

Effect Of Modified Poly-Ether-Ether-Ketone (Peek)As A Material For Bar And Clip Attachment On Retention Of Mandibular Implant Supported Overdentures

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ABSTRACT

Objective: The objective of this in vivo study was to evaluate the retention force of PEEK clips on PEEK bars in comparison to the conventional Poly-Oxy-Methylene (POM) clips on metallic Cobalt Chromium (Co-Cr) bars when used as attachments to retain mandibular implant overdenture supported by two implants in the interforaminal area. **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. All patients firstly received conventional upper and lower complete dentures, and two conventional implants in the interforaminal region by the aid of surgical guide 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 retention force was done by digital force gauge. The evaluation was done at time of loading (Base line), 6, 12, and 18 months after loading. **Results:** The results showed that, the test group had statistically significant higher values of the retention force than the control group at the base line with subsequent statistically significant lesser values of decrease in retention force from each follow-up time to the next. **Conclusions:** Using modified PEEK for construction of the bars and their clips provided more enhancement in the retention of the mandibular implant overdentures than that provided by the conventional metallic Co-Cr bars with POM clips due to the higher modulus of elasticity, and wear resistance of the PEEK material.

KEY WORDS: Mandibular implants overdenture, bar attachment, retention force, PEEK bar, PEEK bar clips

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I. INTRODUCTION

According to WHO, edentulous patient considered handicapped, disabling, and physically impaired as, it affects eating and speaking which considered two necessary functions for the patient to live and communicate with others. 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, 2)

The conventional complete dentures especially mandibular ones can be 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 change and limit their mandibular movements, and change their food choice to the limit that can prevent displacement of the denture, and prevent pain that can arise from the denture.^(3, 4)

Implant supported overdentures provided a reliable success in solving most of the problems of the conventional complete dentures especially with 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.^(5, 6)

The presence of implants that can stabilize the prosthesis during all mandibular movements will allow the tongue and other perioral musculature to maintain its normal function without the need for added function from them to control the movement of unstable mandibular complete denture with subsequent enhancement in all functions that achieved by tongue and other muscles like speech and mastication.^(7, 8)

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The bar and clip attachments are probably the most widely used attachments for implant supported overdentures. The assumed advantages of bar attachments are they offer greater mechanical stability, have more wear resistance than solitary attachments, allow better transmission of forces between the implants due to the primary splinting effect, have the least post insertion maintenance, and distal extensions or cantilevers can be used to provide a high level of stability against lateral forces.^(9, 10)

Up to few years ago, non-precious-metal alloys as Cobalt Chromium (Co-Cr) alloy 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 bar attachment which is better distribution of the forces between the implants.⁽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, corrosion resistance, biocompatibility, low plaque affinity, chemical stability, minimal creep, high wear resistance, reduced specific weight, and has shock absorption or stress breaking effect as, it is torsionally flexible material like healthy bone allowing natural physiological torsion of the jaw when used for construction of bar splinting implants with subsequent reduction in the stresses accumulated around the implants during function of the jaw.^(12, 13)

PEEK also can be used in 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.

This study aimed to evaluate the retention force of PEEK clips on PEEK bars in comparison to the conventional POM clips on Co-Cr bars when used as attachments to retain mandibular implant overdenture supported by two implants in the interforaminal

II. SUBJECTS AND METHODS

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

Patient's approval was obtained by signing a written informed consent then, diagnosis of each patient was carried out by taking medical and dental history, and performing clinical examination, laboratory investigations, and examination of diagnostic casts to ensure 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 ethical point of view, all patients received upper and lower complete dentures constructed by the conventional method before performing radiographic examinations to avoid exposing 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) then 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.

Prophylactic antibiotic, anti-inflammatory, anti-edematous, and antiseptic mouth wash were prescribed the day before the surgical procedures for inserting the implants that were done as follow:

1. Bilateral infiltration anesthesia was administered opposite to the proposed implant sites then, the surgical guide was fixed by drilling through the fixation sleeves, and inserting the fixation pins.
2. The mucosal soft tissue over the osteotomy sites was removed by tissue punch through the guiding sleeves then, preparation of the osteotomy sites was done following the sequence of drilling recommended by the manufacturer for inserting two implants of 3.5mm diameters, 13mm lengths (Bnxevo® implant system; Ghams, Italy).
3. The surgical guide then removed, and the implants were transferred to the osteotomy site by the ratchet fixture driver, then inserted to its full length by torque ratchet wrench. The inserting torque considered not to be less than 35 N/cm while reaching to the full depth to ensure adequate primary stability.
4. Patients were given full post-operative instructions, and recalled after period of healing of at least three months to complete the prosthetic procedures.

Before prosthetic procedures, patients divided randomly into two equal groups containing 8 males, and 7 females for each group as follow:

Group I (Control group): The over dentures retained by digitally constructed Co-Cr bars, and readymade POM clips.

Group II (Study group): The overdentures retained by digitally constructed PEEK bars, and custom made PEEK clips.

Prosthetic procedures were performed as follow:

1. Impression was taken at implant level by open tray impression technique.
2. Titanium bases (Ti-bases) connected to the implant analogues in the cast, and scanned by desktop scanner (Medit T300®; Medit corp., South Korea).
3. 3D dental CAD/CAM software (Exocad® GMBH Dental CAD; Darmstadt, Germany) used to design resilient bar on the Ti-bases based on resilient form of specially designed bar (OT bar multiuse®; Rhein83, Italy) that provided in the library of the software.
4. 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.
5. The milled bars cemented to the Ti-bases by chemically cured resin cement (Multilink Speed®; Ivoclarvivadent, Germany).
6. Two bar clips (Yellow Medium retention bar clips of 1.8kg; Rhein83, Italy) attached to the bars.
7. An impression was taken for the bar with the attached clips to produce cast with stone replica of the bar with the attached clips that scanned by desktop scanner for designing a framework over the bar with the attached clips.
8. The STL file of the designed frame exported to 3D printer (Form 3+®; Formlabs, USA) to be printed into castable wax based resin (Wax castable®; Liqcreate, Netherland).
9. The wax based resin frame then casted by the conventional lost wax technique into Co-Cr alloy (Wironit®; Bego, Germany).
10. The lower denture then rebased by the flask method with suspending the metal frame within the new base.
11. For group I, two readymade bar clips inserted in the metal housings of the frame, and tried over the metallic bar.
12. For group II, the readymade bar clips converted into modified PEEK (BIOHPP® granules for pressing; Bredent, Germany) by thermopressing process using specially designed thermopressing under vacuum device (For 2 press® vacuum press device; Bredent, Germany).

Assessment of retention force was performed as follow:

1. Based on geometrical principles⁽¹⁴⁾, the geometric center of the lower overdenture determined by bisecting angles of triangle drawn between two basal points at the centers of the retro-molar pads, and a head point at the lingual mid-line then, the free ends of wires forming “C” shaped hook over the point of meeting of the bisecting lines were attached to the previously determined points.



Figure 1 : “C” shaped hook at geometric center

2. Based on a reliable, standardized model described by Thu et al.⁽¹⁵⁾, a facebow (Bio-art® standard facebow; Bredent, Germany) used to standardize the head position of the patient, and to make a vertical pulling force perpendicular to the occlusal plane.
3. One end of nylon thread was tied to the “C” shaped hook, and passed through a hole located perpendicular to it in acrylic plate attached to the fork of the facebow.
4. The other end of the thread was tied into a loop and hooked onto a portable force gauge (Exttech FG-5000®; Exttech instruments Co., USA).

5. The arms of the facebow were firmly held parallel to the floor by an assistant, and the thread then pulled in parallel with the arms of the facebow by the force gauge until the prosthesis dislodged.
6. The measuring process repeated three times, and the average value was recorded.
7. Retention measurements were performed at time of loading (base line), and after 6, 12, and 18 months of loading.
8. All results were collected and tabulated using Microsoft Office Excel® 2013, and the statistical analysis was performed using SPSS® version 22.

III. RESULTS

ANOVA test for repeated measures used to compare between the retention forces at different follow-up times within each group. It was found that, the amount of retention force decreased from each follow-up time to the next for both groups. The difference between the retention forces at all follow-up times was statistically significant for both groups as shown in table 1, and figure 2

Independent samples T-test used to compare between the initial retention forces of both groups at base line, and to compare between the decreases in the amount of the retention force from each follow-up time to the next in both groups. It was found that, the initial retention force for group II was greater than that for group I, and the difference was statistically significant. The decrease in the retention forces for group I was greater than that for group II at all follow-up intervals (base line to 6 months, 6 to 12 months, 12 to 18 months, and the overall base line to 18 months), and the difference was statistically significant as shown in table 2, and figure 3

Table 1 : Mean values of retention forces \pm SD in Newton (N) 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	9.46	0.81	7.56	0.97	6.30	1.06	4.99	0.75	0.000*
Group II	12.81	0.99	12.65	1.00	12.42	1.01	12.22	1.05	0.000*

Table 2 : Mean values of initial retention forces, decrease in the retention force \pm SD in Newton (N) at each follow-up interval, and P-values for both groups.

Time of comparison	Group I		Group II		P- value
	Mean	SD	Mean	SD	
Base line (0)	9.46	0.81	12.81	0.99	0.000*
0 to 6 months	1.90	0.49	0.15	0.06	0.000*
6 to 12 months	1.25	0.40	0.23	0.09	0.000*
12 to 18 months	1.30	0.59	0.20	0.12	0.000*
0 to 18 months	4.46	0.68	0.59	0.16	0.000*

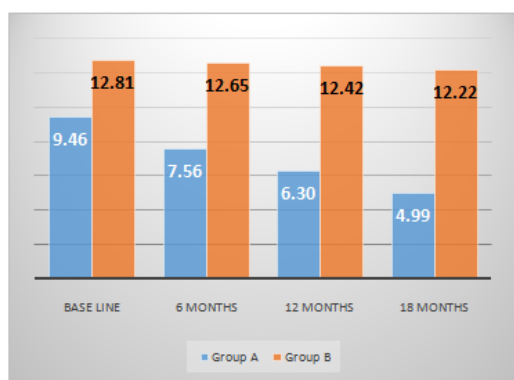


Figure 2 : Retention forces at each follow-up time.

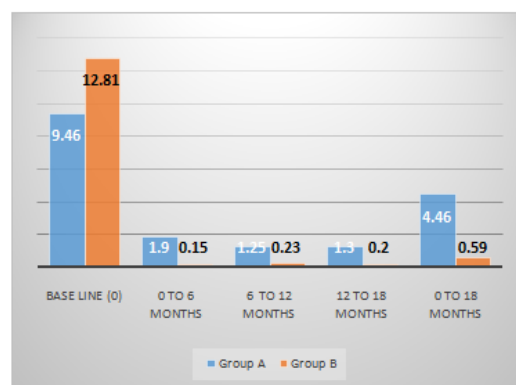


Figure 3 : Retention force at base line, and decrease in

IV. 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.⁽¹⁶⁾

Retention of the mandibular implant overdenture was an important factor to be evaluated in this study because of its high responsibility in providing satisfaction for the edentulous patients.⁽¹⁷⁾

In this study, a simple method based on the method described by Thu e al.⁽¹⁵⁾ was used to apply a vertical dislodging force similar to the occlusal dislodging force in patient mouth to obtain more reliable results. This method could be applied on the dental chair using only a facebow to standardize the head position at each follow-up time, and the portable force gauge.

The main property of PEEK material that could affect retention force of bar clips was its high wear resistance. In this study to clarify the effect of that property, the bar clips for the second group were converted into modified PEEK material. This property played an important role in preservation of the retention force of bar clips to high extent along this study when compared to the first group.^(18, 19)

The mean value of the retention force of bar clips in group I at the base line was 9.46 ± 0.81 N which decreased to be 4.99 ± 0.75 N after 18 months with about 47% loss of the retention force at the base line. On the other hand, the mean value of the retention force of the bar clips in group II at the base line was 12.81 ± 0.99 N which decreased to be 12.22 ± 1.05 N after 18 months with about 4.6% loss of the retention force at the base line.

The change in the initial retention of the bar clips of the two groups might related to the difference in the mechanical properties especially modulus of elasticity and flexural strength of the Poly-Oxy-Methylene (POM), and PEEK materials. Emam et al.⁽²⁰⁾ found that, flexural strength at thickness of 1mm under dry conditions was 125.27 for PEEK, and 24.67 for POM. EL-segai et al.⁽²¹⁾ found that, the modulus of elasticity of POM material was about 2.4 GPa, while that of PEEK material was about 4.0 GPa then, Partial denture clasps made from PEEK material showed significantly higher retention force compared to POM clasps.

From base line to 6 months, the decrease in the retention force in group I was 1.90 ± 0.49 N, while in group II was 0.15 ± 0.06 N that represented only about 8% of the decrease in group I. From 6 to 12 months, the decrease in the retention force in group I was 1.25 ± 0.40 N, while in group II was 0.23 ± 0.09 N that represented only about 18% of the decrease in group I. From 12 to 18 months, the decrease in the retention force in group I was 1.30 ± 0.59 N, while in group II was 0.20 ± 0.12 N that represented only about 15% of the decrease in group I. This difference could be related to the difference in the wear resistance between the POM material of the bar clips in group I, and the PEEK material of the bar clips in group II.⁽²¹⁾

In an in-vitro study, Hammas et al.⁽²²⁾ evaluated the effect of the bar and clip attachment with different materials on the retention forces after wear simulation. At zero cycles, there was statistically significant difference between the initial retention force of POM clips on metal bars (8.86 ± 0.73 N), and that of PEEK clips on PEEK bars (14.11 ± 0.71 N). This was coincide with the findings in our study in regard to the comparison of the initial retention forces at the base lines of the two groups. At 450 cycles that simulated 6 months, there was statistically significant difference between the retention force of POM clips on metal bars (5.95 ± 0.40 N), and that of PEEK clips on PEEK bars (9.22 ± 0.31 N). This was coincide with the findings in our study in which, there was statistically significant decrease in the retention forces after 6 months when compared to the initial retention force for both groups but, the amount of decrease in the retention force of POM

clips on metal bars was (3.27 ± 0.33 N), while that of PEEK clips on PEEK bars was (4.89 ± 0.40 N), this was in contrary to the findings in our study in which, there was lesser statistically significant decrease in the retention force of PEEK clips on PEEK bars when compared to POM clips on metal after 6 months. The differences assumed to be related to the difference in the design of the two studies, and the difference in the methods of measuring the retention force.

Nassar et al.⁽²³⁾ conducted an in-vitro study to compare between the retention force of digitally designed PEEK bar clips, and readymade nylon clips. The results were coincide with our study up to the second year in which, there was statistically significant greater retention force of PEEK clips when compared to nylon clips but, after 3 years of simulated use, the retention of PEEK clips decreased by 58.66%, while the retention of nylon clips increased by 2.99% recording. They assumed that hardening of the nylon clips was responsible for the increase in their retention forces after 3 years.

V. Conclusion

Within the limitations of this study, it could be concluded that:-

Mandibular overdentures retained by two splinted implants considered an acceptable treatment modality regardless the material used for construction of the bars or their clips.

Using modified PEEK material for construction of the bars and their clips provided more enhancement in the retention of the mandibular implant over dentures than that provided by the conventional metallic Co-Cr bars with the readymade POM clips due to the higher modulus of elasticity, and wear resistance of the PEEK material.

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