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Mimicking Bone Technology
A Golden Standard Technology

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Safety and performance of coated PEEK implants:

Resistance of coated or modified polyetheretherketone implants against abrasion under simulated use.

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Resistance of modified PEEK implants against abrasion under simulated use.

Introduction. With a growing need for coating technologies to functionalize the surface of 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 or dental implants, to antimicrobial silver coatings on catheters. But there are also various risks associated with the materials and methods mentioned above: amongst others, delamination, wear debris, abrasion, particle migration or corrosion.

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. This paper is meant to give insights into the safety and performance characteristics of the most commonly used coating materials and methods.

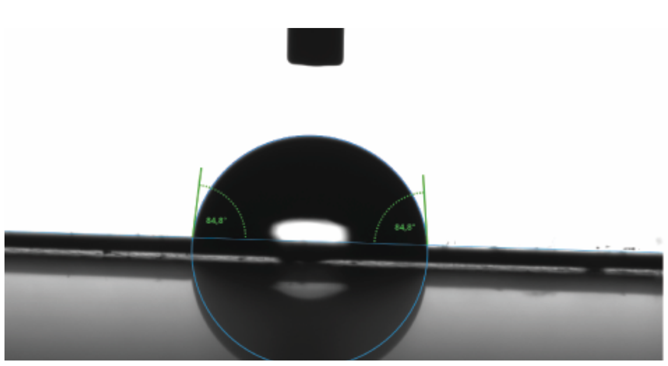
Material and methods. Most common used coating materials and technologies are analyzed and evaluated during different test set-ups simulating the predictable way of use.

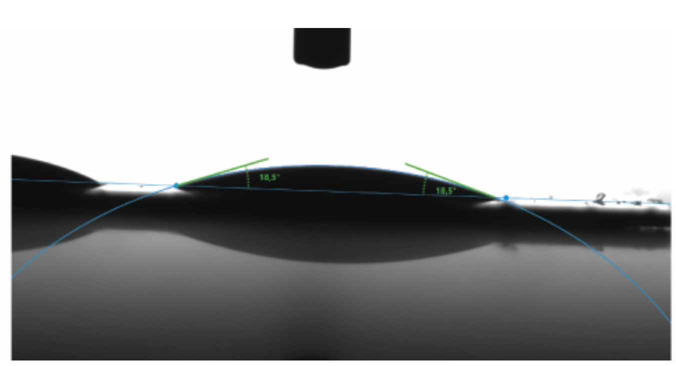
Results. Only implant surfaces treated with mimicking bone technology (referred to as MBT) address all safety and performance requirements of a coating material by way of Mechanical stability, biocompatibility, enhanced clinical effects.

Conclusion. With the patented mimicking bone technology (MBT) the authors have developed an new and innovative surface functionalization technology that avoids potential adverse effects and risks associated with other coating materials and methods, such as corrosion, wear debris, delamination or particle migration.

Key words: PEEK, coating, abrasion, delamiation, osseointegration, health risks, nanomaterial, nanocoating, calcium phosphate, titanium, plasma spray coating, dip coating

Picture 1(a), 2(b): ASTM D 3359 - 97 Standard Test Methods combined with contact angle measurement for assessing the adhesion of coating films to (metallic) substrates by applying and removing pressure-sensitive tape over cuts made in the film.





Overview of different materials and methods to enhance osseointegration by surface modification

TITANIUM PLASMA SPRAY COATINGS

Titanium Plasma Spray Coating (Ti-PSC) is a 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 NANOCOATING

Coating implant surfaces with titanium, most supplier use the above-mentioned plasma spray coating, enabling them to achieve coatings of up to 100-300 µ in thickness. In developing a titanium sputter coating application, the authors have developed an alternative to Ti-PSC (Titanium Plasma Spray Coating) known as TSC (Titanium Sputter Coating. This being a physical vapor deposition technique). The key to success is nano-coating the polymer with titanium, in the approx. 250-nanometer range (thus, up to 1,000 times thinner than Ti-PSC).

HA PLASMA SPRAY COATING / CAP THERMAL SPRAY COATING

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. Plasma-sprayed HA layers, applied as coating material on osseous contact surfaces, stimulate the on-growth of bone. Thermal spray technique has the ability to produce HA layer with thickness from 30 to 200 µm depending on the coating condition.

CAP NANOCOATING

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

PEEK-OPTIMA HA enhanced is a material enhancement in spinal device technology. Hydroxyapatite (HA), a well-known osteoconductive material, becomes fully integrated, not coated (!), within a PEEK-OPTIMA matrix, making it available on the surfaces of a device only after processing the implant material by milling.

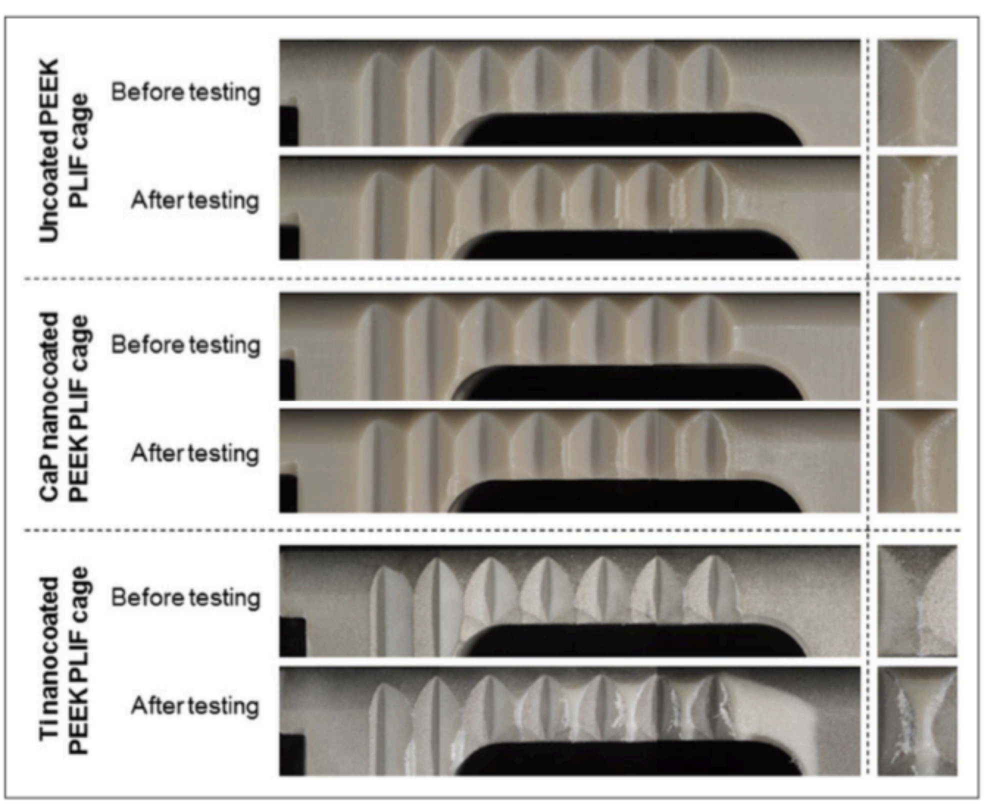
Analyzing safety and performance characteristics under simulated use

Almost all commonly used coating materials and technologies suffer from debris, delimitation and abrasion. Below, we try to summarize the achieved test results during simulated use of different test implants which are modified with different surface functionalization technologies and materials. 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.

TITANIUM / CAP NANOCOATINGS

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 (cage) control-group was uncoated. Six samples were tested in each of the groups. The experimental setup was designed to mimic cage impaction into the intervertebral disc space using polyurethane (PU) foam blocks as vertebral body substitutes. The cage surface was inspected before and after impaction, and their respected weight measured. [1]

Picture 3: Representative macro photos of the cage surfaces before and after impaction. Abrasion of the tip of the ridges (see close-up photograph on the right-hand side) 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. [1]



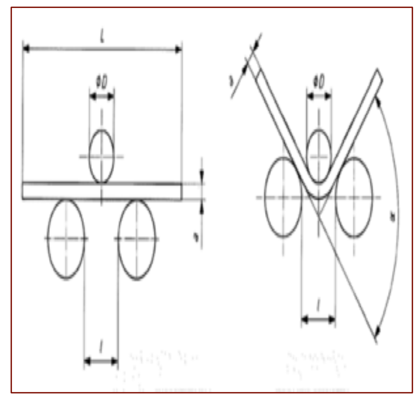
Sample no.	#1	#2	#3	#4	#5	#6	mean	SD
Uncoated PLIF cage	−0.28	−0.35	−0.38	−0.50	−0.54	−0.31	**−0.39**	0.10
CaP nanocoated PLIF cage	−0.37	−0.68	−0.52	−0.67	−0.62	−0.57	**−0.57**	0.12
Ti nanocoated PLIF cage	−0.86	−0.82	−0.62	−0.73	−0.63	−0.86	**−0.75**	0.11

Picture 4: Weight loss due to impaction in mg for each single cage (#1 to #6) with mean value and standard deviation (SD). [1]

PLASMA / THERMAL SPRAY COATINGS USING TI / HA / CAP

The weight loss of standard plasma spray coated cages is significantly higher compared to that of the nanocoated cages. There may be various reasons for this. First, a thicker coating can lose more material. Also, bonding strength between the different types of coating may also differ, as can be mentioned, there are also differences in surface roughness. [1]

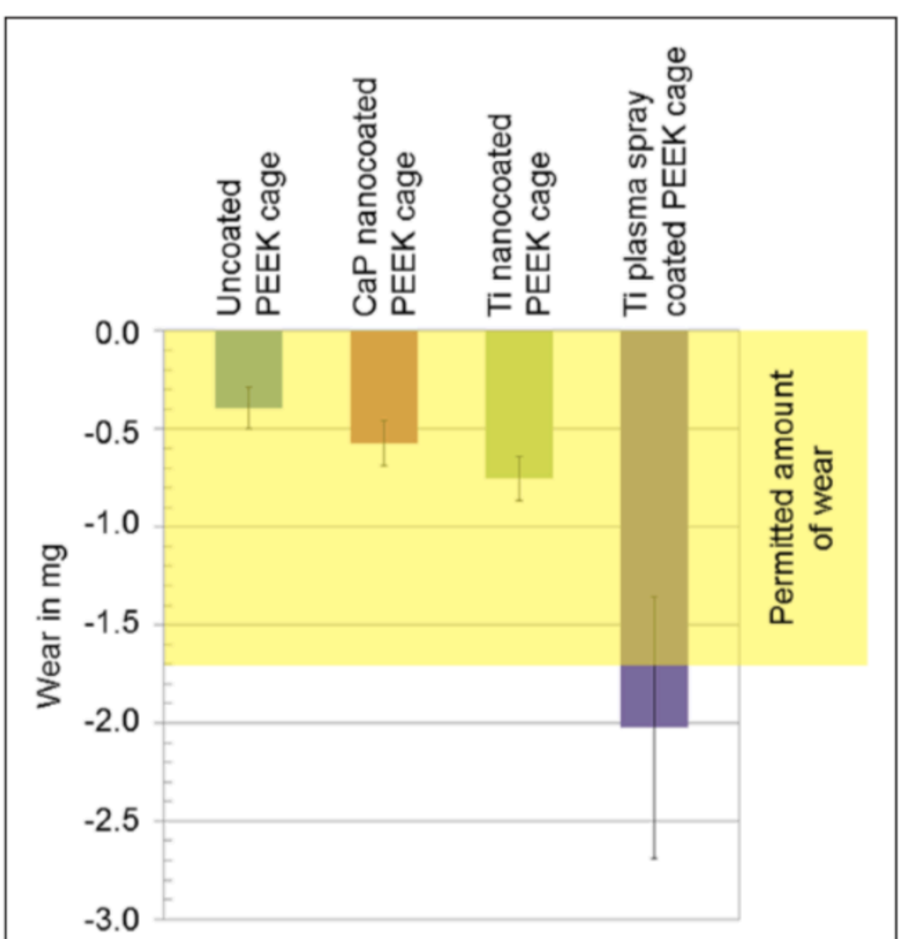
Picture 5,6: EN ISO 7438 TESTING of PLASMA SPRAY COATINGS. In-house research.



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.

Furthermore, according to EN ISO 7438, appropriate tests were performed to evaluate adhesion and elongation of the coatings under bending-tension. In order to do this, PEEK samples, with dimensions of 100 mm / 20 mm / 4 mm had been coated. During the test, the test samples showed cracks and began delimitation, a strong indication for abrasion and wear debris, something that may cause post-operatively problems for the patient.

However, 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.



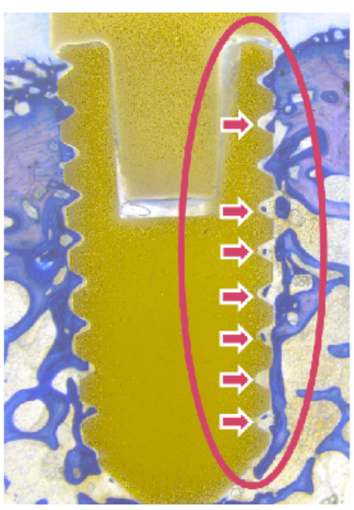
Picture 7. Mean wear of all tested specimens with standard deviation. The yellow area represents the permitted amount of weight loss (assigned to the implant surface, which was in contact to the vertebral body substitutes) derived from FDA Guidance Document 946. [1]

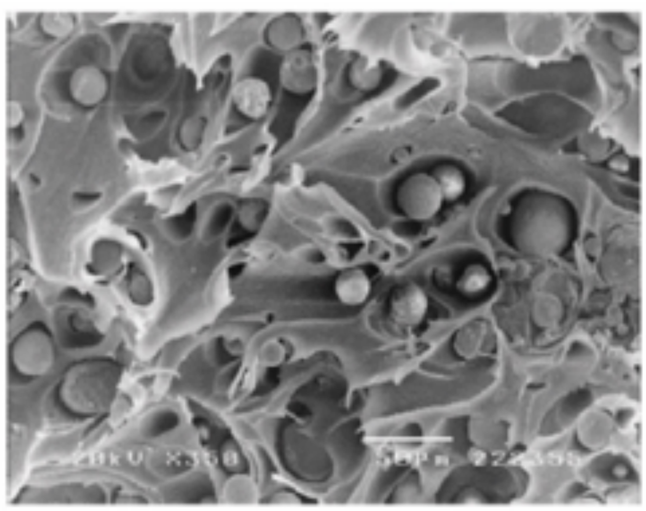
Safety and performance risks associated with PEEK composites: HA enhanced PEEK

Both in vitro and in vivo studies have shown encouraging results regarding the bioactivity of HA enhanced PEEK, however reports pertaining mechanical characterization are diverse, addressing different disadvantages with respect to clinical applications. Loading PEEK with HA particles resulted in an increase of tensile modulus and microhardness, but a decrease of the tensile strength and strain to fracture.[2,3]

Histological analysis of HA enhanced PEEK implants show that bone cells do not grow homogeneously to the implant's surface. These findings may indicate uneven distribution of HA in the PEEK matrix. SEM micrograph of a PEEK-HA composite fracture area, demonstraTE a debonding of HA particles from the PEEK matrix.

Picture 8 (left): Histological analyzes of HA enhanced PEEK implants. In-house research.
Picture 9 (right): SEM micrograph of a PEEK-HA composite fracture area. Reprinted from [3] with permission from Elsevier. Scale bar 50 µm





However, in contrast to carbon and glass fiber additives, HA, in particular, 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 (Figure 7). Thus, these PEEK-HA composites show promising perspectives as bioactive implants but may involve a trade off in load-carrying capacity relative to pure PEEK.[3] The limited load-carrying capacity of HA-enhanced PEEK material, the development of implants, e.g. spine fusion implants are limited in design freedom when using this particular material. Evidence below, where the picture shows HA enhanced PEEK test implants which couldn't withstand the applied ASTM testing.

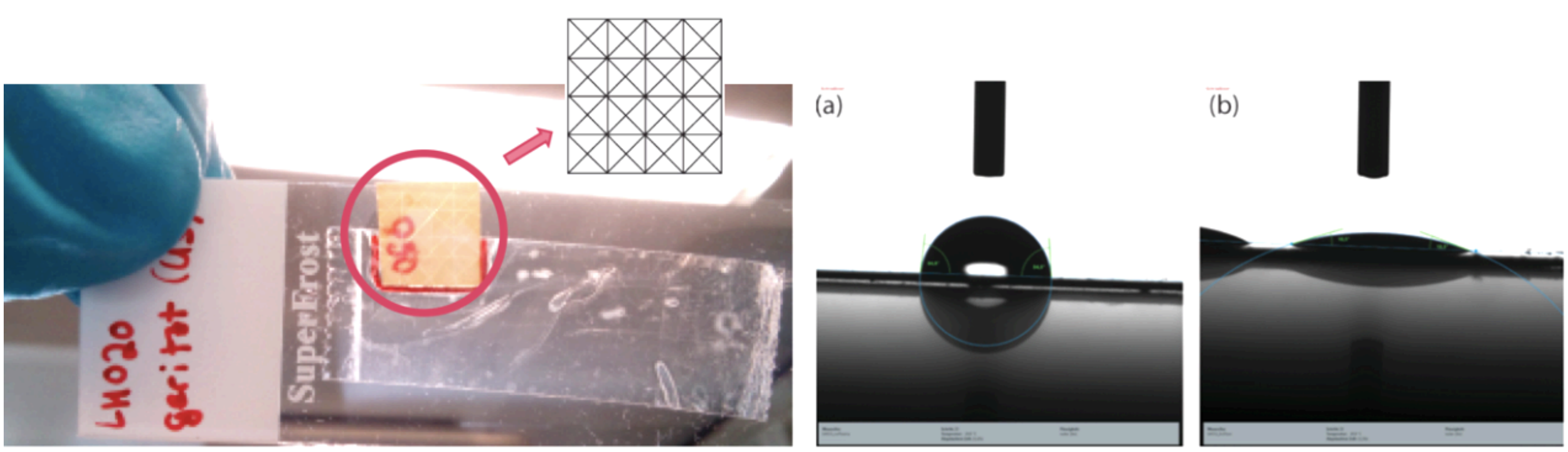
Picture 10: Failed ASTM testing of HA enhanced PEEK implants. In-house research.

stimOS MBT: Bio-chemically covalent bonded surface functionalization technology

Implant loosening and inflammatory reactions due to inert implant materials is a well-known and documented problem, for a long time. To date, this problem hasn’t been appropriately addressed. The idea of many industry-competitors is, to simply apply a coating on the implant surface and consider it innovative within a me-2 driven implant segment. Unfortunately, solutions like this are problematic: The coating process often damages the implant material and serious problems with regard to abrasion and delamination may occur.

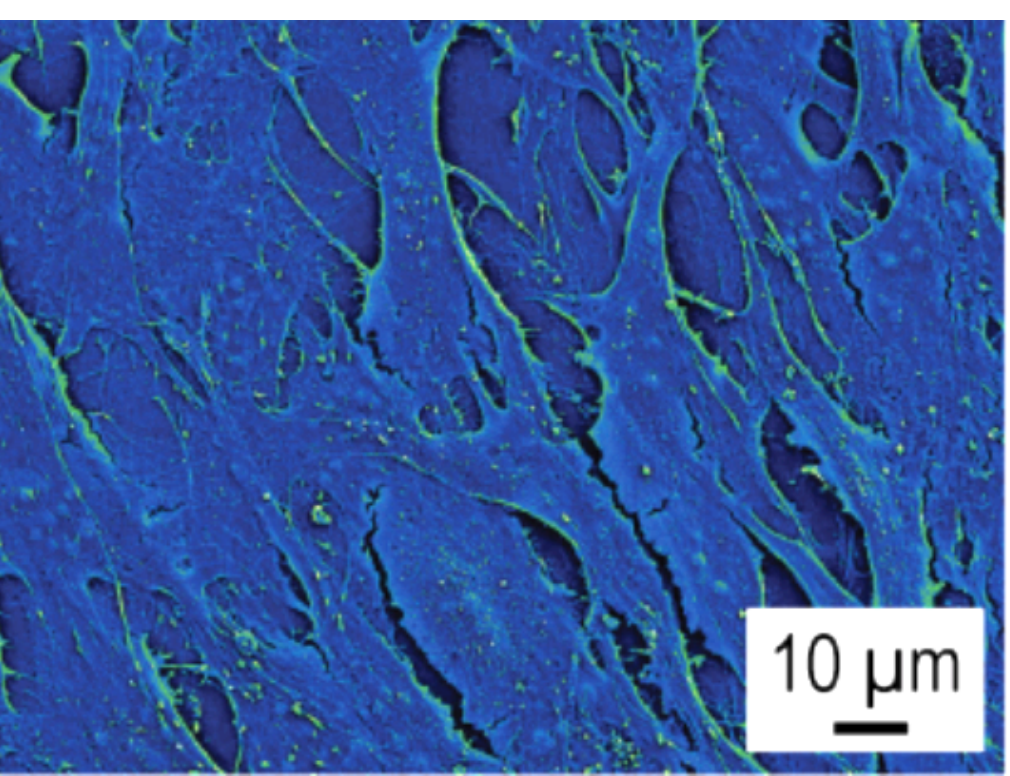
With stimOS signature MBT, stimOS offers the surgeon and his patients a completely new and innovative solution. Not relying on coating technologies, stimOS restructures the implant materials biochemically by way of a covalently bound activation layer.

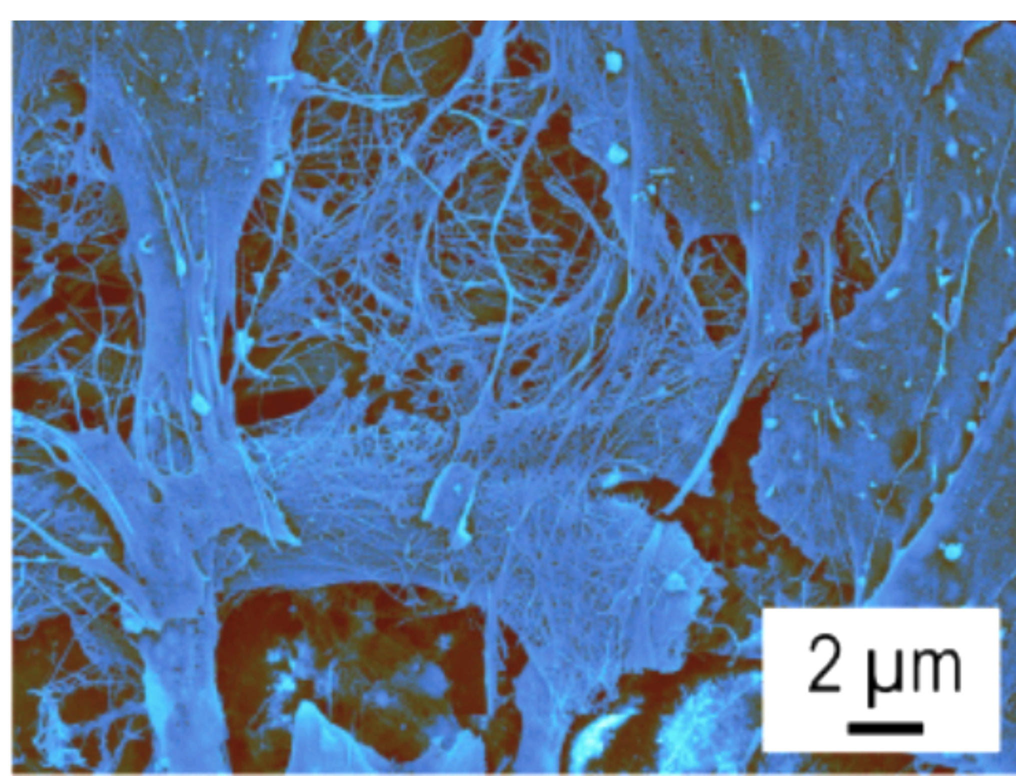
Doing this, stimOS gives inert materials biological features as close to nature as today possible. With MBT, a evolutionary material with unique characteristics was created, made to support early bone formation and proper anchorage, best described as cell-attractive and anti-inflammatory. Due to the wettability of PEEK (a) and MBT PEEK (b) being very different, a drop test in combination with ASTM D3359 was most suitable to confirm adhesion of MBT to the implant‘s surface: During the ASTM D3359 testing the wetability of MBT surfaces show consistent angulations.



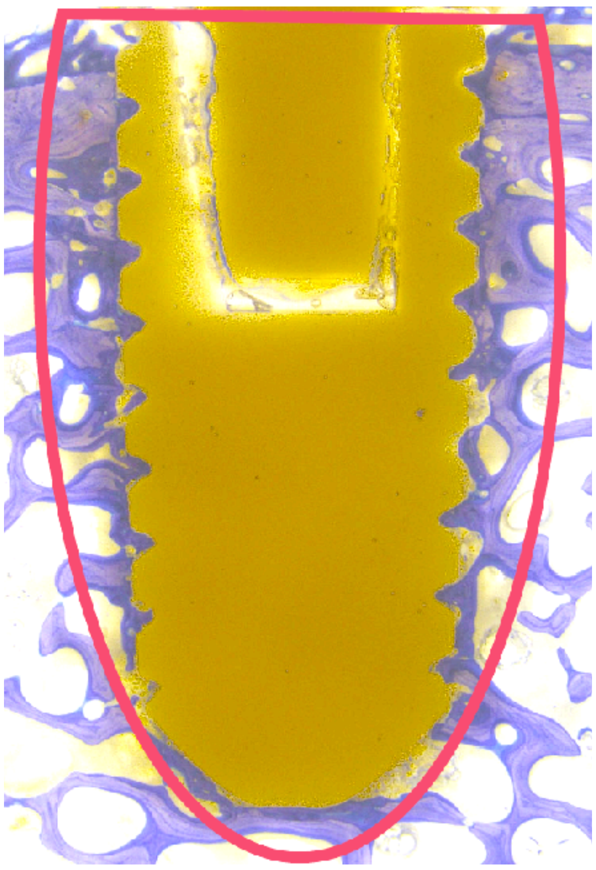
Picture 11: ASTM D 3359 in combination with drop test measurement proves stable adhesion of MBT to the surface. In-house research.

Pictures 12,13: SEM micrographs displaying cell spreading of osteoblasts on PEEK-MBT respectively after 24 h of cell incubation. Images are displayed in false colors for better visualization. In-house research.





The stimOS developed MBT surface functionalitzation technology shows a covalently bonded 3D continuous biomimetic surface layer for inert implant materials using a cost-effective chemical approach. Its nano-layer exhibits an excellent combination of surface free energy and mechanical stability but most importantly, the combination of PEEK and MBT (PEEK-MBT) shows a high cytotolerance for bone constitution and ingrowth relevant cell lines.



Picture 14: Homogenous BIC on MBT implants. In-house research.

When testing for their growth behaviour, the cells display superior attachment, proliferation and differentiation on mineralized MBT-PEEK. The observed collagen deposition begin marking, within 24h, early bone formation and shows that this implant functionalization actively promotes bone formation and connection to the existing bone tissue.

After a short period of 8 weeks in-vivo, PEEK-MBT implants show significantly higher bone implant contact (BIC) than both, titanium, as the gold standard, and a HA-filled PEEK material, which is advertised as being particularly osseointegrative.

The successful combination of PEEK's desirable mechanical properties with MBT's bone-mimetic, osseointegrative surface structures constitutes a unsurpassed implant material and paves the way for the preparation of biomimetic implants for long-term use. We further collected evidence that the osseointegration of conventional implant materials, like titanium, can be enhanced as well using this bioinspired MBT coating.

From a clinical perspective, the most important question is whether abrasion has associated risks and possible complications for the patient. In general, where coating has wears off, it can no longer improve osseointegration. Furthermore, there is evidence of inflammatory reactions caused by Ti wear particles. Local, mild, or medium inflammatory reactions have been reported in various animal and clinical studies [4,5,6]. Inflammation seems to be associated with local osteolysis, bone resorption, implant loosening, and pseudarthrosis [4] and not only depends on the amount of particles but also on their size and shape [7].

However, more testing and studies need to be conducted as today it is still unknown what amount of wear, the human body is able to tolerate but it is dependent, for sure, on the chemical composition of the wear particles, their size, and shape. So in view of this lack of knowledge, it is recommended to keep wear to a minimum and to use a coating that strongly adheres to the substrate, as resistant to abrasion as possible [8].

Only then shall the implant preserve its biological function and prevent inflammatory reactions to abraded material.

Our Mission statement at stimOS is to give both physicians and their respected patients the best treatment options possible and to ensure a life free of Post-operative pain and complications.

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You need no coating, all you need is MBT.

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