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Qualitative and Radiographic Assessment of PEEK Bar Versus Titanium Bar Fabricated by CAD-CAM in Mandibular Hybrid Prosthesis: a randomized controlled clinical trial

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Aim: This study aimed to compare the qualitative and radiographic outcomes of polyether-ether-ketone (PEEK) bars versus titanium bars fabricated using computer-aided design/computer-aided manufacturing (CAD/CAM) technique for use in mandibular hybrid prostheses.

Materials and Methods: A total of 14 patients with completely edentulous mandibular arches opposing natural dentition were selected and divided into two groups; seven patients in each. All patients received implant-supported hybrid prostheses with a bar fabricated utilizing CAD/CAM milling technique on four dental implants. The bar was fabricated from titanium in Group I (control), while it was fabricated from PEEK in Group II. Furthermore, the study compared the two groups as follows: 1) Qualitatively, a questionnaire was used to evaluate patient satisfaction. 2) Radiographically, digital periapical imaging was used to measure marginal bone loss around implants. Finally, the results were statistically analyzed.

Results: The patients in both study groups demonstrated increased levels of satisfaction, with no significant difference between them, except in terms of aesthetics, as the PEEK group exhibited superior aesthetic outcomes. In terms of marginal bone loss, a reduced marginal bone loss in the PEEK group was observed between the two groups during the 6- and 12-month assessments.

Conclusion: PEEK material has proven to be a valuable alternative for bar fabrication in implant-supported hybrid prostheses for patients with a single edentulous mandible as the patients with PEEK bars demonstrated higher satisfaction and less marginal bone loss than those with titanium bars.

Keywords: Edentulous mandible, Prostheses and implants, Hybrid prosthesis, CAD-CAM, PEEK.

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Introduction

The management of edentulous mandibles with natural teeth present in the opposing arch is a significant issue in the field of dentistry. [1] Conventional dentures are commonly utilized for the management of such cases. However, patients often encounter challenges associated with these removable prostheses, including diminished stability and compromised chewing function in comparison to natural teeth or fixed prosthetics. [2]

Implant-supported restorations demonstrated efficacy and reliability as a viable solution for the rehabilitation of patients with edentulous mandibles. These restorations can be in the form of removable prostheses, fixed prostheses, or fixed-detachable prostheses with processed acrylic teeth, known as 'hybrid prostheses'. These hybrid prostheses enhance patients' stability, functionality, and aesthetics. [3] According to the existing literature, implant-supported screw-retained prostheses provide reliable outcomes in terms of improved stability, functionality, and patient satisfaction compared to conventional removable dentures. [4]

Typical materials utilized in the fabrication of hybrid prosthesis bars include titanium, gold, and cobalt chrome. However, challenges such as high elastic modulus, metal density, hypersensitivity concerns, casting issues, porosity, aesthetic limitations, and compatibility issues with imaging techniques have spurred the exploration of alternative materials. Recent advancements have introduced pure polymers and polymer composites as substitutes for metals in the field of orthopedic and dental prostheses. [5]

Polyetheretherketone (PEEK) has gained popularity for implant-supported dental prostheses due to its biocompatibility and excellent physical and chemical properties, such as toughness, hardness, and elasticity. [6] PEEK is a highly favorable material for load cushioning capacity in prosthetic elements due to its modulus of elasticity, comparable to bone. [7]

The widespread use of CAD/CAM systems in the fabrication and design of fixed and removable prostheses is due to their precision, durability, and predictability. Additionally, it is the only method for fabricating dental restorations composed of high-strength polymers. [8] By utilizing CAD/CAM, it is possible to create precise and well-designed frameworks consistently. This allows for a shift from conventional casting methods, significantly improving implant treatment's cost efficiency. [9]

To the best of our knowledge, the literature lacks a comprehensive evaluation of the performance of the PEEK framework in full-arch dental prostheses. Due to the inherent unpredictability regarding the biomechanical behavior of the PEEK framework, this gap continues to exist. In light of the aforementioned factors, the objective of this study was to conduct a comparative analysis of CAD/CAM-fabricated PEEK and titanium bars within a single mandibular hybrid prosthesis.

Materials and Methods

This prospective randomized controlled clinical trial study was approved by the Local Ethics Committee, Faculty of Dentistry, Tanta University, Egypt (number RP/02-21/4). The purpose of the present study was explained to the patients. In addition, all patients provided informed consent based on the human

research guidelines established by the research ethics committee.

Dataset

This study included fourteen patients who were completely mandibular edentulous patients with completely dentulous or some of the natural teeth were lost that were restored after finishing the final prosthesis. The included patients aged 40 to 60 years and were edentulous for at least six months with moderate bone height and width, excluding any systemic disorders that may influence soft or hard tissues. [10]

The patient's general health was evaluated by taking a complete medical history. All patients underwent specialized laboratory tests to ensure that all patients were free from systemic diseases that might influence implant osseointegration.[11] The intraoral examination included existing restorations, oral hygiene assessment, periodontal examination, occlusal status, the quantity and quality of the mucosa and the underlying bone, and the interarch space.

Presurgical phase and Treatment planning

This study aimed to assess the qualitative and radiographic outcomes of using peek bar versus titanium bar in mandibular hybrid prostheses.The minimum sample size(n) was a total of twelve patients based on the results of the power analysis calculated by G-power 3.0.10 software. [12] This was increased to fourteen patients to compensate for lost-to-follow-up cases. The fourteen patients were divided into two groups, each with seven patients. All of the selected patients were restored with a mandibular conventional denture and then underwent CBCT (Scanora 3D, Soredex Co., Tuusula, Finland) in order to assess the quantity and quality of bone at the implant sites precisely, which was necessary for surgical guide preparation and implant planning. The design of a surgical guide supported by mucosa was accomplished through the utilization of 3Shape Implant Studio (3Shape, Copenhagen, Denmark) and printed using a Mogassam Dent2 printer (Mogassam Co., Cairo, Egypt).

Implants placement

Four implants (Bredent Gmbh & Co kg, Senden, Germany) were inserted intraforaminal in the patient's mandibular arch according to the virtually designed treatment plan. [13,14] The implants were left unloaded during the healing period of three months. One month after the surgery, a conventional denture was lined with a soft liner and used as a temporary prosthesis until the final prosthesis was obtained.

After three months (the healing period), a periapical radiographic X-ray (Planmeca ProMax 2D, Helsinki, Finland) was taken for each patient to check for osseointegration and the absence of radiolucency around the implant fixtures. Appropriately sized healing abutments were attached to the implants at the canines and the second premolars implant and left for two weeks until complete gingival healing.

Bar Fabrication

An open tray implant level impression (direct) method was used for the mandibular arch via impression-transfer copings (Bredent Gmbh & Co kg, Senden, Germany), which were tightened to the fixtures and periapical radiographs were obtained to ensure that each one was adequately seated on each implant. The four implants were splinted using dental floss and Composan LCM flowable composite (Promedica, Neumunster, Germany) around them. The additional silicone impression material (Elite HD+,

Zhermack, Marl, Germany) was used for impression making. Four scan bodies were placed on the cast and tied to the implant analogues then the master cast was scanned by extraoral scanner. Next, the scanned file of the master cast was saved in the STL format and exported to Exocad software (Exocad Dental 2015; Exocad GmbH, Darmstadt, Germany) for verification jig designing and fabrication.[15]

The bars were designed using Exocad software according to the saved STL file of the master cast and the primary jaw relation that was taken on the jig. The resulting STL files of the bars had a minimum thickness of 3 mm, as recommended by Taylor et al. [16] In this study, nonengaged abutment connections and mechanical retentive means were utilized at the top of the bar. Finally, the bar designs were thoroughly examined to identify any alterations and were subsequently saved as STL files. The files of Group I were milled from titanium (manufactured by Shaanxi Yunzhong Metal Technology Co., Ltd., China) whereas, the files of Group II were milled from PEEK (manufactured by Bredent, breCAM. BioHPP, Senden, Germany).

The passive fit of the bars was detected intraorally by the Sheffield test[17] (Figure 1) by tightening one screw at one terminal implant. Subsequently, the fit on the remaining implants was assessed for both types of bars. In addition, digital periapical and panoramic radiographs were utilized to assess the fit of the titanium and PEEK bars.

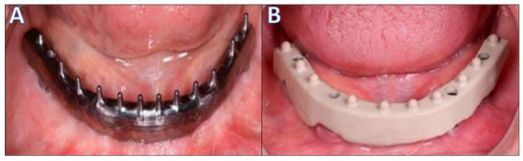

Figure 1: Bar try-in for checking the passive fit. A- Mandibular titanium bar. B- Mandibular PEEK bar.

Prosthesis fabrication

Following the establishment of a definitive bite registration, it was transferred to a semi-adjustable articulator, where the crosslinked semi anatomic acrylic teeth (Acrostone, El-Salam City, Egypt) of the final prosthesis were arranged then tried for vertical dimension and occlusion in the patient's mouth to check the aesthetics and phonetics of the patient. Following the contour adjustments, the prosthesis was then brought back to the laboratory to have an occlusal silicone index by which the positions of the teeth on the framework were determined using cold cure acrylic resin. Finally, the prosthesis was flasked and subsequently treated with heat-curing acrylic resin (Acrostone, El-Salam City, Egypt). The final prosthesis was finished and polished (Figure 2) and delivered to the patients after periapical and panoramic radiographs (Figure 3) were taken to verify its complete seating to the implants.

Figure 2: Final hybrid prosthesis: acrylic denture base supported by bar (A) titanium (B) PEEK.

After confirmation of the fit of the prosthesis on X-ray, the abutment screws were retightened to the recommended torque of 30 N using a calibrated torque wrench attached to the screwdriver after 10 minutes. [18] Then, a small piece of Teflon (PTFE thread seal tape, Italy) was placed into each screw access channel, and the openings were filled with self-cure polymethylmethacrylate(Acrostone, El-Salam City, Egypt) (Figure 4).

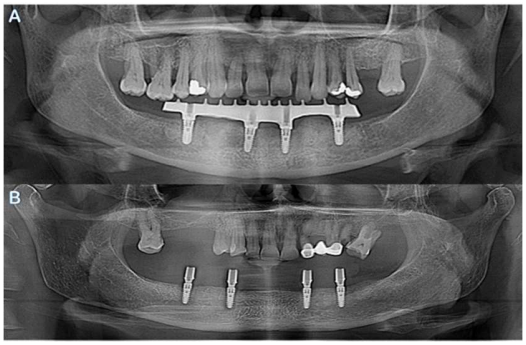

Figure 3: Panoramic radiographs: final hybrid prostheses intraorally (A) titanium (B) PEEK.

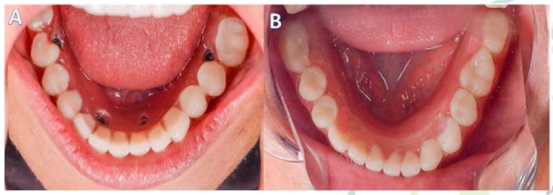

Figure 4: Final hybrid prostheses intraorally from occlusal view (A)Tighted abutment screws (B) Closure of screw access channel

Evaluation

1.Qualitative assessment: Patient satisfaction was evaluated through a patient questionnaire for both groups in certain aspects; patient comfort, esthetics, ability to eat, phonetics, self-confidence, general health, and general satisfaction were assessed through direct patient questions, and the answers recorded with value definition ranged from very unsatisfied to very satisfied: 1 for very unsatisfied, 2 for unsatisfied, 3 for intermediate satisfaction, 4 for satisfied and 5 for very satisfied. [19, 20]

2.Radiographical assessment: Marginal bone levels were measured at 6 and 12 months post-implant abutment screwing using digital intraoral standardized periapical radiographs; the image of each implant was taken for every patient using the long cone paralleling technique with a Rinn XCP (Rinn Corporation, XCP instrument, Elgin, Illinois, USA) film holder and custom - fabricated putty rubber base bite blocks above the prosthesis where each implant position was determined by its screw access channel. The sensor was inserted into a slot in the bite block to ensure accurate re-positioning of the film every time the radiograph was taken. The X-ray tube was positioned flushing with the ring and the exposure was done. Time and dose of exposure were standardized in all patients. After the exposure, the image was displayed on the computer screen and stored on the patient card. The image was exported from the sensor software as grey scale image to be interpreted via imaging analysis software SIDEXIS XG 2.52 software (Sirona Dentsply), to evaluate marginal bone height loss around implant. [21] Measurements were taken from the implant-abutment connection to the most coronal contact point between the bone and the implant on the mesial and distal sides.

Statistical analysis

The data were analyzed blindly using the IBM SPSS software package V 26 (IBM Corp., Armonk, New York, United States). Qualitative data are presented as numbers and percentages. The Shapiro–Wilk test was used to verify the normality of the distribution. Quantitative data are presented as the range (minimum and maximum), mean, and standard deviation. The significance of the obtained results was determined at the 5% level. For categorical variables, the chi-square test was used to compare different groups. Fisher's exact test or Monte Carlo correction was used for chi-square correction when more than 20% of the cells had an expected count of less than 5. For normally distributed quantitative variables, the Student's t-test was used to compare two studied groups, and the Mann–Whitney test was used for abnormally distributed quantitative variables. The analysis of variance (ANOVA) with repeated measures was

employed to compare multiple periods or stages for quantitative variables that followed a normal distribution. Pairwise comparisons were conducted using the post hoc test.

Results

An original sample of 14 patients complied with the eligibility criteria with a survival rate of 100% in all groups.

Qualitative assessment of patient satisfaction

Table 1 displays the descriptive statistics pertaining to patient satisfaction, including factors such as patient comfort, esthetics, ability to eat, phonetics, self-confidence, general health, and general satisfaction. The results indicate that there were no instances of dissatisfaction (values 1 & 2) observed in the assessment for any of the categories. Furthermore, when comparing Group I and Group II, there were no significant differences in the evaluation of any of the categories. However, in terms of aesthetics, there was a significant difference between the two groups under study.

Radiographic evaluation of marginal bone loss (MBL)

In both groups, no noteworthy difference in MBL was observed before the patients transitioned to the hybrid denture (baseline stage). Nevertheless, a significant difference emerged between Group I and Group II after 6 and 12 months of usage. Additionally, Table 2 depicts a comparison between the two studied groups in terms of MBL at various follow-up periods. Figure 5 shows the use of digital periapical radiographs to assess MBL around implants during the 12-month follow-up period. Enhanced bone loss was identified around a dental implant supporting a titanium bar, while minimal bone loss was observed around a dental implant supporting a PEEK bar.

Table 1: Patient satisfaction analysis of hybrid prostheses between Group I and Group II

Satisfaction value	Group I (n = 7) %	Group II (n = 7) %	χ^2	P
Patients comfort				
4	57.1	14.3	2.8	^{FE}p=0.27
5	42.9	85.7		
Esthetics				
4	85.7	14.3	7.14*	^{FE}p=0.029*
5	14.3	85.7		
Ability to eat				
3	14.3	14.3	0.39	^{MC}p=1.000
4	28.6	28.6		
5	57.1	57.1		
Phonetics				
3	14.3	14.3	0.67	^{MC}p=1.000
4	42.9	28.6		
5	42.9	57.1		
Self-confidence				
4	28.6	28.6	0	^{FE}p=1.000
5	71.4	71.4		
Gingival health				
3	14.3	14.3	0.39	^{MC}p=1.000
4	57.1	57.1		
5	28.6	28.6		
General satisfaction				
3	14.3	14.3	1.52	^{MC}p=0.76
4	57.1	28.6		
5	28.6	57.1		

χ2: Chi-square test, MC: Monte Carlo, FE: Fisher's exact test, p: p-value for comparisons between the studied groups *: significant where p-value ≤ 0.05, 3: intermediate satisfaction, 4: satisfied, and 5: very satisfied.

Table 2: Inter and intragroup marginal bone loss comparison metrics at the 0-, 6- and 12-month follow-up periods.

Metric	Group I (n = 7)	Group II (n = 7)	T	P
Baseline				
Min. – Max.	0.15 – 0.33	0.15 – 0.26	0.974	0.349
Mean ± SD	0.24 ± 0.07	0.21 ± 0.04		
6 months				
Min. – Max.	0.81 – 0.93	0.70 – 0.84	3.194*	0.008*
Mean ± SD	0.85 ± 0.05	0.76 ± 0.05		
12 months				
Min. – Max.	1.13 – 1.51	1.02 – 1.21	3.716*	0.016*
Mean ± SD	1.25 ± 0.12	1.11 ± 0.07		
p	<0.001*	<0.001*		

SD: standard deviation, T: Student's t-test, P: p-value for comparison between the studied groups, and *: statistically significant at $p \leq 0.05$. Significance between periods intragroup was done using Post Hoc Test (adjusted Bonferroni)

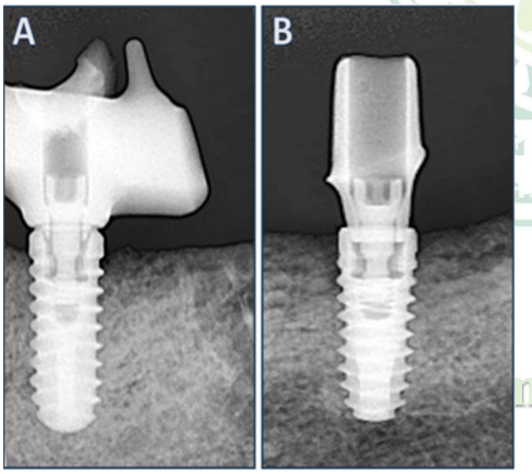

Figure 5: Marginal bone loss evaluation via digital periapical radiographs of titanium (A) and PEEK (B) bars.

Discussion

Dental implant rehabilitation poses a significant challenge for patients with fully edentulous in the mandibular arch. These challenges are related to bone resorption around implants, particularly when the opposing maxillary arch is predominantly dentate.[22] In such instances, there is a lack of standardization regarding the impact of opposing occlusion and its influence on force transmission. [23] The objective of this study was to investigate a different method for creating reinforce bars for full-arch mandibular hybrid prostheses by using PEEK as a substitute material for constructing bars. This approach could reduce the transmission of forces to the underlying bone, as PEEK can function as a shock absorber, thereby providing protection to the bone surrounding dental implants. [24]

A significant advancement in implant prosthodontics has been incorporating engineering principles through the utilization of CAD/CAM technology to fabricate implant prostheses. The prosthetic components could be designed and manufactured to a similar quality and predictability to industrial workpieces with high precision, simpler fabrication protocols, and minimal human intervention. These advantages make CAD/CAM ideal for quality assurance, precision production, and cost-effective manufacturing. Additionally, it has become the sole method of producing durable tooth-colored, metal-free components and prosthetic frameworks in dental practice. [25]

The use of acrylic resin teeth and denture bases has been suggested to provide greater shock absorption of impact forces on prostheses [26]. Moreover, the utilization of acrylic resin material in full-arch hybrid PEEK implant-supported prostheses is associated with minimal biological and mechanical complications. Another reason was the reduced possibility of chipping and fracturing veneering material when the acrylic resin was used instead of other materials. Furthermore, acrylic resin can be utilized

to perform adequate lip support and address bone resorption and discrepancies in jaw relations. [27]

A non-engaging abutment is typically used to connect dental prosthetic units, allowing for correction and ensuring a proper fit of the prosthesis. This is because using hex abutments for this purpose is challenging, as their placement can be difficult due to the insertion line. On the other hand, hex abutments are commonly used for dental restorations that may rotate in the mouth, like single crowns. [28]

Fixed implant hybrid prostheses demonstrated significantly enhanced biopsychosocial outcomes. These improvements were attributed to the enhanced stability, comfort, phonetics, and chewing ability associated with fixed implant restorations.[29]

Moreover, the literature has recorded increased patient satisfaction and improved oral health-related quality of life after rehabilitation via fixed hybrid restorations.[30] Additionally, the enhanced aesthetic result observed in hybrid dentures featuring PEEK bars can be ascribed to the white pigmentation of the PEEK material, in contrast to the grayish appearance associated with metal. [31]

Regarding the challenge of arch dynamics in completely edentulous mandibles, the placement of four implants anterior to the mental foramen, specifically in the premolar and incisor regions, along with their splinting using a rigid structure, is deemed an optimal approach for mandibular rehabilitation. This design effectively counteracts the flexure or torsion of the mandible during function and opening. The concept of preventing mandibular flexure through such a prosthesis design, incorporating occlusion at the first molar and a distal cantilever. [32,33]

The observed decrease in marginal bone resorption in the PEEK group compared to the metal group can be attributed to the lower modulus of elasticity, capacity for dampening occlusal forces, and shock absorption capability of PEEK. Furthermore, the elastic nature of PEEK, comparable to that of bone, results in stress breaking, reducing the occlusal forces transferred to both the restoration and the implants.[24] In contrast, a metal framework may increase peri-implant strain due to the increased weight of the prosthesis and the greater modulus of elasticity of the metal. Consequently, it leads to greater stress transmission to the implants. Additionally, the use of PEEK material allows for the fabrication of lighter prostheses, resulting in heightened patient satisfaction and comfort while simultaneously reducing the stresses transmitted to the implants. [31]

The findings of this study align with those of Erkmen et al. [34], who illustrated that employing a less rigid material for the superstructure of implant-retained prostheses leads to a reduction in stresses within the framework. The incorporation of PEEK frameworks with PMMA veneers could offer an elastic cushioning effect against chewing pressure and potentially yield beneficial outcomes for the soft tissue surrounding the implant. Conversely, frameworks made of metal exhibit a high modulus of elasticity, which might lead to stress concentration at the alveolar crest among the implants.[35,36]

This study's strengths lie in its comprehensive approach, encompassing both clinical and experimental evaluations which achieved the hypothesis of using PEEK as an alternative b material for mandibular

hybrid prostheses. To our knowledge, there is a scarcity of data regarding the utilization of PEEK as a support material for hybrid prosthesis frameworks. In addition, it would be beneficial to conduct further research on the utilization of PEEK material in maxillary hybrid prostheses or its potential application in the simultaneous rehabilitation of both maxillary and mandibular hybrid dentures. Moreover, extending the follow-up period could contribute to a more comprehensive evaluation.

Conclusions

Within the limitations of this study, the utilization of a digitally designed and CAD/CAM-milled PEEK bar has demonstrated its reliability as an alternative material for constructing bars in implant-supported hybrid prostheses, as evidenced by rising levels of patient satisfaction. Furthermore, the degree of bone loss around the implants was less pronounced with PEEK bar compared to titanium.

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Competing interests

None.

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