Press Review JANUARY – DECEMBER 2021

GOLDEN STANDARD TECHNOLOGIES

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February	April	June	August	October	December

stimOS GmbH MEDTECH OUTLOOK TOP 10 ORTHOPEDIC SOLUTION PROVIDERS IN EUROPE - 2021

JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC

With this highly recognized publication stimOS demands for a voluntary quality seal and starts its transparency offensive related to safety and performance features of stimOS patented MBT (Mimicking Bone Technology).

DOWNLOAD THE COMPLETE PUBLICATION HERE:
https://onlinelibrary.wiley.com/doi/abs/10.1002/pi.6162

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Perspective

Received: 17 October 2020 Revised: 2 December 2020 Accepted article published: 10 December 2020 Published online in Wiley Online Library: 30 December 2020

(wileyonlinelibrary.com) DOI 10.1002/pi.6162

Polyetheretherketone implant surface functionalization technologies and the need for a transparent quality evaluation system

Dietmar Schaffarczyk,[a,b*] Jennifer Knaus,[b] Gunther Peeters,[b] Dieter Scholl,[a] Andreas Schwitalla,[c] Christoph Koslowski[d] and Helmut Cölfen[e*]

Abstract

For bone implants, osseointegration resulting in a good and fast bone–implant contact is of primary importance to secure a proper implant function and to avoid implant loosening or inflammation resulting in necessary revision surgeries causing pain to the patients and immense costs. In particular, polyetheretherketone (PEEK) is a promising implant material due to the close mechanical properties to bone, but it is entirely bio-inert, hindering osseointegration and making surface functionalization necessary. Many different surface functionalization technologies have been reported of both physical and chemical nature. The same is true for the other prominent implant materials titanium and ceramics. Although they already have inherently better osseointegration than PEEK, they are much harder and stiffer than bone and brittle in the case of ceramics. Surface functionalization, which can be subdivided into surface coating and material modification, needs to be judged from a quality and safety viewpoint. However, a literature research resulted in the realization that no quality standard yet exists for implant surface functionalizations. This makes it difficult to near impossible to compare the safety and performance of different surface-functionalized bone implants, clearly showing the need to establish a transparent quality evaluation system for bone implants. This perspective article gives the state of the art and then develops a quality evaluation system based on six main categories as important benchmarks for the quality of surface-functionalized bone implant materials. A simple catalog of questions can be answered, and from the resulting scores the Safety and Performance Evidence Level (SPEL) representing the safety and quality of a given implant can be calculated as a percentage. This simple SPEL system allows an easy and transparent judgment and comparison of bone implants, ensuring the easy identification of safe and well-performing high-quality bone implants in the future.
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Keywords: bone implant; polyetheretherketone (PEEK); surface functionalization; quality evaluation; safety and performance evidence level (SPEL)

INTRODUCTION

Surgeons and patients, as well as medical device manufacturers, are frequently confronted with postoperative implant failures due to implant loosening or inflammatory reactions. These complications are often the reason for pain after surgery and lead to revision surgeries resulting in increased healthcare costs. These failures are not limited to certain indications or surgical techniques: they occur in all applications where implants must be placed in the patient's body. Reasons for failed surgeries can be (i) the implant materials available do not have the best biological performance due to their material characteristics; (ii) the surrounding bone – where the surgeon has to place the implant – is not stable or dense enough due to the patient's age and/or osteoporotic skeletal bones; or (iii) the surgeon is not adequately trained or educated. The table below (Table 1) decribes the most important abbreviations, terms and definitions used in the publication.

Implant materials that are approved for their use in humans can be roughly divided into three material categories: metals,

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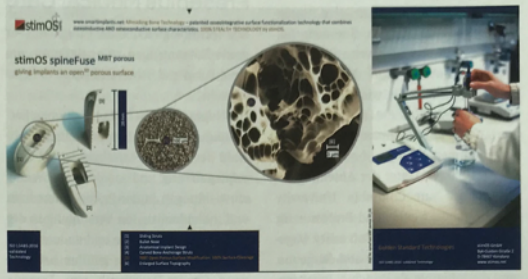
DEUTSCHE KRANKENHAUS GESELLSCHAFT

Markt

Unternehmens-/Marktentwicklung

Deutsches Medizintechnik-Start-up stimOS setzt neue Maßstäbe bei Implantatoberflächen und Beschichtungstechnologien



stimOS GmbH, ein Start-up aus Baden-Württemberg, das sich auf die Entwicklung knochenähnlicher Implanatmaterialien spezialisiert hat, wird in Kürze mit seiner patentierten, innovativen Mimicking-Bone-Technologie (MBT), neue Maßstäbe in Sachen Oberflächentopographie und Beschichtungstechnologie setzen.

Mit der finanziellen Unterstützung des High-Tech Gründerfonds (HTGF), der MBG Baden-Württemberg und der WEFA Inotec GMBH entwickelte und erprobte stimOS ihre patentierte Mimicking Bone Technology (MBT). MBT ist ein einzigartiges biochemisches Verfahren, das nach erfolgter Implantation frühes Knochenwachstum initiiert und dadurch Implantate im gesunden wie auch im osteoporotischen Knochen optimal verankert und einheilen lässt. Darüber hat die Technologie entzündungshemmende Eigenschaften.

Die kovalent gebundene, komplett biomimetische 3D-Oberflächenschicht wurde von stimOS auch für inerte Implantatmaterialien wie PEEK entwickelt: Mit MBT „wachsen" auf der Implanatoberfläche knochenähnliche Nanoschichten, die eine ausgezeichnete Kombination aus freier Oberflächenenergie und mechanischer Stabilität aufweisen. Am wichtigsten ist jedoch, dass das so kombinierte MBT-Implantat hohe Zytotoleranz für optimale Knocheneigenschaften und für das Einwachsen von Knochenzellen aufweist. MBT ist (a) biokompatibel, (b) vermeidet Infektionen, (c) bewahrt den gesunden Knochen, (d) stimuliert die Knochenneubildung und führt zu einem (e) insgesamt hohen BIC (Knochen-Implantat-Kontakt).

stimOS MBT verleiht auch inerten Materialien biologische Merkmale, wie sie nur die Natur hervorbringt.

„MBT ist keine herkömmliche Beschichtungstechnologie, sondern restrukturiert Implantatmaterialien biochemisch durch eine kovalent gebundene Aktivierungsschicht", erklärt Dr. Jennifer Knaus, Laborleiterin bei stimOS.

„Wir alle kennen seit Langem die Probleme mit Implantatlockerungen und Entzündungsreaktionen durch inerte Implantatmaterialien. MBT wird dieses Problem erfolgreich lösen. Unsere Marke stimOS MBT wird sowohl Ärzten als auch Patienten völlig neue und innovative Lösungen bieten", sagt Gründungsmitglied und CEO Dr. Dietmar Schaffarczyk.

Jedes Implantatmaterial kann mit MBT veredelt werden. „Es entstehen dadurch keine höheren Zulassungsanforderungen oder -kosten" erklärt Schaffarczyk, der auch Lead Auditor für Medizinprodukte (Diplom SAQ /EOQ) ist.

Diese Erklärung ergänzt Priv. Doz. Dr. Andreas Schwitalla von der Charité – Universität für Medizin Berlin: „MBT hat das Potenzial, neue Standards bei Implantatbeschichtungen zu setzen". Die Charité, Abteilung für zahnärztliche Material- und Biomaterialforschung, Berlin, hat zusammen mit der Universität Zürich die stimOS-Implantate einem Belastungstest unterzogen und ist von den erzielten Ergebnissen überzeugt. Die vergleichenden Tierstudien wurden von der Universität Zürich und der Charité Berlin durchgeführt.

Weitere Informationen unter:
www.smartimplants.net oder
www.stimos.net ■

About **German Hospital Federation**

DEUTSCHE KRANKENHAUS GESELLSCHAFT

The German Hospital Federation (**DKG – Deutsche Krankenhausgesellschaft e.V.**) is the representative organ of all German hospitals. It bundles and advocates their interests regardless of the kind of ownership. Public, private for profit and private not for profit or charity based hospital owners are unionised in the **DKG** via its member organisations: 16 associations on the Federal States level (Bundesländer) are providing special services to the hospitals in their region, e.g. negotiating hospital plans and prices. The other type of members are the twelve national associations, dedicated to each type of ownership who bundle the special interests of their hospitals. On this broad basis, DKG represents the whole range of interests of the providers of hospital care.

stimOS GmbH | MEDTECH OUTLOOK TOP 10 ORTHOPEDIC SOLUTION PROVIDERS IN EUROPE - 2021

German Hospital Federation realizes a New Golden Standard in stimOS MBT (Mimicking Bone Technology).

P.M. by Gruner & Jahr, with a reach of ONE million readers and 150,667 copies sold, introduces stimOS' Mimicking Bone technology to its scientifically interested readership.

Muss ich die kennen?

JENNIFER KNAUS, BIOCHEMIKERIN

WER IST DAS?
Jennifer Knaus ist Laborleiterin bei StimOS, einem Start-up, das Beschichtungen für Implantate entwickelt.

WAS MACHT SIE?
Sie forscht an Hochleistungsmaterialien nach dem Vorbild der Natur, die aus Mineralien und Proteinen bestehen.

WAS BILDET SIE NACH?
Sie hat unter anderem Materialien aus Hydroxylapatit und Gelatine entwickelt, die in Aufbau und Zusammensetzung unserer Knochensubstanz ähneln.

WEM BRINGT DAS WAS?
Allen Menschen, die Implantate brauchen. Die sind meist aus Titan; ihr Abrieb kann Beschwerden verursachen. Besser ist der Medizinkunststoff PEEK, doch der wächst schlecht in den Knochen ein. Eine dünne Beschichtung aus Knaus' Material ändert das: Sie gaukelt dem Körper vor, das Implantat sei ebenfalls ein Stück Knochen.

WIE GEHT ES WEITER?
Im Frühjahr werden die beschichteten Implantate erstmals klinisch getestet, an Patienten mit Wirbelsäulenschäden. In fernerer Zukunft könnten künstliche Zähne und Knochen nicht nur mit Mineral-Protein-Mischungen beschichtet, sondern vollständig daraus gefertigt werden (siehe auch Seite 70).

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DeviceMed

Das Community-Portal

Start Szene Konstruktion Fertigung Management Regulatory Affairs E-Health Forschung Services Seminare

JEC WORLD 2022 The Leading International Composites Show

March 8-10, 2022 | PARIS-NORD VILLEPINTE

Konstruktion › Material für ein Knochenimplantat

Medizintechnik-Patent der Woche

Material für ein Knochenimplantat

15.02.2021 | Redakteur: Julia Engelke

Heute: Material für ein Knochenimplantat. Die Medizintechnik-Industrie ist führend bei der Anmeldung von Patenten. Aus der Fülle an Einreichungen beim Deutschen Patent- und Markenamt wählt die Devicemed-Redaktion wöchentlich ihr Patent der Woche.

Material für ein Knochenimplantat.
(Bild: DPMA)

Die Erfindung geht aus von einem Material (10, 10a) für ein Knochenimplantat (12, 12a) umfassend: (a) eine Oberfläche (14), umfassend ein Material (16), ausgewählt aus der Gruppe bestehend aus metallbasierten Materialien, Metalllegierungen, oxidischen Keramikmaterialien, Polymermaterialien, Kompositmaterialien oder Kombinationen davon, (b) eine kovalent an diese Oberfläche (14) gebundene organisch polymere Matrix (18, 18a), (c) eine an diese organisch polymere Matrix (18, 18a) angebundene oder eingelagerte Metallionen oder Nanopartikel bindende Substanz (20) und (d) in diese organisch polymere Matrix (18, 18a) eingelagertes Calciumphosphat (22). Mit einer solchen Ausgestaltung kann erreicht werden, dass das Material(10, 10a) für ein Knochenimplantat (12, 12a) biokompatible ist und mit der Korrosion verlangsamt oder gar verhindert werden kann.

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MEDTECH OUTLOOK TOP 10 ORTHOPEDIC SOLUTION PROVIDERS IN EUROPE - 2021

DeviceMed, the Medtech Community Portal, honours stimOS technology with the prestigious >>Patent of the Week<< award.

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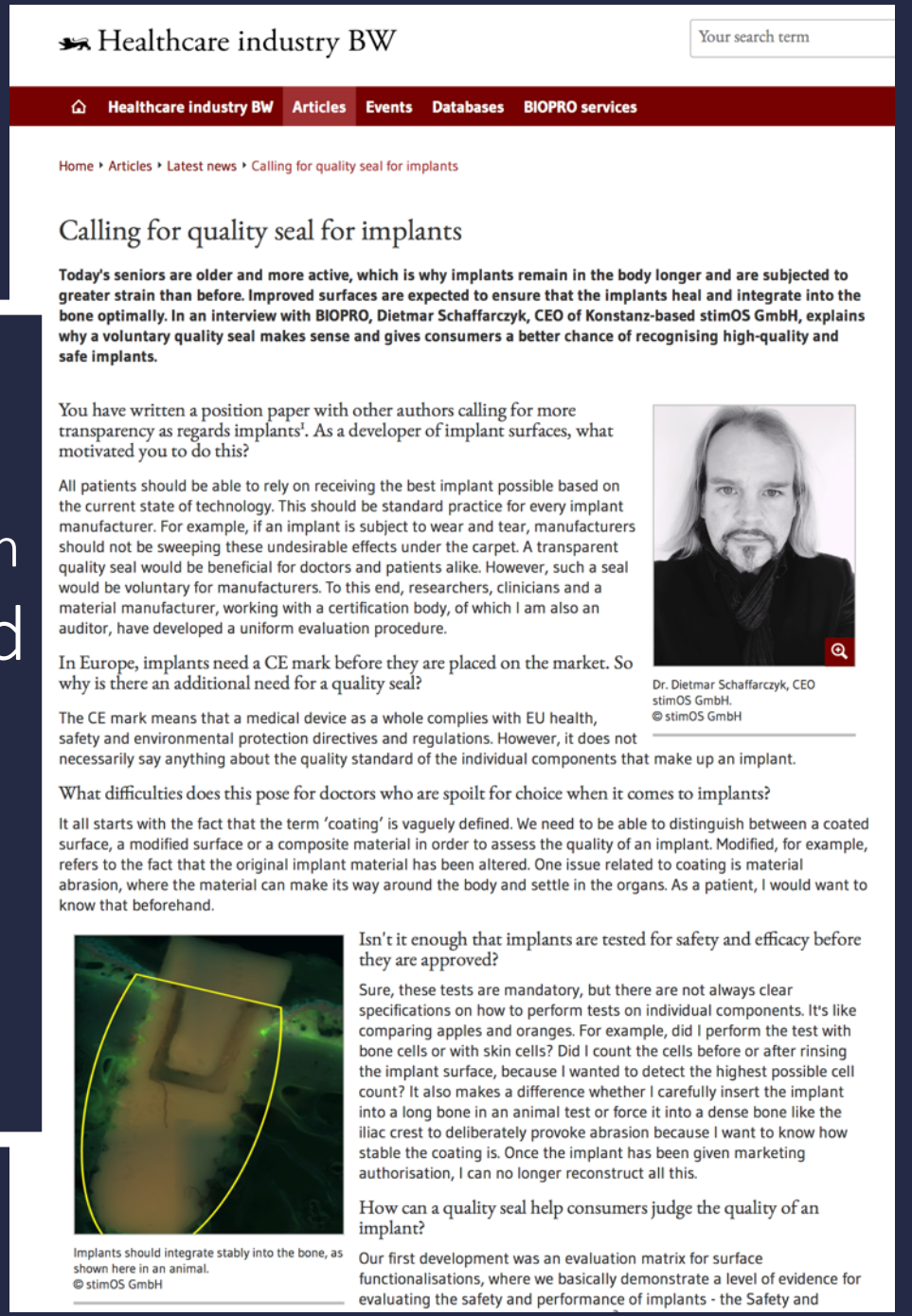
The official online portal Healthcare Industry Baden-Württemberg promotes S.P.E.L. the voluntary quality seal for implant surface functionalization technologies. stimOS' MBT is additionally certified according this safety and performance quality standard.

DOWNLOAD THE COMPLETE PUBLICATION HERE:
https://www.gesundheitsindustrie-bw.de/en/article/news/calling-quality-seal-implants



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Home ▸ Articles ▸ Latest news ▸ Calling for quality seal for implants

Calling for quality seal for implants

Today's seniors are older and more active, which is why implants remain in the body longer and are subjected to greater strain than before. Improved surfaces are expected to ensure that the implants heal and integrate into the bone optimally. In an interview with BIOPRO, Dietmar Schaffarczyk, CEO of Konstanz-based stimOS GmbH, explains why a voluntary quality seal makes sense and gives consumers a better chance of recognising high-quality and safe implants.

You have written a position paper with other authors calling for more transparency as regards implants[1]. As a developer of implant surfaces, what motivated you to do this?

All patients should be able to rely on receiving the best implant possible based on the current state of technology. This should be standard practice for every implant manufacturer. For example, if an implant is subject to wear and tear, manufacturers should not be sweeping these undesirable effects under the carpet. A transparent quality seal would be beneficial for doctors and patients alike. However, such a seal would be voluntary for manufacturers. To this end, researchers, clinicians and a material manufacturer, working with a certification body, of which I am also an auditor, have developed a uniform evaluation procedure.

Dr. Dietmar Schaffarczyk, CEO stimOS GmbH.
© stimOS GmbH

In Europe, implants need a CE mark before they are placed on the market. So why is there an additional need for a quality seal?

The CE mark means that a medical device as a whole complies with EU health, safety and environmental protection directives and regulations. However, it does not necessarily say anything about the quality standard of the individual components that make up an implant.

What difficulties does this pose for doctors who are spoilt for choice when it comes to implants?

It all starts with the fact that the term 'coating' is vaguely defined. We need to be able to distinguish between a coated surface, a modified surface or a composite material in order to assess the quality of an implant. Modified, for example, refers to the fact that the original implant material has been altered. One issue related to coating is material abrasion, where the material can make its way around the body and settle in the organs. As a patient, I would want to know that beforehand.

Implants should integrate stably into the bone, as shown here in an animal.
© stimOS GmbH

Isn't it enough that implants are tested for safety and efficacy before they are approved?

Sure, these tests are mandatory, but there are not always clear specifications on how to perform tests on individual components. It's like comparing apples and oranges. For example, did I perform the test with bone cells or with skin cells? Did I count the cells before or after rinsing the implant surface, because I wanted to detect the highest possible cell count? It also makes a difference whether I carefully insert the implant into a long bone in an animal test or force it into a dense bone like the iliac crest to deliberately provoke abrasion because I want to know how stable the coating is. Once the implant has been given marketing authorisation, I can no longer reconstruct all this.

How can a quality seal help consumers judge the quality of an implant?

Our first development was an evaluation matrix for surface functionalisations, where we basically demonstrate a level of evidence for evaluating the safety and performance of implants - the Safety and

Special Print of MedDEV Quaterly: S.P.E.L. is introduced to a broad community of readers.

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stimOS is co-founder and co-initiator of AG PolyMORE expert panel.

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AG PolyMORE

Intelligent solutions in medical technology:

AG PolyMORE - Consortium and expert panel founded

Berlin, Constance, Zurich - 2021-09-07. **The advances made in healthcare over the last decade in manufacturing, optimization and delivery of medical products within a shortened supply chain bring both benefits for patients and further challenges for manufacturers and users of these types of products. In recent years, the high-performance polymer polyetheretherketone (PEEK) has become increasingly popular in medical applications due to its good mechanical properties, making it an excellent alternative to metallic materials for load-bearing applications.**

The healthcare industry is undergoing a profound transformation: one of the key enablers of this transformation is the proliferation of point-of-care (POC) technologies that can improve clinical outcomes and reduce costs through better access. POC technologies have the potential to improve the management and treatment of various diseases and conditions, especially in resource-limited settings where healthcare infrastructure is weak and access to quality and timely care is challenging.

Polymers versus Metals

While personalized or functionalized implants or medical devices made from metals have been reentering the market for years and in some cases define the golden standard in orthopedic applications, polymer materials are hardly used in this field.

PEEK products with sophisticated shapes and controlled architecture can currently be manufactured using various 3D printing technologies. However, the mechanical properties, surface functionalities, and biocompatibility of 3D-printed PEEK and its composites are still unclear and partly only explored in an academic-experimental set-up.

Therefore, representatives from industry and academia have now joined forces to make the use of polymers in personalized medical technology available to users - surgeons and orthopedic surgeons from a wide range of disciplines - in a way that is (a) industrially scalable, (b) fundable by patients and insurance companies and (c) certifiable by regulators: *"Together we are planning a consortium of highly specialized polymer experts. Our goal is to reach and integrate in this project as many researchers and experts as possible, from industry, academia, and the authorities. This is exactly the right time to discuss smart polymers, smart manufacturing methods and smart regulatory strategies"*, explains Dietmar Schaffarczyk [A1, I3], Expert for Regulatory Strategies and Surface Functionalization.

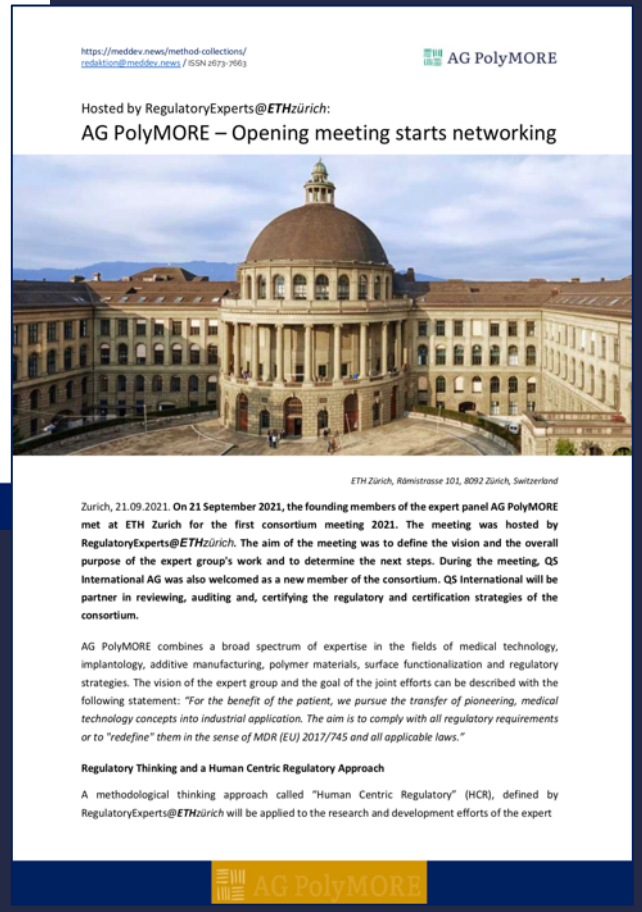
AG PolyMORE

AG PolyMORE academic partners:

***ETH**zürich*

Charité Universitätsmedizin Berlin

Carinthia University of Applied Sciences



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AG PolyMORE

Hosted by RegulatoryExperts@***ETH**zürich*:

AG PolyMORE – Opening meeting starts networking

ETH Zürich, Rämistrasse 101, 8092 Zürich, Switzerland

Zurich, 21.09.2021. **On 21 September 2021, the founding members of the expert panel AG PolyMORE met at ETH Zurich for the first consortium meeting 2021. The meeting was hosted by RegulatoryExperts@*ETH**zürich*. The aim of the meeting was to define the vision and the overall purpose of the expert group's work and to determine the next steps. During the meeting, QS International AG was also welcomed as a new member of the consortium. QS International will be partner in reviewing, auditing and, certifying the regulatory and certification strategies of the consortium.**

AG PolyMORE combines a broad spectrum of expertise in the fields of medical technology, implantology, additive manufacturing, polymer materials, surface functionalization and regulatory strategies. The vision of the expert group and the goal of the joint efforts can be described with the following statement: *"For the benefit of the patient, we pursue the transfer of pioneering, medical technology concepts into industrial application. The aim is to comply with all regulatory requirements or to "redefine" them in the sense of MDR (EU) 2017/745 and all applicable laws."*

Regulatory Thinking and a Human Centric Regulatory Approach

A methodological thinking approach called "Human Centric Regulatory" (HCR), defined by RegulatoryExperts@***ETH**zürich* will be applied to the research and development efforts of the expert

AG PolyMORE

stimOS GmbH: Intelligente Lösungen in der Medizintechnik

15.09.2021

D-Konstanz | Konsortium und Expertengremium zum Einsatz von Polymeren in der personalisierten Medizintechnik gegründet

Vertreter aus Industrie und Wissenschaft haben sich zusammengeschlossen, um den Einsatz von Polymeren in der personalisierten Medizintechnik für die Anwender – Chirurgen und Orthopäden unterschiedlichster Fachrichtungen – industriell skalierbar, von Patienten und Krankenkassen finanzierbar und von den Aufsichtsbehörden zertifizierbar zu machen: „Gemeinsam planen wir ein Konsortium aus hochspezialisierten Polymerexperten. Unser Ziel ist es, möglichst viele Forscher und Experten aus Industrie, Wissenschaft und Behörden zu erreichen und in dieses Projekt einzubinden. Dies ist genau der richtige Zeitpunkt, um über intelligente Polymere, intelligente Herstellungsverfahren und intelligente Regulierungsstrategien zu diskutieren“, erklärt Dietmar Schaffarczyk, Experte für Regulierungsstrategien und Oberflächenfunktionalisierung.
Zur Pressemeldung: HIER

(Quelle: Pressemeldung AG PolyMORE, 07.09.2021)

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Intelligent Medtech Solutions: BioLAGO promotes AG PolyMORE.

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MBT avoids inflammatory reactions and promotes osseointegration: stimOS presents its revolutionary results during Global Spine Congress 2021, hosted by AO Foundation.

On the future design of bio-inspired PEEK spinal implants: Giving implants a bony surface avoids inflammatory reactions and postoperative complications

Global Spine Congress 2021

Schaffarczyk, D.[(a)*] | CEO | stimOS GmbH Arts, M.[(b)] | MD | Haaglanden Medisch Centrum Schwitalla, A.[(c)] | PD, MD | Charité-University Medicine Berlin

INTRODUCTION

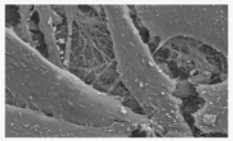
Surgeons, patients and medical device manufacturers are frequently confronted with post-operative implant failures due to implant loosening or inflammatory reactions. These complications occur in all applications where implants must be placed in the patient's body.

To enhance the biological performance of implants, they are often coated with Titanium (Ti). But the high risk for patients with these kind of composites are abrasion and delamination of Ti-nanoparticels, as Ti and TiO_2 is suspected to be toxic and carcinogenic.

In the case of medical implants and prostheses – such as spinal fusion implants or artificial discs – wear debris and ions release produced due to the loss of material by bio-tribocorrosion of implant surfaces have been related to tissue inflammatory reactions.[1,2,3]

MATERIALS & METHODS

To avoid risks for the patients associated with the use of Titanium or Titanium composites the authors have analysed a new surface modification technique called Mimicking Bone Technology (MBT), invented to add best osseointegrative characteristics to pure PEEK surfaces.



PEEK-MBT:Secretion of a large amount of extra-cellular collagen matrix after already 12 hours.

36 test-implants are placed in the iliac crest of 3 female Swiss Alpine (AS) sheep.

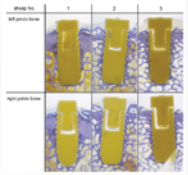
RESULTS

MBT surface modifications are process-validated technologies. The technology has been subject of statistically significant comparative in-vitro cell tests performed by the faculty of biology, University Constance, showing superior results regarding cell adhesion, cell viability and cell proliferation compared to PEEK, Titanium and HA-enhanced PEEK materials. PEEK-MBT surface turned out to be the most suitable candidate for healing into the bone tissue among all tested materials due to high osteoblast proliferation and cell adhesion, and due to the most intensive formation of mineralized bone nodules (follow up 12h / 24h).

To confirm the outstanding results achieved in in-vitro cell tests, a comparative animal model (PEEK, Titanium, HA-enhanced PEEK and PEEK-MBT) was conducted together with the University of Zurich (Team Prof. B. v. Rechenberg) and Charité-University Medicine Berlin to demonstrate that stimOS MBT implant surface modification has evolutionary unique characteristics designed to support early bone formation, proper implant anchorage, able to avoid inflammatory reactions and/or infections.

These statistical relevant results could also be demonstrated with the use of fluorescence pictures and histologic pictures. Fluorescence images are taken after two weeks of implantation. It could be clearly observed that bone in-growth into the threads only starts with MBT after this period in time. With MBT a high BIC % can be seen already after two weeks. This is a strong indication for avoiding aseptic loosening.

Analysing histologic longitudinal section 8 weeks post-op, only MBT test implants anchored completely in surrounding, healthy bone. Screw thread was fully filled: No fibrotic layer, giant cells or macrophages could be observed.

8-week results, in-vivo	Titanium	HA-enhanced PEEK	PEEK MBTg	Histology MBTg
BIC cancellous bone (%)	31,47	37,58	**74,12**	
BIC cortical bone (%)	40,72	49,79	**80,15**	
Fibrotic layer	0,63	0,41	**0,16**	
Macrophages	0,52	0,22	**0,1**	*Longitudinal sections of six MBTg-PEEK implants after 8 weeks in-vivo. Absence of foreign body giant cells (FBGC) could be observed.*
Lymphocytes	0,76	0,55	**0,15**	

CONCLUSIONS

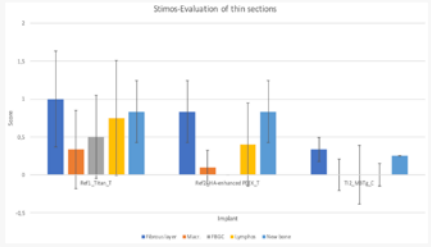
Intensive testing in vitro and in vivo demonstrated safety and performance of the biochemical implant surface PEEK-MBT. Test set up was chosen to compare MBT surfaces against Titanium and HA-enhanced PEEK. PEEK-MBT showed osseointegrative characteristics that are significant superior to PEEK, HA-enhanced PEEK and Titanium, known as the golden standard for orthopedic and dental implant materials. The animal model and in vitro cell tests demonstrated the overall biocompatibility of the new developed surface modification MBT:

Inflammatory reaction was strongest with titanium implants and weakest with MBTg. This is a strong indication that MBT avoids aseptic loosening.[4]

A connective tissue layer was found at all implants, strongest / thickest in titanium implants and weakest with MBT.

Bone deposition was most pronounced with MBT.

A high %rate of new bone is not appreciated; the goal is to preserve "Healthy Bone". This could be observed best with MBT. The overall BIC % was highest with MBTg.



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ACKNOWLEDGEMENTS

(a) developed the patented MBT implant surface modification. MBT is an ISO 13485:2016 validated technology. (c) received a grant from the Berlin Institute of Health to fund the animal study (TT-Fund MedDev 2017) and organized and conducted together with (a) the comparative setting in the sheep pelvic bone model. (b) evaluated the study results concerning their impact in spinal fusion surgery.

FURTHER INFORMATION

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Web: www.smartimplants.net

stimOS GmbH is founding member of AG PolyMORE

CONFLICTS OF INTEREST

(a) is managing partner at stimOS GmbH, the developing company & patent-holder of MBT.

LITERATURE CITED, cont.

[4] *Rechenberg, B. et al., An experimental animal model of aseptic loosening of hip prostheses in sheep to study early biochemical changes at the interface membrane, BMC Musculoskeletal Disorders 2004*

stimOS GmbH

AO SPINE

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Introduction: Back pain, which can be caused by degenerative disc disease (DDD), is a major cause of pain and disability worldwide and confers substantial socioeconomic ramifications. Currently, there is a dearth of evidence regarding the efficacy and safety of mesenchymal stem cells (MSCs) for the regeneration of the intervertebral disc (IVD). This review aims to critically appraise and narratively synthesise evidence from animal and human studies on the use of mesenchymal stem cells (MSCs) to treat degenerative disc disease (DDD). **Material and Methods:** A systematic search of PubMed, Embase, Science Direct and Cochrane Central Register of Controlled Trials databases as well as Clinical Trials.org, to January 2020, was carried out using predetermined search terms. Bibliographies of published narrative and systematic reviews were also screened to identify other relevant publications. The quality of eligible studies was assessed, and study characteristics and data were tabulated for analysis. **Results:** From 1680 potentially relevant citations, twenty studies met the inclusion criteria-sixteen studies focused on animal models and four studies involved human participants. 10/16 animal studies reported favourable radiological outcomes; this was based on either restoration of the disc height or enhanced MRI T2 signal intensity following MSC transplantation. All animal studies that incorporated histology (11/16) demonstrated improved histological outcomes. 10/16 animal studies reported positive molecular findings in terms of matrix restoration. Data across the four human studies suggested improvement in pain and function relative to baseline; however, a majority of changes were not deemed to be statistically significant. Safety data was sparse and poorly detailed with 19/20 studies reporting no adverse events relating to MSC transplantation. **Conclusion:** The overall strength of evidence for the efficacy and safety of MSCs for DDD was low due to inconsistencies in methodological design and outcome parameters, small sample sizes and lack of comparator interventions. The limited findings across animal and human studies continue to support the conjecture that MSCs have regenerative potential that can be safely utilised to treat degenerated discs. Robust animal models that can more closely replicate the human condition and high-quality comparative studies are now needed to assess whether MSCs can truly enhance the armaments at the disposal of the clinician in the treatment of DDD.

1605
P497: On the Future Design of Bio-Inspired PEEK Spinal Implants: Giving Spine Implants a Bony Surface Avoids Inflammatory Reactions and Postoperative Complications

Dietmar Schaffarczyk[1]

[1]*stimOS GmbH, Bio-Material Research, Konstanz, Germany*

Introduction: To enhance the biological performance of PEEK implants, these materials are mixed with HA or coated with Titanium. But the high risk for patients with these kinds of composites are abrasion and delamination of Ti-nanoparticels, as Ti and TiO_2 is suspected to be toxic and carcinogenic. In the case of medical implants– such as spinal fusion implants – wear debris and ions release produced due to the loss of material by bio-tribocorrosion of implant surfaces have been related to tissue inflammatory reactions. An association between ultrafine TiO_2 (<100 nm in diameter) particles and adverse biologic effects have been reported in the literature. **Material and Methods:** To avoid risks for the patients associated with the use of Titanium or Titanium composites the authors developed and analyzed a new surface modification technique called Mimicking Bone Technology (MBT) invented to add best osseointegrative characteristics to pure PEEK surfaces. The surface modification technique is not a coating technique but an bio-chemically covalently joined surface functionalization resulting in bone-identic, mineralized PEEK-MBT implant surfaces eliminating the risks of abrasion, wear debris and TiO_2 diffusion. To confirm the results achieved in-vitro, an animal model was conducted to demonstrate that MBT surface modification has unique characteristics designed to support early bone formation and proper implant anchorage. **Results:** MBT modifications are process-validated technologies. The technology has been subject of statistically significant comparative in-vitro cell tests showing superior results regarding cell adhesion, viability and proliferation compared to PEEK, Titanium and HA-enhanced PEEK materials. PEEK-MBT surface turned out to be the most suitable candidate for healing into the bone tissue among all tested materials due to high osteoblast proliferation and cell adhesion, and due to the most intensive formation of mineralized bone nodules (follow up 12h / 24h). In-vivo, PEEK-MBT demonstrated superiority in osseointegrative characteristics compared to Titanium and HA-enhanced PEEK: Bone in-growth into the implant-screw threads starts with MBT after a 2 week period in time. With MBT a high BIC % can be seen already after two weeks. This is a strong indication for avoiding aseptic loosening. Histologic examination shows:

1. Titanium: Dense new bone is only observed in the upper part of the implant. Screw thread is not filled homogenous with bone. No stable anchorage of implant in the surrounding bone.
2. HA enhanced PEEK: Bone is only observed on one side of the implant: Screw thread is not filled homogenous with bone. No stable anchorage of implant in the surrounding bone.
3. MBTv: Test implant is anchored completely in surrounding (new) bone. Screw thread is fully filled: No fibrotic layer.
4. MBTv: Test implant is anchored completely in surrounding (new) bone. Screw thread is fully filled: No fibrotic layer.

Conclusion: In vitro and in vivo testing demonstrated safety and performance of the implant surface PEEK-MBT. PEEK-MBT showed osseointegrative characteristics that are statistically significant superior to PEEK, HA-enhanced PEEK and Titanium, known as the golden standard for orthopedic materials. The animal model (sheep) and cell tests demonstrated the overall biocompatibility of the new surface modification MBT.

stimOS MBT is published "open access" in the Global Spine Journal, one of the most important scientific spinal journals.

DOWNLOAD THE COMPLETE PUBLICATION HERE:
https://journals.sagepub.com/doi/pdf/10.1177/21925682211047969

stimOS GmbH

MED TECH OUTLOOK TOP 10 ORTHOPEDIC SOLUTION PROVIDERS IN EUROPE - 2021

JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC

stimOS introduces S.P.E.L. during the most important Spine Congress of the year: GSC 2021, hosted by AO Foundation.

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This biomechanical model was able to successfully apply repetitive forces with a variety of moment arms and shear forces that can be increased independently from one another. Moment can be increased independent of shear force by increasing the rod length attached to the UIV + 1; adjusting the water level in the loading weight will modulate moment and shear in tandem. The Python angle measurement script was able to successfully interact with a commonly available Logitech webcam to act as an optical tracker, and successfully record the relative angles of the UIV and UIV + 1 endplates. Evaluation of 46 measurements of the same marker position showed a standard deviation of 0.16 degrees suggesting that this method is adequate for measuring angle changes less than half a degree. **Conclusion:** This is the first description of a novel biomechanical model that can successfully test long thoracolumbar constructs with repetitive flexion and accurately measure the relative change of angles of individual endplates. This model can be used to provide information regarding optimal tension parameters in junctional tethers, as well as fatigability testing for a variety of spine applications.

899

A287: Association of Facet Tropism at the Last Mobile Segment with Sacralisation of the L5 Vertebrae

Sasidharan M D S[1,2], and Davis John Thelekatt[1]

[1]KMC Manipal Hospital, Spine Surgery, Mangaluru, India
[2]Apollo Hospital, Spine Surgerty, Chennai, India

Introduction: An association between asymmetry of the lumbar facet joints and disc pathology has been studied previously. Researchers have shown a relationship between facet tropism and disc herniation. The present study aims at finding an association between facet tropism at the last mobile segment with sacralisation of L5 vertebrae. There have been many literatures on facet joint degeneration at the L5 vertebrae as well as sacralisation of L5 vertebrae but limited knowledge on its association with the mobile segment or transition segment of a sacralised L5 and facet joint asymmetry. **Materials and Methods:** The sampling was done by dividing the total study group into two on the basis of the MRI findings. Group A included patients with sacralisation of the lumbar vertebrae (L5) and Group B included the patients with normal lumbosacral vertebral morphology, all who had low back pain. The sample study included 230 patients and divided into 115 patients in each group. Analysis is done by using Chi square test, Odds Ratio, Kappa ratio and Student's t test. A statistical analysis is conducted using IBM, SPSS 17.0 and $P < .05$ is considered as significant. **Results:** Among the 230 patients selected for the study 53% of the patients were males and 47% were females. Among the females in the study 65.4% of them had sacralised vertebrae and 36.5% males had sacralised vertebrae. 27% of the total patients suffered from both low back pain and sciatica. 70% of the total patients suffered from disc degeneration. All patients in the age group 30-40 years who presented with low backpain were found to have facet tropism. 90.9 % of the total study group who had facet tropism in the sacralised vertebrae were in the age group less than 40years. In the group B, the patients who had sacralised vertebrae 83 % of them had developed disc degeneration, but facet tropism was found to be 79% of the total study group. The association of facet tropism with sacralisation using chi square test of independence was found to be highly significant at $X^2 (1, N = 230) = 53.010$ $P < .001$. The association of facet tropism with disc degeneration and age was also found to be significant. **Conclusion:** This study showed significant association of facet tropism at last mobile segment with sacralisation of L5 vertebrae. The statistical analysis shows that facet tropism is eight times more likely to be seen in sacralised vertebra when compared with non sacralised vertebra. The age group less than 40 years who had low back pain showed higher incidence of facet tropism and disc degeneration. Similar to literature, our study also found significant association between facet tropism and transitional vertebra with disc degeneration. Using regression coefficient the study also found to have statistical significance for transitional vertebra to predict disc degeneration. Patients with sacralised vertebrae showed early disc degenerative disease when compared with patients who did not have sacralisation of L5 vertebrae.

1726

A288: Implant Surface Functionalization Technologies and the Need af a Transparent Quality Evaluation System

Dietmar Schaffarczyk[1] and Helmut Cölfen[2]

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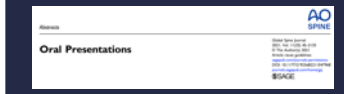
[2]University of Konstanz, Physical Chemistry, Konstanz, Germany

Introduction: For bone implants, osseointegration resulting in a good and fast bone-implant contact is of primary importance to secure a proper implant function and to avoid implant loosening or inflammation resulting in necessary revision surgeries causing pain to the patients and immense costs. Especially Polyetheretherketone (PEEK) is a promising implant material due to the close mechanical properties to bone but it is completely bio-inert hindering osseointegration and making surface functionalization necessary. Many different surface functionalization technologies have been reported both of physical and chemical nature. The same is true for the other prominent implant materials titanium and ceramics although they already have a naturally better osseointegration than PEEK but are much harder and stiffer than bone and brittle in case of ceramics. Surface functionalization, which can be subdivided into surface coating and material modification



Oral Presentations

needs to be judged from a quality and safety viewpoint. **Material and Method:** However, a literature research resulted in the fact, that no quality standard yet exists for implant surface functionalization. This makes it difficult to impossible to compare the safety and performance of different surface functionalized bone implants clearly showing the need to establish a transparent quality evaluation system for bone implants. **Results:** In this perspective article, we give the state of the art and then develop a quality evaluation system, which is based on 6 main categories as important benchmarks for the quality of a surface functionalized bone implant material. A simple catalogue of questions can be answered and from the resulting scores, the Safety Performance Evidence Level (SPEL) representing the safety and quality of a given implant can be calculated in %. This simple SPEL system allows an easy and transparent judgement and comparison of bone implants, which will hopefully assure the easy identification of safe and well performing high-quality bone implants in the future. **Keywords:** bone implant, polyetheretherketone (PEEK), surface functionalization, quality evaluation, safety and performance evaluation level (SPEL)

OP33: Robotics, Navigation and VR

1310

A289: Learning Curve in Pedicle Screw Insertion Using an Intraoperative Computertomography (ICT) Guided Navigation

Benedikt Trnovec[1,2], Bastian Stemmer[3], Heiko Mueller[3], Svorad Trnovec[4], Ehab Shiban[3], Kamil Kolejak[1], and Volkmar Heidecke[3]

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[3]Universitätsklinikum Augsburg, Neurosurgical department, Augsburg, Germany
[4]University Rostock, Neurosurgical department, Rostock, Germany

Introduction: iCT navigation guided screw placement has an extraordinary low misplacement rates. There is a lack of evidence concerning the learning curve in this technique. Aim of this single center retrospective study is to show the effect of learning curve in the first year of use. **Methods:** A retrospective analysis of all patients undergoing pedicle screw instrumentation within the first year (October 2015 and December 2016) of introducing iCT navigated spinal instrumentation was done. In each surgery, an intraoperative CT scan for referencing the navigation was performed and subsequently one or more CT scans for intraoperative control of screw placement accuracy where performed. The cases were divided into three equal intervals for analysis. **Results:** Sixty five patients were identified. There were 55.4% female and 44.6 male patients. Median age of 68 years. According to the Gertzbein and Robbins classification grades, there was proper placement (A + B grade) in 85,5%, 88.8% and 87%in the first, second and third time interval, respectively. The intraoperative revision rate was 10.5%, 6.5% and 5.8% in the in the first, second and third interval, respectively. None of the patients required secondary surgery caused by screw misplacement or had any neurovascular damage. **Conclusion:** The learning curve for iCT was evident after 3 months. There was no difference in accuracy or revision rates between the second and third interval.

852

A290: The trends in robot-related complications, operative efficacy, radiation exposure, and clinical outcomes after robot-assisted spine surgery: a multicenter study of 722 patients and 5,005 screws from 2015 to 2019

Nathan Lee[1], Ian Buchanan[1], Venkat Boddapati[1], Justin Mathew[1], Paul Park[1], Eric Leung[1], Avery Buchholz[2], John Pollina[3], Ehsan Jazini[4], Colin Haines[4], Thomas Schuler[4], Christopher Gooed[4], Joseph Lombardi[1], and Ronald A. Lehman[1]

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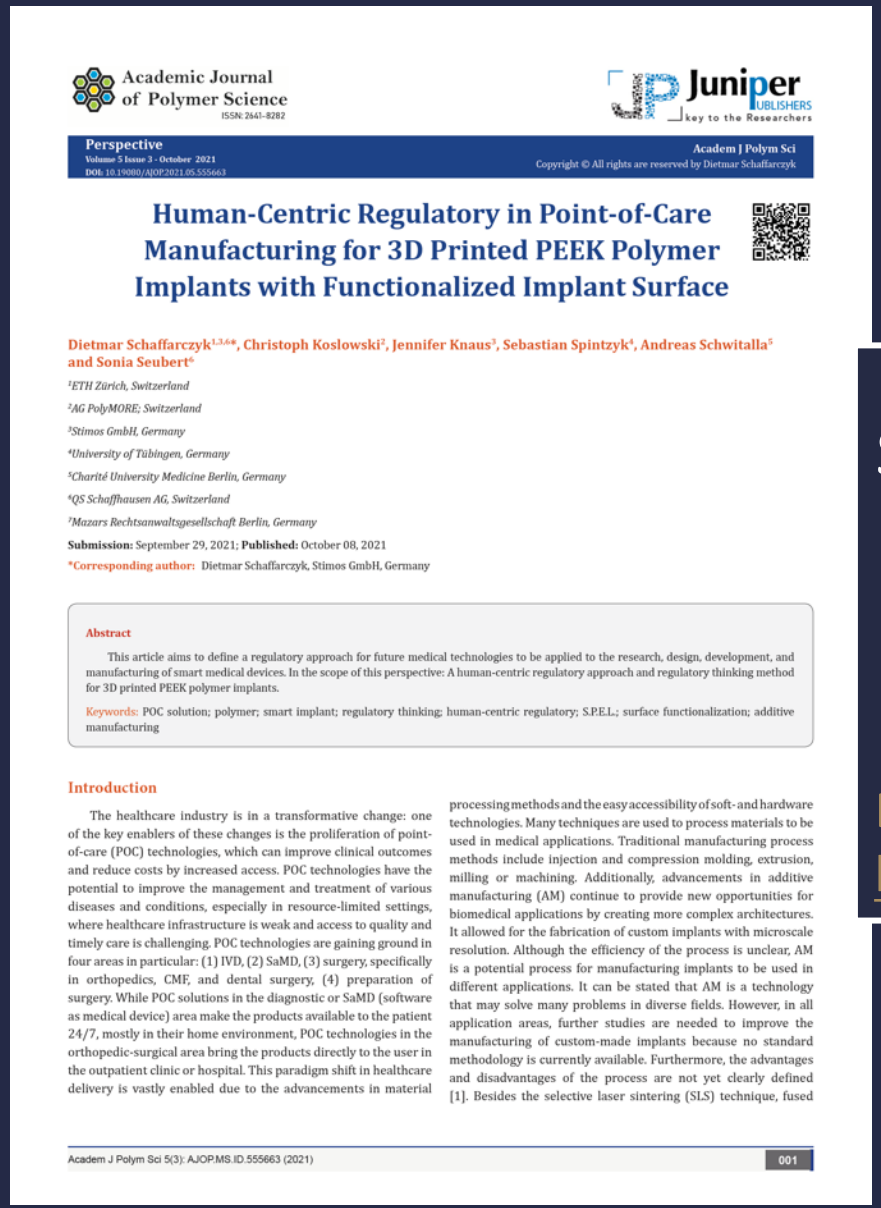
[2]University of Virginia Health System, Charlottesville, USA
[3]State University of New York, Buffalo, USA, [4]Virginia Spine Institute, Reston, Reston, USA

Introduction: With the arrival of robot-assisted spine surgery nearly twenty years ago, there has been a growing amount of literature that suggests robots are safe and can achieve comparable outcomes to conventional techniques. However, much of this literature is limited by small sample sizes and single-surgeon or single center series. Furthermore, it is unclear what the impact of robotic technology has made on operative and clinical outcomes over time. This is the first and largest multicenter study to examine the trends in outcomes and complications after robot-assisted spine surgery over a five-year period. **Material and Methods:** We included adult (≥18 years old) patients who underwent robot-assisted (Mazor Renaissance, X, and Stealth) spine surgery from 2015-2019. Several perioperative factors were compared across the years of surgery. Outcomes of interest included operative efficiency (robot time per screw), radiation exposure (fluoroscopy time per screw), robot complications (e.g. screw exchange, robot abandonment), and clinical outcomes (e.g., length of stay, 90-day reoperations). The minimum



Academic Journal of Polymer Science
ISSN: 2641-8282

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Perspective
Volume 5 Issue 3 - October 2021
DOI: 10.19080/AJOP.2021.05.555663

Academ J Polym Sci
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Human-Centric Regulatory in Point-of-Care Manufacturing for 3D Printed PEEK Polymer Implants with Functionalized Implant Surface

Dietmar Schaffarczyk[1,3,6*], Christoph Koslowski[2], Jennifer Knaus[3], Sebastian Spintzyk[4], Andreas Schwitalla[5] and Sonia Seubert[6]

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Submission: September 29, 2021; **Published:** October 08, 2021

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Abstract

This article aims to define a regulatory approach for future medical technologies to be applied to the research, design, development, and manufacturing of smart medical devices. In the scope of this perspective: A human-centric regulatory approach and regulatory thinking method for 3D printed PEEK polymer implants.

Keywords: POC solution; polymer; smart implant; regulatory thinking; human-centric regulatory; S.P.E.L.; surface functionalization; additive manufacturing

Introduction

The healthcare industry is in a transformative change: one of the key enablers of these changes is the proliferation of point-of-care (POC) technologies, which can improve clinical outcomes and reduce costs by increased access. POC technologies have the potential to improve the management and treatment of various diseases and conditions, especially in resource-limited settings, where healthcare infrastructure is weak and access to quality and timely care is challenging. POC technologies are gaining ground in four areas in particular: (1) IVD, (2) SaMD, (3) surgery, specifically in orthopedics, CMF, and dental surgery, (4) preparation of surgery. While POC solutions in the diagnostic or SaMD (software as medical device) area make the products available to the patient 24/7, mostly in their home environment, POC technologies in the orthopedic-surgical area bring the products directly to the user in the outpatient clinic or hospital. This paradigm shift in healthcare delivery is vastly enabled due to the advancements in material processing methods and the easy accessibility of soft- and hardware technologies. Many techniques are used to process materials to be used in medical applications. Traditional manufacturing process methods include injection and compression molding, extrusion, milling or machining. Additionally, advancements in additive manufacturing (AM) continue to provide new opportunities for biomedical applications by creating more complex architectures. It allowed for the fabrication of custom implants with microscale resolution. Although the efficiency of the process is unclear, AM is a potential process for manufacturing implants to be used in different applications. It can be stated that AM is a technology that may solve many problems in diverse fields. However, in all application areas, further studies are needed to improve the manufacturing of custom-made implants because no standard methodology is currently available. Furthermore, the advantages and disadvantages of the process are not yet clearly defined [1]. Besides the selective laser sintering (SLS) technique, fused

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stimOS introduces S.P.E.L. in the 3D Printing Medtech Community.

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In alphabetical order:

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Electro Medical Systems
GO Implants
ImplanTec
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LINK Orthopaedics
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United Orthopedic

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Bio-inspired Approach to a Pain-free Life

Going through surgery is hard enough but having to go under the knife again because of healing abnormalities or undesirable body reactions caused by an implant is traumatic. These repeat procedures are not uncommon, but it is evident that repeatedly opening a wound deteriorates the patient's already compromised immune system. Often the life of orthopedic implants is severely hampered by infections, corrosion, excessive inflammation, toxicity, poor osseointegration, and foreign body effects. In many instances, when an implant doesn't heal properly, it results in severe discomfort, amputation, hospitalization, and, in some circumstances, more fatal consequences. Adding to the woes is the age-old challenge of implant loosening and inflammatory reactions caused by inert implant materials, which is yet to be successfully addressed. For years, material manufacturers, medics, and implant manufacturers have been looking for an implant material that heals and anchors optimally in the patient's body while being free of negative side effects. This is where stimOS comes in, with its innovative smart implant technology providing patients with the best treatment possible while minimizing revisions due to botched procedures.

Germany-based stimOS's ISO validated and certified revolutionary smart implants modification processes address the patient's requirement for improved osseointegration and less inflammatory reactions. With the patented stealth innovation, Mimicking Bone Technology (MBT) offered by stimOS, the company is able to functionalize implant surfaces, conceal the undesired qualities of the original material, and provide osseointegrative, antibacterial, or corrosion-protective capabilities as required. This one-of-a-kind biochemical technology promotes early and healthy bone formation, provides optimal anchoring in osteoporotic bone, is anti-inflammatory, and respects all regulatory requirements. This is demonstrated by the company's voluntary quality seal S.P.E.L. As one of the first companies stimOS informs patients and users about the Safety and Performance Evidence Level of the technology during design and development. This transparency offensive is just as unique and revolutionary as the surface technology itself.

The primary goal of stimOS is to transform implant surfaces from an artificial barrier in the patient's body to a bone-identical implant body interface to eliminate inflammatory responses, infections, and re-operations. "MBT masks the implant material in a way that the patient's anatomy no longer recognizes implants as foreign bodies," says Dietmar Schaffarczyk, CEO and managing partner of stimOS.

Schaffarczyk points out that other solution providers in the market merely put a covering on the implant surface. However, methods like this are troublesome since the coating process frequently negatively affects the implant material, and there are major issues with abrasion, delamination, and/or metal ion leakage. With MBT, stimOS provides a completely new solution. Rather than depending on coating methods, the company biochemically restructures implant surfaces with a covalently bonded activation layer. By doing so, stimOS provides inert materials with biological properties similar to those found in nature.

Benchmark in Smart Implant Technology

With a commitment to providing the highest quality products, services, and technologies, stimOS not only assists the medical device sector, but also supports surgeons and hospitals, in implementing additive manufacturing processes. This includes everything from manufacturing services to evaluating, building, and operating competence centers. Along with innovative smart implant technology, stimOS also provides 3D printed implants and instruments, as well as point of care solutions to doctors, enabling them to deliver the best possible treatment to patients and ensure a pain-free life after surgery.

> **MBT masks the implant material in a way that the patient's anatomy no longer recognizes implants as foreign bodies**

To showcase stimOS' expertise, Schaffarczyk draws attention to a project done with an exclusive network —AG PolyMORE network, in which the company was able to produce an additively manufactured polymer implant for the cardio surgery department of a renowned university hospital. The network is home to a consortium of experts that combine knowledge in filament and composite material manufacturing with construction and additive manufacturing know-how, as well as medical 3D printing manufacturers' expertise. Alongside this team of experts, stimOS was able to produce one of the first additively manufactured, 3D printed polymer cardiovascular implants in a unique competence center setting using a patient-matched manufacturing method. This was not traditional 3D printing because the majority of 3D printed implants or additive manufactured implants are fabricated from titanium by electron beam melting or other 3D printing techniques. Adding into the bargain, this project also exemplified the effective combination of antimicrobial implant surfaces, polymer materials, additive manufacturing of polymer implants, and approval expertise in a patient-benefiting project.

With an outstanding value proposition already in place, Schaffarczyk believes stimOS has a lot more to offer in the upcoming years. The company is currently actively working towards the success of two important milestones; implantation of surface-modified spine and 3D printed polymer implants as well as complete metal-free highly osseointegrative dental implants in a point of care manufacturing setting. Over the next few years, stimOS intends to expand into drug and pharmacy distribution via implant surfaces, as well as address antibacterial properties not inside the pharmacy but by biochemically transforming the surface. Additionally, the company also intends to share its findings and its industrial scalable process with any industry partner interested in this technology, as the stimOS technology is evolutionary and has the potential to create a new gold standard in the implant market.

stimOS is awarded TOP 10 Orthopedic Company Europe 2021

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Zusammenstoß bei der Ausfahrt vom Grundstück

Ein 27-jähriger Renault-Fahrer wollte am Donnerstag gegen 13 Uhr aus einem Grundstück auf die Fritz-Arnold-Straße abbiegen. Dabei übersah er laut Pressenotiz der Polizei den Nissan eines 54-jährigen Mannes. Durch den Zusammenstoß der beiden Fahrzeuge entstand laut Mitteilung ein Gesamtschaden von über 9000 Euro. Verletzt wurde bei dem Unfall niemand.

AUSSTELLUNG

Werke von Heinz Mack gibt es auch online

Impressionen der Räume sowie alle Werke der Ausstellung „Heinz Mack – Colors", die zurzeit in der Galerie Geiger gezeigt werden, können jederzeit auch im Internet unter der Adresse www.galerie-geiger.de betrachtet werden. Darauf weist die Galerie Geiger, die sich seit Oktober am neuen Standort in der Reichenaustraße 39A befindet, in einer Pressenotiz hin. Weitere Infos gibt es während der Öffnungszeiten der Galerie (Dienstag bis Freitag von 13.30 bis 18 Uhr, Samstag 11 bis 17 Uhr) unter Telefon (0 75 31) 91 75 31.

OLD MARY'S PUB

Jazz- und Rockschule lädt zum Konzert ein

Am Montag, 27. Dezember, um 20 Uhr veranstaltet die Jazz- und Rockschule Konstanz ein weiteres Konzert im Old Mary's Pub in der Kreuzlinger Straße 19 in Konstanz. Dabei trifft der Tabla-Virtuose Florian Schiertz auf den Schlagzeuger Patrick Manzecchi. Die Konzertbesucher erwartet laut der Einladung der Schule ein besonderes Rhythmus-Erlebnis aus indischer Klangakrobatik und modernen Jazz-Drums. Der Eintritt zum Konzert ist frei, die beiden Musiker freuen sich wie immer über eine Hutspende. Weitere Infos gibt es unter www.jrsk.de

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VON MICHAEL BUCHMÜLLER
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Die Produktion der besonders beschichteten Implantate soll künftig in Radolfzell erfolgen. Das Bild zeigt Geschäftsführer Schaffarczyk an einer neu installierten Reinraumwerkbank.
BILD: MICHAEL BUCHMÜLLER

Konstanz – Dietmar Schaffarczyk ist ein Tausendsassa. Er ist Mitgründer der Medizintechnikfirma Stimos. Und außerdem studierter Philosoph, Wissenschaftsjournalist, Lehrbeauftragter an der ETH Zürich und inzwischen auch Prüfer für Zulassungen von medizintechnischen Produkten in Europa. Schaffarczyk kann und macht vieles. Hauptsächlich kümmert er sich aber um seine Firma. Diese stellt ein biochemisches Verfahren zur Verfügung, das Implantate so im Körper anwachsen lässt, dass dieser das Ersatzteil nicht als Fremdkörper wahrnimmt und womöglich abstößt. „Mehr als 15 Prozent aller Implantats-Operationen müssen wiederholt werden", sagt Schaffarczyk. Meist, weil an der Schnittstelle zwischen Künstlichem und Körper Infektionen entstehen oder Implantate sich nach einer Zeit lockern.

Stimos will diese Infektionen verhindern, „indem wir den Körperzellen ein attraktives Angebot machen, sodass sie gerne an das Implantat andocken". Schaffarczyk greift zu anschaulichen Bildern, damit man den komplexen Vorgang versteht. „Und das schaffen wir, indem wir den Implantaten eine Art biochemische Tarnkappe überziehen." Damit erkenne die Körperzelle gar nicht mehr, aus welchem Stoff das Implantat eigentlich ist. Implantate bestehen meist aus Metallen, Keramiken oder Kunststoffen. Also aus Stoffen, bei denen der Körper erst einmal keine rechte Lust hat, mit denen eine engere Verbindung einzugehen. Um aber genau diese Lust zu wecken, werden bisher Implantatoberflächen vorwiegend mit Titan beschichtet. Das kann allerdings allergische Reaktionen nach sich ziehen. „Wir verwenden für die Tarnkappe das Material, was auch im Knochen vorkommt: Gelatine und Kalziumphosphat", erklärt Schaffarczyk. Was zur Folge hat: Die Körperzellen zeigen sich angetan, weil ihnen das Gegenüber irgendwie ähnlich ist. Sie kommen interessiert näher. Und die Schnittstelle verwächst im besten Fall infektionsfrei.

Zur Serie

Die Gründerszene von Konstanz ist lebendiger, als manch einer glauben mag. Und auch an Unterstützungsangeboten herrscht in der größten Stadt am Bodensee kein Mangel. Doch wer sind die Leute hinter den Innovationen und Förderprogrammen? Welche neuen Ideen werden in Konstanz gerade entwickelt? Wo kann ich mich mit dem Plan, ein Unternehmen aufzubauen, hinwenden? Wer nimmt mich an die Hand, wenn ich vor dem bürokratischen und finanziellen Aufwand zurückschrecke? Und für welche Probleme sollte ich mich wappnen? SÜDKURIER stellt in dieser Beitragsreihe Start-ups und Gründungshelfer vor. (sf)

Studien belegten, so Schaffarczyk, dass es bei dem Verfahren einen signifikant positiven Unterschied zu den sonst verwendeten Standardmaterialien gibt.

Weiter führt er aus, dass sich das Unternehmen als Dienstleister verstehe, das nicht einfach ein Patent anmeldet, um damit dieses Marktsegment zu beherrschen. „Wir bieten Lizenzen an, sodass andere Medizintechnikfirmen unser Verfahren für ihre Produkte einsetzen können." Erste Gespräche mit einer Firma, die Implantate für Mund-Kiefer-Gesichtschirurgie herstellt und vertreibt, seien schon geführt worden. Andere klopfen bereits an. „Uns geht es primär um das Wohl des Patienten", betont Schaffarczyk. Möglichst viele Menschen sollen in den Genuss eines störungsfrei anwachsenden Implantats kommen. Dem Philosophen nimmt man das ab. Das Unternehmen hat sich freiwillig zu einer Transparenzoffensive verpflichtet und stellt allen interessierten Anwendern und Patienten sämtliche Unterlagen und Testergebnisse zu den sicherheitsrelevanten Eigenschaften des Materials zur Verfügung. Diese Transparenz ist auf dem Markt ebenso einzigartig wie die Technologie selbst, ist sich Schaffarczyk sicher.

2015 wurde Stimos gegründet, 2017 zertifiziert, da stiegen die Mittelständischen Beteiligungsgesellschaften (MBG) und der High-Tech-Gründerfonds (HTGF) bereits als Gesellschafter ein. Und im Juli 2020 kam auch noch eine Firma aus der Region hinzu: Wefa Inotec aus Singen. Die beschichten auch. Vorwiegend Autoteile. In naher Zukunft dann auch die Oberflächen von Implantaten? Schaffarczyk erklärt, seine Firma werde vermehrt die Implantate selbst herstellen, und Wefa werde gefragt sein, seine Kompetenz in der Hochpräzisionsmechanik einzubringen: Eine Zusammenarbeit mit einem Familienunternehmen vor Ort, auf die sich der Geschäftsführer von Stimos freut. Und wie sieht die Zukunft aus? „Sicher wird die 3D-Technik auch in unserem Bereich Einzug halten." Passgenaue, für jeden Patienten angepasste Implantate, am besten im Krankenhaus ausgedruckt, das wird irgendwann kommen, ist sich Schaffarczyk sicher. „Und dann könnten die irgendwann so beschaffen sein, dass sie sich biologisch abbauen und durch körpereigene Zellen ersetzen lassen." Doch das ist noch Zukunftsmusik, wobei es hier vor allem um Synchronizität, um Gleichzeitigkeit, gehen wird. Um in der Bildsprache zu bleiben: Eine Körperzelle wird dem Implantat sagen müssen: „He, du kannst dich abbauen! Ich bin jetzt hier, um dich zu ersetzen." Stimos wird sich also weiterhin darum kümmern, dass die Kommunikation zwischen dem Körper und ihm eingepflanzten Fremdkörpern nicht abreißt.

Das lesen Sie zusätzlich online

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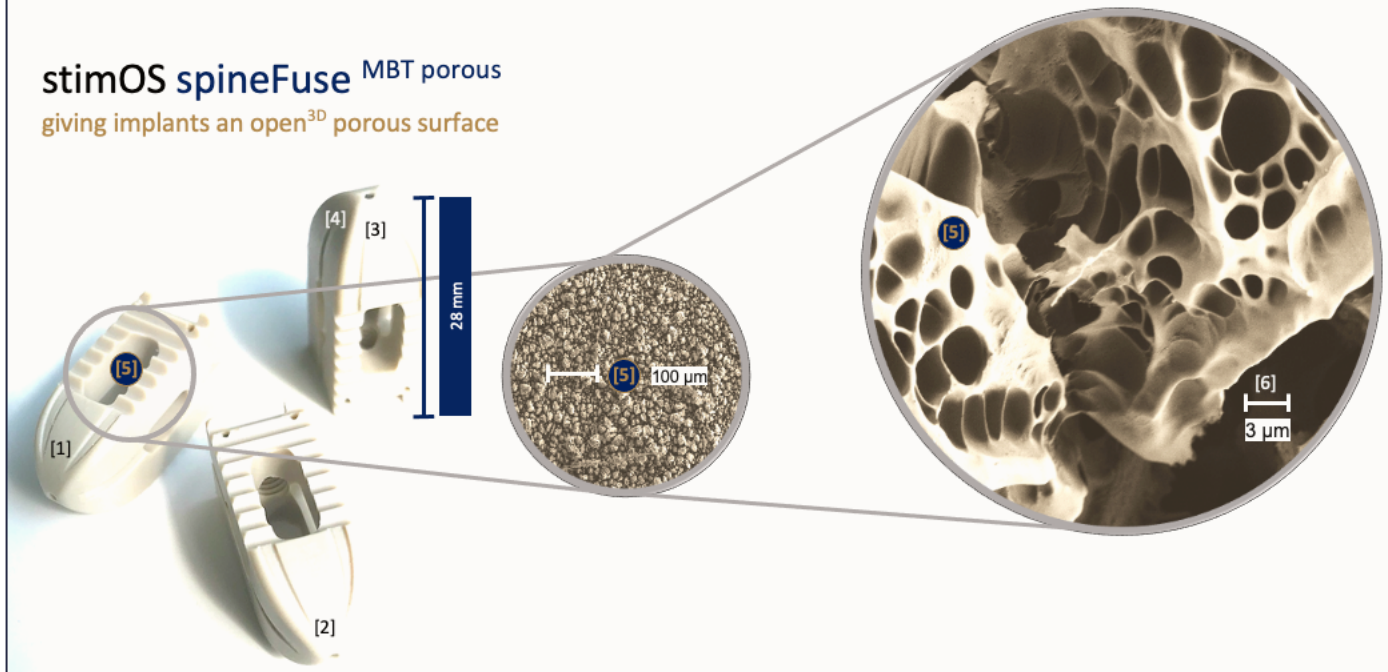

ISO 13485:2016 validated Technology

[1] Sliding Struts
[2] Bullet Nose
[3] Anatomical Implant Design
[4] Carved Bone Anchorage Struts
[5] MBT Open Porous Surface Modification: 100% Surface Coverage
[6] Enlarged Surface Topography

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