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Marginal integrity and clinical evaluation of polyetheretherketone (PEEK) versus lithium disilicate (E-Max) endocrowns: Randomized controlled clinical trial

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***Abstract*---**Aim: Evaluate the marginal integrity and Clinical performance of PEEK endocrowns compared to lithium disilicate (E-Max) ceramic endocrowns. Methodology: Twenty six endocrowns were fabricated for posterior endodontically treated teeth. Patients were divided into two groups according to the material used for fabrication of the restorations; Group 1(control group) received E-Max endocrowns while Group 2 (intervention group) received Bio HPP PEEK endocrowns. The marginal integrity and internal fit were assessed using the silicon replica approach, in which each replica was sectioned into four segments, each with five reference points that were evaluated using a digital microscope at 35X magnification. After final cementation, the clinical performance of the restorations was evaluated according to the USPHS criteria in terms of marginal adaptation, fracture, and retention. These measurements were

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repeated after three, six, nine and twelve months respectively. Results: The marginal and internal gaps of both groups were within the clinical acceptable range, but E-Max group recorded statistically significant higher internal gap mean value than PEEK group. Regarding the clinical performance all restorations showed 100% alpha and there was no significant difference between both groups for all tested outcomes (Marginal adaptation, fracture, and retention) over one year. Conclusions: (1) PEEK endocrown restorations revealed better internal fit than E-Max. (2) The marginal and internal fit for E-Max press and Bio HPP PEEK press endocrown restorations revealed a clinically acceptable range. (3) Both E-Max press and Bio HPP PEEK endocrown restorations showed high successful clinical performance in terms of marginal adaptation, fracture, and retention over a period of one year.

***Keywords*---**Marginal Integrity, Clinical evaluation, PEEK, Lithium disilicate, Endocrowns.

Introduction

Endodontically treated teeth often have major coronal mutilation, which compromises their structural integrity and puts them at a greater risk of biomechanical failure than vital teeth [1].For many years, post and core supported restoration was the standard treatment option. The preparation for post-insertion, on the other hand, might weaken the remaining tooth structure, increasing the risk of catastrophic tooth fracture. Recently the endocrown proved as an alternative more conservative choice and gained great popularity. Since then many studies searched for the best material to fabricate this type of restoration and found that the material of choice was the lithium disilicate glass ceramics yet drawbacks, including greater stiffness and rigidity which could compromise marginal adaptation were reported. Furthermore, high stress values will be created with a negative impact on the biomechanical behavior of the restorative system when used to replace dentin [2].

Bio HPP PEEK is 20 % ceramic reinforced polymer that was recently introduced as a new type of PEEK material and has been proposed for various prosthodontic applications [3, 4]. From a biomimetic standpoint, the less brittle PEEK restorations have mechanical characteristics that are similar to those of human dentin, allowing them to function as a cushion and absorb forces [5]. But very limited data used it for fabrication of endocrowns. Consequently this study aimed to investigate the marginal integrity and the clinical performance of polyetheretherketone (PEEK) versus lithium disilicate (E-Max) endocrowns.

Participants and Methods

Sample size calculation

Based on a previous study by Elalem, et al. (2019) [6] indicated that the Mean± SD of the control group with marginal gap was 73.49±5.29 microns. As no randomized controlled clinical trials that compare both groups were done before, the minimum clinically important difference was estimated by a clinical expert and the estimated marginal gap of the intervention is 80 microns. Using power 80 % and 5% significance, a sample size of 11 restorations in each group would be needed.

Research ethics approval

This study and the template informed consent form reviewed by the Ethics Committee of Scientific Research - Faculty of Dentistry – Cairo University, and approved in July 2019.

Study design

This study was performed in Fixed Prosthodontics Department clinics of Faculty of Dentistry, Cairo University, Cairo, Egypt. A total of 26 endocrowns were fabricated in this study. They were divided equally into 2 groups (n=13). All procedures starting from diagnosis till delivery were carried out by the same investigator who followed a meticulous clinical procedure for standardization. The endocrowns were fabricated by the same dental technician to eliminate any variations.

Participant's selection

A total of 26 patients were selected for the study. Their chief complaint was to restore their posterior endodontically treated teeth back to normal and to prevent further damage like fracture. Each participant received endocrown for a molar.

Randomization

To avoid selection bias in our study, the participants were randomly divided into 2 groups with a 1:1 allocation ratio by using random sequence generator of web site (WWW.RANDOM.ORG).

Allocation concealment

The patients were numbered from (1-26) on folded papers placed in opaque sealed envelopes.

Blinding

This clinical trial was double blinded to avoid risk of any bias the assessors and the statistician were blind throughout the whole procedures and follow-up visits.

Prosthetic steps:

Diagnostic phase: Intra-oral examination, photographs, diagnostic casts, diagnostic wax up, scaling and polishing, and shade selection were done.

Tooth preparation phase: A proper occlusal reduction of 2 mm was performed using a wheel stone bur to have enough room for the endocrown material thickness and to obtain a 90° butt joint margins. The minimum width and height of the axial walls were 2 mm to have proper bonding of the endocrown restoration and to ensure having enough strength of the remaining tooth structure. A central retentive cavity with a depth of at least 3 mm that extended into the pulp chamber space was also created to ensure sufficient resistance and retention, along with occlusal divergence of 8 to 10 degree. All internal wall transitions were smoothed. In order to decrease stresses a smooth flat pulpal floor preparation design was obtained by the help of flowable composite [5, 6, 7, 8]. Using a graduated periodontal probe, the researcher measured and checked the depth of the pulp chamber cavity, as well as the width and height of the cavity walls. A putty rubber impression index was taken before the secondary impression to guarantee adequate endocrown preparation and to check for any irregularities in the pulp chamber.

Impression making phase: Final impressions were taken using addition silicon in two step impression technique.

Provisionalization: Using bisacrylate composite resin material (Dento Crown. ITENA, France).

Master cast construction: The final impression was poured with a type IV dental stone.

Endocrown fabrication: First an extra oral scanner (Ds Mizar) was used to scan the master cast. Then Designing was done using Exocad software. After that the try in was milled from PMMA blocks using 5-axis milling machine (Shera eco mill 5x, Germany). After try in approval the CAD/CAM wax-patterns were designed and milled; which was full anatomy for E-Max endocrowns and copings for Bio HPP PEEK endocrowns.

Bio HPP endocrown fabrication

The milled wax pattern coping was sprued in the ring, investment mixed and poured then transferred to a preheating oven for wax elimination. After that a suitable amount of Bio HPP granules were added and melted then the plunger was inserted and the mold was then transferred into the 2 press system which is a special system for peek pressing. The Bio HPP coping was then sandblasted and veneered with composite according to the manufacturer instructions where the visio.link adhesive material was applied then cured in special bench top light polymerization device for 90 seconds. Then a mix of opaquer combo.lign base and catalyst was made and placed on the surface of the core and light cured for 180 seconds which enhances bonding to the following layers of composite and act as a wash opaque. Composite layers were then applied started with Crea.Lign opaquer, then dentin layer, followed by the enamel layer. Each composite layer was polymerized for 360 seconds. And finally the visio paint was used for staining and characterization and then cured for 180 seconds. Finishing was done using the Ceragum rubber polisher, pre-polishing was carried out using a goat hair brush dipped in Acrypol polishing paste, and polishing was done using high luster polishing paste and cotton buffing wheel to have a highly polished endocrown restoration.

Lithium disilicate endocrown fabrication

The IPS Press VEST premium, together with the IPS Ring System were used to invest the wax pattern. Preheating and wax elimination were done using Programat EP3010 system. After that the investment was loaded with emax press ingot. Plunger was inserted and pressing started. After finishing and polishing the final restoration was glazed using a fluorescent glazing paste.

Silicon replica fabrication

Before the restoration delivery a silicon replica was fabricated by injecting a light-body silicon replica in the fitting surface of endocrown restoration then inserting it over its corresponding preparation inside the patient mouth for 2-3 minutes. After removal putty silicon was applied over it to stabilize it. Each replica was then sectioned buccolingually and mesiodistally into four segments. The digital microscope was used for measuring the thickness of the light-body silicone for all replicas at 5 reference points: Two points located at the pulpal floor (A,B), one midpoint of the axial wall (C), one point at the line angle (D), and one point at the cavosurface angle (E), in which (A, B, C) points were used to assess the internal fit, while (D, E) points were used to assess the marginal integrity.

Bonding of endocrowns:

- Bio HPP endocrowns surface preparation for bonding: After being checked in the patient's mouth the PEEK endocrowns were cleaned in an ultrasonic cleaner, blasted with aluminium oxide particles, then Moistened with "Visio.link" adhesive material and cured for 90 seconds.
- E-Max endocrowns surface preparation for bonding: The inner surfaces of the E-Max endocrowns were etched by hydrofluoric acid; after that they were rinsed with water and air dried giving the chalky white appearance then a single coat of the ceramic primer was applied to the endocrowns.
- Final cementation of the restoration: Both PEEK and E-Max restorations were bonded using Self-adhesive dual cured resin cement.

Postoperative instruction and care

The patients were instructed that Brushing and flossing should be done on a regular basis using a non-abrasive fluoride tooth paste and a soft brush.

Follow up protocol

Over one year every three months, each patient had a follow-up session to assess the marginal adaptation, fracture, and retention clinically. The following up was done in accordance with the USPHS grading (United States Public Health Service). During follow up period, all patients attended in the control group and the intervention group.

Statistical analysis

All Data was collected, checked, revised, tabulated and entered into the computer. The results were analyzed using Graph Pad Instat (Graph Pad, Inc.) software for windows. A value of $P < 0.05$ was considered statistically significant.

For numerical quantitative data (marginal and internal gap) Continuous variables were expressed as the mean and standard deviation. After homogeneity of variance and normal distribution of errors had been confirmed, one-way analysis of variance was performed followed by Tukey's post-hoc test if showed significance. Student t-test was done for compared pairs. Correlation between internal and marginal gap was detected by Pearson correlation. Sample size (n=13) was large enough to detect large effect sizes for main effects and pair-wise comparisons, with the satisfactory level of power set at 80% and a 95% confidence level. For qualitative data (clinical performance in terms of marginal adaptation, fracture, and retention) were presented as frequency & percentages. As all restorations showed 100% alpha no statistical comparison performed.

Results
Regarding marginal and internal gaps using replica technique:

For Peek group, it was found that the highest gap mean value was recorded at pulpal site (67.56 μm) followed by axial site (52.99 μm) while the lowest gap mean value was recorded at marginal site (51.53 μm) and this was statistically significant as designated by ANOVA test ($P=0.02 < 0.05$). Pair-wise Tukey's post-hoc test showed non-significant ($p > 0.05$) difference between axial and marginal sites. Totally it was found that with peek group the internal gap (pulpal + axial) was statistically non-significantly higher than marginal one as proven by paired t-test ($p =0.1652 > 0.05$)

For E-Max group, it was found that the highest gap mean value was recorded at pulpal site (88.41 μm) followed by axial site (76.61 μm) while the lowest gap mean value was recorded at marginal site (58.78 μm) and this was statistically significant as proved by ANOVA test ($P=0.0015< 0.05$). Pair-wise Tukey's post-hoc test showed non-significant difference between (axial and pulpal) sites. Totally it was found that with E-Max group the internal gap (pulpal + axial) was statistically significant higher than marginal one as confirmed by paired t-test ($p =0.003 < 0.05$)

Comparison between Peek group and E-Max group at different sites

Comparison of gap results in microns showing mean, standard deviation (SD), minimum, maximum and 95% confidence intervals (low and high) values between both groups as function of measurement sites are summarized in table (1) and graphically drawn in figure (1).

Internal gap

Pulpal site, it was found that E-Max group recorded statistically significant higher internal gap mean value (88.41 µm) than Peek group (67.56 µm) as indicated by student t-test (P=0.0096 < 0.05).

Axial site, it was found that E-Max group recorded statistically significant higher internal gap mean value (76.61 µm) than Peek group (52.99 µm) as showed by student t-test (P=0.0035 < 0.05).

Marginal gap

Marginal site, it was found that E-Max group recorded statistically non-significant higher marginal gap mean value (58.78 µm) than Peek group (51.53 µm) as indicated by student t-test (P=0.2338 > 0.05).

Table (1)
Comparison of gap results in microns (Mean values SDs) between both groups as function of measurement sites

Variables		*Mean*	*± SD*	*95% CI*		*Statistics*
				Low	*High*	*P value*
Pulpal	*Peek group*	67.56	15.41	59.18	75.94	0.0096*
	E-Max group	88.41	21.83	76.54	100.27	
Axial	*Peek group*	52.99	17.52	43.47	62.51	0.0035*
	E-Max group	76.61	19.65	65.93	87.29	
Marginal	*Peek group*	51.53	14.61	43.59	59.48	0.2338 ns
	E-Max group	58.78	15.63	50.29	67.27	

*; significant (p<0.05) ns; non-significant (p>0.05)

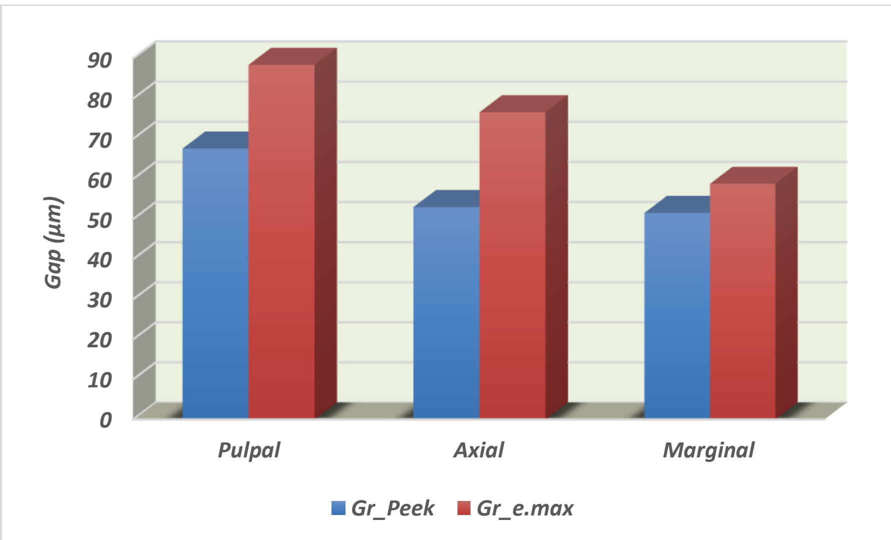

Figure (1) Column chart comparing gap mean values between both groups as function of measurement sites

Regarding the clinical performance

All restorations showed 100% alpha and there was no significant difference between both groups for all tested outcomes (Marginal adaptation, fracture, and retention) over one year.

Discussion

In the present study, all teeth included were posterior teeth. It was restricted to endodontically treated molars. Molar teeth were mainly selected because the endocrown restorations in molar teeth had been proven to owe high success rate by having larger pulp chamber so, more surface area available for bonding. Also molar teeth had more favorable stress distribution in relation to premolar teeth that could contribute in lateral movements in cases having group function occlusion [1, 8].

Scaling and polishing of the teeth were performed few days before tooth preparation to remove any calculus, and deposits to avoid having poor gingival health that might affect the accuracy of secondary impressions and consequently affect the final outcome of the restoration. To eliminate any irregularities in the pulp chamber a smooth flat pulpal floor preparation design was obtained by the help of flowable composite and checked by a putty rubber impression index that was taken before the secondary impression. This way for standardization was also followed by [6]. The choice of butt joint margins was used to minimize the complexity of designing and therefore less marginal and internal discrepancies. Also butt joint preparation design is more conservative [7].

The material used for fabrication of the final restoration in the control group of this study was lithium disilicate glass ceramic. Heat-pressed lithium disilicate had been chosen due to its excellent properties, that the material possesses including high fracture toughness (2-3 MPa), high flexural strength (360 MPa to 440 MPa), high thermal shock resistance because of its low thermal expansion, and having lithium disilicate crystals which enable minimizing the micro cracks propagation combined with its high esthetics properties and bonding availability which makes it the golden standard between all glass ceramics restorations. According to previous studies the use of Heat-Pressed Ceramics had the advantage of reducing sintering shrinkage during ceramic firing and hence improving the marginal adaptation, hence E-Max Press showed better results in terms of marginal and internal fit than E-Max CAD [9, 10, 11, 12].

Although there were great debates with in studies regarding the mechanical properties superiority of E-Max press over E-Max CAD [13, 14]. Yet due to the larger and longer crystals in E-Max press and the avoidance of micro cracks produced by milling machines it was believed that E-Max press restorations were very slightly superior to that of E-Max CAD [11].

Lithium disilicate material can be used as a monolithic restoration as it had high optical properties by its own [15]. It could also be veneered with Lithium Disilicate Ceram of appropriate shade for superior esthetic results [12]. In our study teeth received monolithic lithium disilicate restorations due to the fact that they were in posterior region and although good esthetics was still required yet we believed that the esthetic properties of lithium disilcate restorations were good enough and no need for veneering in those restorations. Moreover our restorations were in a high stress posterior zone and the veneering material may add the risk of being chipped especially in such brittle restorations. Also in clinical practice it is more common to use lithium disilicate endocrowns as monolithic restorations. Although lithium disilicate is still widely used to fabricate endocrowns [1] however, ceramics have drawbacks that might impair the result of endocrowns, including greater stiffness and rigidity which could compromise marginal adaptation. (Prina 2016)

Furthermore, high stress values will be created with a a negative impact on the biomechanical behavior of the restorative system when used to replace dentin, especially in those teeth that were already weakened by losing its vitality and mising great amount of tooth structure [2]. Also being brittle means that they display high compressive strength but low tensile strength. So these drawbacks motivated the development of a novel material (Bio HPP) to overcome these disadvantages, regardless of its esthetic outcome.

For the intervention group, Bio HPP PEEK was the material of choice owing to its amazing properties, having modulus of elasticity near the tooth structure; so it acts as a cushing effect by distributing the stresses, also having good mechanical properties with high strength. One more advantage was being able to have good bond strength with both resin cement and the veneered composite material [5, 16, 17, 18].

A study held by Ghajghouj and Taşar-Faruk (2019) [19] concluded that PEEK endocrowns had higher fracture resistance compared to lithium disilicate and Vita Suprinity. PEEK may be treated in a dental technical laboratory by pressing the material using a specific vacuum-pressing apparatus. PEEK is utilized for this purpose in the form of industrially pre-pressed pellets, or granules. It can also be milled utilizing CAD/CAM technologies [20]. In our study we preferred to fabricate PEEK copings with the press technology in order to have standardization in the method of fabrication of both groups (control, and intervention).

When compared to natural teeth, Bio HPP is opaque, has a white to grey tint, and has a low translucency. The material couldn't be used as a monolithic restoration since it was not aesthetically pleasing. As a result, a veneering layer made of extra resin composites was necessary [5, 16]. Yet very little documentation was present regarding the use of such material in endocrown restorations.

The wax pattern used for the lost wax technique was fabricated using CAD/CAM technique; to ensure its accuracy; as it was a critical step that might affect the internal fit of the endocrown restoration. Therefore, this technique was used to reduce human error and control all the variables to decrease the margin of errors [6]. The choice of accurate scanners to create precise digital scans combined with the 5-axis milling machines results in accurate fit between the restoration and the preparation [21].

The restorations were designed on Exocad software which gives easy and proper designing of the restorations with a large built-in library available with different outlines to choose from [22]. The marginal and internal fit of the restorations are two of the most critical characteristics that impact the lifetime of any restoration and are highly essential for the clinical result of the dental restoration. Increased marginal and internal differences will cause luting cements to dissolve in the oral environment which may negatively affect the longevity and increase the failure rate of the restorations [11, 23].

Evaluations of the marginal and internal fit were performed by silicon replica technique, as it is the most widely used and well-validated for evaluation of marginal integrity and internal fit [24]. An overall of twenty reference points that could accurately represent the marginal and internal fit of the restorations were measured in each replica sample and was measured using a digital microscope in order to guarantee the most accurate results.

After the restorations had been tried, adjustments made, they were re-polished and cleaned to remove saliva remnant which could affect bond strength to the tooth structure. Lithium disilicate endocrowns were cleaned with 37% phosphoric acid according to Lapinska et al (2019) [25] in order to achieve the ceramic restoration's long-term adherence and clinical efficacy. Bio HPP endocrowns cleaned in ultrasonic cleaner according to manufacturer`s instruction.

IPS E-Max press and Bio HPP endocrowns were cemented using dual-cure self-adhesive resin cement to reach optimum bond strength with dentin [26]. Dual cured resin cement was chosen as the thickness of some areas might be me more than 2 mm which ensures complete polymerization in these areas.

Due to its importance the marginal integrity was evaluated in our study by two methods which were 1- The silicon replica technique before cementation, and 2- Clinical evaluation using direct vision and explorer after cementation and with follow up sessions up to 1 year. The clinical performance of lithium disilicate restorations was found satisfying in multiple studies over the years [27]. Yet failure did occur in some cases. Among the main causes of failure were fracture and loss of retention [1]. Consequently clinical evaluation of fracture and retention were assessed in our study.

Multiple elements, including the prep design, the optical scanner, the interface settings provided in the design software, the manufacturing process, and the kind of material utilised to build the restoration, may impact marginal adaption. [28]. Therefore, in this study, meticulous attention to all the previously mentioned details was done to reach the best results and have standardization with the only variable was the type of material used to fabricate the restorations.

The null hypothesis that there would be no difference in the marginal integrity, internal fit, and Clinical performance of PEEK endocrowns compared to lithium disilicate (E-Max) ceramic endocrowns was accepted in all outcomes except the internal fit since the E-Max endocrown group recorded statistically significant higher internal gap mean value than PEEK endocrown group.

The marginal and internal fit for E-Max press and Bio HPP PEEK press endocrown restorations revealed a clinically acceptable range. This might be explained as the lithium disilicate crystals allow for good compressibility and flowability of the material during pressing [29]. Moreover, the heat-Pressing technique could reduce the sintering shrinkage during ceramic firing and hence improving the marginal adaptation [11, 12] and due to the semi crystalline structure of PEEK which contains fillers embedded in resin matrix and for the fact that PEEK is a polymer based material that exhibit good adaptation [30, 31], Moreover, PEEK material has no sintering shrinkage hence improving the marginal adaptation [11, 12]. This was in agreement with Elalem, et al. (2019) [6], AL-Zomur, et al. (2021) [32], Hasanzade, et al. (2020) [33], Meshreky, et al. (2020) [34] and Roy, et al. (2019) [35]. While against Sağlam, et al. (2021) [36] who recorded that the marginal gap of E-Max press endocrowns was 122.49 ± 28.37 µm. The difference in results might be due to the manual technique of fabrication of wax patterns which might be prone to human errors as improper handling. And were also Godil, et al. (2021) [37] where the mean values of internal gap of lithium disilicate endocrowns was 158.2 ± 11.1 µm and the mean value of internal gap of PEEK endocrowns was 199.1 ± 13 µm. However the difference in results might be explained as their study was in vitro that differ from the clinical situations also due to difference in construction and measurement techniques.

The lower marginal and internal gaps of the PEEK group may be explained by the fact that PEEK is a polymer based material that exhibit better adaptation than the more brittle materials (ceramics) as it was easier in finishing without the fear of chipping as proved by Makky, (2020) [38], Hassan, et. Al. (2021) [31], Ewadh, and Jasim (2021) [30] and Park, et al. (2017) [39].

Concerning the clinical performance, all restorations showed 100% alpha for all tested outcomes (Marginal adaptation, fracture, and retention) with 100 % survival rate in this short-term period of one year. The excellent clinical performance of lithium disilicate endocrowns in our study was in agreement with Belleflamme, et al. (2017) [40], Mahrous, et al. (2017) [41], Carlos, et al. (2013) [42] and Biacchi, et al. (2013) [15] and might be due to the long term success of lithium disilicate restorations over years and also for being heat-Pressed reducing sintering shrinkage during ceramic firing and hence improving the marginal adaptation and due to the satisfactory thickness of the restoration (2 mm) that was maintained which enables it to withstand masticatory forces. Also by having lithium disilicate crystals in their microstructure which enable minimizing the micro cracks propagation and for being a member of the etchable glass ceramics that had high bonding strengths with tooth structure. While the excellent clinical performance of PEEK endocrowns in our study was in agreement with (Zoidis et al 2017) [5] and (Tammam, R. 2021) [43] and could be explained based on the material amazing properties, having modulus of elasticity near the tooth structure, so it acts as a cushing effect by distributing the stresses, also having good mechanical properties with high strength. One more advantage was being able to have good bond strength with both resin cement and the veneered composite material [5, 16].

Conclusion

Within limitations of this study, the following conclusions could be drawn as follows:

- PEEK endocrown restorations revealed better internal fit than E-Max endocrown restorations.
- The marginal and internal fit for E-Max press and Bio HPP PEEK press endocrown restorations revealed a clinically acceptable range.
- Both E-Max press and Bio HPP PEEK endocrown restorations showed high successful clinical performance in terms of marginal adaptation, fracture, and retention over a period of one year.

Recommendations

- Further long-term randomized clinical trials, on a larger population, are recommended to confirm the results of this study.
- Further studies are required to evaluate clinically other criteria not covered in this study (Anatomic form, surface roughness, restoration staining, marginal discoloration, color match, and patient satisfaction).
- Further long-term randomized clinical trials are recommended to evaluate Bio HPP PEEK endocrown restorations on premolar and anterior teeth.

Clinical Implementations

It is advisable for clinician to use PEEK or E-Max for fabrication of endocrown restorations.

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