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Original Research Article

Clinical evaluation of tooth supported single crowns fabricated by modified polyether ether ketone (Bio HPP® PEEK) copings processed through CAD/ CAM technology veneered by indirect composite materials: A pilot study

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Abstract

Purpose: To evaluate the clinical performance of tooth supported crowns fabricated with Bio-High Performance Polymer® polyetheretherketone (BioHPP® PEEK) material copings processed by CAD/CAM technology and veneered with compatible indirect composite materials.

Materials and Methods: Sixty patients with endodontically treated teeth in the posterior region of oral cavity were selected and divided in to two groups. Group A (Control Group) with 30 teeth rehabilitated with conventional tooth supported porcelain fused to ceramic (PFM) crowns. Group B (Test group) with 30 teeth rehabilitated with CAD/CAM processed BioHPP® PEEK tooth supported single crowns. Crowns were assessed on functional and biological parameters at baseline; 06 months and 12 months posttreatment follow up. The inter-group statistical comparison was tested using 'Chi-Square test' or 'Fisher's exact probability test' and intra-group comparison done using 'Wilcoxon's signed rant test'.

Results: On functional parameters of crown decementation, fracture of PFM/composite veneering, fracture of coping and incidence of wear of opposing teeth, evaluated using 'Chi-Square test', 'Fisher's exact probability test' and 'Wilcoxon's signed rant test' did not differ significantly (P>0.05). Similarly on biological parameters, statistically the distribution of bleeding on probing and plaque index among the cases studied did not differ significantly (P>0.05).

Conclusion: Within the limitations of this study, it can be concluded that the BioHPP® PEEK crowns processed through CAD/CAM technology can be considered as an effective and alternate treatment modality to PFM crowns in the stress bearing posterior region of oral cavity.

Keywords: BioHPP PEEK, CAD/CAM Technology

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1. Introduction

Intense environmental concerns in recent times have impelled dentistry to evaluate the performance and environmental impact of all existing dental materials including the materials used in fixed prosthodontics. Traditionally, dental crowns are made out of metals, porcelain, polymers/resin and ceramics. Over the years 'Porcelain Fused to Metal' crowns have established themselves as 'Gold standard'. Nowadays, all-ceramic prostheses are replacing, more and more, metal-based restorations.[1,2] However, these systems have problems like the toughness of the material has raised some concerns about friction against the tooth root and wearing down opposing teeth. Clinically they are too white and more opaque, cohesive and adhesive failures like delamination of ceramic facing, fracture of ceramic core and 'chipping' are recurrent complications and are most important clinical failures of all ceramic restorations.[3] It was quest for overcoming these short comings that led to introduction of one of the aesthetic material i.e. PEEK. Polyetheretherketone (PEEK) is semi crystalline high-performance polymer, synthesized via nucleophilic substitution reaction from bi-phenolate salts and aromatic dihalides.[4] Its biocompatibility, favourable mechanical properties, good dimensional stability at high temperatures, high melting point (about 343°C) and chemical stability to nearly all-organic and inorganic chemicals make it a favourable material for restorative dentistry.[5,6]

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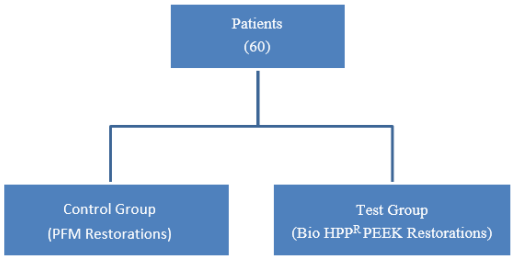
The introduction of modified PEEK material known as 'Bio HPP' ('High Performance Polymers') and compatible veneering composite material can overcome the shortcomings of metal ceramic and zirconia based restorations. The abrasive properties of 'BioHPP® PEEK ' are excellent. Despite of significantly low elastic moduli and hardness, abrasive resistance of BioHPP® PEEK are competitive with metallic alloys.[7,8] However, no clinical studies have attempted to compare the abrasion produced by BioHPP® PEEK crowns on teeth. Hence, it is still unknown if BioHPP® PEEK crowns can function efficiently in harmony with dentin and enamel. Due to limited research on the subject, this study was designed to evaluate the clinical performance of tooth supported crowns fabricated with BioHPP® PEEK material copings processed by CAD/CAM technology and veneered with compatible indirect composite materials.

2. Materials and Methods

Sixty patients with endodontically treated teeth in the posterior region of oral cavity were selected out of which 30 teeth were rehabilitated with conventional tooth supported Porcelain fused to ceramic crowns (gold standard) making Group A (Control Group) whereas 30 teeth were rehabilitated with CAD/CAM processed BioHPP® PEEK tooth supported single crowns making Group B (Test group). Crowns were assessed on functional and biological parameters at baseline, 06 months and 12 months post treatment follow up.



The inclusion criteria were patients (male or female) within the age group of 20 to 55 years, absence of any systemic diseases, patients requiring single crowns on endodontically treated teeth in the posterior region of the oral cavity, adequate crown height and patients having good oral hygiene. Exclusion criteria were a medical history that would complicate the outcome of the study, such as uncontrolled diabetes mellitus, alcohol or drug dependency, history of smoking, poor health or any other medical, physical or psychological reason that might affect the prosthodontic treatment and required follow- up, patients on radiotherapy, patients with TMJ disorders, opposing natural tooth should not be restored with any restoration, crown and should not be a part of any fixed or removable prosthesis, uncooperative and poorly motivated patients. A total of 60 patients who required single crown on endodontically treated teeth in the posterior region of maxillary and mandibular arches including premolars in the age group of 20 – 55yrs were selected for the study.

Patients were selected from the OPD of Department of Dental Surgery and Oral Health Sciences, Armed Forces Medical College, Pune, India. Patients were screened and included based on the inclusion and exclusion criteria listed above. During the screening appointment, medical history was reviewed and Intra Oral Periapical radiographs (IOPA) were taken to check the status of root canal obturation. Cases with adequate crown height (minimum preparation height 4 mm) only were selected for the study. Patients were educated about the research and clinical procedure and informed consent were obtained from them. Patients were asked to be available for up to one year for recall appointments.

The patients were divided into two groups by using block randomization. First group consisted of subjects which were rehabilitated with conventional 30 tooth supported Porcelain fused to ceramic (PFM) crowns. This group of patients were rehabilitated with conventional technique which formed group A, also acted as control group. In second group, subjects were rehabilitated with 30 CAD/CAM processed BioHPP® PEEK tooth supported single crowns which formed group B (test group) **[Figure 1]**.

Prior to any treatment instituted, baseline data measurements were made for shade selection, Bleeding on probing (BOP) and Plaque index (PI) **[Figure 2]**. Tooth shade was chosen using a Vita classic shade guide. BOP and PI were measured using a Williams periodontal probe. Teeth requiring a build-up for appropriate resistance or retention form were treated with composite core prior to crown preparation. All crown preparations were done by a single operator keeping in view all the biological and mechanical principles of tooth preparation. All teeth were prepared using standard recommended preparation guidelines for PFM crowns with water-cooled diamond burs **[Figure 3]**.

The crowns were fabricated as per manufacturer's protocol. Once fabricated and found accurate upon inspection, all the crowns were luted with conventional Type I Glass Ionomer Cement **[Figure 4]**.

Post operatively all the teeth in both the groups were evaluated with the following clinical (biological and functional) parameters at baseline, 6 months, and 12 months post treatment follow up. Any crown showing loss of retention in the follow up period was luted back. For evaluating the functional parameters the 'Modified United States Public Health Service (USPHS) Guidelines' developed by Cvar and Ryge was used in this study. Biological parameters evaluated were bleeding on probing using 'Modified sulcus bleeding index' and Plaque index using 'Loe and Silness plaque index' to assess plaque deposition. The guidelines followed for collating of datas are mentioned below as Modified USPHS Ryge's Criteria, bleeding on probing, plaque index.

2.1. Functional parameters (Modified USPHS Ryge's Criteria)

1. Crown Decementation.

Score	Criteria
0	Intact crown
1	Displacement/ mobility
2	Complete decementation/ loss of crown by patient

2. Fracture of PFM/ composite veneering

Score	Criteria
0	Intact porcelain layering of PFM/ composite veneer of BioHPP PEEK
1	Less than 1/4 th of porcelain layering/ composite veneering loss
2	Porcelain/ composite veneer loss between 1/4th to 1/2 of whole structure
3	More than 1/2 of layering/veneering lost

3. Fracture of coping

Score	Criteria
0	No fracture/ crack in the coping anywhere
1	Crack/fracture through the coping

4. Wear of opposing teeth

Score	Criteria
0	Smooth- the surface of the opposing tooth/teeth surface feels smooth on polishing
1	Rough- the surface of the opposing tooth/teeth has wear facets/feels rough, pitted or grooved or altered anatomy

2.2. Biological parameters

1. Bleeding on probing: Modified sulcus bleeding index (Mombelli et al) was used to assess the BOP score as under:

Score	Criteria
0	No bleeding when periodontal probe was passed along the gingival margin
1	Isolated bleeding spots visible
2	Blood forms a confluent red line on margin
3	Heavy or profuse bleeding

2. Plaque index: Loe and Silness plaque index was used to assess plaque deposition with following criteria:

Score	Criteria
0	No detection of plaque
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.
2	Moderate accumulation of soft deposits within the gingival pocket, or on the tooth arid gingival margin which can be seen with the naked eye.
3	Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

2.3. Statistical data analysis

Data was collected and tabulated and subjected to statistical analysis. The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS Version 22.0, IBM Corporation, USA) for MS Windows. The inter-group statistical comparison of distribution of categorical variables was tested using 'Chi Square test' or 'Fisher's exact probability test' (for 2 x 2 contingency table). The intra-group statistical comparison of distribution of categorical variables is done using 'Wilcoxon's signed rant test' (Non-parametric test for paired data).

3. Results

In the entire study, the p-values less than 0.05 are considered to be statistically significant.

3.1. Distribution of crown decementation between two study groups

The distribution of crown decementation among the cases studied did not differ significantly between two study groups (P-value>0.05).

3.2. Distribution of Fracture of PFM/Composite Veneering between two study groups

The distribution of Fracture of PFM/Composite Veneering among the cases studied did not differ significantly between two study groups (P-value>0.05) **(Table 1)**.

3.3. Distribution of fracture of coping between two study groups

Again the distribution of fracture of coping among the cases studied did not differ significantly between two study groups (P-value>0.05).

3.4. Distribution of wear of opposing teeth between two study groups

Of 30 cases studied only in Group A, 1 (3.3%) case had rough- the surface of the opposing tooth/teeth feels rough, pitted or grooved or altered anatomy at 12-month follow-up. The distribution of incidence of wear of opposing teeth among the cases studied did not differ significantly between two study groups (P-value>0.05) **(Table 2)**.

3.5. Distribution of bleeding on probing (Modified sulcus bleeding index) between two study groups

Of both the groups studied only in Group B, 28 cases (93.3%) had no bleeding when periodontal probe was passed along the gingival margin, 2 cases (6.7%) had isolated bleeding spots visible both at 6 month and 12-month. However statistically the distribution of bleeding on probing among the cases studied did not differ significantly between two study groups (P-value>0.05) **(Graph 1)**.

3.6. Distribution of plaque index between two study groups

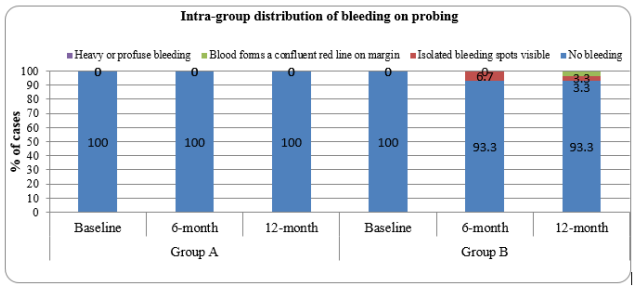
Of 30 cases studied in Group A, none had detection of plaque. Of 30 cases studied in Group B, 2 cases (6.7%) had plaque recognized by running a probe across the tooth surface or crown at 12-month. The distribution of modified plaque index among the cases studied did not differ significantly between two study groups (P-value>0.05) **(Graph 2)**.

Table 1: Intra-group distribution of Fracture of PFM/Composite Veneering among the cases studied.

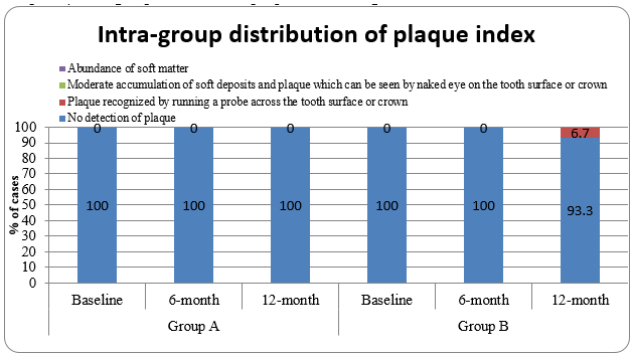
Fracture of PFM/Composite Veneering		**Group A (n=30)**		**Group B (n=30)**	
		N	**%**	**n**	**%**
Baseline	Intact	30	100.0	30	100.0
	Less than 1/4th of PFM /composite veneering loss	0	0.0	0	0.0
	Porcelain/ composite veneer loss between 1/4th to 1/2 of whole structure	0	0.0	0	0.0
	More than ½ of PFM /composite veneering loss	0	0.0	0	0.0
6-months	Intact	30	100.0	30	100.0
	Less than 1/4th of PFM /composite veneering loss	0	0.0	0	0.0
	Porcelain/ composite veneer loss between 1/4th to 1/2 of whole structure	0	0.0	0	0.0
	More than ½ of PFM /composite veneering loss	0	0.0	0	0.0
12-months	Intact	30	100.0	28	93.3
	Less than 1/4th of PFM /composite veneering loss	0	0.0	1	3.3
	Porcelain/ composite veneer loss between 1/4th to 1/2 of whole structure	0	0.0	1	3.3
	More than ½ of PFM /composite veneering loss	0	0.0	0	0.0
P-value (Intra-group	Baseline vs 6-months	0.999^{NS}		0.999^{NS}	
	Baseline vs 12-months	0.999^{NS}		0.180^{NS}	
	6-months vs 12-months	0.999^{NS}		0.180^{NS}	
Values are n (% of cases), P-value by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. NS-Statistically non-significant.					

Table 2: Intra-group distribution Wear of opposing of teeth among the cases studied.

Wear of opposing teeth		**Group A (n=30)**		**Group B (n=30)**	
		N	**%**	**n**	**%**
Baseline	Smooth- the surface of the opposing tooth/teeth surface feels smooth on polishing	30	100.0	30	100.0
	Rough- the surface of the opposing tooth/teeth feels rough, pitted or grooved pr altered anatomy	0	0.0	0	0.0
6-months	Smooth- the surface of the opposing tooth/teeth surface feels smooth on polishing	30	100.0	30	100.0
	Rough- the surface of the opposing tooth/teeth feels rough, pitted or grooved pr altered anatomy	0	0.0	0	0.0
12-months	Smooth- the surface of the opposing tooth/teeth surface feels smooth on polishing	29	96.7	30	100.0
	Rough- the surface of the opposing tooth/teeth feels rough, pitted or grooved pr altered anatomy	1	3.3	0	0.0
P-value (Intra-group	Baseline vs 6-months	0.999^{NS}		0.999^{NS}	
	Baseline vs 12-months	0.317^{NS}		0.999^{NS}	
	6-months vs 12-months	0.317^{NS}		0.999^{NS}	
Values are n (% of cases), P-value by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. NS-Statistically non-significant.					



Graph 1: Intra-group distribution of bleeding on probing (Modified sulcus bleeding index) among the cases studied.



Graph 2: Intra-group distribution of plaque index among the cases studied.

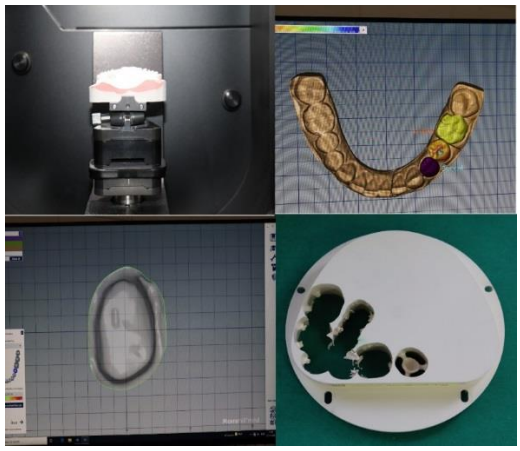


Figure 1: BioHPP® PEEK (Bredent, UK)

Figure 2: Pre Op clinical evaluation

Figure 3: Tooth preparation

Figure 4: Bio HPP® PEEK crown in situ

4. Discussion

Most often the dental crown is the chosen modality for restoration of root canal treated teeth. Porcelain-fused-to-metal (PFM) crowns have been considered the gold standard for restoration of a damaged teeth. PFM crowns have good mechanical properties, satisfactory esthetic results, and an acceptable biological quality needed for periodontal health. However, PFM have poor esthetics because of greyish hue as one of the limitations. Also, the cost of precious metals has risen markedly making PFM relatively unattractive from an economic standpoint. Metal free restorations have been developed for better esthetic outcomes to meet the patient's expectations. Newer materials like dental ceramics and synthetic polymeric materials have provided viable options for metal free crown material. Historically, resin-based crowns were the first metal-free crowns to be used, but they were abandoned because of their low fracture resistance. However the recent advances and better understanding of synthetic polymeric based materials have led to increased popularity of Polyetheretherketone (PEEK) based dental materials. PEEK is the most significant representative of polyaryletherketone (PAEK). PEEK (polyetheretherketone) is a high-performance polymer from the group of polyaryletherketones and is their most important representative.

Traditionally, many of these restorations and prosthetics contained a reinforcing metal framework or substructure that can be replaced with a high-performance polymer (HPP) substitute instead. This has seen PEEKs being used in wider applications such as removable denture frameworks and

implant-borne prosthetic frameworks. In keeping with the advancement of digital technology, many companies have produced CAD/CAM disc devices made from PEEK-based compounds (e.g., BreCAM, Bredent, Germany or Dentokeep, NT-Trading, Germany).

It is important to check on the indications for use prior to selecting a disc for the manufacture of a particular part. With the increasing patient and clinician demand for metal free restorations, there is increased interest surrounding the use of HPPs such as the PEEK as metal alternatives for such cases. Such a material is extremely interesting for use as the framework for metal free prostheses due to its proven biocompatible nature and resilience[7,8] and the potential shock absorbing nature of the PEEK material. If the crown fabricated from BioHPP PEEK like materials gives comparable clinical results, it can be advocated as an alternative to present metal ceramic restorations in the posterior region of the oral cavity producing better clientele satisfaction.

Prersently, very few clinical studies are available that clinically assess this material in the high stress zone of posterior region hence; there is a need to clinically evaluate this material. Therefore this novel study was taken up for clinical assessment and comparison of the both crown materials using functional parameters like crown decementation, fracture of composite veneering, coping fracture and wear of the opposing teeth. Biological parameters like bleeding on probing and plaque index were also evaluated for the both crown materials.

For evaluating the functional parameters the 'Modified United States Public Health Service (USPHS) Guidelines' developed by Cvar and Ryge[9-13] was used in this study. Biological parameters evaluated were bleeding on probing using 'Modified sulcus bleeding index'[14,15] and Plaque index using 'Loe and Silness plaque index' to assess plaque deposition.[16]

All the clinical parameters including gender and age distribution between Group A and Group B at the baseline were comparable to each other and statistically insignificant.

On the clinical parameter of crown decementation it was observed that both Group A and Group B had no failure as far as the decementation distribution was evaluated. Both study groups data did not differ statistically significantly when their data distribution was compared at baseline, 6 months and 12 months follow up (P-value > 0.05). This is consistent with findings of a previous study by Zoidis P et al.[17]

All the study subjects when evaluated for intact crown, displacibility or complete decementation/ loss of crown by patient at 6 months and 12 months showed that both had statistically insignificant result. When the values were subjected to intragroup 'Chi-Square test' and 'Wilcoxon's signed rank test' statistically insignificant results were obtained. The results showed that both the materials are comparable as far as retentive properties are considered when proper luting protocols are followed. The use of BioHPP® PEEK crowns material not only showed good retention but further reduces the modulus to 4 GPa, protecting the weakened root and tooth structures subsequent to root canal therapy. These results are consistent with the study conducted by Zhou L et al.[18]

The intergroup distribution of fracture PFM veneering loss or composite veneering loss when evaluated using 'Chi-Square test' were found to be statistically insignificant at baseline and 6 months time interval however they were statistically significant at 12 months interval with loss of veneering of various degree observed in study Group 2. The Modified USPHS Ryge's Criteria based intragroup evaluation using 'Wilcoxon's signed rank test' for comparison of fracture of PFM veneering or loss of composite veneering among the study groups did not differ significantly suggesting that when manufacturer's direction for layering of porcelain or layering of composites compatible to the BioHPP® PEEK crowns are adhered, both crown materials showed comparable results (**Table 1**). The bond strength of BioHPP® PEEK with veneering composite resin material and the tooth structures have been demonstrated to be adequate and this was ensured with use of manufacturer prescribed layering technique and use of proper bonding agent and luting cement. The combination of BioHPP® PEEK veneered with indirect composite resin resulted in an uncomplicated clinical evaluation and occlusal adjustment before cementation without the complication of fracturing the veneering material. The esthtetic appearance can be equal to that of ceramics since they were layered with compatible composite material.

Both the study groups showed excellent results when evaluated for fracture of the copings. There was no fracture or crack propagation in any of the study groups showing that BioHPP® PEEK crowns exhibited good strength properties comparable to metal copings. PEEK exhibits a modulus of elasticity of 4 GPa, which could dampen force transmission, thereby preventing the tooth and subsequently the root from overloading and breakage.[19] PEEK as a core material further reduces the elasticity of the composite resin veneering material from 8 to 10 GPa to 4 GPa. Therefore a BioHPP® PEEK foundation restored with indirect composite resin complete crown could be another possible solution. Similar findings were reported in previous studies.[19-22] This type of restoration can be faster, simpler and economic option offering the stress breaking effect with good esthetic results.

Etman[23] reported in his investigation that the metal-crowns produced the least tooth wear and the Procera AllCeram veneered with feldspathic porcelain (Ducera) was the most abrasive ceramic which caused more tooth wear than the metal-ceramic (Simidur alloy veneered with IPS Classic)

and the other experimental glass-ceramic (IPS Empress/lost wax technique); it also suffered the greatest loss of test material. On the contrary Silva[24] results showed that the metal-ceramic crowns (Argendent alloy veneered with IPS.d.SIGN) caused the highest tooth wear volume compared to the other tested all-ceramic crowns. The results of present study were in agreement with Silva[25] as we found that in study Group 1 wear of opposing tooth was observed after 12 months period (**Table 2**). However 'Chi-square test' and 'wilcoxon's signed rank test' analysis results didn't differ significantly when evaluating the wear of the opposing teeth. Ceramics are considered high stiffness materials with a high modulus of elasticity. This high stiffness could result in excessive loading and wear of opposing teeth may have negative impact on the biomechanical properties of abutment teeth and opposing teeth. More often PFM crowns if not properly evaluated before luting may cause wear of opposing teeth.[23-25] BioHPP® PEEK with a lower modulus of elasticity and composite resins have been proved to reduce occlusal stress and wear of opposing teeth by acting as stress breaker.[26,27] The results of this study are in agreement with studies by Costa PS[26] and Gracis S[27] as we found no opposing tooth wear over one year period in Group 2 study sample which consisted of BioHPP® PEEK material based crowns.

For the long-term survival of restorations like crowns the periodontium must also remain healthy or vice versa. In this study we found that gingival and plaque indexes to be better in PFM crowns when compared to BioHPP® PEEK crowns (Graphs 1 & 2). This may be attributable to numerous factors[28,29] like type of finish line, location of margins, luting cement used, finish of the material etc. The one big disadvantage of BioHPP® PEEK crowns is that they cannot be polished intraorally. However the finding of this study showed that the biological parameters like bleeding on probing or plaque indexes were not statistically significantly different for both the materials. These findings are in agreement with studies conducted by Sinha N,[9] Najeeb S,[30] and Zoidis P.[17]

Owing to the advances in CAD-CAM and restorative materials, better accuracy of prostheses and large volume restorations can be achieved with BioHPP® PEEK crowns. No statistical differences were detected between the BioHPP® PEEK crowns and PFM crowns and clinical and biological parameters indicated that BioHPP® PEEK crowns could meet the requirements of crowns in the posterior region of the oral cavity. This study found that BioHPP® PEEK exhibited relatively good properties especially, good retention of the copings and not causing abrasion to opposing arch teeth with excellent esthetic properties, however the high cost of armamentarium and material required to fabricate PEEK restorations as compared to PFM restorations should be considered as one of the factors during selection of material for full coverage restorations.

5. Limitations

Smaller sample size and short follow up period are the major limitations of the present study. Therefore it would be desirable to carry out a study with a larger sample size and a longer follow up to validate the use BioHPP® PEEK crowns as viable alternative to porcelain fused to metal restorations. Also the control and test group are studied in different patients, so there is a risk of bias in the results due to non-standardization of various oral factors. So it is recommended to conduct split mouth studies so as to standardize various factors which can affect the outcome of the restoration.

6. Conclusion

Considering the mean observation time of a year, BioHPP® PEEK single crowns seem to exhibit promising clinical survival rates with excellent patient satisfaction and not much of mechanical failure and biological reactions as well. Within the limitations of this pilot study, it can be concluded that the BioHPP® PEEK crowns processed through CAD/CAM technology can be considered as an effective and alternate treatment modality to PFM crowns in the stress bearing posterior region of oral cavity.

7. Source of Funding

AFMRC Project (5018/2018).

8. Conflict of Interest

None.

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