

One-Year Clinical Evaluation of Patient Satisfaction for CAD/CAM BIOHPP PolyEtherEtherKetone (PEEK) Versus Zirconia Veneered Single Crowns (Randomized Controlled Clinical Trial)

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Abstract

Aim: Comparing the clinical performance of CAD/CAM BioHPP PEEK- based crowns to zirconia veneered crowns through evaluation of patient satisfaction.

Methodology: 24 full coverage crowns were fabricated for Molars. Scaling and polishing were performed for all the patients one week prior to preparation. Regarding crowns' material patients were divided into 2 main groups: In Group 1 (control group) patients received Zr veneered crowns while in Group 2 (intervention group) patients received PEEK crowns. Supra- gingival, chamfer finish line is performed for all teeth during preparation as a method of standardization. CAD/CAM (CAM5-S1) machine with software (Exocad) was used for performing try-in and provisionalization. All restorations were veneered and surface treated regarding the manufacturer's instructions. All the crowns were cemented by using self-adhesive resin cement (by BISCO). During follow up visits evaluation of shade and function to determine patient satisfaction by questionnaire. Measurements were repeated every (2- 4- 6- 8- 10 and 12 months respectively).

Results: Fisher's Exact test was used in comparison between groups. There was no statistically significant difference between the 2 groups (P-value = 1, Effect size = 0.478) for every time.

Conclusion: Both PEEK crowns and Zr veneered crowns revealed successful clinical performance from patient satisfaction and clinical performance aspect. The two materials showed no significant difference; regarding the patient satisfaction and clinical performance.

Keywords: Patient Satisfaction; Biocompatibility; Zirconium Veneered Crowns; PEEK Crowns

Introduction

The field of esthetics in dentistry is of increasing importance, especially in the anterior region. The missing metal margin and the much better translucency of all ceramic compared to metal-ceramic restorations made full ceramic restorations the first choice. To facilitate the application of esthetic veneer a core framework is placed over the prepared teeth to increase the strength of final restoration [1,2]. As the core material faces multidirectional forces for many years so its mechanical properties are important [3,4]. Their esthetic properties were usually very poor so it needed veneering materials to reach patients satisfaction. Yet, that led to more complications such as cracks, chipping of veneering materials, and fracture which affect esthetics of restoration. Zirconia crowns have highly smooth surface which reduce plaque accumulation and eliminates darkening around the gingival area, due to absence of

metal margins so it is considered highly biocompatible material. Zirconia is highly opaque material so it needs to be veneered with a veneering material to reach ideal esthetic properties. Zirconia has high toughness so its friction against opposing teeth may lead to wearing down the opposing teeth [5]. In the last few years, more tolerable material such as Polyaryletherketones (PAEKs) are raised to meet patients demands and expectations for a very high quality work, it is a high- performance thermoplastic material, that used at planes and cars manufacturing because of their low weight and good mechanical properties [6]. PEEK can be used for a wider range of possible products due to its combination between crystalline and amorphous material properties. PEEK as a new material still needs more clinical studies to compare this it with other gold-standard dental materials [7]. Moreover, PEEK based restorations

have cushion effect. The low modulus of elasticity of which absorb occlusal forces and act like natural teeth, so it was important to study the clinical performance of polymer PEEK restorations as a valuable alternative to the classic metal framework materials and Zr framework [8].

Materials and Methods

Study design

This study was performed in clinics of Fixed Prosthodontics Department, Faculty of Dentistry, Cairo University, Egypt. Twenty-four esthetic crowns were fabricated by the researcher who followed the 5 phases of fabrication of full coverage restoration: diagnosis, preparation design, temporization, material construction and cementation. 2 groups (each group included 12 crowns) were included in our study. All restorations were fabricated by one experienced dental technician.

Patients' selection

A total of twenty-four patients were selected for this study with an age range between twenty-three to fifty years old. Each patient received a full coverage crown for carious tooth in molar region. Their chief complaint was to improve their functional mastication, smile and appearance.

Patient education and approval

All patients have been subjected to sessions of patient education about crown importance, advantages, maintenance and care. The whole treatment plan, prosthetic procedures and follow up consultations were explained for each patient. Patients required to sign a consent form to participate in the study before proceeding to clinical work. All patients were motivated to maintain good oral hygiene measures. For badly decayed teeth or endodontically treated teeth there must be at least 1 mm of tooth structure above the gingival margin, glass-fiber posts (FibreKleer 4X, Pentron clinical. USA.) and composite cores (Build-It FR, Pentron clinical. USA.) were used to give adequate resistance and retention form.

Inclusion criteria:

1. From eighteen to fifty years old, who can read and sign the informed consent document.
2. Have no active pulpal or periodontal diseases, have teeth with good restorations.
3. healthy participants able to withstand usual dental procedures.

4. Patients with problems in their teeth indicated for single posterior crowns (Teeth restored with large filling restorations - Badly decayed teeth - Endodontically treated teeth - Malposed teeth - Malformed teeth - Spacing between teeth in molar region.
5. Committed for follow-up examinations and evaluation.

Exclusion criteria:

1. Young patient less than 18 or old patients more than 50 years.
2. Patient with active periodontally affected teeth.
3. Patients with poor oral hygiene and uncooperative patients.
4. Pregnant women.
5. Patients in the growth stage with partially erupted teeth.
6. Unrealistic expectations or psychological problems.
7. Smokers.
8. Patients with para-functional habits.
9. Missing opposing teeth.

Randomization sequence generator

Participants were allocated in 2 different groups with 1:1 allocation ratio by using computerized sequence generation (www.randomizer.org).

Group A	Group B
11	23
15	2
4	12
21	16
13	5
18	22
9	6
1	17
24	20
7	14
10	8
3	19

Blinding

participants and the outcome assessors were blind to the material but the operator was not as there is difference in restorative material presentation and application protocol. All patients were divided into two groups (each group included 12 patients):

1. Group (1) control group: Teeth with full coverage Zr veneered restoration in the molar zone.
2. Group (2) intervention group: Teeth with full coverage PEEK restoration in the molar zone.

Scaling and polishing

Scaling and polishing procedures were done for all participants before beginning of study to remove any dental plaque or calculus which may interfere with the shade selection and final results.

Photographs

Pre-operative photos were captured for all participants using 105 mm Nikon macro lens with twin flash R1C1 mounted on Nikon D7100 DSLR camera (Nikon, Japan).

Tooth preparation

A putty silicon index was done for each participant. Condensation silicon impression material (Zetaplus, Zhermack, Italy) was used. For standardization and assessment of the amount of preparation, one index with vertically cut and another index with horizontally cut at the middle of the tooth requiring the restoration. Another putty index was made on the diagnostic wax up cast for making temporary restorations later on. Teeth preparation was performed following the guidelines of all ceramic restoration preparation criteria as the axial wall reduction (1 mm) by tapered stone with round end (head length=10mm and end Ø =1.1 mm) (850-314-016, Komet, Germany), 2 mm occlusal reduction with 1 mm deep chamfer finish line and 90 degrees cavo-surface to prevent unfavorable distribution of forces on the crown. And to avoid stress concentration all line angles and point angles were rounded and smoothed (Figure 1).



Figure 1: Preparation of teeth.

Sample grouping

Group (I) control group	Group (II) intervention group	Total number
Zirconia veneered crowns (n = 12)	BioHPP crowns (n = 12)	N = 24

Table 1: Sample grouping.

Impression

Final impression was taken with 2 steps impression technique using vinylpolysiloxane addition silicon in plastic stock trays. first step was taken just before finishing of the preparation with heavy viscosity then to produced homogenous mix the light viscosity was applied using auto mixing tips and dispensing gun.

Provisionalization

The silicon index fabricated over the waxing up was used for making temporary restoration. Bis-acrylate resin composite temporary material (RelyX Temp NE, 3MESPE, USA) applied in the putty index and placed on the prepared teeth. After final setting of the material, the index was removed. the Provisional restoration was removed. Finishing and polishing of the restoration. Non-eugenol, acrylic-urethane polymer based temporary cement was used for temporary cementation.

Crowns fabrication

An extra oral scanner was used to scan the master casts and a three-dimensional image was obtained for abutment teeth on the computer screen.

Designing for the final restoration was done using Exocad software (Exocad software, Exocad GmbH, Germany), The software calculated virtual model from the captured pictures which were saved in the preparation folder. The margin finder tool was used to detect the margin of the preparation. Marginal thickness was set at 0.3 - 0.5 mm and axial wall thickness and occlusal thickness at 0.3 - 0.5 mm, for Zr copings according to manufacturer instructions. While axial wall thickness was set at 0.5 mm and the occlusal thickness at 1 mm for Emax veneering material, according to manufacturer instructions.

In PEEK copings, marginal thickness was set at 0.7 - 1 mm and axial wall thickness at 0.7 - 1 mm, according to manufacturer in-

structions. While the axial wall thickness was set at 0.3 mm and the occlusal thickness at 0.5 mm for composite veneering according to manufacturer instructions. The cement space was determined by the software to be 50 μ for both materials. For milling of all temporary and final restorations 5-axis milling machine (CAM 5S-S1, VHF CAMFACTURE, Germany) was used. CAD wax disc (Kurary Noritake wax 14 mm) was used for CAD/CAM wax-patterns try in, PMMA blocks were used for temporary restorations, while zirconia was used for final restoration frameworks of the control group and PEEK for the intervention group. The milling burs sizes used were (2.5 mm, 2 mm, 1 mm and 0.5 mm).

Try in

The try-in was made by using the CAD/CAM milled Polymethyl methacrylate (PMMA). All surfaces of prepared teeth were cleaned by polishing brush then washed by water. CAD/CAM PMMA was tried to check marginal fit, contacts, shape, anatomy, contour and then its overall integration with cheeks and finally with the teeth faces. This was used as the functional try in and temporary restoration. The wax patterns from the same design were performed by CAD wax to make framework of each crown. First try in was done by PMMA material to adjust occlusal plane and proximal contacts then use it as temporary restoration for each patient. The second try in was made by CAD wax for adjustment of proximal surfaces and occlusal contacts then it was scanned after adjustment. The overlap the adjusted scanned CAD wax over the original design made on the software before milling of the final restorations. This was made to eliminate any minute discrepancies found in the final restorations according to Wassell, *et al.* 2002 [9]. Glaze firing was done in the IPS EP 3010, using a fluorescent glazing paste. After mixing the glaze paste with the IPS e.max Ceram Glaze and Stain Liquids to the desired consistency, the glazing material was applied in an even layer to the restoration.

Cementation of the crowns

Preparation for bonding

Polishing paste and brush mounted on low-speed contra angled hand piece was used to clean the tooth surfaces before bonding to clean any remnants of temporary cement. To avoid weakening of bond strength of final cement. 37% phosphoric acid used for etching of tooth surfaces for 30 seconds then rinsed with water then dried. A layer of bond was applied and cured for 20 seconds. Then, rubber dam was used for granted isolation.

Preparation for bonding of PEEK crowns

The fitting surface of the crowns were prepared for bonding by placing crowns in ultrasonic cleaner. Then sandblasting by Al_2O_3 (110 μ m) at 2 to 3 bar blasting pressure. Moistening then performed by light-hardened PMMA and Composite Primer "Visio.link" and frequent polymerization was performed with a light polymerization device for 90 seconds according to the "Visio.link" processing instructions.

Preparation for bonding of zirconia veneered crowns

Crowns were cleaned with 9% hydrofluoric acid, then rinsed with water after the try in.

The entire internal surfaces of the Zr crowns were etched with 9.5% buffered hydrofluoric acid for 20 seconds to clean all surfaces according to the manufacturer instructions. Then crowns were rinsed by water for 20 seconds and air-dried. Following this regime, the crown surfaces would be clean and had chalky white appearance similar to etched enamel. Ceramic primer was applied to the fitting surface of the crowns and remain for 1 minute then thinned by air Then dried for 5 seconds.

Dual cured adhesive resin cement (BisCem[®], Bisco, U.S.A) was added to the fitting surfaces of each crowns using auto mixing tip. All crowns were seated to their corresponding teeth in position till complete seating just using finger pressure. Sharp explorer was used to remove excess cement removed after 2 seconds of light polymerization then light curing by 480 mW/cm for 40 seconds from each surface of every tooth. For removal of inter-proximal excess cement a waxed dental floss was used. Moreover, any occlusal interference after complete curing will be checked by using an articulating paper.

Follow up visits

The outcomes of every group were assessed by three different evaluators over the one year duration of this study. The data Collected from the patients pre- operatively then post cementation (Base-line data), then after 2- 4- 6- 8- 10 and 12 months.

Outcome

Outcome listed in table 2.

Outcome	Measuring unit	Patient assessment
Patient satisfaction Numerical from 0 = unsatisfied to 10 = satisfied	Satisfaction about the "Shape" of the crown	
	Satisfaction about the "Size" of the crown	
	Satisfaction about the "Color" of the crown	
	Satisfaction about the "Mastication Efficiency"	
	Satisfaction about the "Ease of Cleaning" of the crown	
	Satisfaction about the "Sound" of the crown during occlusion and mastication (Clicking)	

Table 2: Outcome and measuring units.

Patient satisfaction as we performed a questionnaire delivered to the patient asking him/her about shade, shape, size, masticatory efficiency, ease of cleaning and sounds during function. Then they gave scores about their satisfaction ranging from 0-10 as Zero = totally unsatisfied and 10 = totally satisfied.

The main investigator recorded the phone numbers and address of the patients involved in the study. All the patients were receiving a phone call before the next appointment. great efforts were made to promote participant retention such as, sending messages greetings in the feasts, any celebration and in his/ her birthday.

Results

Qualitative data were presented as frequencies and percentages. For comparison between groups Fisher’s Exact test was used. For studying time changes within each group Friedman’s test was used. Normality tests and data distribution were used to check the data (Kolmogorov-Smirnov and Shapiro-Wilk tests). Age data showed normal (parametric) distribution while patient satisfaction scores showed non-normal (non-parametric) distribution. Data were presented as mean, standard deviation (SD), median and range values. To compare between age mean values which is parametric data in the two groups Student’s t-test was used. To compare between the groups’ non-parametric data, Mann-Whitney U test was used. For time changes within each group Friedman’s test was used. And for pair-wise comparison Dunn’s test was used when Friedman’s test is significant. Significance level was $P \leq 0.05$. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp. was used for statistical analysis.

Comparison between the results the 2 groups (Table 3). After 2, 4, 6, 8, 10 as well as 12 months; there was no statistically sig-

nificant difference between the two groups regarding satisfaction with shape, size, color, masticatory efficiency, ease of cleaning as well as sound of the crown (clicking). There was also no statistically significant difference between the 2 groups regarding total satisfaction score.

Results of the changes by time in each group (Table 3). As regards ZR group; the overall score was constant through the study period; so, no statistical comparisons were performed. In PEEK group; patient’s satisfaction by time had a statistically significant difference (P -value < 0.001 , Effect size = 0.547). Pair-wise comparisons between the follow-up times revealed that there was no statistically significant change in patient’s satisfaction scores after 4 months as well as from 4 to 6 months followed by a statistically significant decrease in satisfaction scores from 6 to 8 months regarding shade of the restorations PEEK crowns appeared darker after this period by one degree. From 8 to 10 as well as 10 to 12 months; there was no statistically significant change in patient’s satisfaction scores (Table 3 and figure 2).

Discussion

This study was double blinded randomized clinical trial. Randomization was done using (www.randomizer.org) to prevent the bias in patients’ selection. This study was designed as randomized clinical controlled trial (RCT) to translate the research data into clinical practice [12].

As for United States Public Health Service criteria, evaluating patient’s satisfaction for comparison of clinical performance of PEEK crowns to Zr veneered crowns.

All teeth involved in the study were molars. Conventional preparation for full coverage restoration was done. All teeth were

Time	ZR (n = 12)		PEEK (n = 12)	
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)
2 months	9.3 (8.5-9.7)	9.2 (0.4)	9.4 (8.5-10) ^A	9.3 (0.4)
4 months	9.3 (8.5-9.7)	9.2 (0.4)	9.4 (8.5-10) ^A	9.2 (0.5)
6 months	9.3 (8.5-9.7)	9.2 (0.4)	9.4 (8.3-9.7) ^A	9.2 (0.4)
8 months	9.3 (8.5-9.7)	9.2 (0.4)	9.3 (8.3-9.7) ^B	9.1 (0.4)
10 months	9.3 (8.5-9.7)	9.2 (0.4)	9.3 (8.2-9.7) ^B	9.1 (0.5)
12 months	9.3 (8.5-9.7)	9.2 (0.4)	9.3 (8.2-9.7) ^B	9.1 (0.5)
P-value	Not computed		<0.001*	
Effect size (w)			0.547	

Table 3: Median and range values for patient’s satisfaction scores in the two groups.

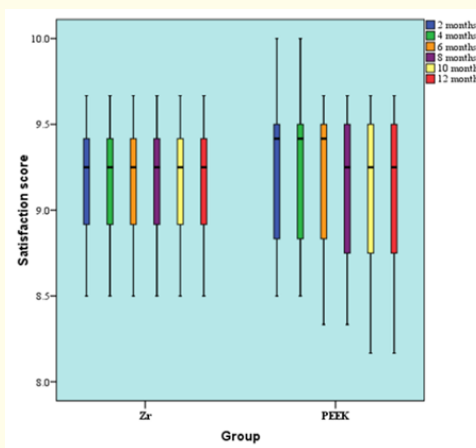


Figure 2: Box plot representing median and range values for patient’s satisfaction scores in the two groups.

prepared according to manufacturer’s guidelines. All contours and angles were prepared, rounded and smooth. 1 mm thickness chamfer finish line equi-gingival with rounded internal angles, 2 mm occlusal reduction was done and 2 planes labial reduction. For standardization of tooth preparation, silicon indices were done prior to preparation, the first was done with vertical cut and the second index with horizontal cut for checking of final preparation. This procedure secured uniform reduction of teeth for all involved cases.

Extra oral scanner was used for master models scanning with and Exocad software was used to make the design of the final

restoration. Frameworks’ thickness was determined according to manufacturer instructions [13]. The try-in was fabricated from Polymethyl methacrylate (PMMA) blocks. It was first used for trying in the marginal fit, the contours, contacts and the final shape of the restoration. This PMMA crowns were then used as temporary restoration and were made with the same digital processes used for fabrication of final restoration. PMMA has many advantages including good marginal fit, much more comfortable for the patient, natural-look, highly esthetic, very durable and they’re the strongest temporary restoration available. The temporary restorations were cemented using non- eugenol, provisional cement to avoid inhibition of polymerization of the resin final cement [14].

The marginal fit of PMMA temporary crowns made by CAD/CAM showed better results than temporary crowns made by bis-acrylic composite- based auto-polymerizing resins [15,16].

5-axis CAM 5-S1 milling machine was used to fabricate the restorations instead of three-axis milling machine to gain better shape dimensions and fit of the restoration to the abutment. As 5-axis CAM 5-S1milling machine is more efficient in milling complicated restoration in single setup in less time, and also eliminates operator error. The short cutting tools with decreasing the head size and accurate orientation of the cutter resulting in higher cutting speeds without too excessive pressure that allow the machine to produce complex parts. Also, it improved tool lifespan by maintaining a constant chip load and adequate cutting position [17].

Zr was used in our study because of the high mechanical properties and good esthetics when used with veneering materials such as Lithium disilicate (LD) [18].

In the control group zirconia core restorations were veneered with Lithium disilicate (LD), as it is evidence based in previous studies as a successful veneering material. is biocompatible lithium disilicate glass-ceramic through which lithium oxide crystals are dispersed [19]. The needle-like crystals and the incorporation of fluorapatite crystals in the glass matrix of IPS e.max are responsible for strength, durability and the high optical properties of the material. The LD restoration is chemically stable and has excellent compatibility with surrounding periodontal tissues. To decrease plaque retention Glazing was done to the final restoration to provide a smooth surface. While, due to the few studies and documentation of the performance and biological reaction of soft tissue and periodontium to PEEK restorations so it was used as the intervention group in our study. Bio HPP is a high-tech thermoplastic polymer based on PEEK containing ceramic fillers with a size of about 0.3-0.5 microns which occupy 20% of Bio HPP which enhance polishing of the restorations leading to better shade stability and less plaque retention [20,21].

9% buffered hydrofluoric acid for 20 seconds was used for surface treatment of the internal surface of zirconia restorations, to provide clean surface with higher surface area and micromechanical retention with the resin cement. A layer of silane coupling

agent was placed for 60 seconds on the etched surface, to create a chemical bond with the hydroxylated porcelain and the resin matrix of the resin cement. It also improve the wettability of the resin cement. While for PEEK crowns Cera-lign was placed after moistening with light-hardened Composite Primer "Visio. Link" and light cured for 90 seconds in accordance with the "Visio.link" processing's instructions for PEEK crowns [22-24].

Bis Cem dual-cure self-adhesive resin cement was used for cementation of all restorations in our study following the manufacture instructions to prevent variations during the bonding step. According to previous studies resin cement bonding with the tooth surface micromechanically and chemically and that increase retention and decreases the marginal discrepancies. The use of self-adhesive resin cements simplified the procedures and eliminated the technique sensitivity of multiple-step systems [24].

Etching and bonding or priming of the abutment teeth was done prior to cementation to provide micromechanical bonding with resin cement. Then cement was added on the crowns then seated with finger pressure and excess cement was removed.

After cementation of the crowns, follow up visits were scheduled every 2- 4- 6- 8- 10 and 12-month respectively. At least one year follow up was done because the current outcomes were objective and to understand the changes on these objective outcomes, sufficient repeated measurements are needed over long period of time [25].

And also, the nature of self-report and the inability to blind allocation status could produce a significant non-specific placebo effect. According to a review performed by Kangas., *et al.* [26], which found only little differences between various psychological interventions or mood related interventions. That's based on a placebo or Hawthorne effect, which is mostly provisional. Repeated recall visits and measurements done an adequate time span could resolve this question.

In the current study the follow-up visits were done every 2 months to improve the maintenance of treatment plan which is useful in objective outcomes. Moreover, this improved the motivation of the patient and eliminate the deterioration of the case [25].

Patient satisfaction was used as an outcome in this study as several authors have reported discrepancies between the treatment needs perceived by patients and those assessed by dental professionals. Thus, patients in this study were provided with questionnaires to determine their satisfaction based on mastication and shade stability.

Results revealed high patient satisfaction in patients received Zr veneered crowns, while there was statistically non significance decrease in patient satisfaction after 6 months in patients received PEEK crowns. As 3 patients from the PEEK crowns group noticed that the crowns' shade became darker after 6 months from cementation. That's may be due to its composition, as PEEK is 70% polymer filled with 30% glass fillers, [26] as bisphenol glycol dimethacrylate (bis-GMA), triethyleneglycol dimethacrylate (TEGDMA) and urethane dimethacrylate (UDMA) are parts of polymer components of PEEK and they are hydrophilic; so, they perform water sorption and strong intermolecular interaction, exhibited low degree of conversion and was prone to water uptake as reported to be common properties in all polymer-based restorations. Moreover, PEEK contained organic-modified filler which increase the water sorption; this could explain change in shade after 6 months [26].

Conclusion

Within limitations of the current study, the following conclusions could be drawn: Both zirconia veneered and PEEK crowns revealed successful clinical performance regarding patient satisfaction.

PEEK crowns could be considered as an acceptable alternative restoration material to all ceramic crowns.

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