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EFFECT OF MODIFIED POLY-ETHER-ETHER-KETONE (PEEK) AS A MATERIAL FOR BAR AND CLIP ATTACHMENT ON MARGINAL BONE LOSS AROUND IMPLANTS SUPPORTING MANDIBULAR OVERDENTURE

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ABSTRACT

Objective: This in vivo study was aimed to radiographically evaluate the marginal bone loss around implant-supported mandibular overdenture retained by PEEK clips on PEEK bars compared to the conventional Poly-Oxy-Methylene (POM) clips on metallic Cobalt Chromium (Co-Cr) bars. **Subjects and Methods:** Thirty completely edentulous patients (16 males and 14 females) were selected free from any systemic or local diseases that contraindicate implant placement or preclude the final results of the study. Each patient firstly received conventional complete denture, and two conventional implants in the interforaminal region then, divided in to two equal groups; in group I (control group), patients received mandibular implant overdentures retained by two POM clips on Co-Cr bar, and in group II (study group), patients received mandibular implant overdentures retained by two PEEK clips on PEEK bar. Assessment of marginal bone loss around the implants was performed radiographically at the time of loading (Base line), 6, 12, and 18 months after loading. **Results:** The results represented statistically significant decrease in bone height from each follow-up time to the next for both groups. Group I showed statistically significant greater bone loss when compared to group II. **Conclusion:** Using modified PEEK for the construction of bar and clip attachments can decrease bone loss around implants supporting mandibular overdenture when compared to Co-Cr bars with POM clips due to the stress-breaking effect of the PEEK material.

KEY WORDS: Implants, bone loss, PEEK, bar attachment.

INTRODUCTION

According to WHO, edentulous patients considered handicapped, disabled, and physically impaired as, edentulism affects eating and speaking which are considered necessary functions for the patient to live and communicate with others. The edentulous patient may prefer isolation from society, and can't participate in its activities so, loss of teeth can affect the overall quality of life for the patient[1-3].

The conventional complete dentures especially mandibular ones usually displaced from their places in the mouth with subsequent interruption of many functions like speaking and mastication. Edentulous patients with conventional complete dentures usually try to modify their mandibular movements,

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and change their food choice to the limit that can prevent displacement of the denture, and to avoid pain that can arise from the denture[4,5].

Implant supported overdentures provided a reliable success in solving most problems of the conventional complete dentures especially the problems related to the edentulous mandibles. McGill Consensus statement stated that, an overdenture supported by minimum of two dental implants should be the first treatment option for the edentulous mandible[6,7].

Implants supporting overdentures can improve stability, retention, and support for the prosthesis. They can function like tooth roots that integrate with the jaw bone with subsequent reduction in the rate of bone loss which occurs under conventional complete dentures[8].

Bar and clip attachments are used widely for Implant-supported overdentures. They offer high mechanical stability, have more wear resistance than solitary attachments, allow better distribution of forces between the implants due to the primary splinting effect, and distal extensions or cantilevers can be used to provide more stability against lateral forces[9].

Up to a few years ago, non-precious metal alloys such as Cobalt Chromium (Co-Cr) alloys were considered the materials of choice for bar construction. These hard alloys seemed to introduce a sufficient rigid splinting of the implants that give the main advantage of better distribution of the forces between the implants[10,11].

Poly-Ether-Ether-Ketone (PEEK) is a high-performance polymer that can be utilized as a metal substitute for fixed and removable restorations. This material has several advantages such as favorable strength to weight ratio, high wear and corrosion resistance, high biocompatibility, low plaque affinity, high chemical stability, minimal creep, reduced specific weight, and representing shock absorption or stress breaking effect, it is a torsionally flexible material like healthy bone allowing natural physiological torsion of the jaw when used for construction of a bar splinting implants with subsequent reduction in the tresses accumulated around the implants during function of the jaw. PEEK also can be used in the construction of bar clips instead of conventional Poly-Oxy-Methylene (POM), or nylon clips that have a main disadvantage of susceptibility to wear during insertion and removal of the overdenture with subsequent loss of their retention forces[12,13].

The objective of this study was to radiographically evaluate the marginal bone loss around implants supporting mandibular overdenture retained by PEEK clips on PEEK bars compared to POM clips on Co-Cr bars.

Null hypothesis was there would be no significant difference between the two bar and clip attachments of different materials in regard to marginal bone loss around implants supporting mandibular overdenture. The alternative hypothesis was that PEEK bar and clip attachment would preserve the marginal bone around implants due to its stress breaking effect.

SUBJECTS AND METHODS

This study was designed to be a randomized controlled clinical trial in which, thirty completely edentulous patients (16 males and 14 females) were randomly selected from the Outpatient Clinic, Department of Removable Prosthodontics, Faculty of Dental Medicine, Al-Azhar University, Boys, Cairo.

Patient's approval was confirmed by signing a written informed consent after obtaining ethical approval for the study by the Ethics Committee in Faculty of Dental Medicine, Al-Azhar University (Boys, Cairo) under ethical code of 904/3512 then, the diagnosis of each patient was carried out to ensure the suitability of the patients for implant overdenture treatment option without systemic or local conditions that might preclude the results of this type of treatment.

From the ethical point of view, all patients received complete dentures constructed by the conventional method before performing radiographic examinations to avoid exposing the patients to radiographs more than one time before inserting the implant, and to supply the patients who didn't fulfill the clinical inclusion criteria by an alternative treatment modality.

Dual scanning protocol by Cone Beam Computed Tomography (CBCT) used for radiographic examination and surgical guide construction by scanning the lower denture with attached radio-opaque markers separately outpatient mouth then, scanning the patient wearing the denture to produce two images that were superimposed for dental implant planning at the canine regions, and designing the surgical guide.[14]

The surgical procedures started by administering infiltration anesthesia, and the surgical guide was fixed by drilling through the fixation sleeves, and inserting the fixation pins. Preparation of the osteotomy sites was done following the sequence of drilling recommended by the manufacturer for inserting two implants of 3.5mm diameters, and 13mm lengths (Bnx evo® implant system; Ghiams, Italy).

The surgical guide then removed, and the implants were inserted to their full lengths by torque ratchet wrench in which, the torque considered not to be less than 35 N/cm while reaching the full depth to ensure adequate primary stability. Patients were given full post-operative instructions, and recalled after at least three months to complete the prosthetic procedures.

Before prosthetic procedures, patients divided randomly using block randomization method depending on computer-generated random number tables for male, and female patients using Microsoft Office Excel® to ensure obtaining two groups containing equal sample sizes of eight males, and seven females for each group. In group I (Control group), the overdentures retained by readymade POM clips on digitally constructed Co-Cr bars, and in group II (Study group), the overdentures retained by custom made PEEK clips on digitally constructed PEEK bars.

Prosthetic procedures then started by taking impression at implant level by open tray impression technique. Titanium bases (Ti-bases) connected to the implant analogues in the cast, and scanned by a desktop scanner (Medit T300®; Medit corp., South Korea). 3D dental CAD/CAM software (Exocad® GMBH Dental CAD; Darmstadt, Germany) used to design a resilient bar on the Ti-bases based on the resilient form of a specially designed bar (OT bar multiuse®; Rhein83, Italy) that provided as a digital version in the library of the software.

The STL file then exported to CAD/CAM milling machine to be milled in Co-Cr alloy (Mediloy® M-Co; Bego, Germany) for group I, or to be milled in modified PEEK (BioHPP®; Bredent, Germany) for group II. The milled bars cemented to the Ti-bases by chemically cured resin cement (Multilink Speed®; Ivoclar vivadent, Germany), and screwed to the implants in the patient mouth.

Two bar clips (Yellow Medium retention bar clips of 1.8kg; Rhein83, Italy) attached to the bars. An impression was taken for the bar with the attached clips to produce a cast that scanned by the desktop scanner for designing a framework over the bar with the attached clips. The STL file of the designed frame was exported to a 3D printer (Form 3+®; Formlabs, USA) to be printed into a castable wax based resin (Wax castable®; Liqcreate, Netherland). The wax based resin frame then casted by the conventional lost wax technique into Co-Cr alloy (Wironit®; Bego, Germany). The lower denture then rebased by the flask method with suspending the metal frame within the new base.

For group I, two readymade bar clips inserted in the metal housings of the frame, and tried over the metallic bar, and for group II, the readymade bar clips converted into modified PEEK (BIOHPP® granules for pressing; Bredent, Germany) by thermopressing under vacuum in a specially designed device (For 2 press® vacuum press device; Bredent, Germany).

Assessment of Marginal Bone Height (MBH) around implants was performed using digital periapical radiographs with long cone paralleling technique. XCP positioning set (Digital sensor positioning anterior set-up; RINN DENTSPLY, USA) mounted without interference with the occlusion on a radiographic stent that fabricated by duplicating the lower overdenture, and attached to the bar by two bar clips to standardize the position of the x-ray cone, and the digital sensor during each follow-up time. The radiographic stent with digital sensor (Kavo Dig Exam®; Kavo Dental Excellence GmbH., Germany) placed inside the positioning set holder attached to the bar, and the x-ray cone oriented to the positioning set ring to perform the radiographic exposure.[15]

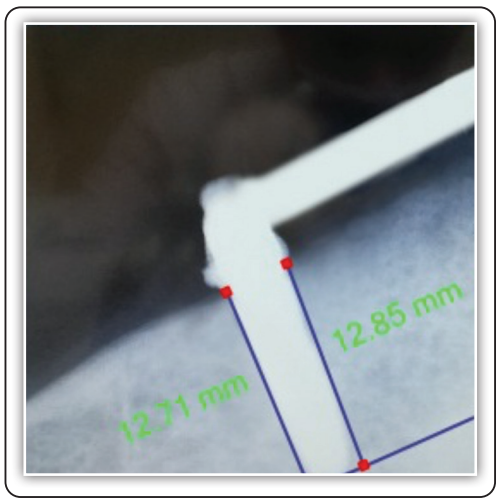

FIG (1) Linear measurements of mesial and distal MBH around the implant.

The produced image exported to an integrated software (VixWin® platinum 3.5; Gendex co., USA).upon which linear measurements were performed. The mesial and distal MBHs calculated from the first point of contact between the crestal bone and the implant to a horizontal line drawn tangent to the implant apex.

MBH evaluated at the time of loading, and after 6, 12, and 18 months of loading. The Marginal Bone Loss (MBL) at particular time was calculated by the formula MBH at that time – MBH at the base line. All results were collected and tabulated using Microsoft Office Excel® 2013, and the statistical analysis performed using SPSS® version 22.

RESULTS

ANOVA test for repeated measures used to compare the average MBH at different follow-up times within each group. MBH decreased from each follow-up time to the next, and the difference was statistically significant for both groups as shown in table 1, and figure 2.

Independent samples T-test used to compare the average Marginal Bone Loss (MBL) at each follow-up intervals (base line to 6 months, 6 to 12 months, 12 to 18 months, and base line to 18 months) in the two groups. MBL was greater for group I than that for group II at all follow-up intervals, and the difference was statistically significant as shown in table 2, and figure 3.

TABLE (1) Mean values of MBH ± SD in Millimeters (mm) at each follow-up time, and P-values for both groups.

Group	Follow-up times								P-value
	Base line		6 months		12 months		18 months		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Group I	12.38[a]	0.18	11.62[b]	0.21	11.05[c]	0.21	10.55[d]	0.24	0.000*
Group II	12.50	0.22	11.94	0.26	11.53	0.24	11.33	0.25	0.000*

ANOVA test for repeated measures. *; significant (P<0.05).

Means with different letters in the same row indicate statistically significance difference

TABLE (2) Mean values of MBL ± SD in Millimeters (mm) at each follow-up interval, and P-values for both groups.

Time of comparison	Group I		Group II		P- value
	Mean	SD	Mean	SD	
0 to 6 months	0.76	0.09	0.56	0.08	0.000*
6 to 12 months	0.57	0.13	0.41	0.07	0.000*
12 to 18 months	0.50	0.12	0.20	0.03	0.000*
0 to 18 months	1.84	0.18	1.18	0.062	0.000*

Independent samples T-test. *; significant (P<0.05).

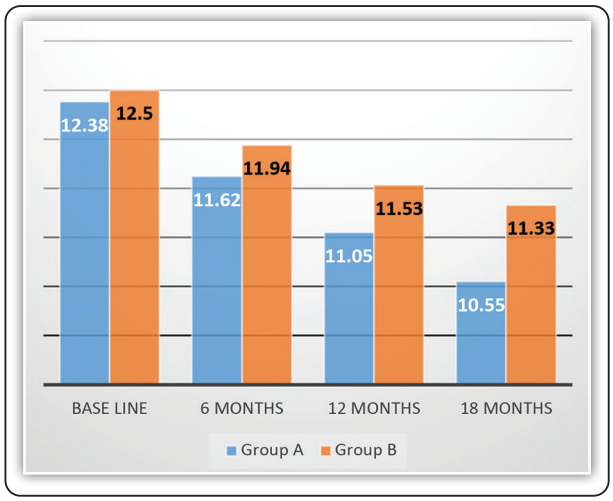

FIG (2) MBH at ach follow-up time

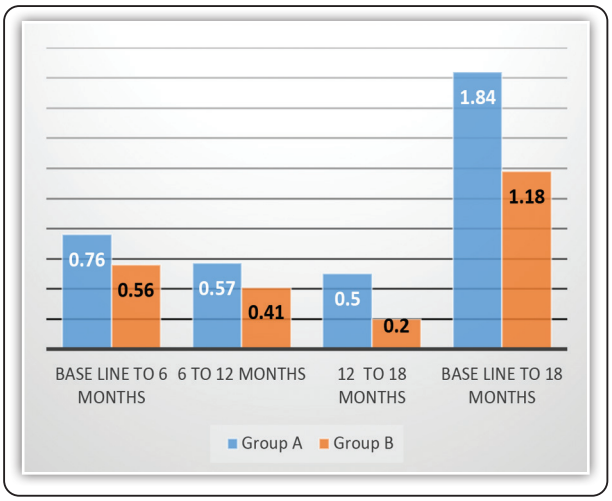

FIG (3) MBL at each follow-up interval.

DISCUSSION

Mandibular implant overdentures were constructed opposing conventional maxillary dentures as, most problems occur with the mandibular conventional dentures due to resorption of the bone as well as, the movement of the tongue, cheeks, and lips. Patients with mandibular implant supported overdentures are more likely to positively modify their diet than patients with conventional dentures[8,11].

It is known that, despite the high success rate of the dental implants, the systemic diseases may complicate or even contraindicate this form of the treatment so, the patients were selected free from any systemic diseases that contraindicate surgery or might adversely affect the condition of the bone or soft tissues with subsequent negative effect on the results of the study[16].

Computer-generated surgical guides used to insert the implants to help in accurately identifying the position and orientation of the implants. The main purpose of the surgical guide in this study was to adjust the parallelism of the two implants to avoid unfavorable direction of the occlusal forces along the axis of the non-parallel implants with accumulation of stresses around them resulting in more crestal bone resorption[17].

In this study, the two implants were splinted by bar attachment as, the primary splinting effect of the bar attachment could provide load sharing effect, and favorable distribution of the occlusal stresses between the two implants with subsequent preservation of the marginal bone around the implants, the adequate hardness of Co-Cr alloy could provide the required rigidity for the bar to play its role in the primary splinting, and load sharing effect. On the other hand, the advantage of the modified PEEK material of being as elastic as bone allowed natural physiological torsion of the jaw when used for construction of the bar with subsequent stress breaking effect that could reduce the occlusal stresses transferred to the implants resulting in preservation of the marginal bone around them. The effect of the two materials on the marginal bone around the implants was assessed in this study[9, 10, 13].

CAD/CAM technology used for designing, and fabrication of the bars in both groups as, it has the advantages of being more accurate with little or no errors like dimensional changes or intra-structural defects, and time saving with lesser number of steps when compared to the conventional casting procedure for the Co-Cr alloy or the pressing under vacuum procedure for the PEEK material that based on lost wax, and injection molding technique. The dimensional changes that might be produced by the conventional fabricating methods could result in non-passive fit of the bar on the implants with subsequent stress accumulation, and stimulation of the crestal bone resorption around the implants[12, 18].

The amount and rate of marginal bone loss considered an important indicator for the success of the implants. The assessment of the changes that occurred in the level of the marginal bone around the implants required accurate and reproducible radiographic technique. The standardization of the periapical radiographs was achieved by the long cone paralleling technique. By this technique, the digital sensor could be oriented in the same precise position, angulation, and distance from the evaluated implant during each follow-up time. Other advantages include higher sharpness and resolution of the obtained images, no or minimal distortion of the image, extremely low exposure dose, and low cost when compared to other radiographic methods[19].

In this study, a radiographic stent that designed to be attached to the bar, and upon which the XCP positioning set was mounted without interference with the occlusion to allow the patients to occlude firmly on the occlusal surface of the stent was used to provide adequate fixation of the stent during the radiographic exposures.[15]

In this study, the highest amount of bone loss was found during the first follow-up interval from the base line to 6 months for both groups. This might be due to the effect of the surgical trauma, and remodeling of bone around the implants for creation of a new biological width under the implant abutment[20].

Kant et al [21] conducted a study to evaluate the amount of crestal bone resorption during healing and loading period in single versus two implant mandibular overdentures. The radiographs showed decrease in the amount of bone loss from each follow-up time to the next with statistically significant overall bone loss after 6 months of placing the implants for both groups.

Abdel Baseer et al [22] conducted a study to evaluate the crestal bone height changes around laser grooved implants with mandibular overdenture. They found that, the highest amount of bone loss was from baseline to 6 months, the amount of bone loss then decreased from 6 to 12 months.

In the current study, it was found that, the amount of bone loss was greater for the first group when compared to the second group at all follow-up intervals. This could be explained by the shock absorption or stress breaking effect of PEEK material that resulted from its young's modulus of elasticity that was very close to that of the natural jaw bone[12,23].

Villefort et al[24] found that, PEEK could be suggested as a material to reduce the bone strain around the implants, and the stress concentration in the bar structure for implant-retained palatal obturator. In another study, Villefort et al [25] found that, the superior shock absorbance of PEEK resulted in a lower stress concentration on the prosthetic screws, and on the bone around the implants for all-on 4 prosthesis. Pillai et al [26] found that, PEEK superstructures could reduce stresses at bone–implant interface with subsequent preservation of the bone around the implants for two mandibular implant overdenture.

The total marginal bone loss around the implants after 18 months was 1.84 ± 0.18, and 1.18 ± 0.062 for the first and the second groups respectively. These values were within the accepted ranges for the successfully osseointegrated implants that described by Misch et al [27].

CONCLUSION

PEEK bars and clips could provide more preservation for the marginal bone around the supporting implants than the metallic bars with the ready-made POM clips due to the inherent shock absorbance effect that resulted from its modulus of elasticity that was very close to that of the natural jaw bone.

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