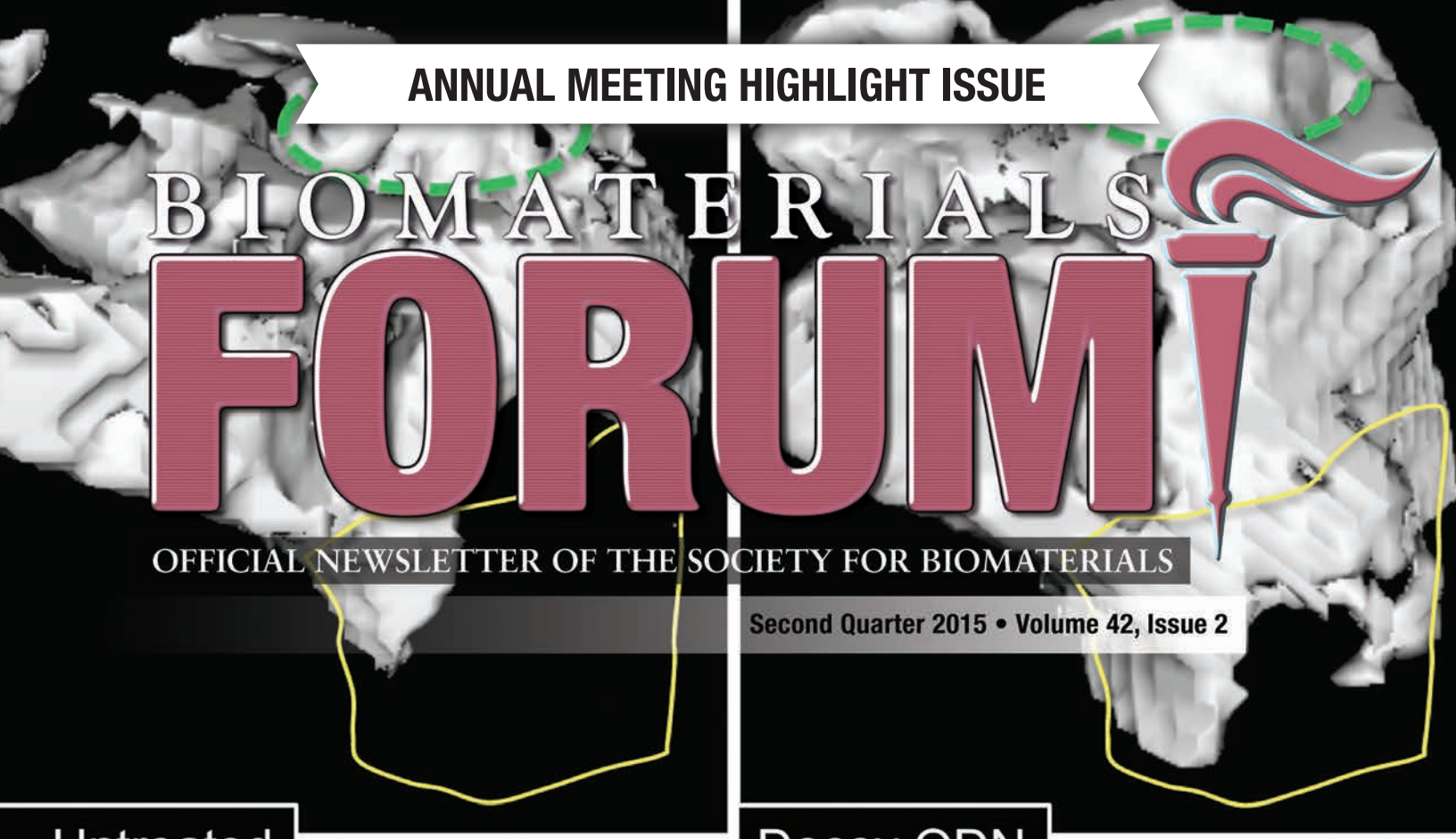
ANNUAL MEETING HIGHLIGHT ISSUE

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Second Quarter 2015 • Volume 42, Issue 2



Also Inside:

- Q & A with Glenn D. Prestwich
- Encouraging STEM Education
- Letter from the New President

Biomaterials Forum, the official news magazine of the Society For Biomaterials, is published quarterly to serve the biomaterials community. Society members receive Biomaterials Forum as a benefit of membership. Non-members may subscribe to the magazine at the annual rate of $48. For subscription information or membership inquiries, contact the Membership Department at the Society office (e-mail: info@biomaterials.org) or visit the Society's Website, www.biomaterials.org.

Editorial contributions to Biomaterials Forum are always welcome. Contributions should be sent to the Executive Editor and are subject to the terms and conditions of the Editorial and Publication Release. Authors should refer to the Author Guidelines, which are available on the Society's website, when writing submissions. The publisher accepts no responsibility for return or safety of artwork, photographs or manuscripts. Submission of editorial content does not guarantee acceptance or publication.

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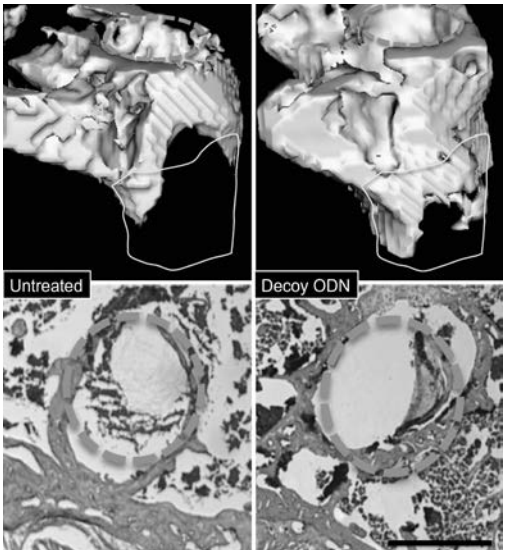
Requests for advertising information should be directed to Kimberly Quevedo at kquevedo@ahint.com or (856) 437-4707. Information is also available on the Society's website, www.biomaterials.org.

Scientific photos may be submitted for cover consideration in future issues. Submit color photo, no larger than 4" x 6", along with credit information and scientific description, to the Executive Editor.

BIOMATERIALS
FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 41, Issue 2

Special Interest Group Reporters



Contents

The Torch

News & Updates

On the cover: NF-κB decoy oligonucleotide (ODN) mitigates bone loss in the murine femur during continuous polyethylene (PE) wear particle infusion. Alzet mini-osmotic pumps with a mean pumping rate of 0.15 µl/hour were connected to silicon tubing and a hollow titanium rod that was placed in the distal femur of male athymic mice that were 10–15 weeks old. The pump was filled with various combinations of UHMWPE particles at 0.43 µm in average size (15 mg/ml), decoy ODN (50 µM), lipopolysaccharide (1 µg/ml) and connected to the rod implanted into the right distal femur.

Upper images: MicroCT 3D reconstructions of thick slices of trabecular bone structures in the distal femur. Untreated (left) and treated with OCN (right). Region of interest (ROI) was generated by selecting the region inside cortical bone on a 2D image for every 10th slice for five sections (from 1 mm to 3 mm from the distal femur). Yellow lines circumscribe the area of major bone loss induced by UHMWPE particles and LPS infusion (right) that was mitigated by ODN (right). A green-dotted circle (in 3D and histologic image) indicated the inserted titanium rod channel from intra-condyle region at distal femur.

Lower images: Tissue sections stained with H&E (obtained from 2 mm to 3 mm from the distal femur) further demonstrate the reduced bone loss from treatment with ODN. Scale Bar = 500 µM

Photo courtesy of Dr. Tzu-hua Lin and Professor Stuart B. Goodman, Stanford University.


Liisa Kuhn

GREETINGS FELLOW BIOMATERIALS SCIENTISTS,

In case you missed it, the Society For Biomaterials' (SFB) Annual Meeting in Charlotte, North Carolina in April went smoothly, thanks to the excellent leadership of the program chairs, Helen Liu and Peter Edelman. For this issue of the Forum, we've prepared a multipage spread titled, "SFB Annual Meeting 2015" with photos and a few symposium summaries submitted by the symposium/session chairs. There is also a historical flashback to the 1990 Annual Meeting, courtesy of Bob Baier and Mark Stachowski, that follows the 2015 meeting review. It's fun to see what was being debated 25 years ago!

Here are some other highlights from this issue of the Forum:

Assessing the biological response to an implanted biomaterial through preclinical studies is a major and critically important activity within our field. The **Biomaterials Tissue Interaction SIG** article ("Improved Implant Performance Through Design," contributed by Peggy Lawlor, PhD, of Histion, Inc.) and the cover art and caption (from Dr. Stuart Goodman's orthopaedic research lab at Stanford University, California) deals with this topic.

Engineering a biomaterial to guide and control cellular activity is another key area within our field. Adam Feinberg of Carnegie Mellon University has compiled a short review of articles about engineering the cellular microenvironment for the **Engineering Cells & Their Microenvironments SIG** members in this issue**.** This is a great example of the kind of technical article that SIG officers or reporters can write that provides value for their members.

Do you know who the founders of SFB were and who Buddy D. Ratner's PhD advisor was? Find out in the **Historical Flashback** column.

Biomaterials Career Story — This issue features an interview with Glenn Prestwich, faculty member and entrepreneur extraordinaire.

Cell therapy research and commercialization continue to grow by leaps and bounds. The UK is investing heavily in this area as reported in the **Government News** article.

Several of our SFB members have received prestigious professional awards and grants, have been promoted or have had patents issued this year. Read the **Member News** column to find out who is being honored this quarter and be inspired by what your colleagues have achieved.

Book reviewer Lynne Jones asked the SFB Presidential Advisory Council (i.e., the past presidents of our society) the following question, "What three books would you recommend that every biomaterials scientist should have in their own personal library?" Their responses can be found in the **Book Review** column. In addition, Julie Stenken (Immune Engineering Forum Reporter) has contributed a book review about Macrophages in this issue. Browse this column to find some new books to help with your research and teaching or just for some fun summer reading. There are a few philosophical books that could fit this category!

Industrial News — Read this for an overview of the latest product releases, mergers, acquisitions, regulatory issues and other notable corporate achievements or concerns.

Education News — Education Editor Yusef Khan reports on the latest strategies used in recently established university programs to increase the number of science, technology, engineering and math (STEM) educators.

As you may have heard, I've had the privilege of being elected as your next President-Elect. I am thrilled to be given this opportunity. Thank you! In order to best focus on that activity, I'm going to be stepping down as executive editor of the Biomaterials Forum early next year. We are now recruiting a replacement. If you're interested in being the next editor of the Forum, please respond to the RFP included in this issue.

Best wishes,

LIISA KUHN, PhD
Biomaterials Forum Executive Editor
Associate Professor
University of Connecticut Health Center

Please consider contributing a bulleted list of your own favorite articles of the quarter or year. I'd particularly like to request one from those biomaterials folks who like to tweet! I've been following a few of them and want to thank them for drawing my attention to some interesting publications in our field. If you'd like quick updates of what's happening in our field I suggest you start with following Nicholas Peppas on Twitter.

Thomas J. Webster

IT IS AN EXTREME PLEASURE TO BE (GLOBALLY) HERE!

As we all relax after a busy and fun-filled Annual Meeting in Charlotte, North Carolina, it is now time to turn to our World Biomaterials Congress year. It is time to remember about all those plans for collaborations, commitments to the Society For Biomaterials (SFB) and, yes, to keep in touch. I continue to be energized and excited about the potential for the future of SFB and can think of no better year than a World Biomaterials Congress year to continue to expand our international efforts via our website for the betterment of our membership. A World Biomaterials Congress year gives us the opportunity to emphasize the importance of our global biomaterials community, as we must continually increase our already strong global presence — providing leadership and collaboration, and learning from our vast world on our collective pathway to improve biomaterials research and education.

To help increase our global presence, this year we will be unrolling at least one webinar per month to increase the global value of being a SFB member. We are bringing SFB to the world in ways we never have before. We have an exciting lineup of webinars geared toward international biomaterials efforts, including a forum from experts all around the world discussing recent funding trends unique to that part of the globe — however, we will have more than just webinars focused on global biomaterials efforts.

Additionally, we will have one webinar a month to maintain biomaterials excitement until we meet again. For example, we will have a webinar for our industrial members, including one to help keep abreast of the latest in medical regulatory policies in these hectic changing healthcare times. To help foster collaboration between industry, academics and clinicians, we will have a webinar about best practices working with industry. We will also have webinars about how to run your own lab and how to secure an academic or industry job — a great value for our youngest members (or even older members looking for a job change). For our clinicians, we will have a webinar about how to build collaborations with academics and industry, identifying the most pressing clinical problems that need to be solved today.

Of course, critical to our mission statement is promoting biomaterials education, so we will have a webinar that shares best practices and how to elevate the visibility of biomaterials at your company or institution (anyone interested in starting a Biomaterials Center at your institution, attend that one!). It is critical for our younger generation to be excited about biomaterials and one of the best ways is through hands-on experiences. Thus, we will have a webinar about how all members can become involved in biomaterial design projects. Go ahead — create an experience at your institution!

To help increase our global presence, this year we will be unrolling at least one webinar per month to increase the global value of being a SFB member.

Lastly, entrepreneurship could not be more valued among our members, so we will have a webinar for all members to learn how to become more involved in commercialization efforts. We have a mixture of presentations, panel discussions and forums to keep our webinars fresh and innovative so that members can actively participate to get the best value.

So roll up your sleeves, put on your SFB cap, turn on your WiFi and help us innovate. Get involved. Remember the fun from the Annual Meeting in Charlotte, North Carolina, and keep the momentum going. Numerous biomaterials collaborations, learning experiences, research and education occur between our annual chances to rendezvous, and we are introducing the Web this year to help. It is an extreme pleasure to be part of SFB, build off of our successful history and create new initiatives for continued global leadership.

THOMAS J. WEBSTER, PhD
The Arthur W. Zafiropoulo Department Chair
President, Society For Biomaterials

BY DEB DUPNIK, ASSISTANT EXECUTIVE DIRECTOR

Hello from the Society For Biomaterials (SFB) headquarters! Our thanks and appreciation to the beautiful city of Charlotte, North Carolina, for hosting the 2015 Annual Meeting! With the beginning of a new program year, the SFB's Board of Directors, governing council, committees, task forces and special interest groups (SIGs) will be working to advance SFB's mission as described below.

ANNUAL BUSINESS MEETING

The Society's annual business meeting took place April 17, 2015 in Charlotte, North Carolina. Results of the spring election were announced, and the following people have been elected as officers for the SFB Board of Directors.

2015–2016 President-Elect: Liisa Kuhn, PhD, University of Connecticut Health Center
2015–2017 Secretary/Treasurer-Elect: Shelly Sakiyama-Elbert, PhD, Washington University
2015–2016 Member-At-Large: Elizabeth Cosgriff-Hernandez, PhD, Texas A&M University

The members present approved the proposed changes to the bylaws (to allow for an increase in the size of the Finance Committee if desired by the Finance Chair and the SFB President), and they elected four new members to the Awards, Ceremonies and Nominations Committee. In addition, Secretary Treasurer, David Kohn, reported SFB is in good health financially, and the Board of Directors and council will be looking to invest more in developing and delivering services to members.

ELECTION OF 2015–2016 AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE

The following were elected by the members present.

Karen Burg, PhD, Kansas State University
Phillip B. Messersmith, PhD, University of California, Berkeley
David Puleo, PhD, University of Kentucky
Christine Schmidt, PhD, University of Florida

NEW COUNCIL

The following members will be serving as chairs of committees, and, along with the Board of Directors, will comprise the 2015–2016 Council.

Awards, Ceremonies and Nominations: Joel Bumgardner, PhD
Bylaws: Ben Keselowsky, PhD
Devices and Materials: Peter Edelman, PhD
Education and Professional Development: Huinan Liu
Finance: Shelly Sakiyama-Elbert, PhD
Liaison: David Puleo, PhD
Long Range Planning: Liisa Kuhn, PhD
Meetings: Tom Webster, PhD
Membership: Lijie Grace Zhang, PhD
President's Advisory: Nick Ziats, PhD
Program: Chris Siedlecki, PhD, and SuPing Lyu, PhD
Publications: Alan Litsky, MD, ScD
Student Chapter President: Evelyn Bracho-Sanchez

Members elected or appointed to committees will be posted on the SFB website at **biomaterials.org.**

UPDATES FROM THE 2014–2015 CHAIRS

AWARDS, CEREMONIES AND NOMINATIONS

CHAIR JAMES ANDERSON, MD, PhD

Results of the 2015 election were announced. The following awards were presented during the Annual Meeting:

Founders Award: Paul Ducheyne, PhD, University of Pennsylvania
C. William Hall Award: Carl R. McMillin, PhD, Synthetic Body Parts, Inc
SFB Service Award: Lynne C. Jones, PhD, Johns Hopkins University
Technology, Innovation and Development Award: Frederick J. Schoen, MD, PhD, Brigham and Women's Hospital
Clemson Award for Applied Research: Xingdong Zhang, PhD, Sichuan University
Clemson Award for Basic Research: Jennifer West, PhD, Duke University
Clemson Award for Contributions to Literature: Lonnie D. Shea, PhD, University of Michigan
SFB Young Investigator Award: Craig L. Duval, PhD, Vanderbilt University
Student Award for Outstanding Research: Amanda Chen, University of Cambridge
Student Award for Outstanding Research, PhD: Michael J. Mitchell, PhD, Massachusetts Institute of Technology, and Lindsey Sanders, PhD candidate, Clemson University
2015 C. William Hall Scholarship: Shamik Mascharak, Stanford University
Acta Biomaterialia Gold Medal: Jack Lemons, PhD, University of Alabama
IJN Distinguished Scientist Award: Rebecca Carrier, PhD, Northeastern University

BYLAWS

CHAIR ANNE SALAMONE, PhD

The Bylaws Committee presented their recommendations to the council with changes to the composition of the Finance Committee to allow for a larger committee. After some discussion, the proposed amendment passed with overwhelming support.

DEVICES & MATERIALS

CHAIR SHROJAL DESAI, PhD

The Chinese SFB will host its 2015 national meeting in Haikou, China, Nov. 19–23, 2015. They would like to host the third U.S.-China workshop at this time and a U.S. delegation has been invited to attend. Professors Xingdong Zhang and Arthur Coury have agreed to serve as co-chairs. The group is working to identify session topics and speakers.

EDUCATION & PROFESSIONAL DEVELOPMENT

CHAIR TIM TOPOLESKI, PhD

Since the fall council meeting the Education & Professional Development Committee has evaluated nominations for the C. William Hall Awards, the STAR program, student chapter travel grants and the revised Biomaterials Day application from the University of Wisconsin. The council also approved a recent Education & Professional Development Committee proposal to increase the interest of under-represented minorities in the field by providing a scholarship for an undergraduate student to attend SFB's Annual Meeting.

FINANCE

CHAIR LISA FRIIS, PhD

Income and expenses are in line with projections, and SFB is in good health.

LIAISON

CHAIR DAVE PULEO, PhD

The Liaison Committee continues its efforts to coordinate and collaborate with other societies. This is especially important in the World Biomaterials Congress years since SFB does not hold an Annual Meeting during that time. So far, the Liaison Committee has received seven preliminary proposals for 2016 joint symposiums. The committee is following up with the organizers of the proposals to identify which symposia will best serve the SFB members.

LONG RANGE PLANNING

CHAIR TOM WEBSTER, PhD

The Long Range Planning Committee is investigating methods to increase participation from industry members, extend SFB's reach into the clinical community and provide additional member services in career development and resource sharing. Priorities for 2015 include identifying ways to enhance the quality of membership and increasing public relations efforts for SFB. A strategic planning session for the Board of Directors and council members is scheduled for June 9–10, 2015.

MEETINGS

CHAIR NICHOLAS ZIATS, PhD

Request for proposals (RFPs) were sent out to 10 cities for the 2017 and 2018 Annual Meetings. The Meetings Committee is working to finalize the meeting venues and will make a final recommendation to the council for those meeting locations.

MEMBERSHIP

CHAIR F. KURTIS KASPER, PhD

Last year, a program was implemented, offering a $10 discount to active local student chapters of the National Student Section. The primary envisioned purpose of the Student Membership Incentive Program is to promote student membership in SFB, while supporting the growth and sustained viability of local student chapters. Additionally, last fall, the SFB Board of Directors approved a proposal to collect membership dues at the time of meeting registration in one lump sum, which has been available since the registration site went live in February. The primary purpose of this change was to accommodate changes in reimbursement from federal funding agencies, where meeting registration fees are reimbursable, but society memberships are not.

PROGRAM

CHAIRS PETER EDELMAN, PhD, AND HELEN LU, PhD

The 2015 SFB Annual Meeting and Exposition in Charlotte, North Carolina, saw 1,061 attendees. Major themes of the conference included biocompatibility and immune engineering; biofabrication; and multifunctional design. The Bash was held at the Nascar Hall of Fame and provided attendees a chance to catch up with old friends, network with colleagues and test their Nascar driving skills on the simulator track. Abstracts from the meeting have been posted online and can be viewed at **2015.biomaterials.org.**

PUBLICATIONS

CHAIR ALAN LITSKY, MD, ScD

The Publications Committee reported that SFB's publisher of the *Journal of Biomedical Materials Research (JBMR)*, Wiley, has plans to transition JBMR A and B to an online-only format in January 2016. Accompanying this transition, Wiley has promised to increase the page allocation for the two journals by 5 percent per year from 2016 to 2020 to help relieve some of the publishing backlog.

NATIONAL STUDENT CHAPTERS

PRESIDENT JORDAN GILMORE

Over 200 students attended a student lunch at the Annual Meeting in Charlotte, North Carolina. The Student Membership Incentive Program provided a discount of $10 to student members from active local student chapters of the National Student Section of the SFB. Students who join SFB also receive complementary membership to any special interest group (SIG).

If you have any questions, require any information or have suggestions for improved services, please feel free to contact the Society's headquarters office:

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Fax: 856-439-0525
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www.biomaterials.org

SPECIAL INTEREST GROUPS

REPRESENTATIVE STEVE LITTLE, PhD

Newly elected officers for the 2015–2017 term have been installed. The new SIG representative to the Board of Directors (Brendan Harley) has established the following priorities for each of the SIGs.

1. Complete proposals for 2016 proposed satellite sessions
2. Submit budget proposals by Aug. 15, 2015
3. Submit ideas to recognize the 25th anniversary of the SIGs in 2016
4. Identify content for the *Journal of Biomedical Materials Research* (JBMR) virtual issues
5. Appoint student, Web, forum and industry representatives

Biomaterials Forum Cover Contest

Submit photos of biomaterials from your lab to be used on the cover of the Biomaterials Forum by August 1 to Executive Editor Liisa Kuhn at lkuhn@uchc.edu. Once all submissions are in, those that meet the initial requirements for content will be put on the SFB Facebook page for voting to rank the top 10 pieces of artwork. The top five will be used on the cover for future issues of the Forum and the remaining five will be published within the Forum.

The 9th European Symposium on Vascular Biomaterials

October 16–17, 2015 • Strasbourg, France • Esvb.net

New Endovascular Technologies — From Bench Test to Clinical Practice

2015 topics include:

- New technologies for thoraco-abdominal and abdominal aortic aneurysms treatment
- Review of infrainguinal technologies/techniques
- Review of debulking technologies/devices

Request for Proposals: Biomaterials Forum Editor for the Society For Biomaterials

Objectives of Editor

Organize, develop and upgrade the quarterly Society For Biomaterials (SFB) newsletter, Biomaterials Forum with the support of Association Headquarters and other members of the SFB team as available. SFB's management office will provide hands-on design and publication service.

Terms

The term of office shall be for five years, with continuation at the consent of the Editor, Council of the Society, and Board of Directors. Detailed terms of the editor agreement will be made available to candidate editors upon submission of a proposal. Candidates must be an active or senior member in good standing of the United States Society For Biomaterials, and must remain so for the term of service. Candidates must provide, at their own expense, computers, telephone access and Internet access. No hardware or contract services shall be provided, although reasonable expenses shall be reimbursed.

Format of the Proposal

A. Resume including biomaterials and publications experience

B. Vision statement for Biomaterials Forum (not more than one page)

C. Up to three letters of reference stating qualifications and experience appropriate for editorship

All of the above information should be forwarded in one package to the Executive Director, Dan Lemyre, at dlemyre@biomaterials.org by ***July 6, 2015.*** Service will begin at a time agreed upon by the Editor and the Council of the Society. Candidates will be contacted on a rolling basis beginning immediately.

Skills and Requirements of Proposed Editor

The Editor should have experience with scientific publications and newsletter design, content and editing. The candidate must be a biomaterials scientist from any recognized professional discipline and should describe relevant experience for the proposal (note: because the Editor shall be expected to make judgment on appropriate content for the website that could be of a technical nature, a biomaterials-related technical or clinical education is considered a minimum level of experience). Additional publication or graphic design experience will also be considered to demonstrate talent of the candidate. All hands-on work will be provided by Association Headquarters or as directed by the Editor.

Responsibilities of Editor of Biomaterials Forum

A. Establish an editorial schedule with help and guidance of the Managing Editor at Association Headquarters

B. Solicit content from regular contributors, a.k.a. reporters

C. Solicit related feature articles and top stories

D. Author content based upon current press releases, key news items and public domain information

E. Edit and approve content from members, officers, SIGs and committees

F. Author "compiled from reports" as needed for "Top Stories"

G. Identify potential advertisers

In the proposal discuss how the candidate may provide the above stated services and offer other suggestions that may be relevant to Biomaterials Forum.

Members in the News

BY HORST VON RECUM, 2014-2015 MEMBER-AT-LARGE

Hello all! This issue marks my final Members in the News for the Biomaterials Forum. I have enjoyed hearing from all of you with your wonderful accomplishments and recognitions. I would like to introduce you to Elizabeth Cosgriff-Hernandez, who is your new Member-at-Large, and who will be handling Members in the News for the coming year. Please forward any interesting news, either about yourself or your colleagues, to her at cosgriff.hernandez@tamu.edu.

Some amazing folks we want to recognize this quarter include:

Dr. Art Coury, long-time member and Past President of the Society For Biomaterials (SFB) and University Distinguished Professor at Northwestern University, was elected co-chair of the SFB Chinese-American Forum in Haiku, China.

Dr. Rebecca Carrier, associate professor and associate chair for research at Northwestern University, was recognized with the 2015 International Journal of Nanomedicine Outstanding Scientist Award. Dr. Carrier's research is on the quantitative, mechanistic understanding of compound transport in the body to enable rational design of drug-delivery systems, streamlining the resource-intensive, drug-development process and enabling viable pharmaceutical products to be developed from promising drug candidates.

Dr. Buddy D. Ratner, professor of bioengineering and chemical engineering at the University of Washington and the Michael L. and Myrna Darland endowed chair in technology commercialization, has been selected as a 2015 Langmuir Lecturer. Langmuir Lecturers are selected by representatives from the American Chemical Society (ACS) Colloid and Surface Chemistry Division and representatives from the journal *Langmuir*. Each Langmuir Lecturer will deliver a plenary lecture in a special session of the Colloid and Surface Chemistry Division program at the 2015 ACS Fall National Meeting in Boston, Massachusetts.

Please congratulate **Professor Molly Shoichet** from the University of Toronto, for receiving the L'Oreal Unesco Award for Women in Science. This is a prestigious award recognizing the top women in science around the world. Molly Shoichet is a polymer scientist and engineer working on new ways to deliver drugs to the spinal cord and brain to prevent damage and promote recovery after injuries, such as a stroke. Shoichet is one of five women around the world being honored with the award this year. Each award will come with a $139,633 grant. The awards were presented at a ceremony in Paris, France on March 18.

The University of Memphis Research Foundation (UMRF) has been granted United States patent No. 8,993,540, "Compositions and Methods for Delivering an Agent to a Wound." It is the 20th patent granted to UMRF. The product covered by this patent was invented in the University of Memphis Herff College Of Engineering's Department of Biomedical Engineering (BME). The inventors are **Dr. Warren Haggard** and **Dr. Joel Bumgardner**, both professors of BME, and **Dr. Scott Noel** of Bionova Medical, who earned his PhD under Haggard's supervision. The Sentrex BioSponge (Bionova Medical) covered by the patent is being used in medical centers around the country to aid in local management of a variety of wound types.

Professor Christopher Jewell, assistant professor in the Fischell Department of Bioengineering at the University of Maryland, has been named one of six 2015 Damon Runyon-Rachleff Innovators by the Damon Runyon Cancer Research Foundation. According to the foundation, the Damon Runyon-Rachleff Innovation Award is designed to support the next generation of exceptionally creative thinkers with high-risk/high-reward ideas that have the potential to significantly impact the prevention, diagnosis or treatment of cancer. Dr. Jewell's lab designs new materials for therapeutic vaccination. As a Damon Runyon-Rachleff Innovator, Dr. Jewell will receive flexible support to develop a polymer-based cancer vaccine aimed at controlling T-cell differentiation to combat tumor relapse. Dr. Jewell is a member of the Immune Engineering special interest group (SIG) and co-chaired a session on biomaterials and adaptive immunity at the national meeting this year in Charlotte, North Carolina.

Dr. Paulette Spencer, an active member of the Dental/Craniofacial SIG and one of the SFB representatives to the International Union of Biomaterials Fellows, has received a Faculty Fulbright Fellowship to Brazil. Dr. Spencer is the Ackers distinguished professor in the department of Mechanical Engineering and director of the Bioengineering Research Center at the University of Kansas, School of Engineering. Spencer and her research team are designing and creating new dental restoration materials that will function better and last longer than those currently used for composite restorations. To create a new dental restoration material that is superior to products already used by dentists, Spencer's team modifies the chemistry and then

tests how the new material functions in the research lab. By adding a carboxylic acid group to the material, they made it easier to mix with water. By adding a vinyl group, they improved mechanical performance. The name of their colorless liquid creation is BMPMOB, which stands for 4-((1,3-Bis(methacryloyloxy) propan-2-yl)oxy)-2-methylene-4-oxobutanoic acid.

Congratulations to the 2015 **American Institute for Medical and Biological Engineering** (AIMBE) **Inductees.** AIMBE is a non-profit organization headquartered in Washington, DC, representing 50,000 individuals and the top 2 percent of medical and biomedical engineers.

Kimberly Anderson, PhD, University of Kentucky
Jianjun Cheng, PhD, University of Illinois
Christopher J. Damien, PhD, Dentsply International
Shrojal Desai, PhD, Hospira Inc.
Michael Detamore, PhD, University of Kansas
Peter G. Edelman, PhD, Boston Scientific
Agata Exner, PhD, Case Western Reserve University
Darrell J. Irvine, PhD, Massachusetts Institute of Technology
Johnna Temenoff, PhD, Georgia Tech/Emory
Xingdong Zhang, Sichuan University

Dr. Jeffrey Jacot, was awarded a promotion to associate professor with tenure in the Department of Bioengineering at Rice University. Dr. Jacot specializes in the study of congenital heart disease and heart defects, and in the translation of novel regenerative cardiac therapies for young patients of various stages in their growth and development. He works alongside surgeons, clinicians, radiologists and biologists to understand the clinical needs in congenital heart defect management and repair, analyze the mechanical and biological processes in heart tissue development, and develop novel biomaterials for tissue-engineered heart muscle.

Dr. Kristopher A. Kilian, assistant professor at the Department of Materials Science and Engineering at the University of Illinois, Urbana-Champaign received an NSF CAREER Award entitled, CAREER: Mechanochemical Signaling During Somatic Cell Reprogramming. Dr. Kilian's research group engineers biomaterial interfaces at the molecular, nanometer and micrometer scale to mimic the structure and properties of the extracellular environment for exploring and directing cell fate and function.

Dr. Agata Exne was awarded a promotion to full professor in the Department of Radiology at Case Western Reserve University. Dr. Exner's laboratory for Image Guided Therapeutics has been working in the area of image-guided drug delivery since its inception in 2003, and their efforts have resulted in several techniques for noninvasive characterization and modulation of drug delivery on a broad scale — from in situ forming implants to multifunctional nanoparticles.

Dr. Jeff Capadona was awarded a promotion to associate professor with tenure in the Department of Biomedical Engineering at Case Western Reserve University. Dr. Capadon's laboratory has the long-term goal of developing advanced materials for neural interfaces that will seamlessly assimilate within the neural tissue to facilitate sustained molecular level connections with individual neurons.

An Interview with Glenn D. Prestwich

BY LIISA KUHN, EXECUTIVE EDITOR, BIOMATERIALS FORUM

Dr. Glenn D. Prestwich, BSc, PhD

Dr. Glenn D. Prestwich, BSc, PhD, is the presidential professor of medicinal chemistry and the special presidential assistant for faculty entrepreneurism at the University of Utah. He has also directed two Utah Centers of Excellence: the Center for Cell Signaling (1997–2002) and the Center for Therapeutic Biomaterials (2004–2008). His passion for translational research and scholarship led to his appointment as director of the Entrepreneurial Faculty Scholars program at the University of Utah (2008–current). He was elected as a Fellow of the National Academy of Inventors (2014–present) and a Fellow of the American Institute for Medical and Biological Engineering (2005–present).

He has launched over nine small life science companies in the last 20 years, including Clear Solutions Biotech in Stony Brook, New York (1994–2001); Echelon Biosciences, Inc. in Salt Lake City, Utah (CSO, 1997–2003); Sentrx Surgical, Inc. in Salt Lake City, Utah (CSO, 2003–2004); Carbylan BioSurgery, Inc. in Palo Alto, California (2004–present); Sentrx Animal Care, Inc. in Salt Lake City, Utah (2005 –present); Glycosan BioSystems, Inc. in Salt Lake City, Utah (CSO, 2005–2011); GlycoMira Therapeutics, Inc. in Salt Lake City, Utah (CSO, 2008–present); Metallosensors, Inc. in Salt Lake City, Utah (CEO, 2011–2014): Deuteria Agrochemicals LLC in Reno, Nevada (2013–present); and Deuteria Biomaterials LLC in Reno, Nevada (2013–present). He is currently a Scientific Advisor for Echelon-Frontier Scientific, University Medical Pharmaceutics, Elastin Specialities, AshaVision, Jade Therapeutics, American MedChem, Organonovo, Modern Meadow and BioTime.

He received the Utah Governor's Medal for Science and Technology in 2006, was awarded the 1998 Paul Dawson Biotechnology Award and the 2008 Volwiler Research Award of the American Association of Colleges of Pharmacy. In 2010, he received the University of Utah Distinguished Scholarly and Creative Research Award, as well as the 2010 Rooster Prize of the International Society for Hyaluronan Science for outstanding contributions to hyaluronan-derived products. During his 37 years as a faculty member, he has published over 650 technical papers, patents and book chapters, and has trained over 125 postgraduate scientists. In 2011, he was invited to serve as a member of the editorial advisory board for *Science Translational Medicine*. His university research programs included new reagents for lipid signaling in cell biology and cancer treatment; biomaterials for wound repair, cartilage repair, tissue engineering, scar-free healing, toxicology and xenograft models; and sulfated glycosaminoglycan analogues as inflammation modulators for clinical use.

In what subject area did you get your undergraduate and graduate degrees?

I received my Bachelor of Science in Chemistry from Caltech in 1970 — I decided I would go there in 8th grade to become a mathematician or astrophysicist. Math and physics at Caltech were above my pay grade, but I had an inspirational chemistry professor, Jürg Waser, and I liked to cook, so I became enamored with the art and science of synthetic organic chemistry. I received my doctorate in organic chemistry at Stanford. This seemed like the only logical choice, from professional "son" (Ireland) to "father" (WS Johnson) as mentor.

Did you complete postdoctoral studies?

Yes, but it is an odd story. I was supposed to be an assistant professor at the University of Sao Paulo, but funding by the United States National Academy of Sciences (NAS) collapsed. In January 1974, I pivoted from learning Portuguese to learning Swahili, and headed off, in June 1974, as a Meinwald-Nakanishi postdoc with the National Institutes of Health (NIH) postdoc fellowship to Cornell for a few months to learn insect natural products chemistry, and then to Nairobi, Kenya at the International Center for Insect Physiology and Ecology. I spent three years working on natural products of insects, such as termites, ticks, army worms, tsetse flies, bugs, beetles and mosquitos.

How did your postdoc help you with your career development? What did you learn during your postdoc that you hadn't learned during your doctorate?

It literally changed everything. I went from being a pure synthetic chemist to a cross-disciplinary scientist with a market focus. In the first three years, my "customers" were all entomologists and insect biochemists, and this continued into my academic career at SUNY Stony Brook for the next 12 years. My role was to be the chemist who made molecules — radiolabeled, chemically modified, affinity labels, agonists or antagonists — for scientists everywhere in the world studying insect behavior, insect development and insect physiology. It was a life and career-changing experience. I was on my own, and began a side career as an actor, and also as a photographer — culminating in writing and photographing an article, Termites: Dwellers in the Dark for National Geographic (April 1978).

To find out more about Dr. Prestwich's organizations, visit **pharmacy.utah.edu/medchem/prestwich/index.html** or **utah.edu/innovate.**

What jobs have you held throughout your career?
In addition to the standard assistant/associate/full professor positions, I directed a Center of Advanced Technology in Biotechnology at SUNY Stony Brook for four years. This was a major career pivot, in which I embraced, rather than eschewed, commercialization of technologies by building a biotech sector in New York, helping faculty start companies. When I ran into brick walls in New York, I moved to the University of Utah as Chair of Medicinal Chemistry, and ended up starting up a total of some eight companies, mostly from my research, growing now to a total of 11 companies, including one non-profit. At Utah, I also became adjunct faculty in the Chemistry, Biochemistry, Bioengineering and, most recently, Surgery Departments. I also created the role of Special Assistant to the President for Faculty Entrepreneurism, and in 2007 I started, and still direct, the now oft-imitated Entrepreneurial Faculty Scholars program at the University of Utah.

What attracted you to the position at your present institution?
My frustration with barriers in New York and the openness, collaboration-welcoming and can-do entrepreneurial attitudes at the University of Utah got me where I am now. The continued desire to create and develop a culture of impact has propelled my career to a different level and different place than I ever thought possible or probable based on the first 15 years of my academic career.

When did you first take your first *real* job? How long did you work there?
My first academic job was in the department of Chemistry at SUNY Stony Brook, beginning in 1977. I was there for 19 years, moving to the University of Utah in 1996. I have now been at Utah for 19 years.

What different positions have you held throughout your career?
Many, and also many C-level positions in startup companies, including CSO for Echelon Biosciences, Sentrx Surgical, Glycosan Biosystems and GlycoMira Therapeutics. I've been CEO of Metallosensors. I am currently President of the non-profit Sounds of Science Commissioning Club and manager of three LLCs (Clear Solutions Biomedical, Deuteria Agrochemicals and Deuteria Biomaterials).

How is the line drawn between basic science and applied science at your place of work? What particular research directions are of high priority or profile at your place of work?
Line? What line? There is a continuum basic research, or the creation/discovery of new knowledge, becomes — being first applied to solve research problems and then applied to address the needs of society in health, energy, transportation, etc. Recognizing the importance of people as the ultimate customers of science helps us realize that communication and creative arts can also contribute to translating technology to useful products.

What are some of your favorite aspects about working at your institution?
I get to be creative, inspire young students and be inspired by students' passion and no-guts-no-glory approach to living and learning. I have the good fortune to have my entrepreneurial tendencies not simply tolerated by the university administration, but embraced and placed at the highest priority on their agenda. It's my pleasure to work with the smartest, the most creative and the most interesting people on campus, and have this be my job!

What do you do in a typical week? How do you divide your time between those activities?
I've now outsourced all research and development activities to my physician mentees and to my start-up companies. My days are focused on six main activities, 1) working with physician scientists in my labs and their research teams to understand inflammation and how to clinically manage it in the bladder, mouth and sinonasal regions; 2) building relationships among entrepreneurial faculty and students in science, engineering and medicine to maintain and grow the university's culture of impact; 3) managing and advising research and product development at several of my start-up companies; 4) connecting university entrepreneurs with the business community to realize the optimal societal potential of their inventions; 5) working nationwide and internationally to assist other universities with their commercialization, impact and entrepreneurial aspirations; and 6) creating new and unprecedented initiatives to connect and integrate the creative arts and design communities with the science, engineering and medicine communities.

Do you set your own priorities and deadlines and how do you do that? Any advice for young biomaterials scientists about time management?
At this point in my career, I set and manage everything to suit my own schedule and priorities. When I was getting started, and developing an independent career, the key was to prioritize what would make the most difference and do that. Ask yourself, will this activity "move the needle" on my future plans, or is it a time sink/treading water/back-sliding activity? Avoid the latter; emphasize the former. This includes well-

planned experiments. Oftentimes what you plan is routine, incremental and, ultimately, boring and forgettable. Take chances. Follow tangents. But then always keep asking yourself whether you are wasting your time or creating your future.

How did your college education and postdoctoral training prepare you for the job you do today?
College and graduate school provide the background and give you breadth and some minimal depth in specific skills — in my case synthetic organic and natural products chemistry. Everything else I learned on the fly, as needed. I advocate this approach. Become an expert in something first. Then broaden and learn a little about a lot of things, deepening your knowledge as it becomes required to take the next step. In my case, for my first 15 years as a professor, I knew nothing about clinical needs, biomaterials, commercialization, medicine, cell biology, engineering or anything else that I'm now considered knowledgeable about. I learned on sabbaticals, I learned from collaborations, I learned by embracing my own ignorance and working with experts in their own right who needed my expertise in chemistry.

What courses or activities would you recommend that college students take to be prepared for a job like yours?
There is no pathway other than what I've outlined above. Become the best at something, than add new areas of expertise, with collaborations, that make you unique because you can bridge disciplines others are stuck inside. My advice, which encapsulates my career, comes from Yogi Berra, "When you come to a fork in the road, take it." I've gone in multiple directions all at once in my life; there always comes a time when you have to decide, but when the time comes, decide with evidence accumulated, rather than excluding the options at the outset. Look for opportunities because in most cases the real jobs will be 5–10 years in the future. Prepare yourself for the future! Be a leader, not a follower.

Glenn's outside interests include singing first tenor in the Utah Symphony Chorus, using his commercial pilot license to fly non-emergency medical patients for AngelFlight West and serving on the Board of Directors of the Orcas Island Chamber Music Festival and the Salt Lake City NOVA Chamber Music Series.

What are key qualifications or job expectations for someone seeking employment at your institution?
Embrace complexity. Engineer versatility. Deliver simplicity. This is the essence of translational science, and we neglect these three all-important phrases at our own peril, and at the peril of the public understanding/appreciation of what we do as scientists and engineers.

What is some of the best career advice you've been given?
Actually, my dad suggested when I was 13 that I should learn to distinguish between sales and marketing. Scientists are terrible at this — we all tend to be salespeople, trying to hawk our brilliance and our whiz-bang new technologies. In contrast, engineers are trained to focus on a market, on design criteria to build something for a specific customer. Academic engineers often stray into sales, creating cool stuff without adequate consideration for the end user. This tendency should be avoided; staying focused on the end users — in biomaterials that means patients, physicians, healthcare providers and payers.

What do you think are the most exciting new biomaterials/tissue regeneration developments as of today and where do you think the future of biomaterials/tissue regeneration is going?
The most important things to do is to avoid overhyping stem cell therapies and underestimating their timelines, costs and regulatory pathways. Yes, it's the future. Yes, it's coming. Yes, it will change all of our lives. But don't mislead or over-encourage the public. Celebrate the successes as they occur in the clinical pipeline, but reinforce your concerns and your cautionary notes. The public will thank you for your honesty. Replacing organ transplants with engineered tissues is wonderfully compelling science — fiction — which means, yes, eventually, but the market incentives and regulatory hurdles are just out of reach. This kind of organ-replacement tissue engineering is still, as it was in 1996, 10–20 years in the future. What is coming first is adoptive cell therapy — using stem cells to heal and cure with local implants for regenerative medicinal purposes, or for slow release from a hydrogel or other depot for long-term trophic effects. What is coming first is techniques to provide a bridge to transplantation, keeping needy recipients alive longer and with better quality of life.

SFB Annual Meeting 2015

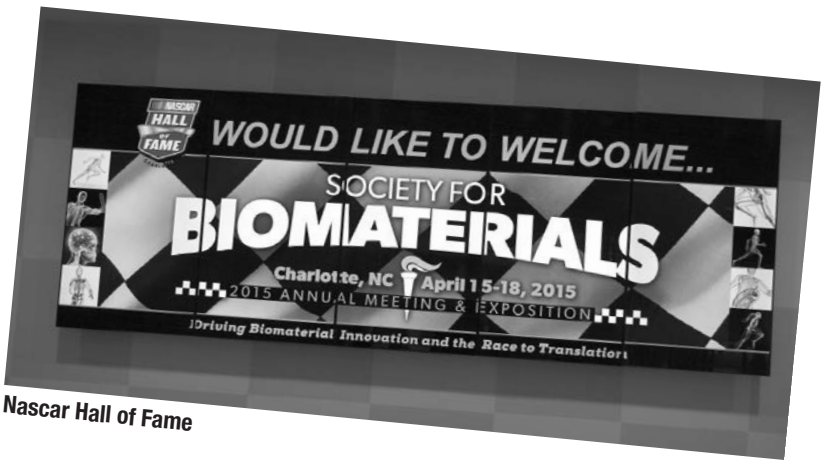
BY LIISA KUHN, EXECUTIVE EDITOR, BIOMATERIALS FORUM

Poster Session

Nascar Hall of Fame

Liisa Kuhn and Lynne Jones

Nick Ziats, Carl McMillin, James Anderson



Nascar Hall of Fame

BIOMATERIALS FOR REGENERATIVE ENGINEERING

SUBMITTED BY CO-CHAIRS GULDEN CAMCI-UNAL, YUSUF KHAN, LAKSHMI NAIR

The sessions of the 2015 Society For Biomaterials (SFB) Annual Meeting covered a wide range of topics, including tunable fibrous scaffolds for growth factor delivery; biologically functionalized hydrogels for chondrogenesis; stem cell therapy for spinal cord injury; oxygen-generating scaffolds for wound healing; pre-vascularized and 3D printed scaffolds for regeneration of bone; and engineered hydrogels for modulation of cell behavior. Additionally, invited speaker Professor Cato Laurencin, MD, spoke about the theory and practice of regenerative engineering. The sessions also highlighted some new developments in musculoskeletal tissue engineering: regeneration for large osteogenic defects; delivery of growth factors in microparticles or hydrogels for acceleration of bone growth; stem cell-based approaches for regeneration of ACL; composite engineered muscle for directing stem cell fate; and neuron-endothelial cell co-cultures for development of engineered muscle constructs.

CERAMICS AND COMPOSITES IN BONE TISSUE ENGINEERING AND DRUG DELIVERY

SUBMITTED BY CHAIR DAVID KOHN

This symposium focused on recent advances in ceramics and ceramic composites used in musculoskeletal regeneration. Papers spanned the spectrum of the synthesis of new ceramics and composites to characterization of new and existing ceramics to designing biological responsiveness into ceramics to in-vivo evaluation of materials. A paper by Chen and Kohn introduced calcium phosphate-polycarbonate composites for bone tissue engineering, while Ostrowski et al presented work on magnesium phosphate ceramics. Krishnamurthy et al presented fundamental work on twinning-induced enhancement of fracture toughness in HA composites.

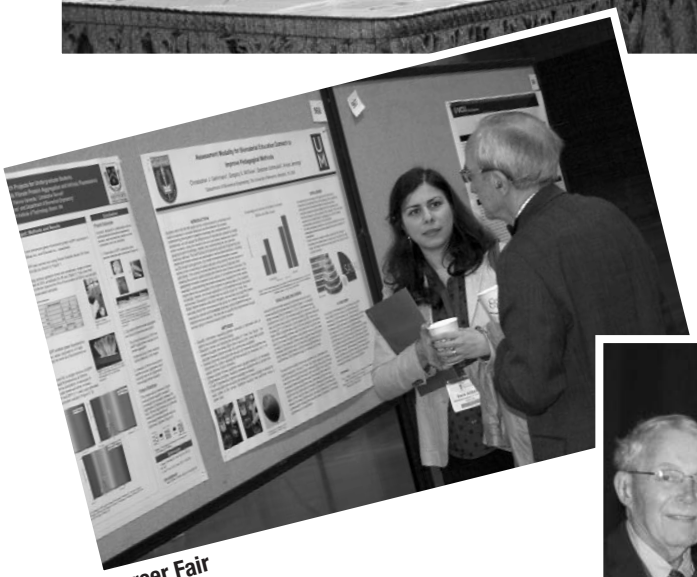
Several other papers highlighted how ceramics can be modified to orchestrate specific biological responses. Stolzoff and Webster showed anti-cancer and anti-microbial properties of polymer scaffolds doped with selenium nanoparticles. Gu, et al, demonstrated the release of simvastatin from calcium sulfate and calcium phosphate ceramics. Ramaraju and Kohn showed how peptides discovered from phage display can serve as tethers between ceramic surfaces and human stem cells and offer specificity in cell adhesion. A last set of papers, by Knabe et al and Ishikawa, et al, highlighted the in vivo response to different forms of tricalcium phosphate and porous carbonated apatite grafting materials, respectively.

This symposium fit well in the multi-functional biomaterial design theme area of this year's SFB meeting. The papers presented in this symposium demonstrate how ceramics have evolved beyond a space-filling role and into the realm of biohybrid materials, which can combinatorial achieve structural and biological functionality.

Business Plan Competition

Liisa Kuhn, Lynne Jones, Peggy Lalor, Dan Lemyre and Alan Litsky

Business Plan Competition



Career Fair

STEM CELL AND BIOMATERIAL INTERACTIONS

SUBMITTED BY CO-CHAIRS JASON BURDICK AND WILLIAM MURPHY

This session represented diverse studies related to controlling and understanding stem cell behavior through biomaterial interactions, with both adult and pluripotent cells. The invited speaker, Professor Kevin Healy, started the session by describing hydrogel systems where features, like growth factor binding, mechanics and adhesion, could be controlled to modulate cell fate. Other presentations worked toward the formation of bone, cardiac, cartilage and neural tissues through control over stem cell fate.

Clemson Basic Research Awardee: Jennifer West, with (from left to right) Jim Anderson, Nick Ziats and Guigan Zhang.

International Journal of Nanomedicine Distinguished Scientist Awardee Rebecca Carrier with Tom Webster.

Nascar Hall of Fame

SFB Staff members, Sarah Mercer and Becky Riedesel with Joel Bumgardner

BIOFABRICATION AND BIOMANUFACTURING IN TISSUE ENGINEERING AND REGENERATIVE MEDICINE (TERM) SESSION 1

SUBMITTED BY CO-CHAIRS OZAN AKKUS AND SANG JIN LEE

The keynote speaker, Professor Utkan Demirci of Stanford, introduced two cutting-edge fabrication methods during his presentation. The first was microscale assembly of cells in liquid environment using Faraday waves by using simple components, such as function generators and vibration shakers. The second method enabled sorting of cells based on differences in densities using magnetic levitation enabled by paramagnetic fluids and permanent magnets. Two presentations focused on application of dissolved polymeric solutions with a technology stemming from airbrush concept and their applications focused on bioadhesives. Two presentations aimed to address the fundamental problem of fabricating vascularized tissues, one by patterning patent channels in hydrogels in 3D by photocavitation and the other by using sacrificial channels made by sugar.

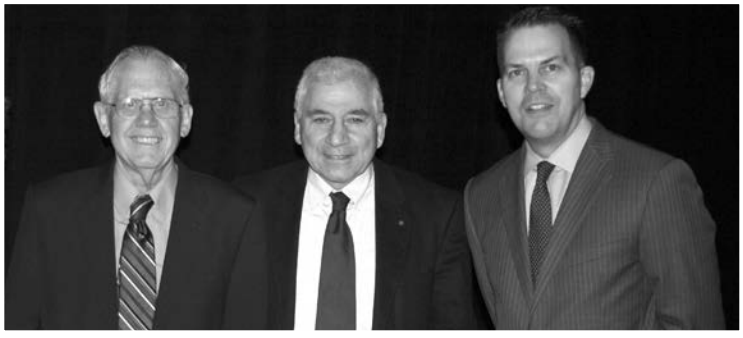
BIOFABRICATION AND BIOMANUFACTURING IN TISSUE ENGINEERING AND REGENERATIVE MEDICINE (TERM) SESSION 2

SUBMITTED BY CO-CHAIRS SANG JIN LEE AND OZAN AKKUS

Professor James J. Yoo of Wake Forest Institute for Regenerative Medicine was a keynote speaker for this session. He spoke about 3D organ printing technology in regenerative medicine research. He indicated that the 3D organ printing technology could provide a leap forward in our ability to fabricate tissue constructs that could be used in translational applications. Four more speakers presented 3D bioprinting related topics, including the development of novel hydrogel-based bio-inks; fabrication of the organized skeletal muscle tissue construct; and bioprinted liver organoids for toxicology testing. Dr. Akkus' group talked about the development of a CAD/CAM-based technique to manufacture pure collagen scaffolds with controlled microporosity that could potentially be used for the repair of a tendon, a hernia, urinary stress incontinence and thoracic/abdominal wall.

Nascar Hall of Fame

Plenary Session III, (from left to right) Jack Lemons, Art Coury and Bill Wagner



Flashback to the 1990 SFB Annual Meeting

BY PROFESSOR ROBERT BAIER, SUNY AT BUFFALO, AND DIRECTOR MARK STACHOWSKI, NPS PHARMACEUTICALS

The hydrophobic/hydrophilic debate was a hot topic at the SFB Annual Meeting in 1990, as seen in this reprint of the Biomaterials Forum from 1990, and continues to be discussed in 2015 (e.g., abstracts with titles such as "Improving Silicone Elastomer Hydrophilicity" and "Interfacial segregation of PEG in hydrophobic polymers and its influence on protein adsorption")

The Bash at Middleton Place provided a taste of the graceful antebellum South.

Society's Financial Health Reviewed

by Buddy Ratner

At the last general business meeting of the Society, (May 22, 1990) concerns were expressed about the financial health of the Society based upon year-end financial statements from Lovoy and Sommerville, the Society's contract accounting firm. On June 6 and 7, 1990, Alastair Clemow and Buddy Ratner visited the Society office in Birmingham. After a detailed review of all financial records in the presence of Polly Gaskins, C.P.A., no significant irregularities were uncovered.

The apparent decrease in assets is not real and is explained by the cash accounting system used, the significant increase in membership over the last two years, the *Journal of Applied Biomaterials* subsidy to the membership, late dues submissions, and an overpayment to John Wiley (which was discovered and rectified well before the visit to the Birmingham office). A detailed accounting will be presented to the ad hoc committee appointed to investigate Society finances (B. Ratner, A. Clemow, P. Ducheyne, J. Parr and S. Shalaby), and, with the concurrence of this committee, a summary report to the membership will be prepared and published in BIOMATERIALS FORUM.

1990 Annual Meeting Well Attended

submitted by Frank Young

More than eight hundred fifty attendees participated in the recent 1990 Annual Meeting. U.S. and Constituent Society members represented forty-seven percent of the attendees. One hundred forty-eight students attended, of whom forty-eight received monetary assistance. The assistance and underwriting of the program was made possible by the generous contributions of the Corporate Sponsors. Thanks to the Corporate Sponsors for their continued support. Bashers shared a glimpse of plantation life at Middleton Place, and a ''Splash of Spoleto'' at the Annual Awards Banquet.

The 1990 Annual Meeting was the first to employ a professional management company to assist with the meeting; the results of the work by ARDEL, Inc. was illustrated by the smooth operation of all facets of the meeting. On behalf of the Local Arrangements and Program Committees, the efforts of all who helped to make the meeting so successful are greatly appreciated, and a warm southern invitation is extended to all attendees to return to Charleston again soon.

In case you wondered… SFB Annual Meeting attendees:

850 IN 1990 AND 1,250 IN 2015

The newsletter of the SOCIETY FOR BIOMATERIALS - the TORCH

MEMBERS MAKING NEWS

Dr. Robert C. Eberhart, Professor and Head, Department of Bioengineering, University of Texas Southwestern Medical Center in Dallas and University of Texas at Arlington, receiving the C. William Hall Research Award from Dr. Hall at the Eighth Southern Biomedical Engineering Conference held in Richmond, Virginia. Also shown (from left to right), Dr. Bill Krause, the conference chairman and Dr. Saha, the chairman of the C. William Hall Awards Committee who started this conference series in 1982. All four are long time members of the SOCIETY FOR BIOMATERIALS.

Bob Baier, outgoing Chairman of Professional Development Committee, and Fred Schoen, outgoing President, were presented with personalized SOCIETY FOR BIOMATERIALS lab coats by the national student chapter in appreciation of their help and support through the first organizing year.

Bundy awarded Senior International Fellowship

Kirk Bundy has been awarded a Senior International Fellowship from the Fogarty Center of NIH for his sabbatical leave research project "Factors Affecting the Adhesion of Soft Tissues to Biomaterials" being conducted at the Laboratory for Experimental Surgery in Davos, Switzerland in collaboration with Stephan Perren and Berton Rahn.

Members are USA Delegates to ISO/TC 194

According to an article in the May-June issue of AAMI NEWS, the following members of the SOCIETY FOR BIOMATERIALS represented the USA at the April ISO/TC 194 Committee meeting at Bordeaux France. Paul Didisheim of the NHLBI led the delegation which included among the twelve delegates, Society members: James Anderson of Case Western Reserve, Donald Gibbons of 3M, Ed Mueller of the FDA, and Sharon Northup of Baxter Healthcare.

Dr. Anderson chaired the working group (subcommittee) WG 1, Systemic approach to biological evaluation and terminology, which produced the first TC 194 document to reach ballot stage. Dr. Didisheim chaired the working group known as WG 9, Effects on blood for standard tests on hemocompatibility testing.

Numerous other working groups met and considered implantation standards, clinical investigations in humans, retrieval and analysis, irritation/sensitization, mucosa contact, cytotoxicity, genotoxicity, and standards issues in general. BIOMATERIALS FORUM welcomes articles from any delegate to the Committee and will continue to bring current information on the standards activities to the readers through the generous cooperation of AAMI and Society member delegates.

WHAT WOULD HAVE TO CHANGE IN BIOMATERIALS TO QUALIFY AS A *QUANTUM LEAP*

by Robert E. Baier

What we clearly need is a change of paradigm: admit that *hydrophilic* and *hydrophobic* terminology and concerns are **insufficient** to describe biomaterials surface properties!

Consider surface energy, or any other approach except surface charge (which, after 25 years since the pioneering work of SFB Clemson Award winner Phil Sawyer, has in my experience been thoroughly evaluated and found wanting). Remember the simple hypothesis, for example, that net negative charge on a cardiovascular biomaterial will repel circulating negatively charged platelets, ignoring Hymie Nossel's finding (confirmed by others) that net negatively charged surfaces activate Hageman Factor (XII).

Here is how *hydrophilic versus hydrophobic* fails: the insides of living blood vessels are hydrophilic; the polished struts of 20-year successful Starr-Edwards heart valves are hydrophobic; both are demonstrably thromboresistant over long blood contact times. Another example: polytetrafluoroethylene (Teflon) is hydrophobic, and thrombogenic; polydimethylsiloxane (fillerfree, medical grade silicone) is hydrophobic, and nonthrombogenic. Other cases: Teeth are hydropilic and very bioadhesive (dental plaque ugh!); the inside of the cheek is hydrophilic too, and bioabhesive (nonstick; How often does one have to brush the inside of one's cheek to keep it free of plaque and adherent debris?). The skins of dolphins and killer whales always fouling free are hydrophilic, while equally hydrophilic algal fronds foul considerably. But let us stay with blood contact, here, and do some serious pondering.

In the general case, we start with the question of whether or not particular biomaterials have measurable surface properties similar to or different from endothelial cells or circulating particles in human blood (like erythrocytes or platelets)*. The goal is to draw some implications regarding the relative blood compatibilities of various materials or their surface modifications.

With contact angle data in mind, it is quite surprising that some *hydrophilic* biomaterials in air can give Zisman-plots (results of contact angle analyses) indicating low (waxlike) apparent critical surface tensions of about 22 dynes/cm. **The good news is that the actual pattern of contact angle behavior, especially including the critical surface tension intercept for the dispersion-force-dominated liquids in the low 20's dynes/cm zone, is nearly identical to that obtained for human red cells, red cell ghosts, and human endothelial cells as well as many other surfaces that show (and have shown) good longterm blood compatibility!!** A report of a critical surface tension value in the low 20's dynes/cm requires here as for red blood cells some explanation in face of the generally expected surface domination of all biological structures (under water) by their polar groups (of higher critical surface tension). Although the entire answer cannot yet be attempted, there are excellent clues for this apparent dichotomy in the contact angle data themselves, as reflected in the plotted data points that fall (far off the line) near the contact angle = 0 ($\cos 0 = 1$) axis. Some (but certainly not all) biomaterials **do show the instant wetting behavior by water and water-miscible H-bonding liquids** expected for materials that circulate without excessive aggregation or sedimentation in aqueous suspensions. **Yet, when challenged by contact with other materials** (e.g. the normal alkanes, and perhaps similar side chains from flexing proteins, etc.) **having only the potential for dispersive, or Van Der Waals, interactions, they present an equally bland, low energy** (nondenaturing, one might argue) **superficial array.**

The important point is that some biomaterials (say hydrogels), like many biological structures for which they are simpler surrogates, are capable of expressing either face (polar or apolar) rapidly as requirements for minimization of interfacial free energies dictate. It is not a correct assumption that minimization of the interfacial free energy between solid (or gel, or tissue, or liposome, or ??) and water assures minimization of the interfacial energy between those substrata and approaching molecules (like proteins) that must enter into a **mutually dehydrated** interaction with the substrata for adhesion to occur at all.

What I teach is that the **appropriate** interfacial tension to minimize is that between the *dry* (not totally, obviously, but just absent any frank liquid phase) substratum and the *dry* biological substance. It is the Zisman-type, dispersive dominated critical surface tension that provides the best and most correlatable information on the interaction energies of interest. Anomalously, contact angle measurements underwater are **less useful** in this regard, and generally correlate with little of thermodynamic, biological interest. Rather, underwater data are useful as being quite predictive of the kinetics of biointeractions with various nonphysiologic materials. The more waterloving of these take longer to foul, but foul more tenaciously when interfacial dehydration events take place (as they always do, stochastically, even at the faces of medical hydrogels). As a personal example, some may note how their *soft* contact lenses, very waterloving and comfortable for a while, become very dirty and distressing as fouling debris from the eye eventually binds almost irreversibly.

As a bottom line, then, avoid the assumption that **hydrophilic** versus **hydrophobic** qualities of biomaterials can teach you how tightly biological things will stick. Hydrophilic vs hydrophobic qualities can tell you how fast biology will come into contact with your material, but **not** how hard it will be to get it back off. A new paradigm is required! I propose. . .(to be continued). . .

Editor's Note: Bob Baier is the Society's current secretary-treasurer-elect and may be contacted through the Industry/University Center for Biosurfaces, University at Buffalo, New York.

*For data, see my generally overlooked chapter with Anne Meyer, *Surface Chemistry and Physics Relevant to Platelet Interactions With Prosthetic Devices and Other Biomaterials*, Chapter 5, pages 174227, in Blood Platelet Function and Medicinal Chemistry (A. Lasslo, ed.), Elsevier Biomedical, NY, 1984.

A Brief Note from Dr. Allan Hoffman

BY GUIGEN ZHANG, CLEMSON UNIVERSITY

For this issue's historical flashback, I asked Dr. Allan Hoffman of the University of Washington to share with us some of his memories from his association with the Society For Biomaterials (SFB), as Dr. Hoffman is a prominent figure in the biomaterials field. He served as the President of SFB from 1983–1984 and he was the recipient of the prestigious Clemson Award for Contribution to Literature in 1984. There was a technical symposium to celebrate his 80th birthday in Maui, Hawaii, in 2012. If you read the flashback piece from Buddy D. Ratner in the last issue of the Forum, you may know already that Dr. Hoffman is Buddy's mentor and lifelong friend. Well, due to Dr. Hoffman's busy travel schedule (yes, he still keeps an active schedule), he could only write me a brief note for now, with a promise to provide a more detailed flashback later this year. So be patient, I promise it will be great. In Dr. Hoffman's brief note, he reflects about a few items from the "good old golden days."

"I remember the cheerful Professor Sam Hulbert of Clemson, who always welcomed us at his bashes with huge buckets of iced shrimp and beer cans. At the Clemson meetings of SFB there were always a lot of good discussions after the paper presentations, and that the polymer guys were mostly involved with National Heart, Lung and Blood Institute (NHLBI) grants on the artificial heart and polymer-blood interactions, while the ceramic guys were mostly involved with bone substitutes like Larry Hench's "Bioglass." Some of the NHLBI people were Steve Bruck, John Watson and Fran Pitlick.

I also remember learning a lot about blood proteins and platelets from very active discussions with Ed Leonard, Jim Anderson and others. The meetings always attracted the top cardiac surgeons, like Bill Hall, Adam Wesolowski and others, and Bill used to organize small discussion groups in hotel rooms with some of the surgeons and a few of us artificial heart bioengineers — and several bottles of good scotch. I was lucky to be included in a number of them.

Also, I remember being so proud of Buddy D. Ratner, my postdoc, when he gave his first professional presentation at the first SFB meeting at Clemson in 1975."

Wow, early SFB meetings were scientific gatherings of engineers and surgeons with shrimp, beer and good scotch! No wonder he calls those days the "good old golden days." Following my curiosity about these names, I dug out the whole list of charter members — the pioneers of SFB — and here they are.

Charter Members, by state and country 1974

USA:
Alabama
Wartan A. Jemian
Jack E. Lemons
Arkansas
Carl L. Nelson
California
Paul Kahn
James A. Stubstad
Paul Ehrlich
William C. McMaster
Charles O. Bechtol
Stephen L. Cannon
Dale E. Grenoble
Caesar F. Orofino
Richard C. Capozza
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IMPROVED IMPLANT PERFORMANCE THROUGH DESIGN: A STUDY IN SHEEP

BY PEGGY LALOR, PhD, HISTION, LLC

Of interest to the Biomaterials Tissue Interaction SIG and other Society For Biomaterials (SFB) members is the following data generated during preclinical testing of a biocompatible titanium alloy interbody fusion cage manufactured using a 3D printing process to create an open, strut-configured device that more closely mimics the mechanical properties of vertebral bone than conventional interbody fusion designs.

Approximately 100,000 lumbar spine fusion surgeries are performed annually in the United States in patients with lower back pain due to degenerative disc disease, deformity, unstable spine trauma or spondylolisthesis. Treatments for disc degeneration, one of the principle causes of lower back pain[1-3] afflicting people of all ages, range from conservative exercise to spine fusion surgery. Spine interbody fusion devices (IFD) are used to maintain or restore disc height and facilitate fusion. Most traditional cage devices currently used for interbody procedures are made from polyether ether ketone or titanium. They are relatively small, porous and hollow, and fall into two broad categories — threaded cylindrical cages and variations on a ring design.

These designs are capable of performing their intended function of distraction, height restoration, pain reduction and restoration of lordosis.[4] While they can facilitate successful fusion when used in combination with autograft, allograft or bone-regeneration devices, the device designs are dissimilar to normal vertebral bone, and, as such, have an inherent disadvantage of non-physiological load-transfer between the implant and the surrounding bone and other biological structures. Use of traditional design fusion cages is associated with stress shielding, cage migration and fibrous tissue formation around the devices, which can ultimately lead to instability, failure of the devices and nonunion.

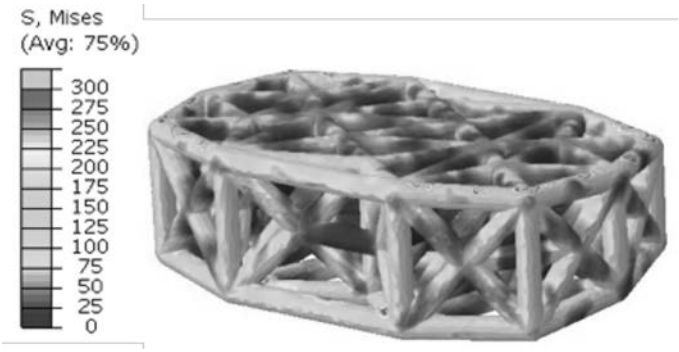

Figure 1. The Spine Truss System (STS) cage, modeled under compression, shows that the device is capable of multidimensional load bearing throughout the truss design.

Implant Design

A novel titanium intervertebral fusion device, named the Anterior Lumbar Interbody Fusion (ALIF) Spine Truss System (STS), was designed by 4WEB Medical Inc. in Frisco, Texas, to have a truss configuration that would distribute force under compression and tension, similar to the bone, with an open architecture of up to 75 percent porosity, which can be used in combination with autograft, allograft or commercially available bone-graft materials used to facilitate rapid bone formation. The implant intended for interbody fusion was designed to be strong enough to maintain vertebral height and space, while transferring multidirectional load to the surrounding trabeculae in a manner similar to that of normal trabecular bone. Finite element analysis showed that the STS Implant design does transfer force through multiple planes via struts that hold both compressive and tensile loads (Figure 1).

Study Design and Results

To test the implant design in vivo, an IACUC-approved ovine interbody lumbar spine fusion study was completed, in collaboration with Dr. A. Simon Turner and Dr. Howard Seim, using two different strut thicknesses of similarly configured implants filled with autograft, three, six and 12 months following implantation. Radiographs showed no evidence of implant collapse at any point in time for either device design. At six months, 100 percent fusion was seen with both designs, with cage-filled bone morphology architecturally similar to surrounding bone and little cartilage or fibrous tissue at the implant surface (Figure 3).

The noticeable lack of fibrous tissue, cartilage and fibrocartilage results seen microscopically for the STS devices are superior to the six month[5,6] sheep results

reported for conventional titanium cages used in combination with autograft. In those studies, compared to the STS devices, obviously greater amounts of fibrous tissue and cartilage are present at the bone/implant interfaces at six months,[5, 6] and even 12 months.[5] These results indicate that the improved 4WEB design, which has been shown to transfer load in a manner similar to normal trabecular bone, can facilitate an improved spine fusion result compared to conventional designs.

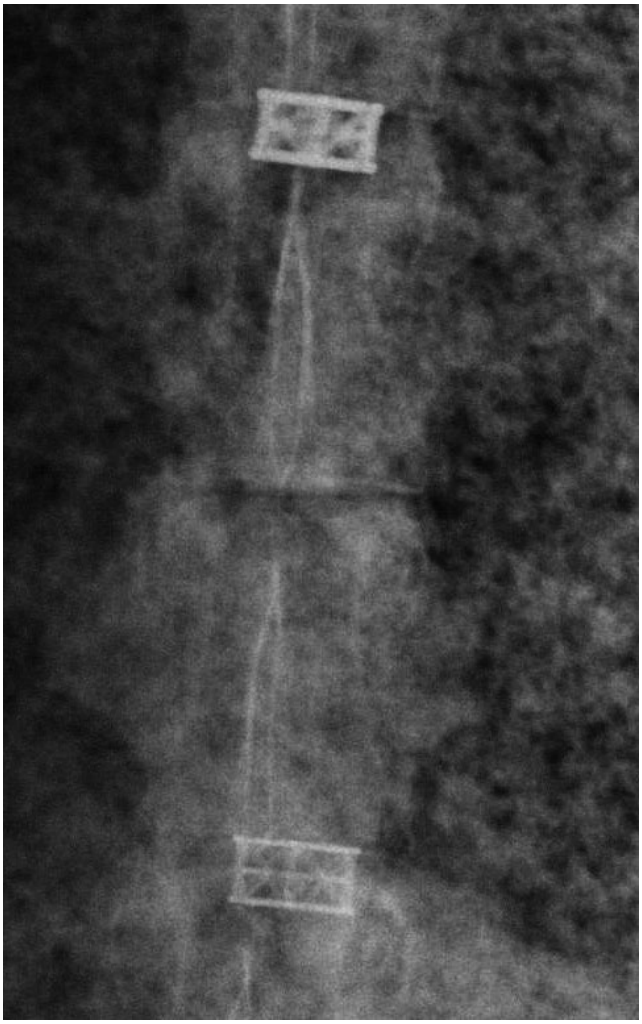

Figure 2. This radiograph of a spine harvested from a six-month animal shows both implanted devices with the 0.75 mm STS in place at the L3/L4 treated level (bottom) and the 1.5 mm STS in place at the L2/L3-treated level (top). The bone can be seen within the cages and neither device shows evidence of structural collapse.

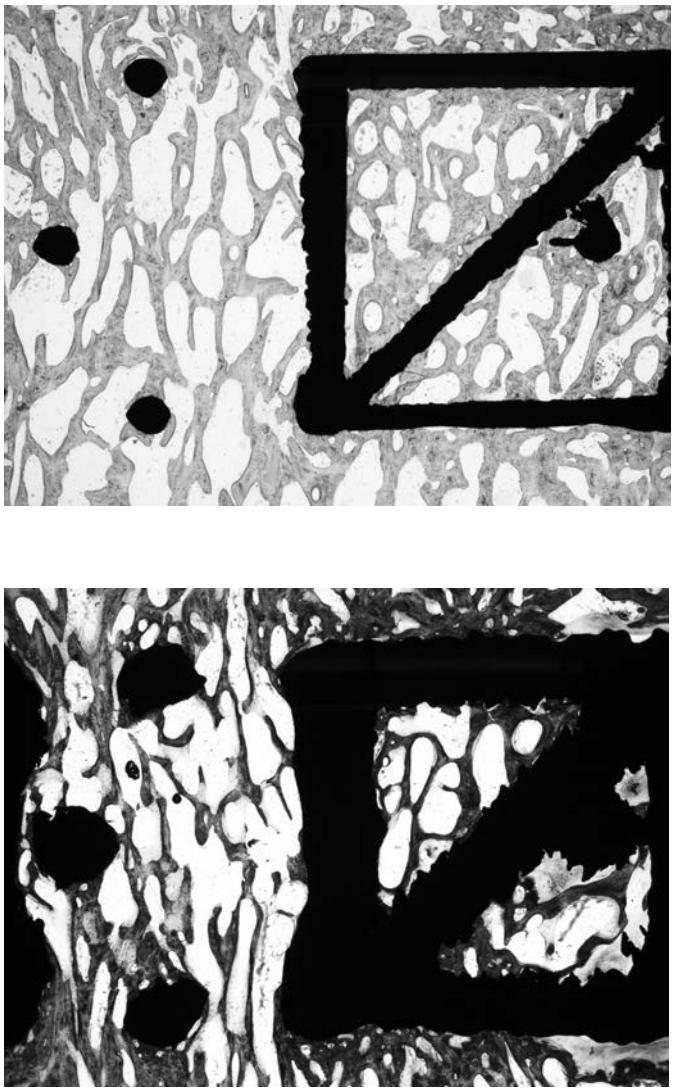

Figure 3. The bone, with an architecture similar to that of the surrounding vertebral bone, can be seen within the 0.75 mm STS implant shown on the left and within the 1.5 mm STS implant shown on the right at six months. Predominantly bone and bone marrow can be seen at the surfaces of both implants.

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News from the Engineering Cells & Their Microenvirontments SIG

ADVANCES IN ENGINEERING THE COMPLEXITY OF THE CELLULAR MICROENVIRONMENT

BY ADAM W. FEINBERG, PhD, DEPARTMENT OF MATERIALS SCIENCE AND ENGINEERING, DEPARTMENT OF BIOMEDICAL ENGINEERING, CARNEGIE MELLON UNIVERSITY

The in vivo microenvironment is complex and dynamic, with cells continually communicating with each other and the extracellular matrix (ECM) through both soluble and insoluble signaling mechanisms. In order to better understand these interactions, researchers have developed a range of in vitro systems that better recapitulate the physical, mechanical and biochemical properties found in vivo. Importantly, these techniques also enable scientists to selectively perturb the microenvironment to better understand how cells interpret these signals and how they respond to their disruption, often with the goal of mimicking known disease states. Recent advances from literature focus on how the microenvironment can be engineered in novel ways to better mimic in vivo conditions, as well as purposely drive cells toward specific, controlled responses.

microfluidic device designed to re-create the in vivo HSPC niche within a small hydrogel in a lab-on-chip format.[1] A microfluidic mixing platform was employed to generate 3D hydrogels containing stable, overlapping gradients of cell and matrix signals inspired by HSPC niches within the bone marrow (Figure 1).

Primary HSPCs remained viable during mixing and culture within the bone marrow biochip platform. Analytical methods at multiple scales were used to examine hematopoietic cell bioactivity, from the single cell to whole construct scales. Uniquely, the sub-regions could be extracted for analysis using conventional molecular biology techniques. The long-term goal of this work is to create niches to study the role of biophysical cues and niche

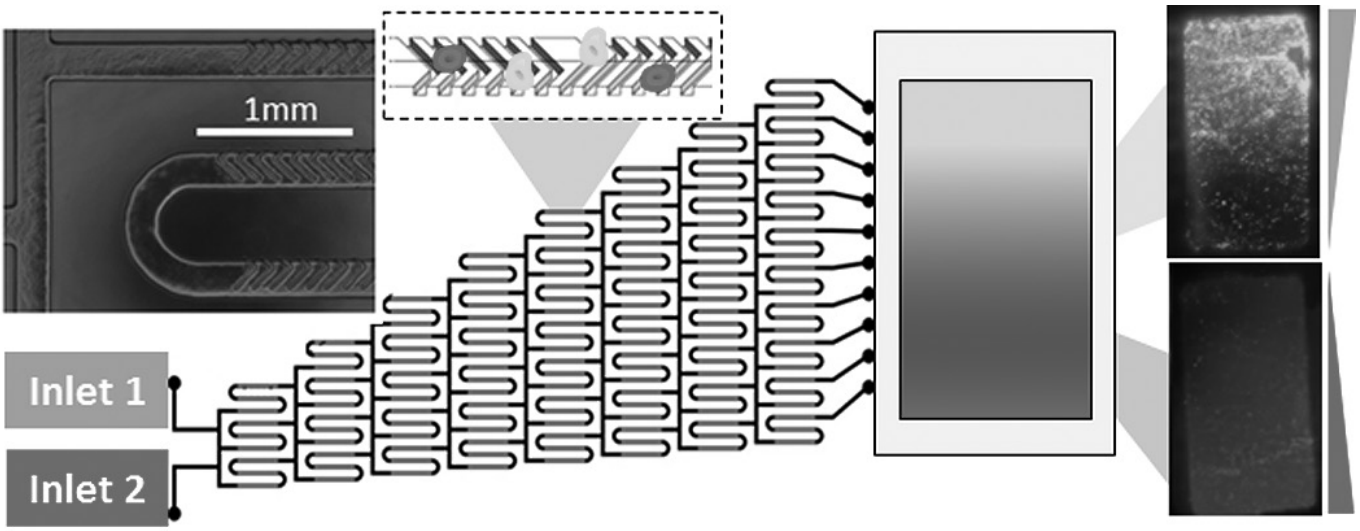

Figure 1. The hematopoietic stem and progenitor cell (HSPC) niche in bone marrow, consisting of overlapping gradients of cell and matrix signals, is recreated using a microfluidic mixing platform. Pictured is proof-of-concept of two gradients generated using green and red microspheres immobilized within a collgen hydrogel is shown.

In both health and disease, the in vivo microenvironment can play a critical role in cell and tissue function. For example the stem cell niche, such as that in the bone marrow, has long been recognized as a providing both bone marrow-derived mesenchymal stem cells and hematopoietic stem and progenitor cells (HSPCs) with the cues to undergo self-renewal and proliferation. Bhushan, et al reported on a cell paracrine, signaling on HSPC fate decisions. This type of approach could also be expanded to study overlapping gradients of cell and matrix signals in other types of stem cell niches.

Many cancers also develop within well-defined microenvironments, often formed directly by the cancer

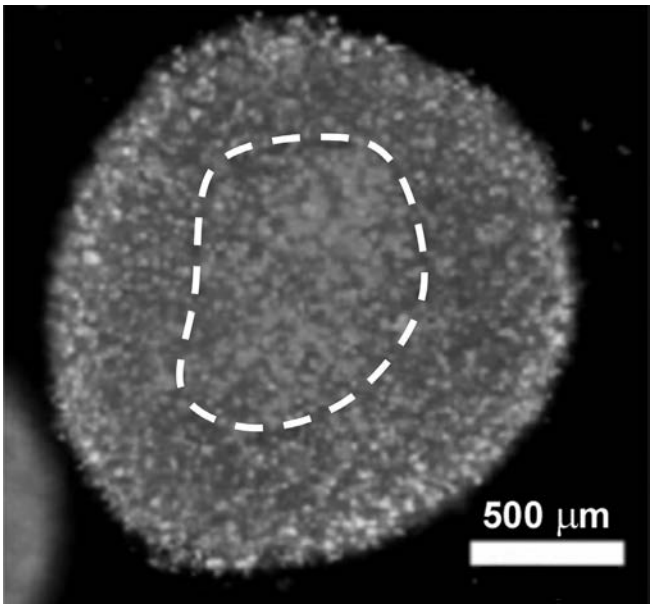

Figure 2. A "tumor millibead" consisting of breast cancer cells in a hydrogel sphere with a necrotic core demarcated using live/dead staining (white dashed line).

cells as the tumor grows. To facilitate physiologically relevant in vitro studies, engineered tumor tissues need to replicate the heterogeneous tumor microenvironment, including areas of hypoxia and cell death. To address this challenge, Pradhan et al developed a novel surface tension-based fabrication technique in order to create millimeter scale hydrogel spheroids with encapsulated breast cancer cells (Figure 2).[2] These "tumor millibeads" were larger than previously reported microscale hydrogel spheroids, highly uniform in shape and size, and had a high degree of consistency between batches. During long-term culture, a core region of dead cells surrounded by healthy, viable cell layers at the periphery was established, mimicking observations of native tumor tissues. While still at the initial stage, the ability to recreate tumor microenvironments with appropriate necrotic cores is important for studies of basic cancer biology and also has potential for high-throughput screening of anticancer drugs in preclinical trials.

Cell response to microenvironmental cues is clearly important at the single cell level, but it can also have important implications at larger spatial scales. In the case of skeletal muscle tissue, contractile function is dependent on the organization of the constituent myotubes. Sun, et al recently explored this relationship by using microenvironmental ECM cues to engineer skeletal muscle thin films with well-defined tissue architecture and quantify the effect on contractility (Figure 3).[3] The optimization of the width and spacing of micropatterned fibronectin (FN) lines was used to increase C2C12 myoblast differentiation into functional myotubes and maximize uniaxial alignment within a two-dimensional sheet. Results showed that a FN line width of 100 μm and line spacing of 20 μm maximized the formation of aligned muscle tissue that could generate a positive force–frequency relationship and a normalized peak twitch stress of 9.4 ± 4.6 kPa. Interestingly, it was found that FN lines 50 μm wide supported myoblast adhesion and growth, but inhibited fusion into myotubes, even under differentiation conditions. These results demonstrate that engineering the microenvironment in terms of ECM geometric cues can control skeletal muscle differentiation and tissue architecture and result in distinct changes in tissue-scale contractile function. Future work will, in part, probe these structure-function relationships further to determine how ECM protein composition, micropattern geometry and substrate mechanics regulate human skeletal muscle myogenesis.

While engineering of the microenvironment in vitro is often targeted toward mimicking conditions in vivo, there are also unique opportunities to purposely perturb the microenvironment in order to evaluate cellular response. Toward this end, Tseng, et al developed a dynamic scaffold that can initiate a shape-memory-actuated change in fiber alignment.[4] In this work a thermoresponsive scaffold was programmed to change macroscopic shape and microscopic architecture during cell culture (Figure 4). A shape memory polymer (SMP) was electrospun and the randomly oriented fibers were aligned by stretching the scaffold and then fixing it in this temporary, but stable position. Human adipose-derived stem cells seeded and cultured on the strain-aligned scaffold initially aligned in the fiber direction, but after the thermally triggered transition went back to a random fiber orientation the cells lost their alignment. These shape-memory-actuated changes in scaffold fiber alignment are notable because it provides dynamic control of cell morphology, while maintaining attachment and high viability. Future SMP's scaffolds have potential applications in the delivery and dynamic control of tissue engineering scaffolds and the in vitro and in vivo study of mechanobiology.

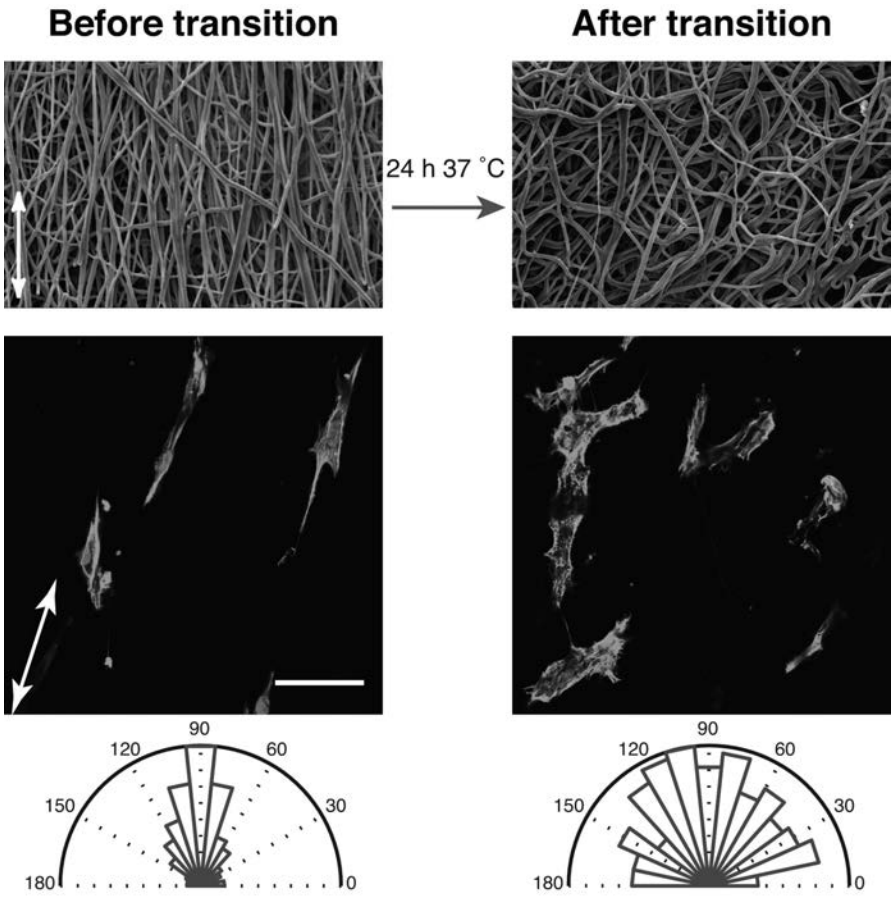

Figure 3. Left, microcontact printed lines of FN were used to direct the alignment and differentiation of C2C12 myoblasts into skeletal muscle myotubes (red = myosin heavy chain). Center, patterning these myotubes onto a muscular thin film (thin PDMS film) enabled quantification of contractile force based on film curvature. Right, contractile stress generated as a function of pacing frequency showed a positive force-frequency relationship and the ability of the muscle tissue to achieve tetanus at high pacing rates.[3]

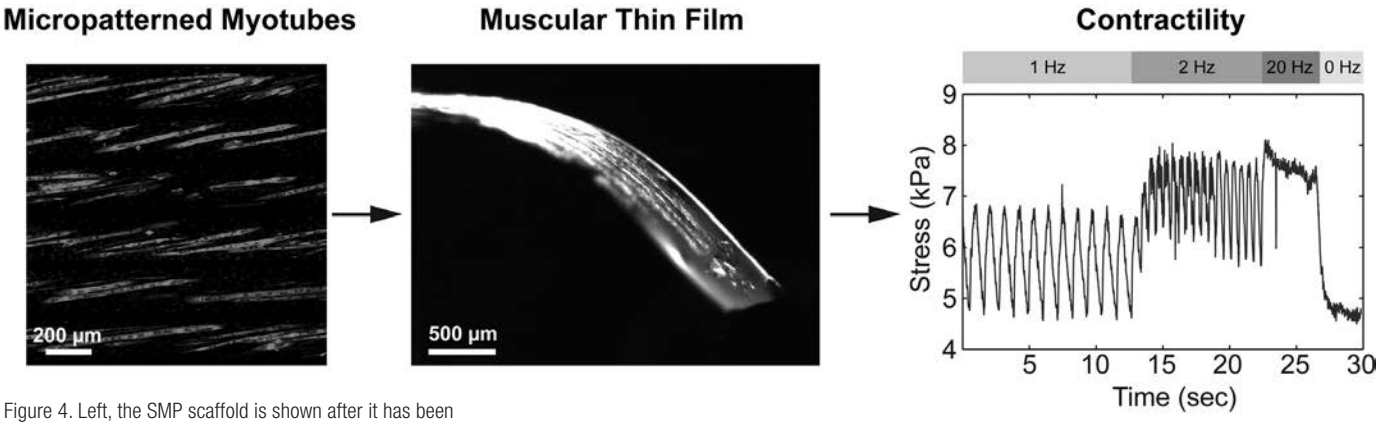

Figure 4. Left, the SMP scaffold is shown after it has been stretched and fixed in position to align the fibers. Seeded human adipose-derived stem cells preferentially align in the fiber direction. Right, after thermal transition the SMP scaffold recovers its random fiber alignment. The attached human adipose-derived stem cells remain viable and lose the initial alignment and adopting and isotropic morphology. Cells are stained for actin (green) and nuclei (orange), scale bars are 50 µm.[4]

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ENCOURAGING UNDERGRADUATE STEM STUDENTS TO PURSUE STEM EDUCATION FULL-TIME

CONTRIBUTED BY YUSEF KHAN, EDUCATION NEWS CONTRIBUTING EDITOR

"Education is learning what you didn't even know you didn't know." — Daniel J. Boorstin

A recent focus of this column has been science, technology, engineering and math (STEM) education, from K-12 and beyond. In previous columns we have discussed the state of K-12 STEM education in this country and, more recently, whether post-secondary education has adequately prepared its graduates for careers in teaching. It is estimated that only 16 percent of high school students intend to pursue STEM fields in higher education, which is a stark contrast to the predicted 9 million STEM-trained individuals necessary for the workforce in 2018. In 2009, the Obama administration initiated the Educate to Innovate initiative, which sought to add 100,000 new STEM teachers to the workforce over the following 10 years. One significant program that is working toward this goal is the UTeach Program.

UTeach is a teacher certification program developed in 1997 by the University of Texas, Austin College of Natural Sciences and the College of Education to begin to address the shortage of STEM educators in secondary schools in this country. The program knits itself within traditional science, math and computer science degree programs to encourage and attract these students to careers in secondary STEM education. A 2007 National Academy of Science (NAS) report, Rising Above the Gathering Storm, discussed the challenges faced by the United States in staying competitive in science and technology worldwide and identified the need to improve K-12 science and math education as a key recommendation. The UTeach program was mentioned as an important example of how that need could be met.

UTeach has grown over the past 18 years and its core program has now been implemented at 44 other universities within the United States. The UTeach approach has been formalized into an UTeach Operations Manual that supports consistency of its program between its partner organizations.

The program provides a curriculum for students that culminates in a secondary school teaching certification, not in place of, but rather in parallel to, an undergraduate degree in a STEM field. At the completion of the program the student has achieved both an undergraduate degree in a STEM field and a teaching certificate within the four-year timeframe of a traditional undergraduate education. The program is also flexible enough that students can join at any point during their four years of study.

The curriculum teaches classes that cover topics like pedagogy; how to connect theory and practice within a lesson plan; using classroom interactions to promote learning; and developing project-based curricula. The curriculum also offers courses less focused on traditional teaching methods, focusing more on a greater perspective to the student of the relevance of math and science in practice; a historical perspective of math and science; practical research methodologies; and applications of mathematical functions and modeling.

The curriculum also provides real-world teaching opportunities for the students to prepare and deliver lesson plans to elementary, middle and high schools at various points within the program and an apprentice teaching experience in which they fully engage in teaching in a secondary school environment and are observed, critiqued and mentored by their instructors, all over a total 12 weeks.

The program has been very successful. In early 2014 there were almost 7,000 students enrolled in UTeach programs over 19 states nationally. UTeach anticipates that by 2020 they will have produced 9,000 teachers in STEM fields. President Obama sought to add 100,000 new STEM teachers by 2020. UTeach is on pace to be responsible for almost 10 percent of that goal single-handedly.

California Teach, another program identified by NAS as an example of how to improve K-12 math and science education, is a program designed to encourage University of California students majoring in STEM fields to consider a career in K-12 STEM education. Similar to UTeach it provides structured teaching experience in elementary, middle and high school environments throughout the student's four years of undergraduate education. This program also leads to teacher certification through the Science Teacher Education Program (STEP), as well as a master's degree in education, by combining the last year of undergraduate education with their first year of graduate studies.

While these new programs focus on K-12 education, it is important to recognize that there are existing programs that are doing their part to address the shortage of STEM educators in this country. Perhaps these programs could be extended to serve those destined for post-secondary education as well.

Is your University an UTeach affiliate? Do you have any experience with the California Teach program? If so, and you'd like to share your experience, send me an email at ykhan@uchc.edu, and perhaps we can feature your program in a future column.

Industry News

BY STEVE LIN, INDUSTRIAL NEWS CONTRIBUTING EDITOR

To maintain its position as the worldwide leader in **medtech innovation**, the United States medical device industry must overcome weaknesses, including an innovation plateau, the medical device tax, a tough regulatory environment, inferior government subsidies for research and development and a lack of venture capital for startups.

Innovation Plateau — A major reason for slowing growth in the medtech industry has been a gradual shift from risky blue-sky research to more evolutionary research. Especially, large, established corporations have turned to more predictable research with a more easily measured return on investment (ROI).

Medical Device Tax — The medical device sector has been negatively impacted by a 2.3-percent excise tax on sales of medical devices in the U.S. implemented in 2013. The higher tax rate reduces companies' resources for capital investments, research and development (R&D), clinical trials, manufacturing improvements and investments in startups.

Regulatory Environment — Increased regulatory scrutiny by the Federal Drug Administration (FDA) has led to increased costs for the development of new products. Foreign regulations are also an issue in China, where the pursuit of policies that favor domestic manufacturers is occuring, and also in the European Union (EU), where new laws will soon replace the EU's Medical Device Directives.

Inferior Government Subsidies for R&D — The U.S. currently ranks 22nd in the world for federal R&D tax subsidies, with countries in Europe, Asia and South America providing greater incentives for businesses to move there.

Venture Capital — Venture capital firms allocated just 7 percent of their funding to healthcare in 2013, down from 13 percent in 2009. Due the long amount of time it takes to get a product to the market and stringent FDA regulations, early-stage companies have had an especially hard time attracting venture capital.

U.S. investment in medical research slowed to a compounded annual growth rate of 0.8 percent a year between 2004 and 2012, after a decade of 6 percent annual growth, according to reports from researchers in the latest issue of the *Journal of the American Medical Association*. Research financed by biomedical, medical device and pharmaceutical companies slowed between 2004 and 2012, but financing from the National Institutes of Health (NIH) declined during the same period. The compounded annual growth rate for NIH financing during the eight-year period was -1.8 percent compared with 7.3 percent from 1994 to 2004. As a result, industry financing accounted for 58 percent of U.S. medical research funding in 2012, compared with 46 percent in 1994. In a regional global ranking of the pace of investment between 2004 and 2011, the U.S. placed last, with the growth of 1.5 percent per year, compared with 4.1 percent in Europe, 4.5 percent in Canada and 9.4 percent in Asia. In China, the compounded annual growth rate was 16.9 percent. China accounted for 30 percent of global life science patents in 2011, followed by the U.S. with 24 percent.

After six years of heading the FDA, **Margaret Hamburg, MD**, will resign her post as commissioner in March. In the past year alone, Hamburg presided over FDA efforts of food safety, tobacco control opioid abuse, antibiotic resistance, pharmacy compounding and nutrition. She also worked to fast-track the approval of novel drugs and medical devices. Stephen Ostroff, the agency's chief scientist and a former official at the Centers for Disease Control and Prevention (CDC), will be the interim commissioner until President Obama names a successor. Robert Califf, MD, who Hamburg appointed on Jan. 26 as commissioner for medical products and tobacco, is widely expected to succeed her, according to news reports. Califf is a prominent cardiologist from Duke University.

Johnson & Johnson has agreed to make detailed clinical trial data on its medical devices and diagnostic tests available to outside researchers through a collaboration with Yale University, making it the first large device manufacturer to systematically make such data public. The Institute of Medicine (IOM), of the National Academy of Sciences (NAS), is also calling on all sponsors of clinical trials to share detailed study data with outside researchers, and recommended that such data be made available within 30 days of a product's approval. **Medtronic**, another large device maker, had previously allowed Yale to evaluate data on a controversial spinal treatment, but the agreement with Johnson & Johnson is the first time a device manufacturer has made data available in a systematic way.

It's not often that you hear that a startup raised $80 million from well-known investors, is revenue-generating and has technology that has been hailed by the Cleveland Clinic, but then was shut down. California startup **Sonitus Medical** developed the SoundBite Hearing System, billing it as the world's first "removable bone conduction hearing device that transmits sound via the teeth." FDA cleared the product for patients who suffer from one-sided deafness and conductive hearing loss in 2011. But late last year, when the Centers for Medicare & Medicaid Services (CMS) declined to cover the FDA-cleared device — deeming it to be a hearing aid, which is not covered, and not a prosthetic as the company had hoped — Sonitus Medical was cut off at the knees. It ceased operations in mid-January, and is in the process of a liquidation sale. "FDA operates under the mantra of 'safe and effective,' but not everything that is 'safe and effective' is considered 'reasonable and necessary' by Medicare for coverage," says Edward Black, president of the St. Paul, Minnesota-based consulting firm Reimbursement Strategies. He advises medtech companies developing new products run reimbursement assessments at the same time as they are going through the FDA process.

A new report by **Transparency Market Research** finds that the global home healthcare market will increase to $303.6 billion in 2020, up from $176.1 billion in 2013. According to the World Health Organization (WHO), the number of people age 65 and older is expected to increase to 2 billion by 2050, up from 605 million in 2000. The market is broadly divided into devices and services. The home healthcare devices market can be further subdivided into diagnostics and monitoring devices, therapeutics devices, mobility assist devices and medical supplies. The market for diagnostics and monitoring devices segment account for the lion's share of the home healthcare devices market overall. The fastest growing segment is therapeutics devices, which is expected to grow at more than 10 percent compound annual growth rate (CAGR) from 2014 to 2020. They comprise insulin delivery devices, nebulizers, ventilators and CPAP devices to treat sleep apnea, IV equipment and dialysis equipment. The services segment is the largest within the overall global home healthcare market, providing services like rehabilitation, telehealth and telemedicine, respiratory therapy, infusion therapy and unskilled home healthcare services.

Where is **Medicare** going? In a nutshell, the U.S. government is incentivizing health providers to be more concerned about how efficiently and effectively they manage patient populations through Medicare — versus the former fee-for-service model's focus in which they counted how many devices, procedures and services they were able to sell. Presently, about a fifth of Medicare payments are already going toward alternative payment methods, such as Accountable Care Organizations (ACOs) or bundled payment arrangements. The new U.S. Department of Health and Human Services (HHS) goal is to raise the percentage to 30 percent by next year and 50 percent by 2018. On top of that, HHS wants 85 percent of all traditional Medicare payments tied to quality or value by 2016 — 90 percent by 2018. Competition is already becoming fierce among medical device companies when it comes to being able to offer a full cafeteria of products and services (e.g., Medtronic isn't just a pacemaker manufacturers; it's a chronic heart disease management company now).

DePuy Synthes Companies announced the addition of four new products to its adult deformity portfolio, as well as a new education offering, continuing its expansion of one of the broadest spine portfolios in the industry. The products were displayed by DePuy Synthes Spine at the 81st annual meeting of the American Academy of Orthopaedic Surgeons (AAOS). The products included the EXPEDIUM Osteotomy System (for use during spinal reconstruction) and VIPER® Cortical Fix X-Tabs (for enhanced fixation in percutaneous surgery). The company also recently added **VIVIGEN® Cellular Bone Matrix** for the repair or reconstruction of musculoskeletal defects and enhancements to the SYNAPSE™ System of implants and instruments, designed to provide more surgical options and flexibility required to accommodate variations in patient anatomy during posterior stabilization of the upper spine. VIVIGEN® Cellular Bone Matrix (which was developed by LifeNet Health, a world leader in allograft bio-implants and cellular therapies) provides a viable alternative to autograft that delivers all the properties required for bone formation. VIVIGEN, a Human Cells, Tissues and Cellular and Tissue-based product (HCT/P), is composed of cryopreserved viable, lineage committed bone cells within a cortical cancellous bone matrix and demineralized bone. DePuy Synthes Spine and DePuy Synthes Biomaterials have an exclusive worldwide agreement to market and promote VIVIGEN.

Student News

Student Chapter Update

BY JORDON GILMORE, NATIONAL STUDENT CHAPTER PRESIDENT, CLEMSON UNIVERSITY

I'd like to introduce the new student leaders for the Student Section of the Society For Biomaterials (SFB), which were announced at the recent SFB Annual Meeting. We have some motivated and enthusiastic student leaders ready to work with our student chapters to grow student involvement and benefits within SFB.

Evelyn Bracho-Sanchez

Our next Student Section President for 2015 – 2016, Evelyn Bracho-Sanchez is a doctorate candidate in biomedical engineering at the University of Florida. Florida has a strong student chapter and Ms. Bracho-Sanchez was the catalyst in increasing student membership involvement at the local and national levels of SFB. Her experiences within SFB also include participation in the annual Biomaterials Education Challenge and organization of the University of Florida Biomaterials Day. She also served as the 2014 –2015 President-Elect of the Student Section. Ms. Bracho-Sanchez is excited to increase student activities and participation both during the year and at the Annual Meeting. Some of her key goals are increasing communication between student chapters and Student Section leadership and working to provide more value for the student membership to SFB.

Our newly elected Student Section President-Elect is Christopher Gehrmann. Mr. Gehrmann is a doctoral candidate in bioengineering from the University of Memphis.

Christopher Gehrmann

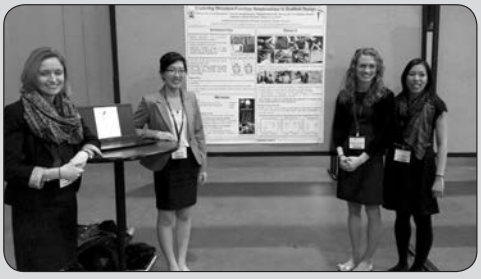
The University of Memphis has a strong history of involvement in SFB, particularly at the student chapter level. Mr. Gehrmann has served as president of the student chapter at the University of Memphis, helping organize Biomaterials Days, and participating in it. One of his major focus areas is the outreach efforts of our student chapters in providing mentorship and motivation to the next generation of biomaterial scientists. He has some very exciting ideas on how student chapters can be effective with this type of outreach at the local level.

We also welcome newly elected officers, Amanda Chen (Secretary/Treasurer-Elect from the Massachusetts Institute of Technology) and Caroline Addington (Bylaws Chair from Arizona State).

I am excited about the future of the Student Section of SFB and I think we are in very good hands moving forward. But these student leaders need your help and participation to make our involvement in SFB as beneficial as possible for everyone. Please reach out to them and send them your ideas, student news and any accomplishments that you would like shared with SFB. Thank you for a great year as Student Section President for 2014 – 2015. It was a very beneficial experience and I look forward to staying engaged with the Student Section during the next stages of my career.

Thank you everyone and get excited about SFB!

Biomaterials Education Challenge Results



First place winners from Columbia University (from left to right) Danielle Bogdanowicz, Dovina Qu, Margaret Boushell and Nancy Lee (President Columbia SFB student chapter).

The Biomaterials Education competition, sponsored by the Burroughs Wellcome Fund, encouraged student teams to develop innovative and practical approaches to biomaterials education. Teams were challenged to develop an educational module for middle school (6th–8th grade) science classes. Each educational module demonstrated fundamental biomaterials concepts, with scientific principles that were understandable to a middle school audience, designed for a 45-minute class period. Each presentation was evaluated by three separate judges and the student chapter. The project judged to have the greatest potential for educational impact was awarded a first place prize of $2,500.

Congratulations to:

1st Place, $2,500: Columbia University, **advisor:** Dr. Helen H. Lu, c**hapter members:** Danielle Bogdanowicz, Margaret Boushell, Nancy Lee, Amy Silverstein and Christopher Mosher

2nd Place, $1,500: Texas A & M University, **advisor:** Dr. Elizabeth Cosgriff Hernandez, **chapter members:** Kirsten Brink, Jake Carrow, Remington Harwell, Faraz Jivan, Lauren Cross, CW Peak and Alisha Kishan

3rd Place (tie) $750 each: Case Western Reserve University, **advisor:** Dr. Nicholas Ziats, **chapter members:** Preethi Siva, Clarissa Kos and Christa Modery-Pawlowski; North Carolina Agricultural and Technical State University, **advisor:** Dr. Narayan Bhattarai, **chapter members:** Cindy Nelson, Nava Rijal and Shek Rahman; University of Florida, **advisor:** Dr. Gregory Hudalla, **chapter members:** Laura Villada, Evelyn Bracho-Sanchez, Antonietta Restuccia and Elliot Mackrell

Government News **News & Updates**

CELL THERAPY CATAPULT

BY CARL G SIMON JR., GOVERNMENT NEWS CONTRIBUTING EDITOR

Cell Therapy Catapult (CT-Catapult) is a not-for-profit organization, which started in 2012. It aims to increase the United Kingdom's (UK) health and wealth and is supported with 80 million pounds from the UK government and 10 million pounds from industry contracts through 2018.[1]

CT-Catapult's vision is to make the UK a global leader in the development and commercialization of cell therapies and be a place where businesses can start, grow and develop cell therapies — rapidly, efficiently and with confidence. CT-Catapult currently employees 70 staff, which have surveyed good manufacturing practices (GMP) in the UK[2] and have compiled a list of UK-eligible funding opportunities for cell therapy research.[3] There are 45 active cell therapy clinical trials in UK and CT-Catapult staff maintain a database on these trials.[4] The staff has also composed a white paper on the commercial viability of cell therapies that lack patent protection[5] and have organized a three-day course on cell manufacturing. The staff can provide direct assistance in assay and process development through a variety of mechanisms.

CT-Catapult is a center of excellence located in Guys Hospital in London and has both laboratories and meeting space. They recently announced an award of 55 million pounds to build a UK cell therapy manufacturing center, which will provide large-scale cell manufacturing facilities for late-phase clinical trials for the European Union (EU) and, potentially, for global supply. The aim is to retain manufacturing activity within the UK, attract UK-investment and boost UK exports. The plan includes 1,200 square meters of manufacturing space (the location is still being determined) that will open in 2017/2018.

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Macrophages: Biology and Role in the Pathology of Disease

Book Review

REVIEWED BY JULIE STENKEN, UNIVERSITY OF ARKANSAS, IMMUNE ENGINEERING FORUM REPORTER

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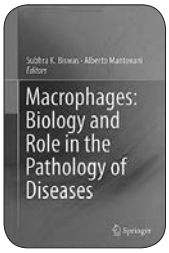

Macrophages are cells of the immune system that play key roles in maintaining homeostasis, providing host defense and affecting different aspects of disease. The editors of this book have effectively synthesized the significant research that has occurred within the last 10 years, including tools to study macrophages, the concept of macrophage polarization and systems biology of macrophages. Thus, I believe this highly comprehensive text would be of significant value to biomaterials scientists.

The text is divided into six different parts with 29 chapters. Part I, Macrophage: Origin, Activation and Polarization, contains four chapters covering these essential topics. Of particular interest to biomaterials scientists are chapters two, three and four, which cover macrophage polarization, activation and regulatory macrophages. Part II covers macrophages and their many diverse functions, with information about phagocytosis and antimicrobial functions. Part III covers different types of macrophages, including alveolar macrophages, liver (Kupffer cells), microglial cells (brain) and the intestine. Part IV discusses macrophages in pathology with chapters discussing the wound macrophages, tumor macrophages and adaptive characteristics of macrophages. Part V discusses transcriptional and epigenetic mechanisms with updates about NF-κB activation and STAT-SOCS signaling. The control of gene expression in macrophages is also presented in Part V. Finally, Part VI is the shortest subsection, focusing on systems biology of macrophages with two chapters describing the macrophage transcriptome and 'omics approaches.

This is an excellent comprehensive book covering the state-of-the-art topics in the field of macrophage biology. All of the chapters are well organized with extensive references. While the references are listed in alphabetical order in the chapters, I would estimate each chapter has, on average, 150 references associated with each topic. Thus, one can quickly envision that this is a highly important reference text for any individual working with macrophages. In addition to the extensive references, it is also highly current, as most of the references have been published within the last decade.

There is one major drawback to this book that I have found quite odd. The book does not have an index. However, the vast information in the book, with well-organized chapters, may overcome this major limitation.

Recommended Books for the Biomaterials Scientist

BY LYNNE C. JONES, PhD, JOHNS HOPKINS UNIVERSITY

Several months ago, I posed the following question to the members of the Society For Biomaterials (SFB) Presidential Advisory Council (PAC), "What three books would you recommend that every biomaterials scientist should have in their own personal library?"

Their responses encompassed everything from basic biomaterials textbooks to the more philosophical books. Interestingly, as many of our Past Presidents (i.e., the members of the PAC) are leaders in the field, they have written or co-written many books that can be found on the shelves of many scientists.

Several individuals recommended *Biomaterials Science. An Introduction to Materials in Medicine*.[1] A review of this book can be found in the Biomaterials Forum 2013 first quarter issue on page 19. Several other basic biomaterials textbooks recommended, include:

- *Biomaterials: An Introduction.*[2]
- *Introduction to Biomaterials. Basic Theory with Engineering Applications*.[3] This was reviewed in the Biomaterials Forum 2013 third quarter issue on page 24.
- *Biomaterials: The Intersection of Biology and Materials Science.*[4]
- *Comprehensive Biomaterials (6 Volume Set)*.[5] A review can be found in Biomaterials Forum, 2012 second quarter issue on page 8.
- *Handbook Of Biomaterials Evaluation: Scientific, Technical and Clinical Testing of Implant Materials, Second Edition*.[6]

In today's age, a list of biomaterials textbooks would not be complete without books addressing tissue engineering. The recommended books included:

- *Tissue Engineering.*[7]
- *Biomaterials and Regenerative Medicine*.[8]
- *Regenerative Engineering*.[9] This was reviewed in the Biomaterials Forum 2013 fourth quarter issue on page 18.

There were also several books recommended that evaluated biomaterials from the biological perspective. A number of Past Presidents recommended *Biological Performance of Materials: Fundamentals of Biocompatibility*.[10] Many of us have used elements of this book to lecture undergraduate and early graduate students. Another book that comes highly recommended from several Past Presidents is *An Introduction to Tissue-Biomaterial Interactions*.[11] This book, written as a true undergraduate textbook, describes the basics of wound healing, inflammation, protein-surface interactions, the various biological responses to implants (innate and acquired) and bioengineering approaches to modifying the surface of implants. While many of us have older editions of *Medical Physiology*,[12] the more contemporary edition is easily available.

For the more philosophical amongst us, two books are recommended that challenge us to think differently when observing and analyzing the scientific world.

- *Blood, for Simple Curiosity and Scientific Philosophy. A Classic*.[13]
- *Popper.*[14]

In completing our library collection, the following books are also recommended.

- A good dictionary. With the advent of search engines and the Web, the younger generations may never open up a dictionary. While online dictionaries may have definitions, synonyms and antonyms, they often are missing some of the other topics contained within a good dictionary including English language, signs and symbols, and handbooks of style.
- *Alice in Wonderland*.[15] This may better be placed in the preceding chapter on philosophy. Others have discussed this story in the context of innovation and exploration, scientific discovery and mathematics.
- *Good to Great*.[16] While this is a book about how businesses succeed, it also is so much more. It is about leadership and introduces the Hedgehog Concept asking, "What lights your fire (passion)?" "What could you be best in the world at (best at)?" and "What makes you money (driving resource)?"
- *Seven Habits of Highly Effective People*.[17] There have been so many spinoffs of this book that we sometimes overlook the original. It is worth reading as it will have an impact on your personal life, as well as your professional life.

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