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METAL VERSUS POLYETHER-ETHER KETONE (PEEK) FRAMEWORK REINFORCEMENTS FOR MAXILLARY PALATELESS BALL RETAINED IMPLANT OVERDENTURES. ONE YEAR CLINICAL AND RADIOGRAPHIC OUTCOMES

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ABSTRACT

Objectives: This study aimed to investigate both the clinical and radiographic outcomes of metal and Poly ether-ether ketone (PEEK) framework reinforcement materials for maxillary palateless ball retained implant overdentures after one year follow-up period .

Materials and methods: Eight edentulous patients with edentulous maxillary ridges and implant retained mandibular overdentures who complained from lack of retention of their maxillary dentures were classified into 2 groups; group 1 included 4 patients who received palateless maxillary overdentures with cobalt chromium metal reinforcement, group 2 (included 4 patients who received palateless maxillary overdentures with PEEK reinforcement. All patients received 4 implants in canine and second premolar areas of maxilla. After 6 months, overdentures were attached to the fixtures with O/ring attachments. Clinical outcomes included Plaque indices, bleeding indices, depth of probing and implant mobility) and radiographical evaluation included marginal bone resorption. All outcomes were evaluated at prosthesis delivery, 6 months and one year after prosthesis delivery.

Results: The survival rate of the implants showed significant difference, as it was 83% and 100% for metal and PEEK groups respectively. Plaque and bleeding scores, as well as pocket depth increased significantly from base line to 12 months. Bone resorption progressed significantly from 6 months to 12 months in both groups. PEEK group showed significantly lower plaque scores, bleeding scores, probing depth and bone resorption than metal one. No significant differences in mobility of the implants in-between observation times or groups were noted.

Conclusion: Within the scope of this study, PEEK reinforcement for maxillary palateless implant overdentures is recommended more than metal cobalt chromium reinforcements as it showed favourable clinic and radiographical responses after one year of overdenture insertion.

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INTRODUCTION

Implant-retained maxillary overdentures are predictable treatment modality for edentulous maxilla[1,2]. Maxillary implant overdentures are indicated as an alternative to fixed prosthesis in many cases such as resorbed maxillary ridge, short implants, pneumatized maxillary sinuses (as an alternative to bone grafting), medically debilitated patients, unfavourable arch relationships[3,4]. Moreover, they are recommended in patients with high lip-line, long teeth, buccal inclined ridge, intermaxillary distance beyond 15mm, abnormal skeletal relationships, crossbite and incongruence of implant location. It also recommended than fixed restorations to provide good lip and cheek support, and when cost is a factor (as few implant number is used)[5]. In addition, hygiene access can also be obtained with implant maxillary overdenture compared to fixed prosthesis[6]. O-rings on ball abutments are widely used anchors as they are simpler, less cost as well as little time consuming, providing more space for artificial teeth and easier of use and maintenance as compared with bar superstructures. Additionally they have different retention values and act as shock absorber (transfer less forces to the implants)[7].

Maxillary implant overdentures involve installation of 4 implants in the anterior region of maxilla to enhance retention, support, and stability and thus reduce the necessity for palatal tissue coverage[8]. The removal of palatal coverage (palateless maxillary denture) improves oral sensation and comfort for the patients due to exposure of natural palatal mucosa [9], gives more room for the tongue, and exposes additional palatal tissue for better appreciation of food texture[10]. Also palateless overdentures are indicated with gagger patients, individuals with torus platainus or bony prominences, actors (due to changes in speech caused by palatal coverage), and patients with no experience of wearing of maxillary denture[11]. However, omission of palatal coverage adversely affects load transmission to the implants as it reduces the area for tissue support (especially support from stress bearing areas of the palate) and diminishes the retention of maxillary denture[9,12]. Ochiai et al.[9] reported that complete palatal coverage reduces load transfer to supporting implants and distributes stress between implants and adjacent soft tissue than palateless designs. Some investigators have shown clinical success as determined by survival of prostheses and implants in management of individuals with a palateless implant retained maxillary overdentures with a minimum of 4 supporting implants,[2, 13, 14]while other authors recommended palatal coverage when 4 or less implants are used[9, 15].

Polymethyl methacrylate as a denture base material, has low-mechanical-strength and are vulnerable to deformation during the mastication process. Therefore, reinforcing materials are needed to improve its mechanical properties[16]. Implant palateless maxillary overdentures have been reported to be associated with denture base deformation and fracture at the implant sites in addition to the midline[17]. In an invitro study, greater denture base deformation and strains have been reported to occur in the anterior palatal area of palateless implant maxillary overdentures and when the dentures were reinforced, significantly less strain and deformation were observed than dentures without reinforcement[18]. The clinical consequences of denture base deformation are denture fracture, and biological problems as mucosal ulceration, ridge resorption, implant overload, peri-implant bone loss and implant loss. Increased functional load that exceed physiologic adaptive capacity of the bone may cause micro-fractures at the bone–implant interface, fracture of the implant, loosening of components of the implant system, and unwanted bone resorption[19]. Reinforcement of the maxillary implant overdenture was reported to decrease stress around implants with partial palatal coverage regardless of the implant distribution [20].

El Ghazali et al.[21] reported that metal frameworks reduced the functional deformation and problems of

the supporting tissue. However, metal frameworks are heavier, require complicated fabrication steps, and in some patients possibility of hypersensitivity may exsists[16]. Materials other than metal for denture reinforcing were tested to avoid bad appearance and the reduced adhesion of metal to acrylic resin of the dentures [22]. These materials include carbon fibrils, fiber glasses, or rigid polyethylene fiber. Such materials may decrease denture deformation; however, they consume time and less accurate than that constructed by CAD/CAM technologies[23]. Recently, Polyether-ether-ketone (PEEK) which is thermoplastic resin was introduced to be used as a frame for fixed and removable prosthesis instead of metal. This material has comparable low absorption properties, corrosion resistance, radiolucent, has reduced wear, biocompatible, and not allergic, and has reduced modulus of elasticity than metal and ceramic materials[24]. It also has low creep, high wear resistance and good shock absorption property [25, 26]. The material frames for prosthesis can be constructed by either milling or thermo-pressing .

The aim of the present study was to evaluate clinical and radiographic outcomes of metal and Poly ether-ether ketone (PEEK) framework reinforcement materials for maxillary palateless ball retained implant overdentures after one year.

MATERIALS AND METHODS

This study was conducted on 8 completely edentulous patients (4 males and 4 females) who had 2 implant retained mandibular overdentures and complained from lack of stability and retention of their maxillary complete dentures. All patients were selected from the out-patient clinic of prosthodontics, faculty of dentistry, Beni-Suef University. The inclusion criteria were: 1) Completely edentulous maxillary ridges with healthy mucosa and absence of remaining roots and implant retained mandibular overdentures with either ball or bar attachments, 2) Adequate quantity (width and height average 15-20mm) and quality of maxillary ridge bone (as verified by preoperative cone beam CT) for the placement of 4 implants without bone augmentation 3) adequate inter-arch distance 4) age average 50-60y and 5) Absence of smoking habits. Patients with the following diseases were excluded: bone metabolic disorders (as diabetes mellitus), radiation to head and neck as well as liver, heart and autoimmune diseases that do not permit implant surgery . Consent was signed by all patients. The study was approved by committee of ethics of the Faculty of Dentistry, Beni-Seuf University . The patients were categorized by age, gender, and bone height in the maxillary anterior region and were randomly assigned into 2 groups using balanced randomization, then comparison of baseline criteria between groups was made to ensure that there was no difference in age, gender, and bone height between groups to avoid selection bias. Group I included 4 patients who received metal reinforced maxillary palateless overdentures, and group II included 4 patients who received PEEK reinforced maxillary palateless overdentures

Surgical and prosthetic procedures

The patient's existing denture should firstly evaluated regarding its centric relation position, vertical dimension of occlusion and teeth setting. The maxillary denture could not be adequately retained, but it should be precisely adapted to the underlying soft tissues ensuring that the surgical template would later seat in the mouth as accurately as the original denture did .Putty rubber base occlusal index was made while the patient wearing his denture and closing in centric position .

Ideal location and angulation of the implants and the correct implant length were assessed virtually and hence prototyping of surgical guide was made by using double –scan technique . Either the original maxillary denture itself or its duplicate was used to make as a radiographic template through using Gutta purcha as radiopaque markers that were fixed to the

polished (buccal, labial ad palatal) surfaces of the of the denture at different levels from the occlusal surface [27]. A radiographic template and cone beam CT (CBCT, i- CAT Vision®, Imaging Sciences International, Hatfield, PA, USA) were performed using double scan protocol. Each patient was firstly scanned while wearing the denture (radiographic template) that was stabilized in its correct centric position guided by the occlusal index, then the second cone beam scan was made for the denture only (radiographic template) that was oriented as it was in the patient mouth by the aid of occlusal index . The 3D image-based software (OnDemand3DApp Software; CyberMed Inc) superimposed exactly the two separate scans resulting in virtual planning of the implant positions and subsequent prototyping of a mucosal supported surgical guide (fig 1) . A surgical kit including sleeves and standardized drills (supplied by the manufacturer) was used for osteotomy preparation.

Each patient received 4 implants (3.6×12mm, Dentium SuperLine, South Korea), in the anterior part of the maxilla at canines and second premolar areas using the flapless surgical approach. All surgeries were carried out with infiltration anaesthesia (lidocaine with epinephrine). The surgical guide was fixed to the maxillary bone using fixation screws of the surgical kit. Standardized drills supplied with the kit was used for osteotomy preparation through the sleeves of the guide .The osteotomy sites preparation was followed by the drilling sequence as provided by the manufacturer's surgical universal kit. Implants were inserted with a minimum 35Ncm torque. In case of reduced bone quality (Class III and IV quality bone[28]), the final drill was not used to obtain good primary implant stability. 3.6-mm twist drills were used as the final drills. Healing abutments were connected and the maxillary dentures were relined with soft liner 2 weeks after implant placement. Post-operative panoramic radiographs were made to verify implant orientation (fig 2).

Six months after implant insertion (after osseointegration), primary maxillary impressions were made using alginate impression material (CA 37, Cavex Holland BV, Haarlem, Netherlands). A special tray was constructed over the cast with openings opposing to implant areas to be used for open tray impression technique[29]. Long transfer impression copings were threaded into the implants and splinted with resin pattern (Pattern Resin LS; GC America) to avoid movement of the transfer copying during the impression (fig 3). The light consistency rubber base was injected around the copings and the impression was completed with putty material. The implant analogues were attached to the impression post and the impression was poured

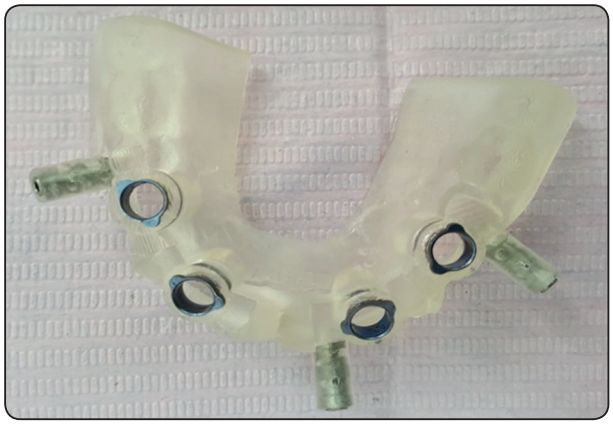

Fig. (1) The surgical guide

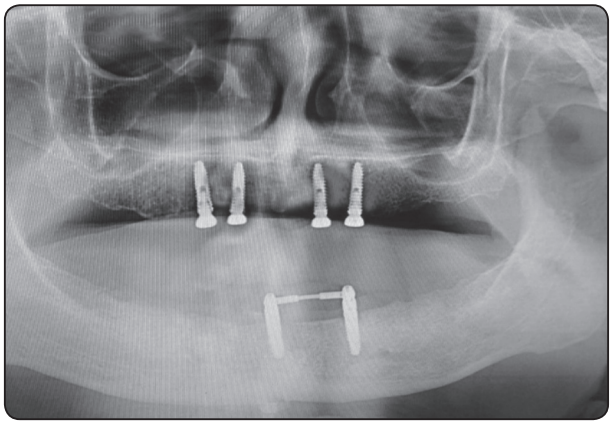

Fig. (2) Postoperative panoramic radiograph

to obtain the master cast. Ball abutments were connected to the analogues and metal housing with O/rings were snapped over the abutments.

The cast was scanned using CAD/CAM device (Ceramill Map400, Amann Girrbach AG. Koblach, Austria). Using the software of the device, the reinforcement frame was designed with a 1.0 mm-thickness to cover the crest of the ridge and the attachment after providing relief space for attachment of the metal housing and saved as STL file. The designed frame was either printed (using additive method) into castable resin using a laser sintering device (EOSINT, Germany) for group I or milled in PEEK blocks using CAD/ CAM subtractive manufacturing for group II.

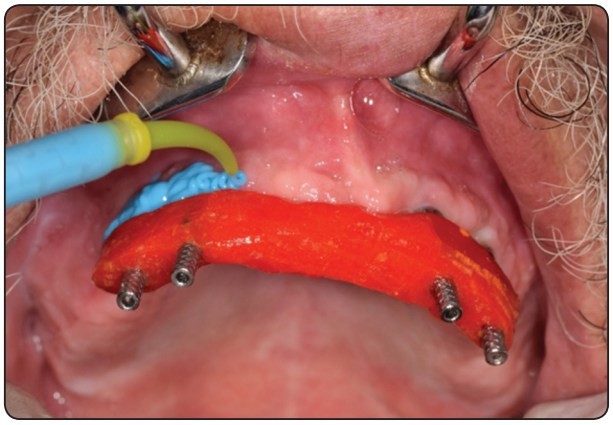

Fig. (3) The impression technique

For Group I, the castable resin frames (GC Pattern Resin, GC Corp, Tokyo, Japan) were invested, cast in cobalt chromium metal frame (fig 4). For group II, frames were milled in modified PEEK discs (BioHPP, high performance polymer, Bredent GmbH & Co.KG, Weißenhorner Str. 2, 89250 Senden, Germany) (fig5) .The thickness of both metal and PEEK frames was standardized at 1mm[23]. Record blocks were made on the master casts and Jaw relationships were recorded. The palatal portion of the denture bases were removed (horse shoe design). The frames were placed over the attachments on the master cast and packing of acrylic resin and denture processing were performed in the usual manner.

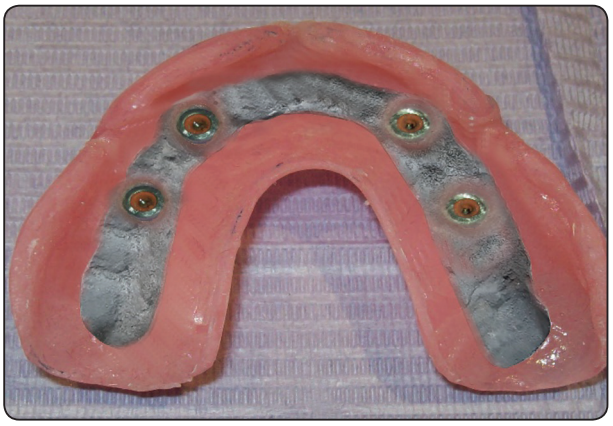

Fig. (4) Group I: Metal reinforced palateless maxillary overdentures with O/ring attachment (fitting surface)

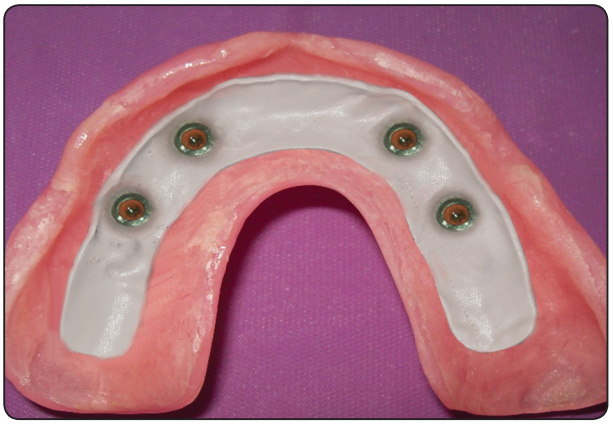

Fig. (5) Group I: PEEK reinforced palateless maxillary overdentures with O/ring attachment (fitting surface)

Ball abutments were screwed to the implants intraorally at 25 Ncm torque (fig 6). Dentures were delivered to the patients after performing necessary adjustments with emphasis on performing adequate oral hygiene. Regular follow up visits were scheduled for collection of data. The outcomes were evaluated at prosthesis delivery (base line), 6 months and one year after delivery.

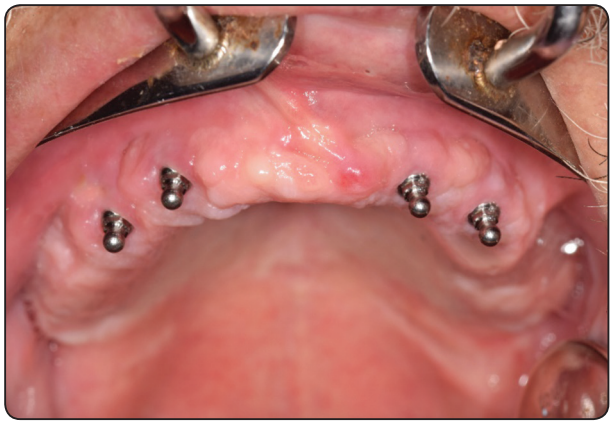

Fig. (6) Ball abutments in patient mouth

Clinical evaluation

The implant success rate was estimated using the parameters described by Albrektsson et al[30] (i) absence of implant mobility; (ii) absence of peri-implant radiolucency; and (iii) absence of persistent signs and symptoms such as pain, infections or paraesthesia .While, Survived implant is the implant that still functions but not necessarily to follow the Albrektsson criteria and does not need explanation why it is still working.

Plaque Index (PI) and Bleeding Index (BI) were measured as suggested by Mombelli and coworkers[31]. Periodontal probe used to measure the distance from free gingiva to the depth of probing as pocket depth (PD). Plaque index, bleeding index and probing depth were evaluated at lingual, mesial, buccal, and distal aspect of each implant. Implant mobility (stability, ISQ) was measured by resonance frequency analysis (RFA, OsstellTM; Osstell AB, Gothenburg, Sweden)[32, 33]. The increased ISQ values indicated increased implant stability[27].

Radiographic evaluation

Evaluation of marginal bone loss was made using cone beam computerized tomography (i-CAT device; Imaging Sciences Intl) at base line, 6 months, and one year after overdenture insertion. The marginal bone resorption was measured at mesial, distal, buccal and lingual surface of each implant. Using a curve tool of the software (OnDemand3DApp Software; CyberMed Inc), a curve was drawn to bisect each implant from the occlusal (axial) view. The images were reconstructed by the software cross sectional image for each implant and panoramic images for all implants. Mesial and distal peri-implant bone resorption was measured at the panoramic images. Buccal and lingual bone resorption was calculated at cross sectional images. The distance from implant abutment junction (point A) to the bone contact with implant (point B) was measured to give bone level[34] (fig 7). Bone loss was estimated as the difference in bone levels at 6m and 12m from values at base line. The bone loss measurement for right and left canine and premolar implants were averaged

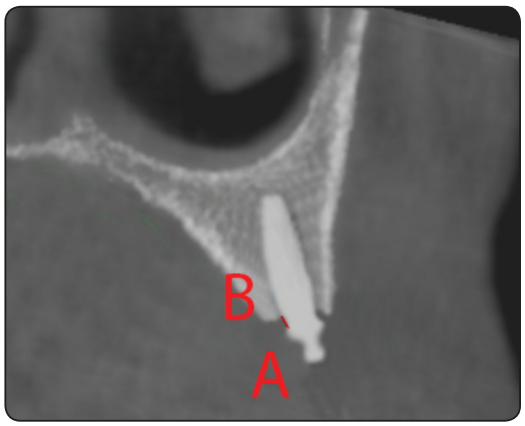

Fig. (7) Measurement of buccal and lingual marginal bone loss in cross-sectional images of the CBCT

Statistical Analysis

Data analysis was performed with SPSS program (SPSS Inc., V. 22, Chicago, IL, USA). The data was non parametric as verified by Shapiro-Wilk test. Descriptive statistics of all parameters were reported as median (minimum-maximum). To calculate the survival rate, a Kaplan-Meier method was used. To detect the difference in tested outcomes between observation times, Friedman test was utilized. To test the significant difference between each 2 times,

Wilcoxon signed ranks test was used for pair wise comparison. Comparison of all outcomes between prostheses was made using Mann Whitney test. P is significant if < 0.05. The confidence interval was set at 95%.

RESULTS

1- Survival analysis

Three implants in the same patients failed in Metal group in the first 6 months after final overdenture insertion resulting in 83% survival rate in this group. No implants failed in PEEK group resulting in 100% survival rate in this group. PEEK group recorded significant higher survival rate of implants than metal group (log rank test, p=.048*). The failed implants were associated with bone loss, suppuration and mobility. The patient (in group I) was excluded from the study without affecting the results since intention to treat analysis was followed in this clinical trial. Survival analysis using Kaplan-Meier method for both groups is presented in (fig.8).

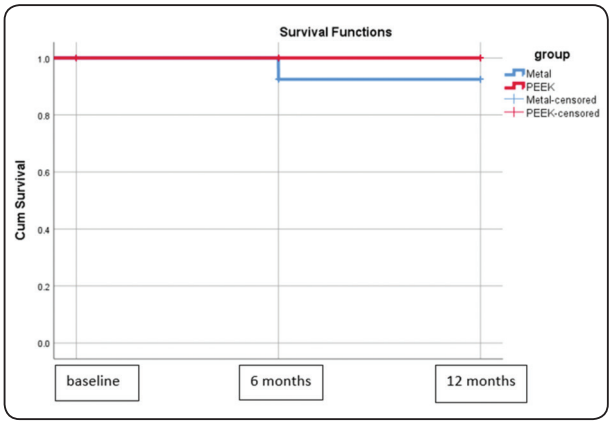

Fig. (8) Survival analysis using Kaplan-Meier method for both groups

2-Effect of time

Comparison of all tested parameters between time intervals and between prostheses is presented in table 1. Plaque scores increased significantly from base line to 12 months (p=.012) for Metal group. There was a noted difference in plaque scores between each 2-time intervals. For PEEK group, there was no difference in plaque scores between observation times. Bleeding scores increased significantly from base line to 12 months (p=.035) for Metal group. There was a significant difference in bleeding scores between baseline and 6 months and between base line and 12 months, however no difference was noted in bleeding scores between the three observation times For PEEK group. Pocket depth increased with passage of time in both groups (p=.014 and .021 for metal and PEEK respectively), also for both groups, there was a significant difference in pocket depth between each 2-time intervals. No difference in implant mobility between time intervals was noted for both groups. Peri-implant bone resorption increased from 6 months to 12 months for both groups (p=.025 and .030 for metal and PEEK respectively).

3-Effect of group

Comparison of all tested parameters between groups is presented in table 1. At base line (at over-denture insertion), no difference between groups was noted regarding all parameters. Metal group showed significant higher plaque scores than PEEK group at 6 (p=.004) and 12 months (p=.011). Metal reinforced prosthesis showed higher gingival scores than PEEK reinforced prosthesis at 6 (p=.024) and 12 months (p=.033).Similarily metal reinforced prosthesis showed significant higher pocket depth than PEEK reinforced prosthesis at 6 (p=.020) and 12 months (p=.010). No significant difference in implant stability between groups was noted at 6 and 12 months. Metal group showed significant higher bone resorption than PEEK group at 6 (p=.010) and 12 months (p=.005).

TABLE (1) Comparison of plaque, bleeding indices, probing depth, implant mobility and bone resorption between time intervals and between groups

	Base line	**6 months**	**12 months**	**Freidman test (p value)**
Plaque scores				
Metal Med(Mini-Maxi)	.00(.00-1.00) a	2.00(1.00-.300) b	2.5(2.00-3.00)c	.012*
PEEKMed(Mini-Maxi)	.00(.00-1.00)	.00(.00-1.00)	0.00(0.00-1.00)	1.00
Mann Whitney Test (p value)	. 87	.004*	.011*	
Bleeding scores				
Metal Med(Mini-Maxi)	.00(.00-.00) a	1.00(0.00-.200) b	1.00(.00-2.00) b	.035*
PEEK Med(Mini-Maxi)	.00(.00-.00)	.00(.00-.00)	.00(.00-.00)	1.00
Mann Whitney Test (p value)	1.00	.024*	.033*	
Probing depth				
Metal Med(Mini-Maxi)	.78 (.23-1.4)a	1.9 (1.5-2.6)b	3.0(2.23-3.3)c	.014*
PEEK Med(Mini-Maxi)	.81 (.24-1.23)a	1.6 (1.0-2.1)b	2.0 (1.4-2.20)c	.021*
Mann Whitney Test (p value)	.075	.020*	.010*	
Implant stability				
Metal Med(Mini-Maxi)	65.45±1.77	65.01±1.68	66.40±1.59	.098
PEEK Med(Mini-Maxi)	66.70±1.61	66.40±1.62	67.80±1.01	.066
Mann Whitney Test (p value)	.30	.31	.20	
Marginal bone loss				
Metal Med(Mini-Maxi)	-	.99(.7-1.2) a	1.26(.9-1.4) b	.025*
PEEK Med(Mini-Maxi)	-	.81(.6-1) a	.98(.73-1.1)b	.030*
Mann Whitney Test (p value)	-	.010*	.005*	

Med= median, mini= minimum; maxi= maximum; different letters in the same raw indicate significant difference between each 2-time intervals (Wilcoxon signed ranks test, p<.05). Same letters indicate no difference between time intervals. *= p is significant at .05 level

DISCUSSION

In this study, The flapless surgical approach was used in this study as it has several advantages including; minimal post-operative discomfort, reduced edema, (no sutures or open wound)[35,36], reduce the peri-implant bone loss as reflection of the flap cause mucoperiosteal stripping that may induce bone loss around the implants[37]. Cone-beam computed tomography (CBCT) was used for evaluation of marginal bone loss in buccal and lingual sites beside mesial and distal which is not applicable in case of periapical radiographs[38], as CBCT provides three-dimensional images and consequently additional information in comparison with the two-dimensional periapical radiographs [39].

The incorporation of a rigid metal framework is a common practice to strengthen the overdentures, increase flexure strength especially if the palatal portion is removed to avoid denture flexion or fracture. The use of a PEEK overdenture over ball anchors was previously suggested to strengthen the over denture for patients who have metal allergy[40]. Another advantage of modified PEEK is high bond strength with acrylic resin and composite resin provided by the manufacture through the primer (visio.link; Bredent GmbH & Co. KG)

Since clinical and radiographic outcomes of PEEK reinforced overdenture prosthesis was not evaluated previously, comparison of the results of this study with other authors findings was not possible. In this study, the survival rate of PEEK reinforced group (100%) was significantly higher than metal reinforced group (83%). The increased survival rate of the implants in PEEK group concurred with the results of Malo et al.[41] Who reported that 100% implant survival rate for PEEK fixed All on four maxillary prosthesis after one year. On the other hand, the reduced survival rate in the metal group may be attributed to the heavy weight of the prosthesis which transmits more forces to the implants.

Plaque and bleeding scores significantly increased with metal group, however, for PEEK group, these parameters did not change with time. Also PEEK showed significantly lower plaque and bleeding scores than metal group . The increased bleeding scores for metal group could be attributed to the increased plaque scores which make more gingival inflammation and bleeding, as the causal relation between plaque and gingival inflammation was previously reported[41]. The decreased Plaque scores in the PEEK groups may be due to the reduced affinity of PEEK material to plaque accumulation with favorable chemical stability[42, 43]. The reduced plaque and bleeding scores in PEEK group was in line with findings of Klur, et al. [44] who found that PEKK-made restorations offer a good and stable alternative to CoCr-made restorations particularly in improving the oral hygiene.

Probing depth increased significantly with time with significant difference between groups. This could be related to the high plaque scores, increased bone loss and gingival enlargement, as the peri-implant mucositis is infectious diseases caused by bacterial biofilm and the edentulism by itself is not protection from peri-implant disease[45]. Moreover the relation between increased plaque scores, gingival scores and increased pocket depth was previously reported by Pontoriero et al.[46] who found that increase in mucositis severity, including inflammation of the soft tissues was associated with peri-implant pockets. The lack of difference in implant mobility between the two prostheses was not surprising and concurred with the results of other authors[47, 48] and may be attributed to the increased bone to implant contact and increased implant anchorage in the bone as functional implant loading was performed after complete osseointegration (after 6 months) in both groups.

Bone resorption progress significantly with time in both groups. This may be due to bone remodeling which occurs after implant placement and bone response to healing combined with function stresses[49] The reduced bone loss after one year in the PEEK group (.98mm) compared to metal group (1.26mm) concured with finding of other study in which the authors found that PEEK maxillary fixed all on four prosthesis was asscociated with 0.37 mm bone loss after one year[41]. However, for both groups, the bone loss values are located within the accepted range reported in the literature[30]. The reduced marginal bone resorption of PEEK group compared to metal group may be attributed to the reduced modulus of elasticity, dampening of the occlusal forces, and shock absorption capability of PEEK compared to cobalt chromium framework reinforcements[25, 26]. Moreover, the BioHPP material is elastic as bone, which acts as a stress breaker and reduces the occlusal forces transferred to the restoration and implants [50]. On the other hand, metal reinforcement may increase peri-implant strains due to increased prosthesis weight and the modulus

of elasticity of metal which transfer more stresses to the implants during insertion and removal of the prosthesis. Additionally, PEEK material allow construction of lighter female housing and consequently, lighter prostheses, providing high patient satisfaction and comfort during function and reduce stresses transmitted to the implants[24]

In line with these findings, Zoidis et al.[40] suggested that PEEK materials for overdentures reduced stresses transmitted to the natural teeth abutments since PEEK has modulus of elasticity similar to that of dentin, but the metal has higher one. Overall, the PEEK reinforcement material was associated with reduced plaque, bleeding scores, pocket depth and marginal bone resorption compared to metal reinforcement. However, there were limitations for this study including the small sample size, the short evaluation period and lack of evaluation peri-implant tissues in the healing period. Therefore, long term randomized clinical trials with sufficient sample size are still needed.

CONCLUSION

Within the scope of this study, PEEK reinforcement for maxillary palateless implant overdentures is recommended than metal cobalt chromium reinforcements as it recorded favourable clinic and radiographical outcomes after one year of overdenture insertion.

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