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RADIOGRAPHIC AND CLINICAL EVALUATION OF CAD-CAM MILLED PEEK AND PEKK PARTIAL DENTURE FRAMEWORK ON SUPPORTING STRUCTURES VERSUS METALLIC ONE: COMPARATIVE RANDOMIZED CLINICAL STUDY

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ABSTRACT

Aim: The purpose of this study was to evaluate the effect of partial denture framework material on both abutments' supporting structures and bone supporting residual ridge of bilateral free edentulous areas through evaluating CAD-CAM milled PEEK and PEKK frameworks compared with the conventional cast Cobalt-chromium framework.

Materials and methods: Eighteen partially edentulous patients with mandibular bilateral free end saddle areas (class I Kennedy) were selected and divided randomly into three equal groups. Group I (Gr I) received removable partial denture (RPD) made of conventional metallic Cobalt – chromium framework, Group II (Gr II) received RPDs CAD-CAM milled PEEK frameworks, while Group III(Gr III) received RPDs with milled PEKK frameworks. The abutments were evaluated clinically through measuring the probing depth . Cone Beam Computed Tomography (CBCT) was used to evaluate radiographically the bone height supporting the abutments distally, mesially and bucco-lingual (BL). Also, the bone height and bucco-lingual width of residual ridge at the area of missed 1st and 2nd molars were measured using CBCT. The patients underwent evaluations at the time of RPD insertion (baseline), then at 6-, 12- and 18-months post –insertion.

Results: The Gr I generally showed the highest value of probing depth that became significant from Gr II and Gr III at 12 and 18 months, however Gr II and Gr III expressed insignificant values from each other. Generally, bone height on all tested sides of abutments was mostly reduced in Gr I, followed by Gr II and Gr III was the least in bone height reduction around abutments, this was clear and significant on distal side followed by mesial one, but BL height results mostly were insignificant. Regarding bone height reduction of residual ridge, there was no significance between the three groups, however Gr II showed the greatest reduction followed by Gr III that was comparable to that of Gr I. But Gr II expressed significant reduction bone width BL along all follow up periods, followed by values of Gr III that were insignificant from Gr I.

Conclusion: Milled Pekk RPD framework was nearly as preservative as Peek framework for abutments periodontium and supporting bone. Cobalt-chromium RPD framework was the most preserving for the bone of residual ridge followed by milled Pekk, where their results were nearly comparable to each other regarding the changes of the height and BL width of the residual ridge.

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INTRODUCTION

The main target of tooth- mucosa supported removable partial dentures (RPDs) is to provide prosthetic restoration of missing teeth and associated structures. [1,2] But the support of this type of restoration is based on two functionally different structures, the teeth and associated periodontal membrane and the edentulous ridges causing axial and rotational stresses on terminal abutment with denture movement during mastication [3,4]. So, the greatest challenge for any prosthodontist is to make the prosthesis by utilizing both systems of support without exposing the tissues to high stresses causing bone resorption around both natural abutment and residual ridge. [5,6] To solve this problem the implants may be placed where either fixed or removable implant retained prosthesis could be constructed. [4] However, the RPDs remain a viable and cost –effective treatment option, since the implant treatment alternative could be unfeasible for several reasons. [7,8]

Dental biomechanics involve both that of oral structures and prosthetic restorations. The long-term serviceability of any dental treatment is mainly dependent on the biomechanical interaction between supporting structures and the overlying prosthesis, to ensure firstly preserving all remaining supporting structures (the residual ridge, natural teeth and the surrounding soft tissue) and secondly allowing efficient work of the prosthesis.[5,6] Hence the good prognosis of RPDs is directly proportional to the extent of control of various stresses induced by them on the supporting structure. This concept is achieved by the optimal design and proper materials selection of RPDs' framework for bringing the stresses to be within the physiologic limits of the supporting structures. [8]

Cobalt-chromium alloy is the most traditional and familial metallic material used for constructing RPDs frameworks ,as it is characterized by high strength and excellent biocompatibility. But it has proved demerits including transmission of stresses to the bone supporting the abutment teeth due to its high modulus of elasticity in relation to alveolar bone and so all efforts have been exerted in framework design maneuvers to optimize stress distribution between abutments and residual ridge. [9]

Nowadays, there is a great patient concern about esthetics of dental restorations. So non-metallic materials have been tried to overcome the bad esthetics of metallic framework and in parallel preserve remaining supporting tissues. Nylon framework was used providing advantages of good esthetics and low elastic modulus with subsequent reduction of torque on abutments but lacks enough rigidity to sink on residual ridge causing rapid resorption of its supporting bone together with inability to make relining. Acetal resins having adequate mechanical properties allow designing supportive elements, retentive clasps and connectors, yet they lack natural translucency and transmit great stress to the residual ridge. [10-14] Recently, fibre-reinforced thermoplastic polymer Polyaryletherketone (PAEK) has been introduced in dentistry , it is characterized by strong damping power , high biocompatibility , resistance to pressure and a modulus of elasticity which is comparable to that of dentin, enamel or bone to reduce stresses transmitted to abutment , in addition, off-white color gives it a major aesthetic benefit , relative flexibility and lightness all particularly valuable from a clinical point of view for patient satisfaction. [15] PEEK (poly-ether-ether-ketone) ,the first version of PEAK has great popularity in dentistry to be used in implantology, fixed and removable prosthesis including maxillofacial obturators [16,17]. Modified PEEK (BioHHP) material containing 20% ceramic fillers has good mechanical performance and hence used in partial denture framework providing clinical results comparable to that of cobalt-chromium one. [18,19] PEKK ((POLYETHERKETONEKETONE) material is the latest generation of the PAEK family; it has the highest quality within the family of thermoplastics, unlike PEEK, PEKK displays both amorphous and crystalline material properties which makes PEKK have unique interesting mechanical (80% higher compressive strength than PEEK), physical and chemical properties. [15]

PEEK and PEKK are used in the digital dental CAD/CAM workflow to mill removable partial denture frameworks. Milling of these plastics involves subtraction of prefabricated solid blocks without alteration of their mechanical properties providing dimensional accuracy, adaptation to the underlying structures and durable retention of retentive components of RPDs. [19-21]

Literature that compared the clinical performance of PEEK framework with conventional metallic tooth-mucosa supported partial denture has focused on the stresses transmitted to the abutment teeth by both types of frameworks, the studies that evaluate stresses on the bone of residual ridge by either PEEK or metallic framework are mainly in-vitro studies [22-24]. Since the concept of preservation involves bone supporting both the abutments and the residual ridge, so thorough radiographic evaluation of bone resorption in free edentulous areas under different materials of RPDs' framework provides clue about the future prognosis.

Cone beam computed tomography is the best suitable quantitative radiographic technique that accurately evaluates the bone resorption around abutment teeth as well as the bone supporting the edentulous areas hence providing an idea about the stress distribution in all directions. As the incitement of cone-beam computed tomography (CBCT) became a unique example of two-dimensional (2D) to a 3D approach to data acquisition and image reconstruction. [25-27] The accuracy of measurement with CBCT is also commendable because there are negligible chances of superimposition and positioning errors. This relatively recent technology is currently used to measures various bony changes. Moreover, the several advantages offered by CBCT over conventional computed tomography (CT) in terms of less exposure, less scan time, and cost-effectiveness led to speedy ingress into the field of dentistry with demand for the commitment of dental professional and dental educators to explore the applications of CBCT technology. [28]

This clinical trial was performed to investigate clinically and radiographically the influence of milled PEEK and PEKK RPDs frameworks on the supporting abutments and residual ridge supporting mandibular bilateral free end saddle cases (Kennedy class I) as compared to conventional cobalt – chromium frameworks. The null hypothesis states that there is no difference either clinically around abutments or radiographically regarding the changes of bone loss around abutments and in the residual ridge for any of the used RPDs frameworks.

MATERIALS AND METHODS

1- Patients enrollment

Eighteen (6 males and 12 females) partially edentulous patients were selected from the outpatient clinic of Removable Prosthodontic Department, Faculty of Dentistry, Beni-Suef university. The age of the selected patients ranged from 45 up to 60 years.

Inclusion criteria included: patients with mandibular Kennedy class I arches with missing mandibular first and second molars and probably premolars; opposing maxillary arches were partially edentulous that were restored by acrylic RPDs, participants had neither metabolic or hormonal disorders that may enhance bone resorption. Teeth extraction was not caused by periodontal problems to avoid any negative bone factor (and this was confirmed by radiographic assessments), additionally the history of extraction did not exceed five years. All the included participants signed consent forms about the study protocol and objectives. This clinical trial followed the strategies of committee of ethics of the

Faculty of Dentistry, Beni-Suef University. Patients were then randomly assigned to three groups equal in number and gender according to a computer-generated randomization schedule. Patients of Group I received a mandibular distal extension RPD fabricated from cobalt- chromium, Group II patients received bilateral mandibular distal extension removable partial denture made of Polyether ether ketone (PEEK), while patients of the last group Group III received a mandibular distal extension RPD fabricated from Polyether ketone ketone (PEKK).

2- Patients diagnosis

Intra-oral examination was done as usual with careful evaluation of the oral hygiene that had to be acceptable to avoid presence of deep pockets, also the depth of lingual vestibule was measured to ensure that it is at least 8 mm to be suitable for construction of lingual bar major connector., also area of residual ridge had to be well formed, rounded, and covered by firm mucoperiosteum. Radiographic examination was routinely performed to evaluate bony support of abutments which must show at least (1:2 crown root ratio).

3- Clinical Procedures

After proper diagnosis, maxillary, and mandibular primary impressions (Tropicalgin alginate impression material, Italy) were poured into stone (Type III dental stone Lascod SP, Sestofino, Italy) to obtain diagnostic casts that were mounted on the articulator by using tentative jaw relation records. Occlusion was evaluated and any necessary adjustments were performed before starting the prosthetic phase.

Diagnostic casts were also used for planning the suitable design where all the maneuvers reducing the stresses on abutments were followed such as using stress-releasing clasps (I-bar or reverse Aker or RPI as determined by the presence of gingival undercuts and sites of retentive undercuts on abutments), using principal rests on far zone away from edentulous areas and using multiple rests whenever available, additionally the sites of indirect retainers were determined.

All diagnostic casts of Gr I were surveyed (Dentsply Ney Dental Surveyor, USA) determining the path of insertion and sites of guiding planes as well as the retentive undercut areas. Whereas the diagnostic casts belonging to both Gr II and Gr III were scanned using extra-oral desk scanner (Straumann Cares 3 series (SC), Switzerland) to make virtual tentative surveying using CAD software (EXOCAD) and determine all necessary intra-oral adjustments and preparations.

Preparations of abutment teeth were performed (reshaping, occlusal rest seats, guiding planes and restoration if needed) for all the patients. Customized special trays were used for all cases to make final impressions that recorded the edentulous areas in their functional form, accordingly the borders of the tray in the edentulous region were meticulously molded using green stick impression compound (Perfectin, modeling compound, Argentha) that should especially confine the impression material over buccal shelf of bone. Border molding was followed by the application of elastic rubber impression material (elite P&P addition silicone – Zhermack Italy) under hand pressure. The master casts were then poured using hard dental stone.

3- Prosthetic procedures

Group I

The usual steps of lost wax technique for making conventional chrome cobalt metal framework were followed. Then metal try- in was done in the patient's mouth, followed by jaw relation record, teeth try-in and finally processing the acrylic RPD base that was then finished, polished, and delivered to the patients after checking the occlusion and performing any necessary adjustments.

Group II and Group III

Master casts were scanned using extra-oral desktop scanner, then on CAD software the casts were virtually surveyed to determine the suitable size and location of retentive undercuts taking into consideration that PEEK and PEKK retentive arms should engage 0.5 mm to provide effective and prolonged amount of retention comparable to that of metal [29], then the design of the virtual frameworks was made using CAD software (EXOCAD) (Fig.1)

The STL file of each design was sent to the milling machine where PEEK blocks (BioHPP, Bredent GmbH, Senden, Germany) were used for Gr II and PEKK blocks (Bredent GmbH, Senden, Germany) were used for Gr III. The milled frameworks were finished and polished and then tried in the patients' mouths. Jaw relation registration step followed by try-in of frameworks with acrylic teeth were performed followed by the usual steps of processing and finishing of acrylic bases. RPDs were delivered to the patients after refinement of occlusion. (Fig. 2)

4- Post insertion instructions for patients of the three groups

Patients were given thorough oral hygiene instructions and were recalled frequently for inspection and hygiene prophylaxis and maintenance during the follow-up period and thereafter.

5- Methods of evaluation

Clinical and radiographic evaluations were performed at the time of denture insertion, six, twelve and eighteen months later.

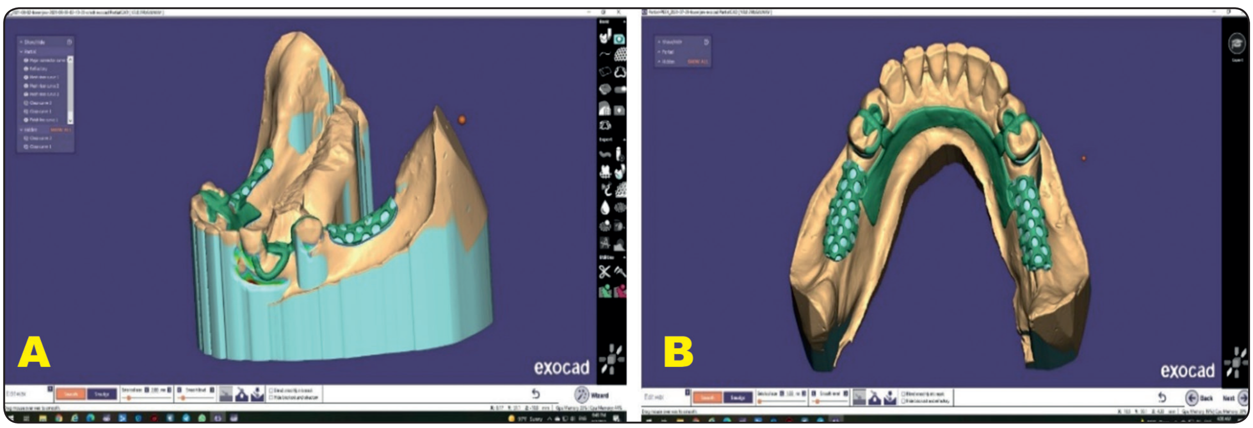

Fig. (1) a) automatic blocking out of undercuts and relief b) CAD/CAM framework virtual design sent to the milling machine

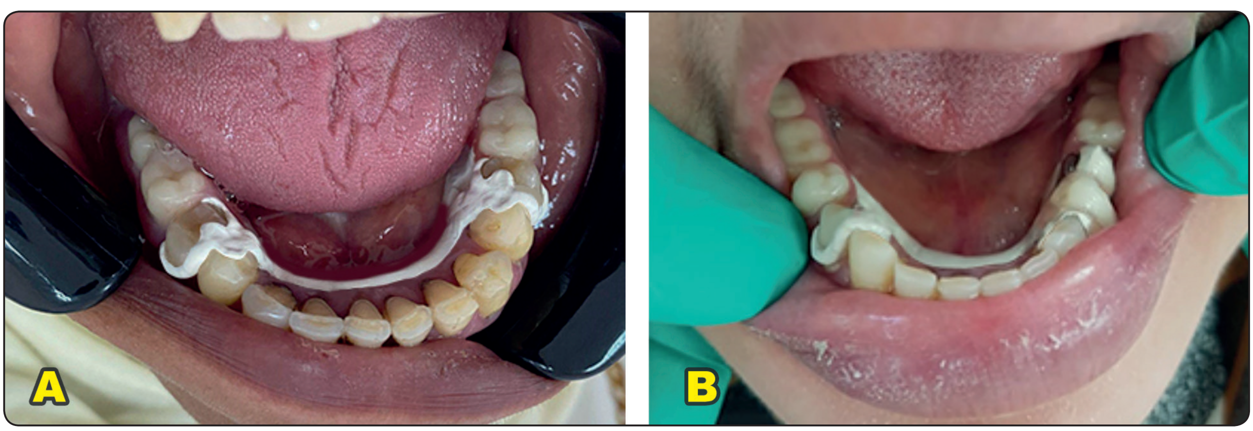

Fig. (2) a) Finished RPD with PEEK framework intraorally b) Finished RPD with PEKK framework intraorally

A) Clinical Evaluation (measurement of probing depth)

Probing depths were measured from the gingival margin down to the gingival crevice using a periodontal probe at six points: 3 buccally (mid-buccal, mesiobuccal and distobuccal line angles) and 3 lingually (mid-lingual, mesiolingual and distolingual). Midpoints were guided by the cusp tips and mesial and distal marginal ridges proximally. The average of the six measurements was calculated for each abutment.

B-Radiographic Evaluation

The CBCT images were obtained using cs8100 3D CBCT machine Carestream, operating at 90 kVp, 3.2mA, Using DDS-PRO third-party software for image analysis. Adjustment of coronal and sagittal reference lines to be parallel to the long axis of each abutment and then linear point to point measurement of bone starting from alveolar crest at each abutment surface to the inferior border of mandible was done. The buccal and lingual bone heights were measured on the sagittal view, while the mesial and distal bone heights were measured on the coronal view.

Radio-opaque marker (gutta percha) was placed within prepared small, rounded grooves in the fitting surface of the finished dentures directly under the center of occlusal surfaces of first and second molars on both sides. Linear measurements were done where vertical line was extended through the radio–opaque marker down to the inferior border of the mandible and another horizontal line was extended bucco-lingual guided by the radio-opaque marker (Fig 3).

The CBCT measurements were done by the same radiologist using the same technique and were repeated twice with an interval of 2 weeks to evaluate the reproducibility of the measurements, and the precision was calculated blind to the details of age and sex of the patients using the digital image communication in medicine (DICOM file) twice in different time to take reading (FIG. 4). Each time of follow up the same technique was followed and the radio-opaque marker was placed in the prepared grooves in the fitting surface of dentures and the same radiologist made the measures. The intra-class coefficient (ICC) was used to determine intra-observer reliability. The mean intra –observer ICC of > 0.9 was confirmed for the entire variables.

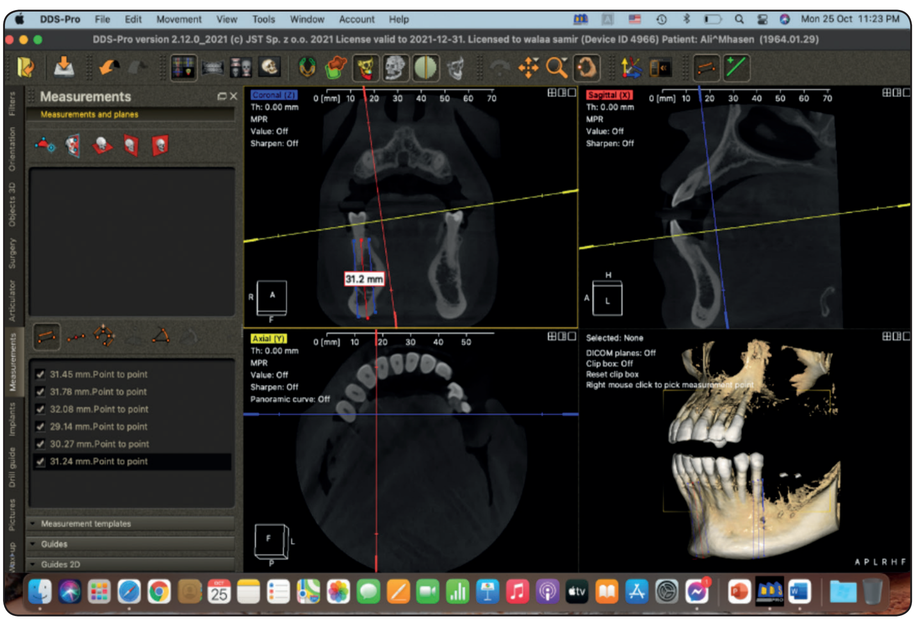

Fig. (3) Bone measurements at abutment after adjustment of coronal and sagittal CBCT view on DDS-PRO software.

The mean value of distal bone heights of all abutments at each follow-up session was calculated, similarly the mean value of bone heights mesially of all abutments was obtained. While the BL bone height mean value was obtained by calculating both the buccal and the lingual bone heights readings of all abutments at each follow up session.

The mean values of bone height and BL width of residual ridge at areas of both 1st and 2nd molars were taken at each session of follow up.

Statistical analysis

Data were presented as means and standard deviation (SD) values. Mean bone height (in mm) and width as well as probing depth (in mm) showed normal distribution so; parametric tests were used. One-Way ANOVA was used to compare between the three groups at all follow-up periods and between the follow up periods within each group. Duncan's multiple range test (Duncan, 1955) was used to test differences within means of treatments while level of significances was set typically at minimum ($P \leq 0.05$). Statistical analysis was performed with IBM® SPSS® (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 22 for Windows.

RESULTS

1-Radiographic Evaluation of Bone Changes Around Abutments

Gr I expressed significant bone height changes distally along all intervals, while that of Gr II and Gr III were only significant in the 1st interval (Table 1). At both 2nd and 3rd follow up interval, the same trend of bone reduction distally occurred but Gr II values were insignificantly higher than Gr III. On comparing the bone changes distally within each group, the1st interval of all groups showed the greatest reduction of height and then followed by less reduction of bone height throughout 2nd and 3rd intervals.

Table (1) also showed the mean values of bone height differences along follow up intervals at mesial sides of abutments, Gr I had the greatest significant loss of bone height as compared to both Gr II and Gr III whose values of bone loss mesially were insignificant from each other. Bone height changes mesially within each group, both Gr I and Gr II values were significant along all follow-up intervals, where 1st interval had the greatest significant loss of bone as compared to 2nd and 3rd intervals that were insignificant from each other. Gr III mean values of bone loss mesially had no statistical difference along follow up intervals .

Bucco-lingual (BL) height changes around abutments were insignificant in between groups at 1st interval (table 1), however at 2nd and 3rd intervals there was significant reduction of height (BL) for Gr I as in relation to Gr II whose values were insignificantly higher than that of Gr III. Within each group, (BL) height changes showed significant reduction along all intervals, but the highest value of change was significant at 1st interval relative to 2nd and 3rd intervals whose values were only statistically significant within both Gr I and Gr II.

Table (2) demonstrated that the highest reduction of bone was on the distal side of abutments followed by the mesial ones and the least was the (BL) changes within all groups. On comparing the three sides of abutments in Gr I along all intervals, there was significant height reduction distally followed by mesial and bucco-lingual height changes. While Gr II had only significant changes within the 1st interval. Gr III had no significant changes along the three intervals.

2- Probing Depth Around Abutments

Table (3) showed that the probing depth of Gr I had the highest mean values at all periods of follow up in comparing to Gr II and Gr III that showed nearly similar values, however Gr I showed only significant increase in probing depth at 12 and 18

TABLE (1): Mean of Bone height changes (mm) around abutments:

Measurement	Group / Intervals	Group I		Group II		Group III		P1-Value
		Mean	±SD	Mean	±SD	Mean	±SD	
Distally	**Base Line – 6 months**	1.018 A a	± 0.12	0.748 B a	±0.14	0.538 C a	±0.20	0.0004
	6 – 12 months	0.607 A b	±0.10	0.403 B b	±0.04	0.373 B ab	±0.10	0.0002
	12 – 18 months	0.480 A c	± 0.03	0.393 AB b	±0.11	0.335 B b	±0.03	0.0001
	P2-Value	0.0001		0.0001		0.0005		
Mesially	**Base Line – 6 months**	0.775 A a	±0.15	0.558 B a	±0.03	0.530 B a	±0.05	0.0009
	6 – 12 months	0.572 A b	±0.13	0.393 B b	±0.06	0.380 B a	±0.09	0.0010
	12 – 18 months	0.490 A b	±0.02	0.362 B b	± 0.06	0.357 B a	± 0.11	0.1005
	P2-Value	0.0003		0.0002		0.0865		
Bucco-Lingually	**Base Line – 6 months**	0.532A a	±0.02	0.528A a	± 0.01	0.523A a	± 0.02	0.8283
	6 – 12 months	0.465 A b	±0.03	0.368 B b	±0.03	0.348 B b	±0.05	0.0006
	12 – 18 months	0.395 A c	±0.03	0.320 B c	±0.03	0.305 B b	±0.05	0.0007
	P2-Value	0.0001		0.0001		0.0001		

P1 value: Significance In-between groups, different capital letters.

P2 value: Significance within each group, different small letters. ***SD: Standard Deviation.***

TABLE (2): comparison of bone height changes (mm) around abutments' surfaces within groups at differed follow-up intervals

Measurements	Follow up intervals	Distally Mean± SD	Mesially Mean± SD	Bucco-lingual Mean± SD	P-value
Gr I	Base line-6 months	1.018 ±0.12a	0.775±0.15b	0.532±0.02c	0.0001
	6 –12 months	0.607±0.10a	0.572±0.13a	0.465±0.03b	0.0055
	12 - 18 months	0.480±0.03a	0.490±0.02a	0.395±0.03b	0.0001
Gr II	Base line-6 months	0.748±0.14a	0.558±0.03 b	0.528±0.01b	0.0010
	6 – 12 months	0.403±0.04	0.383±0.09	0.368±0.03	0.6335
	12 -18 months	0.393±0.11	0.362±0.06	0.320±0.03	0.3155
Gr III	Base line-6 months	0.538 ±0.20	0.530±0.05	0.523±0.02	0.9776
	6 – 12 months	0.393±0.06	0.370±0.10	0.348±0.05	0.6170
	12 -18 months	0.355±0.11	0.337±0.03	0.305±0.02	0.4631

P≤ 0.05: value Significance within each Group. ***SD: Standard Deviation***

months (p value = 0.0001). Probing depth mean values increased within each group throughout the follow-up periods. For groups I and II, this increase was statistically significant at 6- and 18-months follow-up only. For group III, the increase was statistically significant at the first 6 months only and continued to increase insignificantly at 12- and 18-months follow-ups.

3- Radiographic Evaluation of Residual Ridge Bone Changes

Table (4) revealed statistical analysis of bone height changes in the residual ridge at areas of 1st and 2nd molars: there was insignificant reduction of bone height at areas of 1st and 2nd molars in between the three groups at three follow up time intervals, however Gr II showed the highest mean values of bone reduction followed by Gr III and the least one was Gr I. While within each group comparison, there was significant reduction of bone height at the 1st interval as compared to the 2 nd and 3rd intervals that had insignificant values from each other (Table 4).

Table (4) also showed the means of bucco-lingual (BL) bone width reduction at areas of 1st and 2nd molars, there was significant reduction of bone in between groups along all intervals, where the Gr II had the highest significant loss of BL width, then Gr III and finally Gr I that had the least reduction of bone width. There was statistically insignificant difference between Gr III and Gr I at all time intervals. Within Gr II and GrIII, the bone width reduction (BL) was significantly high along the first interval and then decreased insignificant along 2nd and 3rd intervals. However, the BL width reduction of residual ridge was significant along all time intervals of Gr I where 1st interval expressed the highest value followed by the 2nd and 3rd interval respectively .

Table (5) compared the rate of bone resorption at area of 1st molar with that at area of 2nd molar within all groups. The results of both vertical (height) and horizontal (BL width) bone loss expressed no significant difference within all groups along all-time intervals. However, area of 1st molar had generally higher rate of bone loss than that of 2nd molar area.

TABLE (3): Effect of time on probing depth(mm) in between groups as well as within each group

Measurement	Group Period	Group I		Group II		Group III		P1-Value
		Mean	±SD	Mean	±SD	Mean	±SD	
Probing depth	Base Line	2.36^{c}	±0.06	2.33^{c}	±0.05	2.33^{b}	±0.07	0.6826
	6 months	2.75^{b}	±0.33	2.61^{b}	±0.06	2.60^{a}	±0.07	0.3945
	12 months	$2.97^{A\ ab}$	±0.09	$2.66^{B\ ab}$	±0.07	$2.66^{B\ a}$	±0.07	0.0001
	18 months	$3.06^{A\ a}$	±0.13	$2.69^{B\ a}$	±0.05	$2.69^{B\ a}$	±0.06	0.0001
	P2-Value	0.0001		0.0001		0.0001		

P1≤ 0.05: value Significance In-between Groups (different capital letters)

P2≤ 0.05 value: Significance within each Group (different small letters)

TABLE (4): Means of Bone reduction height and BL-width (mm) of residual ridge at areas of 1st and 2nd molars:

Measurement	Group / Interval	Group I Mean ± SD	Group II Mean ± SD	Group III Mean± SD	P1-Value
Bone height	**Base line-6 months**	0.763 ±0.16 a	0.967 ±0.06 a	0.925±0.3 a.	0.2226
	6 – 12 months	0.565 ±0.07 b	0.675 ±0.08 b	0.607 ±0.15 b	0.3201
	12 -18 months	0.517 ±0.05 b	0.610 ±0.06 b	0.572 ±0.015 b	0.2502
	P2 value	0.0040	0.0001	0.0242	
Bone Width (Bucco-Lingual)	**Base line-6 months**	1.012 ± 0.05 B a	1.517 ± 0.34 A a	1.273± 0.31 ABa	0.0195
	6 – 12 months	0.515 ± 0.02 B b	0.752 ±0.06 A b	0.555 ±0.04 B b	0.0001
	12 -18 months	0.340 ±0.02 B c	0.523 ± 0.03 A b	0.427 ± 0.12 B b	0.0029
	P2 value	0.0001	0.0001	0.0001	

P1≤ 0.05 value: Significance In between groups, different capital letters.

P2 ≤ 0.05 value: Significance within groups, different small letters.

SD: Standard Deviation

TABLE (5): Comparison of bone height and width changes(mm) mean at area of 1st molar and that of 2nd molar area:

Measurements	Group Interval	Group I			Group II			Group III		
		1st molar Mean± SD	2nd molar Mean± SD	P-Value	1st molar Mean± SD	2nd molar Mean± SD	P-Value	1st molar Mean± SD	2nd molar Mean± SD	P-Value
Bone height	**Base line-6 month**	0.827 ±0.14	0.700 ±0.21	0.26	1.033 ±0.08	0.900 ±0.12	0.06	0.933 ±0.31	0.933 ±0.29	1.0
	6 – 12 month	0.627 ±0.12	0.503 ±0.09	0.09	0.650 ±0.13	0.698 ±0.12	0.54	0.655 ±0.15	0.557 ±0.21	0.39
	12 -18 month	0.597 ±0 .08	0.437 ±0 .10	0.15	0.640 ±0.15	0.547 .±0.08	0.22	0.613 ±0.18	0.530 ±0.22	0.50
BL - Bone width	**Base line-6 month**	1.025 ±0.09	0.995 ±0.09	0.59	1.530 ±0.25	1.500 ±0.65	0.93	1.297 ±0.08	1.245 ±0.63	0.85
	6 – 12 month	0.520 ±0.05	0.507 ±0.05	0.68	0.758 ±0.14	0.742 ±0.09	0.82	0.582 ±0.07	0.523 ± 0.07	0.13
	12 -18 month	0.350 ±0.02	0.325 ±0.03	0.21	0.540 ±0.07	0.498 ±0.07	0.36	0.453 ±0.022	0.397 ± 0.07	0.57

P≤ 0.05: value Significance In-between Groups BL: Bucco-Lingual

DISCUSSION

This clinical trial was done to evaluate the effect of partial denture framework material on both abutments' supporting structures and bone supporting residual ridge of bilateral free edentulous areas through evaluating CAD-CAM milled PEEK and PEKK frameworks compared with the conventional cast Cobalt-chromium framework. There were differences between the results of both clinical and radiographic effects of the three tested RPD frameworks materials on the abutment supporting structures . Also the radiographic results of the three tested materials were different regarding bone height and BLwidth loss of residual alveolar ridge at areas of missing 1st and 2nd molars bilaterally .Based on these findings , the null hypothesis of this trial was rejected.

It was stated that the best way to manage bone resorption was to avoid tooth extraction. This is especially true for the prosthetic management of partially edentulous patients having one or more of free end edentulous areas that remains to face challenges due to the difference in the resiliency of the periodontal ligament of abutments and that of mucosa covering the edentulous area [30]. This difference of resiliency resulted in settling of RPD on highly resilient mucosa during function with subsequent great rotational and horizontal stresses on the abutments causing loss of supporting bone. Moreover, settling of RPD leads to deflection of denture base on residual alveolar bone and the denture users have radiographically more residual bone resorption compared with non- partial denture users [31]. Components of the RPD are subjected to stresses and, at the same time, can produce stresses in the supporting structures as well as causing settling and its hazards [32,33]. The amount of these stresses could be managed by both design of the prosthesis and biomechanical characteristics of framework material [5,6]. Design of the prosthesis and its fabrication in this trial, had followed all the rules of stress reduction on abutments and proper distribution of forces on abutments and ridge. Hence in this study, all the variables of design produced stresses on supporting structures were nearly standardized except the type of direct retainer that were stress releasing action clasp that decrease the tipping stresses transmitted to the abutment teeth during tissue ward movement of the partial denture by moving into deeper undercut teeth producing the Class II lever effect, permitting rotation of the RPD base towards the tissues without torquing the clasped tooth. The axis of rotation is designed around the mesial rest and this is especially true when the length of saddle area bilaterally is nearly symmetrical [34 ,35].

The effect of biomechanical behavior of the framework material on the bone supporting the abutments could be easily distinguished in the results of the mean differences of bone height in-between groups, where Gr I showed the highest level of resorption followed by Gr II and then Gr III at all the three time intervals. However, GrII and GrIII expressed comparable results during the last two intervals. These results could be attributed to the low modulus of elasticity of both PEEK and PEKK that are almost like that of dentin and bone, so these materials are flexible and at the same time elastic (strong damping power) to reduce the distal torque and the stress on the abutment teeth with settling of RPD base. On the contrary cobalt-chromium framework has high modulus of elasticity to be rigid. According to the recent literatures, the modulus of elasticity and nano-hardness of a material are factors that directly affect the amount of pressure transmitted by the material and the extent of the area to which it is transmitted [36-38]. Hence rigid cobalt- chromium transmits great rotational and lateral stresses to the abutment through the small area of the occlusal rests.

The results of bone loss around abutments within each group were greatly significant within the first 6 months following insertion as compared to the other follow-up periods where they became diminished and insignificant, as the clinical studies [(39-41)] suggested a tendency of reduction of torque exerted on abutment teeth as the denture-wearing period increases. The unavoidable "settling" period lasts for about 1 to 1.5 months from the time of insertion of new RPDs and is attributed to changes of jaw movement in the frontal plane, adaptation of the oral tissues to the denture, properties of the alveolar mucosa, or changes in the chewing points of the RPDs [(42)]. Also, our results were in line with other clinical studies [(43,44)] that indicated also maximum loss of bone around abutments was observed 6 months following insertion of RPD and then decrease thereafter.

The means of probing depth values in-between groups confirmed that of bone loss around abutments where the deepest gingival crevice was also observed in Gr I followed by G II and GrIII that showed comparable results. As well as within groups, the means of probing depth were in line with that of bone resorption. This could be attributed to the hypothesis that bone loss may be accompanied by loss of periodontal tissue. Other studies suggest that increased probing depth may be due to the fact that the oral environment is complicated by wearing RPD that restricts the flow of food and the self-cleaning action by the surrounding movable tissues, with subsequent accumulation of the dental plaque on the prosthesis and the surrounding tissues. This in turn increases the risk for the development of gingivitis and periodontitis [(43-45)]. In this study the effect of bone loss on periodontium was present alongside with alteration of oral media despite the use of the lingual bar which is more hygienic than the lingual plate as the latter covers the gingival margin hence depriving the gingiva from the cleaning action of the tongue. But we observed that the increase of probing depth along the 18 months of follow-up did not proceed into pocket formation especially in PEEK and PEKK groups whose materials have great biocompatibility together with the precise designing and manufacturing by milling CAD-CAM that ensures accurate adaptation and fitness of the denture framework components[(46 ,47)]

Also, the oral hygiene of patients was thoroughly followed, and this should be continued as long as the prosthesis is used especially for patients of Gr I as the increased probing depth enhances the risk for future clinical attachment loss [(48,49)].

Since three-dimensional cone beam computed tomography was used for evaluation of bone loss around abutments, it was interesting to evaluate the bone height distally, mesially and bucco-lingually and correlate the mean difference of bone loss clinically with in-vitro studies made using either photo-elastic analysis or finite element analysis (FEA) [(50,51)]. Results revealed that the mean bone loss was the highest distally, followed by mesial side and finally bucco-lingually. These results were in line with FEA study that reported concentration of stresses at the distal side of the terminal abutments [(52)]. Moreover, the distal side showed the highest significant bone loss along all-time intervals in Gr I (with the rigid framework). For the PEEK group (Gr II), which represents an elastic flexible framework, bone loss was significant during the first interval only. PEKK group (Gr III) however showed the most preservative results, with insignificant differences between all vertical and horizontal bone loss changes at all time intervals. This could be due to the fact that PEKK is flexible, elastic yet its compressive strength is 80% higher than the PEEK [(15)].

As regards the vertical and horizontal bone changes in the supporting residual ridge, it was found that the alveolar bone resorption was higher in the RPD wearing patients when compared to dentate and partially edentulous patients not wearing RPDs [(53)]. Since CBCT was used for radiographic evaluation of bone, so the bone resorption could be evaluated vertically as well as horizontally. According to an FEA study, the deflection of denture base on mucosa causes mainly stress concentration at the occlusal and lingual side of short span saddles

[54], so we evaluated the reduction of bone width bucco –lingually especially at areas of first and second molars where stresses of mastication usually concentrate.

As mentioned earlier, settling of an RPD on viscoelastic mucosa occurs mainly within the first few months following denture insertion and then diminishes gradually with more adaptation. This also explains why both the vertical and horizontal bone loss within each group were highly significant in the first-time interval and then decreased gradually during the 2nd and 3rd intervals.

Unlike the results of bone loss around abutments, the rigid metallic framework seemed to distribute the stresses on a wider area of the residual bone with the least deflection of base leading to the least amount of bone loss throughout the follow-up periods. PEKK group followed the metallic framework group one with lesser bone loss than that of the PEEK group that showed the greatest loss of bone at the residual ridge areas. As the PEKK framework is flexible and elastic at the same time, it could be deflected under functional loading without transmitting great stresses to the underlying bone because of its great compressive strength [55,56]. The PEEK frameworks on the other hand have greater elasticity and lesser compressive strength when compared to that of the PEKK causing their deflection under functional forces which transmit greater stresses to the bone of residual ridge [15].

Results of the current study indicate that the amount of bone loss that occurred in the 1st molar area is comparable to the amount of bone loss in the 2nd molar area regardless of the RPD framework material. The only significant difference in bone loss between the three groups regarding horizontal bone resorption (BL width) found could be attributed to the concentration of the occlusal stresses lingually and hence causing more deflection of the frameworks on the lingual side and because of the nature of bone on the lingual aspect of the mandible which is more cancellous particularly at the posterior area which will be readily affected by the stresses and subjected to faster bone resorption [53.57].

In this study, we proposed the use of milled PEKK as viable RPD framework material providing esthetics and preserving the abutments and residual ridge through comparing its clinical and radiographic effects with that of milled PEEK and conventional cast cobalt-chromium frameworks, however more studies are required taking into consideration the current study limitations that included the number of the patients involved, follow-up period that should be longer to make accurate estimation of bone resorption and complete standardization of design of the frameworks.

CONCLUSIONS

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

1- PEEK and PEKK frameworks produced lesser stresses than rigid metallic framework on abutments and hence caused less bone resorption around abutments.

2- Metallic framework produced the greatest probing depth at all intervals.

3- Metallic framework produced the least loss of bone height and width of the residual ridge, followed by PEKK while PEEK framework was the worst regarding the loss of bone at the residual ridge area.

RECOMMENDATIONS

In the future studies, it is recommended to include larger study sample, longer follow-up period and to standardize the design of the RPDs frameworks. PEKK framework could be the material of choice for esthetic RPD that preserve both abutments and bone of residual ridges in cases of mandibular free end saddles. However, fatigue resistance and durability of PEKK RPD framework could not be evaluated and need more prolonged clinical studies.

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