Materials and Surface Technology for Implants

Tuesday, 5th November 2024

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General Information

Venue

Concert Hall (Konzertsaal) Solothurn
Untere Steingrubenstrasse 1
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Exhibition, breaks, catering:	**Large hall, ground floor**
Sessions:	**Small hall, upper floor**

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5	Gloor Instruments AG
6	Evonik Operations GmbH
7	Rösler Schweiz AG
8	Osypka AG
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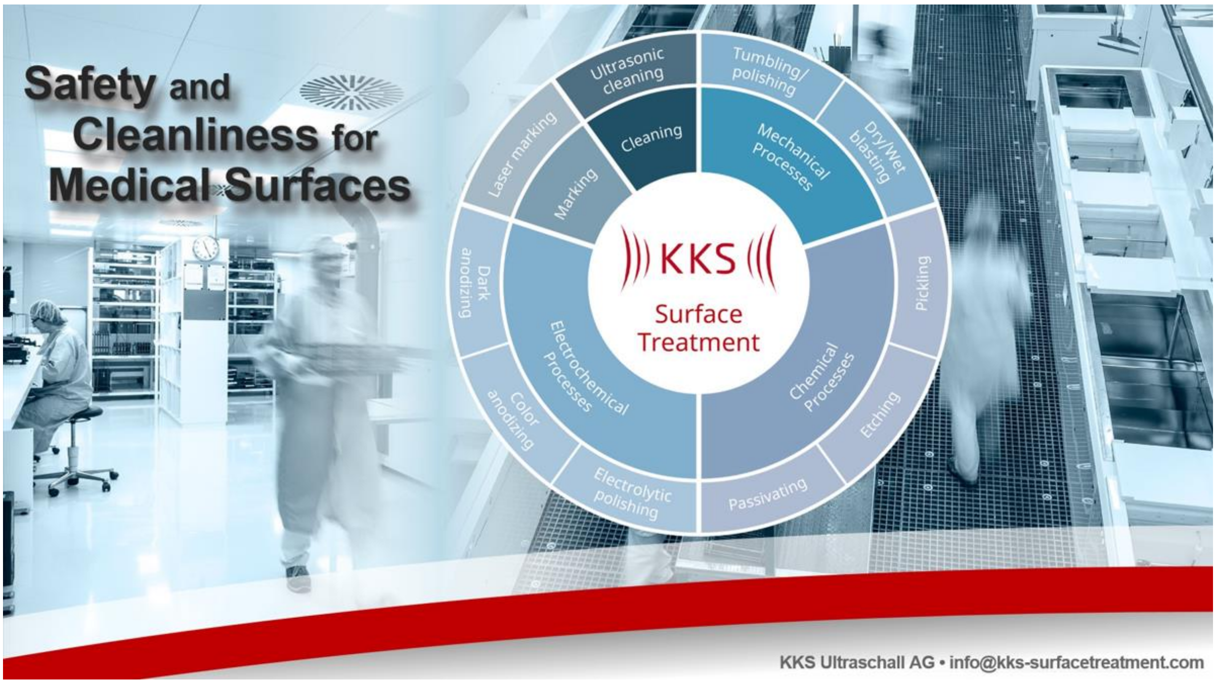

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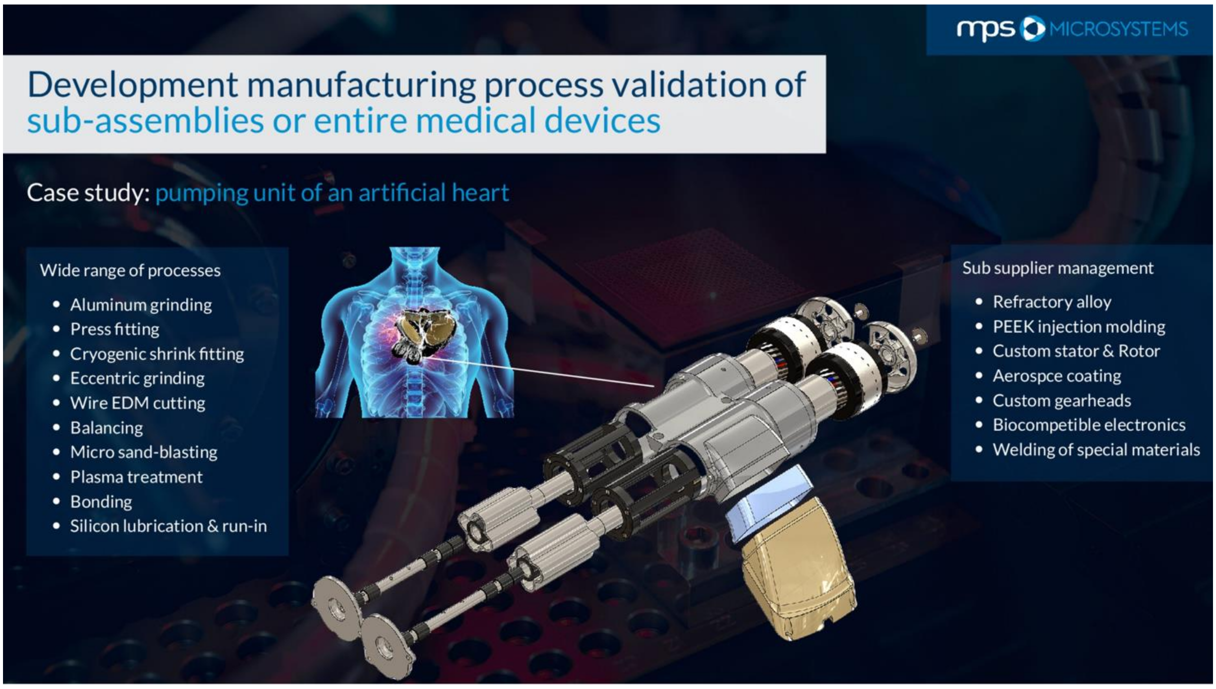

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Meeting Program Tuesday 5th November 2024

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Virtual Evaluation of Implant Designs: Assessing the Impact of Osteotomy and Implant Geometry on Primary Stability

P. Wili[1], S. Fabbri[2], J. Waser[2], P. Zysset[1]

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[2]*Thommen Medical AG, Grenchen, CH*

INTRODUCTION: Achieving primary stability, which refers to the mechanical stability of a dental implant immediately after placement, is crucial for successful osseointegration, particularly in immediate implant placement and cases of compromised bone quality. However, despite advances in dental implant technology, limited knowledge exists about the bone-implant interactions during implant placement and its influence on primary stability. To address this need, this study aimed to investigate the primary stability of a new tapered implant design (B, Thommen Medical AG, Fig. 1a) using virtual stability testing. The cylindrical implant design (A, Thommen Medical AG, Fig. 1a) served as a control. Three different osteotomy types I, II and III, originating from different drilling protocols, were used (Fig.1b).

METHODS: This study evaluated the primary stability of four implant-osteotomy combinations (AI, AII, BII, BIII, Fig. 1ab) in bovine trabecular bone samples using a combination of experiments and finite element analyses in Abaqus/Explicit. This low-density bone model was subdivided into two BV/TV (bone volume/total volume) ranges: 0.16-0.26 and 0.27-0.38. To assess primary stability, the implant-bone system was loaded in compression mode by displacing the implant vertically in respect to its axis until collapse. For this reason, the bone samples were reconstructed from µCT scans, converted to a finite element mesh and combined with the implant to a simulation model. The implants were modeled as rigid bodies. The study quantified insertion torque (IT), stiffness (K), and ultimate push-in/pull-out force (UF) of the four retained implant-osteotomy combinations. Ultimate force (UF) can be used as an objective indicator of primary stability, as it quantifies the load-bearing capacity of the implant bone fraction. To analyze the performance of different versions within the specified BV/TV range, descriptive statistics were employed, using pairwise comparisons illustrated with boxplots.

RESULTS: BIII generally exhibited higher IT values than AI. Moreover, BIII displayed greater K and UF than AI, particularly in the (BV/TV) range 0.27-0.38 (Fig. 1c). AII and BII (under preparation) showed faster IT increases compared to AI and BIII. The simulations indicated that implant geometry had a stronger influence on K and UF than the osteotomy type. Osteotomy type II increased IT but did not improve the other stability parameters (K & UF) for the cylindrical implant A. The tapered implant B consistently showed superior stability (K & UF) regardless of the osteotomy type used.

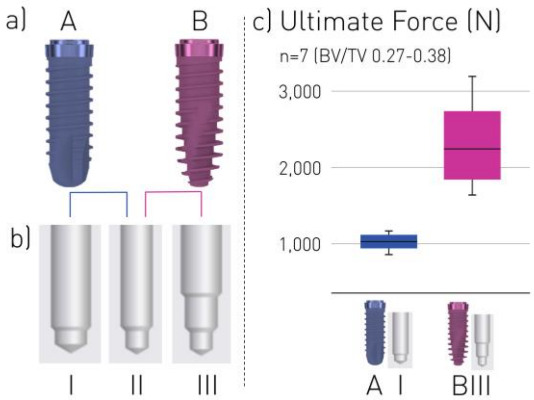

Fig. 1ab: I: osteotomy cylindrical implant A, II: underprepared osteotomy, III: osteotomy tapered implant B. 1c: UF simulation for AI and BIII.

DISCUSSION & CONCLUSIONS: Overall, the study provided descriptive findings for smaller subsamples, but key trends highlight the critical role of implant geometry in mechanical performance. The tapered implant design B generally reached a higher primary stability (IT, K & UF) compared to the cylindrical implant design A. The tapered implant design B provided increased stability without the need for underpreparation.

ACKNOWLEDGEMENTS: We thank the members of the ARTORG machine shop for their friendly support. This study was funded by Thommen Medical AG.

REFERENCES: Vautrin A, Thierrin R, Wili P, et al. J Mech Behav Biomed Mater. 2024; 158:106688. doi:10.1016/j.jmbbm.2024.106688

Air contamination during Titanium 3D printing

R. Nardini[1]

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INTRODUCTION: Additive machining of Titanium alloy powder in an inert gas environment is prone to undesired oxidation reactions with residue elements of ambient air.
State of the art Laser powder bed fusion (LPBF) machines measure Oxygen content of the inert gas environment as a means of process monitoring and control.
Potentially, this kind of monitoring and control, bears risks of undesired results due to the following side effects:

- Chemical interference between the process and the measurement
- Measurement type choice
- Technical interference between the process and the measurement

METHODS: All machining was performed using an off-the-shelf Laser powder bed fusion (LPBF) system, offering a build volume of approx. 1 dm^3. The machine was manufactured in 2019 and specifically intended for reactive powders like Ti6Al4V, as used in this case.
Samples manufactured were used for static tensile testing and for hot gas extraction analysis.

RESULTS: Samples machined with the default setup repeatedly showed low elongation at break of as little as 1% compared to 10% as standardised e.g. by ASTM F3001-14.

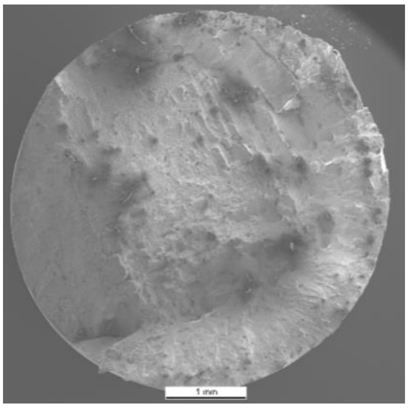

Fig. 1: 5mm Static tensile test sample lot 200054, elongation 2%)

Oxygen content repeatedly showed values exceeding 1300 weight ppm, a limit given by ASTM F136-13 for example.
With basic changes to the machining conditions, elongation typically will exceed 10% and bulk Oxygen content is usually limited to 1300 weight ppm.

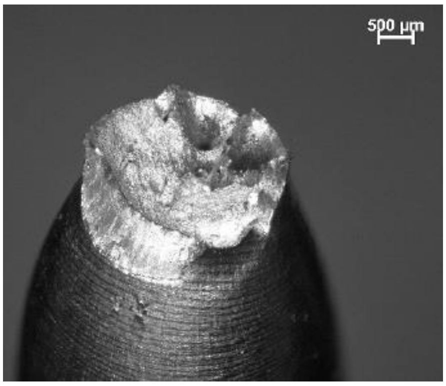

Fig. 2: 5mm Static tensile test sample lot 200039, elongation 18%).

DISCUSSION & CONCLUSIONS: Titanium and its alloys is known as being highly reactive. This property can cause undesired effects during additive machining. Adequate protection using inert gas is widely used and can provide state of the art material properties.

The suggested causalities between the available data and the three mentioned side effects were not scientifically proven. They are based on quantitative data from in-house Qualification activities and on a few qualitative test results.

ACKNOWLEDGEMENTS: We thank Berner Fachhochschule Jürg Dänzer, RMS Foundation Roman Heuberger, EMPA Christian Rohrer, EMPA Renato Figi for their support regarding the choice and execution of the sample testing.

REFERENCES: BFH Kurzbericht 17.05.2021, RMS Bericht O20_0029, EMPA laufender Auftrag 5213.00273.100.01, EMPA Prüfbericht Nr. 5213.00273.100.02_01

PEEK polymer 3D printing as alternative to metals for next-generation implants

M. Knebel[1], P. Engel[1], T. Perl[1]

[1]*Evonik Operations GmbH, Germany*

As material producer Evonik is an enabler to produce PEEK implants, using novel 3D printing processes. In 2019, Evonik launched worlds‘ first PEEK filament for 3D printing of PEEK implants using FFF printing with full documentation and has since consistently expanded the portfolio to meet specific application requirements (Fig. 1).

Figure 1: VESTAKEEP® PEEK filaments available for wide range of applications

The technology has developed rapidly and has now reached day-to-day clinical use. In all major regions - Europe, America and Asia - 3D printed PEEK implants are approved. Filament printing, in particular, enables the realization of point-of-care treatment and is already successfully implemented in several clinics in Europe (e.g. Universitätsspital Basel), due to its easy handling and integration into digital process flows.

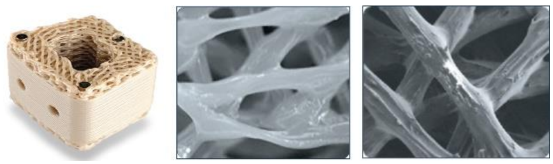

Figure 2: 3D printed Curiteva spinal cage using Evonik VESTAKEEP® i4 3DF PEEK filament material. Magnification x40 (middle) and x100 (right)

Furthermore, the technology opens up new design freedom that allows the design of natural biological structures and functions. The company Curiteva, USA, has developed a design with a fully interconnected porous trabecular lattice structure. It has a pore size between 100-600 µm to promote osteoconjunction. The diamond shaped pores possess superior biomechanical and biological properties and have an e-modulus of ~1GPa like cancellous bone (Fig. 2)

Additive manufacturing has been scaled to commercial production by Curiteva and 510K approval for cervical as well as trabecular spinal cages.

Within one year more than 50 surgeons have successfully treated more than 1.000 patients. Clinical data show the excellent patient treatment and fast healing (Fig. 3).

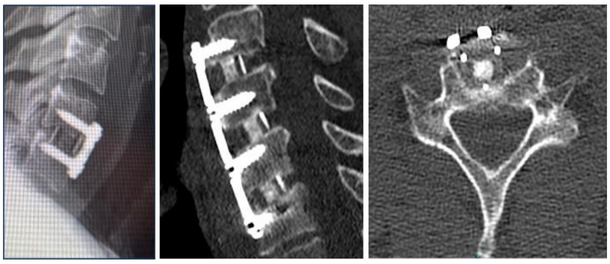

Figure 3: X-ray images of 1-level spinal implant (left), 3-level spinal implant (middle) and cross section (right) © Curiteva.

Hundreds of 1 to 3 level spinal surgeries have been performed with this new technology and to date no cases of pseudoarthrosis or implant related reoperations have occurred.

Table 1: Track record of 3D printed spinal cages in clinical use

Type of implant	Number of patients
1-level	403
2-level	385
3-level	232

With the increasing number of patients treated the production of 3D printed implants and the advances in Point-Of-Care treatment for PEEK implants show that this new technology is now scaled and ready for commercial use.

ACKNOWLEDGEMENTS: We Thank our partners Curiteva, 3D-Systems and Universitätsspital Basel

MDR compliant implant production at the Point of Care

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INTRODUCTION: New technologies, such as 3D printing, have revolutionized surgical practices, allowing for precise and personalized patient care. In 2022, the University Hospitals in Basel and Salzburg initiated a PEEK (polyetheretherketone) 3D printing process for patient-specific cranial implants technically and regulatory supported by POC APP. This presentation gives an overview of the implementation of the end-to-end production process under MDR 2017/745 Article 5/5 and the outcomes during its first year.

METHODS: The cranial PEEK 3D printing process was integrated into the clinical workflow at both University Hospital Basel and University Hospital Salzburg. A collaboration between radiologists, surgeons, biomedical engineers, and technicians, as well as the suppliers, was established to ensure the seamless production of patient-specific cranial implants.

To achieve a regulatory-compliant end-to-end production process, 3D Systems Corporation [www.3dsystems.com] provided advanced 3D printing technology tailored specifically for medical applications, while POC APP implemented a QMS tailored to the needs of a 3D Printing Lab and developed a streamlined workflow, including the evidence for compliance with the general safety and performance requirements of MDR 2017/745 Annex I, including e.g. clinical evaluation.

During operations, POC APP functioned as the QA and RA partner, ensuring compliance with MDR 2017/745 Article 5/5. Patient-specific CT scans were converted into 3D models to design PEEK implants. These models were printed on a medical 3D printer (3D Systems' EXT220 MED, formerly Kumovis R1, Germany) using the implant-grade PEEK filament (Vestakeep i4 3DF, Evonik Industries GmbH, Germany) and post-processed under controlled conditions. POC APP enforced stringent QA protocols to ensure anatomic accuracy, mechanical integrity, biocompatibility, and sterility. A post-market clinical follow-up process was performed to assess the safety and efficacy of the in-house produced medical devices.

RESULTS: Over the course of the first year, more than 50 patients received patient-specific PEEK cranial implants. The overall safety and efficacy of the implanted devices are currently under review. The average surgical time, compared to the standard in-situ molded PMMA cranial plate, was reduced by more than 25% due to precise pre-surgical planning and implant fabrication. The production lead time could be reduced to three days compared to several weeks when sourced externally.

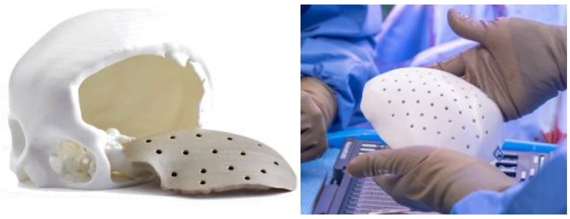

Fig. 1: Printed cranial PEEK implant (left) cranial PEEK implant in OR (right).

DISCUSSION & CONCLUSIONS: The first-year outcomes of the cranial PEEK 3D printing process at the University Hospitals in Basel and Salzburg demonstrate significant clinical benefits, including reduced operation times and enhanced patient recovery. The interdisciplinary collaboration has proven effective in integrating advanced 3D printing technology directly into clinical workflows. The success of this initiative supports continued application and potential expansion of 3D printing solutions in other surgical disciplines. Future studies will focus on long-term outcomes and cost-effectiveness of PEEK implants 3D printed at the Point of Care.

REFERENCES: Sharma N, et al. Quantitative assessment of point-of-care 3D-printed patient-specific polyetheretherketone (PEEK) cranial implants. Int J Mol Sci. 2021;22(16):8521.

Pöppe JP, et al. Point-of-Care 3-Dimensional–Printed Polyetheretherketone Customized Implants for Cranioplastic Surgery of Large Skull Defects. Operative Neurosurgery 10.1227/ons.0000000000001154, April 17, 2024.

Eco-friendly electropolishing of 3D printed medical implants

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INTRODUCTION: Additive manufacturing of metallic parts by Electron Beam Melting (EBM) is widely used in the medical domain. The use of EBM requires post-processing steps due to surface defects (porosities, non-melted powder particles). Electropolishing (EP) is a suitable solution to improve the surface quality of the 3D-printed metallic parts. EBM-manufactured complex-shape medical parts (screws, cages) made from TiAl6V4 alloy were subjected to EP using a non-toxic acid-free electrolyte.

METHODS: The parts (medical screws and model cages) were produced from TiAl6V4 powder by Electron Beam Melting process. Afterwards, the parts were subjected to heat treatment by Hot Isostatic Pressure (HIP).

Electropolishing (EP) experiments were carried out in a non-toxic acid-free electrolyte containing a metal chloride salt and ethylene glycol (EG). The voltage was kept constant at the values ranging from 25 to 40 V. The electrolyte temperature was kept fixed at different values (20 and 30°C). The stirring speed of the workpiece was varied from 0 to 15 rpm. The polishing duration was between 5 and 30 min. Special 3D counter-electrodes, with the shape adjusted to that of the polished parts, were designed. The anode-cathode distance was kept constant.

Surface topography was examined by optical confocal microscopy. The scanned surfaces were 3.04 mm x 2.54 mm (large scale, cut-off 0.8 mm) and 0.84 mm x 0.82 mm (small scale, cut-off 2.5 µm). Additionally, Scanning Electron Microscopy observations of the polished parts were performed.

RESULTS: The influence of experimental conditions, such as voltage, time, temperature, anode-cathode distance and anode rotation speed were studied with respect to the linear surface roughness (Ra) of the polished parts. It was shown that voltage is one of the major parameters influencing the surface roughness, Ra (both at large and small scales), *Table 1*. The initial process time of 10 minutes plays a considerable role on the surface quality. After 20 min of EP, the Ra values do not decrease anymore, the surface quality is satisfactory. Under optimal conditions, the surface layer removal was about 700 µm across the diameter of a medical screw (Fig.1) after 30 minutes.

Finally, heat treatment (HIP) has a major effect on the quality of polishing because it is necessary to remove surface porosities inherent to the manufacturing process before starting the EP.

Table 1. Voltage vs. roughness (Ra) after 30 min of EP. The initial Ra values (untreated screws) were between 10 and 14 µm

Voltage	Ra (scan @large scale)	Ra (scan @small scale)
25 V	2.8 µm	0.180 µm
30 V	1.5 µm	0.089 µm
35 V	0.95 µm	0.086 µm
40 V	0.94 µm	0.09 µm

Fig. 1: Medical screw (diameter 7.8 mm) before (left) and after (right) electropolishing.

DISCUSSION & CONCLUSIONS: «Green» electropolishing (EP) process was successfully applied to complex shape EBM-printed TiA6lV4 industrial parts (medical screws & model cages).

HIP is a necessary post-treatment step to achieve the required quality of a polished surface. The optimal EP process performed on the HIP-treated parts results in the roughness (Ra) reduction from 14 µm to less than 1 µm (large scale) and about 60 nm (small scale).

ACKNOWLEDGEMENTS: This research was supported by the Swiss Innovation Agency *Innosuisse* in the frame of the project “EP-Ti-AM” (no. 100.686 IP-ENG).

Tuning performance of biomaterials through composition and structure

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INTRODUCTION: The ageing population and associated health issues such as osteoporosis and osteoarthritis are posing significant challenges for modern societies. As a consequence, there is a rising demand for joint and bone replacement. Current challenges in bone-implant interaction include poor osseointegration, stress shielding, implant loosening, and bacterial infection. As these complications often require costly revision surgeries, novel solutions for tackling these issues by an intelligent design of the implant surface in contact with the body are needed. Here, different possible solutions to this problem will be presented based on rapid materials discovery, nano- and microstructuring of surfaces, as well as micro-3D printing of porous structures to achieve optimized biological and mechanical performance of the biomaterial.

METHODS: A novel method was developed based on physical vapour deposition (PVD) of thin film material libraries followed by high throughput material screening. The resulting multimodal dataset consisting of information on material composition, phases, mechanical, corrosion, and biological properties. To address the aspect of coating architecture, a combination of lithography with electrodeposition was used to create microstructured bioactive coatings with tunable mechanical and biodegradation behaviour. Electrochemical process parameters were optimized to achieve a high coating performance. Resulting microstructure, texture, mechanical and corrosion properties were quantified using scanning electron microscopy, nanoindentation, micropillar compression and cyclic voltammetry.

RESULTS AND DISCUSSION: Mo-Ag materials library with composition gradient of more than ±20 at.% of individual elements was created using the novel methodology based on combinatorial PVD. Strong variations in hardness and corrosion behaviour were found in the performance of the Mo-Ag alloys that could be related to the change in chemical and phase composition. Initial high-throughput material screening was followed by biological testing allowing to assess *in vitro* performance of the biomaterial. Using an alternative approach for creating complex-shape coatings using template-assisted electrodeposition highlighted the possibility of creating structured coatings with a high repeatability. Mechanical performance of the deposited bioactive Zn coatings was outstanding with compressive strength in excess of 800 MPa. Corrosion properties were assessed by electrochemical methods and immersion tests and showcased the potential of this method for tuning apparent biodegradation behaviour.

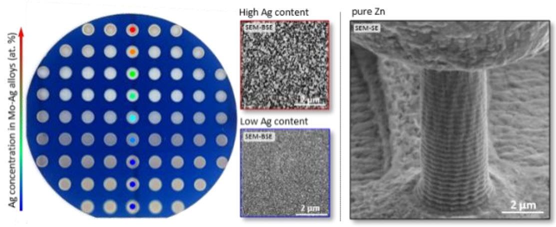

Fig. 1: Left: Thin film Mo-Ag material library synthesized by PVD. Right: Electrodeposited Zn micropillar (Ø5µm) tested under compression inside an electron microscope.

CONCLUSION: Different methods for optimizing composition, microstructure and architecture of biomaterials and -coatings were developed. The accelerated discovery of novel material compositions in a multidimensional space allows for the rapid development of optimized solutions for different biomedical applications. Novel concepts for synthesizing microstructured bioactive coatings were furthermore developed that feature significantly improved mechanical performance and widely tunable apparent biodegradation behaviour with a wide range of applications. This showcases the potential of these technologies for the development of future solutions in the biomedical field.

ACKNOWLEDGEMENTS: The authors kindly acknowledge funding through SNF Postdoctoral Fellowship 217017 and Innosuisse innovation project 109.352.1 IP-ENG ORALCOAT.

Microstructures, phase and mechanical characterization of Al_2O_3-ZrO_2-TiO_2 coating produced by atmospheric plasma spraying

Cynthia Sin Ting Chang[1], Marcus Wyss[2], Michal Andrzejewski[1,3], Geoffrey Darut[4], Lukas Graf[5], Vladimir Novak[1], Margie Olbinado[1,6], Susanne Erpel[2], Alexander Vogel[2], Simon Bode[7], Michael de Wild[5] and Armando Salito[8]

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INTRODUCTION: In this work, we aim at producing the promising ternary Al_2O_3-ZrO_2-TiO_2 coating with the cascade plasma torch technology by atmospheric plasma spraying (APS). The phases and microstructures in the coating are fully characterised and mechanical properties are also obtained. From the results, the potential of Al_2O_3-ZrO_2-TiO_2 coating in medical applications is shown.

METHODS: Al_2O_3-ZrO_2-TiO_2 coatings were manufactured by APS using the Debye-Larmor cascaded torch. Synchrotron X-Ray Diffraction (S-XRD) has been performed for phase analysis at the Materials Science (MS) beamline at the Swiss Light Source (SLS). The micro- and nanostructures were investigated by Scanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM). Synchrotron Laminography was performed on the coating at ID19 of the European Synchrotron Radiation Facility (ESRF) for defect analysis. Microhardness and scratch tests were also performed on the Al_2O_3-ZrO_2-TiO_2 coating to investigate on the mechanical properties.

RESULTS:

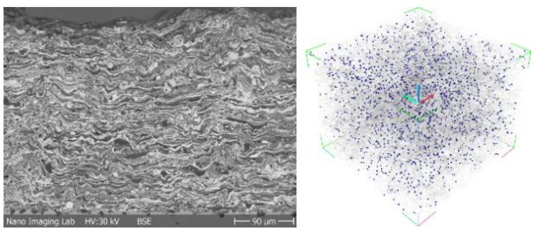

Fig.1 (left) SEM image of the cross-section of the coating. (right) The analysed volume from the laminography showing the pores with the size of 1 x 10^{-8} mm^3 to 0.8 x 10^{-8} mm^3.

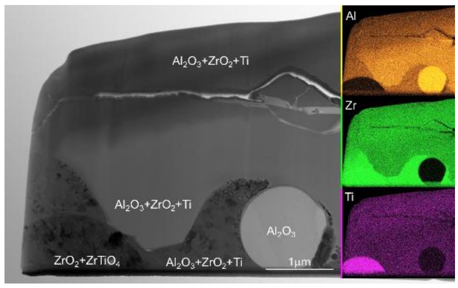

Fig.2 EDX mapping of the TEM image and summarizing phases and elements found.

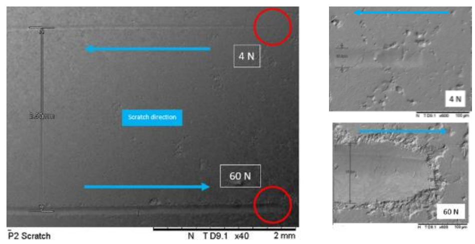

Fig. 3 SEM TOPO image of scratches. The scratch direction is indicated by blue arrows. Plastic deformation is visible from the start (red circles), breakouts are visible at higher values.

DISCUSSION & CONCLUSIONS: Al_2O_3-ZrO_2-TiO_2 coatings thermally sprayed using the Debye-Larmor cascaded plasma torch is compact with no delamination nor trans-granular cracks. Pore fraction is around 1%. The coating has a typical lamella microstructure with single phase α-Al_2O_3, m-ZrO_2 and a dual phase of varying content of Al_2O_3 and ZrO_2. The coating has a hardness of 794 ± 42 HV. The progressive scratch tests showed plastic deformation but no delamination.

ACKNOWLEDGEMENTS: This work is partly funded by the Innosuisse cheque project 61047.4 INNO-ENG.

Zirconia in dentistry - the story of a schizophrenic material

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INTRODUCTION: Zirconia has been introduced to dentistry mid 1990s when CAD/CAM technologies evolved. As an opaque high-strength material, reinforced with 3 mol% yttria, it has replaced gold-alloys as framework material for crowns and fixed dental prostheses. By adjusting sintering temperatures and adding varying dopants, translucency of zirconia was improved, better mimicking the natural teeth and the application spectrum subsequently broadened to monolithic restorations. Additionally, zirconia implants have been introduced as an alternative to titanium and its alloys. To fabricate restorations or implants, processing of the zirconia material is required, affecting its properties. The aim was to thoroughly study different zirconia materials to gain insights in how the material composition and its surface treatment affect ultimately clinical success.

METHODS: Different zirconia materials for restorations as well as for implants were thoroughly characterized by their mechanical, chemical and crystallographic properties. Also, the effect of surface treatments as polishing, heat-treatment and aging were studied. Further, it was investigated how surface treatments are affecting cell behavior and adherence of bacteria.

RESULTS: By increasing the amount of yttria added to zirconia, the crystal grain sizes increase (Fig. 1). The presence of such micro-structures can be steered by the surface treatment. Polishing eliminates these structures, while it can be re-exposed by thermal etching using heat-treatments above 1250°C.

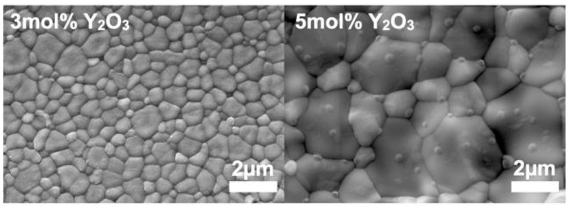

Fig. 1: Same same but different: Zirconia crystal grain sizes depend on the yttria content.

The polishing procedure increases strength, while it is again slightly reduced after heat treatment. Highest strength and reliability are commonly found for materials with 3 mol% yttria, here shown in comparison with a 5 mol% yttria material (Fig. 2).

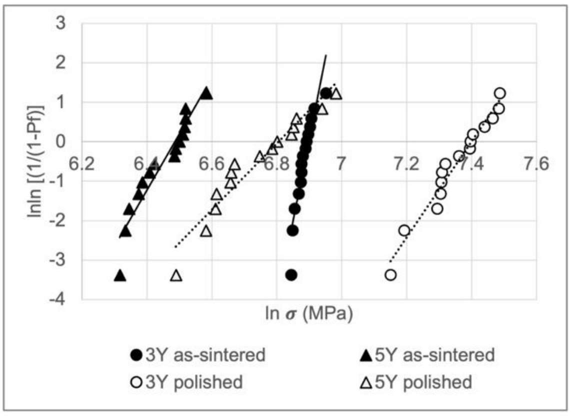

Fig. 2: Weibull graph based on biaxial flexural strength values for a 3/5mol% yttria stabilized zirconia material with surfaces that were as-sintered or polished.

DISCUSSION & CONCLUSIONS: Zirconia is a complex polycrystalline material, that is highly affected by numerous parameters, as the amount of yttria-content and heat-treatment during and after sintering. As the surface finish affects mechanical, chemical and crystallographic properties as well as the interaction with surrounding tissues or bacteria in the oral cavity, the final surface treatment is crucial for the clinical success of a zirconia restoration or implant.

ACKNOWLEDGEMENTS: The author would like to thank her research group Biomaterials & Technology at UZB and collaborators for their contributions.

Rosler Surf Finishing Technology

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INTRODUCTION:
Providing the right and required surface finish to an Orthopaedic Implant is a very important step in the manufacturing process. Mass finishing machines like drag finishing are used since more than 20 years and can be found all over the industry. Even if the requirements on the surface are still the same other factors like a repeatable and reliable processes are coming into the picture. Growing quantities and higher efficiency are more and more important. The influence of manual labour can be reduced by finishing systems with a higher level of automation. New materials like titanium with different coatings or ceramic materials can be also found and need to be processed with the same high level quality.

METHODS:
Rosler Oberflächentechnik GmbH is known as a turn key supplier and process development company not only for the medical industry.

The development of new finishing technologies is mandatory for Rosler. During the last years we introduced a new finishing method other than Drag Finishing – the Surf Finishing technology .

On the example of a femur knee implant the main objective is it to reduce manual labour and bring the implant from a machined level to a high gloss finish of less than Ra 0,02 µm. Whereas regular drag finished parts do still need a certain manual polishing especially in the box area, the new technology allows to finish the implant in one operation including the box area. Certain areas of the part can be processed specifically. The material removal can be controlled. To do so the raw part quality and the right machining setup are playing an important role. The starting roughness after machining spreads from Ra 0,6 µm for a CBN grinded surface up to RA 1µm for a milled part. The finishing goal is usually Ra 0,02 µm and below.

The Surf Finishing process also provides a faster finishing process with a high level of material removal. The process can be easily adjusted to other materials like ceramic which would need a higher cutting action compared to CoCr or Ti materials.

It is important to understand the relation between parts material, material removal rate and finishing goal. Further it needs to be considered the material hardness in relation to the abrasive media, media size and shape.

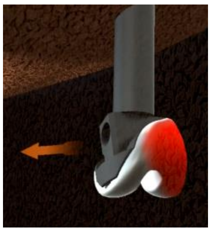
The new technology is approx. 4 -5 times faster compared to regular drag finishing systems.

The Surf Finishing process for medical implants is usually done in several steps. The grinding steps do require the use of process water which contains a chemical compound. The water quality plays another important role and shall be monitored. Rosler developed a digital online tool to help the user to control and monitor the process water without chemical knowledge.

The software allows to set tolerance levels for up to 13 parameters such as water hardness, pH-value, compound concentration, conductivity and bacterial content just to name some of them.

By adding the right data into the software, the operator is informed about possible deviations from the tolerance levels and receives recommendations for action to keep the process water system stable and within the tolerance levels.

RESULTS:



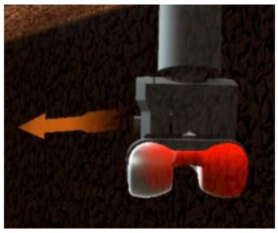


Fig. 1 & 2 directed process of specific areas of a femur

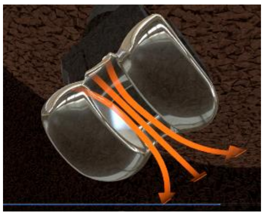


Fig. 3 media flow through the box area

Fig.4 Rosler Smart Solutions – Digital Process water Management

The regulatory challenges for Swiss manufacturers and suppliers

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Ceramic implant = safe? Not sure. Some improvements.

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INTRODUCTION: Nowadays, orthopedic implants are working well. The patients implants may have lifetime beyond 15-20 years. It has dobled in 20 years. By optimizing the design, by testing in vitro implants the research community did contribute to increasing lifetime. What about the debris effect on biology, human organism ?

One may pay attention on ceramic debris toxicity. No toxicity was highlighted with osteoblasts and osteoclasts till now. What about the toxicity with chondrocytes, the precursor of osteoblasts? Ceramic implants were degraded by hip walking simulator and shock machine and debris were cultivated with chondrocytes.

METHODS: The job was consistent to produce enough debris thanks to shocks machine and hip walking simulator and autoclave to mimic ageing. Some works were published 10 years ago [1,2]. Ceramic material has very low wear rate compared to polymer as instance. That is the reason why tests were so long. Moreover the debris extraction protocol was modified to avoid the acid using because of cells culture, i.e chondrocytes.

RESULTS: Ceramic debris involve prostaglandin rate 5 times higher than the control, i.e without debris, Figure 1. Prostaglandin is inflammation sign. Extracellular matrix was modified according to debris presence. Figure 2 presents various debris in presence of cells. The Figure 2 A) presents control. Inflammation beginning is highlighted with UHMWPE (Ultra High Molecular Weight PolyEthylene), Figure 2B). Ceramic debris highlighted, Figure 2C) et D), significantly inflammation signs of extracellular matrix, death marks or dysfunction of chondrocytes. Marks are higher with ceramic than the ones with polyethylene, UHMWPE. Notwithstanding ceramic debris quantity is so low but they do involve deleterious interactions with chondrocytes.

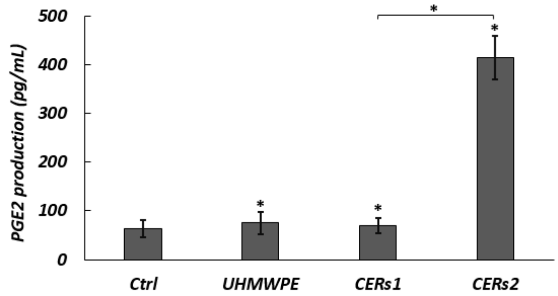

Figure 1: prostaglandin quantity, PGE2, according to particles sort, debris, polymer and/or ceramic, CER.

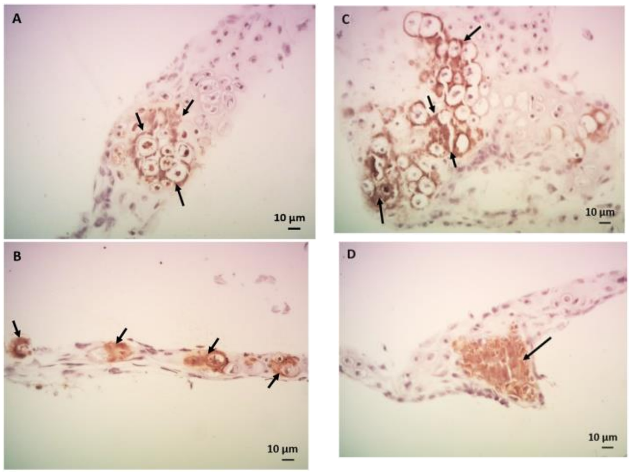

Figure 2: Extracellular matrix of chondrocytes with debris (Von Kossa staining method) A) no particles (no mineralization), B) UHMWPE particles, C) ceramic particles µmetric size, D) ceramic particles nano metric size.

DISCUSSION & CONCLUSIONS:

Shortly, ceramic debris highlight high toxicity (inflammation) compared to UHMWPE debris [3]. Ceramic debris are in low quantity but involve so high inflammation signs.

ACKNOWLEDGEMENTS: The authors acknowledge the AURA Région for its sponsorship. The companies, essentially SERF, are responsible of these tasks.

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[3] J Biomed Mater Res B Appl Biomater. 2022 Feb;110(2):338-349.
doi: 10.1002/jbm.b.34910. Epub 2021 Jul 21.

Segmentation models trained on synthetic images for quantitative analysis of bacterial colonies

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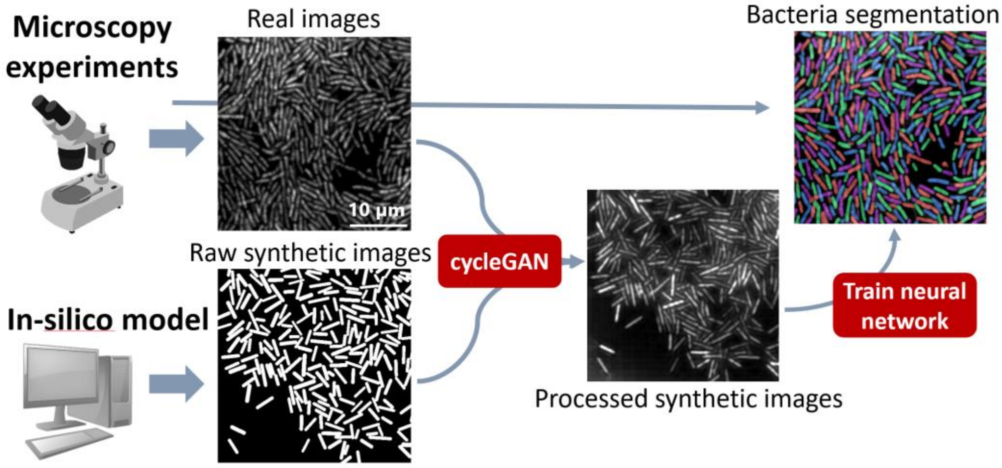

Figure 1: Schematic of workflow for synthetic image creation, processing, and real image analysis using cycleGAN and ML-based segmentation algorithms for single-cell segmentation.

INTRODUCTION: Quantitative image analysis in the life sciences has undergone tremendous progress thanks to recent advances in machine learning (ML) and artificial intelligence. However, a significant limitation is the tedious and error-prone process of creating training data through manual annotation. The resulting lack of widely accessible single-cell segmentation tools leaves many open questions about the underlying mechanics of how collections of living cells interact at surfaces. In particular, the underlying self-organization of bacteria that leads to dangerous infections through biofilm formation and multi-species collaboration remains poorly understood.

METHODS : Here, we adapt image-to-image translation methods to create synthetic training data that require no human labelling (*1*). Algorithms trained on these images achieve single-cell segmentation for bacteria at surfaces, even in systems relevant for research in the life sciences that are not optimized for image quality. We image colonies of *Pseudomonas aeruginosa* and *Staphylococcus* aureus grown on patterned PDMS films in custom microfluidic devices to study the effects of surface properties on bacterial collective behaviors.

RESULTS: Using our novel segmentation approach, we quantify the spatiotemporal organization of the bacteria at different surfaces as a function of cell density and morphology. The accuracy of segmentation models trained entirely on synthetic images exceeds the accuracy of pre-trained models trained on real images available with state-of-the-art segmentation software. Additionally, we achieve simultaneous segmentation and classification of multi-species colonies of *P. aeruginosa* and *Staphylococcus aureus* without differential staining of the two species.

DISCUSSION: Through quantitative imaging in complex environments, these advances promise to provide new insights into the self-organization of bacteria at surfaces. Our live imaging approach through microfluidics may be used as a testing platform to shed light on the mechanisms of novel antibacterial therapies. The use of synthetic images processed by cycleGANs for the creation of bespoke segmentation algorithms could be immensely useful for quantitative image analysis throughout the life sciences.

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Evaluation of the Potential to Improve Medical Device Development by Leveraging Databases

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INTRODUCTION: In the highly regulated field of medical device development, leveraging data offers opportunity to reduce uncertainty and optimize the development process. This work examines the potential of leveraging existing safety and recall data to support and enhance product development activities in the medical industry. Through an example analysis of non-active implants safety notices, the research categorizes failure types, demonstrating the value of data-driven insights for future product iterations and research directions.

METHODS: The following example is provided for illustrative purposes, demonstrating the manner in which existing medical device data can be handled. The example initially illustrates the means of collecting and processing the data and subsequently evaluates its potential utilization within the product development process. For this analysis a German data base form the Federal Institute for Drugs and Medical Devices (BfArM) was used due to the availability of original safety and recall notices issued by the manufacturers, which provide comprehensive details about the events in question. All available safety information and recall notices until June 2024 were investigated. These safety notices are available on the BfArM hompage, along with the original documents issued by the manufacturers can be viewed by the public. The BfArM system lacks the functionality to filter by specific categories, such as product groups or manufacturers, which presents a challenge for analysis. Since there is no option to filter, all entries were scanned with a web crawler, to create an own data base with the following information: date of notification, information category, product group, reference number, subject, manufacturer and PDF-URL. Subsequently the AI Model GPT-4 was used to analyze the documents for the following questions: What was the reason for the notice? What is the root cause? What are the patients' and medical professionals' risks and what actions are taken?

RESULTS: As an example, what information output we can generate, one product group was chosen. Therefore, the notifications were filtered for the product group "non-active implants – bone surgery". In total 685 notices with this product group were found issued by 370 different manufacturers from January 2012 until June 2024. For this purpose, only reports issued in 2024 were considered.

Table 1. Failure categories and amount of entries in 2024 published by BfArM (Germany)

Failure Categories	Amount of reports
Labelling and packaging errors	11
Manufacturing Defects	7
Post-market safety concern	3
Packaging integrity issues	3
Marking and engraving issues	2
Design Flaws	1
Total	27

In 2024 the most common reason for safety issues of on-active implants for bone surgery were summed up under the category labelling and packaging errors, followed by manufacturing defects (Table 1).

DISCUSSION & CONCLUSIONS: Analysing recall information when carried out accordingly can highlight areas that are prone to errors. In order to exploit this potential, the use of AI and LLMs can help to automate this process and analyse the data. Thereby, this information can be used for improving product development processes.

This work demonstrates that medical device databases contain valuable information that, when analyzed systematically, has the potential to support companies and academia in finding areas for improvement to decrease the probability of product failures in the market.

ACKNOWLEDGEMENTS: The authors would like to thank the KIT Center of Health Technologies for the collaboration in this project.

Artificial Intelligence in Orthopaedics: Current Applications and Future Prospects

D. Mathis

Praxisgemeinschaft Clarahof Basel and University of Basel

SHORT ABSTRACT:
We are currently in a phase of exponential growth in the use of AI. Nearly 90% of AI research in orthopedics and traumatology has been published in the past three years. In the majority of studies, AI has been used for image interpretation or as a clinical decision-making tool. As data collection improves, so do the AI-associated possibilities for more accurate diagnostics, patient-specific treatment approaches, improved outcome predictions, and enhanced training. There are also increasing applications of this powerful technology in the field of implant manufacturing. AI offers a potential way to support physicians while maximizing the value of treatment. A fundamental understanding of what AI entails and how it can impact orthopedics and patient care is essential

Poster Session

1	*Real-Time Control of Selective Laser Melting for Fabrication of Miniaturized Structures* L. Wasmer[1], D. Seiler[1], J. Hänggi[1], G. Ragonese[2], M. de Wild[1] [1] University of Applied Sciences Northwestern Switzerland, FHNW, School of Life Sciences HLS, Institute for Medical Engineering and Medical Informatics IM², Muttenz, CH, [2] Politecnico di Torino, Department of Mechanical and Aerospace Engineering, Torina, IT
2	*Advanced selective titanium anodization of machine-readable codes* Ali Mohamad Mahmoud[1], Pierre-Antoine Gay[1], Camille Cardot[2], Amandine Fluchot[2], Joël Matthey[1,2] [1] University of Applied Sciences Haute Ecole Arc Ingénierie CH, [2] Positive Coating SA, CH
3	*Towards Biocompatible Immobilized Antibacterial Coatings on Titanium which kill bacteria on contact* J.J.T.M Swartjes, T. Loontjes, R. Li, Y. Sheng [1] Bioprex Medical, Blauwborgje 31, 9747 AC, Groningen, the Netherlands
4	*Heterogeneity in surface oxides of Ti-based implants* Y. Streit [1], C. Cancellieri [1], P. Hoffmann [1], P. Schmutz [1], M. Cihova[1] [1] Empa - Swiss Federal Laboratories for Materials Science and Technology
5	*Cobalt-based implants: can carbides improve their performance?* Martina Cihova[1], Roberto Cestaro[1], Zoe Bischoff[1], Patrik Schmutz[1] [1] Empa - Swiss Federal Laboratories for Materials Science and Technology
6	*Towards an accurate prediction of magnesium biocorrosion by closer mimicking the in-vivo environment* M. Yalcinkaya, A. Bruinink, M. Cihova, P. Schmutz Laboratory for Joining Technologies and Corrosion, Empa - Swiss Federal Laboratories for Materials Science and Technology, Dübendorf CH-8600, Switzerland
7	*Influence of different potentials during electropolishing on the corrosion behaviour of a magnesium alloy* J. Kloiber[1,2], U. Schultheiß[1,3], V. Anetsberger[1], H. Hornberger[1,2,3] [1] Biomaterials Laboratory, Faculty of Mechanical Engineering, Ostbayerische Technische Hochschule (OTH) Regensburg, Seybothstraße 2, 93053 Regensburg, Germany, [2] Regensburg Center of Biomedical Engineering (RCBE), Ostbayerische Technische Hochschule (OTH) Regensburg, Seybothstraße 2, 93053 Regensburg, Germany, [3] Analytics Center, Faculty of Mechanical Engineering, Ostbayerische Technische Hochschule (OTH) Regensburg, Seybothstraße 2, 93053 Regensburg, Germany
8	*Monitoring the technical cleanliness of implants using correlative microscopy* M. Hiltl[1], C. Gohil[1], H. Brandenberger[2] [1] Carl Zeiss Industrial Quality & Research, Oberkochen, Germany, [2] Gloor Instruments AG, Kloten, Switzerland
9	*Sub-micron X-ray CT accuracy thanks to metrological scan trajectory* S. Burkhard[1], A. Küng[1] [1] Federal Institute of Metrology METAS, Bern-Wabern, Switzerland
10	*Grain size measurement of ceramic materials using deep learning* S. Jakobs[1] [1] RMS Foundation, Bettlach, Switzerland
11	*The identity of implant materials governs the antimicrobial efficacy of SET-M33* A. Maranesi[1,4], S. Mohammadi[2], I. Castañon[3], C. Falciani[3], W. Unger[2*], A. Ferrari[4*] [1] Universitat Politècnica de Catalunya, Department of Material Science and Engineering, Barcelona, Spain,[2] Erasmus University Medical Centre, Department of Pediatrics, Rotterdam, Netherlands, [3] Dipartimento di Biotecnologie Mediche, Universita` degli Studi di Siena, Siena, Italy, [4] Hylomorph AG, Technopark, Zurich, Switzerland

Real-Time Control of Selective Laser Melting for Fabrication of Miniaturized Structures

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INTRODUCTION: The miniaturization of additive manufacturing technologies like Micro-Selective Laser Melting (µSLM) enables the production of increasingly smaller structures with exceptional precision. However, the exact control of the laser melting process within the powder bed plays a critical role.[1] Maintaining a consistent laser power is essential to avoid inhomogeneous heat distribution across different geometric regions within the component. Inadequate control like local overheating can result in undesirable outcomes such as geometric deformities, porosity, warping, distortion, agglomeration, and surface irregularities and compromises the creation of fine structures.

METHODS: By utilizing high-speed pyrometer, optimal target temperatures for the melt pool can be identified. In state-of-the-art µSLM systems, laser power can then be dynamically regulated through a pyrometer-based real-time feedback loop, ensuring precise control of the laser power over various time scales. We demonstrate the application of a µSLM system (ø55 mm platform diameter, 400 W single-mode cw fiber laser, spot size 40 µm, AconityMINI, Aachen, Germany) equipped with dual pyrometry for monitoring the thermal radiation emitted by the melt pool in CoCr powder (d_{50} = 13.5µm, Nanoval, Berlin, Germany).

RESULTS: Fig. 1 shows the positive influence of the pyrometer-controlled feedback.

DISCUSSION & CONCLUSIONS: Our research showcases that the implementation of real-time control mechanisms in the manufacturing process using µSLM technology leads to the production of finer CoCr structures, improved overhangs, smoother surfaces, and denser microstructures. This highlights the potential of in-process control strategies in enhancing the quality and efficiency of additive manufacturing processes. This advancement presents novel opportunities, particularly in the realm of medical applications. However, the establishment of the material-dependent set value and PID parameters for real-time control of the pyrometer target value is a prerequisite.

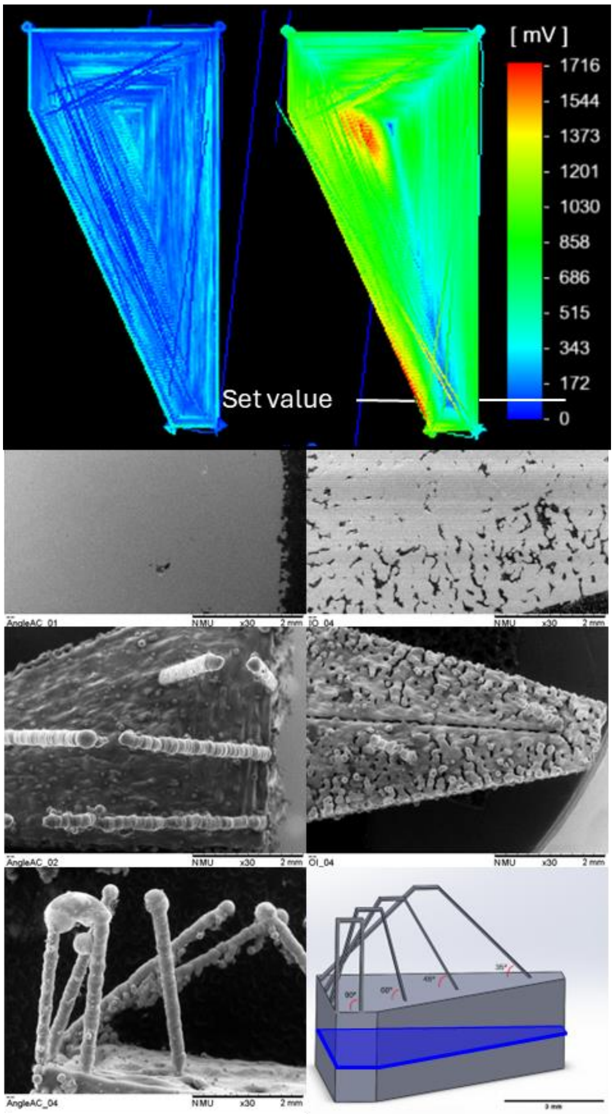

*Fig. 1: Comparing µSLM with (left) and without (right) pyrometric feedback:
1st row: Spatially resolved pyrometric mapping of heat emission. 2nd: SEM of cross section through solid part (1%, resp. 20% porosity). 3rd/4th: SEM and CAD model of ø220 µm struts with 35°, 45°, 60° and 90° inclination.*

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Advanced selective titanium anodization of machine-readable codes

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INTRODUCTION: The Unique Device Identification (UDI) is a distinctive numeric or alphanumeric code related to a medical device or an implant. It consists of a clear and unambiguous identification of specific devices on the market, and it facilitates their traceability throughout their entire life cycle. One approach to generate such codes is laser marking the surface.

METHODS: The interaction of a laser beam with titanium alloys can locally modify the surface properties, namely it can weaken the corrosion resistance of the textured zone. To reinforce the surface properties, a selective titanium anodization process has been developed by means of the Atomic Layer Deposition (ALD). ALD is known to produce pinhole-free and conformal oxide thin films. Sarting with either bare or pre-treated titanium, an amorphous alumina thin film of 160 nm is grown by ALD at 150°C. The precursors used to form the Al_2O_3 coating are trimethylaluminum and water vapor. The aim is to electrically insulate the surface. Then, laser marking is performed with a femtosecond laser system to remove locally the dielectric coating and, simultaneously, smoothly engrave the surface (depth few microns). The outcome is the formation of a current divider at the surface due to freshly ablated titanium and the dielectric properties of the remaining alumina. By applying a controlled voltage, the next step is to anodize selectively the laser-textured code in a sulfuric acid solution (2% vol.), stabilized at 20°C. The final step consists of dissolving the amorphous alumina in an ultrasonic alkaline solution (pH 12.5). Even though titanium alloy properties have been modified by the laser beam, the converted oxide offers an extra protection against corrosion.

RESULTS: The feasibility of a corrosion-resistant 1.5 mm x 1.5 mm machine-readable code has been demonstrated. Not only the performances are increased but also the colored UDI can be used as a marketing vehicle.

Fig. 1: UDI code obtained with the selective the titanium anodization process

DISCUSSION & CONCLUSIONS: By combining chemical vapor deposition, laser and electrochemical technologies, a selective titanium anodization process has been developed. The innovation relies on the substitution of standard lacquer masking methods by an ultrathin amorphous alumina coating. The benefit of the sacrificial ALD masking can be found in the fact that it allows the production of loose parts. Additionally, the mask stripping process does not require any solvent. Finally, the process can be easily scaled up to the industry.

ACKNOWLEDGEMENTS: The authors thank ZimVie company for providing the samples.

Towards Biocompatible Immobilized Antibacterial Coatings on Titanium which kill bacteria on contact

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INTRODUCTION: Antibiotic resistance is one of the largest threats towards global health. Infections are the number one cause of implant failure and with an aging population and improving healthcare in developing countries, its costs and consequences are expected to rise dramatically. Preventing infection by antibacterial coatings is an attractive alternative compared to treatment only. Here, we present an immobilized contact-killing coating, based on a Quaternary Ammonium Compound, successful in preventing bacterial adhesion and subsequent infection.

METHODS: Titanium surgical plates (10 x 4 x 1 mm) were dip coated using a solution of 10% (w/w) hyperbranched polymer, followed by a solution of 25% (w/w) polyethyleneimine. Both steps were followed by curing at elevated temperature for several hours. Quaternization was achieved by addition of 10 mM NaI. Antibacterial activity was tested using the Japanese Industry Standard (JIS) test, using several clinically relevant bacterial strains.

RESULTS: Bacterial strains were tested for their adhesion on coated titanium and reduction ranged from 90 to 100%. SEM images confirmed killing of bacteria by contact, as indicated by the disruption of the cell structure and the release of internal proteins and other substances. An *in-vivo* murine infection model confirmed the ability to prevent infection *in-situ* and showed good biocompatibility.

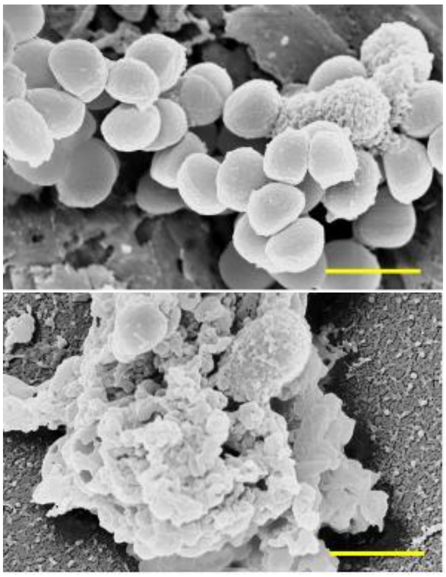

Figure 1. *SEM images of bacteria on untreated titanium (top) and titanium coated with HBP-PEI followed by quaternization with NaI (bottom). Scale bars represent 1µm.*

DISCUSSION & CONCLUSIONS: Implant associated infection are notoriously hard to eradicate due to the resistant nature of biofilms. Prevention by conventional methods such as antibiotics is suffering from antimicrobial resistance and alternatives are scarce. Here, we present a QAC capable of killing bacteria upon contact with the surface, preventing their formation of biofilms. The polyurea coating is durable, withstanding forces commonly seen during placement of (orthopaedic) implants and since its working mechanism is not based on release, it is not depleted during use, offering prolonged protection.
Preliminary *in-vivo* results show good biocompatibility as well as reduction of bacterial challenge for up to at least 4 days, the complete study duration.

Heterogeneity in surface oxides of Ti-based implants

Y. Streit [1], C. Cancellieri [1], P. Hoffmann [1], P. Schmutz [1], M. Cihova [1]

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SHORT ABSTRACT:

The success or failure of Titanium-based implant materials in harsh bodily environments depends on the properties of a thin, passivating native oxide layer (TiO_2) at the implant surface that protects the underlying metal from corrosion and guides catalytic and biological reactions. To optimize biomedical outcomes, MedTech commonly employs various laser and electrochemical surface treatments that result in oxide heterogeneities with neighbouring dissimilar oxide crystal phases. However, the impact on the oxide's barrier properties and implant biocorrosion resistance are insufficiently understood. This study aims to elucidate fundamental structure-reactivity correlations in laterally heterogeneous TiO_2 surfaces that contribute to oxide instability in biological fluids.

Thin-film model systems with systematically varied oxide-phase heterogeneities are synthesized through atomic layer deposition and laser-processing routes. Their bulk and surface properties are analysed through detailed solid-state (AFM, SEM, XRD, Raman spectroscopy) and electrochemical surface analytics (impedance spectroscopy, photo-electro-chemistry), with a particular focus on phase boundaries, which present potential sites for micro-galvanic coupling and preferential corrosion attack. This study will lay the foundation to establishing structure-property relationships that link reactivity of proteins and oxide stability with crystallographic, electronic and topographic properties, and ultimately serves as a fundamental analytical strategy to better understand the implant-biology interaction.

Cobalt-based implants: can carbides improve their performance?

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SHORT ABSTRACT:

Continuous materials development has pushed the optimization of cobalt–chromium–molybdenum (CoCrMo) alloys' composition and microstructure towards maximized mechanical performance. However, the concomitant impact on the resistance towards biocorrosion was left behind. In clinical practice, two CoCrMo alloys of different carbon content are specified by ASTM: low (LC, <0.14 wt.%) or high-carbon (HC, 0.15-0.35 wt.%). The latter contain a significant volume fraction of carbides to boost hardness, though their impact on biocorrosion susceptibility and implant durability remains unclear.

In this study, we scrutinize the biocorrosion behavior of HC-CoCrMo alloy in comparison to LC-CoCrMo. Their corrosion behavior is studied in correlations to the underlying microstructure, aiming at establishing a thorough understanding of the microstructure–corrosion susceptibility correlations in relevant physiological media. Analytical scanning electron microscopy (SEM/EDS) confirmed the presence of carbides in HC-CCM only, and Kelvin Probe Force Microscopy (KPFM) revealed that these carbides differ in their surface potential from the surrounding matrix – a key risk contributor for localized corrosion through formation of micro-galvanic cells. We further relate these local observations with macroscopic electrochemical investigations (impedance spectroscopy and wear-assisted corrosion analysis) to assess the implications of micrometer-sized carbides on the overall implant durability and their role in clinically observed implant failure.

Towards an accurate prediction of magnesium biocorrosion by closer mimicking the in-vivo environment

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INTRODUCTION: Magnesium (Mg) has attracted great interest as a biodegradable metallic implant due to the formation of bioresorbable corrosion products during its degradation in the body. Yet, a challenge in the reliable prediction of degradation mechanism is that currently performed in-vitro experiments typically induce the formation of corrosion products with different chemical structures and transport properties than those observed in animal studies (in-vivo) [1].

From a materials perspective, another complexity level is generated by the low solubility of alloying and impurity elements in magnesium, resulting in the formation of cathodic secondary intermetallic phases (IMP's) [2]. As the majority of published in-vitro studies involved such heterogeneous Mg surfaces, it remains unclear, if the corrosion product layer actually limits magnesium's anodic oxidation or decreases the cathodic reactivity of secondary phases.

To investigate the influence of these cathodic secondary phases on the Mg corrosion behavior in a physiological mimicking environment, an experimental setup was developed to include often overlooked in-vivo aspects such as solution flow, physiological pH buffering on Mg surface. Two very different materials were compared: low-purity Mg (99.9 wt% Mg; Fe >200 ppm), which contains a high amount of Fe-rich intermetallic phases, and ultra-high purity magnesium (XHP) (>99.999 wt% Mg; Fe <1 ppm) as a homogenous substrate without any secondary phase.

METHODS: Samples were exposed to our new formulation, based on an extensive literature review of the real measured values of inorganic ions and organic species, of a simulated interstitial body fluid (SIBF) that mimics the composition of human interstitial body fluid [3]. The pH of SIBF is regulated with dynamic bicarbonate buffering and flown over Mg. The electrochemical reactivity of Mg samples was then evaluated by performing Electrochemical Impedance Spectroscopy (EIS). The samples were subsequently characterized using Scanning Electron Microscopy/Energy Dispersive X-ray Spectroscopy (SEM/EDS).

RESULTS: Fig.1 shows that the precipitation of corrosion products forms a micrometer-thick porous intermediate layer allowing but limiting ionic/water transport on the Mg matrix and IMP's.

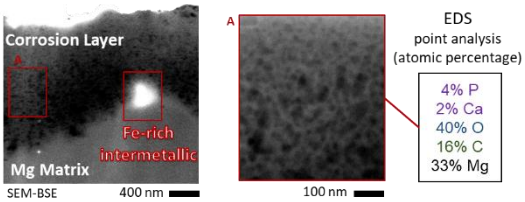

Fig. 1: Ion-milled cross-section of low-purity Mg, after 24 in SIBF (37 °C, 1 µl/sec, pH 7.4)

The EIS results further indicated dramatically reduced cathodic reactivity of IMP's, where the obtained values became comparable to the one obtained for ultra-high purity Mg.

To reveal the individual effect of precipitations, ion-specific products properties were studied for both purity degrees. This approach made it possible to isolate and assess the barrier effect of Mg-hydroxide, Mg-phosphate, and Ca-phosphate on a heterogonous and homogenous surface.

DISCUSSION & CONCLUSIONS: Free Ca^{2+}, Mg^{2+} and PO_4^{3-} ions levels can cause opposite effects on corrosion mechanisms depending on the presence of Fe-rich intermetallic phases. Therefore, observed microstructure-dependent variations between in-vivo and in-vitro studies may be mainly caused by non-physiological test solutions and pH buffering. We further aim to understand how organic compounds and pH levels affect corrosion products to provide a more nuanced understanding of Mg biocorrosion.

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Influence of different potentials during electropolishing on the corrosion behaviour of a magnesium alloy

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INTRODUCTION: Electropolishing is an attractive surface treatment to improve the corrosion behaviour of magnesium for temporary implant applications [1], but it is not well known how different polishing potentials affect the degradation of this bioresorbable metal.

The aim of this study was to investigate the influence of a potential variation during electropolishing on the corrosion behaviour of AZ31.

METHODS: Electropolishing of the AZ31 samples was carried out in a mixture of phosphoric acid, ethanol and deionized water at different potentials from the Open Circuit Potential (OCP) to the transpassive region (vs. Ag/AgCl 3M) (Fig. 1, left).

The degradation behaviour was observed by potentiodynamic polarization in Dulbecco´s Modified Eagle´s Medium (DMEM) (Fig. 1, right).

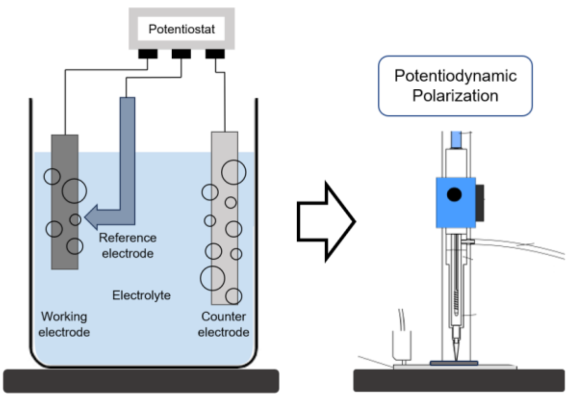

Fig. 1: Schematic illustration of the electropolishing setup (left) and the in vitro testing of the degradation behaviour of electropolished AZ31(right).

RESULTS: The developed electropolishing process improved the magnesium surface by providing a bright and mirror-like surface, a low roughness and a low corrosion rate. Electropolishing reduced the corrosion rate to 0.1 mm/year (at 200 mV) compared to 1.28 mm/year after mechanical grinding (MGrid) (Fig. 2).

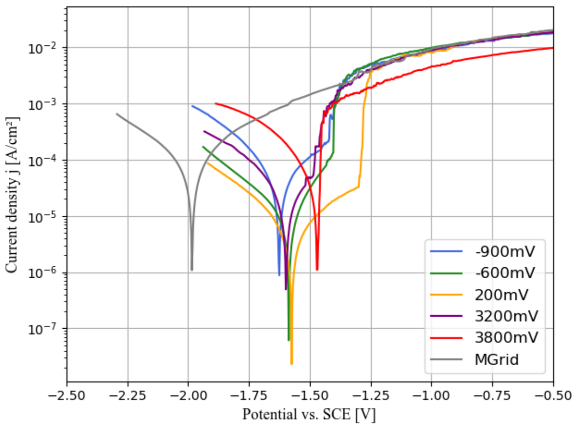

Fig. 2: Corrosion behaviour of a mechanically ground magnesium alloy AZ31 compared to the electrochemically treated samples electropolished at five different potentials.

DISCUSSION & CONCLUSIONS: In principle, potentials in the passive and transient range not only lead to a reduction in roughness, but also to a significant increase in corrosion stability. To assess the long-term corrosion behaviour, future investigations of the surface layer formed after electropolishing must be carried out.

ACKNOWLEDGEMENTS: We gratefully thank Regensburg Center of Biomedical Engineering (RCBE) for the support of laboratory consumables.

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MONITORING THE TECHNICAL CLEANLINESS OF IMPLANTS USING CORRELATIVE MICROSCOPY

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INTRODUCTION: Medical products, such as implants, have a direct impact on peoples' lives, and producing a contaminated product would pose a high health risk to the patient. To avoid such cases, medical technology companies need to fulfill stringent regulatory requirements stipulated by various authorities regarding quality. For this reason, technical cleanliness plays a key role in quality assurance, within all aspects of the medical industry, e.g., manufacturing, production, production environment, packaging and even transportation. Solutions are ready for deployment at every step of the process to detect and characterize particulates that should not be present; a mandatory requirement when looking to comply with regulations, whilst improving productivity through reduced scrap and/or rework.

METHODS: The analysis of residual dirt or particulate contaminants arising during an individual production process can (in addition to light microscopy) also be determined by automated particle analysis using a Scanning Electron Microscope (SEM). The SEM allows a high spatial resolution down to nanoscale, a high depth of field and combined with Energy Dispersive X-ray Spectroscopy (EDS) provides vital elemental composition of each particulate contaminant. Light and electron microscopes are complemented by the correlative solution approach (correlative microscopy) which is also open to other analytical methods. The correlative workflow allows quick and easy relocation of regions of interests, across different imaging methods and analysis technologies. The coordinates of a critical particulate contaminant or a critical area can easily be transferred between each system and thus allowing to use various visual and analytical methods, all from the exact same location.

RESULTS: *This supplementary multi-modal data from the various correlative methods, provides more answers to the key questions of* where, why, and how many contaminates are being detected. This approach allows to take preventive steps, which eliminates contamination, ensures high quality standards, optimum functionality and longevity of the medical implants being produced.

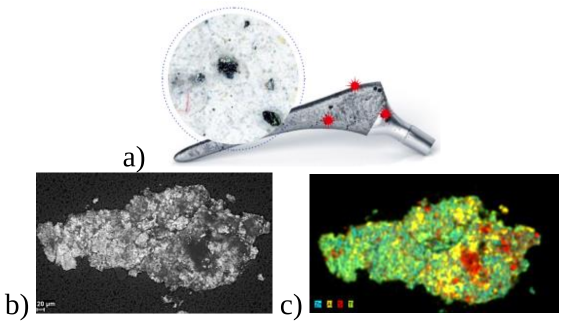

Fig. 1: Contaminated implant: Correlative particle analysis using a) light and b) electron microscope with c) EDS elemental mapping. Ti [green], Si [red], Al [yellow], Zn [blue].

DISCUSSION & CONCLUSIONS: Medical manufacturers, suppliers and end users demand ever-increasing quality standards, so advanced technical cleanliness is fundamental to eradicating contamination from manufactured parts and components, including the relevant quality gates along the entire production chain. The automated workflow and the correlative microscopy approach are a step forward in detecting and classifying particulate contamination, and facilitating to comply with industry quality standards, including GxP regulations. The GxP good practice makes the analyzes steps traceable and therefore compliant with regulations and certification requirements (e.g., VDI 2083 Part 21).

SUB-MICRON X-RAY CT ACCURACY THANKS TO METROLOGICAL SCAN TRAJECTORY

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INTRODUCTION: Real case studies are presented of a unique X-ray computed tomography (CT) system for technical applications which is capable of reaching sub-micron accuracy for small objects (< 4 mm) with dimensional traceability, providing exceptional measurement capabilities for complex-shaped objects.

This level of accuracy is made possible by precisely measuring the full CT system geometry for every projection during a scan and incorporating this geometrical information in the reconstruction of the scan volume, combined with highly stable environmental conditions. In addition to correcting unwanted movements of the setup during a scan, this metrological setup can also be used for extending conventional circular scans to flexible trajectories, improving image sharpness uniformity throughout the scan volume.

METHODS: The metrological measurement of the CT system geometry relies on 3 different methods (Fig. 1):

1. The positions of the rotation axis and detector stages along the X-ray beam axis and the vertical position of the sample are measured using calibrated infrared laser interferometers
2. Mechanical movements of the X-ray tube and transverse movements of the rotation axis and detector stages are tracked using laser beams in the visible range directed at CMOS sensors
3. Movements of the X-ray focal spot relative to the X-ray tube are detected by analysing the projected positions of markers mechanically mounted on the X-ray tube in the radiographies.

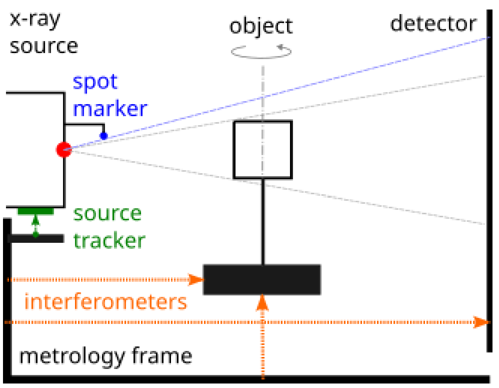

Fig. 1: Schematic of the metrological CT setup

The projective magnification of the System is calibrated using a traceably characterized reference object. The interferometric measurement of changes in the rotation axis and detector stages preservers traceability of the system unless an interferometer beam is disrupted.

RESULTS: While the general accuracy of this system has previously been demonstrated for sphere centre distances [1], which have limited sensitivity to image blurring and surface determination offsets, the incorporation of all geometrical information and focal spot movements in particular for the volume reconstruction can lead to a significant improvement of local image sharpness (Fig. 2).

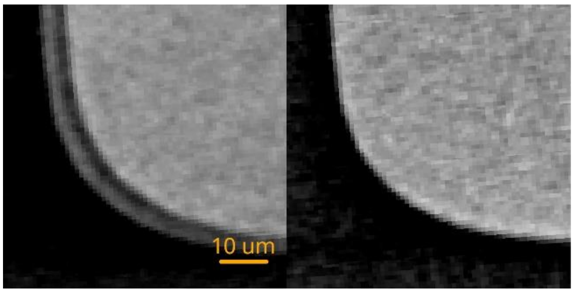

Fig. 2: Example of local image sharpness of conventional circular reconstruction (left) vs. metrological reconstruction (right) of the same data of a steel object at a voxel size of 0.9 µm.

DISCUSSION & CONCLUSIONS: Such an X-ray CT system is capable of reliably producing traceable dimensional measurements with sub-µm accuracy for small objects (< 4 mm for 1 µm voxel size). Measurements of hole diameters with < 1 µm accuracy (relative to tactile reference measurements) have even been achieved in 8 mm steel samples with 2.15 µm voxel size.

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Grain size measurement of ceramic materials using deep learning

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INTRODUCTION: Grain size determination is crucial for characterizing materials, particularly ceramics, as their microstructure impacts properties and performance of the material. Traditional manual methods like line-intercept counting are labour-intensive and prone to human error. According to [1], manual determination of grain size will deviate by ±10% from the true grain size, depending on the number of grains evaluated, the number of phases and the homogeneity of the material.
Machine learning, particularly neural networks like U-Net [2], offer a more efficient and consistent approach, processing large datasets. This study applies a U-Net Algorithm to SEM images of Al_2O_3 & ZrO_3 ceramic material, demonstrating its effectiveness in grain boundary segmentation.

METHODS: The dataset consisted of 30 raw images, each 2048×1536 pixels in resolution. 15 images were randomly chosen and split into 90% training and 10% test sets. The remaining 15 images were used for validation of the process at the end. In the first 15 images, the grain boundaries were labelled red by hand and the image was then converted to a binary image so that only the grain boundaries remained (see Fig. 1). Once the image with the binary grain boundaries is available, the grain sizes can be analysed using classical methods (e.g. watershed algorithm). For the input into the neural network, all images were divided into 512×512 patches, and data augmentation (rotation and mirroring) increased the dataset eightfold, resulting in 96 patches per image. The U-Net model, widely used for image segmentation, was structured with five layers and contained 1.9 million parameters. The model's performance was assessed using IoU (Intersection over Union) and Dice scores, with comparisons made against manually measured grain sizes following ISO standards [1].

RESULTS: For the evaluation of the procedure, the 15 validation holdback images underwent manual analysis, and the results were compared. The average deviation from manual analysis was 4.5%. The determination of the grain size was separated by phase using histogram thresholding of the grey values of the images (see Fig. 2).

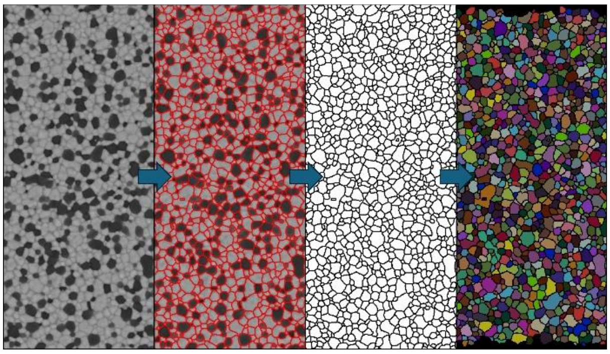

Fig. 1: Once the neural network has been trained, the labour-intensive labelling step can be done by the algorithm.

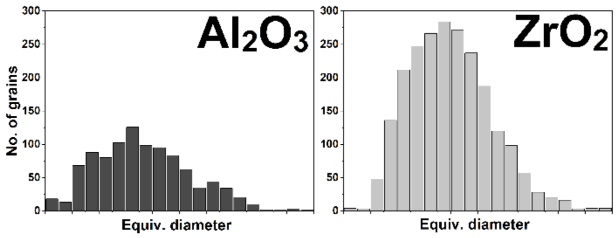

Fig. 2: Result of the segmentation of Fig. 1, with differentiation by phase.

DISCUSSION & CONCLUSIONS: This study emphasises the effectiveness of neural networks for automatic grain size measurement in SEM images of ceramic materials. The neural network provides a consistent assessment, reduces subjective bias and offers a reliable alternative to manual segmentation. In addition, more data can be obtained in less time. New characteristics of the grains, such as aspect ratio or orientation, could also be analysed without additional effort. Histograms, as shown in Figure 2, are also very difficult to produce manually. Visual evaluation remains important, as IoU and Dice scores do not always align with visual impressions.

ACKNOWLEDGEMENTS: This project was internally funded by RMS Foundation.

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THE IDENTITY OF IMPLANT MATERIALS GOVERNS THE ANTIMICROBIAL EFFICACY OF SET-M33

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INTRODUCTION: CIED implant infections are challenging due to their recurrence and resistance to standard antibiotics, despite antiseptic protocols. Opportunistic pathogens like Staphylococci and E. coli are common[1]. Antimicrobial peptides (AMPs) such as SET-M33 offer a solution by targeting bacterial membranes without fostering resistance[2]. This study explores SET-M33's efficacy when used with CIED implant materials (titanium, silicone, PTFE) and protective envelope materials (Biocellulose, PLGA electrospun membrane, and PGA mesh).

METHODS: Material surface properties (roughness, hydrophilicity, porosity) were assessed. SET-M33 was synthesized via Fmoc chemistry, functionalized with TAMRA, and tested for diffusion through protective envelopes. Materials soaked in SET-M33 were inoculated with E. coli and S. aureus and incubated overnight. Antimicrobial efficacy was evaluated by colony counting.

RESULTS: The tested materials displayed distinct surface characteristics, with porosity being a critical factor in the diffusion of SET-M33 through the envelope materials, with PGA mesh having the highest porosity and BC the lowest. BC retained 56% of the peptide, reducing its efficacy, while PGA allowed complete release in 90 minutes.

SET-M33 combined with envelope materials showed enhanced antibacterial activity compared to direct coating on titanium and silicon, with BC achieving full bacterial inhibition. However, low-porosity materials limited diffusion, restricting the effect to treated sides**.**

Table 1. Diffusion rates and effective diffusion coefficients of TAMRA-SETM33 across three types of membranes: BC, Espn, and Mesh

Envelope materials	Diffusion rate (mg/h)	D_{eff} (cm^2/h)	Drug loss (%)
BC	$0.7\times10^{-3} \pm 5.9\times10^{-5}$	0.0083 ± 0.0005	56.3 ± 1.7
Espn	$1.4\times10^{-3} \pm 5\times10^{-5}$	0.003 ± 0.001	14.3 ± 1.7
Mesh	$4.126\times10^{-1} \pm 0.007$	1.07 ± 0.11	0

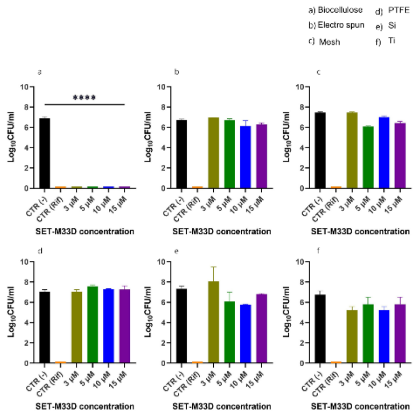

Fig 1. Quantitative growth of S. aureus on BC (a), Espn (b), Mesh (c), PTFE (d), Si (e) and Ti (f) treated with increasing concentrations of SET-M33D, compared to untreated and Rifampin treated controls.

DISCUSSION & CONCLUSIONS: SET-M33 has potential as an antimicrobial agent for protecting CIED implants, either through direct coating on implant materials or in combination with protective envelope materials. However, its current formulation is less effective when applied as a simple coating on implant surfaces. The efficacy of SET-M33 improves when used with envelope materials, which can better absorb the peptide solution. Nonetheless, low-porosity membranes limit diffusion, leading to partial antimicrobial protection. Future research will focus on optimizing the peptide structure to reduce steric hindrance or improve interactions with surfaces of varying roughness and hydrophilicity, enhancing its protective capability

ACKNOWLEDGEMENTS: This work was supported by a European Union Horizon Europe MSCA DN-ID grant (grant number 101073263)

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Notes

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