LETTER FROM OUR NEW PRESIDENT • HIGHLIGHTS FROM THE CVB SIG AND IE SIG

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Third Quarter 2016 • Volume 38, Issue 3

ALSO INSIDE

HISTORICAL FLASHBACK BY CARL McMILLIN

MEET THE WINNERS OF THE INAUGURAL LAURENCIN TRAVEL FELLOWSHIP

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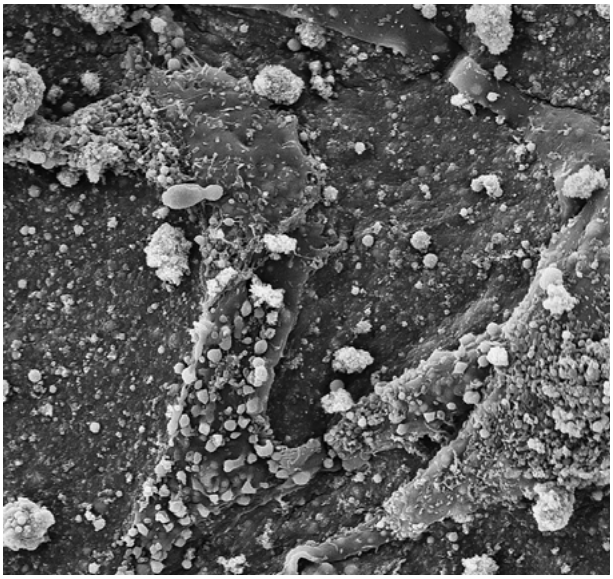
BIOMATERIALS
FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 38, Issue 3

Special Interest Group Reporters



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On the cover: The cover image, provided by the research group of Akhilesh K. Gaharwar at the Texas A&M University, demonstrates cellular response on nanoengineered biomaterials. The image shows that cells readily adhere and spread on the surface of nanoengineered hydrogels loaded with hydroxyapatite nanoparticles. The elastomeric characteristics of nanoengineered hydrogels render it useful for understanding cellular behavior under dynamic mechanical loading. The image was obtained using Field Emission Scanning Electron Microscope and then false colored with Adobe Photoshop.

SEEKING CONVERGENCE TO ADVANCE BIOMATERIALS INNOVATION

Guigen Zhang

At the SFB Awards session during the WBC 2016 in Montreal, Canada, Cato Laurencin commented, via recorded video, on the need for CONVERGENCE in taking on the challenges in the fields of regenerative medicine. This prompted me to recall the 2014 report by the National Research Council of the National Academies, calling for convergence—the coming together and transdisciplinary integration of insights and approaches from originally distinct fields including life sciences, physical sciences, engineering—to address difficult problems. In light of the fact that two active SFB members, Cato Laurencin and Nicholas Peppas, were on the committee leading the development of the report, I was wondering how the SFB could play a proactive role as a professional society in facilitating convergence in education, research and innovation.

Clearly, the call for convergence is in reflection of the fact that our traditional compartmentalized approaches are becoming insufficient for dealing with the unknowns and uncertainties of the real-world. However, looking around us, we will notice ubiquitous evidence that compartmentalized disciplines still characterize higher education as we describe universities in terms of traditional disciplines.

Tracing back, the origin of disciplines is likely the result of our cognitive dealing with the world we live in through a reductive process. Reductive thinking helps reduce a complex issue to small independent pieces by neglecting and discarding as much as possible factors and issues that we have no knowledge or comprehension of at the moment. By doing so we can avoid complexity and ambiguity, and gain the comfort of simplicity and clarity, as Roger Martin put it. The formation of disciplines not only makes the simplification of complex phenomena possible, but also offers compartmentalized frameworks and guidelines through which we explore, understand and interact with the world.

With the disappearing of so-called "low-hanging fruits" in innovation, however, we can no longer ignore the complex and interwoven issues. Sticking to the compartmentalized approaches makes researchers look like "blind men touching an elephant." In the fabled story, according to Wikipedia: a group of blind men touches an elephant to learn what it is like. Each one feels a different part, but only one part, such as the side or the tusk. They then tell their individual "knowledge" of the elephant. As you can imagine, they ended with complete disagreements; they were not wrong in a reductive way but none was complete, hence none was correct.

A transdisciplinary approach, in the spirit of seeking convergence, encourages knowledge integration rather than reduction. Integrative thinking requires one to actively seek commonalities and patterns from various different angles to sort out potentially relevant factors; embrace complexity; welcome missing links; consider multi-directional and nonlinear relationships and interdependencies; see all factors in a systems view; perform integrative investigations; and carry out holistic development in order to derive a complete (or close to it) solution to a problem.

Bioengineering is a field that exemplifies the essence of transdisciplinary needs. Problems are solved based on myriad laws of physics and thermodynamics, as well as biochemistry and biology, among others. At a population level, statistical rules (e.g., Bayesian probability) may play an influential role as well. For this very reason I believe that the SFB is in the right place to play a crucial role as a professional society in facilitating convergence through brainstorming on the meaning, needs, ethics and challenges in seeking convergence in scientific learning, exploration and investigation, and through identification of best practices for pursuing convergence in education, research and translational innovation to advance biomedical science and quality of life.

In closing, let me briefly mention what we have in store for you in this issue. In the letter from SFB's new President, Liisa Kuhn, you will hear heart-felt perspective on being a resilient biomaterials researcher. You will read member news from our new member-at-large, Andres Garcia; a staff update from Deb Dupnik; and student news from our new student representative, Christopher Gehrmann. If you have news about yourself or someone else that you would like to share with our members in future issues, please send your news to them. In the SIG sections, you will read about the latest advances in the Cardiovascular Biomaterials SIG and the Immune Engineering SIG. In our regular columns, you will find the latest industry news from Steve Lin and government news from Carl Simon. You will also read viewpoints on STEM programs for minority students from Yusuf Khan, and a book review from Lynne Jones. In the historical flashback column, Carl McMillin shares with us his perspective on implant materials unavailability.

Sincerely,

Guigen Zhang
Executive Editor, Biomaterials Forum

RESILIENCE AND RESEARCH

Liisa Kuhn

Given the few times experiments actually work according to plan, it's amazing that we continue to be biomaterials scientists. Given the few times grant applications are funded, despite the number of long hours we work on them, it's amazing that we continue to be biomaterials scientists. Given the few times our manuscripts are readily accepted for publication, it's amazing that we continue to be biomaterials scientists. Given the few times that our administration listens to us about what direction the institution or corporation should take to support research and development, it's amazing that we continue to be biomaterials scientists.

But we do continue to be biomaterials scientists. We even like biomaterials research or product development and we remain fascinated by it. Why? Challenges are normal and we all have them, but sometimes they can get you down. In this letter I'll talk about good strategies to keep coming back and not giving up.

My daughter graduated from elementary school this past June and her principal gave a powerful speech about resilience that had a lot of relevant points that apply to biomaterials scientists just as much as to a graduating 10-year-old kid. My experiments haven't been working as well as I envisioned they would lately and so I'm sharing these tips just as much for myself as for anyone else struggling with their research and product development. So from Principal Jeff Sousa, Braeburn Elementary School in Connecticut, here it is:

"We all know that to be successful in this era, we have to be creative to come up with new and interesting ways of doing things or solving problems. Sometime we think it takes a flash of genius to be creative or a bolt of lightning. However it might just be that to be creative, you have to be really resilient.

What does it mean to be resilient? It means you need to be willing and able to keep trying things even when what you are doing doesn't work the first time, or the second time, or the hundredth time. Don't give up. Just keep trying. Keep trying until you are successful. Say to yourself: If at first I don't succeed, I will try again. And if the first strategy doesn't work, try a different one.

In Senator John McCain's book, Character is Destiny, *his role model of resilience is Abraham Lincoln. President Lincoln had a very hard life, losing many of the people he loved, losing more elections than he won. He often struggled to succeed. He was often sad, but he never gave up. After becoming President he persevered against all odds to keep our country together. What helped him to be resilient? Senator McCain says he had three qualities: 1) Lincoln had a sense of humor. He could laugh about the problems no matter how bad they were; 2) constant hard work, plugging away day and night, never giving up; 3) his dedication to his idealistic goals—that he just had to help America be more and just. Born in poverty and obscurity, his heart burdened with grief, beset by criticism and misfortune, he would not yield until he had saved the country he loved. He triumphed against the odds; showed righteousness in the face of iniquity, hope in adversity; and made sacrifices for a cause greater than self-interest. In closing, there is nothing circumstantial when it comes to people who achieve greatness. In fact, they achieve greatness as a result of their own character."*

In addition to resilience, McCain shares stories about other character traits, exemplified by heroes, that can provide role models for how to achieve happiness and satisfaction with our lives: honor (honesty, respect, authenticity, loyalty, dignity); purpose (idealism, righteousness, citizenship, diligence, responsibility, cooperation); strength (courage, self-control, confidence, industry, hopefulness); understanding (faith, compassion, mercy, tolerance, forgiveness, generosity); judgment (fairness, humility, gratitude, humor, courtesy); creativity (aspiration, discernment, curiosity, enthusiasm, excellence); and love (selflessness and contentment).

So in closing, here are a few tips for how to be a successful biomaterials scientist. Be resilient, maintain your sense of humor and curiosity and keep your focus on making this world a better place through biomaterials that improve human health. You're doing great work and keep going!

LIISA KUHN
SFB President

On Implant Materials Unavailability

Historical Flashback

BY CARL McMILLIN

We live in a litigious society where product/implant failures are often followed by lawsuits directed toward everyone involved. This is a big business and law firms are more than willing to help patients sue and advertise widely to recruit cases regarding the latest device/drug that has failed to meet ultrahigh expectations in hopes of big settlements. To control potential liability, from 1992 to 1994 most major polymer manufacturers (along with some metals manufacturers) specifically banned the use of their materials in medical implants creating a "biomaterials crisis." The Biomaterials Access Assistance Act of 1998 was intended to protect materials manufacturers from product liability from the use of their materials.

Now 18 years after the law was enacted, few of those companies have returned to selling materials for implants. As a member of the Society For Biomaterials (SFB), I have joined others affected by biomaterials issues in a Special Interest Group (SIG) where we have shared information and discussed approaches necessary to continue to manufacture implants.

Potential product liability in the medical field is not a new issue. As a graduate student and post-doc, I worked with at the Cleveland Clinic. Dr. Kolff, the former head of the Artificial Organs Department who developed the first practical kidney dialysis machine in the Netherlands in 1943, came to the Cleveland Clinic in 1950 and continued development of the device with Dr. Yukihiko Nosé who joined Dr. Kolff in 1964. Initial prototypes of the dialysis machines in the United States used Maytag washing machines bought from Sears by Dr. Nosé as shown here. I was told by Dr. Nosé that when Maytag found that their machines were being used for the experimental new kidney dialysis process, they became concerned about potential liability and refused to sell Dr. Nosé any more washing machines.

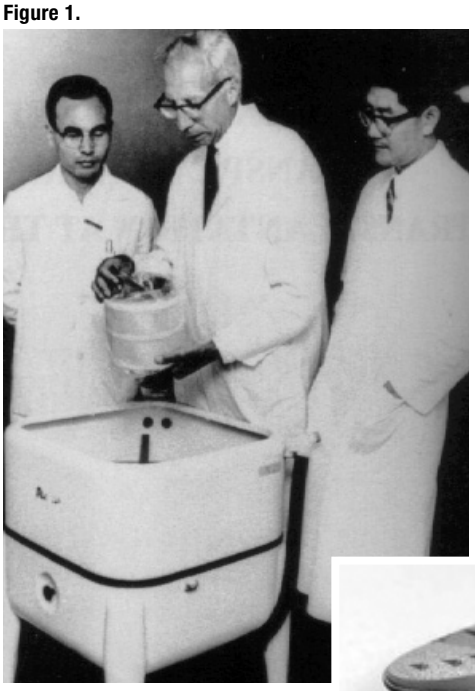
In the early 1970s at the Cleveland Clinic, I started working with Hexsyn, a polyhexene based Goodyear rubber provided free to the Cleveland Clinic for artificial heart pump diaphragms. In the 1980s, it appeared that artificial hearts might make it into humans and Goodyear gifted a patent license, use of personnel and cash to the University of Akron to avoid potential corporate liability. I was selected to oversee this program.

I later used this rubber as the basis of the first functional artificial spinal discs to be clinically implanted in the U.S. (shown in Figure 2). At AcroMed Corporation, I contracted for the pilot plant at the University of Akron to synthesize the rubber until 1994, when the University of Akron suggested that AcroMed find alternate polymerization facilities because of potential product liability.

I also designed similar spinal discs using Silastic that were implanted clinically. When Dow Corning withdrew their polymers from medical device usage, we were informed that after the end of our contract, they would not sell us additional Silastic. 1994 was a particularly bad year for my device development. I conducted much of the initial evaluation of polyetherketones for medical use and had many different orthopedic devices under development when Victrex PEEK and BASF Ultrapek were removed from the supply chain. I helped develop spine stabilization devices (e.g., the Graf device) that were made from Dacron and Spectra, which both became unavailable. We were refused sale of memory metal for a scoliosis correction system under development and also tantalum X-ray marker beads for use in spine fusion cages.

The unavailability of materials for medical implants is still an issue. I recently had the SFB send an email to all of the members of the Biomaterials and Medical Products Commercialization SIG and talked with members of our SIG in Montreal in an unsuccessful attempt to find a medical or implant grade of high density polyethylene for use in a new ear tube implant.

Figure 1.



Maytag dialysis unit pictured here: Dr. Kolff (center), Dr. Nosé (right) and an unknown person (left). Photo source: http://web.stanford.edu/dept/HPS/transplant/html/kolff.html

Figure 2.

AcroFlex Artificial Spinal Disc

Members in the News

BY ANDRES J. GARCIA, PhD

I am honored to serve as your 2016-2017 Member-at-Large representative. I thank Elizabeth Cosgriff-Hernandez for her outstanding service in this role last year. As Member-at-Large, I serve as YOUR representative on both the Board of Directors and the council of SFB. I will also serve as your representative on other committees (e.g., Long Range Planning Committee) so that members have a clear voice for direction of SFB. I plan to focus my efforts on three areas: (1) be a voice for all the Members; (2) roster scientific excellence and a nurturing environment; and (3) expand the impact of SFB. I encourage all members to send me your ideas and feedback about the SFB (andres.garcia@me.gatech.edu). With your help, we can continue to improve the SFB and increase the value for all members. I also write this column highlighting member news and accomplishments.

Cato Laurencin (University of Connecticut) has been elected a foreign member of the Chinese Academy of Engineering. Dr. Laurencin is the first foreign member from the U.S. to be elected in the field of biomaterials and one of the youngest foreign members to be elected in its history.

The National Cell Manufacturing Consortium (NCMC), an industry-academic-government partnership led by **Krishnendu Roy** (Georgia Tech), recently released the National Roadmap for Advanced Cell Manufacturing. This national 10-year roadmap is designed to chart the path to large-scale manufacturing of cell-based therapeutics for use in a broad range of illnesses including cancer, neuro-degenerative diseases, blood and vision disorders and organ regeneration and repair. NCMC, comprising over 25 companies and 15 academic institutions, was established through the Advanced Manufacturing Technologies (AMTech) grant from the National Institute of Standards and Technologies (NIST).

Michael Mitchell (MIT) was named one of ten recipients of the 2016 Burroughs Wellcome Fund Career Award at the Scientific Interface for his project "High-throughput in vivo nucleic acid delivery screening via molecular barcoding of nanoparticles for bone marrow-related diseases."

Working with collagen-based hydrogels, **Akhilesh Gaharwar** (Texas A&M University) has developed a method for modulating their stiffness without affecting chemistry or structure for stem cell research. This research was published in *ACS Nano.*

The first edition of *Oxidative Stress and Biomaterials*, co-edited by **Tom Dziubla** (University of Kentucky), has been recently published. This work provides an expert summary of oxidative stress analysis methods, focusing on the considerations/limitations of each method and reviewing state-of-the-art research into the application of oxidative stress concepts in the design of biomaterial.

After spending three years as the Vice President of Research, **Mauli Agrawal** has now assumed the role of Interim-Provost at UTSA. Prior to Vice President of Research, he was Dean of Engineering for eight years.

The paper "Ex vivo engineered immune organoids for controlled germinal center reactions" published by **Ankur Singh** (Cornell University) and his group in Biomaterials was selected as one of three winners of the 2015 Biomaterials Outstanding Paper Award.

Cherie Stabler (University of Florida) will serve as a Member of the NIH Bioengineering, Technology, and Surgical Sciences (BTSS) study section for the term beginning July 1, 2016 and ending June 30, 2020. The BTSS Study Section reviews grant applications in the interdisciplinary fields of surgery and bioengineering to develop innovative medical instruments, materials, processes, implants, and devices to diagnosis and treat disease and injury.

Ioannis Yannas (MIT) was inducted to the National Inventors Hall of Fame for his 1983 MIT patent "Method of Promoting the Regeneration of Tissue at a Wound" (Yannas IV, Burke JF, Orgill DP, Skrabut EM, U.S. Pat. 4,418,691, Dec. 6, 1983). This is the first patent that claimed a process of regenerating an organ in an adult mammal.

Susan Thomas (Georgia Tech) was awarded a highly competitive Career Catalyst Grant from the Susan G. Komen Breast Cancer Research Foundation. This three-year project will develop sentinel lymph node drug targeting technologies leveraging biomaterials for breast cancer immunotherapy.

A recent paper by **Melissa Grunlan** (Texas A&M University) in *Acta Biomaterialia* describes a new material that molds itself to fill irregular gaps in bone while promoting bone growth could more effectively treat cranio-maxillofacial bone defects.

Christopher Jewell (University of Maryland) has been named a 2016 Cellular and Molecular Bioengineering Young Innovator. Dr. Jewell's work to study and reprogram the local lymph node environment with biomaterials will be featured along with the other Young Innovators in the upcoming issue of the journal. The goal of the annual Young Innovators Program is to highlight "the best and brightest" young faculty working in the area of cellular and molecular bioengineering.

Larry Gettleman (retired, University of Louisville) received a Distinguished Alumnus Award by the Harvard School of Dental Medicine.

Ali Khademhosseini (Harvard Medical School) was appointed as a Fellow in the Royal Society of Chemistry. The Royal Society of Chemistry, established in 1841, has 51,000 members and continues to support and unite chemical scientists together from all over the world.

Staff Update

BY DEB DUPNIK, ASSISTANT EXECUTIVE DIRECTOR

Greetings from Society For Biomaterials (SFB) headquarters! All SFB committees are beginning to work on the charges presented to them by the Council at its meeting in Montreal. Council will be meeting again in July to continue to advance the strategic plan for the Society. In 2015, the following four goals were defined along with the strategies to achieve them:

1. **Visibility/Public Relations** – SFB will raise the visibility, impact and stature of the Society and membership on national/international and regional/local levels for advancing biomaterials science/engineering research and development, education and professional development.
2. **Meetings** – SFB will increase the value and quality of annual meetings and extend accessibility of annual meeting information beyond meeting dates and locations.
3. **Membership** – SFB will continue to develop and support a diverse membership, including clinical and industrial members, as well as basic applied science/engineering researchers and students. Efforts will be made to increase value to members.
4. **Education & Professional Development** – SFB will promote professional development, education and networking for scientists/researchers, clinicians, and industry and governmental agency personnel.

The board is refining its charges to each of the SFB committees within the context of the Society's strategic plan and the committees will continue their work in the coming year.

AUDIT COMMITTEE

CHAIR NICK ZIATS, PhD

SFB received an unqualified opinion ("clean") audit report for 2015. The financial position of the SFB as of December 31, 2015, and the changes in its net assets and its cash flows for the year, were prepared in accordance with U.S. generally accepted accounting principles. 2015 taxes have been filed and the work of this year's audit committee will begin in 2017.

AWARDS, CEREMONIES AND NOMINATIONS

CHAIR TONY MIKOS, PhD

The committee spent the summer reviewing the materials for all candidates whose nominations were eligible to be carried over for consideration in 2017. New nominations have been received throughout the summer. The committee is actively seeking/recruiting visionary leaders for officer positions. Nominations for President-Elect, Secretary/Treasurer-Elect and Member-at-Large are due to the committee by September 23. The committee will investigate means to increase member participation in the annual board election.

BYLAWS

CHAIR BEN KESELOWSKY, PhD

There will be some changes proposed to the bylaws at the 2017 annual meeting, regarding some committees including restructuring and updating roles and responsibilities.

DEVICES & MATERIALS COMMITTEE

CHAIR SPIRO MEGREMIS, PhD

The committee will be working on the third annual business competition for the 2017 annual meeting and providing input and direction to the Board and Program Committee for program content of interest to industry.

EDUCATION AND PROFESSIONAL DEVELOPMENT

CHAIR ELIZABETH COSGRIFF-HERNANDEZ, PhD

Requests for SFB's endorsement of other meetings continue to be received and evaluated by the E&PD over the summer. Later in the fall, the committee will be reviewing submissions for Biomaterials Days grants. The committee continues to oversee the process for Student Chapter travel grants, evaluate applications and award the 2017 C. William Hall Scholarship and Cato T. Laurencin Travel Fellowship and the Biomaterials Day grant program.

FINANCE

CHAIR SHELLY SAKIYAMA-ELBERT, PhD

In 2013, with more than $1.5 million in reserves, there was a conscious and strategic decision by the SFB Board to invest in membership benefits and services. Major investments include:

- Website and online community
- 2016 Public Relations Initiative
- 2016 Satellite Symposia

The Society will continue to carefully monitor revenue and membership to make sure the Society remains in good financial health. The 2017 Annual Budget will be prepared to deliver a modest net income; this may mean nominal increases in dues and/or registration rates, and/or a reduction or cessation of some programs.

LIAISON

CHAIR TIM TOPOLESKI, PhD

Satellite meetings for 2016 were organized to provide additional opportunities for members and to liaise with other societies in a WBC year. The liaison committee will request feedback from each of the satellite symposium organizers including the number of people who attended, and opportunities for further outreach.

LONG RANGE PLANNING
CHAIR DAVID KOHN, PhD*
The Long Range Planning Committee is charged with increasing membership, especially from industry and clinical sectors; furthering international collaborations; increasing the visibility of SFB through public relations efforts; governmental/policy issues; and potential collaborations with other organizations. SFB continues to engage the public relations firm of Schneider Associates to:

- Build awareness for and advance the brand image of the SFB
- Increase visibility for the SFB among key audiences including stakeholders, members of the biomaterials and broader science communities
- Position the SFB board, members and membership as thought leaders on the organization's research and policy issues
- Position the SFB staff as advocates for the membership by demonstrating organizational value add and thought leadership

MEETINGS
CHAIR LIISA KUHN, PhD*
The 2018, SFB Annual Meeting & Exposition will take place in Atlanta, Georgia, April 11-14, 2018. The committee presented board members with proposals for possible locations for the 2019 annual meeting. After careful consideration, board members selected Seattle, Washington, for the week of April 2-5, 2019. Over the next months, the Meetings Committee will be considering potential sites for the Bashes in Minneapolis and Atlanta.

MEMBERSHIP
CHAIR LIJIE GRACE ZHANG, PhD
The committee will be gathering information and reviewing marketing strategies for societies similar to SFB in order to discover best practices that could be adopted by the SFB. The membership committee will investigate potential options to maintain revenue and membership levels, including strategy for WBC years' value proposition.

PRESIDENT'S ADVISORY COMMITTEE
CHAIR TOM WEBSTER, PhD
The President's Advisory Committee (PAC) will work with the education committee to put together a panel on ethics for 2017. They will use case scenarios and establish responsible conduct in research. The ethics document will be targeted toward scientists, engineers, physicians/clinicians and industrialists. The PAC will also increase its role in monitoring and addressing ethics concerns going forward.

PROGRAM
CO-CHAIRS SUPING LYU, PhD AND REBECCA CARRIER, PhD
The call for abstracts will go out in early September with a November deadline. The committee will meet to finalize the 2017 program in January 2017. There will be a focused push to develop proposals for the 2017 annual meeting to increase industry participation and content on regulatory issues. Efforts will be made to incorporate an industry backbone into the sessions to better serve "Medical Alley" in Minnesota.

PUBLICATIONS
CHAIR TBD
The Wiley Book series has a new manager, Dr. Gudrun Walter (Editorial Director Global Research, Europe, Asia and RoW). There are plans for organizing the SFB "body of knowledge." The Publications Committee is developing a plan to consolidate, update and make accessible our collective wisdom. The goal is to create one searchable archive where it would be possible to find any reference to a search term in any SFB-related literature—abstracts, keynotes, Biomaterials Forum, awards, videos and perhaps images, Biomaterials Bulletin and JBMR.

NATIONAL STUDENT CHAPTERS
PRESIDENT CHRISTOPHER GEHRMANN
National Student Chapter officers will be working with the Education and Professional Development Committee to refine the Biomaterials Day grant program with an eye on converting participants to SFB members. There are currently 19 student chapters and efforts are being made to increase this number.

The national student section officers are also making efforts this year to help improve the value of membership through increasing volunteering, networking and training opportunities for our students. The officers this year are

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Please contact Society For Biomaterials headquarters directly with any questions or concerns.

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Students Motivated to Increase Membership Benefits

BY CHRISTOPHER GEHRMANN, STUDENT NEWS EDITOR

Students at the World Biomaterials Congress enjoyed a wonderful conference full of research in the field of biomaterials accompanied by many fun activities around the city of Montreal. The congress allowed for students to make connections with professors and peers across the globe aiding our knowledge of research in other countries and diversifying our global perspectives. A recent Memphis alumni and SFB Student Member, Joshua Herwig (now CTO and co-founder of Somavac Medical Solutions) expressed the benefits of attending the congress, which included "meeting other aspiring entrepreneurs and innovators from around the world helped to fortify my goal of pursuing my own company."

The student section held its business meeting during the congress and discussed the future direction and goals. As we increase the number of student chapters, we aim to enhance member benefits and increase opportunities for our students by offering volunteering, networking, and training opportunities for all student members.

A crucial activity we will continue to support is the outreach programs for primary school education in biomaterials and the tools we create to keep these programs active. Outreach is a key component of what our students can provide for the SFB and we wish to recognize our students' contributions while challenging others to do the same. By collecting and sharing the tools we use to teach primary school students about biomaterials we hope to facilitate other chapters in providing similar experiences for their communities and members. Working as educators in our communities helps increase the positive impact our organization provides while building lifelong skills for our members.

Many students may seek career paths after graduation outside academia. As such, we wish to provide information and opportunities to students on careers in industry, government or even entrepreneurship. We hope to provide this opportunity to our members by creating networking events at a local level through our Biomaterials Days, which bring together multiple SFB chapters and local companies for a day-long conference. These Biomaterials Days events are funded by the SFB and organized by our student members providing invaluable experience to help the students become successful in their future careers. For example, after the recent Memphis Biomaterials Day, at least two students were hired by a sponsoring company and one started a company locally using connections from the event.

Annually our student chapter holds business meetings to update our members and request feedback, but we often find our meetings do not provide enough incentive to attend. We aim to change this for the coming year and future years to come as we begin to implement various skill training opportunities for our students. Not only will our business meetings provide updates and collect feedback from our students, but we also hope to impart a specific skill which will help our students in their academic or professional careers. By creating value in our business meetings, we look forward to increasing the value of our student section and providing member benefits directly at the national SFB meetings.

Our student section this year is full of ambitious and dedicated members who will continue to provide benefits for our students, and we have open ears to any and all feedback.

Third Annual "Regenerative Medicine Summer School" a Success

The McGowan Institute for Regenerative Medicine held its Third Annual "Regenerative Medicine Summer School" the week of June 19, 2016. The Summer School week, endorsed by the SFB and the Tissue Engineering and Regenerative Medicine International Society (TERMIS).

Initiated and led by McGowan Institute faculty member Bryan Brown, PhD, the Summer School week was aimed at providing both international and regional undergraduate students with a hands-on learning program in regenerative medicine. The students interacted through lectures and laboratory activities with the faculty members of the McGowan Institute and participated in networking and career building activities. This is the first and only regenerative medicine summer program in the United States that is focused on undergraduates. The program is open to all undergraduates, but targets students at universities where they may not be exposed to bioengineering and regenerative medicine with a goal of recruiting top students from these universities into the field. This year's class consisted of 20 students from across the U.S. and internationally, many of whom come from backgrounds considered to be under-represented in the field of regenerative medicine. Lab activities included preparation of biological scaffolds, tissue culture, and 3-D printing. The students also experienced an

introduction to the Artificial Heart Program and the Center for Biological Imaging.

Mid-Atlantic Biomaterials Day Coming in Spring 2017

SFB Student Chapters at Johns Hopkins University, City College of New York, University of Rochester and Columbia University are currently planning the first Mid-Atlantic Regional Biomaterials Day! The event will be scheduled for either February or March 2017 in New York City, at a currently to be determined venue. Dr. Liisa Kuhn, Associate Professor of Reconstructive Sciences at the Center for Regenerative Medicine and Skeletal Development in UConn Health and current SFB President, will be the keynote speaker. We will be featuring additional speakers, including faculty and members of industry from multiple universities, companies and organizations from Washington, DC to Boston. We are currently looking for speakers, so if you have interest, or wish to advertise yourself or company at the event, please send an email to jhu.sfb@gmail.com. The event will also feature poster and oral presentations from students, with monetary prizes awarded to the top student presenters. Lunch will be provided for all attendees. An official website for abstract submission and registration will be set up over the next few months. Throughout this event, we look forward to instilling the core values of SFB, including education and research, while also fostering the formation of new SFB student chapters in the Mid-Atlantic Region.

Society For Biomaterials students exchanging research and making connections with international students at World Biomaterials Congress. From left to right: Annalisa Neri, Imperial College London; Mamado Diallo, University of Memphis; Miryam Mebarki, Institut Mondor de Recherche Biomedicale; Christopher Gehrmann, Univeristy of Memphis; Allen Mamaril, University of Memphis; Gillen Gonzalez, University of Memphis.

Meet the Winners of the Inaugural Laurencin Travel Fellowship


Dwight Meggie


Julian Rose


Robert De Loera

Echoing the finding by organizations including the National Science Foundation on the underrepresentation of African-Americans, Latinos, Native Americans and Native Alaskans in the field of science technology, engineering and math (STEM), the SFB recognizes that this uneven representation hinders success in the biomaterials field and believes this barrier can be broken through mentorship and increased opportunities for minorities.

To promote diversity, inclusion and success within STEM fields, the SFB has created the **Cato T. Laurencin, MD, PhD Travel Fellowship.** The fellowship was named in honor of Dr. Cato Laurencin, Founding Director of the Institute for Regenerative Engineering and the Founding Director of the Raymond and Beverly Sackler Center for Biomedical, Biological, Physical and Engineering Sciences at the University of Connecticut. A recipient of the Presidential Award for Excellence in Science, Engineering and Math Mentoring from President Barack Obama, Dr. Laurencin has served as an exemplary leader in the field of biomaterials and a supporter of diversity among those in this field to promote its success.

To encourage minority representation in the field, the travel fellowship provides undergraduate students with the resources needed to become a member of the SFB and attend the annual meeting. Fellows are paired with a mentor to serve as a guide as well as to advise them in pursuing advanced degrees and their career goals.

Three undergraduate students won the fellowship in its inaugural year based on their academic performance and career and research goals. They are Robert De Loera of the University of Chicago, Julian Rose of the University of Connecticut and Dwight Meggie of the University of Connecticut.

According to De Loera, receiving the fellowship solidified his interest in biomaterials and his desire to make a meaningful contribution in the field. Attending the World Biomaterials Congress enabled him to meet other undergraduates, graduate students and post-docs and learn about a variety of research areas. Most important, De Loera said the fellowship validated that all of his hard work paid off.

"The award served as a source of inspiration for me," said De Loera. "Watching Drs. Cato Laurencin, Molly Stevens and Rocky Tuan present their research during the SFB awards ceremony must have been the highlight of the Congress for me. Their research is so amazing and revolutionary. It was an absolute honor being there."

Dwight Meggie said the fellowship means most to him of all of the awards he has received, as the accolade has provided him the opportunity to join the largest and oldest scientific organization in the field of biomaterials.

"This advantage has not only allowed me to meet a few of the many great scientists who are pioneers in the field of biomaterials, but also has allowed me to stay current about the research in progress," said Meggie. "This award has opened such a tremendous door for me and is named after a distinguished member of the Society For Biomaterials, Dr. Cato T. Laurencin. I am proud to say that Dr. Laurencin is my mentor and it is such an honor to receive an award in his name."

For more information about the Cato T. Laurencin, MD, PhD Travel Fellowship or an application, visit biomaterials.org/awards/cato-laurencin-travel-fellowship.

To make a donation to the fellowship in honor of Dr. Laurencin, please contact the Society For Biomaterials headquarters directly at 856-439-0826 or at info@biomaterials.org, or visit www.biomaterials.org/donate. As a 501(c)(3) organization, all donations are tax deductible.

FROM DURABLE COATED DRUG-ELUTING STENTS TO NON-POLYMER-BASED INTRAVASCULAR DRUG DELIVERY TECHNOLOGIES: MECHANISMS UNDERLYING SUSTAINED ARTERIAL RETENTION

RAMI TZAFRIRI, PhD, CBSET, DEPARTMENTS OF APPLIED SCIENCES; ELAZER R. EDELMAN, IMES, MIT AND CARDIOVASCULAR DIVISION, BRIGHAM AND WOMEN'S HOSPITAL, HARVARD MEDICAL SCHOOL

Endovascular drug-eluting stents (DES) have revolutionized the treatment of atherosclerosis in coronary and peripheral vasculature. First-generation DES employed durable polymer coatings to adhere therapeutic drug loads to the stent and slowly release them over the course of several months with the aim of maintaining efficacious drug levels across the artery wall. Concern for persistent adverse responses to these coatings prompted development of more biocompatible second generation durable or bioerodible coatings that are resorbed over the course of stent implantation. However, in doing so, simultaneous control of duration and distribution of drug became even more challenging[1] prompting reconsideration of these long-held assumptions of role and even of the presence of the polymeric material. Indeed, the success of catheter and balloon-based drug delivery modalities in inhibiting intimal hyperplasia forced reconsideration of the need for sustained release.[2-4]

Here we briefly review a range of non-polymer based drug delivery technologies and highlight the mechanisms by which they sustain drug in the tissue for weeks to months. This focus on mechanisms of drug delivery and retention suggests a classification of the technologies based on the physical state of the delivered drug, (e.g., whether they elute the drug in its diffusible form, or deliver the drug laden coating and rely on solubilization to render the drug pharmacologically active).

Drug-eluting technologies

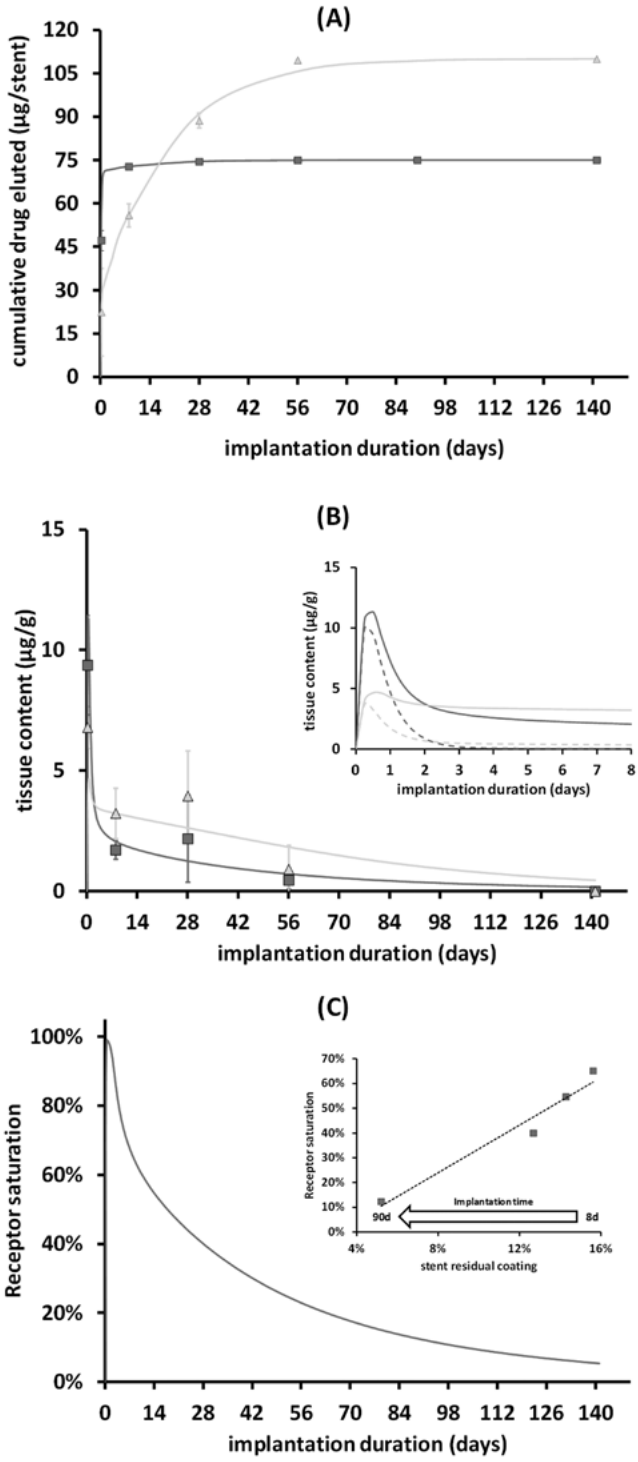
Local drug elution from stent coatings and infusion catheters and balloons requires a different mindset than systemic administration as issues of targeting, penetration and retention now dominate over dosing. At the extreme, local clearance forces can render the therapy inefficacious even when diffusible drug initially saturates the target tissue. Thus for example, though heparin pharmacology is well-suited to countering the acute and sustained vascular responses to angioplasty, balloon-based and catheter-based delivery of this drug were plagued by high rates of restenosis. This was attributed to the fast tissue clearance of heparin owing to its aqueous solubility.[5] Namely hydrophilic molecules such as heparin have a greater propensity for distributing into blood than into tissue, and within the tissue tend to reside in extracellular spaces. By contrast, lipophilic drugs exhibit a preference for tissue over blood and can passively enter cells, but this chemical property alone cannot account for effect. When endowed with antirestenotic properties, lipohilic compounds like paclitaxel and sirolimus analogs, though smaller than heparin more sustainably retained by arterial tissue in a manner that correlates with tissue expression of drug bindings sites[6-8]; these properties underlie their emergence as the drugs of choice for stent and balloon based delivery in coronary and peripheral vascular beds.

And yet affinity for lipid domains cannot account for the efficacy of these drugs as their retention within lipid-laden domains of atherosclerotic lesions is actually substantially reduced, not increased.[9] Drug lipophilicity promotes retention via nonspecific binding with micromolar affinities but it is important to recall that drugs such as paclitaxel and sirolimus bind their intracellular receptors with nanomolar affinities.[10] When either the non-specific or specific binding sites are displaced, say by lipid, binding is reduced, and when delivery is matched to binding site density retention can be optimized. In a recent study[10] we illustrated that tissue retention of sirolimus analogs can be achieved even with fast elution kinetics following rapid coating erosion, with computational modeling identifying binding to tissue receptors as the mechanism of prolonged retention (Figure 1). The composition of drug-eluting coatings can then be designed for optimal biocompatibility rather than predominantly for sustained drug elution kinetics. Improved biocompatibility can be achieved via use of fast eroding synthetic or natural polymers as carriers, or through polymer-free loading of anti-restenotic drugs directly onto stent-surface micropores or reservoirs.[1] These concepts are validated by recent clinical data that suggest that certain polymer-free DES may allow use of shorter adjunct antiplatelet therapy.[11]

Coating delivery technologies

Whereas metallic stents can provide a scaffold for sustained intravascular drug elution, drug coated balloons (DCB) are only inflated for a matter of minutes and typically deliver their drug load as part of a coating that is transferred or

Figure 1. Receptor Mediated Sustained Tissue Retention



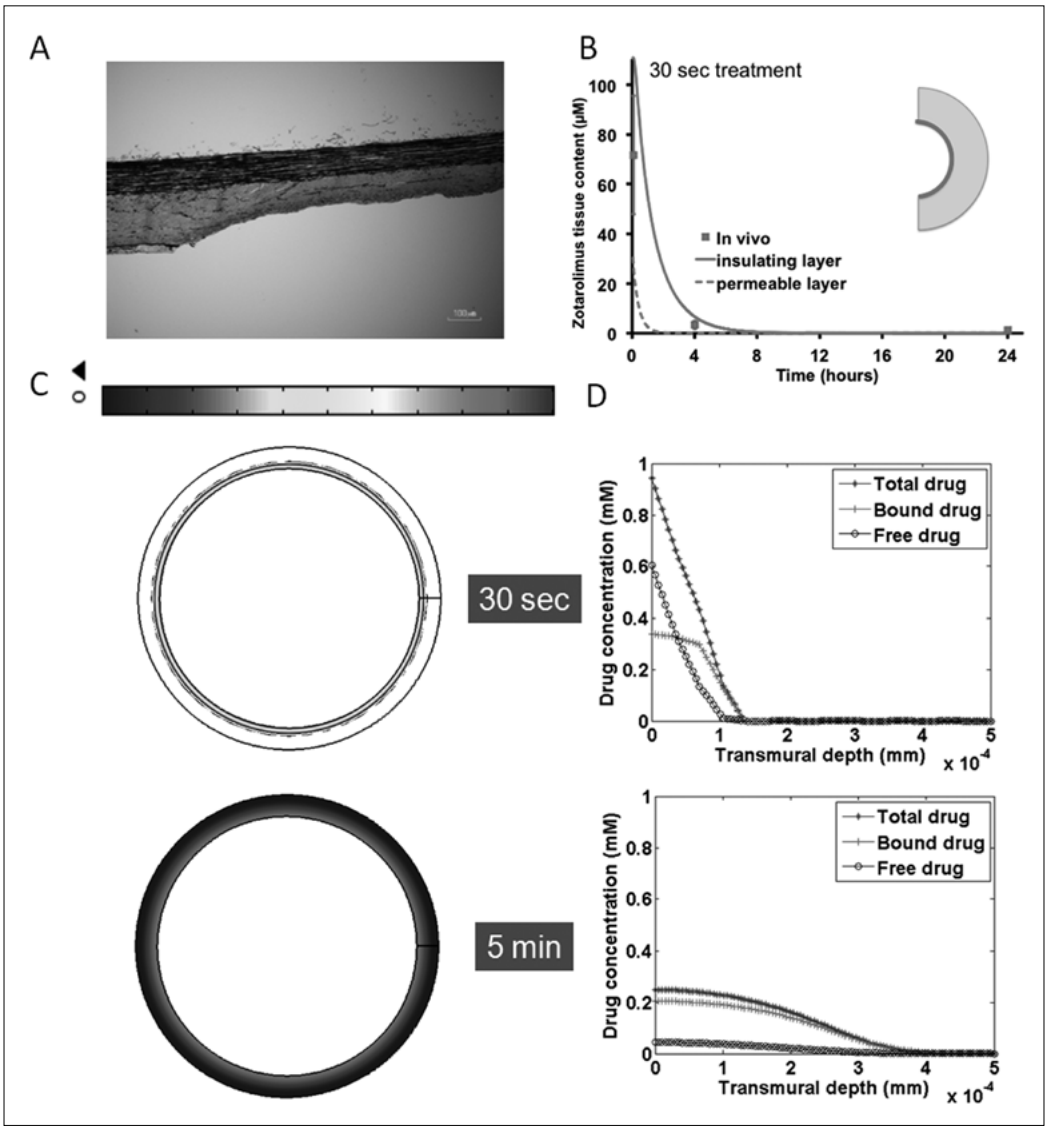
(A) In vivo release kinetics of a first generation sirolimus eluting stent (green) and a novel sirolimus analog (corolimus) eluting stent (red). Despite the faster release of corolimus vs sirolimus, tissue contents (symbols) for both DES are comparable up to 56 days post implantation and closely predicted by a computational model that accounts for high affinity drug binding to FKBP12 (lines). The inset illustrates that modeling that does not account for high affinity drug binding to FKBP12 (dashes) predicts unrealistically fast tissue clearance. (C) Model predicted FKBP12 saturation by corolimus (red line) correlates linearly with in vivo coating absorption (insert). Reproduced with permission of Elsevier publishing.[1]

"painted" onto the blood-tissue interface (Figure 2A). Different coatings transfer by a range of mechanisms, either as embolized or pre-formed drug- laden particulates or as islands that "paint" contiguous areas on the tissue surface. As a result, compared to DES, delivery by DCB is more variable and relies on additional forces to retain the delivered drug at the target tissue. While avid tissue binding remains a requisite for successful delivery from DCB,[12] a recent review by a pioneering group in the field[13] highlighted the importance of slow dissolution of transferred drug particles as a dominant mechanism of sustained tissue retention in first and second generation paclitaxel DCB. Notably, drug delivery strategies have now moved from balloons to stents, as certain novel DES designs also deliver drug laden coating particles to the tissue and rely on dissolution to slowly elute the drug within the tissue.[14] However, slow dissolution of transferred drug is not the sole mechanism by which DCB can enhance arterial drug retention. Our study of a zotarolimus-coated balloons illustrated that a fraction of the drug-loaded coating transfers as an adherent mural layer (Figure 2A) with computational modeling identifying impedance of luminal clearance as mechanism of prolonged retention (Figure 2B). Computational modeling can then predict drug distribution maps over time (Figure 2C) and locally resolve drug concentration into the free/diffusing component and the bound/immobilized component (Figure 2D). In so doing, computationally validated models can provide unique insights in support of local drug delivery innovation of optimization.

Conclusion

More than a decade after the approval of DES, unmet clinical needs and new data continue to fuel the development of innovative intravascular drug delivery devices. Durable polymer coatings have been superseded by erodible polymer and polymer-free coatings on stents and balloons. Sustained drug delivery is no longer considered an imperative for local anti-restenontic therapies, as binding, intra-tissue particle dissolution and modulation of luminal drug washout can sustain therapeutic drug concentrations in the tissue long after drug release from the device.

Figure 2. Coating Adherence Can Impede Drug Washout



(A) Adherence of a zotarolimus loaded DCB coating to a pig artery wall. (B) Following a 30 sec inflation of the DCB, arterial concentration of zotarolimus is consistent with a binding-diffusion model only when the adherence coating is allowed to impede luminal drug washout. Computational 2D maps of total drug concentration (C) and of radial distribution of total, free and bound drug concentrations in the tissue (D) provide additional insights as to the influence of time and binding. Reproduced from[12] with permission from the AHA.

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SUPRAMOLECULAR PEPTIDE BIOMATERIAL VACCINES FOR ADDICTION AND NEUROLOGICAL DISORDERS

JAI S. RUDRA, PhD, DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY, SEALY CENTER FOR VACCINE DEVELOPMENT, UNIVERSITY OF TEXAS MEDICAL BRANCH

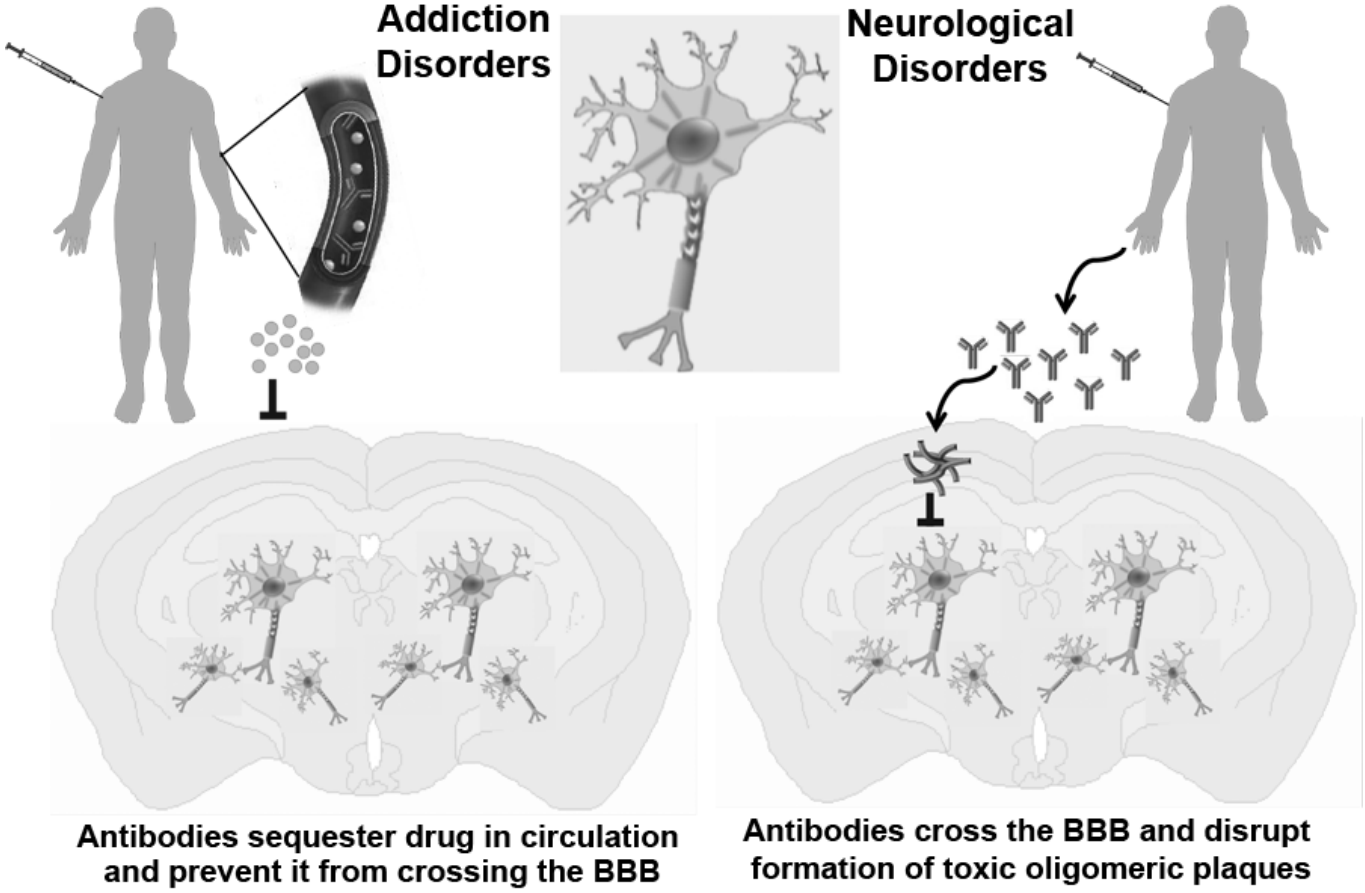
Immune engineering is an emerging field of materials research focusing on the development of vaccines and immunotherapies based on synthetic and natural biomaterials.[1] In the last decade, collaborative efforts by engineers and immunologists have generated promising materials-based avenues for prevention and treatment of pathogenic infections, cancer, and autoimmune diseases.[1] In a latest development, a new research focus has emerged towards the development of supramolecular peptide biomaterial vaccines for addiction and neurological disorders.

Neuropsychiatric disorders related to the use of psychostimulant drugs and age-related loss of cognitive function are a significant public health concern in the U.S. with heavy economic, social and emotional burden for the individuals and to those around them.[2] Addiction is a chronic disease of the brain circuitry characterized by impaired abstinence, craving and a diminished recognition of significant problems with a person's own behavior.[2] Preclinical and early-stage clinical studies suggest that vaccines that elicit effective anti-drug antibodies and prevent penetration across the blood-brain barrier can interrupt reward and possibly prevent relapse.[3] Therefore there is a necessity and likewise an opportunity for the merger of knowledge gained from biomaterials immunoengineering with current advances in neuropsychiatry toward the development of vaccines against drug addiction (Figure 1). One of the active areas of research is the development of synthetic vaccines based on self-assembling peptides that form supramolecular nanofibers in physiological buffers[4] for treating cocaine addiction.

Cocaine use in the U.S. is highly prevalent with ~1.4 million current users aged 12 or older and accounts for nearly half of the illicit drug-related medical emergencies.[5] Currently, there are no FDA-approved therapies for acute overdose or treatment of cocaine addiction.[5] The current landscape of cocaine vaccine development relies on conjugation of the drug to bacterial toxins and formulating the conjugates into emulsions using exogenous adjuvants.[6] Recently, a cholera toxin B-cocaine conjugate vaccine (TA-CD) in combination with alum adjuvant has undergone Phase III testing.[7] After 5 rounds of immunizations ~33% of the patients failed to achieve anti-cocaine antibody titers and adverse events such as induration and erythema at the injection site were reported.[7] To overcome these limitations, we investigated whether supramolecular peptide nanofibers can elicit anti-cocaine antibodies without the need for added adjuvants. In a recent study[8] we reported the synthesis of peptide nanofiber-based cocaine vaccines. Cocaine was modified at the P3 site with a carboxylic acid linker and coupled to the N-terminus of a self-assembling peptide domain. The conjugate assembled into nanofibers in physiological buffers, which when injected into mice, raised anti-cocaine antibodies. A broad distribution in antibody levels was observed and approximately 30% of the mice did not respond to the vaccine (characterized by antibody levels comparable to PBS controls), which is similar to what has been observed in clinical trials of cocaine-carrier conjugate vaccines (~67% response rate). Behavior analysis in a 60-min test session following cocaine challenge indicated significantly reduced hyperactivity in vaccine responders compared to control mice receiving PBS. Furthermore, a significant negative correlation was observed between antibody levels and cocaine-evoked hyperactivity for individual mice suggesting that vaccination efficacy was based on the amount of antibody in circulation. Importantly, cocaine-evoked hyperactivity in vaccinated non-responder mice did not differ relative to PBS control mice confirming that anti-cocaine antibodies were responsible for the reduced hyperactivity. This is the first reporetd biomaterials-based vaccine against cocaine addiction and we are currently investigating the immunologocal effects of linker length, linker chemistry, hapten positioning and incorporating CD4+T helper epitopes on vaccine efficacy.

It has also been reported recently, in a study focusing on the development of immunotherapies to prevent neurodegenerative effects associated with Ab-42 oligomers in Alzheimer's disease (AD)[9] that antibodies generated against aggregated peptide motif "VIAVIA" (double repeat of VIA corresponding to the terminal 3 residues in Ab-42 peptide) were able to specifically bind Ab-42 oligomers in the brains of transgenic Alzheimer's mice (Tg2576) and humans with AD. These antibodies are useful for diagnosing the accumulation of toxic oligomeric species in AD and other neurodegenerative diseases and could possibly serve as therapeutics following active vaccination. Currently, we are investigating nanofiber vaccines composed of VIAVIA antigen linked to a self-assembling peptide and investigating therapeutic protection in animal models of neurodegenerative diseases.

Figure 1. Applications of Biomaterials-Based Vaccines for Combating Neuropsychiatric Disorders Such as Drug Addiction and Neurodegerative Diseases



Supramolecular peptide biomaterials are attractive as antigen delivery scaffolds due to their inert and biocompatible nature. Synthetic peptides can be easily produced through standard peptide synthesis protocols and peptides incorporating non-natural amino acids or non-peptidic moieties can be designed to reduce proteolysis and degradation of the vaccine *in vivo*. The chemical versatility of the self-assembling peptide platform allows for conjugation of TLR agonists and/or CD4+T helper epitopes during synthesis for enhanced immunogenicity and antibody production. However, questions regarding the immunological mechanisms of action of supramolecular peptide nanofiber vaccines and their *in vivo* fate and toxicity will need to be assessed prior to their efficient translation in to the clinic.

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Programs that Encourage Underrepresented Minorities to Pursue a Career in STEM

BY YUSUF KHAN, EDUCATION NEWS CONTRIBUTING EDITOR

In a previous column here (fourth quarter 2014) I discussed science, technology, engineering and mathematics (STEM) education—specifically, what it is, the urgency behind it and the numbers substantiating the urgency. I discussed how the current level of student interest was not projected to keep up with projected industry demands, and I mentioned some federally funded programs that were intended in part to encourage students to pursue STEM fields. Some of those programs, the Research Experience for Mentoring (REM) from the National Science Foundation for instance, are specifically oriented towards encouraging students who are considered underrepresented minorities in the STEM fields.

As a follow-up to this, I'd like to briefly highlight a program with a similar goal that exists at the regional level. In that previous article I mentioned that only 16 percent of high school students intend to pursue STEM in college. Of the students who do go on to higher education, less than half intend to pursue a STEM field and less than one-third actually complete the degree. That drop in students who start college in a STEM field to students actually graduating in a STEM field often occurs after their first year, perhaps because they were unprepared for the rigors they were about to face. The University of Connecticut BRIDGE Program seeks to ease those rigors seen in the first year of college. BRIDGE is offered to underrepresented students within the STEM fields, which includes Women, African-Americans, Hispanics, Puerto-Ricans and Native Americans, during the summer after senior year of high school and before freshman year of college. The program is specifically open to students that will be attending UCONN in the fall and is designed to prepare them for the UCONN engineering curriculum.

During the five-week program, students attend classes in calculus, physics, chemistry and computer programming while working with tutors and fellow BRIDGE program participants (which number about 50 each summer) to get a jump start on the rigorous upcoming curriculum and to learn valuable study skills. BRIDGE students take classes together, form study groups together and build relationships with each other in advance of the beginning of the first semester so when that time comes they are well-prepared for the rigor ahead and have already developed a support system to lean on as the workload builds. Students also have the opportunity to become acquainted with the laboratories and engineering-related facilities that they will encounter as full-time students, again preparing them for what is to come. The students get to live on campus and eat in campus dining halls during the five weeks so they truly get insight into the college experience.

However, the summer program isn't limited to campus life. The students also travel off-campus to visit engineering companies ranging from the biotech industry to power plants, to learn about life after college and how their engineering education will have a direct role in their future endeavors. During these visits, students are introduced to professionals and have the opportunity to connect with industry before they start their education. Many participants in the program, which as been around since 1987, have developed life-long friends and mentors from their experience.

The BRIDGE program provides important exposure to incoming freshmen by demystifying some of the first-year challenges and giving them a head start in the more challenging courses they will face. It also gives them a chance to form bonds with fellow students early, so their first days of college are less isolating. And it gives them the opportunity to see first-hand what their education will do for them and how it can be applied to the real world after graduation. These are enormously important advantages for young incoming freshmen, and can make the difference between having the confidence to stay within a STEM field and feeling overwhelmed. Does your university offer a similar program? If so please share, and perhaps a future column in this space can highlight it.

EDUCATION QUOTE OF THE QUARTER

"Knowledge will bring you the opportunity to make a difference."

– Claire Fagin

Two Regenerative Medicine Bills before Congress

BY CARL G. SIMON JR.

There are currently two regenerative medicine bills before congress.[1,2] One is the "REGROW Act," which would "amend the Federal Food, Drug and Cosmetic Act with respect to cellular therapies."[1] If enacted, it would create a "conditional approval" pathway for cell therapies "if the sponsor of such product demonstrates preliminary clinical evidence of safety and a reasonable expectation of effectiveness." Another bill, the "Advancing Standards in Regenerative Medicine Act," would "support the establishment of a Standards Coordinating Body (SCB) in Regenerative Medicine and Advanced Therapies." The function of the SCB would be "to identify opportunities for the development of laboratory regulatory science research and documentary standards" that "support the development, evaluation and review of regenerative medicine products." Several regenerative medicine bills have been proposed in the U.S. Congress but were not enacted.[3-5] There has been extensive industry discussion surrounding the development and regulation of regenerative medicine products that lead to these bills being introduced.

USP Deploys CD34+ Cell Reference Standard

U.S. Pharmacopeial Convention (USP) recently deployed a CD34+ cell reference standard that may be of use to the cell therapy and regenerative medicine industries. Counting live CD34+ cells is a key measurement for hematopoietic stem cell therapies and bone marrow transplantation. "The Reference Standard is made from mobilized peripheral blood collected by apheresis of a G-CSF mobilized donor. The reference standard contains human leukocytes, erythrocytes and CD34+ cells that have been fixed and lyophilized." Users resuspend the cells in 0.5 mL of water and then follow their normal flow cytometry protocols, including labelling with anti-CD34 antibodies. An inter-laboratory study with 16 participants assigned a value of 25 CD34+ cells per microliter (after resuspension in 0.5 mL), with a range of 16 to 34 CD34+ cells per microliter. By determining how well their results agree with the assigned value, a user may assess the performance of their cell counting measurement system. The development of reference standards such as this is key to the advancement of the regenerative medicine industry, which has identified a lack of reliable methods and control materials for characterizing cell-based products as "possibly the single greatest challenge for the field."[7,8] Although cell counting and flow cytometry may be the most fundamental of cell measurements, they suffer from large variabilities and uncertainties. It is quite revealing that the range for the 16 expert labs was 16 to 34, which is a 72 percent range [(34-16)/25=0.72]. A 72 percent range on this key measurement makes it challenging to advance cell-based therapies to the clinic. Thus, we are presented with a great opportunity to improve cell counting and flow cytometry measurements.

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Events Happening in the Industry

BY STEVE LIN, EXACTECH

Zimmer Biomet Holdings, Inc. recently announced two separate acquisitions. The first was to acquire Cayenne Medical, Inc. based in Scottsdale, Arizona. The financial terms of the transaction were not disclosed. This acquisition will strengthen Zimmer Biomet's Sports Medicine capabilities and portfolio of technically advanced soft tissue reconstruction solutions for knee, shoulder and extremities procedures. The second was to buy LDR Holding Corporation, a France-based medical device company specializing in surgical solutions for spine disorders, in a deal worth $1 billion. LDR's portfolio of products establishes Zimmer Biomet's foothold in fast-growing spine businesses: cervical disc replacement (CDR) and other minimal incision surgical (MIS) technologies. The acquisition will accelerate Zimmer Biomet's spine business, and position the company as a key player in the $10B global spine business.

Abbott Laboratories will buy **St. Jude Medical** for $25 billion in its biggest-ever acquisition, giving it a competitive edge across the cardiovascular market. Abbott also said it has financed for both the St. Jude transaction and the previously announced $6 billion purchase of Alere. St. Jude Medical's strong positions in heart failure devices, atrial fibrillation and cardiac rhythm management complement Abbott's leading positions in coronary intervention and transcatheter mitral repair. With combined sales of about $8.7 billion, the expanded Abbott expects to hold the No. 1 or 2 positions across the cardiovascular device markets.

Medtronic is utilizing the same approach for its new orthopedics venture: a low-cost knee and hip replacement portfolio tied to the new bundled payment model by the Centers for Medicare and Medicaid Services (CMS), designed to slash costs to these most common surgical procedures, which cost Medicare about $7 billion in hospital bills each year. The plan encourages hospitals to use less costly implants that result in target clinical outcomes, such as reduced readmission rates or shortened recovery duration. Medtronic said it purchased Responsive Orthopedics, a niche maker of lower-cost artificial knees and hips, to make its implants. Responsive Orthopedics' total knee replacement system was FDA-cleared in the U.S. last year, and the company is still developing its hip replacement system.

Boston Scientific plans to open a new research and development facility in Gurgaon, India. The new R&D center will focus on developing products to meet the clinical needs in high-burden diseases specific to emerging markets in the Asia Pacific, Middle East and Africa regions, and to serve as a global product engineering site. As 1 of 7 strategic global R&D sites for Boston Scientific, the R&D center in India has the potential to be the largest outside of the U.S. The Gurgaon facility is slated to go on line by 2017. Boston Scientific also said that there will be an unspecified number of layoffs in its next stage of the turnaround engineered by chairman & CEO Mike Mahoney.

Danaher Corp. will split into two companies on July 2, completing the separation into two independent, publicly traded ventures that it announced in May 2015. The company that will retain the Danaher name will consist of its existing life sciences, diagnostics, and dental businesses, as well as its water quality, and product identification businesses. These generated $16.5 billion and $3.9 billion in sales in 2015 and the first quarter of 2016, respectively. A new company, Fortive Corp., will house Danaher's existing test and measurement, industrial technologies, and petroleum businesses, which together produced $6.2 billion and $1.5 billion of revenue in 2015 and the Q1 2016, respectively. Fortive will keep 22,000 of Danaher's 81,000 employees in 40 countries, and is expected to generate revenue of $6 billion a year. It will be headquartered in Everett, Washington, while "new" Danaher will remain in Washington, DC.

Mostyn Law filed the petition on behalf of a lead patient plaintiff in a federal class action lawsuit against *Boston Scientific.* The petition asks FDA to announce an immediate Class I recall of Boston Scientific products it claims were made with the counterfeit material from China. The petitioners also want the agency to send warnings to customers, users, and patients of products allegedly made with counterfeit resin, and to treat this situation like a 2010 Class I recall of counterfeit C.R. Bard surgical mesh. Boston Scientific denied the petition's claims in an April 1 public statement by stating "Boston Scientific does not use 'counterfeit' or 'adulterated' materials in our medical devices." "Boston Scientific has a robust quality system and dedication to patient safety. We stand behind our products, the materials used in those products and our commitment to women's health."

EQT, a Swedish private equity group, plans to sell off BSN, which specializes in wound care, vascular care, and orthopedic products. EQT is reportedly working with JP Morgan to facilitate the sale, which could be worth over $2.2 billion. EQT first acquired BSN in a $2.3 billion deal, beating out bids from Kimberly Clark and BC Partners. If EQT can secure a buyer for BSN, the deal will be the second major exit for the company this year. Last month, EQT sold prosthetic voice implant maker Atos Medical in a $958 million deal with PAI Partners.

The U.S. Securities and Exchange Commission and the Department of Justice had charged imaging-device maker **Analogic** (Peabody, MA) and subsidiary BK Medical under the Federal Corrupt Practices Act with issuing fake, inflated invoices to distributors and funneling the money to third parties.

Dentsply Sirona said that it has reached a definitive agreement to acquire all the shares of **MIS (Make It Simple) Implants Technologies** at estimated $375 million. It sells a wide array of dental implants and prosthetics, as well as grafting materials and guided surgery services in more than 65 countries worldwide. News of the acquisition comes nearly four months after Dentsply International and Sirona Dental Systems completed their $14.5 billion "merger of equals." The company has an estimated $3.8 billion a year in annual revenue and 15,000 employees.

The MiniMed 640G insulin pump, which its maker **Medtronic** touts as the world's first hybrid, closed-loop artificial pancreas, now has an application submitted before FDA, according to Bloomberg. Medtronic officials expect a ruling from FDA within a year. The MiniMed 670G with the Enlite 3 continuous glucose monitoring has already boosted Medtronic's insulin pump sales outside of the United States. The 640G marks the fourth of six stages Medtronic is going through to develop what has been a holy grail for diabetes devices for decades: an almost entirely automatic "closed-loop" insulin pump system that does away with the constant glucose testing and insulin adjustments that diabetes patients presently go through. Medtronic has been boasting of a 124-patient study that found the 670G increased the amount of time patients were in the desired blood-glucose range, without any severe complications, according to a report in the *Star Tribune* of Minneapolis.

Staff Update (continued from page 7)

excited to utilize all of the resources our organization provides such as the Special Interest Groups (SIGs) to use current member benefits in more proactive ways. This year aims to be an especially rewarding year for student members in SFB.

SPECIAL INTEREST GROUPS

REPRESENTATIVE BRENDAN HARLEY

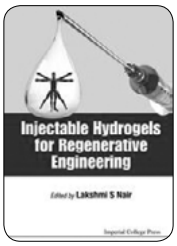
The SIGs worked in concert with the Liaison Committee to develop targeted regional workshops and meetings with other organizations during this World Biomaterials Congress year to provide added value to the SFB membership. The SIGs spent the summer submitting proposals for the 2017 meeting in Minneapolis and planning their budgets for 2017. The publication of the SIGnal newsletter continues on a monthly basis.

** Note: The Long Range Planning and Meetings Committees responsibilities are being transferred to the Board of Directors. A Bylaws change in 2017 is expected to codify this operational shift.*

Injectable Hydrogels for Regenerative Engineering

Book Review

REVIEWED BY LYNNE JONES



Nair, Lakshmi S. (editor)
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Hydrogels are rosslinked, polymeric networks that are hydrophilic and water-absorbing in nature. The hydrogels can be modified or "tuned" to create a wide range of material, structural, mechanical, or biological properties. As such, hydrogels can be prepared as injectables so that they can be used as tissue adhesives, space-filling biomaterials, drug delivery, and tissue engineering (Chapter 2). Cells can be encapsulated within hydrogels thereby expanding the versatility of hydrogels for a number of medical applications. There has been increasing interest in utility of injectable hydrogels for minimally invasive reconstructive procedures. Significant advancements have been made in the design of injectable hydrogels fueling the interest in this biomaterial for regenerative medicine.

The book, *Injectable Hydrogels for Regenerative Engineering*, introduces the reader to the application of injectable hydrogels for tissue regeneration and repair. Chapters 1 and 2 set the context for the remainder of the book providing overviews on regenerative engineering and the role of injectable hydrogels. Chapters 3, 4, and 5 examine the different approaches to hydrogel crosslinking: physical, chemical, and enzymatic. Chapters 6-10 summarize the various medical applications for hydrogels including their use as tissue adhesives and for regeneration of intervertebral, neural tissue, articular cartilage, and cardiac tissues. While there is some redundancy between chapters, this actually permits each chapter to be used as a stand-alone review of its topic.

The first chapter defines tissue engineering as a convergence of tissue engineering and regenerative medicine. It then proceeds to describe the three elements that may be used in isolation or combination: scaffolds, biological molecules (including growth factors), and cells. The second chapter provides the basics of hydrogels with a focus on injectable hydrogels. Both of these chapters are very effective reviews of their subject matter and can easily be understood by both undergraduate and graduate students.

The next three chapters focus on mechanisms of crosslinking hydrogels to create injectable biomaterials. The chapters are very pragmatic in nature, reviewing general concepts for each of these approaches include characterization and applications of each approach. Chapter 3 includes discussion of design of injectable physical hydrogels, characterization of the structure and mechanics, associative polymer gels, micellar gels, fibrillary gels, colloidal and macrophase-separated gels. Chapter 4 contains a thorough description of chemical crosslinking methods for *In Situ* gelation. Chapter 5 describes commonly used enzyme systems for hydrogel preparation.

The remaining chapters describe various medical applications of injectable hydrogels for tissue regeneration. Chapter 6 reviews injectable hydrogels as tissue adhesives and defines tissue adhesives and describes how adhesive hydrogels are created and characterized. This application is relevant to several medical disciplines associated with wound healing and tissue engineering. The next three chapters relate to orthopaedic, neurosurgery and spine surgery: intervertebral tissue (Chapter 7), neural tissue (Chapter 8) and articular cartilage (Chapter 9). Each chapter provides the context (anatomy, pathology of the tissue) as well as the types and uses of injectable hydrogels for treatment of the pathology. The final chapter is focused on cardiac tissue regeneration and the use of injectable hydrogels for post-myocardial infarction. It provides a detailed description of injectable materials that are protein-based, polysaccharide-based, synthetically-derived, and natural and synthetic polymer hybrid materials.

I recommend this book for students, researchers, and clinicians who are looking for an overview of injectable hydrogels. With the knowledge gained from this book, the reader will be adequately positioned to dive further into the published literature regarding the in vivo studies and clinical experiences.

Additional Reading

- Ballios BG, Cooke MJ, Donaldson L, et al. A Hyaluronan-Based Injectable Hydrogel Improves the Survival and Integration of Stem Cell Progeny following Transplantation. *Stem Cell Reports.* 2015;4(6):1031-45.
- Loh XJ, Scherman OA, Gale P. *Polymeric and Self Assembled Hydrogels: From Fundamental Understanding to Applications.* RSC Publishing; 2012 (Reviewed Biomaterials Forum, 3rd Q, 2013.)
- Ma P. (ed) *Biomaterials and Regenerative Medicine.* Cambridge: Cambridge University Press; 2014. Chapters 14-19.
- Peppas NA, Hoffman AS. *Hydrogels in Biomaterials Science. An Introduction to Materials in Medicine.* 3rd ed. New York: Elsevier-Academic Press; 2013. Chapter 1.2.5, p. 166-178.
- Wang RM, Christman KL. Decellularized myocardial matrix hydrogels: In basic research and preclinical studies. *Adv Drug Deliv Rev.* 2016;96:77-82.

Upcoming Events in Biomaterials

Oct. 9–Oct. 11, 2016
14th NJ Symposium on Biomaterials Science
New Brunswick, NJ
Hosted by New Jersey Center for Biomaterials, Rutgers University. The goal of the Symposium series is to exchange information and ideas across the full spectrum of scientists working in the biomaterials field, by focusing on research and development topics that represent the most current promising directions for ultimate medical application.

Oct. 14, 2016
Southeastern Biomaterials Day
Atlanta, GA
Hosted at Georgia Institute of Technology, Co-hosted by Clemson University, Bioengineering Department

Oct. 14–Oct. 15, 2016
Case Western Reserve University, Carnegie Melon University, and the University of Michigan Biomaterials Day
Ohio
This event is collaboratively and comprehensively organized by Society For Biomaterials members at Case Western Reserve University (CWRU), Carnegie Mellon University and University of Michigan Ann Arbor.

GET YOUR BIOMATERIALS IMAGES ON THE COVER!

We are soliciting submissions of scientific images to be featured as cover art of the *Biomaterials Forum.* We are particularly interested in images and visual creations that illustrate unique phenomena and findings from biomaterials research and innovation.

Deadline: Accepted continuously

Selection Process: Submissions will be reviewed timely and the artwork selected will be featured as cover art on the front cover of a near-future issue of *Biomaterials Forum*.

Benefits: Winners will receive a print copy (may request extra copies) of the issue in which their artwork is featured for showcasing purpose.

Multiple Submissions: Individuals may submit more than one piece at a time. Previously featured work will not be considered.

Format: An electronic version of the artwork in high resolution as a .gif, .tiff, or .jpeg file.

Submission Instructions: Please send submissions electronically as file attachments to SFB headquarters and the Executive Editor of the *Biomaterials Forum*, Guigen Zhang, info@biomaterials.org, GUIGEN@clemson.edu. Please include the title of the image, the creator's name, affiliation, and an approximately 75-word description summarizing the subject of the image and its biomaterials relevance (to be included in the featured issue).

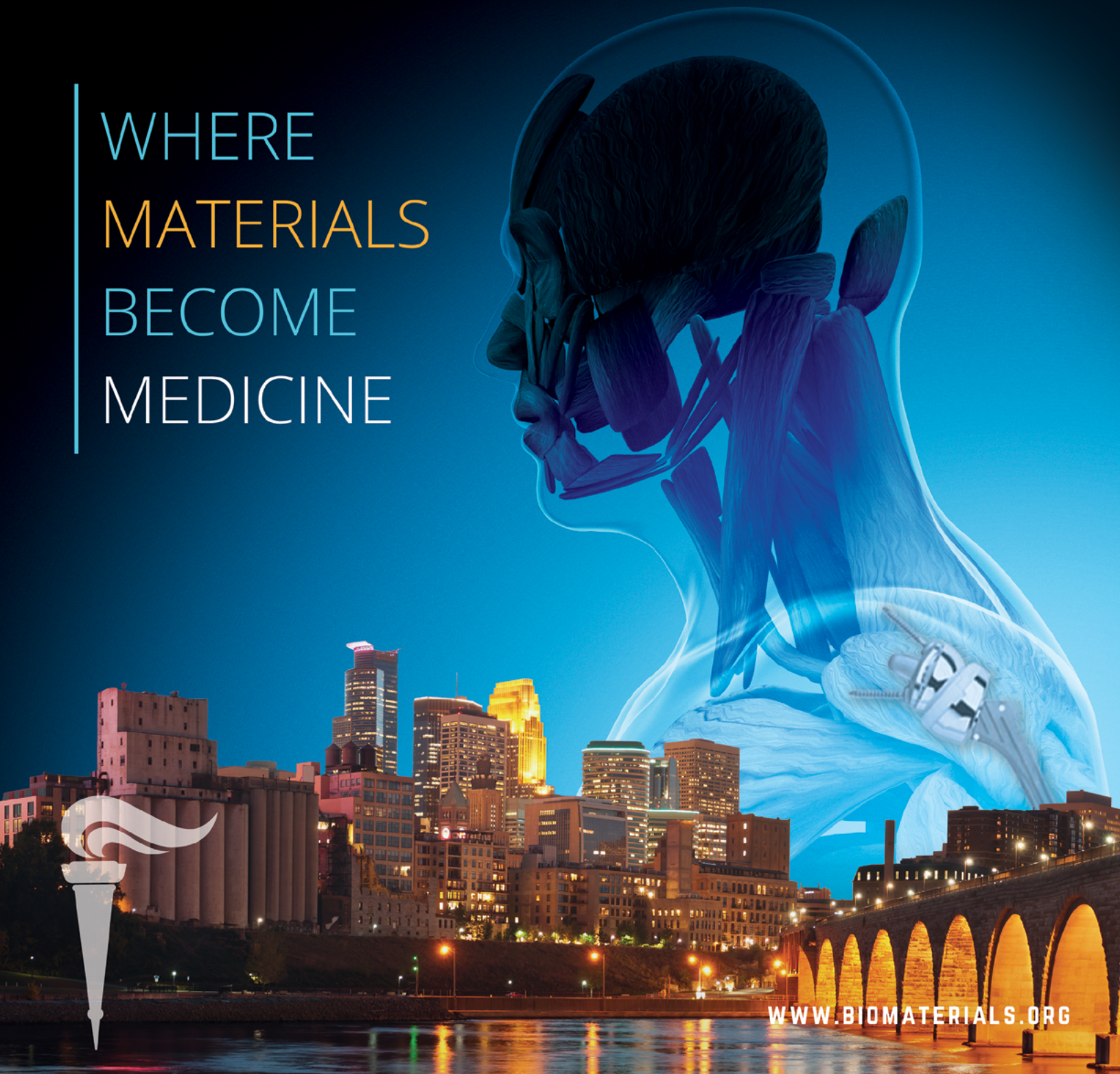
Note: Editorial contributions to *Biomaterials Forum* are always welcome. Contributions should be sent to the Executive Editor and are subject to the terms and conditions of the Editorial and Publication Release. Authors should refer to the Author Guidelines, which are available on the Society's website 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.

SOCIETY FOR BIOMATERIALS

2017 ANNUAL MEETING & EXPOSITION

MINNEAPOLIS, MINNESOTA • APRIL 5-8, 2017

WHERE
MATERIALS
BECOME
MEDICINE



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