

CLINICAL, RADIOGRAPHIC, AND PROSTHETIC OUTCOMES OF POLY ETHER ETHER KETONE (PEEK) VERSUS POLY ETHER ETHER KETONE (PEKK) FRAMEWORK IN MANDIBULAR FIXED-DETACHABLE IMPLANT-SUPPORTED PROSTHESIS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Purpose: To evaluate the clinical, radiographic, and prosthetic outcomes of Poly Ether Ether Ketone (PEEK) versus Poly Ether Ketone Ketone (PEKK) frameworks in mandibular implant-supported fixed detachable prosthesis.

Materials and method: Fourteen completely edentulous patients received complete dentures for three months. Four implants were inserted in the mandible at the canine and molar-premolar areas bilaterally following two-stage surgical technique. All patients were planned to receive mandibular fixed-detachable prostheses with individual zirconia crowns. The patients were randomly allocated to two groups according to the prosthesis framework material. Group A received a prosthesis with PEEK framework while group B received a prosthesis with PEKK framework. The implant success rate, modified Plaque Index (mPI), simplified Gingival Index (sGI), modified Sulcus Bleeding Index (mSBI) and Peri-implant bone loss (PIBL) were evaluated at loading, 6- and 12-months follow-up visits. Additionally, the total prosthetic complications were measured after a one-year follow-up period.

Results: All implants had a 100% success rate. The PEEK group showed statistically significant higher mPI, sGI and mSBI compared to the PEKK group at the 6 and 12 follow-up visits. Regarding PIBL results, no statistically significant difference was found between the two groups. The prosthetic complications in the PEEK and PEKK groups were four and eight events respectively. The most frequent complication was abutment screw loosening.

Conclusion Within the limitations of this study, the fixed-detachable implant-supported prosthesis with PEEK or PEKK framework can be a clinically successful treatment option for the rehabilitation of edentulous mandible. However, the fixed-detachable prosthesis with the PEKK framework may provide superior soft tissue health outcomes and fewer prosthetic complications compared to those with the PEEK framework.

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INTRODUCTION

Rehabilitation of edentulous mandible with four Implant supported fixed-detachable prosthesis is a highly predictable and successful treatment option^{1,4}. The patients' demands, financial status, manual dexterity, maxillomandibular relationship, ridge anatomy, hygienic maintenance and inter-arch distance are the major factors affecting the choice of the definitive prosthesis⁵. In cases with extensive residual ridge resorption fixed implant-supported prosthesis may not be feasible. Hence, the prosthodontist may choose screw-retained prosthesis as an alternative treatment to restore the missing soft and hard tissues offering better esthetics. This treatment option provides retention characteristics of a fixed prosthesis as well as esthetics and oral hygiene maintenance of a removable prosthesis⁶.

Superior success rates are maintained post-implant loading depending on biomechanical issues as the material, technique of construction and design of the prosthesis framework⁷. Gold alloys were the frameworks material of choice in the past. Nevertheless, since the Cobalt-Chromium (Co-Cr) alloys introduction, their usage became prevalent in the fabrication of implant-supported frameworks due to their good clinical performance. Fixed-detachable prosthesis with a casted metal framework and ceramic teeth is one of the most used definitive prostheses used in edentulous mandible due to its versatility, low cost, and predictable structural performance⁸. Despite this fact, the casted metal high density, casting problems, porosity, incompatibility with imaging techniques, impaired esthetics, hypersensitivity cases and metallic taste urged the research to develop other alternative framework materials⁹. Additionally, during process of applying an esthetic veneer to a metallic framework, the metal distortion can result in marginal misfit. Failure at the metal-ceramic or metal-resin interfaces leads to clinical complications^{10,11}.

As a versatile and convenient alternative to metal, the poly aryl ether ketones (PAEKs), which

are high-performance thermoplastic polymers (HPTPs), have been employed in construction of metal free prosthetic frameworks. The poly ether ether ketone (PEEK) and poly ether ketone ketone (PEKK) are the most eminent polymers in the PAEK family¹². They are semi-crystalline high-temperature thermoplastic polymers with linear chain structures with an aromatic backbone molecular chain, interconnected by functional ether and ketone groups with different ratios¹³. Both polymers have excellent physical and mechanical properties comparable to those of metal alloys. Furthermore, they are inert, light in weight, nonallergenic, radiolucent, biocompatible, chemically stable, and high temperature resistant^{14,15}. Compared to metal alloys, the PEKK and PEEK cause less stress to the abutments as partial denture framework material¹⁵. Also, the HPTPs accumulate less biofilm than metal alloys and ceramics¹⁶. Although modulus of elasticity of PEKK is Higher than that of PEEK, both are comparable to modulus of elasticity of dentin and bone unlike other framework materials. Compared to titanium and zirconia, both polymers have relatively low elastic modulus causing stress reduction in the prosthetic frameworks¹⁷.

The PEEK and PEKK frameworks can be fabricated by computer-aided design and computer-aided manufacturing (CAD/CAM) resulting in an improved marginal fit and fracture resistance with enhanced patient acceptance and comfort compared to conventional casting procedures in metal alloys frameworks¹⁸⁻²⁰. With the improvements in CAD/CAM techniques, the frameworks are expected to be more precise with accurate dimensions, better fit with superior passive adaptation to implant abutments which encourages the conservation of implant-bone interface²¹.

The PEEK has been used in fabrication of frameworks in fixed detachable prostheses recently due to its favorable biomechanical properties²². It possesses superior mechanical properties including

wear resistance, adequate strength-to-weight ratio, shock absorbing effect, and reduced creep^{18,23-27}. The PEEK is available in unfilled and filled forms. The fillers as nanoceramics, carbon fibers or titanium dioxide are added to PEEK occupying 20% of the total volume to provide better performance with better polish as an attempt to improve the modulus of elasticity^{28,29}. Accordingly, in certain cases when torsional forces occur, the chewing pressure is transmitted as to the supporting structures as gentle as possible reducing the risk of failure³⁰. Moreover, filled PEEK provide better resistance to abrasion compared to unfilled PEEK¹⁴.

As a chemical structure, the PEKK has a second ketone group with stronger polymer chains which increases the backbone rigidity and polarity. Accordingly, the PEKK has a higher melting and glass transition temperature compared to the PEEK. Additionally, reinforcing the PEKK with titanium dioxide (TiO₂) improves its wear resistance and hardness. The PEKK exhibits both crystalline and amorphous behavior producing different products^{31,32}. The PEKK possesses superior mechanical properties i.e., superior tensile and flexural strength as compared to the PEEK. Moreover, the PEKK possesses superior long-term fatigue properties, and its compressive strength is approximately 80% higher compared to the unfilled PEEK. The mechanical response of the PEKK is superior to the PEEK, particularly in shear compression and shock absorbance ability. This superior shock absorbance of PEKK as compared to PEEK reduces stress concentration in the prosthetic screw and base in screw retained prostheses. Consequently, the fracture risk of the acrylic base and screw loosening clinically might decrease^{13,20,33,34}.

Monitoring the implant supported prostheses over time is critical to assess the success of such treatment option. It is required to evaluate the health of the supporting tissues i.e., the peri-implant bone loss (PIBL) and soft tissues to detect early signs of

disease and avoid any complication⁵. In addition, the prosthetic complications and maintenance events are crucial in determining the success of any implant supported prosthesis as it directly affects the patient satisfaction, quality of life and the cost of the treatment⁸.

Reviewing the literature, few research work was conducted to investigate the effect of fixed detachable prosthesis framework material on the supporting structures and the majority were invitro studies³⁵⁻³⁸. A recent literature review stated that the long-term clinical performance of the High-performance polymers as a framework in implant supported prostheses remains unclear³⁹. Moreover, it is important to explore the effect of using HPTPs on peri-implant bone and soft tissue which is considered a primary outcome determining the success of any treatment option. Most of the research was concerned with PEEK rather than PEKK frameworks in implant-supported prostheses. Besides, these studies were few; most were case reports, and randomized clinical trials were more scarce. Almost all these randomized clinical trials compared metal alloys to PEEK as a framework material⁴⁰⁻⁴⁶. Despite the versatility in manufacturing PEKK and its rising popularity, rare studies explored the clinical performance of PEKK and most of them were case reports^{32,47-50}. Almost all studies comparing PEEK to PEKK were invitro studies^{12,13,17,23,26,35}. Hence, this study was conducted to evaluate the effect of using PEEK versus PEKK as a framework material in mandibular implant supported fixed detachable prostheses on marginal bone loss, soft tissue health and prosthetic complications after one year of clinical service in fully edentulous patients. The null hypothesis was that there could be no significant difference between the PEEK versus the PEKK frameworks in mandibular implant-supported fixed detachable prostheses regarding peri-implant bone loss, soft tissue health, and prosthetic complications throughout a one-year follow-up period.

MATERIALS AND METHODS

Patients' selection

Fourteen completely edentulous patients were randomly selected from the outpatient clinic of the prosthodontic department, faculty of dentistry, Minia university. Their age range was from 55 to 65 years old. The inclusion criteria were: (1) patients having adequate bone volume (sufficient height and width) in the mandible to accommodate implants of 3.75 mm diameter and 13 mm length at least as verified by a preoperative cone beam computed tomography (CBCT) scan by a CBCT machine (i-CAT, Imaging Sciences International ISI, Pennsylvania, USA), (2) sufficient inter-arch space to accommodate a fixed-

detachable mandibular prostheses as verified by the preliminary jaw relations and the primary casts mounted on a semi-adjustable articulator. Exclusion criteria were: (1) patients with any systemic disease that contraindicated implant surgery such as bleeding disorders (2) patients receiving radiation therapy and/or immunosuppressive therapy (3) patients with metabolic diseases which might affect osseointegration such as uncontrolled diabetes mellitus and osteoporosis (4) patients receiving bisphosphonates therapy (4) patients with parafunctional habits. All the participants were informed precisely about the nature of the study and treatment plan. All patients signed a printed detailed consent (fig.1).

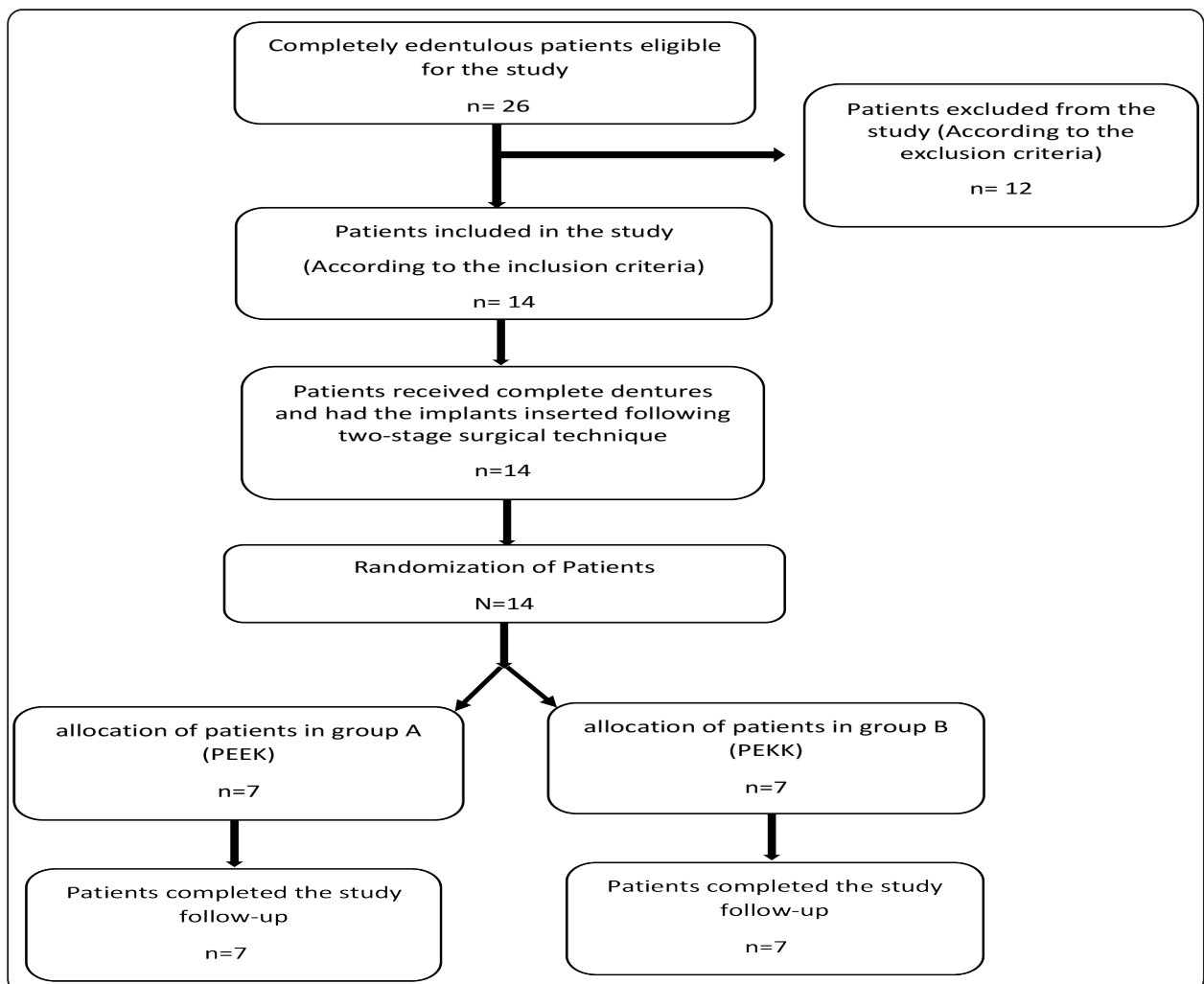


Fig. (1) The flow chart of the patients in the study

Each patient received a complete denture which functioned as a provisional prosthesis for occlusion evaluation, insuring patient's neuromuscular accommodation and adaptation. Each denture was fabricated according to conventional denture construction procedures. A preliminary impression was made with irreversible hydrocolloid material loaded on stock tray (Cavex CA37, Normal Set, Holland) to get primary casts. The Secondary impressions were done by the aid of a border molded self-curing acrylic resin special tray (Palapress Vario Heraeus Kulzer, Hanau, Germany) loaded with eugenol-free Zinc-oxide impression material (Cavex impression paste, Holland) to attain the master cast from improved stone material (GH stone type 3 hard Egypt). Mandibular and maxillary trial denture bases were made to record the jaw relations. On a semi-adjustable articulator (HANAU Modular; Whip Mix Corporation, Farmington Ave, Louisville, KY, USA) the master casts were mounted. The maxillary cast was mounted using maxillary face bow record and centric relation record with check-bite technique at the appropriate vertical dimension was used to mount the mandibular cast. Protrusive and lateral records were used to adjust the condylar guidance of the articulator. Setting up of teeth was done using high wear resistant cross-linked acrylic teeth (Acry Rock, V code, Ruthinium group, Italy). The waxed-up denture was tried in patient's mouth then processed using heat cured acrylic resin base material (Acrostone, WHW, England). Laboratory remounting was made, then finishing, polishing and delivery of the denture to the patient. After one week the patient was recalled for checkup, clinical remounting, and occlusal adjustments. Instructions for usage and denture hygiene were given to the patient. The denture was evaluated regularly for a period of three months before implant insertion.

Moreover, the received complete denture was used in the dual scan technique by CBCT for fabrication of surgical guide as follows: the primary scan was done while patient was wearing the denture

with radiopaque martial (gutta-percha markers) used as scan markers (radiographic stent) at the intended implant sites and the subsequent scan was made for the denture alone on the CBCT machine table (with the denture long axis in line with the table long axis). The resultant CBCT scans were transformed into digital images, overlapped, sent to the implant planning software (OnDemand3D Dental, Cybermed, South-Korea). Virtual model planning software was used to identify the locations for implants' insertion and anchor pins of the surgical guide the construction of a stereolithographic surgical guide was done using rapid prototyping three-dimensional (3D) technique with four sleeves located over planned implant sites. Each patient was instructed to take Antibiotics (amoxicillin 875 mg+ clavulanic acid 125mg, Augmentin® 1gm) before surgery and continued for one week later twice daily. Corticosteroids (Dexamethazone®, 8 mg/2 ml) was injected immediately after surgery to reduce postoperative edema and inflammation. An anti-inflammatory medication (ibuprofen®, 600 mg) was prescribed for five days post-operatively. the flapless protocol was followed for implant insertion surgically under local anesthesia. Stabilizing the surgical guide was in its planned place guided by interocclusal record and fixing it to the mandibular arch using anchor pins. With the aid of surgical guide four implants (Frontier ®, GMI, Lleida Spain) were installed in the mandibular canine and molar-premolar areas bilaterally following two-stage surgical technique. Through the sleeves of the surgical template, successive drills (from the surgical kit supplied by the manufacturer) were used to prepare the osteotomy sites. The implants were inserted by 35 N torque wrench. The primary stability of each implant was ensured. The implant fixtures were covered by their cover screw to be loaded after three months at least to ensure successful osseointegration. The denture was relieved at the area opposing the implants sites and relined using resilient liner (COE-SOFT™, GC America).

After three months of osseointegration, the four implants were exposed using punch technique. The impression copings were inserted on top of implants and screwed with long screws then splinted with stainless steel wire and fixed with the application of self-cure acrylic resin to avoid any movement. Modification of the impression stock tray to be opened at the top of impression copings was done and full mandibular impression with light and putty vinyl siloxane material (Zeta plus, Zhermach, Italy). The light consistency rubber base was injected around the copings while the stock tray was loaded with the heavy consistency then placed over the copings. After setting of the impression, the long screws were unscrewed. Removal of impression material covering the long screws of impression copings was done carefully. The four implant analogues were placed into the impression and secured in place by screwing the long screws. The mandibular impression was poured with improved stone. After the stone setting, the impression tray was removed by unscrewing the long screws and the cast was ready for framework construction.

The maxillary pick-up impression was made for the maxillary complete denture when seated in its place intraorally using irreversible hydrocolloid impression material in a modified border molded stock tray, then poured with improved stone.

Four titanium bases (Frontier®, GMI, Lleida Spain) were fixed to the implant analogue on the mandibular stone cast and then both the mandibular and maxillary cast was scanned by laboratory scanner (Roland DGA, Japan). Later, the occlusion block was fabricated on the mandibular cast for jaw relation registration. After registering the jaw relation with the aid of previous denture vertical dimension and centric relation, scanning of the relation between maxillary and mandibular casts in occlusion was performed by the laboratory scanner.

The designing of the fixed-detachable (screw-retained) prosthesis was done by a CAD software (Exocad GmbH, Darmstadt, Germany). The prosthesis was designed to restore the lost gingival tissue, bone, and teeth (fig. 2). All prostheses were designed to have no distal cantilevers or one molar

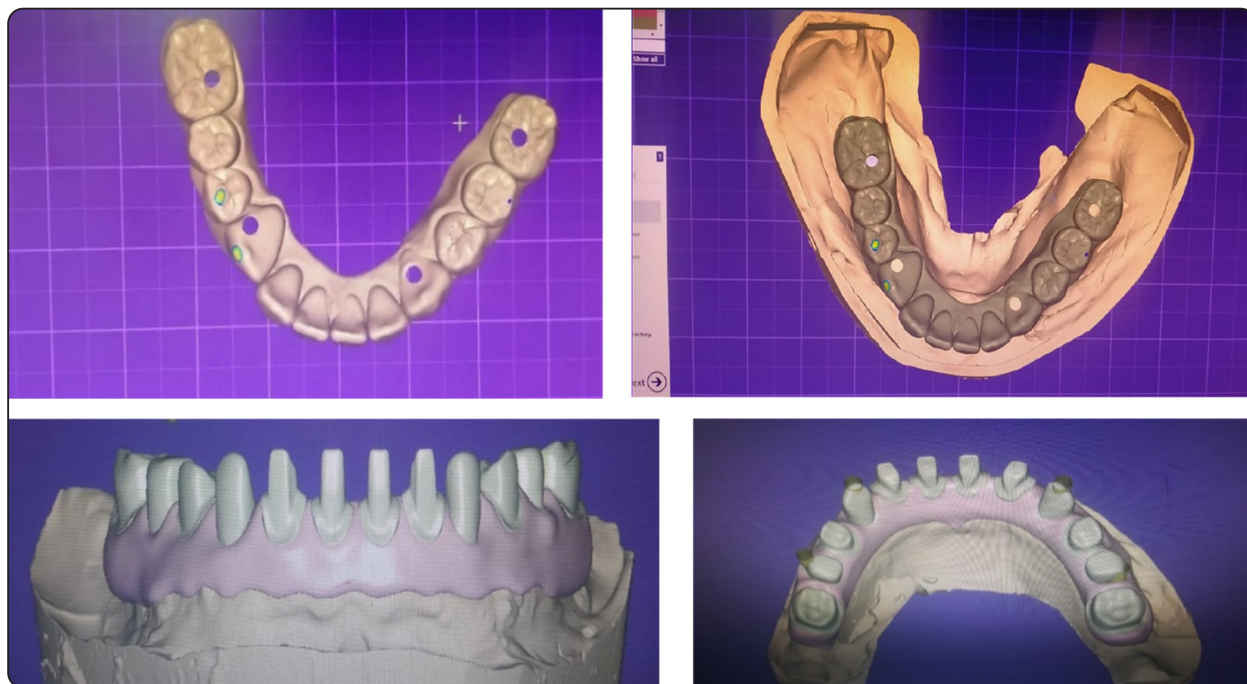


Fig. (2) The digital designing of the mandibular fixed-detachable prosthesis

as a distal cantilever at most. The framework and twelve overlying zirconia unit crowns were designed sequentially. The occlusal scheme applied was medial positioned lingualized occlusion. After designing according to the inter arch distance and determination of screw holes positions, the Stereo Lithography (STL) file was sent to the milling machine software (Roland DG SRP Player CAM software, Japan) to mill the framework by the milling machine (DWX-52D, Roland DGA, Japan). First, a temporary prosthesis was milled from poly methyl methacrylate (PMMA) to be tried in intraorally for further checking of the accuracy of prosthetic design and passive fit. Accordingly, if the try in was accepted, the framework was milled from the assigned material disc according to the group allocation.

Randomization of the patients was done by random generated numbers using a computer software program (Minitab 17.0, Pennsylvania, USA). The Patients were allocated into two different groups according to the framework material of the fixed-detachable prosthesis. **Group A** patients received a fixed-detachable prosthesis with Poly Ether Ether Ketone (PEEK) framework (breCAM. BioHPP, Bredent GmbH & Co.KG,

Senden, Germany) and individual zirconia crowns. On the other hand, **Group B** patients received a fixed-detachable prosthesis with Poly Ether Ketone Ketone (PEKK) framework (Pektkon ivory; Cendres+Métaux SA, Switzerland) and individual zirconia crowns. The randomization and allocation of patient into the two groups was performed by a general dentist blinded by the nature of the study and the different treatment groups. This blinding and randomization were done to avoid bias and to obtain an accurate outcome as much as possible.

Finally, after milling of the framework (from the PEEK or PEKK discs) was done, the frameworks were finished, polished. The framework was cemented to the titanium bases (Ti-bases) on the cast using a primer (MKZ Primer; Bredent, GmbH, UK) and dual-polymerizing resin cement (DTK Kleber adhesive cement, Bredent, GmbH, UK). The screw access holes were sealed. The framework with the titanium bases were tried intraorally for checking of passive seating and fit. A light-polymerizing pink composite veneer material (visio.lign, bredent GmbH & Co KG) and adhesive (visio.link Bredent GmbH & Co KG) were applied on the gingival part of the framework to simulate gingival tissue. Later, the framework was tried intraorally (fig.3)

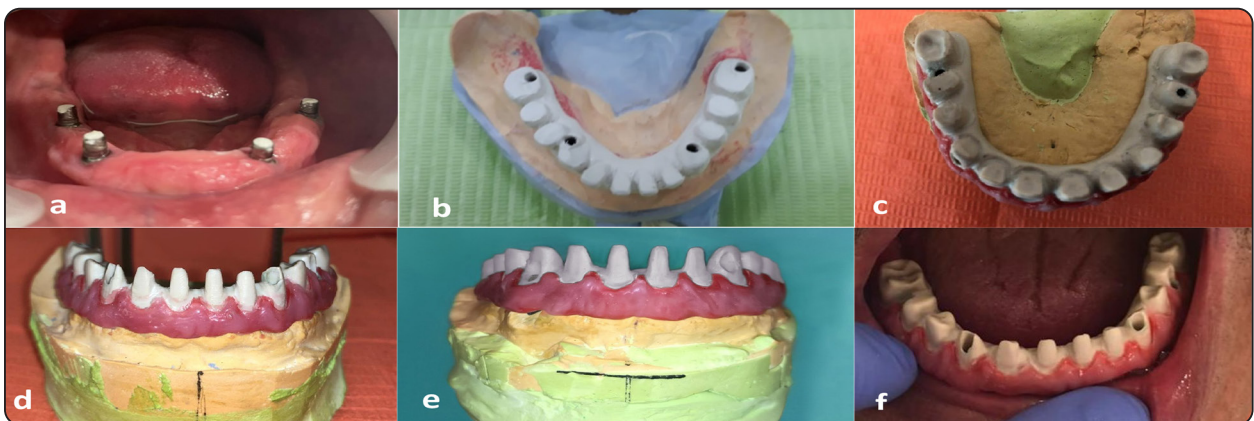


Fig. (3) a) The four titanium bases intraorally, b) The occlusal view of the PEEK framework on the cast, c) the occlusal view of the PEKK framework on the cast, d) The pink gingival composite on the PEEK framework, e) The pink gingival composite on the PEKK framework, f) checking the framework intraorally.

The milling of the zirconia crowns from zirconia discs (Zolid HT, Ammann Girrbach, Austria) was done. The crowns were cemented to the framework with a zirconia primer and dual-polymerizing resin cement (BISCO BISCEM, USA) while sealing the designed holes for screwing of titanium-bases with Teflon material. The whole assembly of titanium bases, framework and overlying zirconia crowns was delivered to the patient and secured in place using the tightening screws. The holes of zirconia crowns were blocked with composite resin (3m Filtek Z350 XT, USA) of the same shade. All the patients were instructed to follow oral hygiene measures strictly and were followed up for one year after implant loading. The outcomes were measured at implants loading (0-baseline), six-, and 12-months follow-up visits.

Clinical outcomes

• Implant success rate

The following success criteria were used⁵¹. (1) no pain or dysesthesia, (2) no peri-implant infection, (3) no mobility, and (4) bone loss < 1.2 mm after 12 months. The implant was considered to have “survived” if it was still functioning but did not fulfill these criteria.

• Soft tissue health evaluation

The soft tissue health was evaluated clinically using modified Plaque Index (mPI), simplified

Gingival Index (sGI) and modified Sulcus Bleeding Index (mSBI). These indices were evaluated at four possible regions for each implant at the labial, distal, mesial, and lingual surfaces. The total of scores of each implant were added but then divided by four to find its score. This index is established on scale from 0 to 3 as follows:

- i) **Modified Plaque Index (mPI)**⁵² was used to evaluate plaque accumulation; score 0: no detection of plaque, score 1: plaque only recognized by running a probe across the smooth marginal surface of the implant. score 2: plaque can be seen by the naked eye and score 3: abundance of soft matter.
- ii) **Simplified Gingival index (sGI)** which is the modified gingival index simplified by Apse et al⁵³. It was used to evaluate peri-implant gingival tissues; score 0: normal gingival with no inflammation, score 1: mild inflammation, slight change in color, slight edema and no bleeding on probing, score 2: moderate inflammation, redness, edema, glazing and bleeding on probing, score 3: severe inflammation, marked redness, edema, ulceration and exemplified by spontaneous bleeding
- iii) **Modified Sulcus Bleeding Index (mSBI)**⁵² was used to evaluate the bleeding tendency of

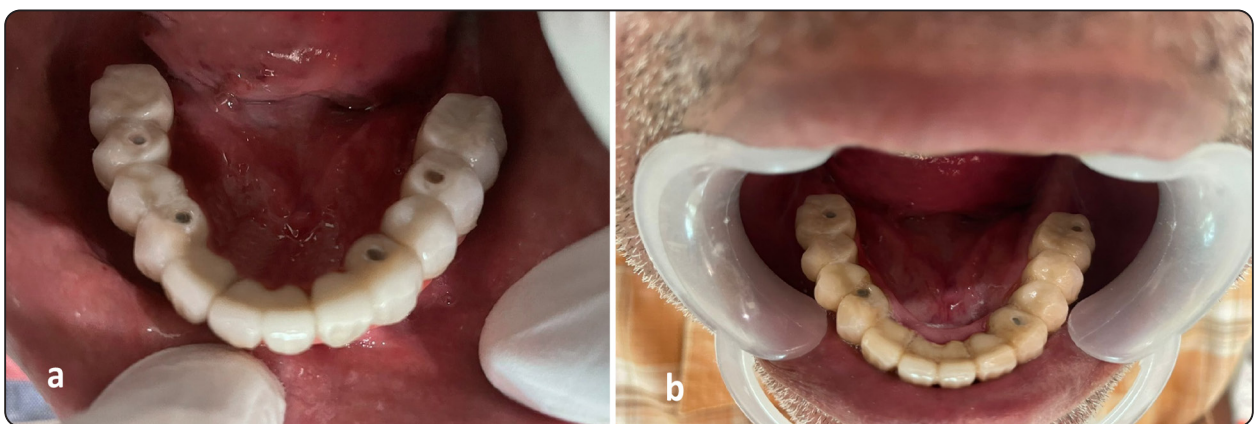


Fig. (4) Intraoral view of the zirconia crowns with the a) The PEEK framework, and b) The PEKK framework

per-implant tissues; score 0: no bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant, score 1: isolated bleeding spots visible, score 2: blood forms a confluent red line on margin. score 3: heavy or profuse bleeding.

Radiographic outcomes

- **Peri-implant bone loss (PIBL):**

Radiographic evaluation of peri-implant bone loss (PIBL) was done utilizing periapical radiographs following the standardized long cone paralleling technique. The measurements of mesial and distal peri-implant bone height to the implants were made at zero month (baseline), six, twelve post-implant loading. The radiographs were obtained using a Rinn periapical film holder (XCP Extention Cone Paralleling, DENTSPLY Rinn Corporation, USA), the x-ray tube was mounted by a long cone. In each visit, Rinn technique was followed utilizing the XCP instrument for extension cone paralleling technique and a phosphorus x-ray plate to receive the image. To preserve the identical cone-implant distance and film-implant distance, the film holder was fixed to a customized cold cure acrylic resin interocclusal jig to attach the bite blocks of the Rinn XCP. Hence, a reproducible and steady positioning of the phosphorus x-ray plate in every follow-up visit is executed to obtain standardized radiographs

For further standardization, the same x-ray machine (Fona XDC, Fona, Assago, Italy) was used at 8 milliamperes and 70 kilovolts for 0.6 seconds with a focal film distance of 35 cm. The same exposure parameters were for applied all the patients in all the follow-up visits. To obtain a digital image, a scanner was utilized to scan the plate. On the computer screen, digital images were viewed and checked before saving them. Later, the images were to be examined by a computer software (Romexis Viewer software, Planmeca, Helsinki, Finland) to measure the linear measurements of peri-implant

bone height. A horizontal line perpendicular to its long axis and tangential to the implant apex was drawn. Next, two vertical lines were drawn tangential to the implant mesial and distal surfaces extending from the horizontal line to the highest implant- bone. The mesial and distal per-implant bone height were measured in millimeters (mm) (fig.5). A calibrated clinician blinded by the nature of the study evaluated the images and did the measurements. The peri-implant bone loss was calculated by subtracting the peri-implant bone height measurements at the six- and twelve-month follow-up visits from the baseline (0 months) measurements. Moreover, the peri-implant bone loss was calculated by subtracting the peri-implant bone height measurements at the twelve-month follow-up visits from the six- months measurements.

For Additional calibration and standardization of the measurements to avoid any human, procedural or magnification error; the actual known length and diameter of each implant was matched to the visible radiographic implant dimensions for each implant measured in each image.

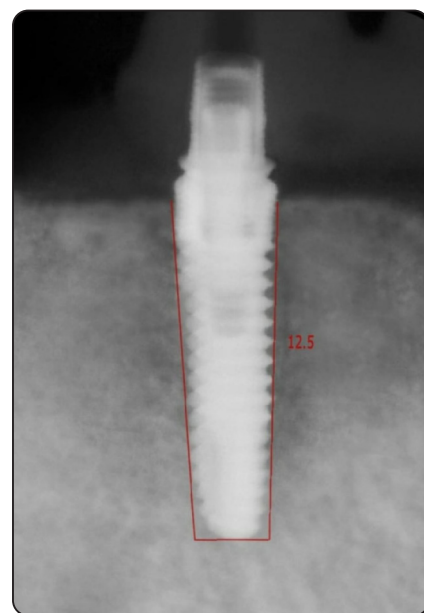


Fig. (5) The linear measurement of peri-implant bone loss

Prosthetic outcomes

• Prosthetic complications and maintenances

Along the study follow-up period (12 months); the technical prosthetic complications and maintenances were recorded to compared between the two groups A and group B for each patient. The patients who faced prosthetic complications throughout the follow-up period went to the clinic, maintenance services were performed and recorded. Additionally, there were scheduled checkup visits every six months to monitor the performance of the prosthesis and check the hygiene measures.

The following prosthetic complications' categories for each patient in both groups were recorded: Abutment screw loosening or fracture, prosthetic framework fracture, implant fracture, discoloration of the framework, abutment fracture, artificial gingival composite veneer chipping or fracture, zirconia crowns loosening (separation) or fracture. The sum of all complications in each category and their percentages to the whole complications in one group were calculated to be compared with that of the same category of the other group at the end of follow-up period.

Statistical analysis

The statistical software program Minitab (Minitab 17.0, Pennsylvania, USA) was utilized to analyze the collected tabulated data. The normality of data was explored using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The parametric Data were presented as mean \pm standard deviation (SD), while non-parametric data were expressed as median, range (minimum-maximum) and mode. The peri-implant bone loss (PIBL) data were analyzed utilizing repeated measures Analysis of variance (ANOVA), student t-test, Tuckey post Hoc test and paired t-test. The soft tissue outcomes were analyzed utilizing Freidman, Dunn's post hoc and Mann-Whitney tests. The prosthetic complications and maintenance data were presented

as total maintenance events in each category throughout the twelve-months follow-up period and their percentages from the whole complications and maintenance needed in each group. In all the statistical analysis, any P-value ≤ 0.05 was considered as the level of significance.

RESULTS

This clinical trial was conducted on fourteen completely edentulous patients (11 males and 3 females) with a mean age 59 years (range 55-65). The participants were randomly assigned to this study. New complete denture was constructed and delivered to each patient. Each patient had four root form implants inserted in the mandibular arch following delayed implant-loading protocol. Three months later, each patient received a fixed detachable prosthesis. The patients were randomly allocated in two groups. The grouping was assigned according to the material of the prosthesis framework. In **group A**, patients received screw retained prosthesis with **PEEK** framework and individual zirconia crowns. In **group B**, patients received screw retained prosthesis with **PEKK** framework and individual zirconia crowns. The follow-up period was twelve months after implant loading. One year later, no drop out was observed. According to the success criteria followed in this study, all implants had a 100% success rate in both groups at the end of the follow-up period.

Soft tissue outcomes

• Modified Plaque Index (mPI), simplified Gingival Index (sGI), modified Sulcus Bleeding Index (mSBI)

The comparisons of the modified Plaque Index (mPI) simplified Gingival Index (sGI), modified Sulcus Bleeding Index (mSBI) results at zero, six, twelve months follow-up visits are listed in (Table 1). On exploring the time effect on soft tissue health in both groups, the mPI, sGI and mSBI increased

significantly with time within group A (PEEK) comparing follow-up visits results ($p < 0.05$). Similarly, there was a statistically significant difference between the mPI, sGI and mSBI between all follow-up visits compared pairwise to each other within group A ($p < 0.05$). On the contrary, no statistically significant difference was found ($p > 0.05$) between the mPI, sGI and mSBI at follow-up visits within group B (PEKK). On comparing the mPI, sGI and mSBI between both groups at the follow-up visits, no statistically significant difference was found at the 0-month follow-up visit between the two groups ($p > 0.05$). On the other

hand, a statistically significant difference was found between mPI, sGI and mSBI of both groups at the six- and twelve-months follow-up visits ($p < 0.05$). The PEEK group had a significantly higher mPI, sGI and mSBI than the PEKK group at the six- and twelve-months follow-up visits.

Radiographic outcomes

Peri-implant bone loss (PIBL)

The PIBL was calculated at the mesial and distal side of each implant in Group A and B during the different follow-up intervals (0-6m, 6-12m, and 0-12m). A paired t-test was compared the

TABLE (1) The analytical data of the modified Plaque Index, (mPI) simplified Gingival Index (sGI) and modified Sulcus Bleeding (mSBI) in group A and B at all visits

Follow-up visit	Group A (PEEK) (n=7)		Group B (PEKK) (n=7)		Mann-Whitney test P-value
	Median (manimum-maximum)	Mode	Median (manimum-maximum)	Mode	
Modified Plaque Index (mPI)					
0 month (baseline)	0.00 (0.00 -0.00) ^a	0	0.00 (0.00-0.00) ^a	0	1.00
6 months	1.00 (0.00-1.00) ^b	1	0.00 (0.00-1.00) ^a	0	0.014*
12 months	1.50 (0.00-2.00) ^c	2	0.00 (0.00-1.00) ^a	0	0.002*
Friedman Test	0.004*		0.89		
P-value					
Simplified Gingival Index (sGI)					
0 month (baseline)	0.00 (0.00 -1.00) ^a	0	0.00 (0.00-1.00) ^a	0	1.00
6 months	1.00 (0.00-2.00) ^b	2	1.00 (0.00-1.00) ^a	1	0.015*
12 months	2.00 (0.00-3.00) ^c	3	0.00 (0.00-1.00) ^a	0	< 0.001*
Friedman Test	0.003*		0.94		
P-value					
Modified Sulcus Bleeding Index (mSBI)					
0 month (Baseline)	0.00 (0.00 -1.00) ^a	0	0.00 (0.00-1.00) ^a	0	1.00
6 months	1.00 (1.00-1.00) ^b	1	0.00 (0.00-1.00) ^a	0	0.017*
12 months	1.00 (0.00-2.00) ^c	2	1.00 (0.00-1.00) ^a	1	0.028*
Friedman Test	0.002*		0.91		
P-value					

P-value ≤ 0.05 is considered significant. Within each outcome, similar superscript letters indicate non-statistically significant difference

PIBL at distal and mesial sides of each implant. No statistically significant difference was found between distal and mesial PIBL in each implant in both groups ($P > 0.05$). Consequently, the mean of the distal and mesial PIBL for each implant was calculated. On exploring the effect of time on PIBL within each group individually, the PIBL showed a statistically significant difference within group A and B separately between follow-up intervals ($P < 0.05$). Accordingly, a Tuckey post-hoc test was done to make pairwise comparisons between PIBL in different follow-up periods within each group individually. A statistically significant difference was found in PIBL between all follow-up intervals when compared to each other ($P < 0.05$).

To investigate the effect of framework material on PIBL, an independent t-test was done to compare PIBL in group A and B in each follow-up interval. Although the means of PIBL in group B were lower than that of group A in all follow-up intervals, no statistically significant difference between group A and B in PIBL was found ($P > 0.05$) at any follow-up interval (table 2).

TABLE (2) The analytical data of the Peri-implant bone loss (PIBL) measured in mm for group A and B at all follow-up intervals

Follow-up Interval	Group A (PEEK)	Group B (PEKK)	Independent t-test P-value
	Mean±SD	Mean±SD	
0-6 months	0.65 ± 0.48 ^a	0.54 ± 0.39 ^a	0.731
6-12 months	0.39 ± 0.28 ^b	0.35 ± 0.29 ^b	0.367
0-12 months	1.04 ± 0.45 ^c	0.90 ± 0.56 ^c	0.240
ANOVA P-value	< 0.001*	0.045*	

P-value ≤ 0.05 is considered significant. Within each outcome, similar superscript letters indicate non-statistically significant difference

Prosthetic outcomes

• Prosthetic complications and maintenances

The prosthetic complications and maintenance incidences according to the specified category during the study follow-up period (twelve months) were listed, tabulated and their percentages to the total prosthetic complications and maintenances noted for each group individually were presented as number of complication incidences (their percentage from the whole complications for the group) in table 3. In the current study, the prosthetic survival rate was 100%. Absence of fracture of the Ti-base, the framework, the abutment screw, implant, and the abutment in both groups was detected. The prosthetic complications and maintenance incidences were fewer and less frequent in group B (PEKK) compared to group A (PEEK) in all categories. Moreover, the total sum of complications and their percentages in group A and B compared to the total prosthetic complications of both groups were 8 (66.7%) and 4 (33.3%) respectively. The most frequent prosthetic complication in both groups was the abutment screw loosening 83.4% of the whole prosthetic maintenance requirements. The latter complication was relatively higher in group A than group B. Six abutment screws were loose and retightened in group B. On the other hand, four abutment screws were loose and retightened in group A. One framework in group A displayed minimal discoloration in its fitting surface in proximity to the Ti-bases. Chipping of the gingival composite in one prosthesis in group A was recorded and was fixed by creating retentions in the PEEK framework with the use of a tungsten bur to improve mechanical retention and the application of a different bonding primer to enhance the bond tensile strength between the framework material and the gingival composite.

DISCUSSION

The compromised masticatory efficiency and

TABLE (3) The prosthetic complications and maintenance events throughout the whole study follow-up period (twelve months) for group A and B

Prosthetic complication and maintenance	Group A (PEEK) Number (percentage)	Group B (PEKK) Number (percentage)	Total Number for the two groups
Abutment screw loosening and retightening	6 (75%)	4 (100%)	10 (83.4%)
Implant fracture and replacement	0 (0%)	0 (0%)	0 (0%)
Abutment screw fracture and retrieval	0 (0%)	0 (0%)	0 (0%)
Discoloration of the framework	1 (12.5%)	0 (0%)	1 (8.3%)
Prosthesis fracture (framework fracture)	0 (0%)	0 (0%)	0 (0%)
Zirconia crown loosening and re-cementation	0 (0%)	0 (0%)	0 (0%)
Abutment fracture	0 (0%)	0 (0%)	0 (0%)
Chipping of fracture of gingival composite	1 (12.5%)	0 (0%)	1 (8.3%)
Fracture of Zirconia crowns	0 (0%)	0 (0%)	0 (0%)
Total	8 (66.7%)	4 (33.3%)	12

instability are the most frequent complaints of complete denture wearers especially with the mandibular denture^{54,55}. Several prosthetic options can be used in conjunction with dental implants for edentulous mandible providing superior outcomes. Four Implant supported fixed-detachable prosthesis with metal framework and ceramic teeth is a highly predictable and commonly reported treatment option in literature^{1-4,56}

The survival rate of the prostheses in both groups was 100%. Accordingly, the successful clinical performance of the PEEK and PEKK as framework materials in implant supported prostheses individually is reported in the current study. This higher success was documented in limited clinical studies^{32,22, 40-50} and scarce invitro studies that compared the PEEK to PEKK^{12,26,35}. The superior biomechanical properties of both materials encouraged their use in implant screw retained prosthesis. Unlike the more rigid metal alloys with higher elastic modulus, the lower elastic modulus of PEEK and PEKK (comparable to native bone and

dentin) and their use as a framework material may lead to lower stress concentration in the supporting structures. Additionally, their relative flexibility compared to metal frameworks may be more efficient in reducing stresses⁵⁷⁻⁵⁹. It was reported that rigid framework materials with a higher modulus of elasticity were more resistant than frameworks with lower modulus of elasticity to bending forces generated by the natural mandibular flexure during functional movements⁶⁰. This fact may also have an impact on reducing the amount of stress and magnitude of forces falling on the opposing arch.

Several studies recommended investigating the clinical performance of both materials with long term follow-up periods^{12,13,23}. Hence, this study was conducted to investigate and compare their effect on supporting structure in implant supported screw retained prostheses clinically. The null hypothesis which stated that there is no significant difference between the effect of PEEK and PEKK frameworks in screw retained prostheses on the peri-implant bone loss was accepted. While the null hypotheses

which stated that there is no significant difference between the effect of PEEK and PEKK frameworks in screw retained prostheses on the soft tissue health and prosthetic complications were rejected.

The implant success and the prosthetic survival rates in the PEEK and PEKK groups were (100%) after one year follow-up. These findings are comparable to other studies' findings^{22,46,61} comparing the PEEK to the metal frameworks in fixed-detachable prostheses. These high rates can be attributed to the strict patient selection criteria, appropriate cases diagnosis, forethought treatment plan, meticulous surgical procedures, proper choice of implant system with advanced double-grip surface enhancing osseointegration, delayed loading of the implants after ensuring successful osseointegration, properly designed and precisely constructed prostheses. Moreover, patients were instructed to follow ultra-careful oral hygiene measures.

The plaque accumulation is primarily affected by the surface roughness of dental materials as rough surfaces enhance bacterial adhesion as a result of increased surface area. Consequently, the bio-adhesion can be dramatically reduced with low surface roughness materials^{62,63}. On comparing the mPI, sGI and mSBI results in both groups, their values in the PEKK were significantly lower than that of PEEK in 6- and 12-months follow-up visits. Moreover, the mPI, sGI and mSBI values showed no statistically significant difference between the different follow-up visits within the PEKK group. On the contrary, their values within the PEEK group showed a progressive increase and a statistically significant difference between the different follow-up visits values. This finding may be attributed to the results obtained by another study which stated that the surface roughness of the PEKK ($0.502 \mu\text{m}$) is approximately half that of the PEEK ($1.186 \mu\text{m}$) used in this study⁶⁴. This relatively higher surface roughness of the PEEK compared to that of the

PEKK may have been the reason behind the higher plaque affinity and accumulation in the PEEK group compared to that of the PEKK group. Likewise, the bacterial adhesion to the PEKK surface is significantly lower than that of the PEEK by 37%⁶⁵. Hence, this may also contribute to the lower plaque accumulation and significantly lower PI in the PEKK group compared to the PEEK group. The relatively increased plaque accumulation in the PEEK group compared to the PEKK group may have triggered the elevated sGI and mSBI values owing to gingival inflammation and irritation. This relationship between plaque accumulation and gingival inflammation was documented^{22,46}. Hence, the results of the sGI and mSBI followed the same pattern as that of the mPI in both groups. Regarding the PEEK group, the significantly higher plaque index results contrasted the results of two studies which reported that the PEEK has low plaque affinity^{23,24}. This disagreement with the current study results may be because one of them was an in vitro study comparing PEEK to titanium and zirconia²³, while the other was only a case report²⁴.

The mean peri-implant bone loss (PIBL) was less than 1.2 mm at the end of the follow-up (twelve months) period for both groups. This outcome complies to the accepted standards for implant success criteria⁵¹ and compares equally with other studies which evaluated the peri-implant bone loss for full-arch restorations^{66,67}. The favorable PIBL results at the end of the follow-up study may be attributed to the previously mentioned reasons for implant success and the fact that the PEEK used in this study is A modified PEEK reinforced by 20% nano-ceramic fillers which improves its biomechanical properties⁶⁸. Additionally, the PEKK used in this study is another high-performance polymer reinforced with 20% titanium dioxide with superior mechanical properties. Hence, PEEK and PEKK can provide a favorable metal alternative as a framework material when used in combination with high-

strength veneering glass-ceramic for the implant supported prostheses especially in the high-stress-bearing areas⁶⁹. Several review articles stated that both materials can provide a superior promising alternative to metal or zirconia as a framework material^{14,19,70}.

Both polymers are light in weight, non-allergenic and biocompatible. Less biofilm is accumulated on their surfaces compared to the metal alloys^{14,15,16}. Compared to other framework materials, both polymers have relatively low elastic modulus, comparable to bone and dentin, causing stress reduction in the prosthetic frameworks¹⁷. This may be accredited to the shock absorbing nature of both materials which may have transmitted less stress to the supporting bone. Also, the CAD/CAM method used in the fabrication of frameworks is a major reason of their superior marginal and passive fit. Absence of passive fit may cause occlusal inaccuracies, increased stresses around implants and eventually bone loss^{11,71}.

Although the mean peri-implant bone loss in the PEKK group after six and twelve follow-up periods was lower than that of PEEK group, no statistically significant difference was found, this may be attributed to the superior shock absorbing capacity, mechanical response to shear stress, compressive and tensile strength of the PEKK compared to that of PEEK^{13,34}. Another possible reason for the insignificant difference in peri-implant bone loss between both groups may be the relatively short follow-up period.

The peri-implant bone loss showed significant increase with time; from implant loading till the end of this study in both groups. This finding may be caused by the reaction of bone in the healing process and its reorganization to functional stresses. This outcome was documented by other studies which reported that peri-implant bone loss increased with time in mandibular implant screw-retained prostheses^{56,72}.

Regarding the high prosthesis survival rate (100) % and the relatively low incidence of prosthetic complications and maintenance interventions in both groups, this may be attributed to the design of the prosthesis, good treatment planning, the superior biomechanical properties of the prosthetic components and the method of framework fabrication. It was reported that frameworks fabricated by CAD/CAM methods can be more precise, providing superior passive fit and resistance to fracture⁷³. In addition, this finding can be credited to the exclusion of patients with parafunctional habits. According to a systematic review, parafunctional habits represent extreme overload on the prosthesis and are considered a crucial reason for prosthetic fracture and failure⁷⁴. The low incidence of prosthetic complications with high performance polymers was reported in other studies^{22, 46,32}. The higher incidence of prosthetic complications especially abutment screw loosening in the PEEK group compared to the PEKK group may be attributed to the lower elastic modulus of the PEEK compared to PEKK which increases the stresses on the screws⁷⁵. Moreover, the PEKK possesses superior mechanical properties in terms of tensile, flexural, and compressive strength as compared to the PEEK. The mechanical response of the PEKK is superior to the PEEK, particularly in shear compression and shock absorbance ability. This superior shock absorbance of PEKK as compared to PEEK reduces stress concentration in the prosthetic screw and base in screw retained prostheses. Consequently, the fracture risk of the acrylic base and screw loosening clinically might decrease^{13,20,33}. Furthermore, in a Three-Dimensional Finite Element Analysis study³⁴, it was reported that the PEKK -compared to the PEEK- as a framework material resulted in a lower stress concentration on the prosthetic screw and prosthetic base. This finding was attributed to the superior shock absorbing capacity of PEKK compared to PEEK. One PEEK framework displayed minimal

discoloration in its fitting surface close to the Ti-bases. The lower wear resistance of PEEK compared to that of PEKK³¹ against Titanium might have caused this complication. Regarding the chipping of gingival composite incidence on the PEEK group, it may be due to the fact that durable bonding of composite to the PEEK framework is challenging as reported by a prospective cohort clinical study which stated that bonding to the PEEK substructure was the most problematic situation and represented the most frequent mechanical complication²².

CONCLUSION

Within the limitations of this study, the fixed-detachable implant-supported prosthesis with PEEK or PEKK framework can be a clinically successful treatment option for the rehabilitation of edentulous mandible. However, the fixed-detachable prosthesis with the PEKK framework may provide superior soft tissue health outcomes and fewer prosthetic complications compared to those with the PEEK framework.

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