and patterns consistent with their respective package labels. For cream adhesives, 1 g was weighed out and applied to the maxillary denture and 0.6 g to the mandibular denture. For the strips, three strips were applied to the maxillary denture and two strips to the mandibular denture.

Statistical analyses

Statistical methods included calculating the natural log of maximum bite force for each subject in each period of the study.

Table 3 Kapur Index (Olshan Modification)

	No adhesive (N = 37) LS mean (SD)	Unmarketed cream adhesive (N = 37) LS mean (SD)	Super-Poligrip® Free (N = 36) LS mean (SD)	Super-Poligrip® Strips (N = 36) LS mean (SD)
Maxillary denture				
Retention	3.65(0.92)	4.95(0.23)*	4.92(0.37)*	4.61(0.64)*
Stability	3.59(0.64)	4.00(0)*	3.97(0.17)*	3.92(0.28)†
Mandibular denture				
Retention	3.0(1.05)	4.92(0.36)*	4.72(0.66)*	4.11(1.14)*
Stability	3.30(0.74)	3.97(0.16)*	3.92(0.28)*	3.67(0.68)†

LS Mean = least square mean; SD = standard deviation; *$p < 0.0001$; †$p < 0.001$.
Retention scale: 5 = excellent, 4 = very good, 3 = good, 2 = fair, 1 = poor, 0 = none.
Stability scale: 4 = excellent, 3 = good, 2 = fair, 1 = poor, 0 = none.

Table 4 Denture dislodgements while eating an apple

	No adhesive (N = 37)	Unmarketed cream adhesive (N = 37)	Super Poligrip® Free (N = 36)	Super Poligrip® Strips (N = 36)
Mean (SD) number of bites needed to consume an apple	24.54(9.78)	22.35(8.54)	23.44 (10.48)	24.56 (9.48)
Mean (SD) number of patients who experienced a dislodgement	28	15	18	22
Mean (SD) number of bites to first dislodgement	3.11(3.51)	9.93(7.27)*	5.78 (5.29)*	4.82 (6.22)†
Mean (SD) number of dislodgements‡	14.76(15.34)	4.84(9.41)*	7.86 (10.90)*	10.83 (13.18)*

SD = standard deviation; *$p < 0.0001$; †$p < 0.001$; ‡Statistical testing was done on the rate of dislodgement (number of dislodgements divided by the number of bites needed to consume the apple). The mean is the average number of dislodgements.

Peanut particle migration was measured by weight of food particles retrieved. Kapur Index determination was based upon retention and stability of the dentures. Analysis was done on both the composite variable (sum of retention and stability scores) and on retention and stability separately.

Mixed models were used in the analysis of maximum log bite force, food occlusion, and Kapur Index with period and treatment as fixed effects and subject as a random effect. Pairwise Dunnett adjustments of multiple comparisons were performed at a 5% significance level to compare each of the three treatments to the control (no adhesive). Two-sided, 95% confidence intervals were constructed. Masticatory efficacy consisted of the number of bites to consume an apple, the number of denture dislodgements, and the number of bites to first dislodgement. The number of bites and number of dislodgements constitute count data, which was analyzed by SAS GENMOD, where the underlying distribution is Poisson with a log link function. Subjective responses were analyzed using mixed models as described above.

Results

Demographics (Table 2)

Thirty-seven patients were randomized to treatment, 36 completed treatment, and one discontinued treatment and was lost to follow-up. The average age of the patients in this study was 70.65 years, well within the expected range of complete denture wearers. The average age of the set of dentures tested in this study was 6.4 years; however, the patients had been wearing dentures for an average of 23 years, making them experienced denture wearers.

Kapur Index (Table 3)

The values for the modified Kapur Index taken in this study indicate the maxillary dentures had good to very good retention and good to excellent stability without adhesive. Likewise, the mandibular dentures had good retention and stability without adhesive. Compared to no adhesive, all three denture adhesives significantly increased denture retention and stability. The increases associated with the cream adhesives were highly significant compared to no adhesive ($p < 0.0001$). For strips, increases in stability were significant ($p < 0.001$), and increases in retention were highly significant.

Bite force (Fig 1)

The use of denture adhesive resulted in an increase of 2 to 4 lbs of bite force 1 hour after application. This was statistically significant compared to no adhesive. As with the Kapur Index, increases associated with the cream adhesives were highly significant ($p < 0.0001$).

Denture dislodgement (Table 4)

Although the number of bites needed to consume an apple remained fairly constant in all treatment groups, patients were able to take significantly more bites before experiencing a

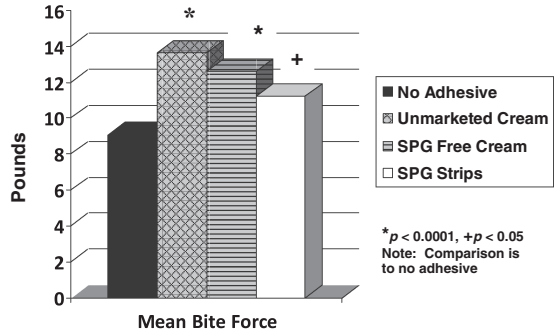

Figure 1 One-hour incisal bite force.

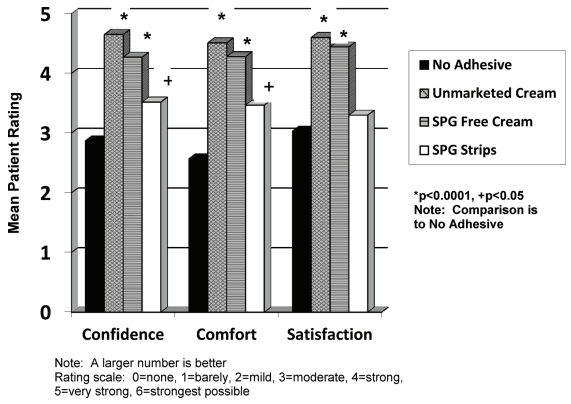

Figure 2 Denture dislodgement: subjective ratings of comfort, confidence, and satisfaction while eating an apple. Note: A larger number is better. Rating scale: 0 = none, 1 = barely, 2 = mild, 3 = moderate, 4 = strong, 5 = very strong, 6 = strongest possible.

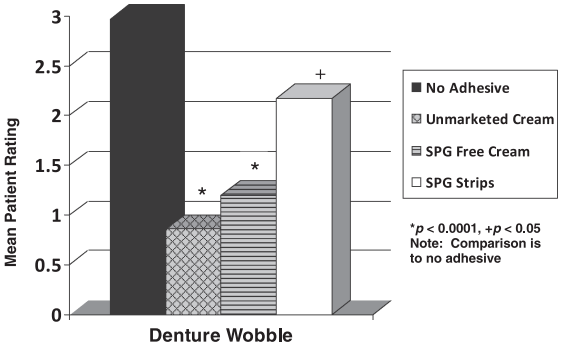

Figure 3 Denture wobble: subjective rating while eating an apple. Note: A smaller number is better. Rating scale: 0 = none, 1 = barely, 2 = mild, 3 = moderate, 4 = strong, 5 = very strong, 6 = strongest possible.

dislodgement and experienced significantly less dislodgement while eating the apple when adhesive was applied to their dentures. These performance benefits translated into perceptible and statistically significant gains in patient ratings of confidence and comfort and satisfaction with dentures, with the exception of no difference in the satisfaction score between the no adhesive control and the test strips (Fig 2). Patients also detected significantly less denture wobble associated with the use of denture adhesive while eating an apple (Fig 3).

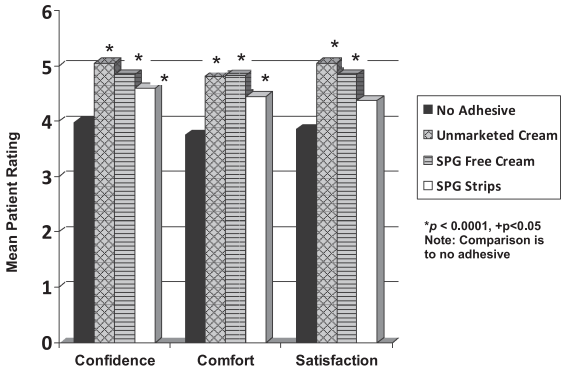

Figure 4 Peanut particle migration: subjective ratings of comfort, confidence, and satisfaction with dentures while eating panuts. Note: A larger number is better. Rating scale: 0 = none, 1 = barely, 2 = mild, 3 = moderate, 4 = strong, 5 = very strong, 6 = strongest possible.

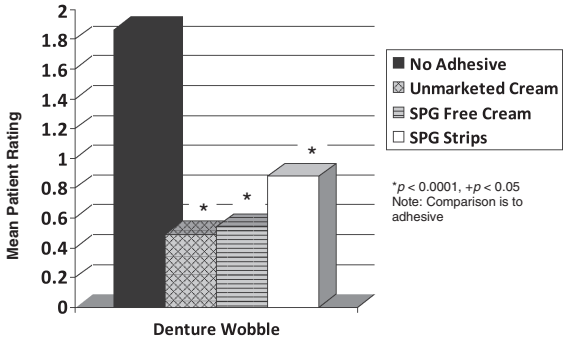

Figure 5 Denture wobble: subjective rating while eating peanuts. Note: A smaller number is better. Rating scale: 0 = none, 1 = barely, 2 = mild, 3 = moderate, 4 = strong, 5 = very strong, 6 = strongest possible.

Peanut particle migration

Peanut particle migration was evaluated as the weight of peanut residue recovered from under the dentures. The amount was minimal ($\leq$ 0.02 g) in all four groups. When denture adhesive was used, patients reported better scores for confidence, comfort, and satisfaction while eating peanuts (Fig 4). These scores were all statistically significant compared to no adhesive, with the exception of the score for satisfaction between no adhesive and the test strips. Similar to the results for perceived denture movement (wobble) associated with eating an apple, the mean amount of denture wobble associated with eating peanuts with no adhesive was significantly reduced when adhesive was used (Fig 5).

Safety

No serious adverse events were reported in this study, and only oral adverse events were coded. A total of 16 oral adverse events were reported by ten patients. All oral adverse events were classified as mild, and all adverse events were followed up until resolution.

Discussion

All three denture adhesives tested in this study resulted in a significantly improved modified Kapur Index, maxillary bite force, and denture dislodgement, indicating increased retention and stability and decreased movement in function. Similarly, comfort, confidence, and satisfaction were rated significantly higher, and significantly less movement (wobble) was detected by patients when adhesive was used. Although direct statistical comparisons were not made between the adhesives, the results indicate that the unmarketed cream adhesive had the best performance, followed by the test cream and then the test strip. The performance of the unmarketed cream adhesive is likely due to the chemistry of the long-acting adhesive polymer in this formulation, which increases adhesive strength and resistance to washout. The difference between the creams and the strip product is likely due to the fact that strips do not contain a long-acting synthetic polymer.

The results of this study are in agreement with other studies that have shown using similar as well as different test methods and adhesive formulations, that adhesive use can augment the retention, stability, and function of well-fitting conventional dentures.[7,8,12] Fujimori et al[13] examined the effects of a paste-type denture adhesive on well-fitting complete dentures using maximum biting force recorded at the first molar region, masticatory performance, and electromyography of the masseter muscle. The application of denture adhesive had a positive effect on all performance measures that was more significant for denture wearers with poor denture-bearing tissues. Tarbet et al[14] had previously come to a similar conclusion after finding that a powder adhesive increased incisal bite force in all patients tested but especially in full denture wearers with unsatisfactory support tissues.

Tarbet et al[7] also used a similar method of counting denture dislodgements during normal eating of standardized portions of food and found significantly less dislodgement after the application of adhesive to well-fitting dentures. Chew et al[8] used kinesiographic instrumentation to demonstrate that paste and powder adhesives containing long-acting polymer, PVM-MA, or gantrez salt improved retention and stability of both well- and ill-fitting dentures. Pradies et al[12] tested two denture adhesives that differed with respect to physical properties and again confirmed increased bite force in well-fitting dentures associated with both formulations. Finally, recent studies, including a large practice-based investigation among 194 patients,[15] have validated the use of a disposable gnathometer and demonstrated that denture adhesive increases maxillary incisal bite force in both newly fabricated and in previously worn dentures.[16,17] Taken together with the results of the present study, these various lines of evidence support the conclusion that denture adhesive in powder, paste, and strip form increases retention and stability and decreases movement in function of well-made dentures.

Denture wearers report that dentures move, and studies have successfully measured this in well-fitting dentures using an alternating magnetic field tracking device.[18,19] These studies found that mandibular denture movements were significantly greater than maxillary denture movements, adhesive significantly reduced maxillary and mandibular denture movement during chewing and biting, and that denture adhesive increased the mean chewing rate up to a rate that approximated nondenture wearers. This situation may cause discomfort by allowing food particles to migrate underneath dentures and contributes to mucosal irritation from rubbing. Therefore, a secondary benefit to denture adhesive use recognized subjectively in the dental literature, but not yet quantified, has been the ability of adhesive to act as a barrier to help prevent food particles from migrating under dentures and causing discomfort.[7] In the present study, an attempt was made to quantify the amount of peanut particles that could be retrieved from under dentures with some success. Although only a small amount of peanut particles could be retrieved from under dentures without adhesive, the amount retrieved from under the mandibular denture was greater than the maxillary denture. Despite this observation, retrieval of the very small weight of particles left very little room for improvement; therefore, the benefit associated with the use of adhesive could not be quantitatively differentiated from the no-adhesive state. Nonetheless, patients reported a significant increase in comfort, confidence, and satisfaction with dentures when adhesive was used. Since Garrett et al[20] noted that particles under dentures were among the attributes highly correlated with chewing comfort and overall patient satisfaction, it may be suggested the quantitative portion of the test method in the present study may require some further development to increase the sensitivity of detection of the weight of food particles retrieved.

The functional tests of denture dislodgement and peanut particle migration, including the ratings of comfort, confidence, and satisfaction, were conducted without adhesive as well as 2 hours after the placement of adhesive. The question arises whether the improvements measured with adhesive use would be sustained beyond the 2-hour limit of this test to a degree that would maintain a difference between adhesives and the no-adhesive control. Studies using patient responses support the ability of this form of measurement to be sensitive to differences in adhesive versus no adhesive[15] and to be able to discriminate preferences between different adhesive formulations.[9,21] In at least one of these studies, all the adhesives included in the test were less effective after 6 to 12 hours. Nonetheless, the discriminating capability of the method was retained, and patients were able to designate a preference, based on chewing ability and duration in mouth, for an adhesive with a long-acting polymer over another without polymer. Therefore it seems likely that the difference between adhesive and no adhesive measured in the present study after 2 hours would continue to be measurable for a longer duration that might be defined by the practicalities of the test method.

Denture adhesives are available globally. Although they may be regulated differently in various countries, sometimes as cosmetics, medical devices, nonregistered medicines, or other miscellaneous classifications, they are always available as consumer products. There are some precautions associated with the use of marketed zinc-containing adhesives,[22] therefore it is important for consumers to follow the manufacturer's label instructions. Dental professionals can play a key role in providing guidance to all denture patients on the proper use and application of these products, while taking the opportunity to educate patients to expect that, with time, their dentures will need to be refitted or relined. Importantly, since denture adhesive is not intended to be a substitute for this procedure, patients also

need to be informed that adhesive need only be used sparingly and educated to recognize that excessive use, either in quantity or frequency of application, may be a sign that dentures have become ill-fitting. Informed patients will be likely to use denture adhesives properly and understand that, although they are missing natural teeth, they still need to see a dentist regularly to evaluate denture fit and to check for cancer or other diseases in the mouth.

Conclusion

The results of this study provided proof of principle that Super Poligrip® denture adhesives increased retention and stability of well-fit and well-made dentures. In addition, denture movement measured both objectively and subjectively was decreased. A single application of denture adhesive to well-fitting and well-made dentures also increased comfort, confidence, and satisfaction with dentures in conjunction with chewing hard and brittle foods.

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