[MEET THE EXPERT]

Material and Surface Technology for Implants

11th/12th April, 2011

Casino Kursaal
3800 Interlaken, Switzerland

medical cluster

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General Informations

How to get to the Casino Kursaal Interlaken (CKI)

The Casino Kursaal Interlaken is easily accessible by car and by train. For directions please visit www.casino-kursaal.ch

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

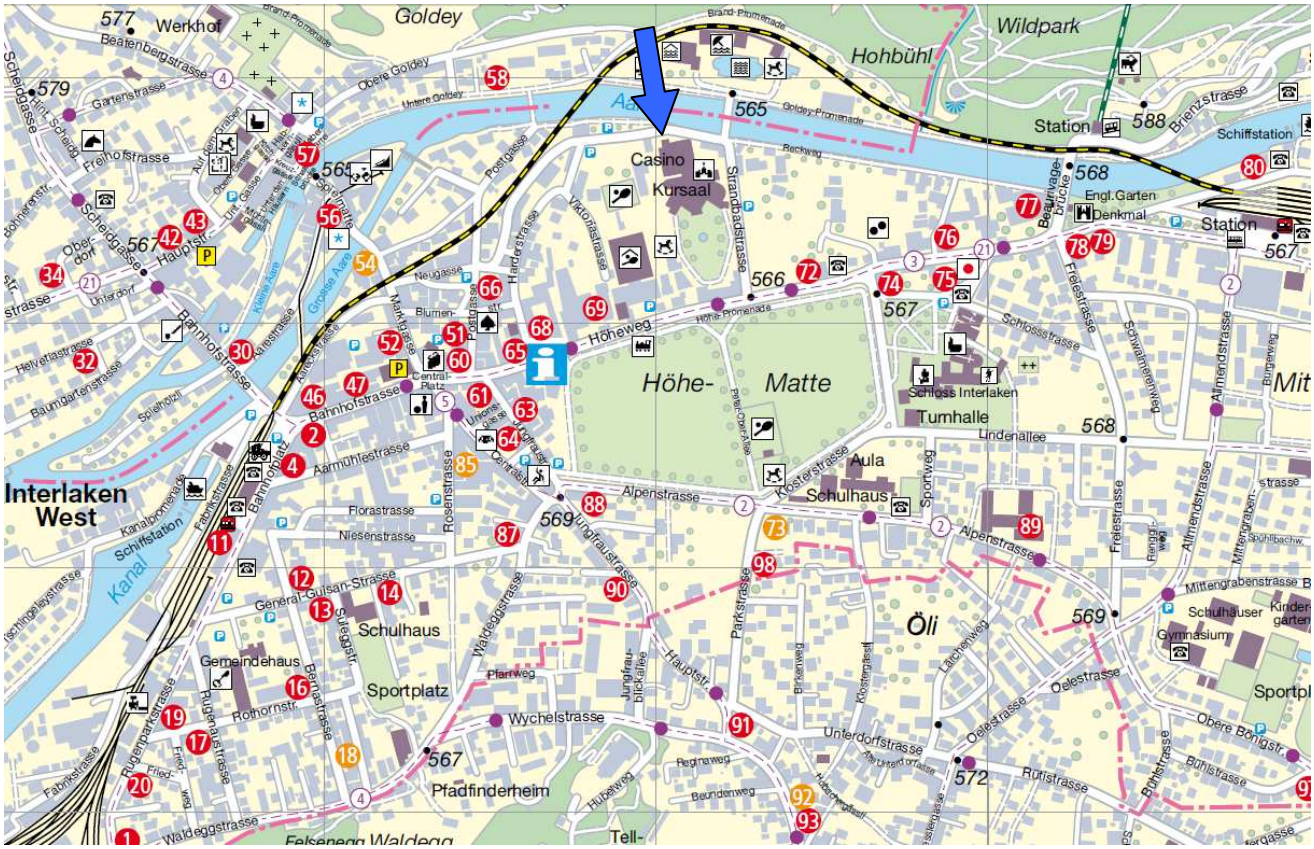
The parking lot of the Casino Kursaal can be used. Congress-Tickets for CHF 6.00 per day are available at the information of the CKI.

Wardrobe

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

Site plan / Hotel accomodation

All of our recommended hotels are within walking distance from the Casino Kursaal Interlaken. For the location of the hotels please see the following site plan.



Hotels:

89 Hotel Artos

78 Hotel Carlton-Europe

68 Hotel Metropole

Dinner

The Conference Dinner is included in the conference fee and will be held on Monday 11th April **19:30 h** at the **Restaurant Spycher**. The Folklore Restaurant Spycher is integrated in the Casino Kursaal Interlaken and is located in the eastern part of the site.

Conference Secretariat

The conference secretariat is managed by Mrs Celinda Hampe.

Availability during the meeting: Tel +41 (0) 78 897 54 55.

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
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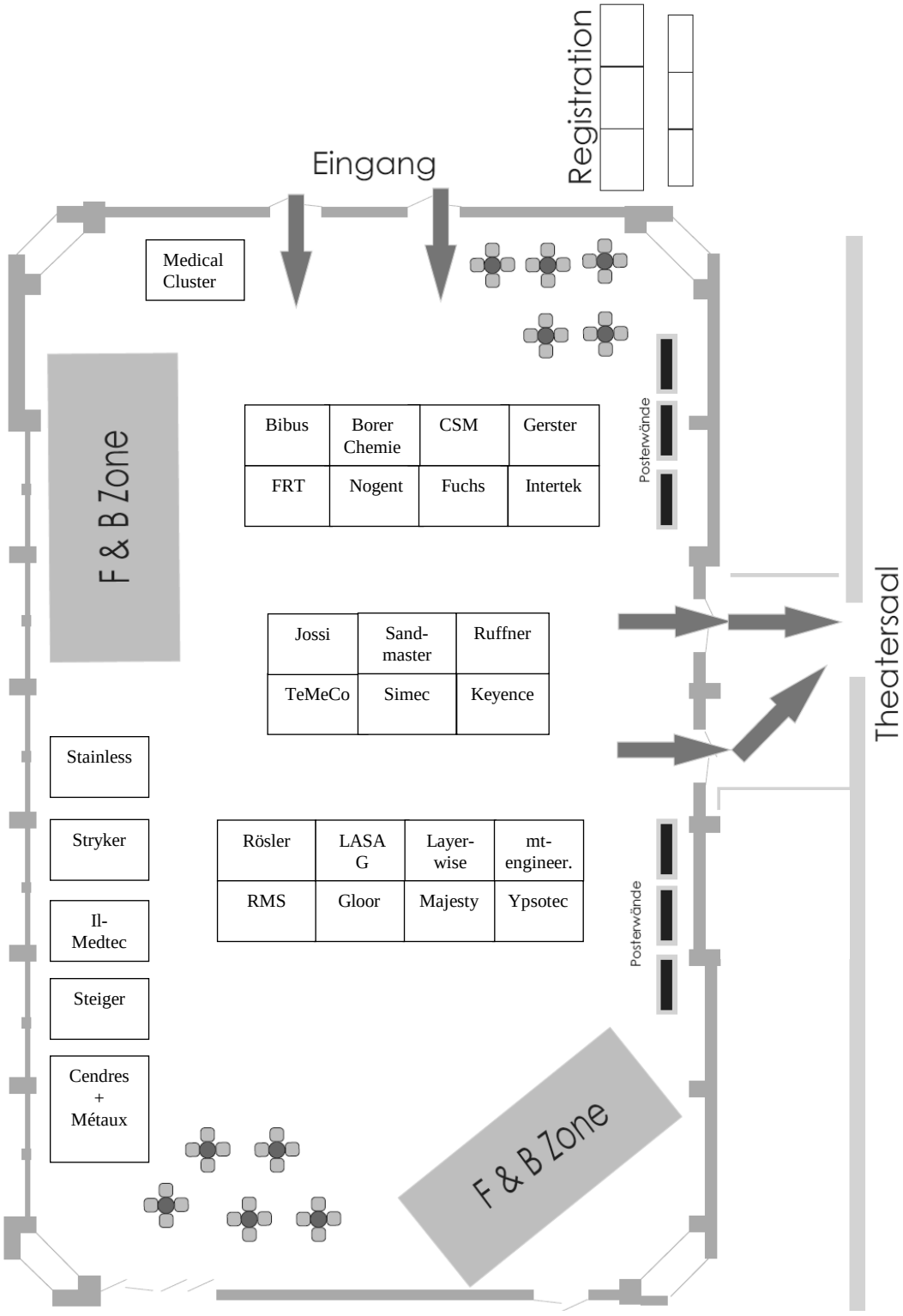

Meeting Program

Monday 11th April 2011

From 09:30	Registration
10:00-10:15	Welcome Peter Biedermann / Lukas Eschbach
	Session 1: Coatings - Chairperson: Dr. Lukas Eschbach
10:15-11:00	Invited Lecture 1: Innovation bei PVD-Beschichtungen für die Medizinaltechnik; Fred-R. Grohmann, Grohmann Solutions GS, Port, Schweiz
11:00-11:20	Material and Surface Technology for Implants; Ph.D. Eng. Francesco Bucciotti, Eurocoating Spa, Pergine Valsugana - Trento, Italy
11:20-11:40	Innovation: Antimicrobial PVD-TiN; Dipl. Ing. Albert Janssen, Oerlikon Balzers, Balzers, Liechtenstein
11:40-12:15	Flash Presentations Exhibitors (1 min. each)
12:15-13:30	Lunch
	Session 2: Polymers - Chairperson: Dr. Lukas Eschbach
13:30-14:15	Invited Lecture 2: Anwendungen von PCU an Gelenken; Dr. Sabine Mai, Vitos Orthopädische Klinik Kassel, Deutschland
14:15-14:45	Keynote Lecture 1: Design of novel Multi-walled Carbon Nanotube-PMMA cement systems for joint replacement surgery; Dr. Nicholas Dunne, Queen's University of Belfast, Northern Ireland
14:45-15:00	Flash Presentations Posters (1 min. each)
15:00-15:30	Break (Exhibition and Poster)
	Session 3: Production - Chairperson: PD Dr. habil. Christiane Jung
15:30-15:50	Kundenspezifische Implantatoberflächen mit standardisierten Verfahren und Formelementen; Dr. Martin Schmidt, Jossi Orthopedics AG, Islikon, Schweiz
15:50-16:10	Technologie und Eigenschaften der martensitisch rostfreien Stähle; Dr. Alkan Göcmen, Härterei Gerster AG, Egerkingen, Schweiz
16:10-16:30	Cutting strategies for Nitinol stents with pulsed Nd:YAG lasers, fiber lasers and short pulse lasers; Noémie Dury, LASAG Industrial Lasers, Thun, Switzerland
16:30-16:40	Short Break
	Session 4: Additive Manufacturing - Chairperson: Prof. Dr. Michael de Wild
16:40-17:00	Manufacturing of Surgical Implants Using Additive Manufacturing; MSc Ruben Wauthlé, LayerWise NV, Heverlee, Belgium
17:00-17:20	Beeinflussung des elastischen Verhaltens von künstlich hergestellten Knochenersatzstrukturen aus Titan; Dipl. Ing. Ralf Schumacher, Fachhochschule Nordwestschweiz - Hochschule für Life Sciences, Muttenz, Schweiz
17:20-17:40	Innovatives Implantat mit inneren Funktionskanälen und –hohlräumen; Dr.-Ing. Bernhard Müller, Fraunhofer IWU, Dresden, Deutschland
17:40-18:00	Fabricating NiTi shape memory scaffolds by Selective Laser Melting; Dipl.-Ing. Therese Bormann, Fachhochschule Nordwestschweiz - Hochschule für Life Sciences, Muttenz, Schweiz
18:00-19:00	Exhibition / Poster / Aperitif
19:30	Dinner at the Restaurant Spycher

Meeting Program

Tuesday 12th April 2011

	Session 5: Hip and Wear - Chairperson: Dr. Lukas Eschbach
08:30-09:15	Invited Lecture 3: Modern concepts in hip replacement: the impact of minimal invasive operative techniques (MIS), patient selection and postoperative setup; PD Dr. Thomas Ilchmann PhD, Kantonsspital Liestal, Switzerland
09:15-09:45	Keynote Lecture 2: Biological effects of wear particles; Dr. Klaus Vosbeck, Dr. Klaus Vosbeck GmbH, Biotech Consulting, Oberwil, Switzerland
09:45-10:05	Polyethylene acetabular wear volume after hip replacement. Accuracy of radiographic volume calculation studied from retrieved cups; PD Dr. Thomas Ilchmann PhD, Kantonsspital Liestal, Switzerland
10:05-10:30	Break (Exhibition and Poster)
10:30-12:00	**Session 6: Cleanliness (Symposium) - Chairperson: PD Dr. habil. Christiane Jung**
	Prüfung der Sauberkeit von Implantatoberflächen nach der Fertigung; Dipl.-Ing. Steffen Lutz, NMI Naturwissenschaftliches und Medizinisches Institut an der Universität Tübingen, Deutschland
	Instrumentenwiederaufbereitung - Top-Reinigungsleistung bei höchster Materialverträglichkeit mit einem 2-Komponenten Reinigungssystem; Dr. Urs Rosenberg, Borer Chemie AG, Zuchwil, Schweiz
	Cleanliness: How Clean is Clean Enough – Guidance for Industry; Dr. Reto Luginbühl, RMS Foundation, Bettlach, Switzerland
	Reinigungsvalidierung - Voraussetzung, Durchführung, Monitoring; Markus Wipf, AXXOS GmbH, Erlinsbach, Schweiz
	Reinigungsvalidierung - Chemische Prüfung und Beurteilung der Sauberkeit von Medizinprodukten; Daniel Zurbrügg, Niutec AG, Winterthur, Schweiz
	Biological Safety Testing in the Field of Microbiology; Dr. Jörg Degen, BSL BIOSERVICE, Planegg, Germany
	Panel Discussion
12:00-13:15	Lunch
	Session 7: New Materials and Processes - Chairperson: Prof. Dr. Michael de Wild
13:15-13:35	Intelligent Robotized medical implants polishing driven by optical deflectometry; Prof. Yves Surrel, VISUOL Technologies, Metz, France and Prof. Philippe Liscia, Haute Ecole Arc, Switzerland
13:35-13:55	Kombinierte elektrophysikalische Produktionsverfahren; Rico U. Ruffner-Kaiser, Ruffner Engineering, Zuchwil, Schweiz
13:55-14:15	Zementierte Fixierung von Keramikimplantaten - Möglichkeiten zur optimierten Knochenzement-haftung; Dipl.-Ing. Thomas Oberbach, Mathys Orthopaedie GmbH, Deutschland
14:15-14:35	Evaluation of effects of gamma sterilization on biomedical polyurethanes for implant use; Dr. Markus Kraft, Synthes GmbH, Oberdorf, Switzerland
14:35-14:45	Short Break
14:45-15:30	Invited Lecture 4: Innovationen in der Dentalimplantologie; Dr. Falko Schlottig, Thommen Medical AG, Waldenburg, Schweiz
15:30-15:50	Evaluation of biomaterials using an in vitro test battery; Dr. Arie Bruinink, EMPA, St. Gallen, Switzerland
15:50-16:10	3D Surface Modelling using a SEM; Dr. Harry Brandenberger, Gloor Instruments AG, Uster, Switzerland
16:15	Conference Ends

Abstracts: Table of Content

Innovation in the PVD coating for medical technology

Fred – R. Grohmann

Grohmann Solutions GS, Port, Switzerland

INTRODUCTION: First PVD coating systems for industrial use were presented in 1988. Clinical investigations and first theses on the biocompatibility were carried out on TiN coatings. With the newest PVD equipment dated 2010 together with the acquired knowledge on coating adherence and coating structure it was possible to significantly improve the quality of the coatings compared with the early days of the PVD technology [1-2].

METHODS: The presented coatings were produced with the PVD ARC process as well as with DLC coating systems. We will specially focus on studies done at the ETH Zürich which were supported by two KTI projects. This work could be finalized with two doctoral dissertations. The project in question was called "CPDN project" (Control Pour Distance Nano) 3. In multiple applications (e.g. metal cutting) the rounding of (cutting) edges upon PVD coatings represents an undesired disadvantage; it is here used as main benefit enabling the production of special emulsions. Furthermore we present PVD coatings on surgical instruments and implants which not only enhance the biocompatibility, but also considerably reduce the wear.

RESULTS: With the presented method, very gentle emulsions are produced which have a reproducible drop size of less than 3 µm. in addition so called double emulsions can be realized, for example, W/O/W. Hereby <1 µm sized droplets are build-in in the above described <3 µm drop. The pharmaceutical and cosmetic companies are very interested in this issue, in particular in view of producing emulsions for artificial nutrition (see photo).

In the case of surgical instruments the coatings reduce the reflection of light and therefore increase the contrast to the tissue significantly. Furthermore the reduction of wear is highly welcome, especially for joint implants.

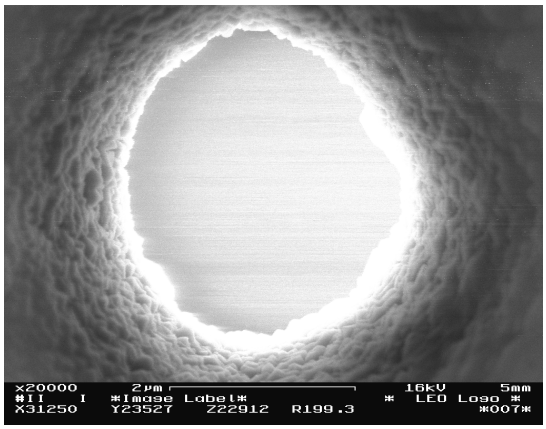

Fig. 1: SEM image of a mechanical hole: hole diameter before coating approx. 5 µm, hole size after PVD coating approximately < 2µm.

SUMMARY: While in the past PVD coatings were primarily used for decorative purposes they find more and more functional applications and are appreciated in different fields. The medical field is a very challenging one and medical coatings should not be considered as a side activity in a coating center. The requirements of producers of medical instruments and implants are high and the risks are considerable. The coatings in this field have to be carried out based on certifications and strict documentation.

REFERENCES: [1] Habilitationsschrift Holger Brauner, Universität Erlangen 1991, "Titannitrid in der dentalen Technologie"

[2] Dissertation Daniel Turin, Universität Bern 1993 „Titannitridbeschichtungen eine Alternative zur elektrolytischen Vergoldung von Stahlgerüsten"

[3] Dissertation Muriel Graber, ETH Zürich 2010 „Transport Phenomena in Rotating Membrane Processed W/O/W Emulsions".

Materials and Surface Technology for Implants

F. Bucciotti[1], P. Robotti[1]

[1]*Eurocoating S.p.A, Italy*

INTRODUCTION: Osseointegration is an essential outcome for cementless orthopaedic prostheses and dental implants. In clinical applications there are many surface treatments able to improve osseointegration. Among them plasma spray (PS) coatings may be effective surface treatments with wide and well documented evidence of long term positive results. In other clinical cases a further step in osseointegration (bone ingrowth) is considered an essential benefit. Such a feature can be accomplished e.g. with large size and interconnected porous metal structures. Technologies like PS and Additive Manufacturing (AM) have been shown to permit large freedom in metal surface design and fabrication up to structures suitable for bone ingrowth. Complex geometries can be handled with greater flexibility using AM in comparison with traditional manufacturing methods (i.e. casting, forging, machining, etc.).

MATERIALS & METHODS: Coatings consist of Titanium (Ti), Hydroxyapatite (HA) or both of them (Ti+HA) on in the same device with HA on top. Coatings are manufactured (Eurocoating spa) in Air (e.g. Osprovit®) or in Vacuum (by VPS, e.g. Ti-Growth®). Both approaches have clinical successful evidences. However plasma atmosphere has a strong influence on the characteristics and morphology of the coatings. Alternatively osseointegrative surfaces in Ti-cp or Ti-alloy (Ti6Al4V) may be manufactured by Direct Metal Laser Sintering (DMLS) or Electron Beam Melting (EBM) (both available at Eurocoating spa). By using AM it is possible to design and build up the whole medical device in one single manufacturing step (compact structural bulk and porous surface structure).
Surfaces and materials developed were characterised by mechanical testing (adhesion), image analysis (SEM), in vitro (cells vitality and proliferation) and in vivo (implantation in goats) investigations.

RESULTS: HA Osprovit® (Fig. 1) may be applied with a thickness from 30 to 150 µm according to the specific component requirements, porosity is in the range 8-10 %. Adhesion with substrate exceeds 15 MPa. Titanium VPS coatings have higher thickness (in the range 150-600 µm) and porosity (30-50 %). Adhesion with substrate exceeds 35 MPa. Ti-Growth® is an innovative Ti sponge coating, specifically designed to enable bone ingrowth with open and interconnected pores in the range 100-800 µm, porosity between 40-70 % with pores and interconnections diameters around 300 µm (Fig. 2). Both Ti and HA coatings can be applied not only onto Ti alloys substrates but also onto critical substrates like CoCrMo or PEEK.
DMLS and EBM foams are designed with an accuracy of pore dimensions and struts up to 150 µm and 500 µm respectively (Fig. 3).
In vitro tests highlighted cells capability to colonize large pore size structures [1] (Fig. 4).
In vivo tests confirmed excellent performance in term of bone ingrowth, bone implant contact and push-out strength [2] (Fig. 5).

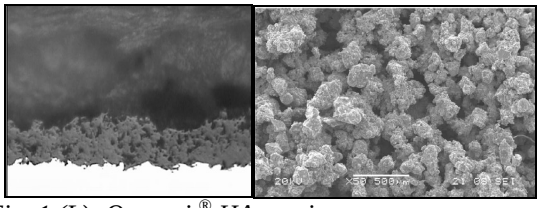

Fig. 1 (L): Osprovit® HA coating.
Fig. 2 (R): Ti-Growth® Ti sponge plasma coating.

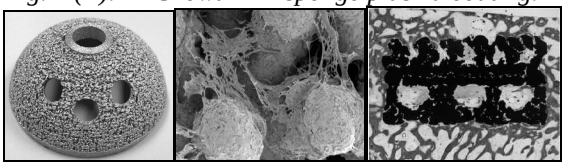

Fig. 3 (L): Acetabular Cup with foam (EBM)
Fig. 4 (M):(hMSCs) attach and spread on the porous surface structures
Fig. 5 (R): Histology for EBM foam structures

DISCUSSION & CONCLUSIONS: Plasma Spray surfaces when properly designed and manufactured show clinical success in long term application. AM topographic structures showed promising pre-clinical results and short term follow up.

REFERENCES: [1] The effect of ebm engineered surface structures on proliferation and differentiation of hMSCs. E. Biemond et al.; 22nd ESB, 08-12 September 2009, Lausanne, CH.
[2] In vivo assessment of bone ingrowth potential of 3D ebm produced implant surfaces and the effect of additional hydroxyapatite coating. E. Biemond et al.; J. Biomaterials Appl. 2011.

Medical coating innovation: Antimicrobial PVD TiN

C. Piñero[1], A. Janssen[1], G. Sinicco[1], A. Ewald[2]

[1]OC Oerlikon Balzers AG , Headquarters, Iramali 19, LI-9496 Balzers

[2] Dept. of Functional Materials in Medicine and Dentistry (FMZ), University Hospital of Wuerzburg, Pleicherwall 2, D-97070 Wuerzburg

INTRODUCTION: The use of antibiotics to prevent infections when bound to or incorporated into orthopedic and medical devices has met with limited success. Furthermore the high incidence of nosocomial infections has promoted the development of new antibacterial products in order to diminish the occurrence of these diseases [1]. Therefore Oerlikon Balzers has developed a new antimicrobial wear resistant PVD Ag/TiN coating for orthopaedic and medical devices.

METHODS: Ag/TiN coatings were produced using PVD techniques. Hardness, colour, roughness, substrate temperature during coating deposition, antibacterial action and process flexibility for adjusting the antibacterial action were the highly significant parameters that were considered in order to develop the most suitable deposition process for the production of Ag/TiN coatings and their most efficient variants. Coatings having silver concentrations of about 0.1 up to 30 at% were synthetized and characterized on different steel substrates - including medical quality steel samples. Coating composition and structure were investigated by secondary ion mass spectrometry (SIMS), X-ray diffractometry (XRD) and transmission electron microscopy (TEM) techniques. Bacterial activity tests (performed with E. coli, S. epidermidis and S. aureus) on Ag/TiN-coated medical steel substrates were accomplished by FMZ.

RESULTS & DISCUSSION: We found that the most suited deposition process for the synthesis of the antibacterial Ag/TiN coatings was a combined arc/sputter ion plating process (AIP/MSIP). The presence of separated Ag and TiN phases in the coating structure could be confirmed by XRD-examinations. Characteristic Ag peaks were detected in XRD spectra of the synthesized antimicrobial Ag/TiN coatings. However the observed Ag peaks were wider than typical characteristic ones, particularly by coatings having lower silver concentrations. Wider Ag peaks can be explained by the nanometer grain size of the silver particles, which was confirmed by TEM examinations. TEM pictures (Fig. 1) show the formation of island shaped agglomerations having grain sizes of about 8-10 nm x 3-4 nm in Ag/TiN coatings containing 2,5 at% and 6,5 at%.

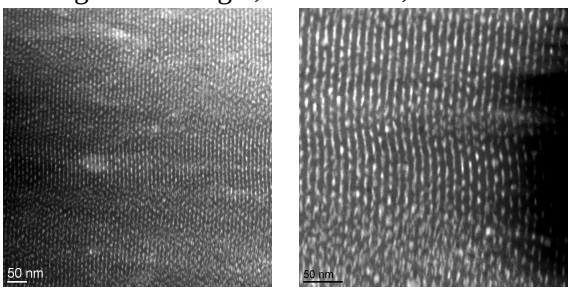

Fig. 1: TEM micrographs of Ag/TiN coatings; left 2.5 at% Ag, right 6.5 at% Ag

Experiments examining the antimicrobial activity of these coatings reveal very promising results using E. coli (Fig. 2)

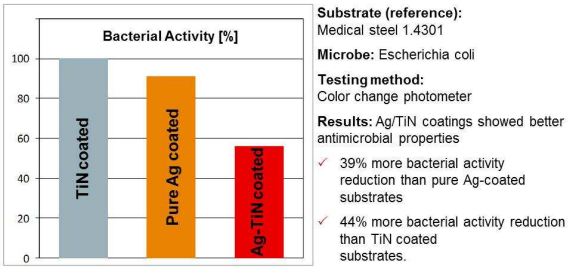

Fig. 2: antimicrobial activity of Ag/TiN coatings

Further coating variants designed as yet attained about Log 1 by Log-reductions using S. epidermidis as microbe and medical steel 1.4542 as reference.

CONCLUSIONS AND FURTHER WORK: Developed Ag/TiN coatings showed better antibacterial action than pure PVD Ag sputtered coating and TiN coatings without silver. Further investigations for adjusting antibacterial action and long-time antibacterial according to particular customer requirements will be performed in cooperation with interested customers.

REFERENCES: [1] Ewald A. and et al.; BioMedical Engineering OnLine, 2006, 5:22

Anwendungen von PCU an Gelenken

S. Mai

Vitos Orthopädische Klinik Kassel, Deutschland

Polyurethan (PU) wurde erstmals 1937 synthetisiert und ist ein vielseitig verwendetes Material, das hart und spröde, aber auch weich und elastisch sein kann. Die Elastomere besitzen eine hohe Reißfestigkeit. Die Eigenschaften verändern sich durch die aromatische oder aliphatische Basisstruktur und die Auswahl der Polymere. Im Vergleich zu anderen Kunststoffen ist die Produktion schwieriger und teurer. Polyurethane haben eine sehr hohe Biokompatibilität. Es finden sich nur geringe Gewebsreaktionen. Allergien sind nicht bekannt.

1960 wurde PU erstmalig von Townley als Hüftkappe, die gegen eine Metallschale lief, vorgestellt, was sich aber nicht bewährt hat. Seit 1975 wurden PUe im Menschen zunächst bei Schrittmachern eingesetzt, später bei Kathetern, Herzklappen und Gefäßprothesen und auch als Beschichtung, da sie gerinnungsbeständig sind.

Für die **Anwendungen in der Orthopädie** wird das Material durch Hinzufügen von Carbonaten verstärkt. 1994 wurde Polycarbonat-Urethan (PCU) in der **Wirbelsäulenchirurgie** zur dynamischen Stabilisierung als Dynesis® Implantat angewendet. Die lumbale LP-ESP Bandscheibenprothese (seit 2003, entwickelt in Frankreich) imitiert mit einem flexiblen Kissen aus PCU die Funktion des Nucleus. Seit 2009 gibt es auch ein Bandscheibenimplantat ausschließlich aus PCU.

In der **Handchirurgie** findet PCU in Fingerimplantaten als kugeliger Gelenkteil zwischen CoCrMo-Gelenkzapfen (ESKA), PU-Urea als degradierbarer Spacer (Artelon) Verwendung.

In den 90er Jahren wurde eine **Hüftpfanne** entwickelt, die die Funktion des Knorpels nachahmen soll ohne die Nachteile des Polyethylens (PE) und anderer Metall- und Keramik-Gleitpaarungen. Das PCU mit ähnlichen elastischen Eigenschaften wie der Knorpel soll seine Stoßabsorptionsfunktion imitieren. Bei In-vitro-Versuchen hat es einen siebenmal geringeren Abrieb als PE. Die PCU-Abriebpartikel sind größer als bei PE mit dadurch reduzierter relativer Oberfläche, wodurch eine geringere Bioreaktion zu erwarten ist. Das hydrophile Material begünstigt die mikroelastische hydrodynamische Lubrikation zwischen Pfanne und Hüftkopf. Keime haben zu hydrophilen Oberflächen eine geringere Affinität.

Das seit 2006 bestehende TriboFit® Hüftsystem besteht aus einer Metall-Pfannenschale, dem Inlay aus PCU und einem großen Hüftkopf aus Cobalt-Chrom. Die 3 mm dicke PCU Pfanne kann auch direkt in das Acetabulum eingesetzt werden. Bisher wurden weltweit über 1000 Implantationen ohne implantatbezogene Komplikationen durchgeführt. Bei Revisionen von reinen PCU-Pfannen fanden sich lediglich einige Fremdkörperreaktionen ohne weitere Auffälligkeiten. Die Rückseite der Implantate zeigte Hinweise auf eine Bewegung zwischen Implantat und Knochen, deren Auswirkung aber bisher unklar bleibt. Ein reguläres Einwachsen erfolgt nicht. Radiologisch scheint sich bei alleiniger Verwendung des PCU der Knochen hinter der Pfanne zu verdichten. Der Harris Hip Score ist vergleichbar mit anderen Nachbeobachtungsstudien in der Hüftendoprothetik. Interessant ist die Option, auch bei kleinem Acetabulum und schlechter Compliance des Patienten, einen großen Hüftkopf verwenden zu können und damit die Luxationsgefahr zu verringern. Besonders knochensparend ohne die Problematik der Metall-Metall-Paarung ist die Implantation der PCU-Pfanne in Kombination mit einer Hüftkappe.

Seit 2010 wurde bisher bei 19 Patienten ein **Meniskusimplantat** aus PCU im Knie erfolgreich eingesetzt. Am Rand ist es mit PE-Fasern verstärkt. Eine Fixation ist nicht notwendig.

Zusammenfassend ist PCU ein vielseitig verwendbares, interessantes und besonders gut verträgliches Material. Allerdings stehen die Langzeitergebnisse bei allen medizinischen Anwendungen in Gelenken noch aus.

Design of novel multi-walled carbon nanotube-PMMA cement systems for joint replacement surgery

N. Dunne[1], R. Ormsby[1], P. O'Hare[3], G. Burke[3], T. McNally[1], C. Mitchell[2],

[1]School of Mechanical & Aerospace Engineering, [2]School of Medicine, Dentistry & Biomedical Sciences, Queen's University Belfast, UK, [3]Nanotechnology and Advanced Materials Research Institute, University of Ulster, UK.

INTRODUCTION: Fracture of PMMA bone cement due to damage accumulation is a major factor in the mechanical failure of implant fixation and a primary cause of aseptic loosening. Additionally, the polymerisation reaction is highly exothermic; temperatures can exceed 100 ºC causing cellular bone necrosis and also contributing to aseptic loosening [1-2]. The objective of this study was to investigate augmentation of PMMA bone cement using multi-walled carbon nanotubes (MWCNT) powders. The mechanical, rheological properties of MWCNT-PMMA cement and the effects of MWCNT on cure rate have been characterised. Finally the cellular response has also been investigated.

METHODS: Unfunctionalised (UNF), carboxyl (COOH) and amine (NH_2) functionalised MWCNT (Nanocyl S.A., Belgium) at varied wt% loadings (0.1-1.0) were incorporated into the MMA prior to cement mixing using ultrasonic agitation [1-2]. Rheology was used to determine time of onset of cure (t_{ons}) and critical gelation time (gel-time). Static mechanical and thermal characterisation was conducted as per ISO 5833:2002. Dynamic mechanical properties were determined in tension—tension (0.3-22 MPa) at 2 Hz [3]. To determine the cellular response, MG63 cells (ATCC) were cultured in MEM (Sigma) supplemented with 10% foetal calf serum and antibiotic/antimycotic (PAA Lab. GmbH, Austria). Crystal violet attachment and 1, 3 and 7 day MTT viability assays were carried out to determine MWCNT effect on cell growth.

RESULTS:

Table 1: Effect of MWCNT on cell response.

Cement	MWCNT (wt%)	Absorbance OD (570nm) Cell Attachment 4h	Cell Viability 1 day	Cell Viability 7 day
Control		0.25 ± 0.02	0.16 ± 0.03	0.62 ± 0.02
MWCNT-UNF	0.10	0.45 ± 0.09	0.17 ± 0.04	0.58 ± 0.09
	0.25	0.48 ± 0.04	0.13 ± 0.07	0.56 ± 0.08
MWCNT-NH_2	0.10	0.72 ± 0.07 ***	0.145 ± 0.04	0.44 ± 0.06
	0.25	0.73 ± 0.06 ***	0.12 ± 0.08	0.32 ± 0.03 **
MWCNT-COOH	0.10	0.75 ± 0.06 ***	0.17 ± 0.06	0.39 ± 0.05 ***
	0.25	0.76 ± 0.06 ***	0.15 ± 0.05	0.32 ± 0.01 ***

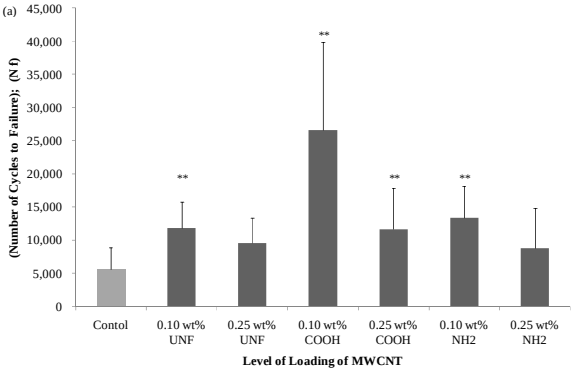

Fig. 1: Effect of MWCNT on fatigue properties.

DISCUSSION & CONCLUSIONS: Incorporating MWCNT (≤0.25 wt%) into cement significantly improved the static and dynamic mechanical properties (Fig. 1). The extent of this effect was dictated by MWCNT functionality and the wt% used. Improvements were attributed to the MWCNT arresting crack propagation. The exothermic polymerisation reaction for PMMA cement was significantly reduced when thermally conductive MWCNT were added. This was supported by the rheological characterisation as adding MWCNT significantly altered t_{ons} and gel-time. Adding MWCNT significantly increased cell attachment after 4 h (Table 1). Cell viability was over 7 days *in vitro*; however a decrease in viability was noted for MWCNT-PMMA cements when compared with the control after 7 days. Initial observations indicate this may be due to the surface area of samples being insufficient to support cell proliferation rate for the study duration.

REFERENCES: [1] Ormsby et al., J Mater Sci Mater Med. 2010 Aug;21(8): 2287-92.[2] Ormsby et al., J Mech Behav Biomed Mater. 2010 3(2):136-45.[3] Dunne et al., Biomaterials. 2003 24(2): 239-45.

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Customised Implant Surfaces with Standardised Processes and Design Elements

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COMPANY: Jossi Orthopedics Ltd. develops and produces components and instruments for providers of orthopaedic and surgical implants, based on innovative and cost-saving technologies.

MOTIVATION: From discussions with clients, the following can be concluded: (1) proven design elements are the backbone of most innovations, (2) there is increasing cost and time pressure, (3) solutions are desired rather than mere production of components. A recent study confirms these trends[1]. How Jossi Orthopedics reacts to these challenges can be illustrated with the development and production of acetabular shells for cementless implantation.

PROCESSES: Like from a toolbox, the client is able to combine shapes, design elements and surface structures to obtain an individualised product component.

Basic shape: mainly derived from a hemisphere, also with flanges (Fig. 1), made from Ti-6Al-4V as well as cpTi, stainless steel or CoCrMo. Jossi Orthopedics forms shells preferentially from sheets to readily get near net-shape. Forming is, compared to forging, a relatively cold process without alteration of the material's micro structure. Wall thicknesses can be between 0.3 and 10 mm. Tight tolerances are achieved by final CNC machining.

Design elements: screw holes, fins, polyhedrons and barbs, can be formed out (Fig. 2).

Surface: There are additive, subtractive and forming processes. Macro structures are supposed to increase friction between implant surface and osseous bed to achieve stable primary fixation, whereas micro structures aim at secondary fixation through osteointegration.

- Additive: All types of coatings and sintered structures, produced by partners or directly by the client.
- Subtractive: Chemical and mechanical processes, mostly used to clean, passivate, or to create micro structures, e.g. through etching, electropolishing or grit blasting.
- Forming: It is by far the fastest and most economic way of fabricating surface macro structures, as far as necessary, combined with CNC machining. This process also allows low-cost product lines since forming is more advantageous than coating. Forming is possible for repeated fine structures as well as for singular features like fins.

Fig. 1: Some different basic shapes of acetabular shells. From left: revision shell, primary press fit shell, thin metal back.

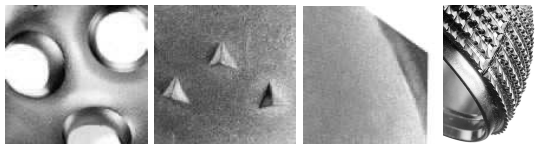

Fig. 2: Some formed-out design elements to structure surfaces. From left: screw holes, polyhedrons, fins, barbs.

CONCLUSIONS: Combining forming and machining ("HybridManufacturing™") leads to individually structured implant surfaces with excellent primary and secondary fixation, even without costly additional coatings, regardless of the utilised material. The first acetabular cup that Jossi Orthopedics helped to structure by forming processes has been clinically successful for 15 years. In the light of increased cost pressure, forming is more relevant than ever.

REFERENCES: [1] P. Biedermann et al., The Swiss Medical Technology Industry 2010 Report (2011).

Technology and Properties of Martensitic Chromium Steels

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INTRODUCTION: Surgical instruments are predominantly made of martensitic chromium steels. Beneficial product properties in terms of strength, toughness, surface hardness and corrosion resistance can be realised by proper selection of steel composition and heat treatment. Vacuum furnaces are preferably being used for the heat treatment of surgical instruments for reasons of product performance, surface finish and process reliability. Advanced vacuum furnace technologies provide new opportunities to enhance corrosion resistance and surface hardness based on a solution nitriding process[1].

SOLUTION NITRIDING: The application of a nitrogen pressure during a heat treatment cycle provides a thermodynamic driving force for nitrogen up-take of steel products[2]. Diffusion rates of nitrogen within austenite enable nitrogen indiffusion into a depth of up to about 0.5mm at hardening temperatures in the range between 1000 and 1100°C. Pressure dependent nitrogen up-take and resulting microstructure can be predicted based on modern phase calculation tools like ThermoCalc® (figure 1). On this basis achievable surface hardness and corrosion resistance can be assessed.

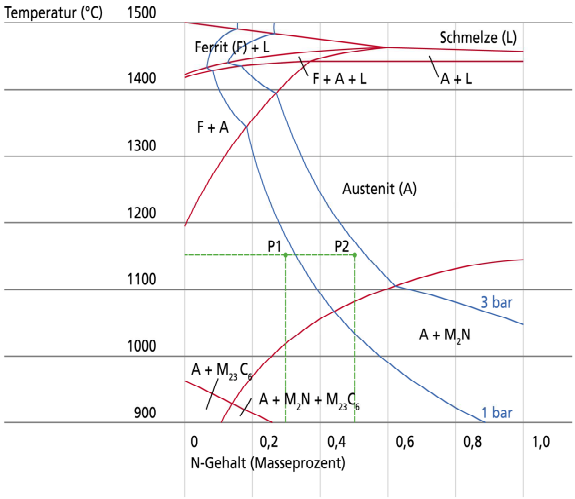


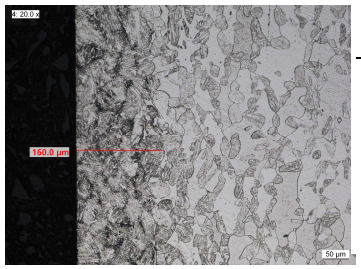
Fig. 1: Phase diagram of X20Cr13 (420) calculated by Ruhr University of Bochum

The effect of dissolved nitrogen on corrosion resistance can be assessed using pitting resistance equivalent numbers (PREN)[3]:

PREN = %Cr+3.3%Mo+16%N

It follows from pitting resistance equivalence number that nitrogen additions in the range between 0.2 to 0.5% can lift pitting corrosion resistance of 12%Cr steel (420) up to the level of austenitic 18%Cr-8%Ni steels (304) and those of 17%Cr-1%Mo (434) steel up to the level of austenitic 18%Cr-12%Ni-2.5%Mo (316). The effect is stronger the lower the interstitial content of the base alloy. This fact leads to the concept of case hardening of stainless steels.

CASE HARDENING OF STAINLESS STEELS: Using solution nitriding new products can be designed that can offer an exceptional combination of surface hardness, corrosion resistance and core toughness. Two possible material strategies can be pursued: (1) solution nitriding of low interstitial, nickel containing martensitic steels based on 14%Cr-3%Ni and (2) solution nitriding of extra low interstitial ferritic stainless steels based on 17%Cr-1%Mo. A representative microstructure for a solution nitrided ferritic stainless steel is shown in figure 2.



x [mm]	hardness HV1
0.1	606
0.2	513
0.4	277
0.5	240
0.6	228
0.7	229

Fig. 2 Microstructure and corresponding hardness profile of ferritic grade X7Cr17 (430) after a solution nitriding treatment at 1100°C

REFERENCES: [1]R. Zaugg et al. (2005) Z. Werkst. Wärmebeh. Fertigung **60**: 1; [2]M. Gavriljuk & H. Berns (1999) *High Nitrogen Steels*, Springer, p. 215ff.; [3]J. Truman (1987), U.K. Corrosion 87, Inst. of Corr. Sci. and Tech., Brighton, p.111.

Cutting strategies for Nitinol stents with pulsed Nd:YAG lasers, fiber lasers and short pulse lasers

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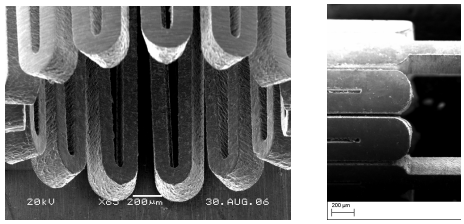
INTRODUCTION: Even today, laser cutting of medical stents is considered to be a reference benchmark for laser cutting at its highest precision and quality.
The reason for this is a unique combination of high demands regarding cutting quality (and thus laser beam quality), and the precision and the dynamics of the handling systems, not to mention the characteristics of the processing materials and the required optimization of all marginal conditions in the process.
In tracing developments over the past years, one notices that, in addition to lamp-pumped pulsed Nd:YAG lasers, considerable efforts have been made to obtain existing beam qualities with new laser technologies, as well.
In addition to the diode as pump source, alternative pump media and resonator concepts, such as fiber and disk, have found their way into the field of industrial laser technology. Other objects of research include ultra short-pulse technologies via fs and ps lasers with the goal of reducing thermal heat input during materials processing.

METHODS: Laser cutting will be discussed here with nitinol material as an example, since nitinol is gaining in significance in the field of stent production due to its form-memory properties.
The need to minimise both the heat transfer as well as the damage caused by oxidation can obviously be deduced from this. In practice, this is done by reducing the laser energy and pulse duration to a minimum. This takes for granted a high energy density and hence good beam quality of the laser and results in a narrow cutting gap in conjunction with the appropriate processing lens.

Inert cutting gases are used in the process to protect the material from oxidation. In addition, a patented tube flushing system using fluids to ensure protection of the opposite side against the still focused beam on one hand and fast heat dissipation of the process heat on the other while also binding cutting dusts can be used.



a) *b)*

Fig. 1 a) Laser cut of a Nitinol stent [1]
b) "cold" fs Laser processing

RESULTS: By reducing the cutting gap, the aspect ratio of the gap is reduced on one hand, while the gas flow has increasing difficulty with cutting gaps of 10 µm and less in expelling the molten mass from the cutting gap. The result is adhesion of the cutting gap and an increase in the permanently adhering slag formation at the lower edge of the cut. Acceptable cutting results with cutting gaps less than 10 µm can be achieved only with a marked reduction in the cutting speed. The cutting speed for a material thickness of approximately 250 µm and gaps of less than 10 µm is typically less than 200 mm/min.
In modulated cw-fibre lasers controlling the pulse forming technology can be seen as a key aspect that prevents plasma from being created.
One additional option is to use shorter pulses in the ps or in the fs range. These pulses are short enough to prevent plasma generation in the pulse with the result that work can be done entirely in the evaporation range. This is true even for organic stent material.

DISCUSSION & CONCLUSIONS: In summary it can be stated that a whole range of challenges could be solved with the laser technologies available and in use today. New laser technologies can be considered for laser cutting in addition to the existing solutions. Their suitability for flexible stent cutting of all materials and thicknesses still has to be examined.

REFERENCES: [1] Admedes Schuessler GmbH, (2006).

Manufacturing of Surgical Implants Using Additive Manufacturing

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INTRODUCTION: Additive Manufacturing (AM) techniques like Selective Laser Melting (SLM) offer unlimited geometric freedom, direct digital production and short lead times. Also the use of biocompatible materials and the possibility to make patient specific or custom designs are advantages for the manufacturing of orthopaedic implants using AM. For cases with major bone loss or large bone defects, porous bone scaffolds with mechanical properties close to human bone can be integrated in the implant design for better long-term fixation through bone ingrowth.

METHODS: SLM is an innovative manufacturing technique to make complex metal parts. The process uses a laser beam to melt thin layers of metal powder together. This results in complex parts with fully dense material properties. The materials available for medical implants currently are: commercially pure titanium (Ti CP1 & Ti CP2), titanium alloys (Ti6Al4V & Ti6Al4V ELI) and cobalt chromium (CoCr).

RESULTS: Scaffolds can have different geometries and properties, depending on the unit cell geometry (geometrical shape which repeats itself in the bounding geometry), the strut size and the pore size. This way it is possible to design and manufacture scaffolds with desired porosity and mechanical strength, but then the repeatability of the manufacturing process is very important. Fig. 1 shows the repeatability of the ultimate compressive strength of 3 different Ti6Al4V scaffold geometries over several batch productions[1].

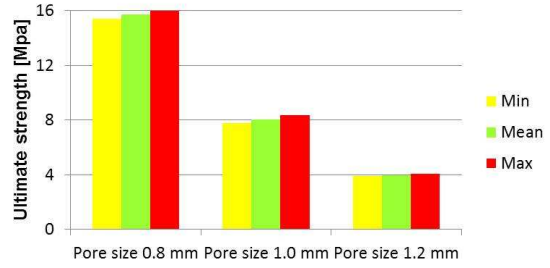

Fig. 1: Ultimate compressive strength of three different Ti6Al4V scaffold geometries over several batches in time.

Porous scaffolds will allow bone ingrowth and can be integrated in any design of surgical implants. Fig. 2 shows the integration of a patient-specific porous structure in a custom made hip implant. The porous structure can be rigidly connected to the implant or completely separate from the rest of the implant. Instead of using a porous coating on the flanges, an integrated porous region allows better attachment of the implant to the bone.

Fig 2. Custom made hip implants with porous structure rigidly connected to the implant for a severe pelvic discontinuity (left) and separate parts in a multi component revision (right). Courtesy: Mobelife NV, Leuven, Belgium.

DISCUSSION & CONCLUSIONS: AM offers many innovations like porous structures for bone ingrowth. Besides patient-specific joint prostheses, implants for spinal and CMF applications and trauma fixation can also be manufactured. Besides custom implants, the additive manufacturing technology can also be used for series production of surgical implants.

REFERENCES: [1]Van Bael S. et al., Proc. ECCOMAS - International conference on tissue engineering.

ACKNOWLEDGEMENTS: The research results on the Ti6Al4V scaffolds were performed in collaboration with the Catholic University of Leuven, Department of Mechanical Engineering and Department of Metallurgy and Materials Engineering.
The photos of the custom hip implants are used with kind permission of Mobelife NV.

Manipulation of the elastic behaviour of artificial Titanium bone grafts

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INTRODUCTION: To cover large bone defects after e.g. tumour resections, autologous bone grafts are still gold standard. However, artificial and synthetic substitutes are upcoming alternatives. Such alloplastic bone grafts, manufactured with layer-by-layer strategies which offer more freedom of design, will end up in novel bone replacing implants.
It is known that the biomechanical compatibility at the interface between bone and implant is crucial for a successful treatment. Therefore the mechanical properties of the implant, like the Young's Modulus, should locally be adapted to the bony counterpart at any place of the interfacing region in order to prevent stress shielding and loss of bone substance [1].
This mechanical adaption could be performed by controlling the porosity of an open porous scaffold [2].

METHODS: This project investigates the influence of the architecture of specifically designed bone graft structures to its elastic behaviour. Therefore two different designs (diamond and spherical like structures, Fig. 1 left and right) were chosen. For the spherical design, the cell size was varied in a range of 1.25-2 mm and the sphere size was adapted in order to end up at a porosity of 60 %.

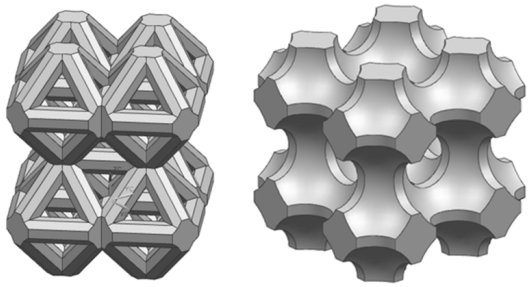

Fig. 1: Left: diamond like structure, right: spherical structure.

The SLM 250HL (SLM-Solutions) equipped with an Ytterbium fibre laser of 200 W was used to process cp Titanium grade 2 powder (spherical particles of diameter between 10 µm to 60 µm). Scaffold cubes of 10 mm x 10 mm x 10 mm were produced in layers of 30 µm. To avoid oxidation during production, the powder and the process chamber was flooded with inert argon gas of high purity (4.8). As a post process, the cubes were heat treated (T=550 °C for 1h under argon gas). The cubes were then compressed on a universal test bench (Walter & Bai, DCC series, F_{max} = 50 kN).

RESULTS: The titanium cubes showed an elastic behaviour, which can be adjusted by adapting the porosity. Therefore the Young's Modulus for the spherical cells could be varied between 13 kN/mm^2 (at 40 % porosity) and 2 kN/mm^2 (at 80 % porosity).
In addition, the cell design (diamond) showed some minor influence on the Young's Modulus [3]. On the contrary, the influence by the cell size was negligible (Fig. 2).

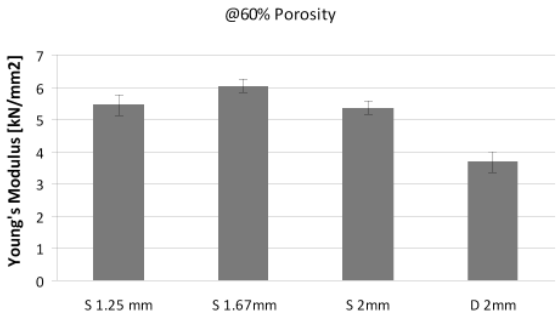

Fig. 2: The Young's Modulus (at 60 % porosity) in dependency on the cell size and cell design: S=sphere, D=diamond. The numbers next to the letters represent the cell size.

DISCUSSION & CONCLUSIONS: Since the cell size has almost no influence to the elastic behaviour, it could be adapted in order to achieve the best bone cell in-growth. Through the porosity and the cell design, the biomechanical characteristic of metallic SLM implants could be specifically designed for bone replacing applications.

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[1] Wintermantel E. Der Chirurg, 1999
[2] Ondracek G. et al. Proceeding of Colloquium, Interfaces in Materials, Brussels, 1988
[3] Lin C.Y. et al. J. of Biomechanics 37:623-636, 2004.

Innovative implant with inner functional channels and cavities

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INTRODUCTION: At the current state of the art, endoprostheses are predominantly manufactured by cutting, forming or casting technologies. Another, rather new way of manufacturing implants is the Additive Manufacturing (AM) process called Beam Melting. In particular the customized production with no need for any type of tooling, combined with the unique freedom of design, sparks interest in this technology to manufacture complex and patient-specific implants.

ADDITIVE MANUFACTURING OF IMPLANTS: With Beam Melting, the implant is manufactured based on 3D CAD data by layer-wise local melting of metal powder using a laser or electron beam. Different bio-compatible and medically approved materials like pure titanium, titanium alloys (TiAl6V4, TiAl6Nb7) and Cobalt Chromium alloys (CoCrMo) can be selected. Limitations of conventional manufacturing methods can be neglected. The use of Beam Melting enables the fabrication of endoprostheses with almost any design of inner and outer geometries. Implants with completely new shape and function can become reality, e. g. surface structures for better ingrowth [1] or even volume structures to adapt the implant's stiffness to that of human bone [2]. Beam Melting allows direct digital manufacturing of individual implants based on CT or MRI scan data [3] as well as (series) Rapid Manufacturing of standardised implants [4].

INTEGRATION OF NEW FUNCTIONS IN ENDOPROSTHESES: The design freedom of Beam Melting technology enables not only the manufacturing of implants with cellular structures but also the integration of complex inner channels and cavities for a variety of new functions in endoprostheses. Using a hip stem as reference, an implant with inner functional channels and cavities, which can be designed in any desired shape according to specific requirements, has been developed (see fig. 1). This way a better fixation also of cement-free endoprostheses can be achieved by selective supply of bio-resorbable filler through the inner channels to the implant-bone interface after implantation to bridge gaps due to fitting deficits or unexpected bad bone conditions.

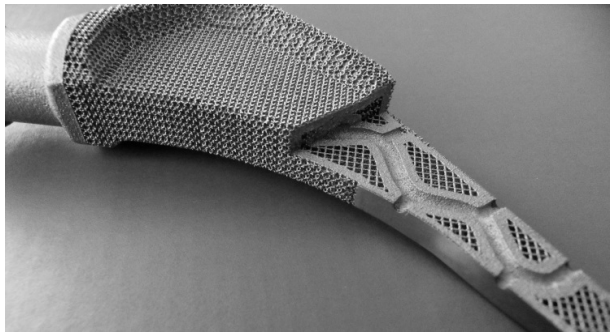

Fig. 1: Beam Melted hip stem with functional channels and cavities, internal cellular structure and macro-porous surface areas.

Furthermore this way implant loosening can be prevented or treated even years after implantation. Another added value is the possibility of post-operative medication by a steady drug release out of a cavity inside the implant (drug depot) via dedicated channels to the surrounding bone and soft tissue. Wound healing can be promoted as well as the implant's ingrowth, pain can be relieved and infections can be prevented. If necessary, inner channels can as well be used for post-operative drainage of blood and wound oozing. Another option is to design the channels in a way to use them for endoscopic examination of the contact area between implant and bone and surrounding tissue, adding another option for minimally invasive inspection to CT and MRI. Even revision operations can be supported through local application of a soluble for easier and quicker explantation with less damage to sound bone structure. Functional channels and cavities can be integrated in individual implants as well as in standardised ones for series production.

REFERENCES: [1] T. Laoui et al., 4th Int'l LANE Conference, Erlangen 2004. [2] A. Christensen, MoldMaking Technology 2007 (12). [3] M. Janssens, et al., Int'l COMA Conference, Stellenbosch 2007. [4] P. Cremascoli et al., 4th Int'l VRAP Conference, Leiria 2009.

Fabricating NiTi shape memory scaffolds by selective laser melting

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INTRODUCTION: Shape memory alloys (SMAs) like NiTi can change their form as a result of thermal or mechanical stimuli. Due to these properties, FDA-approved NiTi is successfully applied in the field of biomedical engineering [1]. The layer-wise additive manufacturing process of Selective Laser Melting (SLM) enables the build-up of complex three-dimensional geometries, see Fig.1. In this study we investigate the influence of SLM process parameters and following heat treatments on properties of SMA NiTi-structures.

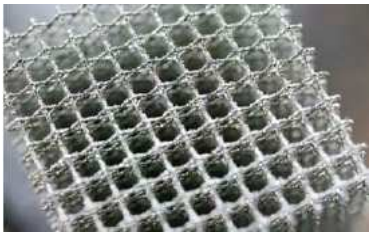

Fig. 1: Open porous NiTi lattice with 200 µm struts produced by SLM.

METHODS: SLM (Realizer 100, SLM Solutions, Lübeck) served for fabrication of complex-shaped NiTi specimens with shape memory properties [2]. Starting material was pre-alloyed NiTi-powder (MEMRY GmbH, Weil am Rhein, Germany). Subsequent to fabrica-tion, heat treatments were carried out at 500 °C and 800 °C, respectively. All processing steps were accomplished under Ar atmosphere. Optical microscopy served for metallographic investigation. After each processing step, the oxygen content was determined by means of inert gas fusion method (Galileo G8, Bruker, Karlsruhe, Germany). Furthermore, X-ray diffraction and differential scanning calorimetry investigations were conducted to examine the present crystallographic phases as well as the related phase transition temperatures.

RESULTS & DISCUSSION: The SLM fabricated NiTi-samples show a highly textured microstructure (see Fig. 2). The crystallites are elongated, whereas their orientation refers to the direction of heat transfer, which is equal to the building direction. In addition, the samples reveal the processing route, as the laser trajectories can clearly be identified as dark welding traces (see Fig. 2). Their perpendicular orientation refers to the scanning strategy of the laser, which hatches the slices alternating in x- and y-direction.

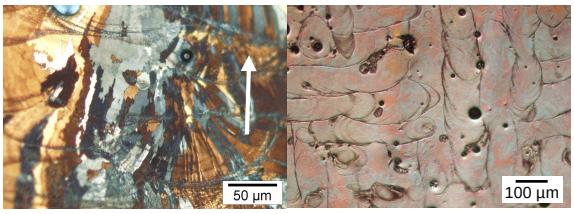

Fig. 2: Optical micrographs of a solid SLM NiTi-part. Left: Microstructure with elongated grains, arrow indicates building direction. Right: Traces of the laser in x-y-plane.

The SLM process leads to an increase of the oxygen content of about 0.025%, as shown in Table 1. Heat treatments at 500 °C don't lead to a further significant change of the oxygen content whereas heat treatments at 800 °C result in a slight increase of the oxygen content.

Table 1. Oxygen content of NiTi specimens after fabrication by SLM and heat treatments at 500 °C and 800 °C, respectively.

	Powder	SLM	500 °C	800 °C
O [%]	0.075	0.102	0.101	0.118
SD_O	0.004	0.019	0.005	0.003

CONCLUSIONS: SLM is a useful tool to fabricate complex-shaped NiTi micro-structures with shape-memory properties. The process can be qualified monitoring chemico-physical properties after the individual process steps. The fabrication process will be further optimized to create medical implants. Furthermore, the adaptation of our porous SMA-microstructures opens perspectives concerning the bio-functionality for the benefit of patients.

REFERENCES: [1] M.Es-Souni et al., Anal Bio-anal Chem, Vol. 381 (2005) 557-567. [2] T.Bormann et al., Proc. of SPIE, Vol. 7804 (2010) 78041.

ACKNOWLEDGEMENTS: We gratefully acknowledge the financial support of the Swiss National Science Foundation within the program NRP 62 ‘Smart Materials‘.

Biological Effects of Wear Particles

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INTRODUCTION: Particulate wear debris plays an important role in hip joint implant failure due to osteolysis and aseptic loosening [1]. Ultra-high molecular weight polyethylene (UHMWPE), metal and ceramic particles exhibit different properties and exert different biological effects.

PROPERTIES OF WEAR PARTICLES: Wear particles derived from implanted devices have been studied extensively using patient tissue materials obtained post mortem or at revision surgery, as well as using joint simulators. A provisional consensus has been reached in this difficult field. Particles that are generated from UHMWPE hip joint replacements exhibit diameters between 0.1 and 10 μm with a maximum around 0.5 μm. The presence of very large numbers of UHMWPE particles correlates with osteolysis and implant failure. Particle numbers in excess of 10^9 to 10^{10} per gram of tissue are observed. Particles derived from metal-on-metal implants are approximately ten times smaller (0.01 to 0.1 μm diameter) but also more numerous [2].

ACTIVATION OF MACROPHAGES AND OSTEOLYSIS: Most biological effects of particles are initiated by the activation of macrophages [3]. Phagocytosis of particles by macrophages induces expression and release of different cytokines, chemokines and proteases that lead to the formation of an inflammatory exudate and the activation of osteoclasts and osteoblasts. Particles in the size range of 0.1 to 10 μm are most active in this respect. In the presence of large numbers of particles, the delicate balance of bone metabolism may be disturbed and a localized net loss of bone mass, osteolysis, occurs.

ALLERGIC REACTIONS: UHMWPE and ceramic particles are chemically inert, whereas metals are prone to corrosion and formation of metal ions [2, 4]. Metal particles are thought to increase the risk of eliciting a T-cell dependent type IV hypersensitivity in some individuals. Alternatively, a pre-existing metal allergy may exacerbate. Granulomas and "pseudotumors" may form as a consequence of lymphocyte influx, antigenic stimulation and proliferation. To date no generally accepted diagnostic tests for the detection of metal allergies to implants are available. One reason may be that the responsible allergens are ill defined and may show large patient specific variability.

IN VITRO TESTS FOR MACROPHAGE ACTIVATION: Biological test systems currently used for implantable devices, such as cytotoxicity testing according to ISO 10993-5, do not detect macrophage activation. The most recent edition of the European Pharmacopoeia contains a new chapter on Macrophage Activation Tests (MAT, chapter 2.6.30) that may be useful. New developments include the use of genetically modified reporter gene cell lines that respond to macrophage activators.

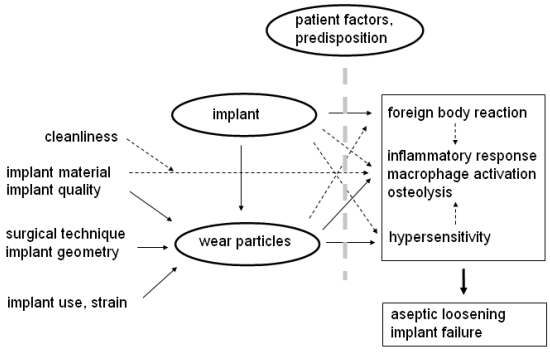

Fig. 1: Contribution of various interconnected parameters to implant failure due to inflammatory response.

CONCLUSIONS: In the absence of a complete understanding of the complex and variable cellular interactions that lead to osteolysis and implant failure, efforts must concentrate on a controlled high quality of devices to avoid preventable implant failures.

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[4] Hallab, N. et al., J. Bone Joint Surg. (Am) (2001), 83-A: 428 – 436.

Acetabular polyethylene wear volume after hip replacement. Accuracy of radiographic volume calculation studied from retrieved cups

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ABSTRACT: Wear of polyethylene is one reason for inflammation, osteolysis and loosening after hip replacement, making in vivo wear assessment of volumetric wear on larger series of radiographs necessary. The aim of this study is to provide knowledge on the accuracy of linear wear assessment and volume calculation from clinical anterior-posterior (a.p.) radiographs of the pelvis.

21 polyethylene acetabular components retrieved at revision were analysed. Linear penetration depth and direction were measured on clinical a.p. pelvis radiographs. Direct measurements on the cups were made with a 3 dimensional (3D) surface detection method and with fluid displacement (FDM). Wear volume was calculated using various previously published formulae.

Mean radiographic linear wear was 1.48-1.54 mm, depending on the method of measurement. Mean wear volume with FDM was 1090 mm^3, and mean calculated volume 1013-1175 mm^3, depending on method of measurement and calculation. All measurements and calculations correlated well with the 3D and the FDM. Not taking the direction of wear into account led to an overestimation of the worn volume. Errors of measurement are more important than probable wear in the sagittal plane. Radiographic measurements in the film-plane can provide a reliable estimation of the worn volume.

Testing the Cleanliness of Implant Surfaces after Fabrication

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INTRODUCTION: The final cleaning after fabrication of medical devices is becoming more and more important. Based on the background of the 4th amendment of the Medical Device Directive, the validation of cleaning processes has become more significant, so that the notified bodies increasingly demand proof of the chemical cleanliness and absence of particles on product surfaces. Against this background the NMI has carried out an industrial joint research project in cooperation with 22 implant manufacturers from Germany and Switzerland with the objective of a qualitative entire as well as quantitative and therefore objective validation of chemical cleanliness of implant surfaces.

METHODS: Characteristic implant surfaces made from material grades like titanium, stainless steel and CoCrMo were contaminated with auxiliaries used in the fabrication and were subjected to a standardized cleaning process. Afterwards the cleaned surfaces were characterised with interface- and microstructural analysing technologies. The examinations were focused on X-ray photoelectron spectroscopy (XPS) and scanning electron microscopy (SEM).

RESULTS: The examinations offered the chemical composition and surface structures of accepted clean surfaces according to the current state of the practice in fabrication of medical products on multiple of common implant materials in medical technologies and especially in implantology.

The analyses yield the concentration of every chemical element (except hydrogen and helium) and the chemical compounds of residues on the surface, but also potential changes in chemical composition. Furthermore the structure of the surface of the material grades itself was examined.

DISCUSSION & CONCLUSIONS: According to the used analysis methods, it has been concluded that residues of the fabrication could be identified and also quantified concerning their entire complexity.
In contrast to other methods like OPA, TOC, GC, IR etc. all chemical elements and compositions can be detected. In addition the examinations are carried out directly on the surface. XPS analysis in contrast avoids typical uncertainties of elution methods such as the possible incomplete ablation and, therefore, incomplete analysis of the contaminations.

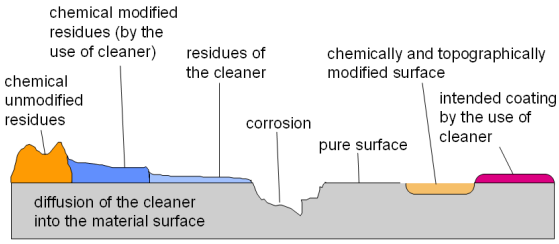

Fig. 1: Chemical composition of a cleaned material surface.

The compiled results are building the basis for the generation of our XPS standard surfaces. These are used for an objective benchmarking for the cleanliness of implant surfaces and also other medical products. Hence XPS standard surfaces by now are suitable within the framework of the approval of medical devices and quality assurance in fabrication processes.

Moreover the use of our analysis methods provides information about the material surface itself, particularly with regard to their functionality. In comparison to the documented structures of new products a benchmarking of the functionality of corresponding reprocessed products with idem product numbers can be conducted.

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Surgical Instrument Reprocessing – Top Cleaning Results and Best Possible Material Compatibility with a 2-Component Cleaning System

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INTRODUCTION: For implant surgery, instruments and tools are being used, some of them with very complex geometries and built with materials susceptible to attack by alkaline process chemicals e.g. disinfectants and detergents. Nevertheless, these precious medical devices have to be reprocessed in a way which allows them to be used on the next patient without putting him in danger.

A few years ago, we have developed our first, neutral-enzymatic 2-component cleaning system which was shown to have an outstanding cleaning efficacy[1]. A second, mild-alkaline system has now been scrutinized within a special project.

METHODS: In this cooperative project organized and executed by SMP GmbH in Tübingen, Germany and financed by 39 medical device manufacturers, the cleaning of 62 different instruments of various complexities was investigated. These instruments were contaminated with coagulating sheep blood traced with Technetium 99m-labelled macro-albumin. Cleaning efficacy was determined by quantification of residual radioactivity after cleaning. Experiments were carried out in three different washer-disinfectors with 5 different detergent systems applied in 6 different cleaning processes.

RESULTS: The cleaning trials in two standard washer-disinfectors were run with a) a strong-alkaline detergent, b) a "traditional" neutral-enzymatic detergent, c) a mild-alkaline enzymatic 2-component cleaning system and d) a strong-alkaline / oxidative cleaning system (Oxivario process).

Results showed that processes with c) and d) were clearly superior to processes a) and b). The performance of c) and d) were very similar.

Table 1. Comparison of performance data for different cleaning processes

**) The amount of pre-cleaning required for good overall cleaning results was calculated by giving all possible steps a weighting factor and summing over all weighting factors. The weighting factors were defined as follows: brushing:1, water-jet-pistol:1, ultrasonic bath:2, all pre-cleaning treatments plus immersion in cold water:4.*

Process	a)	b)	c)	d)
Total no. of evaluations	52	53	58	52
No. of evaluations with > 5 counts/s	4	7	4	2
Average counts/s in case of values < 5 (good results)	0.9	1.5	0.5	0.8
Average amount of pre-cleaning per exp. with good result*	1.0	1.2	0.7	0.8

DISCUSSION & CONCLUSIONS: Why 2-component cleaning systems? A high performance of the detergent system in a washer-disinfector process is of particular importance since unlike in a dishwasher process, the effective cleaning time is only very short. 2-component cleaning systems allow the combination of ingredients in the use solution in a way which is not possible in a storage-stabile solo detergent. Formulation compromises which have to be accepted in case of a solo product are not necessary with a 2-component cleaning system.

The results of the discussed cooperative project clearly show the equality in cleaning performance of the mild-alkaline enzymatic 2-component system and the rather aggressive strong-alkaline / oxidative system which actually requires a total of 3 products at higher costs. While the latter system is not compatible with anodized aluminium and titanium, the enzymatic 2-component system is so. This is a very important characteristic, if one thinks of e.g. orthopaedic motor systems.

REFERENCES: [1] U. Rosenberg (2005) *Zentr Steril* **13**: 244-270.

ACKNOWLEDGEMENTS: Thanks are given to Dr. Ludger Schnieder and Mr. Klaus Roth, the organizers of the cooperative project at SMP GmbH, Tübingen.

Cleanliness: How Clean is Clean Enough – Guidance for Industry

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INTRODUCTION: It has been 10 years since the medical device industry witnessed a substantial recall action due to insufficiently cleaned orthopaedic implants. Medical device industries and regulation agencies realized that neither the best biomaterial nor the most inventive device design solutions are guarantees for success unless the chain of processing, including device cleaning, is well understood and tightly controlled. Medical devices are exposed to a plethora of different process aids during manufacturing, and if the cleaning processes are not carefully matched to these processing aids, process residues may remain on the implant surfaces. Analysis of cleanliness is as important as the cleaning process. There are many different analytical techniques available with sensitivities down to the ato-mol (10^{-18}) detection limit, yet there has been little guidance for industry so far on what to measure and how to establish acceptance limits.

REPORTING OF RESIDUES: The American Society for Testing and Materials International (ASTM international), has recently issued recently a new standard F2847-10 "Standard Practice for Reporting and Assessment of Residues on Single Use Implants"[1]. The standard practice instructs how the cleanliness of single use implants as manufactured has to be reported. The requirements include the classification and reporting as according to Table 1.

Table 1. Format for Reporting Residues.

Categories	Results of Analysis	Set Limit Values	Detection limit	Applied Analytical Methods
Inorganic **Organic** **Biological**	[mass/implant] [mass/surface area]			
Bioburden	[CFU/implant]			
Endotoxin	[EU/implant]			
Particulate	[mass/implant] [mass/surface area] [Number/implant] or [cm^2/cm^2], [Atomic-%] or [Molecular-%]			
Visual Inspection	[Optical observations]			

Furthermore, a series of analytical methods are proposed that can be used for identification of critical compounds.

CONSIDERATIONS FOR SETTING LIMIT VALUES: Limit values for residues on medical devices are defined as the maximum allowable amount(s) of substance(s) at the surface of an implant not yet found to be harmful for the surrounding tissues and organs. The establishing of limit values for different classes of residues is mandatory and also a prerequisite for proper validation of cleaning processes. It may be, however, difficult to establish limit values as a value has to be set for the unknown unknown. Therefore, a risk-based approach is appropriate for considering where and how residues can be introduced. Often, it may be most straight forward use historical, clinical analytical data and experience with the particular devices or analogous devices. Alternatively, toxicological assessments have to be done based on acute local tissue reactions, or on data as specified in standards and guidance documents. Guides such as ISO standard 10993-17 may be consulted[2]. The calculation of limit values based on classical toxicological calculations are, however, whole organism approaches that are not applicable for medical devices as their performance depend on local the material-tissue interface, and such effects are not considered in these calculations. *In vitro* testing with relevant cells and the assessment of their phenotype, inflammation and apoptosis markers would yield the most reliable results, as are historical results from clinical studies of implants with similar residue levels.

DISCUSSION: The expert group of ASTM on cleanliness has recently addressed these problems in a workshop[3] and prepares currently new documents that should help industry to set limit values with a reasonable effort[4].

REFERENCES: [1] ASTM F2847-10, [2] ISO 10993-17, [3] ASTM cleanliness workshop, [4] ASTM WK32535

ACKNOWLEDGEMENTS: To all ASTM F04.15.17 committee members who actively participate in standardization efforts.

Cleaning Validation: Precondition, Implementation, Monitoring

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INTRODUCTION: Cleaning of medical devices is a widely discussed topic in the device manufacturing industry. Reliable cleaning processes that remove contact materials, chemicals and debris are of high importance to both internal and external customers and regulators. Qualification of cleaning facilities and validation of cleaning processes is one of the most demanding tasks for medical device manufacturers. The key to generating reliable and complete documentation is to apply a highly structured and risk based approach.

PRECONDITIONS: Cleaning processes must be clearly defined with reproducible cleaning procedures. In addition, facilities must be identified, water qualities and cleaning detergents defined. Also, maintenance plans must be in place to address planned and unexpected events.

Other keys to success include: defining cleanliness requirements for the products, determining if pre-cleaning is required, and is a clean room required for cleaning. Obviously establishing different qualitative and quantitative values is important to define, but setting limit values is not part of this paper.

Many companies do not have the internal skill sets to adequately address this validation task. Ensuring you have the proper laboratories and individuals with (bio)chemical expertise avoids unplanned changes in the middle of a project. Repeating validation runs and testing is very costly.

Before validation runs start, it is highly recommended to run planned and controlled test batches in tight collaboration with experts and laboratory personnel. The evaluation of these basic "footprint" measurements is needed for planning the qualitative and quantitative validation steps. Quality test batches/pretests will ensure cost effect validation runs.

QUALIFICATION OF THE FACILITIES: According to an established and released validation plan, qualification of water treatment[3], tubing, cleaning baths and environment if applicable must be completed.

Facilities and equipment must be assessed by IQ (installation qualification) and OQ (operational qualification) where the IQ confirms appropriate installation, calibration and documentation and the OQ verifies correct operation over the required functionality. For facilities that are newly built, specifications must be developed and DQ (design qualification) must be carried out[1].

In parallel worst case products and conditions should be determined. Profound knowledge of the cleaning process and a risk based approach that addresses (cross) contamination and cleanablitiy of the products is necessary[2]. Material properties, surface structure, geometries, processes and process aids have to be taken into account. The worst cases have to be written down and integrated in the validation plan.

Prior to release, validation plans shall be reviewed for applicable acceptance criteria and reasonable statistical rationale for the sampling.

Validations will be performed according to the validation plan. Nonconformities must be addressed via the validation or the company's CAPA program.

MONITORING: Once validation has been completed, reasonable monitoring activities must to be established. Monitoring accomplishes two goals:

- Preservation of the validated status
- Observation of key values to detect adverse trends

REFERENCES:

[1] GHTF/SG3/N99-10:2004 *Quality Management Systems - Process Validation Guidance*

[2] FDA Guidance for Industry, *Process Validation: General Principles and Practices, January 2011*

[3] Guide to Inspections of high purity Water Systems, 7/93.

Cleaning Validation: Chemical Testing and Cleanliness Assessment of Medical Devices

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INTRODUCTION: Cleanliness testing and validation has been a regulatory requirement for years. But there are still many questions how to test and assess the cleanliness.
The ASTM F2847-10[1] suggests over 20 test methods and describes the reporting of residues. But there is no standard or regulation which exactly specifies the required testing or gives limit values for cleanliness.
While the ISO 10993-1 concludes the requirements for biocompatibility testing, it cannot be applied for cleanliness testing. Therefore the evaluation of appropriate test methods is an important part of the cleaning validation.

EVALUATION OF TEST METHODS: For the evaluation of the appropriate test methods the potential contaminants have to be known. This information should be available from the risk assessment or from the list of used processing aids. The potential residues can then be classified as organics, inorganics, particulates or biologics[1]. Based on this information the analytical techniques are evaluated according to Table 1. The used methods must fulfill the following criteria:

- Potential residues must be detectable
- Quantification limits below limit values
- Result represents the total implant surface
- ISO 17025 accredited or GLP
- Economical (cost and trough put time)

Table 1. Analytical techniques for organics (1), inorganics (2), particulates (3), biological (4)[1]

AAS: 2	GC-MS: 1	Peptides: 4
Auger: 2,3	GC-TOF: 1	RAMAN: 1,2,4
Bioburden: 4	Gravimetry:1-3	SEM: 3
EDS: 2,3	HPLC: 1,4	TOC: 1
EDXA: 2,3	ICP-MS: 2	TOF-SIMS:1-3
Endotoxin: 4	ICP-OES: 2	UV/Vis: 1,2,4
FTIR: 1,2,4	Optical 1-3	XPS: 1-3

The analyses can be performed directly on the implant surface or indirectly after an extraction. Each procedure has its advantages but none of them covers all cleanliness requirements.

Direct methods may be applied for almost all classes of residues. With in situ techniques like SEM/EDX, XPS and TOF-SIMS only small spots can be analyzed and no information of the whole implant surface is obtained. XPS is most powerful to identify and quantify localized residues at lowest levels.
Indirect methods allow extraction and quantification of residues from the whole implant surface including blind wholes and pores. To get an appropriate extraction efficiency polar (aqueous) and non polar (organic solvent) extractions are required using ultrasound. Based on our long term experience the method combination in Table 2 allows to quantify a broad range of potential contaminants:

Table 2. Indirect methods (extraction) covering a broad range of residues

Potential residues	Extraction media/method	Standards
Water soluble organics	Water/ TOC	USP<643> EP 2.2.44
Water soluble ions	Water/ Conductivity	USP<645> EP 2.2.38
Non polar organics	Org. solvent/ FTIR	ASTM F2459[2] JAI 13391[3]
Particles by mass or by number	Water, solvent/ Gravimetric or Counting	ASTM F2459[2] USP<788>

CLEANLINESS ASSESSMENT: It is the manufacturer's responsibility to prove the cleanliness of the medical devices. Hence company internal alarm and limit values have to be established e.g. on a risk based approach[1].

CONCLUSIONS: Still no regulation defines limit values or specifies the required chemical test methods. Therefore acceptance criteria and the evaluation of appropriate test methods for cleanliness validation must still be specified by the manufacturer's specialists or an expert advisor.

REFERENCES: [1] ASTM F2847-10, [2] ASTM F2459 - 05, [3] D. Zurbrügg, J. ASTM, ID 13391 Feb 2006, Vol. 3, No. 2.

Biological Safety Testing in the Field of Microbiology

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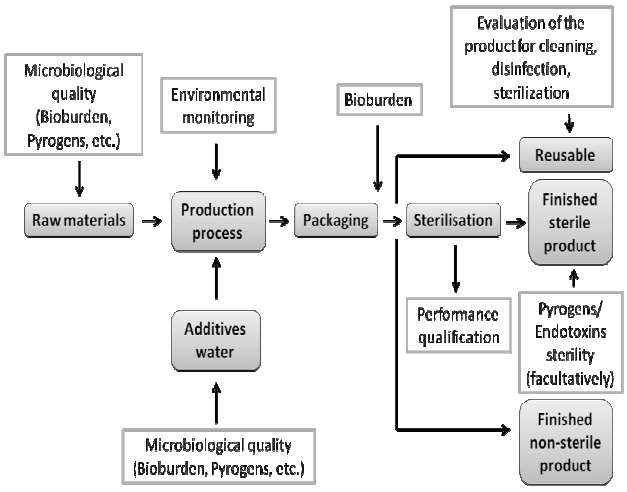
INTRODUCTION: Biological safety testing is an essential part within the development of any medical device. Depending on the materials and their history of use, different panels of biocompatibility studies according to the ISO 10993 series are mandatory. Besides basic standard endpoints, such as irritation and sensitisation, further proofs of biocompatibility can be requested. The demand for biological safety can be broad and also include functional implantation studies.

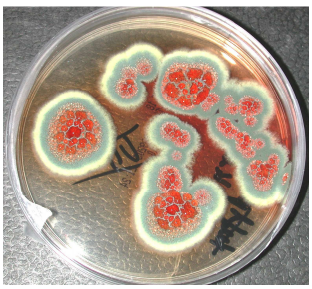
Complete safety testing also involves microbiological endpoints to cover the whole process from the manufacturing to the final product. A panel of different testing systems for all production steps leads to products which are under the critical value of safety parameters.

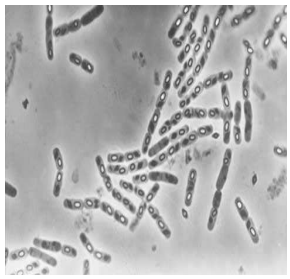
COMPENDIUM: Regarding the microbiological safety, it is mandatory to control the hygienic status of manufacturing, to validate the steps of the production process and to control the final product. Therefore microbiological testing should include the routine testing of raw materials, accompanying environmental monitoring, verification of water quality and the microbial load (Bioburden) of the product prior to sterilisation.



Bioburden tests are performed on standard media, which allows the finding of a broad spectrum of different types of microorganism. An aberration of the normal microbial load can be based on a change or irregularity of the production process. This may be caused by the production process itself, the used raw material or hygienic standard in the facility and consequently lead to unsatisfying sterilisation results

Depending on the chosen sterilisation process manufactures also have to assure the sterility of the products by regular sterility testings or the regular revalidation of the whole sterilisation process. According to the legal guidelines of the EP, USP and certain ISO standards a proof of sterility of the product has to be performed by the methods of membrane filtration or direct inoculation. Depending on the guideline the product has to be tested on one or more culture media. After an incubation period of 14 days the sterility can be verified.





For the verification of microbiological safety a further very essential aspect for implants is non-pyrogenicity. A preferred and acknowledged testing system is the LAL (Limulus Amoebocte Lysate) test for endotoxins. Endotoxins are the main pyrogenic agents, which derive from viable or dead Gram-negative bacteria and are not eliminated by standard sterilisation processes. LAL testing is to be seen as an alternative to the traditional Pyrogenicity test *in vivo*.

As coating of implants with antimicrobial agents becomes more and more important, the efficacy of this finishing should be proven. For those products a panel of tests systems are available to examine and attest the antimicrobial effect.

SUMMARY: Biocompatibility and microbiological safety is mandatory for the release of high quality medical devices. The main microbiological aspects encompass the estimation of bioburden, sterility and non-pyrogenicity. Antimicrobial efficacy testing further proves the high quality and safety of implants and other medical devices.

Combined electrophysical technologies (CET) for the processing of implants

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INTRODUCTION: The processing of implants made of common metals like steel and titanium and their alloy remains a sequencing of classical processing such as milling, drilling, turning, thread whirling, deburring, polishing, passivation and anodization.
The surface should be engineered and modified to enhance cell growth onto dental implants or to inhibit the cell growing onto screws with application in traumatology.
The combination of physico-chemical processing such as electro-chemical, plasma-chemical and photo-chemical processing with classical or non-classical shaping leads to unsurpassed productivity and surface quality.

METHODS: An electro-chemical process within a bipolar field was used to shape parts with an electrode as a master. Controlled by the variations of certain physical parameters an electrolytical plasma ignition and its selective deletion were used to further polish and to anodize parts made of titanium.
A resonant high voltage (up to 400 volt) bipolar power generator with peak current up to 125 ampere with either direct-current or impulses as short as 3 microseconds has been developed to be integrated in a fully automated process.
Using the root tool kit from CERN we built up a system to analyze the response and the transfer function for the electro-physical system.

RESULTS: It was found that the basic approach with an electrode as master is usable for 3D shaping of titanium and also for steel with a clearance angel of about 3°, with an aspect ratio of about 1:20 and a progressive feed with one millimetre in 80 seconds.
The polishing time of about 120 seconds without an electrode was reduced to 7 seconds with an electrode. The rework to polish parts done by a classical shaping like thread whirling by cutting tools is possible but took a similar processing time as done without electrode. It was possible to prove that massive parallel processing is possible by higher current and identical voltage both for shaping and polishing to further reduce the overall processing time.

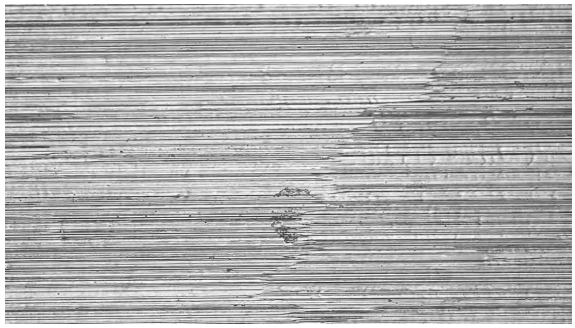

Fig. 1: Surface finish and roughness in the groove of threads of a TiAl6Nb7 screw processed by thread whirling, Ra = 0.2 µm. Mag. 700 x

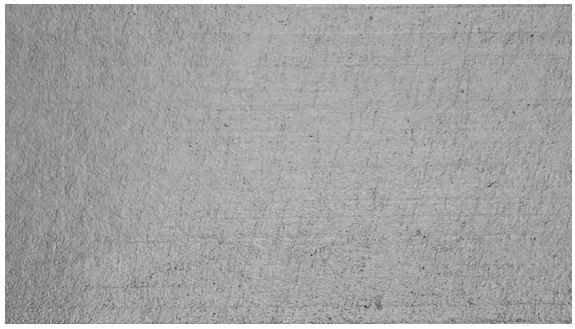

Fig. 2: Surface finish of the same TiAl6Nb7 screw as in Fig. 1 after rework by CET processing, Ra = 0.07 µm. Mag. 700 x

DISCUSSION & CONCLUSIONS:
This combined setup to cover the processing of the form and the surface in one single process in one machine simplifies the production of implants, improves the precision and the quality and at the same time cuts costs massively.

REFERENCES: [1] Internal studies and documents without former publication.
[2] Report A09_1156_1 by RMS Foundation.

ACKNOWLEDGEMENTS:
These developments where done by their joint efforts of Ruffner Engineering and the ingenious advice of W. Adamitzki.

Cemented Fixation of Ceramic Implants – Possibilities for an Optimized Bone Cement Adhesion

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INTRODUCTION: According to their very good wear characteristics today more and more ceramic components are used in endoprosthetics. For the direct cemented fixation of ceramic prostheses at the bone it is necessary to be aware of the adhesion of the compound ceramic / bone cement, because implant loosening is one of the main reasons for the failure of endoprosthetics. In the present study the influences of different roughness, adhesives, mixing techniques and bone cements on adhesive tensile strength between ceramic and bone cement as well as their resistance in physiological environment are investigated. The combination blasted CoCr/bone cement served as a reference.

METHODS: Samples of Al_2O_3-ceramic (Bionit®), ATZ-ceramic (ceramys®) and CoCrMo as well as the bone cements Palacos® and Palamed® were used for testing the adhesive tensile strength.

All tests were carried out according to the ISO EN 582. Five samples for each series are used in order to obtain representative values.

The diameter of the circular surface to be tested was 25 mm.

The sample for adhesive tensile strength testing was clamped in a torque-free manner and the force was measured when the compound fails.

The adhesive tensile strength was calculated by the quotient from this force and the surface area.

By blasting at various conditions and on samples in presintered or ground state different roughness grades were created. The blasting of the samples took place vertically on the surface with alumina particles (grain size of 355-500 µm) with a pressure of 4 bars during 10 seconds.

With help of silication and silanization a chemical bond between bone cement and ceramic was made.Some series of the *as fired* test specimens were silicated first (firing of the SiO_2 solution with 1000 °C) and than silanized with Silicer® (Heraeus Kulzer). The one component system Silicer® is a frequently used adhesion promotor for the oral restoring of ceramic restaurations. The silanization with Silicer® was done on the silicated samples by means of a thin brushing. After drying the bone cement was applied immediately.

RESULTS: Due to blasting in the presintered status the roughness was very high as a result of the low green body strength. However, the sharp edges were being round off again while sintering. Therefore higher adhesion strength was reached with the ground blasted surface in spite of lower roughness. Here additional undercuts were created due to the blasting which supports fixation of the bone cement.

As a result of mechanical treatment of ceramic surfaces in either case the adhesive tensile strength is enhanced by blasting. The greatest increase is achieved at the blasted ground state.

With help of silanization and silication the adhesive tensile strength was essential enhanced in all tested systems and exceeded the adhesive tensile strength of the compound blasted CoCrMo / bone cement at least 15 %. Also the exposure in bovine serum of the silicated/silanizated samples did not influence the adhesive tensile strength [1-3].

DISCUSSION & CONCLUSIONS:

With both ceramics similar results were reached. With help of silication and a following silanization a very good bond between ceramic and bone cement was established. This coincides with the results from Vetter and Lohbauer. Both reached the best results by means of silication and silanization [1, 4].

Furthermore, it was possible to further increase the adhesive tensile strength by the combination of mechanical and chemical surface modification. However, it still has to be investigated if the blasting of the ceramic causes damages.

In consideration of all results a lasting fixation of ceramic prostheses by means of bone cement could be possible.

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Evaluations of Effects of Gamma Sterilization on Biomedical Polyurethanes for Implant Use

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INTRODUCTION: Biomedical polymers are important classes of material that have found increasing use with implantable and single use medical devices over the past 10 years. This paper will focus upon one important class of medical polymers - thermo-plastic Poly-carbonate Urethane (PCU) - and studies under-taken to evaluate and characterize the effects of gamma irradiation.
Gamma irradiation is an effective terminal sterilization method for implantable medical polymers. However, as was observed with UHMWPE (ultra high molecular weight polyethylene) employed in joint replacements, gamma irradiation can have an array of effects upon polymer networks.

METHODS: Standard specimens of Bionate 55D resins (PCU commercialized by DSM PTG) were irradiated under different gamma doses, both under air and nitrogen.
The free radical generation was examined using continuous-wave electron paramagnetic resonance (cw-EPR) spectroscopy. The cw-EPR spectra were analysed to provide information on three aspects of the free radicals present: (a) the amounts of radical produced; (b) their stability over time and (c) the hyperfine structure of the EPR spectra were used to suggest possible loci of the different radicals produced.

RESULTS: The cw-EPR spectrum provides a useful spectroscopic technique to quantify the concentration of radical species present in polymers following gamma sterilisation (see Fig. 1) including the course of radical decay with time (Fig. 2). In addition the fine structure of the radical species with modelling techniques provides insights into structural features of these short-lived radicals.

DISCUSSION & CONCLUSIONS: Gamma sterilization at standard doses does interact with the polymer network to form short lived but stabilized free radicals that are subsequently quenched by interaction with oxygen (a di-radical). Oxygen if present in packaging is able

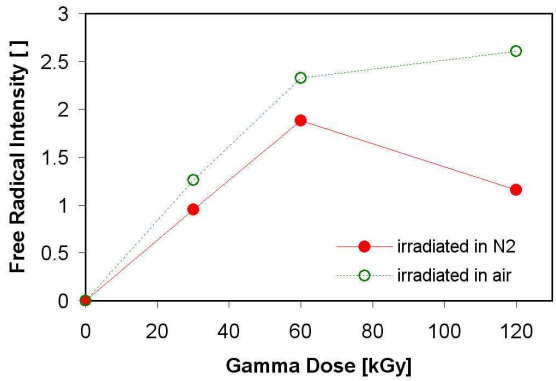

Fig. 1: Effect of gamma dose on free radical concentration, measured after irradiation in nitrogen or air, material: Bionate 55D UR.

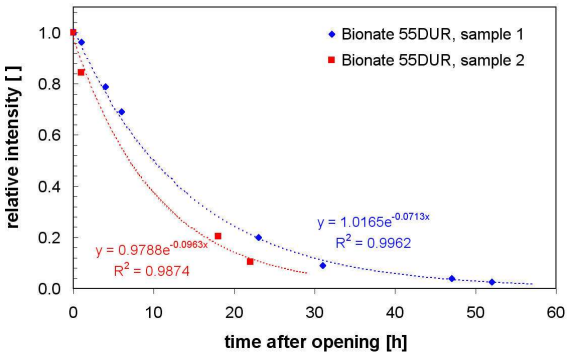

Fig. 2: Typical time-course of radical decay after irradiation in air, material: Bionate 55D UR.

to diffuse through the polymer network and interact with the polymer leading to property changes. Radicals also are able to interact with polymer chains resulting in a small level of crosslinking as is evidenced by the changes in the mechanical properties [1]. Therefore to maintain the excellent properties of these new biomedical polymers one needs to consider the effects of gamma sterilization and also if there is a need to protect the polymer in inert packaging systems

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ACKNOWLEDGEMENTS: This study has been supported by Synthes GmbH, Oberdorf BL, Switzerland.

Evaluation of biomaterials using an *in vitro* test battery

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INTRODUCTION: The proof of cytocompatibility (absence of cytotoxicity and presence of bioactivity) is a crucial step in developing new implant (and scaffold) materials and their surfaces. Currently, cytocompatibility is evaluated using ISO 10993-5 standards to prove that no toxic compound is released. Bioactivity is shown by seeding single cells of one cell type onto sample surfaces measuring at least cell adhesion, spreading and proliferation. The *in vivo* niche around the implant is however composed of multiple cell types which are subjected to complex interactions with each other in competing for the implant surface space. Furthermore, three-dimensional (3-D) tissues are contacting the implant. It is assumed that the clinical success and fate of the implant is ultimately determined by these interactions. So far this aspect is only taken into account by evaluating implant materials using animal studies. *In vivo* models remain extremely challenging due to the complexity of the system and the inability to individually elucidate the numerous mechanisms behind specific host responses particularly at the cellular level. Systematic approaches with a high number of material variation and multiple time-point evaluation are practically limited due to the cost, time and effort needed to conduct animal studies.

The aim of the present study was to define an intermediate step between the current *in vitro* and *in vivo* tests having the advantages of the *in vitro* environment while mimicking at least some aspects of the *in vivo* environment.

PROPOSED TEST BATTERY

The proposed test battery is shown in Fig. 1. Generally, going down in the test sequence each test of the test battery has an increasing degree of specificity and complexity. The first two tests evaluate the potential release of toxic components based on ISO 10993-5: extract test and ISO 10993-5: contact test. The subsequent 4 tests assess the bioactivity of the material by seeding cells directly on top of it. Evaluated is i) cell adhesion and spreading, ii) cell outgrowth out of a tissue-like cell reaggregate, iii) effects on cell proliferation and differentiation and iv) cell-cell competition/ interaction evaluating of each cell type of the coculture cell proliferation and differentiation. The latter and final test has the potential to predict which cell type finally covers the implant surface. After each test promising materials are selected and tested in the next level. Materials that perform adequate in all test levels are thought to be optimal and ready for subsequent *in vivo* testing. We recently started to assess the strength of this test battery especially of 3-D reaggregate and cell-cell coculture tests [1-2].

The proposed test battery has the potential to reduce time to market and cost per new developed implant that positively passes the human trials.

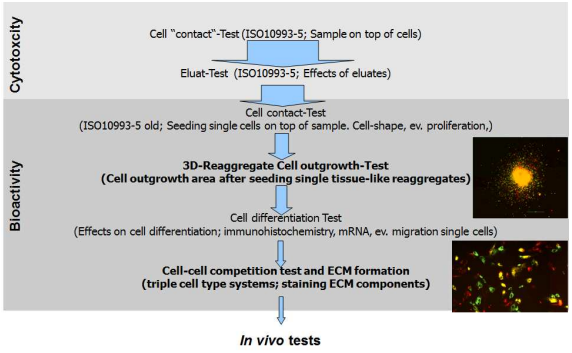

Fig. 1: The tests battery represents a sequence of in vitro tests with increasing complexity and costs. Each test focuses on a different aspect of the cell-material interactions. The arrow width illustrates the number of test materials entering the next test.

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ACKNOWLEDGEMENTS:

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3D Surface Modelling using a SEM

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INTRODUCTION: The surface structure and roughness of implants is of importance for biocompatibility, process and quality control. Numerous methods are available to measure 3D surfaces, however, with limitations in resolution, shape, or time, respectively.
A new method is presented to make a quantitative 3D surface model in a SEM (scanning electron microscope). A Ti dental implant surfaces is presented as example.

METHODS & MATERIALS: The 3D surface reconstruction in a SEM is an established method based on two images acquired under different tilt angles (also called stereoscopy). This pair of images allows a precise reconstruction with height information and can be further used for roughness determination. However, this method is time consuming due to the tilting needed.

The new 3D surface modelling (3DSM) is based on shading: 4 images are acquired from a multi-segment detector enabling to reconstruct a 3 dimensional surface (figure 1). Due to the obsolete tilting and the direct link between 3DSM and electron microscope, the model is obtained within less than 15 seconds.

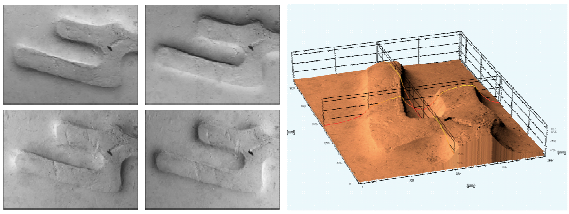

Fig. 1: a) images of the 4 BSE detector segments, b) reconstructed surface

This method is exemplified by roughness measurements of sandblasted and/or etched Ti surfaces as used for dental implants. The roughness of the etched structure superposing the sandblasted macro structure cannot be easily measured by conventional metrology tools. Thus, the aim of this study was to compare roughness values of the 3DSM with established methods.

RESULTS: Figure 2 shows the SE image of a sandblasted and etched surface. The different cavities based on the mechanical and chemical process are nicely visible.

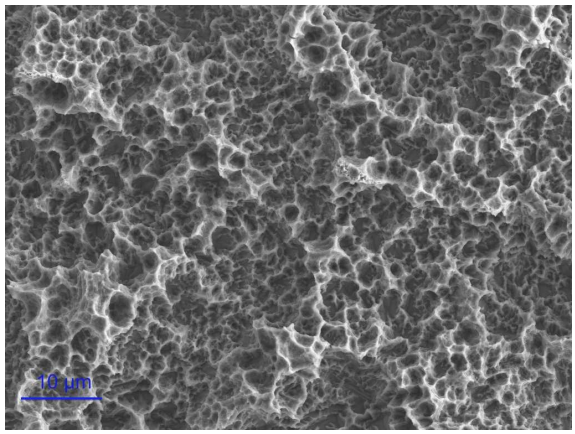

Fig. 2: Surface of sandblasted and etched Ti

The result of the 3D reconstruction is presented in figure 3.

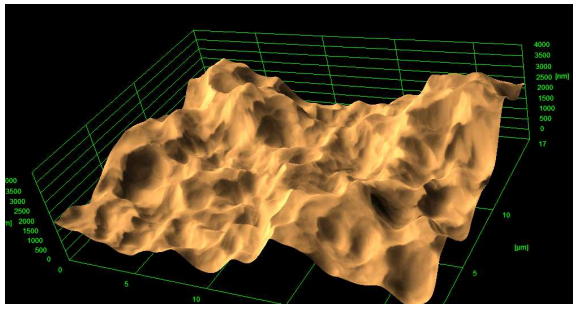

Fig. 3: 3D reconstruction

Roughness parameters can be determined or the 3D image can be exported to established metrology tools. The roughness can be measured even for very small structures in the submicron range due to the high resolution of the FE-SEM. These small features are typically not accessible with conventional roughness microscopes based on light or on tactile sensors. The roughness parameters determined with the SEM will be compared to values obtained with a confocal microscope.

DISCUSSION & CONCLUSIONS: The presented method combines the SEM ability of high resolution imaging with fast and accurate 3D reconstruction and metrology.

Poster Session

Antibacterial HA coatings for implant applications
Stefanie Lischer, Empa, St. Gallen, Switzerland

Atomic layer deposition of bioactive TiO2 coatings for titanium implants
Irina Grigal, Moscow Institute of Physics and Technology, Dolgoprudniy, Russia

Coated Titanium Implants - in-vitro microbiological efficacy testing results
Prof. Dr. Klaus-Dieter Kühn, Heraeus Medical GmbH, Wehrheim, Germany

Automatisiertes Schleifen und Polieren von Implantaten
Pierre Rottet, INSYS Industriesysteme AG, Münsingen, Schweiz

Klassifizierung von Defekten für polierte Stahloberflächen
Dipl.-Ing. Barbara Behrens, Fraunhofer Institut für Produktionstechnologie, Aachen, Deutschland

Effect of cavitation in ultrasound-assisted cleaning of medical devices
PD Dr. habil. Christiane Jung, KKS Ultraschall AG, Medical Surface Center, Steinen, Switzerland

High Precision Cleaning Processes
Pascal Senentz, NGL Cleaning Technology SA, Nyon, Switzerland

Fasteners and Fricition Coefficients
Dipl.-Wirtsch.-Ing. Martin Teichmann, mt engineering gmbh, Kaiseraugst, Switzerland

Untersuchung chemisch induzierter Fehler an Kunststoffmaterialien - Methodik und Fallbeispiele
Dr. Bert Schatowitz, Intertek Expert Services, Basel, Schweiz

Einfluss der Bearbeitung auf die Beständigkeit von nichtrostenden Stählen
Dr. Rudolf Morach, Intertek Expert Services, Basel, Schweiz

Metal ion levels in the blood of patients with metal-on-metal (MoM) joint articulations. Does storage of blood samples matter?
Dr. Martin Lindberg-Larsen, Køge Sygehus, Denmark

Implant manufacturers use Additive Manufacturing to reduce production costs and increase profits
Patrik Ohldin, Arcam AB, Mölndal, Sweden

3d nano-composite and ceramic architectures via robotic deposition of UV curable pastes
Dr. Yoram de Hazan, EMPA, Duebendorf, Switzerland

VESTAKEEP PEEK the unbreakable choice
Marc Knebel, Evonik Degussa GmbH, Marl, Germany

Trockene mechanische Zerspanung
Mark Maurer, PanGas AG, Dagmersellen, Schweiz

ANTIBACTERIAL HA COATINGS FOR IMPLANT APPLICATIONS

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INTRODUCTION: After an implant surgery there is always a competition between tissue integration and bacterial colonization. The incidence of infections for total hip and knee arthroplasties is currently in the range from 1% to 3% [1]. Therefore, implant materials should provide antibacterial properties and enhance tissue integration at the same time. The application of Hydroxyapatite (HA) which is known to promote osseointegration and the additional integration of silver into the HA coating creates an antibacterial implant due to the silver release.

METHODS: HA coatings containing silver were produced by vacuum plasma spraying (VPS). X-ray diffraction was used to determine the crystallinity and the composition of the coatings. The coatings were subjected to adhesion tests according to ISO 13779. The antibacterial activity of the coatings was analyzed by standard agar diffusion test as well as biofilm formation on the coating with two bacteria strains *S. aureus* (Gram-positive) and *P. aeruginosa* (Gram-negative). The cytotoxicity assay is based on the ISO 10993-5 *biological evaluation of medical devices* and quantified by MTT and DNA assay.

RESULTS: HA coatings with a range of crystallinity and different concentrations of silver could be produced by VPS technology. The coating characterisation showed that the material properties are in line with the regulations. Coatings with high concentrations of Ag exhibited antibacterial properties to *S. aureus* and *P. aeruginosa* whereas low concentrations of Ag showed no antibacterial effect. The results of the cytotoxicity showed that HA coatings with and without silver are biocompatible to primary human bone cells.

CONCLUSIONS: Silver releasing implants might reduce the incidence of bacterial infections in orthopaedic surgery especially infections caused by antibiotic-resistant strains. In this project silver containing HA coatings, that are antibacterial and cytocompatible, could be produced in a reproducible way.

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ACKNOWLEDGEMENTS: The commission for Technology "CTI Medtech" is acknowledged for financial support of the project under the contract 9071.1PFLS-LS.

Atomic layer deposition of bioactive TiO_2 coatings for titanium implants

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INTRODUCTION: Atomic Layer Deposition (ALD) is a promising technique of growing uniform, conformal and reproducible thin film coatings for various industrial applications [1]. The bioactivity of TiO_2 coatings grown by ALD on titanium surface have been demonstrated [2]. However, the bioactivity dependence on the TiO_2 coating chemical and structural properties haven't explored yet. This work is aimed at the study of the correlation between bioactivity and structural properties of the TiO_2 coatings on titanium surface.

METHODS: A hot-wall low pressure (15mbar) ALD reactor (Sunale R-150, Picosun OY) was used for TiO_2 thin films deposition from ethoxide and water at 300 °C. The number of deposition cycles was varied in the range of 100-2000. Commercially pure polished titanium Grade4 plates and (100) p-type 4 inch silicon wafers were used as the substrates.
The ALD grown TiO_2 coatings were investigated by Rutherford backscattering spectrometry, X-ray diffraction, atomic force microscopy and scanning electron microscopy.
To evaluate the bioactivity by hydroxyapatite forming ability on TiO_2 coatings samples were soaked in Simulated Body Fluid for nine days at 37 °C. A commercially available Dulbecco's phosphate buffered saline (D8662, Sigma-Aldrich) with pH = 7.4 was used. The cells MC3T3-E1 were used to evaluate the coatings bioactivity by determination the proliferation, differentiation and adhesion ability.

RESULTS: The changing TiO_2 structures from amorphous to polycrystalline anatase form were found at the thickness of 12 nm and over. The similar transition was observed for the films deposited on silicon using as model substrates due to its smoothness.

After immersion in simulated body fluid X-ray diffraction and scanning electron microscopy showed that amorphous TiO_2 coating did not induce the hydroxyapatite growth whereas anatase TiO_2 resulted in the hydroxyapatite forming on the samples surfaces (Fig. 1).
The samples with anatase coatings revealed increasing alkaline phosphatase activity on 18% in comparison with pure titanium.

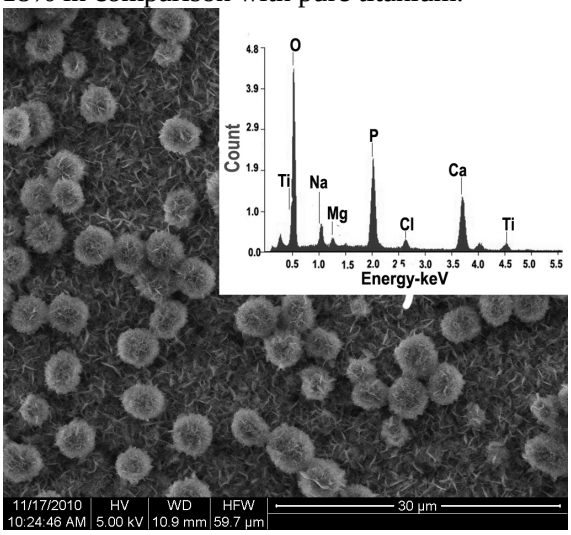

Fig. 1: SEM image of TiO_2 anatase coating deposited on titanium substrates after immersion in simulated body fluid.

DISCUSSION & CONCLUSIONS: The strong correlation between growth of anatase coating and hydroxyapatite appearance was demonstrated. The bioactivity of ALD grown TiO_2 coating in anatase form is also confirmed by an extensive alkaline phosphatase formation during the osteoblast cells MC3T3-E1 investigations.

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ACKNOWLEDGEMENTS: This work was partially supported by Russian Ministry of Science and Education (Contract No. 02.740.11.0786), Conmet.

Coated Titanium Implants – in vitro Microbiological Efficacy Testing Results

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INTRODUCTION: Implant-associated infections still represent a serious problem in arthroplasty, which is devastating for the patient and costly for any health care system[1]. Currently, a safe antibiotic protection from bacterial colonisation is not possible in uncemented implants. This is surprising, as recent data show a significantly higher increase of infection numbers in revision in uncemented compared with cemented prostheses using antibiotic-loaded bone cement[2]. The aim of this study is to prevent the development of a biofilm on titanium surfaces.

METHODS: Gentamicin palmitate (GP) was prepared. For all incubation experiments dilutions were performed in CSL Media (Casein soya bean digest broth, Oxoid LTD., England) and for detection of germ numbers the analogous CLS Agar was used. We used *S. aureus* for all our experiments. Inhibiting aerola testings were done on Müller Hinton Agar (MHA) plates (in-house production). Our test objects were flat titanium discs and bone cement discs (15.6 mm diameter). For adherence testing discs were incubated with *S. aureus* suspension containing $1 \cdot 10^3$, $5 \cdot 10^3$ and $1 \cdot 10^4$ germs/mL. Suspension testing: Discs were incubated for 24 h at 37°C with either germs (10^2, 10^4, 10^6 CFU/mL) or media alone and subsequently detected. Inhibiting areola testing: 0.5 McFarland was diluted 1:100 and swabbed all-over MHA plates. On the Agar contact side the discs were moistened with 10 µl of phosphate buffered saline (PBS) and kept for 1 h at room temperature to enable adherence. Diameters were measured on the bottom side of the petri dishes after 24 h incubation at 37°C. Kinetics: The germ suspension was shaken at 96 rpm for 2 h. After this preincubation period antibiotics and discs were added. Samples were drawn after 15, 30, 45 and 60 min, and then every hour, last sample after 24 h. Given an area of around 3.9 cm^2 per disc, the total amount of GP on the discs was approximately 840 µg GBase for "high" or 400 µg GBase for "low".

RESULTS: All GP containing discs showed the same antimicrobial effect. Suspension testing: Growth was not inhibited by discs or PMMA (polymethylmethacrylate) moulds without antibiotics. All discs with antibiotics showed antibacterial activity. No viable germs could be recultivated after 24 h. Inhibiting areola testing: Inhibiting areolas were comparable by all different discs, only the PMMA moulds showed slightly reduced diameters reaching 88% of the diameter of discs tested. The reference discs (uncoated) did not show any inhibiting areolas. Kinetics: In our studies the bacterial number showed a rapid decrease within the first hour.

DISCUSSION & CONCLUSIONS: Infections were responsible for revision in 14.8% and the most common reason for arthrotomy or removal of the prosthesis in 74.3% cases [3]. Due to that, it is obvious that not only the period of hospitalisation of each patient is prolonged but also pain and costs are increased. One common way to fight infections is systemically given prophylaxis and therapy with antibiotics before and after surgery which is often less effective. Bone cements as well as new surface coatings with GP (AntibiotiCoat®G) are able to deliver antibiotics locally and by this very effective against bacteria. Here, bone cement and GP covered discs act very similar in their effectiveness against *S. aureus*. Both can eliminate germ numbers ranging from 10^2 to 10^6 within 24 h and still have enough depots to prevent further growth of bacteria in the next four to five days postoperatively. The kinetic experiments showed clearly details about the rapidness of the disposal of gentamicin. As the calculated "pool" of GBase on a "high" disc is 840 µg, we used 84 µg/mL GBase in 10 mL of media. Our results clearly demonstrate the potential of GP coverage in an efficient elimination of bacteria. Because the high release rate effects only local tissue and GBase is not spread systemically, toxic side effects can be excluded.

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Process strategies for polished steel surfaces

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INTRODUCTION: According to DIN 8589, polishing is not a manufacturing technique in its own right and is only used in combination with other manufacturing processes such as grinding, honing or lapping. In the mould and die making industry, the different "polishing levels", e. g., brush finish, gloss or high-gloss, are considered the subjective opinion of the polisher. The divergence in quality standards often leads to disputes or even legal proceedings between steel manufacturers, polishing specialists and the plastics processing companies.

Furthermore to improve the surface quality, the fundamentals of the polishing process have to be understood; especially the origins of different types of defects and defect structures, which still lack of sufficient explanatory models. The Fraunhofer IPT has scientifically analysed the factors influencing the polishing process. The aim was to determine a conclusive explanation for the causes of polishing defects.

METHODS: Process technological experiments on ten tool steels were performed to get better explanations of the origin of defects. The final goal was to find a system that will minimize the manual polisher's monotonous work under unhealthy conditions [1].

The polishing experiments were accomplished on two different polishing machines; one from the metallography for plane samples and one typical manual polishing system for free formed surfaces.

The samples were qualitatively assessed with a light microscope, a SEM (scanning electron microscope) and measured with a white light interferometer, to get quantitative roughness parameters e.g. S_a and S_z (arithmetical mean height and maximum height of the surface) [2].

RESULTS: One main result of various polishing experiments was the classification of surface defects. In cooperation with Halmstad University in Sweden, the Fraunhofer IPT has taken a first step towards standardising the vocabulary involved in polishing through the creation of the defect chart according to the European Standard EN ISO 8785.

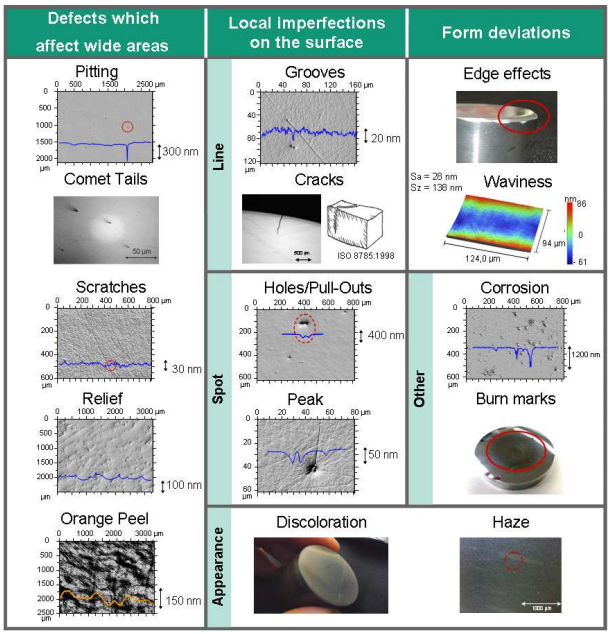

Fig. 1: Defect Chart

DISCUSSION & CONCLUSIONS: This table was used in the project to derive strategies in order to prevent polishing defects. The strategies can be found at www.polierstrategien.de. For future projects, this strategies will be expanded to include more materials, e. g., plastics, ceramics.

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[2] Deutsches Institut für Normung, DIN EN ISO 25178, Oberflächenbeschaffenheit: Flächenhaft – Teil 2, 2008.

ACKNOWLEDGEMENTS: The investigations presented in this paper were carried out within the research project SFB/TR4-T3 "Development of Process Strategies for the Manufacturing of Defect Free Surfaces for the Polishing of Tool Steels" funded by the German Research Association, Deutsche Forschungsgemeinschaft (DFG).

Effect of cavitation in ultrasound-assisted cleaning of medical devices

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INTRODUCTION: Aqueous cleaning is an essential step during manufacturing and surface treatment of medical devices. Four factors play a critical role for an efficient cleaning [1]: (i) chemical composition and concentration of the cleaning solution, (ii) solution temperature and cleaning time, (iii) efficient rinsing protocol and (iv) application of ultrasound as agitating source. Although ultrasound is routinely used in cleaning processes the relation between ultrasound parameters and cleaning efficiency is not clearly understood. In particular, validation of cleaning processes requires well defined and quantitative relations between ultrasound parameters and cleaning effect. We have studied the cleaning effect for artificially soiled titanium plates under well defined ultrasound conditions. An interrelationship between cavitation noise level and percentage of removal of the soil was found.

METHODS: Plates made from cpTi grade 2 (6.5 cm x 6.5 cm x 0.5 cm) were soiled with a gravimetrically determined amount of a polishing paste, dried for 30 min at 250 °C and weighed again. After the cleaning experiment the plates were rinsed, dried 30 min at 250 °C and finally gravimetrically analyzed. The percentage of cleaning was determined from the mass difference before and after the experiment. Cleaning was performed in a bath of the dimension 36 cm x 36 cm with a filling height of 39 cm. The tank had a set of 16 ultrasound transducers mounted each at the bottom and at the side wall. Ultrasound at 27 kHz and 80 kHz with a power of 400 W for each frequency at each side was used. Cleaning was performed in an alkaline tenside-containing solution at 60 °C for 10 s, 30 s or 60 s. Nine titanium plates were placed symmetrically in space diagonal plane oriented 45° to the side and the bottom plane of the transducer-attached walls in such a way that the ultrasound wave meets the surface of the plates. The ultrasound pressure frequency spectrum was monitored using a hydrophone connected to a cavimeter (ELMA Hans Schmidbauer GmbH & Co. KG, Singen, DE). The cavitation noise level $LKRZ = 20 \cdot \log(KRZ)$ with cavitation noise KRZ as defined in [2] was determined in the frequency range of 183 ± 0.5 kHz at the positions of the 9 plates in the bath.

RESULTS: Cleaning experiments were performed for the dual-frequency mode with the combinations 80 kHz and 27 kHz from bottom as well as from side wall (80B-80S, 27B-27S, respectively), 27 kHz from bottom and 80 kHz from side wall (27B-80S) and *vice versa* (80B-27S) for each experiment. The cleaning efficiency in each experiment was scaled to the value of the combination 80B-27S. Finally, the data of three independent experiments were averaged. The error for the cleaning data is 15 %. Without ultrasound no cleaning was observed. For ultrasound application a larger cleaning efficiency with increasing cavitation noise level was found (Fig. 1).

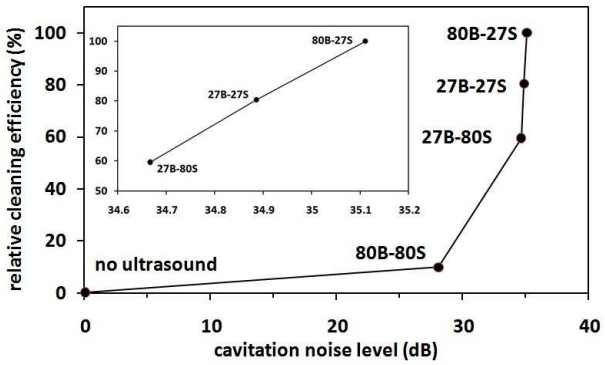

Fig. 1: Plot of the relative cleaning efficiency (averaged 10 s to 60 s) versus the cavitation noise level (averaged over the positions of the nine titanium plates).

DISCUSSION & CONCLUSIONS: It has been generally accepted that the ultrasound-induced cavitation in the solution is the relevant phenomenon for the cleaning effect [3]. Oscillation and collapse of cavitation bubbles in the ultrasound field induce microstreaming and shock waves producing the so-called acoustic noise which can be quantified by the cavitation noise level. The observed interrelationship between the cavitation noise level and the cleaning efficiency suggests that the cavitation noise level might be an appropriate parameter to use for the validation and monitoring of ultrasound-assisted cleaning processes of medical devices.

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Fasteners and Friction Coefficients

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mt engineering gmbh, Kaiseraugst, Switzerland

INTRODUCTION: Fasteners and their technology are one of the major construction techniques in medicine. When it comes to the qualitative evaluation of assembled fasteners, important facts are missing. One of them are the friction coefficients in the thread and under the head during assembly. Calculations and improvements can't be done without knowledge of these coefficients[1].

As friction is the characteristics of a system, the main influencing parameters are:

- Roughness (texture)
- Strength
- Combination of materials
- Contact geometry
- Lubrication
- Sliding speed (speed profile)
- Temperature

Primary aim for applying a threaded geometry is the produced force/load.

METHODS: Metric fasteners M1.4 to M6 have been tested in their original sterile status, - dry and wetted, plane or with conus. Different contact materials like Ti-Ti and Ti-Ceramic have been combined.

On specific test benches, real assembly situations have been simulated. Torque and clamp load have been measured dynamically, - simultaneously. With a special sensor partial friction coefficients (μ_{thread} and μ_{head}) are evaluated.

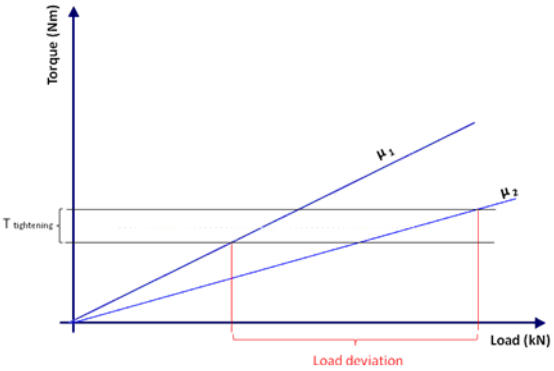

Fig.1: Importance of small torque deviation

RESULTS: Often – depending on the influencing parameters – the partial friction coefficients are not constant.

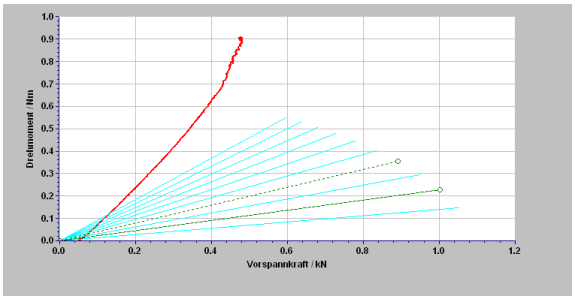

Fig.2: Friction coefficient: rising progressively up to fracture

Stick-slip (oscillating static and sliding friction during assembly) occurs at some material combinations.

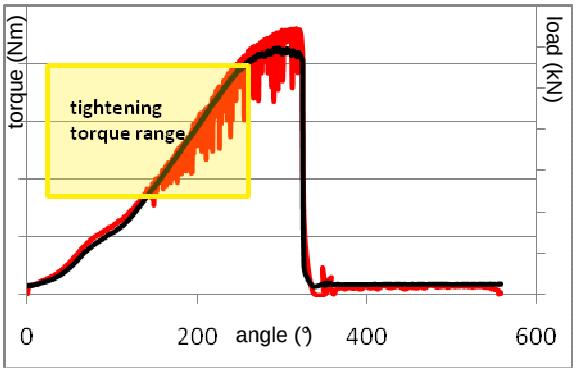

Fig.3: Stick-slip (red=torque, black=load)

CONCLUSIONS: It is evident that friction coefficients based on tables and figures in literature or resulting from the ball-on-disc method are unusable for simulations, calculations or improvements of fasteners because of geometrical and load discrepancies.

Total friction coefficients don't represent the assembly situation correctly.

With a better controlled and documented assembly the assembly quality can be assured. For this purpose a one-piece sterilisable digital torque wrench has been developed[3].

Better than assumptions for or neglection of friction coefficients are tests which have been carried out.

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Investigation of Chemically Induced Failures in Plastic Materials – Methodology and Case Studies

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INTRODUCTION: Plastics are highly valuable materials and also used for a variety of different purposes in medical devices. In the area of implants plastic materials are used for breast implants, knee joints, heart valves, spinal discs, stents, artificial blood vessels, catheters, drug depot implants and many more.

Plastic materials are very complex systems of one or several base polymers, polymer additives and potential impurities or contaminants. The most important polymers are polyethylene, polypropylene, polyamides, polyesters, polyvinyl chloride, polystyrenes, polyurethanes, silicones and rubbers.

The properties of polymers like hardness, elasticity, tensile strength, thermal and chemical resistance can be modified to a large extend by selecting raw materials, production processes and additives. Depending of raw materials and production process polymers contain residual monomers, oligomers, catalysts and other process chemicals as potential impurities. The addition of a multitude of available polymer additives is required to stabilise the polymer and to provide further plastic properties like softness, colour, and electrostatic, rheological or antimicrobial properties.

But beside the intended effect of the additives these chemicals as well as the impurities and contaminants in the base polymer may be a source of different plastic failures, e.g. cracks, pin holes, blooming or discolouration. Investigation of such plastic failures is needed to understand its root cause and therewith being able to avoid failures in future and improve the quality of the plastic materials.

METHODOLOGY: A failure analysis should be target-oriented and efficient. The huge diversity of different chemical substances present in the complex plastic material and even partially present only at trace level require a set of different analytical methodologies – the analytical toolbox. It consists of adequate sample preparation techniques, chromatographic separation techniques coupled to specific and sensitive detectors, spectroscopic instrumentation as well as surface analysis and imaging capabilities like:

- GC-MS-MS
- HPLC-MS-MS
- High resolution NMR
- High resolution MS
- FT-IR-imaging
- Raman imaging
- XPS
- Transmission and scanning electron microscopy with EDX detector
- ICP-MS

CASE STUDY: A typical example presents the investigation of a blown defect in a plastic film. Scanning electron microscopy in the backscattered electron imaging mode (SEM-BSE) was used. The results are shown in the figure 1.

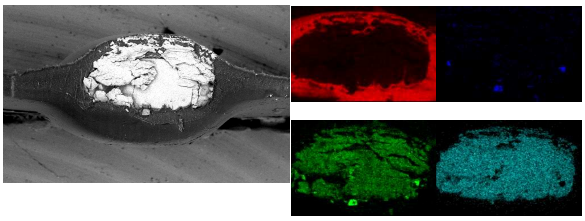

Fig. 1: SEM-BSE of defect:SEM image (left); carbon-, sodium-, titanium- and oxygen-map (clockwise from top left) (right).

The SEM-BSE pictures show that an imperfect dispersed titanium dioxide was the cause of the plastic defect.

CARTILAGE & DISC: REPAIR AND REGENERATION (Metal ion levels in the blood of patients with metal-on-metal (MoM) hip joint articulations. Does storage of blood samples matter?)

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INTRODUCTION: Patients with MoM joint articulations have elevated levels of chromium(Cr) and cobalt(Co). These elevated levels of metal ions (Chromium and Cobalt) are shown to be associated with increased wear[1] of the MoM joint articulation and related to undesirable side effects.[2,3] A recent British Medical device alert[4] have suggested monitoring at-risk patients using the blood metal ions as one of the diagnostic tools. The usual procedure of freezing blood samples immediately and shipping on frost becomes work intensive and costly for the individual samples and simply posting the blood sample in the mail would simplify the logistics of metal ion testing. However, the blood sample could be left at room temperature for days and the degrading of the blood sample may alter the chrome cobalt result. Before introducing new methods it is important to validate their accuracy. The aim of this study is to find out whether the metal ion value in the blood is stable whether the blood samples are frozen immediately or not.

METHODS: Following sample size calculations based on a Co and Cr value of 1 ppb, a sd of 0.05 and a MIREDIF of 0.2 ppb eight patients with large diameter MoM joint articulations were included after informed consent. Trace element tubes were used for whole blood samples. The first vial was discarded, two were frozen immediately, and the last blood samples were stored at room temperature for four and thirty days before freezing. Levels of Cr and Co were analysed at ALS lab in Sweden on a Finnigan ELEMENT ICP-SFMS with a limit of quantification(LOQ) of Cr(0.1 μg/l) and Co(0.1 μg/l). Data were analysed in STATA 11.1 and the individual differences were evaluated with a Bland-Altman 90% Limit of Agreement Analysis.[5]

RESULTS: We found Co ranging from 0.64 to 10.9 ppb and Cr from 0.76 to 5.16 ppb Mean cobalt immediate = 2.71, immediate repeated = 2.76, 4 days = 2.90 and 30 days = 2.89 ppb. Mean chromium immediate = 2.40 immediate repeated = 2.49, 4 days = 2.41 and 30 days = 2.36 ppb.
We found no systematically reduction in the mean level of chromium and cobalt of the eight patients as we compared results from the blood frozen immediately with the blood frozen after four and after thirty days. There was a tendency to greater variation (limits of agreement) in the results of the individual blood samples after four and after thirty days, but these increases were non-significant(p values: 0.21, 0.71, 0.08, 0.23).

DISCUSSION & CONCLUSIONS: In a population of patients with MoM joint articulations the variation of Co and Cr ions in blood kept at room temperature up to thirty days is within clinically acceptable levels for diagnosing excess wear and monitoring pseudotumour at-risk patients. The sample did not show any trend in overall concentration level over time. There is no need for immediate freezing and shipping on frost when handling Cr and Co blood samples of whole blood. When monitoring a MoM population we suggest introducing a method where whole blood is collected and posted directly in the mail. In this way the logistics of metal ion testing would be simplified.

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Implant manufacturers use Additive Manufacturing to reduce production costs and increase profits

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INTRODUCTION: On a market with eroding prices, orthopedic implant manufacturers are using Additive Manufacturing (AM) to reduce production costs and protect their bottom line.

They achieve this by producing their implants with integrated trabecular structures, thereby eliminating the need to apply a porous coating in an expensive and time-consuming secondary process.

BACKGROUND: An implant that does not provide long-term fixation and needs to be replaced prematurely causes unnecessary trauma for the patient, as well as additional social costs that often are not taken fully into account. It is therefore vital to reduce the risk of this occurring to a minimum.

The orthopedic implant manufacturers Adler Ortho and Lima-Lto are known for their innovative product designs, and with their Fixa Ti-Por and DELTA TT acetabular cups they have taken this innovativeness one step further.

Both were investigating alternative means to promote bone ingrowth when they discovered Arcam's Electron Beam Melting (EBM) technology, and realized how it can be used to build implants with full material properties and an integrated, engineered trabecular structure for improved osseointegration.

The EBM technology manufactures parts by melting thin layers of metal powder. The energy source is an electron beam gun, and the process takes place in a vacuum chamber.

EBM-produced implants feature a chemical composition within stipulated standards, fully dense material with fine microstructure, high ductility and excellent fatigue characteristics.

The technology's additive, layer-based nature also enables the production of implants with the integrated trabecular structures that enhance the osseointegration.

The companies therefore decided to develop completely new acetabular cups, able to take advantage of the full range of possibilities that the technology offers. The material of choice was Ti6Al4V with its combination of strength and excellent biocompatibility.

COST SAVINGS WITH AM: Conventionally manufactured press-fit acetabular cups require a porous coating, which is applied in a time-consuming and expensive secondary process.

The cost to apply this porous coating can be anything from 30 to 60 € per cup.

With Additive Manufacturing the cups are produced with an integrated porous structure, which eliminates this extra cost.

Moreover, when the cups are produced from bar typically 60-70% of the stock material must be machined away as scrap.

With Additive Manufacturing only the material that is actually needed to produce the acetabular cups is used. The remaining powder metal is recycled and reused.

RESULTS: More than 10.000 EBM-manufactured cups have been implanted since the market introduction in 2007.

The surgeons' post-op feedback is excellent: the primary fixation granted by the hemispherical press-fit is supported by the strong surface grip of the cup designs. Lima reports a BIC (Bone Implant Contact) of 95% in 26 weeks.

Post-market clinical follow-ups are also in place to fully evaluate the medium and long-term results of the products.

PRODUCTION: The Fixa Ti-Por and DELTA TT cups are now in series production at Adler Ortho and Lima-Lto, and the two companies are ramping up their production volumes in order to meet the market demand.

Their respective engineers are also working on other new and innovative implant designs to be produced with Additive Manufacturing.

In addition to the application mentioned above, the spinal implant manufacturer Advanced Medical Technologies uses the EBM technology for the production of lumbar cages. Their FUSE cage was launched in 2009.

In 2010 U.S. implant manufacturers received FDA clearance for implants manufactured with the EBM technology.

3d nano-composite and ceramic architectures via robotic deposition of UV curable inks

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INTRODUCTION: Shaping of colloidal inks in the micrometre range is becoming a vital step for the realization of novel materials and devices used for environmental protection, biomedicine, renewable energy, and MEMS. We here present a novel approach for producing predetermined, complex 3d ceramic architectures by robotic deposition where UV radiation is used for solidification [1-2].

METHODS:
The 44 vol.-% colloidal ink was prepared by mixing α-alumina powder (150 nm, Taimei, Japan), monomer (PEG200DA, Rahn, CH) and surfactant (TODS, 1% pp, Sigma Aldrich, CH) in a planetary ball mill (Retsch PM400, Germany). After the addition of a photo-initiator (LTM, Rahn, CH) the ink was extruded continuously using a PHD 2200 syringe pump (Harvard, USA) through a 160 μm orifice on a programmable xy table using robotic deposition (Fisnar I&J7300, USA), as shown in Fig. 1. The solidification of the filaments (curing) is done by UVA illumination using a 100 W iron bulb (Dr. Hönle, Germany). Curing for 2 minutes was done after deposition of 2 layers and after folding.

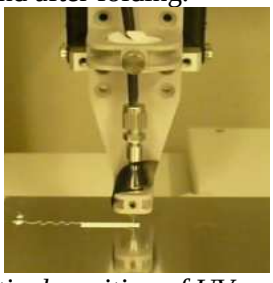

Fig. 1: robotic deposition of UV curable pastes.

RESULTS: Fig. 2 shows several printed structures obtained with the robotic deposition of the solvent free UV curable ink (44 vol.-% 150 nm α-alumina). These include 2 layered lattice structures of different nominal cell sizes, multilayered structures (0.5 mm cell) and a folded and bonded structure. The latter, which is produced by folding of a 2-layer cured lattice (0.75 mm cell) having an additional uncured bonding layer printed on top of it, demonstrates the versatility of the UV curable ink technology to produce complex 3d architectures.

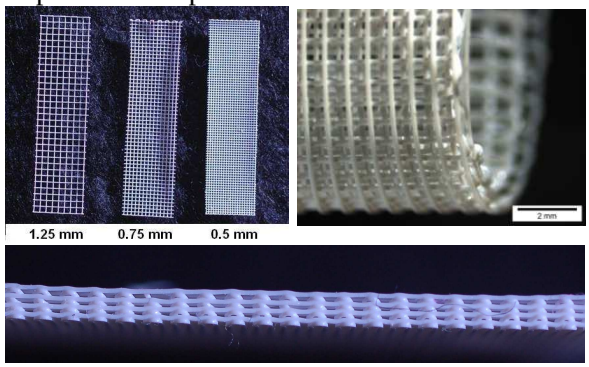

Fig. 2: architectures produced by printing of UV curable inks. 2-layer ceramic lattices with different nominal cell sizes (indicated) sintered at 1300°C (top left), folded 3d composite structure (top right), multilayered composite structure (bottom). Fibres are ~160 μm in diameter.

The various 3d architectures retain their shape and transform to high quality (nano)ceramics after conventional debinding and sintering procedures (Fig. 2, top left).

DISCUSSION & CONCLUSIONS:
The new inks and solidification mechanism open up some unique possibilities. The mechanical properties of the solidified nano-composite fibres (e.g. flexibility for shaping by post printing processes) can be controlled by the resin formulation and its cross-linking degree. The use of lithographical techniques (masks or lasers) enables further structuring by selective solidification [1]. Various post printing manipulations such as folding/bonding strategies are being explored for the realization of complex 3d architectures. The general method is currently being adapted to other biomaterials such as HA or Titanium.

REFERENCES: [1] de Hazan et al., WO/2010/040243. [2] de Hazan et al., J. Am. Ceram. Soc., 93 (2010) 2456–2459.

VESTAKEEP® – The Unbreakable Choice

M. Knebel

Evonik Degussa GmbH, High Performance Polymers, 45764 Marl, Germany

WHO WE ARE: Evonik Industries is an innovative German company, with specialty chemicals as its core business. As the technology leader for high-performance polymers, we supply Polyether Ether Ketone molding materials for the medical sector. Our VESTAKEEP® M-Grade and I-Grade PEEK polymers are particularly useful for medical technology applications due to their outstanding biocompatibility and biostability.

VESTAKEEP PEEK – CUSTOMIZED FOR THE HUMAN BODY: In the extensive trials conducted, independent test institutes have proven the biocompatibility of VESTAKEEP® I-grade polymers. VESTAKEEP's® I-Grade biocompatibility is principally attributable to the polymer's high chemical resistance. Not only is VESTAKEEP's® I-Grade biocompatibility outstanding, but also its biostability, due to its high chemical resistance.

FOR SHORT TERM AND LONG TERM USE: The biocompatibility of a material determines its basic suitability for implants – it must not be cytotoxic, mutagenic, or carcinogenic. It must not have any allergenic properties and has to be stable in the biological environment. The requirement for the biocompatibility of the finished medical product depends on the type of contact (skin, blood, fat tissue, etc.) as well as the duration of the contact. VESTAKEEP® PEEK is offered in different grades for medical applications, depending on what kind of contact it will have with the body and for how long: VESTAKEEP® M is used for short term contact, while VESTAKEEP® I is used for long term / permanent implant contact.

WHERE OTHER MATERIALS REACH THEIR LIMITS: VESTAKEEP® PEEK is lighter than titanium and more flexible than cobalt chrome. Because implants are supposed to last a lifetime, the materials used must be both biologically stable and mechanically durable. Throughout history, titanium, cobalt chrome and stainless steel were the materials of choice. Now, however, VESTAKEEP® I-Grade polymers provide numerous advantages over metal.

Metal implants reach their limits when it comes to imaging methods. Because of their density, metals absorb X-rays and produce artefacts on the radiographic image. PEEK, however, is transparent to X-rays. In cases where the doctor desires to see the implant – for example to check its position – the implant can be modified accordingly.

Another weakness of metals is the modulus of elasticity, which is much higher than that of bone. The implant therefore assumes a large share of the mechanical load, reducing the stress on the bone. This stress-shielding effect can have far-reaching consequences: Because bones need the mechanical stress to be regenerated in the healing process and also remain strong in the long term, this may slow their healing process and, over the years, possibly breaking down the bone from which the stress has been eliminated. The elasticity of VESTAKEEP® I-Grade PEEK is closer to the cortical bone than metal and has a higher elasticity than metals based on the dimension of bones. This deters the stress-shielding effect on the bone and allows for a longer, healthier life.

Besides the mentioned advantages compared to metal implant material VESTAKEEP® also offers superior fatigue behaviour and ductility when compared to other PEEK implant grade materials.

Fast and effective – "dry machining" of metals and plastics with CO_2

M. Maurer[1] & N. Lehming[2]

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INTRODUCTION: With CO_2-cooling devices – Friogenic® - internal or external cooling - most of the machining processes can be dramatically accelerated. The processes stay oil-, water- and emulsion-free. Most of the following cleaning steps will be needless. The dry process is particularly suitable for machining of Titanium, high-temperature alloys, composites, ceramics and even engineering plastics in the production process. Todays medical-, car- and aerospace-industry forces the use of "dry manufacturing processes" more and more, 1st to manufacture in line with international standards, 2nd to extend product life, and 3rd to cut down product costs.

METHODS: During machining the temperature profile and an optimized chip control will be managed by CO_2.
In the machining process managed by external cooling – e.g. turning, drilling or grinding – compressed air and liquid CO_2 will be delivered to the cutting edge by patented spray-nozzles. Instantly the dry ice particals sublimate (100 % residue-free) to gasous CO_2 and the cutting edge of the tool will be cooled.
In the machining process managed by internal cooling – e.g. drilling, milling, turning – liquid and gasous CO_2 will be pressed through cooling-channels in the tool and delivered precisely at the cutting edge. Instantly the dry ice particals sublimate (100% residue-free) to gasous CO_2 and the cutting edge of the tool will be cooled.

RESULTS: No need of oil, water or emulsion for machining. Excellent thermal management of the cutting process by precisely delivered and dosed CO_2. The machining temperatures are dramatically lower. The appearing heat discharge in the machining process through improved chip control is remarkable. No recycling of lubricants and no extra charge for disposal. No expensive recycling of contaminated chips. No subsequent cleaning or drying needed. Tool life increases by up to 500 % compared with conventional coolant systems. With CO_2 you use a much more environment-friendly lubrication agent. The CO_2 for the above-named applications had been extracted from by-products of ammonia-, alcohol- and fertilizer-production. The Friogenic® cooling device is easily adaptable to most common CNC-machinery.

Fig. 1: environmental - friendly machining process with CO_2.

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Scope - eCM provides an international and interdisciplinary forum for publication and discussion for research in the cells and matrices of the connective tissues of the musculoskeletal system and dental field, and the materials used in the replacement, repair or regeneration of these tissues. Cross-disciplinary papers that go across our scope areas are particularly welcomed. The clinical relevance of the work must be included within the abstract, Introduction and Discussion.

• **Assessment of materials for biomedical use in the musculoskeletal system or dental field & interaction with tissues/ prokaryotic / eukaryotic cells.** Must have an important biological dimension reporting effects at the cellular, tissue or organismic levels; clinical data are acceptable. Papers focussing on material properties, including descriptions of physical, chemical and mechanical characteristics, will not be entertained. In vitro cytocompatibilty studies should use primary cells or more than one cell line & provide more than just simple descriptions of cell spreading, proliferation etc.
• **Tissue Engineering and Regenerative Medicine** - Aspects of repair or regeneration of connective tissues within the musculoskeletal system or dental field with tissue engineering approaches of all types.
• **Structure, function, biology of connective tissues** - Structure of bone, teeth, cartilage, intervertebral discs & other related connective tissues.
• **Stem and Progenitor Cells -** Stem cell characterization and mechanisms of differentiation as they relate to the connective tissues of the musculoskeletal system or dental field.

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