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Bite force, masticatory efficiency and patient satisfaction in patients with non-metal clasp dentures: a randomized cross-over study

Mohamed H. Abdelnabi[1] and Amal A. Swelem[2]

[1]Professor, Oral and Maxillofacial Prosthodontic Department, Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia; and Removable Prosthodontic Department, Faculty of Dentistry, Minia University, Egypt.
[2]Associate Professor, Oral and Maxillofacial Prosthodontic Department, Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia; and Removable Prosthodontic Department, Faculty of Oral and Dental Medicine, Cairo University, Egypt.

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ABSTRACT

Objective: The aim of this randomized controlled cross over study was to compare the effect of two different designs of non-metal clasp removable partial dentures (NMCRPD) versus conventional metal clasp removable partial dentures (CRPD). Assessed objective variables included: maximum bite force (MBF) and masticatory efficiency (ME). Patient satisfaction (PS) was evaluated as a patient based outcome. **Materials and methods**: A total of 36 Kennedy class III partially edentulous male patients were initially included in this prospective randomized cross over investigation. 32 participants concluded the study. Each subject received non-metal clasp RPD with no metallic framework (Gp I), non-metal clasp RPD with metallic framework (Gp II) and conventional RPD with metallic framework with polymethylmethacrylate denture bases (Gp III). The order of the type of RPD received by each participant was randomized among the patients. Each denture was worn for 90 days. A capacitive sensor was used to evaluate unilateral MBF. Sieve method was implemented for ME assessment. PS questionnaire evaluated 7 main items (comfort, esthetics, ability to speak, stability, ease of chewing, hygiene maintenance and overall satisfaction) using visual analogue scale. MBF and ME were assessed after 30, 60 and 90 days of denture wear. PS was evaluated 90 days post-insertion. Level of statistical significance was set at $p < 0.05$. **Results:** RPDs with frameworks (Gp II and Gp III) showed significantly higher MBF, ME, and PS (stability, comfort and ease of chewing) in comparison to RPDs without framework (Gp I). For all groups, both MBF and ME did not significantly change with time of denture wear. MBF and ME showed correlation in Gp II and Gp III but not in Gp I. PS with esthetics of both NMCRPDs (Gp I and Gp II) were significantly higher than with the conventional RPDs (Gp III). Overall satisfaction with NMCRPD with framework (Gp II) was the highest. Conclusions: Non-metal clasp removable partial dentures with metal frameworks had both the advantages of superior MBF and ME in addition to better overall patient satisfaction. RPDs of that group were stable, functional, comfortable, and benefited from the superior esthetics of thermoplastic resins.

Keywords: Non-metal clasp dentures, bite force, masticatory efficiency, patient satisfaction

Introduction

The demand for removable partial dentures (RPDs) is expected to increase in the upcoming years due to the increase in the elderly population and the associated increase in partial edentulism. RPDs represent a widely used treatment modality that proved to be predictable and has a positive impact on the oral health-related quality of life (OHRQoL) (Douglass *et al*., 2002; Marcus *et al*., 1996; Jones et al., 2010; Fueki *et al*., 2017).

Esthetics play a major role in patient acceptance of RPDs. Conventional metallic clasp assemblies in the esthetic zone represent a major disadvantage (Budtz-Jorgensen *et al*., 2000; Beaumont, 2002; Donovan and Cho, 2003). The use of the more esthetic thermoplastic resins to

Corresponding Author: Mohamed H. Abdelnabi, Professor, Oral and Maxillofacial Prosthodontic Department, Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia; and Removable Prosthodontic Department, Faculty of Dentistry, Minia University, Egypt.
E-mail: dr_mohamed_h@hotmail.com

fabricate non-metal clasp dentures (NMCDs) is on the rise as a more cosmetically pleasing alternative (Ito *et al*., 2013; Fueki *et al*., 2014a). There are two popular design approaches for NMCDs, the first uses resin clasps extending as a part of the thermoplastic denture base, while the second incorporates a preformed resin clasp in the conventional polymethylmethacrylate (PMMA) denture base (Sakar, 2016). Thermoplastic materials used for the first design include polyamides, polyesters, polycarbonates, polypropylenes and polyacetal resin. The second design uses a group of materials including polyetheretherketon, polyetherketonketon, polyoxymethylene and acetal resin (Fueki *et al*., 2014a; Fueki *et al*., 2014b; Sakar, 2016).

The modulus of elasticity of the thermoplastic resin is a key factor in determining the design features of the resin retainers. Furthermore, thermoplastic materials as polyamides with lower modulus of elasticity and thus rigidity can be used to engage deeper undercuts. The more rigid polyoxymethylene with the higher modulus of elasticity can only be used to engage shallower undercuts (Fueki *et al.*, 2014a; Fueki *et al.*, 2014b; Sakar, 2016).

Based on the recommendations of Japan Prosthodontic Society, metallic rests and connectors are to be used in definitive NMCDs. RPDs with rigid major connectors and rests as parts of a metallic structure minimize impingement of and damage to periodontal tissues and the residual ridge. Denture base sinking and flexion are minimized (Fueki *et al*., 2014a; Sakar, 2016). Fueki *et al*., (2017) recommended further studies to support the above-mentioned recommendation with NMCDs because the literature to support the different designs with thermoplastic materials is still limited.

Advantages of thermoplastic resins used in NMCDs include: superior esthetics; improved patient comfort; low water sorption; minimal or no free monomer; and high fatigue strength. On the other hand disadvantages include: difficulty in polishing; low resistance to scratching, difficulty to repair and adjust; and the need for extra tooth and tissue coverage to achieve adequate retention may result in periodontal problems and tissue irritation (Fueki *et al*., 2014a; Fueki *et al*., 2014b; Sakar, 2016). It is worth mentioning that the dental literature lacks adequate number of studies to confirm the previously mentioned advantages and disadvantages from a clinical perspective. Thus the aim of this randomized controlled cross over study was to compare the effect of two different designs of non-metal clasp removable partial dentures (NMCRPD) versus conventional metal clasp removable partial dentures (CRPD). Assessed objective variables included: maximum bite force (MBF) and masticatory efficiency (ME). Patient satisfaction (PS) was evaluated as a patient based outcome.

Materials and Methods

A total of 36 Kennedy class III partially edentulous male patients were consecutively enrolled for this study. The age ranged from 38-59 with a mean age of 47. Patients were selected from the outpatient's clinic of Minia University and from the authors' private clinic. The study protocol and procedures were in accordance with the ethical guidelines of the university. The study took place in the extended period from 2012–2017.

All subjects were Kennedy class III modification 1 partially edentulous cases for a minimum of 2 years. The mandibular arch had 4 – 6 missing teeth while the maxillary arch was either intact or restored with fixed dental prostheses. The need for at least one esthetic clasp on anterior or premolar teeth was a prerequisite. Presence of at least one posterior occluding pair of natural teeth was among the inclusion criteria. All participants were free from any signs or symptoms of temporomandibular disorder and were non-bruxers. Residual ridges showed no excessive undercuts and had no redundant mucoperiosteum. All included subjects had Angle class I jaw relationship and adequate inter-arch space to accommodate the RPDs. None of the subjects suffered from xerostomia, allergy to either acrylic resin or metal. Possible alternative treatments were explicitly explained to all participants. The different phases of the study were explained verbally and in written material. Written informed approval consents were signed as a pre-requisite for enrolment.

All participants received three RPDs: Gp I: non-metal clasp polyamide (Valplast; Valplast, United States of America) RPD with no metallic framework (12 participants); Group II: non-metal clasp RPD with metallic framework (12 participants); and Group III: conventional RPD with metallic framework with PMMA denture bases (12 participants). The order of the type of RPD received by each participant was randomized using computer based randomization among the patients.

Patients were instructed never to sleep with the prosthesis. They were supplied with oral hygiene aids. The importance of plaque control was emphasized. Participants were informed, both verbally and in written consent forms, that negligence in maintaining oral hygiene or adhering to the follow up will result in exclusion from the study. Regular use of the removable prosthesis in all phases of the study was a prerequisite for the participant to continue in this investigation.

Capacitive sensor was used to assess unilateral MBF. Sieve method was implemented for ME. PS evaluated 7 items using visual analogue scale (VAS). The objective variables (MBF and ME) were assessed with the RPD after 1, 2 and 3 months of insertion. PS was evaluated 3 months after RPD insertion.

The iLoad Mini miniature load cell kit (Loadstar Sensors, Fremont, CA, USA) was used to measure the maximum bite force. The kit included a load cell with a rounded dome on top and with a flat bottom adapter, a DQ1000U frequency to USB interface that converts the frequency output from mini load cell into USB output and LV100 load VUE load cell display software which displays, logs and plots the data on a PC in real time. The assembly is fully calibrated in compression mode. This type of load cells has the advantages of using capacitive sensing techniques. It offers high sensitivity in small sized rugged tough packages that can withstand much higher loads than a similar electric resistor sensor, that implements resistance strain gauge technology. The noise levels are reduced. The improved signal to noise ratio results in a signal of better quality. This reduction allows to pack more features into the sensors – in the form of built in digital communication modules with USB/WiFi/XBee. Wireless/Serial protocols, algorithms to convert raw signals into readily usable calibrated data and easy to use ASCII command set to access the finished data (Stefanescuand and Anghel, 2013). Vertical MBF was measured at the recall visits on the RPD constantly at the same location. The bite force transducer was covered with a layer of polyvinyl siloxane dental impression material (Exafast, GC, IL, USA). The PVS layer fitted the profile of each subject's teeth and guaranteed a reproducible position of the load cell at the different measurement sessions. A cube shaped PVS block with imprints of teeth of the other side was placed during MBF measurements to achieve occlusal stability. As recommended by the manufacturer, the load cell was allowed to warm by connecting it to the power supply for at least 30 minutes before the measurement procedure. The sensor was then connected to PC through USB cable. The patient was seated in an upright position. Each measurement was repeated 3 times. The highest values for each side were recorded. A relaxation period of 10 minutes was given to obtain reliable MBF values (Geckili *et al*., 2012a; Geckili *et al*., 2012b).

ME was evaluated using filtered food remnant weight sieving method (Cheng *et al*., 2012a; Cheng *et al*., 2012b). Dried peanuts were weighted and packed in sealed plastic bags 2.0 g each. Participants were directed to chew the pre-packed 2.0 g of peanuts in 30 s and then to expectorate the bolus in a dry container. The collected material was sieved through a filter with 2.4 mm diameter holes. The remnants of the peanuts that did not pass through the sieve were dried in a desiccator set at 60° C for 6h and then weighed. The formula used to determine the masticatory efficiency in terms of a percentage was as follows: Masticatory efficiency = [(Total weight - Remnant weight)/Total weight] x 100%. This procedure was repeated 3 times for each test condition and the average was used to represent the masticatory efficiency.

Patient satisfaction was evaluated after the enrolled participants wore each denture for 3 months. A 100 mm Visual Analogue Scale (VAS) was used to rate each prostheses. Descriptors were anchored at each end of VAS, zero corresponds to "completely dissatisfied", and the 100 mm opposite end represents "completely satisfied". Patients were instructed to rate each denture type as regards: comfort, esthetics, ability to speak, stability, ease of chewing, hygiene maintenance and overall satisfaction. The participants were always blinded to their previous scores.

All subjects were instructed to complete a socio-demographic questionnaire including: age, gender, marital status, educational level and occupation. Statistical analyses were carried out to ensure that these potential confounding variables did not affect participants' PS scores.

Statistical analyses were carried out with SPSS (Statistical Package for Social Sciences) (Version 15.0 for Windows, SPSS). Kolmogorov – Simrnov test was used to analyze relevance of data to normal distribution. Data were displayed as means and standard deviations. ANOVA followed by post hoc Duncan multiple range statistical inferential tests were implemented for the normally distributed MBF and ME results. Kruskal Wallis succeeded by Dunn post hoc non-parametric tests were carried out for patient satisfaction VAS scores as their distribution did not conform to a normal distribution. The relationship between MBF and ME was assessed by Pearson's coefficient of correlation. Significance level for statistical analyses was set at p<0.05.

Results

32 of the initially 36 enrolled participants concluded the study. 10 from the 12 participants of group I concluded the study. Contact was lost with one participant, another case showed poor adherence to oral hygiene regulations and was thus excluded. In groups II and III, 11 out of the 12 subjects were available for the 3 months study period. The other two subjects did not show up.

Unilateral MBF results showed significantly higher values in Gp II and Gp III in comparison to readings obtained in Gp I that lacks a metallic framework. The differences between MBF after 1, 2 and 3 months of denture wear were insignificant for all groups. Comparisons between Gp II and Gp III were also insignificant at all follow up periods (Table 1).

Table. 1: Unilateral maximum bite force in Newtons (Mean ± SD) 1, 2 and 3 months after RPD insertion.

Group	1m	2m	3m
I (n= 10)	181 ± 45 a	174 ± 49 a	175± 38 a
II (n= 11)	270 ± 84 b	273 ± 94 b	277 ± 59 b
III (n= 11)	279 ± 89 b	282 ± 81 b	280 ± 90 b

m = month. Values with dissimilar letters in columns (between groups) show significant statistical differences. Differences in rows (between different follow up periods were insignificant) ANOVA followed by post hoc Duncan multiple range statistical test p<0.05).

ME was expressed as percentage of comminuted food particles that passed through the sieve holes. Significant improvement was observed in Gp II and Gp III in contrast to conventional Gp I. The achieved improvement was stable with no significant differences between values recorded after 1, 2 and 3 months post-insertion. Differences between Gp II and Gp III were insignificant (Table 2).

Table. 2: Masticatory efficiency % (Mean ± SD) 1, 2 and 3 months after RPD insertion.

Group	1m	2m	3m
I (n= 10)	71 ± 21 a	70 ± 25 a	72 ± 22 a
II (n= 11)	80 ± 22 b	84 ± 29 b	85 ± 27 b
III (n= 11)	82 ± 26 b	85 ± 24 b	88 ± 29 b

m = month. Values with dissimilar letters in columns (between groups) show significant statistical differences. Differences in rows (between different follow up periods were insignificant) ANOVA followed by post hoc Duncan multiple range statistical test p<0.05).

Analysis of the relationship between MBF and ME implementing Pearson's coefficient revealed a significant correlation in Gp II and III but not in Gp I.

Table. 3: Patient satisfaction VAS scores (Mean ± SD) 3 months after denture insertion.

Variable	Group I	Group II	Group III
Comfort	72 ± 26	88 ± 24 *	85 ± 29 *
Esthetics	90 ± 31**	94 ± 29**	70 ± 22
Ability to speak	89 ± 27	92 ± 32	91 ± 29
Stability	69 ± 21	90 ± 28 *	92 ± 34 *
Ease of chewing	80 ± 25	88 ± 29 *	91 ± 31 *
Hygiene maintenance	82 ± 28	83 ± 31	89 ± 20
Overall satisfaction	79 ± 26	92 ± 34 **	87 ± 32 *

*= statistically significant differences between values in the same row at p< 0.05; **= high statistically significant differences between values in the same row at p<0.001.

Patient satisfaction VAS scores in Gp II and Gp III showed statistically significant improvement in 3 items namely: stability, comfort and ease of chewing in comparison to Gp I. A highly significant improvement ($p<0.001$) was observed in esthetics in Gp I and Gp II in contrast to Gp III with the metallic clasp assemblies. Changes in ability to speak and in hygiene maintenance were insignificant. Overall satisfaction was the highest in Gp II followed by Gp III and then Gp I (Table 3).

Potential confounding variables including: age, marital status, educational level and occupation were statistical insignificant between the three study groups. The reported results of this study could thus be contributed to the prosthetic variables.

Discussion

The randomized study at hand employed a cross over and not a parallel design to increase the statistical power. This advantage is especially valid because of the wide variability of the pattern of tooth loss and the consequent RPD design. However a drawback of the cross over design is the limited period that was available for the each of the 3 RPD designs. (Macura-Karbownik *et al*., 2016; Fueki *et al*., 2017). Another reason for the relatively short follow up period was to minimize the possible effects of time on residual ridge resorption and the retention of thermoplastic clasps (Tallgren *et al*., 2003; Tumrasvin *et al*., 2006; Osada *et al*., 2013).

In this study, MBF and ME were used to objectively assess the functional state of the masticatory system. A number of variables were reported to affect MBF and ME including: occlusal factors (such as the number of missing teeth, number of opposing teeth pairs and occlusal force (Slagter *et al.,* 1993b; Bakke, 2006; Paphangkorakit *et al.,* 2008); factors related to dental prostheses (Slagter *et al.,* 1993a); implant treatment (van Kampen *et al.,* 2002); temporomandibular disorders (TMDs) (Ahlberg *et al.,* 2003) and neuromuscular disease (Granger et al., 1999). All subjects included in this study were free of TMDs and neuromuscular disease to exclude the adverse effects of such factors on the study outcomes.

When comparing and contrasting studies assessing MBF it is important to critically analyse the methodology of the recording technique (Bakke, 2006). Important factors include location of MBF measurement within the dental arch (incisors, premolars or molars), number of teeth included (Ferrario *et al.,* 2004), dimensions of the bite force transducer (thin pressure-sensitive sheet versus bite transducer) (Shinogaya *et al.,* 2000; Ikeba *et al.,* 2005). In the study at hand the same calibrated transducer was used throughout the study. A customized layer of impression on surfaces of the transducer contacting the occlusal surfaces of teeth was used to ensure that the transducer was positioned in the same location for each patient at the different experimental conditions. This technique has been implemented by van Kampen *et al.,* (2002) and van der Bilt *et al*. (2008). Another significant variable is whether the measurement was conducted unilaterally or bilaterally. Bilaterally measured MBF was reported to be 30%–40% larger than the unilateral measurements (van der Bild *et al*., 2008). The values of unilateral MBL in the study at hand are comparable to those reported by Macura-Karbownik *et al*., (2016).

In this study, all participants were males, so gender as a confounding variable was excluded. Hatch *et al*., (2000) considered that age has an indirect effect on bite force which was caused by decrease in the occlusal units. In the study at hand, the number of occluding units were comparable, thus this might have minimized the effect of age.

Studies that assessed masticatory function implemented both subjective and objective methodologies. Subjective assessment is conducted by asking patients questions concerning chewing food (Hatch *et al*., 2000). Objective evaluation of masticatory performance include sieve method (Cheng *et al*., 2012a; Cheng *et al.,* 2012b), colour changes in test food usually chewing gum (Hayakawa et al., 1998), sugar loss from chewing gum (Heath., 1982), release of dye when chewing raw carrots using a colorimeteric method (Kayser and Hoeven, 1977), quantification of colour changes by photometric methods (Nakasima *et al*., 1998), and by optical scanning of chewed particles (van der Bild *et al.,* 1993).

In the study at hand, and in the majority of chewing performance studies, ME was assessed by the sieve method. A similar methodology has been by Cheng *et al*., (2012a; 2012b). Other studies used synthetic material to avoid possible variations in consistency due to seasonal and geographical variations (Fontijn-Tekamp *et al*., 2000). It was however preferred to use a natural product purchased from a single supplier and stored at constant temperature and humidity in closed packages. The advantage was that participants were accustomed with that normally consumed product. (Hatch *et al*., 2000).

MBF and ME turned out to be the highest in case of Gp II and III with metallic frameworks in contrast to Gp I RPDS that lacks metallic frameworks. As mentioned earlier, all participants were males hence gender as a confounding variable that may have affected the results could be excluded. Therefore these findings could be attributed mainly to the different materials used in the current study. It seems that as the modulus of elasticity of the denture base materials and clasps decreased, the MBF and ME decreased. To the best of the authors' knowledge, the effects of various denture base and clasp materials on the MBF and ME in partially edentulous patients are scarce. Arada and Arikan, (2005) compared forces for insertion and removal of cobalt-chromium clasps to that of acetal and reported higher values of the former. Osada *et al*., (2013) in an in-vitro study of various polymeric clasps showed that clasps with lower modulus of elasticity had lower retentive forces. They even added that longer time of denture wear resulted in further decrease of retention. It is well known that decreased retention leads to decreased stability which in turn adversely influences ME and MBF. This could explain the results of the current study.

Furthermore, a study conducted by Wadachi *et al*. (2013) reported that denture base materials as polyamide with a modulus of elasticity less than that of PMMA is relatively easy to deform with a resultant larger load transmission to the underlying mucosa. In the study at hand higher MBF and ME values, in addition to better comfort, stability, ease of chewing and overall satisfaction were observed in RPDs with higher rigidity and modulus of elasticity of Gp II and Gp III in contrast to those of Gp I. These findings could be interpreted in accordance with the above mentioned studies that emphasized the positive impact of high rigidity and modulus of elasticity of RPDs. An RPD with inadequate rigidity might result in its increased mobility, decreased stability, possible pain that will lead to decreased MBF, ME and PS. On the contrary, a more evenly distributed load to the underlying mucosa relieves it from excessive mechanical stress and thus increases MBF and ME (Murata *et al*., 2002; Shinomiya *et al*., 2006; Kimoto *et al*., 2006).

As regards effect of time, Aras *et al*. (2009) in a one year study reported insignificant changes in ME throughout the follow up period. Macura-Karbownik *et al*. (2016) in a cross over trial assessed both bite force and ME and similarly reported insignificant effect of time. The findings of these studies are in accordance with that of the study at hand.

Fontijn-Tekamp *et al*. (2000) and Hatch *et al*. (2000) have reported the large influence of bite force on masticatory performance in subjects with conventional complete dentures, overdentures as well as natural dentition. It was concluded that bite force explains over 60% of variance in masticatory performance. In the study at hand, a significant correlation was found between MBF and ME in Gp II and III but not in Gp I. The insignificant correlation between MBF and ME in Gp1 could be interpreted by the fact that MBF was measured as the maximum vertical force. In the absence of rigid skeleton with rigid bracing arms, chewing induces significant lateral forces, which emphasizes the role of RPD retention, stability and the supporting tissues quality in the process. Fontijn-Tekamp *et al*., (2000), reported that occlusal forces in complete denture wearers with high and low residual ridge height were comparable. However, the group with low residual ridge height showed lower chewing efficiency due to the decreased bracing effect or resistance to lateral forces. Zmudzki *et al*., (2013) pointed out in a finite element study the great influence of lateral masticatory forces and the associated sliding destabilizing effect in complete dentures and in implant retained overdentures. Macura-Karbownik *et al*., (2016) suggested that a similar phenomenon might occur in RPDs depending on the rigidity of both the clasp assemblies and denture bases.

A number of factors were reported in the dental literature as potential confounding variables that might affect patient satisfaction assessments. These factors include: age, gender, marital status, educational level and occupation (Walton *et al*., 2009). These variables were identified in a socio-demographic questionnaire that participants were instructed to answer. All included subjects were males. Groups were matched as regards the remaining potential confounding variables. Statistical analyses were carried out to ensure that these variables did not affect participants' scores.

Participants in the current study assessed their RPDs 3 months after denture insertion. It has been reported that this period is adequate for patients adaptation to give stable responses to satisfaction questionnaires. The construct and content validity of the questionnaire implemented in this study has been previously established in previous studies (de Grandmont *et al*., 1994). High test re-test reliability has been reported (Awad and Feine, 1998). Tang *et al*. (1997) has shown that general satisfaction is sensitive enough to reveal small differences between different prosthetic designs.

In the study at hand, patient satisfaction variables improved significantly in stability, comfort and ease of chewing in Gps II and III. This preference could be related to the presence of metallic frameworks and more rigid designs in both groups in comparison to the absence of these features in Gp I RPDs.

In this study no differences in hygiene maintenance was observed between the polyamide denture bases (Gp I and II) and PMMA denture bases of Gp III. Kawara *et al*. (2014), reported that the thermoplastic denture base resins are more liable to scratching and mechanical stimulation than heat cured PMMA. However, the short follow up period of the current study may be the reason behind lack of significant differences in hygiene maintenance between the different RPD groups in spite of differences in the surface roughness reported in the literature (Fueki *et al*., 2017).

Fueki *et al*. (2014a), concluded that NMCDs have a number of disadvantages including: increased fracture risk, lack of long term colour stability, increased caries susceptibility, and higher chances of periodontal and denture bearing mucosa inflammation. None of these complications were observed in the present study. This also could be attributed to the short follow up period. Similar results have been reported in other short term studies (Macura-Karbownik *et al*., 2016; Fueki *et al*., 2017).

The favorable esthetic outcomes of resin clasps agree with those of Fueki *et al*. (2017), who compared the efficacy of NMCDs with regard to OHRQoL to conventional metal clasp-retained dentures. Their results supported by a previous study (Inukai *et al*., 2008), showed that improved oral appearance was associated with better OHRQoL in patients with RPDs.

Conclusion

Non-metal clasp removable partial dentures with metal frameworks had both the advantages of superior MBF and ME in addition to better overall patient satisfaction. RPDs of that group were stable, functional, comfortable, and benefited from the superior esthetics of thermoplastic resins.

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