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

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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.

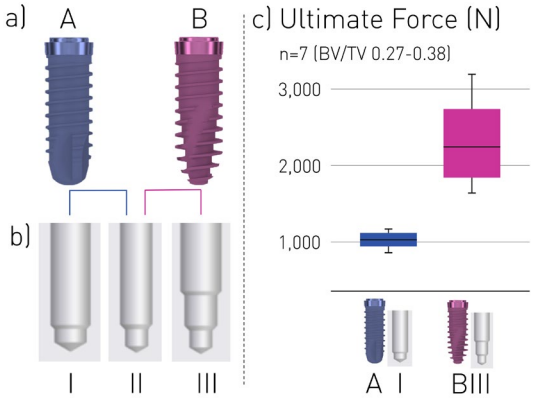

Fig. 1ab: I: osteotomy cylindrical implant A, II: underprepared osteotomy, III: osteotomy tapered implant B. 1c: UF simulation for AI and BIII.

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

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

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INTRODUCTION: 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).

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

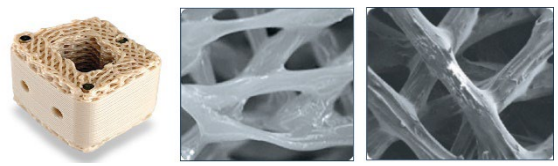

Figure 2: 3D printed Curiteva spinal cage using Evonik VESTAKEEP® i4 3DF PEEK filament material. Magnification x40 (middle) and x100 (right)

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.

RESULTS: 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).

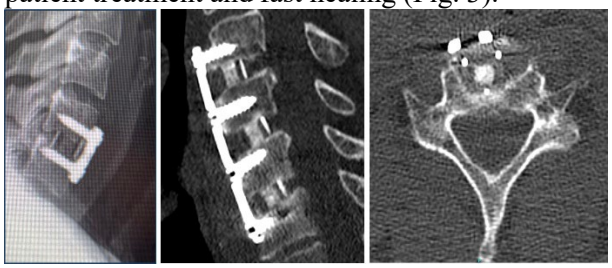

Figure 3: X-ray images of 1-level spinal implant (left), 3-level spinal implant (middle) and cross section (right) © Curiteva.

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

DISCUSSION & CONCLUSIONS: 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.

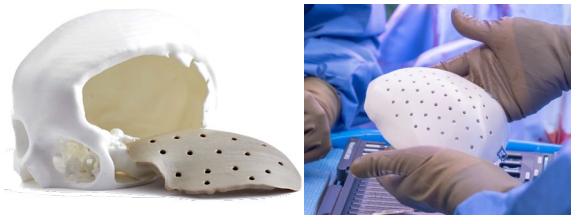

Fig. 1: Printed cranial PEEK implant (left) cranial PEEK implant in OR (right).

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

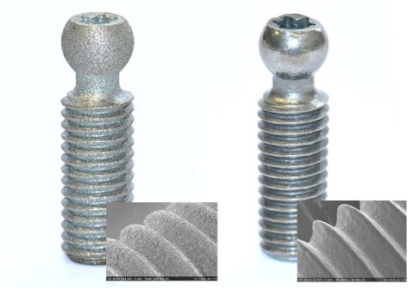

Fig. 1: Medical screw (diameter 7.8 mm) before (left) and after (right) electropolishing.

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).

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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.

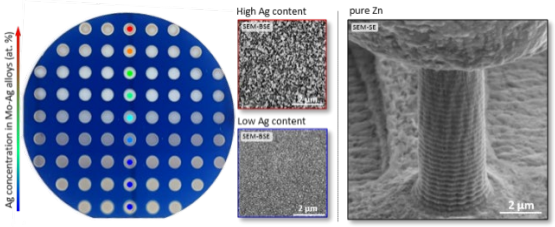

Fig. 1: Left: Thin film Mo-Ag material library synthesized by PVD. Right: Electrodeposited Zn micropillar (Ø5µm) tested under compression inside an electron microscope.

CONCLUSIONS: 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.

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

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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:

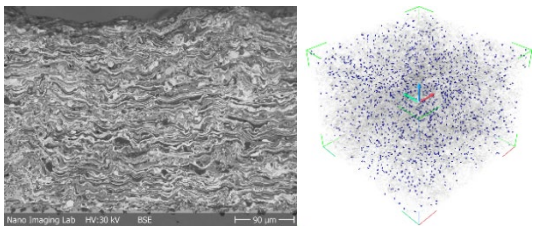

Fig.1 (left) SEM image of the cross-section of the coating. (right) The analysed volume from the laminography showing the pores with the size of 1 x 10^{-8} mm^3 to 0.8 x 10^{-8} mm^3.

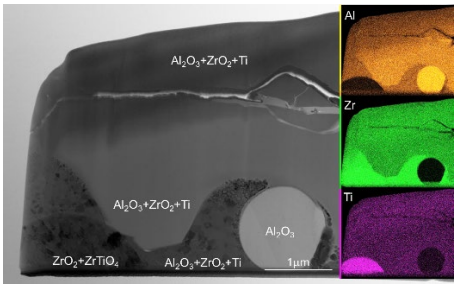

Fig.2 EDX mapping of the TEM image and summarizing phases and elements found.

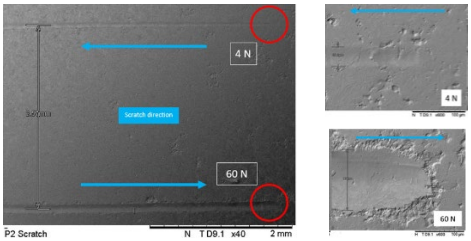

Fig. 3 SEM TOPO image of scratches. The scratch direction is indicated by blue arrows. Plastic deformation is visible from the start (red circles), breakouts are visible at higher values.

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.

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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.

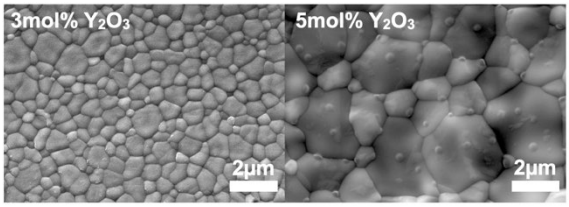

Fig. 1: Same same but different: Zirconia crystal grain sizes depend on the yttria content.

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).

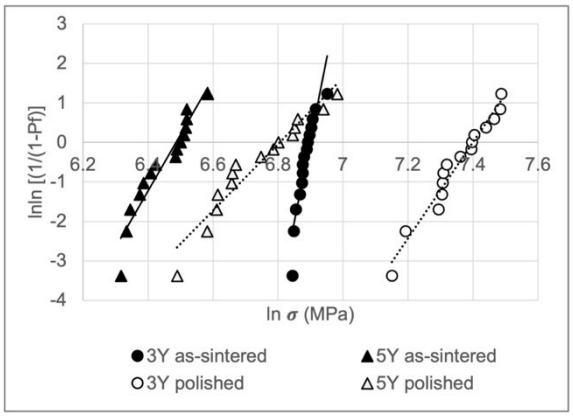

Fig. 2: Weibull graph based on biaxial flexural strength values for a 3/5mol% yttria stabilized zirconia material with surfaces that were as-sintered or polished.

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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Rosler Oberflächentechnik GmbH, Switzerland

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.

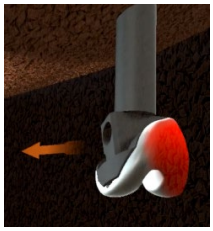
The new technology is approx. 4 -5 times faster compared to regular drag finishing systems.

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:



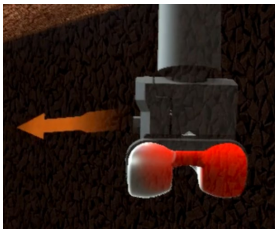


Fig. 1 & 2 directed process of specific areas of a femur

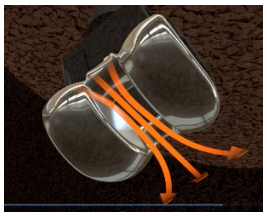


Fig. 3 media flow through the box area

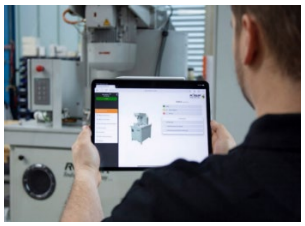


Fig.4 Rosler Smart Solutions – Digital Process water Management

Ceramic implant = safe? Not sure. Some improvements.

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INTRODUCTION: Nowadays, orthopaedic implants are working well. The patients implants may have lifetime beyond 15-20 years. It has doubled 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 to 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 a very low wear rate compared to polymer for 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 involves prostaglandin rates 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 the presence of cells. 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.

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

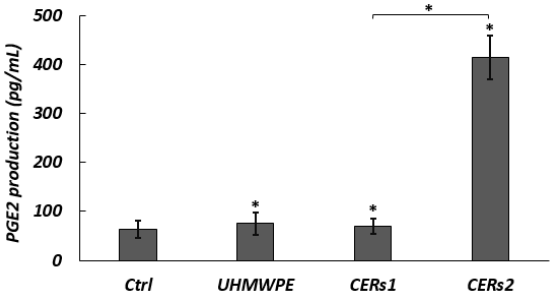

Figure 1: prostaglandin quantity, PGE2, according to particles sort, debris, polymer and/or ceramic, CER.

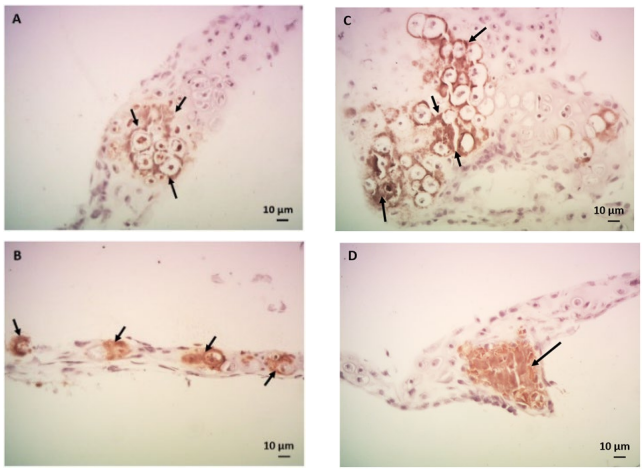

Figure 2: Extracellular matrix of chondrocytes with debris (Von Kossa staining method) A) no particles (no mineralization), B) UHMWPE particles, C) ceramic particles µmetric size, D) ceramic particles nano metric size.

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REFERENCES:

[1] Materials (Basel). 2017 May 24;10(6):569. doi: 10.3390/ma10060569.

[2] J Mech Behav Biomed Mater. 2017 Jan;65:600-608. doi: 10.1016/j.jmbbm.2016.09.019. Epub 2016 Sep 19.

[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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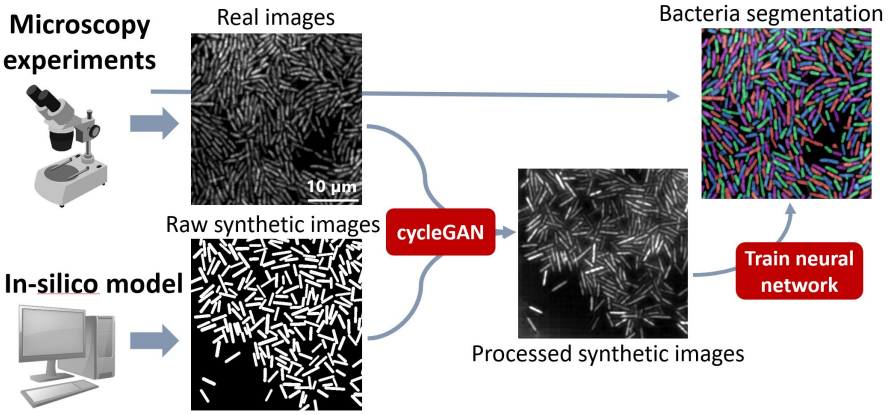

Figure 1: Schematic of workflow for synthetic image creation, processing, and real image analysis using cycleGAN and ML-based segmentation algorithms for single-cell segmentation.

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.

REFERENCES:

1. V. Hickl, A. Khan, R. M. Rossi, B. F. B. Silva, K. Maniura-Weber, arXiv:2405.12407 (2024).

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 way 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 homepage, 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 number of entries in 2024 published by BfArM (Germany)

Failure Categories	Number 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.

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