KEYNOTE ADDRESS

MATERIALS INNOVATION: DRIVING THE REVOLUTION IN CARDIOVASCULAR INTERVENTIONS

ELAZER EDELMAN, MD, PHD

Dr. Elazer Edelman is the Thomas D. and Virginia W. Cabot Professor of Health Sciences and Technology at MIT, Professor of Medicine at Harvard Medical School, and a coronary care unit cardiologist at the Brigham and Women's Hospital in Boston. He and his laboratory have pioneered basic findings in vascular biology and the development and assessment of biotechnology. Dr. Edelman directs the Harvard-MIT Biomedical Engineering Center (BMEC), dedicated to applying the rigors of the physical sciences to elucidate fundamental biologic processes and mechanisms of disease. BMEC programs span a wide range of disciplines, with its resources made available to investigators from MIT and Harvard.

His research melds his clinical and medical training and interests, focusing on understanding how tissue architecture and biochemical regulation contribute to local growth control. Edelman and his students were among the first to validate the hypothesis that proliferative vascular diseases are the sum of effects from endogenous growth promoters and suppressors. Their characterization of how heparin-like compounds serve as suppressors and heparin-binding growth factors as promoters contributed to the creation of a rigorous framework by which to appreciate how these agents interact with one another in vivo. Additional studies enabled further definition of the nomenclature and kinetics for the FGF-2 receptor complex, characterization of synergy between many growth factors, and demonstration that the mode of growth factor or inhibitor delivery determines biologic effect. The applied aspects of their work flow from the umbrella of growth modulation. They reasoned that the optimal way to control a biologic event was by recapitulating natural means of regulation. Hence, polymeric controlled drug delivery systems should mimic natural release systems, and vascular implants should be devised with an intimate knowledge of the injury they induce. The development and mathematical characterization of perivascular and stent-based drug delivery is an example of the former, and design of an endovascular stent from first principles is an example of the latter. The basic and applied aspects of his operation are intimately joined. Work with antisense oligonucleotides, HDL receptor biology and tissue engineered endothelial implants are a few examples where these two fields come together in his laboratory. Many of his findings are now in clinical trial validation.

SYMPOSIA

A Symposium is designed to focus our attention on a specific topic within the large disciplines that make up the Society's membership. The symposium highlights a well-defined topic that is not addressed by the regular sessions of the annual meeting. The format includes a lead speaker followed by related abstracts. The lead speaker either presents the current concepts of the topic or presents cutting-edge research within the area.

Animal Models for Biomaterial and Medical Device Testing
Contributing SIG: Cardiovascular SIG
Invited Speakers: Allison Hayward and Butch Stanley

Chairs: Natalie Artzi and Vipul Dave

The advent of novel biomaterials has ushered in a renaissance in innovative interventions. The composite nature of these devices offers the promise of melding of advances in materials science, pharmacology, tissue engineering and drug delivery. Yet, it also heralds the possibility of complex interplays that govern efficacy and induce unanticipated and counterintuitive toxicity. Animal model systems have therefore risen in importance and sophistication to the development, industrial, academic and regulatory communities. This symposium will feature presentations that cover state-of-the-art developments in animal model systems for biomaterials and emerging medical devices and promises to be of great interest to a range of SIGs including those with interest in pathology, drug delivery, tissue engineering, and cardiovascular biomaterials.

Benchtop Tissue Surrogates to Model Drug Uptake and Efficacy
Contributing SIGs: Drug Delivery, Tissue Engineering
Invited Speaker: Anthony Bahinski, PhD, MBA, FAHA

Chairs: Julie Barbick and Brian Wamhoff

There is a clear need to move away from animal models when determining drug uptake and efficacy of drug eluting devices and other drug delivery technologies. Tissue surrogates and models are starting to be used for early feasibility work in lieu of animal studies. Benchtop models can reduce time and cost, increase sample size and statistical significance, and avoid ethical issues surrounding in vivo studies. Engineered systems can be used in testing new technologies which interact with healthy, healing, diseased, or cancerous tissues, among others. Regulatory bodies are also looking for non-animal testing protocols for drugs and devices, meaning that benchtop systems used in feasibility work may one day be used for data to support introduction to the market. These benchtop models should accurately predict in vivo results in order to be accepted by the field.

Biologically Derived Materials from Natural Resources
Contributing SIGs: Drug Delivery, Orthopaedic Biomaterials, Tissue Engineering

Invited Speaker: Nuno Neves

Biologically derived polymers and composites offer excellent opportunities in the biomaterials field. This versatile class of materials includes biopolymers (polyhydroxy alkanoates, hyaluronic acid), polysaccharides (starch, chitin/chitosan, alginate) or proteins (collagen, fibrin, silk fibroin) enabling developing engineered systems with enhanced biological performance. The innovative use of its characteristics, taking advantage of the similar structure or composition with respect to biological tissues, enables designing high performance solutions for biocompatibility, biodegradability and bioactivity of biomaterials. Also the advanced areas of tissue engineering, drug delivery and smart/active/adaptative systems may benefit from the wealth of natural polymers existing in nature.

Biologically Inspired Biomaterials Approaches for Cancer Research
Contributing SIG: Tissue Engineering
Invited Speaker: Delphine Gourdon

Chairs: Claudia Fischbach and Hyung Joon Kong

Microenvironmental conditions play an important role in the development, progression, and therapy of cancer, and biomaterials may be invaluable in the generation of more appropriate culture models that will help to identify the underlying mechanisms and effects. This session will focus on the design and utilization of biologically inspired model systems to gain a better understanding of the pathology and treatment of cancer. It will highlight biomaterials in the context of cell and tissue engineering to evaluate tumorigenesis as a function of specific cell-microenvironment interactions including but not limited to cell-cell and cell-extracellular matrix interactions and mechanical cues. Additionally, it will provide a forum to evaluate tumor-mimetic culture models as drug testing systems for industrial applications. This session will provide a communication platform for biomaterials scientists and cancer biologists interested in the development and utilization of innovative and biologically relevant culture microenvironments.

Biomaterial Microenvironment for Stem Cell-Based Cartilage and Intervertebral Disc Regeneration
Contributing SIGs: Engineering Cells and Their Microenvironments, Orthopaedic Biomaterials, Tissue Engineering
Invited Speaker: Robert L. Sah

Chair: Peter Ma

Traumatized and diseased joint cartilage and intervertebral discs (IVD) are leading causes of disability. Tissue engineering opens a new avenue to the biological repair of these tissues. However, the engineered tissues remain not satisfactory for clinical applications. Biomaterials may be designed as advanced microenvironment to facilitate stem cell differentiation for tissue regeneration. This symposium will focus on novel scaffold/template material design for cartilage and intervertebral disc regeneration.

Biomaterials Design and Tissue Engineering via Synthetic Biology
Invited Speaker: Timothy K. Lu

Chair: Chao Zhong

Synthetic Biology is an emerging interdisciplinary field that seeks to apply principles of chemistry and engineering to important biological processes. This field promises new opportunities in designing novel biomaterials, advancing tissue engineering, and contributing to nanomedicine. This session is designed to introduce the biomaterials community to this emerging field by focusing on promising applications of synthetic biology to biomedical-relevant research and to stimulate new ideas at the interface of synthetic biology and biomaterials. Accordingly, multidisciplinary abstracts are particularly encouraged. Potential topics include but are not limited to: (1) Reprogramming the genetic code

to produce new materials such as peptide, proteins and carbohydrate-based biomaterials (2) Synthetic Biological strategies for treating genetic and infectious diseases (3) Directed-evolution strategies applied to biomedical applications such as the discovery of new biomaterials and the delivery of therapeutic genes (4) Cell-reprogrammed tissue engineering (5) Application of genetic circuits in biomedical research (6) Synthetic Biology-enabled nanomachines, robots, and biosensors (7) Synthetic Biology-enabled stem cell engineering (8) Industrial manufacture of biomaterials via synthetic biology.

Biomaterials for Cardiac Repair
Contributing SIG: Tissue Engineering
Invited Speaker: Smadar Cohen

Chairs: Karen Christman and Milica Radisic

Biomaterial scaffolds have the potential to offer new therapies for a variety of cardiac repair applications including myocardial infarction, heart failure, and congenital defects. While numerous clinical trials with injected stem cells are ongoing, this approach continues to be limited by poor cell retention and survival. Biomaterial scaffolds are expected to enhance these cellular therapies by improving the structural and functional repair of the heart as well as offer acellular alternatives that encourage endogenous cell infiltration and repair. The aim of this symposium is to bring together leaders in the field of cardiac tissue engineering and biomaterials to present recent innovative approaches and discuss challenges related to both cellular and acellular approaches for repairing and regenerating the myocardium. Both patches and injectable scaffolds for treating various cardiomyopathies, such as myocardial infarction, heart failure, and congenital defects, will be covered.

Biomaterials in the Forth Dimension – Controlling Temporal Properties
Contributing SIG: Engineering Cells & their Microenvironment
Invited Speaker: Kristi Anseth

Chairs: Jason Burdick and Bill Murphy

Dynamic cell-biomaterial interactions play a critical role during wound healing, development, and new tissue formation. Understanding and harnessing the dynamics of cell-biomaterial interactions is a highly challenging, but critically important frontier in biomaterials science. This symposium will highlight strategies to design biomaterials that change their properties in a predictable or even programmable manner, resulting in temporally regulated cell behavior. This may encompass changes in material mechanical properties, the presence of adhesive ligands, the delivery of molecules from a material, or the surface charge of a material at an interface with cells. It is expected that the symposium will cover novel chemical synthesis, material characterization, and in vitro and in vivo environments.

Nanostructured Biomaterials and Porous Scaffolds
Contributing SIGs: Drug Delivery, Orthopaedic Biomaterials, Tissue Engineering
Invited Speaker: Rui Reis

Chairs: Nuno Neves and Rui Reis

The topics covered in the symposium will span from micro- and nano-particles developed to obtain injectable systems for controlled and sustainable release of drugs and bioactive molecules, to nanofibre-based biomaterials obtained by electrospinning, hydrogels and patterned surfaces to generate and explore specific functionalities or to explore self-assembling systems following bottom-up strategies as analogues of the biological processes. This forum will unfold the unique properties of the biomateriais at the nanoscale and the opportunities derived from the control of its structure at the submicron and micron level. Namely, the possibility to design materials mimicking the extra-cellular matrix or interacting with this milieu at the same scale, the new routes of gene therapy enabled by systems internalized by the cells and tailored to play an active role in the intra-cellular space or the ability to construct surfaces that not only have controlled activity but also have the ability to tailor smart, active, addaptative, signalling and functional activities of the materials when in contact with cells and biological fluids.

Stem Cell Biomaterial Interactions
Invited Speaker: Christopher Chen

Chairs: Treena Arinzeh and Jeremy Mao

Stem cells are a promising cell source in the tissue engineering field. Stem cells may be derived from embryonic, nonembryonic/adult sources or derived from adult somatic cells that can be genetically reprogrammed. Recent advances have shown that the microenvironment can influence stem cell self-renewal and differentiation. This session will feature presentations that describe studies examining the influence of biomaterials on stem cell behavior.

The Role of Antioxidants in Biomaterials
Invited Speaker: Mohamad Al-Sheikhly

Chairs: Venkat Narayan and Anuj Bellare

In recent years, antioxidants have begun to play a significant role in biomaterials applications, such as in orthopedic implants, ophthalmology, stents, drug delivery, medical tubing,

tissue engineering constructs and several other biomedical applications. For example, Vitamin E or alpha-tocopherol and a synthetic hindered phenol are now FDA approved for use in polyethylene components of orthopedic implants, butylated hydroxytoluene is often incorporated into polyethylene oxide to prevent degradation, and antioxidants are grafted onto degradable polymers to modulate the biological response of degradation products of tissue engineering scaffolds. In this symposium, studies will be presented on the mechanisms of in vitro and in vivo oxidative degradation in biomaterials, synthetic and processing routes to incorporate antioxidants into biomaterials, the efficacy of antioxidants in preventing oxidation in permanent implants or in tissue as they are released from resorbable polymers, in vitro aging methods to assess oxidation in biomaterials, biocompatibility of antioxidants and related topics.

Wound Dressings That Do More Than Covering the Wounds
Contributing SIG: Surface Characterization and Modification
Invited Speaker: Terry Treadwell

Chairs: Shrojal Desai and Ankit Agarwal

More than 5000 new research articles are published on wound healing every year, bringing attention to the clinical need for improved wound care dressings and surgical devices. This session will discuss advanced biomaterials in development for wound dressings and their role in establishing and maintaining optimal wound environment, preventing microbial wound infections, and regenerating tissue growth. Abstracts for this symposium can be related to: (1) Biomatrices and scaffolds for wounds; (2) Microfilm or nanofilm dressings; (3) Microbead or nanoparticle-based dressings; (4) Bioactive dressings containing antibacterial agents or growth factors, and; (5) Tissue adhesives for wound closure. The structural and material properties of these products under development, as well as their potential clinical use in addressing burns, acute wounds, surgical wounds, or chronic wounds, will be discussed from the scientific and clinical perspectives. The session will also discuss possible combinations of therapies to achieve desired outcome of complete wound closure.

GENERAL SESSIONS

A General Session is a topic that is familiar to the general membership. Abstracts reflect the most current research in that field.

Advances in Drug Delivery for Regenerative Medicine
Contributing SIG: Drug Delivery

The tunable release of bioactive agents is a critical feature of nearly all regenerative medicine strategies. In this session, exciting advances in the design of biomaterials for controlled drug delivery related to wound healing and growth factor delivery are presented.

Advances in Ophthalmic Biomaterials and Ocular Drug Delivery
Contributing SIG: Ophthalmic Biomaterials

Ophthalmic biomaterials arena is a rapidly growing area for advanced biomaterials research with wide-spread clinical applications. The demand for advanced ophthalmic care (non-elective procedures such as cataract surgery, glaucoma surgery, age-related macular disease treatments) is growing at a rapid pace. The 2013 SFB meeting, will present on the progress of biomaterials research toward next-generation ophthalmic care. The scope of the session will encompass novel biomaterials technology, ocular drug delivery, and implant pathology in the ophthalmic arena.

Advances in Polymeric Nano-/ Microparticle Formulation Techniques
Contributing SIG: Drug Delivery

Biodegradable polymeric nano-/ microparticles have shown great promise as delivery vehicles for organic drugs, proteins, and nucleic acids. These delivery systems have a wide range of biomedical applications, including chemotherapy, imaging, protein/gene delivery, and vaccines. This session will review recent advances in formulation technology that can yield well defined particles with consistent drug loading and release characteristics. These polymer-based formulations include micro-/ nanospheres, hydrogels, and micelles, and particles with stimulus-responsive properties. One of the aims of this session is to promote dialog between academic and industrial researchers on the topic of advanced microparticle formulations and their potential for clinical translation.

Advances in Tissue Engineering Scaffolding

The complex architecture and cellular organization of natural tissues suggests that new paradigms in scaffold design and synthesis are needed to engineer functional tissues. Some major challenges in tissue engineering include: 1) The difficulty in uniformly seeding cells throughout a scaffold; 2) The lack of vascularity in tissue engineering constructs; and 3) The inability to mimic complex three-

dimensional (3D) cell-cell and cell-substrate interactions, in particular with multiple cell types. This session will focus on recent advances in the design, synthesis and application of such biomaterial scaffolds for use in regenerative medicine.

Biofunctional Polymers for Gene Delivery

Development of non-viral synthetic biofunctional vehicles capable of enhancing gene delivery selectivity and transfection efficiency is essential for success of gene therapy. This session will emphasize on novel structures and properties of synthetic vectors that have been developed and promising results in preclinical work.

Bioinspired Smart Materials for Regenerative Medicine Applications

The regeneration of complex tissues requires innovative materials that provide appropriate cues to the surrounding host and/or implanted cells to rebuild tissue. Bioinspired smart materials are being sought that can sense changes in the environment and adapt by altering their properties to enhance repair. This session will cover biomaterials inspired by natural materials, which can adapt by releasing factors, altering cell adhesion, providing physical cues such as mechanical and electrical stimulation or other properties, and their application in regenerative medicine.

Biomaterial Strategies for Innervation, Nerve Repair and Integration
Contributing SIGs: Proteins and Cells at Interfaces and Tissue Engineering

The development of effective therapeutic interventions for severe neurological deficits has escaped our community, despite significant developments in synergistic research areas. This symposium will solicit abstracts that facilitate a robust discussion pertaining to the combination of principles required to modulate inflammation, secondary damage, and plasticity, while promoting natural repair and neural regeneration. Presentations should begin to explore the role of advanced biomaterials (natural vs. synthetic), micro-fabricated devices, engineered interfaces, tissue engineering strategies, and an understanding of cell-biomaterials interactions, in order to provide a critical foundation for the next-generation of functional neural rehabilitation.

Biomaterial Strategies for Large-Area Bone Regeneration
Contributing SIGs: Orthopedic Biomaterials, Tissue Engineering, Dental/Craniofacial Biomaterials, and Drug Delivery

Healing large bone defects has been a significant challenge in orthopedic surgery. Tissue engineering approaches for bone regeneration have been promising; however the regeneration is only limited to small areas of bone. In order to develop tissue-engineering strategies for large bone defect healing, one needs to develop biomaterial scaffold systems that allow for large areas of bone regeneration. This is possible only by designing scaffold systems that overcome diffusion constraints, induce early vascularization and bone formation. This symposium will focus on several strategies that can lead to advanced scaffold systems, which support large areas of vascularized bone formation. Also, in vivo studies that show large craniofacial and long bone defect repair and regeneration using the recently developed scaffold systems will be covered as part of this symposium.

Biomaterials for Modulating Immune and Inflammatory Processes
Contributing SIGs: Cell Organ Therapies, Implant Pathology, Proteins and Cells at Interfaces, Tissue Engineering

Biomaterials are increasingly being applied to actively direct immune and inflammatory processes, both in the context of tissue engineering and towards new immunotherapies for disease. This session focuses on elucidating fundamental mechanisms of biomaterials immunomodulation and designing therapeutic strategies that exploit this new knowledge. Examples of topics include novel adjuvants for immunotherapies, strategies for tolerizing biomaterials that would otherwise be pro-inflammatory or immunogenic, understanding the role of cells such as macrophages, dendritic cells, T cells, B cells, and other inflammatory or immune cells in host responses to biomaterials, and developing receptor-targeted biomaterials for the guided activation of specific immune cells (e.g., for cancer vaccines and other immunotherapies).

Biomimetic Surfaces: From Multi-scale Fabrication Methods to Diagnostic Therapeutic and Clinical Applications
Contributing SIG: Surface Characterization and Modification

Development of biomimetic structures across several length scales has led to diverse applications, ranging from modulation of cell-substrate interactions in biomaterials and tissue engineering, to the creation of biomolecular arrays, multi-analyte biosensors and clinical assays. This session aims to bring together researchers and industrial professionals to share their vision and expertise on the current trends and the state of the art in the research and development of biomimetic surfaces. The session will focus on the fabrication methods, therapeutic

potentials, clinical applications of biomimetic surfaces, including but not limited to bio-inspired patterned surfaces, nanostructured surfaces, chemically or biomolecule modified surfaces, self-assembled surfaces, bio-sensing and bio-analytic interfaces, and anti-infection or anti-inflammation surfaces. In addition, special highlights will be given to those biomimetic surfaces with immediate industry potential or in the process of commercialization, and the manufacturing techniques with a mid to high maturation level for commercialization sought by start-ups as well as implant companies.

Cardiovascular Biomaterials
Contributing SIG: Cardiovascular Biomaterials

Biomaterials are employed in the fabrication of a wide range of medical devices and drug delivery applications. As such they play an important role in the cardiovascular field as well. New materials and applications are constantly developed in academia and R&D laboratories all over the world. These two sessions will review current state of the art and key challenges involved in the development of cardiovascular biomaterials.

Ceramics and Composites in Bone Tissue Engineering and Drug Delivery
Contributing SIGs: Orthopaedic Biomaterial, Dental Material, Nanomaterial

The session on "Ceramics and Composites in Bone Tissue Engineering and Drug Delivery" aims to provide an international forum for scientists and engineers to report latest research findings, to exchange ideas and information to establish research links of the recent advances in ceramics at the nanoscale towards bone implant and drug delivery applications. Industry participation will be encouraged. This symposium will discuss general areas of Ceramics and composites in coatings, resorbable scaffolds, and drug delivery in both orthopaedic and dental applications. In specific, the symposium will focus on these general topics: a) Nanoscale calcium phosphates (CaP) in bone graft and drug delivery; b) Chemistry and grain size effects on properties of bioceramics towards tissue interactions; c) Surface modification of metallic implants; d) Bioceramics in antimicrobial coatings / applications; e) Resorbable CaPs scaffolds in bone tissue engineering and drug delivery; f) Ceramics in dental applications.

Dental/Craniofacial Materials
Contributing SIG: Dental/Craniofacial Biomaterials

The Dental/Craniofacial Biomaterials SIG focuses on the basic, applied, and clinical research of innovative biomaterials ranging from the synthetic to the biologic. These biomimetic biomaterials are designed to restore oral tissue structure, function, and reestablish soft/hard tissue. Recent innovation in dental biomaterial technologies include advanced inorganic and organic materials, smart materials, drug delivery strategies and surface modified materials.

Developing the Next Generation of Cardiovascular Devices – From Concept to Implantation (An Industry Perspective)
Contributing SIG: Cardiovascular Biomaterials

The scope of this session is focused on presentations related to development of new cardiovascular devices, ranging from devices in concept stage to those that have progressed onto implantation studies (animals or clinical trials). This session will include presentations on devices such as, but not limited to, peripheral vascular grafts, hemodialysis access grafts, ventricular device conduits, stents and other related devices (sutures). While the session is geared toward industry presentation of new technologies, submission of medical device research by academic institutions in these areas is encouraged in order to provide cross-talk between academia and industry. This session, which will not require release of proprietary information on device synthesis in order to encourage industry participation, will still require presentation of scientific data (e.g. physical testing, biologic testing, tissue culture analysis, animal or human trial results).

Drug Delivery
Contributing SIG: Drug Delivery

Biomaterials continue to be refined to suit the needs of more and more specialized applications, and at the forefront of these refinements is the controlled release or presentation of pharmacologically active agents. In this session, advances in the use of active biomaterials and clever biomaterials design for drug delivery are presented.

Drug Delivery for Inflammatory Diseases
Contributing SIG: Drug Delivery

Although seemingly distinct, all inflammatory diseases, including, but not limited to, rheumatoid arthritis, asthma, atherosclerosis, inflammatory bowel disease, ocular inflammatory disease, vasculitis, and hepatitis, can be linked through: (1) abnormalities in the levels of pro- and/or anti-inflammatory mediators and; (2) leukocyte recruitment. In addition, the resident cells within the diseased site(s) often aid in the inflammatory response by overexpressing receptors

for the pro-inflammatory mediators. This session will highlight technology aimed at exploiting the latter characteristics to aid in the treatment and/or diagnosis of inflammatory diseases.

Drug Delivery in the Treatment of Cancer
Contributing SIG: Drug Delivery

Despite decades of research, cancer therapy remains a grand challenge to the medical community. At the forefront of multiple strategies are biomaterials which can target cancerous regions for release of selective anticancer payloads. In this session, advances in biomaterials design related to cancer therapy are presented.

Engineering Bone
Contributing SIG: Orthopaedics

Co-Chairs: Sachin Mamidwar and Robert Hastings

Tissue engineering is defined as the application of biological, chemical, and engineering principles towards the repair, restoration or regeneration of tissues using cells, factors, and biomaterials alone or in combination. By combining appropriately engineered biomaterials, cells, and stimulatory condition; strategies may ultimately be found to produce bone graft substitutes capable of providing bony repair. Biocompatible materials, including biodegradable polymers and composites have been fabricated using various techniques into multi-dimensional scaffolds that mimic the bone architecture and have inductive capacity to modulate the regenerative process. During regeneration, the biocompatible scaffold provides structural and mechanical support to the damaged tissues, promotes integration with the host tissue and is degraded or absorbed and remodeled to be replaced with new regenerate tissue. Additionally, stimulation of the wound site using growth factors or mechanical stimulation, such as ultrasound contributes to the tissue formation capacity, and modulates the cellular response. It was discovered that proteins sequestered within demineralized bone possessed osteoinductive properties, and bone morphogenetic protein-2 was found to be of high potency, however it has a short half-life in vivo and thus require a carrier system to effectively delivery active and controlled doses. Composites fabricated using TCP are highly bioactive and readily remodeled in vivo to promote balanced tissue regeneration.

Engineering Cells and Their Microenvironments
Contributing SIG: Engineering Cells and Their Microenvironments

The Engineering Cells & Their Microenvironments Special Interest Group concentrates on technologies and approaches focused at the single cell level and encompassing engineering cell microenvironments, biomaterial-induced cell signaling, stem cell manufacturing and differentiation, immunoengineering, and biomaterials for cell-based detection and diagnosis.

Engineering Instructive Cues Biomaterials
Contributing SIG: Engineering Cells & their Microenvironment

The native extracellular matrix is instructive, providing a dynamic and spatially heterogeneous constellation of microstructural, mechanical, and compositional cues that can influence cell behavior. The next generation of experiments in cellular function and tissue regeneration requires a versatile toolbox of similarly patterned, heterogeneous, or dynamic biomaterials that can provide a defined, instructive microenvironment. These instructive materials may ultimately contain an appropriate assembly of critical cues to allow specific regulation of key cell behaviors in fields as wide ranging as developmental biology, immunology, regenerative medicine, and stem cell biology. Topics of interest include: tunable topographic cues; covalent immobilization; transient sequestration, or delivery of biomolecules; response of the material to its environment via changes in biomolecular, structural, or mechanical properties.

Implant Pathology
Contributing SIG: Implant Pathology

Evidence is accumulating that implanted metals that produce wear particles are capable of initiating a variety of innate and adaptive immune responses. Does this development preclude the use of metals in high impact applications such as orthopaedics?

Nanomaterials
Contributing SIG: Nanomaterials

This session will focus on technology, innovative design and synthesis of nanobiomaterials useful in the creation of new and better devices, diagnostics and therapeutics for biomedical applications.

Orthopaedic Biomaterials
Contributing SIG: Orthopedic SIG

The development of new orthopaedic biomaterials has been relatively lagged compared to other types (e.g. drug delivery) of biomaterials. This session will update the development of some advanced orthopaedic materials based on new materials development and surface modification. Recent progress on degradable metal implants, tissue

engineering scaffolds, and unique surface treatments of conventional orthopaedic biomaterials will be presented. Pre-clinical and clinical studies are also expected.

Orthopaedic Polymers
Contributing SIG: Orthopedic SIG

Polymers such as UHMWPE, polyethylene and PEEK are extensively used in orthopedic implants for various purposes. Although these polymers possess a unique set of surface and bulk properties that determine their ultimate performance and have a long history of use in orthopedics, further developments enable the industry to develop superior implants. This session focuses on long and short-term studies discussing current state-of-the-art advances in various polymeric biomaterials used in orthopedic implants.

Patterning Microenvironments for Tissue Engineering and Morphogenesis
Contributing SIGs: Engineering Cells and Their Microenvironments, Tissue Engineering

Cellular processes such as tissue morphogenesis and regeneration are both critical and complex multicellular events that lead to the formation or repair of architecturally diverse tissues. These processes require specific structural, mechanical, and biochemical cues for proper progression. Inspiring and controlling these events remains a critical challenge in biomaterials design and has led to many strategies attempting to spatially or temporally define the biomaterial microenvironment. Further, as our field has begun to emphasize 3D scaffold materials where cellular in-growth and metabolic support into the scaffold is essential, new modification methods and patterning approaches will be required to overcome the challenges encountered by the traditional methods (such as depth of penetration in case of photo-grafting) for modifying these materials. This symposium will address both new methods for patterning instructional cues in 2D and 3D environments and the biological insights uncovered from using patterned biomaterials to study such events.

Physical Parameters in the Design of Drug Delivery Systems

Physical parameters like size, shape, morphology, surface characteristics, mechanical modulus, etc. play an important role in influencing the in vivo performance of drug delivery systems. The effect of such physical parameters can be in modulating transport characteristics within vascular and tissue compartments, interactions with proteins and cells in the biological milieu, and pharmacokinetics of the drug delivery systems and their payload. The focus of this session will be on understanding these unique physical aspects of drug delivery system design, to provide insights on (a) how such parameters enhance device performance, (b) technologies that allow creation and characterization of these parameters, and (c) the challenges and possible solutions of incorporating these parameters in terms of scale up, reproducibility, and mechanistic elucidation of in vivo performance.

Proteins and Cells at Interfaces
Contributing SIGs: Proteins and Cells at Interfaces

This session organized by the Proteins and Cells at Interfaces Special Interest Group will highlight recent findings on understanding of cell and protein interactions with biomaterial interfaces to produce targeted responses by proteins and cells to new or exisiting materials. Some of the topics related to proteins include: 1) relating surface chemistry to protein adsorption or specific binding and 2) studying the activation or inactivation of protein function at interfaces, including complement activation. Cell topics include: 1) the response of cells to differing chemistries and microstructures (roughness or porosity), 2) the evaluation of multiple cell and tissue response parameters (attachment, growth, migration, differentiation, inflammation, fibrosis), 3) the role of surface receptors in cell responses, and 4) all relevant cell types including bacteria.

Role of Biological Factors in Osteoconduction and Bone Engineering
Contributing SIGs: Dental, Orthopedic, Tissue Engineering

The clinical use of biological growth factors like bone morphogenetic proteins and platelet derived growth factors has significantly increased in recent years. Commercial products incorporating such growth factors (Infuse by Medtronic, GEM-21S) are already approved by US FDA and are in extensive clinical use. Research is being conducted to develop more efficient carrier vehicles for such growth factors as well as to develop more effective growth factors. Significant research is also directed towards the appropriate dosages and forms of such growth factors. More information is also being obtained about the interactions cell have with such growth factors and the exact mechanisms they trigger to stimulate bone formation. This has resulted into an approach where we are regenerating lost bone rather than replacing it. The session will be focused on various carriers that are being used to deliver growth

factors and biologic agents, various growth factors and biologic agents that are being developed studied and characterized and the mechanisms through which they act.

Surface Characterization and Modification
Contributing SIG: Surface Characterization and Modification

This general session covers a wide range of techniques that are recently developed to modify the surfaces of biomaterials for a variety of applications including non-fouling, micropatterning, cell sheet fabrication, cell adhesive biomolecule immobilization, tissue engineering, and improving lubricity, wear, and corrosion resistance. These novel surface modification techniques can be applied to a variety of orthopedic, cardiovascular, and dental biomedical implants and devices. This session also highlights the responses of cells to these modified surfaces. A special emphasis is provided to the novel surface characterization techniques that are employed to study the modified surfaces in detail.

Surface Modification of Biomaterials for Local Therapy and Diagnostics
Contributing SIGs: Surface Characterization and Modification, Drug Delivery, and Nanomaterials

This general session will focus on the recent advances in the surface modification of biomedical implants and nanomaterials for local therapy and diagnostics. The delivery of drugs from the implant surfaces provides the significant advantage of site-specific therapy without systemic toxicity. Similarly, the immobilization of drugs and a variety of biomolecules on the nanomaterial surfaces facilitates targeted drug delivery and noninvasive imaging applications. This session will cover the novel surface modification techniques that are used to immobilize drugs and biomolecules on implants and nanomaterials for a variety of applications including cardiovascular, orthopedic, neural, and cancer treatments. A special emphasis will be provided to the use of different

characterization methods to study the drug and biomolecule coatings on implants and nanomaterials.

Surface Modification Strategies for Antimicrobial Medical Devices

Medical devices are responsible for a large portion of nosocomial infections, particularly in critically ill patients. These infections put a huge drain on the limited medical staff /resources and accounts for an increasing number of deaths as well as high medical costs. Bacterial colonization of the indwelling device can be a prelude to both infection and malfunction of the device. Many different strategies have been developed to decrease the incidence of medical device related infection. One way to prevent infection is by modifying the surface of the devices in such a way that no bacterial adhesion can occur. Traditional surface-modifying preventive approaches have largely focused on antimicrobial coating of devices and resulted in variable clinical success in preventing device-associated infections. However, researchers in academia and medical device industry have experimented newer innovative approaches, such aspeptide chemistries for biofilm modification and bacterial interference. This general session should provide an opportunity for researchers to share their latest findings on antimicrobial approaches using surface modification strategies for short and long-term implantable medical devices.

Surgical Meshes – Recent Development and Application

Surgical meshes are a unique group of medical devices. They find use in surgical procedures to reinforce soft tissues where weakness exists, such as hernia repair, urinary incontinence and plastic surgery. Different applications require different characteristics which may include mechanical properties, pore size, degradation, biological coating, constructure, etc. This symposium is designed to summarize recent advances in surgical meshes. The symposium will provide researchers with an opportunity to present their work in the field of implantable meshes and to interact with each other. The emphasis will be placed on the current status in development and application. Abstracts related to all areas of surgical meshes are welcomed. These may include, but are not limited to, absorbable and non-absorbable meshes, composite meshes, processing, mechanical and analytical testing, biological and biocompatible evaluation, animal models, and clinical application. It is hoped that the symposium will contribute to the advancement of biomaterials science, particularly in the area of meshes.

Tissue Engineering
Contributing SIG: Tissue Engineering

Tissue engineering has emerged as a promising alternative for the reconstitution of lost or damaged organs and tissues, circumventing the complications associated with traditional transplants. This session will review current state of the art in the development and characterization of tissue engineering constructs. Specific areas to be covered are the use of appropriate materials (synthetic and natural) with cells (either native or from a donor source) and/or biological response modifiers (e.g., growth factors, cytokines and other recombinant products) to replace tissue and organ functions.

Translational Research in Nano-biomaterials
Contributing SIG: Nanomaterials

New capabilities enabled by the unique performance enhancements of nanomaterials promise to revolutionize the biomedical field. The general session is committed to providing a fertile and stimulating forum for presentation and discussion on recent nanomaterials innovations which maximize the impact to the medical field. This session will include a comprehensive range of nanomaterials including nanoparticles, nanoporous substrates, nanofibers, nanocoatings, nanocomposites, etc. in various biomedical applications including as implants, tissue engineering materials, drug delivery devices, etc. for variety of areas such as orthopedic, dental, vascular, neural, etc.

Tribocorosion of Metallic Biomaterials
Contributing SIG: Orthopedic Biomaterials

This session will present the latest research on tribocorrosion (the combined mechanical-corrosion interactions) of orthopedic devices. The focus will be on the surface reactions related to fretting corrosion, surface triboelectrochemical mixing of surface layers, and the biological reactions to corrosion processes including pseudotumor formation, osteolysis and other ion-related issues. Papers are on modular implants (including the latest neck-stem taper junctions and metal-on-metal hip resurfacing devices), fundamentals of mechanically assisted corrosion behavior and development of novel hard coatings for resistance to tribocorrosion.

WORKSHOPS

The Workshops will provide an in-depth educational experience on topics relating to biomaterials with a significant amount of time dedicated to discussion and questions and answers.

Standards in Biomaterials Development: SFDA (China); USFDA; ISO and ASTM

Panelists: Art Coury, Xie Jiangbing, Shipu Li, Jeff Rouleau, Ning Zhu

The Society For Biomaterials will host a forum focusing on the use of standards for biomaterials development and manufacture with representatives from the US FDA, the Chinese SFDA, ASTM Inc., and the International Organization for Standardization (ISO). The goal of this forum will be to provide perspectives on how standards are used by regulatory agencies overseeing the medical device development and manufacturing processes in the United States and the People's Republic of China. The forum will provide a series of talks from representatives from regulatory departments, medical device companies, and academia followed by a panel of the speakers to enable discussion and address audience questions.

Recent Advances in Rapid Prototyping of Biomaterials

Invited Speakers: Jennifer Lewis, Roger Narayan, James Yoo

Several investigators have recently examined fabrication of three-dimensional biomaterials through additive joining of materials in a layer-by-layer manner, including microcontact printing, fused deposition modeling, selective laser sintering, inkjetting, and laser direct writing, to overcome the limitations associated with conventional biomaterials processes. This workshop will review recent developments in rapid prototyping technologies for processing biomaterials into artificial tissues as well as biosensors, drug delivery devices, and medical instruments; several topics related to rapid prototyping, including processing of radiographic images, development of computer models, novel rapid prototyping technologies, and novel materials for use in rapid prototyping, will be discussed. This workshop will create collaboration and discussion among the many groups involved in the development and use of rapid prototyping technologies, including biomaterials engineers, medical scientists, medical device manufacturers, equipment manufacturers, and clinicians.

PANEL DISCUSSIONS

Panel Discussions are a format that foster open debate on a topic. The invited guests include renowned experts in the area of focus and the chair allows time for open discussion with the audience.

Battlefield Injuries

Invited Speaker: Hassan Tetteh, MD, Cardiothoracic Surgeon, Commander, United States Navy

Panelists: Barbara Boyan, Lynne Jones, Tony Mikos, Hassan Tetteh, Tim Topoleski

With the global efforts of our military, there is an increasing need for advanced treatment options for severely injured servicemen and women. One of the primary goals of this session is to discuss how we in the field of biomaterials can help ensure the survival and successful treatment of the wounded soldier. Because of battlefield injuries, a wounded soldier may ultimately need a specific long-term treatment. Optimization of treatment, beginning with those used by first responders and continuing with those used throughout their care regimen, will ultimately increase the success of the soldier's recovery and rehabilitation.

BMP2, The Bone Growth Factor
Contributing SIGs: Orthopaedic Biomaterials

Panelists: Scott Guelcher, Stuart Goodman, Howard Seeherman, Mike Yaszemski, Stephan Tripple

The development and the clinical use of recombinant human bone morphogenetic protein (rhBMP-2 and rhBMP-7) for bone growth/repair and regeneration have experienced much promise with past evaluations and assessments, recent debates on past studies and future questions on the most effective uses. This Society of Biomaterials Panel Discussion will explore and discuss each of these areas for improved understandings and new directions for scientific and technical studies. The scheduled panel speakers are Howard Seeherman from Restituo, Michael Yaszemski from the Mayo Clinic and Stephan Trippel from Indiana University School of Medicine. The Panel Discussion Moderators are Stuart Goodman from Stanford University and Scott Guelcher from Vanderbilt University.

Cell Therapy Regulatory Consensus Motif & Functional Intelligence

Panelists: Hoda M. Elgendy, Jordan Green , Jeffery Hollinger, Elias Zambidis

Novel emerging technologies such as tissue engineering, which utilize the approaches of molecular and cell

biology, biotechnology, as well as materials science and engineering, are being used in the development of a wide range of biomedical products developed by industries regulated by the U.S. Food and Drug Administration. There are many challenges associated with characterizing and quantifying cells for use in cell- and tissue-based therapies. From a regulatory perspective, these advanced treatments must not only be safe and effective but also be made by high-quality manufacturing processes that allow for on-time delivery of viable products. Although sterility assays can be adapted from conventional bio-processing, cell- and tissue-based therapies require more stringent safety assessments, especially in relation to use of animal products, immune reaction, and potential instability due to extended culture times. Furthermore, cell manufacturers who plan to use human embryonic stem cells in their therapies need to be particularly stringent in their final purification steps, due to the unrestricted growth potential of these cells. This panel discussion will review the current issues in characterization and quantification for cell- and tissue-based therapies, dividing these challenges into the regulatory themes of safety, potency, and manufacturing quality. Importantly, this panel session will highlight the requirement for basic research to improve current knowledge on the in vivo destiny of these treatments; as well as an improved stakeholder negotiation process to identify the measurement requirements that will ensure the manufacture of the best possible cell- and tissue-based therapies for the most patient benefit.

Medical Products Regulatory Processes & Biomaterials/Biomedical Engineering Curricula

Panelists: Julie Budnick, John Fisher, Anne Meyer, Mark Van Dyke, Nicholas Ziats

This panel discussion will focus on teaching medical products regulatory concepts in biomaterials and biomedical engineering curricula at the undergrad and/or graduate levels. For years, we have heard about how engineering schools have worked with medical schools to develop biomedical engineering curricula that are responsive to future healthcare needs and that are acceptable to ABET. The American Medical Association is preparing to discuss how to strengthen medical school curricula by including more engineering concepts. These are excellent examples of concerted efforts to reduce the "silo-effect" within academia in order to (a) prepare our students for increased understanding of their own, highly technical fields as well as (b) preparing them to make future advances in collaboration with their professional colleagues in other fields. One key component of "ground truth" for both medical practice and biomedical engineering practice is the central role that FDA regulations play in the development and availability of all medical products (devices, drugs, biologics, combination products) sold for use in this country. What are we doing to prepare our students for this major dose of reality? Can they talk the talk? Walk the walk? What expectations does the medical products industry have in this regard when they are considering hiring scientists and engineers? Are the recently-developed M.S. programs in regulatory affairs making a positive impact? How do professional societies fit into the picture? Are there data and "best practices" available from existing biomaterials and biomedical engineering degree programs?

Scaffolds for Tissue Engineering: Successful Academia-Industry Collaborations
Contributing SIG: Tissue Engineering

Panelists: Barbara Boyan, Amol Janorkar, David Kaplan, Anita Sawyer, Anthony Ratcliffe

Tremendous research has been done in recent times to use biomaterials to guide three dimensional tissue formations both in vitro and in vivo. As this tissue engineering research progresses into more successful outcomes, interdependence and partnership between academia and industry take immense importance. Panelists will discuss their interactions with academia or industry regarding the latest developments in creating three dimensional scaffolds on an industrial scale, challenges encountered, and their solutions.

Translational Medical Device Development using Biomaterials: What's Important?

Panelists: Elazer Edelman, Roger Kitterman, Frederick Schoen, Werner Cautreels, Michael Davidson, William Reichert

This session will bring together key perspectives from leaders in academia, industry, technology transfer, and patient care to provide an overview of key challenges and considerations in the implementation and commercialization of medical devices using biomaterials. We will focus on the concepts of "validation" and "value". The participants in this session have considerable experience in key aspects of biomaterials and medical device development and clinical translation of innovative technologies.

TUTORIALS

The purpose of a Tutorial is to teach attendees about a specific technology or focus area. It may include up to two presenters and time for questions and answers. The invited speakers are selected for their experience in the field, as well as their ability to teach fundamental topics that are of increasing importance to a wide range of biomaterials scientists and engineers. Attendance at the tutorial is included with the general meeting registration.

What is the Role of Formal Ethical Analysis in Product Development?
Contributing SIGs: Implant Pathology, Biomaterials Education and Biomaterials and Medical Products Commercialization

Chair: Howard Winet

The ethical/moral decision one makes depends on what he/she values. In a liability proceeding a biomaterials scientist/engineer may be testifying for the prosecution (e.g. as a whistleblower) or the defense (e.g. as a supporting employee of the accused). The judged validity of their subjective decisions could well rest on validity of their reasoning process, starting from their values and ending with their behavior. If the process is logical, conforming to established consequential or non-consequential moral theories, validity is enhanced. This tutorial will describe the application of moral theories to decisions of participants in real cases, a process known as moral analysis.

Integrating Modeling and Experimental Approaches for Biomaterials Design

Chair: David Kaplan

Invited Speakers: Markus Buehler, Joyce Wang

Tailored materials with tunable functional properties are desirable for many biomaterials needs ranging from medical devices to scaffolding in tissue engineering and regenerative medicine and for drug delivery. To achieve an increased predictability of biomaterials functionality, multiple parameters in polymer design need to be considered and appropriate models must be available that can be used to engineer tailored material solutions, including at different scales of structural hierarchy. The importance of multiscale engineering and the combined use of modeling and experiment in advancing designs of biomaterials will be the focus. This is an emerging field where modeling can inform polymer design and vice versa.