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Materials and Surface Technology for Implants

Tuesday, 19th March 2019

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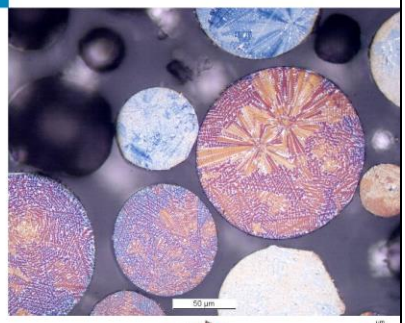

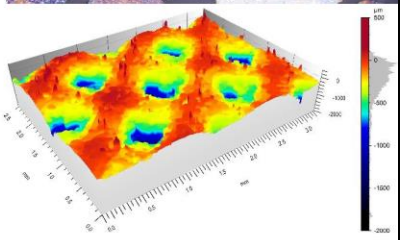

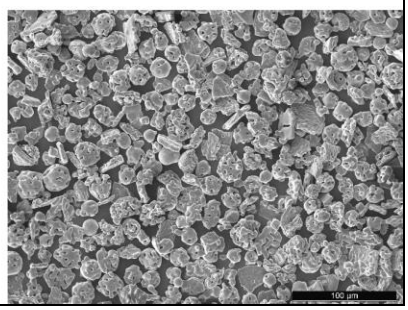

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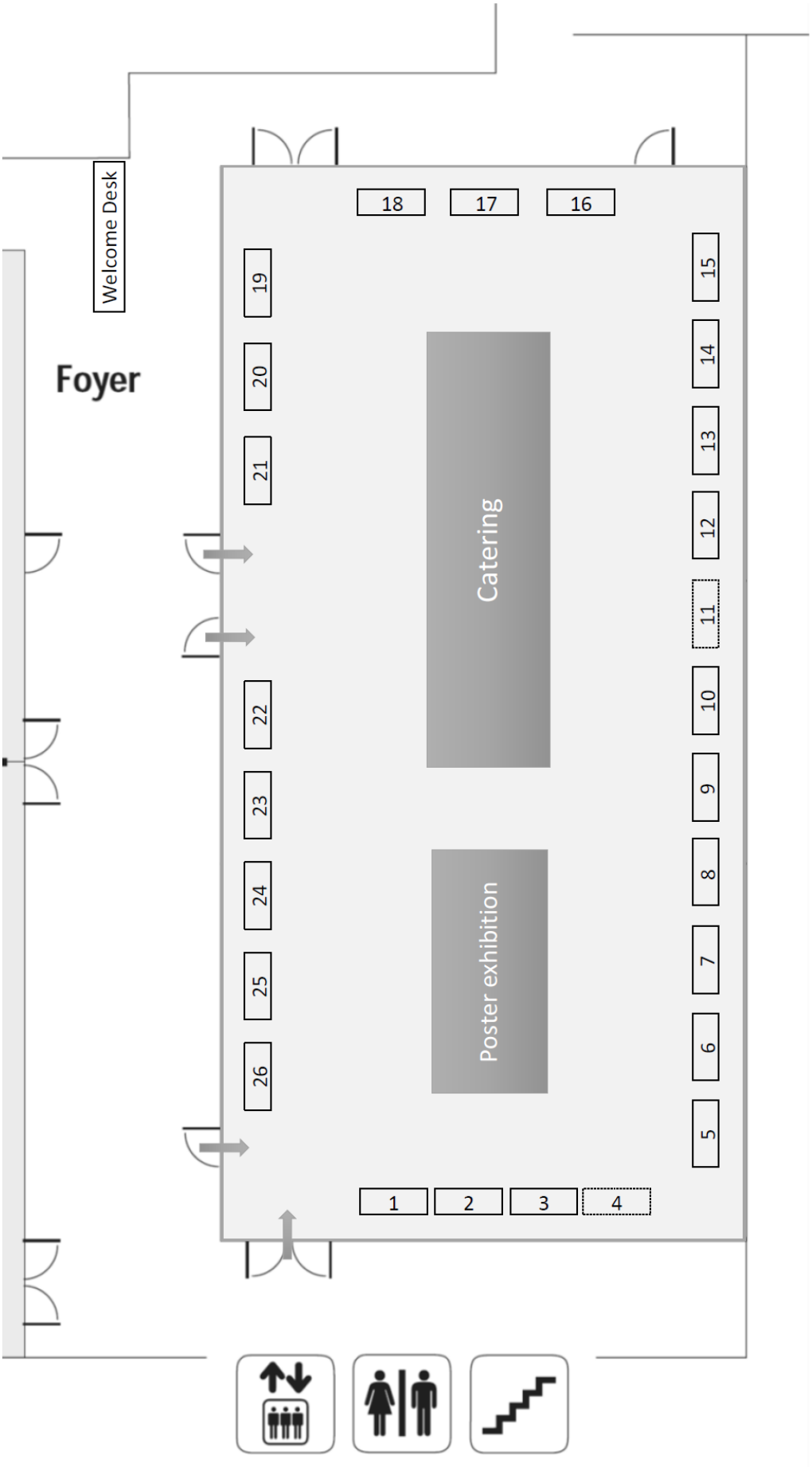
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Catering
Poster exhibition

Meeting Program

08:30	Registration / Welcome Coffee
09:00-09:15	Welcome message
	Session 1: *Infections* Chairperson: Lukas Eschbach
09:15-09:45	Keynote 1: Dr. Mario Morgenstern, Universitätsspital Basel, Switzerland: *The role of biomaterials in prophylaxis and treatment of fracture related infections*
09:45-10:30	Flash Presentations Exhibitors and Posters (1 min. each)
10:30-11:00	Break (Exhibition and Poster)
	Session 2: *Surfaces / Coatings* Chairperson: Michael de Wild
11:00-11:20	Dr. Cyril Voisard, Medicoat AG, Mägenwil, Switzerland: *Porous coating by vacuum plasma spray on ceramics hip resurfacing implants*
11:20-11:40	Dr. Agnese Carino, Paul Scherrer Institut, Villigen PSI, Switzerland: *Implant surface modification by a controlled biomimetic approach*
11:40-12:00	John Disegi, Advanced Biomaterial Consulting LLC, Reading, USA: *Development of an Anodized Titanium Implant Film with Antimicrobial Properties*
12:00-12:20	Jakob Oranskiy, Dento-L-Master, LLC, Moscow, Russia: *Protective coating application for individual dental superstructures from CoCr alloys*
12:20-12:40	Simona Rohrer, RMS Foundation, Bettlach, Switzerland: *Characterization of particulate contaminants and its challenges*
12:40-14:00	Lunch (Exhibition and Poster)
	Session 3: *Material Integrity* Chairperson: Francisco Faoro
14:00-14:30	Keynote 2: Dr Lari Sapoznikov, Basal Implantology Center, Tel Aviv, Israel: *Autogenic dentin as ever best grafting material*
14:30-14:50	Dr. Jean Geringer, Mines Saint-Etienne, Saint-Etienne, France: *Effect of Ti on the wear properties of CoCrMo alloy. Investigation under fretting corrosion*
14:50-15:10	Dr. Roman Heuberger, RMS Foundation, Bettlach, Switzerland: *Particles and Ions Generated in Total Hip Joint Prostheses: In Vitro Wear Test Results of UHMWPE and XLPE Acetabular Components*
15:10-15:30	Antoine Pfeil, ICUBE Laboratory, University of Strasbourg, INSA, Strasbourg, France: *Evaluation of gamma irradiation impact on 3D-printed multimaterial polymer*
15:30-16:00	Break (Exhibition and Poster)
	Session 4: *Surface / Quality* Chairperson: Simon Berner
16:00-16:30	Keynote 3: Martin Schuler, AO Foundation, Zurich, Switzerland: *Surviving the medical device regulation*
16:30-16:50	Dr. Ella Dehghani, Ernst & Young, Zurich, Switzerland: *How advancement in surface science and technology will support the challenges of upcoming regulations*
16:50-17:10	Dr Boopathy Dhanapal, Zimmer Biomet, Winterthur, Switzerland: *Cleanliness aspects of coated orthopaedic devices*
17:10-17:30	Prof. Michael de Wild, FHNW, Muttenz, Switzerland: *Holographic identification of titanium implants*
17:30-17:45	Roundup
17:45	10th Anniversary Aperitif

Porous coating by vacuum plasma spraying on ceramics hip resurfacing implant

C Voisard[1], S Berner[1], C Halewood[2], P Gruner[1]

[1] Medicoat AG, Mägenwil, CH. [2] Embody Orthopaedic Ltd, London UK

INTRODUCTION: Clinical complications following metallic ions release from metal-on-metal hip resurfacing implants has led to an early reduction in the deployment of this type of material combination [1]. The need for low wear material pairing and large diameter implants for lower dislocation risks remains though and drives development of alternative solutions like ceramics-on-ceramics bearings and full ceramics implants. Coating the ceramic liner suppresses indeed the need of a metallic case (cup) and allows larger ceramics design. In this study a new coating process of titanium and hydroxyapatite using vacuum plasma spraying (VPS) has been specifically developed for a high strength zirconia-toughened alumina (BIOLOXdelta from CeramTec, Plochingen Germany) and applied to a new resurfacing full ceramics design [2].

METHODS: A rough and porous titanium coating subsequently covered by a hydroxyapatite (HA) coating has been applied to a new resurfacing ceramics prosthesis consisting of a femoral head and an acetabular cup, both made of BIOLOXdelta ceramics [2]. The titanium layer was directly coated on the smooth ceramic surface. Conventional grit blasting process of the surface has been prevented to avoid reduction in fracture strength. Furthermore, a pull off test [3] was developed to assess the adhesion strength directly on the implant surface in addition to the tests required by the international standards [4] like adhesion strength [5], biaxial flexural strength [6] performed with flat coupons.

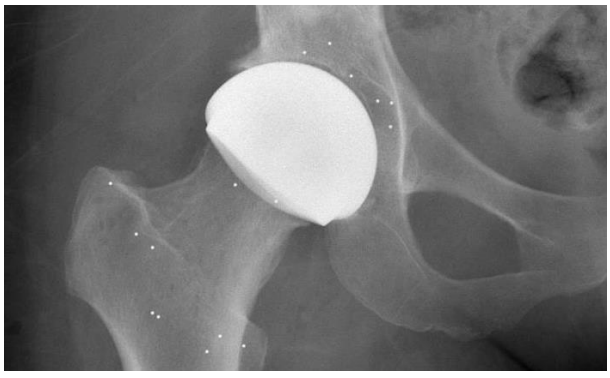

Fig. 1: Post Op X-Ray of H1 resurfacing system (Courtesy Embody Orthopaedics Ltd.).

RESULTS: Biaxial flexure strength of the ceramics substrate of 773 MPa as measured on test coupons is not significantly reduced by the VPS coating process. Nor is the static adhesion tensile strength of 86 MPa influenced by the ceramics surface preparation, as measured on various surfaces (as-fired, milled, ground and polished). Autoclave heat treatment to simulate hydrothermal aging and immersion in Ringer solution slightly reduced the adhesion strength to values in the order of 75 MPa but without reaching the critical value of 22 MPa [4]. The coating adhesion strength could be verified directly on implants with the local pull out test.

DISCUSSION & CONCLUSIONS: Both as-coated and aged coatings have been tested and high adhesion strengths could be demonstrated under various conditions, well above the minimum value of 22 MPa defined by various international standards. The novelty of this process is that the implants are not grit blasted and thus the integrity of the ceramics could be preserved as demonstrated with biaxial flexure strength.

REFERENCES: [1] Sershon et al (2016) *Curr Rev Musculoskelet Med* **9(1)**:84-92. [2] Multicentre Observational Study Evaluating the Clinical Outcome of the H1 Ceramic Hip Resurfacing Arthroplasty (H1HRA), *ClinicalTrials.gov* Identifier: NCT03326804. [3] ASTM D4541: Standard Test Method for Pull-Off Strength of Coatings Using Portable Adhesion Testers. [4] ISO 13179-1 Implants for surgery-Plasma sprayed unalloyed titanium coatings on metallic surgical implants. [5] ASTM F1147: Standard test method for tension testing of calcium phosphate and metallic coatings. [6] ASTM C1499: Standard Test Method for Monotonic Equibiaxial Flexural Strength of Advanced Ceramics at Ambient Temperature.

Implant surface modification by a controlled biomimetic approach

A Carino[1], A Testino[1], E Mueller[2], M de Wild[3], F Dalcanale[3], P Gruner[4], W Moser[5], B Hoechst[6]

[1] Paul Scherrer Institut, ENE-LBK, Villigen, CH. [2] Paul Scherrer Institut, BIO-EMF, Villigen, CH. [3]School of Life Sciences FHNW, Institute for Medical Engineering and Medical Informatics, Muttenz, CH. [4] Medicoat AG, Maegenwill, CH. [5] Atesos Medical AG, Aarau, CH. [6] Hager & Meisinger GmbH, Neuss, DE

INTRODUCTION: Titanium and its alloys are the most frequently used biocompatible materials in medical engineering. Accelerated osseointegration can be achieved by modifying the Ti surface with a layer of calcium phosphate (CaP). Current processes typically generate a relatively thick CaP (e.g., by plasma spray) and only a few thin coatings are available [1, 2]. We developed a cost-effective protocol for Ti surface modification with a thin CaP layer using a wet biomimetic route [3].

METHODS: A sand-blasted and acid-etched Ti grade 4 material is used as starting substrate. The surface topography is similar to that of commercially available dental implants. The novel surface treatments consist of two steps. In the first step (a modified version of the Kokubo method [4]), the formation of a highly porous layer of hydrogen sodium titanate ceramics is promoted. This layer is strongly joined to metal and renders the implant surface able to accelerate the formation of apatite (grafting layer, Figure 1A). In a second step, a thin layer of synthetic bone (CaP) is grown by a wet chemistry technique. The physicochemical parameters which allow the controlled growth of the synthetic bone are calculated by means of an accurate thermodynamic-kinetic model of the aqueous system [5]. The CaP deposition occurs in the porosity of the grafting layer and on top of it (Figure 1B). During the whole process pH, ionic strength, temperature, and saturation level of the system are controlled on-line and in-situ ensuring the steady state conditions and the reproducibility of the process. Therefore, careful control over thickness, chemical phase, and morphology of the deposited synthetic bone is achieved.

RESULTS: A thin bioactive synthetic bone layer on Ti implant surface is attained. The layer does not alter the roughness induced by blasting or acid-etching and the implant surface results to be homogenously modified, regardless of its micro- and macroscopic shape. The synthetic bone layer is firmly grafted to the metal. Mechanical tests demonstrate that the modified surface is preserved upon implantation and the layer does not delaminate. The mechanic stability is obtained thanks to the optimized metal-ceramic joining of the grafting layer, whereas the modified surface with synthetic bone offers an ideal substrate for natural bone growth after implantation.

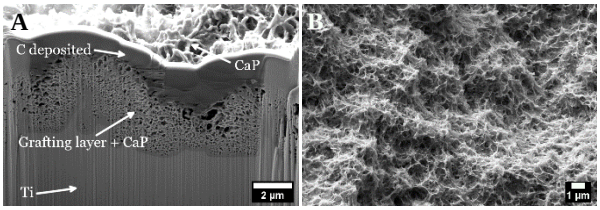

Fig. 1: Modified surfaces: (A) FIB cross-section; (B) surface after step 2.

Thanks to the control over the process, a <100 nm layer hydroxyapatite (HA) or octacalcium phosphate (OCP) can be deposited. In particular, OCP is considered the most bioactive CaP phase, being the precursor of natural bone in the osteogenesis. Reduced healing time and faster transition between primary and secondary stability of the implant can be expected. Moreover, the synthetic bone layer has a solubility higher than that of mature hydroxyapatite, which could promote remodelling to natural bone.

DISCUSSION & CONCLUSIONS: Ti implant prototypes with biomimetically modified surface have been produced and show promising chemical and mechanical in-vitro properties.

REFERENCES: [1] Promimic AB, Sweden, www.promimic.com. [2] L. M. Svanborg et al (2014) Evaluation of bone healing on sandblasted and Acid etched implants coated with nanocrystalline hydroxyapatite: an in vivo study in rabbit femur. *International Journal of Dentistry* 197581. [3] PCT/EP2018/076267. [4] T. Kokubo et al (2010) Bioactive Ti Metal and its Alloys Prepared by Chemical Treatments: State-of-the-Art and Future Trends. *Advanced Biomaterials* **12**:B597. [5] A. Carino et al (2018) Formation and transformation of calcium phosphate phases under biologically relevant conditions: Experiments and modelling. *Acta Biomaterialia* **74**:478.

ACKNOWLEDGEMENTS: We thank the Swiss Nanoscience Institute and Medicoat AG for the financial support, and Hager & Meisinger for supplying the implants.

Development of an anodized titanium implant film with antimicrobial properties

J Disegi[1], S Williamson[2], M Roach[2]

[1] *Advanced Biomaterial Consulting LLC, Reading PA, USA.*
[2] *University of* Mississippi *Medical Center, Jackson MS, USA*

INTRODUCTION: Anatase and rutile allotropic forms of titanium dioxide (TiO_2) demonstrate photocatalytic properties that have been shown to suppress bacterial activity [1]. A pulsed titanium anodization waveform was investigated in order to determine if a crystalline TiO_2 structure could be produced with antimicrobial properties.

METHODS: Test coupons consisted of 2.00 mm thick CP Ti Grade 4 sheet that met ASTM F67 standard. Coupons were cleaned, immersed in HNO_3-HF, and gold anodized in H_2SO_4 or neutral salt bath to provide amorphous TiO_2 controls. Four carbon counter electrodes and a copper bar were used for pulsed anodization trials. Two-theta X-Ray Diffraction (XRD) scans were performed between 23° - 30° at a continuous scan rate of 2° per minute. Surface morphology was evaluated via Zeiss Supra 40 SEM, Clemex image analysis, and Veeco Bioscope Catalyst AFM. Triplicate colonies of S. sanguinis (associated with dental infections) and Methicillin Resistant Staphylococcus Aureus (MRSA) were grown to logarithmic phase (10^8 colony forming units/ml) for exposure periods of 24 or 48 hours at 37 °C. Near-UV light activation was performed at 350-385 nm wavelength based on documented information. One-way ANOVA analysis determined significant differences ($\alpha = 0.05$) and post-hoc Tukey analysis separated significant groups.

RESULTS: Previous evaluations indicated 5.6 M H_2SO_4 maximized a gold anatase structure, 2.8 M H_2SO_4 maximized a dark green anatase structure, and neutral salt bath anodizing was ineffective. Dark green anodizing had the highest anatase and rutile peak intensities. A SEM micrograph of a dark green anodized sample is shown in Fig. 1.

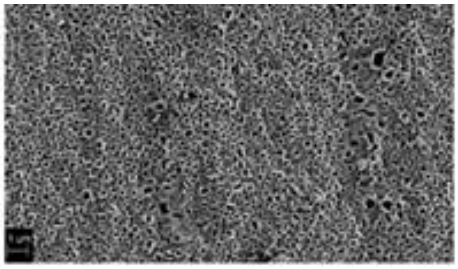

Fig. 1 SEM micrograph of dark green anodized sample with a 5% duty cycle (on-off time) in 2.8 M H_2SO_4. (1 micron marker in lower left).

Triplicate pore measurements yielded 15.7 ± 0.6 % porosity, 10.7 ± 0.9 μm^2 density, and 138 ± 5 nm mean diameter. MRSA antimicrobial activity is shown in Fig. 2.

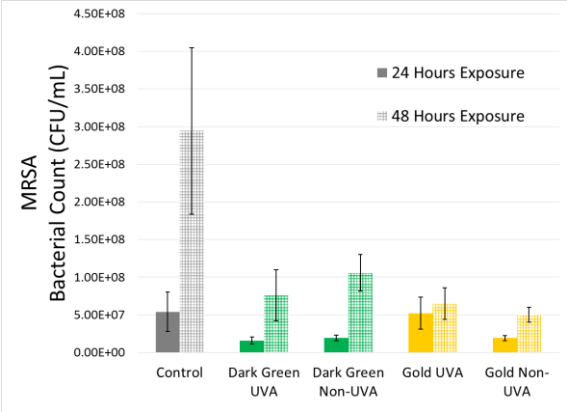

Fig. 2: MRSA bacterial count after 24 and 48 hours. All values represent significant differences versus control except for gold UVA at 24 hours.

DISCUSSION: Pulse anodization trials in H_2SO_4 produced dark green anodized TiO_2 films that demonstrated statistically significant antimicrobial activity against S. sanguinis and MRSA. Near-UV light activation at 350-380 nm wavelength improved. S. sanguinis antimicrobial response but was inconclusive for MRSA. Other researchers [2] have shown that textured stainless steel reduced E.coli bacterial cells after 48 hours exposure. Photocatalytic TiO_2 response and nano surface features may have both contributed to antimicrobial activity. The nanometer surface film should improve osteoblast adhesion, durability, and adherence when compared to bulk coatings. Regulatory pathway should be straightforward since the TiO_2 surface contains no intentionally added substances.

REFERENCES: [1]L Visia et al (2011) Titanium oxide antibacterial surfaces in biomedical devices; *Int J Artif Organs* **34 (9)**:929-46. [2]Y Jang et al (2018) Inhibition of Bacterial Adhesion on Nanotextured Stainless Steel 316L by Electrochemical Etching; *ACS Biomater Sci Eng* **4(1)**:90-7.

ACKNOWLEDGEMENTS: DePuy Synthes provided funding for this research project.

Protective coating for individual dental superstructures from CoCr alloy

J Oranskiy[1], DV Tetyukhin[2], SA Molchanov[2], EN Kozlov[2]

[1] Dento-L-Master LLC, Moscow, Russia. [2] CONMET LLC, Moscow, Russia

INTRODUCTION: Presently, individually milled superstructures made from CoCr alloys are widely spread due to the availability of CAD/CAM technologies. However, CoCr alloy application has the following disadvantages: oxidation of metal surfaces that were not coated by dental ceramic during the sintering process under high temperatures. The need for oxidized layer removal (e.g. by sandblasting treatment) leads to a change in shape and size of the superstructure interface and, consequently, increase of micro-mobility and hermeticity loss in the implant-abutment connection and emergence of a galvanic pair with titanium implants. Deposition of submicron nanocrystalline coating of Al_2O_3 with the thickness of 0.1 - 0.5 μm allowed to solve the issues.

METHODS: For coating individually milled superstructures an atomic layer deposition method (ALD) was applied. The method allows applying thin and conformal metal oxide coatings [1]. Aluminium oxide is chosen due to its high heat resistance, strength and bio-inertness. To confirm the protective properties, experiments were performed on CoCr samples of dental superstructures and its pre-mills with Al_2O_3 coatings with a thickness of 0.1 μm and 0.15 μm. To test the heat resistance, the samples were subjected to cyclic heating in an atmosphere according to the standard mode for facing CoCr alloy frame with ceramic masses. Then the samples were checked for the integrity and stability of the oxide layer. For assessing the barrier properties of the coating, its dielectrical strength was being determined. Spherical electrodes with a diameter of 4 mm were applied to the flat or cylindrical surface of coated samples. A constant voltage from the DC power supply was applied stepwise by 0.05 V to electrodes. The emergence of breakdown was determined by the appearance of a current in the circuit, which was limited to 0.001 A.

RESULTS: The created Al_2O_3 submicron coating with 0.15 μm thickness allowed to protect the surface of individual dental superstructures from thermal oxidation during the sintering process (5 cycles of heating up to 1000 °C (Fig. 1)), and to improve as well the barrier properties of the surface due to the high dielectrical strength of the coating (Table 1), significantly reducing the risk of the galvanic pair emergence.

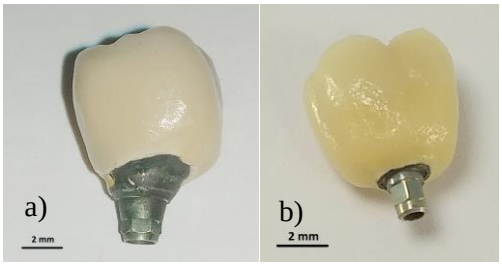

Fig. 1: Individual dental superstructures after 5 cycles of ceramic facing a) without the protective coating, b) with the protective coating.

Table 1. Dielectric strength of Al_2O_3 coatings on CoCr samples.

No	Description of samples	Coating thickness, μm	Breakdown voltage, V
1	Pre-mill with coating	0.1	0.775 ± 0.025
2	Pre-mill with coating	0.15	2.45 ± 0.05
3	Individual superstructure with coating and ceramic facing	0.15	2.45 ± 0.05

DISCUSSION & CONCLUSIONS: The conducted studies confirm that the use of Al_2O_3 coating in the manufacturing process of superstructure produced from CoCr alloys excludes interface oxidation during the dental ceramic sintering process, as well as formation of dielectric barrier between the superstructure and a titanium implant. Taking into account innovativeness of the ALD-method it is necessary to conduct additional research, *in vitro* and *in vivo* studies.

REFERENCES: [1] V. Miikkulainen, M. Leskelä, M. Ritala, and R. L. Puurunen (2013) Crystallinity of inorganic films grown by atomic layer deposition: Overview and general trends; *J. Appl. Phys.* **113**:021301.

Characterization of particulate contaminants and its challenges

S Rohrer[1], D Streit[2], F Bigolin[2], R Wirz[1], N Döbelin[1], M Bohner[1]

[1] Bioceramics & Biocompatibility Group, [2] Materials Group, RMS Foundation, Bettlach, CH

INTRODUCTION: Manufacturers of medical devices are being requested by the FDA to indicate the level and type of particle contamination of their product and to evaluate the potential risk for the patients. As part of a 510(k) premarket approval submission, a client had to determine the particle contamination of the polymeric film component of its negative pressure wound therapy kit, and to compare it to that of a predicate device.

METHODS: Contaminant particles were extracted from the polymer films and from blanks in three different solvents at 50 °C, according to ISO 10993-12:2012 [1] and to special requirements of the FDA. The particles were then collected on a polyamide filter, counted and divided into non-metallic, fibres, and metal particles with an automatic filter analysis system of JOMESA (JOMESA HFD), and characterized by FTIR (Bruker LUMOS) or EDX (Zeiss Evo MA25). All experiments were done in triplicate.

RESULTS: The highest total number of particles determined per client or predicate device film was 516 and 1233, respectively. The highest number of ≥ 25 µm particles determined per client or predicate device film was 155 and 542, respectively. While the amounts of particles extracted from the client's films were always below the thresholds specified in the USP <788> standard (max. 300 ≥ 25 µm particles and 3000 ≥ 10 µm particles) [2], the amount of ≥ 25 µm particles extracted from one predicate device film was above this threshold.

Overall, 16 types of particles were detected in the extracts of the client's films (e.g., a non-alloy steel particle shown in Fig. 1a). Comparing, 36 types of particles were detected in the extracts of the predicate device film and 20 types in the blank controls presumably due to residual particles from the clean room environment. Regardless of the extraction medium, the vast majority of the particles found were non-metallic particles. The most abundant contaminants in the extracts of the client's film were PU particles, cellulose fibers, CrNi steel particles, the antioxidant, cellulose, polyamide, and polypropylene particles. Except for the CrNi steel particles, all these particle types were also repeatedly observed in the extract of the predicate device films. However, these extracts additionally contained particles out of proteins (possibly skin residues), wool (animal derived), and nail polish.

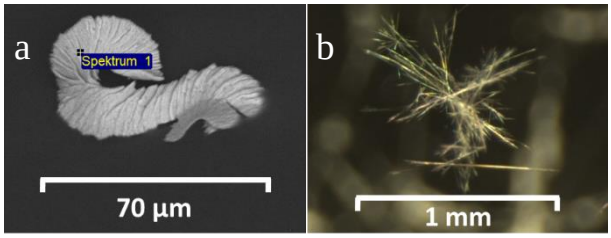

Fig. 1: Microscopy images of different particles – a) shows an unalloyed steel particle found in a water extract from the client's polymer film. b) shows a crystallized antioxidant found in all hexane extracts of polymer films.

The polymer films of the client and the predicate device showed partial decomposition in hexane and ethanol. Fine needles (Fig. 1b) precipitated during hexane cooling. These needles were identified as the antioxidant N,N′-Hexamethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnamamide), which is used in the raw material of the films. Extraction in 95 vol% ethanol resulted in the formation of fine white particles in the sediment, which were identified as polyurethane film base material.

DISCUSSION & CONCLUSIONS: Difficulties were encountered at different levels such as: (i) the design of the extraction experiments, (ii) the large size, surface area, and electrostatic behaviour of the film; (iii) the technical limitations of optical microscopy and FTIR chemical identification; (iv) the partial decomposition of the films in hexane and ethanol; (v) the contaminants present in our clean room; (vi) the statistical analysis. However, the results demonstrated that the client product contained fewer contaminant particles than the threshold values set in the standard USP <788> and that their chemical compositions were unproblematic. Contrarily, a predicate device contained too many particular contaminants, and some were critical, such as nail polish and wool / proteins.

REFERENCES: [1] ISO 10993-12:2012: Biol. evaluation of medical devices - Part 12: Sample preparation and reference materials. *International Organization for Standardization* (07-2012).

[2] USP <788>: Particulate Matter in lnjections. *United States Pharmacopeia* (01-07-2012).

ACKNOWLEDGEMENTS: The authors would like to thank the client for the possibility to publish their case.

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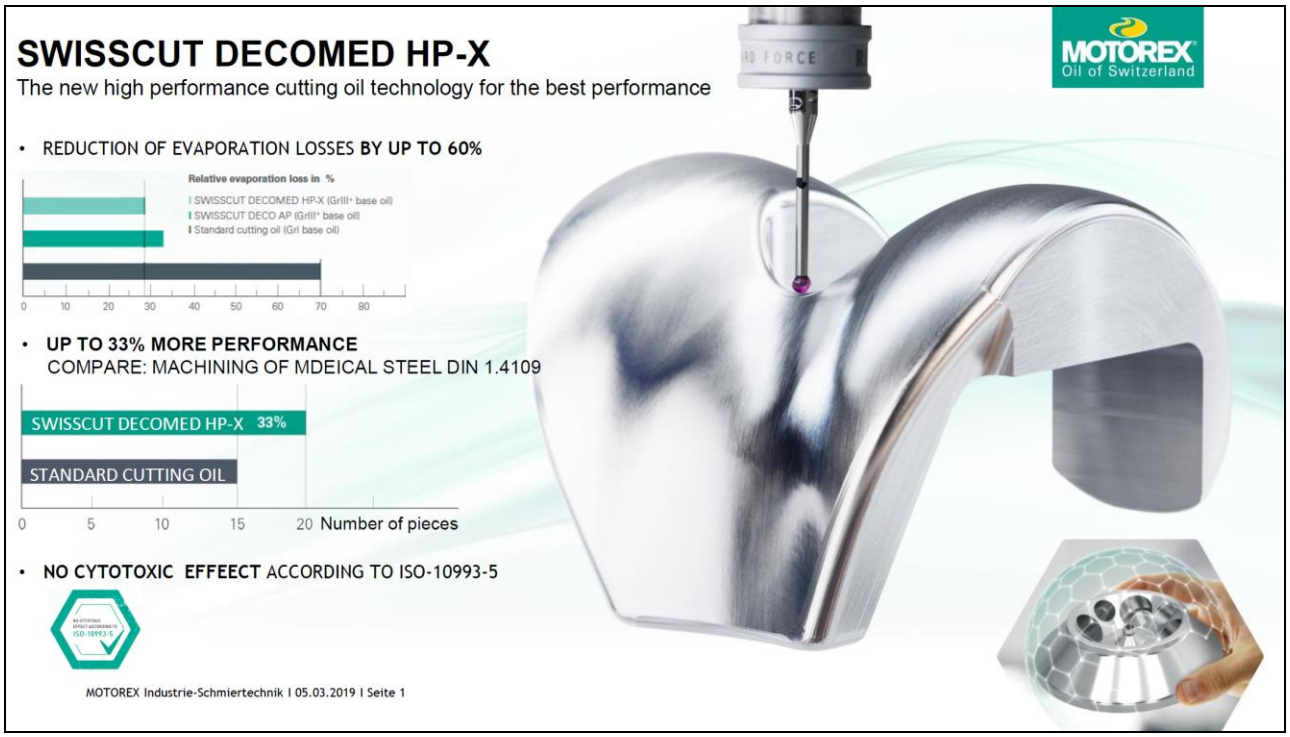
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Autogenic dentin as ever best grafting material

L Sapoznikov

Basal Implantology Center, Tel Aviv, Israel

SUMMARY: It has been known for many years that human dentin has the same properties and consistence as that of bone, especially cortical one and can be used as bone substitute. However, extracted teeth remain to be clinical waist and are simply discarded being autologous graft material (golden rules of grafting and transplantation).

In this presentation, I want to show the clinical procedure for using autogenic dentin from extracted teeth for every day practice as for general dental practitioners as well as for implantologists and maxillofacial surgeons.

Effect of Ti on the wear properties of CoCrMo-alloy: Investigations under fretting corrosion

K Maeda[1], S Nakahara[1], T Masanori[1], K Ueda[1], T Narushima[1], F Farizon[2], J Geringer[3]

[1] Dpt of Materials processing / Tohoku University, Japan. [2] University Hospital of Saint-Etienne, CHU-COT, INSERM U1059, Saint-Etienne, France. [3] Health Engineering Center, Mines Saint-Etienne, INSERM U1059, Saint-Etienne, France

INTRODUCTION: Fretting corrosion phenomenon can lead to wear and corrosion of many contact surfaces found in a corrosive media. Fretting corrosion can occur in motors of cars, turbines, and sometimes this phenomenon can occur on some parts of the metallic surfaces of orthopaedic implants, thus resulting in wear particles release that can be deleterious for the patient's health. Decreasing the wearing of metals in vivo as a result of fretting is an important point to achieve, thereby decreasing the level of allergic reactions and immune responses to metallic wear particles in the human body. CoCrMo is an alloy which is widely used in industry for manufacturing of artificial joints.

METHODS: This study focuses on understanding the effect of 1 % Ti on the resistivity of CoCrMo-alloy against wearing when subjected to fretting corrosion conditions. The fretting corrosion experiments were conducted with CoCrMo and CoCrMo with 1 % Ti alloys (Fig 1). The samples were subjected to fretting against different polymers such as PMMA (Polymethyl-methacrylate), PEKK (polyetherketoneketone), and PEKK with 30 % carbon fibres. The goal was to compare the wearing resistivity of the CoCrMo-alloy with and without 1 % Ti against different types of polymers. The duration of the experiment was 4 hours in 0.1 M NaCl + 30 g/L albumin solution and the displacement was 80 µm. In addition, 3D profilometric and SEM images were taken to characterize the shape of the worn zones on the surface of the metallic samples.

RESULTS: Wearing of CoCrMo was the highest against PMMA. On the other hand, CoCrMo showed lower wearing against PEKK and the lowest wearing was against PEKK with 30 % CF. As for CoCrMo with 1 % Ti, the wearing was lower against the 3 polymers compared to CoCrMo upon fretting against PMMA, PEKK and PEKK with 30 % carbon fibres. The effect of 1 % Ti on CoCrMo alloys was a better resistance against fretting corrosion phenomenon.

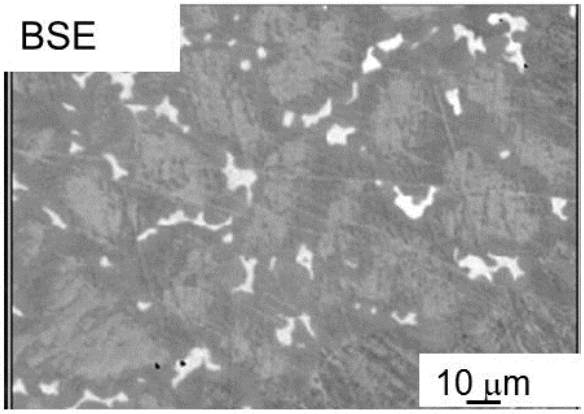


Fig. 1: Back Scattering Electron Image of the Co-28Cr-6Mo-0.25C-1Ti.

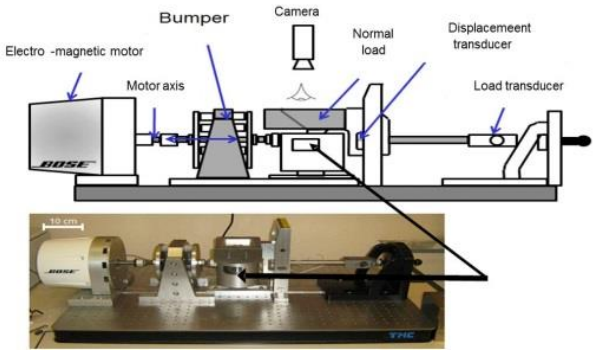


Fig. 2: Fretting corrosion machine

DISCUSSION & CONCLUSIONS: The CoCrMo-alloy with 1 % Ti might be a good candidate to decrease the wear under fretting corrosion conditions.

REFERENCES: [1] K. Ueda, M. Kasamatsu, M. Tanno, K. Ueki, J. Geringer, T. Narushima (2016) *Materials Transactions* 57:2054-9.

Particles and ions generated in total hip joint prostheses: in vitro wear test results of UHMWPE and XLPE acetabular components

H Zohdi, B Andreatta, R Heuberger

RMS Foundation, Bettlach, CH

INTRODUCTION: The accurate and detailed characterization of wear particles and ions released from total hip joint prostheses is essential to understand the cause and development of osteolysis, aseptic loosening and hypersensitivity.

METHODS: The wear particles and ion release of 22 different test liquids from hip simulator studies were investigated. Wear particles generated from acetabular components made of ultra-high-molecular-weight polyethylene (UHMWPE) or cross-linked polyethylene containing vitamin E (XLPE, all from Mathys Ltd. Bettlach, CH) were isolated by acidic digestion and characterised using scanning electron microscopy (SEM) and laser diffraction. Additionally, we investigated the effect of accelerated ageing, running-in versus steady-state, head materials and calcium sulphate third-body particles [1] on the morphology and size of the created debris.

The Fe, Ni, Mn, Nb, Co, Mo and Al ions released from femoral heads made of stainless steel, CoCrMo and alumina ceramic were analysed using inductively coupled plasma mass spectrometry (ICP-MS).

RESULTS: The wear particles were predominantly in the submicron range and of globular shape, with occasional fibrils (Fig. 1). The size distributions of the UHMWPE and XLPE particles were similar (Fig. 2); however, more fibrils were observed among the UHMWPE particles [2]. The average particle size decreased for most samples in the steady-state phase compared to the running-in. The accelerated ageing and the presence of third-body particles generally caused larger UHMWPE wear particles only.

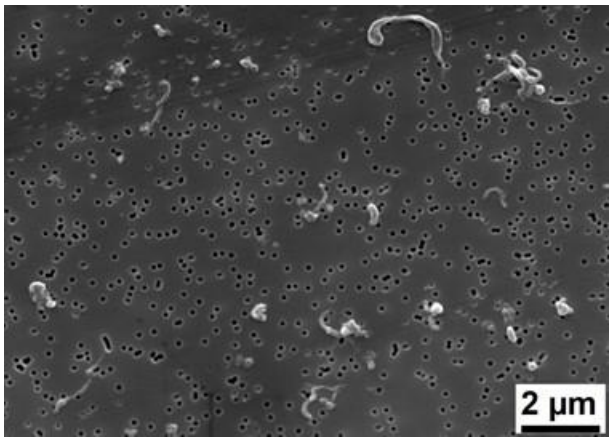


Fig. 1: SEM-image of globular wear particles and fibrils from an aged UHMWPE liner.

The ion concentrations were very low and close to the detection limit. However, increasing the size of the stainless steel femoral heads led to an increased ion level [2].

DISCUSSION & CONCLUSIONS: Although SEM is the most standardized technique to characterize the morphology of wear debris, it led to an over-estimation of the particle size (Fig. 2). However, the combination of SEM and laser diffraction was very powerful to analyse both the morphology and the particle-size distributions of the polyethylene wear particles.

Most particles were in the submicron range and globular, whereas the size distribution from UHMWPE and from XLPE particles were similar. Low concentrations of ions were released from the head materials.

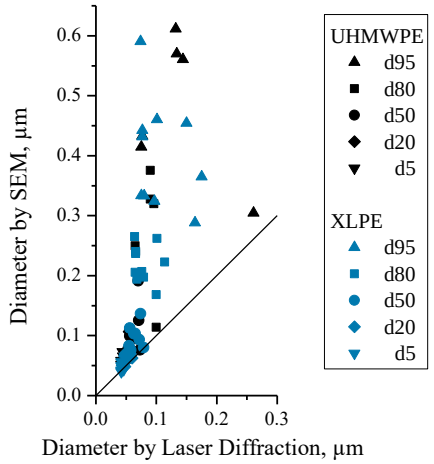


Fig. 2: Percentiles of the equivalent diameter of polyethylene particles determined with SEM vs. diameter determined using laser diffraction.

REFERENCES: [1] R. Heuberger, P. Wahl, J. Krieg, E. Gautier (2014) *eCM* **28**:246. [2] H. Zohdi, B. Andreatta, R. Heuberger (2017) *Tribol Lett* **65**:92.

ACKNOWLEDGEMENTS: We thank O. Loeffel and T. Imwinkelried (both RMS Foundation) for their help and the RMS Foundation for the financial support.

Evaluation of gamma irradiation impact on 3D-printed multimaterial polymer

A Pfeil[1], F Schuler[2], L Barbé[1], F Geiskopf[1], M de Wild[2], P Renaud[1]

[1] *INSA-ICUBE, Strasbourg, France.* [2] *FHNW-HLS, Muttenz, CH*

INTRODUCTION: Multimaterial additive manufacturing may offer new possibilities for design of medical devices thanks to the freedom of shape and material. Rigid and flexible biocompatible materials are now available so polymer devices could benefit from the materials and the novel production process [1-2]. To this purpose, we investigate the impact on mechanical performance of ɤ-irradiation, a standard sterilization process, to polymer parts.

METHODS: Polyjet technology (Stratasys Ltd, USA) is being studied with a Connex 350 system processing UV-curing resins. A rigid material, commercialized as *Verowhite Plus*, and a flexible one, *TangoBlack Plus*, are assessed. Mechanical performance is tested using tensile tests according to ISO 527-1 for the rigid material, with type 1A specimen. For the flexible material, a sample is designed to have a length of reduced section of 25 mm, and a cross section of 4*4 mm^2. Five specimens of rigid materials and one of flexible material are tested, before and after irradiation at 34 kGy. In addition, an assembly of 3D-printed parts of both materials to build a pneumatic medical actuator [3] is tested in terms of biopsy-needle positioning velocity before and after irradiation.

RESULTS: The stress-strain curves of the rigid material are shown in Fig. 1. The Young's modulus (mean±std) of the unexposed and the ɤ-exposed specimens are equal to 1830±38 MPa and 2810±37 MPa, respectively. ɤ-irradiation has a significant stiffening effect. It is also to be noted that 2 out of 5 specimens show a rupture before 4.5 % of strain. The other 3 specimens present a stress increase in the plastic domain, that was not observed before irradiation. No significant impact is noted for the flexible material. The pneumatic actuator (Fig. 2) is still functional after irradiation despite the Young's modulus increase of rigid material, with no significant variation of velocity.

DISCUSSION & CONCLUSIONS: The 53 % increase of the Young's modulus and the stress-strain relationship of the rigid material could be explained by a reticulation of the polymer structure under gamma exposition. This work allows the designer to compensate the stiffening effect during design for additive manufacturing process. The insignificant impact on flexible material and the satisfying behaviour of pneumatic actuators are encouraging to further test the materials and perform microbiological testing of ɤ-exposed materials.

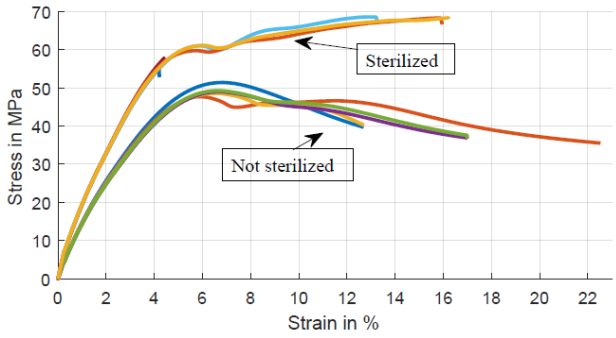


Fig. 1: Stress-strain curve of the rigid polymer specimens, before and after ɤ-sterilization.

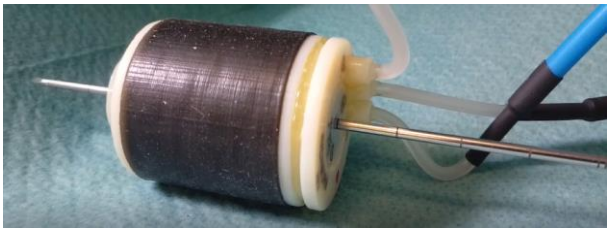


Fig. 2: 3D printed multimaterial pneumatic medical biopsy actuator after gamma irradiation.

REFERENCES: [1] N. Nagarajan, A. Dupret-Bories, E. Karabulut, P. Zorlutuna, N.E. Vrana (2018) Enabling personalized implant and controllable biosystem development through 3D printing; *Biotechnology Advances* **36(2)**:521–33. [2] A. Amelot, M. Colman, J.-E. Loret (2018) *The Spine Journal* **18(5)**:892–9. [3] A. Pfeil, L. Barbé, B. Wach, A. Bruyas, F. Geiskopf, M. Nierenberger, et al (2018) A 3D-Printed Needle Driver Based on Auxetic Structure and Inchworm Kinematics. *ASME IDETC* V05AT07A057.

ACKNOWLEDGEMENTS: The SPIRITS project is supported by the Region Grand Est, Land Baden-Württemberg, Land Rheinland-Pfalz, Cantons Baselstadt, Basellandschaft, Aargau, Swiss Confederation and by the program INTERREG Upper Rhine from the ERDF (European Regional Development Fund).

How advancement in surface science and technology will support the challenges of upcoming regulations

ES Dehghani

Ernst & Young, Zurich, CH

INTRODUCTION: As the populations are aging, the need for medical devices and specifically implants are increasing. Although these devices have saved many lives, they have – at times – been detrimental to patients' health, as several scandals have come into light. Notably, EU-Medical Device Regulations (EU-MDR) was introduced to ensure that customer's safety and needs are met, by focusing on how medical devices, including implants are designed, manufactured, distributed, and tracked through their life-cycle. Specifically, this regulation takes a closer look at what is present at the surface of the medical devices, and it requires the brand to provide specifications of the chemical and physical nature of surfaces. Specifically, EU-MDR specifies that "Devices shall be designed and manufactured in such a way as to reduce – as much as possible – the risks posed by substances or particles, including wear debris, degradation products and processing residues that may be released from the device". The new emphasis on substances leaking from the device and their wear debris, requires the medical device companies to take a closer look at Materials Specification Sheet and the manufacturing processes which are used, to determine the exact chemical composition and debris size of the medical device surface.

These challenges bring a new breath into an industry which has been using the same procedures and manufacturing over the last several decades. Advancements in surface science will bring new light on how brand and label medical device companies design and manufacture their products. In this talk, an introduction to the regulations focusing on surface science will be provided.

TECHNIQUES: In this talk, X-ray photoelectron spectroscopy (XPS), attenuated total reflection (ATR), scanning electron microscopy (SEM), X-ray diffraction (XRD), Fourier transform infrared analysis (FTIR), transmission electron microscopy (TEM), nuclear magnetic resonance (NMR), thermogravimetric analysis (TGA), gel permeation chromatography (GPC), and mass spectrometry will be discussed in regards to their capabilities, applications, advantages and disadvantages.

CONCLUSION: At the end of this lecture, target audiences and medical device companies will have a better understanding on how to employ technical expertise to meet the EU-MDR requirements.

Cleanliness aspects of coated orthopaedic devices

B Dhanapal

Analytical Testing Services, Quality Assurance, EMEA, Zimmer Biomet, Winterthur, CH

INTRODUCTION: Cleaning orthopaedic implant devices commonly involves aqueous detergent based processes. The detergent solutions can be acidic, alkaline, neutral or enzymatic and ultrasonic may also be utilized. Typically, coated devices represent challenges for cleaning, as the cleaning process must remove manufacturing materials, processing aids, and other contaminations, but retain the coated surface unaffected. Ultrasonic cleaning removes not only the contaminations but also a part of the coating materials.

For Hydroxyapatite-coated (HA) devices, first of all it is essential that the raw material is in compliance to ASTM F1185 [1]. During coating, masking materials are used to cover areas of the implant that are not intended to receive surface treatments. The masking material residue shall be removed with an appropriate solvent.

Purified water based cleaning may be detrimental to HA-coated implants because HA is partly soluble in water and has high affinity to a broad range of contaminations. For instance bacterial endotoxins are adsorbed to the surface. Extraction according to ASTM F2459 [2] method accounts for polar and non-polar contaminations. An ultrasonic assisted process does not only remove contamination, but also parts of the coating material, which is intended to be present by design. This makes it challenging to use only gravimetric methods for residual analysis. Therefore it is essential to use or combine more specific analytical methods, such as ICP and HPLC as described in ASTM F2847 [3].

METHODS: In our approach, the test parts were assayed for extractable residues by Fourier Transform Infrared spectroscopy (FT-IR), for water extractable residues by Total Organic Carbon (TOC), and for water extractable insoluble particulate matter by gravimetric method.

RESULTS: Based on our experience using ASTM F2459 to quantify residuals gravimetrically, the typical detection limit (DL) for soluble residues of 0.3 mg/part is more than a factor ten (0.02 mg/part) higher than the FT-IR method described there. Lower DLs may be necessary to assure a reliable assessment of the cleanliness of certain products in a statistical manner.

DISCUSSION: There are challenges with respect to manufacture and quality control of coated devices. In this presentation we focus on manufacturing, cleaning and quality assurance of the device.

Although ASTM F2459 has made a significant contribution to the orthopaedic industry in regards to evaluating the cleanliness of 100 % metallic medical devices, more standardization is needed especially in the case of coated devices.

CONCLUSIONS: Relationship between biological evaluation, cleaning validation, and sterilization validation is illustrated in the ISO 19227 standard [4]. Control of critical in-process cleaning is essential in order to achieve clean coated devices according to ISO 19227. Cleaning validation can be declared complete only when the sterilization validation and the biological evaluation of the implants are completed in accordance to ISO 10993-1.

REFERENCES: [1] ASTM F1185, Standard composition of hydroxyapatite. [2] ASTM F2459, Standard test method for extracting residues from metallic medical components and quantifying via gravimetric analysis. [3] ASTM F2847, Standard practice for reporting and assessment of residues on single use Implants and single use sterile Instruments. [4] ISO19227 Implants for surgery, Cleanliness of orthopaedic implants – General Requirements.

ACKNOWLEDGEMENTS: Thanks to the active collaboration of ASTM F04, ISO/TC 150 and Zimmer Biomet colleagues.

Holographic identification of titanium implants

M de Wild[1], R Krähenbühl[2], D Kallweit[2], R Marek[1], M Estermann[3], M Schnieper[2]

[1] *University of Applied Sciences Northwestern Switzerland, School of Life Sciences, Muttenz, CH.*
[2] *Centre Suisse d'Electronique et de Microtechnique CSEM, Muttenz, CH.*
[3] *Thommen Medical AG, Grenchen, CH*

INTRODUCTION: An innovative design attribute was developed as Unique Device Identification (UDI) for medical devices. [1] Holographic security features and highly complex Diffractive Optical Elements (DOE, revealing images like QR codes, logos, article or lot numbers when illuminated by a laser, see Fig. 2) are integrated directly into the titanium implant material to ensure traceability or brand protection to prevent product counterfeiting. This nanostructured surface-labelling is fully tissue-compatible because the embossing process is based on a physical structuring of the implant surface without additives or coating. The underlying holographic nanostructures are resistant to all conventional sterilization methods.

METHODS: A structured, ultra-hard steel stamp was used to emboss the surface of titanium parts for holographic labelling. The visibility of the created holograms was investigated for different process parameters and the precise and detailed sub-micrometer structure of the embossed surface was qualified by SEM and AFM. Wear tests have been performed for up to 5'000 stamping cycles on a moving titanium plate to prevent the same spot from being repeatedly stamped.

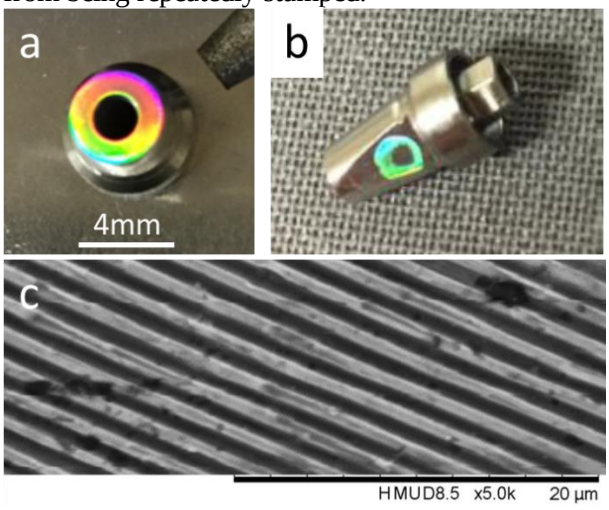


Fig. 1: a, b) Clearly visible embossed holograms on Ti abutments. c) Scanning Electron Microscopy image shows the periodicity of the diffractive structure on the tooled titanium surface.

RESULTS: The holographic structures can be transferred from the stamp to the surface of the titanium components. Diffractive characteristics like iridescent light effect can be detected visually under white light (see Figures 1a and b) and the corresponding periodic pattern can be observed by SEM (Figure 1c). The most important process parameters identified were the temperature, the contact force per unit area and the surface roughness of the area to be stamped. With constant forming force, the embossing process becomes more efficient at higher process temperature and decreasing surface roughness of the stamping area.

The durability test of the stamp revealed a serviceability up to 5'000 tooling cycles. Although the average grating height of the master structure on the stamp was reduced by 32 %, the holographic effect is still nicely visible on the stamp and on the imprinted Ti devices. Even incompletely embossed patterns work as long as there is periodicity.

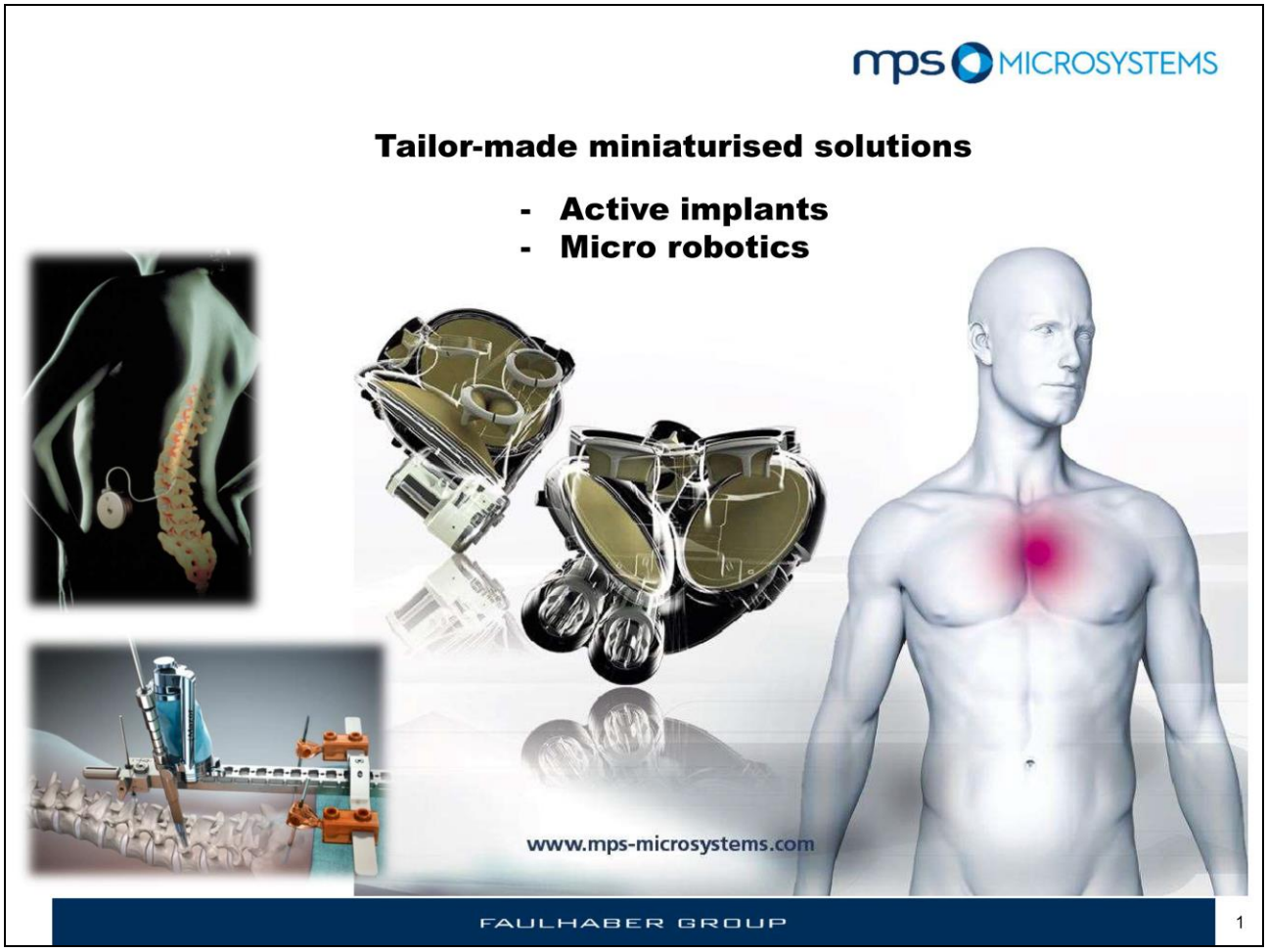
Fig. 2: A DOE-diffracted laser produces a visible, precalculated image on a screen.

DISCUSSION & CONCLUSIONS: It has been demonstrated that it is possible to transfer diffractive sub-micrometer structures such as visible holograms and Diffractive Optical Elements into titanium implant material. This unique holographic identification feature allows verification of the authenticity of implants, prosthetic parts or instrument and could serve as a UDI for medical devices.

REFERENCES: [1] Unique Device Identification (UDI) for medical devices, Task Order No. 24, food and drug administration (2012).

ACKNOWLEDGEMENTS: This study was supported by InnoSuisse grant 18679.2 PFIW-IW.

Sponsors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Poster Session

1	*Bioactivity in osseointegration of tantalum oxynitrides coatings for dental implants* Joël Matthey, Haute Ecole Arc Ingénierie, La Chaux-de-Fonds, Switzerland
2	*Delayed Delamination Mechanisms of DLC Coatings on Articulating Implants* Emilija Ilic, Empa / EPFL, Dübendorf, Switzerland
3	Hydroxyapatite coating delaminated from hip stem after 14 months in-situ – a case report Christoph Sprecher, AO Research Institute Davos, Davos, Switzerland
4	*Cleaning of 3D-Printed Titanium Implants* Dr. Clément Cremmel, KKS Ultraschall AG, Steinen, Switzerland
5	*Towards functional Silicon Nitride Coatings on Joint Replacements* Dr. Susann Schmidt, IHI Ionbond AG, Olten, Switzerland
6	*Experimental Mapping of Contact Stresses Related to Hip Arthroplasty Using Dual Mobility Cup* Dr. Jean Geringer, Mines Saint-Etienne, Saint-Etienne, France
7	*Direct Part Laser Marking in the Medtech Industry – How to make UDI-Code Marking safe and compliant* Son Tran, FOBA Laser Marking + Engraving I Alltec GmbH, Selmsdorf, Germany
8	*Bridging cartilage defects: Could a metal foam/polymer-compound be an option?* Dr. Thomas Imwinkelried, RMS Foundation, Bettlach, Switzerland
9	*Increasing the primary stability of cementless monoblock cups* Dr. Martin Schmidt, Jossi Orthopedics AG, Islikon, Switzerland

Bioactivity in osseointegration of tantalum oxynitrides coatings for dental implants

J Matthey[1], O Banakh[1], S Durual[2]

[1] *University of Applied Sciences (Haute Ecole Arc Ingénierie HES-SO), La Chaux-de-Fonds, CH.*
[2] *University of Geneva, School of Dental Medicine, Geneva, CH*

INTRODUCTION: Since decades, surface engineering plays a key role in the medical industry. Nowadays, coating technology research grows fast and offers novel solutions to improve the quality and durability of medical devices. Among new materials, metal oxynitrides are considered promising for applications in implantology due to their potential to accelerate early osseointegration [1]. The purpose of this study was to assess the osseointegration potential of sputtered tantalum oxynitride (TaOxNy) coatings with different nitrogen and oxygen contents grown on a standard dental implant material.

METHODS: TaOxNy coatings with different nitrogen and oxygen contents have been deposited by Magnetron Sputtering and High Power Impulse Magnetron Sputtering technologies onto micro-rough titanium and micro-rough stainless steel substrates. The coating thickness was set to 300 nm. Tailoring the coating composition can be performed with help of the target current hysteresis effect. Ion-induced secondary electron emission increases with the nitrogen flow while it decreases with the oxygen flow. Regarding surface preparation, Metal-Ion-Etching (MIE) clearly showed a modification of the titanium substrate micro-roughness. In some experiments, water vapor replaced oxygen in the process in order to bind hydroxyl groups at the coating surface. The micro-rough titanium surface was chosen as control and all obtained thin films were evaluated for their influence on cell proliferation with HOS osteoblast cells using a resazurin assay at days 4, 8, 14 and 21. Regarding the corrosion resistance, coated samples were tested in Ringer's solution + 0.2M sodium fluoride.

RESULTS: All developed coatings showed cell proliferation values comparable to the micro-rough titanium control and can therefore be considered cyto-compatible. The same coatings deposited onto micro-rough stainless steel showed significantly higher cell proliferation at days 14 and 21 than the uncoated control. The replacement of oxygen by water vapor demonstrated an improvement of the corrosion resistance in isotonic solution as well as a slight enhancement of cell adhesion compared to bare micro-rough titanium. It is worth noting that coated dental implants do not exhibit any significant damage during a screwing procedure into artificial bone (cellular foam).

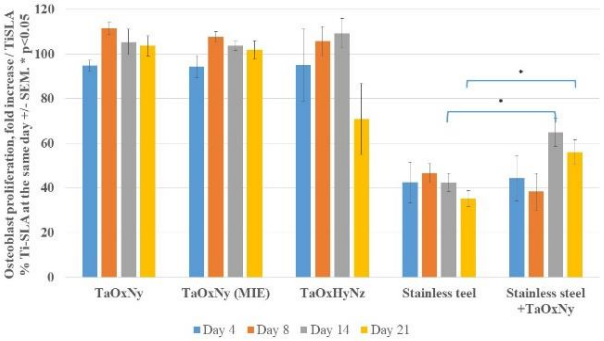

Fig. 1: Osteoblast proliferation assessed with a resazurin assay at days 4, 8, 14 and 21. Results were expressed as % of micro-rough titanium at the same day.

DISCUSSION & CONCLUSIONS: On micro-rough titanium samples, surface biocompatibility of coated samples was equal to bare control samples irrespective of the coating composition. The cell proliferation on micro-rough stainless steel was largely improved by tantalum oxynitride coatings. This shows a potential to apply tantalum oxynitrides coatings on other substrates than titanium (e.g. CoCr).

REFERENCES: [1] S. Durual, P. Rieder, G. Garavaglia, A. Filieri, M. Cattani-Lorente, S.S. Scherrer and A. Wiskott (2013) TiNOx coatings on roughened titanium and CoCr alloy accelerate early osseointegration of dental implants in minipigs, *Bone* **52**:230–237.

ACKNOWLEDGEMENTS: Interreg V France-Switzerland Program for its financial support in the frame of project "OXYTAN".

Delayed delamination mechanisms of DLC coatings on articulating implants

E Ilic[1,2], A Pardo[1], R Hauert[1], P Schmutz[1], S Mischler[2]

[1] *Empa, Laboratory for Joining Technologies and Corrosion, Dübendorf, CH.*
[2] *EPFL, Tribology and Interfacial Chemistry Group, Lausanne, CH*

INTRODUCTION: Diamond-like carbon (DLC) coatings are promising materials for improving the wear resistance of articulating biomedical implants, due to their hardness and durability. However, despite successful in vitro high-force load testing, some DLC coated hip and knee replacements still failed after a few years in patients, mainly due to coating delamination induced by corrosion of the adhesion promoting interlayer, silicon (Si) [1]. Currently the performance of artificial joints is evaluated through articulating simulators that assess fatigue related problems, however these do not take into account slow corrosion processes, which may develop as a function of time in a corrosive media.

The aim of this work is to gain a better understanding of the corrosive mechanisms responsible for coating delamination at an interlayer/interface, and to use this information to ultimately achieve a more accurate prediction of the implant`s lifetime.

METHODS: The buried interlayer/interface is revealed through low-angle flat milling with an ion beam, then by utilizing a micro-electrochemical technique (consisting of a glass micro-capillary that acts as a miniaturized electrochemical cell), the coating/substrate interface is targeted and locally attacked, providing electrochemical data which can be used to predict the speed of deterioration of the coating in the corresponding electrolyte (HyClone® Wear Test Fluid (WTF)).

RESULTS:

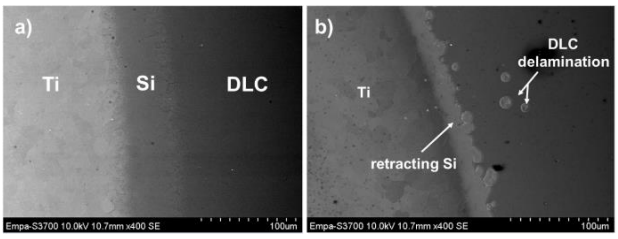

Fig. 1: a) SEM image of 1 µm DLC/100 nm Si/Ti flat-milled sample before immersion. b) SEM image of the same sample after immersion in HyClone® WTF for 1.5 years.

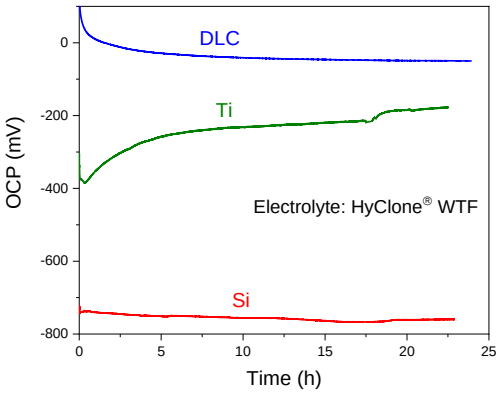

Fig. 2. Evolution of the OCP on DLC, Ti, and Si interlayer, measured with a 40 µm diameter capillary filled with HyClone® WTF.

DISCUSSION & CONCLUSIONS: Fig. 1a shows a SEM image of a flat-milled 1 µm DLC/100 nm Si/Ti sample, and Fig 1b shows the same sample after 1.5 years of immersion in HyClone® WTF. The initial Si interlayer has dissolved and the DLC has delaminated close to the interlayer interface. Contrary to lengthy immersion tests, Fig. 2 shows 24 h OCP measurements conducted on the initial flat-milled sample (Fig. 1a), with a 40 µm HyClone® WTF filled capillary. The DLC and Ti substrate show stable potentials plateauing at ca.-50 mV and -250 mV, respectively. While the Si interlayer shows a significantly lower potential, ca. -780 mV. The equilibrium potential of Si is ca.-1000 mV at ca. pH 7.4 (from the Si-H_2O Pourbaix system). The influence of proteins and additional species (phosphate, chloride, etc.) in HyClone® WTF can increase this equilibrium potential, narrowing the SiO_2 stability domain, so that a potential of ca. -780 mV results in SiO_2 dissolution. It can be concluded then that Si is an unstable interlayer in synovial-like fluid, and with micro-electrochemical characterization of the flat-milled sample, this conclusion can be reached much faster, as opposed to waiting 1.5 years with an immersion experiment.

REFERENCES: [1] R. Hauert, K. Thorwarth, and G. Thorwarth (2013) *Surf. Coatings Technol.* **233**:119–30.

Hydroxyapatite coating delamination – A case report 14 months after total hip arthroplasty

P Wahl[1], C Meier[1], S Milz[2], A Dommann[3], A Neels[3], CM Sprecher[4]

[1] Cantonal Hospital Winterthur, CH. [2] Anatomy LMU Munich, Germany.
[3] EMPA, St.Gallen, CH. [4] AO Research Institute Davos, CH

INTRODUCTION: In uncemented total hip arthroplasty (THA) Hydroxyapatite (HA) coating has become very popular [1]. The increased porosity and specific surface topography of this coating might help accelerate integration into surrounding bone especially when compared to roughened titanium [2,3]. However, the interface between such a coating and the underlying metal represents a potentially weak zone. In the present case, the HA coating separated from the metal stem and this contributed to early failure after THA.

CASE REPORT: In another clinic a HA coated hip stem was implanted without cement in a 68 years old osteoporotic, deaf and dumb male patient for treating a femoral neck fracture. Following a minor trauma 14 months later, a periprosthetic fracture required a removal of the loose stem. The stem could be recovered without any instrumentation and a new implant was set. Early postoperative recovery and rehabilitation for now 14 months followed without adverse events.

METHODS: Clinical follow-up x-rays documented the reaction of the mineralized tissue around the implant. Tissue specimens removed during operation from the medullary cavity of the proximal femur have been examined by µ-CT and PMMA histology. Cut and ground undecalcified sections were stained with Giemsa-Eosin. The crystallographic phases of the HA coating were determined by X-ray diffraction (XRD) methods.

RESULTS: Conventional x-rays identified a thin and dense line parallel to the medial edge of the implant. Analysis of the corresponding tissue samples by µ-CT identified this as the HA coating which seemed well attached to the bone (Fig. 1). Histologically, this could be confirmed and the bone appeared viable with numerous nuclei in the osteocyte lacunae. No adverse reaction to either metal or HA particles could be observed. HA was the main crystallographic phase determined by X-ray diffraction in the coating layers that were attached to stem and bone.

DISCUSSION & CONCLUSIONS: Selection of an obviously under-sized stem at primary uncemented THA in an osteoporotic bone contributed to the fracture which followed the minor trauma [4]. The tissue samples obtained during the reoperation showed that bone was intimately grown to and connected with the HA coating. This could be documented with µ-CT as well as with histological investigations. However, delamination of a HA coating from a metal stem after only 14 months in situ is a fairly poor result for a permanent implant. Although the biomechanical situation with an under-sized stem might be more challenging than with a suitably sized implant, this type of failure required more attention. Further investigations of the interface between the hip stem and the coating and the bonding strength of the coating phases are needed. It is also necessary to closely monitor patients with comparable implant designs in order to get further information on the long-term durability of these coatings.

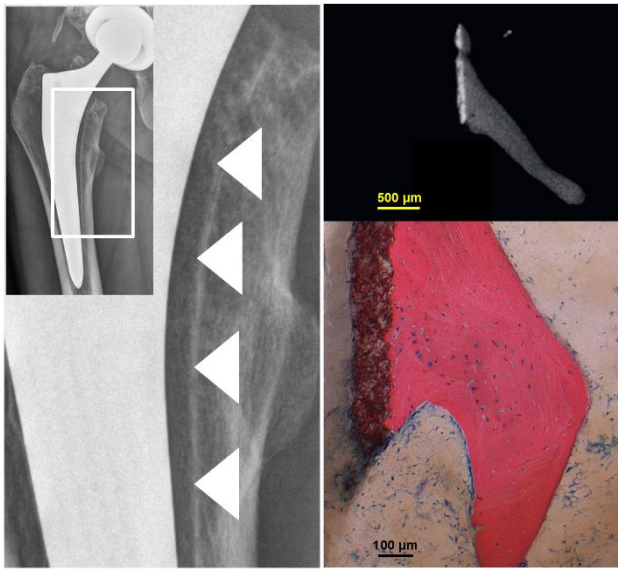

Fig. 1: In the clinical x-ray, the bright line (marked with arrows) of the delaminated HA coating is clearly visible. In the µ-CT image the coating (bright grey) with an on-grown trabecular bone (grey) could be shown and in the histological section the osteocyte nuclei (blue dots within red bone) can be seen.

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Cleaning of 3D-printed titanium implants

CVM Cremmel

KKS Ultraschall AG, Steinen, CH

INTRODUCTION: The interests in printing metals grew in the last few years, while the techniques start to be mature enough to generate reproducible and reliable results. Parts produced using these techniques can now rely on qualified equipment and highly reproducible powders. Such high quality of equipment and raw materials allowed the development of 3D-printing for medical device applications [1], as well as for other industries.

While 3D-printing is often seen as a tool where no limits are given, the post-processing of the parts remains as of today challenging. The obtained surfaces often present high roughness and a high number of half-embedded particles, which could be the origin of critical issues during further applications, in particular for medical implants made from metals.

Approaches for cleaning 3D-printed parts of different metals and geometry are presented.

METHODS: Grid samples and sponge-like structure of selective laser melting 3D-printed titanium alloy Ti6Al4V ELI were received either as printed or after a heat treatment. The samples were first pre-cleaned in an ultrasonic bath with an alkaline cleaner. A further treatment with an aqueous solution of proprietary composition and proprietary parameters was performed to remove the half-embedded powder remains. Surface topography was further analyzed using SEM (Hitachi, TM3000) or light microscopy. Roughness measurements were performed using a Hommel Tester T1000 (Jenoptik).

RESULTS: The use of ultrasound alone does not achieve the removal of half-embedded particles, and this independently of the used frequency (Figure 1a and 1b).The new wet process developed by KKS Ultraschall AG enables the removal of the surface embedded particles on all exposed surfaces and generates fully clean surfaces (Figure 1a and 1c). This surface treatment allows to remove particles in any complex geometry such as grids or bone-like meshes.

A stable surface is only achieved after heat treatment, which then allows color-coding.

The roughness of the treated parts is slightly decreased by the treatment, as shown in Figure 2.

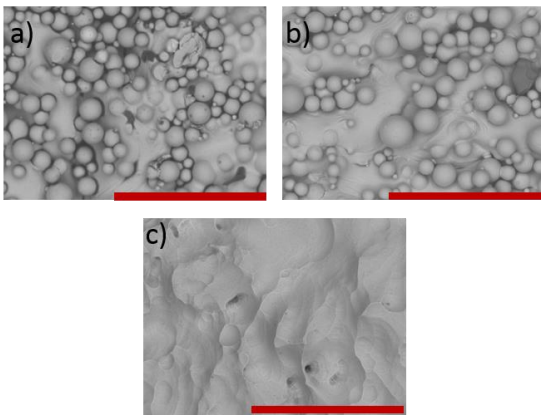

Fig. 1: SEM micrographs of titanium 3D-printed parts. a) As received after printing, b) after ultrasonication and c) after KKS surface treatment. Scale bar is 200 µm.

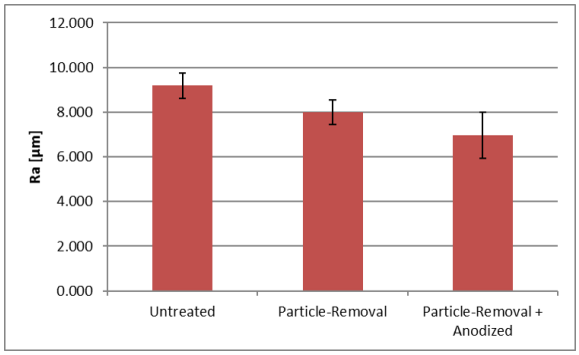

Fig. 2: Ra Value of 3D-printed titanium before and after treatment as well as after anodization.

DISCUSSION & CONCLUSIONS: It is shown that application of ultrasound of different frequencies is able to remove remaining loosely attached metal powder but not the half-embedded particles coming from the selective laser melting process. The developed proprietary method enables the removal of the surface-embedded particles remaining after 3D-Printing. The method is based on a wet process which allows the cleaning of parts even of very complex geometry, and a further color-coding. In contrast, standard techniques such as sand-blasting or electropolishing do not allow the removal of the half-embedded particles due to their line-of-sight effects.

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Experimental mapping of contact stresses related to hip arthroplasty using dual mobility cup

A Dangin[1], S Boulat[1], B Boyer[1], F Farizon[1], J Geringer[2]
[1] *University Hospital of Saint-Etienne, CHU-COT, INSERM U1059, Saint-Etienne, France.*
[2] *Health Engineering Center, Mines Saint-Etienne, INSERM U1059, Saint-Etienne, France*

INTRODUCTION: The concept of dual mobility developed by Prof. Gilles Bousquet concerning total hip prostheses has shown its clinical interest concerning the reduction of hip dislocation risk. However, there is the problem of implants wear which is one of the main causes of long-term failures. The study of dual mobility explants revealed specific wear of the polyethylene insert of dual mobility prostheses. The objective of the study is therefore to establish the causal link between the distribution of the stresses applied on the polyethylene insert and the wear observed on the explants. The experimental model was based on the use of a pressure sensor placed between the acetabular cup and the polyethylene insert, first time concerning Hip prosthesis.

METHODS: The first step of our study was to demonstrate the reproducibility and the repeatability of the experimental model using a pressure sensor in static conditions. Secondarily, the consequences of the different artifices constituting the experimental model to support dynamic stresses were analysed. These results were then compared with the explants wear to determine the relevance of the model. Finally, the analysis of an interface protein suspension was investigated to determine the consequence of physical mechanisms induced by the adsorption phenomenon.

The experimental model was based on the use of an MTS 855 Bionix walking simulator equipped with a standard dual mobility prosthesis with an ultra-high molecular weight polyethylene and a 22.2 mm metal femoral head. The stresses distribution and values were collected using the TEKSCAN® piezoelectric pressure sensor 4402 K-Scan placed between the insert and the acetabular cup. To analyse the effect of adsorption phenomenon, a protein suspension was applied between the insert and the sensor.

RESULTS: The experimental values were reproducible and repeatable under static conditions (typically 15 % and in the best case about 2 % of difference). There was no statistically significant difference when analyzing the insert position using a polyvinylidene chloride film. During the dynamic simulations we were able to observe the displacement of the stress peak maximum reproducing wear zones described on the explants (high stress means high wear). The presence of a suspension also didn't show any statistically significant difference.

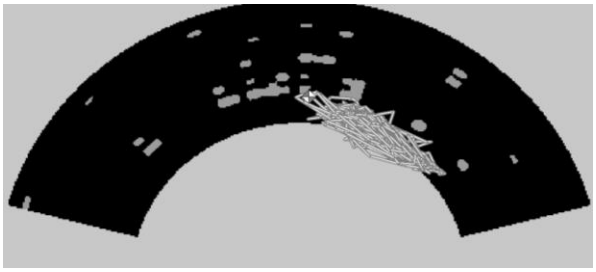

Fig. 1: Displacement of the maximum of the pressure peak (grey mark) on the film, running conditions.

DISCUSSION & CONCLUSIONS: The experimental model allowed reproducing the wear pattern on the explants. The study of the effects of a protein suspension didn't reveal any difference. However, many other settings should be analysed to optimize the model. Furthermore, the sensor fixation to the cup should be improved to support hip natural movements and stresses by any operator. The development of an experimental model for dual mobility hip arthroplasty will allow understanding more the wear phenomena. The experimental measurements are assessing the wear patterns isolated on explants [1]. By evaluating all parameters potentially involved in wear, it will allow improving the design and the material choice concerning the insert.

REFERENCES: [1] J. Geringer, B. Boyer, F. Farizon (2011) Understanding the dual mobility concept for total hip arthroplasty. Investigations on a multiscale analysis - highlighting the role of arthrofibrosis; *Wear* **271(9-10)**:2379-85.

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Bridging cartilage defects: Could a metal foam/polymer-compound be an option?

T Imwinkelried[1], S Eggli[2]

[1] RMS Foundation, Bettlach, CH. [2] Orthopaedic Clinic Sonnenhof, Bern, CH

INTRODUCTION: Small cartilage defects in the knee might be bridged temporarily by a metal foam /polymer compound. An osteoconductive titanium foam acts as an anchoring material in the subchondral bone. The infiltrated UHMWPE functions as gliding material in contact with the remaining natural cartilage.

METHODS: Titanium foam cylinders (Ø38 mm) with porosities ranging from 57 % to 77 % were produced by powder metallurgy [1] with two different grain sizes of the space holder (fine: 340 ± 110 µm, coarse: 530 ± 160 µm). The sintered titanium foam cylinders were infiltrated with UHMWPE powder (P) on one end and bulk (B) at the other end, at two different temperatures (160 °C, 200 °C) using a constant pressure of 20 MPa for 15 minutes.

Smaller cylinders (Ø16 mm) were retrieved from the compound material by water jet cutting. The infiltration depths were determined by optical microscopy. The mechanical anchoring of the UHMWPE was measured by a shear test and the mechanical properties of the titanium foam were verified by a subsequent compression test.

The tribological behaviour was investigated using a cartilage pin sliding against a UHMWPE disc with a simulated gap.

RESULTS: Figure 1 shows a titanium foam cylinder with infiltrated UHMWPE after water jet cutting and after a shear test at one end. The only statistical differences in infiltration depth (Table 1) were found between fine and coarse pores (student's t-test, $p < 0.01$).

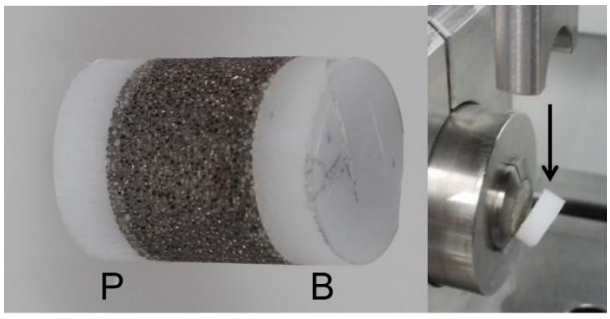

Fig. 1: Titanium foam cylinder (Ø16 mm / left) infiltrated with UHMWPE as powder (P) and as bulk (B). Compound after a shear test (right).

The shear strength of the compounds exceeded the values obtained for a UHMWPE-cylinder alone with maximum forces ranging from 2800 - 4000 N.

Table 1. Average infiltration depth (± standard deviation) of UHMWPE into titanium foams with different porosities (n = 4)

pore size	temp.	infiltration depth /mm	
		powder	bulk
fine	160 °C	1.26 ±0.08	1.27 ±0.13
	200 °C	1.20 ±0.04	1.26 ±0.11
coarse	160 °C	1.72 ±0.08	1.67 ±0.19
	200 °C	1.57 ±0.13	1.51 ±0.18

Mechanical properties of the titanium foam obtained during uniaxial compression were in the expected range [1]. Strength and stiffness values were depending on porosity but not on pore size. All samples could be compressed to at least 50 % of their initial height without the appearance of macroscopically visible cracks (Figure 2).

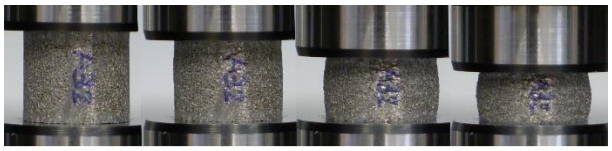

Fig. 2: Compression test of a Ø16 mm titanium foam cylinder with sheared-off UHMWPE ends.

Preliminary tribological tests were carried out in order to prove the feasibility of the current concept.

DISCUSSION & CONCLUSIONS: The feasibility of a titanium foam / UHMWPE-compound material to gap small cartilage defects in the knee was tested *in vitro*. A pre-clinical study with an adequate animal model [2] will be needed to investigate safety and performance of the present concept.

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Increasing the primary stability of cementless monoblock cups

M Schmidt

Jossi Orthopedics AG, Islikon, CH

INTRODUCTION: Cementless, macro structured, modular acetabular cups proved to be safe and effective implants with excellent clinical results. Their production costs are significantly lower than those of porous coated or 3-D printed cups. Thus, macro structures are the design of choice, especially for thin-walled shells, in markets with high volumes but low budgets.

This is why the proven PrimeFit macro structure (Fig. 1) has been proposed for so-called monoblock designs, applied especially to cementless dual mobility shells and factory assembled ceramic monoblocks consisting of a metal back and a ceramic insert (Fig. 2). For both designs, the goal is to offer the largest possible ball head diameter for good joint stability which implies the use of shells with minimum wall thickness.

CHALLENGE: In some high volume markets, such as India and China, it is state-of-the-art to secure a modular press fit cup with 2 bone screws. The excellent primary stability of the proven PrimeFit structure alone could not convince orthopaedic companies. But, as a matter of fact, monoblock designs do not offer the opportunity to place screw holes. The only way to overcome this dilemma was to modify the implant design, without changing instrumentation and handling.

SOLUTION: Our development lead to an arc-shaped macro structure, trademarked PrimeFit Arcus (Fig. 3). It can be impacted like any other press fit cup, with identical reaming and impaction procedure. During impaction the shell performs a slight turn of less than 5°, and the surgeon neither feels this little twist nor a change of impaction force.

But how is primary stability affected? PrimeFit Arcus was tested against a market leading macro structured cup with identical press fit in PU blocks, density 15 PCF, regular and with defects.

RESULTS: Mean push out force was 822 N vs 550 N (+49%, N=4). Lever out moments were 37 Nm vs 23 Nm (+61%, N=2) and in blocks with defects 14 Nm vs. 7 Nm (+100%, N=4) in the direction of the defect (worst case). These results have been confirmed in a client's lab.

CONCLUSION: If a cup has the characteristics of a screw, even though with a small turn, the discussion to set additional bone screws becomes obsolete. This is valid for monoblock designs as well as modular primary acetabular cups. Handling and instrumentation remain unchanged, and being able to avoid bone screws saves costs and OT time.

Fig. 1: The PrimeFit structure, developed by Jossi Orthopedics, has been adopted by 3 orthopaedic companies. So far, approx. 15'000 PrimeFit cups have been implanted.

Fig. 2a (left): Design proposition for a dual mobility shell with PrimeFit structure. Fig. 2b (right): PrimeFit Monoblock, a project with CeramTec.

Fig. 3: PrimeFit Arcus, an arc-shaped macro structure, with doubled primary stability compared to a market leading macro structured cup under worst-case conditions.

List of Participants, Part 1

Participant	Company Name	Location
Thomas Paulin	aap Implantate AG	Berlin, Germany
John Disegi	Advanced Biomaterial Consulting LLC	Reading, USA
James Smith	Advanced Bionics LLC	Valencia, USA
Nils Warfving	AnaPath	Liestal, Switzerland
Florian Rummel	Anton Paar GmbH	Ostfildern, Germany
Dr. Martin Schuler	AO Foundation	Dübendorf, Switzerland
Dr. Christoph Sprecher	AO Research Institute Davos	Davos, Switzerland
Jürg Aebi	Bangerter Microtechnik AG	Aarberg, Switzerland
Philipp Hofmann	Bangerter Microtechnik AG	Aarberg, Switzerland
Dr. Lari Sapoznikov	Basal Implantology Center	Tel Aviv, Israel
Esther Montigel	Basler Versicherungen	Basel, Switzerland
Prof. Dr. Daniel Zahnd	Bern University of Applied Sciences	Bern, Switzerland
Luca Canton	Biotec srl	Povolaro di Dueville (VI), Italy
Marco Zotto	Biotec srl	Povolaro di Dueville (VI), Italy
Aimen Bouhlila	Cendres+Métaux SA	Biel, Switzerland
Alain Denzer	Cendres+Métaux SA	Biel, Switzerland
Robinson Frrokaj	Cendres+Métaux SA	Biel, Switzerland
Dr. Olivier Zinger	Cendres+Métaux SA	Biel, Switzerland
Evgeny Kozlov	CONMET, LLC	Moscow, Russia
Sergey Molchanov	CONMET, LLC	Moscow, Russia
Dr. Heinz Müller	CORTRONIK GmbH	Rostock-Warnemünde, Gemany
Jakob Oranskiy	Dento-L-Master, LLC	Moscow, Russia
Suryo Nedunkanal	Depuy Synthes	Zuchwil, Switzerland
Adrien Verhulst	Depuy Synthes	Zuchwil, Switzerland
Oliver Bösl	Dr. Knoell Consult Schweiz GmbH	Basel, Switzerland
Vincent Gatineau	Electro Medical System SA	Nyon, Switzerland
Dr. Roland Hauert	Empa	Dübendorf, Switzerland
Emilija Ilic	Empa / EPFL	Dübendorf, Switzerland
Dr. Ella Dehghani	Ernst & Young	Zurich, Switzerland
Samuel Estoppey	Estoppey-Reber SA	Aegerten, Switzerland
Jörg Petrullat	EXCO Consulting GmbH	Root Längenbold, Switzerland
Jürgen Spielberger	EXCO Consulting GmbH	Root Längenbold, Switzerland
Thomas Wolf	EXCO Consulting GmbH	Root Längenbold, Switzerland
Dr. Federico Dalcanale	FHNW	Muttenz, Switzerland
Prof. Dr. Michael de Wild	FHNW	Muttenz, Switzerland
Son Tran	FOBA Laser Marking + Engraving I Alltec GmbH	Selmsdorf, Germany
Ivan Orlando	Früh Verpackungstechnik AG	Fehraltorf, Switzerland
Markus Fuchs	Fuchs AG	Hallau, Switzerland
Denis Lyet	GF Machining Solutions Management SA	Meyrin, Switzerland
Erik Poulsen	GF Machining Solutions Management SA	Nidau, Switzerland
Dr. Armando Salito	Gulhfi Consulting AG	Wohlen, Switzerland
Dr. Oksana Banakh	Haute Ecole Arc Ingénierie	La Chaux-de-Fonds, Switzerland
Joël Matthey	Haute Ecole Arc Ingénierie	La Chaux-de-Fonds, Switzerland

List of Participants, Part 2

Antoine Pfeil	ICUBE Laboratory, University of Strasbourg, INSA	Strasbourg, France
Dr. Susann Schmidt	IHI Ionbond AG	Olten, Switzerland
Dr. Martin Stöckli	inspire AG	Zürich, Switzerland
Dr. Florian Dalla Torre	Institut Straumann AG	Basel, Switzerland
Dr. Roman Dittmar	Institut Straumann AG	Basel, Switzerland
Francisco Faoro	Institut Straumann AG	Basel, Switzerland
Raphael Wagner	Institut Straumann AG	Basel, Switzerland
Dr. Marianne Wink	Institute of Polymer Nanotechnology, FHNW	Windisch, Switzerland
Pascal Verplaetse	INVENTEC PERFORMANCE CHEMICALS SA	Yverdon-les-Bains, Switzerland
Josefin Bolz	Invest in Mecklenburg-Vorpommern GmbH	Greifswald, Germany
Dr. Martin Schmidt	Jossi Orthopedics AG	Islikon, Switzerland
Daniel Oertle	Kaltbrunner AG	Grenchen, Switzerland
Dr. Clément Cremmel	KKS Ultraschall AG	Steinen, Switzerland
PD Dr. habil. Christiane Jung	KKS Ultraschall AG	Steinen, Switzerland
Jürg Luginbühl	KKS Ultraschall AG	Steinen, Switzerland
Dr. Albrecht Poth	knoell Germany GmbH	Mannheim, Germany
Viola Mai	Mathys AG	Bettlach, Switzerland
Dr. Christian Zietsch	mdc medical device certification GmbH	Stuttgart, Gemany
Hans Peter Paulus	Medartis AG	Basel, Switzerland
Dr. Adrian Spiegel	Medartis AG	Basel, Switzerland
Dr. Cyril Voisard	Medicoat	Mägenwil, Switzerland
Dr. Simon Berner	Medicoat AG	Mägenwil, Switzerland
Dr. William Enns-Bray	Medidee Services SA	Lausanne, Switzerland
Nadia Neumayer	Metoxit AG	Thayngen, Switzerland
Dr. Benedikt Seeber	Metoxit AG	Thayngen, Switzerland
Dr. Jean Geringer	Mines Saint-Etienne	Saint-Etienne, France
Marcel Mollet	mollet Präzisionsmechanik AG	Lengnau, Switzerland
Andrea Heiland	Morgan Sindall	Zürich, Switzerland
Peter Oberli	MOTOREX AG LANGENTHAL	Langenthal, Switzerland
Dr. Parvin Zare	MOTOREX AG LANGENTHAL	Langenthal, Switzerland
Peter Brombach	MPS Micro Precision Systems AG	Biel-Bienne, Switzerland
David Lopez	MPS Micro Precision Systems AG	Biel-Bienne, Switzerland
Andrej Mahr	MTS Systems GmbH	Berlin, Germany
Lucio D'Ambrosio	Niutec AG	Winterthur, Switzerland
Javier Ratia	Nobel Biocare	Kloten, Switzerland
Raquel Tschopp	Nobel Biocare AG	Kloten, Switzerland
Maria Teresa Barletta	Nobel Biocare Services AG	Kloten, Switzerland
Ainara Irastorza Landa	Nobel Biocare Services AG	Kloten, Switzerland
Florian Schmitt	Oerlikon Balzers	Balzers, Liechtenstein
Olivier Vecten	ORTHOMANUFACTURE	Puiseux en France, France
Philippe Planche	ORTHOMANUFACTURE - Epic & MIC sarl	Puisieux en France, France
Dr. Agnese Carino	Paul Scherrer Institut	Villigen PSI, Switzerland
Yves Jaccaud	Portmann Instruments AG	Biel-Benken BL, Switzerland
Lucien Steinmann	Positive Coating SA	La Chaux-de-Fonds, Switzerland

List of Participants, Part 3

Herbert Hauser	ProWaTech AG	Flaach, Switzerland
Tobias Scheffelmaier	ProWaTech AG	Flaach, Switzerland
Karin Ettlin	QUO AG	Glattpark, Switzerland
Rainer Vogt	QUO AG	Glattpark, Switzerland
Fabrizio Bigolin	RMS Foundation	Bettlach, Switzerland
Dr. Marc Bohner	RMS Foundation	Bettlach, Switzerland
Anita Erzer	RMS Foundation	Bettlach, Switzerland
Dr. Lukas Eschbach	RMS Foundation	Bettlach, Switzerland
Dr. Beat Gasser	RMS Foundation	Bettlach, Switzerland
Cornelia Haldi	RMS Foundation	Bettlach, Switzerland
Dr. Roman Heuberger	RMS Foundation	Bettlach, Switzerland
Dr. Thomas Imwinkelried	RMS Foundation	Bettlach, Switzerland
Stefan Jakobs	RMS Foundation	Bettlach, Switzerland
Bastien Le Gars Santoni	RMS Foundation	Bettlach, Switzerland
Dr. Yassine Maazouz	RMS Foundation	Bettlach, Switzerland
Simona Rohrer	RMS Foundation	Bettlach, Switzerland
Wirz Ronny	RMS Foundation	Bettlach, Switzerland
Dr. Christoph Stähli	RMS Foundation	Bettlach, Switzerland
Urs Meyer	Rösler Schweiz AG	Kirchleerau, Switzerland
Dr. Elisa Barisone	Schaefer-Tec AG	Kirchberg, Switzerland
Dr. Jean-Claude Puippe	Steiger Galvanotechnique SA	Châtel-St-Denis, Switzerland
Dr. Andac Armutlulu	Straumann Group	Basel, Switzerland
Dr. Christian Mathis	SuSoS AG	Dübendorf, Switzerland
Peter Biedermann	SWISS MEDTECH	Bern, Switzerland
Stefan Dudé	Synthes GmbH	Zuchwil, Switzerland
Christof Dutoit	Synthes GmbH	Zuchwil, Switzerland
Dario Zurbriggen	Synthes Produktions GmbH	Raron, Switzerland
Reto Lüchinger	teltec systems ag	Bremgarten, Switzerland
Marcel Estermann	Thommen Medical AG	Grenchen, Switzerland
Ulrich Kolb	UCM AG	Rheineck, Switzerland
Dr. Mario Morgenstern	Universitätsspital Basel	Basel, Switzerland
Lea Dal Fabbro	ZHAW	Winterthur, Switzerland
Dr. Boopathy Dhanapal	Zimmer Biomet	Winterthur, Switzerland
Walter Gross	Zimmer Biomet	Winterthur, Switzerland
Nadege Sachot	Zimmer Biomet	Winterthur, Switzerland
PhD Claude Rieker	Zimmer Biomet EMEA	Winterthur, Switzerland
Dr. Michael Homm	Z-Systems AG	Oensingen, Switzerland
Richard Monteil	Z-Systems AG	Oensingen, Switzerland
Claude Theubet	Z-Systems AG	Oensingen, Switzerland

Authors, Chairpersons, Organizers

Participant	Company Name	Location	E-Mail	Function
Dr. Simon Berner	Medicoat AG	5506 Mägenwil, Switzerland	s.berner@medicoat.ch	Program Committee
Peter Biedermann	SWISS MEDTECH	3007 Bern, Switzerland	peter.biedermann@swiss-medtech.ch	Organisation
Fabrizio Bigolin	RMS Foundation	2544 Bettlach, Switzerland	fabrizio.bigolin@rms-foundation.ch	Organisation
Dr. Marc Bohner	RMS Foundation	2544 Bettlach, Switzerland	marc.bohner@rms-foundation.ch	Organisation
Dr. Agnese Carino	Paul Scherrer Institut	5232 Villigen PSI, Switzerland	agnese.carino@psi.ch	Speaker Session 2
Dr. Clément Cremmel	KKS Ultraschall AG	6422 Steinen, Switzerland	clement.cremmel@kks-ultraschall.ch	Poster 4
Prof. Dr. Michael de Wild	FHNW	4132 Muttenz, Switzerland	michael.dewild@fhnw.ch	Program Committee / Speaker Session 4
Dr. Ella Dehghani	Ernst & Young	8005 Zurich, Switzerland	ella.dehghani@ch.ey.com	Speaker Session 4
Dr. Boopathy Dhanapal	Zimmer Biomet	8404 Winterthur, Switzerland	boopathy.dhanapal@zimmerbiomet.com	Speaker Session 4
John Disegi	Advanced Biomaterial Consulting LLC	19607 Reading, USA	disegi.john@hotmail.com	Speaker Session 2
Anita Erzer	RMS Foundation	2544 Bettlach, Switzerland	anita.erzer@rms-foundation.ch	Organisation
Dr. Lukas Eschbach	RMS Foundation	2544 Bettlach, Switzerland	lukas.eschbach@rms-foundation.ch	Organisation / Program Committee
Francisco Faoro	Institut Straumann AG	4052 Basel, Switzerland	francisco.faoro@straumann.com	Program Committee
Dr. Beat Gasser	RMS Foundation	2544 Bettlach, Switzerland	beat.gasser@rms-foundation.ch	Organisation
Dr. Jean Geringer	Mines Saint-Etienne	42023 Saint-Etienne, France	geringer@emse.fr	Speaker Session 3 / Poster 6
Cornelia Haldi	RMS Foundation	2544 Bettlach, Switzerland	cornelia.haldi@rms-foundation.ch	Organisation
Dr. Roman Heuberger	RMS Foundation	2544 Bettlach, Switzerland	roman.heuberger@rms-foundation.ch	Organisation / Speaker Session 3
Emilija Ilic	Empa / EPFL	8600 Dübendorf, Switzerland	emilija.ilic@empa.ch	Poster 2
Dr. Thomas Imwinkelried	RMS foundation	2544 Bettlach, Switzerland	thomas.imwinkelried@rms-foundation.ch	Organisation / Poster 8
Stefan Jakobs	RMS Foundation	2544 Bettlach, Switzerland	stefan.jakobs@rms-foundation.ch	Organisation
PD Dr. habil. Christiane Jung	KKS Ultraschall AG	6422 Steinen, Switzerland	christiane.jung@kks-ultraschall.ch	Program Committee
Bastien Le Gars Santoni	RMS Foundation	2544 Bettlach, Switzerland	bastien.santoni@rms-foundation.ch	Organisation
Dr. Yassine Maazouz	RMS Foundation	2544 Bettlach, Switzerland	yassine.maazouz@rms-foundation.ch	Organisation
Joël Matthey	Haute Ecole Arc Ingénierie	2300 La Chaux-de-Fonds, Switzerland	joel.matthey@he-arc.ch	Poster 1
Dr. Mario Morgenstern	Universitätsspital Basel	4031 Basel, Switzerland	Mario.Morgenstern@usb.ch	Keynote Speaker 1
Jakob Oranskiy	Dento-L-Master, LLC	123308 Moscow, Russia	oransky@mail.ru	Speaker Session 2
Antoine Pfeil	ICUBE Laboratory, University of Strasbourg, INSA	67000 Strasbourg, France	a.pfeil@unistra.fr	Speaker Session 3
Simona Rohrer	RMS Foundation	2544 Bettlach, Switzerland	simona.rohrer@rms-foundation.ch	Organisation / Speaker Session 2
Wirz Ronny	RMS Foundation	2544 Bettlach, Switzerland	ronny.wirz@rms-foundation.ch	Organisation
Dr. Lari Sapoznikov	Basal Implantology Center	5848503 Tel Aviv, Israel	Lari.sapoznikov@gmail.com	Keynote Speaker 2
Dr. Martin Schmidt	Jossi Orthopedics AG	8546 Islikon, Switzerland	martin.schmidt@jossi-orthopedics.ch	Poster 9
Dr. Susann Schmidt	IHI Ionbond AG	4600 Olten, Switzerland	susann.schmidt@ionbond.com	Poster 5
Dr. Martin Schuler	AO Foundation	8600 Dübendorf, Switzerland	martin.schuler@aofoundation.org	Keynote Speaker 3
Dr. Christoph Sprecher	AO Research Institute Davos	7270 Davos, Switzerland	christoph.sprecher@aofoundation.org	Poster 3
Dr. Christoph Stähli	RMS Foundation	2544 Bettlach, Switzerland	christoph.staehli@rms-foundation.ch	Organisation
Dr. Martin Stöckli	inspire AG	8005 Zürich, Switzerland	stoeckli@inspire.ethz.ch	Program Committee
Son Tran	FOBA Laser Marking + Engraving I Alltec GmbH	23923 Selmsdorf, Germany	stran@foba.de	Poster 7
Dr. Cyril Voisard	Medicoat	5506 Mägenwil, Switzerland	c.voisard@medicoat.ch	Speaker Session 2

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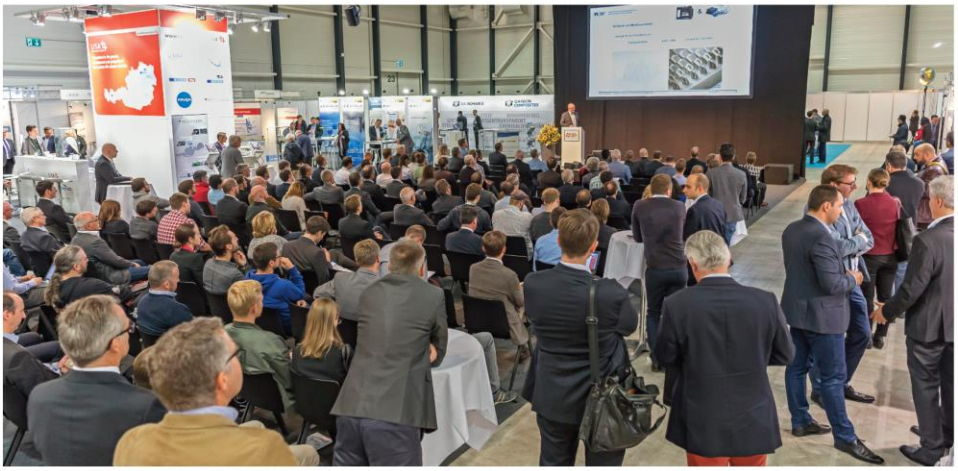

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