Material and Surface Technology for Implants

23rd/24th April 2012

Congress Centre Kursaal Interlaken
CH-3800 Interlaken

Conference Documentation

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General Informations

How to get to the Congress Centre Kursaal Interlaken (CKI)

The Congress Centre Kursaal Interlaken is easily accessible by car and by train. For directions please visit http://www.congress-interlaken.ch/en/home.html

Please use the north entrance at the Strandbadstrasse 44 (Riverside, see arrow). You can find the reception and registration desk immediately at this entrance.

Parking

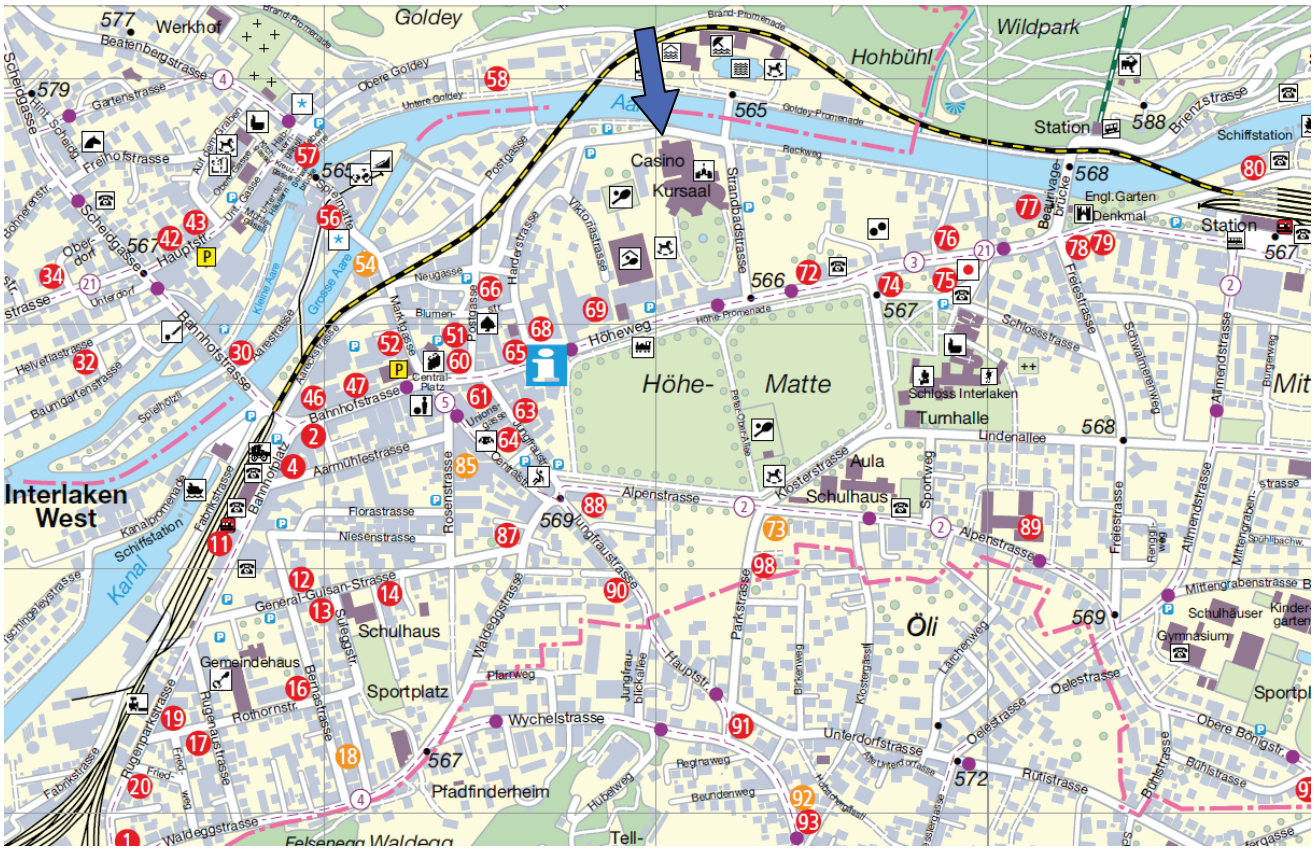
The parking lot of the Congress Centre Kursaal can be used. Congress-Tickets for CHF 6.00 per day are available at the information of the CKI.

Wardrobe

An unattended cloakroom is next to the reception of CKI in the basement (no liability).

Site plan / Hotel accomodation

A number of hotels are within walking distance from the Congress Centre Kursaal Interlaken. For the location of the hotels please see the following site map.



Hotels:

78 Hotel Carlton-Europe

68 Hotel Metropole

Dinner

The Conference Dinner must be booked at the registration. It will be held on Monday 23rd April **19:30 h** at the **Hotel Metropole**. The Hotel Metropole is located close to the Congress Centre Kursaal on Höheweg 37.

Conference Secretariat

The conference secretariat is managed by Mrs Michelle Meyer.

Availability during the meeting: Tel +41 76 324 31 15

michelle.meyer@medical-cluster.ch

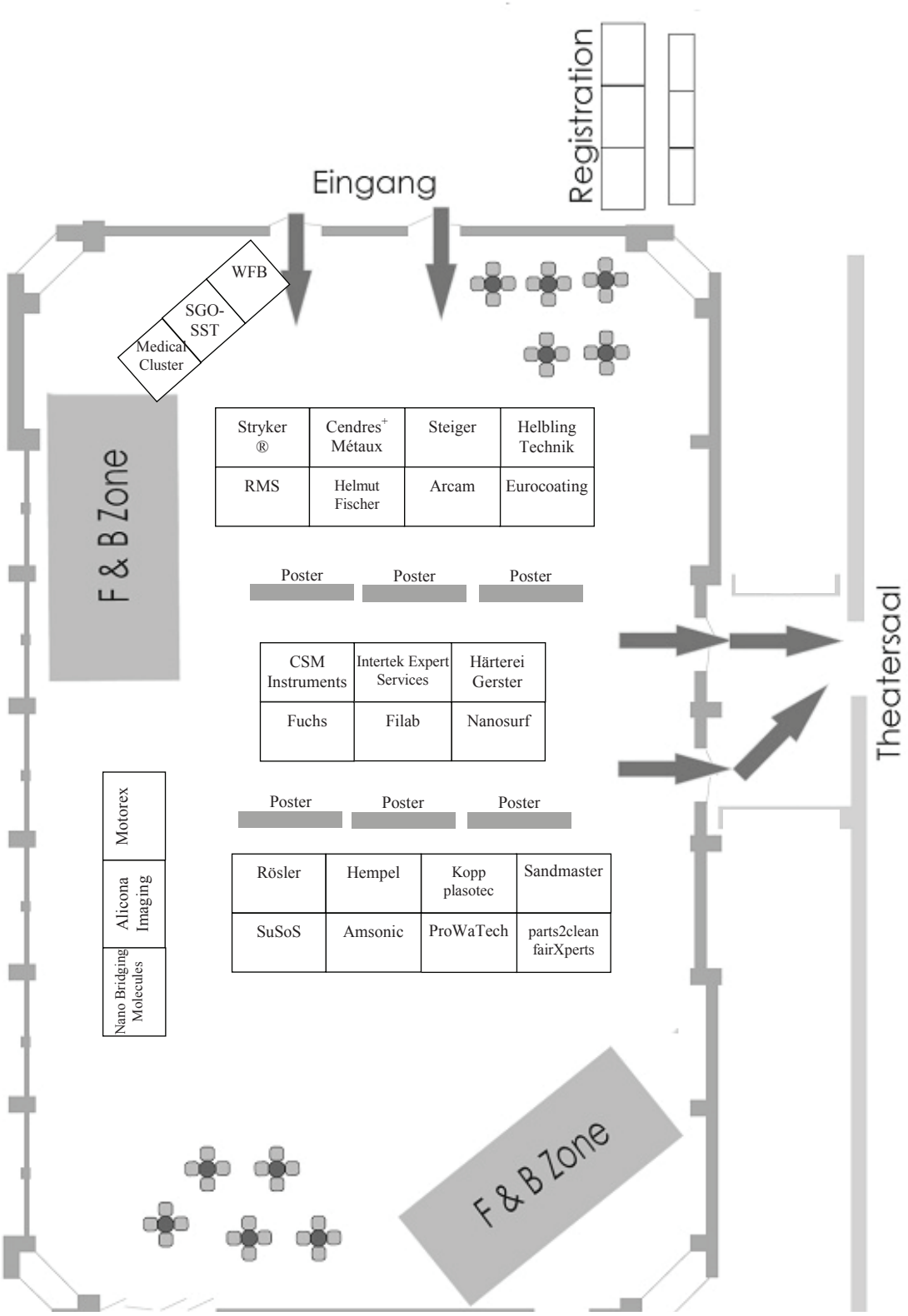
Powerpoint Presentations

The PowerPoint Presentations shown at this event remain in the property of the authors and presenters. Medical Cluster will not distribute the presentations. Please contact the corresponding author if you wish to receive more information on a specific presentation. E-Mail addresses of the authors can be found on the list of authors at the end of this documentation.

Publication

All submitted abstracts will be published online in a Supplement volume of the Journal eCells & Materials (eCM). www.ecmjournal.org
See at the back cover of this documentation for more information.

Exhibition Area



Meeting Program

Monday 23rd April 2012

From 09:30	Registration
10:00-10:15	Welcome Peter Biedermann / Dr. Lukas Eschbach / Dr. Patrik Schmutz
	Session 1: Biological interactions of implant surfaces - Chairperson: Prof. Dr. Michael de Wild
10:15-11:00	Keynote Lecture 1: Interactions at the interface of Implant Material and Biosystems (EN); Dr. rer. nat. Lutz Scheideler, University Tübingen, Germany
11:00-11:20	A new dental implant surface treatment for accelerated and improved bone healing (EN); Dr. Björn-Owe Aronsson, Nano Bridging Molecules SA, Gland, Switzerland
11:20-11:40	In vitro model for the osseointegration of rough implant surfaces (EN); Dr. Thomas Hefti, Thommen Medical AG, Waldenburg, Switzerland
11:40-12:15	Flash presentations exhibitors (1 min. each)
12:15-13:30	Lunch
	Session 2A: Physical and chemical surface modification - Chairperson: Dr. Patrik Schmutz
13:30-14:15	Keynote Lecture 2: Influence of modifications of biomaterial surfaces (EN); Prof. Dr. Marcus Textor, Department of Materials Science, ETH, Zurich, Switzerland
14:15-14:35	Parylene: Surface Modifier for Implanted Devices (EN); Lonny Wolgemuth, Specialty Coating Systems, Indianapolis, USA
14:35-15:00	Flash presentation posters (1 min. each)
15:00-15:30	Break (Exhibition and posters)
	Session 2B: Physical and chemical surface modification - Chairperson: Dr. Patrik Schmutz
15:30-15:50	Thin films on implant surface (EN); Dr. Antonio Santana, Ionbond AG, Olten, Switzerland
15:50-16:10	Microtopography for non-metallic bone implants (EN); Dr. Gilles Weder, CSEM SA, Neuenburg, Switzerland
16:10-16:30	Nanometer scale structuring of titanium oxide surfaces by anodization in the presence of particles (EN); Dr. Arthur Ganz, EPFL, Lausanne, Switzerland
16:30-16:40	Short break
	Session 2C: Physical and chemical surface modification - Chairperson: Dr. Lukas Eschbach
16:40-17:00	Entwicklung funktionaler Hartanodisationsschichten auf medizinischen Titanlegierungen (DE); Dr. Ing. Jost Friedrich, fem Research Institute Precious Metals & Metals Chemistry, Schwäbisch Gmünd, Germany
17:00-17:20	Plasmapolieren – Neue Möglichkeiten der Bearbeitung von Edelstahl und Titan (DE); Guido Besimo, Metallveredlung Kopp AG, Wettingen, Switzerland
17:30-18:30	General meeting SGO-SST
17:30-19:00	Exhibition / Poster / Aperitif
19:30	Dinner at Hotel Metropole

Meeting Program

Tuesday 24th April 2012

	Session 3A: Clinical aspects of implant surfaces - Chairperson: PD Dr. habil. Christiane Jung
08:30-09:15	Keynote Lecture 3: Medical device associated hospital infections (EN); Prof. Dr. Wolfgang Witte, Institute Robert Koch, Berlin, Germany
09:15-09:35	Untersuchung der Interaktion von pyrogenen Kontaminationen mit Implantatoberflächen mittels eines humanspezifischen Vollbluttests (DE); Dr. Stefan R.M. Fennrich, University Tübingen, Germany
09:35-09:55	N,N-dodecyl,methyl-PEI Coatings Inhibit Biofilms and Support Bone Healing During Infection (EN); Dr. Thomas Schaer, University of Pennsylvania, USA
09:55-10:20	Break (Exhibition and posters)
	Session 3B: Clinical aspects of implant surfaces - Chairperson: Prof. Dr. Michael de Wild
10:20-10:40	Antibakterielle Funktionalisierung der Oberfläche von Titanimplantaten mittels elektrochemischer Deposition von Kupfer (DE); PD Dr. habil. Christiane Jung, KKS Ultraschall AG, Steinen, Switzerland
10:40-11:00	Material science for electro-active implants – Practical needs from an engineering development perspective (EN); Jean-Noël Fehr, Helbling Technik Bern AG, Liebefeld, Switzerland
11:00-11:20	AziGrip4™-LUB: Ultrathin lubricating coating for medical applications (EN); Dr. Samuele Tosatti, SuSoS AG, Dübendorf, Switzerland
11:20-11:40	Coatings and Combination Devices - beginning of an orthopaedic revolution! (EN); Prof. Philip Procter, Stryker, Divonne-les-Bains, France & Dr. Joerg Arnoldi, BioMedTec Consulting, Bettlach, Switzerland
11:40-12:00	Biologic fixation – A systematic approach (EN); Dr. Hans Schmotzer, SigmaRC GmbH, Cham, Switzerland
12:00-13:30	Lunch
	Session 3C: Clinical aspects of implant surfaces - Chairperson: Dr. Lukas Eschbach
13:30-14:15	Keynote Lecture 4: Metallimplantatallergie (DE); Prof. Dr. med. Peter Thomas, Clinical Center of the University Munich, Germany
14:15-14:35	Risk factors for aseptic loosening of Müller-type straight stems - A register-based analysis of 828 consecutive cases with a minimum follow-up of 16 years (EN); Dr. Martin Clauss, Canton Hospital Liestal, Schweiz
14:35-14:45	Short break
	Session 4: Process validation and regulatories - Chairperson PD Dr. habil. Christiane Jung
14:45-15:30	Keynote Lecture 5: Regulatory requirements for Implants with innovative surfaces – Are Drug-device combinations overregulated? (EN); Dr. rer. nat. Franziska Baumgarten, BSI Healthcare, Darmstadt, Germany
15:30-15:50	Risk assessment of the RM titanium particle coating (EN); Dr. ès sciences Reto Lerf, Mathys AG Bettlach, Switzerland
15:50-16:10	ISO 14644-9 Klassifizierung von Oberflächenreinheit mittels Partikelkonzentration (DE); Werner Straub, Cofely AG, Zurich, Switzerland
16:15	Conference end

SurfLink® Dental Implant: A Novel Implant Surface for Accelerated and Improved Bone Healing

M. von Salis[1], B. von Rechenberg[1], S. Ferguson[2], S. Buchini[3], R. Curno[3]
P. Pechy[3], B.-O. Aronsson[3]

[1] *Musculoskeletal Research Unit, Dept. of Vet. Surgery, University of Zurich, Zurich, CH,*
[2] *Institute for Biomechanics, ETH Zurich, Zurich, CH,*
[3] *Nano Bridging Molecules SA, Gland, CH*

INTRODUCTION: SurfLink® Dental is a novel surface treatment by NBMolecules® and has shown the potential to establish a rapid and stable bone-to-implant interface, an essential requirement for successful implant integration and patient prognosis. SurfLink® binds covalently to titanium producing a nano-meter thin molecular monolayer. The treated implant is highly hydrophilic by virtue of its biomimetic phosphate-like groups. This results in enhanced biocompatibility. In the clinical situation, such enhanced biocompatibility can be expected to result in increased osseointegration and long-term implant stability, significantly reducing the risk of micromotion and increasing implant success.

METHODS: Dental implants with a roughened surface finish (SPI® Element, Thommen Medical) with either SurfLink® Dental treatment or no treatment (control) were placed in the left and right pelvis of 24 sheep according to a well-established animal model. Animals were sacrificed after 2, 8 and 52 weeks. Overall integration of SurfLink® Dental implants was assessed by histological, biomechanical and scanning electron microscopy (SEM) evaluations at short and long-term time points.

RESULTS: Implants from all groups were partially or fully surrounded by cortical and cancellous bone after 2, 8 and 52 weeks, as shown by histological analysis.

In cancellous bone at 2 weeks, SurfLink® Dental treated implants showed greater integration over control implants, as evidenced both by a higher new bone formation (+ 43 % New/Old bone) and slightly higher Bone-to-Implant Contact (BIC) values (+ 3 %). This is a significant observation, as over time, failure rates are more commonly caused by a lack of implant stability from the cancellous bone. At 8 weeks, SurfLink® Dental treated implants showed a 13 % increase in new bone formation over control implants. After 52 weeks bone remodelling appeared to slow down, with mature lamellar bone structures seen around dental implants of all groups. Compared to control implants, SurfLink® Dental treated implants showed a 39 % increase in BIC values.

SurfLink® Dental treated implants showed greater integration over control implants with higher torque and stiffness values at 2 weeks (+ 32 % and + 37 % $p \leq 0.05$, respectively). Furthermore, at 52 weeks, long term fixation and stability continued to be reflected by superior torque and stiffness values (+ 7 % and + 21 %, respectively).

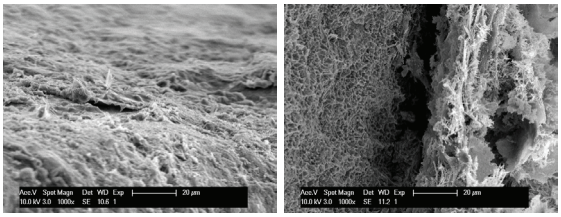


Fig. 1: SEM of implants retrieved after 52 weeks showing fracture within bone on SurfLink® Dental treated implant (left), and separation at the bone-to-implant interface on control implants (right).

SEM observations of SurfLink® Dental implants showed abundant bone coverage with fractures occurring within bone rather than at the bone to implant interface (Figure 1). This indicates a high degree of adaptation and adhesion integrating the treated surfaces with the surrounding bone.

DISCUSSION & CONCLUSIONS: In conclusion, SurfLink® Dental was shown to greatly enhance early and long-term implant fixation and overall implant osseointegration.

In vitro Model for the Osseointegration of Rough Implant Surfaces

T. Hefti[1,2,3], H. Hall[2], F. Schlottig[3], ND. Spencer[1]

[1] *Laboratory for Surface Science and Technology, Department of Materials, ETH, Zürich, CH*
[2] *Cells and BioMaterials, Department of Materials, ETH, Zürich, CH*
[3] *Thommen Medical AG, Waldenburg, CH*

INTRODUCTION: Bone remodelling is considered to be a driving force for osseointegration of implants. The resemblance between osteoclastic resorption pits and rough implant surfaces has barely been explored and could possibly help to understand the role of surface roughness in osseointegration. Therefore osteoclastic resorption pits on native bone surfaces were characterized and compared with state-of-the-art titanium and zirconia implant surfaces. Further, a model surface was designed and tested *in vitro*.

METHODS: The RAW264.7 osteoclast cell line, differentiated with RANKL, was used to generate osteoclastic resorption pits on cortical bovine bone. The dimensions of the resorption pits in bone and on subsequently collagenase-treated bone were measured with stereo-SEM and compared to three types of sandblasted and acid etched titanium surfaces and to a sandblasted and alkaline etched zirconia surface. Based on the data of the dimension of osteoclastic resorption pits a biomimetic osteoclastic resorption pattern (BORP) was designed and produced by means of eximer-laser processing and then coated with 40 nm of titanium. Subsequently, MC3T3 osteoblasts were grown on a titanium-coated BORP, on smooth and on one of the above described rough titanium implant surfaces. Cell morphology was analyzed by light microscopy and SEM. Cell differentiation after 13 days was analyzed by quantifying ALP (alkaline phosphatase) content and mineralization.

RESULTS: It was found that resorption pits from native bone and surface features of the sandblasted and etched titanium and zirconia surfaces were quite similar in their dimensions. As illustrated in Fig. 1 the engineered BORP surface resembles the structure of osteoclastic resorption pits and could be produced on a large scale. Osteoblasts grown on BORP showed similar differentiation markers, such as ALP and mineralization, to those seen for osteoblasts grown on the rough titanium surface, whereas osteoblasts cultured on the smooth surface showed significantly different levels of ALP and mineralization.

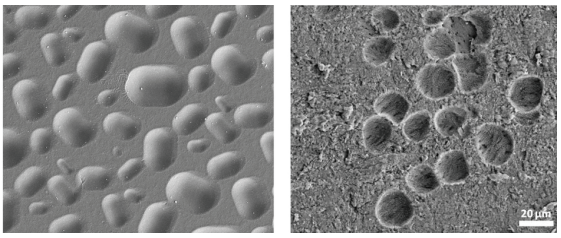


Fig. 1: Comparison between a biomimetic osteoclastic resorption pattern (BORP) (left) used as a model surface for osteoclastic resorption pits on bone (right).

DISCUSSION & CONCLUSIONS: An *in vitro* model for bone remodelling in the vicinity of implant surfaces was established with the design of an artificial biomimetic osteoclastic resorption pattern (BORP). This model might help to explain why rough implant surfaces, with roughness values in the range of osteoclastic resorption pits, show superior osseointegration properties.

REFERENCES: Hefti T et al. Biomaterials 2010 **31**, 7321-7331

ACKNOWLEDGEMENTS: TH received a scientific fellowship from Thommen Medical.

Influence of Modifications of Biomaterial Surfaces

M. Textor

ETH Zurich, Department of Materials, Zurich, CH

SURFACE MODIFICATIONS based on biochemical or biological principles are important tools for the fabrication of biosensor chips, biomedical devices such as implants, and of drug delivery carriers. Moreover, well-designed model biointerfaces have substantially contributed in the last decade to a better insight into fundamental aspects of cell-surface interaction and how this translates into cell function and tissue regeneration.

In the first part of my talk I will provide an **overview on tools** enabling the surface engineer to tailor the interface of biomaterials with special emphasis on self-assembly of functional polymers, eliminating undesirable non-specific adsorption and adding to such a silent surface biological functionalities such as peptides, carbohydrates / sugars, proteins / antibodies, growth factors or vesicles. Design criteria will be discussed in regard to the choice of material (polymers) and quantitative aspects of the polymeric interface architecture.

FUNCTIONAL SURFACE PATTERNING (adhesive islands in a non-adhesive background) and gradients have become a valuable tool to study fundamental aspects of cell-surface interactions and cell function, highlighting the role of cell shape, adhesion cues as well as substratum mechanical properties (stiffness / rigidity) on tissue cell adhesion, survival, proliferation and differentiation. Comparatively little is known about bacteria colonization on micro-patterned surfaces. Fabrication of adhesive patterns using combined lithography and self-assembly of functional polymers is described in a second part of my talk. Such platforms are believed to be a potentially valuable tool to learn how for example defined bacterial microcolonies develop in the context of biofilm formation.

Many types of bacteria including pathogenic ones have developed the ability to adhere to non-biological (and biological) materials through a range of rather different adhesion mechanisms. This is a complex and despite a great number of publications still poorly understood field of research, one reason being that adhesion depends on many factors including both unspecific and biospecific interactions, bacterial (surface) properties, type of substratum material and its surface, and the culture conditions (medium composition; presence or absence of serum (glyco)proteins; stagnant versus flow conditions). The biomaterial surface properties are known, at least *in vitro*, to strongly affect adhesion, colonization and biofilm formation, but the conclusions from the many publications are often controversial as for example the role of surface chemical composition or surface topography / roughness. Partly this is a consequence of the observation that different bacterial strains or culture conditions can show vastly different responses to surfaces.

As one example the effect of surface properties on the **adhesion and colonization of *E. coli,*** in general and with a special emphasis on different strains of *E. coli* expressing or lacking fimbriae (pili) will be discussed. Fimbriae can entirely change the mechanism of adhesion to synthetic surfaces and its dependence on presence/absence of interfacial proteins and shear force (flow).

Finally, I will show **examples of engineered surfaces** that present specific cues for the attachment and proliferation of tissue cells, but are at the same time repulsive to bacteria, which may have potential for implant applications where tissue integration and reduced risk of biofilm formation and infection are key for their performance.

REFERENCES:

«Titanium in Medicine: Material Science, Surface Science, Engineering, Biological Responses and Medical Applications». Editors: D. Brunette, P. Tengvall, M. Textor, P. Thomsen, Springer Verlag, Heidelberg and Berlin, 2001.

«Intelligent Surfaces in Biotechnology: Scientific and Engineering Concepts, Enabling Technologies, and Translation to Bio-Oriented Applications». Editors: Michelle Grandin & Marcus Textor.
Wiley & Sons, Inc., Hoboken, New Jersey, 2012

Parylene: Surface Modifier for Implanted Devices

L. Wolgemuth
Specialty Coating Systems, Indianapolis, IN USA

INTRODUCTION: When the structural and bulk requirements of a material meet an implant's requirements but the surface properties prove to be unsatisfactory, surface modification may offer a solution. Surface modification can eliminate objectionable surface properties while retaining the substrate's desirable mechanical characteristics.

Parylene coatings are utilized in medical devices to modify surfaces for numerous reasons, not the least to provide or enhance the biocompatibility of a device. Parylene coatings can also enhance electrical and frictional properties, provide various barrier capabilities, facilitate the application of other coatings (the tielayer role) and provide control of extraction/release rates of compounds from beneath the coating or within the substrate.

PARYLENE: In a classic case of serendipitous discovery, poly(para-xylylene) was discovered by Dr. Michael Szwarc in the UK at the University of Manchester in 1947. Dr. Szwarc heated several gaseous compounds, including xylylenes, to very high temperatures and then observed the degradation products as a function of temperature. Downstream from the high temperature zone, in the cooler glassware, a film formed. Dr. Szwarc correctly deduced this film to be the polymerization of a specific reaction product of p-xylyene. This was the world's first vapour deposited poly(para-xylylene), Parylene, which in its pure and colourless form we know today as Parylene N.

Dr. Szwarc's work inspired vigorous research in a number of industrial laboratories, most notably at Union Carbide Corporation in the United States. There, Dr. William F. Gorman proposed using stable powdered dimer as the feedstock for an industrial vapour deposition polymerization (VDP) process to produce Parylene. His work culminated in the issuance of a patent in 1967 and the availability of a new polymeric coating system, the Parylenes. Today the vapour deposition polymerization process, also known as the Gorham Process, is the commercial Parylene coating process utilized throughout the world.

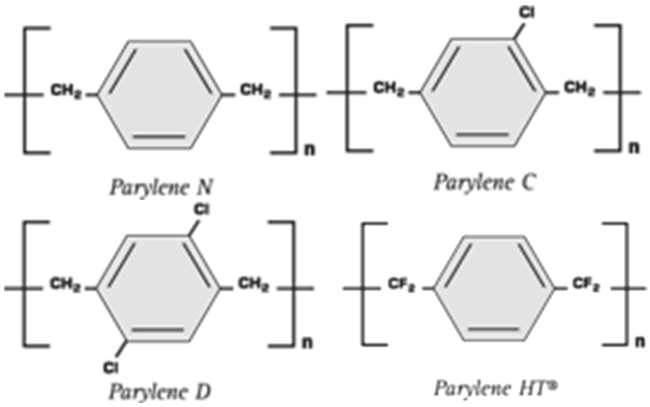


Fig. 1: Available Parylenes

PRESENTATION: Having passed an array of ISO 10993 [1] and USP Class VI biological evaluations, and used in/on implanted devices for over 35 years, biostable and biocompatible Parylene has found renewed attention for its role in one of today's most successful implanted devices … the drug-eluting stent [2,3]. This paper discusses poly(para-xylylene), the unique polymer known as **Parylene**. Parylenes are solvent, catalyst and plasticizer-free organic coatings having an impressive array of attributes: excellent chemical inertness, superior chemical, fluid, gas, moisture and electrical barrier properties, coefficients of friction in the PTFE range, and temperature performance to 450 °C.

REFERENCES: [1] International Organization for Standardization (ISO) 10993 Standards. [2] Instructions for Use: Cypher Sirolimus-Eluting Coronary Stent on Raptor Over-the-Wire Delivery Systems" [online] (Rockville, MD: FDA, 2005); available from Internet: www.fda.gov/cdrh/pdf3/P020026.pdf.
[3] Wolgemuth L.,"A Look at Parylene Coatings in Drug-Eluting Technologies", Medical Device & Diagnostics Industry, 2005, pp. 102-106.

Thin Films for Implant Articulation Surfaces: From nm to a few Microns you Tailor Surface Properties with Low Risk

A. Santana, R. Fontana, C. Davies, N. Goebbels, G.J. van der Kolk

Ionbond Group, Olten, CH

INTRODUCTION: Despite the existence of smart solutions with binary alloy monolayer ceramic thin films already on the market, new PVD/PaCVD dense thin films (ternary alloys multi-layers, nanocrystalline and amorphous) have been developed to substantially reduce surface wear, improve corrosion protection and interface adhesion. Three major opportunities for improvement have been observed in today's state of the art implant and coating systems:

1. Pinholes originating from droplets in the coating, that are removed in a post-polishing step (typical situation in Arc Evaporation technology – PVD)
2. Interface stresses between the thin film and substrate demand the right chemistry, atomic bonding and multi-layer design, especially when thin films are applied on highly loaded joints.
3. Low fracture toughness of Ceramic on Ceramic joints (CoCrMo)

METHODS: Physical Vapour Deposition (PVD) and plasma enhanced chemical vapour deposition (PaCVD) with Ionbond PVD/PaCVD equipment was used. The coatings have been characterized using micro scratch testing, linear tribotest, nanoindentation and scanning electron microscopy (SEM).

RESULTS: In all cases, multilayers evidenced denser structure when compared with monolayers. Thin film multilayers were obtained in two ways: i) alternating CrN with ZrN and ii) CrN with ADLC respectively in a PVD ARC process and in a PVD/PaCVD magnetron sputtering process.

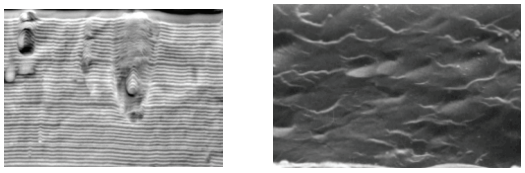


Fig. 1: Example of thin film multilayers [1] (left) vs. amorphous ADLC (right). Both films are in the range of 3 to 4 microns thickness.

Both coatings have a critical load Lc_3 superior to 50 N when applied on substrates with hardness of at least 45 HRC as in the case of CoCrMo. The wear, measured by tribotest, was lower on ADLC top layer films.

DISCUSSION & CONCLUSIONS:
The challenges of reducing wear in these different tribological contact surfaces appears environment specific. Firstly, to reduce polyethylene wear, either (i) the intrinsic properties of the polymer are tuned and/or (ii) the counter face is enhanced to prevent third body wear and roughening over time (as has been observed in vivo [2]) and/or to increase lubricity. Enhanced lubricity has been shown in the very limited cases of such ceramic coatings being used clinically [3] (e.g. multilayer coating – Aesculap / Ionbond [5]; Oxinium - Smith and Nephew) [4]. The nanocrystalline multilayer or amorphous coatings have the potential to reduce long-term UHMWPE wear, due to:

1. Increased resistance to third party body damage
2. Reduction in interface stress (hardness gradient)
3. Low friction
4. High scratch resistance
5. Enhanced fracture toughness of the system.

ACKNOWLEDGEMENTS: A. Karimi EPFL, Ecole Polytechnique Fédérale de Lausanne Institut de Physique de la Matière Condensée (ICMP). Lausanne, Switzerland.

REFERENCES: [1] 2009 Society of Vacuum Coaters 505/856-7188, 52nd Annual Technical Conf. Proc., Santa Clara, CA, May 9–14, 2009 ISSN 0737-5921. [2] Hall R.M. et al (1997) Med Eng Phys 19 (1997) 711-9. [3] Bourne, R.B. et al; (2005) Clin Orthop Rel Res, 441: 159-167. [4] Evangelista, G.T. et al (2007) JBJS-B, 89(4), 535-7. [5] Iv Patent EP 2 051 666 B1

MICROTOPOGRAPHY FOR NON-METALLIC BONE IMPLANTS

G. Weder, M. Giazzon, N. Matthey, M. Liley, H. Heinzelmann

CSEM SA, Swiss Centre for Electronics and Microtechnology, Neuchâtel, CH

INTRODUCTION: Every year more than half a million patients receive orthopedic implants worldwide. Almost all of these implants are made of stiff titanium-based alloys that cannot be used in osteoporotic patients. A new generation of bone implants made of non-resorbable fibre-reinforced composites (FRC) is being developed. These new implants will be less stiff than conventional metallic implants, which will reduce the stress shielding effects and the resulting local bone loss and even fractures that are associated with existing implants.
CSEM is working on the surface texture of the implants with the aim of improving osseointegration. A number of different surface parameters play a role in the interactions between cells/tissues and implants; a crucial one is surface topography.

METHODS: Several microstructures were developed in non-metallic materials (dimethacrylate resins). Combinations of microtopographies and chemical treatments were compared through different *in vitro* and *in vivo* biological tests.
The implant material to be structured is a UV-setting polymer based on BisGMA/TEGDMA (70:30 (w:w)) resins. Surface structuring is done by casting the resins in a structured mould. Demoulding was facilitated by using polydimethylsiloxane (PDMS) as a soft mould material. Original microstructures were microfabricated in quartz and positively replicated in PDMS to perform the final replication in resins.

RESULTS: Proliferation studies made on planar samples using an osteosarcoma cell line (SaOs-2) indicate that the cell grows well and colonizes the structured surfaces (Fig. 1 & 2). Moreover, proliferation on the structured resin disks appears much better than on control surfaces made of titanium alloys currently used in conventional bone implants.
Results show that the most promising structure consists of quasi-hemispherical pits with diameter of about 27 µm, a depth of 9 µm and space between pits of around 12 µm. This micro-structure was selected to be used in *in vivo* tests on mini-pigs (Fig. 3).

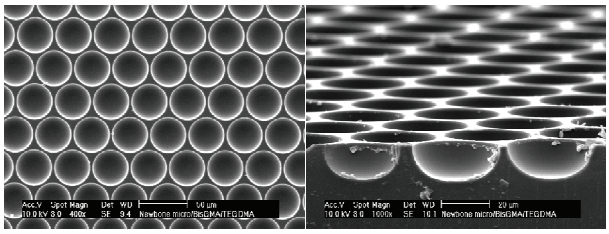


Fig. 1: Scanning electron microscopy images of different views of hemispherical pits (diameter 36 µm) replicated in BisGMA/TEGDMA resins.

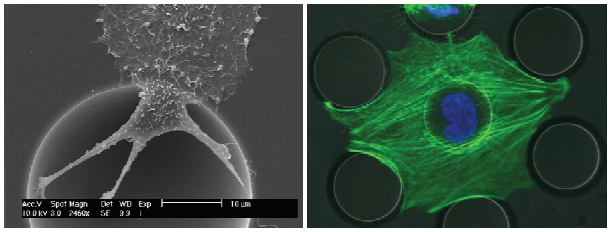


Fig. 2: Human osteoblasts on hemispherical pits by scanning electron microscopy and confocal microscopy (actin in green and DNA in blue).

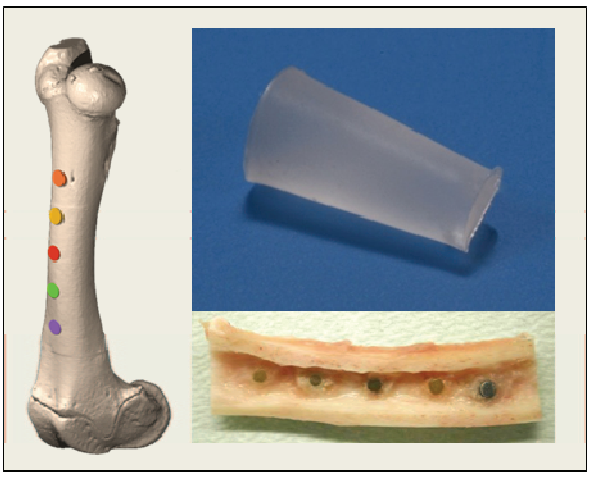


Fig. 3: Textured 3D samples were implanted for a period of 12 weeks before histological analysis.

DISCUSSION & CONCLUSIONS: This new generation of non-metallic implants shows better *in vitro* cell proliferation than titanium implants. *In vivo* tests showed that the presence of microtopography positively influences the results of the mechanical push-out tests and hard tissue histology.

Nanometre Scale Structuring of Titanium Oxide Surfaces by Anodizing in the Presence of Particles

A. Ganz, H. Hofmann

Powder Technology Laboratory, Ecole Polytechnique Fédérale de Lausanne, Lausanne, CH

INTRODUCTION: Electrochemical surface structuring of titanium oxide is a promising concept that finds applications in various fields such as biomedical engineering [1–3] and micro-systems applications [4]. Electrochemical methods to modify in a controlled and ordered way the micro- and nanometre scale topography of surfaces could be desirable in the field of biosensors, biomaterials or catalysis, where ordered arrays of nanometre size topographic features are often required. In this work, adsorbed particle monolayers are used as masks during the anodizing of titanium surfaces to obtain ordered topographic features in the nanometer range.

METHODS: Titanium strips were electropolished in 3 mol/L sulphuric acid solution in methanol so as to obtain extremely smooth starting surfaces. Monodisperse polystyrene (PS) spheres of 500 nm in diameter were deposited on these surfaces from suspension by controlled drop drying. The particles were then modified by heat and plasma treatments to optimise their contact area with the surface. Anodizing was done in 0.5 mol/L aqueous sulphuric acid at different voltages between 20 and 100 V. The particles were then removed from the surface by a 15 minutes plasma treatment, and the topography of the underlying anodic oxide layer was investigated by atomic force microscopy and scanning electron microscopy.

RESULTS: Ordered self-assembled monolayers of particles were successfully deposited, as can be seen on figure 1.

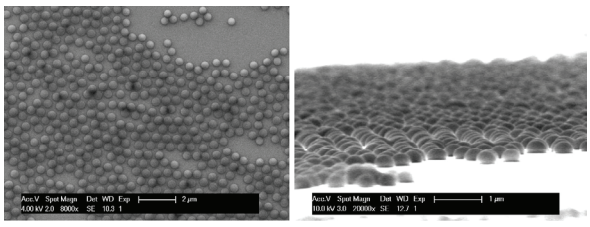


Fig. 1: Ordered array of polymeric particles deposited on smooth titanium surface.

During anodizing, the sample was oxidised on the whole surface, including underneath the particles. Wall-like protrusions of titanium dioxide between 30 and 100 nm in height were created between the particles, resulting in a honeycomb-like ordered topography (fig. 2).

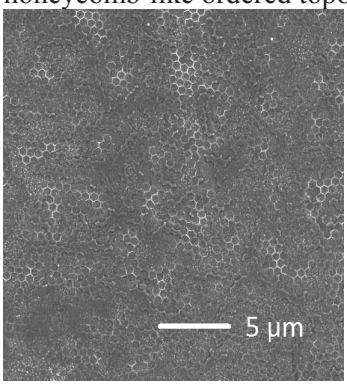


Fig. 2: SEM image of underlying anodic layer after anodizing and removal of the particles by plasma etching. A regular honeycomb structure is observed.

DISCUSSION & CONCLUSIONS: Anodizing is not prevented by the presence of particles, but the topography of the anodic oxide layer is affected by it, especially in the vicinity of the rims of the particles. Anodizing voltage, as well as the anodizing voltage profile has a strong influence on the topography. Surface structuring by anodizing in the presence of particles was shown to be a valid concept which can produce ordered topographic features in the nanometre range. It is a bottom-up approach that can potentially be easier and cheaper than top-down lithography techniques, while achieving a good control of feature size by the appropriate choice of particles and anodizing conditions.

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ACKNOWLEDGEMENTS: This work was supported by the Entwicklungsfonds Seltene Metalle (ESM) in Zürich.

Development of Functional Hard Anodizing Layers on Medical Titanium Alloys

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INTRODUCTION: Titanium alloys have high specific strengths and good fatigue properties. They are implanted in the body after bone fractures as screws, nails or plates. However, titanium has bad tribological characteristics that can express itself in heavy-gauge adhesion wear. A recharge of cell toxic acting ions and particles in the tissue released by wear processes can cause wound healing disturbances and hypersensitivity reactions. A solution is to change the chemical nature and hardness of the titanium surfaces. For this, the plasma-electrolytic oxidation (PEO) is applied to further strengthen the natural oxide layer of titanium. The study deals with the influence of pre-treatment processes, the anodizing process and glass bead blasting on the characteristics and tribological properties of the generated layers.

METHODS: Samples were made of pure Ti, Ti6Al4V, Ti6Al7Nb and Ti15Mo and anodized under variation of electrolyte concentration and temperature, electric voltage and current. An extensive characterization of the produced hard material coatings followed, such as penetrant testing and roughness measurements using the tactile scanning method. Against the background of friction and corrosion behaviour, the chemical composition of the layer became interesting. The investigations showed that, despite the electrical insulation properties of titanium dioxide, a semi-quantitative analysis of most layer elements was possible by means of glow discharge optical emission spectroscopy (GD-OES). The standardized parameters "friction coefficient" (DIN 50281) as well as "wear amount" (DIN 50321) were measured with the pin-on-disk test system. It is beneficial that these tests can be done both in air and under the influence of physiological testing solutions on the friction system.

RESULTS: For the PEO, a uniform course of spark is crucial to build up a uniform layer. This is the case with a favourable concentration ratio of the electrolyte solution of sodium hydroxide to water glass. Electrolyte temperatures between 25 and 50 °C are required. Beyond there is a risk of electrolyte decomposition, underneath precipitation can occur. Anodizing voltage should range between 40 and 65 V, and current density between 1 and 4 A/dm^2. Typically the layer structure consists of a base layer which is firmly adhering to the substrate material and a porous surface. The surface is mechanically little robust, and must be removed with a suitable procedure. For this glass bead blasting can be applied. The result is a close oxide layer with a greasy shine and excellent feel. Its hardness readings lie between 900-1600 HV. In contrast, the hardness of a non-coated titanium specimen is approx. 250 HV (Ti6Al4V). Its roughness values are Rz=.0 µm and Ra=0.6 µm, and thus twice as high as on a non-coated titanium surface. Measurements with the pin-on-disk test system showed, that the friction coefficients of the base layer to a 100Cr6-friction partner were higher than the friction coefficients of uncoated titanium samples (µ=0.67 vs. µ=0.59). In spite of the increased value of friction the layers however proved very stable. Even after 10’000 revolutions and a test load of 1 N, the layers were still free from traces of wear.

DISCUSSION & CONCLUSIONS: The present results show that the tribological properties of titanium alloy surfaces can be significantly influenced by a 1 µm thick titanium dioxide layer only. The scientific challenge is to demonstrate the influence of coating parameters by methods of layer characterization to derive hereof the behaviour of the implant in the human body.

ACKNOWLEDGEMENTS: The IGF project No.: 16965 N of Research Association fem Verein für das Forschungsinstitut für Edelmetalle und Metallchemie e.V. was funded via the AiF within the framework of the programme for the funding of the Industriellen Gemeinschaftsforschung und –entwicklung (IGF) of the Federal Ministry of Economics and Technology on the basis of a decision of the German Bundestag.

Electrolyte-Plasma Polishing of Metal Surfaces in Medical Technology

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INTRODUCTION: Building on research from the 1980s to create the fundamentals of electrical discharge processes in electrolyte solutions, the research topic "Innovative plasma processing of metal components" was taken up in 2001. Between 2001 and 2004, the theoretical and practical bases for the new, innovative plasma polishing process were placed in the context of the development programme "PRO INNO". These fundamentals were compiled in an alliance of enterprises consisting of several companies and the Beckmann Institute for Technology Development from Saxony in Germany.

OPERATION: Plasma polishing is an electrolytic finishing method, where, through process-related shaping of a plasma skin and using thermal and electrochemical procedures, anodically polarised metallic parts achieve a surface quality previously unattainable with classic polishing methods.

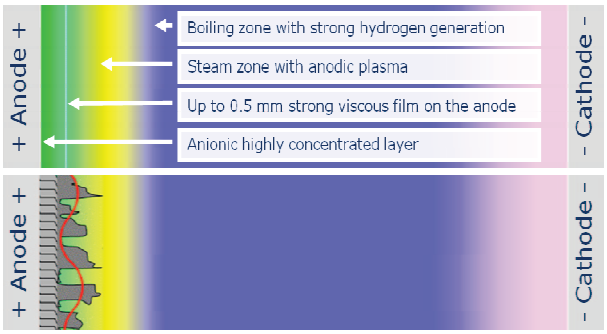

Fig. 1: Reaction mechanisms during plasma polishing

To date, electrolytes have been developed for finishing stainless steel, CrCoMo alloys, brass, copper, nickel, titanium and titanium alloys (in the development phase).

RESULTS: Apart from the levelling of micro roughness accompanied by minimal mass loss, burrs as well as organic and inorganic surface impurities are completely removed. The finished surfaces were examined cytotoxicologically and fulfil the exacting requirements of medical technology. In addition, depending on the material, considerable corrosion inhibition of finished metal surfaces can be observed.

With attainable roughness values < 0.003 µm, this process can also be used as a complement and a problem solver for existing surface finishing methods

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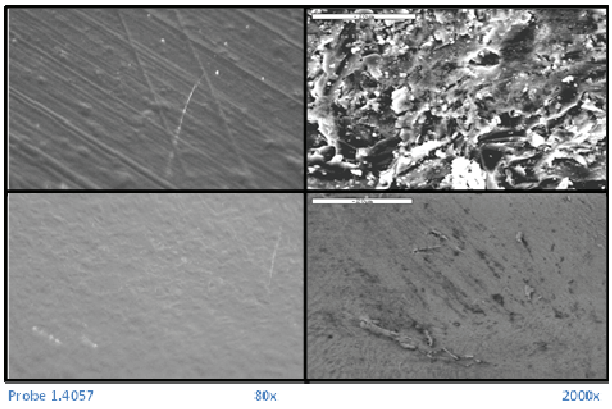

Fig. 2: Test 1.4057 SEM image, top to bottom after processing

DISCUSSION & CONCLUSIONS: Currently work is being conducted on transferring the process to finishing interior surfaces of stainless steel pipes. Should this step succeed, a great surge in innovation in the finishing of high-quality stainless steel pipes for the pharmaceutical industry, the food industry and medical technology can be anticipated.

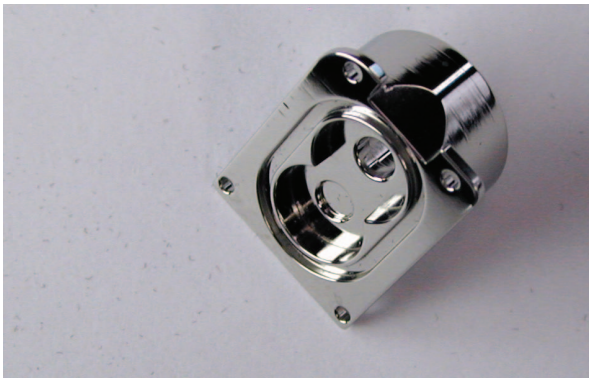

Fig. 3: Surface optimisation of an implant pump from Sequana Medical

ACKNOWLEDGEMENTS:
Beckmann-Institut für Technologieentwicklung e.V., Sequana Medical AG

Medical Device Associated Hospital Infections

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INTRODUCTION: The use of biomaterials such as joint endoprosthesis and plastic materials (e.g. catheters) has largely contributed to the medical progress during the past decade. However, infections associated with biomaterials endanger this progress. Most of the cases are hospital associated infections. An overview about the relevant bacterial strains and the main mechanistic aspects of bacterial infections and their dissemination as well as approaches to prevent infections are discussed.

METHODS: The presented overview bases on published studies, case descriptions and data from the Robert Koch Institute [1].

RESULTS: Infections of hip and knee endoprosthesis are still comparably rare in Central Europe, they are, however, now on the rise at low level (for 0.5% of infected TEP to ~2.5% during the past decade) [2-3]. A particular problem poses methicillin-resistant *Staphylococcus aureus* (MRSA) as therapeutic options are limited. Furthermore, particular hospital associated strains possess a pronounced capacity for spreading in nosocomial settings. Among coagulase negative staphylococci *S. epidermidis* is a frequent case of catheter associated infections [4].

DISCUSSION & CONCLUSIONS: A prerequisite to infections of biomaterials is the capacity to form a biofilm (Figure 1), for which an intracellular adhesion, ica, is of central significance. The ica gene cluster is ubiquitous in *S. aureus*. In *S. epidermidis*, ica is contained by a particular subpopulation which is mainly association with hospitals.

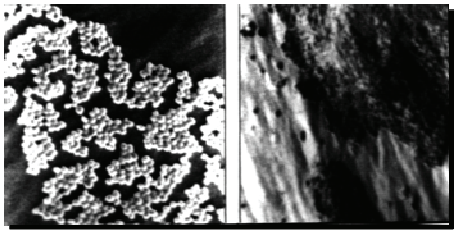

Fig. 1: Staphylococcus epidermidis adhered to a hydrophobic surface (A), and embedded into a biofilm (B) (from Christensen et al. [5]).

The most effective way to prevent infections of biomaterials is of cause hospital hygiene, but furthermore, there are different ways to equip biomaterials with an antibacterial outfit. The first approaches which are still in use were based on incorporation of antibiotics and other antibacterial substances into bone cement or into plastic materials with the disadvantage of only short time setting fee of sufficient amounts of the antibacterial.

More recent and promising are coatings of the biomaterial with either active molecules or nanoparticles. Free heavy metal ions such as Cu^{2+} and Zn^{2+} bear the risk of resistance development. If corresponding resistance genes are contained by transferable elements containing antibiotic resistance genes (e.g., SCCmec containing mecA) coselection of antibiotic resistance becomes likely.

There are interesting new ways: coating with modified antibacterial cationic peptides and with substances which inhibit biofilm formation (for review see [6,7]).

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Investigating the Interaction of Pyrogenic Contaminations with Medical Devices using a Human Specific Assay

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INTRODUCTION: Any medical device which will come into contact with blood needs to be tested on its haemocompatibility as well as pyrogenic activity, since contaminations and surface contact can start pro-inflammatory reactions and activation of cascades within the haemostasis[1]. The ISO 10993-4 regulates quality assessments for haemocompatibility and the interactions of medical devices with blood, whereby endotoxins interfere with haemostasis but are not specifically determined. Recently, a novel detection method for pyrogenic activity has been implemented into the Pharmacopoeia (EP 6.7, 2010[2,3]) as an *in vitro* substitute for the rabbit pyrogen test and supplement to the Limulus assay. While the Limulus detects endotoxins only, the novel PyroDetect detects all pyrogens, i.e. endotoxins and non-endotoxins such as Gram-positive and fungal pyrogens. Here we demonstrate the suitability of this test to detect pyrogenic activity in various medical devices and raw materials.

METHODS: Slides made of clinical grade steel were tested on their haemocompatibility according to standard procedures in our GLP certified laboratory in compliance with ISO 10993-4. The monocyte activation test (MAT) was then used to detect pyrogenic activity on the steel slides and other medical devices (stents and stent systems). Critical steps were performed under sterile conditions in a laminar air flow. Briefly, the devices were transferred into pyrogen-free 6-well-plates and incubated with increasing concentrations of endotoxin (WHO standard, *E.coli* O113:H10:K) and freshly drawn human whole blood. After overnight static incubation the blood cells were pelleted and the supernatant fluid tested on the interleukin-1β content.

RESULTS: Initially, clinical grade steel as raw material used for many medical devices was tested on its haemocompatibility and all tests showed no specific activation. The same material was then used in the MAT where also no interference of the materials was detected. Further devices were tested, directly in contact with the human whole blood as sensor, yielding good and specific recovery of pyrogens on bare metal stents (see Fig. 1) and stent systems.

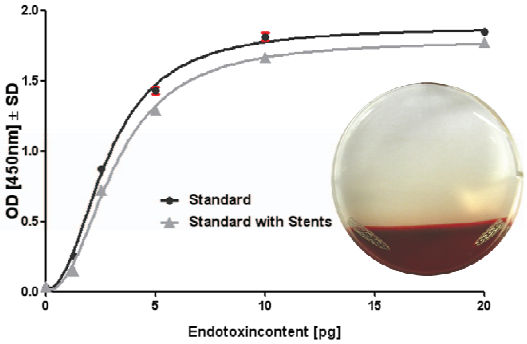

Fig. 1: Effect of medical devices on endotoxin-induced interleukin-1β production in human whole blood: Bare metal stents, fit into 6-well-plates (insert), did not alter the interleukin-1β production in human whole blood.

DISCUSSION & CONCLUSIONS: The MAT proved to be ideal for detecting pyrogenic contaminations on medical devices. With its human specific setup and detection of all pyrogens, it exceeds the spectrum of the LAL assay which detects only endotoxins. In addition, using the MAT, the material to be tested is in direct contact with the "sensor blood". Using the LAL the contaminations need to be washed off the surface with an unknown recovery. Therefore, we propose the implementation of the MAT into the ISO in order to cover the current gap in detection of the whole spectrum of pyrogens.

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ACKNOWLEDGEMENTS: The authors would like to thank Qualimed for providing stents and stent systems as well as Doris Armbruster for the excellent technical help in the haemocompatibility testing.

N,N-dodecyl,methyl-PEI Coatings Inhibit Biofilms and Support Bone Healing During Infection

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INTRODUCTION: Implant associated infections contribute to increased patient morbidity and cost. Adhesion of serum proteins to the implant and low vascularity in the area of trauma create an ideal environment for bacterial adherence. Within a biofilm, bacteria synthesize an extracellular matrix that protects them from the host's immune response and systemic antimicrobials. Importantly, bacterial coloni-zation onto substrates appears to be the critical step in biofilm formation. We have focused our attention on surface modifications that inhibit the adherence of bacteria to implants and thereby prevent the root cause of orthopedic infections. We hypothesized that coating ortho-pedic fracture plates with certain hydrophobic polycations could favorably influence bone healing in a large animal fracture infection model.

METHODS: Twelve mature female sheep were enrolled in a prospective study using a previously validated long bone infection model. A unilateral mid-diaphyseal transverse tibial osteotomy was performed. The osteotomy was reduced using a narrow 4.5mm eight or nine hole stainless steel 316L locking compression plate (LCP). After soft tissue closure, 10^6 CFUs of *Staphylococcus aureus* ATCC25923 were inoculated via a temporary catheter. Six sheep received a HPC coated implant (treatment cohort) and the remaining six animals received a non-coated implant (control cohort). Implants were dip-coated intraoperative in parallel with aliquots of LCPs for in vitro verification of adequate HPC coating. Radiographs were obtained immediately postoperative and at one month before euthanasia and scored by three blinded reviewers for presence of septic osteomyelitis and callus morphology. The left hind limb was harvested and aseptically prepared for implant retrieval. A sterile culture was taken before implant removal. Tibias underwent μ-CT for qualitative 3-D reconstructions. The osteotomy region was harvested and processed for histology and sections were scored by a blinded veterinary pathologist. Plate pieces were processed, for SEM and viewed at 1500x and 3000x for evidence of bacterial colonization. Statistical analysis was carried out on scores from radiographic, histologic and explant eva-luations. A paired t-test was used to form preliminary associations and a statistical significance of $p<0.05$ was used for all tests.

RESULTS: All animals completed the study. Radiographic evaluation revealed significantly greater healing and bony remodeling consistent with normal "fracture healing" in treatment animals compared to controls ($p<0.05$). Gross evaluation revealed the osteotomy sites in control animals to be grossly unstable with evidence of infection ($p<0.05$). Micro-CT and histological evaluation corroborated radiographic and macroscopic data with lower scores in treatment when compared to controls ($p<0.05$) consistent with normal bone healing. SEM visualization of explanted LCPs displayed abundant biofilm formation covering >95% of the plate surface in control plates compared with no bacterial growth on HPC coated implants.

DISCUSSION & CONCLUSIONS: Advantages of HPC surface modification are (1) the ease with which the coating can be applied intraoperative to any geometry implant, (2) death of the bacteria by mechanical disruption of the cell wall is less likely to create multi-drug resistant bacteria[1]. Conferring protection from pathogenic bacteria to an orthopedic implant of industrial size and geometry *in vivo* is promising for reducing implant-associated infections in the orthopedic patient.

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ACKNOWLEDGEMENTS: Supported by the PENN VET Comparative Orthopaedic Research Laboratory and also by the U.S. Army through the Institute of Soldier Nanotechnologies contract DAAD-19-02-D0002.

Antibacterial Functionalization of the Surface of Titanium Implants by Electrochemical Copper Deposition

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INTRODUCTION: The growing number of cases of implant-associated infections is a serious problem not only for the patient but also for the healthcare system. Furnishing the implant surface with antimicrobial properties is regarded to be promising to prevent infection because it acts locally at the site of infect initiation. We have deposited the antimicrobial agent copper on the rough, fine-porous surface of titanium samples and studied the antibacterial effect.

METHODS: Discs of cp Ti (gr. 4, ∅ 14 mm, 1.5 mm thick) were mechanically pre-treated and ultrasonically cleaned. Samples were anodized according to the spark-assisted anodizing (SAA) method [1] to produce a rough, fine-porous surface. Copper was electrochemically deposited using proprietary electrolytes and process parameters. The copper deposits were characterized by SEM/EDX. For determination of the total amount, the deposited copper was digested in nitric acid, quantified by AAS and set in relation to EDX values. The copper release kinetics were studied in simulated body fluid. Antimicrobial activity was determined by dilution series with *E. coli K12 DH5α* and *Staphylococcus aureus* and live/dead staining of the modified surfaces. The lethal dose for MG-63 osteosarcoma cells was determined by serial dilutions of a copper standard solution and a colorimetric assay.

RESULTS: The anodized samples show a fine-porous oxide layer with Cu deposits of different cluster forms and surface distribution (Fig. 1).

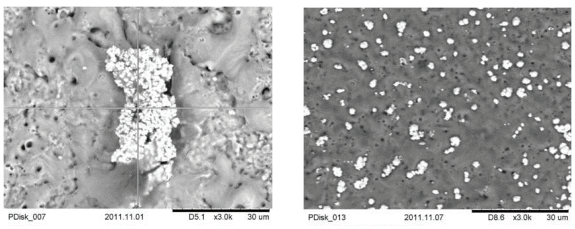

Fig. 1: SEM pictures of the surface of the titanium discs (3000x magnification). Copper appears as white spots in clusters (left) or as small single deposits (right).

The lethal copper doses for *E. coli K12 DH5α*, *S. aureus* and MG-63 osteosarcoma cells have been determined to be 100 µg/ml, 5 µg/ml and 60 µg/ml, respectively [2]. Fig. 2 demonstrates the rate of release of the deposited copper from the titanium discs. After 10 days, release experiments at 37 °C were continued at 80 °C to simulate the long-term effect [3].

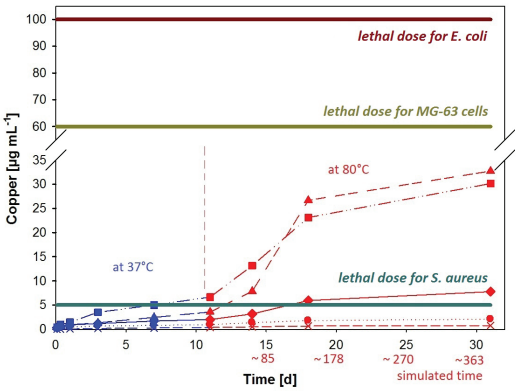

Fig. 2: Released copper from the titanium surface into simulated body fluid at 37 °C for 10 days and at 80 °C after 10 days. The horizontal lines indicate the lethal doses which have been determined in independent experiments.

DISCUSSION & CONCLUSIONS: Copper has been successfully deposited on SAA-modified titanium surfaces. Further studies are required to improve the homogeneity and size of the copper deposits. *S. aureus* can be completely killed after ten release days while much longer time is required for *E. coli K12 DH5α*. Further tests on other bacterial strains will show whether this is a general effect. Antibacterial functionalization of titanium implants by copper is possible.

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ACKNOWLEDGEMENTS: This research activity belongs to the project "NAPTIS", funded by the Swiss Nanoscience Institute.

Material Science for Electro-Active Implants – Practical Needs from an Engineering Development Perspective

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[2] *Elenza Inc., USA*

Material science and **process development** are key aspects in the development of electro-active implants. The trend to miniaturization leads to the need of integrating multiple functions onto internal and external surfaces of electro-active implants, e.g., biocompatibility in combination to adhesion of polymers, deposition of metallic layers or electro-active structures like photovoltaic PV-cells or thin-film batteries. In addition to physical and chemical functionality, long-term stability throughout manufacturing and lifetime of the implant are key requirements.

Due to high technology variability vs. project needs, successful technology and product developments require strong partnerships with technology providers satisfying the following needs:

- material and process development for surface functionalization of implant casings
- description of process parameters (e.g., physical treatment, chemical composition, residues) to show design compatibility
- support product and process certification compliant to US and European regulations
- support lifetime analysis by providing test data and/or experimental evaluation methods
- biocompatibility studies by providing samples and test data

As an example, **Elenza, Inc.**, is developing the world's first electronic Auto-Focal Intraocular Lens (AF-IOL), which is designed to give patients a complete visual range, providing effective near, intermediate and distance vision. With reference to Figure 1, the electro-active IOL uses a proprietary combination of liquid-crystal chemistry, electricity, and integrated-circuitry to create smart optics, which will provide patients with the ability to see more naturally and clearly over the full range of vision. The technology includes an electro-active switchable element that automatically adjusts focusing power electronically, in milliseconds, to maintain constant in-focus vision for various working needs and/or light environments. The lens is controlled by a micro-sized power-cell with an expected 50+ year rechargeable cycle life.

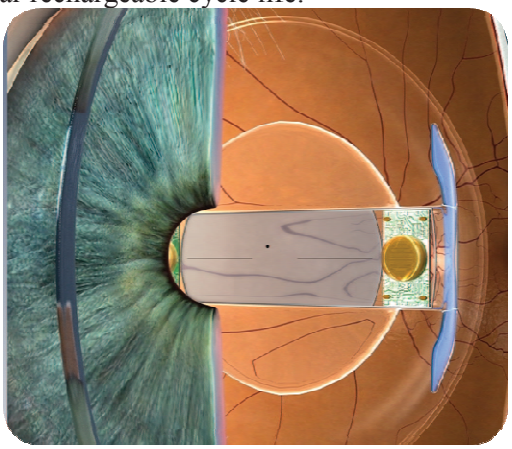

Fig. 1: Elenza's AF-IOL providing effective near, intermediate and distance vision.

The conference talk emphasizes on the following specific **material science** and **process development** needs in Elenza's AF-IOL program:

- transparent and biocompatible material for encapsulation of the AF-IOL
- surface treatment to improve eye implantation
- high performance adhesion of conductive films
- non-destructive methods for controlling inter-metallic layer and soldering steps
- thin-film and photovoltaic material, deposition process, system integration and long-term stability

Helbling Technik is a worldwide active Swiss contract engineering and innovation company present in Zurich, Bern, Wil, Aarau (Switzerland), Munich (Germany) and Boston (USA). The business center in Bern has been developing electro-active implants for many years, among them hearing aids, drug delivery devices, neurostimulators and ophthalmic applications. It relies upon experience, resources, design and lab infrastructure to provide services in the field of project- and medical quality management, mechanics, optics, electronics, firmware, software, micro-fluidics, acoustics, micro-actuators, material science and usability development.

Coatings and Combination Devices - Beginning of an Orthopaedic Revolution!

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[1]*Medical Device Consultant, Divonne les Bains, F,* [2] *BioMedTec Consulting, Bettlach, CH*

INTRODUCTION: The first combination orthopaedic products are appearing in the European marketplace. Bioretec's resorbable CiproScrew and the Synthes Expert Tibial Nail, both deliver an antibiotic via trauma implants. Additionally companies are developing local delivery of antiporotics (bisphosphonates): Addbio has clinically evaluated screw implants that release via a fibrinogen nanolayer interface and Graftys is developing injectable CaP cement as the release media. Two companies focus upon screws which are the most frequently implanted orthopaedic device with an estimated 100mil implanted annually WW.

THE CLINICAL PROBLEM: The main clinical issues in orthopaedic procedures using screws are: infection (typically 1-2%) and screw loosening/migration in poor quality bone which is by far the greater issue. For example cut-out of hip screws in hip fracture treatment ranges from 2-8% whilst in proximal humeral locking plates screw cut-out ranges from 15 to 40% [1]. Orthopaedic bone screw applications require sufficient early (days/weeks) and late (weeks/months) screw fixation, as well easy removal at a revision procedure.

AN ENHANCED FIXATION STRATEGY: Whilst HA coatings or CaP cements may be used to enhance screw fixation, an alternative candidate is local delivery of an antiporotic drug such as a bisphosphonate. Some surgeons have expressed concern over side effects of such drugs, however they are widely used in the treatment of osteoporosis and osteopenia and there is very good clinical data on both their beneficial and side effects[2]. A number of studies have looked at implants and bone substitutes used in combination with bisphosphonates. For example Moroni et al[3] demonstrated that HA coated Ex-Fix pins become better fixed to the bone in patients receiving systemic bisphosphonates. Local delivery may overcome the objections to systemic delivery since this class of drugs bind to calcium and do not migrate far from the implant that releases them. A recent landmark prospective study evaluated the effects of local delivery of bisphosphonates via dental implants[4] (Addbio's Zolidd Technology). Implant fixation in the coated group, assessed by measuring resonant frequency, showed a clinically relevant improvement at six months, whilst marginal bone resorption was less at both two and six months. These results represent clinical proof of the principle of improving implant fixation by use of a drug coating. This is a substantial basis for the development of combination products based upon this principle.

DISCUSSION: The larger orthopaedic implant producers are not visibly pursuing combination products. It may be that they cannot afford the high R & D spend with combination products and they may cherry pick winners among the smaller companies already in this race. An exception is the recent alliance of J & J, Synthes and Eli Lilly who between them have the competences and resources necessary to establish combination medical devices. It is the author's opinion that this alliance and the emergence of the first combination products in Europe signal the beginning of an Orthopaedic Revolution. In this future environment there will be just a few winners whose technologies share factors crucial in determining competitive advantage. These include: ability to influence bone quality both short and long term, efficacy proven (by indication) in patients, reimbursable by healthcare payers, and for screw implants the ability to remove safely and easily at revision.

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Biologic Fixation – a Systematic Approach

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Osseointegration, i.e. the load carrying, bony anchorage of long-term implants in bone is an essential element for the success of modern dental or orthopaedic implants. The process of osseointegration consists of two distinct phases: (1) a healing phase during which the (mechanical) primary stability transforms into a (biological) secondary stability and (2) a maintenance phase during which the biological anchorage adapts continuously to intrinsic and extrinsic factors. Figure 1 illustrates schematically this process.

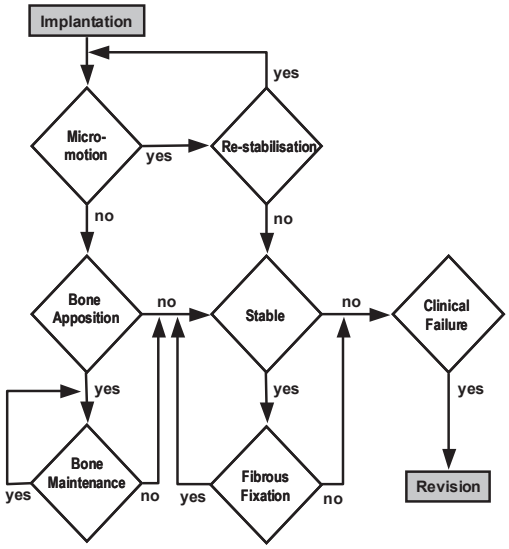

Fig. 1: Process of osseointegration

One key parameter in phase 1 is a bone-friendly surface. In the past surface research focussed on the development of surfaces which have a high probability and predictability in obtaining osseointegration under various conditions and within an acceptable time span. Modern surfaces achieve this goal and demonstrate excellent clinical long-term results. Current research focuses on the development of surfaces with added benefits like antimicrobial properties to obtain excellent results also under adverse conditions.

However, in addition to the surface characteristics, other factors are critical and need to be systematically analysed and considered during the development of "cementless" implant systems. One of these critical parameters is the ability to obtain primary stability which needs to be maintained during the healing process and is influenced by site-specific parameters, surgical technique and implant design. A biomechanical analysis and simulation yields information regarding the anticipated load profiles and helps to predict the magnitude of micromotion at the bone-implant interface as shown in Figure 2 for a dental implant (NobelActive 3.0, Nobel Biocare AB, SE). Based on literature data this micromotion should stay well below 100 µm[1,2].

Finally, the biological environment around the freshly inserted implant needs to be taken into account. Well-known examples which have potentially a negative impact are the presence of Co- and Cr-ions released from metal-on-metal bearings or microorganisms around dental implants.

A solid understanding of these complex interdependencies is a prerequisite for "cementless" implant systems to deliver clinically relevant benefits.

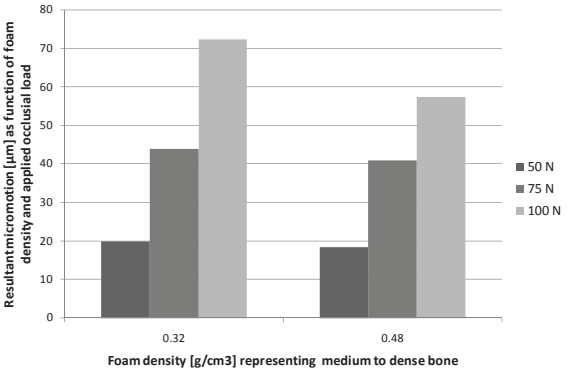

Fig. 2: Micromotion assessment of a dental implant

REFERENCES: [1] Brunski JB., Clin Mater. 1992; 10(3): 153-201.[2] Pilliar RM et al., Clin Orthop Rel Res. 1986; Jul(208): 108-13.

ACKNOWLEDGEMENTS: This work was supported by grants from Smith&Nephew and Nobel Biocare Services AG (grants 2010-934/936).

Metal Implant Allergy

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ABSTRACT: Some patients instead of tolerating implanted metal alloys may develop complications upon osteosynthesis or arthroplasty that are not explained by common causes like infection or mechanical problems. In such patients, hypersensitivity (allergy) may be the underlying mechanism. Allergic reactions have been described as local or generalized eczema, urticaria, impaired wound or osseous healing, seroma formation and implant loosening. It is still under discussion, whether the recently described recurrent groin pain and local "pseudotumour" formation to metal-on-metal hip arthroplasty may also result from hypersensitivity. Cutaneous metal allergy is rather frequent in the general population with sensitisation rates of approximately 13 % to Ni, 2 % to Co and 1 % to Cr. Correspondingly, these three metals are also typical elicitors of allergy to (stainless steel based) osteosynthesis or arthroplasty. Occasionally also bone cement components (acrylates or additives like antibiotics) may provoke hypersensitivity reactions. Apart from allergological diagnostics by patch test and assessment of lymphocyte reactivity, also analysis of periimplantar tissue may indicate the T-cellular hyperresponsiveness. The histological pattern linked with hypersensitivity are diffuse, perivascular or even lymph follicle like lymphocytic infiltrates. As we are running a special ambulatory for metal implant allergy patients, we are investigating immuno-allergological properties of such patients. Based on a series of patients, characteristic clinical and in-vitro findings will be presented.

LITERATURE: Schafer T, Bohler E, Ruhdorfer S, Weigl L, Wessner D, Filipiak B, Wichmann HE, Ring J. Epidemiology of contact allergy in adults. Allergy 2001; 56:1192-6.

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Thomas P, Braathen LR, Dorig M, Aubock J, Nestle F, Werfel T, Willert HG. Increased metal allergy in patients with failed metal-on-metal hip arthroplasty and peri-implant T-lymphocytic inflammation. Allergy 2009; 64: 1157-1165.

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Risk Factors for Aseptic Loosening of Müller-type Straight Stems – A Register-based Analysis of 828 Consecutive Cases with a Minimum Follow-up of 16 Years

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INTRODUCTION: Even small design variables of the femoral stem may influence the outcome of a hip arthroplasty. We performed a risk factor analysis for aseptic loosening with special emphasis on design modifications of cemented Müller-type straight stems.

METHODS: We investigated 828 total hip replacements carried out with 4 different versions of cemented Müller-type straight stems (Fig. 1). These replacements were carried out at our institution, and patients were followed prospectively in the in-house register. All stems were operated in the same setup, using Sulfix-6 bone cement and a second-generation cementing technique. Demographic and design-specific characteristics were analysed using an adjusted Cox regression model.

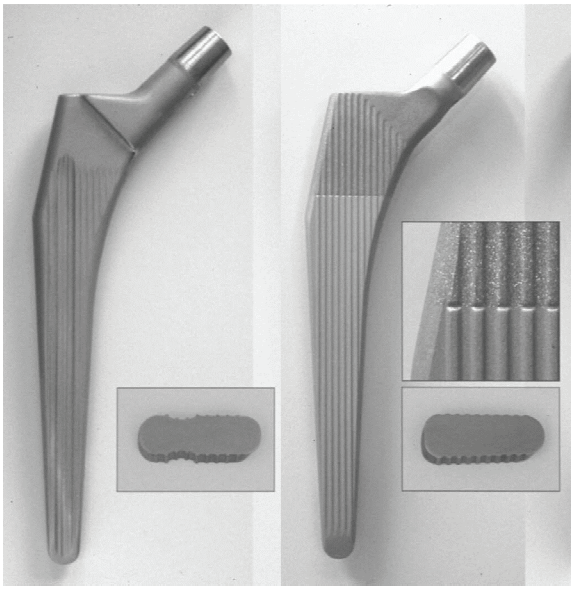

Fig. 1: Implants used (MSS Muller straight stem, SL modified Muller straight stem) both of them are made of CoNiCrMo and Ti-6Al-7Nb

RESULTS: The 4 versions showed marked differences in 15-year stem survival with aseptic loosening as the endpoint: 93.9% (MSS CoNiCrMo), 83.0% (SL CoNiCrMo), 81.4% (MSS Ti-6Al-7Nb) and 64.3% (SL Ti-6Al-7Nb, Fig. 2). The Cox regression analysis showed a relative risk (RR) of 3.811 for aseptic loosening for stems made of Ti-6Al-7Nb. The RR for aseptic loosening of the SL design was 2.129. Overall, the risk ratio for aseptic loosening of the stem increased to 7.486 (95% CI: 3.758-14.912) when comparing the most and the least successful designs (MSS CoNiCrMo vs. SL Ti-6Al-7Nb).

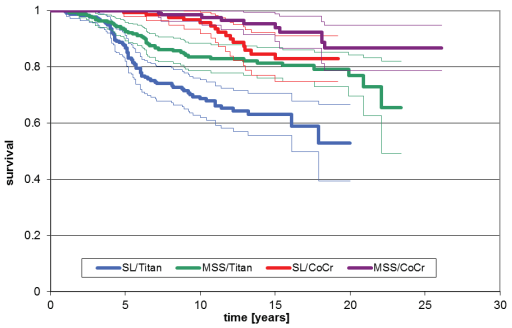

Fig. 2: Kaplan-Meier survival analysis with aseptic loosening as endpoint

DISCUSSION & CONCLUSIONS: Cemented Müller-type straight stems should be made of a material with high flexural strength (e.g. CoNiCrMo). The surface finish should be polished (R_a <0.4 µm), and high offset should be avoided. These technical aspects in combination with modern cementing techniques, should improve the survival of Müller-type straight stems. This may also hold true for all types of cemented stems.

ACKNOWLEDGEMENTS: None of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article, benefits have been received but were directed solely to a research foundation, with which one or more of the authors are associated.

Regulatory Requirements for Implants with Innovative Surfaces Are Drug-Device Combinations Overregulated?

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INTRODUCTION: "One fits all" versus "tailor made", increasing competitive pressure, substantial progress in technology have been drivers for the development of drug device combinations in recent years. This trend will continue and, as estimated, even will pick up speed. Two huge industry blocks are involved - Medical Device manufacturers and Pharmaceutical Industry. European regulations and national laws are influenced and shaped by different requirements: Medical devices' regulations follow the proportionality principle, for medicinal products they follow the precautionary principle.

METHODS: Approaches demonstrated:

Classification basics [1-5]

- Device/Drug Combination Products – Class III, Rule 13
- Steps to CE Marking for a Device Drug Combination
- Medicinal Consultation and Timelines
- Pitfalls
- Involvement, assessment, and responsibilities of Notified Bodies

RESULTS: The regulation process for drug device combination products is complex, yet the number of successful submissions to the European market demonstrates that it is efficient and feasible.

DISCUSSION & CONCLUSIONS: Many aspects have to be covered to accomplish production of safe and effective products on the European market on the border of medical devices and drugs. People involved in production and marketing of these devices have to be knowledgeable of state of the art of both regulations and an interdisciplinary approach is important.

Additionally - for medical devices - development of new regulations is still ongoing. Marketing measures have to consider that, otherwise product development will be slowed down, which is costly. Some of these milestones are: classification, risk management, and clinical evaluation.

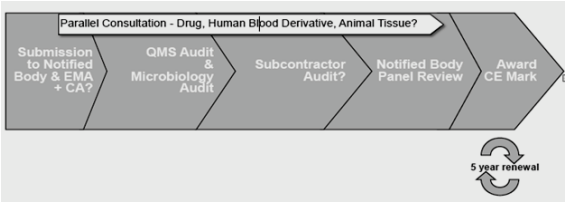

Fig. 1: Steps to CE Marking for a Combination Product

REFERENCES: [1]MEDDEV 2.4 /1 rev 9 Classification of MD. [2]MEDDEV 2.1 / 3 rev 3 Borderline products, drug delivery products and medical devices. [3]Medical Devices Expert Group on Borderline and Classification. [4]Manual on borderline and classification in the Community- Regulatory framework for medical devices. [5]http://ec.europa.eu/health/medical-devices/index_en.htm.

Risk Assessment of the RM Titanium Particle Coating

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Mathys Ltd Bettlach, Bettlach, CH

INTRODUCTION: In 1984, the RM Classic acetabular cup was introduced and has proven clinical success with a survival rate as high as 97 % after 15 years. A new design and new material for this non-cemented, Ti coated polyethylene mono-bloc cup were developed, i.e. RM Pressfit and the cross-linked, vitamin E stabilised vitamys® polyethylene. However, for the approval of implants with RM particle coating in new countries, a risk assessment respecting the nowadays "safety and effectiveness" requirements has to be established.

METHODS: A review of published follow-up studies summarises the clinical history. An in-depth physical, chemical, mechanical and metallographic characterisation of the coating powder as well as the coating itself was undertaken. Furthermore, hip simulator studies elucidated the wear behaviour of the cup under different conditions, such as according to standard, artificially aged and with coating particles as third bodies in the articulation.

RESULTS: Ihle et al analysed the data of a prospective study with 93 unselected consecutive non-cemented hip arthroplasties in 80 patients using the titanium-coated RM Classic acetabular component [1]. Survival after 20 years was 83%. In a retrospective study presented by John et al at the SOFCOT 2010 the survival rate reached 96.9 % after 15 years [2]. Analysis of the Ti powder confirmed a narrow particle size distribution and the spongy morphology of the Ti powder grains. Using scanning electron microscopy, the RM coated surfaces show no visible difference in the morphology of the coating between the three different types of RM cups. Metallographic characterisation of the coating in cross-section analogue to ASTM F1845 provide mean coating thickness (MCT) and volume per cent void (VPV). For all 3 types of RM cups, MCT was about 100 µm and VPV about 30 %. The adhesion of the RM particle coating was evaluated in tensile testing after sterilisation. In all specimens tested, the breakage occurred in the Ti coating itself. The indenter as well as the cup showed still titanium-powder residues. Hip simulator studies confirm the low wear of RM Pressfit cups made of conventional UHMWPE. Wear rates are below 20 mg/Mc combined with all head materials. Adding Ti particles increases the wear rate to 35 mg/Mc. After removal of the particles, the wear rate drops to 19 mg/Mc, even with the scratched metal heads. Wear rates of RM Pressfit vitamys® are non-sensitive to test conditions: the wear rate remains below 8 mg/Mc when altering head material and head diameter, taking artificial aged vitamys® and even adding Ti particles (cf Fig 1.).

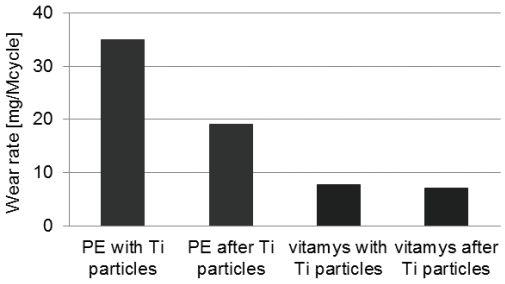

Fig. 1: Hip simulator wear rate of conventional RM Pressfit hip cups and RM Pressfit vitamys® with Ti particles added and after removal of these particles. Head Ø 32mm, CoCr

DISCUSSION & CONCLUSIONS: The documented history of mono-bloc acetabular cups with RM Ti coating confirms that this particle coating is clinically safe and effective. Chemical and mechanical characterisation of the coating powder and the coating itself as well as the stability of the coating during stocking, transportation and implantation show that the quality and morphology of the Ti powder as well as the resulting coating is controlled and adequate for direct fixation in bone. The coating has no or only a minor influence of the stiffness of the UHMWPE mono-bloc cup and its wear properties, even under third body conditions.

REFERENCES: [1] M. Ihle et al (2008), *JBJS [Br]* **90-B**:1284. [2] T. John (2010) *SOFCOT, Conférences d'enseignement 2010 (n°99)*, p. 208 ELSEVIER.

ACKNOWLEDGEMENTS: Most of the experimental work was done by RMS Foundation, Bettlach (Switzerland).

Classification of Surface Cleanliness by Particle Concentration

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INTRODUCTION: Products and processes in global industries such as aerospace, microelectronics, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare) benefit from the control of contamination. ISO 14644-1 to ISO 14644-8 and ISO 14698-1 and ISO 14698-2 (biological contamination) deal exclusively with airborne particle and chemical contamination [1].
ISO/FDIS 14644-9 "Cleanrooms and Associated Controlled Environments", Part 9 (ISO 14644-9) provides a classification for the determination and designation of surface cleanliness levels based on particle concentrations.

Considerations for setting classifications: ISO 14644-9 applies to all solid surfaces in cleanrooms and associated controlled environments such as walls, ceilings, floors, working environments, tools, equipment and products. The classification of surface cleanliness by particle concentration (SCP) is limited to particles between 0.05 µm and 500 µm. The following issues are not considered in this International Standard:

- requirements for the cleanliness and suitability of surfaces for specific processes;
- procedures for the cleaning of surfaces;
- material characteristics;
- references to interactive bonding forces or generation processes that are usually time-dependent and process-dependent;
- selection and use of statistical methods for classification and testing;
- other characteristics of particles, such as electrostatic charge, ionic charges, microbiological state, etc.

METHODS: The class of surface cleanliness by particle concentration (SCP) shall be designated by a classification number, *N*, specifying the maximum total particle concentration per m^2 on surfaces permitted for a considered particle size *D*.

RESULTS: Figure 1 provides a representation of the selected classes in graphical form.

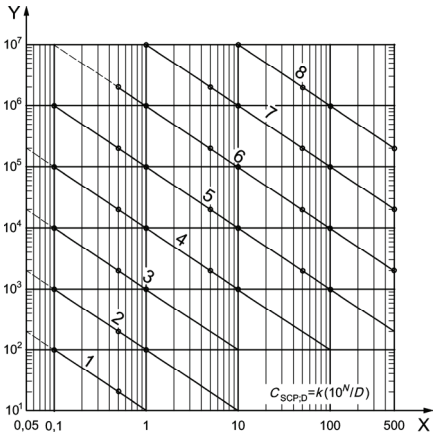

Figure 1 — SCP classes

Furthermore, within the Annexes A to D of ISO 14644-9 additional information is provided such as:

- A Surface characteristics,
- B Descriptor for specific particle size ranges,
- C Parameters influencing the SCP classification
- D Measurement methods for determining surface cleanliness by particle concentration

DISCUSSION & CONCLUSIONS: In order to give additional assistance for the application of the standard, a recently formed ISO TC209 Ad-Hoc Group [2] came to the conclusion that additional information about suitable cleaning methods should be provided in order to reach a certain surface cleanliness level for both SCP Classification of surface cleanliness by particle concentration and SCC Classification of surface cleanliness by chemical concentration (ISO/DIS 14644-10 in progress).

REFERENCES: [1] ISO 14644-1 to 9. [2] ISO TC209 Ad-Hoc Group 2011

ACKNOWLEDGEMENTS: To all ISO TC209 committee members, in particular to the working group WG 9 delegates who participated actively in the standardisation efforts.

Poster Session

1	Measurement of surface topography and cell adhesion by AFM and FluidFM Dr. Patrick Frederix, Nanosurf AG, Liestal, Switzerland
2	Modification des surfaces des matériaux prothétiques : de quoi parlons-nous? Jérôme Goux, Filab, Dijon Cedex, France
3	In vivo evidences of improved bone-implant fixation using Additive Manufactured titanium screws Pierfrancesco Robotti, Eurocoating, Pergine Valsugana (Trento), Italy
4	Spontaneously formed nanostructures on titanium SLActive surfaces Dr. Simon Berner, Straumann Institute, Basel, Switzerland
5	3D-Laserpoliertechnik für Oberflächen Jean-Claude Prélaz, SYSMELEC SA, Gals, Switzerland
6	Präzisions- und Mikrofertigung für Implantatoberflächen Jan Edelmann, Fraunhofer IWU, Chemnitz, Switzerland
7	The green revolution in inter-operation cleaning Jean-Louis Gautron, NGL CLEANING TECHNOLOGY, Nyon, Switzerland
8	Preclinical testing of the hemocompatibility of blood contacting devices according to ISO 10993-4 Prof. Dr. Hans Peter Wendel, University Hospital Tübingen, Germany
9	Einfluss der Implantation bioresorbierbarer Implantate auf die Phagozytoseaktivität Dr. Peter Ferlic, Medical University Graz, Austria
10	Investigation on Bactericidal Effects of Silver Doped HA Structures Philippe Chavanne, School of Life Sciences FHNW, Muttenz, Switzerland
11	Antimicrobial efficacy studies Dr. Anja Friedrich, BSL BIOSERVICE, Planegg, Germany
12	High Precision Abrasion Measurement of Implants by use of Optical Interferometers Dr. Wilfried Boeck, TRIOPTICS GmbH, Wedel, Germany

Histological and Biomechanical Characterization for an Additive Manufactured Titanium Surface

P. Robotti[1], S. Stübinger[2,3], I. Mosch[2], M. Sidler[2], S.J. Ferguson[4] and B. von Rechenberg[2,3]

[1]Eurocoating spa, Trento, IT; [2]MSRU, Vetsuisse Faculty, University Zurich, CH; [3]CABMM, University of Zurich, CH; [4]ISTB, University Bern, CH

INTRODUCTION: Macroporous metal structures are becoming a very popular strategy to reach a tough and time resistant bone fixation in joint replacement components. Scope of this study is to highlight the osseointegrative potential of titanium additive manufactured macroporous surfaces (TiAMMS). TiAMMS are expected to favour bone ingrowth and thus device fixation-retention.

MATERIALS & METHODS: The additive manufacturing technology used was Direct Metal Laser Sintering (DMLS), suitable to replicate complex shapes titanium items with designable porous topography.
Samples (Eurocoating Spa): screwed cylindrical implants, diameter 4.1 mm, length 9 mm, with three different surfaces: machined (M, standard control), sandblasted and etched surface (SE, qualified control) or TiAMMS.
Surgery and histomorphometric analysis (MSRU): in 6 sheep were placed n=18 implants in the right and left iliac shaft of the pelvis. Samples were explanted after 2 and 8 weeks.
Per each surface group n=3 implants were examined histologically (BIC: bone-to-implant-contact). Additionally a semi-quantitative histomorphometrical and qualitative fluorescent microscopic analysis was performed.
n=6 implants were tested (ARTORG Institute) by a removal torque out. Torque-out moment (Nmm) was measured using a MTS Mini Bionix 858; (MTS Systems Corp., Eden Prairie, USA).

RESULTS: All implants could be placed without complications and with good primary stability. Qualitative microscopic evaluation demonstrated new bone formation, visible as dark-bluish stain, adjacent to the implant surface in all of the samples. After 2 and 8 weeks a significant difference ($p \leq 0.05$) of the BIC value between the M (2w: 20.33±11,50 %; 8w: 25.33±4,61 %) and SE surfaces (2w: 43.67±12,22 %; 8w: 53.33±8,96 %) could be found. The TiAMMS showed a significant increase of the BIC between 2 and 8 weeks (2w: 20.48 ± 5,18 %; 8w: 44.90±9,69 %). Histomorphometrically in all three groups a subsequent percentile gain of new matrix formation was obvious. At both time points the SE surface revealed the highest values (2w: 14.19±9.13 %; 8w: 18.06±18.25 %). Yet there were no significant differences. Fluorescent labelling revealed clearly marked trabecular and lacunae after 8 weeks.

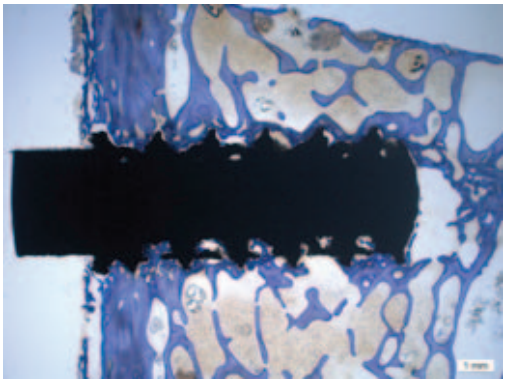

Fig.1: Histology at 8 w – Ti A.M. Macroporous Surface. Bone ingrowth visible inside pores

Removal-torque-test value showed significant differences ($p \leq 0.001$) of the M (198.93±88,04 Nmm) and SE (730.08±151,89 Nmm) surfaces in comparison to the TiAMMS (1891.82±308,44 Nmm) surface after eight weeks. The TiAMMS surface also showed the highest increase of torque values between 2 weeks and 8 weeks.

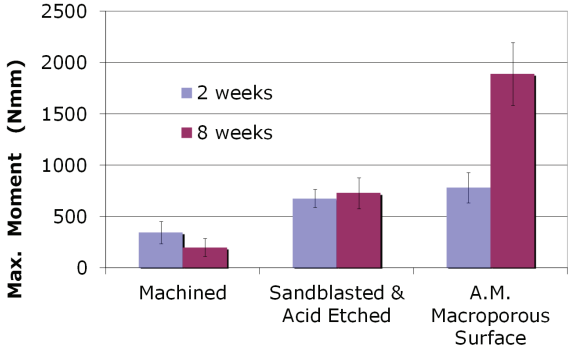

Fig. 2: Removal torque test. Implants with TiAMMS showed significant stronger fixation after 8 w.

CONCLUSIONS: Histologically all titanium surfaces showed favourable osseointegration with no signs of a fibrous encapsulation. Thereupon the additive manufactured implants with macro-porous surface proved increased torque values after two and eight weeks.

ACKNOWLEDGEMENTS: this study was cosponsored by Provincia Autonoma di Trento, IT.

Spontaneously Formed Nanostructures on Titanium SLActive Surfaces

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INTRODUCTION: Nanostructures on implant surfaces have gained a lot of interest in connection with osseointegration in the last years [1,2].
In the here presented experiments the nanostructure formation on Ti SLActive surfaces was analysed. The evolution was investigated as a function of storage time and conditions as well as surface modifications [3].

METHODS: Different surface modifications were prepared and characterized in order to investigate the nanostructure formation on the Ti surfaces. Besides SLA (sand blasted and acid etched) and SLActive (SLA stored in 0.9% NaCl solution in order to prevent exposure to air) differently prepared surface modifications like SLActive stored in pure water, mod A (only acid etched, stored in 0.9% NaCl solution) and TiZr (15% Zr) SLActive were characterized [3].
The surfaces were analysed with scanning electron microscopy, interferometry, contact angle measurements and X-ray photoelectron spectroscopy.

RESULTS: The Ti SLA surface has no nanostructure, whereas distinct needle-like nanoparticles are present on the Ti SLActive surface (Figure 1). The nanostructure consists of TiO_2 as observed by the chemical analysis. Particularly, the nanostructure does not consist of crystallized NaCl nor is NaCl needed for the formation of the structures [3].
The nanostructures evolve on the titanium surfaces on the time scale of about two weeks and are then stable over time (also when exposed to air). Nanostructures are formed on Ti and TiZr SLActive surfaces, although the morphology and distribution are quite different between the two materials.

DISCUSSION & CONCLUSIONS: The formation of the TiO_2 nanostructures was not dependent on the presence of NaCl in the aqueous storage solution. The nanoparticle formation did occur on commercially pure titanium samples and on TiZr alloy, although morphology and distribution are quite different. Acid etching in combination with storage in aqueous solution leads to the reorganisation of the outermost titanium oxide layer into well-defined nanostructures. The needle-like shape of the nanostructures indicates that their crystal structure is rutile rather than anatase TiO_2.

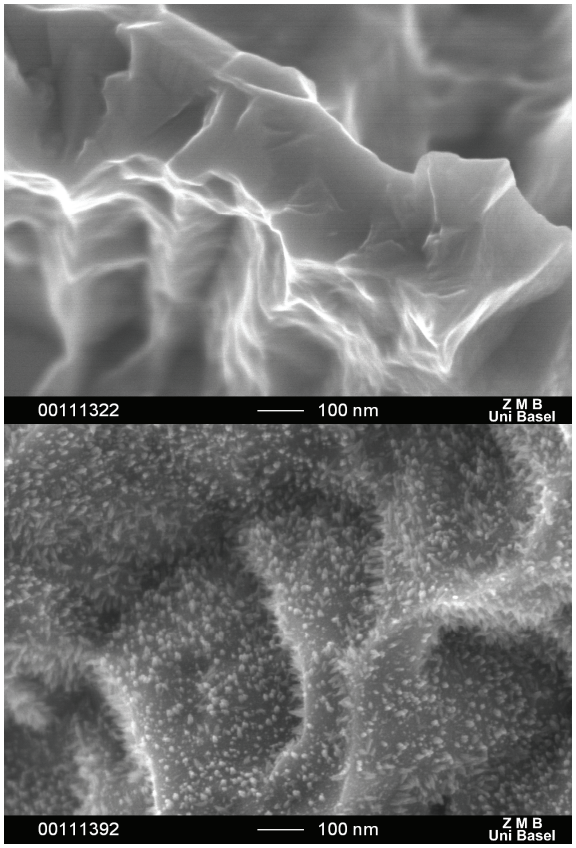

Fig. 1: Scanning electron microscope images of Ti SLA (top) and Ti SLActive (bottom). The distinct nanostructure on SLActive is clearly visible.

REFERENCES: [1]G. Mendonça et al., Biomaterials, 2008, 29, 3822-3835. [2]L.M. Svanborg et al., J. Biomed. Mater. Res. B, 2010, 92, 462-469. [3]A. Wennerberg et al., Clin. Oral Impl. Res. 2012, doi :10.1111/j.1600-0501.2012.02429.x

ACKNOWLEDGEMENTS: The University of Basel is gratefully acknowledged for the SEM measurements.

3D – Laserpoliertechnik für Oberflächen

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Unitechnologies SA, SYSMELEC®, Gals, CH

EINLEITUNG: Die 3D-Laserpoliertechnik für Oberflächen kommt nun zur Marktreife und zeigt bereits ausgezeichnete Resultate für Materialien wie Titan und die entsprechenden Legierungen oder Edelstahl. Das Grundprinzip des Laserpolierens besteht aus dem Schmelzen einer sehr dünnen Materialschicht. Das so polierte Material weist damit keinerlei Mikro-Ritzen an der Oberfläche auf, wie sie nach dem mechanischen Polieren zu finden sind.
Diese Technologie ergänzt die chemischen Poliervorgänge, die zurzeit zum Polieren von Implantaten in Gebrauch sind.

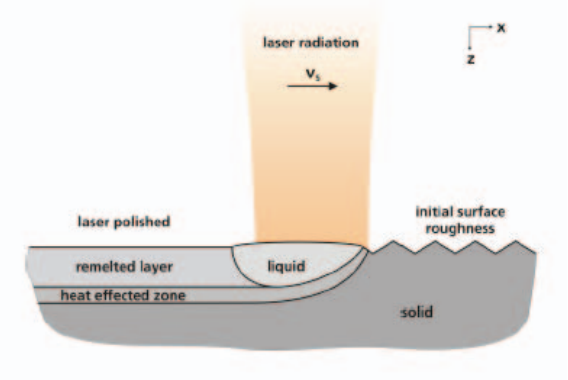

Fig 1: Laserpolieren - Grundprinzip

TYPISCHE ANWENDUNGEN:
- Selektives Polieren von begrenzten Oberflächen
- Polieren von Oberflächen mit Mikrostrukturierung ebenfalls mit Laser ausgeführt (zum Beispiel zur Verbesserung der Hafteigenschaften.)
- Selektives Entgraten.

VORTEILE DES LASERPOLIERENS:
- Ausgezeichnete biologische Eigenschaften für statische und dynamische Implantate, dank der Abwesenheit von scharfkantigen Kratzern oder versteckten Oberflächen-defekten.
- Bis zu 10-mal schneller als herkömmliche mechanische Methoden.
- Ein Faktor 3 bis 10 verbesserte Rauheit, je nach Anfangsrauheit und Material.

ZELLE ZUR LASER-OBERFLÄCHENBEARBEITUNG:
Unitechnologies wird ab Anfang 2013 eine Zelle zur Laser-Oberflächenbearbeitung auf den Markt bringen. An der laufenden Entwicklung mitbeteiligt sind die EPFL für den Kinematik- und Zellsteuerungsteil und das ILT in Aachen für den Prozessteil. Diese Zelle wird basierend auf den Modularitätsprinzipien und mit dem Ziel einer hohen Produktivität entwickelt. In diesem Sinne wird es möglich sein, jede Zelle mit einem automatischen Lade/Entlade-Modul der zu bearbeitenden Komponenten auszurüsten, oder mit einer Sicherheitskammer die dem Laser die Arbeit in einer inerten Umgebung ermöglicht.
Diese Zelle wird Strukturierungs- und Poliervorgänge verbinden können.

LASERPOLIEREN ERGEBNISBEISPIELE:

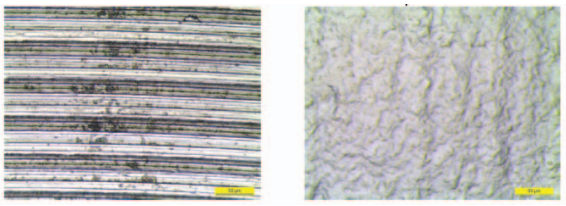

Fig 2: Laserpolieren Titanium-Legierung – Anfangsrauheit R_{ai} = 0.45 µm; Endrauheit: R_{af}= 0.18 µm; Poliergeschwindigkeit: 7 sec/cm²

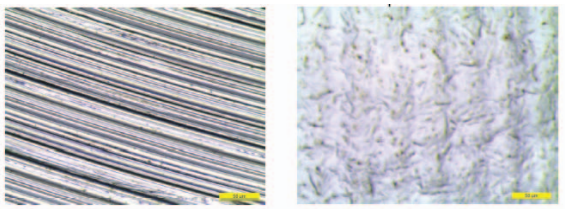

Fig 3: Laserpolieren – Edelstahl – Anfangsrauheit: R_{ai} = 1.24 µm ; Endrauheit: R_{af} = 0.25 µm ; Poliergeschwindigkeit: 3 sec/cm²

DANK: An die ILT für die Bilder in diesem Dokument, die zur Verfügung gestellt wurden.

Precision- and Micromanufacturing for Implant Surfaces

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INTRODUCTION: Modern implantology poses extremely high demands on production engineering. Prostheses often exhibit complex geometries, which have to be manufactured with high precision and surface quality. This has to be realized reliably and economically using difficult to process materials. The design of implant surface needs to be specifically focused on as this surface is in direct contact with the tissue.
Osseointegrated surface structures can be realized, for example, by roughening of the titanium surface using various blasting processes [1-3]. Improved osseointegration of implants can be accomplished by creating biomechanical coupling. Microstructures can be applied in this process.

METHODS: The investigation will focus on microstructuring of titanium surfaces by hot forming. The method is based on thermally assisted, near-surface forming of the material. For this purpose, the Fraunhofer IWU developed a specific system technology which reaches forming temperatures of up to 1100 °C and press capacities of up to 600 kN. In addition to process development, manufacturing of suitable microstructure tools plays an important role. A tool (Fig. 1 left) made of high-temperature resistant ceramics with a surface of 75 mm² was microstructured using a laser. The generated drillings have a diameter of 100 µm and a depth of approx. 200 µm. Subsequently, the embossing process was carried out as a backward extrusion process using varying parameters to generate microstructured cylinders.

RESULTS: Microstructuring of titanium was realized at an embossing temperature of 850-1050 °C using hot forming. Fig. 1 (right) shows the microstructure generated at a specific pressure of 20 N/mm². A structure height of 70 µm and a base diameter of approx. 100 µm were reached.

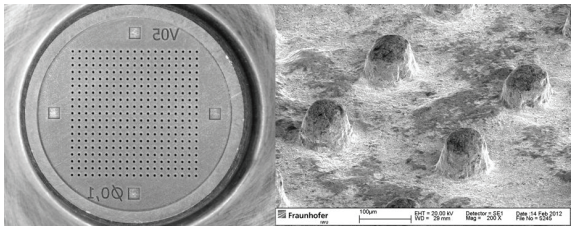

Fig. 1: Hot embossing titanium: Embossing tool (left) embossed microstructure (right).

DISCUSSION & CONCLUSIONS: At first, microstructured surfaces were generated in titanium. During the next process step, the produced microstructures were investigated in the cell culture test with structure heights of up to 120 µm.
It was found that hot embossing is suitable for forming of biomechanically designed, titanium-based surfaces with a high degree of miniaturization. At the same time, this hot embossing shows a high dimensional accuracy. In order to achieve successful forming of titanium it is essential to structure the active component and to select the coating material and the process control.

REFERENCES: [1] Schuh et al., Oberflächenuntersuchungen an Glaskugelgestrahlten Titanimplantaten in der Hüftendoprothetik. Zentralbl. Chir., 2004; 129: 225- 229. [2] Schuh et al., Restpartikelfreie raue Oberflächen nach Stahldrahtkornstrahlen in der Hüftendoprothetik. Biomed. Technik 2005; 50: 404- 407. [3] Gehrke P. Mechanismen der knöchernen Integration: Biotechnologie für eine beschleunigte Osteogenese. Implantologie Journal 8/2004; 14-19

ACKNOWLEDGEMENTS: The project is funded by the Federal Ministry for Education and Research under grant number 01EZ 1124B.

The Green Revolution in Inter-Operation Cleaning

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INTRODUCTION: Pioneer of water-based cleaning, NGL Cleaning Technology, the Swiss manufacturer based in Nyon, can rely on his R&D department and already offers a large variety of solutions to its customers, including a complete range for interoperating cleaning using green chemistry.

SUSTAINABLE DEVELOPMENT: To produce with minimal environmental and health impact has become a goal of many companies. The concept of sustainable development will continue to grow. This is why NGL always anxious to preserve the environment by the formulation of environmentally friendly products, has focused on designing a wide range of products adapted to manual cleaning.

PRODUCTS SUBJECT to MASTERFILES:

- NEOCLEAN line
- BIO-TOP line

RESEARCH & DEVELOPMENT: NGL products and methods are the result of research and experiments, primarily realized in areas of high technology. This expertise covers environmental aspects in the context of advices to companies regarding their waste water management mode. ISO 9001 - ISO 14001 and OHSAS 1800 certified, NGL Cleaning Technology formulates, manufactures and markets a wide range of ecological products meeting needs of extremely careful washing in areas such as dental implants, surgical prostheses, watch industry, precision technology, vacuum metal deposition or optical and many other sectors in which, until recent years, washing was done only with solvents.

Preclinical Testing of the Hemocompatibility of Blood Contacting Devices According to ISO 10993-4

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INTRODUCTION: In order to evaluate the hemocompatibility of medical devices we used an in vitro model with fresh human whole blood. In a closed system the influence of artificial surfaces on corpuscular blood components as well as the activation or inhibition of different haemostatic parameters can be displayed effectively without the autogenic regulation of the patient attempting to equalize these effects. Therefore, before clinical application it is imperative to test the hemocompatibility of medical devices under standardized conditions.

METHODS: The aim of this study was to establish a novel in vitro model for hemocompatibility testing of coronary artery stents according to ISO 10993-4. The model consists of a modified Chandler-Loop design with closed heparin-coated PVC Loops and a temperature controlled water bath (Fig. 1). The tests were performed with anticoagulated fresh human whole blood.

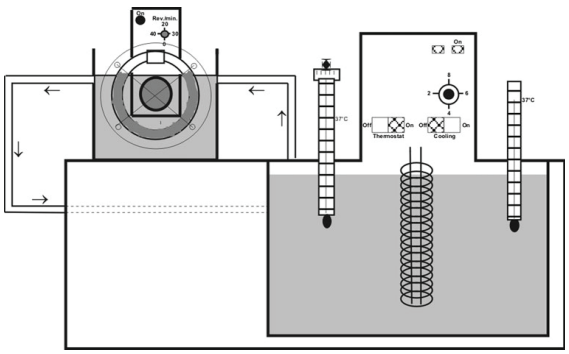

Fig. 1: Modified Chandler-Loop system.

After incubation in the loop, blood was analyzed for coagulation, platelet and inflammatory activation markers (TAT, b-TG, sP-selectin, SC5b-9 and PMN-elastase). Three different stent types with varying thrombogenicity were tested.

RESULTS: Statistically significant differences were found between the three stent types in measures of coagulation (Fig. 2) and platelet activation. Platelet activation was assessed through b-thromboglobulin and sP-selectin measurements, both of which showed the highest activation at the copper coated stent (‘‘lib cop’’) with b-TG values of 1630.45 IU/ml ± 329.59 and sP-selectin values of 62.84 ng/ml ± 9.46.

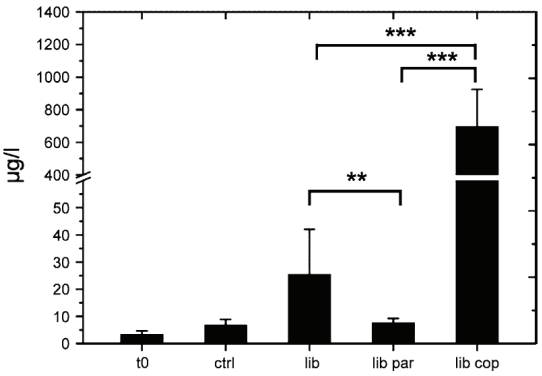

Fig. 2. Concentration of coagulation activation marker thrombin antithrombin complex before (‘‘t0’’) and after 120 min of circulation in the loop without a stent (‘‘ctrl’’) and with three different stents types exemplifying the range of thrombogenicity.

DISCUSSION & CONCLUSIONS: Within this study we established a novel in vitro model based on a modified Chandler-Loop system. This system could be helpful to test the hemocompatibility of new stent designs or stent coatings before they are clinically introduced. The main advantages of this new stent test model are the high standardization of test conditions and the potential to compare data from different stent types directly. The new Chandler-Loop model may be an alternative to animal models and current in vitro test systems, especially for early events after stent implantation. Because they are fast and fairly inexpensive, Chandler-Loop experiments should be included in conjunction with animal models when testing new stents, allowing direct comparison of in vitro and in vivo data.

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Phagocytic Activity after Implantation of Bioresorbable Implants in Rats

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INTRODUCTION: Beside trauma done to the bone and soft tissue during surgery also biomaterials implanted into the bone may have an impact on the function of immune cells. The aim of this study was to evaluate the influence of biomaterials implanted into the bone of growing rats on the innate immune system.

METHODS: A bioresorbable implant, PHB (Polyhydroxybutyrat +3% Zirconium), was placed in the femur of growing rats (Figure 1).

Blood samples were taken before operation and weekly for the first 3 postoperative weeks. Phagocytic activity of phagocytic cells was evaluated with the Phagotest (Bd Biosciences) and compared between the group with implants (B), a control group (C) and a sham group (S) (Table 1).

Level of significance was set at $p<0.05$.

RESULTS: Before surgery similar basic values for phagocytic activity were observed in all groups. After one week we observed a significant lower phagocytic activity in group C (mean: 56%) and B (mean: 41.1%) compared to the sham group (mean: 68.5%). Lowest levels of phagocytic activity were observed in the group with PHB implants. After two weeks groups C (mean: 79%) and B (mean: 69.3%) showed significantly higher phagocytic activity than the sham group (mean: 60.8%). After 3 weeks we observed similar values in all groups again.

The phagocytic activity within in each group over the course of 3 weeks showed constant values in group S, while we observed an increase of phagocytic activity in group C with a peak at week 2. Group B showed a marked decline in the phagocytic activity after 1 week, however not being significantly different to its starting values.

Table 1. Different groups studied and interventions performed.

Group	**S**	**C**	**B**
n	6	6	6
Surgery	no	drill hole through femur	drill hole through femur
Implant	no	no	polyhydroxy-butyrat +3% zirconium

DISCUSSION & CONCLUSIONS: The surgery and trauma to the bone, as well as implanted biomaterial seem to have impact on the function of the innate immune system in growing rats, especially in the first weeks after implantation. Bone healing seems to have a rather stimulative effect on the phagocytic activity, while the presence of the bioresorbable implant (PHB) seems to have a negative effect in the first week after surgery. After 3 weeks when bone healing is completed similar results could be observed in all groups again.

Investigation on Bactericidal Effects of Silver Doped HA Structures

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INTRODUCTION: Ceramic scaffolds are increasingly used for bone replacement in regenerative medicine as an alternative to autografting and allografting [1]. Alloplastic implants can be treated to induce antibacterial effects in order to avoid inflammatory loosening [2], e.g. by adding silver to the implant material. Towards animal cells, silver is a non toxic, inorganic antibacterial agent, yet capable of killing about 650 microorganisms that can cause diseases [3].

METHODS: An adapted 3D-Printing system (Z-Corp, Z-510) was used to produce hydroxyapatite HA (Medicoat, grain size between 10 and 45 µm) cylinders of Ø 5 x 5 mm and porous structures as shown in Fig. 1. These samples were sintered (> 1400°C, for 3 h, Carbolite RHF1500) and Ag doped. The doping process is based on an ion exchange between Ca^{2+} and Ag^{+} origin from $AgNO_3$, which is accompanied by a change in pH from 7 to 9.5. All HA samples were doped with 925 ppm silver.

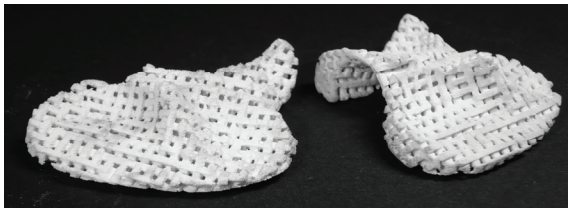

Fig. 1: Design Sample: 3D printed and Ag doped HA orbit reconstruction implants.

To initially evaluate the doping process, the Ag content of doped specimens was determined using X-ray fluorescence (XRF) analysis. During a simulated implantation (30 days in Simulated Body Fluid (SBF) E3024 at 37°C with marginal imitated metabolic rate and 300 rpm agitation) Ag releasing rate was evaluated by means of ICP-MS. Specimens were therefore immersed in 1 mL SBF which was exchanged after 4 h and 0.5, 1, 4, 13, 30 days. Antibacterial effects were assessed by incubating (37°C, 120 rpm, over night) 10^4 *Escherichia coli* DH5-Alpha bacteria with 120 µL of sampled and Ag contaminated SBF.

RESULTS: XRF measurements unveiled an influence of the surface/volume ratio of specimens on the doping efficiency. In fact, the doping process on solid HA specimens demonstrated a reduced efficiency of up to 76% compared to HA. In addition, an inhomogeneous silver deposition on the specimen surface could be observed. During the simulated implantation, the cylinders with a doped Ag concentration of 925 ppm exhibited an almost logarithmic decreasing rate of silver release, from initial 222.4 ppb/h to 2.6 ppb/h, as illustrated in Fig. 2. The released amount equals to 9.9 % of total doped Ag content.

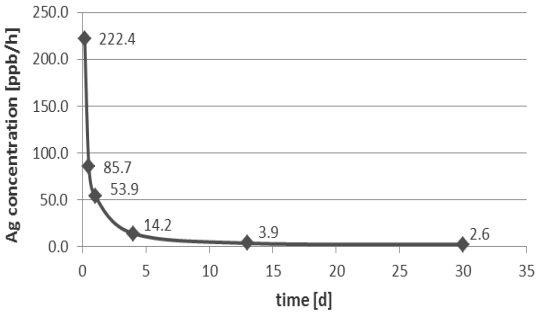

Fig. 2: Ag release of 925 ppm doped specimens during a simulated 30 day implantation.

Ag contents between 0.69 and 1.06 µg/ml were measured on probes of all sampling points. These concentrations were found sufficient to act bactericidal on the *E. coli* bacteria. 0.25 ppm was the minimal required silver concentration to show fully antibacterial effect

DISCUSSION & CONCLUSIONS: The doped cylinders (Ag = 925 ppm) exhibited an antibacterial effect on *E. coli* DH5-Alpha bacteria during a simulated 30 day implantation. These findings correspond to earlier observed antibacterial effects of silver doped HA powder (Ag doping 1670 ppm on powdery HA, 10^5 *E. coli* bacteria [4]).

REFERENCES: [1] Yarlagadda et al, Biomed Mater Eng, 15:159–77, [2] Zhao et al, BioMetals, 1998, 11: 27-32, [3] Jeong et al, Journal of Material Science, 2005, [4] Kim et al, Journal of Material Science, 1998, 9: 129-134

ACKNOWLEDGEMENTS: Support by the *Swiss-Nanoscience Institute (SNI)* is gratefully acknowledged.

Biological Interactions of Implant Surfaces: Antimicrobial Efficacy Studies

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INTRODUCTION: The increasing number of infection rates is a severe problem in health care facilities. Medical devices coated with or including antimicrobial compounds contribute to prevent infections e.g. after implantation.
Numerous test systems are available to examine the antimicrobial efficacy described in various guidelines. The suitable test design is chosen depending on the material of the product. In this abstract some study designs and the evaluation of the results are introduced.

METHODS & RESULTS:
Solutions/soluble products: A dilution series of the product is examined with a test strain by a microdilution method in 96-well plates. The lowest concentration inhibiting bacterial growth (= minimum inhibitory concentration MIC, see Figure 1) or reducing bacterial growth to 99.9% (= minimum bactericidal concentration MBC) is determined as evaluation criteria [1].

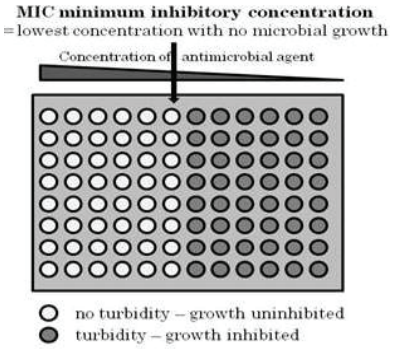

Fig. 1: Microdilution method: determination of MIC

Solid materials (metal surfaces, plastics): In the "dynamic contact test" samples of surface-bound material are shaken in a concentrated bacterial suspension [2]. In the "direct contact test" solid specimens are inoculated with the test strain in a static system [3]. In both tests the antimicrobial effect is shown by the reduction of the microbial count within a defined time interval in comparison to a reference material without antimicrobial properties.
In the "Proliferation Assay" [4] bacterial cells adhere to the material. In a second incubation step the time-proliferation curve of daughter cells is determined by measurement of the optical density. Antimicrobial agents delay the bacterial growth (see Figure 2). The onset OD at 0.2 of samples with and without the anti-microbial compound is compared.

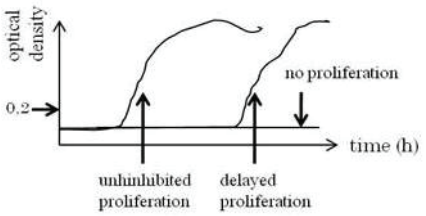

Fig. 2: Proliferation assay: comparison of growth

Textiles/solid materials: In the "agar diffusion plate test" samples are incubated on agar plates with the test strain. Bacterial growth inhibition zones (see Figure 3) indicate the antimicrobial activity and are evaluated by a score system [5].

Fig. 3: Bacterial growth inhibition zones caused by an antibacterial agent

In the "direct contact test" samples are inoculated with the test organism. The reduction of the microbial growth is determined in comparison to reference [6].

DISCUSSION & CONCLUSIONS: A broad range of test systems to show the antimicrobial effect of a product is available. The suitable study design must be chosen thoroughly depending on the type of material and the aim of study, as it has a great impact on the results.

REFERENCES: [1]DIN 58940 part 7 (2009). [2]ASTM E 2149 part 10 (2010). [3]ISO 22196 (2007). [4]Alt et al. (2004) *Antimicrobial Agents and Chemotherapy* **48**: 4085-4088. [5]DIN EN ISO 20645 (2004). [6]DIN EN ISO 20743 (2007).

High Precision Abrasive Measurement of Implants by use of Optical Interferometers

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INTRODUCTION: An essential point for the quality and lifecycle determination of artificial joints is the abrasion. Conventional measurements use tactile equipment after a life-cycle test of some million motion cycles. Drawback of that procedure is the

- Limited accuracy (< 1 µm)
- Missing areal information
- Long measurement time

METHODS: µPhase interferometer is an optical measurement device. A spherical wavefront created by the interferometer will be back-reflected by the ball or calotte of the artificial joint and internally superimposed by a reference wavefront. The result is the difference from a perfect surface due to attrition.

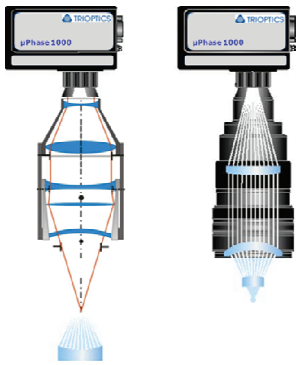

Fig. 1: Interferometric measurement of balls and calottes

RESULTS: The advantage of this µPhase interferometer is:

- Immediate measurement of the relevant area
- Touch-less
- Measurement time just a few seconds
- Accuracy < 50 nm = 0.05 µm
- Detection of non-symmetries
- Calculation of abrasive volume possible
- Reliably testimony about attrition within a short time frame

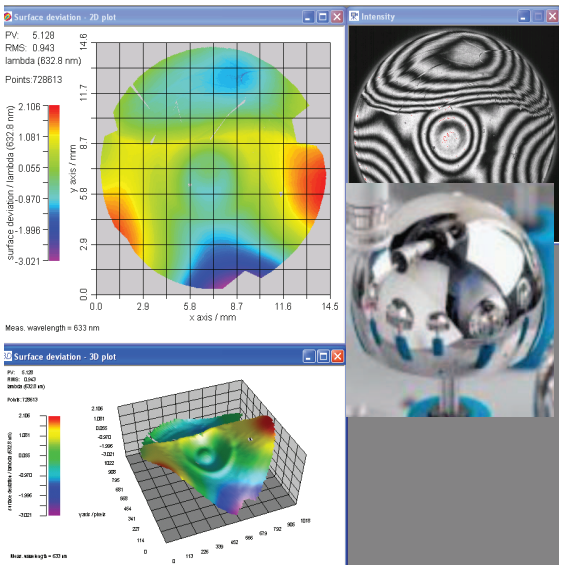

Fig. 2. Surface deviation of an implant ball

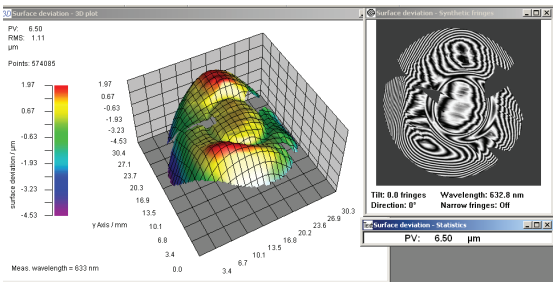

Fig. 3. Surface deviation of an abrasive ball

DISCUSSION & CONCLUSIONS: µPhase interferometers are able to measure abrasions of artificial joints with an incomparable accuracy. So life-time calculations are possible after considerable shorter cycle tests. That leads to lower costs and higher reliability.

ACKNOWLEDGEMENTS: Some of the measurements were done by Prof. Dr. Andreas Ettemeyer, NTB Hochschule für Technik Buchs Switzerland.

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Material and Surface Technology for Implants

23rd/24th April 2012

Congress Centre Kursaal Interlaken
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