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**IMPLANTS**

## Materials and Surface Technology for Implants

Tuesday, 13<sup>th</sup> March 2018

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Riggenbachstrasse 16  
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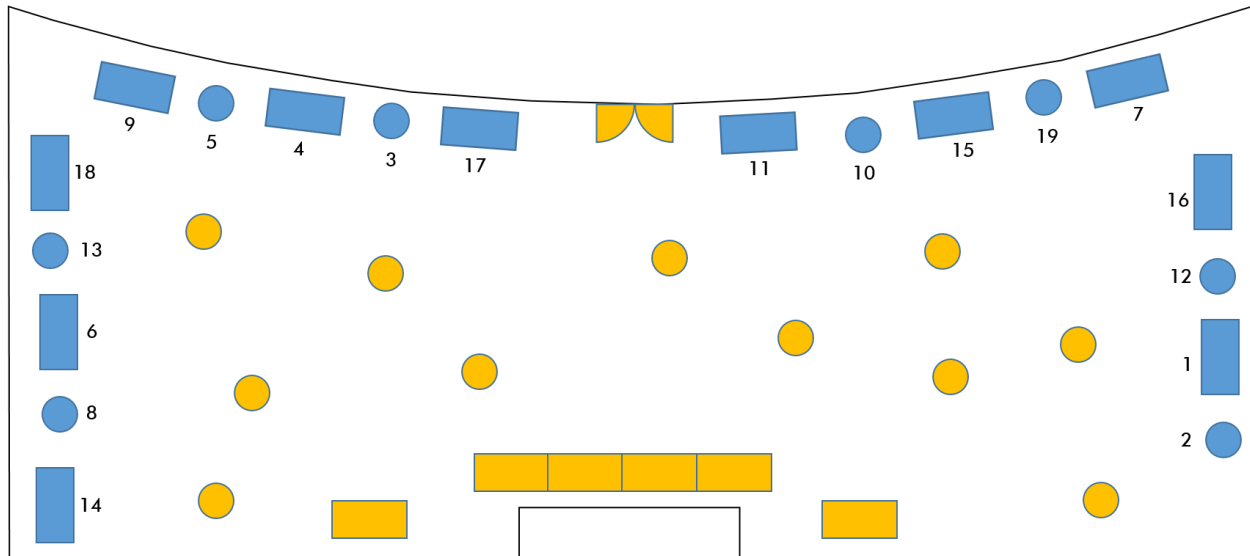


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## Meeting Program

Tuesday 13<sup>th</sup> March 2018

08:30	Registration
09:00-09:15	Welcome message
	<b>Session 1: Polymers</b> Chair: Lukas Eschbach
09:15-09:45	Keynote 1: Dr. Claude Rieker, Zimmer Biomet, Winterthur, Switzerland: <i>Polymers and Orthopaedics – Where are we today?</i>
09:45-10:30	Flash Presentations Exhibitors and Posters (1 min. each)
10:30-11:00	Break (Exhibition and Poster)
	<b>Session 2: Materials</b> Chair: Simon Berner / Francisco Faoro
11:00-11:30	Keynote 2: Prof. Dr. med. dent. Dr. rer. nat. Jens Fischer, VITA Zahnfabrik, Bad Säckingen, Germany: <i>Meet the nature – ceramics in esthetic dentistry</i>
11:30-11:50	Dr. Markus Rottmar, Empa, St.Gallen, Switzerland: <i>An advanced in vitro model for ceramic dental implant surface development</i>
11:50-12:10	John Disegi, Advanced Biomaterial Consulting LLC, Reading, USA: <i>Properties of Mo-47.5Re Implant Alloy</i>
12:10-12:30	Dr. Andreas Hogg, Coat-X AG, La Chaux-de-Fonds, Switzerland: <i>Improved Parylene thin-film coatings for long-term implantable medical devices</i>
12:30-14:00	Lunch (Exhibition and Poster)
	<b>Session 3: Surfaces</b> Chair: Christiane Jung
14:00-14:30	Keynote 3: Prof. Dr. med. dent Meike Stiesch / Dr. Nico Stumpp, Medizinische Hochschule Hannover, Germany: <i>Biofilm-related Implant Infections</i>
14:30-14:50	Dr. Qun Ren, Empa, St. Gallen, Switzerland: <i>Antimicrobial coatings: the discrepancy of their effectiveness in the laboratory and in the application</i>
14:50-15:10	Dr. Roland Hauert, Empa, Dübendorf, Switzerland: <i>Accelerated tests for coating adhesion lifetime estimation in body fluid</i>
15:10-15:30	Dr. Martin Schmidt, Jossi Orthopedics AG, Islikon, Switzerland: <i>Appropriate surface structure as success factor for implants</i>
15:30-16:00	Break (Exhibition and Poster)
	<b>Session 4: Manufacturing</b> Chair: Michael de Wild / Martin Stöckli
16:00-16:30	Keynote 4: Philippe Chavanne, Institut Straumann AG, Basel, Switzerland: <i>Market Overview Medical Additive Manufacturing</i>
16:30-16:50	Dr. Federico Dalcanale, FHNW, Muttenz, Switzerland: <i>Reduction of particles on SLM surfaces</i>
16:50-17:10	Dr. Clément Cremmel, KKS Ultraschall AG, Steinen, Switzerland: <i>Cleaning of 3D-printed medical devices</i>
17:10-17:30	David Soldan, Rösler Oberflächentechnik GmbH, Untermerzbach, Germany: <i>Directional Single Part Process With Mass Finishing</i>
17:30-17:45	Roundup

## Polymers and orthopaedics – Where are we today?

CB Rieker

*Zimmer Biomet EMEA, Winterthur, CH*

**INTRODUCTION:** After the introduction of Ultra High Molecular Weight Polyethylene (UHMWPE) in orthopaedics by Sir J. Charnley in 1962, UHMWPE is still the key polymer today in orthopaedics. Almost all total joint arthroplasties (hip, knee, shoulder ...) use UHMWPE as a bearing surface.

Even if UHMWPE is undoubtedly the polymer of choice for bearing surfaces, the UHMWPE wear and its biological consequences are still today the main cause for the late implant loosening. Macrophages phagocytize UHMWPE wear particles and this phenomenon results in osteolysis and loss of periprosthetic bone.

This mode of failure (particles disease) was already described in the mid-seventies by Willert and Semlitsch and was the continuous motivation to progressively lower the amount of UHMWPE wear particles.

**HISTORICAL DEVELOPMENTS:** The first development made to lower the UHMWPE wear was the introduction of alumina femoral heads for total hip arthroplasties already in the mid-seventies, which allowed a decrease of the amount of the volumetric wear by a factor 2 compared to metallic femoral heads.

The second development was the sterilization of UHMWPE under inert atmosphere to minimize the risk of oxidation, which greatly lowers its toughness and its wear resistance. The development was made in the early nineties and allowed to greatly reduce the risk of UHMWPE delamination, which is mainly seen with total knee arthroplasties.

The third development was the introduction of highly cross-linked polyethylenes (XLPEs) in the late nineties allowing a second significant wear reduction (factor 3 to 8). These different XLPEs

are now on the market for the last 15 years and allow lowering the aseptic loosening of total hip arthroplasties and total knee arthroplasties as demonstrated recently by many national joints registries. Also, as these XLPEs are much more forgiving in respect to malpositioning of the implants than hard-on-hard bearings, the national joints registries (Australian registry is a typical example) demonstrate that XLPEs have definitively a better survivorship than hard-on-hard bearings.

As some minute amount of oxidation has been detected by chance during the first and second in-vivo decade of XLPEs, the fourth and last improvement developed since approximately 2008 was the chemical modification of these XLPEs by adding less than 1 % of an active antioxidant (typically vitamin E). This addition allows an active protection against the possible long-term oxidation (more than 20 years) of the XLPEs. The first available publications with a short follow-up (typically between 2 and 5 years) demonstrate a stable behaviour with a low amount of volumetric wear with no visible oxidation.

**DISCUSSION & CONCLUSIONS:** These recent developments are justified by the new requirements of the current patients. Not only the patients operated in 2018 are younger, heavier, and more active than the patients operated 30 years ago, but these present patients do not accept any limitations with their total joint arthroplasty and they do not hesitate to take legal actions if the results of their implant (hip, knee, shoulder) do not fully fulfil their realistic or unrealistic expectations.

## Meet the nature – ceramics in esthetic dentistry

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<sup>2</sup> VITA Zahnfabrik, Bad Säckingen, Germany

**INTRODUCTION:** Restoring human teeth is challenging due to their complex structure composed of a dentin core and an enamel layer. Mechanical and esthetic properties as well as biocompatibility are prerequisites for restorative materials used in the oral cavity. Ceramics fulfill these requirements to a great extent. However, esthetic properties and mechanical strength are opposing.

**RESTORATIVE MATERIALS:** Silicate ceramics based on natural or synthetic feldspar provide superior esthetics and biocompatibility (Fig. 1). However, the low flexural strength in the range of 100-150 MPa limits the indication to single tooth restorations milled from a densely sintered bloc as well as veneering materials, provided as powders for layering and sintering on load bearing frameworks for bridges. Stronger but still sufficiently esthetic silicate based glass ceramics were developed in the lithium-silicate-system. Flexural strength values of 400-500 MPa allow for short bridges in order to replace one missing tooth in areas with reduced masticatory forces. A quantum leap was reached with the implementation of yttria stabilized zirconia in dentistry. Zirconia stabilized with 3 mol% Yttria (3YZ) exhibits a flexural strength of up to 1400 MPa due to a transformation toughening mechanism. Thus, the material is suitable for long span bridges. However, due to the opaque appearance 3YZ must be veneered with a feldspathic ceramic as described above to obtain esthetic results. 4YZ and 5YZ provide better esthetics due to a higher amount of cubic phase associated with a higher translucency. But transformation toughening is less effective in 4YZ and 5YZ thus leading to decreased mechanical strength of about 800 MPa and 600 MPa, respectively. YZ still has considerable potential for improvement and extension of its indication [1].

**IMPLANTS:** Replacing missing teeth is done either by a bridge or an implant. Today, implants are generally produced from titanium. The grayish color of titanium could be compromising in esthetically demanding regions. 3YZ offers the opportunity to provide ceramic implants due to its mechanical strength, biocompatibility and tooth-



Fig. 1: Replacement of a resin crown by a veneered zirconia restoration on the right central incisor. The esthetic improvement is significant.

like color. In-vitro studies with cell cultures [2] as well as animal studies on osseointegration suggest that cell response to zirconia is similar to that on titanium. To create an osseointegrative surface is a challenge with zirconia implants. Three steps have to be performed to get a surface with a roughness and topography, which is close to the surfaces known to be successful in titanium implants: sandblasting, etching and annealing [3]. Three-year results of a clinical study demonstrate the eligibility of zirconia for dental implants [4].

**DISCUSSION & CONCLUSIONS:** A wide range of ceramic materials allows for esthetical and biocompatible restorations including implants. The antagonism between esthetics and mechanical strength is the impetus for further research in dental materials.

**REFERENCES:** <sup>1</sup>I. Denry and J.R. Kelly (2014) Emerging ceramic-based materials for dentistry. *J Dent Res* **93**:1235-1242. <sup>2</sup>C. Bergemann, K. Duske, J.B. Nebe, A. Schöne, U. Bulnheim, H. Seitz and J. Fischer (2015) Microstructured zirconia surfaces modulate osteogenic marker genes in human primary osteoblasts. *J Mater Sci Mater Med* **26**:5350-5361. <sup>3</sup>J. Fischer, A. Schott and S. Märtin (2016) Surface micro-structuring of zirconia dental implants. *Clin Oral Impl Res* **27**:162-166. <sup>4</sup>M. Balmer, B.C. Spies, K. Vach, R.J. Kohal, C.H.F. Hämmerle, and R.E. Jung (2018) Three-year analysis of zirconia implants used for single-tooth replacement and three-unit fixed dental prostheses: A prospective multicenter study. *Clin Oral Implants Res*. Jan 12. doi: 10.1111/clr.13115. [Epub ahead of print].

## An advanced in vitro model for ceramic dental implant surface development

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**INTRODUCTION:** Titanium and titanium alloys have been the “gold-standard” for dental implant systems, but in case of thin gingival biotype or buccal bone loss a greyish region may appear through the gingiva. While yttrium-stabilized zirconia implants are promising alternatives, surface modification research has not yet achieved to recreate the osseointegration potential of state-of-the-art titanium surfaces. Efficient implant surface development is currently hampered by the limited predictive power of standard in vitro assays as well as the low throughput and high cost of in vivo experimentation.

Recently, we established an advanced in vitro model that mimics the in vivo situation during implantation [1]. In this study, this model was used to better understand the early interaction of implant surfaces with blood and how this influences subsequent osteogenic fate decisions of human primary bone progenitor cells (HBCs). For this, zirconia surfaces (ZLA) were compared to well-established titanium surfaces (SLA<sup>®</sup> and SLActive<sup>®</sup>) and analyzed for protein adsorption, blood coagulation and mineralization of HBCs.

**METHODS:** Microstructured hydrophobic (SLA) or hydrophilic (SLActive) titanium and zirconia (ZLA) surfaces (supplied from Institut Straumann AG) were incubated with freshly taken, partially heparinized (0.43 IU ml<sup>-1</sup>) human whole blood (ethical approval BASEC Nr. PB\_2016-00816) in a custom device made out of PTFE for 12-15 min at room temperature. After washing with PBS, coagulation on the samples was analyzed by SEM, immunohistochemistry, and ELISAs. HBCs were then cultured on top of the blood-incubated surfaces and analyzed for osteogenic differentiation after 28 d via quantification of Ca<sup>2+</sup>.

**RESULTS:** Analysis of the blood coagulation on top of the surfaces revealed a dense fibrin network on SLActive and ZLA, but almost no fibrin on SLA (Figure 1). The same trends were observed when quantifying the concentrations of fibrin on top of the surfaces, the activation status of platelets (i.e. CD62P positive platelets; Figure 1) and the levels of molecular markers of coagulation, e.g. platelet factor 4, in the

supernatants after incubation. When cultivating HBCs on blood-incubated surfaces, the cells homogeneously adhered to all surfaces and no significant differences in HBC numbers were observed amongst the different surfaces. Osteogenic differentiation was found to be higher on zirconia (ZLA) surfaces in comparison to SLA<sup>®</sup>, but was significantly lower than on SLActive<sup>®</sup> surfaces. Notably, this is in agreement with results from in vivo experiments reported in literature.

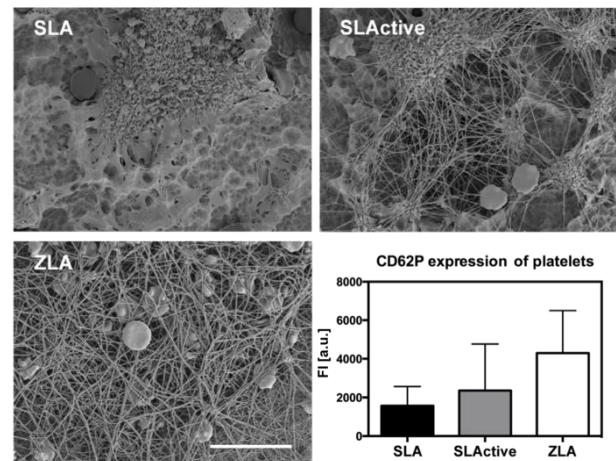


Fig. 1: SEM images of SLA, SLActive and ZLA surfaces after incubation in human whole blood. Quantification of CD62P expression of platelets on the different surfaces. Scale bar 20  $\mu$ m.

**DISCUSSION & CONCLUSIONS:** The advanced in vitro model allows to investigate the material’s impact on blood coagulation and following osseointegration potential, thereby enabling the development of dental implant surfaces with improved osseointegrative potential.

**REFERENCES:** <sup>1</sup> Kopf, B. et al. (2015) *Acta Biomaterialia* **19**:180-190.

**ACKNOWLEDGEMENTS:** We thank the Swiss Commission for Technology and Innovation CTI (Grant No: 16873.2 PFNM-NM) for financial support.



# Properties of Mo-47.5Re implant alloy

J Disegi

Advanced Biomaterial Consulting LLC, Reading, USA

**INTRODUCTION:** Wrought MoRe powder metallurgy (PM) alloys were originally developed for high temperature heat treating and aerospace components. The Nuloy coronary stent from Icon Interventional was clinically evaluated per CE certification 574558. A Mo-47.5Re (MoRe) alloy composition was selected to investigate potential orthopedic applications.

**METHODS:** Composition, physical, tensile and biocompatibility properties are compiled in ASTM F3273-17 standard [1]. Dynamic fatigue properties in air were compared for MoRe, CoCr, and TAV ELI bent spine rods according to ASTM F1717 except runout load was documented at 2.5 million (M) rather than 5 M cycles. Bone implantation testing per ISO 10993-6 compared 1.5 mm Ø X 6 mm long MoRe and TAV ELI pins in rabbit mid-shaft femurs containing a cortical defect.

**RESULTS:** Mo-47.5Re alloy limits in Table 1 include fourteen interstitial and residual elements which define a very pure binary implant alloy.

Table 1. Mo-47.5Re composition limits.

Element	Weight %
N, H, Fe, O, S, Ti, Si	max 0.010
Mn, P, Cu, B, Sn	max 0.010
C,W	max 0.050
Re	46.0-49.0
Mo	balance

MoRe alloy has the highest density (13.52 gm/cm<sup>3</sup>) and highest modulus of elasticity (365 GPa) when compared to contemporary titanium-base, cobalt-base, and stainless steel implant materials. Mo-47.5Re alloy has a lower magnetic susceptibility than commercially pure (CP) titanium and accounts for the reduced amount of magnetic resonance imaging (MRI) artifact. Minimum tensile properties are shown in Table 2.

Table 2. Minimum tensile properties for cold worked (CW) and extra hard (EH) bar.

	CW	EH
UTS (MPa)	1240	1380
0.2% YS (MPa)	1100	1310
Elong (%)	12	10
ROA (%)	40	45

Fatigue properties are highlighted in Table 3.

Table 3. Runout load @ 2.5M cycles for bent spine rods.

Diam (mm)	MoRe (N)	CoCr (N)	TAV ELI (N)
4.0	350	---	---
5.5	---	200	150

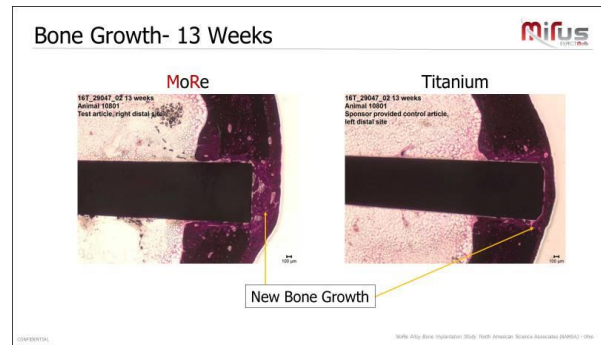


Fig.1: Histological results @ 4X magnification reveal continuous bone maturation at the implant-hard tissue interface and similar cortical and medullary osteoconduction for MoRe (left) and TAV ELI (right).

**DISCUSSION:** Cold working provides high strength and high ductility due to twinning induced plasticity (TWIP) [2]. Prevailing theory suggests cold work nucleates twinning, twinning growth occurs as deformation increases, mean free path is reduced, and dislocation glide is altered. Lower MR artifact indicates that better diagnostic imaging is possible with Mo-47.5Re implants. Fatigue results indicate that downsized implant dimensions may be designed as a result of the unique mechanical properties which can compensate for the high density and modulus.

**REFERENCES:** <sup>1</sup>Standard Specification for Wrought Molybdenum-47.5 Rhenium Alloy for Surgical Implants (UNS R03700). <sup>2</sup>S. Agnew and T. Leonhardt, (undated) *Texture, Anisotropy and the Role of Twinning in Determining the Mechanical Behavior of a Molybdenum-Rhenium Alloy*, Rhenium Alloys Abstract No.19, p.7.

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## Improved Parylene thin-film coatings for long-term implantable medical devices

A Hogg

*Coat-X AG, La Chaux-de-Fonds, CH*

**ABSTRACT:** Coat-X, a Swiss company, is a leading solution provider for critical impermeability issues and expert in thin-film encapsulation. Coat-X's innovative encapsulation technology provide a high-quality solution in form of a thin ( $< 10 \mu\text{m}$ ), biocompatible and multilayered coating to protect critical components of medical devices including implants. The company provides an ultrathin layer coating to protect all sorts of electronics, sensors, and other components for medical devices against corrosion and humidity caused by harsh environmental conditions.

The goal of the technology is to avoid the conventional metal or glass encapsulation for implants by a thin film coating composed of Parylene and ceramics thin-films of a few micrometres in order to further miniaturize the devices and thereby provide less invasive surgical interventions. Already in the early

stage of Coat-X, its encapsulation product could be proven by clinical studies on implantable medical devices for the company Rheon Medical.

This novel combined chemical vapour deposition (CVD/PECVD) process constitutes the core know-how of the company and its unique thin-film encapsulation competence. It allows a deposition at room-temperature and can be applied seamlessly to 3D complexes components. Based on silicon oxide and Parylene-C, the multilayer provides a tightness 2000 times better compared to a traditional Parylene-C coating within a range from 1 to 10  $\mu\text{m}$  layer thickness.

The further steps for Coat-X will be the installation of cleanroom facilities (ISO 4) including the finalization of the ISO 13485 certification for medical devices in order to answer on the demands of the medical industry.

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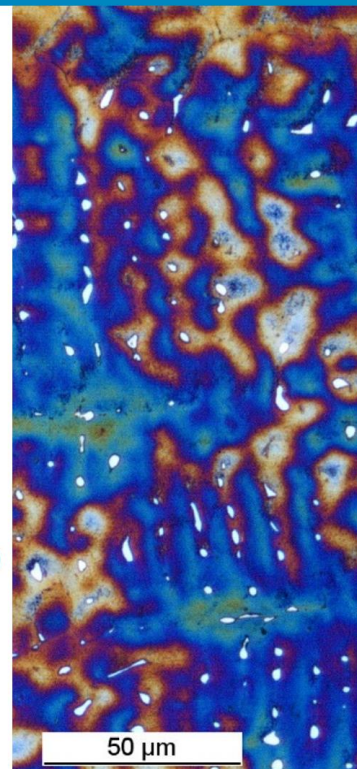
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## Biofilm-related implant infections

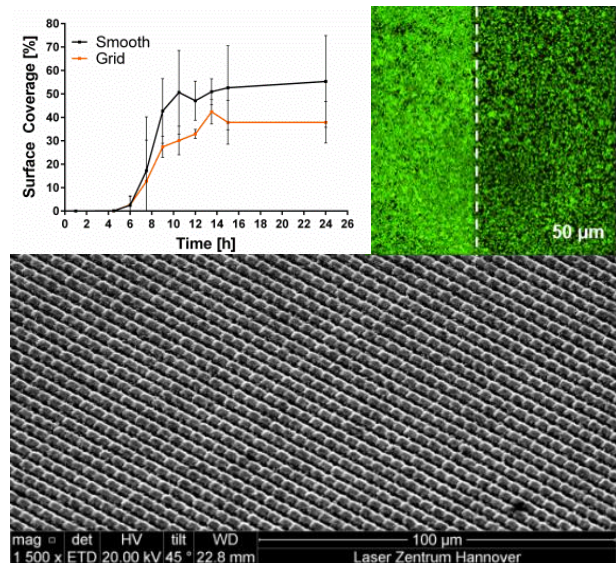
N Stumpp, M Stiesch

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**INTRODUCTION:** Biofilm-related implant infections are still one of the major causes for early and late implant failure, not only in dental implantology, but also in other surgical disciplines. Current research focuses on the development of novel implant materials, -functionalizations and appropriate *in vivo/in vitro* test systems to accelerate clinical translation of innovative medical products.

**METHODS:** Biofilm formation is a naturally occurring process on all surfaces in the oral cavity. Lifestyle and environmental factors can deeply impact oral microbial community structure. As a result, pathogenic biofilm communities may evolve and finally trigger peri-implant infections but also systemic diseases. Omics technologies have tremendously increased our knowledge about the “microbial shift” and helped to identify causative agents of implant infections as well as involved cellular processes. Despite the advances in basic research, treatment of biofilm-related infections remains challenging as sessile microbial communities have developed intrinsic protective measures against external threats, i.e. predation and therapeutic intervention. Through specific surface functionalization, implant materials can be equipped with desired chemical, physical or biological characteristics, increasing infection resistance and/or improve tissue integration capabilities. Current technical approaches are often inspired by the biological world (biomimicry) as microbial adhesion can be an undesired process in the vegetable and animal kingdom as well. Among existing functionalization strategies, micro-/ nanostructures (Fig. 1) are believed to have great potential for medical surfaces improvement as either microbial- and cell adhesion can directly be influenced by the surface topography.

**RESULTS:** Technological advancements have boosted the understanding of biofilm related infection as well as technical implementation options for implant manufacturing and -functionalization. Existing approaches show promising results and will help to improve both patient safety and comfort, and reduce healthcare spending.



*Fig. 1: Micrograph of grid-structured titanium surface showing reduced bacterial adhesion of *S. aureus* after 24h incubation [1]; upper right: CLSM image of *S. aureus* cells on structured- and control surface*

**DISCUSSION & CONCLUSIONS:** Next generation implant systems are likely to be equipped with innovative surface functionalizations that improve long term stability in the human body. However, fighting biofilm infections will probably remain a constant challenge for generations of dentists, physicians and scientists to come.

**REFERENCES:** <sup>1</sup>K. Doll, E. Fadeeva, N. S. Stumpp et al. (2016) *BioNanoMaterials* **17**(1-2):53-7.

**ACKNOWLEDGEMENTS:** This work was supported by the BIOFABRICATION FOR NIFE initiative, funded by the VolkswagenStiftung and the Lower Saxony Ministry for Science and Culture.



## Antimicrobial coatings: the discrepancy of their effectiveness in the laboratory and in the application

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**INTRODUCTION:** Many antimicrobial materials show promising antimicrobial activity in the laboratory but fail in the translation into practice, partially due to the lack of appropriate *in vitro* biofilm models that can be used to mimic the complex situation *in vivo*. The design of predictive *in vitro* biofilm models to predict the long-term antimicrobial and anti-biofilm activity *in vivo* requires a critical analysis of the respective *in vivo* conditions and the consideration of various factors. In this work, two examples, biofilms on ureteral stent and in oral cavity, are used to illustrate the importance of suitable *in vitro* models.

**METHODS:** To develop antimicrobial materials for ureteral stent, the involved relevant bacteria need to be identified. For this, biofilms from clinical ureteral stent samples were extracted using a novel biofilm extraction method and analysed for the biofilm composition and bacterial load by scanning electron microscopy (SEM), quantitative real-time PCR, X-ray diffraction, as well as microbiology methods. To examine the antimicrobial properties of an oral care gel, multi-species biofilms of the oral pathogens and commensals were formed and used to test the antimicrobial efficacy of the gel. BacTiter Glo was used to quantify the cell viability and SEM for analysis of the cell morphology and distribution.

**RESULTS:** We have analysed the *in vivo* setting for biomaterials used for urinary tract and oral care applications for the generation of laboratory *in vitro* biofilm models and for the design and assessment of novel antimicrobial materials.

The analysed ureteral stent biofilm samples comprised large amounts of inorganic crystalline components, whereas bacteria were only present in a subset of samples. For the assessment and development of biomaterials for the urinary tract, the precipitation of urine compounds has to be considered, as well as the growth of calcium oxalate and calcium phosphate crystals, since the antimicrobial biomaterials may become covered and get de-activated by these compounds. Accordingly, we have developed an artificial urine medium based on a urine metabolomics study that allows growth of relevant pathogenic bacteria which may be found in the urinary tract, and it

comprises components relevant for crystal formation.

To assess the efficacy of an oral care gel multi-species biofilm of *Actinomyces naeslundii*, *Fusobacterium nucleatum*, *Streptococcus sobrinus*, *S.mutans mutans*, and *Candida albicans* was formed on glass slides (Figure 1a). The tested oral care gel showed excellent efficacy in treatment of the formed biofilms, even after 24 h no regrowth could be observed (Figure 1b).

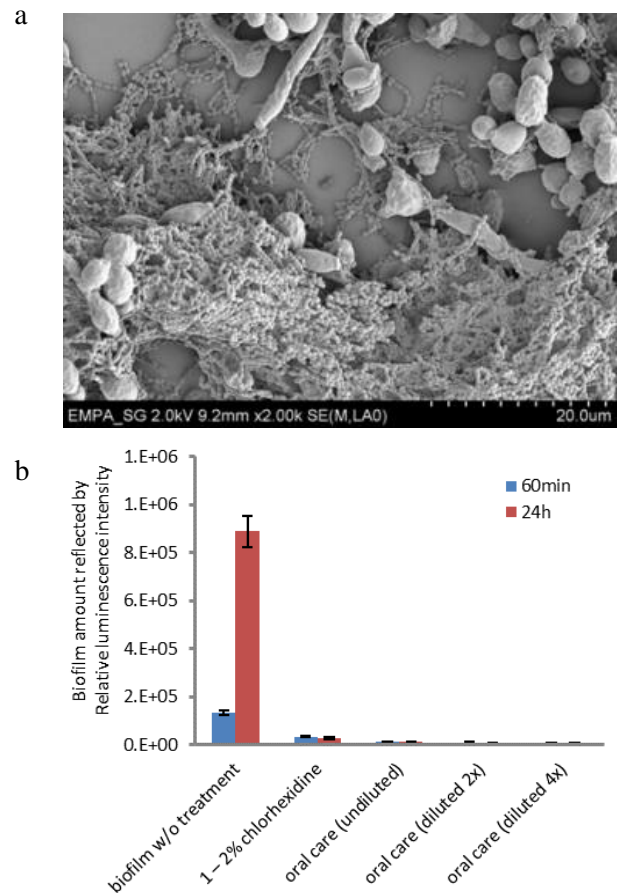


Fig. 1: (a) Multispecies biofilm Visualized by SEM. (b) Efficacy of the tested oral care gel against multispecies biofilms. Biofilm formation was assessed by fluorescent detection of ATP.

**CONCLUSIONS:** The analysis of the *in vivo* setting decides on the required antimicrobial strategy and the appropriate *in vitro* anti-biofilm assessment model.

**ACKNOWLEDGEMENTS:** We thank Luzia Wiesli and Stefanie Altenried for technical support.

## Accelerated tests for coating adhesion lifetime estimation in body fluid

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<sup>2</sup> EPFL, Tribology and Interfacial Chemistry Group, Lausanne, CH

**INTRODUCTION:** Specific coatings on implants can generate desired biological or tribological surface properties. For example, it was shown in simulator testing that diamond like carbon (DLC) coatings can result in wear free articulating joints [1]. However, extreme caution has to be taken since an inadequate interlayer material or even a single atomic row of contamination at the coating/substrate can alter the interface composition. This can result in different mechanical properties and corrosion behaviour. The measurement of a few atomic rows buried under several micrometres of coating is important but difficult. This characterization can be achieved by extremely low angle polishing and laterally resolved Auger electron spectroscopy. Corrosion effects such as crevice corrosion, which run as a function of time in media, cannot be accelerated in simulator testing, leading to false lifetime expectations [2, 3]. Therefore, for accelerated lifetime assessment, crevice corrosion behaviour as well as corrosion fatigue of interfaces and interlayers have to be addressed in separate dedicated experiments. A setup for accelerated crevice corrosion testing in a confined space is under development and preliminary results will be presented. By simulating the alternating load present at a coating/substrate interface, such as that in a joint, a high frequency test to assess interface deteriorating by corrosion fatigue is presented.

**METHODS:** Extremely low angle polishing down to less than 0.06 degrees (less than 1/1000 steepness) was done using a plasma cross section polisher. Crevice corrosion damage was assessed in a confined space using different media, different conditions, and pH determination. Interface damage propagation and corrosion fatigue was measured in a high frequency reciprocating rig by sliding an alumina ball counterpart at different loads over a locally pre-damaged DLC coating.

**RESULTS:** On a failed 4  $\mu\text{m}$  DLC coated hip joint explant, it was measured that the TiAlV/Si interface showed a decreased mechanical adhesion strength in a Rockwell adhesion test [3]. Figure 1 displays a SEM picture of the low angle polished interface region of this TiAlV/Si/DLC-Si/DLC structure where the few nm thick interface is expanded laterally to several micrometres. The

atomic concentrations determined by Auger spectroscopy are included and show the 60 nm Si interlayer as well as a C and O contamination at the TiAlV/Si interface.

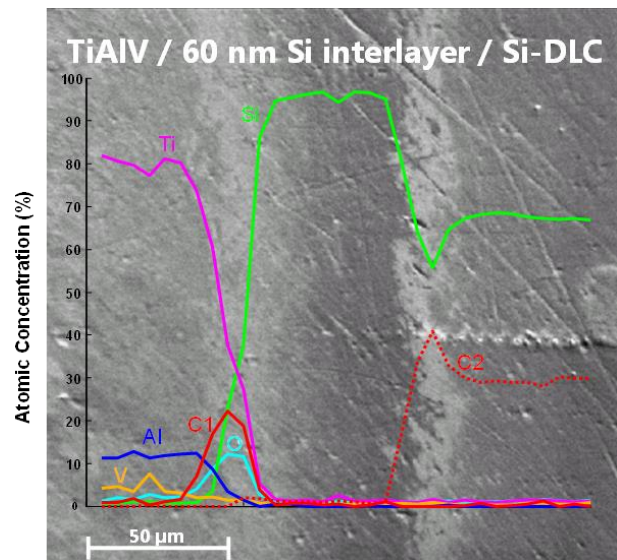


Fig. 1: SEM picture of the very low angle polished TiAlV/Si/DLC-Si interface region of an explant [3]. The Auger analysis shows the expanded 60 nm Si interlayer and a contamination at the weakened TiAlV/Si interface. C1 and C2 (carbide) indicate two different chemical states of C.

**DISCUSSION & CONCLUSIONS:** Small contaminations in the range of a single atomic row at an interface can alter the mechanical anchoring (interface fracture toughness) as well as the interface corrosion behaviour. Interface contamination can be determined by adequate sample preparation and Auger spectroscopy. Crevice corrosion as well as interface corrosion fatigue can be accelerated in different adapted test setups optimized to address these particular interface properties.

**REFERENCES:** <sup>1</sup>K. Thorwarth et al (2014) *Int. J. Mol. Sci.* **15**:10527. <sup>2</sup>R. Hauert et al (2013) *Surf Coat Technol* **233**:119. <sup>3</sup>R. Hauert et al (2012) *Acta Biomater* **8**:3170.

**ACKNOWLEDGEMENTS:** This work was supported by the Swiss National science foundation and Marie Heim-Vögtlin grant no. PMPDP2\_171412 / 1.

## Appropriate surface structure as success factor for implants

M Schmidt

*Jossi Orthopedics AG, Islikon, CH*

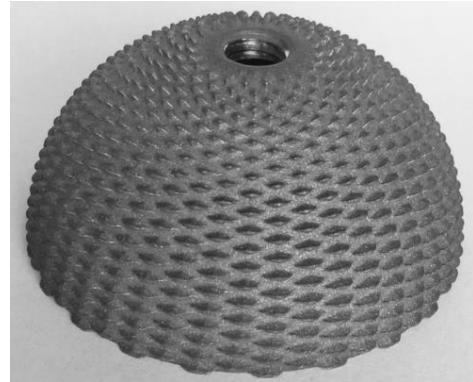
**INTRODUCTION:** Joint reconstruction has been shown to be one of the most highly-effective procedures in the history of medicine. Of hip and knee devices implanted ten years ago, more than 90% remain in place and functional. Revenues in 2016 were USD 17.5 bn (+3.6% vs. 2015) of which hip replacement contributed USD 7 bn. Almost 80 % of the market is controlled by the top 4 orthopaedic companies [1]. For a small, Swiss-based supplier specialised in the manufacture of acetabular cups, this is an extremely challenging environment.

**METHODS & CHALLENGES:** The global market is not only dominated by a few companies but also by a few product concepts with virtually no differentiation, often adapted only to the expectations of surgeons and patients in wealthy countries. Whereas these established markets grow slowly and show destructive competition, emerging markets like China and India, representing one third of the world's population, still offer tremendous growth potential. Due to economic restrictions, price levels for joint implants are very low and influence the choice of implant concepts.

**RESULTS & SOLUTIONS:** Artificial joints for cementless implantation need a macrostructure for primary and a microstructure for biologic fixation. In the case of acetabular press-fit cups, macrostructures can be formed by additive manufacturing, sintered porous or plasma spray coatings, and by mechanical means. From all possibilities, only mechanical macrostructures meet the cost targets for high-growth markets. Being implanted since the mid-1990s, Zimmer Biomet's Allofit cup, macrostructured by cold-forming and machining, shows excellent long-term results, i.e. a 10 year survival rate of 96.2 % [2]. Thus, this is a safe and effective concept to achieve stable primary fixation; and for osseointegration, grit-blasting offers sufficient microstructure.

Jossi Orthopedics further developed this type of macrostructure in order to minimise costs and to be able to customise it, marketed under the name PrimeFit™ (Fig. 1). To date, three orthopaedic companies adopted this solution and received CE approval. Two companies added a PrimeFit™ version to their cup portfolio in order to use existing inserts, among those a top 4 player. The

third company not only adopted the PrimeFit™ macrostructure but also the innovative, cost-effective antirotation device K-Lock™ (Fig. 2) replacing costly scallops. So far, more than 10'000 PrimeFit™ cups have been implanted.



*Fig. 1: Proprietary PrimeFit™ macrostructure: the shape, orientation and position of the barbs can widely be varied and, thus, customised.*



*Fig. 2: The proprietary, serrated K-Lock™ anti-rotation feature for PE inserts withstands torques of >12 Nm which fulfils the FDA standard.*


**DISCUSSION & CONCLUSIONS:** High-growth, low-budget markets need appropriate implant concepts. As known from other industries, as well in orthopaedics, Swiss quality and affordable solutions with viable margins are not a contradiction. Incremental process and product innovation leading to proprietary solutions is appreciated and opens customers' doors.

**REFERENCES:** <sup>1</sup>Carolyn LaWell (2017) *The Orthopaedic Industry Annual Report*, Orthoworld Inc. <sup>2</sup>*Annual Report (2015)* Australian Orthopaedic Association National Joint Replacement Registry.



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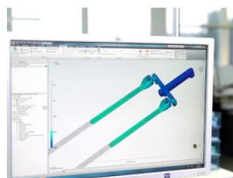
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## Reduction of particles on SLM surfaces

S Zimmermann<sup>1,2</sup>, R Schumacher<sup>1,3</sup>, O Bill<sup>1,4</sup>, F Dalcanale<sup>1</sup>, M de Wild<sup>1</sup>

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<sup>2</sup> Nexilis AG, Liestal, CH. <sup>3</sup> Medartis AG, Basel, CH. <sup>4</sup> Nobel Biocare Services AG, Kloten, CH

**INTRODUCTION:** Medical additive manufacturing meets patient specific needs with tailor-made implants that often possess a unique design not achievable through conventional machining. Examples are titanium lattice structures produced via Selective Laser Melting (SLM) and used as bone-scaffolds for craniomaxillofacial applications. Due to the fabrication characteristic, the implant surface is process-decorated with micro-particles by the starting powder possessing a  $d_{50}$  diameter of about  $60\ \mu\text{m}$ . The aim of this study is to identify the most suitable post-processing method for removing these adhering particles. The method must be able to clean the entire surface of a complex-shaped body, notably on the concave design features of a lattice structure.

**METHODS:** Titanium cube samples with a side length of 15 mm as visible in Fig. 1A, were fabricated via SLM using a ReaLizer 250HL. The lattice structure is composed by  $5 \times 5 \times 5 = 125$  rhombic dodecahedron unit cells, with a designed porosity of 80 % and strut diameter of  $500\ \mu\text{m}$ . Fig 1B reveals the internal element of the sample used for the analysis of the inner solid surface. Three different post-processing methods were compared:

- 1) Vibratory Grinding. The process was conducted at 200 rpm for 250 min using abrasive  $\text{Al}_2\text{O}_3$  particles (Corundum) of size  $150\text{-}212\ \mu\text{m}$ .
- 2) Ultrasonic Cleaning. The samples were immersed in a 1.6 kW ultrasonic bath vibrating at 27 kHz for 270 min. The bath was filled with water containing  $0.8\ \mu\text{m}$  abrasive SiC particles in concentration of 50 g/l.
- 3) Acid-Etching. The samples were kept for 15 min in an aqueous solution of acid combination ( $\text{H}_2\text{SO}_4 : \text{HCl} : \text{H}_2\text{O}$ ) at  $90\ ^\circ\text{C}$  and then rinsed with deionized water.

**RESULTS & DISCUSSION:** Among the considered post-processing methods Acid-Etching gave the best results. As visible in Fig. 1D Acid-Etching leads to the removal of most of the titanium particles left by the manufacturing process. The total mass loss after the acid treatment is about 10 % that is significantly higher compared to the 1.2 % and 0.7 % mass loss after Vibratory Grinding and Ultrasonic Cleaning respectively.

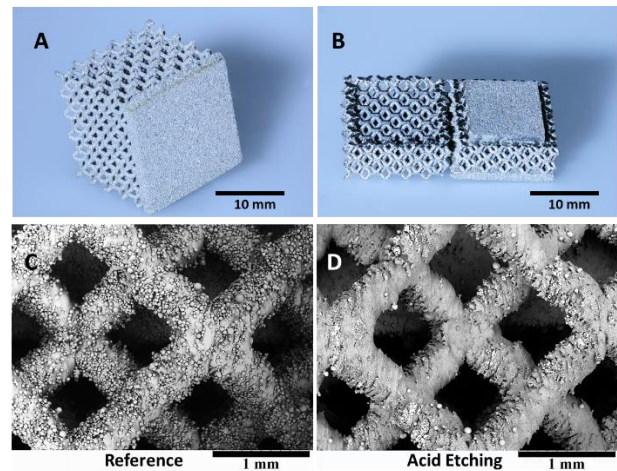


Fig. 1: Image of A) cubic sample fabricated by SLM and B) its reamed section. SEM images display the surface of the outer lattice structure of the C) as-produced sample and D) after Acid-Etching.

These last two methods left the internal surface unaffected. Moreover, the use of corundum and SiC abrasive particles leads to aluminium and silicon contamination of the outer and inner sample surfaces respectively, as determined by EDX. This indicates that corundum particles were ineffective in vibratory grinding because they could not enter the lattice structure due to their size. On the other hand, ultrasonic cleaning does not provide sufficient energy to the smaller SiC particles to scour the inner part of the samples and they remain trapped in the lattice. Acid treatment efficiently eliminates the macroscopic particles, does not leave any contamination and, depending on the etching parameters, forms a micro-rough surface that could enhance osseointegration [1].

**CONCLUSIONS:** Acid-Etching was deemed to be the most suitable post-processing method for SLM produced structures, uniformly removing adhering Ti particles.

**REFERENCES:** <sup>1</sup> B. R. Chrcanovic, A. Wennerberg, M. D. Martins (2015) Influence of Temperature and Acid Etching Time on the Superficial Characteristics of Ti, *Materials Research*; **18**(5):963-970.

**ACKNOWLEDGEMENTS:** The research was granted by the HLS research fund of FHNW.

## Cleaning of 3D-printed medical devices

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 generates some challenges. 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:** Samples of 3D-printed titanium alloy (Ti6Al4V ELI) were received either as printed or after a heat treatment. Samples of 3D-printed Stainless Steel 1.4404, Aluminium (AlSi12) and Copper were received as printed. 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 new wet process developed by KKS Ultraschall AG enables to remove the surface-embedded particles on all exposed surfaces and generates fully clean surfaces (Figure 1).

This surface treatment allows the removal of particles in any complex geometry such as grids or bone-like meshes.

The roughness of the treated parts is slightly decreased by the treatment, as shown in Table 1.

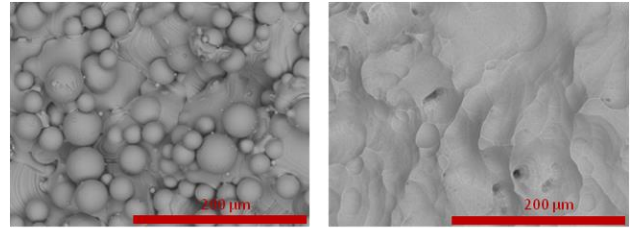


Fig. 1: SEM micrographs of titanium 3D-printed parts. Left part as received after 3D-printing, Right after surface treatment.

Table 1. Roughness parameters of 3D-printed titanium before and after particle-removal treatment.

	Ra [ $\mu\text{m}$ ]	Rq [ $\mu\text{m}$ ]	Rz [ $\mu\text{m}$ ]
As received	$4.4 \pm 0.5$	$5.6 \pm 0.6$	$26.4 \pm 2.2$
After treatment	$3.7 \pm 0.9$	$4.6 \pm 1.2$	$22.8 \pm 6.1$

**DISCUSSION & CONCLUSIONS:** It is shown that application of ultrasound of different frequencies is able to remove remaining loosely attached metal powder but not half-embedded particles. 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 parts even of very complex geometry. 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.

In summary, with the new approach complex geometries can be treated and the treatment shows reliable and reproducible results without altering the mechanical properties of the treated parts themselves.

### REFERENCES:

<sup>1</sup> <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500539.htm>, accessed 14/12/2017.



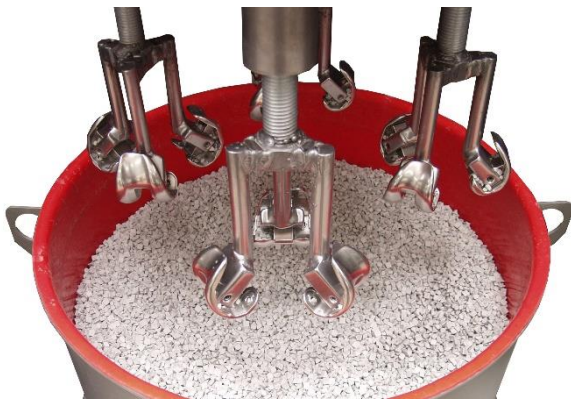
## Directional single part process with mass finishing

D Soldan

*Rösler Oberflächentechnik GmbH, Germany*

Mass finishing is probably the most flexible surface treatment process in existence. It is known to be uncomplicated, transparent, always repeatable and economic. Since the beginning, conventional mass finishing has been used for the surface treatment of instruments and implants designed for endoprosthesis, trauma or spinal surgery. This is owed to the enormous adaptability of the process.

In conventional mass finishing, loose work parts embedded in the grinding/polishing media mass are moved in a relative motion against the grinding/polishing media by either vibrations, a revolving motion or centrifugal force. This type of treatment is both overall and repeatable, but not focused on individual areas. Individual work parts may touch each other in the loose process and might not meet the highest surface requirements.



*Fig. 1: All surface areas of complex components like endoprosthesis implants can be efficiently finished (surface grinding and smoothing) with a high degree of process stability.*

Implementing the Rösler “Drag Finishing” and the newly developed “Surf Finishing” methods constituted a leap in technology. These universally applicable technologies impress with exactly repeatable process parameters compared to manual finishing, grinding and polishing robotic systems, grinding and brushing machines. Both technologies are especially well suited for intricately formed, high-grade, sensitive parts which also require treatment in specific areas. It is impossible that individual parts touch each other during this process. The parts are mounted on fixtures or held by six-axis robotic systems and

then submerged into the grinding or polishing media and processed.



*Fig. 2: The robot fulfils not only a material handling function but also guides the work pieces through the processing medium during the finishing cycle.*

The innovative “Surf-Finisher” now allows for the precise, consistent and cost-effective treatment of high value components, inline with single piece work flow. And it makes no difference whether the entire surface or only certain surface areas of such complex-shaped work pieces must be finished.

A central part of the surf-finishing system, a robot, which immerses one or multiple work pieces – mounted to a specially designed clamping device – into the work bowl and guides the work piece(s) through the media with pre-programmed movements. This allows for the precise finishing of different shapes and contours as well as specific surface areas on the work pieces. During the process the work bowl rotates at a speed of up to 300 RPM. This generates a very high pressure resulting in extremely short cycle times. At the end of the finishing cycle the robot guides the work pieces to an integrated rinse station before depositing them in a pre-defined location.

The combination of different processing media and processing modes (dry or wet), along with the rotational speed of the processing bowl, the movement of the robots and the immersion angle, allows for a broad spectrum of applications.

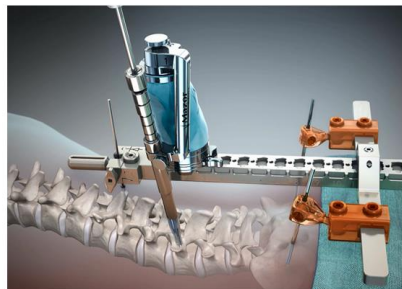
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## Poster Session

- 
- 1 *Lifetime Estimation of Coated Articulating Implants: accelerated testing to address crevice, stress and fatigue corrosion*  
Emilija Ilic, Ainhoa Pardo, Roland Hauert, Patrik Schmutz, Stefano Mischler  
Empa, Dübendorf, Switzerland
  - 2 *Surface Functionalization with Anti-Microbial Peptides*  
Jules Valentin, Qun Ren, Silvia Generelli and Hui Gao  
CSEM, Landquart, Switzerland
  - 3 *Interest of histopathology in the preclinical evaluation of cochlear implants*  
Anne-Laure Leoni, Katrin Weber, Klaus Weber  
Eurofins BioPharma Product Testing Munich GmbH, Planegg, Germany
  - 4 *Vascular Imaging by Novel Contrast Agent to Advance Preclinical Models*  
Nils Warfving  
AnaPath Services GmbH, Liestal, Switzerland
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Wyss Center for Bio and Neuroengineering, Geneva, Switzerland
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LLS ROWIAK LaserLabSolutions GmbH, Hannover, Germany
  - 8 *Surface improvement of PEEK by Multicharge Ion Implantation*  
M. Dadras, O. Sereda, A. Bohlen, K. Vaideeswaran, C. Yamahata  
CSEM, Neuchâtel, Switzerland
-



## Lifetime estimation of coated articulating implants: accelerated testing to address crevice, stress and fatigue corrosion

E Ilic<sup>1</sup>, A Pardo-Perez<sup>1</sup>, R Hauert<sup>1</sup>, P Schmutz<sup>1</sup>, S Mischler<sup>2</sup>

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**INTRODUCTION:** Diamond-like carbon (a-C:H) coatings are promising materials for improving the wear resistance of articulating biomedical implants due to their hardness and intrinsic durability. They can be applied directly onto the implant materials (TiAlNb, CoCrMo), but usually an adhesion promoting interlayer is used (Cr, Ti, Si, a-C:H-Si). However, coating delamination remains a problem due to crevice corrosion (CC) and stress corrosion cracking processes occurring at the interlayer/interface [1]. The aim of this study is to investigate and accelerate the localized corrosive degradation responsible for delamination at a coating-substrate interface, ultimately allowing for a more accurate predication of the Si or a-C:H-Si interlayer and implant coating lifetime.

**METHODS:** CC tests were carried out by clamping together Si wafer pieces and submerging for various durations in either 0.01 M phosphate buffered saline (PBS) or Hyclone (simulated joint fluid, with 30 g/L proteins) at temperatures ranging from 37 to 90 °C. For comparison, single Si wafer pieces were also submerged in each bulk solution.

RF-CVD has been used to deposit 4 µm a-C:H coatings using 90 to 250 nm a-C:H-Si interlayers on TiAlNb substrates. The interface composition with different oxygen contamination levels was analyzed by XPS depth profiles. The influence of alternating applied load on the interface stability was evaluated under dynamic loading of pre-damaged coatings via reciprocating sliding tests performed in PBS at 37 °C, using a 6 mm diameter alumina sphere.

**RESULTS:** Crevice corrosion susceptibility of Si: While no damage was observed on the single Si wafer pieces, crystallographic localized attacks (pits) and overall corroded depths of up to 3 µm were measured on the Si surfaces which had been clamped in crevice conditions, as seen in Fig. 1. Furthermore, the temperature dependent results yielded a linear Arrhenius relation with activation energies ( $E_a$ ) of 106 kJ/mol in 0.01 M PBS, and 109 kJ/mol in Hyclone where active dissolution took place.

In a series of controlled oxygen contaminated deposition conditions, XPS analysis detected an

enhanced oxide formation ( $\text{SiO}_2$ ,  $\text{TiO}_2$ ) with increasing oxygen content exposure and parallel metal carbide reduction at the interface with the substrate.

In the reciprocal sliding test, the critical conditions of failure (load and frequency) have been determined both for a short time period ( $10^4$  Cycles), and under fatigue conditions ( $10^6$  Cycles).

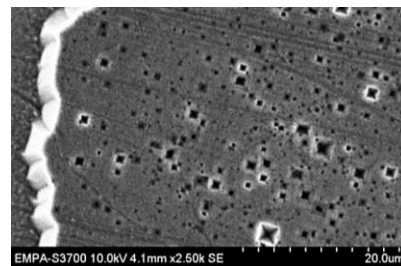


Fig. 1: SEM image of pits on Si surface after clamping against Si in Hyclone at 37 °C for 30 days.

**DISCUSSION & CONCLUSIONS:** The pits shown in Fig. 1 are characteristic of localized corrosion and etching and give strong indication that Si is vulnerable to crevice corrosion attack in physiological environments and should hence not be used as an interlayer material. Concerning the reciprocal sliding test, a comparison with the results in a replica coating tested in the spinal disk simulator [2], allows a fast and reliable test to predict the success of the in-vitro simulation. The methodology is applicable not only in the field of articulating implants but also to the general analysis of buried interlayers under dynamic load in media.

CC and corrosion fatigue susceptibility of interfaces and interlayers should be addressed in separate dedicated experiments to achieve reliable accelerated lifetime estimation of the articulating implants.

**REFERENCES:** <sup>1</sup> R. Hauert et al (2013) *Surf Coat Technol* **233**:119. <sup>2</sup> K. Thorwarth et al (2014) *Int. J. Mol. Sci.* **15**:10527

**ACKNOWLEDGEMENTS:** This work was supported by the Swiss National science foundation and Marie Heim-Vögtlin grant no. PMPDP2\_171412.

## Surface functionalization with anti-microbial peptides

J Valentin, Q Ren, S Generelli, H Gao

*CSEM, Landquart, CH*

**ABSTRACT:** Bacterial colonization of urinary catheters is a common problem leading to catheter associated urinary tract infections (CAUTIs) in patients, which result in high treatment costs and medical complications. Currently, CAUTI is treated mainly with antibiotics. However, due to the dramatic increase of strains resistant to currently available antibiotics, alternatives to classical antibiotics are urgently needed. Antimicrobial peptides (AMPs) are such candidates. In this study, the antimicrobial peptides Colistin (against gram negative bacteria) and Nisin (against gram positive bacteria) were immobilized on the glass surfaces via OptoDex-

based surface functionalization technology, meanwhile a natural antimicrobial enzyme-Lysozyme was also employed in the study. The initial results indicate there is a very strong antibacterial effect of Nisin and Lysozyme coated surface against *Staphylococcus aureus*. No bacterial growth was observed on the Colistin coating surface after 24 hours incubation, which confirms the antibacterial effect of Colistin against *E. coli*. The optimization of coating processes and surface density of antibiotics need to complete in the future, and long-term stability of coating surface as well.

## Interest of histopathology in the preclinical evaluation of cochlear implants

AL Leoni, K Weber, K Weber

*Eurofins BioPharma Product Testing Munich GmbH, Planegg, Germany*

**ABSTRACT:** In 2012, the World Health Organization estimated that 360 million persons in the world suffer from disabling hearing loss (5.3% of the world's population, 91% are adults and 9% children). Based on the type of hearing deficits, either hearing aids in form of small amplifying device fitting on the ear or cochlear implants designed to help severely to profoundly deaf adults and children can be proposed to the patients.

Before manufacturers can bring a new cochlear implant to market, they must submit studies and data to notified bodies, who will review the

information for safety and effectiveness. Cochlear implants are designated as Class III devices, meaning they receive the highest level of regulatory scrutiny. This is because they are surgically implanted near the brain, which increases health risk.

In the poster presentation we will focus on middle and inner ear anatomy of various laboratory animal species and present essential ear histological landmarks that must be evaluated to assess the local tolerance and general safety of cochlear implants.

## Vascular imaging by novel contrast agent to advance preclinical models

N Warfving<sup>1</sup>, R Hlushchuk<sup>2</sup>, K Weber<sup>1</sup>

<sup>1</sup> AnaPath Services GmbH, Liestal, CH. <sup>2</sup> Institute of Anatomy, University of Bern, CH

**INTRODUCTION:** There is a growing interest in high-resolution imaging of vascular structures for different physiological or pathological challenges. Taking advantage of the available and widespread technology: high resolution micro computed tomography (microCT), a novel preclinical microvascular contrast agent allowing three-dimensional (3D) visualization and quantification of tissue vascularity. This combined technology provides high-resolution 3D imaging of microvasculature including the finest capillaries. Characterizing and quantifying vascularization and angiogenesis are important aspects of many preclinical models. Historically, such characterization of vascular abnormalities and angiogenesis involved either measurements made on two-dimensional tissue sections from 3D specimens, often with additional image analysis and immunohistochemistry, or measurements made on corrosion casts.

**METHODS:** Continuous advancements in spatial resolution, sub-micrometer, and decreasing scanning times for commercial microCT makes it a highly efficient technology for investigating strongly absorbing biological samples, such as bone, but fails in differentiating tissue with similar and weak X-ray absorption properties. To overcome the limitations of weak X-ray absorption in microCT several X-ray phase-contrast imaging techniques were recently developed. However, these methods often require sophisticated setups only to be found at large synchrotron facilities, which greatly limits the access to these technologies and its function as a technology for routine usage.

**RESULTS:** Radiopaque perfusion compounds, or contrast agents, used to enhance the contrast of low attenuating materials have become of high interest to researchers hoping to qualify therapeutic effects on the vasculature. Several different radiopaque substances like iodine, barium, and other metallic elements often in combination with a polymer can be injected to aid microCT imaging. A widely used preclinical contrast agent is composed of silicone rubber containing lead chromate. Nevertheless, challenges to overcome includes homogenous distribution of contrast agent throughout the vasculature,

perfusion and diffusion limitations, intensity of radiopaque and more. To the author's knowledge, previously no preclinical contrast agents have enabled visualization of the finest capillaries by commercial microCT technology. The novel contrast agent,  $\mu$ Angiofil [1], has overcome these limitations and demonstrated visualization of even the finest capillaries (Fig. 1) in several tissues from both mice and rats including eye (Fig. 1), kidney, muscle and brain.

**DISCUSSION & CONCLUSIONS:** This new technology could greatly advance preclinical models and the understanding of many therapeutic effects such as accurate volume, quantity and distribution of glomerulus in renal drugs, induced effects on the vasculature from medical devices or quality control of angiogenesis in reconstructed and engineered tissue. The 3D vascular architecture in the brain is crucial to a range of neuropathological processes from dementia to stroke and Alzheimer's disease. Tumors are greatly dependent on vascularization for growth and assessment of microvasculature has become an important tool for studying angiogenesis and monitoring antiangiogenic therapies.

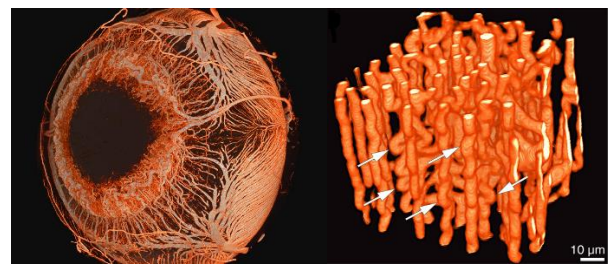


Fig. 1: 3D reconstruction from images of microCT scans showing an overview of a guinea pig eye and a high resolution scan displaying individual capillaries.

**REFERENCES:** <sup>1</sup> L. Schaad, R. Hlushchuk, S. Barré, R. Gianni-Barrera, D. Haberthür, A. Banfi, V. Djonov (2017) Correlative Imaging of the Murine Hind Limb Vasculature and Muscle Tissue by MicroCT and Light Microscopy, *Scientific Reports* 7: 41842, 1-12.

# Thermal dissipation in active implantable medical devices for neuroengineering

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**INTRODUCTION:** Active Implantable Medical Devices (AIMD) employed as Brain-Machine Interfaces (BMI) have the potential to benefit many patients affected by spinal cord injury or motor neuron diseases. Remarkable progress has been achieved in recent years by high-resolution cortical BMIs such as the BrainGate wireless neural interface tested in US clinical trials. Wyss Center for Bio and Neuroengineering has been working in collaboration with the inventors of this device to create a human grade AIMD approved by regulatory agencies in the US and Europe for treatment of neurological disorders. An important part of this endeavour is the mitigation of risks posed by the implanted device to user patients. One of the major challenges in this project is controlling the endogenous heat induced in the titanium canister by eddy currents during wireless power transfer. Consequently, thermal power dissipation in human tissues has been calculated and measured to comply with the FDA standard ISO 14708-1:2000 E that demands that no outer surface of implanted devices rise more than 2 °C above body temperature of 37 °C.

**METHODS:** Finite Element Methods (FEM) and benchtop measurements were performed to quantify heat generation. Our FEM model integrates different material properties and thickness for the scalp (7.5 mm), skull (5 mm) and brain surrounding the active implant, which lays on top of the brain, embedded by craniotomy in the skull and covered by scalp tissue. To quantify the rise in temperature of the tissue in contact with the AIMD, the standard bioheat transfer equation [1] (eq.1) was implemented in COMSOL Multiphysics 5.3 software (Stockholm, Sweden):

$$C\rho \frac{\partial T}{\partial t} = \nabla \cdot (k\nabla T) - Q_{per} + Q_{met} + Q_{ext} \quad (1)$$

where  $\rho$  is the tissue density ( $\text{kg}\cdot\text{m}^{-3}$ ),  $C$  is its specific heat ( $\text{J}\cdot(\text{kg}\cdot\text{K})^{-1}$ ),  $k$  is its thermal conductivity ( $\text{W}\cdot(\text{m}\cdot\text{K})^{-1}$ ),  $Q_{per}$  is heat loss due to blood perfusion ( $\text{W}\cdot\text{m}^{-3}$ ), and  $Q_{met}$  and  $Q_{ext}$  are heat sources arising from internal metabolism and external heating ( $\text{W}\cdot\text{m}^{-3}$ ), respectively.

Out of 2 W of power transmitted wirelessly, 1.4 W are absorbed as eddy currents by the titanium case, which is a normal value for our AIMD [2].

**RESULTS:** Figure 1 shows a calculated thermal equilibrium as function of continuous power transfer and blood perfusion rate. FEM model results are summarised in Figure 2.

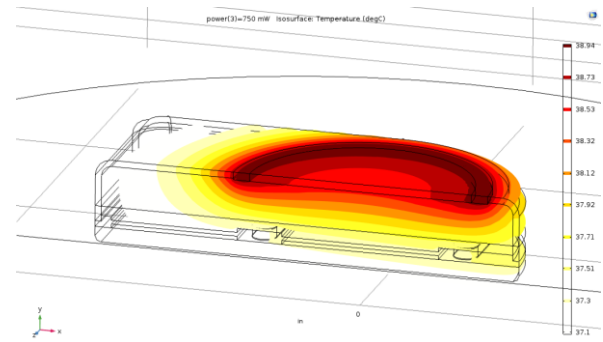


Fig. 1: Steady-state result obtained with 750 mW dissipated by eddy currents and blood perfusion rate of  $3.6 \cdot 10^{-2} \text{ s}^{-1}$ .

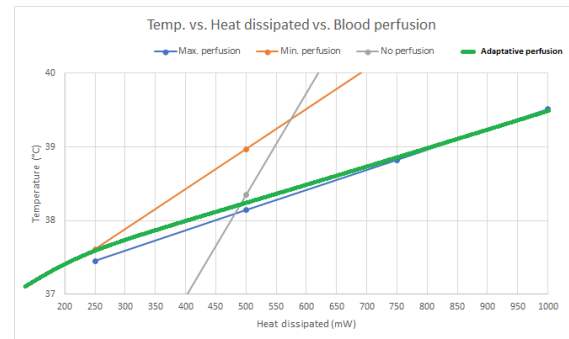


Fig. 2: Maximum temperature rise of tissue in contact with AIMD as function of heat dissipated and blood perfusion rate.

**DISCUSSION & CONCLUSIONS:** Thermal dissipation of AIMDs depends largely on blood perfusion rate. For neural devices, maximum heat dissipation is generally  $6.7 [\text{mW}/(\text{°C}\cdot\text{cm}^2)] * \text{Area}[\text{cm}^2] * \text{Temp.}[\text{°C}]$ , which yields 800 mW for a rise of 2 °C of tissue in contact with our device.

**REFERENCES:** <sup>1</sup> P. D. Wolf (2008) *Indwelling Neural Implants: Strategies for Contending with the In Vivo Environment*, W. M. Reichert, Ed. Boca Raton (FL): CRC Press/Taylor & Francis. <sup>2</sup> D. A. Borton, M. Yin, J. Aceros, and A. Nurmikko (2013) *Journal of Neural Engineering* **10**:2:026010.

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## Future lubrication of dry and wet contacts

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**INTRODUCTION:** Medical devices and instruments frequently depend on tribological performance of one or multiple parts therein. Classical solutions like siliconization or hydrophilic coatings have limitations and industry demands a new solution. While siliconization can serve to reduce dry friction, uncontrolled detachment of molecules has rendered siliconization unsuitable for delicate applications, such as in the field of ophthalmology [1,2]. Hydrophilic coatings on the other hand slide perfectly, however requiring an aqueous fluid to be present.

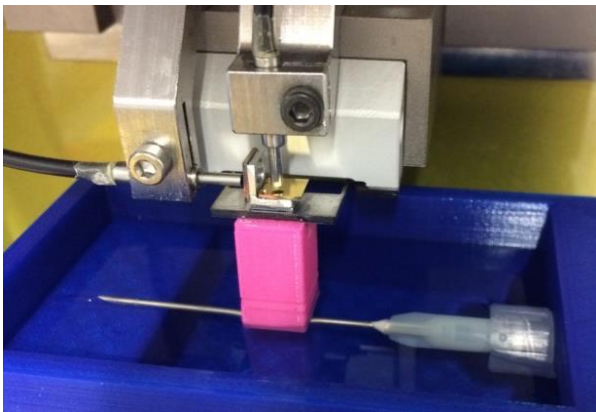


Fig. 1: Experimental setup for evaluating the frictional properties of needle coatings in both dry and wet conditions.

**METHODS:** SuSoS' newest development, the AziGrip4™ WD coating, turns tribological contacts into low friction surfaces under both dry and wet conditions. It does so by combining a hydrophilic functionality as well as a confined dry lubricant. For individual optimization, the coating can be adjusted to comply with a wide range of commercially used medical grade lubricants. Depending on the requirements, structural properties are tuneable to operate under harsh tribological conditions and provide lubrication in alternating dry and wet conditions. Evaluation of the friction performance can be obtained for example through measuring the frictional forces arising, when sliding along a coated or uncoated injection needle surface, as shown in Figure 1 above. To illustrate the effect of the AziGrip4™ WD coating in both dry and wet conditions in comparison with existing industrial coatings, respectively coated needles were tested using a microtribometer setup.

**RESULTS:** The friction force measured during sliding in reciprocal motion along the needle surface was measured for classically siliconized needles and needles coated with the new AziGrip4™ WD coating. The needles were tested both in dry conditions as well as after addition of water after 10 sliding cycles. From Figure 2 it is apparent that AziGrip4™ WD coatings provide a very low coefficient of friction compared to the siliconized coatings. In the dry case, controlled wear can occur dependent on the viscosity of the lubricant confined in the AziGrip4™ WD coating. Under wet conditions the low friction performance endures throughout the testing duration.

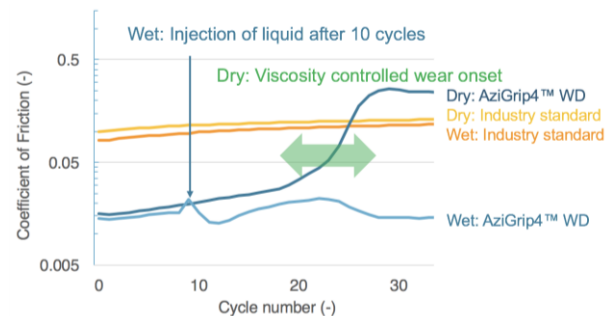


Fig. 2: Coefficient of friction of an injection needle coated with AziGrip4™ WD.

**DISCUSSION & CONCLUSIONS:** Using the example of an injection needle application, we demonstrate how next generation medical devices are enabled to meet the demands of miniaturization and to deliver optimal patient comfort. We illustrate the path from transitioning off existing technologies all the way to implementing the new coating solution to advance next generation medical devices.

**REFERENCES:** <sup>1</sup> E. Krayukhina, K. Tsumoto, S. Uchiyama and K. Fukui (2015) *J. Pharm. Sci.* **104**:527-35. <sup>2</sup> F. Felsovalyi, S. Janvier, S. Jouffray, H. Soukiassian and P. Mangiagalli (2012) *J. Pharm. Sci.* **101**:4569-83.



## Laser based microtomy for advanced histology of hard tissue and implanted tissue

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**INTRODUCTION:** Preclinical studies in the field of regenerative medicine become more and more important due to regulatory requirements and to competitiveness in the market. Histological analysis often is a mandatory, yet laborious part of preclinical study design. Laser microtomy is a novel method for fast and easy preparation of histology sections of hard tissue and tissue containing implants or biomaterials. In this contribution we demonstrate that laser based microtomy of resin embedded tissue enables for applying a broad range of classical histological stainings and may also be suitable for advanced histochemical and immunohistochemical analysis.

**METHODS:** Different types of hard tissue (e.g. bone, cochlea, jaw) or tissue containing implants (e.g. stented vessels, fixing screws) were embedded. Hard tissue was not subject to prior decalcification. Nearly serial sections were prepared by laser microtomy at ~10 µm thickness. Histological, histochemical and immunohistochemical stainings were applied as indicated in the results.

**RESULTS:** The histological slide preparations show that routine stainings can be successfully applied to thin sections performed by laser microtomy as shown by SRS/van Gieson, McNeal or Masson Goldner staining (Fig. 1). The sections show tissue architecture and cellular details clearly. Special detection of enzyme activity inside bone samples was demonstrated by Tartrate-Resistant Acid Phosphatase (TRAP) staining of osteoclasts after laser microtomy (Fig. 2), implicating that the laser cutting did not destroy the enzymes. Immunohistochemistry was performed for antigens as SMA (Fig. 2), Col-I or CD31 (not shown).

**DISCUSSION & CONCLUSIONS:** Femtosecond laser based tissue sectioning opens a new range of possibilities for histological analysis of hard undecalcified or implanted tissues. A range of histological stains, even trichrome stains, can be routinely applied with high quality to plastic embedded samples. The results indicate that thin sections prepared by laser microtomy can be applied to histochemistry or immunohistochemistry and that main enzymes or antigens are not impaired by laser sectioning.

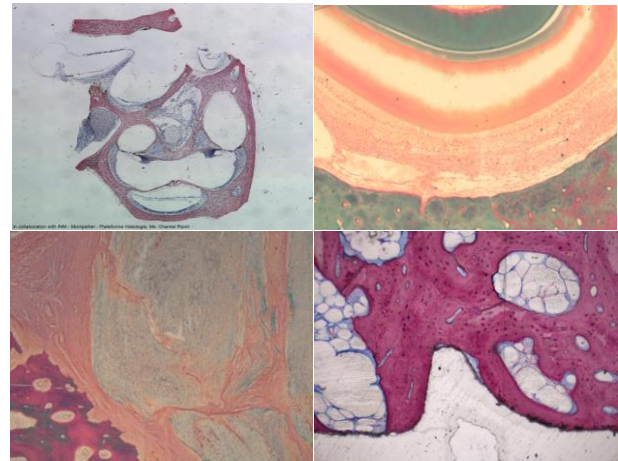


Fig. 1: Histochemical stainings of undecalcified hard tissue: Mouse cochlea stained SRS/van Gieson (upper left), Masson Goldner Trichrome stain of mouse jaw (upper right) and of rat femur with polymer implant (lower left), McNeal stain of bone section from screw implant (lower right).

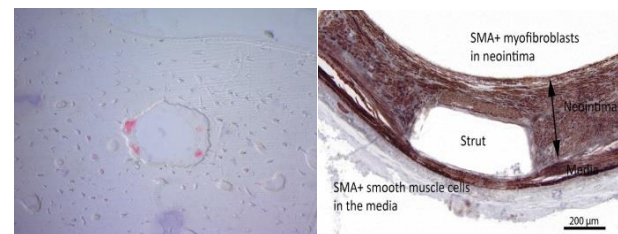


Fig. 2: Enzyme Histochemistry and immunohistochemistry: TRAP staining of mouse femur osteoclasts (left), SMA immunohistochemistry in neointima of stented pig artery (right).

**REFERENCES:** <sup>1</sup> H. Richter, et al (2015) Time- and material saving laser microtomy for hard tissue and implants. *European Cells and Materials* **29**: Suppl.2, p 4. <sup>2</sup> A. Boyde, et al (2017) A distinctive patchy osteomalacia characterises Phospho1 deficient mice. *J. Anat.* **231**:298-308. <sup>3</sup> A.-M. Pobloth, et al (2018) Mechanobiologically optimized 3D titanium-mesh scaffolds enhance bone regeneration in critical segmental defects in sheep. *Sci Transl Med* **10**: eaam 8828.

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## Surface improvement of PEEK by Multicharge Ion Implantation

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**INTRODUCTION:** Biocompatible materials are extremely surface sensitive, with their interactions with the environment being heavily influenced by their surface properties. However, the high dose ion implantation of polymers is of great interest for future biocompatible applications in the medicine field. Influence of ion implantation was studied by different researcher [1, 2] but the influence of Multicharge Ion Implantation (MCII) on tribology properties remains to be clarified.

The main objective of this study is to improve the tribological properties of biocompatible materials, specifically polyetheretherketone (PEEK), by MCII using helium ions.

**METHODS:** An extruded PEEK rod was He implanted using an Electron Cyclotron Resonator (ECR). SRIM Software was used for estimation of the penetration depth for the Helium ions. For a dose of  $0.1 \cdot 10^{16}$  ions/cm<sup>2</sup> accelerated at 20 kV, the maximum concentration of ions was calculated to be around ~280 nm from the surface with a full width half maximum (FWHM) of ~130 nm. ECR technology permits simultaneously implantation of He having different charges (He<sup>+</sup>, He<sup>2+</sup>). Tribology properties as Coefficient of Friction (CoF) and wear was measured using a CSM Instruments Nanotribometer. The applied load, sliding velocity and sliding distance were 5 mN, 0.5 cm/s and 40 m, respectively. The applied loads were limited to 5 mN, corresponding to expected values of contact pressure in implant applications (~10 MPa). The profile of the wear tracks was measured by the WYKO Rough Surface Tester (RST) Light Interferometer.

**RESULTS:** Figure 1 presents the wear rate of samples before and after implantation with different doses and energies.

The wear decreased from  $1.6 \cdot 10^{14}$  m<sup>2</sup>/N to near  $2 \cdot 10^{15}$  m<sup>2</sup>/N for reference sample and implanted one.

Figure 2 shows the surface wear after tribology tests in the case of reference and implanted samples. Nearly no wear trace is observed in the implanted sample.

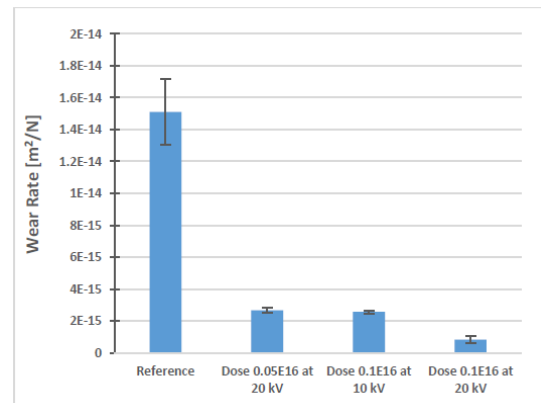


Fig. 1: Wear Rate of PEEK before implantation (reference) and after He ion implantation.

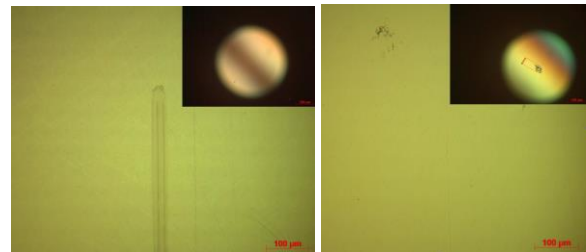


Fig. 2: For sliding distance of 40 m (at 5 mN), the reference PEEK surface (left) shows a clear sliding trace on the surface. The implanted sample at  $0.1 \cdot 10^{16}$  ions/cm<sup>2</sup> at 20 kV (right) shows nearly no trace. The surface of the steel ball (shown in insets) shows no wear for the reference sample, while for all the implanted surfaces a clear wear of the steel ball is observed.

### CONCLUSION:

The study showed that the surface properties of the PEEK can be improved and that a wear resistant surface layer can be formed by helium ion implantation at very low energy.

**REFERENCES:** <sup>1</sup> A. Macková, V. Havránek, V. Švorčík, N. Djourelov, T. Suzuki (2005) Degradation of PET, PEEK and PI induced by irradiation with 150 keV Ar<sup>+</sup> and 1.76 MeV He<sup>+</sup> ions in *Nuclear Instruments and Methods in Physics Research B* **240**:245–249. <sup>2</sup> M. Niklaus, S. Rosset, M. Dadras, P. Dubois, H. Shea (2008) Microstructure of 5 keV gold-implanted polydimethylsiloxane in *Scripta Materialia* **59**:893-896.

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