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 malpositionning 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 approximatively 2008 was the chemical modification of these XLPEs by adding less than 1 % of an active anti-oxidant (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

J Fischer[1,2]

[1] *Department of Reconstructive Dentistry, University of Basel, CH.*
[2] *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-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 osseoconductive implant 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].

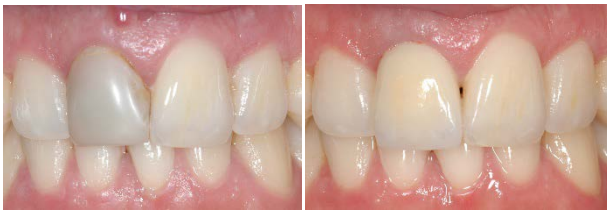


Fig. 1: Replacement of a resin crown by a veneered zirconia restoration on the right central incisor. The esthetic improvement is significant.

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: [1] I. Denry and J.R. Kelly (2014) Emerging ceramic-based materials for dentistry. *J Dent Res* **93**:1235-1242. [2] 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. [3] J. Fischer, A. Schott and S. Märtin (2016) Surface micro-structuring of zirconia dental implants. *Clin Oral Impl Res* **27**:162-166. [4] 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

M Rottmar[1], E Müller[1], S Guimond[1], U Tobler[1],
M Stephan[2], S Berner[2], K Maniura[1]

[1] Biointerfaces, Empa – Swiss Federal Laboratories for Materials Science and Technology, St.Gallen, CH. [2] Institut Straumann AG, Basel, CH

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® and SLActive®) 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^{-1}) 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^{2+}.

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®, but was significantly lower than on SLActive® surfaces. Notably, this is in agreement with results from in vivo experiments reported in literature.

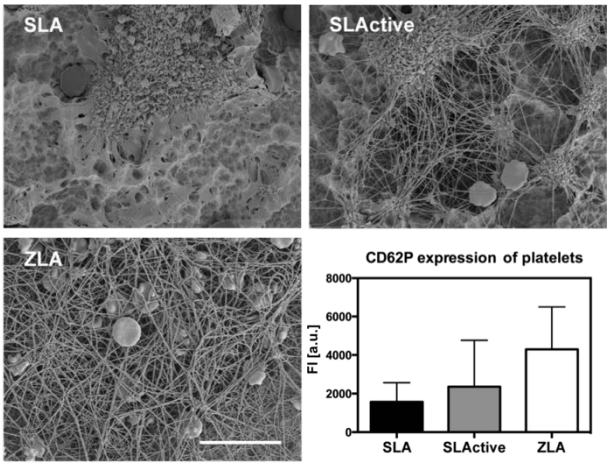


Fig. 1: SEM images of SLA, SLActive and ZLA surfaces after incubation in human whole blood. Quantification of CD62P expression of platelets on the different surfaces. Scale bar 20 µm.

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: [1] 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^3) 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: [1] Standard Specification for Wrought Molybdenum-47.5 Rhenium Alloy for Surgical Implants (UNS R03700). [2] 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.

ACKNOWLEDGEMENTS: MiRus™ LLC is acknowledged for allowing publication of this research work.

Biofilm-related implant infections

N Stumpp, M Stiesch

Department of Prosthetic Dentistry and Biomaterials Science, Hannover Medical School, Germany

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.

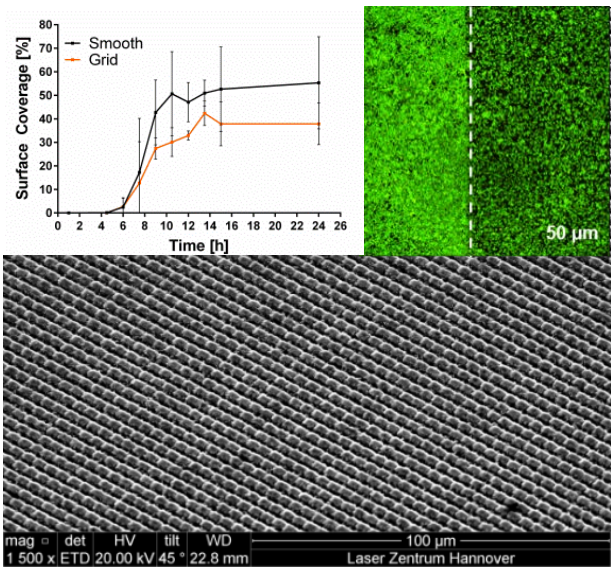


Fig. 1: Micrograph of grid-structured titanium surface showing reduced bacterial adhesion of S. aureus after 24h incubation [1]; upper right: CLSM image of S. aureus cells on structured- and control surface

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: [1] 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

MT Buhmann[1], D Abt[2], F Zuber[1], K Maniura-Weber[1], Q Ren[1]

[1] Laboratory for Biointerfaces, Empa. Swiss Federal Laboratories for Materials Science and Technology, St. Gallen, CH. [2] Department of Urology, Cantonal Hospital St. Gallen, CH

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.

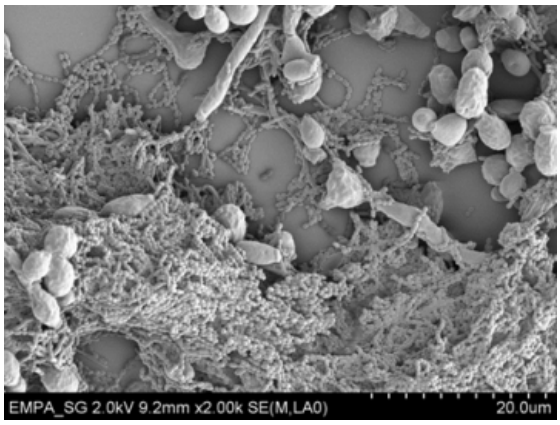
METHODS: To develop antimicrobial materials for ureteral stent, the involved relevant bacteria need to be identified. For this, biofilms from clinical ureteral stent samples were extracted using a novel biofilm extraction method and analysed for the biofilm composition and bacterial load by scanning 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).

a



b

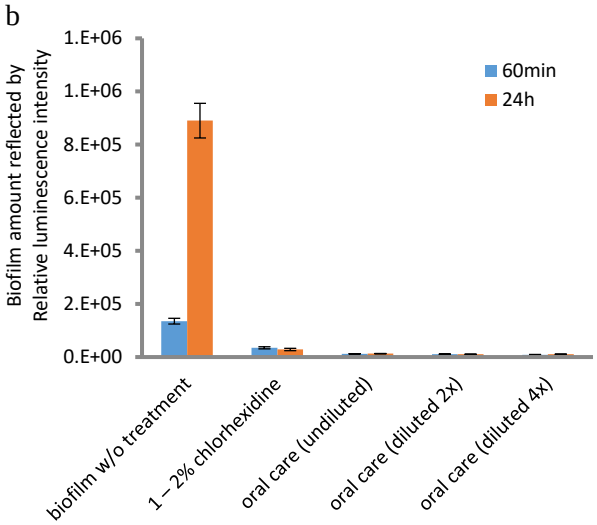


Fig. 1: (a) Multispecies biofilm Visualized by SEM. (b) Efficacy of the tested oral care gel against multispecies biofilms. Biofilm formation was assessed by fluorescent detection of ATP.

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

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

[1] *Empa, Swiss Federal Laboratories for Materials Science and Technology, Dübendorf, CH.*
[2] *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 asses 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 µm 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.

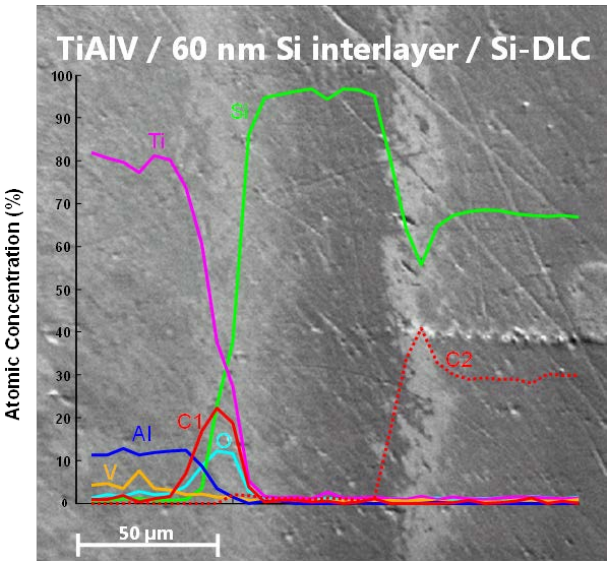


Fig. 1: SEM picture of the very low angle polished TiAlV/Si/DLC-Si interface region of an explant [3]. The Auger analysis shows the expanded 60 nm Si interlayer and a contamination at the weakened TIAlV/Si interface. C1 and C2 (carbidic) indicate two different chemical states of C.

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: [1] K. Thorwarth et al (2014) *Int. J. Mol. Sci.* **15**:10527. [2] R. Hauert et al (2013) *Surf Coat Technol* **233**:119. [3] 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.

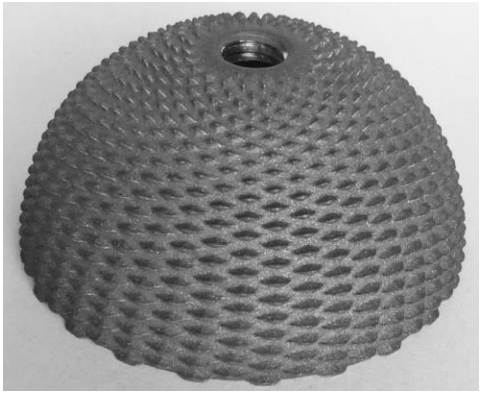


Fig. 1: Proprietary PrimeFit™ macrostructure: the shape, orientation and position of the barbs can widely be varied and, thus, customised.

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: [1] Carolyn LaWell (2017) *The Orthopaedic Industry Annual Report*, Orthoworld Inc. [2] *Annual Report* (2015) Australian Orthopaedic Association National Joint Replacement Registry.

Reduction of particles on SLM surfaces

S Zimmermann[1,2], R Schumacher[1,3], O Bill[1,4], F Dalcanale[1], M de Wild[1]

[1] *University of Applied Sciences Northwestern Switzerland, FHNW, Muttenz, CH.*
[2] *Nexilis AG, Liestal, CH.* [3] *Medartis AG, Basel, CH.* [4] *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 µm. 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 5x5x5 = 125 rhombic dodecahedron unit cells, with a designed porosity of 80 % and strut diameter of 500 µm. 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 Al_2O_3 particles (Corundum) of size 150-212 µm.
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 µm 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 (H_2SO_4 : HCl : H_2O) at 90 °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.

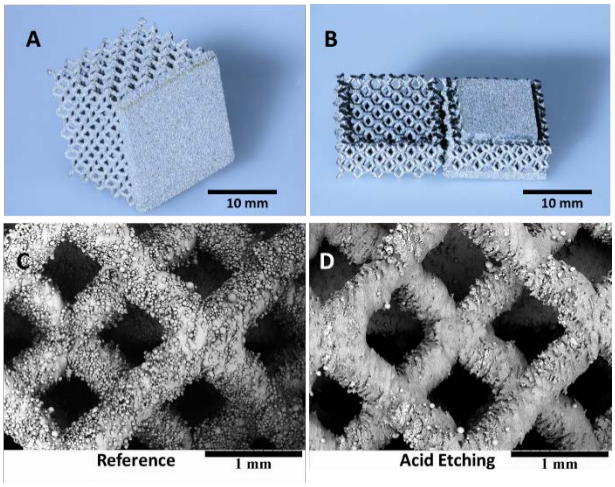


Fig. 1: Image of A) cubic sample fabricated by SLM and B) its reamed section. SEM images display the surface of the outer lattice structure of the C) as-produced sample and D) after Acid-Etching.

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: [1] 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

Clément V.M Cremmel[1]

[1] *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: 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. 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 (see 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.

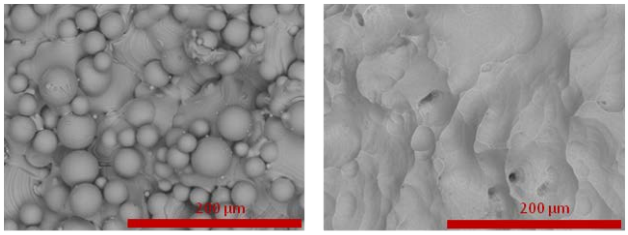


Fig. 1: SEM micrographs of titanium 3D-printed parts. Left part as received after 3D-printing, Right after surface treatment.

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

	Ra [µm]	Rq [µm]	Rz [µm]
As received	4.4 ± 0.5	5.6 ± 0.6	26.4 ± 2.2
After treatment	3.7 ± 0.9	4.6 ± 1.2	22.8 ± 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 of 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:

[1] https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500539.htm, accessed 14/12/2017