The Advantages of BioHPP Polymer as Superstructure Material in Oral Implantology

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The superstructure of dental implants represents the portion that is attached to the implant substructure, by a fixed or movable prosthetic restoration, realized in order to restore the disturbed functions oro-facial system. Recently, a new high performance polymer, BioHPP, based on polyether-ether-ketone (PEEK) polymer was introduced as dental material for manufacturing the superstructure dentures on dental implants.
The purpose of this article is to present the results of the clinical trials referring to the advantages of BioHPP polymer as superstructure in oral implantology. The research has been carried out on 35 patients. The recordings of the advantages in the using this polymer for superstructure on dental implants, in accordance with six evaluation criteria, were performed in three dental schools from Romania, monthly, during one year. The results of survey demonstrate that BioHPP polymer as superstructure on dental implants present many advantages, therefore this PEEK type of dental material represents a beneficial new acquisition for patients' oral health.

Keywords: dental implants, BioHPP polymer, oral implant superstructure

Cultural historical finds indicate that humans tried to replace missing teeth by homeo- or alloplastic materials (human or animal teeth, carved bones, ivory or mother of pearl items) from very early on [1].

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 presents benefits from childhood till geriatric period [2-4].

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. [5,6].

The superstructure of dental implants represents the portion that is attached to the implant substructure by fixed or movable prosthetic restoration, realized in order to restore the disturbed functions oro-facial system [7].

BioHPP (High Performance Polymer) is based on polyether-ether-ketone (PEEK) polymer and was introduced as dental material for manufacturing the superstructure dentures on dental implants by the Bredent factory. Their strength is due to the special ceramic filler (with the grain size of 0.3 to 0.5 μm), which optimised the mechanical properties. Due to this very small grain size, constant homogeneity can be produced. This homogeneity is an important prerequisite for these outstanding material properties and forms the basis for consistent quality. In figure 1 is presented the structural formula of a PEEK molecule, in which the white cloud is an indicator of the ceramic filler which accounts for excellent mechanical material properties, especially for the use in dental techniques [8].

Polyetheretherketone (PEEK) is a polymer that has many potential uses in dentistry. PEEK dental implants have

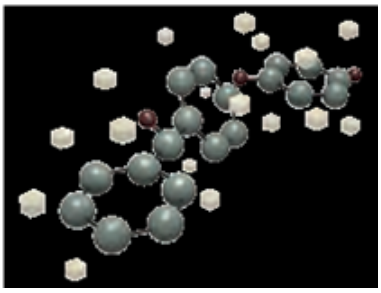

Fig. 1. Structural formula of a PEEK molecule

exhibited lesser stress shielding compared to titanium dental implants due to closer match of mechanical properties of PEEK and bone. PEEK is a promising material for a number of removable and fixed prosthesis. Furthermore, recent studies have focused improving the bioactivity of PEEK implants [9].

Polyetheretherketone (PEEK) is a thermoplastic resin employed in the field of industry and medicine for several years. This semi-crystalline high performance composite offers a unique combination of outstanding physical properties, stability at high temperatures and excellent resistance to chemical damage. These are some of the reasons that allow the use of PEEK as a framework material for removable dental prosthesis, tooth-implant-supported and implant-supported bridges [10].

The PEKK chemical structure guarantees the best mechanical properties of all PAEK. The chemical structure of PEEK polymer is presented in figure 2 [11].

Table 1 present the physical characteristics values for PEEk polymers [12].

BioHPP, approved as a Class II a medical device, is a semi-crystalline and pigmented thermoplastic. Its base

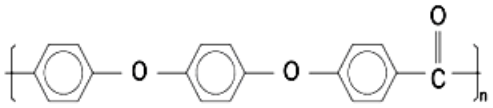

Fig. 2. Chemical structure of PEEK polymer

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Table 1

PHYSICAL CHARACTERISTIC VALUES FOR PEEK POLYMERS

Mechanical properties (DIN EN ISO 10477)	
E-modulus	4,000 MPa
Flexural strength	> 150 MPa (no material
Water absorption	6.5 µg/mm³
Water solubility	< 0.3 µg/mm³
Mechanical properties after 10,000 thermocycling cycles 5°C/55°C (in accordance with DIN EN ISO 10477)	
E-modulus	4,000 MPa
Flexural strength	> 150 MPa (no material
Breaking load tests on three-tooth bridges	
Maximum stress without fracturing (after 24 h immersion in	> 1,200 N
Maximum stress without fracturing (after mechanical and thermal alternating load 1.2 million x 50 N, 10,000 x	> 1,200 N
Other properties	
Melting range (DSC)	Approx. 340°C
Bond strength	> 25 MPa
Density	1.3 to 1.5 g/cm³
Hardness (HV)	110 HV 5/20

material is PEEK and it contains about 20% ceramic filler. With a modulus of elasticity of around 4 GPa, BioHPP is about as elastic as bone, which helps mitigate any stress that might develop and reduces stress shielding. This also means bone-related torsion can also be balanced out to some extent, which is important with larger implant work. In addition, BioHPP is also particularly suitable for patients with allergies because of its very low water solubility of < 0.3 µg/mm^3 and its low reactivity to other materials.

In figure 3 is presented the elasticity comparison for bone and framework materials used in dentistry, in logarithmic representation [13].

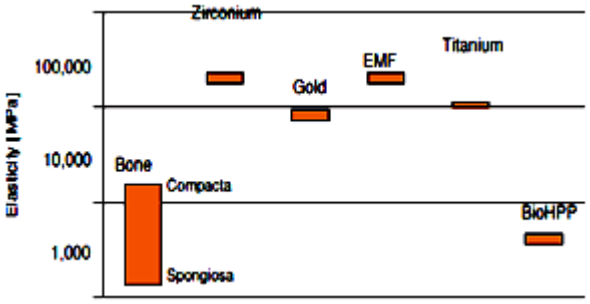

Fig. 3. Elasticity comparison for bone/framework materials

The purpose of this article is to present the results of the clinical trials referring to the advantages of BioHPP polymer as superstructure in oral implantology.

Experimental part

Material and methods

The steps for achievement BioHPP framework begin with the wax model, which is invested in a mould, in a special investment material. The mould is heated between 630°C-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 BioHPP framework is modelled on the abutments and then moulded, polished on the lingual side, and veneered on the vestibular and incisal/occlusal sides, with adhesive being applied inside the mouth [14].

The aspect of BioHPP polymer is presented in figure 4.

Fig. 4. Presentation of BioHPP polymer (Bredent)

The researches were conducted in the Dental Medicine Faculties of Tirgu Mures, Bucharest 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.

The research has been carried out on 35 patients, 17 females and 18 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). Majority of the patients were male (51.42%).

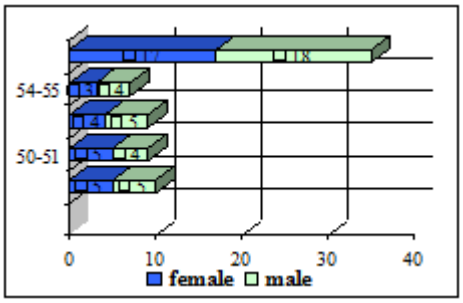

Fig. 5. Distribution of patients after age and gender

After the accommodation period to BioHPP fixed prosthetic restoration (1 week), we conducted the monitoring sessions, which were performed monthly, for 1 year, so were carried 12 determinations of the advantages in the patients' wearer's fixed prosthetic restorations with BioHPP polymer framework. The determinations of advantages were recorded according with 6 criteria, after the examinations of selected patients, in the monitoring sessions:

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

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

Criterion 3 = patients who experienced fracture of the prosthetic restoration;

Criterion 4 = altered colour shade in BioHPP framework;

Criterion 5 = existence of an unpleasant taste of the prosthetic restoration;

Criterion 6 = patients without previous presented symptoms.

In figure 6, 7 and 8 are presented images with a maxillary fixed prosthetic restoration on implant and dental abutments, realised with BioHPP polymer framework.

Fig. 6. Intraoral aspect of the abutments (maxillary right half dental arch)

Fig. 7. Aspect of the fixed prosthetic restoration with BioHPP framework

Fig. 8. Labial aspect of the maxillary fixed prosthetic restoration with BioHPP framework, inserted on abutments

Results and discussions

Table 2 present the obtained results after processing of data's, in reference to the criteria set.

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

- Criterion 1 (lesions of the soft tissues): At first monitoring session, 2 patients and at second, only one patient presented soft tissue lesions, situated in the area of interdental papilla.

- Criterion 2 (allergic reactions of the soft tissues of oral mucosa in contact with the BioHPP framework) and criterion 3 (patients who experienced fracture of the prosthetic restoration): No patient had experienced allergic reactions and/or fracture of restorations.

- Criterion 4 (altered colour shade): The achieved prosthetic restorations showed no discolorations, altered colour shade or early aging of polymeric material after one year.

- Criterion 5 (existence of an unpleasant taste of the prosthetic restoration): At 11-th and 12-th monitoring session, one patient (2.85%) complained about the existence of an unpleasant taste of under the restoration, but this patient became ill in the meantime by diabetes, and presented a high degree of dental plaque.

- Criterion 6 (without previous presented symptoms): In the first monitoring session 33 patients (94.28%), in the second session 34 patients (97.14%), and beginning with 3th session till 10th session, all 35 patients (100%) were without objective or subjective symptoms. At 11-th and 12-th monitoring sessions, only one patient (2.85%) which became ill in the meantime by diabetes, experienced unpleasant taste in mouth, but the other 34 patients (97.14%) were without symptoms.

The fixed prosthetic restorations with BioHPP framework were easily integrated by patients, and they considered these restorations comfortable and low weight.

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 [15].

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 [16].

Long-term success in oral implantology depends on correct timing of temporary splinting, appropriate design and use of the right materials. Because of the differences in the connections between bone and implant and between bone and tooth, movable or rigid joints may be necessary to distribute the forces arising when the implant-tissue junction is stressed [17].

BioHPP polymer 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. BioHPP frameworks can be constructed either via CAD/CAM manufacturing or via the conventional lost wax technique. The clinical use of a BioHPP framework is in present a viable alternative in the prosthetic treatment on implant or / and dental abutments [18,19].

Bio HPP is a physiological esthetic and biocompatible polymer. Extremely rigid prosthetic materials withstand natural torsion of the jawbone. If they are connected to a rigid bridge structure (metal, zirconium, etc.) in the area of the premolars and molars, the tensile and compressive forces are increased in the area of the roots. Natural teeth are able to partly compensate for these forces but fixed osseointegrated implants do not provide this compensating effect. These forces act on implants and the bone at an unfavourable angle and, in the macro area they also affect the physiological movement pattern and have negative effects on the dorsocranial movement capacity, osseointegration or bone atrophy [20,21].

Rehabilitation with BioHPP reduces the stress caused by natural forces and the forces attributed to the prosthetic restoration. Compared to titanium, zirconium or ceramic, rehabilitation with BioHPP significantly reduces peak masticatory forces both for vertical and lateral movement. This property produces a positive effect for the patient and increases the durability of the restoration [14,20].

Considering mechanical and physical properties similar to bone, PEEK polymers can be used in many areas of dentistry. Improving the bioactivity of PEEK dental implants without compromising their mechanical properties is a major challenge. Further modifications and improving the material properties may increase its applications in clinical dentistry [22].

Criteria / Session	1- soft tissue lesions	2 – allergic reaction	3 – fracture	4 – altered colour	5 – unpleasant taste	6 – without symptoms
1	2	-	-	-	-	33
2	1	-	-	-	-	34
3	-	-	-	-	-	35
4	-	-	-	-	-	35
5	-	-	-	-	-	35
6	-	-	-	-	-	35
7	-	-	-	-	-	35
8	-	-	-	-	-	35
9	-	-	-	-	-	35
10	-	-	-	-	-	35
11	-	-	-	-	1	34
12	-	-	-	-	1	34

Table 2
THE OBTAINED RESULTS AFTER PROCESSING OF DATA'S, IN REFERENCE TO THE CRITERIA SET

After Schwitalla and Müller [23], the existing articles in literature indicate that PEEK could represent a viable alternative material for dental implants too.

The combination of its mechanical properties its biocompatibility makes PEEK/ BioHPP material very attractive to medical and dental applications [24].

The material BioHPP is a pigmented, semi-crystalline thermoplastic. The base material is polyetheretherketone (PEEK), which was developed as a veneer-compatible framework material. The good material properties are not impaired during processing [14,21].

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=6.5 µg/mm^3, water solubility <0.3µg/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 [18, 25].

After the researches of Vosshans et al [26], BioHPP as a framework material have a lot of advantages like: preparation of restorations with a low specific weight, elasticity similar to that of bone, sock-absorbing effect, metal-free restorations, low material fatigue, no viscoplastic fractures, high biocompatibility, low plaque accretion, no corrosion. So, this polymer used for dental restorations, satisfy various requirements: osseointegration of implants, stress-free primary framework, fixedness of prostheses, convenient insertion/removal of movable prostheses for patients, good hygiene, plaque resistance, colour stability, low weight. In the material BioHPP the authors have found the alternative we have been looking for to be used on a day-to-day basis in both practices and laboratories.

After the study of Wiesli and Ozcan [27], HPP polyetheretherketone consisting of a single monomer and featuring a low Young modulus may be advantageous. PEEK seems to lead to less osteolyses and healing problems and no scattering in radiation was observed. Some animal studies showed direct contact between PEEK and the bone with high biocompatibility and no evidence for cytotoxicity, mutagenicity, carcinogenicity, and immunogenicity to the present day.

Figure 9 shows the structure of BioHPP magnified 5000 times [18, 20].

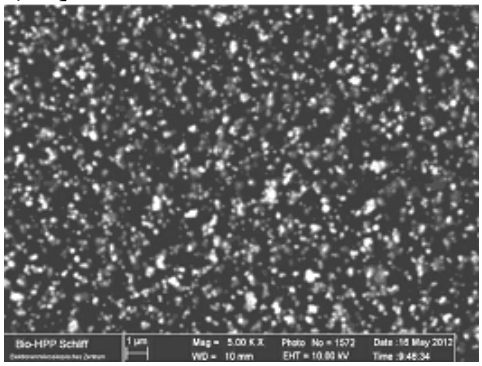

Fig. 9. The structure of BioHPP (5000 x magnification)

After the researches of Kistler et al [28], BioHPP is extremely resistant to abrasion, have highly dense structures and also have excellent anti-discolouration properties. Unlike traditional plastics, stress tests involving coffee, tea, tobacco, methylene blue, and red wine recorded average levels of discolouration when compared with ceramic materials. In cases of extreme stress involving damage, the plastic (unlike restorations with ceramic veneers), can simply be repaired. There is no need for time-consuming drying of the framework and it is also possible to carry out repairs in the mouth if necessary using light-curing systems.

BioHPP developed by Bredent GmbH has been developed especially for dental applications. This polymeric material has been tested in the Universities of Jena and Regensburg, and the tests have been shown that the elasticity of the material resembles strongly to the elasticity of human bone, property which makes it a very interesting material for the restoration of dental implants. Implants are osseointegrated without the formation of a periodontal ligament compared with a natural tooth. Conventional materials such as metal and zirconium have very little elasticity, which can lead to fractures or TMJ problems [14,25].

Denture framework are conventionally made from Chrome-Cobalt. BioHPP can be a viable alternative to Chrome-Cobalt as it is lighter, does not cause any galvanic elements (corrosion) when in contact with other metals in the mouth. BioHPP which can be pressed seems to offer slightly less bulky structures but long term in vivo tests are not available yet [29, 30].

Considering mechanical and physical properties similar to bone, PEEK can be used in many areas of dentistry. Improving the bioactivity of PEEK dental implants without compromising their mechanical properties is a major challenge. Further modifications and improving the material properties may increase its applications in clinical dentistry [22].

The numerous disadvantages of classic thermo-polymerisable acrylic dentures are well known: poor resistance to deformation and wear, poor long-term performance and stability, poor tolerance, usual presence of residual monomer which induces allergies in a high percentage of the patients, porosity which helps the development of microorganisms and deposits [31].

Multidisciplinary studies present the benefits for the knowledge of biomaterials' properties, in reducing the failures of their using, and for their optimization of biomechanical performances of the dentures and their lifetime, with an evident influence on senior's oral health [32].

The system solution based on BioHPP as a highly cross-linked polymer, the "for 2 press" compression-moulding process tailored to it, and their use within a monolithic or veneered application represent a viable alternative to metallic or even full ceramic restorations in terms of either implant-based prosthetics or restorative therapy. Since it is white in colour, it is ideal for aesthetic restoration purposes. The material is associated with a high level of stability, very good polishing qualities, and a low affinity for plaque. With bigger implant projects, however, bone-related torsion can still be balanced out by the elasticity of the material, which is similar to that of bone. Its insolubility in water and low reactivity with other materials mean the material PEEK is also very suitable for patients with allergies. This means BioHPP favours new approaches to treatment based on familiar manufacturing methods. There is no need for time-consuming and costly training for new systems. The added value associated with any restorations is kept within the

laboratory, not least because the high investment costs for things like milling units do not apply [13].

Conclusions

Prosthetic restorations with BioHPP framework showed no allergic reactions, no discolorations, no fractures and was easily integrated by patients, reasons that determine us to consider this new high precision dental material as an innovator polymer, with multiple advantages for patients.

The results of survey demonstrate that BioHPP polymer as fixed prosthetic restoration like superstructure on dental and implant abutments present many advantages, therefore this PEEK type of polymeric dental material represents a beneficial new acquisition for patients' oral health.

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