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EFFECT OF RETENTIVE CLIP MATERIALS OF BAR ATTACHMENT ON THE PROBING DEPTH OF IMPLANT-RETAINED OVERDENTURE: RANDOMIZED CONTROLLED CLINICAL STUDY

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ABSTRACT

Background Nowadays implant-retained overdentures retained by bar attachment are used on a wide scale as a substitute for the conventional complete denture thus further studies are required to verify this replacement.

Methodology Fourteen completely edentulous patients were randomly categorized into two equal groups. In the control group (Group I) patients received implant-retained overdentures retained by bar attachment with retentive plastic clips, while in the test group (Group II) patients received implant-retained overdentures retained by bar attachment with retentive clips made of Poly Ether Ketone Ketone (PEKK) material. All the patients were scheduled for recall visits and probing depth was recorded at the time of loading, six months, and twelve months.

Results: Regarding probing depth: (Group I) was significantly higher than (Group II) after 6 and 12 months. Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Data were summarized using mean and standard deviation. Comparisons between groups were done using an unpaired t-test. Comparison over time within the same group was done using paired t-test. P-values less than 0.05 were considered statistically significant.

Conclusion: Within the limitations of this study, Implant retained overdentures retained by bar attachment with plastic retentive clip material are less recommended than implant-retained overdentures retained by bar attachment with PEKK retentive clip material.

KEYWORDS: Poly ether ketone ketone, bar, retentive clips, probing depth

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INTRODUCTION

Many edentulous patients are satisfied with their mandibular complete dentures, but other patients are suffering from many problems such as poor retention and instability of the complete denture, decrease in chewing efficiency as well as problems in mastication. One common solution is a combination of implants and attachments to solve the problem of support and retentions [1-3]

Nowadays, oral rehabilitation of edentulous patients with splinted or unsplinted implants is considered a useful line of treatment in cases of mandibular edentulism as implant-retained overdentures have many advantages in comparison with the conventional complete dentures including good retention and stability as well as improved function and reduced bone resorption of the residual ridge. [4,5]

Many attachment systems have been used successfully with removable implant overdentures such as stud, bar, magnetic attachment, and telescopic attachment to improve the retention of the prosthesis. [6,7] The choice of attachment is dependent upon the amount of retention required, jaw morphology and anatomy, oral function, mucosal ridge, and the cooperation of the patients. [8,9]

Bar attachment has many advantages over the other attachments as it provides greater retention, splinting the implants by its splinting effect so provide force distribution which leads to decreases torque to each implant, and it can also correct severe un-parallelisms. [10.11] The main disadvantages of bar attachments are the need for a large inter arch space which may not be available in most cases, also bar attachments can cause mucosal hyperplasia and need proper oral hygiene measurements as they cause oral hygiene problems. [12,13]

Bar attachments consist of a metal bar that splints two or more abutments and a clip retentive mechanism processed within the tissue surface of the overdenture which snaps on the bar to retain the prosthesis. [14]

There are two basic types of bar attachments based on the action performed, (Resilient type) which allowed movements between the male and female parts of the attachments while the Bar units type (Rigid type) allowed no movement between the male and female parts. [15,16]

Many bar materials are available such as Cobalt-Chromium-Molybdenum Alloy as an Example of High Strength Materials, Gold Base Alloy as an Example of Precious Metals, and Zirconia Ceramics. [17] . CoCrMo alloys are well-known alloys in medical and dental applications, CoCrMo alloys have good mechanical properties, excellent corrosion and biodegradation resistance, as well as CoCrMo alloys has high ultimate tensile and good biocompatibility. [18]

Different clip material types may be used for the bar attachments. the most common type is the plastic clip which is used easily and replaced at chairside when their retention has decreased, Polyetheretherketone (PEEK) materials, and polyether ketone ketone (PEKK) materials. [19]

PEKK line offers crystalline as well as amorphous structures which means a wider range of products can offer with the crystalline version of PEKK products with improved mechanical properties, stiffness and chemical resistance can be obtained while amorphous products reach higher flexibility and are easier to process also geometrically-complex forms can be produced through casting and compressing the piece under high temperature and this is due to its ideal viscosity and due to its large working temperature range, also one of the most advantages of this materials shows lower shrinking rate which makes it more accurate. [20,21]

Materials used for the attachment system should resist wear to provide constant retention forces in the course of time.

The purpose of this study was to evaluate the effect of PEKK clip and plastic clip of bar attachment on the probing depth of the implants time of denture insertion, six months after delivery and twelve months

The hypothesis for this study was null i.e. that there will be no influence of different clip materials on the probing depth around the implants over time and there will be no difference between both treatment modalities

MATERIALS AND METHODS

Patient's enrolment

Fourteen completely edentulous patients were selected from the outpatient clinic, Prosthodontic Department, Faculty of Dentistry, Beni-Suef University. The Faculty of Dentistry Beni-Suef University Research Ethics Committee approved the protocol with approval number (#REC-FDBSU/02062022-04/ER) Patients eligible for the study were male patients with age ranged from 55 – 65 years and were free from any systemic diseases that may affect bone metabolism. Diagnostic cone-beam computed tomography was taken for each patient. Patients with bone height and width of more than 13 mm and 5 mm respectively in the anterior region of the mandible were included in the study. Exclusion criteria included inadequate interarch distance, severe maxillomandibular skeletal discrepancy, clenching habits, bruxism, tempromandibular joint disorders, smokers, drug abuse, history of head and neck radiation and systemic disorders that may prevent surgery, affect bone quality or contribute to bone resorption.

Patient's approval

Information concerning the line of treatment, procedure, and materials was described to the patients. All patients' data were kept confidential. Patients were also informed about their benefits from the research including obtaining a well-fitted and retentive denture. In case of failure of implants, patients were informed that a conventional mandibular complete denture will be constructed. A preoperative digital panoramic radiograph was taken for each patient to detect the presence of any remaining roots or any pathological changes within the bone. The ridge height was measured at the canine areas from the crest of the ridge to the inferior border of the mandible. A minimum height of 13 mm was necessary to include the patient in the study. The width of the ridge was clinically measured at the canine area of all cases by using an intra-oral bone caliber. The width ranged from 5.4-6 mm. An Alginate (Cavex CA 37: Cavex Holland BV, Hollad) impressions had been taken and poured to obtain diagnostic casts for the maxillary and mandibular edentulous ridges. Maxillary and mandibular diagnostic casts were mounted on an articulator using jaw relation record. This was important to evaluate inter-arch distance, especially at the implant proposed sites to accommodate the future prosthesis. For all the patients involved in the study, maxillary and mandibular complete dentures were constructed following the conventional method.

Radiographic stent fabrication

The finished mandibular denture was duplicated following the conventional method to construct a radio-opaque acrylic resin stent. Two gutta-percha markers were fixed to the proposed future position of the implants along the buccal side of the canine area bilaterally on the transparent acrylic stent.

Measuring the Bone Height

The radiographic stent was tried in the patient's mouth to check the proper seating. The patient's mandible was radiographed using a Cone Beam Computed Tomography scanning machine. During imaging, each patient was instructed to wear his stent. The stent was stabilized by asking the patient to bite on two cotton rolls. The available bone height was measured from the cone-beam computed tomography by measuring the distance from the crest

of the residual ridge just beneath the gutta-percha markers to the mandibular canals. The radiographic stent was prepared to be used as a surgical stent for inserting two interforaminal implants.

Surgical stent fabrication

The radiographic stent was converted into a surgical stent by removing the gutta-percha and two holes of 5 mm width were made through the fitting surface of the stent corresponding to the canine regions.

Surgical procedure

For each patient, two implants (Legacy 3 implant, Implant Direct Sybron Manufacturing LLC, Thousand Oaks, USA) with dimensions (3.2 x 11.5 mm) were inserted bilaterally in the canine region at an equal distance from the midline, parallel to each other and perpendicular to the occlusal plane. All implants were placed by the same oral surgeon using a surgical template and following two-stage surgical protocol. Covering screws were threaded into the implants which were left to heal for three months.

Prosthetic procedures

Following three months healing period, the implants were exposed to receive healing collars. After two weeks, the healing collars were removed, and the soft tissue was assessed for healing. A definitive impression was taken using an open-tray impression technique for all the patients involved in the two groups using addition silicone impression material (Addition silicone, Zhermack, Italy). After the removal of the impression from the patient's mouth, the implant analogs were then screwed to the copings and the impressions were left for 30 minutes before pouring with a type IV dental stone.

Bar fabrication:

For the two groups of patients, the following steps were carried out as follows: The transfer copings which are used as abutments too were adjusted and prepared and then wax pattern coping was fabricated on each abutment and was connected to a preformed castable bar (Short Bar 3.7mm Height, 50 mm length, Implant Direct Sybron Manufacturing LLC, Thousand Oaks, USA with wax). The bar was adjusted to be away from the anterior ridge by about 2-3 mm to facilitate proper hygiene measures. The wax pattern was then sprued and casted into cobalt- chromium alloy following the usual manner (Figure 1)

Fig. (1) : Metal bar attachment

Patient's grouping

For group I patients (control group), ready-made retentive plastic clips were used for the pickup, while for group II (test group) patients, retentive clips fabricated from PEKK material were used.

Fabrication of PEKK retentive clips

For each patient involved in group II, the ready-made retentive clip was sent to the lab for scanning using extra-oral desktop scanner, then the STL file of the scanned clip was sent to the milling machine where PEKK blocks (Bredent GmbH, Senden, Germany) were used to mill two clips for each patient in the group II.

Pick-up impression

For the two groups, the following steps were carried out:

The prepared abutments were unscrewed from implant analogues and screwed to implants inside the patient's mouth after the removal of healing collars using a 1.25mm diameter hex tool. The proper seating and adaptation of the bars were checked before final cementation. The areas of screws of the abutments were blocked out using a small pellet of cotton and a small piece of silicon base material. The resin cement (3M ESPE RelyX™ Unicem Self-Adhesive Universal Resin Cement) was prepared following the manufacturer's instructions and injected into the copings, then the bar with the copings were firmly seated in position over the prepared abutments. After the complete setting of cement, any excess material was removed using a probe. A suitable block out for the undercut beneath the bar was carried out, and the two retentive yellow clips (Retevtive yellow clips, Implant Direct Sybron Manufacturing LLC, Thousand Oaks, USA) were placed over the bar for group I patients, and two retentive clips fabricated from PEKK material were placed over the bar for group II patients. Figure. (2)

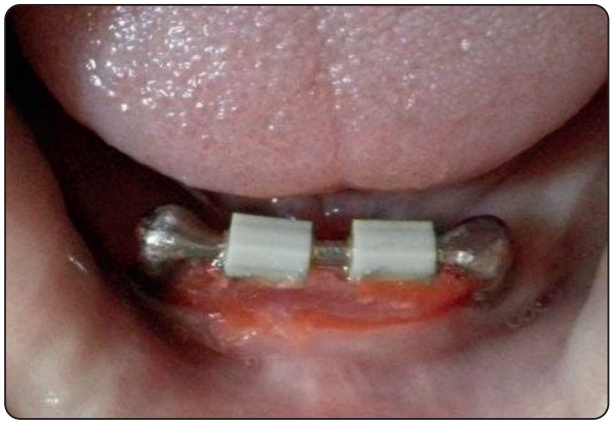

Fig. (2): PEKK retentive clips on the bar ready for the pick-up

The areas of the fitting surface of the mandibular denture opposite to the implants and between them were inspected and marked. Then sufficient relief was made in the fitting surface of the denture to accommodate the bars. Castable self-cured acrylic resin (Pi-Ku-Plast HP 36, bredent, Germany) was inserted in the relieved areas to pick up the retentive clips. Then the denture was inserted into the patient's mouth till completely seated. The patient was instructed to close in the centric occluding relation with maximum biting force until complete polymerization of the acrylic material. Finally, the denture was removed from the patient's mouth, and excess material around the clips were removed, finished, polished, and delivered to the patient. Figure. (3)

All the patients were instructed and motivated to maintain their oral and denture hygiene. After denture insertion, the patients were recalled after one week for inspection and making any necessary adjustments.

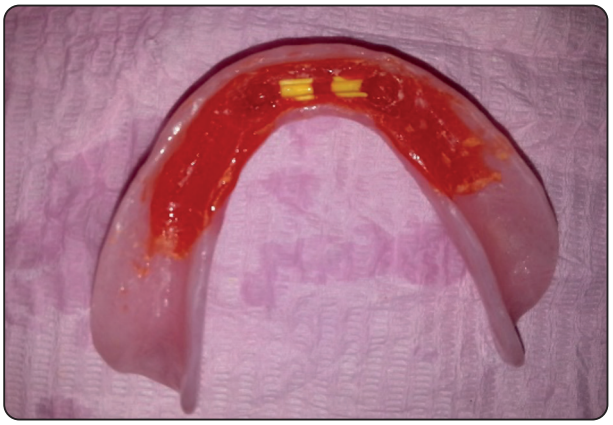

Fig. (3): Plastic retentive clips after the pick-up

Pocket depth evaluation

By using a plastic periodontal probe (Periowise. Premier, USA), the periodontal pocket depth was measured by applying constant pressure during all the measurements and the pocket depth was measured in six sites (the mid-buccal, mid-lingual, mesiobuccal, mesiolingual, distobuccal and distolingual around each implant in the two groups.

RESULTS

Statistical methods

Data was coded and entered using the statistical package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Data were

summarized using mean and standard deviation. Comparisons between groups were done using an unpaired-test. Comparison over time within the same group was done using paired t-test ***(Chan, 2003)***. P-values less than 0.05 were considered statistically significant.[22]

1. Effect of PEKK clip and the plastic clip of bar attachment on the probing depth of the implants at the first interval period (0-6 months)

At the first interval period (0-6 months) it was found that The calculated mean of probing depth around the implants retained by PEKK clip of bar attachment was (1.57) when compared to the calculated mean of probing depth around the implants retained by the plastic clip of bar attachment which was found (3.81), significant differences between both groups at the first interval period where (p<0.001) as shown in Table (1) and Figure (4)

TABLE (1): The mean, standard deviation (SD) values of probing depth of different groups after 6 months

	PEKK clip		plastic clip		P value
	Mean	SD	Mean	SD	
Probing depth (6 months)	1.57	0.31	3.81	0.43	< 0.001

significant (p<0.05) ***ns; non-significant (p>0.05)***

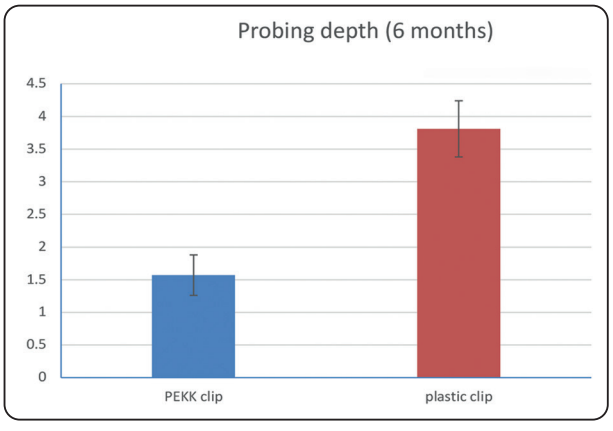

Fig. (4) : Bar chart representing probing depth for different groups after 6 months

2. Effect of PEKK clip and the plastic clip of bar attachment on the probing depth of the implants at the second interval period (6-12 months)

At the second interval of loading (6-12 months) the calculated mean of probing depth around the implants retained by the PEKK clip of bar attachment was found (1.93) when compared to the calculated mean of probing depth around the implants retained by a plastic clip of bar attachment which was found (4.44), significant differences between both groups at the second interval period where (p<0.001) as shown in Table (2) and Figure (5)

TABLE (2): The mean, standard deviation (SD) values of probing depth of different groups after 12 months

	PEKK clip		plastic clip		P value
	Mean	SD	Mean	SD	
Probing depth (12 months)	1.93	0.42	4.44	0.37	< 0.001

significant (p<0.05) ***ns; non-significant (p>0.05)***

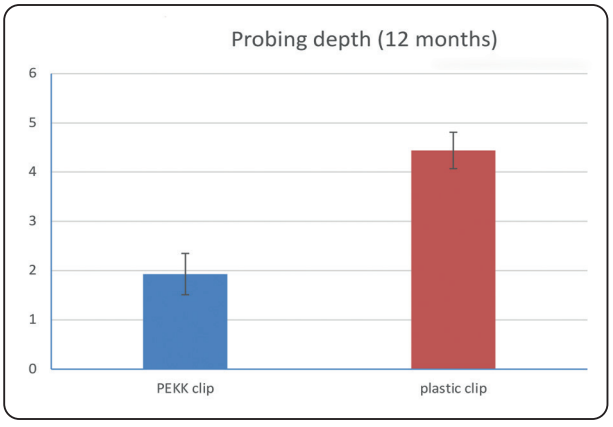

Fig (5): Bar chart representing probing depth for different groups after 12 months

3. Effect of PEKK clip of bar attachment on the probing depth of the implants after six and twelve months respectively.

At the first interval loading (0-6 months) The calculated mean of probing depth around the implants retained by the PEKK clip of bar attachment was found (1.57) while at the second interval period (6-12 months) The calculated mean of probing depth around the implants retained by PEKK clip of bar attachment was (1.93), a significant difference between both evaluations follow up periods where (p<0.001) within the same group as shown in Table (3) and Figure (6)

TABLE (3) The mean, standard deviation (SD) values of pocket depth within same group (PEKK clip materials) after 6 months and 12 months

	PEKK clip		P value
	Mean	SD	
Probing depth (6 months)	1.57	0.31	< 0.001
Probing depth (12 months)	1.93	0.42	

significant (p<0.05) ***ns; non-significant (p>0.05)***

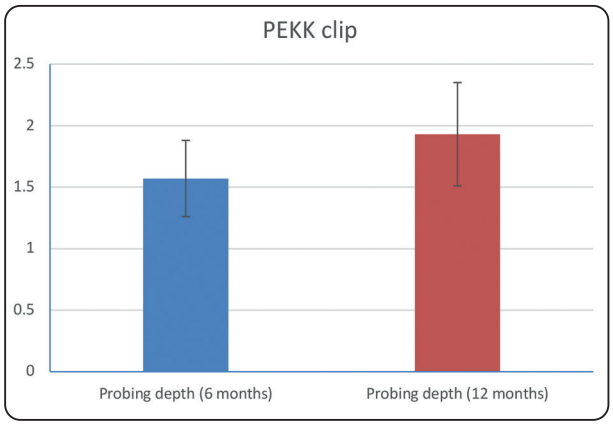

Fig (6) : Bar chart representing pocket within same groups (PEKK clips materials) after 6 and 12 months

4. Effect of the plastic clip of bar attachment on the probing depth of the implants after six and twelve months respectively.

At the first interval loading (0-6 months) the calculated mean of probing depth around the implants retained by the plastic clip of bar attachment was found (3.81) while at the second interval loading (6-12 months). The calculated mean of probing depth around the implants retained by the plastic clip of bar attachment was found (4.44), significant differences between both evaluation follow up periods where (p<0.001) within the same group as shown in Table (4) and Figure (7)

TABLE (4) The mean, standard deviation (SD) values of pocket depth within the same group (Plastic clip materials) after 6 months and 12 months

	Plastic clip		P value
	Mean	SD	
Probing depth (6 months)	3.81	0.43	< 0.001
Probing depth (12 months)	4.44	0.37	

significant (p<0.05) ***ns; non-significant (p>0.05)***

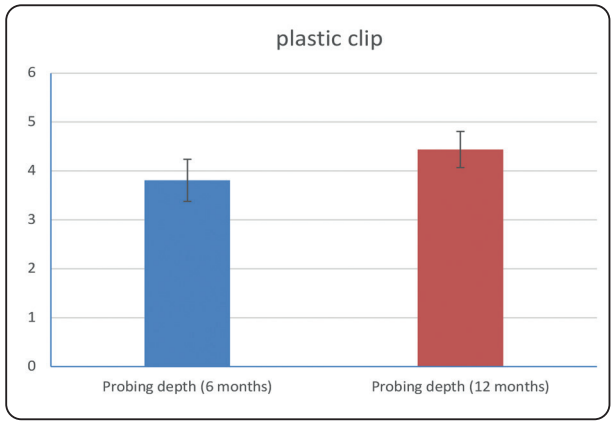

Fig (7) : Bar chart representing pocket within same groups (Plastic clips materials) after 6 and 12 months

DISCUSSION

Middle-aged patients were chosen in this study to avoid the possible effect of age-related changes on the periodontium, mucosa, residual ridge as well as the healing process of the surgical implant site.[23]

Selection of bone quality and quantity is an important factor in the success of implant treatment

so the mandible of the patients was radiographed using a cone beam computed tomography scanning machine and inadequate bone structure was excluded from this study .[24]

Radiographic stents were used to detect the future implant position and then converted into the surgical stent by removing the gutta-percha and two holes were made through the fitting surface corresponding to the canine to insert the implant in the correct chosen site during surgery[25] , two implants were inserted bilaterally in the canine region for each patient, the canine region was preferred as it is away from the vital structure and bone quality and quantity are best in this mandibular lesion [26]

Two stages of the surgical protocol were used in this study to decrease the bacterial infection risk, prevent the oral epithelium apical migration along the implant body, and reduce the risk of the early implant loading during bone remodeling [27]

The bar was adjusted to be away from the anterior ridge by about 2-3 mm to facilitate proper hygiene measures[6]

The pocket depth of the implant was evaluated using a plastic periodontal probe as plastic prob has greater flexibility than a metal probe as well as it reduces contamination and damage to the implant surface[28]

When values were collected after the first and second interval loading period the results of the current study show a significant increase in the probing depth around the implants retained by plastic clips of bar attachment and a decrease in the probing depth around the implants retained by PEKK clips of bar attachment. Hence these results rejected the null hypothesis that clip materials will not influence the probing depth around the implants on both treatment modalities.

Our study revealed that the PEKK retentive clips showed reduced values of probing depths around implants which were significant during both follow-up intervals when compared to plastic retentive clips during the same follow-up periods. These results could be attributed to the low modulus of elasticity of PEKK which is almost comparable to that of bone. According to recent literature, the modulus of elasticity and nano-hardness of a material are important factors that directly affect the amount of pressure transmitted by the material and the extent of the area to which it is transmitted. [29-30-31]

Some studies mentioned one of the important properties of PEKK which agree with our study results that the PEKK materials are flexible and elastic and reduce the stress on the abutment teeth as well as reduce torque on the abutment when used as a partial denture framework [32]

In another systematic review, the author agrees with our observation that PEKK materials cause favorable stress distribution as when using PEKK farmework over implants it shows less stress on the implants and tissue [33,34] and these results could be attributed to its show better stress distribution[35]

For both the test group and the control group, it was found that there was a statistically significant difference between the first interval loading period and second interval loading period within the same group this increase in bone loss around the implants after 12 months is less than the increased bone loss after 6 months within the same group and this is due to bone remodeling which occurs within the first six months [36] and the increase in probing depth at twelve months is due to undesirable occlusion forces subjected to the prosthesis. [37]

More longitudinal studies with a larger sample size are required associating different factors to preserve the bone around the implants in implant-retained overdenture.

CONCLUSIONS

Within the limitations of this study: implant-retained overdenture retained by bar attachment with plastic clip is less recommended over implant-retained overdenture retained by bar attachment with PEKK clip as a PEKK clip preserves probing depth around the implants and decreases strain on it more than a plastic clip

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