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CLINICAL ASSESSMENT OF THE BITING FORCE IN PATIENTS RECEIVING MODIFIED AND UNMODIFIED BRE-FLEX AESTHETIC CLASP CAD/CAM DENTURES: A RANDOMIZED CROSS-OVER STUDY

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ABSTRACT

The study was performed to assess the magnitude of biting force. For patients with two types of cad cam esthetic clasp dentures (modified and unmodified Bre-Flex denture base material).

Methodology: A total of five mandibular Kennedy class I partially edentulous male patients were included in this study. All patients received two successive esthetic clasp removable partial dentures (modified and unmodified Bre-Flex). For each patient the mean biting force was measured at the time of insertion and after 2 months of using the dentures with one-month tissue rest between the two types.

Results: One way ANOVA test was conducted to assess the significance between the two RPD types at time of insertion and after two months of use, the data revealed that the mean biting force for the modified group at time of insertion was 0.1172+0.135 and after two months was 0.1264+0.3 with no significant differences. The mean biting force for the unmodified group at time of insertion was 0.108+0.0924 and after two months was 0.1236+0.104 with P value 1.00, indicating no significant differences. There were no statistically significant differences between the two groups in relation to the patient's maximum biting force. (P value was 0.22).

Conclusion: For each group (modified and unmodified partial denture base materials), there was no significant difference regarding the mean biting force at time of insertion and after two months of use. There were no statistically significant differences in relation to the patient's maximum active biting force between the two groups. (P value was 0.22).

KEYWORDS: Removable partial denture, BRE-Flex, Maximum biting force

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INTRODUCTION

Removable Partial Denture (RPD) is a frequently used method for replacing missing teeth in individuals with partial tooth loss. It is considered a feasible and affordable treatment. [1]

Removable partial dentures are alternative treatments or implant-supported rehabilitation. These treatment techniques guarantee that patients maintain the required occlusal contacts, which is crucial for sustaining good chewing efficacy, improving the patients' quality of life, and promoting a nutritious diet regime. [2], [3]

The main aim of RPDs is to offer prosthetic restoration for lost teeth and related structures, while preventing any more loss of the remaining teeth. Removable partial dentures (RPDs) are recommended when there is a significant number of missing teeth that need to be replaced both horizontally and vertically. [4]

RPDs are selected for their capacity to enhance both aesthetic appeal and masticatory efficiency. This is particularly accurate when the degree of tooth loss is too extreme to be addressed by conventional fixed dental restorations. [5]

Removable partial dentures provide prosthetic replacement for missing teeth and associated structures, while also avoiding further loss of the remaining teeth. RPDs are recommended when there is significant loss of teeth in both horizontal and vertical dimensions, making conventional fixed dental restorations unsuitable due to the potential for considerable bone loss after tooth extraction. RPDs are selected for their ability to offer both aesthetic and functional advantages. [6]

On the contrary Traditional RPDs are often considered unsatisfactory due to their noticeable and unattractive clasps and rests, as well as their bulkiness, which can affect chewing effectiveness. [7]

Research has shown that people who use removable partial prostheses have reduced chewing performance, bite forces, and masticatory efficacy compared to those with natural teeth or permanent prosthesis. The maximal biting force (MBF) is a reliable measure of occlusal force and is used to assess the functioning state of the masticatory system. [8]

In general, the forces generated while chewing are distributed as follows: the occlusal-articular complex transmits the forces to the periodontium, which in turn distributes them to the underlying bone structure. Nevertheless, the complicated biological composition of the orofacial system, which is responsible for disseminating biting forces, is complex and distinct from the physiological method of pressure transmission. [7], [9]

Masticatory load in natural dentition is 200N, but the maximum pressures exerted during mastication of complete dentures (CDWs) range from 60N to 80N. The absence of teeth and subsequent utilization of prosthetic alternatives not only diminishes the biting force by 20% to 50% in comparison with natural teeth, but also results in additional complications such as eventual bone deterioration. [10]

Various methods have been utilized to quantitatively assess the forces applied during the process of chewing various food types. **Black** is recognized as the pioneer who first employed measurements and calculations of chewing forces, as well as performed laboratory feeding research studies using a device, he named a Phagodynamometer. The measured values ranged from 90N to 360N. **Howell and Brudevold** developed a method to directly quantify the forces applied during mastication in the oral cavity. [11]

Both muscle strength and the quantity of functional teeth play vital roles in the act of chewing. The purpose of measuring MBF is to quantify the force exerted by the muscles that are responsible for raising the lower jaw. A correlation exists between

the magnitude of biting force and patients' comfort levels with complete dentures, as well as the type of food they consume and the amount of bone resorption that occurs under the prosthesis. [8], [12]

Various materials have been employed in the construction of RPD, including polymethyl methacrylate (PMMA), which is sometimes referred to as poly [1-(methoxy carbonyl)-1-methyl ethylene]. It is the polymer most used for prosthetic bases. Conventional removable partial dentures (RPDs) are commonly made of either polymethyl methacrylate (PMMA-RPD) with stainless steel clasps or a cast metal alloy (CoCr-RPD). [13]

Several polymers, including polyamide, epoxy, polystyrene, and vinyl-acrylic resins, have been investigated to improve functional performance. Nevertheless, these materials have not yielded completely satisfactory results. [14]

Although there were earlier limitations, there is a need for an alternative within the polyamide category. When selecting from various commercial polyamides, such as Valplast® from Corp 200 Shames Drive Westbury, NY, USA; Valplast Flexite® from Flexite company, Mineola, NY, USA; Luci-tone Versacry® from Dentsply Sirona, NY, USA; Vertex® from Dentimex, Zeist, Netherlands; and Bre-flex® and Brecrystal® from Bredent medical GmbH & Co. KG, Senden, Germany, the decision is influenced by the numerous advantages of polyamide/PMMA, including its impact strength. [13]

Bre-flex is a thermoplastic polymer made from nylon. Chemically, the primary form of nylon is PA 12, which stands for polyamide. Bre-flex demonstrates superb flow properties because of its low melting point. The thermoplastic material is subjected to a pressure of 7.0 bar during the processing. High pressure minimizes shrinkage and guarantees long-lasting dimensional stability, resulting in dentures that fit precisely and prevent plaque buildup. [15]

Breflex Second Edition is a polyamide-based thermoplastic material that is a denture base material that can be used to make unbreakable, flexible partial dentures. The material is 100% free of monomers. The color pigments used in Breflex Second Edition do not contain cadmium and metal oxide and comply with the biological test standard for dental materials. [14]

The second generation of Breflex stands out due to its remarkable mechanical durability, ability to withstand impact and abrasion, enduring longevity, and efficient fabric ventilation. The flow characteristics of Breflex Second Edition are outstanding. During the melting process, the molten material becomes very fluid, allowing to produce thin and precise denture moulds with a thickness of up to 0.5 mm. [15]

The main difference between Bre-flex Second Edition and its previous version is its improved ability to be easily adjusted, resulting in a prosthetic limb that has a more visually appealing appearance.

2-methacryloyloxyethyl phosphorylcholine (MPC) is a compound that contains a methacrylate group with a polar group of phospholipids attached to its side chain [16]. Previous studies have shown that MPC, due to its ability to be compatible with living organisms and its attraction to water, has strong characteristics in preventing proteins from sticking and inhibiting adhesion [17]. Previous studies have demonstrated that including MPC into dental composites and adhesives leads to a notable reduction in adsorption of protein and adhesion of bacterial , while preserving the essential mechanical, physical, and bonding properties. [18,19]

Currently, there is no data available regarding the integration of MPC into a novel, very effective self-curing acrylic resin denture base called Lucitone HIPA (produced by Dentsply Sirona). Additionally, the prospective advantages of utilizing this resin in the treatment of DS have not been reported.

This study investigated the MBF exerted by the patients using an RPD fabricated from modified Bre Flex and unmodified Bre-Flex. Since these different kinds of RPD strongly affect the MBF and occlusal forces.

This study aimed to assess the magnitude of biting force in two cad cam non-metal removable partial dentures

Methodology

This study included a consistent enrolment of 5 male patients with partially missing teeth in the lower jaw, classified as Kennedy class I . Participants were recruited from both the outpatient clinic of Zagazig University and the private clinic of the authors.

Ethical approval

Participants were provided with a thorough explanation of all study procedures, and they were required to sign written informed consent forms before they could be enrolled. The study protocol and methodology received approval from the Dental Research Ethical Committee of the faculty of dentistry at Sinai University, with approval code proth 1-7-022

Sample size calculation

The sample size for this study was calculated according to (**El Mekawy** et al**., 2016**) used the following equation:

$$N = \frac{(Z\alpha)2 \times (SD)2}{(d)2}$$

N = Total sample size.

Zα= Is Standard normal variate and its equal 1.96 at P< 0.05

SD = Standard diversion of variable.

d =Absolute error or precision.

Zα	SD	D
1.96	3.14	2

$$\text{Total Sample size } N = \frac{(1.96) \times (3.14)}{(2)^2} = 4.83 \approx 5 \text{ sample}$$

The total sample size calculations revealed that a sample size should be at Least 5 samples.

The study was conducted on a group of 5 male participants, all of whom were between the ages of 45 and 55. Participants were selected based on the following criteria for eligibility:

They were in good health without any systemic disorders as confirmed by a physician, with acceptable oral hygiene and upper dentulous arch opposed by mandibular bilateral posterior edentulous span. All participants were free from any signs or symptoms of temporomandibular disorder and were non-bruxers. The ridge has a well-developed and shaped structure, with a healthy and undamaged mucosal lining. All patients participating in the study had an Angle class I jaw relation and sufficient inter-arch space to support the removable partial dentures (RPDs). All the participants were free from xerostomia.

A comprehensive oral examination was conducted using panoramic and periapical radiographs to assess the bone index areas and crown root ratio.

Chosen patients were told of their participation at a scheduled follow-up appointment two months after receiving the removable partial denture, as per a written informed consent.

Patients have provided their informed permission, a vital component of bioethics, which guarantees their comprehension of the potential risks and advantages associated with any medical procedure. Ilfeld (2006) asserted that the implementation of informed consent safeguards many patients from being pushed into participating in medical research without comprehending the potential hazards. The mouth was prepared by creating guidelines and preparing rest seats.

RPDs construction:

Oral scaling procedures were performed for all patients as part of their periodontal therapy. Diagnostic models were created by taking preliminary impressions of the maxillary and mandibular areas.

A common RPD design was utilized, containing all the fundamental components that adequately satisfy all the necessary functions.

An analysis was conducted on the diagnostic models of the mandible to determine the survey line and measure the depth of the retentive undercut. This information will be utilized to create the removable partial denture (RPD). The distal extension partial dentures were fabricated utilizing a theoretical stress-releasing design technique that achieves retention, support, reciprocation, bracing, and connection.

A Retentive (RPA) clasp was used, which involved creating a mesial occlusal rest on the abutment and a proximal guiding plane of 1.5 mm on the distal surface of the abutment. Additional distal supports were used to place indirect retainers on the mandibular first premolar. A medium-density elastomeric material was utilized to generate secondary impressions of the maxillary and mandibular arches.

The maxillary impression was filled with extra-hard stone for the fabrication of the master model, while mandibular impression was poured into the master model.

Design of a Virtual RPD Framework

A desktop structured-light 3D scanner was used to scan the mandibular master cast, which was placed firmly on the scanner table (CAD star GmbH, sparkassenstraβe 4, 5000 Bischofshofen, Austria). A stereolithographic file (STL) was generated to produce the master cast.

The RPD was created by the digital process of loading the master cast's STL file into a reverse engineering software called Exocad Dental CAD 3.0, developed by Exocad GmbH in Germany. This software utilises a sequence of digital processes that replicate the traditional laboratory steps.

Utilizing digital survey techniques allows for the automatic computation of the insertion path. The software evaluates the parallelism and calculates the depth of undercuts. The cast was manipulated in three dimensions to determine the optimal angle for the insertion path. These equations were used to calculate the survey line based on these estimations. We utilized computational techniques to eliminate undesired undercuts and determined the optimal locations for the retentive clasp tip.

Virtual wax was applied in thin layers to the relief parts, resulting in the formation of the meshwork patterns. Subsequently, the process involved the creation of necessary connections and supports. A three-dimensional model of the clasp assembly was generated.

Selective laser sintering of the RPD framwork

The selective laser sintering (SLS) system employed a VM120 direct metal laser sintering machinery manufactured by Vulcan Tech in Germany. The sintering process was carried out by aligning the occlusal surfaces of the rests and the base plate of the sintering machine, ensuring they were completely parallel with a printing angle of 0 degrees. The STL file was split into cross-sectional layers and subsequently converted to a metal format.

The automated printing machine used numerical inputs from the RPD framework design to build the prototype. The powder alloy, namely the Starbond simple Pulver 30 from Scheftner dental in Germany, is fused to the pre-determined structure using powerful laser beams. The beams are aimed towards a powder bed composed of tightly packed powdered particles. The machine utilizes the 3D data to melt metallic powders together in a sequential layer-by-layer process, resulting in the creation of 3D objects.

Laser sintering machines utilized for SLS framework production possess the subsequent specifications: a laser spot diameter that varies between 0.08 and 0.1 mm, a sintering speed ranging from 1100 to 1200 mm/s, and a layer thickness of 0.02 mm. The SLS frames were disassembled from the base plate and the supports were disconnected. The homogenization process was carried out at a temperature of 1150◦C for a period of 30 minutes.

metal framework was inserted in the patient's mouth, register jaw relation, casts mounting on a semi-adjustable articulator, the teeth set up, trying in the waxed up partial denture, for processing of the final denture base.

Grouping of the study

All participants received two successive RPDs with intervals of one-month tissue rest between the two types. According to the type of denture base material the final RPD processed in, the patients were grouped to: -

Group A: Biting force for patients received esthetic clasp mandibular RPD fabricated from Injectable Bre-Flex denture base reinforced by metal framework.

Group B: Biting force for patients received esthetic clasp RPD fabricated from Injectable 2-methacryloyloxyethyl phosphorylcholine (MPC) modified Bre-Flex denture base reinforced by metal framework.

Receiving of RPD type by each participant distribution was randomized using computer-based randomization. This was achieved by utilizing a dedicated website called "research randomizer" that specializes in the randomization procedure. **(https://www.randomizer.org/).**

Only a single objective investigator, who was not involved in selecting or treating patients, possessed information regarding the randomization process and had the ability to retrieve the randomized lists stored on their password-secured portable computer. The randomized codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes.

Patients were instructed to choose one envelope, and the investigator who was knowledgeable about the randomization technique was consulted to determine the corresponding group and provide the appropriate treatment.

The first group experimented with Mandibular Kennedy Class I RPDs, which were constructed from Injectable unmodified Bre-Flex thermoplastic material.

The Bre-Flex materials require a temperature of 222 degrees Celsius for a duration of 15 minutes to be injected into the injection molding unit. Figure (1)

Each denture was meticulously completed and polished before being fitted into the patient's mouth. It was then thoroughly examined to ensure the correct vertical dimension of occlusion and a harmonic occlusal relationship. [21]

Fig. (1) Bre-flex material used of fabrication of RPD

For the second group, Mandibular Kennedy Class I RPDs were processed with Injectable 2-methacryloyloxyethyl phosphorylcholine (MPC) modified Bre.Flex thermoplastic material. MPC was purchased from Sigma-Aldrich (Sigma-Aldrich, St. Louis, MO, USA), it was incorporated into the BRE-flex resin at a weight percentage of 4.5%. Figure (2)

Fig. (2) Esthetic clasp mandibular RPD fabricated from Injectable 2-methacryloyloxyethyl phosphorylcholine (MPC) modified and unmodified Bre-Flex.

After the RPD was inserted, patients were given instructions to never sleep while wearing the prosthesis. They were provided with dental hygiene tools. The significance of maintaining plaque control was underscored. The participants were clearly notified, through both oral communication and written consent forms, that failure to maintain oral hygiene or agree with the follow-up procedures would lead to their exclusion from the study. The patient was required to consistently utilize the removable prosthesis throughout the whole trial to remain part of the experiment. Figure (3)

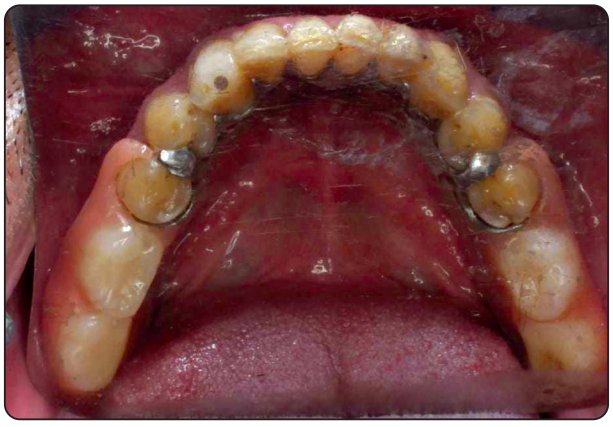


Fig. (3) RPD inserted in the patient mouth

Bite force measurements

For each patient, bite force measurements were performed for each RPD type.

Measurements were taken when the patient was standing straight during the initial placement of the new prosthesis and again after 2 months of using the denture. The occlusal force meter was used to evaluate the bilateral biting force three times in the first molar region. Figure(4)

This gadget employs a hydraulic pressure mechanism and a disposable polyvinyl cover with dimensions of 17 mm in width and 5.4 mm in height.

The measurement range of the GM10 device from Nagano Keiki in Tokyo, Japan ranged from 0 to 1000 N, with an accuracy of ± 1 N. The instrument was strategically positioned to concentrate all bite forces on the centre. The participants were instructed to use maximal force while biting three times on each side, with a 2-minute interval in between. The maximum recorded occlusal force, quantified in Newtons (N), was documented. The mean of the three measurements represented the patient's maximum biting force.. [22]

Statistical analysis was completed using SPSS 20 (IBM, Armonk, NY, USA).

Fig. (4): Occlusal force meter

RESULTS

One way ANOVA test was conducted to assess the significance between the designs at time of insertion and after two months. Table (1) revealed no significant differences between the two groups (P value was 0.22).

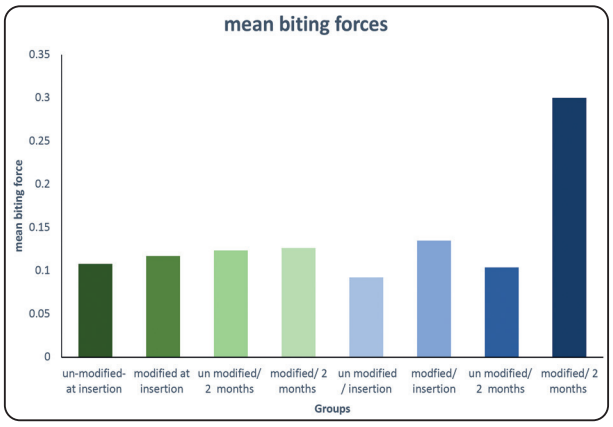
TABLE (1) Significance between two groups

	Bitting force				
	Sum of squares	df	Mean square	F	Sig
Between groups	0.155810	7	0.022259	1.430760	0.22
Within groups	0.497830	32	0.015557		
Total	0.653641	39			

Table (2) showed that, the mean biting force for the modified group at time of insertion was 0.1172+0.135 and after two months was 0.1264+0.3 with P value 1.00, which indicates no significant differences. The mean biting force for the unmodified group at time of insertion was 0.108+0.0924 and after two months was 0.1236+0.104 with P value 1.00, which indicates no significant differences. figure (5)

TABLE (2) Mean biting force between two groups at insertion and 2 month following insertion.

Time	N	Biting Force	
		Modified breflex RPD	Unmodified breflex RPD
Insertion	10	0.1172+0.135	0.108+0.0924
2 months	10	0.1264+0.3	0.1236+0.104
sig		1.00	1.00



Fig, (5) Bar chart showing the biting force between modified and unmodified Bre-Flex for the right and left sides at the time of insertion and after 2 months of denture use.

DISCUSSION

Removable partial dentures (RPDs) are commonly employed to address partial tooth loss in older individuals who are unable to afford more intricate treatments or are unwilling to undergo implant-supported rehabilitation. These rehabilitations offer patients the necessary occlusal contacts, essential for maintaining optimal chewing efficiency, enhancing their quality of life, and promoting a balanced eating regimen. [23]

The utilization of a RPD composed of a mix of thermoplastic material and metal is currently experiencing a rise in popularity among general dentists. This type of RPD exceeds conventional RPDs with metal clasps in terms of both aesthetics and comfort. Metallic framework rigidity ensures equal distribution of forces, while the thermoplastic clasps enhance the overall aesthetic appeal. Therefore, these RPDs offer a combination of aesthetic and mechanical advantages.

The patients selected for the study were specifically aged between 50 and 55 to avoid muscle weakness caused by age-related muscle atrophy. The patients included in this study fall within a consistent age range, which guarantees that they possess comparable levels of muscle efficiency. [24]

The patients selected for the study were primarily males due to the potential presence of psychological and hormonal changes in female patients, as well as their lower chewing efficiency. To reduce variations in muscle efficiency across individuals of different genders. [25], [26]

The patients were administered both types of dentures alternately to prevent biases that could come from individual differences.

This study focused on mandibular bilateral distal extension situations, which were chosen because they are more prevalent than maxillary cases, mostly due to the typical pattern of tooth loss. Moreover, situations involving mandibular distal extension are

considered as the most challenging when it comes to creating dentures that are both adequate and pleasant. This is mostly owing to issues with support and the relatively smaller size of the denture base in relation to the functional load. [27], [28] the relatively short follow up period reason was to reduce possible effects of time on residual ridge resorption and the retention of thermoplastic clasps. [29], [30],[31]

Bite force measurements are widely regarded as an essential indicator for evaluating the chewing ability of various prosthesis devices. Roughness measures are an essential feature in denture materials. Irregular denture surfaces tend to gather a greater amount of plaque and oral proteins, which encourages the growth and spread of microorganisms. [32]

In the present study ,The inclusion of MPC at a weight percentage of 4.5% was preferred rather other than percentages (1.5%,3%) .Such percentage was recommended in a previous study to be the ideal for denture base modification for the prevention of oral microbial infections with a negligible impact on the roughness of denture surfaces. [33]

The digital force gauge was used to assess the maximum voluntary bite force. The device's accuracy and repeatability were evaluated by Nakatsuka et al. [34]

Evaluating the functional condition of the masticatory system can be efficiently and easily accomplished by quantifying the voluntary maximal biting force (MBF). The current study revealed that there was no statistically significant variation in MBF measurements between the patients in the two groups using different partial denture materials (modified and unmodified Bre-Flex). This finding is consistent with previous research indicating that the alloy possesses superior mechanical characteristics compared to polymers, leading to improved stability and retention in comparison to other materials. The clasps and rests establish contact with the abutment teeth and possess enough rigidity to evenly distribute the forces generated during chewing throughout the entire dental arch. [35], [36], [37]

Another study demonstrated that plastic removable partial dentures exhibit reduced retention due to a decrease in modulus of elasticity, which causes their clasps to become twisted during use. Moreover, the denture's significant deformation increases the pressure exerted on the underlying mucosa when it is being used. [38]

CONCLUSION

Within the limitation of this study it can be concluded that:

1. For each group (modified and unmodified breflex esthetic clasp RPD), there was no significant difference regarding the mean biting force at time of insertion and after two months .
2. There were no statistically significant differences between modified and unmodified partial denture base materials in relation to the patient's maximum active biting force. (P value was 0.22).

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