Section A-Research paper
ISSN 2063-5346

RADIOGRAPHIC EVALUATION OF MARGINAL BONE CHANGES WITH CAD/ CAM METALLIC AND POLY ETHER ETHER KETONE (PEEK) PARTIAL DENTURES: A RANDOMIZED CLINICAL TRIAL

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Abstract

Objective The aim of this randomized clinical trial was to evaluate marginal bone changes related to CAD/CAM metallic and PEEK partial denture frameworks in mandibular Kennedy class I

Materials and methods: 24 patients with mandibular Kennedy class I were randomly assigned into two groups treated either with CAD/CAM PEEK or cobalt –chromium PDs. Bone height changes were assessed using standardized digital periapical radiographs with paralleling technique at baseline, 3 and 6 months.

Result: The marginal bone height changes values of PEEK frameworks group were lower than that of the metallic frameworks group, but the difference was statistically insignificant throughout the follow up periods and between groups.

Conclusion: CAD/CAM PEEK Partial dentures showed more favorable effect on abutment teeth than CAD/CAM metallic partial dentures. However, more clinical studies are still needed to evaluate its long term effect.

KEY WORDS: Partial denture, PEEK, Cobalt –chromium PDs, Marginal bone change, CAD/CAM.

Introduction

Prosthetic options for partial edentulism includes; fixed prosthesis retained by teeth and/or implants and removable partial dentures (PDs).[1] Although partially edentulous patients can be successfully treated by osseointegrated implant supported prosthesis, PDs are still the treatment of choice in cases were implant placement is limited by bone quality and quantity, position of vital structures, and when patient refused or couldn't afford the multiple surgeries. Also PDs have the advantages of being non-invasive, less expensive and

can be used as a transitional prosthesis. Moreover, it can restore soft and hard tissues and support orofacial structures for better esthetics.[2,3]

The traditional PDs with cobalt chromium frameworks and clasps have been proven to be inexpensive, accurate, durable and resistant to distortion.[3] On the other hand, they have; unesthetic display of metallic clasps, increased weight, and may provoke an allergic reaction. Because of those drawbacks new metal-free materials have been reported as a replacement of metal alloys in manufacturing PDs, including; high performance polymers such as polyethylene glycol, polyetherketonketon (PEKK), polyaryletherketone (PAEK) and Polyetheretherketon (PEEK).[2,4,5]

Distal extension partial dentures are subjected to rotation and the abutments are subjected to great stresses, because their support is a combination of tooth and soft tissues.[6] Metallic PDs were reported to produce significant higher bone loss in comparison to thermoplastic PD.[7]

Using PEEK and modified PEEK frameworks were claimed to reduce the distal torqueing and stresses on the abutments in Kennedy class I PDs which is thought to be beneficial for periodontal health of the abutments However, there are no clinical trials evaluating the effect of PEEK on marginal bone changes around abutments.[8,9]

So this study was conducted to evaluate the effect of different partial denture framework materials, namely cobalt chromium and PEEK on marginal bone changes around terminal abutments in mandibular Kennedy class I cases.

MATERIAL AND METHODS

Twenty-four patients were recruited for this study. Patients had mandibular Kennedy class I partially edentulous arches opposing intact or fully restored maxillary arch. They had Angle class I maxillo-mandibular relationship with adequate inter-arch space and those with systemic disease affecting bone and periodontal health were excluded. Treatment steps were explained to the patients and informed consent was obtained from each one.

Patients were randomly assigned into two groups using computer generated randomization list (www.Random.org) to receive mandibular partial dentures with either CAD-CAM cobalt chromium ‘group I’ or PEEK ‘group II’ framework.

A thorough clinical examination was done and perioperative periapical radiographs of proposed abutments and any questionable teeth were taken. All patients were treated according to standardized clinical procedures for PD. The design of the frameworks was similar but PEEK required more tooth preparation for rests and deeper retentive undercuts.

Partial dentures in the two study groups were fabricated using the produced master cast of the lower arch. The frameworks were digitally designed on the scanned master casts to produce 3D printed castable resin patterns. For group I; 3D printed castable resin patterns were conventionally casted to obtain cobalt chromium frameworks, while for group II; PEEK frameworks were constructed with the conventional lost wax technique using vacuum pressing (Bredent, Germany).

The PD frameworks were tried intra-orally. All framework components were examined to ensure they were properly placed. The wax wafer method was used for jaw relation record. Finally, the partial dentures were finished in the traditional way and delivered to patients following any required occlusal modifications. (figure 1)

Figure (1): Intraoral delivered metallic “left” & PEEK “right” partial dentures

Outcome measurement:

Marginal bone changes were measured using series of standardized digital periapical radiographs using; long cone paralleling technique and the Digora computerized system (Kavo Kerr, Detroit, Michigan, USA), Rinn XCP periapical film holder (Rinn XCP; Dentsply Rinn, Elgin, IL, USA) and an individually constructed radiographic putty template. For each patient in the two groups, three digital periapical radiographs were taken one for right and one for left terminal abutments at base line, 3 and 6 months follow up.

The digital images were analyzed using Scanora software (Soredex Corporation, Helsinki, Finland) to evaluate marginal bone changes mesial and distal to the principle right and left abutments.

Measuring the mesial and distal marginal bone level was done as follows:

Calibration was done using image plate’s known dimension “length= 41 mm”. After calibration, the bone height changes were measured by drawing 3 lines; first line was tangent to apex and perpendicular to the long axis of the tooth. The other two lines were drawn one on the mesial and one on the distal of abutment tooth starting at highest point of bone and ending perpendicular to the first line. Then a comparison between radiographs were then done for each side in both groups. (figure 2)

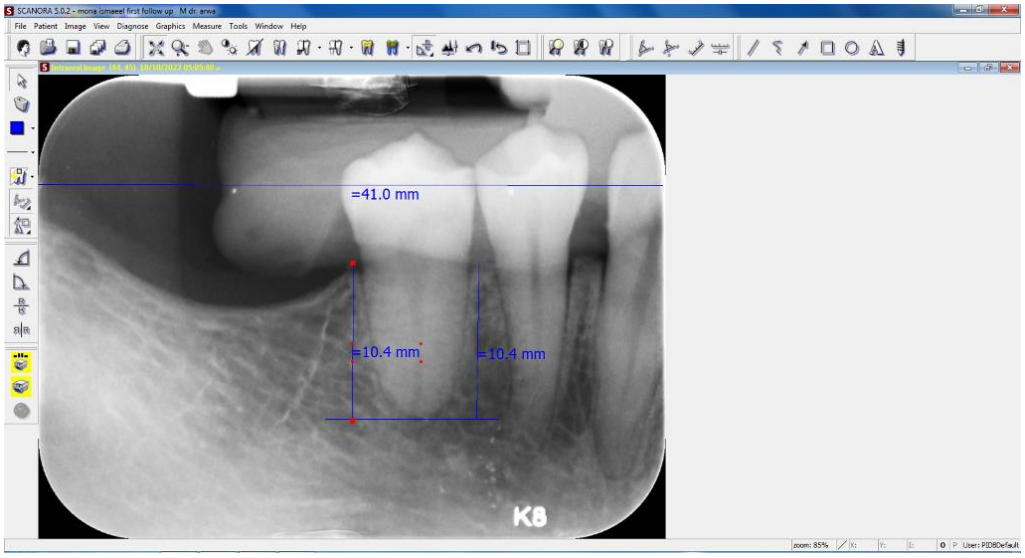

Figure (2): Digital periapical Radiograph with the technique of measuring

Statistical analysis:

Statistical analysis was performed with SPSS 20® (Statistical Package for Social Science, IBM, USA), Graph Pad Prism® (Graph Pad Technologies, USA) and Microsoft Excel 2016 (Microsoft Co-operation) , USA All quantitative data were explored for normality by using Shapiro Wilk and Kolmogorov normality test and presented as means and standard deviation (SD) values.

For parametric data; One Way ANOVA was used for multiple comparisons followed by Tukey`s Post Hoc test, while Independent t test was to compare between both groups. For non-parametric; data Mann Whitney test was used to compare between 2 different groups and Friedman`s test was to compare between more than 2 intervals.

Results:

Marginal bone height change:

1. Effect of time within each group:

Mean and standard deviation of mesial, distal and average “mesial& distal” marginal bone height at baseline, after 3 months and after 6 months regarding metal, PEEK.

Comparison between different intervals (to evaluate effect of time) was performed by using One Way ANOVA test which revealed insignificant difference between them as P>0.05, followed by Tukey’s Post Hoc test for multiple comparisons which revealed insignificant difference. (figure 3, Table 1)

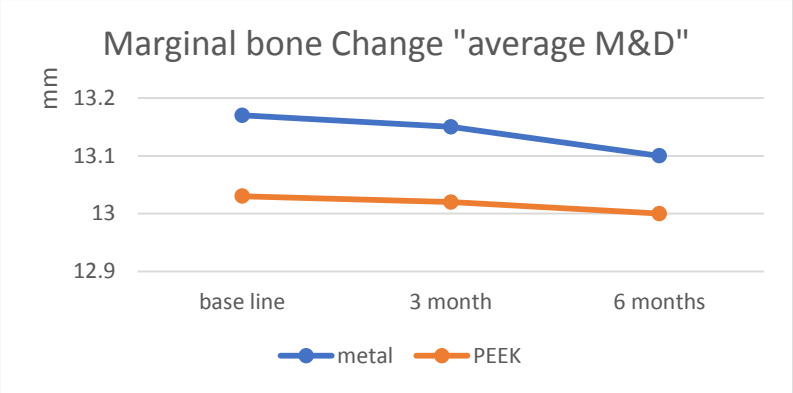

Figure (3): Line chart representing effect of time on marginal bone change average M&D

Table (1): Mean and standard deviation of marginal bone height at mesial, distal and average surfaces within each group

		Marginal bone height change					
		Mesial		Distal		Average (Mesial&Distal)	
		M	SD	M	SD	M	SD
Group I (Metal)	Baseline	13.78 a	1.67	12.55 a	1.27	13.17 a	1.37
	3 Months	13.78 a	1.67	12.52 a	1.27	13.15 a	1.37
	6 Months	13.75 a	1.68	12.45 a	1.26	13.10 a	1.37
	P -Value	**0.99**		**0.98**		**0.99**	
Group II PEEK	Baseline	13.45	1.77	12.60	1.43	13.03	1.51
	3 Months	13.44	1.77	12.59	1.42	13.02	1.50
	6 Months	13.43	1.76	12.56	1.42	13.00	1.50
	P -Value	**0.99**		**0.99**		**0.98**	

*;Significant ($p \leq 0.05$) ns; non-significant ($p>0.05$)

2. Difference in marginal bone change between the two groups:

Mean difference of marginal height bone changes was calculated between different intervals regarding mesial, distal, and average "mesial& distal" surfaces of both groups. Comparison between both groups at different intervals was performed to evaluate the effect of material by using Man Whitney's test (Nonparametric data) which revealed that there was no statistically significant difference regarding mesial, distal and average "mesial& distal" as $P>0.05$. (Table 2)

Table (2): Mean difference and standard deviation of marginal bone height changes between different intervals at mesial, distal, and average surfaces in both groups

				M	SD	difference		P value
						MD	SD	
Mesial	Baseline - 3 months	Metal	0 months	13.78	1.67	0	0	0.75
			3 months	13.78	1.67			
		PEEK	0 months	13.45	1.77	-0.008	0.029	
			3 months	13.44	1.77			
	3 months - 6	Metal	3 months	13.78	1.67	-0.033	0.049	0.31

	months		6 months	13.75	1.68			
		PEEK	3 months	13.44	1.77	-0.008	0.029	
			6 months	13.43	1.76			
	Baseline - 6 months	Metal	0 months	13.78	1.67	-0.033	0.049	0.51
			6 months	13.75	1.68			
		PEEK	0 months	13.45	1.77	-0.017	0.039	
			6 months	13.43	1.76			
Distal	Baseline - 3 months	Metal	0 months	12.55	1.27	-0.033	0.049	0.31
			3 months	12.52	1.27			
		PEEK	0 months	12.6	1.43	-0.008	0.029	
			3 months	12.59	1.42			
	3 months - 6 months	Metal	3 months	12.52	1.27	-0.067	0.065	0.26
			6 months	12.45	1.26			
		PEEK	3 months	12.59	1.42	-0.033	0.049	
			6 months	12.56	1.42			
	Baseline - 6 months	Metal	0 months	12.55	1.27	-0.1	0.085	0.21
			6 months	12.45	1.26			
		PEEK	0 months	12.6	1.43	-0.042	0.067	
			6 months	12.56	1.42			
Average (M&D)	Baseline - 3 months	Metal	0 months	13.17	1.37	-0.017	0.025	0.51
			3 months	13.15	1.37			
		PEEK	0 months	13.03	1.51	-0.008	0.019	
			3 months	13.02	1.5			
	3 months - 6 months	Metal	3 months	13.15	1.37	-0.05	0.052	0.08
			6 months	13.1	1.37			
		PEEK	3 months	13.02	1.5	-0.021	0.026	
			6 months	13	1.5			
	Baseline - 6 months	Metal	0 months	13.17	1.37	-0.067	0.058	0.1
			6 months	13.1	1.37			
		PEEK	0 months	13.03	1.51	-0.029	0.033	
			6 months	13	1.5			

*;Significant ($p \leq 0.05$) ns; non-significant ($p>0.05$)

Discussion:

The current randomized clinical study was conducted to evaluate marginal bone changes related to CAD/CAM metallic and PEEK partial denture frameworks in mandibular Kennedy class I. The radiographic examination revealed that there was no statistically significant difference within or between the two groups regarding marginal bone changes, there was decrease in marginal bone height in both groups. This coincides with the fact of inevitable bone loss after any partial denture.[10]

Mean values of bone change over the follow up periods in PEEK group was lower compared to metal group. Those results can be explained by a previous finite element study[11] that suggested PEEK frameworks to have better force distribution on abutment

teeth and hence, better protection of supporting periodontium compared to conventional metallic frameworks. On the other hand, the same study found that PEEK frameworks result in more displacement of the mucosa in the distal extension area. This finding indicates more light to be shed on effect of PDs on residual ridge crest height, not only on marginal bone changes related to abutment teeth.

From the results of the current study, the amount of marginal bone change in the distal surface of abutments was higher than mesial surface in both groups with no statistically significant difference. Lower mean values of marginal bone change in the distal surface of abutments in PEEK group might be due the elastic nature of this material that might have reduced the distal torque and the stress on the abutment teeth. While the rigid nature of metallic framework resulted on more forces delivered to abutment teeth.

Also, clasps engaging of abutment teeth undercuts exert cyclic load on teeth during insertion and removal. This load lead to periodontal affection and marginal bone resorption. As a result of PEEK clasp flexibility, it might produce gentler load on abutment resulting in less harmful effect. This deduction is augmented by a previous study that claimed that; in comparison to conventional Co-Cr, PEEK clasps are gentler on abutments.[8] Likewise, a finite element study undercuts showed that PEEK clasps exert less stresses on abutments than conventional metallic clasps, due to the lower modulus of elasticity of PEEK.[12]

It should be kept in mind that, the highest mean value of marginal bone change which was found at distal surface of abutments in metal group between baseline and 6 month follow up was below the reported bone loss in previous studies evaluating effect of PD on marginal bone change.[10,13,14] Russo et al. claimed that; there is no significant difference in vertical residual ridge changes after one year in patients with PEEK PDs versus patients with no PDs.[15] Based on the results of our study we agree with Zlataric et al. that a properly designed RDP is a predictive factor for the maintenance of periodontal health and subsequently marginal bone level.[9]

Conclusion

Within the limitation of the current study, CAD/CAM PEEK Partial dentures showed more favorable effect on abutment teeth than CAD/CAM metallic partial dentures. However, more clinical studies are still needed to evaluate its long term effect.

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