Section A-Research paper
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CAD/CAM PEEK partial denture versus CAD/CAM metallic ones in Mandibular Kennedy class I cases: a randomized clinical trial

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Abstract:
Objectives: The aim of this randomized control trial was to compare abutment teeth mobility and gingival health between digitally designed and produced poly ether ether ketone (PEEK) & metallic partial dentures (PDs) in mandibular Kennedy class I cases.
Materials and methods: This study included 24 patients who were partially edentulous with mandibular bilateral free end saddles intended to receive a PD. They were randomly divided into 2 groups; a one to receive a computer aided designed (CAD) PEEK PD as the test group, and the other to receive a CAD metallic PD as the control group. Comparison was made between both groups regarding abutment teeth mobility measured by periotest as well as the periodontal health of the abutments in form of probing depth, gingival index and bleeding on probing.
Results: Mobility values, probing depth, gingival index and bleeding on probing of abutment teeth in both groups were similar with no statistically significant difference.
Conclusion: Both PD framework materials are considered acceptable with no preference regarding abutment teeth mobility and periodontal health
Keywords: CAD/CAM, PEEK, removable partial denture, PD, periotest, abutment teeth, digital partial denture, metal PD, probing depth

Introduction:

PD is a well-established, widely used and valid treatment option for replacing missing teeth. When compared to other treatment options as implants and fixed partial dentures, it is considered to be cost effective and a more conservative treatment option. [1,2]
However, the risk of PD on the periodontal health of the abutment teeth should be considered. Where, its effect on the abutment teeth has been argued in literature. PD may contribute to

plaque retention, which in turn predisposes periodontal inflammation, gingival bleeding and attachment loss. Some studies reported that PD would be harmful to the periodontium of the abutment teeth. However, more recent studies claimed that the risk of gingivitis and periodontal diseases were associated more with a poorly designed PD and/or poor oral hygiene.[1,3]

CAD/CAM technology has been used extensively in PD construction. The use of digital designing and Rapid prototyping technology can improve the fit of the PD and minimize the errors associated with the conventional way of PD construction where multiple time consuming laboratory steps of surveying, block-out, duplication, and wax pattern constructions are digitized and more easily achieved. These would reduce the sources of errors, cost, labor and time. [4–6]

Cobalt-chromium has been commonly used as a PD framework material. It is considered the material of choice for PD for being biocompatible, inexpensive and rigid with good mechanical properties. Moreover, it can be used in thin sections and can conduct temperature allowing for more natural experience. Nonetheless, metallic PD frameworks suffer from some drawbacks as unpleasant display of metal clasp, increased weight of the prosthesis, increased stresses on the abutments, the potential for metallic taste, and possibility of allergic reactions. [7–10]

A number of thermoplastic polymers were introduced in an attempt to overcome problems associated with metallic PD. However, they failed to fulfill the requirements of an acceptable PD. PD frameworks constructed from these polymers suffered from technical drawbacks as the inability to be relined and absence of key PD design features as rests, indirect and direct retention components that could lead to occlusal instability and sinking, especially in Kennedy class I and II cases. This lead to limitation for their wider use. [1,7]

In an attempt in replace metallic components of PD, Poly Ether Ether ketone (PEEK) was reported as PD framework. PEEK is characterized by being high biocompatible, having good mechanical properties with a modulus of elasticity similar to that of the bone resulting in reduced stresses on the abutment teeth, as well as elimination of metal display resulting in better esthetic results. Moreover, they could provide a lighter prosthesis (due to PEEK low specific weight) that can be relined and includes the critical PD design features. Besides, PEEK clasps would allow for healthy periodontium due to the material's low plaque affinity properties. It is assumed that prosthesis with PEEK frameworks in distal extension cases could be beneficial to abutment teeth health. Where, the elasticity of the material would reduce torque force and stresses falling on abutment teeth. [7,9,11]

However, there are no enough studies evaluating PEEK PD as an alternative to metallic ones in terms of its effect on the abutment teeth. The aim of our study was to compare PEEK PD to metallic PD in treating mandibular Kennedy class I regarding abutment teeth mobility and gingival health in terms of: probing depth, gingival index, and bleeding on probing.

Subjects, Materials and Methods:

This randomized clinical trial included 24 patients with partially edentulous mandibular arches. Patients were randomly divided by computer (www.Random.org) into 2 groups (12 patients per

group); one to receive PEEK PD as the study group and the other to receive metallic PD as the control group.

The eligibility criteria included; cooperative motivated patients having bilateral free end saddles in the mandibular arch (Kennedy class I), adequate inter-arch space, opposing dentition intact or restored, Angle's class I maxilla-mandibular relationship, patients with no periodontal diseases and healthy abutment teeth. Patients with systemic disease affecting periodontal health like uncontrolled diabetes were excluded. All patients received detailed explanation about the prosthetic procedures and follow-up periods. Informed consent was obtained from patients who agreed to participate in the study.

PD construction:

All patients underwent thorough assessment clinically and radiographically. Primary impressions as well as diagnostic jaw relation record were taken to obtain mounted study casts. Primary casts were primary surveyed to get the mouth preparation list. Master casts were scanned using bench scanner (DOF – Freedom HD Dental Scanner) and the PD frameworks were digitally designed following the principles of PD and then, 3D printed into castable resin pattern.

The resin pattern was either vacuum pressed into PEEK (Bredent GmbH Germany) framework for the study group, or casted conventionally into metal framework for the control group. After finishing and polishing of PD frameworks, they were seated on master cast and then tried inside the patients' mouth. To obtain the PD, conventional steps of PD construction were followed and delivered to the patients (Figure 1).

Following the insertion of removable partial dentures, oral hygiene instructions were given to each individual. Oral instructions included interproximal flossing, brushing between teeth, and using a soft toothbrush to mechanically clean teeth three times per day. A soft toothbrush was used for mechanical cleaning of removable dentures. Additionally, the subjects were told to soak the denture in water overnight.

Outcomes measurement:

Figure 1: PD insertion (Left: metal PD, Right: PEEK PD)

Effect of PD on abutment teeth was evaluated in terms of abutment teeth mobility, probing depth, gingival health and bleeding on

probing. They were measured before denture insertion, then at 1, 3 and 6 months after PD insertion. The outcome assessor was blinded not knowing the type of PD provided to the patient. Abutment teeth mobility was measured by periotest (periotest classic, © 2023 Medizintechnik Gulden). Periotest is a dynamic instrument developed to measure the periodontium's damping properties in order to provide an objective measurement of tooth mobility. The degree of tooth mobility is showed by a value called periotest value (PTV). This value ranges from -8 to +50 and can be related to clinical tooth mobility grades of Miller (Table 1).[12,13] The hand-piece was held perpendicular to the abutment teeth (Figure 2). To ensure the proper position of the hand-piece, an audible sound is heard from the periotest.

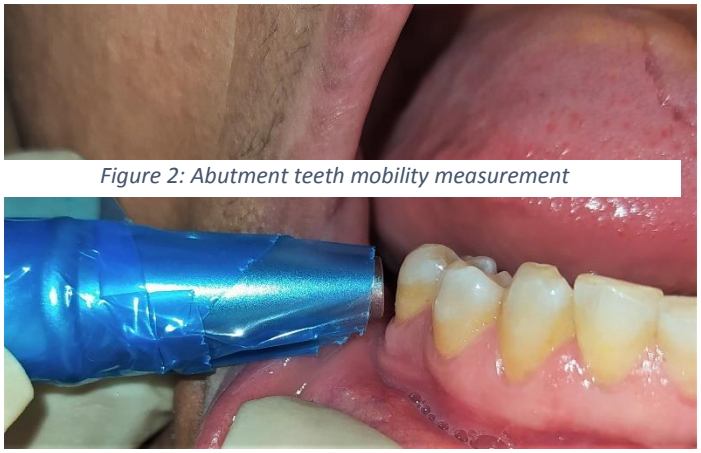

Figure 2: Abutment teeth mobility measurement

Table 1: Periotest values and its relation to scores of tooth mobility [13]:

Periotest value	Mobility (scores)	Miller's original classification
-8 to +9	0	No movement detected
10 to 19	1	First noticeable sign of movement
20 to 29	2	Tooth deviates within 1 mm of its normal position
30 to 50	3	Mobility is easily noticeable, and the tooth moves >1 mm in any direction or can be rotated in its sockets

Probing depth around the main abutment teeth was measured using William's graduated periodontal probe (© 2023 Dentsply Sirona, USA).

Gingival health was evaluated using gingival index of Loe H and Sillness J (1963) with a score of either 0,1,2 or 3 for each main abutment tooth.[14] Score was given as follows:

-Absence of inflammation/Normal gingivae Score of 0

-Mild inflammation, slight change in color, slight edema, no bleeding on probing Score of 1

-Moderate inflammation, moderate glazing, redness, edema and hypertrophy, bleeding on probing Score of 2

-Severe inflammation, marked redness and hypertrophy. Ulcerations and tendency to spontaneous bleeding Score of 3

This was performed visually and with the aid of William's graduated periodontal probe.

Bleeding on probing was evaluated according to Lang. et al. It was reported as 0 for no bleeding and 1 for bleeding on probing.[15] It was performed visually with the aid of William's graduated periodontal probe for each main abutment tooth.

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. In normal data, One Way ANOVA_for multiple comparisons followed by_Tukey`s Post Hoc test was used. To compare between both groups, Independent t-test was used. In non-parametric data, Mann Whitney's test was used to compare between the 2 different groups, while Friedman`s test was used to compare between different time intervals within each group. A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

Results:

24 partially edentulous patients participated in this study with a mean age and standard deviation (±SD) of 39.06 (±5.43). All patients completed the follow up period of 6 months with no dropouts.

Regarding abutment tooth mobility and probing depth, normality test revealed that the significant level (P-value) was shown to be insignificant as P-value > 0.05, which indicated that data originated from normal distribution (parametric data) resembling normal Bell curve in both groups, while in gingival index data normality test revealed nonparametric data.

Abutment teeth mobility:

Results represented in Table 2 and Figure 3 show that comparison between both groups performed using Independent t test (normal data) revealed insignificant difference at all intervals as P>0.05.

Comparison between different intervals in both groups was performed by using One Way ANOVA test (normal data). It revealed insignificant increase in control group (metal) where the PTV slightly increased, while in test group (PEEK) showed insignificant decrease in the PTV values. In both groups, the P-value was higher than 0.05.

Table 2: Mean and SD of periotest values for both groups:

	Control (Metal)		**Test (PEEK)**		**Difference**				
					MD	SED	95% CI		P value
	M	SD	M	SD			L	U	
Baseline	4.50 a	2.20	4.58 a	1.68	-0.08	0.80	-1.74	1.57	0.92
1 Month	4.58 a	2.07	4.33 a	1.72	0.25	0.78	-1.36	1.86	0.75

3 months	4.96 a	1.71	4.00 a	1.60	0.96	0.68	-0.44	2.36	0.17
6 months	5.29 a	1.76	4.17 a	1.53	1.13	0.67	-0.27	2.52	0.11

Means with the same superscript letters were insignificantly different as P>0.05
Means with different superscript letters were significantly different as P<0.05

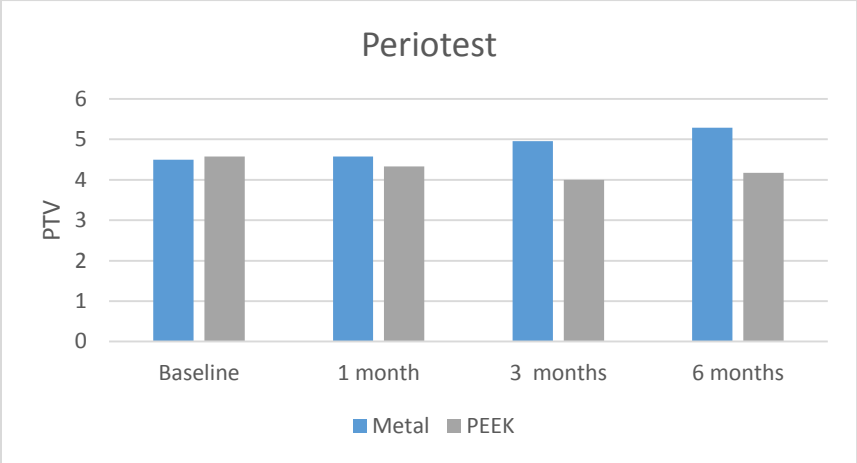

Figure 3: Bar chart representing abutment teeth mobility along time in each group

Probing depth:

Results represented in table 3 and Figure 4 show that there was statistically insignificant difference between both groups at all time periods where P>0.05.

Table 3: Mean & SD of Probing depth for both groups:

	Control (Metal)		**Test (PEEK)**		**difference**				
					MD	SED	95% CI		P value
	M	SD	M	SD			Lower	Upper	
Baseline	1.12 a	0.30	1.04 a	0.26	0.08	0.11	-0.16	0.32	0.48
1 Month	1.11 a	0.27	1.05 a	0.24	0.05	0.10	-0.16	0.27	0.61
3 months	1.15 a	0.31	1.04 a	0.24	0.11	0.11	-0.12	0.34	0.34
6 months	1.16 a	0.32	1.04 a	0.24	0.12	0.11	-0.11	0.36	0.29

Means with the same superscript letters were insignificantly different as P>0.05
Means with different superscript letters were significantly different as P<0.05

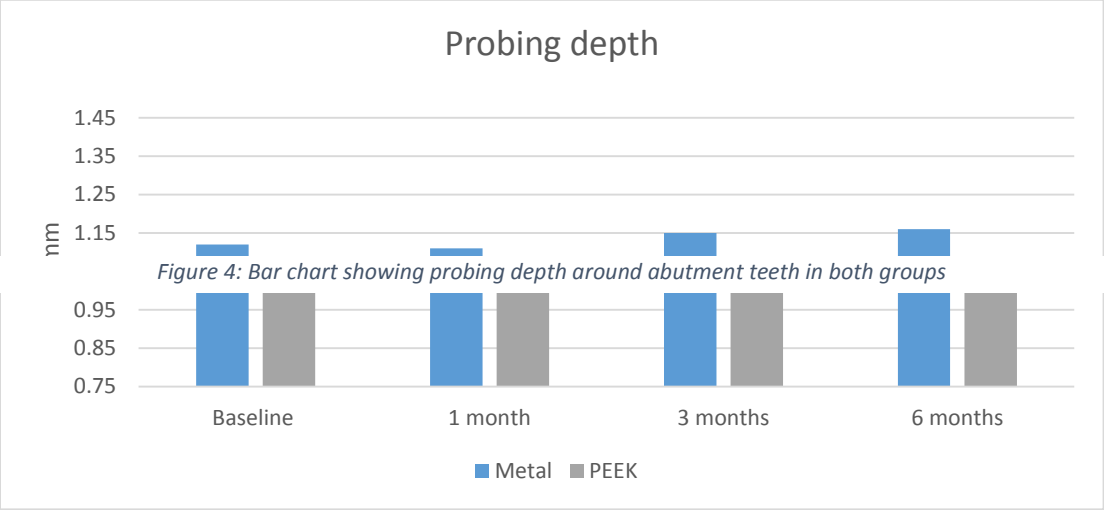

Figure 4: Bar chart showing probing depth around abutment teeth in both groups

Gingival index:

Comparison between both groups was performed by using Mann Whitney's test (non-parametric data) which revealed insignificant difference at all intervals as P>0.05. Comparison between different intervals in both groups was performed by using Friedman`s test (non-parametric data) which revealed insignificant difference in both groups where P>0.05 (Table 4).

Table 4: Mean & SD of gingival index in both groups:

	Control (Metal)		Test (PEEK)		P value
	Mean	SD	Mean	SD	
Baseline	0.75 a	0.45	0.67 a	0.78	0.63
1 Month	0.50 a	0.52	0.67 a	0.65	0.61
3 months	0.33 a	0.49	0.50 a	0.52	0.51
6 months	0.25 a	0.45	0.50 a	0.52	0.31

Means with the same superscript letters were insignificantly different as P>0.05
Means with different superscript letters were significantly different as P<0.05

Bleeding on probing:

Frequency and percentages of presence (1 represented by Yes) or absence (0 represented by No) of bleeding on probing in both groups at all intervals were presented in table 5 and Figure 5. Comparison between both groups was performed to evaluate the effect of treatment by using Chi square test which revealed insignificant difference between both groups as P>0.05

Table 5: Frequency and percentages of presence or absence of bleeding on probing in both groups:

		Absence of bleeding (0) No		Presence of bleeding (1) Yes	
		N	%	N	%
Baseline	Control (Metal)	8	66.7%	4	33.3%

	Test (PEEK)	9	75.0%	3	25.0%
	P value	0.63		0.63	
1 Month	Control (Metal)	9	75.0%	3	25.0%
	Test (PEEK)	7	58.3%	5	41.7%
	P value	0.38		0.38	
3 months	Control (Metal)	9	75.0%	3	25.0%
	Test (PEEK)	8	66.7%	4	33.3%
	P value	0.63		0.63	
6 months	Control (Metal)	9	75.0%	3	25.0%
	Test (PEEK)	10	83.3%	2	16.7%
	P value	0.61		0.61	

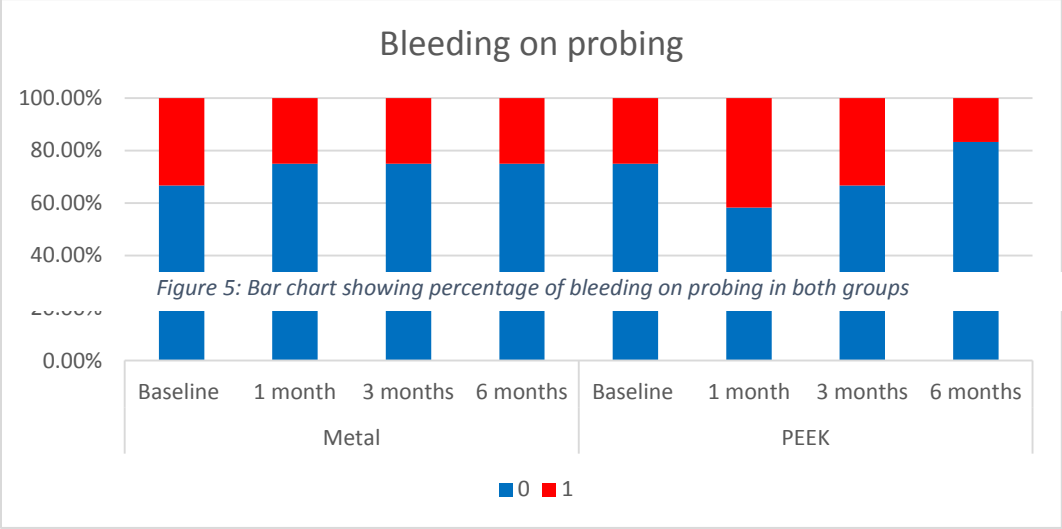

Figure 5: Bar chart showing percentage of bleeding on probing in both groups

Discussion:

Our study was conducted to evaluate the effect of indirectly produced CAD/CAM PD made from metal and PEEK on the abutment teeth. PD in both groups was digitally designed and a resin pattern for the framework was obtained by additive manufacturing technique. This allowed to minimize errors associated with the extensive laboratory steps of conventional method of PD construction allowing for a properly designed PD.

The effect of PD on the periodontium has been argued in the literature. It was reported that PD would be harmful to the periodontal tissue. However, more recent studies claimed that the risk of gingivitis and periodontal diseases were more associated with poor hygiene and/or a poorly designed PD. [1] Where, Longitudinal studies and consensus evaluations have generally concluded that properly designed PDs do not adversely affect the prognosis of the remaining dentition when individuals with PDs maintain acceptable measures of self-performed plaque removal and attend prosthodontic maintenance.[16] Keeping in mind all these as well as the claim of low plaque affinity of PEEK frameworks, the periodontal health of abutment teeth in terms of mobility, probing depth, gingival health and bleeding index were evaluated.

Both subjective and objective methods can be used to evaluate tooth mobility. It is essential to adopt objective methods to evaluate tooth mobility because the use of subjective measures can introduce bias. In the present study, an electro-mechanical device was used to detect mobility. The Periotest was chosen because of its documented ability to produce results that are highly reproducible and its potential to distinguish between minor variations in clinical mobility. It is considered objective, as the readings are automated and the measurements are sensitive.

The results of abutment teeth mobility showed that there was insignificant difference between different time intervals in both groups. The values of both groups across different time intervals remained clinically insignificant where they fell into the range of values corresponding to zero-degree mobility (-8 to 9).[12] This was consisted with Jorge et al who evaluated the mobility of PD abutments. During 6-month follow up period, they did not observe any significant changes in abutment teeth mobility. They suggested that adequate oral hygiene instructions, careful prosthetic treatment planning and regular recall appointments play an important role in preventing changes in abutment tooth mobility caused by PD.

In our study the values of periotest increased slightly in control group and decreased slightly in the study group. This can be attributed to the metal high modulus of elasticity transferring higher stresses to the abutment teeth while that of the PEEK is low similar to the bone which transfers less stress to the abutment teeth.

Upon comparing abutment teeth mobility between both groups, there was no significant difference between them at different time intervals in line with the clinical insignificance of the periotest values where all of them corresponded to zero-degree mobility.

Probing depth showed no significant difference across different time intervals in both groups. There was no significant difference between both groups as well at all follow-up periods. These findings were in accordance with Ali et al.[3] Different results were obtained by Maryod and Taha, who found statistically significant difference between both groups at 6 months. [17] However, in their study they compared digitally designed milled PEEK frameworks to conventionally produced metallic PD. Thus, digital designing and manufacturing acted as another variable rather than the material which may have contributed to the found results.

Gingival index and bleeding on probing showed no statistical significant difference during the follow-up period in both groups as well as between the 2 groups at different time intervals.

The insignificant difference found between the studied groups, can be attributed to the digital designing of the framework regardless of the material used as a framework which helped in reducing errors associated with improper design and laboratory steps. Where, the material did not seem to have an effect on the abutment teeth health. PEEK PD acted similarly to metallic ones. However, further larger studies with longer follow-up period are needed before PEEK PD are recommended for routine use.

Conclusion:

Within the limitation of our study, it can be concluded that digitally produced PEEK PD had similar effect on abutment teeth to digitally produced metallic ones. Both did not show any adverse effects on abutment teeth mobility nor on their gingival health.

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