Individuals with mandibular distal extension partial dentures opposing maxillary complete dentures usually have habitual protrusive biting with increased occlusal pressure on the anterior portion of the maxillary ridge. This situation may result in several degenerative changes known as combination syndrome (anterior hyperfunction). Such changes include ill-fitted maxillary dentures, loss of posterior occlusion, increased anterior occlusal forces, and maxillary bone loss with flabby tissues. An effective approach to prevent this sequela is to insert implants in the anterior maxillary ridge to improve support for the maxillary prosthesis.

Implant rehabilitation of a totally edentulous maxilla is often complicated by reduced bone quality and inadequate bone volume, especially in the posterior regions due to maxillary sinus pneumatization. The use of implant tilting to avoid maxillary sinuses was considered a successful alternative to bone grafting. This approach decreases patient morbidity, costs, and rehabilitation time. The combination of axial and tilted implants together with immediate loading was introduced by Malo et al and is known as the All-on-4 treatment concept (Nobel Biocare). The concept provides several advantages, such as reduction of implant number, reduction of prosthetic cantilevers, better load distribution,
avoidance of bone grafting, and immediate restoration of function and esthetics.\textsuperscript{11} The use of the All-on-4 concept in the maxilla has been demonstrated to be an effective approach with favorable clinical outcomes.\textsuperscript{5,12,13} Immediate restoration of the implants was provided by provisional screw-retained acrylic partial dentures or acrylic dentures after modification. The definitive prosthesis includes hybrid metal-ceramic or metal-acrylic restorations.\textsuperscript{5,14}

Polyether ether ketone (PEEK) is a thermoplastic material used as an alternative to metal for prosthetic frameworks due to its favorable biomechanical properties. PEEK is biocompatible, corrosion-resistant, radiolucent, chemically stable, and has a reduced plaque affinity.\textsuperscript{15,16} The mechanical properties include good strength-to-weight ratio, reduced creep, wear resistance, dampening effect,\textsuperscript{17,18} and reduced weight.\textsuperscript{19} Such material was suggested for full-arch prostheses as a nonmetal alternative.\textsuperscript{20} Also, it may be constructed by CAD/CAM or by injection molding.\textsuperscript{19} In an attempt to improve the modulus of elasticity of PEEK, ceramic fillers were added to produce high-performance polymer, which has an elastic modulus similar to the bone.\textsuperscript{21} Moreover, ceramic-reinforced PEEK can be used for implant superstructures, as it has a shock-absorbing ability and good bond strength to acrylic and composite resin teeth.\textsuperscript{19,22} Reviewing the literature, the use of PEEK material for All-on-4 implant-supported fixed restorations is relatively scarce.\textsuperscript{19,20} Moreover, the evaluation of the clinical and technical outcomes of this material was limited to one study,\textsuperscript{20} in which the author used PEEK frames veneered by acrylic resin teeth. Furthermore, the comparison of the clinical outcomes of PEEK composite with metal-ceramic fixed restorations for All-on-4 implant rehabilitation was not a concern. Accordingly, this study aimed to investigate clinical (primary) and prosthetic (secondary) outcomes of metal-ceramic and PEEK fixed prostheses for maxillary All-on-4 implants opposed by distal extension partial dentures. The null hypothesis was that there would be no difference in the clinical and prosthetic outcomes between the tested prostheses.

**MATERIALS AND METHODS**

**Participants and Study Design**

Thirty participants with edentulous maxillary and distal extension mandibular ridges (class I Kennedy; the remaining dentition included the anterior teeth only or anterior teeth and first premolars) were selected from patients attending the Prosthodontic Department. The inclusion criteria were as follows: (1) patients complaining about looseness of maxillary dentures and preferring fixed prostheses, (2) inadequate amount of bone for implant placement in the posterior maxillary ridges due to sinus pneumatization, (3) good bone quantity (classes III to V according to Ca-wood and Howell\textsuperscript{23}) and density (classes I to III according to Lekholm and Zarb\textsuperscript{24}) in the area between the maxillary sinuses to receive four implants [at least 3.7 mm in diameter and 11 mm in length]). This was verified by preoperative CBCT. The exclusion criteria included all patients with (1) head-and-neck radiotherapy, (2) bleeding disorders, (3) metabolic diseases such as diabetes mellitus and osteoporosis, (4) long-term immunosuppressive and corticosteroid therapy, and (5) smoking habits. Sample size calculation was done to give 95% power based on the results of another report,\textsuperscript{25} which detected a significant difference in pocket depth between two types of prostheses used to restore patients according to the All-on-4 concept (effect size = 1.41 mm, and α [2 tailed] = .05). The G*Power program was used for sample size calculation. The participants were stratified regarding age, sex, maxillary ridge height, and time of edentulism (baseline characteristics), and randomly assigned into two groups using simple random numbers in the Excel (Microsoft) program. Balanced randomization was followed to yield a nonsignificant difference between groups concerning baseline characteristics. Group 1 (metal group) comprised 15 patients who received four implants in the edentulous maxilla according to the All-on-4 concept and fixed porcelain-fused-to-metal restoration. Group 2 (PEEK group) consisted of 15 participants who received four implants according to the All-on-4 concept and rehabilitated by fixed PEEK frame veneered with composite resin. All patients signed informed consent, and the study plan was approved by the ethical committee of the Faculty of Dentistry. Consolidated Standards of Reporting Trials (CONSORT) were used.

**Surgical and Prosthetic Procedures**

For each participant, a dual scan protocol (scan for the denture alone and scan for the patient while wearing the denture) was done using CBCT (i-CAT). Overlapping and reformattin of the images were done using the accompanying software (Cybermed). Planning of the implants was done according to the All-on-4 protocol.\textsuperscript{5,13} Two implants were aligned vertically in the canine–lateral incisor region, and two implants were oriented just anterior to the maxillary sinuses with 30-degree distal inclination. Using the virtual plane, individualized mucosal-borne stereolithographic surgical guides with sleeves over implant sites were printed using laser sintering (In2Guide, Cybermed). The surgical guide was anchored to the maxillary ridge using anchor pins guided by an interocclusal record. Four implants (Dentaaurum) were inserted using the one-stage flapless surgical approach by the same oral and maxillofacial surgeon (A.S.S.). A universal surgical kit (In2Guide) with successive drills that fit into the template sleeves was used for osteotomy preparation (Fig 1). The implants were inserted using 35-Ncm torque or greater to allow immediate loading. Multiunit abutments
Kortam et al.

Metal caps were threaded to the abutments. Implants were immediately loaded by fixed full-arch acrylic prostheses.26 The occlusal contact was relieved over the first molars to prevent increased load on inclined implants. Postoperative medications included antibiotics (amoxicillin 875 mg + clavulanic acid 125 mg, Augmentin 1 g), and corticosteroids (Dexamethazone 8 mg/2 mL) immediately after surgery to reduce postoperative edema and inflammation. Anti-inflammatory medication (ibuprofen, 600 mg) was administered for 5 days. Participants were instructed to use a soft diet and perform adequate cleaning. Modifications and relining of the acrylic prosthesis were done in the follow-up visits.

After 6 months, an open-tray abutment-level impression was made. The transfer copings were splinted with a resin (Duralay, Reliance Dental) to avoid movement during impression removal. Plastic caps (metal group) and titanium caps (PEEK group) were seated to multiunit abutments. The models were scanned, and screw-retained fixed hybrid prostheses that restore alveolar bone, gingival tissues, and teeth were designed using CAD/CAM software (Ceramill Map 400, Amann Girrbach) and saved as STL files. The fixed prosthesis was designed with 12 teeth with no cantilevers or a maximum cantilever of one tooth (first molar) on each side. The design was printed in a castable resin (GC Pattern Resin, GC). For the metal group, the resin was cast in cobalt-chromium alloy and tried for passive fit in the patient mouth using a single screw test. An opaquer was placed over the framework, and porcelain (VITA Zahnfabrik) was fired and glazed (Fig 2). For the PEEK group, the resin was invested and converted to the PEEK framework with the injection mold technique. BioHPP pellet material (Bredent) was pressed into the mold.

Fig 1 (Right) Osteotomy preparation using the stereolithographic template.

Fig 2 (Below) Metal porcelain group. (a) Postoperative panoramic radiograph. (b) Tissue side of the prosthesis. (c) Occlusal view of the prosthesis. (d) The maxillary and mandibular prostheses in the patient mouth.
titanium caps were cemented to the PEEK frame using resin cement. Adhesive provided by the manufacturer (Visio.link) was painted above the framework to facilitate bonding of composite veneer material (Visio.lign) that replaced teeth and gingiva (Fig 3). The design of the distal extension partial dentures in both groups included rigid metal framework, wrought wire, or RPA claps, and acrylic artificial teeth. The group function occlusal scheme was used. Instructions for oral hygiene procedures and follow-up visits were scheduled.

**Evaluation of Clinical and Prosthetic Outcomes**

Plaque Index (PI) and Gingival Index (GI)\(^27\) were assessed. A plastic gingival probe (Vivadent) was used to measure the pocket depth from the marginal gingiva to the pocket depth (PD). The PI, GI, and PD were assessed lingually, mesially, buccally, and distally around each implant. The implant stability quotient (ISQ) was measured using resonance frequency analysis (Ostell, Integration Diagnostics). Marginal bone loss (MBL) was evaluated using digital periapical radiography (Digora, Soredex). The film holder was screwed to the multiunit abutments using the screw of the transfer copings to standardize the film-implant and the cone-implant distances. The distance between the implant-abutment junction (A) and first contact with the bone (B)\(^28,29\) was measured using the accompanied software (Fig 4). Magnification errors were corrected using known implant dimensions. MBL was measured at the mesial and distal surfaces of each implant. The measurements of clinical parameters were carried out by two calibrated prosthodontists (E.M.A. and K.S.A.) after instruction and adequate training. Blinding of examiners to the prosthetic design was not possible. The following success criteria\(^30\) were used: (1) no pain or dysesthesia, (2) no peri-implant infection, (3) no mobility, and (4) bone loss < 1.5 mm after 12 months. The implant was considered to have “survived” if it was still functioning but did not fulfill these criteria.

The incidence (percentage) of the following prosthetic complications were measured for definitive restorations: (1) on the patient level—prosthesis fracture, ceramic/composite veneer fracture, and artificial gingiva fracture; (2) on the abutment level—cylinder
fracture, abutment fracture, abutment screw loosening/fracture, and prosthetic screw loosening/fracture. Clinical outcomes were assessed at the insertion of the prosthetics and 1 year and 3 years later. The overall prosthetic complications were measured after 3 years.

### Statistical Analysis

SPSS software (Version 25, SPSS) was used for data analysis. Interexaminer reliability was tested with the α-Cronbach test. Between-group comparisons for clinical outcomes were performed using the Mann-Whitney U test. The Friedman test followed by the Wilcoxon signed-rank test was used to compare observation times. To test the difference in prosthetic complications between groups, the chi-square test was used. P values < .05 were considered significant.

### RESULTS

Thirty participants (ages ranged from 55 to 64 years) were investigated. Four implants in one patient belonging to the control group and two implants in another patient in the test group failed following immediate loading with provisional restorations. The two patients were men and were excluded from the study. No implant failures occurred after insertion of the definitive prosthesis, and the implant survival rate was 100% in both groups. The correlation coefficients for the reliability of clinical measurements were > 0.80.

Clinical outcomes of metal and PEEK groups at different observations are presented in Table 1. PI increased significantly with time in both groups (P < .001). There was a significant difference in PI between each two observation times for the metal group. For the PEEK group, PI increased significantly from baseline to 1 year. No difference in PI between 1 and 3 years was noted. The metal group recorded higher PI than the PEEK group after 1 (P = .001) and 3 (P = .002) years. GI increased with time in the metal group (P = .023). GI did not differ between observations for the PEEK group. There was a significant difference in GI between each two observation times for the metal group. Metal showed higher GI than PEEK after 3 years only. PD increased with time in both groups (P < .001), with a significant difference between each two observation times. The metal group had higher PD than the PEEK group after 1 (P = .001) and 3 (P = .007) years. There was a significant increase in ISQ
with time in metal ($P = .045$) and PEEK ($P = .002$) groups. For both groups, ISQ significantly increased from baseline to 1 year. No significant difference in ISQ between 1 year and 3 years was noted. MBL increased significantly from 1 year to 3 years for the metal ($P = .006$) and PEEK ($P = .003$) groups. The metal group showed significantly higher MBL than the PEEK group after 1 ($P = .002$) and 3 ($P = .040$) years.

The incidence and percentages of prosthetic complications for both groups are presented in Table 2. No prosthesis frame fracture (prosthesis survival was 100%), no abutment fracture, and no abutment screw fractures occurred in both groups. The most frequent complication was prosthetic screw loosening ($n = 7, 11.6\%$) for the metal group and veneer fracture/separation ($n = 4, 26.6\%$) for the PEEK group. The metal group had higher prosthetic screw loosening than the PEEK group ($P = .028$). The PEEK group showed significantly higher veneer fracture/separation than the metal group ($P = .032$). No difference in artificial gingiva fracture, cylinder fracture/separation, abutment screw loosenings, and prosthetic screw fracture between groups was noted.

**DISCUSSION**

The overall survival rate in both groups (100%) was similar to that obtained by Maló et al.\(^20\) who reported a 100% implant survival rate for the All-on-4 PEEK fixed maxillary prosthesis after 1 year.

Plaque and gingival indices increased with time in both groups. Conversely, Patzel et al\(^32\) reported a progressive decrease in these indices with All-on-4 implant prostheses. The increased plaque accumulation with time for metal and PEEK groups may be caused by reduced manual dexterity of old participants, which is associated with reduced cleaning. Another explanation may be due to the increased plaque retention in the tissue side of the prosthesis around the metal cylinders and the inability to remove the denture by the patients to perform adequate oral hygiene. Also, it appears that patients who participated in this study did not follow the oral hygiene instructions. It should be noted that the results of plaque and gingival scores could be altered if a strict hygienic and cleansing protocol was followed and monitored by a dental hygienist. The reduced PI and GI in the PEEK group compared with the metal group may be due to the reduced affinity of PEEK material to plaque accumulation.\(^15,16\)

Similarly, Wachtel et al.\(^33\) found that PEEK material has a sealing effect against bacterial leakage at the implant-abutment interface, which is advantageous compared with superstructures of conventional cobalt-chromium materials. The reduced Plaque Index in the PEEK group concurred with the results of Sturz et al.\(^34\) who found that veneering of PEEK with composite material can significantly reduce the surface roughness and contact angle after sandblasting and air polishing, thus contributing significantly to the reduction of microbial plaque retention and facilitating oral hygiene. Another explanation of decreased plaque in the PEEK group may be attributed to the smooth self-cleansable surface of the ready-made titanium caps, which minimize plaque retention. In contrast, the rough surface of cast cylinders in the metal group may enhance plaque retention and increase PI. The increased PI could be responsible for increased GI in the metal group due to gingival irritation and inflammation. The causal relation between plaque and gingival inflammation was previously reported.\(^20\) The decreased GI with the PEEK group may

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Comparison of Incidence and Percentage of Measured Prosthetic Complications for Metal and PEEK Groups After 3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Metal</td>
</tr>
<tr>
<td></td>
<td>Incidence</td>
</tr>
<tr>
<td>On patient level</td>
<td></td>
</tr>
<tr>
<td>Prosthesis fracture</td>
<td>0</td>
</tr>
<tr>
<td>Veneer fracture/separation</td>
<td>0</td>
</tr>
<tr>
<td>Artificial gingiva fracture</td>
<td>1</td>
</tr>
<tr>
<td>On implant level</td>
<td></td>
</tr>
<tr>
<td>Cylinder fracture/separation</td>
<td>0</td>
</tr>
<tr>
<td>Abutment fracture</td>
<td>0</td>
</tr>
<tr>
<td>Abutment screw loosening</td>
<td>5</td>
</tr>
<tr>
<td>Abutment screw fracture</td>
<td>0</td>
</tr>
<tr>
<td>Prosthetic screw loosening</td>
<td>7</td>
</tr>
<tr>
<td>Prosthetic screw fracture</td>
<td>2</td>
</tr>
</tbody>
</table>

*Chi-square test; $P$ value is significant at .05.
be attributed to the decreased plaque accumulation, which is also responsible for the lack of difference in GI between observation times. The increased PD with time may be due to the increased bone resorption and gingival enlargement of the peri-implant mucosa in the maxilla. A similar observation was noted in a previous study for All-on-4 prostheses in the mandible. In contrast, Landázuri-Del Barrio et al reported a stable soft tissue situation with a reduction of pocket depths over time in the vast majority of implants. However, in the study by Landázuri-Del Barrio et al, pocket depth was evaluated for mandibular implants. The increased thickness of keratinized mucosa around maxillary implants compared with mandibular implants could be responsible for increased pocket depth in the present study. The reduced PD with the PEEK group may be caused by decreased PI and GI. Similarly, Pontoriero et al found that an increase in mucosal inflammation of the soft tissues around the implants was associated with increased peri-implant pocket depth.

The obtained ISQ values were > 58. The increased ISQ values from baseline to 1 year in both groups could be attributed to the increased bone-to-implant contact with time, which increases anchorage of the implants in the soft maxillary bone. A similar observation was noted by Chen et al, who found a significant increase in ISQ values of maxillary implants from baseline to 1 year after loading. The lack of difference in ISQ between metal and PEEK prostheses was not surprising and concurred with the results of other authors. The median values of bone loss after 3 years for both groups was 1 mm. A similar amount (1.1 mm) of MBL was noted in this study due to the lack of data regarding the control group. This presents another critical issue, as Patient sample size and the lack of evaluation of clinical and radiographic parameters in the first 6 months (after loading with professional restoration), as it has been reported in the literature that a significant amount of bone loss may occur in the first year after prosthetic loading.

The prosthetic complications of the provisional restorations during the healing period were not evaluated in this study due to the lack of data regarding the control group. This presents another critical issue, as Patzel et al reported that the most frequent prosthetic complications of All-on-4 restorations are the fracture and loosening of the provisional acrylic prostheses. Regarding the definitive restoration, no prosthesis fractures occurred in both groups, but the survival rate of the prosthesis was 100%. A similar observation was also noted in the study by Maló et al. The most frequent prosthetic complication in the PEEK group was composite veneer fracture/separation (26.6%), which was significantly higher than the metal group. A similar observation was noted in another study. This may be attributed to the inadequate bond strength of composite to the PEEK frame due to the poor wetting capabilities of PEEK material. Moreover, the poor tolerance of the PEEK frame to bending and plastic deformation may also be responsible for the high rate of veneer fracture in this group. Also, the presence of natural teeth in the opposing mandibular arch may increase load transmission to the composite teeth and may contribute to the increased incidence of veneer fracture. The fracture usually occurs in the thin areas around the titanium caps. However, the problem was easy to resolve by roughening of the caps to provide mechanical retention with
the PEEK frame and application of the adhesive again to improve the bond strength. The same reason could be responsible for increasing the artificial gingiva fracture in the PEEK group. However, the difference between groups was not significant. Two titanium cylinders (3.3%) were separated from the PEEK frame. This may be due to the failure of the adhesion of resin cement. However, the low incidence of cylinder separation may be attributed to the serrations of the titanium caps that provide additional means of mechanical retention in addition to the retention of the adhesive cement. The most common prosthetic complication in the metal group was prosthetic screw loosening (11.6%), which was significantly higher than the PEEK group. This may be attributed to the lack of optimal passive fit, the presence of vertical gaps between metal caps and abutments on the microscopic level, and the increased load transmission to the maxillary prosthesis from natural teeth present in the mandible as stated previously. The same reason could apply to justify the occurrence of two prosthetic screw fractures in the metal group. However, the problem was easy to manage with torque-controlling retightening of the prosthetic screws. The reduced incidence of prosthetic screw loosening in the PEEK group agreed with another study\(^2\) and may be attributed to the passive fit of the PEEK veneered prosthesis. The study limitations included the relatively small sample size and the lack of evaluation of clinical and prosthetic outcomes in the critical healing period (first 6 months) after immediate loading of the implants with professional restorations. Although matching was done, the lack of randomization between groups may induce selection bias regarding unknown confounding variables. Moreover, studying patient-reported outcomes is also needed to complete the clinical picture of the tested prostheses.

**CONCLUSIONS**

Within the limitations of this study, a PEEK prosthesis veneered with a composite may be a suitable alternative to a metal porcelain prosthesis for All-on-4 implant rehabilitation in patients with maxillary edentulous arches opposed by distal extension mandibular ridges, as it was associated with acceptable clinical and prosthetic outcomes after 3 years. However, it was associated with an increased rate (40%) of veneer or artificial gingiva fracture.

**ACKNOWLEDGMENTS**

The study was approved by the ethical committee of the Faculty of Dentistry, Mansoura University. The study was self-funded by the authors. The authors reported no conflicts of interest related to this study.

**REFERENCES**


