

Clinical evaluation of performance of single unit polyetheretherketone crown restoration-a pilot study

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Abstract

Aim: The aim of this study was to evaluate the clinical performance and patient satisfaction of PEEK Crowns.
Setting and Design: In-vivo longitudinal pilot study.

Materials and Method: 20 PEEK crowns were placed in 20 patients. 11 were placed in the maxilla and 9 were placed in the mandible. All procedural steps were performed by the same operator. The teeth were prepared with a chamfer finish line of 0.8 to 1 mm. The crowns fabricated were luted using resin cement. Using Modified Ryge's Criteria, the crowns were examined for anatomic form, marginal integrity, surface roughness, restoration staining, marginal discoloration and color match at a time interval of 1 week, 1 month, 3 months, 6 months, one year. Patient satisfaction was also evaluated at the same interval using a questionnaire.

Statistical Analysis Used: The data collected was evaluated using fisher's exact test.

Results: Based on modified Ryge's criteria, almost 90% of the crowns were rated satisfactory. Fracture was registered in only one crown. Slight chipping off was seen in two crowns. No significant difference was seen in any other factors assessed. Slight variation was seen in the periodontal status of 3 patients.

Conclusion: Within the limitations of this study the following conclusions were drawn that the PEEK crowns demonstrated by the use of Modified Ryge's Criteria, its capability to produce quality prostheses that were rated satisfactory with a relatively low rate of fracture over the relative mean period of one year.

Keywords: Longitudinal studies, patient satisfaction, polyetheretherketone, resin cements

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Received: 19th June, 2019, **Revision:** 10th October, 2019, **Accepted:** 20th November, 2019, **Publication:** 27th January, 2020

INTRODUCTION

The advancement of porcelain fused to metal (PFM) procedures has represented PFM restorations as the "gold standard" for years together. However, in this ever-evolving field of dentistry, the growing patients' demand for highly esthetic and natural appearing restorations has led to the

development of new materials with improved mechanical characteristics providing suitable longevity. Material science has metamorphosed and seen a widespread evolution in the types of materials being used such as precious metals to all ceramic to zirconia to polyetheretherketone (PEEK). Zirconia is one of the most promising restorative materials

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Quick Response Code:	Website: www.j-ips.org
	DOI: 10.4103/jips.jips_228_19

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How to cite this article: Sulaya K, Guttal SS. Clinical evaluation of performance of single unit polyetheretherketone crown restoration-a pilot study. J Indian Prosthodont Soc 2020;20:38-44.

because it yields very favorable mechanical properties and acceptable aesthetics. However, failures related to both biologic complications like secondary caries and technical problems such as fracture of the bridge or chipping of the veneering ceramic have been reported.^[1] This led to the introduction of PEEK into dentistry.

Materials used for prosthetic rehabilitation are always subjected to complex and changing humid and wet oral environment which is physiologically characterized by natural saliva and its components. There will be a wide fluctuation in the results that are procured *in vitro* and *in vivo*. PEEK has been extensively used for implant abutments but its use as a tooth supported prosthesis is limited. The reason for this is due to its opaque nature and grayish color. However, this has been overcome by the use of suitable layering materials such as composites. The usage of composites as a layering material for the permanent full-crown restoration is quite rare but there are various studies done previously advocating this. Alonso and Caserio^[2] conducted a long-term assessment of the clinical behavior of direct composite full-coverage crowns using transparent strip crowns as a matrix. The long-term outcomes in the cases performed using these clinical techniques are satisfactory. Therefore, composite material has proven to be effective in emerging as one of the permanent restoration layering material for prosthodontic restorations. The use of this material as layering option is beneficial to manage postoperative repairs and can be easily blended with the changes seen with time due to dynamic occlusion. So composite layered over the PEEK copings may be effective as a viable aesthetic restoration. After scrutinizing its properties, use of PEEK in fixed dental prosthesis is gaining popularity. Majority of the studies conducted till date are *in vitro*,^[3-9] and very few clinical studies^[10-12] document the longevity

of the restoration and its clinical performances. Although taking into consideration the favorable mechanical properties of PEEK, there is lack of acceptance. Therefore, this study was conducted to intraorally check the durability, longevity, and performance of PEEK crowns.

MATERIALS AND METHODS

This was a pilot study conducted on twenty patients who required crown placement (on vital/non vital tooth) in the posterior segment. The sample size was estimated using the formula $N = Z^2 \sigma^2 / E^2$. The patients were selected based on certain inclusion and exclusion criteria.

The inclusion criteria considered for selection of the patients were that the tooth may be vital or nonvital which is periodontally healthy also with no signs of bone resorption or periapical pathology. Tooth with adequate occlusogingival height was considered. Patients having a complete dentition in the opposing arch were selected. Patients with unacceptable oral hygiene, periodontal disease, and reduced crown length were excluded.

Procedure

Informed consent from the patients and ethical clearances from the committee was taken with the IRB No. 2016/P/PROS/76. All procedures performed in the study were conducted in accordance with the ethical standards given in 1964 Declaration of Helsinki, as revised in 2013. For all of the twenty patients, the same procedure enlisted below was followed. Preoperative status of the gingival tissue of the tooth to be restored was assessed. Radiographs and diagnostic casts were made to analyze the periapical status and contour and height of the tooth, respectively. The tooth preparation was done according



Figure 1: Inner surface of the peek crown



Figure 2: Outer composite layering

to standard operative procedures. The standard operative procedures were developed based on the guidelines given by Shillingburg *et al.*^[13] The tooth to be restored was prepared with a chamfer finish line of 0.8–1 mm and an overall reduction of 2 mm. 1.5–2 mm of occlusal clearance was given. After tooth preparation was completed, isolation was carried out, and then, gingival retraction cord (Ultapak, USA) was placed using a cord packer into the gingival sulcus. This helped in achieving sufficient retraction following which impressions of the prepared tooth were made using stock trays loaded with putty (Dentsply Sirona, Germany) and light body elastomeric impression material (Reprosil light body, Dentsply, USA). The impression of the opposing arch was made as well. Temporary crowns were fabricated using 3M ESPE PROTEMP 4. They were finished and cemented using noneugenol-based temporary luting cement (Provicol, Germany).

The models were made from the final impression using die stone (Elite rock, Zhermack, Italy) which were then scanned using a scanner. The coping was designed using a CAD program. The PEEK (Auvaro, United Kingdom) coping was milled using CAM. PEEK frameworks were coated with Visioliink (Bredent, Germany) followed by layering with composite (ADORA Composite, Shofu Ceramage) as per design [Figures 1 and 2]. The final restoration was then checked intraorally for any premature contacts. Once all aspects were evaluated the restorations were cemented using resin cement (RelyX™ U200, Germany). The patient was recalled after a week and rubber base impressions were made. Interocclusal wax records were made using aluwax for future analysis of anatomical form and occlusal wear. This was done by measuring the cast in terms of cuspal height of the restored tooth using a digital Vernier caliper.

The patient was recalled at intervals of 3 months and 6 months and 1 year. At the recall intervals, the restorations were evaluated using modified Ryge's criteria.^[14] The criterion included assessment of anatomical form, restoration staining, marginal discoloration, color match, surface roughness, marginal adaptation [Table 1], and periodontal status [Table 2]. At the recall visit of 1 year, the crowns were evaluated on the same basis as done on the previous two recall visits and the patients were asked to fill a self-administered questionnaire developed for this study to assess their level of satisfaction, on a 5-point Likert scale. Patient satisfaction was evaluated using this questionnaire that allowed patient to grade their fixed crowns according to a scale from 1 to 5, in which 1 was least favorable [Annexure 1]. The data were thus recorded and evaluated. The data obtained was systematically organized, and statistical analysis was carried out.

Table 1: Modified Ryge's criteria

Anatomical form (percentage of tooth volume lost)
I. <10% loss
II. 50%-90% still remaining
III. <50% still remaining
Restoration staining (Labial/incisal surfaces only)
I. None - No staining on the surface of the restoration is visible
II. Mild - <25% of the surface of the restoration is stained
III. Moderate - <50% of the surface of the restoration is stained
IV. Severe - >50% of the surface of the restoration is stained
Marginal discoloration (Whole labial margin only)
I. No staining - No staining of the margin is visible
II. Staining - Staining of the margin is visible
Color match
I. Acceptable - The restorative material matches the adjacent tooth structure
II. Unacceptable - The match between the restorative material and adjacent tooth structure is beyond an acceptable range
Surface roughness
I. Smooth - The surface of the restoration feels smooth to the probe
II. Rough - The surface of the restoration feels rough, pitted or grooved
Marginal adaptation
I. No catch - The probe does not catch when drawn over the margin of the restoration
II. Catch - The probe does catch when drawn over the margin of the restoration

Table 2: Periodontal status

Periodontal status
I - Healthy gingiva
II - Mild inflammation - Slight color change and edema, no bleeding on probing
III - Moderate inflammation - Redness, edema and glazing, bleeding on probing
IV - Severe inflammation - Marked redness and edema, tendency to spontaneous bleeding

RESULTS

A total of 20 participants received PEEK crowns, all of which had complete occlusal contact with the opposite arch. No participants were lost to follow-up during the observation period.

The survival rate at 1 year was 95%. There was one fracture of framework that had to be replaced during the observation period. A modified Ryge's rating of satisfactory was given for 100% of the crowns at all examinations.

As for restoration staining, at the time interval of 3 and 6 months, 3 crowns (15%) had mild stains. At the 1-year follow up, 2 crowns (10%) had mild staining and 1 crown (5%) had moderate stains [Figure 3]. The color match of all the crowns were satisfactory and did not vary much from the baseline to the 1-year follow-up except for one crown (5%) for which $P = 1.00$. Similarly, when marginal discoloration was measured, 4 crowns (20%) showed slight staining at the margins. P value thus calculated was 0.137

Table 3: Scores recorded at various time intervals

	Anatomic form			Staining				Periodontal status				Marginal discoloration		Color match		Surface roughness		Marginal adaptation	
	I	II	III	I	II	III	IV	I	II	III	IV	I	II	I	II	I	II	I	II
Baseline	100	-	-	100	-	-	-	100	-	-	-	100	-	100	-	100	-	100	-
3 months	95	5	-	85	15	-	-	85	15	-	-	80	20	100	-	95	5	100	-
6 months	95	5	-	85	15	-	-	80	15	5	-	80	20	100	-	95	5	100	-
1 year	90	10	-	85	10	5	-	60	30	10	-	80	20	95	5	95	5	85	15

n=20. Scores of patient evaluation in percentage

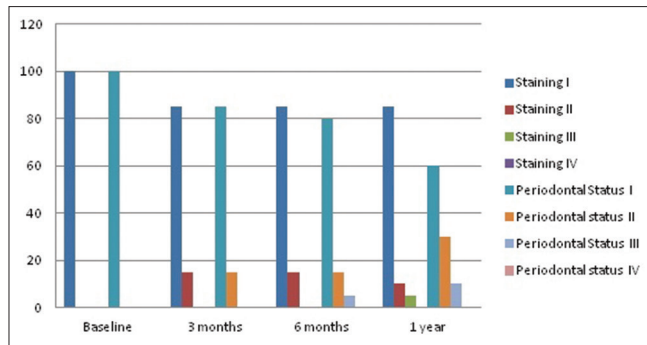


Figure 3: Staining and periodontal status evaluation at different time intervals using modified Ryge's criteria

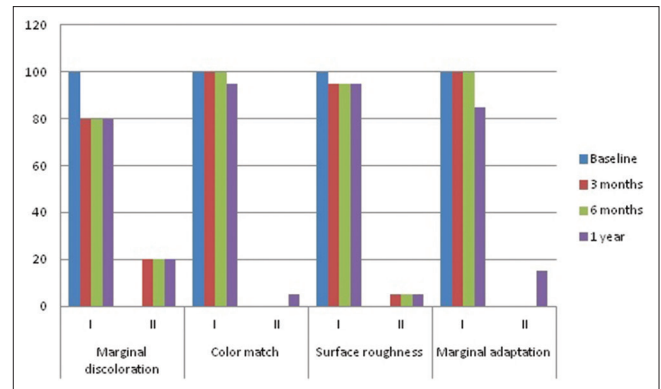


Figure 4: Evaluation of marginal discoloration, color match, surface roughness, and marginal adaptation at different time intervals using modified Ryge's criteria

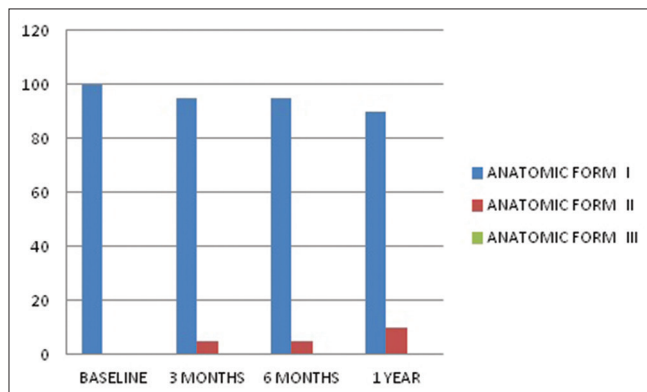


Figure 5: Evaluation of anatomic form at different time intervals using modified Ryge's criteria

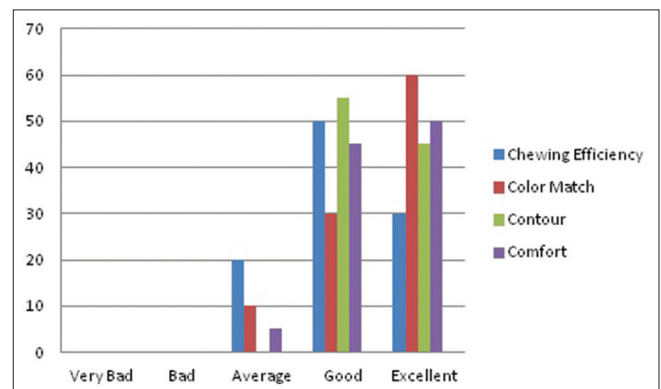


Figure 6: Evaluation of the crown by the patient

[Figure 4]. The surface roughness was observed in one participant (5%) and $P = 1.00$. The marginal adaptation was ranked as excellent in 85% of the restoration after 1 year. P value calculated was 0.056 for the same [Figure 4]. During the assessment of anatomic form, it was found that one crown had fractured at the time interval of 3 months and had been replaced. There was a slight chipping of composite in 2 of the crowns at the interval of 6 months and one year, respectively. P value obtained using Fisher's test was 1.00 [Figure 5].

Significant difference was seen between the periodontal status at baseline and at 1-year recall. At 3 months, 3 (15%) patients had mild inflammation, and at 6 months, 3 (15%) patients had mild inflammation and 2 (10%) patients showed moderate inflammation. This was statistically significant as well with $P = 0.029$ [Figure 3 and Table 3].

Patient satisfaction regarding esthetics and comfort was positive at all examinations. All patients had graded the prosthesis with a score of 3–5 on an average [Figure 6 and Table 4]. Three patients (15%) reported of sensitivity/pain in the tooth but no changes were seen periapically [Table 5].

DISCUSSION

The first factor assessed was the anatomical form. The results showed that 90% of the crowns had retained its anatomic form. There was a fracture seen in a crown at 3 months which was on the buccal surface. More than 50% of the composite had fractured. Even though special care was taken during occlusal adjustment to minimize occlusal load, this fracture may be due to

Table 4: Patient satisfaction scores

	Very bad	Bad	Average	Good	Excellent
Chewing efficiency	0	0	20	50	30
Color match	0	0	10	30	60
Contour	0	0	0	55	45
Comfort	0	0	5	45	50

n=20. Scores of patient evaluation in percentage

Table 5: Patients evaluation of sensitivity

	Present	Absent
Sensitivity	85	15

n=20. Scores of patient evaluation in percentage

localized biting forces, premature contact at the crown margin, or tensile stress. At 6 months' recall, there was a slight chipping off seen in another crown which did not require any repair. This may also be due to a premature contact. There was a slight wear in a crown seen at the end of 1 year recall. This may be due the friction that occurred in the patient due to tooth movement as the patient was undergoing orthodontic treatment. In a similar study conducted previously by Crisp *et al.*^[14] to assess the all ceramic crowns, no fracture or chipping off of the ceramic was observed. Uhrenbacher *et al.*^[15] conducted a study and after surface pretreatment different adhesive systems were coated over the surface and they concluded that the adhesion of the tested PEEK crowns to dentin was enhanced by the use of additional adhesive systems such as visio link or Signum PEEK Bond after treatment with airborne-particle abrasion or etching with sulfuric acid. A study conducted by Peláez *et al.*^[16] evaluating zirconia crowns stated that 35% of variation in anatomic form was seen with 10% wear. This increased fracture rate may be considered because of increased recall period of 3 years. A study conducted by Taskonak and Sertgöz^[17] evaluated Lithia disilicate based all ceramic crown found chipping in 10% of crowns at 1-year recall interval.

Marginal integrity/adaptation was satisfactory in all cases. 15% of cases showed slight catch this may be due to dissolution of high viscosity luting cements. In studies conducted previously evaluating ceramic and zirconia crowns both showed 1 bridge, respectively, with poor margin adaptation. The study evaluating Lithia disilicate crown showed poor margin adaptation, i.e., 40% crowns had a catch and in 20% of the crown, the enamel/dentin was exposed.^[16,17]

There was a significant difference in the periodontal scores from the baseline to 1-year recall. This may be because no standard oral hygiene protocol was implemented. On the contrary, in the study evaluating all ceramic bridges, there

was an improvement in the gingival status of the patient from 82 to 85% to 95%–100%. However, in the study conducted to evaluate zirconia crowns, no such changes were seen. A study evaluating Lithia disilicate crown recorded 70%–80% of patients with healthy gingiva and 20%–30% with mild inflammation.^[14,16,17] The surface roughness evaluated in this study gave a score of 5%. This may be due to slight wear or chipping off etc. In the study done on zirconia crowns, 5 participants of 20 complained of roughness of the surface.^[14] Participant of the all ceramic study complained of surface roughness and 20% patients in the Lithia disilicate study complained about the same.^[14,16,17]

Almost 95% of color match was found in this study which is quite comparable to the all ceramic study and the zirconia study where 5% mismatch was seen. This may be related to the operators' error in color matching. 80% of color match was observed in the Lithia disilicate crowns. 20% of the crowns showed marginal discoloration and staining which may be due to various habits of the patient or may be improper finishing of the prosthesis. No staining was seen in any studies that were conducted to evaluate all ceramic or zirconia crowns.^[14,16,17]

Patient satisfaction in this study was considered, and on an average, around 50%–60% of the participants had given a score of 5 (excellent) and around 20%–30% scored it at 4 (good) and around 10%–20% scored it at 3 (average). In a previous study done on zirconia, 72% of the participants scored it at 1 (excellent) and 18% scored it at 2 (good).^[16] In this study, 15% of the patient complained of sensitivity with respect to the tooth. No clinical evidence was found to confirm the same. In a similar study evaluating Lithia disilicate crowns, 5% of participants reported of sensitivity, and in a study done on all ceramic bridges, 3 out of 37 patients complained of sensitivity.^[16,17]

Implant healing abutments can be fabricated using PEEK because of its biocompatibility. A randomized clinical trial conducted by Koutouzis *et al.* suggested that there is no significant difference in the bone resorption and soft tissue inflammation around PEEK and titanium abutments. And also, the oral microbial flora attachment to PEEK abutments is comparable to those made of titanium, zirconia, and polymethylmethacrylate. The elastic moduli of bone and PEEK are very much comparable due to which it reduces the stress shielding effects and encourages bone remodeling. Hence, titanium could be replaced by PEEK in near future for construction of implant abutments.^[18,19]

Despite the aforementioned information, the main limitation of this study was that there might have been an operators' error in the accuracy and reliability of methods to measure these factors. May be combination of two or more methods may have been used. In addition to this, there was no standardization of oral hygiene practice, and also, the survival rate of the prostheses needs to be evaluated for a longer term.

Further studies may be carried out to compare the PEEK crowns fabricated using different methods (surface treatment and bonding). A split mouth study can also be done to compare it with another material.

CONCLUSION

Within the limitations of this study, it can be concluded that the high level of accuracy of fit (crown retention, marginal quality and marginal accuracy) and esthetic accomplished with PEEK material was deemed very satisfying. During the observation period no marginal discoloration or caries were noticeable. The patients also were extremely satisfied by the feel and comfort of the crown. Even though these crowns could not completely mimic the translucency of natural teeth still were capable enough to give a good esthetic match and provide good patient satisfaction. Considering the mean observation time of a year, 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.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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ANNEXURE

Annexure 1: Questionnaire

1. How do you rate your prosthesis with respect to chewing?

1	2	3	4	5
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2. How do you rate your prosthesis with respect to color matching?

1	2	3	4	5
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3. How do you rate your prosthesis with respect to contouring?

1	2	3	4	5
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4. How do you rate your prosthesis with respect to comfort?

1	2	3	4	5
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*1-Very bad 2-Bad 3-Average 4-Good 5-Excellent

5. Is there any sensitivity/pain with respect to the tooth?

1	2
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*1- Yes 2-No