Comparative prospective clinical evaluation of computer aided design/ computer aided manufacturing milled BioHPP PEEK inlays and Zirconia inlays

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Abstract
Aim: The aim of the present study was to clinically assess the performance of BioHPP PEEK material when used for inlay restoration and to compare it with widely used zirconia inlays. This clinical study was undertaken to evaluate their performance in terms of retention, colour matching, marginal discoloration, marginal adaptation, secondary caries, surface texture, wear-anatomic form, postoperative sensitivity and fracture resistance using the modified Ryge’s criteria.

Settings and Design: In vivo - prospective clinical study.

Material and Methods: A total of 40 patients were selected based on inclusion and exclusion criteria requiring inlays. The patients were further divided in two groups: Group A - Consisted of 20 permanent maxillary and mandibular carious posterior teeth restored with BioHPP PEEK inlays and Group B - Consisted of 20 permanent maxillary and mandibular carious posterior teeth restored with CAD/CAM zirconia inlays (sintered monolithic zirconia, Zolid, Amann Girrbach AG, Koblach, Austria). Two prosthodontists, who were blinded to the study groups, evaluated the restorations. In cases of widely different scores, the observers re-evaluated the restorations and reached a consensus. Restorations were evaluated at the end of 1 week (base line), 3 months, 6 months, and 12 months, using modified Ryge's criteria.

Statistical Analysis Used: Chi-square test, ‘Fisher’s exact’ test and ‘z’ test.

Results: 90% of the BioHPP PEEK inlays were rated satisfactory in comparison to 95% of zirconia inlays. Sensitivity score was 10% in BioHPP PEEK inlays and 15% in zirconia inlays. No significant difference was encountered with other parameters in this study.

Conclusion: The BioHPP PEEK when used as indirect aesthetic restorations was found to be satisfactory with relatively low rate of fracture over an observation period of one year in comparison to zirconia inlays in posterior teeth. The BioHPP PEEK can be a suitable alternative with high level of accuracy in terms of retention, marginal quality and aesthetics.

Keywords: BioHPP PEEK, inlay, modified Ryge's scale, zirconia

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INTRODUCTION

Tooth-coloured restorations for posterior teeth are gaining popularity among patients primarily due to aesthetic considerations, whereas clinicians are more concerned about the biological and functional requirements of restorative materials.\(^\text{[2,3]}\) Longevity of the teeth is determined by remaining tooth structure and vital pulp, especially in cases, where a large amount of tooth tissue has been compromised due to abrasion or injury.\(^\text{[4]}\) In cases of the fractured teeth and large caries in addition to traditional full coverage crowns simplified designs with inlays have been recommended.\(^\text{[5]}\) Computer aided designing - Computer aided manufacturing (CAD-CAM) restorations have been proven to be strong and long lasting hence are being routinely used for a wide range of dental restorative indications such as inlays, onlays, laminate vencers, partial and all-ceramic crowns.\(^\text{[6]}\)

Varieties of materials are being used for posterior teeth for inlay restorations ranging from resins to ceramics. CAD/CAM zirconia restorations are more popular because of its strength, fracture resistance, and biocompatibility.\(^\text{[7-9]}\) Polyetherketone has shown promising results as dental restorative biomaterial. It is a thermoplastic high-performance polymer with a melting point of about 343°C. Biocompatible High-Performance Polymer (BioHPP) is a variant of polyetherketone (PEEK) developed by Bredent (Bredent, GmbH Senden, Germany) for dental applications. This has been modified by adding 20% ceramic filler with a grain size between 0.3 to 0.5 μm to resin matrix. The smaller filler particles have resulted in homogeneity of the restoration with good polishability.\(^\text{[10]}\)

Even though zirconia is popular material for inlay restorations, it carries the disadvantage of abrasion of the opposing enamel by virtue of its hardness, which is clinically significant over a period of time.\(^\text{[11]}\) BioHPP PEEK inlays are comparatively resilient and don’t abrade opposing natural teeth.\(^\text{[12]}\) Over the recent years, lot of research has been done in evaluating the clinical performance of zirconia as biomaterial including their role as inlay material. BioHPP PEEK is a relatively new material and its performance is sparsely reported in the literature. This study was undertaken to clinically assess the performance of BioHPP PEEK inlays and to compare it with popularly used zirconia inlays. Clinical features like retention, colour matching, marginal discoloration, marginal adaptation, secondary caries, surface texture, wear-anatomic form, postoperative sensitivity and fracture resistance were evaluated in this study using the modified Ryge’s criteria.\(^\text{[13,14]}\)

MATERIALS AND METHODS

This study was conducted on forty patients requiring inlay restoration (on vital tooth) in the posterior segment. List of the patients requiring inlay restorations was prepared and they were serially numbered. All even numbered patients were taken up for zirconia inlays and odd numbered patients were taken up for BioHPP PEEK inlays. The patients with permanent maxillary and mandibular posteriors with dentinal caries, available for the entire period of observation and with sound periodontium and class I occlusion patients with full complement of minimal 28 teeth excluding third molars were included in the study. Patients with large pulp chamber, necrotic pulp, poor oral hygiene, requiring pulp therapy and those with heavy occlusal forces/TMJ disorders were excluded from the study.

Consent from the patients and ethical clearance from the institutional ethical committee (IEC/AFMC/Dental Surgery/DL08/18-19) was obtained. Prerestorative oral prophylaxis was undertaken in all the required cases. Diagnostic casts were made and radiographs were taken to analyse the contour, position and height of tooth. Inlay preparation was done following all the principles of inlay tooth preparation with tungsten carbide burs (SKU: 18049, SS White Inlay/Onlay kit).\(^\text{[15]}\) On completion of inlay tooth preparation, calcium hydroxide cavity liner (Dycal, Dentsply) was placed over the prepared pulpal floor. Final impressions were made using elastomeric impression materials with two-stage putty wash technique. The prepared tooth was restored with eugenol-free provisional restorative material.

The internal fits of restorations were evaluated. The intaglio surface of zirconia inlay was sandblasted to enhance surface roughness and BioHPP PEEK inlay was etched with 10% hydrofluoric acid for 3 minutes, followed by rinsing and drying. Etched inlay surfaces were treated with a silane coupling agent (Scotch bond, BioHPP PEEK primer, 3M ESPE, USA) for 5 min. Tooth surface were etched and applied with dentine bonding agent as per the manufacturer’s instructions. All the inlays were luted adhesively with resin cement (Relly U200 resin cement, 3M ESPE USA); occlusion was evaluated and adjusted as necessary.

Two prosthodontists evaluated both the restorations, who were blinded to the study groups. In cases of different scores, the observers re-evaluated the restorations and reached a consensus [Figures 1 and 2]. The patient was re-evaluated by the same prosthodontists at intervals of 3 months and 6 months and 1 year [Figures 3-7]. At the recall intervals, the restorations were evaluated using modified United States Public Health Service/Ryge’s criteria [Table 1].
and periodontal status (Periodontal Index, Russel, 1956) [Table 2]. SPSS (Statistical package for social sciences (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.) was used to analyse data. Data was summarised and presented as numbers and percentages. ‘Chi-square test’, ‘fisher’s exact test’ and ‘z test’ were used to compare the difference between the two groups where applicable. \( P < 0.05 \) was considered significant.

### RESULTS

A total of 40 teeth were selected and divided into two groups. 20 were restored with BioHPP PEEK inlays and remaining with zirconia inlays in the other 20 teeth. Over a period of 1 year, none of the participants dropped out at the follow-up observational period. As no fracture or dislodgement of the restorations was reported during the entire observational period, the
survival rate was assumed to be 100% for both groups. A satisfactory rating for inlay survival can be given to both the type of indirect aesthetic restorations as per modified Ryge’s criteria.

In terms of anatomic contour, at the end of 03 months, 5% of BioHPP PEEK inlays had more than 10% slight flattening and in zirconia inlays 100% of cases had no change in contour i.e., <10% flattening ($P = 0.31$). At the end of 1 year, slight change in one case did occur in zirconia inlay where surface concavity was seen with explorer, whereas, in BioHPP PEEK inlays two cases (i.e., 10%) had more than 10% loss of existing anatomic form. This difference however was not found to be significant ($P = 0.54$), [Tables 3 and 4].

As for the marginal integrity, no change was seen at 1 week (baseline). However, at 3 months, 5% in BioHPP PEEK inlays and none in zirconia showed mild visible crevice indicating that the edge of restoration does not adapt closely to tooth structure ($P = 0.31$). At the end of 6 months, 10% in Group A and 5% in Group B showed visible crack but the dentin was not exposed ($P = 0.54$). At the end of 1 year, in two cases with BioHPP PEEK inlays the probe extended into crevice and dentoenamel junction with moderate extent and 2 restorations were mildly exposed in both the groups ($P = 0.37$), [Tables 3 and 4].

Minor difference was seen between the periodontal status at baseline and at 01-year recall. At 03 months, three (15%) patients had mild inflammation in group A ($P = 0.71$). At 06 months, three (15%) patients in Group A and one patient in Group B had overt area of inflammation in the free gingival ($P = 0.29$). By the end of 1 year, two patients with mild and two patients with inflammation circumscribing the tooth with no break in epithelial attachment was seen in Group A and only two patients were seen with mild gingivitis in Group B ($P = 0.37$) [Tables 3 and 4]. The periodontal status between the two groups was not found to be significantly different at any of the time intervals ($P = 0.71, 0.29, 0.37$).

Similarly, when marginal discoloration was assessed, at 03 months only one case showed slight staining in the BioHPP PEEK group ($P = 0.31$). At 6-month interval, 10% in Group A and 5% in Group B showed mild stains ($P = 0.54$). By 01 year, three patients reported with slight staining and one with moderate discoloration at restoration tooth interface in Group A and two patients showed only mild staining in Group B ($P = 0.37$). The color match of all the inlays in both the groups was satisfactory and did not vary much from the baseline to the 01 year follow-up except for one inlay in both the groups (5%), [Tables 3 and 4].
During the assessment of surface texture, one inlay each in both the groups showed rough gritty texture during 3-month, 6-month, and 1-year observation period. Thus, the surface texture was comparable between the two groups and no significant difference was observed at any time interval. As for secondary caries, one inlay at 6 months...
and two inlay at 1 year in the BioHPP PEEK group showed visual evidence of caries, whereas, in zirconia group, only one case showed secondary caries at the end of 1 year; however, these differences were not found to be significant ($P = 0.31, P = 0.54$).

While assessing the patient satisfaction, score 5 (excellent) was seen in around 50%–70% of the participants, 20%–40% scored it at 4 (good) and 10%–20% scored it at 3 (average) in BioHPP PEEK group. In zirconia inlay group 50%–75% of the participants had given a score of 5 (excellent), 15%–40% scored it at 4 (good) and 5%–10% scored it at 3 (average). However, the percentage of participants with the various scores was not significant between the two groups ($P > 0.05$), [Tables 5 and 6].

While assessing sensitivity, 10% of the patient complained of sensitivity in BioHPP PEEK inlay restored teeth and 15% showed response to sensitivity in the zirconia inlay group and was statistically insignificant ($P = 0.10$), [Table 7].

![Class II inlays in Rt mandibular 1st molar (Zirconia) & Rt maxillary 1st premolar (BioHPP PEEK)](image)

**Figure 7:** Class II inlays in Rt mandibular 1st molar (Zirconia) & Rt maxillary 1st premolar (BioHPP PEEK)

### Table 3: Distribution of patients (percentage) according to the scores recorded at various time intervals for CAD/CAM milled BioHPP PEEK inlay ($n=20$)

|                      | Anatomic contour | Marginal integrity | Periodontal status | Marginal discolouration | Colour match | Surface texture | Secondary caries |
|----------------------|------------------|--------------------|--------------------|-------------------------|--------------|----------------|------------------|
|                      | I I I            | I I I              | I I I I I I        | I I I I I I I I I I I I | I I I I I I I | I I I I I I I | I I I I I I I    |
| Baseline             | 100 - -          | 100 - -            | 100 - - - -       | 100 - - - - - - - - - - | 100 - - - - - | 100 - - - - - | 100 - - - - -    |
| 3 months             | 95 5 -           | 95 5 -             | 85 15 - - -       | 95 5 - - - - - - - -   | 100 - - - -   | 95 5 - - -    | 100 - - - -     |
| 6 months             | 95 5 -           | 90 10 -            | 85 10 5 - -       | 90 10 - - - - - - -   | 100 - - - -   | 95 5 - - -    | 100 - - - -     |
| 1 year               | 90 10 -          | 80 10 -            | 80 10 10 - - -    | 80 15 5 - - - - -   | 95 5 - - -   | 95 5 - - -    | 90 10 - - -    |

*a*At the end of 3 months only 1 case showed flattening and 2 cases by the end of 1 year, *b*Visible crevice was not seen in 16 cases by the end of 1 year, *c*Overt area of inflammation in the free gingiva with no break in epithelial attachment for 2 cases, *d*Marginal discoloration was increasing for 1 case every 03 months, *e*Colour match of all the inlays was satisfactory, *f*Surface texture was gritty only for 1 case, *g*Visual evidence of caries in only 2 cases.

**Table 4: Distribution of patients (percentage) according to the scores recorded at various time intervals for CAD/CAM milled zirconia inlay ($n=20$)**

|                      | Anatomic contour | Marginal integrity | Periodontal status | Marginal discolouration | Colour match | Surface texture | Secondary caries |
|----------------------|------------------|--------------------|--------------------|-------------------------|--------------|----------------|------------------|
|                      | I I I            | I I I              | I I I I I I        | I I I I I I I I I I I I | I I I I I I I | I I I I I I I | I I I I I I I    |
| Baseline             | 100 - -          | 100 - -            | 100 - - - -       | 100 - - - - - - - - - | 100 - - - -   | 100 - - - -   | 100 - - - -     |
| 3 months             | 100 - -          | 100 - -            | 100 - - - -       | 100 - - - - - - - -   | 100 - - - -   | 100 - - - -   | 100 - - - -     |
| 6 months             | 95 5 -           | 95 5 -             | 95 5 - - -       | 95 5 - - - - - - -   | 100 - - - -   | 95 5 - - -    | 100 - - - -     |
| 1 year               | 95 5 -           | 90 10 -            | 90 10 10 - - -    | 90 10 4 - - - - -   | 95 5 - - -   | 95 5 - - -    | 95 5 - - -     |

*a*At the end of 6 months only 1 case showed flattening and 2 cases by the end of 1 year, *b*Visible crevice was seen in 2 cases by the end of 1 year, *c*Overt area of inflammation in the free gingiva with no break in epithelial attachment for 2 cases, *d*Marginal discoloration was slight in 2 cases, *e*Colour match of all the inlays was satisfactory, *f*Surface texture was gritty only for 1 case, *g*Visual evidence of caries in only 1 case. CAD/CAM: Computer aided design/computer aided manufacturing
Table 5: Patient distribution (percentage) in various satisfaction scores for CAD/CAM milled BioHPP PEEK inlay and CAD/CAM milled zirconia inlay

| Characteristics     | BioHPP inlays | Zirconia inlays |
|---------------------|---------------|-----------------|
|                     | Very bad | Bad | Average | Good | Excellent | Very bad | Bad | Average | Good | Excellent |
| Chewing efficiency  | 0        | 0   | 20      | 30   | 50        | 0        | 0   | 10      | 40   | 50        |
| Colour match        | 0        | 0   | 10      | 20   | 70        | 0        | 0   | 10      | 30   | 60        |
| Contour             | 0        | 0   | 15      | 35   | 50        | 0        | 0   | 10      | 15   | 75        |
| Comfort             | 0        | 0   | 10      | 40   | 50        | 0        | 0   | 5       | 25   | 70        |

Table 6: Comparison of patients (percentage) in both groups for evaluation scores

| Characteristics | BioHPP PEEK | Zirconia | P | BioHPP PEEK | Zirconia | P | BioHPP PEEK | Zirconia | P |
|-----------------|-------------|----------|---|-------------|----------|---|-------------|----------|---|
| Chewing         | 20          | 10       | 0.88 | 30          |           |   | 40          | 0.51     | 50   |
| Color           | 10          | 10       | -    | 20          |           |   | 30          | 0.47     | 70   |
| Contour         | 15          | 10       | 0.63 | 35          |           |   | 15          | 0.14     | 50   |
| Comfort         | 10          | 5        | 0.55 | 40          |           |   | 25          | 0.31     | 50   |

Table 7: Comparison of sensitivity between the two groups

| Sensitivity | Present | Absent | P |
|-------------|---------|--------|---|
| Zirconia inlays | 15      | 85     | 0.28 |
| BioHPP inlays  | 10      | 90     |      |

DISCUSSION

Ever-increasing demand for aesthetic restorations by patients and clinicians has led to the rapid development of newer esthetic dental materials. Increasingly CAD/CAM zirconia is becoming more accepted esthetic biomaterial including for inlay restorations. Numerous clinical studies have shown CAD/CAM restorations to be better than other indirect fabrication and zirconium oxide (ZrO2) has become a product of choice for inlay restorations; due to its superior physical properties and aesthetics and biocompatibility.\[15,16\] Posselt and Kerschbaum\[17\] in their study of 2,328 inlays and onlays placed in 794 patients found a Kaplan-Meier survival probability of 97.4% at 5 years and 95.5% at 9 years. A study by Berg and Dérand\[18\] found that over a period of 5 years, only 03 of the 115 CAD/CAM fabricated indirect restorations were fractured. In recent years, PAEK polymer-based materials like BioHPP PEEK have also gained clinical acceptance as a dental biomaterial. PEEK is a polymeric material, while zirconium oxide is ceramic. Therefore, their performance will be even more dissimilar than would be suggested by the difference in properties. Over the years PEEK has developed a high-density thermoplastic polymer based restorative material alternative, which has highly favourable physical and chemical properties, including hardness and toughness.\[19\] The fracture load of 3D printed PEEK inlays with milled ones, direct resin composite fillings, and sound teeth were compared in a study by Prechtel et al.\[20\] The authors found that indirect PEEK inlays showed a higher fracture load than the expected physiological and maximum chewing forces in the molar region. A literature search showed not many clinical studies have been carried out to compare these two biomaterials. This study was undertaken to compare and assess CAD/CAM zirconia and BioHPP PEEK as inlay restorative materials in posterior teeth.

Retention form is considered a vital factor for inlay restoration success and it is governed by numerous factors like geometry of preparation, size, type of cement used, and other factors. We found no loss retention in both the materials as per modified Ryge’s criteria over a period of one year; there was 100% success of both materials on retention criteria.

The next factor assessed in the study was the anatomical contour [Tables 3 and 4]. It was found that 90% of the crowns had retained its anatomic contour in BioHPP PEEK and 95% had retained in zirconia Group at the end of 1 year. In our study, at the end of 1-year slight change in one case did occur in zirconia inlays where surface concavity was seen with explorer, whereas, these findings are similar to the results obtained by Crisp et al.\[20\] who assessed various all-ceramic crowns and observed no fracture or chipping off of the ceramic in their study. In BioHPP PEEK inlays, two cases had more than 10% loss of existing anatomic form. These changes in BioHPP PEEK inlays may be attributable to patient-dependent biting forces or occlusal prematurity which was not considered in the study. All the restorations showed satisfactory marginal integrity/adaptation. Eighty-percent cases showed no changes in marginal integrity in BioHPP PEEK. 90% showed intact margins were observed in the zirconia group [Tables 3 and 4] at the end of 1 year, which may be attributed to dissolution of high viscosity luting cements.
The periodontal scores were found to be significantly different at the baseline and 1-year recall evaluation. By the end of 1 year 15% had moderate and mild inflammation in the BioHPP PEEK group whereas only 10% had mild symptoms in the zirconia group [Tables 3 and 4] [Figure 2]. This significant difference may be attributable to not adhering to standard oral hygiene protocol. Almost 95% of the color match for both the groups was found satisfactory and did not vary much from the baseline to the 1-year follow-up [Tables 3 and 4]. An all-ceramic restorations based study done by Costa-Palau et al. found similar scores however, they suggested that this may be related to the operator’s error in color matching.

In terms of marginal discoloration, zirconia inlays didn’t show any changes in the first 3 months however mild discoloration was seen in 10% of cases at the end of 1 year. In Bio HPP PEEK inlays slight marginal discoloration was 15% of cases at the end of 1 year.

In our study, the surface texture of both the inlay groups showed the same results and were nonsignificant to each other [Tables 3 and 4]. Giordano et al. conducted an electron microscope-based study to compare production methods quality of traditionally and CAD/CAM fabricated ceramic restorations. The author found that CAD/CAM generated restorations did not exhibit any porosity when compared to powder-liquid mixed group and heat-pressed restorations. The author opined that this may be due to the homogeneity in the production stages of the CAD/CAM blocks.

Numerous studies have cited that secondary caries are the commonest reason for failure of dental restorations in general practice and it affects nearly 50% of all operative dentistry procedures delivered to adult patients. Fasbinder et al. based on their study opined that an increase in marginal gap size may result in degradation of the adhesive bond, which may lead to microleakage and subsequently secondary caries. In our study, secondary caries comparison also showed no significant differences amongst the two groups used in this study as 5% in zirconia inlays and 10% in BioHPP PEEK inlays were advocated at the end of 1 year follow-up. Evaluation of patient satisfaction in this study found that about 50%–70% of the participants had given a score of 5 (excellent), 20%–40% of the participants gave a score of 4 (good) and around 10%–20% gave score of 3 (average) in BioHPP PEEK group whereas about 50%–75% of the participants had given a score of 5 (excellent), about 15%–40% gave a score of 4 (good) and about 5%–10% of the participants scored it at 3 (average) in respect to zirconia inlays. All the parameters were statistically insignificant when compared with each other. In a previous study done on zirconia-based restoration by Peláez J et al., 72% of the participants gave a score of 1 (excellent) and 18% gave a score of 2 (good) for patient satisfaction.

In this study, 10% of the participants managed with BioHPP PEEK inlays complained of tooth sensitivity while, 15% of the participants in zirconia inlay group complained of tooth sensitivity. The results were statistically insignificant ($P = 0.10$), however, no clinical evidence was found to confirm the same.

**CONCLUSION**

Within the limitations of this study, it can be concluded that alongwith excellent aesthetics, a high level of accuracy of fit (on parameters like retention, marginal quality and accuracy) can be achieved in inlay restorations with use of BioHPP PEEK materials. Although zirconia restorations are being extensively used for inlays, BioHPP PEEK can also be used as a suitable alternative. Considering the examination period of a year only, it was observed that BioHPP PEEK inlays showed promising clinical durability with good patient satisfaction and also matched zirconia inlays in terms of mechanical properties and biological reactions. As per the results of this study, it is recommended that BioHPP inlays can be used as suitable alternative to traditionally used zirconia in areas of esthetic demands. Further comparative studies over a longer observation period are required to strengthen the findings of this study.

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**Conflicts of interest**
There are no conflicts of interest.

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