The Benefits of Polyether-Ether-Ketone Polymers in Partial Edentulous Patients

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Skeleton prosthesis is defined as a complex partial movable restoration, which involves a fixed component (dental bridge cemented on the remaining prepared teeth), and movable component part. Recently, a new high performance polymer, BioHPP, based on polyether-ether-ketone (PEEK) polymer was introduced as dental material for manufacturing the framework of these types of partial dentures.The purpose of this article is to present the results of the clinical trials referring to the benefits of skeleton prostheses wearers' patients with BioHPP framework. The research has been carried out on 48 patients. The recording of the benefits in the using this polymer for partial dentures, in accordance with seven evaluation criteria, was performed in three dental schools from Romania, during three years, at every three months.The results of survey demonstrate that BioHPP polymer frameworks for skeleton movable restorations present many benefits and advantages, therefore this PEEK type of dental material represent a beneficial new acquisition for the partial edentulous patients.

Keywords: partial edentation, PEEK, BioHPP polymer framework

The development of resins represented a great step in dental medicine. The first thermo-cured acrylic resins being developed in 1936. Due to their disadvantages, such as the toxicity of the residual monomer, the difficulties in processing, alternative polymeric materials were created, such as polyamides, acetal resins, epoxy resins, polystyrene, polycarbonate resins etc. [1, 2].

The fabrication techniques for polyaryletherketone (PAEK) polymers have undergone constant refinement since the preparation of PEKK was first described in the 1960s [3].

PEEK is a high performance semi-crystalline, non-homogeneous thermoplastic material. This material offers one of the highest strength-to-weight ratios available in a polymer. Their mechanical and physical properties are high (strong abrasion resistance), is chemically resistant and also have a high degree of thermal and dimensional stability. PEEK has an elasticity modulus similar to that of the bone [4]. Therefore, PEEK can be expected to absorb part of the forces generated during mastication [5].

The chemical structure formula of PEEK polymer is presented in figure 1 [6].

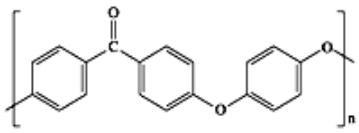

Fig. 1. Chemical structure formula of the PEEK polymer

PEEK matrix permit carbon and glass fibers incorporation of for the development of thermoplastic fiber composites. The addition of carbon fibers significantly increases the dimensional stability, toughness, hardness, flexural strength and resistance of PEEK [4, 7].

Assimilation synthetic macromolecular compounds in chemistry and human health must respond complexity utilization problems that arise from contact, temporary or long-term system of polymeric materials with orofacial tissues. For this reason, polymer biomaterials are those polymers or polymer composites those that are verified as biocompatible in contact with the biostructures [8, 9].

The rapid development of knowledge in the field of technologies for obtaining high molecular compounds was determined using in the field of dental medicine polymeric compounds. A modified PEEK material containing 20% ceramic fillers is BioHPP, a high performance polymer (BioHPP–Bredent, Germany), which presents high biocompatibility, good mechanical properties, high temperature resistance, and chemical stability, and which can be used as support structure (framework) for the skeleton partial dentures [10, 11].

BioHPP polymer is a material which has already been successfully used in operations carried out on humans for many years. This polymer is chemically inert and insoluble in all conventional solvents at room temperature. BioHPP is particularly well suited for producing high-quality prosthetic restorations due to its properties like optimal stability, polish ability and its low plaque affinity [5, 12, 13].

BioHPP (High Performance Polymer) is a PEEK variant that has been specially optimised for the dental field, used today for manufacturing of dental bridges, implant based dentures, a.s. Present high durability, due to the special ceramic filler (particle size of the ceramic filler is from 0.3 to 0.5 microns), and by the fineness of the ceramic filler, BioHPP is suitable for making high quality dentures [14, 15].

In contrast to the framework of the other used dental materials, BioHPP has an elasticity that is suited to the bone; in contrast with ceramics and NPM are approximately 20x as rigid as bone, and gold and titanium are 10x as rigid as bone. This similarity to bone has a beneficial effect, especially in wide-span framework structures (fig. 2) [15].

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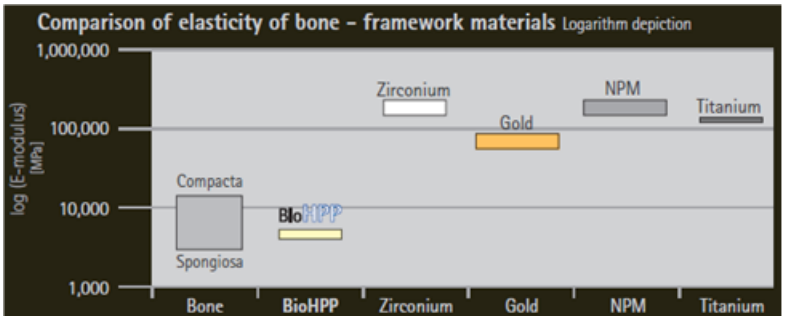

Fig.2. Comparison of elasticity between bone, BioHPP, and other dental materials

The E-modulus of BioHPP lies in the range of 4000 MPa, which very strongly resembles the elasticity of human bone (e.g. in the mandible), so that the chewing forces are therefore cushioned. The maximum fracture resistance indicates the force (in Newtons) at which the sample fails. Values of up to 1200N were reached during the tests which, in comparison to a maximum chewing force of 500N for a human bite, represent an adequate safety margin. The bond strength of BioHPP framework is of over 25 MPa. Gum irritation is ruled out due to the surface quality of the material and its low rough depth of 0.018 µm RA (Jena Uni). Other characteristics of BioHPP polymeric dental material are: flexural strength is >150 MPa, water absorption=6.5µg/mm^3, water solubility <0.3 µg/mm^3, M=melting range (DSC) is approx. 340°C, bond strength >25 MPa, thickness=1.3-1.5 cm^3, hardness (HV)=110 HV 5/20, thermocycling 10,000 cycles 5°C/55°C in accordance with DIN EN ISO 10477, E-modulus=4,000 MPa [13, 16].

Structural formula of a PEEK molecule of BioHPP is presented in figure 3. The white cloud indicates the ceramic filler, which is responsible for the high mechanical material properties, especially for dental technical use [17].

Partial skeleton prosthesis (PSkP) is defined as a complex partial movable restoration, which involves a fixed part (a dental bridge on the remaining teeth), and a part that can be mobilized. The movable part of skeleton denture is anchored by special precision attachment systems on the prepared and covered remaining teeth [18].

The most important reason why patients seek prosthetic replacement of missing teeth is to improve their appearance. Other reasons include the restoration of speech, mastication, confidence, and psychological well-being [19].

Until not long ago, the support structure (framework) of PSkP was metallic and realised by dental alloys, or by using different types of polymers, like nylon-based polymers [20-22].

Experimental part

Materials and methods

The steps for achievement BioHPP framework begin with the wax model of the future framework, which is invested in a mould, in a special investment material. The mould is heated between 630 - 850°C in a pre-heating oven, the wax is melted away and then cooled at 400°C. At this temperature, BioHPP is brought to the melting range of the investment material mould and melted down. The insertion of the press plunger and transfer of the mould into the *for 2 press* system then takes place. By raising the lift, the pressing procedure is triggered automatically and takes place in a vacuum. After completion of the vacuum, the mould is cooled down to room temperature within 35 min maintaining the pressure, and then is devested as usual.

The aspect of BioHPP polymer is presented in figure 4.

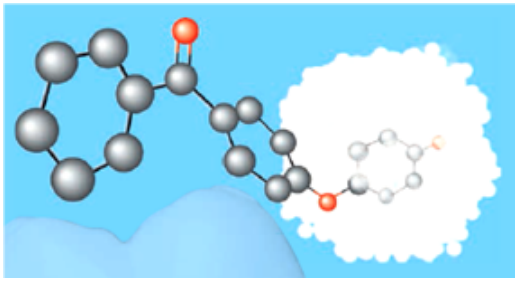

Fig.3. Structural formula of a PEEK molecule from BioHPP

Fig.4. Presentation of BioHPP polymer (Bredent)

The researches were conducted in the Dental Medicine Faculties of Tirgu-Mures, Bucharest, Constanta and Craiova Universities.

The patients were selected after a detailed anamnesis and were attended only by those that have expressed their desire to be part in the research.

From 114 consulted patients, we selected 48 patients which presented first class edentation after Kennedy, with minor odontal injuries or healthy remaining teeth, and without periodontal affections. The research has been carried out on 48 patients, 24 females and 24 males. The age range of the patients was similar, between 48-55 years, with a median age of 51.5 years and a mean of 51.5 ± 3.5 years (fig. 5).

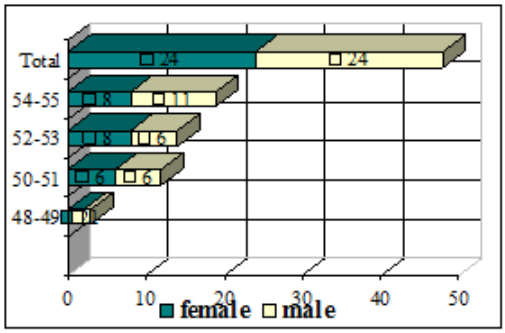

Fig.5. Distribution of patients after age and gender

After the completion of habituation period to BioHPP partial dentures (4 weeks), we conducted the monitoring of results.

The monitoring sessions were performed every three months for three years, so were carried 12 determinations of the benefits in the patients with partial denture with BioHPP polymer framework. The determinations of benefits were realized according with 7 objective and subjective criteria's, recorded after the examinations of selected patients, in the monitoring sessions:

Criterion 1 = decubitus lesions of the soft tissues in oral cavity;

Criterion 2 = allergic reactions of the soft tissues of oral mucosa in contact with the BioHPP base of partial denture;

Criterion 3 = patients who experienced fracture of the denture;

Criterion 4 = altered colour shade in BioHPP framework of PSkP;

Criterion 5 = occurrence of the atrophy of edentulous ridge;

Criterion 6 = existence of an unpleasant taste of the prosthesis;

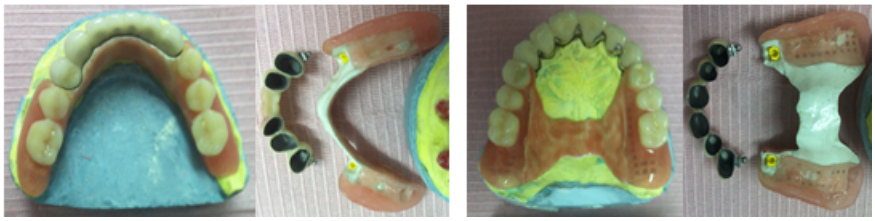

Fig.6. Maxillary and mandibular partial skeleton prostheses with BioHPP polymer framework

Criteria / Session	1- decubitus	2 - allergy	3 – fracture	4 – colour	5 – atrophy	6 – taste	7 – without symptoms
1	11	-	-	-	-	-	37
2	3	-	-	-	-	-	45
3	-	-	-	-	-	-	48
4	-	-	-	-	-	-	48
5	-	-	-	-	-	-	48
6	-	-	-	-	-	-	48
7	-	-	-	-	-	-	48
8	-	-	-	-	-	-	48
9	-	-	-	-	-	-	48
10	-	-	-	-	-	-	48
11	-	-	-	-	-	1	47
12	-	-	-	-	1	1	46

Table 1
THE RESULTS AFTER PROCESSING OF DATA, IN REFERENCE TO THE CRITERIA SET

Criterion 7 = patients without the previous presented subjective and objective symptoms.

In figure 6 are presented images with a maxillary and a mandibular PSkP with BioHPP polymer frameworks.

Results and discussions

In table 1 are presented the results after processing of data, referring to the criteria set of BioHPP polymer framework.

We note that after all monitoring sessions, only 1 patient experienced more than one of the criteria listed above.

Criterion 1: Because BioHPP polymer present a degree of elasticity, less than a third of patients had decubitus lesions, but only the first two months after insertion of PSkP on the prosthetic field, 22.91% in the first month and 6.25% in the second month.

Criterion 2 and 3: No patient carrier of PSkP had experienced allergic reactions and fractures BioHPP frameworks.

Criterion 4: The achieved PSkP from BioHPP showed no discolorations, after 3 years monitoring, altered colour shade in BioHPP framework or early aging.

Criterion 5: Because of a degree of elasticity and low specific weight, this type of PSkP not atrophied the edentulous ridges. We observed only in a single case (=2.08%) a very low level of atrophy of bone at 12-th monitoring session after the use of PSKP with BioHPP framework, but this patient became ill in the meantime by diabetes.

Criterion 6: At 11-th and 12-th monitoring session, one patient (=2.08%) have complained about the existence of an unpleasant taste of the PSkP, but this patient became ill in the meantime by diabetes, and presented a high degree of dental plaque, including on the internal surface of prosthesis.

Criterion 7: In the first monitoring session 37 patients (=77.08%), in the second session 45 patients (=93.75%), and beginning with 3th session till 10th session, all 48 patients (=100%) were without objective or subjective symptoms. At 11th monitoring session two patients (=4.16% experienced unpleasant taste of PSkP) and at 12th monitoring session one patient (=2.08%, which became ill in the meantime by diabetes), experienced atrophy and unpleasant taste of PSkP.

In addition, PSkP with BioHPP framework were more easily integrated by patients, and they considered more comfortable in comparison with their oldest partial acrylic prostheses.

In present, most dental products presented in two-component system powder and liquid, but some manufacturers have launched pasta polymers that have the great advantage represented by the fact that the powder and liquid are pre-measured and thus the ratio of mixing is not optimal, ensure higher quality prosthetic restorations [23].

Currently, the researches are targeted for the improvement and the increasing of the biocompatibility in dental materials, and, in same time, for the increasing of the corrosion resistance of the materials that are in direct contact with the biological tissues. Biocompatibility of dental materials is an important consideration for the patient, clinician, laboratory technician, and manufacturer. Ideally, a dental material that is to be used in the oral cavity should be harmless to all oral tissues, gingiva, mucosa, pulp, and bone [24].

Furthermore, it should contain no toxic, leachable, or diffusible substances that can be absorbed into the circulatory system, causing systemic responses, including teratogenic or carcinogenic effects [25].

The treatment of partial edentulous patients through removable skeleton prostheses with special attachment systems is indicated in specific clinical situations, that exclude the treatment by fixed prosthetic restorations (like bridges). In relation to the location and extension of edentation/edentations occurring disorders of the functions of edentulous maxillary/mandible, in phonetic, esthetic, and/or masticatory function [26, 27].

Toth and all [28], based on the obtained results of their study, concluded that the polymeric biomaterial PEEK may be a useful biomaterial for interbody fusion cages due to the polymer's increased radiolucency and decreased stiffness.

Continuous development and progress of the polymer's industry with application in general and dental medicine has its ground in the importance of these biomaterials in

the health domain. Using of these resins in different technological variants for the restoration of the oral cavity is benefice from childhood till geriatric period [29, 30].

The manufacturing of dental prostheses with metallic framework supposes to perform technical steps that can be associated with errors: vicious adaptation on prosthetic field or defects in material that can lead to the prosthesis fracture [31].

Adverse tissue reactions attributed to the wearing of a metal framework of a partial removable prosthesis are represented, alongside of improper design or poor fit, the allergic manifestation and the high specific weight of dental alloys [32].

Chemical composition and microstructure of the alloys have a strong influence on the corrosion behaviour. After the researches of Porojan [33], the lowest corrosion rates were recorded for a pH of the electrolyte 10 and the highest at a *p*H of 2 for all types of dental alloys (Co-Cr, Co-Cr-Mo and Ni-Cr).

BioHPP material can be used for patients allergic to metals, or who dislike the metallic taste, the weight, and the unpleasant metal display of the denture framework and retentive clasps. BioHPP frameworks can be constructed either via CAD/CAM manufacturing or via the conventional lost wax technique. The clinical use of a BioHPP RDP framework is presented as an alternative for the treatment of partial edentulous patients.

Conclusions

Because the partial skeleton dentures achieved of the BioHPP polymer framework showed no allergic reactions, no discolorations, no allergic reactions and fractures and was more easily integrated by patients, we consider that this new high precision dental material basically represents an innovator polymer, with multiple benefits for patients with partial extended edentations and is suitable for the framework of PSkP.

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References

1.ARDELEAN, L., BORTUN, C., MOTOC, M., Metal-free removable partial dentures made of a thermoplastic acetal resin and two polyamide resins, Mat. Plast., **44**, no. 4, 2007, p. 345
2.BORTUN C., LAKATOS S., SANDU L., NEGRUTIU M., ARDELEAN L., T.M.J, **56**, 1, 2006, 80
3.KURZ S., PEEK Biomaterials Handbook, 1st Ed, William Andrew ed., 2011
4.STEINBERG E.L., RATH E., SHLAIFER A., CHECHIK O., MAMAN E., SALAI M., Carbon fiber reinforced PEEK Optima - A composite material biomechanical properties and wear/debris characteristics of CF-PEEK composites for orthopedic trauma implants. J Mech Behav Biomed Mater., 2013, **17**:221-8
5.ASVANUND P, MORGANO SM. Photoelalastic stress analysis of external versus internal implant-abutment connections. J Prosthet Dent. 2011 Oct;**106**(4):266-71
6.*** www.bredent.com/en/bredent/download/27228/
7.NEUMANN EAF, VILLAR CC, FRANCA FMG, Fracture resistance of abutment screws made of titanium, polyetheretherketone,and carbon fiber-reinforced polyetheretherketone, Braz Oral Res., (São Paulo) 2014;**28**(1):1-5
8.St JOHN K.R., Biocompatibility of dental materials, Dent Clin North Am. 2007 Jul;**51**(3):747-60
9..BOLOS O, C., BORTUN, C.M., CERNESCU, A., ARDELEAN, L., BOLOS, A., RUSU, L.C., Fracture Toughness Evaluation of Some Resins Used in Complete Dentures Technology, Mat. Plast., **50**, no. 1, 2013, p. 28
10.RZANNY A, GOBEL F, FACHET M: BioHPP summary of results for material tests. Research Report. Jena, Germany, University of Jena, Department of Materials and Technology, 2013
11.ZOIDIS P., PAPATHANASIOU I., POLYZOIS G. (2015), The Use of a Modified Poly-Ether-Ether-Ketone (PEEK) as an Alternative Framework Material for Removable Dental Prostheses. A Clinical Report, J Prosthodont. 2015, **1**, 5
12.RIVARD CH, RHALMI S, COILLARD C: In vivo biocompatibility testing of peek polymer for a spinal implant system: a study in rabbits. J Biomed Mater Res 2002;**62**:488-498
13.*** https://bredentmedicalro.wordpress.com/
14.ADLER S, KISTLER S, KISTLER F, et al: Compression-moulding rather than milling: a wealth of possible applications for high performance polymers. Quintessenz Zahntechnik 2013;**39**:376-384
15.*** www.bredent.com/en/bredent/download/26737/
16.*** http://www.bredent.com/de/bredent/products/1/
17.*** www.bredent.com/en/bredent/download/27228/
18.ALAN B. CARR A.B., BROWN D.T., McCracken's Removable Partial Prosthodontics, 13ed, Mosby, 2015
19.JOSHUA OT, OLAIDE GS. Removable partial dentures: Patterns and reasons for demand among patients in a teaching hospital in southwestern Nigeria . Eur J Prosthodont 2014;**2**:82
20.ARDELEAN, L, BORTUN, C., MOTOC, M., RUSU, L., Alternative technologies for dentures manufacturing using different types of resins. Mat. Plast., 2010, **47**, no. 4, p. 433
21.GHIBAN, A., GHIBAN, B., BORTUN, C.M., BUZATU, M., Structural Investigations in CoCrMo(Ti) Welded Dental Alloys, Rev. Chim.(Bucharest), **65**, no. 11, 2014, p. 1314
22.POROJAN, S., POROJAN, L., Evaluation of Co-Cr Dental Alloys Welds Corrosion, Rev. Chim.(Bucharest), **66**, no. 3, 2015, p. 367
23.PHOENIX R.D., CAGNA D.R., DEFREEST C.F., Stewart's clinical removable partial prosthodontics, 4th edition, Hanover Park: Quintessence; 2008; 8-17
24.HANCU, V., COMANEANU, R.M., COMAN, C., FILIPESCU, A.G., GHERGIC, D.L., COTRUT, M.C., In vitro Studies Regarding the Corrosion Resistance of NiCr and CoCr Types Dental Alloys, 2014, Rev. Chim.(Bucharest), **65**, no. 6, 2014, p. 706
25.MOUSAVINASAB S.M., Biocompatibility of composite resins, Dent Res J (Isfahan), 2011 Dec; **8**(Suppl1): S21–S29
26.JONES J.D., GARCIA L.T., Removable Partial Dentures: A Clinician's Guide 1st Edition, Wiley-Blackwell, 2009
27.DUMITRESCU C.S., FILIPESCU A.G., POPESCU A.I., DESPA G.A., GIURESCU R.A., Sistemele magnetice-vârful de lance al supraprotezării în edentaiile pariale întinse, Romanian Journal of Stomatology, 2013, **LIX**, 1, 50
28.TOTH, J.M., WANG, M., ESTES, B.T., SCIFERT, J.L., SEIM, H.B. III, TURNER, A.S. Polyetheretherketone as a biomaterial for spinal applications. Biomaterials. 2006;**27**:324–334
29.BORTUN, C, CERNESCU, A, GHIBAN, N, FAUR, N, GHIBAN, B, GOMBOS, O, PODARIU, AC., Mat. Plast.,**47**, no. 4, 2010, p. 457
30.GHIBAN, N, BORTUN, CM, BORDEASU, I, GHIBANB, FAUR, N, CERNESCU, A, HANGANU, SC, Mat. Plast., **47**, no. 2, 2010, p. 240
31.POP D.M., ROMINU M., TOPALA F.I., SINESCU C., DODENCIU D., ROMINU R.O., ARDELEAN L., RUSU L.C., ANDONI M., PETRESCU E.L., NEGRUTIU M.L., Laser Weldings Versus Electrical Weldings in Dental Technology, A corrosion approach study, Rev. Chim.(Bucharest), 2011, **62**, no. 12, p. 1203
32.GHIBAN, A., GHIBAN, B., BORTUN, C.M., BUZATU, M., Structural Investigations in CoCrMo(Ti) Welded Dental Alloys, Rev. Chim. (Bucharest), **65**, no. 11, 2014, p. 1314
33.POROJAN, S., POROJAN, L., Evaluation of Co-Cr Dental Alloys Welds Corrosion, Rev. Chim.(Bucharest), **66**, no. 3, 2015, p. 367
34. ZOIDIS P, PAPATHANASIOU I, POLYZOIS G. The Use of a Modified Poly-Ether-Ether-Ketone (PEEK) as an Alternative Framework Material for Removable Dental Prostheses. A Clinical Report. Journal of Prosthodontics 2015, **1,** 5

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