ORIGINAL ARTICLE

An international multicenter study on the effectiveness of a denture adhesive in maxillary dentures using disposable gnathometers

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Abstract No consensus has been achieved on whether denture adhesives are beneficial adjuncts in denture-wearers management. The purpose of this international multicenter study was to determine objectively the effect of a denture adhesive (Kukident) on the retention of complete maxillary dentures using disposable gnathometers. The disposable gnathometers have a decimal scale for measuring the incisal force before dislodgement (= maximum incisal force) of maxillary dentures. The intra-observer reliability, the interobserver reliability, and the linearity of the gnathometer units of the disposable gnathometers were examined in three pilot studies. Participants of the international multicentre main study were 88 patients who had been selected for complete maxillary denture treatment. The maximum incisal force of their previous and new denture without and with adhesive was measured using disposable gnathometers. The intra- and inter-observer reliability of the disposable gnathometers was very good, and there was a linear relation between the gnathometer units. The effect of the denture adhesive on the maximum incisal force of complete maxillary dentures was statistically significant in

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M. Özcan · W. Kalk Academic Centre Oral Health, University Medical Centre Groningen, Groningen, The Netherlands previous as well as new dentures, being more pronounced in previous than in new dentures.

Keywords Prosthodontics \cdot Denture adhesive \cdot Maxillary denture \cdot Retention \cdot Gnathometer

Introduction

Denture adhesives bond a denture and the underlying oral tissues via physical and chemical actions. Major elements of adhesive products are ingredients which swell by absorbing water and become viscous and sticky [27]. The purpose of the use of denture adhesives can be described as to subjectively benefit denture-wearers with improved stability, retention and comfort of their dentures, and with improved incisal force, masticatory ability, and confidence.

In the past, the use of denture adhesives has been a conflicted issue among dentists. It was feared that denture adhesives are leading to alveolar ridge resorption, soft tissue hyperplasia, colonization of microorganisms, and an increase in vertical dimension [1]. A recent Delphi technique survey by an American dental schools expert panel achieved consensus that denture adhesives are useful adjuncts. The panelists clearly expressed their concern that neither dentists nor patients should use denture adhesives as a substitute for either good clinical practice or proper denture maintenance routine [28].

Despite the more or less restraining attitude of dentists towards denture adhesives, it has been shown that a substantial proportion of denture wearers (7-33%) had tried denture adhesives in the past or were regular users currently [5, 23]. Responses of patients to questions regarding satisfaction, retention, and eating and masticatory performance of complete dentures demonstrated a subjec-

tive improvement when using a denture adhesive [1, 16, 25, 29]. The improvement in satisfaction and retention was more pronounced in the maxillary than in the mandibular denture [16].

While objectively counting denture dislodgements during normal eating of standardized portions of food without and with a denture adhesive, a significant reduction in dislodgement for maxillary as well as mandibular dentures was found when a denture adhesive was used [30]. Objective improvement of retention of dentures using denture adhesives has been demonstrated by several in vitro tests [4, 7, 17, 24, 31, 33]. In vivo, objective effect of denture adhesives on retention and stability of complete maxillary and mandibular dentures has been demonstrated according to the modified Kapur scale [21]. Using a cineradiography technique in vivo, an assessment was made of maxillary denture mobility during function among complete denture-wearing patients without and with two types of denture adhesives [14]. Neither between the two adhesives nor between the situation without and with denture adhesive was a significant difference in denture mobility found. An in vivo cineradiography intra-individual comparison of the objective effectiveness of a denture adhesive in mandibular dentures revealed a non-significant decrease in mean denture dislodgement, but a significant decrease of peak values [15]. In vivo test methods using a (gnatho)dynamometer or retentiometer for assessing maximum occlusal force revealed objective improvement of retention of maxillary dentures or palatal plates using denture adhesives [2, 3, 6, 9-12, 19, 22]. With a system of multi-channel alternating magnetic field magnetometer tracking, it was demonstrated that a denture adhesive significantly reduced movement of complete maxillary dentures and complete mandibular implant-retained overdentures during mastication [13]. Masticatory performance was improved with a denture adhesive [8, 20, 26]. As assessed with a simple gnathometer, a denture adhesive significantly improved the (protrusive) incisal force needed to dislodge a maxillary complete denture [25]. Since the introduction of a disposable gnathometer (Procter & Gamble, Geneva, Switzerland) facilitating a simple measurement of incisal force at dislodgement of a maxillary denture, it seems easy to demonstrate a more or less objective improvement in retention of maxillary dentures. The aim of the present study was to determine objectively the effect of a denture adhesive on the retention of complete maxillary dentures using disposable gnathometers.

Materials and methods

The main part of this study was conducted for determining objectively the effect of a denture adhesive on the retention



Fig. 1 Disposable gnathometer

of complete maxillary dentures using disposable gnathometers (Fig. 1). Maximum retention of the dentures was determined by registering the maximum incisal force. Maximum incisal force of a complete maxillary denture was defined as the pressure a patient can apply to the frontal teeth until dorsal dislodgement of the denture. The disposable gnathometer registers the maximum incisal force of a maxillary denture using a decimal scale (gnathometer units). In this study, the measurements were rounded down to integers. To test the feasibility of the disposable gnathometers, three pilot studies were achieved previously. The feasibility test contained determining the intra- and inter-observer reliability of the disposable gnathometers, examining the linearity of the gnathometer units, determining the magnitude of the incisal force applied, and estimating the measurement burden for the patients and the measurement time needed. All denture treatments in this study followed a standardized method, including a functional impression with an individual tray using elastomeric impression materials, intra-oral gothic arch registration, and lingualized occlusion [18, 32]. Statistical analyses were carried out using SPSS-10 (SPSS, Chicago, IL). For all comparisons, the level of significance was P < 0.05.

Pilot study 1

To determine the intra-observer measurement error and the corresponding intra-observer reliability of the disposable gnathometers, an international multicentre clinical pilot study was conducted at the dental clinics of the Erasmus University Medical Centre in Rotterdam, The Netherlands, the University of Groningen in Groningen, The Netherlands, the University of Gent in Gent, Belgium, the University of Athens in Athens, Greece, and the University of Marmara in Istanbul, Turkey. In each clinic, five complete maxillary denture-wearing patients who had received a new denture less than 1 month previously were selected. The patients had a stable natural dentition, a fixed

prosthesis, or a stable removable prosthesis in the mandible. A stable removable prosthesis could be an overdenture attached on natural abutments or implants, a partial natural dentition with a stable removable partial denture, etc.

For each patient, at the first session, the maximum incisal force was measured by one of the five experienced prosthodontists involved in this study, using three different disposable gnathometers, successively three times with each gnathometer (Fig. 2). Per patient, nine measurements were conducted with 3-min breaks to enable the patient to reposition the denture comfortably and habitually. One week later, at the same period of the day, for each patient, the measurements were repeated with the same three gnathometers as used in the first session. Within the time schedule for this pilot study, all clinics could conduct the measurements in five patients, except Groningen with three patients only. The measurement error was calculated by the Dahlberg formula, and the Pearson correlation was calculated as reliability coefficient.

Pilot study 2

To determine the inter-observer reliability, a clinical pilot study was conducted at the dental clinic of the Erasmus University Medical Centre in Rotterdam. Twenty-four patients wearing complete maxillary dentures and having a stable natural dentition, a fixed prosthesis, or a stable removable prosthesis in the mandible as in pilot study 1 were selected. For each patient, the maximum incisal force of the complete maxillary denture was measured by three observers using one disposable gnathometer per patient. The observers conducted their measurements in a strictly prescribed order of observers according to the Latin square principle. Over the total group of 24 patients, each observer was equally first, second, and third observer, while he was

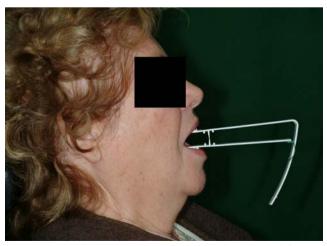


Fig. 2 Disposable gnathometer measuring maximum incisal force of the maxillary denture while the patient is applying pressure to the frontal teeth

Table 1 Inter-observer measurement data of gnathometer units bythree observers (A, B, and C) among 24 patients according to eightLatin squares

Patient	Measurement			
	First	Second	Third	
1	A8	B8	C8	
2	C7	A7	B6	
3	B4	C3	A5	
4	A3	C3	B3	
5	В5	A6	C5	
6	C6	B6	A4	
7	A9	В9	C9	
8	C8	A8	B8	
9	B7	C8	A7	
10	A6	C6	B6	
11	B8	A8	C8	
12	C3	B2	A2	
13	A3	В3	C3	
14	C10	A10	B10	
15	B4	C4	A4	
16	A5	C3	B4	
17	B6	A6	C6	
18	C7	B7	A6	
19	A5	В5	C5	
20	C5	A4	В5	
21	B1	C2	A2	
22	A7	C7	B7	
23	B7	A6	C7	
24	C5	B4	A3	

equally followed by the other two observers (Table 1). The measurements were conducted with 3-min breaks to enable the patient to reposition the maxillary denture comfortably and habitually. Three-way analysis of variance (ANOVA) was applied to test the influence of the observers and of the sequence of the observers because of the possible learning effect, while correcting for patient influences. The interobserver measurement error was calculated by the Dahlberg formula, and the Pearson correlation was calculated as reliability coefficient.

Pilot study 3

To examine the linearity of the gnathometer units and to determine the magnitude of the incisal force applied, a laboratory pilot study was conducted at the University of Gent. A disposable gnathometer was mounted in an Instron universal testing machine (Instron 1103, Instron, Norwood, MA, USA). During force testing, a constant strain rate was employed using a crosshead speed of 2 mm/min and of 8 mm/min. The relation of the strength (incisal force) and the gnathometer units was recorded. The test was repeated five times using the same gnathometer. Five different disposable gnathometers were tested.

Main study

Participants of the main study were 88 patients who had been selected for complete maxillary denture treatment at the dental clinics of the Erasmus University Medical Centre (n=25), the University of Gent (n=25), the University of Marmara (n=25), and the University of Groningen (n=13). In the mandible, the patients had a stable natural dentition, a fixed prosthesis, or a stable removable prosthesis as in pilot study 1. A paste type of denture adhesive containing a calcium/zinc PVM/MA copolymer, paraffinum liquidum, cellulose gum, petrolatum, silica, and aroma was used (Kukident; Procter & Gamble, Geneva, Switzerland). Disposable gnathometers (Procter & Gamble) were used to measure the maximum incisal force of the patients' maxillary dentures. During one of the treatment sessions for the new denture, the maximum incisal force of the previous denture without and with adhesive was measured by one of the experienced prosthodontists involved in this project. Firstly, the maximum incisal force was measured without adhesive. Then, the denture was removed, cleaned, and dried. Adhesive was applied in the denture, four strips of 1 cm at the frontal, dorsal, right, and left border of the hard palate (Fig. 3). Strips were measured with a Boley gauge, and excess was cut off with a sharp instrument (Fig. 4). The denture was replaced in the mouth and with a 3-min break to enable the patient to reposition the denture comfortably and habitually; the maximum incisal force was measured again. About 2 weeks post delivery of the new denture, when the patient was problem-free, the maximum incisal force of the new denture without and with denture adhesive was measured by the same prosthodontist following the same procedures. The effects of the previous versus the new denture, using denture adhesive or not, mandibular dentition or mandibular prosthesis, dental clinic, and possible synergism of denture and denture adhesive effects



Fig. 3 Adhesive applied in maxillary denture, four strips of 1 cm at frontal, dorsal, right, and left border of hard palate



Fig. 4 Strips of adhesive measured with Boley gauge and cut off with sharp instrument

were analyzed by two-way ANOVA, and 95% confidence intervals were calculated.

Results

Pilot studies

The feasibility test of the disposable gnathometers did not result in any patient complaints in terms of measurement burden. The measurement time turned out to be less than 1 min per maximum incisal force measurement. Based on 414 measurements (six times triplicate in 23 patients) of pilot study 1, the overall intra-observer measurement error was 0.7 gnathometer unit. The intra-observer reliability coefficient was 0.91. Table 1 shows the inter-observer measurement data of the three observers in the 24 patients according to the Latin square principle. The overall interobserver reliability coefficient was 0.94. An overall interobserver measurement error of 0.5 gnathometer unit was found. ANOVA showed neither any systematic observer effect (P=0.54) nor a learning effect (P=0.28). A linear relation was found between the gnathometer units (1 to 10) and the displacement force in the testing machine, that is, the increments between gnathometer units were similar (Fig. 5). There was no difference in force versus gnathometer unit between the tests at a crosshead speed of 2 and of 8 mm/min. To arrive at gnathometer unit 10, an average force of 110.6 N (range 94.4-112.0) was required.

Main study

Table 2 shows the mean and the standard deviation of maximum incisal force of patients' previous and new maxillary dentures, without and with denture adhesive, at the dental clinics in Rotterdam, Gent, Istanbul, and

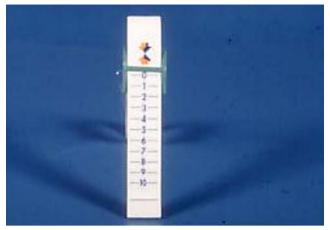


Fig. 5 Decimal scale on disposable gnathometer

Groningen. There were no significant systemic effects of the mandibular dentition or prostheses (P > 0.09). At the dental clinics where the measurements were conducted, different levels of incisal force were observed (0.0005 < P <0.04). The effect of the denture adhesive on the maximum incisal force was significant in previous as well as new dentures (P < 0.0001), except for new dentures in the Groningen dental clinic. Also, the effect of the new versus the previous dentures in both the absence and presence of denture adhesive was significant in the sense that new dentures had a better maximum incisal force than previous dentures (P < 0.0001). Table 2 is the basis for calculation of effects with 95% confidence intervals in Table 3. As shown in Table 3, there was a significant overall synergistic effect of denture adhesive and previous versus new denture in the sense that the effect of the denture adhesive on the maximum incisal force was more pronounced in previous dentures (P=0.006). However, this synergistic effect was not present in Istanbul clinic patients.

Discussion

Important aspects influencing incisal force in patients wearing a complete denture are the individual prosthetic and anatomical characteristics, such as the stability and the retention of the denture and the resorption of the residual alveolar ridge. Neither in the pilot studies nor in the main study measuring the maximum incisal force quantitatively was the purpose as such. The aim was comparing the maximum incisal force without and with denture adhesive in previous as well as new maxillary dentures. Consequently, there was no reason to register the stability and the retention of the denture and the resorption of the residual alveolar ridge. In pilot study 1, in the Groningen dental clinic, only three patients could participate within the time schedule of the study. Statistically, this had no influence on the final overall results. The inter-observer measurement error of 0.5 gnathometer units and the intra-observer measurement error of 0.7 gnathometer units were low when compared to the measurement range, as expressed by the high reliability coefficients (>0.9). The study was conducted by one prosthodontist per patient. If more prosthodontists had participated, presumably, the maximum measurement error between disposable gnathometers would have been more than 0.5, being less negligible when compared to the overall measurement error. For any further research objectives with disposable gnathometers, the poor calibration should be an issue of concern. Because of the simplicity of the disposable gnathometers, it will not be easy to improve the calibration. Consequently, for research purposes, the disposable gnathometers can only be used to compare several measurements with one and the same gnathometer.

The mean improvement of new maxillary dentures' incisal force by the denture adhesive was not statistically significant in Groningen dental clinic patients (Table 2).

Table 2 Mean and standard deviation of maximum incisal force of patients' previous and new maxillary dentures without and with denture adhesive at dental clinics in Rotterdam (R), Gent (G), Istanbul (I), and Groningen (GR)

Denture	Dental clinic	Number of patients	Without adhesive ^a	With adhesive ^a
Previous	R	25	$3.24{\pm}1.96$	5.24±2.09
Previous	G	25	1.60 ± 2.04	$4.04{\pm}2.85$
Previous	Ι	25	2.20 ± 1.22	3.56±1.26
Previous	GR	13	1.92 ± 1.38	3.31±1.89
Previous	Total	88	2.28 ± 1.82	4.14±2.22
New	R	25	7.16 ± 1.62	8.40±1.19
New	G	25	5.52 ± 2.38	7.12±2.30
New	Ι	25	7.28±1.51	8.92±1.15
New	GR	13	5.23 ± 2.42^{b}	$5.54{\pm}2.70^{b}$
New	Total	88	6.44±2.13	7.76±2.14

 $^{a}\pm$ Indicates standard deviation.

^bNo significant difference

Table 3 Mean differences, corresponding standard deviation, and 95% confidence interval (95% CI) of the denture (previous versus new) and adhesive effect (with versus without) on patients' maximum incisal force at dental clinics in Rotterdam (R), Gent (G), Istanbul (I), and Groningen (GR)

Effect	Dental clinic	Number of patients	Mean difference ^a	95% CI
Previous denture				
With-without	R	25	2.00 ± 1.08	1.55-2.45
With-without	G	25	2.44 ± 1.83	1.68-3.19
With-without	Ι	25	1.36 ± 0.49	1.16-1.56
With-without	GR	13	$1.38 {\pm} 0.96$	0.80-1.97
With-without	Total	88	1.85 ± 1.28	0.80-1.97
New denture				
With-without	R	25	$1.24{\pm}0.97$	0.84-1.64
With-without	G	25	1.60 ± 1.71	0.89-2.30
With-without	Ι	25	1.64 ± 1.04	1.21-2.07
With-without	GR	13	$0.31 {\pm} 0.85$	-0.21-0.8
With-without	Total	88	1.32 ± 1.29	1.04-1.59
Without adhesive				
New-previous	R	25	3.92 ± 1.63	3.25-4.59
New-previous	G	25	3.92 ± 2.10	3.05-4.79
New-previous	Ι	25	5.08 ± 2.10	4.21-5.95
New-previous	GR	13	3.31 ± 1.80	2.22-4.39
New-previous	Total	88	4.16 ± 2.00	3.74-4.58
With adhesive				
New-previous	R	25	3.16±2.23	2.24-4.08
New-previous	G	25	3.08 ± 2.52	2.04-4.12
New-previous	Ι	25	$5.36 {\pm} 2.08$	4.50-6.22
New-previous	GR	13	2.23 ± 1.83	1.12-3.34
New-previous	Total	88	3.62 ± 2.46	3.10-4.15

 $a \pm$ Indicates standard deviation.

Explanation for this phenomenon may be that in Groningen dental clinic patients, the differences between maximum incisal force of previous and new maxillary dentures without denture adhesive were relatively small, on average 1.92 and 5.23, respectively, whereas in Istanbul, these figures were 2.20 and 7.28, respectively. The mean prosthetic and anatomical characteristics of Groningen dental clinic patients were favorable when compared to the total international study group of patients. The difference could be that on average, Groningen dental clinic patients were younger, were edentulous during a shorter period of their life, had better stability and/or retention of their maxillary denture, or had less resorption of their maxillary residual alveolar ridge. Statistically, the relatively low number of 13 participating Groningen dental clinic patients may have been of influence as well.

Although the treatment with a new maxillary denture followed a standardized method, the outcome of treatment was very individual and not standard. The stability and retention of a new maxillary denture, when compared to the stability and retention of the corresponding previous maxillary denture, could be improved, could be similar, or could even be worse in some cases. Therefore, it was not a rule that in individual cases, the effectiveness of the denture adhesive was more pronounced in the previous than in the new denture. On average, the effectiveness was more pronounced in previous than in new dentures (1.85 versus 1.32), but not for Istanbul dental clinic patients (1.36 versus 1.64; Table 3). The absence of the synergistic effect in Istanbul dental clinic patients between the denture adhesive and previous versus new denture was probably due to one or more mean prosthetic and anatomical characteristics of Istanbul patients, when compared to the total international group. For instance, the difference could be explained if on average, Istanbul patients were younger, were edentulous during a shorter period of time, were wearing maxillary dentures which were fabricated more recently, had better stability and/or retention of their maxillary dentures, had less resorption of their maxillary residual alveolar ridges, or had received new dentures with poorer stability and/or retention, when compared to the total international group. In the pilot studies as well as in the main study, Kukident was used as denture adhesive. Therefore, all study results are, strictly speaking, only applicable for this denture adhesive and not for other types or brands. Nevertheless, it seems reasonable to assume that similar effective denture adhesives would have provided similar results.

Conclusions

Within the limitations of this study, the following conclusions were drawn:

 The intra- and inter-observer reliability of the disposable gnathometers was very good.

- Kukident as denture adhesive was effective in improving maximum incisal force (= retention) of previous as well as new complete maxillary dentures.
- The effectiveness of Kukident on maximum incisal force was more pronounced in previous than in new complete maxillary dentures.

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