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Biomimetic Coating on Polymeric Implant Surfaces -The Need of a Quality Standard

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Introduction

Polyetheretherketone (PEEK) is a promising implant material because of its excellent mechanical characteristics. Although this polymer is a standard material in spinal applications, PEEK has the disadvantage by its relative bio-inertness [1]. This is the reason why coating technologies have built an impressive catalogue of success in many different applications: With a growing need for coating technologies to functionalize the surface of polymeric medical devices, the medical industry saw enormous growth in coating application onto medical devices. Various types of coatings technologies, coating materials and substances are available to date: Spanning from plasma spray coating technologies to dip coating techniques, from titanium or hydroxyapatite, all which enhance cell attachment onto orthopedic implants. But there are also various risks associated with the materials and methods mentioned above: amongst others, delamination, wear debris, abrasion, particle migration, infection or corrosion. Performing an exhaustive literature research and during different test set-ups simulating the predictable way of use of coated polymeric implants the authors have analyzed and evaluated the most common used and regulatory cleared coating materials and technologies in medical-device-applications. This paper is meant to give insights into the safety and performance characteristics of the most commonly used coating materials and methods onto polymeric implant surfaces.

Analyzing safety and performance characteristics under simulated use

Table 1: Overview of different regulatory cleared coating technologies for polymeric implant surfaces.

Coating technology	Description
Titanium Plasma Spray Coating	Pure titanium coating applied by vacuum plasma spray process. The purity of the basic material corresponds to the ISO 5832-2 implant standard. With a thickness of 100 to 300 micrometers, Titanium Plasma Spray coating contributes effectively to surface roughness, a good primary stability and improved osseointegration.
Titanium Sputter Coating	Physical vapor deposition technique, resulting in a coating layer to promote osseointegration with a thickness in the 3-digit-nanometer range.
Plasma-sprayed HA	Thermal spray technique to produce HA layer with thickness from 30 to 200 μm depending on the coating condition. Due to its chemical identity with the mineral component of bone, hydroxyapatite ceramics (Ca5(PO4)3OH) have proven they're worth as bone replacement material in recent years.
TiO2-CaP Dip Coating	To achieve even thinner coating layers, in the nanometer scale, TiO2-CaP Dip Coating was introduced: The implant surface is masked by improved biocompatible titanium oxide, which has advantageous effects in many fields of medical applications. At the same time, incorporated calcium ions are released to accelerate faster bone ingrowth.
HA enhanced PEEK	Material enhancement in spinal device technology. Hydroxyapatite (HA), a well-known osteoconductive material, becomes fully integrated, within a PEEK matrix, making it available on the surfaces of a device only after processing the implant material by milling.

Almost all commonly used coating materials and technologies suffer from debris, delimitation and abrasion. Coating technologies incorporating titanium additionally are suspected to corrode, particularly in acidic environments and to cause inflammatory reactions [2-5]. The table below summarizes the different disadvantages and drawbacks of commonly known and regulatory cleared coating technologies. The results presented here have been analyzed and evaluated by Pubmed literature searches and/or during simulated use tests performed by the authors and/or affiliated companies and institutes (Tables 1 & 2) (Figures 1-3).

Table 2: Overview of test methods and results to analyse safety and performance of coating technologies.

Coating technology	Test method	Results
Titanium Plasma Spray Coating on PEEK	In-house research.: According to EN ISO 7438, appropriate tests were performed to evaluate adhesion and elongation of the coatings under bending-tension. N=12 (2x6)	Cracks and beginning delamination after EN ISO 7438 testing (Figure 1).
HA Plasma Spray Coating on PEEK		Films deposited by thermal spraying suffer from poor coating–substrate adherence and nonuniform crystallinity, which reduce the lifetime of such coated implants. The thermal spray coating requires high sintering temperature, which may result in crack propagation on the surface of the coating [6].
Titanium Nanocoatings on PEEK	Titanium and CaP nanocoated implants were tested in usability studies. All implant geometries were the same and made out of PEEK. The test implants, as the study-group, were additionally surface coated, either with a CaP nanocoating or a Ti nanocoating, whereas a control-group was uncoated. The experimental setup was designed to mimic cage impaction into the intervertebral disc space. The cage surface was inspected before and after impaction [7]. N=12 (2x6)	Abrasion of the tip of the ridges was detected in all three test groups. Additionally in case of the Ti nanocoated cage, some areas were detected where the coating had almost disappeared [7].
CAP Nanocoatings on PEEK		
HA filled PEEK	In-house research.: In vivo sheep model: Histological analysis after implant extraction. N=12 (2x6)	The HA-filled PEEK compound in this study had an HA content of 20 %. In the cortical bone area in particular, a relatively wide range of BIC values was found in comparison with the other implant groups. This could possibly be attributed to an uneven distribution of the HA particles within the matrix and thus on the implant surfaces (Figure 2). HA does not show a robust physical/chemical affinity to the PEEK matrix itself, due to the high chemical contrast between the two materials, with this resulting in weak binding of the HA particles to PEEK [1]. Compounding the PEEK matrix with HA particles makes PEEK more brittle [8-10].
Bio-chemically covalently bonded mineralized coating (MBT)		Homogenous BIC on MBT implants. Stable anchorage of the coating surface onto the polimeric implant surface (Figure 3).

Figure 1: EN ISO 7438 bending tests of 6 plasma-spray-coated implant surfaces clearly show cracks in the coating layer. A further consequence may be delamination / abrasion. In-house research.

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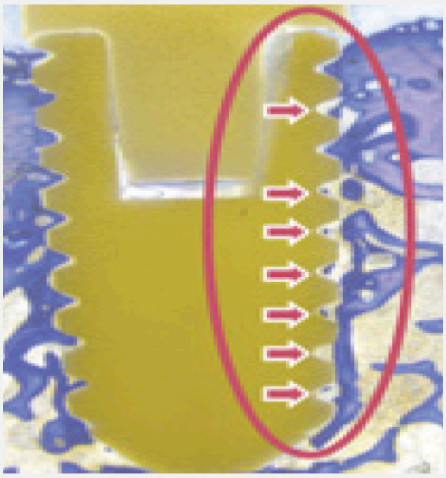

Figure 2: Histological analyzes of HA enhanced PEEK implants: Uneven distribution of HA results in an inhomogeneous BIC. In-house research.

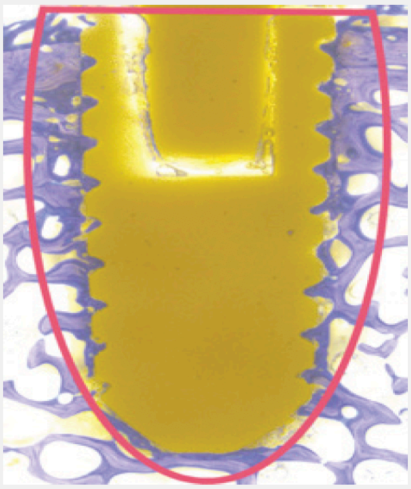

Figure 3: Homogenous BIC on MBT implants. In-house research.

Conclusion

In vitro studies of the above mentioned coating technologies have shown encouraging results regarding osseointegration. But mechanical tests have shown the disadvantages of plasma sprayed coated surfaces, whereas coatings that incorporate titanium may corrode and result in inflammatory reactions. Coatings with a layer-thickness in a 3-digit-micrometer range may influence negatively the engineered topography of 3D-printed implants. With all these different materials and substrates used in coating applications as also due to the various coating technologies, one can get easily lost in a jungle of information: On the one hand side there are some standardized test methods to proof the mechanical stability of the coating layers on the implants surface, on the other hand these methods cannot be used to characterize the mechanical behavior of the various technologies. For biocompatibility testing different set-ups of in-vitro cell test methods and in-vivo animal models can be found in literature. The different coating materials can easily lead to a higher risk-classification of the coated implant. Different and unstructured testing methods and untransparent information may lead to wrong decisions, resulting in reduced safety and performance of polymer-implants. The authors suggest to define and establish an evaluation matrix for different surface functionalization technologies and to introduce a quality standard for coating technologies with transparent safety and performance parameters. To introduce such a quality standard will be subject of further research work, guidelines and publications.

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