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BioHPP FIXED HYBRID PROSTHESIS VERSUS BioHPP BAR OVERDENTURE AS TREATMENT OPTIONS FOR MANDIBULAR EDENTULOUS RIDGE (PROSTHETIC MAINTENANCE AND PATIENTS' SATISFACTION)

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ABSTRACT

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Aims: To evaluate prosthetic maintenance and patients' satisfaction with the BioHPP (biocompatible high-performance polymer) was used as a skeletal substructure for the hybrid (implant fixed detachable) prosthesis versus the BioHPP bar supporting and retaining implant overdenture based on the visual analogue scale (VAS). Materials and Methods: twenty completely edentulous male patients were selected randomly from the outpatient clinic of the Department of Prosthodontics, Faculty of Dentistry, Ain Shams University; the patients complained of ill-fitting mandibular dentures due to ridge atrophy. All patients received new complete dentures; four inter foramina implants were placed using a surgical guide. Three months after osseointegration, the patients divided into two groups received CAD-CAM BioHPP framework hybrid prosthesis (group I) and BioHPP bar supported and retained overdenture (group II). The prosthetic complication was recorded, and the patient's subjective evaluation using a questionnaire based on the VAS includes five points for speech, chewing, comfort, aesthetics, oral hygiene, and general satisfaction was recorded. Results: Patient satisfaction revealed no difference between groups I and II at followup, with both groups highly satisfied after 12 months of follow-up. The general satisfaction for Group I was 4.43 ± 0.34 , while that group II was 4.43 ± 0.50 . Conclusion: The CAD/CAM BioHPP framework materials offer treatment modalities that are a good alternative for mandibular rehabilitation. Excellent levels of subjective patient satisfaction and prosthetic maintenance during the oral function were seen.

KEYWORDS: Edentulous mandible, prosthetic complication, four implants, bar overdenture,

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INTRODUCTION

The most challenging aspect of oral rehabilitation is replacing damaged structures and restoring function and aesthetics. Traditional complete dentures have disadvantages, including increased stability, support, and retention. Discomfort, loss of chewing capacity, and, in some instances, severe discomfort, as well as a reduction in the patient's psychological and social well-being, are examples of these challenges. ^(1, 2,3) In this regard, reconstructing the entire arch with implants is superior to traditional prostheses. It increases the patient's satisfaction and enhances their quality of life. Several treatments are available to help edentulous patients dissatisfied with their retention and stability. Implant-supported overdentures and fixed hybrid prostheses are examples of this. (4,5)

Implant-supported overdentures are usually held in place by a bar or a combination of bars and other attachments that are rigidly connected to multiple implants. So, there must be the correct number of implants. The bar can be made from plastic moulds that have already been milled (castable) or from gold that has already been made.⁽⁶⁻⁹⁾

The term "fixed hybrid prostheses" refers to hybrid prostheses that can be removed by the dentist but cannot be removed by the patient. It stated that this operation is often recommended when the amount and quality of the bone are sufficient for the implantation of the requisite number of implants (usually four or more). Considering all other considerations, such as treatment complexity and expense, the hybrid prosthesis consists of a metal substructure, an acrylic denture base, and teeth. Accepting the prosthesis is recommended when the vertical restorative space is enough or even increased since this expansion can be filled with acrylic to produce an aesthetically acceptable look.^(10,11)

Co-Cr alloys veneered with ceramics are commonly used in implant-supported hybrid prostheses. Both materials showed enhanced stiffness, which may have allowed for more uniform stress distribution. Furthermore, dentistry pioneered new materials, and computer-aided design/computer-assisted manufacture (CAD/CAM) technology has proven effective in producing more accurate prostheses with high patient satisfaction. ^(12, 13)

The BIOHPP (High-Performance Polymer) is based on the polyether-ether-ketone (PEEK) polymer and was introduced as a dental material for manufacturing the superstructure dentures on dental implants Bredent factory. This material combines excellent physical properties with high-temperature stability and resistance to chemical damage. Their strength is due to the special ceramic filler (with a grain size of 0.3 to 0.5 m), optimizing the mechanical properties. Due to this tiny grain size, constant homogeneity can be produced. (15) Furthermore, it has an elastic modulus comparable to the bone, is biocompatible, bioinert, and radiolucent, and is compatible with carbon and glass fibres (15,16). PEEK restorations with CAD-CAM processing have superior and more repeatable mechanical characteristics.

Consequently, this technique is ideally suited for fabricating PEEK frameworks for removable dental prostheses. ^(17, 18) there was a limited study that evaluated BioHPP as a framework and bar. Therefore, the study aimed to evaluate the prosthetic maintenance and patient satisfaction when the BioHPP was used as a skeletal substructure for the hybrid (implant-fixed detachable) prosthesis versus the BioHPP bar supporting and retaining implant overdentures based on the Visual Analog Scale (VAS).

MATERIALS AND METHODS

Patient selection and study design:20 completely edentulous male patients, ranging in age from 50 to 65, were recruited from the outpatient clinic of the Department of Prosthodontics, Faculty of Dentistry, Ain Shams University for this study based on the following criteria: inadequate retention and stability of conventional mandibular

dentures, sufficient bone quantity and quality in the mandibular interforaminal region to install standard implants of at least 10 mm length and 4.2 mm diameter, absence of systemic diseases or disorders, good oral hygiene, normal maxillo-mandibular relationship, absence of parafunctional habits or previous chemotherapy and radiotherapy treatment and patients nonsmokers.

Patients signed consent forms that outlined all phases of the study and the need for periodic recall visits throughout the research. The research ethics committee reviewed this clinical trial (**eth No: 686**) of the Faculty of Dentistry at Ain Shams University and followed CONSORT guidelines for clinical trials.

Surgical and prosthetic procedures: the general, extraoral, and intraoral exams were performed to determine that the conditions for the intended implant treatment were suitable. All patients received new dentures with a balanced occlusal scheme and semi-anatomic acrylic teeth. The participants were advised to wear the dentures for two months before implant insertion to achieve adequate neuromuscular control and adaptation. The patients were separated into two equal groups using computer randomization and computergenerated random software (Excel sheet). All patients were rehabilitated with four parallel interforamina implants and either BioHPP framework. Fixed detachable prosthesis (group I) or a BioHPP bar supported and retained overdenture (group II)

Patient imaging and case planning: the virtual planning for implant placement was made using cone-beam CT software to determine the implant size, length, diameter, and angulation. The composite markers were embedded in the existing mandibular denture at the buccal, labial, and polished lingual surfaces, and the denture was used as a radiographic template. The dual-scan technique used CBCT (1. VGI, QR, Verona, Italy). The first scan was taken for each patient wearing the denture and biting on cotton rolls bilaterally in

centric occlusion, while the second was taken for the denture alone. The Virtual model planning software was used to define the sites for implant placement and anchor pins for the surgical guide. A mucosalsupported stereolithographic surgical template with four4 sleeves positioned over associated implant locations was made with fast prototyping technology (form lab).

Preoperative medications were instructed to be used by the patient before surgery and continued for seven days following surgery. Anesthesia for bilateral mandibular nerve blocks has been administered to the patient. (1:100, 00013 Articaine Chlorohydrate with Adrenaline). Followed by local infiltration and anesthesia in the surgical region to decrease bleeding. The centric occluding relation was used to position the surgical guide fixation.

The osteotomy preparation was performed using the universal surgical kit (. JD Italian guide) supplied by the guide manufacturer (real guide). Osteotomy sites of the implants were sequentially drilled utilizing a series of drills as manufacturing instructions until complete preparation of the osteotomy sites was achieved. Four implants (TRATE AG, Switzerland, Root, and Two-piece Dental Implant) were placed in the interforaminal region of the mandible by the same oral and maxillofacial surgeon using a nonsubmerged flapless surgical technique.

Prosthetic procedures: Three months after the first surgery, the cover screws were unscrewed and replaced by healing abutments. The open tray impression technique was used with the long transfer impression copings threaded onto the implants. The special tray was loaded with rubber base impression material (Zhermack, Italy, Elite) into the patient's mouth; after the set material, the special tray was removed. The implant analogs were fitted accurately into their corresponding mounts in the impression. The implant verification jig (IVJ) was constructed using self-curing acrylic resin in the laboratory. The impression long transfer copings were splinted on the cast after the material set was sectioned by disc into four sections and numbered on a working model. The final impression was taken with an open-tray technique in a single step. The impression material (Supra-implant monoprint (DETAX Germany) was injected under and around the jig to capture the ridge and all anatomical landmarks for a complete denture. The final trial of the verification jig was done on the patient to avoid remaking the framework. The jaw relationship was registered for all the patients, following the same basic principles. The VDO, COR, aesthetics, and occlusion were evaluated in the patient's mouth in a try-in stage. The design of the framework and bar was based on the tooth arrangement.

CAD/CAM Fabrications of the BioHPP Framework and Bar. Lower wax-up denture digitally scanned with 3D shear scan spray. (3D shear scan spray, titanium dioxide free). The opposing denture, the upper denture, and the lower wax-up denture on the semi-adjustable articulator were scanned with a laboratory scanner.

For Group 1 (BIOHPP hybrid prosthesis): the Exocad software (Exocad DentalCAD 2016 GmbH, Darmstadt, Germany) was used, and the main window was opened. It was essential to select the steps: reduced wax-up, adjacent teeth, antagonist, and pontic wax-up; then the type of restoration and material that was designed; and just the implants already previously generated STL files were imported into a CAD program (Exocad DentalCAD 2016 GmbH, Darmstadt, Germany), and the files were overlapped on each other. The virtual cutback was performed with the CAD software to create a screw-retained framework with individual abutment preparations for future multiple crown cementation. The CAD/CAM milled BioHpp framework with ten individual abutment preparations was tried, and the fit was confirmed clinically and radiographically. The BioHPP framework was scanned in the laboratory, then saved the STL files in the CAD software, and merged the STL files to digitally design and fabricate the definitive poly (methyl

methacrylate) (PMMA) resin crowns (Dental VIPI Ltda; VIPI Block Trilux). As shown in figure (1)

The same prosthetic steps were mentioned for Group II (BioHPP bar overdenture). The Dolder bar was selected and designed from the library bar profile (12. VSS Vario Soft Bar (VSP-F) with a posterior parallel walled segment leading to a minimum extension cantilever on which two vertical stud attachments (Variosoft VS3-Mini Attachments (Bredent, Germany) were selected from the present library in the Exocad soft wear. The bar design, with a 5 mm height, a 3,5 mm width, and the size of the tissue bar set to be 1-2 mm clearance to facilitate oral hygiene. After the plan was completed, the PMMA verification jig was milled by the CAM and tried inside the patient's mouth to check passive fitting. The BioHPP blank was clamped to the milling fixture and milled in an exact 5-axis milling unit. As shown in Figure (2)

A visual analogue scale (VAS) questionnaire evaluated the patient's satisfaction and prosthodontic maintenance. The patients were asked to complete questionnaires about their satisfaction with the rehabilitation. The questionnaires were delivered to the patients before and after the treatment at each follow-up visit performed at six months (T6 m) and 12 months (T12 m) from the superstructure insertion. Six factors (speech, chewing, comfort, aesthetic oral hygiene, and general satisfaction were rated on 1 to 5 scores (highly satisfied = 5; satisfied = 4; fair = 3; dissatisfied = 2; highly dissatisfied =1. Prosthetic maintenance was evaluated for both groups every six months. The most prosthetic complication Recorded (Prosthesis fracture. Abutment screw loosening, Crown fracture and replacement, Hyperplasia under the framework or / bar, Periimplantitis, Upper denture fracture, relining upper denture, Flabby tissue upper arch, and Repair, and new dentures) until the end of the follow-up period. As shown in Figure (3)

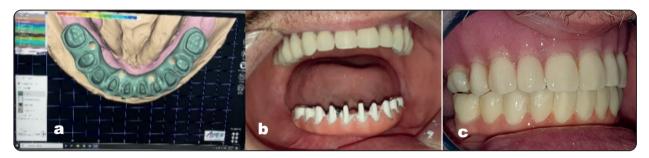


Fig. (1): a) CAD/CAM BIOHPP framework design; b) BIOHPP framework intraoral view; c) final hybrid prosthesis.



Fig. (2): a) CAD/CAM BioHPP bar design; b) BioHPP bar intraoral view; c) final prosthesis



Fig. (3): a) an upper arch flabby ridge; b) periimplantitis; c) a crown fracture

RESULTS

Data were collected, revised, coded, and entered into the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data with parametric distribution were presented as mean, standard deviations, and ranges. Also, qualitative variables were presented as numbers and percentages. The comparison between groups regarding qualitative data was made using the Chisquare test and Fisher's exact test when the expected count in any cell was less than 5. The comparison between two independent groups regarding quantitative data with parametric distribution was made by using an Independent t-test. The confidence interval was 95%, and the margin of error accepted was set to 5%. So, the p-value was considered significant at the level of < 0.05

Patient satisfaction: A comparison between groups revealed an insignificant difference (P > 0.05) in speech, chewing, aesthetics, oral hygiene, and general satisfaction except for comfort; group I (hybrid prosthesis) was a low score compared with group II (bar overdenture) during the first six months. Also, a comparison between general satisfaction revealed an insignificant difference for both groups; both groups were high satisfaction after 12 months of follow-up group I was $4.43 \pm$ 0.34 while group II was 4.43 ± 0.50 As presented in (table 1): Illustration of Patient satisfaction between groups (Table 2) during the 12 months of superstructure insertion.

Prosthetic maintenance:

A comparison between both groups regarding prosthetic maintenance revealed an insignificant

difference (P>0.05) in Prosthesis fracture, Abutment screw loosening, Crown fracture and replacement, Hyperplasia under the framework or / bar, Periimplantitis, Upper denture fracture, relining upper denture, Flabby tissue upper arch, and Repair and new dentures .as shown in **Table(3)** and **figure (4)**

TABLE (1): Illustration of Patients satisfaction between group I (BioHPP hybrid prostheses) and group II (BioHPP Bar SROD) during six months follow-up period

Patients satisfactions	Group 1	Group 2	Test value•	P- value	Sig.
Speech	4.14 ± 0.38	4.00 ± 0.00	1.000	0.337	NS
Chewing	4.14 ± 0.38	4.29 ± 0.49	-0.612	0.552	NS
Comfort	3.14 ± 0.38	4.00 ± 0.00	-6.000	0.000	HS
Aesthetic	4.57 ± 0.53	4.43 ± 0.53	0.500	0.626	NS
Oral hygiene	3.14 ± 0.38	3.43 ± 0.53	-1.155	0.271	NS
General satisfaction	3.83 ± 0.21	4.03 ± 0.21	-1.750	0.106	NS

P>0.05: Non significant (NS); P<0.05: Significant (S); P<0.01: Highly significant (HS)

TABLE (2): Illustration of Patients satisfaction between group I (BioHPP hybrid prostheses) and group II (BioHPP Bar SROD) during12 months of the follow-up period

Patients satisfactions	Group 1	Group 2	Test value•	P- value	Sig.
Speech	4.71 ± 0.49	4.57 ± 0.53	0.522	0.611	NS
Chewing	4.71 ± 0.49	4.57 ± 0.53	0.522	0.611	NS
Comfort	4.14 ± 0.38	4.43 ± 0.53	-1.155	0.271	NS
Aesthetic	4.86 ± 0.38	4.71 ± 0.49	0.612	0.552	NS
Oral hygiene	3.71 ± 0.49	3.86 ± 0.69	-0.447	0.663	NS
General satisfaction	4.43 ± 0.34	4.43 ± 0.50	0.000	1.000	NS

P>0.05: Non significant (NS); P <0.05: Significant (S); P <0.01: Highly significant (HS)

TABLE (3): illustration of prosthetic complication of patients in groups I and II during 18 months:

	Group I	Group II		P-value	Sig.
Prosthetic maintenance	(BIOHPP hybrid)	(BIOHPP bar overdenture)	Test		
	N = 10 N = 10		value		_
Prosthesis fracture	1 (10.0%)	2 (20.0%)	0.392	0.531	NS
Abutment screw loosening	2 (20.0%)	0 (0.0%)	2.222	0.136	NS
Crown fracture and replacement	2 (20.0%)	0 (0.0%)	2.222	0.136	NS
Hyperplasia under the framework or / bar	3 (30.0%)	2 (20.0%)	0.267	0.605	NS
Periimplantitis	3 (30.0%)	2 (20.0%)	0.267	0.605	NS
Upper denture fracture	1 (10.0%)	1 (10.0%)	0.000	1.000	NS
Relining upper denture	1 (10.0%)	1 (10.0%)	0.000	1.000	NS
Flabby tissue upper arch	1 (10.0%)	1 (10.0%)	0.000	1.000	NS
Repair and new dentures	1 (10.0%)	1 (10.0%)	0.000	1.000	NS

P>0.05: Non significant (NS); P<0.05: Significant (S); P<0.01: Highly significant (HS)

Chi-square test

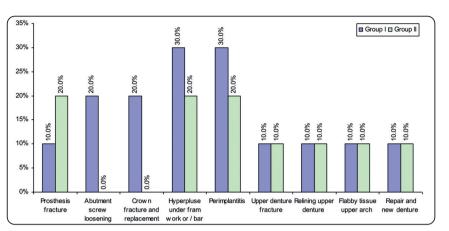


Fig. (4): Prosthetic maintenance of patients in groups I (BIOHPP hybrid and II (BIOHPP bar overdenture)

DISCUSSION

Oral rehabilitation by implant-supported prostheses for an edentulous arch by the implantsupported fixed prosthesis and implant-supported removable prosthesis are popular treatment options for restoring function, and esthetics, improving masticatory efficiency, and patient satisfaction. ⁽¹⁹⁾ Edentulous patients frequently experience problems with their complete mandibular dentures due to a lack of stability and retention of the mandibular denture and a decreased chewing ability. Insertion of implants creates a more favorable restoration in such patients. ⁽²⁰⁾

Patients were precisely selected according to specific criteria to reduce human variables and eliminate any undesirable factors affecting the study results. The study casts were mounted on a mean value articulator by provisional jaw relation in the correct centric relation and vertical dimension to examine an adequate inter-arch space. The intra-arch distance between implant components, BioHpp framework or bar, and PMMA teeth play a significant role in selecting appropriate restoration. A minimum of 15 mm of space has been suggested with mandibular implant-supported fixed prostheses or bar overdenture^(21,22) The inter-foraminal region is chosen due to the absence of any vital structures that may be injured. Also, the most significant height of bone is located in the anterior mandible between the mental foramina.⁽²³⁾

Computer-generated treatment planning and surgical guide construction were used in the current study to ensure implant positioning and alignment standardization, reducing individual operator variability. (24) Therefore, with the dualscan technique, the patient's existing prosthesis is used to ensure accurate adaptation of the dentures to the mucosa and serves as a radiological guide to visualize the mandible anatomy and architecture. (25) The length and width of the implants were standardized in all cases. All implants used were threaded, self-tapping, Two-piece, root-form implants, 10mm in length and 4.2mm in width. This implant design was used to ensure primary stability during the initial healing period and to increase the contact area between the implant and the surrounding bone for better osseointegration.⁽²⁶⁾

The CAD/CAM framework and bar have proven to be more accurate, less time-consuming, and less expensive. These results improve decreased treatment time, experience for the patient, and greater accessibility. ^(27,28) Three items were required for scanning (lower wax-up denture, opposing arch, and mounting costs on the articulator). This technique makes the traditional fabrication of silicone keys unnecessary since the (STL) files contain all the necessary information for tooth position, contours, and spatial orientation.⁽²⁹⁾

BioHPP implant frameworks combined with pre-fabricated high-impact PMMA teeth can be an alternative treatment for all-on-4 implant-supported restorations. It has many advantages, like elasticity similar to that of bone and a shock-absorbing effect. Also, the polymeric biomaterial PEEK may be a valuable material for infrastructure due to the polymer's increased radiolucency and decreased stiffness. ⁽³⁰⁾

This study was designed to estimate the patient's satisfaction level with the BioHPP framework and bar materials for implant mandibular rehabilitation and maintenance period and to evaluate further factors influencing patient satisfaction in function, service, and complications. No scientifically supported link exists between the patient's satisfaction and the prosthesis quality. However, we have seen several attempts to improve our treatment approach in recent years.

This study found that various factors, particularly those connected to complications, influenced implant patients' subjective satisfaction. Patient satisfaction was evaluated (VAS). Unfortunately, certain dogmas have prevented us from performing prosthetic procedures. ⁽³¹⁾ Through the 12-month followup period, all patients reported few post-insertion problems. Within the parameters investigated, all implants used and examined in the study performed well (speech, chewing, and aesthetics^{. (32)} Also, in this study, patients' overall satisfaction with the BioHPP framework (fixed) and BioHPP bar overdenture implant rehabilitation have both been high (4.43 ± 0.34) and (4.43 ± 0.50), respectively.

The equal satisfaction between the two treatment options may be due to using the same number of implants, and the same superstructure materials that it is related to the BioHPP reinforced polymer has many advantages: restorations with low specific weight, elasticity similar to that of bone; shock-absorbing effect; low material fatigue; no viscoplastic fractures; high biocompatibility; low plaque acceleration; and no corrosion and color stability. ^(33,34)

Regarding prosthetic complications, the most common complication was mucosal Hyperplasia and periimplantitis under the BioHPP framework or bar; the reason for this complication was related to the space between the prosthesis and mucosa about the prosthesis design as limited space or no space affected patient access to oral hygiene which was (30.0%) in group I and (20.0%) in group II.

This fixed prosthesis that is held in place by implants needs to be cleaned in a certain way at home. On the one hand, the surface of the prosthesis's teeth should be brushed with a regular toothbrush (either a manual or electric one) to get rid of food particles and bacteria. Still, the most important part of hygiene in these cases is using a different way to clean to get rid of the dirt and dust that builds up under the prosthesis. This requires specialized interproximal brushes and dental floss designed for implants to ensure that dirt, bacteria, and plaque do not accumulate between the teeth or beneath the implant. Furthermore, using a soft-bristled toothbrush or an oral irrigator can also help get rid of food particles and plaque in hard-to-reach areas ^(37,38)

Abutment screw loosening occurs when the joint-separating forces acting on the screw joint are greater than the clamping forces holding the screw unit together. During tightening, the microtoughness of the metal surface that touches the other metal slightly flattens. It makes the distance between the two surfaces smaller. There is a 2–10 % decrease in the preload, known as the settling effect or embedment relaxation. ⁽³⁹⁾ and the crown fracture were higher complications in the fixed hybrid prosthesis; this complication was because the individual crowns were made from PMMA, considered a temporary material. ⁽⁴⁰⁾

Both groups had a comparable incidence of maxillary denture relines and flabby maxillary ridges (10%) due to increased mandibular denture

retention and stability, increased muscle activity, chewing efficiency, and maximum bite force transmit more occlusal forces to the anterior maxillary region. This resulted in greater bone loss and the formation of a flabby ridge. The maxillary ridge resorbs as a result, and maxillary dentures require more frequent relining. However, neither group was impacted by this issue. ⁽⁴¹⁾ However, using acrylic in conjunction with the BioHPP framework and BioHPP bar-supported overdenture by both groups was inconsequential since both showed only minor stresses in the bone focused around the implant ^{(42).}

CONCLUSION

Despite the study limitations, The CAD/CAM BioHPP framework materials offer treatment modalities that are a good alternative for mandibular rehabilitation. Excellent levels of subjective patient satisfaction and prosthetic maintenance during oral function were seen.

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