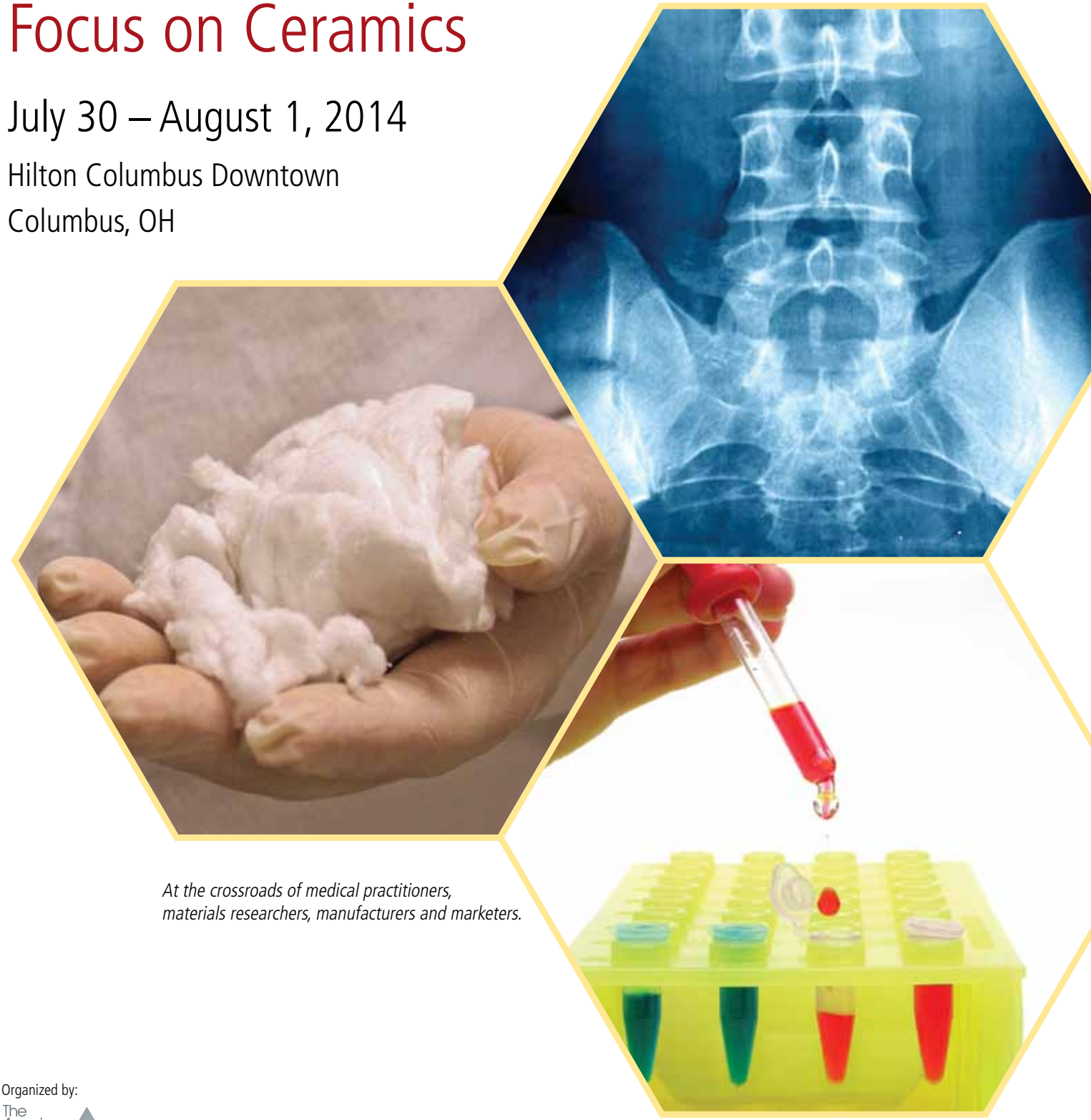
CONFERENCE PROGRAM

Innovations in Biomedical Materials: Focus on Ceramics

July 30 – August 1, 2014

Hilton Columbus Downtown
Columbus, OH



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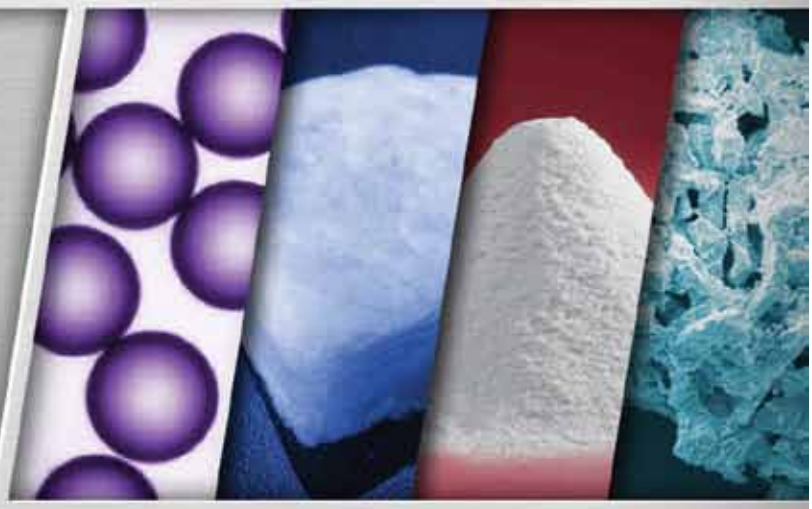

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Welcome

Welcome to the Innovations in Biomedical Materials: Focus on Ceramics 2014 conference (Bioceramics 2014). This conference brings together the materials research, manufacturing and medical communities to explore technological advancements, to facilitate product innovations, and to identify potential new applications.

PLENARY SPEAKERS for Bioceramics 2014 include:

- **Larry Hench**, Florida Institute of Technology, presenting *Affordable Healthcare? Role of Bioceramic Technology*
- **Glenn Stiegman**, Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA), presenting *The Current Regulatory Environment*
- **Safdar Khan**, M.D.,The Ohio State University, presenting *Bone Graft Alternatives for Complex Spine Surgery–What I need in the O.R.*
- **Hyun Bae**, M.D., The Spine Institute, presenting on the topic of *Surgical Trends*

In addition to the plenary talks, the meeting will feature eight panel discussion sessions from experts in the field of Orthopedics; New Technologies; Regulatory, Patents and Intellectual Property; Clinical Testing; Radiotherapeutics; Bioceramic Testing; and Dental Applications. Rapid-fire oral presentations by the poster presenters will precede the welcome reception and posters.

This meeting emphasizes collaboration between R&D, medical practitioners, and biomedical materials manufacturers/marketers. A goal of the meeting is to equip attendees with information, ideas and new contacts that will in turn help them to develop emerging technologies into marketable products.

Special thanks go to our sponsors, including Mo-Sci Corporation, Prosidyan, Inc., Florida Institute of Technology, Keystone Nano, Inc., and NovaBone Products LLC.

Best regards,

Steven Jung

Steven Jung, PhD
chief technology officer
Mo-Sci Corporation

A NEW SHORT COURSE
PRESENTED BY DR. LARRY HENCH

BIOCERAMICS:
ADVANCES & CHALLENGES FOR AFFORDABLE HEALTHCARE

Part of a new series offered in association with The American Ceramic Society, tailored to working professionals in the engineering and healthcare fields with an interest in bioceramics.

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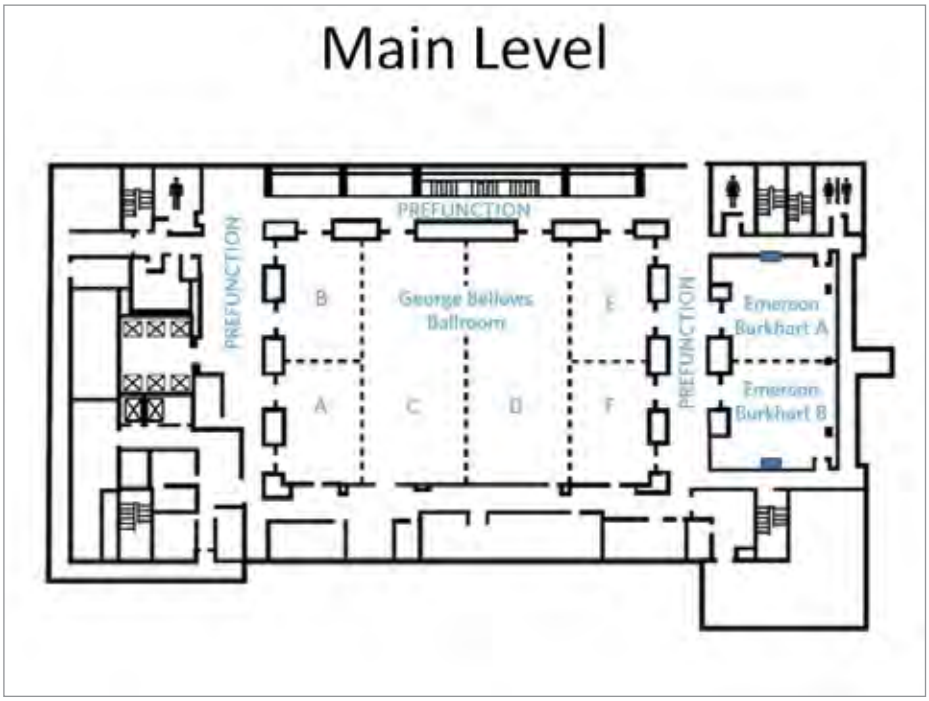

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Schedule of Events

WEDNESDAY, JULY 30

Registration	3:00 – 7:00 p.m.	George Bellows Foyer
Rapid-fire Presentations	4:00 – 5:30 p.m.	Emerson Burkhart A/B
Welcome Reception & Poster Session	5:30 – 7:00 p.m.	Emerson Burkhart A/B

THURSDAY, JULY 31

Registration	7:30 a.m. – 5:00 p.m.	George Bellows Foyer
Plenary I: **Dr. Larry Hench**, Affordable Healthcare	8:30 – 9:30 a.m.	George Bellows E/F
Coffee Break, Sponsor Tables, and Posters	9:30 – 10:00 a.m.	Emerson Burkhart A/B
Panel Discussion: Orthapedics I	10:00 – 11:00 a.m.	George Bellows E/F
Panel Discussion: New Technologies	11:00 a.m. – 12:00 p.m.	George Bellows E/F
Lunch, Sponsor Tables, and Posters	12:00 - 1:30 p.m.	Emerson Burkhart A/B
Plenary II: **Mr. Glenn Stiegman**, Regulatory Environment	1:30 - 2:30 p.m.	George Bellows E/F
Coffee Break, Sponsor Tables, and Posters	2:30 - 3:00 p.m.	Emerson Burkhart A/B
Panel Discussion: Regulatory	3:00 - 4:00 p.m.	George Bellows E/F
Panel Discussion: Radiotherapeutics	4:00 - 5:00 p.m.	George Bellows E/F
Conference Dinner	6:00 - 8:00 p.m.	Emerson Burkhart A/B

FRIDAY, AUGUST 1

Registration	7:30 a.m. – 3:00 p.m.	George Bellows Foyer
Plenary III: **Safdar Khan, M.D.**, Clinical Testing	8:30 - 9:30 a.m.	George Bellows E/F
Coffee Break, Sponsor Tables, and Posters	9:30 - 10:00 a.m.	Emerson Burkhart A/B
Panel Discussion: Clinical Testing	10:00 - 11:00 a.m.	George Bellows E/F
Panel Discussion: Bioceramic Testing	11:00 a.m. - 12:00 p.m.	George Bellows E/F
Lunch, Sponsor Tables, and Posters	12:00 - 1:30 p.m.	Emerson Burkhart A/B
Plenary IV: **Hyun Bae, M.D.**, Surgical Trends	1:30 - 2:30 p.m.	George Bellows E/F
Coffee Break, Sponsor Tables, and Posters	2:30 - 3:00 p.m.	Emerson Burkhart A/B
Panel Discussion: Orthopedics II	3:00 - 4:00 p.m.	George Bellows E/F
Panel Discussion: Dental Applications	4:00 - 5:00 p.m.	George Bellows E/F

Plenary Speakers

Thursday | 8:30 a.m.

LARRY HENCH, Florida Institute of Technology
Title: *Affordable Healthcare? Role of Bioceramic Technology*

Abstract: Affordable healthcare for an aging society will not be achieved by legislation and taxation. Ever increasing desires cannot be met by ever decreasing resources. The only viable solution to the rising costs of healthcare is to achieve revolutions in healthcare technology, distribution, expectations and priorities. Previous revolutions in healthcare, prevention of death and replacement of tissues, need to be augmented with two new, innovative revolutions: tissue regeneration and prevention of tissue deterioration. This lecture addresses the past, present and future revolutions in healthcare and outlines the potential for bioceramics in various forms to be able to provide the scientific and industrial foundation for these revolutionary technological changes. The magnitude of run-away costs of healthcare in the US and world is presented to illustrate the need for alternative technologies for maintenance of high quality of life without increasing cost of care. The technology emphasis is on the following topics: 1) bioactive glasses and ceramics for regeneration of tissues, 2) innovative bio-photonics technology for rapid, inexpensive human cell based screening of biomaterial-cell and tissue interactions and patient specific diagnosis and treatment, 3) control of angiogenesis, soft tissue engineering and repair of chronic wounds.

Biography: Hench is currently University Professor, Biomedical Engineering Program, Florida Institute of Technology, Melbourne, Florida, Professor and Director of Special Projects at the University of Central Florida, Visiting Professor at Kings College/ Guy's Hospital University of London, Guest Faculty at the Department of Bioengineering at Florida Gulf Coast University, and Emeritus Professor at the University of Florida and Imperial College London. For 10 years he served as Co-Director of the Imperial College Tissue Engineering and Regenerative Medicine Centre. He assumed the Chair of Ceramic Materials at Imperial College in 1995 following 32 years at the University of Florida where he served as Graduate Research Professor , Director of the Bioglass Research Center and Co-Director of the Advanced Materials Research Center. Larry completed his Bachelor of Ceramic Engineering degree at The Ohio State University in 1961 and his PhD in 1964. Dr. Hench has received almost all the awards in ceramics, materials science and biomaterials that are possible, including membership in the National Academy of Engineering and A CerS' W.D. Kingery Award. He is also a Fellow and Distinguished Life Member of ACerS.

Thursday | 1:30 p.m.

GLENN STIEGMAN, Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
Title: *The Current Regulatory Environment*

Abstract: As the material science of ceramics and their utility in the body continues to advance, the FDA often times is several years behind industry in how these materials are being used, especially in Orthopedics. As these new materials and uses are being developed and studied, companies want to understand how their device will be regulated and how to approach the FDA with their new material or indication. In addition, companies want to comprehend the various regulatory hurdles that they must overcome including mechanical testing, animal testing, and clinical data. In order to understand how best to gain market clearance or approval of your device, an understanding of how ceramics and bioceramics are regulated for various orthopedic applications. This presentation will not only outline the various regulations for ceramic devices, but also an overview of testing needed to achieve future clearance or approval will be described. Furthermore, this presentation will review a description of some of the hurdles and questions from the FDA as well as consideration when approaching the FDA with your new ceramic or bioceramic. Lastly, the presentation will review how and when to approach the FDA with a new technology to gain the most success with developing your overall regulatory strategy.

Biography: Stiegman is vice president of clinical and regulatory affairs at Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in New York, New York. He leads the submission, regulatory strategy, analysis, and development of products at MCRA. As former chief of the Orthopedic Devices Branch for the US FDA, Stiegman is an expert on the orthopedic industry and guidance and policy for marketed orthopedic devices.

Plenary Speakers (continued)

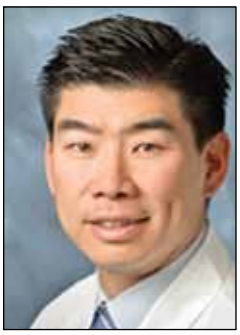
Friday | 8:30 a.m.

SAFDAR KHAN, M.D., The Ohio State University

Title: *Bone Graft Alternatives for Complex Spine Surgery–What I Need in the O.R.*

Biography: Khan joined the Department of Orthopaedic Surgery at The Ohio State University Medical Center in August 2011. He has served on the American Academy of Orthopaedic Surgeons Biological Implants Committee and has received awards for his research from the Orthopaedic Research and Education Foundation, Scoliosis Research Society, Orthopaedic Trauma Association and Western Orthopaedic Association. He is the author of more than 60 peer-reviewed publications and 10 book chapters and has guest edited several major publications. He earned his MD from The Aga Khan University Medical College, Pakistan in 1998 and performed his residency at Orthopaedic Surgery, Department of Orthopaedic Surgery, University of California at Davis.

Friday | 1:30 a.m.



HYUN BAE, M.D., The Spine Institute

Title: *Surgical Trends*

Biography: Bae is a board-certified orthopedic surgeon at the Cedars-Sinai Spine Center, specializing in minimally invasive microsurgery and the treatment of cervical and lumbar spinal disease. Dr. Bae is a national leader in minimally invasive surgery, motion preservation technology, artificial disc replacement and non-fusion technologies. He is co-director of the Spine Fellowship Program. Dr. Bae earned a bachelor's degree in biomechanics from the Columbia University School of Engineering and Applied Sciences. He earned his medical degree, cum laude, from the Yale University School of Medicine. He completed his surgical internship at North Shore University Hospital and his orthopedic surgical residency at the Hospital for Special Surgery in New York. He completed a spine fellowship at Case Western Reserve Hospital in Cleveland.

Final Program

THURSDAY, JULY 31, 2014

10:00 – 11:00 a.m. | **Orthopedics I Panel**

This panel discussion discusses new and emerging bioceramic technologies and technologies that are in the commercial pipeline. It will focus on bioceramics with orthopedic applications, including cranial, facial, orthopedic, bone void fillers, and spinal applications. Individual panelists will discuss the many uses of bioactive glass for the treatment of bone injuries and bone defects in the body. It will explore material properties and forms along with dynamic bioactive bone graft material that can be molded into desired shapes for implantation.

Panelists: (Bios on page 9)

Zehra Tosun, NovaBone Products, LLC

Charanpreet S. Bagga, Prosidyan, Inc.

Markus Reiterer, Medtronic, Inc.

David Dean, The Ohio State University

11:00 a.m. – 12:00 p.m. | **New Technologies Panel**

This panel discussion focuses on emerging technologies containing bioceramics covering wound care, bone grafting, drug delivery and coatings. Specific topics include emerging topics of bioactive glasses, including new frontiers in wound care and bone grafting. Drug delivery will also be discussed, including nanoparticulate alternatives for drug delivery, porous silica microspheres for medical applications, and coating technologies for medical implants.

Panelists: (Bios on page 9)

James H. Adair, Keystone Nano, Pennsylvania State University

George Wicks, Wicks Consulting Service

Orville Bailey, Covalent Coatings Technologies, LLC

Jacob J. Stiglich, Ultramet

3:00 – 4:00 p.m. | **Regulatory Panel**

This panel discussion focuses on the current regulatory environment, Food and Drug Administration trends, how to obtain and maintain compliance, patent trends and protecting intellectual property.

Panelists: (Bios on page 10)

Aditya Sukthankar, MDI Consultants, Inc

Tram Nguyen, MH2 Technology Law Group, LLP

Glenn Stiegman, Musculoskeletal Clinic Regulatory Advisers, LLC

4:00 – 5:00 p.m. | **Radiotherapeutics Panel**

This panel discussion focuses on clinical efficacy of tenured products along with new treatment options from emerging technologies and applications. Panelists will discuss product development, materials requirements, properties of good radiotherapeutic materials, chemical durability, how to maximize specific activity, method of activation and the right type of radioisotope.

Panelists: (Bios on page 10)

Wayne Mullet, BTG International Canada, Inc.

Delbert Day, Missouri University of Science & Technology

FRIDAY, AUGUST 1, 2014

10:00 – 11:00 a.m. | **Clinical Testing Panel**

This panel discussion focuses on the efficacy of a multitude of products from a variety of medical fields and how these products may be improved to get an improved outcome. Panelists will cover preliminary and primary research, testing required for commercialization, and clinical trials.

Panelists: (Bios on pages 10 – 11)

Ben Tempel, NanOpthalmics

Safdar Khan, The Ohio State University

11:00 a.m. – 12:00 p.m. | **Bioceramic Testing Panel**

This panel discussion focuses on test methods currently used for evaluating bioceramics, especially in-vitro and cellular biology. The panelists will also discuss which animal models to use for acceptance by regulatory groups for specific indications of treatment.

Panelists: (Bios on page 11)

Larry Hench, Florida Institute of Technology

David Greenspan, Spinode Consulting

Steven Jung, Mo-Sci Corporation

3:00 – 4:00 p.m. | **Orthopedics II Panel**

This follow-up session to Orthopedics I discusses new and emerging bioceramic technologies and technologies that are in the commercial pipeline. Individual panelists will discuss collagen ceramic products engineered to mimic the composition and pore structure of natural human bone along with bioactive bone graft materials that undergoes a time dependent surface modification upon implanting in living tissue, eventually resulting in the formation of new bone.

Panelists: (Bios on page 11)

Sunil Saini, Integra

John Brunelle, BioStructures LLC

William David Hill, Georgia Regents University

4:00 – 5:00 p.m. | **Dental Applications Panel**

This panel discussion focuses on new and emerging bioceramic technologies and technologies that are in the commercial pipeline with dental applications.

Panelists: (Bios on page 12)

Carolyn Primus, Primus Consulting

Bill Poulson, Biomet 3i

Gregory Pomrink, NovaBone Products LLC

PANELIST BIOGRAPHIES


Zehra Tosun

Tosun has been the senior R&D biomedical engineer since 2012. After completing her BS in chemical engineering, she started her career as a research assistant in University of Oklahoma. In 2010, she relocated to University of Florida, and received her PhD in biomedical engineering in 2012. Her dissertation research focused on the use of ex vivo derived materials designed as implant scaffolds, and focusing on the events during regenerative processes to further detail the progressive changes. Currently at NovaBone, Tosun is responsible for designing and developing medical devices for regenerating bone and soft tissues. In addition, she has a diverse range of responsibilities including project management, IP development and planning and management of preclinical studies


Markus Reiterer

Reiterer received his Diplom-Ingeneur (MS) in materials science in 2000 and his PhD in mining in 2004 from Leoben. He conducted his graduate studies at the Fraunhofer-Institute for Mechanics of Materials in Freiburg, Germany, under direction of Prof. Hermann Riedel. During the next two years he continued his research in the field of computer simulation of powder compaction and sintering of ceramics as a postdoctoral appointee at Sandia National Labs. In 2006, he joined Medtronic and worked for 3 years in the research department of the Medtronic Energy and Component Center working mostly on mechanical design of batteries for implantable medical devices and durability of ceramic, electrical components. Since 2009, he has worked at the Corporate Core Technologies Department, where he currently leads the metals research group. Within Medtronic, he is recognized as expert for welding and joining, hydrogen embrittlement, finite element simulation, and failure analysis of complex systems. In 2013 he was appointed a Medtronic Technical Fellow.


David Dean

Dean is an Associate Professor of Plastic Surgery in the College of Medicine, and a member of the Center for Regenerative Medicine and Cell-Based Therapies, at The Ohio State University in Columbus, Ohio. He earned the PhD degree at the City University of New York (New York, NY) in 1993. He was a Postdoctoral Fellow in Plastic Surgery at New York University (New York, NY) before joining the faculty of the School of Medicine at Case Western Reserve University (CWRU) (Cleveland, OH) from 1994-2013. He directed the Imaging Laboratory of the CWRU Department of Neurological Surgery where he developed and patented methods for the Computer Aided Design (CAD) and additive manufacture (3D printing) of medical implants. He directs the Osteo Engineering Laboratory at The Ohio State University which focuses on craniofacial regenerative medicine. The Osteo Engineering Laboratory's current research includes implant CAD, biomechanical modeling, and additive manufacturing, as well as the use of bone progenitor cells, growth factors, and bioreactor technologies for the production of bone tissue engineered implants.


James H. Adair

Adair received his BS in Chemistry (1975) and his MS (1979) and PhD (1981) in Materials Science and Engineering, all from the University of Florida. From 1981-1982, he was a Fulbright Post-doctoral Fellow at the University of Western Australia in the Department of Soil Science and Plant Nutrition and the Royal Perth Hospital where he studied the biophysical chemistry origin of pathological biomineralization including human kidney stone disease. He was a Principal Research Scientist at Battelle Memorial Institute from 1982-1986. He joined Penn State as a Research Associate at the Materials Research Lab from 1986-1990. Adair was a faculty member from 1990 to 1997 at the University of Florida. Adair is the author or co-author of over 250 publications, thirteen patents, and several copyrights on computer software. He has been chair or co-chair of many symposia related to materials chemistry and colloid and powder processing science at ACerS and American Chemical Society national and international meetings. He is also the co-editor of tweleve books. Adair is a Fellow of the American Ceramic Society and the World Academy of Ceramics.


George Wicks

Wicks is a consulting scientist recently retired from the Savannah River National Laboratory after 40 years, achieving the highest position in the organization's technical ladder. He has more than 200 publications and 16 patents issued, to date, and has authored or co-authored 7 books and 9 invited chapters in texts and encyclopedias, and served as co-chairman for more than dozen international meetings on a variety of topics. He was also the technical lead working with the medical community on a new series of initiatives involving technologies developed within the nuclear field, which are now being tailored and evaluated for potential applications in diagnostics, repair/ replacement, and therapy/ treatment of a variety of medical conditions. Wicks currently works with the Applied Research Center of South Carolina along with licensees of several of the inventions he as been associated with, in spinning out these technologies into the commercial sector.


Orville Bailey

Bailey is a 20-year veteran in the materials and aerospace industry, most recently serving as Director of Manufacturing Quality for Pratt & Whitney. Bailey provided operations and engineering leadership for OEM and aftermarket coating operations while at Pratt & Whitney. He has also worked for General Electric and Galileo Electro-Optics (Corning). Bailey is a materials scientist and certified Shainin Red-X Master.

Stiglich earned his BS in mechanical enginnering from Marquette University in 1961 and his PhD from Northwestern University in 1967. He has 15 years of experience working with companies on research/ process development of metals and ceramic/metal composites and products. Stiglich has more than thirty five years experience in metallurgical technology, and is a recognized expert in ceramic composite fabrication, CVD fluidized-bed powder coating and ordnance materials.

He is an independent consultant working with companies on research and process development for armor, cutting tools, biomedical applications, and wear/corrosion/high temperature resistant coatings.

Final Program

PANELIST BIOGRAPHIES

Aditya Sukthankar

Sukthankar specializes in the preparation, review and submission of traditional and special 510(k) submissions, comprehensive label reviews of food, drugs and biologics. Previously he was customer relations executive at Wockhardt Pvt. Ltd. in India where he communicated with highly qualified nephrologists and oncologists about drug benefits to promote sales of the kidney products. Sukthankar earned his MS in regulatory affairs from Long Island University and his BS in pharmacy from Bharti Vidyapeeth College of Pharmacy. He is a member of member of Regulatory Affairs Professional Society of USA.

Tram Nguyen

Nguyen has experience in all aspects of patent law, including patent preparation, prosecution, client counseling and providing opinions. She has significant experience in medical devices and advising early stage and start-up companies. Prior to joining MH2, Nguyen founded Monument IP Law Group. Nguyen was formerly the director of IP and Legal Affairs for Paradigm Spine LLC and the vice president of IP at Musculoskeletal Clinical Regulatory Advisers. She is also a former associate and technical specialist with the law firms of Finnegan LLP and Nutter, McClennen & Fish LLP. Prior to becoming a registered patent attorney, Nguyen was a patent examiner at the U.S. Patent and Trademark Office, where she examined patent applications related to prosthetics and implants such as cardiac and vascular assist devices, stents, grafts, cardiac pumps, orthopedic and spinal implants, mammary and orthopedic prostheses, and related methods and surgical tools. She earned her Juris Doctor from George Mason University School of Law, her MS in biotechnology from The Johns Hopkins University and her BS in biology with minor in chemistry from George Mason University.

Stiegman

Stiegman is vice president of clinical and regulatory affairs at Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA) in New York, New York. He leads the submission, regulatory strategy, analysis, and development of products at MCRA. As former chief of the Orthopedic Devices Branch for the US FDA, Stiegman is an expert on the orthopedic industry and guidance and policy for marketed orthopedic devices.

Wayne Mullet

Mullett has 15 years of experience in drug discovery/development and medical device commercial support. Dr. Mullett transitioned to BTG from Nordion, where he spent 5 years as the Director, Radiopharmaceutical Development, overseeing Nordion's R&D pipeline and providing technical support for commercial radiopharmaceutical products. Prior to joining Nordion/BTG he was a project team leader at Merck, managing multidisciplinary teams that were responsible for the advancement of drug substance/product candidates from discovery to Phase II proof of concept studies. He holds a BS in Biochemistry (Memorial University of Newfoundland, 1995), a PhD, Bioanalytical Chemistry (Carleton University, 2000) and also completed a 2 year National Science and Engineering Research Council (NSERC) Post-Doctoral Fellowship at the University of Waterloo (Waterloo, Ontario) and Fraunhofer Institute for Toxicology/Experimental Medicine (Hannover, Germany). Dr. Mullett remains involved in the academic community as a previous Adjunct Professor at the University of Waterloo (Waterloo, Ontario) and is presently a member of the Editorial Advisory Board for Journal of Pharmaceutical and Biomedical Analysis. To date he has published over 35 peer review journal publications and holds 1 patent.

Delbert Day

During his career, **Day** has published more than 390 technical papers, edited three books and been granted 61 US and foreign patents. His patents include glass microspheres for medical (radioembolization of malignant tumors) and dental applications, bioactive glasses for wound healing and bone repair, chemically durable iron phosphate glasses for vitrifying nuclear waste, optically transparent composites, and high temperature ceramics. He conducted the first US glass melting experiments in micro-gravity on NASA's Space Shuttle and is co-inventor of special purpose glass microspheres, TheraSphereTM, which are now being used at more than 170 sites worldwide to treat patients with inoperable liver cancer. He is a co-inventor of "Glasphalt," where waste glass is recycled as part of the aggregate in asphalt paving. His numerous honors and awards include election to the National Academy of Engineering, Distinguished Life Member (and past president) of ACerS, The Presidential Award for Research and Creativity and the Presidential Citation for Alumni Service Award, selection as the Nation's Outstanding Young Ceramic Engineer (Pace Award) by the National Institute of Ceramic Engineers, the Hosler Alumni Scholar Medal for Scientific Achievement, and the Chancellor's Medal and Doctor of Science, Honoris Causa.

Ben Tempel

Tempel is formally educated and skilled as an engineer and businessman with two engineering degrees from Georgia Tech and an MBA from Emory. He is an experienced entrepreneur having run his own commercial real estate development company. Tempel has spent his last few years gaining experience within the healthcare industry working for Sunrise Senior Living, the largest assisted living company in the country. His most recent experience has been working for Accredo Healthcare, the specialty pharmacy of Express Scripts, the largest PBM in the country with responsibilities for a portfolio of ten drugs within the pulmonary hypertension product line with P&L responsibility valued at $1.5B.

PANELIST BIOGRAPHIES


Safdar Khan

Khan joined the Department of Orthopaedic Surgery at The Ohio State University Medical Center in August 2011. He has served on the American Academy of Orthopaedic Surgeons Biological Implants Committee and has received awards for his research from the Orthopaedic Research and Education Foundation, Scoliosis Research Society, Orthopaedic Trauma Association and Western Orthopaedic Association. He is the author of more than 60 peer-reviewed publications and 10 book chapters and has guest edited several major publications. He earned his MD from The Aga Khan University Medical College, Pakistan in 1998 and performed his residency at Orthopaedic Surgery, Department of Orthopaedic Surgery, University of California at Davis.


Larry Hench

Hench is currently University Professor, Biomedical Engineering Program, Florida Institute of Technology, Melbourne, Florida, Professor and Director of Special Projects at the University of Central Florida, Visiting Professor at Kings College/ Guy's Hospital University of London, Guest Faculty at the Department of Bioengineering at Florida Gulf Coast University, and Emeritus Professor at the University of Florida and Imperial College London. For 10 years he served as Co-Director of the Imperial College Tissue Engineering and Regenerative Medicine Centre. He assumed the Chair of Ceramic Materials at Imperial College in 1995 following 32 years at the University of Florida where he served as Graduate Research Professor , Director of the Bioglass Research Center and Co-Director of the Advanced Materials Research Center. Larry completed his Bachelor of Ceramic Engineering degree at The Ohio State University in 1961 and his PhD in 1964. Dr. Hench has received almost all the awards in ceramics, materials science and biomaterials that are possible, including membership in the National Academy of Engineering and A CerS' W.D. Kingery Award. He is also a Fellow and Distinguished Life Member of ACerS.


David Greenspan

Greenspan is currently owner of Spinode Consulting, a medical device consulting business. He has served as the vice president of product development for Tutogen Medical and RTI Biologics, chief technical officer and co-founder of NovaMin Technologies, the vice president of research and development and co-founder of USBiomaterials. He began his career with Howmedica, an orthopedic implant manufacturer. He is co-inventor of the NovaMin technology, along with numerous patents for application of bioactive glasses in medicine. His educational background includes a BS in Glass Science from Alfred University and a PhD in Materials Science from the University of Florida. He holds 35 US and International patents and has published and presented scientific papers, with over 40 peer-reviewed publications and more than 65 presentations at international conferences. He is a member of the ASTM F-4 Committee on Medical Devices, as well as a past member of ISO TC 194. He served as Chairman of the External Advisory Board for the Department of Materials Science and Engineering at Pennsylvania State University and is on the External Advisory Board of both Biomedical Engineering and Materials Science and Engineering at the University of Florida.


Steven Jung

Jung graduated from Missouri S&T with a PhD in Materials Science and Engineering in 2010. During his time, he studied bioactive glasses for hard and soft tissue regeneration. Previously, he was a senior research and development engineer at Mo-Sci Corporation, located in Rolla MO, developing glass and ceramic materials for tissue regeneration and other biological applications.


Sunil Saini

Saini has over 12 years of experience in the medical device industry, specifically in the area of regenerative medicine. He currently leads a team of scientists and engineers in developing bone grafting products that encompass a broad spectrum of material technologies including synthetic, human and collagen. Saini received a B.S. degree in Chemical Engineering from the University of Maryland and a Ph.D. in Chemical Engineering from Georgia Tech.


John Brunelle

Brunelle joined BioStructures in April 2012 and has over 12 years of medical device development experience in the areas of sports medicine and orthobiologics. Prior to joining BioStructures, he held management positions at Synovis Orthopedics & Woundcare and Pegasus Biologics where he led the development of biologic-based systems for soft tissue repair. Brunelle started his career at Smith & Nephew Endoscopy developing osteoconductive impants and arthroscopic delivery systems. He holds degrees in mechanical and plastics engineering, as well as a doctorate degree in biomedical engineering from the University of Massachusetts.


William David Hill

Hill is a biomedical research scientist at Georgia Regents University. His research focuses on the use of stem cells in addressing acute and chronic disease. This involves musculo-skeletal injury, including bone defects, orthopedic surgery and osteoporosis. He is targeting ways to modify stem cell niche sites both locally and systemically to improve endogenous stem cell populations and facilitate the engraftment and survival of transplanted stem cells. This includes novel delivery technologies with a current focus on ceramic microspheres. Hill is funded by NIH and the Veterans Administration, has over 69 peer-reviewed publications, serves on 3 editorial boards and is a reviewer for over 20 other journals, has served on numerous grant review panels and holds two patents. He received his PhD in Neurobiology and Anatomy from the Wake Forest University School of Medicine and did his Post-Doctoral fellowship in the Department of Laboratory Medicine and Pathology at the University of Pennsylvania.

Final Program

PANELIST BIOGRAPHIES

Carolyn Primus

Primus, PhD in Materials Science and Engineering, has worked in research and development for the government and private industry. For the last 25 years she has focused on materials for medical devices. She has been awarded 13 patents, 10 in dentistry. Her publications include more than a dozen articles in dental journals and chapters in two dental textbooks. Currently she is a consultant to medical device companies, a reviewer for 4 dental journals, and an adjunct Professor at LECOM in Bradenton, FL. She is also the PI for a SBIR II award and is commercializing her patent pending ideas for dental/medical cements at Avalon Biomed Inc.

Bill Poulson

Poulson earned his BA at the University of Utah. He worked for 12 years in implantable medical devices with Bard Access Systems. For the last six years at BAS, he oversaw the hemodialysis catheter product line and assisted in bringing to market several new product that brought BAS to the forefront of that market segment. Following his tenure with BAS, he joined Ultradent Products, Inc. as their Brand Manager for Endodontic Products where he was able to transform their existing instrumentation system into a novel hybrid approach that addressed many unmet clinical needs. He is currently managing the regenerative technologies portfolio for BIOMET 3i. Emerging technologies in biological and synthetic bone and tissue regenerative products used to support dental implants are current areas of interest.

Gregory Pomrink

Pomrink is an experienced Vice President of Research and Development at NovaBone Products LLC., in an Alachua Florida. Gregory has an MS in Organic Chemistry from Lehigh University and an MBA from Eastern University along with over 25 yrs. of experience in medical device and industrial processing research and development. Mr. Pomrink has a well-rounded medical device background having held key positions at Stryker (Orthovita), Dentsply International and Integra LifeSciences focused on developing materials for dentistry, orthopedics/spine, and neurosurgery along with plastic and reconstructive surgery applications. He has a proven track record of success having been involved in the design, development and commercialization of several class III medical devices. Mr. Pomrink has extensive knowledge of design controls, program management, portfolio development, organic and analytical chemistry in conjunction with materials science and engineering. Gregory is a member of the American Chemical Society, Society for Biomaterials and the Orthopedic Research Society. Mr. Pomrink has 9 US Patents and 4 applications pending along with having filed 10 provisional applications within the last 2 years. In addition, he has more the 20 publications including journal articles, posters and abstracts.

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RAPID-FIRE PRESENTATIONS:

WEDNESDAY, JULY 30, 2014

4:00 – 5:30 p.m. **Room: Emerson Burkhart A&B**

POSTER SESSION

WEDNESDAY, JULY 30, 2014

5:30 – 7:00 p.m.

(BIO-RF-P001-2014) Brazing Characteristics of ZrO_2 and Ti-6Al-4V Active Metal for Dental Implants

Seho Kee, University of Seoul, Korea; Flora Jung, University of Western Ontario, Canada; Youngku Heo, Neobiotech, Korea; Jong-Min Lee, Micro NX, Korea; Wonjoong Kim, Jaepil Jung, University of Seoul, Korea

Active metal brazing is a convenient method of creating a joint of high quality. However, in ceramic/metal joining, the poor wettability of conventional filler metals on ceramics is a critical problem of the brazing method. To improve wettability, active elements such as titanium, zirconium, or hafnium are added to conventional filler metals for the chemical affinity between the active elements and the oxygen in oxide ceramics or the carbon and nitrogen in carbide and nitride ceramics, respectively. ZrO2 and Ti-6Al-4V alloys are the most commonly used biomedical materials and are used especially for dental implants. ZrO2 has high hardness, good corrosion resistance and is biocompatible. Ti-6Al-4V alloy also shows good strength, corrosion resistance and biocompatibility. In this study, brazing characteristics of zirconia and titanium joints using an Ag-Cu-Sn-Ti filler metal was investigated. The brazing sample was heated in a vacuum furnace under 5 x 10-6 torr atmosphere, while the brazing temperature was altered from 700 to 800°C for 30 min. The ZrO2 and Ti-6Al-4V samples were brazed for dental applications using an Ag-Cu-Sn-Ti brazing alloy. The samples were brazed well in the range of 700 ~ 800°C. The microstructure of the brazed joint showed an Ag-rich matrix phase, Cu-rich island shape and two kinds of interfacial intermetallic layers consisting of Ti-Cu-Sn. The thickness of intermetallic layers increased with brazing temperature.

(BIO-RF-P002-2014) Monodisperse, submicron calcium phosphate sphere synthesis in SBF solution at 55°C

A. Cuneyt Tas, University of Illinois, USA

SBF (simulated/synthetic body fluid) solutions, which mimic the blood plasma electrolyte, are developed and historically used for the in vitro testing of synthetic biomaterials at the physiological temperature of 37°C. Calcium phosphate (CaP) forming in an SBF solution can have no cytotoxicity or no issue related to its biocompatibility, if the Tris or Hepes (50 mM), which are not present in human blood plasma, historically used in preparing SBF solutions are also eliminated during the SBF preparation. This study reports how to synthesize monodisperse carbonated CaP spheres (180 to 240 nm in diameter) only by heating a stirred (1000 rpm) SBF solution at 55°C for less than 20 min. Two different Tris- or Hepes-free SBF solutions (of pH 7.4) were developed and both were able to produce such monodisperse CaP spheres. The ion concentrations in such SBF solutions may be multiplied by a factor of 10 to readily increase the yield of CaP spheres. Samples were characterized by SEM, TEM, XRD, FTIR, ICP-AES and BET analyses. Such submicron and monodisperse CaP spheres are suitable for drug delivery, as well as orthopedic and dental applications.

(BIO-RFP-003-2014) Mechanical Analysis of Novel Injectable Cement for Minimally Invasive Treatment of Spinal Fractures

Brett Dickey, Daniel Boyd, Dalhousie University, Canada

An extensive body of literature is devoted to the research for alternatives to conventional injectable acrylic cements indicated for vertebroplasty (VP) and kyphoplasty (KP); procedures for the palliative treatment of vertebral compression fractures. Ideal alternatives are suggested to: i) be injectable for 5-10 min, ii) set within 15 minutes, and iii) exhibit > 30 MPa of compression strength1,2. Aluminum-free glass polyalkenoate cements (GPCs) possess many intrinsic qualities to make them attractive for VP/KP. However, until recently their quick setting nature (c. 2 min) has made them impractical for clinical use. Nascent literature shows the inclusion of germanium in zinc-silicate glasses as the key to improving the clinical utility of these materials3. These Ge based GPCs exhibited working times (a surrogate measure of injectability) up to 10 min, setting times of 15–36 min, matched with 1 day compression strengths of 36–41 MPa. However, the mechanical data of the Ge based GPCs is limited and initial trends indicate significant decreases to < 30MPa after 180 days, hindering the clinical potential of these materials due to impaired long term performance. The objectives of this study are: i) expand the mechanical characterization of the Ge based GPCs, ii) develop mathematical models using design of mixture software to relate the affects of glass composition to GPC mechanical properties, and iii) if these models can be used to mitigate the mechanical decline of maturing Ge based GPCs.

(BIO-RF-P004-2014) Bioactive Ti metal and its alloy with calcium titanate layer releases metal ions effective for bone growth and antibacterial

Seiji Yamaguchi, Shekhar Nath, Takashi Kizuki, Tomiharu Matsushita, Tadashi Kokubo, Chubu University, Japan

The present authors early showed that Ti metal and its alloy form an apatite layer on their surfaces in body environment and bonds to living bone, when they were subjected to NaOH, CaCl2, heat and water treatments to form Ca-deficient calcium titanate on their surfaces. In the present study, various kinds of ions such as Ag+ ion effective for antibacterial effect, and Mg2+, Sr2+, Li+ and Zn2+ ions effective for bone growth were incorporated into the Ca-enriched surface layer. The treated Ti metals released Ag+, Mg2+, Sr2+ and Zn2+ ions slowly up to 7 days in phosphate

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buffered saline, whereas it released Li+ ions rapidly within 3 h due to the formation of soluble LiTi2O4 and Li2Ti2O4. When the treated metals were soaked in a simulated body fluid with ion concentrations nearly equal to those of human blood plasma, all of them formed apatite fully on their surfaces within 3 days. These novel bioactive Ti metal and its alloys could be useful for various types of dental and orthopedic implants.

(BIO-RF-P005-2014) Tetragonal zirconia stabilization in ZPTA ceramic for arthroplasty

Alessandro Alan Porporati, Meinhard Kuntz, Robert Streicher, CeramTec GmbH, Germany

Ceramics are excellently suited for applications in arthroplasty, mainly total hip, knee and shoulder replacement. As the most prominent representative of this demanding type of material, BIOLOX®delta is widely used and very successful in the market for more than 10 years. The ability of zirconia phase transformation (t-ZrO2→m-ZrO2) in zirconia-platelet toughened alumina (ZPTA) ceramics is an indispensable prerequisite for their excellent mechanical properties. The degree of stabilization of the zirconia tetragonal phase at body temperature is essential for the desired toughening mechanism. Y2O3 is the most widely used t-ZrO2 chemical stabilizer; also microstructure and grain size contribute to t-ZrO2 phase stabilization. Stabilization must be achieved such that no material degradation will occur in body environment, i.e. in aqueous liquid (synovia), which is known to potentially trigger phase transformation at the surface of ceramic components. In this study, it is shown how phase stabilization in BIOLOX®delta as a reference material is excellently balanced by means of optimal mechanical performance and environmental stability.

(BIO-RF-P006-2014) Oxide Nano-textured Surfaces Grown from Titanium Alloys for Enhanced Cell Adhesion and Growth

Derek Miller, Sheikh Akbar, The Ohio State University, USA

Recent work has shown that nano-textured surfaces can enhance adhesion and proliferation of bone cells, chondrocytes and bone-derived stem cells to the surfaces of various titanium alloys commonly used as bone and dental implants. The polished titanium alloy surfaces are oxidized in a controlled manner to grow a ceramic layer of oxide nanowires and other nanostructures which provide a better 3D environment on which cells can more readily attach themselves. Electron microscope images have shown a strong interaction of both kinds of cells and the nano-textured surfaces, latching onto and infiltrating into the structures as well as growing in a more three-dimensional manner than the control cells grown on the polished alloy. Enhanced cell proliferation has been shown in human osteosarcoma (HOS) and chondrocyte joint cells grown on the oxide nanowire surfaces. The method of growth is very inexpensive and highly scalable. The method has also proven successful on titanium alloy films sputtered onto ceramic substrates. Ongoing work is also applying these growth methods to new titanium alloys being developed for biomedical implant applications at Ohio State University.

(BIO-RF-P007-2014) The use of ceramic-to-metal seal technology in implantable devices

Emma Gill, Morgan Advanced Materials, USA; John Antalek, Chris Vaillancourt, Stephen Gilbert, Morgan Advanced Ceramics, USA

Implantable electronic biomedical devices are used clinically to diagnose and treat an increasing number of medical conditions ranging from life threatening heart complaints to profound deafness and obesity. The devices employ hermetic packages that often incorporate electrical feedthroughs made with ceramic-to-metal bonding technologies which are described herein. The feedthrough component allows electrical signals to be transferred into and out of the device. Both hermeticity and biocompatibility of such implantable feedthroughs are important, as both moisture and positive mobile ion contamination from the saline environment of the human body can lead to compromised performance or catastrophic failure. As such, all the materials chosen for the feedthrough must be biocompatible, non-porous and not susceptible to degradation but, in addition, the individual materials are chosen to perform specific functions. The feedthroughs discussed consist of platinum conductors, alumina ceramic insulators and a titanium flange to attach the feedthrough to the rest of the device. Typically there are one or more alumina ceramic components that insulate the Pt conductors from one another and from the Ti flange. These can be in the form of 95%+ polycrystalline Al203 ceramics or single crystal synthetic sapphires. Morgan Advanced Materials has two technologies for manufacturing implantable feedthroughs. The brazing technology utilizes a thin film metallization applied to the ceramic to allow gold braze to wet and bond to the ceramic component. Morgan has also developed an innovative high density feedthrough (HDF) technology where the Pt conductors are bonded directly to the alumina. The term “high density” denotes the high concentration of conductive pathways in a given area compared to what is possible with traditional feedthrough technologies. The fabrication process utilizes multilayer high temperature co-fired ceramic technology in conjunction with platinum leads. Before co-firing, green alumina substrates are interleaved with linear, parallel Pt trace arrays. During sintering the shrinkage experienced by the ceramic, along with a reaction between alumina and Pt, create a hermetic bond between the two components. The implementation of such an HDF technology allows for significant package miniaturization, allowing greater flexibility in surgical placement as well as less invasive procedures for implantable electronic biomedical devices. HDFs fabricated using this process with 100 conductors and lead-to-lead spacings as low as 400 microns have been helium leak tested repeatedly and found to exceed industry-accepted standards with helium leak rates in the range of 10^(–11) mbar-l/s.

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(BIO-RF-P008-2014) Longitudinal Evaluation of Bioactive Strip Implanted into the Distal Condyle of New Zealand White Rabbits

Zehra Tosun, NovaBone, USA

Twenty-four (24) NZW rabbits randomly assigned to three (3) study groups (8 per group) underwent bilateral surgery to create a critical sized defect in the distal femoral condyle. The animal's left leg received the Test and the contralateral side (the animal's right leg) received the Control Device. Histopathologic and histomorphometry evaluation found both materials to be substantially equivalent in the ability to induce new bone formation in and around the defect. Defects implanted with the test article showed a statistically significant increase in new or native bone in and around the defects at Day 83 compared to those treated with the control device and the mean measured percent of native or new bone in defects was significantly greater at Day 83 compared to Day 22. Residual implant material in the defect decreased significantly over time for both devices and by the final necropsy interval the amount of residual implant material was comparable between defects treated with either of the two devices. Mechanical compression testing indicated that both materials were substantially equivalent 3 weeks following surgical implantation. At 6 and 12 weeks, maximum load, stiffness, maximum compressive stress, and elastic modulus values for specimens treated with the Bioactive Strip Test Device were significantly higher than for those treated with the predicate Control Device. Mechanical compression testing indicated that both materials were substantially equivalent 3 weeks following surgical implantation. At 6 and 12 weeks, maximum load, stiffness, maximum compressive stress, and elastic modulus values for specimens treated with the Bioactive Strip Test Device were significantly higher than for those treated with the predicate Control Device.

The in vivo performance of the BIOACTIVE Strip 510(k) subject device is substantially equivalent to that of the predicate NovaBone Porous device (K090731/K060432) as demonstrated by implantation in a rabbit model.

(BIO-RF-P009-2014) Cytotoxicity Testing of Aluminum Magnesium Boride Powders for Medical Implant Applications

Matthew Little, South Dakota School of Mines & Technology, USA; Peter Hong, New Tech Ceramics, Inc., USA; Grant Crawford, South Dakota School of Mines & Technology, USA

Wear failures remain a common failure mode of load bearing implants with articulating surfaces. The novel ultra-hard ceramic AlMgB14, also known as BAM, offers a new perspective for reducing wear of load bearing surfaces. BAM is extremely lightweight, is the third hardest material on earth, and has a very low coefficient of friction. We report on the relationship between BAM processing/composition and in vitro cytocompatibilty behavior. Three BAM powders of varying composition and processing (i.e. AlMgB14, AlMgB14 + TiB2, and AlMgB14 + TiB2 densified powder) were first characterized using standard materials characterization methods and subsequently subjected to in vitro cytocompatibility testing in the presence of bone cells (mouse pre-osteoblasts). In addition, solid BAM samples (i.e. AlMgB14 and AlMgB14 + TiB2) were subjected to direct contact in vitro cytocompatibility testing. The results of this study show that BAM is indeed a promising material for biomedical application, especially applications requiring excellent wear resistance.

(BIO-RF-P010-2014) Nanodiamond for Sensing Applications

Nirmal Govindaraju, Jonathan Gonzales, Marshall Harrup, Raj Singh, Oklahoma State University, USA

Diamond is a chemically inert material with high thermal conductivity, Young's modulus, and dielectric breakdown strength which can be functionalized for selective attachment of molecules to its surface. Nanodiamond pillars (NDPs) by virtue of their structure can function as "cantilevers" with distinct resonant frequencies and are well-suited for biological and chemical sensor applications. The resonant properties of NDPs have an intimate relationship with the synthesis conditions and microstructure. Therefore, it is important to delineate the differences in microstructure evolution and phase purity for NDP structures fabricated under different diamond synthesis conditions. This presentation explores two approaches for NDP fabrication – "top-down" and "bottom-up". The "top-down" approach utilizes selective etching by inductively coupled plasma to realize patterned diamond structures on Si substrates. The "bottom-up" approach relies on selected area deposition of diamond on Si to achieve the same result. Three different gas phase chemistries, 99% H2: % 1 CH4, 60%Ar: 39% H2: % 1 CH4, and 85%Ar: 14% H2: % 1 CH4, spanning the microscrystalline and nanocrystalline regime will be used for fabrication. Scanning electron microscopy and Raman spectroscopy results will be shown in order to compare and contrast the microstructure and phase purity of the fabricated structures. These results will lay the foundation for the development diamond-based sensor technology for biological and chemical substance detection applications.

(BIO-RF-P011-2014) Biomimetic Bone Prepared via a Polymer-Induced Liquid-Precursor (PILP) Mineralization Process

Douglas Rodriguez, Laurie Gower, University of Florida, USA

Bone is a hierarchical organic-inorganic composite, which at the nanostructural level consists of an assembly of collagen fibrils that are embedded with uniaxially-aligned nanocrystals of hydroxyapatite. Our in vitro studies have shown that bone's nanostructure can be reproduced using a polymer-induced liquid-precursor (PILP) mineralization process, where the polymeric additive consists of acidic polypeptides (e.g. polyaspartic acidic) or proteins (e.g. osteopontin) that mimic the action of non-collagenous proteins found in bone. The high charge density of the polyanionic additive sequesters ions such that liquid-liquid phase separation occurs, forming nanodroplets of a hydrated amorphous mineral precursor that can infiltrate into the interstices of collagen

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fibrils, leading to an interpenetrating organic-inorganic composite that emulates bone's nanostructure. Through optimization of reaction parameters, compositions matching bone (60-70 wt% mineral) have been achieved in a variety of collagen scaffolds, including both reconstituted type-I collagen and biogenic (bone, dentin, tendon) matrices. We believe that by mimicking the hierarchical structure of bone from the nano- to micro-structural level, it will be possible to match the mechanical properties of bone. Therefore, our current studies are directed at assembling parallel-fibered collagen which can be mineralized in the form of laminated composites, mimicking the lamellar microstructure of bone. With respect to bioactivity, we have found that cell signaling mechanisms provided by the osteopontin additive may provide a means for modulating osteoclast activity, thus providing a means for tailoring the resorption rate of these bone-like composites. The long-range goal of these studies is to prepare bioresorbable load-bearing bone substitutes that can be remodeled through the natural bone remodeling unit (BRU). As opposed to the common approach of using biodegradable implants, which require careful matching of the degradation rate to bone ingrowth, are goal is to modulate the synchronized activity of the multicellular BRU, which would then enable load-bearing capacity to be maintained throughout the remodeling of the implant, as occurs during natural bone remodeling.

(BIO-RF-P012-2014) Fabrication of dipyridamole loaded core-shell polycarbonate urethane nanofibers membranes by coaxial electrospinning for antiplatelet application

Yuansen Qin, The First Affiliated Hospital of Sun Yet-sen University, China; Yong Zhao, Beihang University, China; Zuojun Hu, The First Affiliated Hospital of Sun Yet-sen University, China

Introduction: The patency of synthesis small diameter vascular graft is still far from satisfaction due to acute thrombosis and intimal hyperplasia. To improve hemocompatibility, antiplatelet drug dipyridamole (DIP) was encapsulated in polycarbonate urethane (PCU) core-shell nanofibers mats by coaxial electrospinning.

Methods: PCU solution and DIP/ polycaprolactone compound solution served as sheath and core fluid respectively for coaxial electrospinning process. Three groups of nanofibers with different core fluid flow rate were prepared. Surface morphology and internal structure were characterized by scanning electron microscope (SEM) and transmission electron microscope (TEM), respectively. Physical state and distribution of DIP in nanofibers were detected by differential scanning calorimeter (DSC) and X-Ray diffraction (XRD). Drug release profiles and platelet adhesion test were tested in vitro.

Results: Coaxial electrospinning process was conducted smoothly and continuously under selected conditions. SEM and TEM photographs showed that linear fibers without beads was fabricated and clear core-shell structure was generated. The diameter of nanofibers and core structure increased with the flow rate of internal solution. DSC and XRD revealed that the whole system formed solid dispersion and DIP was dispersed in polymer matrix in an amorphous state. In vitro drug release test presented that the profile had two phases consist of Initial burst release (16.1±1.1%, 53.6±2.6% and 76.4±3.9%, $p<0.05$) and sustained release govern by the first Fick's law and the diffusion mechanism. A more flat curve occurred when the diameter of PCU sheath increased since PCU sheath worked as a barrier restricted DIP release from core drug reservoir. Platelet adhesion text in vitro demonstrated that DIP maintained its antiplatelet effect after coaxial electrospinning process and could present distinguished antiplatelet activity (401±107, 11842±1299 and 26552±3642/ mm2, $p<0.05$) on the 30th day.

Conclusion: DIP loaded core-shell nanofibers mats with good hemocompatibility was fabricated conveniently by coaxial electrospinning, which has great potential in the field of tissue engineering vascular graft.

(BIO-RF-P013-2014) The Potential of Nanostructural Ca-Aluminate based Bioceramics within Odontology

Leif Hermansson, Applied Research Sweden AB, Sweden; Emil Abrahamsson, Doxa Dental Inc., USA

The presentation deals with the chemically bonded Ca-aluminate based bioceramics (CA) and their potential within odontology. Nanostructures including nanocrystals and nanoporosity are easily formed in the CA-system due to a low solubility product of the phases formed. The CA materials were synthesized by Doxa AB. Added phases were glasses or ZrO2 depending on the intended applications. For early hardening a glass ionomer can be used. The nanostructures have been studied using HRTEM in combination with focused ion beam microscopy (FIB) for site-specific accuracy preparation (Ref. 1). Mechanically related properties (flexural strength, compressive strength, fracture toughness and Young´s modulus) and biologically related properties (biocompatibility, bioactivity, tissue integration and antibacterial properties) were evaluated using ISO Standards. The nanostructures contribute to high mechanical strength, and complete sealing of contact zones to surrounding materials. Practically related properties deal with 1) Nanostructural integration with reduced risk of secondary caries and restoration failure, 2) Dimensional stability (no shrinkage) and reduced post-operative sensitivity, 3) Environmental friendliness, 4) Moisture tolerance, and 5) Excellent retention towards different types of tissues and biomaterials. The CA-based bioceramics are close in chemistry to apatite, and the thermal and electrical properties are close to those of hard tissue. Refs. 2-3. Several dental products have been identified based on material data, pre-clinical and pilot studies, and on-going clinical studies; Dental cements, endodontic sealer, bases, restoratives, stabilising materials related to peri-implantitis, and pastes for augmentation, and as coating materials.

Supported by Doxa AB, Sweden.

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(BIO-RF-P014-2014) Nanomaterials for Biomedical Applications

Cheol Woon (CW) Kim, MO-SCI Corporation, USA

Porous-wall hollow glass microspheres (PWHGMs) are a novel form of glass material consisting of a 10 to 100 μm diameter hollow central cavity surrounded by a 1 μm thick silica shell. A network of nanometer-scale channels (10 to 300 nm diameter) completely penetrates the shell. Morphology and potential biomedical applications will be discussed. Surface-enhanced Raman scattering (SERS) active particles can be produced from a sol-gel process. They are silica-encapsulated gold nanoparticles attached with Raman-active optical reporter molecules and can be used for rapid diagnosis of diseases. The features of these SERS particles will be discussed.

(BIO-RF-P015-2014) Cell behavior on etched, crystal-containing poly(propylene fumarate) scaffolds for bone tissue engineering

Ruchi Mishra, Rachel Fishbein, Tyler J. Bishop, Ryan S. Sefcik, Briana A. Swan, The Ohio State University, USA; Martha O. Wang, John P. Fisher, University of Maryland, USA; David Dean, The Ohio State University, USA

Light-based 3D printed poly(propylene fumarate) (PPF) scaffolds for bone regeneration have smooth, somewhat hydrophobic surfaces. Previous studies have shown an osteogenic effect from incorporating hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP) crystals. We added 100 nm, 1 μm, 10 μm or 100 μm size β-TCP and HA crystals to PPF scaffolds. We analyzed canine mesenchymal stem cell spreading via scanning electron microscopy at 4 hours and attachment via MTT assay at 48 hours. We observed a parabolic pattern for cell spreading with values increasing from 12.8 ± 3.7 μm and 11.1 ± 1.6 μm in the β-TCP and HA 100 nm groups, respectively, to 13.4 ± 6.1 μm and 24.1 ± 4.7 μm at 10 μm, and declined in both 100 μm crystal groups. Cell attachment showed a serially decreasing trend from 100 nm to 100 μm groups. The values for 100 nm HA and β-TCP were 0.16 ± 0.03 absorbance units (AU) and 0.14 ± 0.02 AU, respectively, while, the 100 μm values were 0.09 ± 0.02 AU and 0.08 ± 0.00 AU. We conclude: 1) cell spreading presented a parabolic pattern, peaking at the middle crystal sizes (1 and 10 μm), 2) cell attachment showed a serial downward trend.

(BIO-RF-P016-2014) Ion substituted nano CaP bone replacements with extended antibacterial activity

K. Madhumathi, T S Sampath Kumar, Rubaiya Y, Mukesh Doble, Indian Institute of Technology, India

Biomaterials with sustained antibacterial activity are highly beneficial when used as bone substitutes in bone and dental infections. Antibiotic loaded calcium phosphate nanoparticles such as hydroxyapatite (HA) and calcium deficient HA (CDHA) are efficient antibacterial bone fillers. Ions like zinc (Zn), strontium (Sr) and silver (Ag) have well known antibacterial activity. Substitution of such ions into HA/CDHA crystal structure endows them with inherent antibacterial potential independent of antibiotic drugs. Thus, the antibacterial activity of these nanoparticles extends long after the antibiotics are released. In our study, doxycycline was used as model drug to study the effect of ion substitutions in CDHAs on loading and release kinetics. An initial burst release followed by controlled release was observed from ion substituted CDHA which was established by an increase in antibacterial activity compared to pure CDHA. Our studies indicate that drug releasing ion substituted CDHAs can provide long-term protection against hard tissue infections.

(BIO-RF-P017-2014) Treatment of Connective Tissue Wounds with Bioactive Borate Glass Fibers

Steven Jung, Mo-Sci Corporation, USA

Bioactive borate glasses with angiogenic and healing properties were fabricated into nanofibers that mimic the microstructure of a fibrin clot for healing wounds. Several examples including traumatic acute wounds and also chronic non-healing wounds are shown before and during treatment in both humans and animals as examples of the fibers versatility. While wound closure in most examples is dramatic, the reduction in treatment time associated with these wounds is also significant. The wounds treated to date have been diverse, and include the lower leg, bottom of foot (front pad), the heel of the foot, the neck, the lower back, the upper chest (breast), and upper thigh in human patients. In the veterinary space, the fiber has been used to treat gunshot wounds, severe lacerations, jaw bone augmentation after tooth extractions, and damaged shells of sea turtles. The regenerated tissues typically have minimal scarring and the original defect area is difficult to detect visually once treatment is complete. The composition of the glass along with the fibrous microstructure of the pad mimic the initial stage of wound healing (formation of a fibrin clot) and stimulate the growth of new blood vessels to the area treated. The introduction of this fibrous microstructure appears to transform chronic wounds to acute wounds while soluble ions released from the glass aid in the healing process.

WEDNESDAY, JULY 30, 2014

5:30 – 7:00 p.m.

(BIO-P018-2014) Influence of surfaces treatments, cements and aging on bond strength of Y-TZP ceramic

Lais Regiane Silva Concilio, University of Taubaté, Brazil; Marcelo Massaroni Peçanha, University Federal of Espirito Santo, Brazil; Cristiane Aparecida De Assis Claro, Ana Christina Claro Neves, University of Taubaté, Brazil

Objectives: Evaluate the influence of different surface treatments and aging on the bond strength of a phosphate (P) and self-adhesive (SA) resin cement using a yttria-stabilized zirconia (Y-TZP) ceramic material (Lava, 3M ESPE). Methods: One hundred Y-TZP blocks were divided in five groups according to surface treatments: 1-control (no treatment); 2-airborne-particle abrasion with 50-µm Al2O3; 3- tribochemical silica coating; 4-MDP primer and 5- tribochemical silica coating+MDP primer. Each group was divided into two subgroups (n=50), according to the luting agent: SA (RelyX U200, 3M ESPE) and P (Panavia F 2.0, Kuraray). The cements were manipulated according to manufacturer recommendations, placed into plastic tubes on the surface of the Y-TZP ceramic blocks and photoactivated. Half of samples (n=25) were submitted to the aging process (thermal cycling–3.000 times). The bond strength test was conducted and data were statistically analyzed using ANOVA and t Student's tests ($p<0.05$). Results: Before aging for P cement the silica coating (3) and silica coating+primer (5) presented the highest bond strength values (30.52MPa and 29.15MPa); For SA cement, the values did not showed significant differences; comparing the luting agents, there was no statistical difference between them, except in the control group where SA presented a higher value (26.05MPa) when compared to P (20.02MPa). After aging, all bond strength values decreased; P cement the silica coating (3) and silica coating+primer (5) showed highest values (16.36MPa and 15.73MPa); SA cement, there was no statistical difference between the groups except in the control group, which showed the worst result (9.78MPa); luting agent influenced significantly the bond strength values, being that SA cement showed higher values for all surface treatment when compared to the P cement. Conclusions: Aging decreased all bond strenght values for the two luting agents (P and SA); Silica coating provided better results and was considered an essential surface treatment for Y-TZP ceramic, when using P cement; for the SA cement, the surface treatment increased its complexity and may not be necessary because it had little influence on the bond strenght.

(BIO-P019-2014) The fabrication of new zirconia-based dental implants and the evaluation of their osseointegration using a mini-pig

Sheng-Yang Lee, Taipei Medical University, Taiwan; Jen-Chang Yang, Taipei Medical University, Taiwan; Sea-Fue Wang, Chung Kuang Yang, National Taipei University of Technology, Taiwan;

Zirconia implants with modified surface-treated and non-treated were used and compared to implants made of commercially titanium with surface-treated. Experimentally, zirconia implants were introduced into the maxilla and mandible of 10 mini-pigs. These ten mini-pigs were divided into 2 groups for sacrifice after implantation, for 8 weeks and 16 weeks. The implants could be analyzed to following. They are resonant frequency (RF) testing for implant stability, bone to implant volume (BIV%) analysis using Micro-Computed Tomography (Micro-CT). After that the samples were sectioned and analyzed bone to implant contacts (BIC) by scanning electron microscopy (SEM) and Masson Goldner's stain were used to evaluate osseointegration.

At the resonant frequency stability analysis, in the 8 weeks group, majorly showed that upper Zr surface-treated group were better. 16-week group is no statistically significant difference; while the detection time point, the upper Zr surface-treated and Zr surface-untreated which at the 16 weeks were better than 8 weeks group. BIV showed that, in maxilla, 8 weeks and 16 weeks showed Zr surface-treated better than Zr surface-untreated, in mandible, titanium SLA group were better than Zr surface-untreated. BIC either 8 weeks, 16 weeks, SEM or Masson Goldner, are displayed in the maxilla, Zr surface-treated and titanium SLA were no statistically significant difference, and Zr surface-treated were better than Zr surface-untreated. Also, we observed that tissue sections in Masson Goldner staining, more sponge bone and the non-calcified bone were red color in 8 weeks group; also can be observed at week 16 the green mature bone calcification noted, and Zr surface-treated group can find more lamellar bone.

The results demonstrated that zirconia implants with modified surfaces result in a well osseointegration that is comparable with that of titanium implants. Simultaneously, the results from our study suggest that zirconia implants with modified surfaces display good features of osseointegration especially into the bone loss maxilla.

Notes

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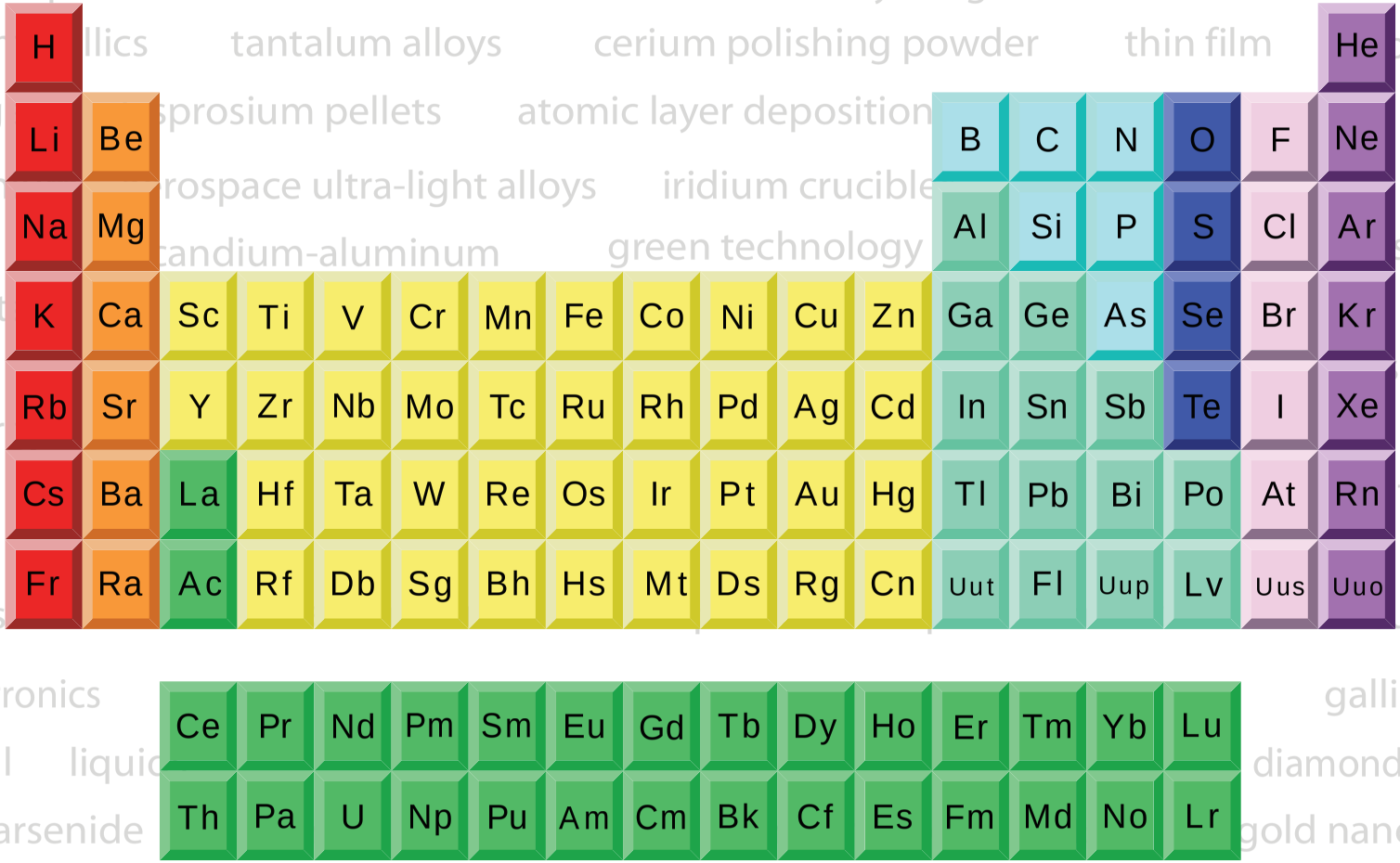

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