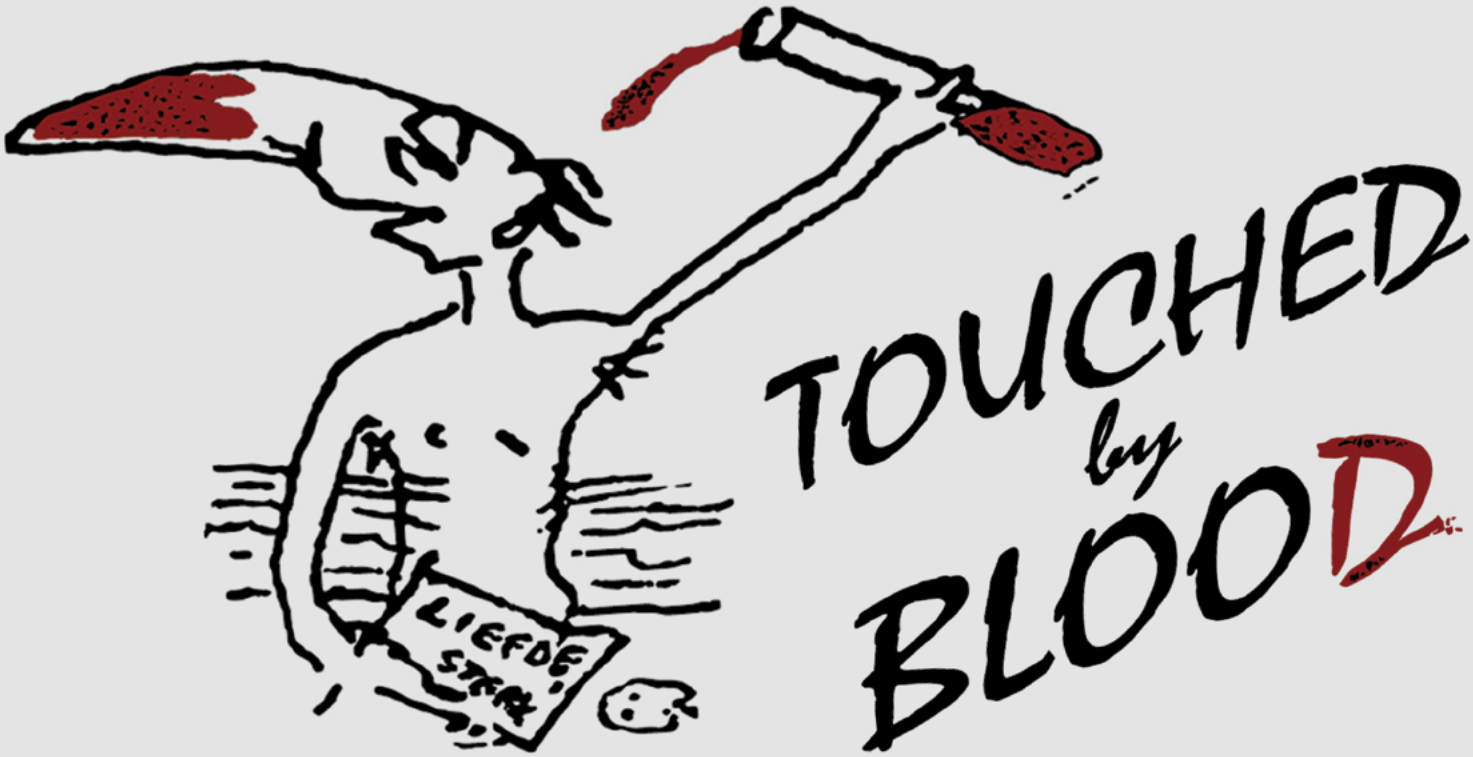
SPECIAL INTEREST GROUP HIGHLIGHT ISSUE

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Third Quarter 2015 • Volume 43, Issue 3



Also Inside:

- Q & A with Elaine Duncan
- Industry News: Patent Reform and More
- Book Review: Musculoskeletal Regenerative Engineering

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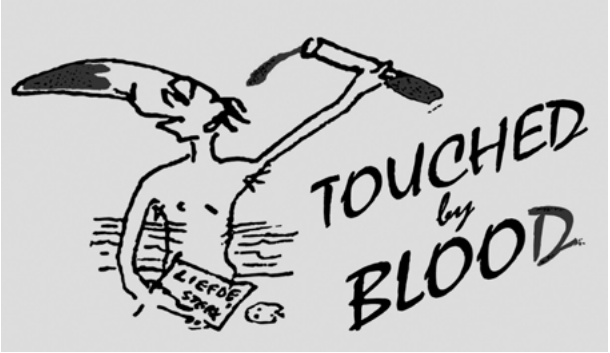
Scientific photos may be submitted for cover consideration in future issues. Submit color photo, no larger than 4" x 6", along with credit information and scientific description, to the Executive Editor.

BIOMATERIALS
FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 42, Issue 3

Special Interest Group Reporters



Contents

The Torch

News & Updates

On the cover: Self-caricature of scientist, artist and poet Leo Vroman (b. April 10, 1915 – d. Feb. 22, 2014), who was a pioneer in the field of biomaterials. He is best known for his work on the hierarchical adsorption of blood proteins, which came to be known as the "Vroman Effect."[1] This self-caricature was used for the play, "Touched by Blood," written by Vroman. The play was performed in April 2015 in Vroman's hometown Gouda, Netherlands to celebrate what would have been Vroman's 100th birthday.

Artwork provided by his daughter, Peggy Vroman Gracey.

1. Vroman L, Adams AL, Fischer GC, Munoz PC. Interaction of high molecular weight kininogen, factor XII and fibrinogen in plasma at interfaces. Blood. 1980;55:156-159.

Liisa Kuhn

GREETINGS FELLOW BIOMATERIALS SCIENTISTS,

Looking to find a network of peers that share the same focused interest as you within the field of biomaterials? Our 14 different Society For Biomaterials (SFB) Special Interest Groups (SIGs) are the place to go. Perhaps you're a member of one or two already, but for those of you who haven't found an affiliation or are looking to change, this issue of the Biomaterials Forum provides information about some of the most active SIGs, and includes summaries of their specific contributions to the Annual Meeting programming and networking events. The names of all of the SFB SIGs are listed inside the front cover. Participation in a SIG offers a way to become connected with others that share your same technical interests in a smaller subgroup of our large society, and it provides an opportunity to get experience in leadership by serving as one of the SIG officers. It's how I got started.

This issue's cover art commemorates Professor Leo Vroman (b. April 10, 1915 – d. Feb. 22, 2014), who was a Dutch-American hematologist, a prolific poet mainly in Dutch and an artist/illustrator. His research about the competitive and hierarchical absorption of blood plasma proteins was so important that the phenomenon was named after him! As you conduct your research, keep in mind that a pristine biomaterials surface is going to rapidly change once implanted in the body where it will contact blood. Those carefully placed ligands waiting for cell receptors are going to be buried quickly under first albumin and fibrinogen and other abundant plasma proteins. Later, those proteins desorb as less prevalent proteins, such as factor XII and high-molecular weight kininogen, will replace them. These proteins guide coagulation and other wound-healing responses. I have no doubt that Dr. Vromans's many artistic diversions synergistically spurred his creativity in science. I very much enjoyed an art class I took this summer and I hope you've recently had a chance to venture beyond the lab and stimulate your creativity as well.

This issue also features a biomaterials career story — an interview with Elaine Duncan, President of Paladin Medical, who agreed to share her fascinating career story with us. Like many of us, she is grateful for the positive influence that SFB has had on her life and career.

Additionally, several of our SFB members have recently received prestigious professional awards and grants and have been promoted. Read the Member News column and be inspired by what your colleagues have achieved. The Industrial news column reports on congressional and senatorial activities that affect patent reform and FDA regulation. You can also find out about our student leaders in the Student News column and learn more about a NIST workshop about cell therapy products in the Government News column. I hope you enjoy this issue!

Best wishes,

LIISA KUHN, PhD
Biomaterials Forum Executive Editor
Associate Professor
UConn Health

You can read more about Professor Leo Vroman, a man of science, romance, peril and art, at elsevier.com/connect/leo-vroman-a-life-of-science-peril-and-romance.

Participation in a SIG offers a way to become connected with others who share your same technical interests in a smaller subgroup of our large society.

BIOMATERIALS INNOVATION, WHAT IS ON YOUR HORIZON?

Thomas J. Webster

For most of us, summertime is a great time to reflect on past year accomplishments and look forward to the upcoming months. Many times this means using the warm summer air and great weather to think boldly and outside-the-box about innovative research, classroom topics, company ideas, thesis and overall key aspects of your professional (and personal) life. What could motivate us more than sitting on a beach watching the endless waves on the horizon, thinking of what lies beyond?

Well, we are doing the same exercise for the Society For Biomaterials (SFB). This summer, the SFB Board of Directors visited Association Headquarters for the first time and brainstormed about how to take SFB to the next level. While the part of New Jersey we were in did not have beaches, palm trees or endless waves (maybe next year), it was not short on motivation and an overwhelming feeling of optimism for where we are, and where we want to go, with SFB.

Yes, we did celebrate our strong history, high-quality scientific meetings, global leadership and ever-growing impactful research, which is changing the world, but we also challenged ourselves to continue to think outside-the-box. Where is SFB headed? What is happening to academic societies all over the world in this technology age focused more on social media than ever before? What can we do to lead in this culture of change, specifically for biomaterials? We continued to ask ourselves poignant questions that focused on a technology-changing society, yet, in many aspects SFB serves it members the same way it did a decade or so ago, before Twitter, Facebook, texting, etc. We talked about our governance structure and whether it best serves our membership today. We talked about breaking tradition, and whether that is good for SFB or not.

Of course, it may not be a surprise to you to learn that we were not short on ideas and conversations as our day-and-a-half retreat in New Jersey was quickly over. We identified the increasing need to develop seminars, workshops and avenues to share ideas via our website (hopefully all members noticed that we held our first webinar in June with over 100 participants and established a goal to hold one webinar per month for the rest of the year based on this popularity).

We developed ideas to have an even larger presence at sister societies to increase our visibility and build collaborations to help us all grow. We continued to expand ideas on the critical leadership role we can play in China, Europe and the world over the next year. We developed a plan to host the World Biomaterials Congress (WBC) in 2024. We accomplished a lot due to the energy, passion and volunteer involvement of our members.

We identified the increasing need to develop seminars, workshops and avenues to share ideas via our website.

This is a crucial time in our history. We have choices to make. As technology continues to change the way we share ideas, we can decide to be part of today's technological advances or not. What we have seen in this short time period is that our members (all ages) embrace these technology advances and are looking for alternative ways to share ideas about biomaterials education and research. We welcome your ideas to build upon this success.

So as you read this as summer comes to a close, take some time to think about how we as a society can be innovative. Share those ideas with us. Engage with us as we look forward to collectively establish our pathway for what lies beyond our horizon.

As always, thank you for your time and involvement in SFB!

THOMAS J. WEBSTER, PhD, PRESIDENT OF SFB
The Arthur W. Zafiropoulo Department Chair
Professor of Chemical Engineering, Northeastern University
Boston, Massachusetts

Staff Update

BY DEB DUPNIK, ASSISTANT EXECUTIVE DIRECTOR

Hello from the Society For Biomaterials (SFB) headquarters! The big news from headquarters this quarter is that the Board of Directors met in June to advance the strategic plan for SFB. The following four goals were prioritized, as were 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 and applied science/engineering researchers and students, and increase value to members.
4. **Education and Professional Development** — SFB will promote professional development, education and networking for scientists/researchers, clinicians and industry and governmental agency personnel.

The board has already charged each of the SFB committees with executing certain aspects of the society's strategic plan for the coming year.

AWARDS, CEREMONIES AND NOMINATIONS

CHAIR JOEL D. BUMGARDNER, PhD

The committee will be reviewing the materials for all candidates whose nominations were eligible for consideration in 2016. New nominations will be accepted until **Sept. 11, 2015**. In addition, nominations for President-elect and Member-at-Large for the 2015-16 term are due by **Sept. 16, 2015**.

Charges to the committee include:

- Recruit award nominations for the presentation at the 2016 World Biomaterials Congress (WBC), with specific attention on student awards for outstanding research
- Consider a new award for mid-career researchers
- Actively recruit visionary leaders for officer positions
- Evaluate and recommend officer and award nominations

BYLAWS

CHAIR BENJAMIN G. KESELOWSKY, PhD

The committee will be reviewing the bylaws and discussing any possible amendments.

Charges to the committee include:

- Re-examine the bylaws with an eye on board and council responsibilities
- Review the current Standing Committee structure and function

DEVICES & MATERIALS

CHAIR PETER G. EDELMAN, PhD

The committee will be reviewing all matters of particular concern to the manufacture of biomaterials.

Charges to the committee include:

- Work with the U.S./China Organizing Committee to execute the third workshop in Haikou, China, Nov. 19–23, 2015
- Work with the Web/Forum editors and staff to develop a job posting program
- Provide input to the webinar taskforce for content of interest to industry members
- Provide input and direction to the Board of Directors and Program Committee for the 2017 Annual Meeting program content of interest to the industry

EDUCATION & PROFESSIONAL DEVELOPMENT

CHAIR HUINAN LIU, PhD

Requests for SFB's endorsement of other meetings have continued to be received and evaluated by the committee. Later in the fall, the committee will be reviewing submissions for Biomaterials Days grants.

Charges to the committee include:

- Promote Biomaterials Days programs and evaluate grant applications
- Oversee the process for student chapter travel grants and evaluate applications
- Review endorsement requests and make recommendations to the Board of Directors
- Provide input and advice to the webinar taskforce on planned activities
- Evaluate applications and award the 2016 C. William Hall Scholarship
- Develop plans for the new scholarship for under-represented minorities

FINANCE

CHAIR SHELLY SAKIYAMA-ELBERT, PhD

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

Charges to the committee include:

- Budget development
- Proposal/request evaluation

- Investment monitoring and policy review
- Review financial reporting

LIAISON

CHAIR DAVID PULEO, PhD

The Liaison Committee continues its efforts to coordinate and collaborate with other societies. This is especially important in the World Congress years since SFB does not hold an Annual Meeting during that time. So far, the committee has received nine 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's members.

Charges to the committee include:

- Expand role as a contributor of program content to related societies
- Work with the 2016 Program Committee to progress the 2016 satellite proposals
- Develop plans for 2017 and beyond
- Consider SFB's role in WBC and the International Union of Societies for Biomaterials Science and Engineering (IUSBSE), and provide input to the Board of Directors and the Long Range Planning Committee with respect to globalization

LONG RANGE PLANNING

CHAIR LIISA KUHN, PhD

As traditional stewards of the long range plan for SFB, this committee was responsible for the development of the current strategic plan. However with the Board of Directors now engaged in a more strategic governance role in operationalizing the strategic plan, this committee's focus will shift to furthering international collaborations; increasing the visibility of SFB through public relations efforts; governmental/policy issues; and potential collaborations with other organizations.

Charges for the committee include:

- Examine and interpret relevant data to identify external opportunities and threats
- Develop a globalization strategy

MEETINGS

CHAIR THOMAS WEBSTER, PhD

The committee is working to finalize the contracts for the 2017 Annual Meeting in Minneapolis, Minnesota, and the 2018 Annual Meeting in Atlanta, Georgia.

Charges to the committee include:

- 2019 site selection — identifying desired cities, executing requests for proposals (RFP), evaluating responses and making recommendation to the Board of Directors
- Work with a task force to develop a pitch for SFB to host the 2024 WBC

MEMBERSHIP

CHAIR LIJIE GRACE ZHANG, PhD

The committee is working to develop strategies to increase membership, especially in industry and clinical sectors.

Charges to the committee include:

- Articulate the value proposition for membership
- Rigorously define/reexamine the target market for membership
- Recruit a diverse membership, including researchers, industry, clinicians and regulatory personnel
- Develop and implement a comprehensive strategy for increasing membership

PRESIDENT'S ADVISORY

CHAIR NICK ZIATS, PhD

The committee will review the code of ethics for SFB and advise the council about any matter requested by the president.

Charges to the committee include:

- Review ethical issues and develop a code of ethics
- Provide advice and input to staff on potential sponsors

PROGRAM

CO-CHAIRS CHRIS SIEDLECKI, PhD AND SUPING LYU, PhD

The committee is working with the Liaison Committee to identify and finalize which 2016 symposia will best serve the society's members. The committee will also be exploring ways to improve SFB's Annual Meeting.

Charges to the committee include:

- Work with staff to streamline a process for identification and selection of new program formats
- Develop a mechanism for directing increased plenary content at the Annual Meeting

PUBLICATIONS

CHAIR ALAN LITSKY, MD, ScD

The committee continues to work on ensuring that publishing information quality and quantity will be of maximum service to members in the field of biomaterials.

Charges to the committee include:

- Review of proposals for Web and Forum editors and make recommendations to the council

- Work with staff to create a plan for organizing and classifying the SFB Body of Knowledge

NATIONAL STUDENT CHAPTERS

PRESIDENT EVELYN BRACHO-SANCHEZ

National student chapter officers will be working with the Education and Professional Development Committee to refine the Biomaterials Days grant program with an eye on converting participants to SFB members.

SPECIAL INTEREST GROUPS

REPRESENTATIVE BRENDON HARLEY, PhD

The Special Interest Groups (SIGs) were tasked with providing content for this SIG highlight issue of the Biomaterials Forum. They are planning their budgets for 2016 and celebrating their 25th year in 2016.

The priorities for the SIGs in 2015 are to:

- Complete proposals for 2016 proposed satellite sessions
- Identify content for the *Journal of Biomedical Materials Research* (JBMR) virtual issues
- Identify content for the 2017 Annual meeting
- Run the publication, SIGnal newsletter on a monthly basis

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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Biomaterials Forum Cover Contest

Submit photos of biomaterials from your lab to be used on the cover of the Biomaterials Forum by Sept. 30 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

Oct. 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

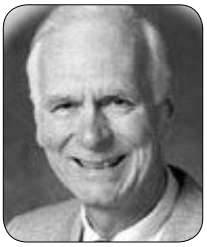
Historical Brain Teaser

BY GUIGEN ZHANG, CLEMSON UNIVERSITY

In the Biomaterials Forum fourth quarter issue of 2014 (Volume 39, Issue 4) there was a short article about the initial establishment of the SFB with a historic photo taken during the first World Biomaterials Congress (WBC) held in Vienna, Austria in 1980. In the caption, three of the people in the photo were identified as unknown.

After reading the article, Dr. Allan Hoffman of the University of Washington contacted me to provide the names of some of the unknown people, although some he could not name immediately. Among those in the photo, one he quickly identified was Walter Zingg of University of Toronto, Canada. Following Dr. Hoffman's lead, I did a bit of digging and found something more about Walter and even communicated with his son, David Zingg, a professor at University of Toronto.

According to a post on the website of the Institute of Biomaterials and Biomedical Engineering (IBBME) of the University of Toronto (where Zingg served as the director from 1983 to 1988):



Professor Walter Zingg

"Dr. Zingg, a Swiss immigrant, was named head of surgical research at the Toronto Hospital for Sick Kids where he pursued numerous research projects, such as the freezing of organs during heart-lung bypass operations. Yet, it was the point where science and engineering intersect that held endless fascination for Dr. Zingg.

Even before receiving his position at Toronto's Sick Kids Hospital, Dr. Zingg was publishing in the relatively unknown field of biomaterials (constructs that interact with biological systems) — in particular, a 1960 paper on the use of a commercial polyurethane for the repair of bone fractures — marking him as one of the first Canadian researchers with a medical degree conducting experiments of this sort.

Dr. Zingg's love of medicine and machines eventually brought him to the University of Toronto's budding IBBME program. At the time, the Institute was known as IBME, or the Institute of Biomedical Engineering. It was here that Dr. Zingg began working in earnest with researchers exploring the frontiers of a new science: biomedical and biomaterials engineering.

Dr. Zingg patented a new tubular membrane design, an important precursor to models currently being used. Later, Dr. Zingg would create a new insulin pump design with other Engineering collaborators, including IBBME's own Professor Michael Sefton.

One of his most notable contributions to the world of science, however, was a project with Dr. Bernard Leibel and Dr. Julio Martin, in which they were able to eliminate diabetes in research subjects through the transplantation of pancreatic cells. 'This was a great accomplishment and my father was justifiably proud,' recalls Professor David Zingg, director of the University of Toronto Institute for Aerospace Study, and Walter Zingg's son, about the day when Dr. Zingg's work became front-page news. 'But I do remember him telling me at the time with typical modesty that it was just a small step and there was a long way to go.'"

I called this column "historical brain teaser" for a good reason. The same photo was on SFB's website and had all the people in it identified, but this exercise shows that it is sometimes beneficial to intentionally hold back some information for it will help stimulate our memory and curiosity. The other two people who were identified as unknown are Harukyuki Kawahara of Japan (I confirmed this with Professor Kazuhiko Ishihara of University of Tokyo) and Franz Burny of Belgium. Both of these gentlemen made tremendous contributions to the biomaterials field in their respective countries. I hope I will be able to find more information about these early members of SFB and report it here in future columns.

Please consider sending your old photos and stories about the early days of SFB to Historical Flashback Column Editor Guigen Zhang at guigen@clemson.edu for publication in future columns.

Members in the News

BY ELIZABETH COSGRIFF-HERNANDEZ, MEMBER-AT-LARGE

Greetings to the members of the Society For Biomaterials (SFB). I am honored to serve as your 2015-2016 Member-at-Large representative. I would like to thank Horst Von Recum for his excellent service in this role last year. I serve as an unencumbered representative of the members 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 would like to encourage all members to send me your ideas and feedback about SFB. With your help, we can continue to improve SFB and increase the value for all members. I will also write this column, which highlights member news and accomplishments. This forum is a great way to catch up on what is happening in the community and see how SFB members are impacting the field. I would love to hear from you, so please take a moment to send me news for future issues.

Dr. Larry Hench of the Florida Institute of Technology, will be honored by the Cade Museum of Creativity and Invention. The museum will honor Dr. Hench with a permanent display once the museum is built. In 1969, Dr. Hench discovered Bioglass, the first man-made material to bond to living tissues. Materials used in medicine or dentistry prior to this discovery were only tolerated by the body and created a non-adherent fibrous layer, isolating living tissues from the foreign material. The concept of bioactive bonding, pioneered by Dr. Hench's discovery, unleashed the field of biomedical materials to innovation, which has led to countless second- and third-generation materials and devices, and revolutionized the approach to repair and regeneration of the body.

Allan Hoffman has been honored by the three Hoffman Family Symposia (HFS) conferences held to recognize his contributions to the field of biomaterials. These conferences are organized by former students and colleagues of Dr. Hoffman in Asia, specifically in Japan, Korea, China, Taiwan and Singapore. The first and second were held in Japan in 2010 and 2014 and the third was held this year in Gwangju, Korea. Over 100 attended the second and third conferences, which were focused on biomaterials and drug delivery. A fourth conference is being organized in Taiwan next year. Dr. Hoffman feels very honored and excited by these conferences, which include the latest research results by his colleagues and their students, many of whom are Dr. Hoffman's academic grandchildren and, in a few cases, even a few academic great grandchildren!

The third Hoffman Family Symposium in Gwangju, Korea (March 2015).

Kevin E. Healy, Jan Fandrianto distinguished professor in engineering at the University of California, Berkeley, in collaboration with scientists at the Gladstone Institutes, developed a process for growing human heart chambers *in vitro* from stem cells. This *in vitro* model, published in *Nature Communications*, has the potential to be used to study early heart development. It may also be used as a screening tool for drugs likely to generate cardiac birth defects during pregnancy.

Susmita Bose, Herman and Brita Lindholm endowed chair of mechanical and materials engineering at Washington State University, was selected by the Washington Biotechnology

Dr. Hench is also author of a series of children's books, featuring Boing-Boing the Bionic Cat, which are being used in the United States and England to promote interest in science, engineering and technology in school children.

and Biomedical Association as one of the Women to Watch in Life Science. Dr. Bose was recognized for her contributions to biomaterials research in the development of 3D printed ceramic bone tissue engineering scaffolds at the Life Science Innovation North West conference on July 1. Dr. Bose has published over 220 technical papers and seven book chapters and has edited six books with over 6,000 citations and an "h" index of 45. She holds three patents, and four are currently pending with the United States Patent and Trademark Office (USPTO).

Tom Webster, fourth from left, installed as the inaugural Art Zafiropoulo Chair in Engineering.

Tom Webster, professor and chair of Chemical Engineering at Northeastern University, was formally installed as the inaugural Art Zafiropoulo Chair in Engineering.

Tony Mikos received the Lifetime Achievement Award and **Lauren Black** received the Young Investigator Award from the Tissue Engineering & Regenerative Medicine International Society, Americas (TERMIS-AM).

Sarah Stabenfeldt, assistant professor at Arizona State University in the School of Biological and Health Systems Engineering, recently received an NSF CAREER award from CBET-BME. The grant, "CAREER: Elucidation and Modulation of Chemotactic Signaling after Brain Injury," seeks to elucidate key signaling events that promote stem cell recruitment after traumatic brain injury. Biomaterials-based therapies will then exploit these signaling mechanisms to tune neural stem cell recruitment.

Chien-Chi Lin, assistant professor in the Weldon School of Biomedical Engineering at Purdue University, was awarded an NSF CAREER award from DMR-Biomaterials. The grant, "A Reversible Dynamic Hydrogel System for Studying Stemness and Drug Responsiveness of Cancer Stem Cells," will develop biomaterials matrices with controllable biophysical and biochemical properties that enable both exploratory and mechanistic studies related to cancer stem cells. Dr. Lin was also invited to participate in the 2015 U.S. Frontiers of Engineering Symposium, which is organized by the National Academy of Engineering.

Nasim Annabi, assistant professor at Northeastern University, developed a new protein-based gel for wound healing, in collaboration with Professor Ali Khademhosseini of Brigham and Women's Hospital (BWH), Harvard Medical School. The combination of this hydrogel with nanoparticles can immediately stop bleeding and promote wound healing. This work was released by BWH and published in Advanced Functional Materials.

Professor at Harvard-MIT's Division of Health Sciences and Technology, Brigham and Women's Hospital and Harvard Medical School, **Ali Khademhosseini**, had his research on 3D printing of blood vessels highlighted in Discover magazine. This article was ranked in the top 100 stories of 2014.

Joachim Storsberg of Fraunhofer Institute for Applied Polymer Research in Potsdam-Golm, was awarded the international "Silver Cornea" research award for "dissemination of knowledge in corneal diseases and recognition of scientific, medical and teaching achievements." He was presented with this award for his research in the development of biomaterials as artificial corneas at the 7th International Symposium on Advances in Diagnosis and Treatment of Corneal Diseases.

Danielle S.W. Benoit, associate professor in the Biomedical Engineering Department at the University of Rochester, was awarded tenure on July 1. Danielle and Pat also welcomed a daughter, Katherine Amelia, to their family on June 3.

Syam Nukavarapu, assistant professor in the Orthopaedic Surgery Department at the University of Connecticut Health Center, received a Junior Investigator Award from the Musculoskeletal Transplant Foundation (MTF). His laboratory will develop Completely Intra-operative Tissue Engineering Strategies (CITES) for bone and osteochondral defect repair and regeneration. Through this award, he will be able to develop an intra-operative strategy to revitalize bone allografts at the point-of-care.

Noam Eliaz, professor and the founding chair of the Department of Materials Science and Engineering (DMSE) at Tel Aviv University (TAU), has recently been elected as a member of The Israel Young Academy.

Kyle Lampe, assistant professor in the Chemical Engineering Department at the University of Virginia, recently had his research highlighted in UVA Today. The Lampe Biomaterials Group is focused on neural tissue engineering and the redox regulation of stem cell fate. A YouTube video highlighting his lab is available at **youtube.com/watch?v=TViUvt0rIg0.**

An Interview with Elaine Duncan, President of Paladin Medical, Inc.

BY LIISA KUHN, EXECUTIVE EDITOR, BIOMATERIALS FORUM

Elaine Duncan (center) with James Anderson (left) and Harold Alexander (right) at the 1992 World Biomaterials Congress (WBC) in Berlin.

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

My undergraduate study in mechanical engineering was a classical degree, but with emphasis on applications for medical devices, particularly fluid mechanics. The master's degree courses were self-designed to incorporate electives in the history of medicine, comparative medicines (anthropology) and history of technology. Another classical mechanical engineering class included heat transfer, which emphasized applications of solar energy. In this class, I designed a model house and analyzed the diurnal heat capacity of various building materials. It worked so well on paper, I built it and still live in it. The course work included a chemical engineering class, which analyzed the performance of various organs and anatomical processes. Neither degree afforded much biomaterials science, but I received that training via the scientists at 3M Company.

Where did you get those degrees and what made you chose those places?

The University of Kentucky was the only place to go to school for me. I didn't look anywhere else for my undergraduate training. The University of Minnesota for my master's was also a geographical choice because I could work full-time at 3M Company and earned my master's a course or two at a time. 3M compensated tuition for any class C or better, and allowed time off during the day to attend one class a semester. Both schools were ahead of their time with biomedical engineering programs.

Did you do a postdoctoral program?

No. I was not allowed by the University of Minnesota to complete my PhD program. This was a major disappointment and set me back in my life. I had all of my course work complete for the PhD, but I could not get an advisor. I appealed and was told I shouldn't want to go to school where I wasn't wanted. I was looking into other schools and was called to join the artificial heart program in Salt Lake City. I don't regret the decision, but I do believe now that I experienced sexual discrimination. Years later, I met another woman who had had the exact same experience from the same department.

Can you give examples of the kinds of things you learned after your formal education was over?

Even without a PhD and without a post-doc, I was able to contribute to the development of the Jarvik VII and one of the first cochlear implants under development at the University of Utah. While at 3M for nine years (my other "degree") I created novel vascular graft materials using spun-bonded polymer technology and magnetic implants. My product development and acquisition assessment work gave me experience in nearly every polymer processing technology and with many cutting-edge biomedical materials, electrical devices and body parts for nearly every part of the body, from the brain to knees. The following five years I worked with cutting-edge vascular graft polymeric technologies. This was all before I was 35 years old.

When did you take your first *real* job?

I was 14 and worked in a pharmacy.

What attracted you to your present position?

I decided to create Paladin Medical, Inc. as a regulatory consulting firm in 1987 to offer my expertise in the specific niche of taking new products through the FDA approval process. Many small firms at the time had no way to afford the equivalent of a vice president of regulatory affairs and quality assurance, and few firms available had a medical device engineer as the lead consultant. I wanted to stay on the cutting edge of the industry and not be pigeon-holed into only one medical specialty area.

What different positions have you held at the company you currently work for?

I have been the President of Paladin Medical, Inc. since its founding in 1987. However, previously I have held various titles in product development, including project manager. I have held titles of director and vice president of regulatory and quality affairs, and also vice president of new ventures.

What is the relationship between basic science and applied science?

Typically if the basic science isn't there, the applied science can't be made up.

What particular research directions are of high priority or profile at your place of work?

We don't do research. Typically the clients have conducted some basic research before trying to develop a product. I specialize in helping clients who have theoretical knowledge to reduce their idea or invention to a practical product that can be evaluated. Sometimes the evaluation requires animal testing or a clinical trial and I assist in the assurance that the protocols will produce data to support the product claims with the Federal Drug Administration (FDA).

What are some of your favorite aspects about working at your company?
I love new things — I am constantly amazed at new materials, new inventions and new medical approaches. This job is never boring. I love "winning" the submission clearance. I keep coming back for more!

What do you do in a typical week? How do you divide your time between those activities?
We have no typical week and no typical clients. We help each client focus their activities to the success of their submission.

Do you set your own priorities and deadlines and, if so, how do you do that?
Typically the priorities are set by the relative urgency of each client's own deliverables. Sometimes a project that won't go to market for years will have an urgent deadline today!

Any advice for young biomaterials scientists about time management?
Learn self-discipline and time management early. Do the most important thing first, no matter how badly you'd rather do something else.

How did your education prepare you for the job you do today?
It taught me to ask questions. "Book learning" was great, but the best education came from the hands-on projects.

What courses or activities would you recommend that college students take to be prepared for a job like yours?
I think practical experience in a large company, like 3M, is a good place to start after a solid college education. Focus on the fundamentals and don't specialize too soon.

What is some of the best career advice you've been given?
Many years ago, Professor Jonathan Black steered me away from applying for a PhD at Clemson. I wanted to complete my degree. Jonathan said I needed to take stock in where I was at the time and where I wanted to be. His actual expression shouldn't be repeated in mixed company, but it was the best advice I ever got. I finally realized that I didn't have to have the PhD after my name to be a scientist and to be a complete person.

Please share where you think the future of biomaterials/tissue regeneration is going.
I think it's more important that I share my biggest concern about the future. If organizations, such as the Society For Biomaterials (SFB) and the Orthopaedic Research Society (ORS), do not take a firm leadership position with the regulatory and standards organizations we are going to see this science stall. From where I sit, the "gatekeepers" would prefer the new biomaterials and tissue regeneration to all go away. These folks are so risk-adverse that if we had to get silicone rubber Foley catheters approved today, they'd require a Premarket Approval (PMA). I'm not speaking of just the FDA; I am stating that FDA advisors, standards committees and commercial testing facilities all have a stake in making the barriers to entry higher and higher with no consequences to themselves. So called "biocompatibility testing," which is really over-kill toxicology testing, is not relevant for so many medical devices, and, yet, companies must pay outrageous prices for these "standardized" tests in order to get a me-too device with a common medical device material through a 510(k). Do we really need genotoxicity testing on titanium? The analysis of surfaces first, and the understanding of the materials (either as primary replacements or scaffolds for regeneration), needs to be rationally analyzed, not "check-boxed." The fundamental biomaterials science has been lost in the all mighty cash register. Plus, we train development engineers to do what they are told, "run the standardized testing and don't rock the boat" because we "need to get it through." Hundreds of check-box tests do not ensure safety and do not advance science, but they make "controllers" feel good all over the world. While we're checking boxes, we are not thinking of the real risks and not paying for the real tests that could prevent device failures. I am an advocate for biomaterials qualification and I advance that cause any chance I get, but if the field of biomaterials and tissue regeneration is to continue to advance we must step out of our comfort zone and reach across the aisle. We need to destroy the many "we-they" barriers that have been created to slow advances in biomedical devices and evolve a "stakeholder" mentality. Years ago I saw the FDA and SFB hold symposia where the topic of interest was debated on neutral ground across company lines, with all the parties engaged in the goal of advancement. Now, in most of these sorts of meetings we all sit politely while we're told what is acceptable and what is not, without scientific challenge to some of these outrageous requirements. Why is that?

What influence has SFB had on your life and career?
When I attended my first SFB meeting in Clemson, South Carolina, I had the opportunity to meet two SFB leaders who had a profound impact on my career and interest in biomaterials. Dr. Bill Hall came up to me and asked me to participate in SFB. He immediately introduced me to the program chairman for the next meeting, which was to be held in Rensselear. He also introduced me to Norman Cranin, the editor of the Journal of Biomedical Materials Research (JBMR*). This began more than 20 years of continuous service to SFB, which, in turn, gave me an opportunity to help to plan the first separate evening "workshop" on histology at a national meeting, and to serve on the editorial board of the SFB's journal and, subsequently, become the newsletter editor. These services to SFB gave me a taste for running a business, and an opportunity to meet some of the leading scientists in biomaterials in the world. For a young, shy (yes I was shy) female engineer, their trust changed my perspective on what I could contribute to the mission of SFB and my own career path. Now, I strive to mentor and pass on the confidence shown to me and to others.*

To find out more about **Ms. Duncan,** visit www.paladinmedical.com.

PROVIDING EDUCATION AND NETWORKING OPPORTUNITIES FOR RESEARCHERS IN THE SURFACE CHARACTERIZATION & MODIFICATION BIOMATERIALS FIELD

BY GOPINATH MANI, PhD, ASSISTANT PROFESSOR OF BIOMEDICAL ENGINEERING, THE UNIVERSITY OF SOUTH DAKOTA

The main goal of the Surface Characterization & Modification (SC&M) SIG is to promote educational and networking opportunities for the researchers in the field of SC&M of biomaterials and medical devices, and to develop a compelling, scientific program in SC&M in the Society For Biomaterials' (SFB) annual meetings. The two major research topics emphasized by SC&M SIG include:

- Improving the understanding of biomaterial surface structure and its relationship to biological performance
- Developing surface modification strategies for biomaterials

Some research areas that fall under these topics include spectroscopic, microscopic and biochemical surface characterization, thin film deposition, chemical and ion surface modification, lubrication, passivation/corrosion, biological films and quality assurance of device surfaces.

We are pleased to announce the newly elected officers for the SC&M SIG 2015-2017 term are Dr. Gopinath Mani as chair, Dr. Ankit Agarwal as vice-chair, Dr. Nihar Shah as secretary/treasurer and Dr. Balakrishnan Sivaraman as program chair. We currently have over 100 members in our SIG from various academic, industrial, business and government organizations. Our members regularly serve as session organizers, session moderators and abstract reviewers for the sessions sponsored/co-sponsored by SC&M SIG in the annual meetings. Also, several members of our SIG provide podium and poster presentations in the annual meetings every year.

At the most recent SFB 2015 Annual Meeting, the SC&M SIG sponsored/co-sponsored 10 sessions, including:

- Surface Modification and Characterization of Biomaterials: Concepts, Principles and Latest Developments
- Biofabrication and Biomanufacturing in Tissue Engineering and Regenerative Medicine 1
- Biofabrication and Biomanufacturing in Tissue Engineering and Regenerative Medicine 2
- Recent Advances in Surface Modification of Biomaterials 1
- Recent Advances in Surface Modification of Biomaterials 2
- Bio-Nanomaterials for Cancer Theranostic Treatment
- Local Delivery of Drugs and Growth Factors from Implant Coatings
- Vascular and Blood Cells Responses to Novel Cardiovascular Biomaterials
- Progress and Challenges in Basic Science and Translation of Orthopedic Biomaterials-Associated Infections

All these sessions were well-received at the meeting.

Traditionally, the SC&M SIG has been very active in collecting students' resumes/CVs prior to the conference and putting them together in a CD for distribution to potential employers who come to the annual meetings. This activity was successfully conducted at the SFB 2015 Annual Meeting with over 50 CDs of students' resumes/CVs distributed to potential employers, creating job opportunities for students.

The SC&M SIG meeting was conducted at the SFB 2015 Annual Meeting with researchers present from academia, industry and the Federal Drug Adminstrations (FDA). Several ideas were discussed in this meeting for the sessions to be organized in the upcoming SFB annual meetings. The suggestions provided included: 1) a panel discussion on why surface characterization of biomaterials is important with a plan to invite speakers from both academia and industry; 2) a symposium on the characterization of proteins, cells and tissue at the materials interface through 3D imaging techniques; 3) the role of surface and interface analysis from the FDA perspective for improved biocompatibility and contamination-free surfaces; and 4) surface analysis from an industry perspective with speakers from various medical device industries. There were also ideas about co-organizing a session with other societies, such as the American Vacuum Society (AVS) and the Materials Research Society (MRS).

Over 50 CDs of students' resumes/CVs were distributed to potential employers, creating job opportunities for students.

Cardiovascular Biomaterials SIG

EXAMINING THE DISCOVERY, RESEARCH, DEVELOPMENT AND USE OF BIOMATERIALS IN CARDIVASCULAR DEVICES AND IMPLANTS

BY RAMI TZAFRIRI, PhD, PRINCIPAL SCIENTIST APPLIED SCIENCES, CBSET INC.

Our mission at the Cardiovascular Biomaterials SIG is to foster the professional interaction and address the common concerns of academic and industrial scientists and engineers, clinicians and regulatory professionals involved with the discovery, research, development and use of biomaterials for cardiovascular devices and implants. These interests often intersect with those of the Drug Delivery SIG, of which we regularly cosponsor sessions, including the session at the 2015 Annual Meeting about drug-eluting stents. We are now looking to build similar relationships with additional SIGs that share the same interests, including Biomaterials and Medical Products Commercialization, Biomaterials-Tissue Interaction and Surface Characterization and Modification.

At the 2015 meeting in Charlotte, our incoming SIG officers highlighted their goal to strengthen ties with clinicians and industry researchers through the organization of joint conference sessions, as part of the SFB annual conferences or as part of clinical conferences. We believe that this will contribute to our vibrancy and help recruit more members from the industry, two important constituencies that currently only account for approximately 20 percent of our approximately 200 members. We want to use this opportunity to call upon our industry and clinician members to make an effort and recruit more of their colleagues to our SIG.

Finally, discussed ideas for an event at the World Biomaterials Congress (WBC) for sessions are:

- Animal models and regulatory considerations for cardiovascular devices and tissue engineered implants
- Drug-coated balloons: novel technologies, preclinical models and regulatory considerations
- Drug-eluting stents and bioresorbable scaffolds: novel technologies and preclinical models

We encourage members to reach out to us regarding the scope of these and other sessions they would want our SIG to sponsor in the upcoming WBC.

Tissue Engineering SIG

GENERATING INTERACTIONS IN A MULTIDISCIPLINARY FIELD

BY ABBY WHITTINGTON, PhD, VIRGINIA TECH

The Tissue Engineering (TE) SIG is a forum dedicated to the exchange of ideas and best practices for the use of biomaterials to replace or regenerate tissues. TE is inherently a multidisciplinary field that benefits greatly from interactions across the boundaries of traditional research silos. As a SIG, we offer many different opportunities for people of varied backgrounds to interact and meet others with similar research interests. Therefore, we seek to engage SFB members in lively discussion between basic scientists, applied scientists, engineers, clinicians, industrial members, professional societies in related fields and regulatory groups through scientific tracks and workshops, STAR awards and social interactions. Two such recent efforts to generate conversation across the various groups are highlighted here.

Social Mixers

We have been focusing on reaching out within SFB via mixers hosted during the annual meetings. Two social hours were held in local venues to highlight regional cuisine and promoted member mingling and scientific discourse. In 2014, more than 50 people joined the joint TE and Drug Delivery SIG Mixer at Wynkoop Brewing Company. This mixer offered members from both SIGs an opportunity to interact across the disciplines and meet possible new collaborators. For the 2015 Annual Meeting, we hosted our second mixer at Blackfinn Ameripub. This event offered members an opportunity to mix with industrial, clinical and scientific groups, all working within the TE field. With the success of these two mixers, we plan to continue offering this interaction at future meetings and are open to combining our efforts with any of the other SIGs.

Future Opportunities

For the upcoming World Congress year, the TE SIG is sponsoring a one-day workshop in conjunction with the Tissue Engineering and Regenerative Medicine Society, Americas (TERMIS-AM) Annual Meeting, which will be held in San Diego, California in the fall of 2016. Many TERMIS-AM and SFB members use materials as support scaffolds for their research, therefore the day will offer state-of-the-art scaffold fabrication and characterization techniques. This pre-conference workshop will focus on two specific areas: 1) novel materials synthesis and characterization and 2) evolving 3D scaffold fabrication techniques. An expert panel will be formed to lead the discussion on each topic and engage attendees. The mission of this workshop will be to generate more interactions between members of SFB and TERMIS-AM, thus enriching the field of tissue engineering. If you are interested in helping out with upcoming meetings, learning more about the TE SIG, please contact any one of our current officers!

AIMING TO BE A THOUGHT LEADER IN THE NANOBIOMATERIALS RESEARCH COMMUNITY

BY DANIEL SIEGWART, ASSISTANT PROFESSOR, UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AND HUINAN LIU, ASSISTANT PROFESSOR, UNIVERSITY OF CALIFORNIA AT RIVERSIDE

The mission of the Nanomaterials SIG is to showcase the unique science and technology present in biomaterials at the nanoscale level through organizing the exchange of ideas involving nanobiotechnology and advocating for its advances. With a focus on fundamental science, the Nano SIG champions the continual push to uncover new knowledge at the nanoscale level, and connect this to macroscale properties and behaviours of biomaterials. With a focus on technology, the Nano SIG fosters innovative design and synthesis of nanobiomaterials useful in the creation of new and better devices, diagnostics and therapeutics for biomedical applications. The Nano SIG emphasizes an interdisciplinary vision to facilitate the translation of nanomaterials to achieve intended biological significance and medical impact. The vision is to establish the Nano SIG to become a thought leader in the nanobiomaterials research community by emphasizing nanoscience discovery, nanotechnology application and clinical translation innovation.

The Nano SIG has recently pursued this vision through sponsorship of social networking events and thematic conference programming. At the last two Society For Biomaterials' (SFB) Annual Meetings, the Nano SIG organized social events to promote a fruitful exchange of ideas and social interaction. In Denver, we gathered at the Paramount Café to discuss nanoscience over dinner and drinks. More recently, in Charlotte, we teamed up with the Drug Delivery SIG at the Rock Bottom Brewery to increase the networking reach and promote further interactions between SIGs, universities and companies.

In the coming year, the Nano SIG aims to:

- Expand industrial involvement with companies and translational science
- Sponsor new sessions and awards
- Develop creative mechanisms to connect graduate students and postdocs with companies for employment opportunities
- Expand our outreach through social networking events

World Biomaterials Congress 2016

The Nanomaterials SIG is pleased to announce the frontier symposium "Nanobiomaterials and Nanotechnology for Implants, Devices and Theranostics," which will be held at the 2016 World Biomaterials Congress (WBC). Nanobiomaterials and nanotechnology have attracted great attention in recent years for clinical applications, from nanostructured scaffolds and surfaces to devices and implants to theranostic platforms. The field has advanced to a stage where many innovations have translated to clinical applications or are in the pathway toward translation. We propose this symposium to deliver a focal point for the researchers in the nanotechnology field to discuss the pressing issues in fundamental understanding of interactions between materials and biological entities (e.g., mammalian cells, bacteria, virus, etc.) at the nanoscale level, *in vitro/ in vivo* studies, mathematical modeling and challenges in clinical translation. The symposium's presentation is anticipated to cover multiple perspectives, including, but not limited to, fundamentals, mechanisms, surface modification, *in vitro* to *in vivo* physical and mathematical models and clinical translation of nanobiomaterials and nanotechnology. We encourage you to submit abstracts for presentations. The keynote speaker will be Thomas J. Webster, Northeastern University, Boston, United States.

Symposium chairs include:
Huinan Liu, Assistant Professor, University of California at Riverside, Riverside, California, United States
Luning Wang, University of Science and Technology Beijing, Beijing, China
Phong Tran, Queensland University of Technology, Brisbane, Australia
Nuno M. Neves, University of Minho, Barco, Portugal
Lei Yang, Soochow University, Suzhou, China

We will again be hosting a networking event in Montreal for the WBC. Details will be announced ahead of the conference. We look forward to seeing everyone in Montreal at our social events and conference session! For more information, visit **wbc2016.org/index.php/program/new-frontier-symposia.**

The Nanomaterials SIG is excited to continue our mission to showcase the unique science and technology present in biomaterials at the nanoscale level.

RESEARCH AND NETWORKING IN THE DRUG DELIVERY FIELD

BY BRENT VERNON, PhD, ASSOCIATE PROFESSOR, BIOMEDICAL ENGINEERING SCHOOL OF BIOLOGICAL AND HEALTH SYSTEMS ENGINEERING, ARIZONA STATE UNIVERSITY

Figure 1. Current SIG Officers (top to bottom): Chair Jordan Green, PhD; Vice-Chair Noelle Comolli, PhD; Secretary/Treasurer Rebecca Bader, PhD; Program Chair Craig Duvall, PhD; Industry Representative Michael Heffernan, PhD; and Biomaterials Forum Reporter Brent Vernon, PhD. Not Shown, Student Representative/Web Contact, Daniel Jordi Hachim Diaz.

The Society For Biomaterials' (SFB) 2015 Annual Meeting in Charlotte, North Carolina, was a successful and productive meeting for the Drug Delivery (DD) SIG. Several sessions that were sponsored by the DD SIG, as well as others co-sponsored by the DD and nano SIGs, offered stimulating and important drug-delivery related research presentations. During the DD SIG meeting, we conducted important business, electing new officers and planning important new initiatives to cultivate future membership in the SIG. Finally, SIG members had an opportunity to network and socialize with other SIG members and with members of the Nano SIG in a combined social event.

DRUG DELIVERY SIG SESSIONS

The Annual Meeting had no shortage of presentations of interest for members of the DD SIG. There were times where concurrent drug delivery focused sessions were available, such as "Drug Delivery for Immunomodulation" and "Macromolecular Drug Delivery." The co-sponsored sessions included "Multifunctional Nano-Materials for Engineering Complex Tissues and Drug Delivery" and "Nanobiomaterial and Drug Delivery Strategies for Dental/Craniomaxillo-Facial Repair/Regeneration." The extensive presence of drug delivery at the meeting points to the crucial interdependence between this field of research and biomaterials.

DRUG DELIVERY SIG MEETING

At the SIG meeting, SIG officers were elected/identified and will be serving until the next SIG meeting. These officers represent multiple institutions and plan to further the goals of the DD SIG. Chair Jordan Green, PhD, is faculty from the Biomedical Engineering Program at Johns Hopkins University; Vice-Chair Noelle Comolli, PhD, is faculty of the Chemical Engineering Program at Villanova University; Secretary/Treasurer Rebecca Bader, PhD, is faculty from the Syracuse Biomaterials Institute at Syracuse University; Program Chair Craig Duvall, PhD, is faculty of the Biomedical Engineering Program at Vanderbilt University; Student Representative and Web Contact Daniel Jordi Hachim Diaz is a student from the McGowan Institute at the University of Pittsburgh; Industrial representative Michael Heffernan, PhD, is from Fannin Innovation Studio; and SIG Biomaterials Forum Reporter Brent Vernon is faculty from the Biomedical Engineering Program at Arizona State University.

NETWORKING WITH THE DRUG DELIVERY SIG

At the joint SIG social, members of the DD SIG were able to network and interact Nano SIG while enjoying great food and drinks. The social was held April 17 at the Rock Bottom Brewery (just a short walk from the meeting hotel).

LOOKING AHEAD

We encourage students conducting drug delivery research to join the SFB and the DD SIG. To this end, the SIG has instituted a new program "The Society For Biomaterials Drug Delivery Special Interest Group Student Awards." This new program is to recognize and encourage student research accomplishments at both the undergraduate and graduate student levels. This is a national initiative that takes place at the local college and university levels across the United States. Awards are granted based on research excellence at a university-wide or regional student research symposium. Student recipients will receive an award plaque, recognition in SFB's Biomaterials Forum and recognition on SFB DD SIG Web page. These awards are open to all undergraduate and graduate students at colleges and universities within the United States. Students that attend university-wide and regional student research symposia where biomaterials and drug delivery research is presented are nominated by faculty members of the SFB DD SIG. The nominated student must have presented his or her research within the field of biomaterials and drug delivery either as a poster or oral presentation at the symposia. Active SFB DD SIG faculty members may nominate one student per event by submitting their nomination to green@jhu.edu within one month of the event. Nominees must be (or agree to become) SFB and DD SIG members if chosen as award recipients.

Figure 2. Members of the Drug Delivery and Nano SIGs enjoying an opportunity to network at the Rock Bottom Brewery in a joint SIG social.

UNDERSTANDING CELL AND PROTEIN INTERACTIONS WITH BIOMATERIALS

BY STEVE FLORCZYK, PhD, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

The Proteins and Cells at Interfaces (PCI) SIG is focused on promoting a better understanding of cell and protein interactions with biomaterials. Since the success of biomaterials in many applications depends on the biomaterial interaction with proteins and cells, the topics addressed in the PCI SIG are applicable to a broad range of areas in biomaterials research, including implants, drug delivery, tissue engineering and immunomodulation.

The PCI SIG had several activities at the Society For Biomaterials' (SFB) 2015 Annual Meeting in Charlotte, North Carolina. At the PCI SIG business meeting, the new PCI SIG officers were introduced to the members. Pranav Soman, the PCI SIG president, reported that PCI SIG membership has grown to 183 members in 2015, up from 143 members last year. The membership has been increasing with the inclusion of one SIG membership with every SFB membership. The PCI SIG held a social at the SFB Annual Meeting at the BlackFinn Ameripub. There was a good turnout for the social and it provided a good environment for members to network and recruit new members to the SIG.

The PCI SIG also sponsored two sessions and symposia at the 2015 SFB Annual Meeting, including "Modulating the Neural Microenvironment" and "Molecular Mechanisms Governing Protein-Surface and Cell-Surface Interactions."

The PCI SIG held its second PCI Student Poster Competition at the SFB Annual Meeting. This competition has now been named for Dr. Rena Bizios (University of Texas at San Antonio), who generously donated money to support the poster competition awards. There were 43 entrants in the competition this year, doubling the number from last year (21).

The winners of the competition were:
First Place: Nicholas Nolta, University of Utah
Second Place: Sho Sakata, University of Tokyo
Honorable Mention: Emily Morin, University of Tennessee-Knoxville
Honorable Mention: Laura Villada, University of Florida

The first and second place awardees received a cash award and a certificate, while the two honorable mentions received a certificate. The PCI SIG congratulates the winners and thanks all of the students that participated in the poster competition!

The PCI SIG had a great 2015 SFB Annual Meeting and is looking forward to the 2016 World Biomaterials Congress (WBC).

The Proteins and Cells at Interfaces SIG has an active social media presence on Facebook and Twitter. Please join us on Twitter (@SFBPCI) and on our Facebook page. We also have a LinkedIn group that is a subgroup of the SFB LinkedIn group.

To learn more about your PCI SIG officers, please see the "This or That" interviews on the SIG page at biomaterials.org.

UNDERSTANDING THE INFLUENCE OF THE PROPERTIES OF AN EXTRACELLULAR MICROENVIRONMENT

BY DANIEL L. ALGE, PhD, ASSISTANT PROFESSOR OF DEPARTMENT OF BIOMEDICAL ENGINEERING AND DEPARTMENT OF MATERIALS SCIENCE AND ENGINEERING, TEXAS A&M UNIVERSITY

Over the past year, the Engineering Cells & Their Microenvironments (ECTM) SIG has enjoyed sustained member involvement and an increase in scientific contributions to the SFB Annual Meeting. Our SIG currently has 138 active members.

We had a strong presence at the 2015 meeting in Charlotte, North Carolina, sponsoring nine sessions on topics spanning from biomaterial design and characterization to probing cell-material interactions for engineering bio-instructive microenvironments in tissue engineering. In addition, we gave out eight poster awards at the conference to recognize exceptional work being done by student trainees. These awards are an important part of our SIG's activity and our effort to engage members. One of our goals moving forward is to more actively promote networking between our members via social media engagement by organizing social events at annual meetings, which should help us build an even more vibrant community. And what better time is there to start than now? As we all plan for the World Biomaterials Congress (WBC), it is exciting to think about having an international presence and showing our peers the value of SIGs.

On the research side of things, our SIG members continue to make exciting advances in understanding how the properties of the extracellular microenvironment can be engineered to influence cell behavior. For example, Palchesko et al from the Feinberg lab at Carnegie Melon recently reported about how 2D elastomeric substrates can be engineered to promote the *in vitro* expansion of corneal endothelial cells.[1] Interestingly, while they screened 36 different combinations of substrate elasticity and protein coatings, they found that substrates mimicking the biochemical and biophysical properties of Descemet's membrane, which is the basement membrane of the corneal endothelium, were most effective (Figure 1). Their work addresses one of the key challenges in producing tissue engineered corneas, and the ability to engineer microenvironments that promote corneal endothelial cell expansion could enable future advances in this area of tissue engineering.

In another microenvironmental screening study, Lam et al from the Segura lab at the University of California Los Angeles used design of experiments methodology to optimize the concentrations of three integrin-binding ligands (RGD, YIGSR and IKVAV) in hyaluronic acid hydrogels for 3D culture of induced pluripotent stem cell-derived neural progenitor cells.[2] While they successfully identified an optimal formulation for promoting neuroprogenitor survival and differentiation that could enable future advances in neurobiology, which was the goal of their study, perhaps a bigger lesson is the value of employing design of experiments

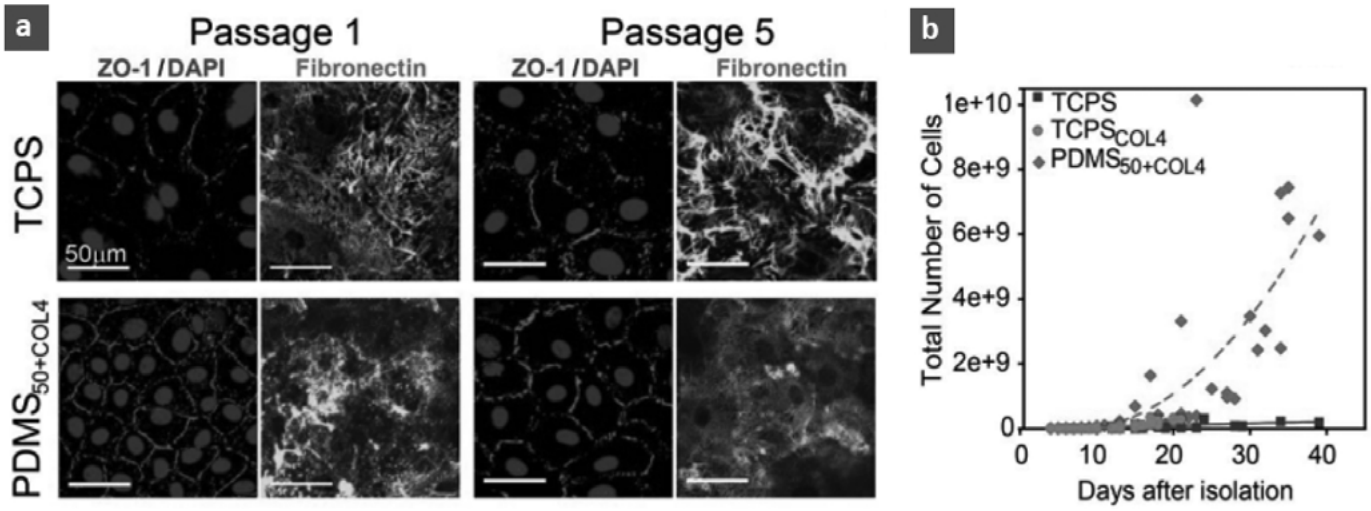


Figure 1. Engineering a biomaterial microenvironment to promote corneal endothelial cell expansion. Immunofluorescence images showing that a 50 kPa poly(dimethyl siloxane) (PDMS) elastomer substrate coated with collagen IV promotes better maintenance of the endothelial cell phenotype in culture compared to tissue culture plastic (TCPS), as indicated by ZO-1 and fibronectin staining (a). Cell proliferation results showing superior cell expansion on the engineered substrates (b). Adapted from Palchesko et al[1] with permission from the Nature Publishing Group.

methodology in the high-throughput combinatorial screening of cellular microenvironments.

Engineering 3D microenvironments to study tumor biology remains an important topic in our field. A recent paper by Pedron, Becka and Harley of the University of Illinois described the use of a microfluidic mixing tool for encapsulating glioblastoma multiforme cells within gelatin-based hydrogels containing spatial gradations in cell density, matrix architecture and biochemical composition.[3] Importantly, they showed that the glioblastoma malignant phenotype changed along the gradients, highlighting the importance of the cellular microenvironment. The tool that they developed could enable new breakthroughs in understanding the etiology, growth and treatment of glioblastoma multiforme, but it could also be broadly applied to the study of other cancers or even stem cell biology.

Ki et al of the Lin lab at Indiana University-Purdue University Indianapolis used a versatile thiol-ene poly(ethylene glycol) hydrogel platform to engineer desmoplasia-mimetic microenvironments for studying pancreatic ductal adenocarcinoma (PDAC).[4] Their results showed that collagen type I-mediated interactions promoted PDAC cell proliferation and induced a more invasive phenotype. However, simply being cultured in a 3D environment rendered the cells resistant to gemcitabine treatment, possibly by enriching the population of cancer stem cells, highlighting the importance of microenvironmental context for evaluating chemotherapeutics.

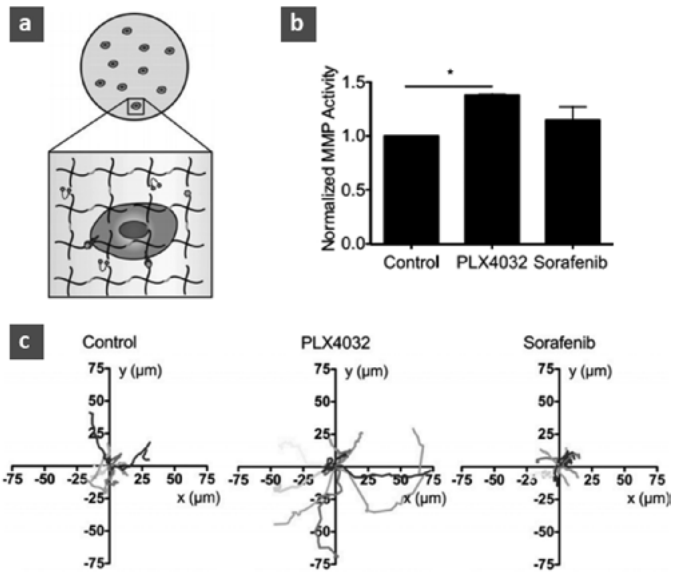


Figure 2. Using an engineered microenvironment to study cancer biology. Schematic of a cancer cell embedded in an enzymatically degradable poly(ethylene glycol)-peptide hydrogel modified with a fluorogenic MMP activity sensor (a). Results showing increased MMP activity (b,c) and migration (b) in melanoma cells after treatment with PLX4032 compared to control cells and cells treated with a different drug, sorafenib (c). Adapted from Leight et al[5] with permission from the National Academy of Sciences, USA.

Using a similar hydrogel platform that was modified with a matrix metalloproteinase (MMP) sensitive fluorogenic probe, Leight et al from the Anseth lab at the University of Colorado studied the relationship between MMP activity and drug treatment in melanoma cells.[5] Interestingly, they found that treatment with a clinically relevant MEK/ERK-pathway inhibitor (PLX4032), which was developed as a chemotherapeutic for metastatic melanoma but failed clinically due to patient relapses, actually increases melanoma cell MMP activity and migration in 3D culture, which could promote metastasis (Figure 2). These results further emphasize the importance of engineered 3D microenvironments in cancer biology and for screening chemotherapeutics.

An interesting emerging area is engineering immune cell microenvironments. The ECTM SIG contributed a wound healing-focused session at the 2015 meeting on this topic, and there were several fascinating talks describing macrophage and neutrophil responses to biomaterial microenvironments.

Considering the well-recognized role of macrophages and immune reactions in wound healing, this is an exciting research area that will certainly continue to grow in importance. However, there are also exciting opportunities in addition to wound healing, such as engineering microenvironments for immune organs. In a collaboration between the Gaharwar lab at Texas A&M University and the Singh lab at Cornell University, Purwada et al reported the use of a gelatin-silicate nanocomposite hydrogel to recapitulate key aspects of the lymphoid microenvironment and engineer B cell-containing tissues that were capable of generating an immune reaction and producing antibodies *in vitro*.[6] The engineered microenvironment was a key aspect of their strategy, which could lead to an improved understanding of immunology. It could also be useful for the production of immunotherapeutics, as the engineered immune organs were able to produce active B cells up to 100 times faster than current platforms based on conventional 2D culture. Overall, though, this work highlights the potential synergy between immune engineering and engineering cell microenvironments.

These are just a few of the recent research advances in our field. ECTM SIG members are also doing exceptional work and advancing fields like neural, musculoskeletal and cardiovascular tissue engineering, among others.

Unfortunately, there is simply not enough room to highlight it all! Clearly though, it is an exciting time to be active in SFB and in the ECTM SIG.

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Orthopaedic Biomaterials SIG

45S5 BIOGLASS® FOR INHIBITION OF FOREIGN=BODY CAPSULE FORMATION AND INTEGRATION TO NATIVE TISSUES PART 1: MATERIAL DEGRADATION AND RELEASE OF IONS

BY ROCHE C. DE GUZMAN, PhD, ASSISTANT PROFESSOR, DEPARTMENT OF ENGINEERING, HOFSTRA UNIVERSITY

Bioglass® is a registered trademarked group of glass biomaterials. A simple PubMed search using the keyword "Bioglass" yielded an exponential pattern ($r^2 = 0.9708$) of hits from the 1970s to the present decade (Figure 1), suggesting that Bioglass® research is very much active and alive. Bioglass® technology still has great untapped potential, particularly in connecting the non-living world of materials to the biological system. Glasses, in material science, are solid materials that are not crystals, i.e., they are amorphous or lacking in long-range order (at nanometer-scale and up) with respect to the arrangement of atoms, ions and molecules locked in place at temperatures below the glass-transition temperature (T_g; a unique property of glasses). The major precursor molecular component of Bioglass® is silicon dioxide (SiO_2), also known as quartz or silica. At very high heat in a furnace, covalent bonds are formed linking separate silica molecules via Si-O bonds, thereby creating an extensive polymeric network structure. Your table-glass drinkwares and Pyrex containers have more silica ingredients compared to a Bioglass®.

45S5 Bioglass®, our Bioglass® of interest, has 45 percent (by mass fraction) silica. The remaining 55 percent of the mixture includes 24.5 percent sodium oxide (Na_2O), 24.5 percent calcium oxide (CaO), and 6 percent phosphorus pentoxide (P_2O_5).[1] In terms of mole fraction, the ratios of components are adjusted to be 46.1 percent SiO_2, 24.4 percent Na_2O, 26.9 percent CaO and 2.6 percent P_2O_5. For every 100 elemental species found in 45S5 Bioglass® precursor, there are 16 silicon, 55 oxygen, 17 sodium, 10 calcium and 2 phosphorus elements. The "45S" nomenclature in 45S5 Bioglass® came from the 45 percent mass fraction of silica, while the "5" after "45S" refers to the molar ratio of calcium to phosphorus (10 calcium per 2 phosphorus species — Ca/P = 10/2 = 5). Hydroxyapatite (HA) has a repeating unit chemical formula of $Ca_5(PO_4)_3(OH)$, hence a Ca/P ratio = 5/3 = 1.67. Bone minerals are carbonated HA, also called hydroxycarbonate apatite (HCA). The addition of carbon to HA does not displace calcium and phosphorus thereby preserving the Ca/P ratio of 1.67. 45S5 Bioglass®, thus, has trice (5/1.67 = 3) more calcium relative to phosphorus deposits than the typical native bone.

Glass made from pure silica (fused quartz) requires a higher temperature for sintering. Addition of sodium ions (Na^+, from Na_2O) lowers this sintering temperature, but the resulting glass (sodium silicate waterglass) is water-soluble. Accordingly, CaO (calcium ion, Ca^{2+} source) is added to make the glass product insoluble and stable in an aqueous

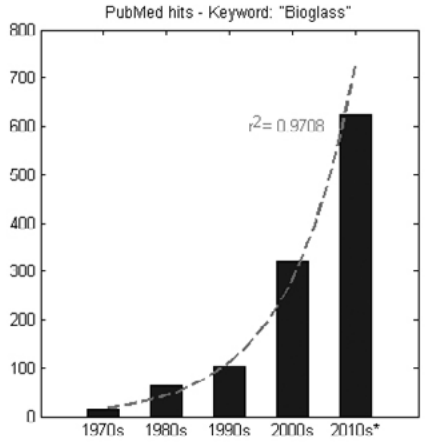

Figure 1. Exponential trend of scientific activity involving Bioglass. *projected

environment. This SiO_2-Na_2O-CaO ternary glass system is the configuration used in your table-glass drinkware and is very stable. 45S5 Bioglass® was developed with the intent of binding to living bone tissues, which contain HCA. A phosphorus source of P_2O_5 was incorporated to the glass system to create a SiO_2-Na_2O-CaO-P_2O_5 quaternary system for the fabrication of 45S5 Bioglass®. Phosphorus, like silicon, is network-forming (both Si and P will become part of the continuous backbone or matrix of the material); the higher the amount of Si and P, the more crosslinking covalent bonds are formed leading to higher stability and more resistance to degradation and water dissolution. The primary network-former is silicon because of its relative abundance to phosphorus (16 Si vs. 2 P species). Silicon can be occupied by up to four oxygen atoms to form a tetrahedral structure, SiO_4. SiO_4 has a silicon network connectivity, $NC_{Si} = 4$. Decreased amount of Si network-former while increased network modifiers, sodium and calcium, results in $NC_{Si} < 4$ or lower instances of SiO_4 structure formation. Na^+ and Ca^{2+} generated during heating interact ionically or electrostatically to negative oxygen ions attached to silicon ($-Si-O^-$), competing with Si-O intermolecular covalent bond assembly. The NC_{Si} of 45S5 Bioglass®, using the formula[2-3]:

$$NCSi = \frac{4(^{x}\text{silica}) + 6(^{x}\text{phosphorus pentoxide}) - 2(^{x}\text{sodium oxide}) - 2(^{x}\text{calcium oxide})}{x\text{silica}}$$

Where x is, it is equal to mole fraction of precursor compounds and was computed to be $NC_{Si} = 2.12$, indicating that the short-range order of the silicon network in 45S5 Bioglass® is mostly SiO_2 structures and that polymeric chains have alternating orders of oxygen and silicon (e.g., -O-Si-O-Si-O-Si-O-) arranged linearly or even circular. At this silicon network connectivity value, the material can still form a glass structure, but at the same time allows for the release of Na^+ and Ca^{2+} when immersed in aqueous media.

45S5 Bioglass® binds to adjacent bone without inducing a foreign-body capsule (FBC) formation.[1,3,4] Contact to the biological liquid environment (such as the interstitial fluid and blood plasma) upon implantation releases the cations, Na^+ and Ca^{2+} from the surface of the material. Phosphorus is relatively more stable since it is integrated into the network in the form of phosphate (PO_4^{3-}). The solid matrix of 45S5 Bioglass®, hence, is expected to have a decreasing Ca/P ratio over time. It makes sense to have a starting Ca/P value (Ca/P = 5) higher than 1.67 if one of the goals is to ultimately match the Ca/P ratio of HCA bone mineral. The release of sodium and calcium cations simultaneously leads to hydrogen ions (H^+) electrostatically binding to the negatively charged Bioglass® network surface (cation exchange). The loss of H^+ from the surrounding medium increases the local solution alkalinity (to a basic pH level) and increases the amount of hydroxide ions (OH^-). OH^- species then attack and break the Si-O bonds of the silica network producing soluble silica, as silicic acid ($Si(OH)_4$).[5]

This is the initial mechanism of Bioglass® surface erosion. PO_4^{3-} anions entrapped in the matrix are also released as the material degrades when Si-O bonds are destroyed. The released calcium and phosphate ions interact, precipitate onto the surface of the Bioglass® and eventually crystallize into HA.[4] The influence of the biological system (to be discussed in part two of this series), containing carbonates forms HCA crystals,[3] therefore converting the Bioglass® layer to the mineral component of a living bone. HCA is biocompatible[6] and does not invoke the immune system of the body to produce an FCA fibrous layer.

In summary, the release of sodium, calcium and phosphate ions and the availability of the remaining 45S5 Bioglass® surface for nucleation of HCA crystal formation play significant roles in the integration of 45S5 Bioglass® to native bone tissues.

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Embolization of Hydrophilic Coating from Catheters: Can Animal Models Predict Clinical Risk

BY RAMI TZAFRIRI PhD AND JAMES STANLEY, DVM, MS, DACVP, CBSET, DEPARTMENTS OF APPLIED SCIENCES AND PATHOLOGY, LEXINGTON, MASSACHUSETTS (FROM THE CARDIOVASCULAR SIG)

Medical catheters permit minimally invasive external access for monitoring, imaging, sampling and local delivery of therapeutic agents, and placement of devices like endovascular stents, aneurysm coils and transcatheter valves. To improve ease of manipulation and deliverability the exterior surfaces catheters and sheaths are often coated with lubricious hydrophilic materials, typically composed of synthetic polymers,[1-2] such as polyvinylpyrolidone (PVP), polyacrylamide and polyethylene oxide.

While the ability to imbibe and exude water is central to the lubricious action of hydrophilic coatings, these properties render them prone to shearing, stripping and embolization. Though benchtop testing[1-2] of coating lubricity and durability, torque response and hydrophilic-coating jacket adhesion seeks to minimize such risks, the rate of adverse clinical events associated with hydrophilic coatings seem to have risen throughout the last decade as catheter-based interventions have become more common and complex and sheath diameters have grown.[3] Such adverse events have been histologically correlated with the presence of foreign materials in the affected tissues[4-6] that resembled, and in certain cases were verified to be spectroscopically identical to, shavings of the coatings shed during benchtop manipulation of the suspected device.[7] Reported clinical complications typically involved patients that were treated with numerous and different interventional devices, rendering definitive identification of culprit devices and the conditions leading to coating detachment and embolization challenging.

Animals are ideally suited for studying device performance under controlled, clinically relevant conditions, yet there have been surprisingly few reports of coating embolization in animals, compared to humans.[1,8] The current article therefore aims to highlight the under-recognized clinical complications associated with hydrophilically coated catheters[6] and to review findings in animal models that may help characterize and optimize catheter safety.

Clinical Adverse Events Following Cardiovascular Interventions

Most reported adverse events with hydrophilic-coated catheters involve local inflammation following radial artery insertion of primarily PVP coated Cook catheters[4,9] and, in rare cases, acrylamide copolymer-coated Terumo sheaths.[10] Adverse events were histologically correlated with intralesional foreign material that appeared filamentous, non-birefringent and blue-grey, with hematoxylin-eosin (H&E) staining and a similar appearance to hydrophilic coating scraped from the exterior surface of suspected devices.[4]

Recent reports of hydrophilic coating embolization in coronary catheterization are even more worrisome due to the potential for blockage of downstream myocardial vasculature, thrombosis and infarction.[5] This has been forcefully highlighted in retrospective analysis of coronary interventions performed in an Academic Medical Center in Amsterdam from 2005 to 2013, which revealed[11] a 10-percent incidence of detachment and embolization from hydrophilically coated coronary guidewires and that 45 percent of reviewed thrombus aspirations contained a foreign material, which was histologically identical to tissue the embedded samples of the respective guidewire coatings. Foreign material was reported to be most likely present in thrombus after the use of HT Whisper (71 percent), followed by the HT BMW Universal (46 percent) and the HT Floppy (19 percent), all from Abbott Vascular,[11] and could be explained by differences in coating substrates, which was highest when the hydrophilic coating was solely applied to a polymer-covering of the guidewire (HT Whisper) and lowest when it is solely applied to metallic surfaces (HT floppy).

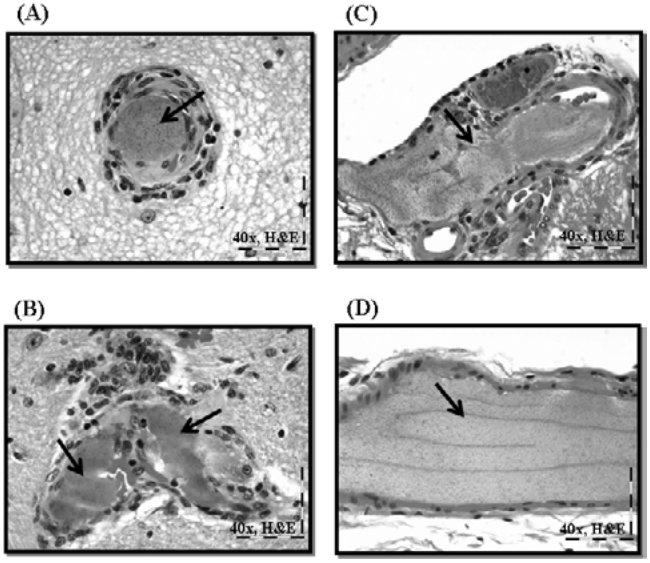

Figure 1. Intra-arterial foreign material (the arrows) in brain sections following deployment of the PVP-coated guiding sheath and distal peripheral stenting. Examples of amorphous, stippled, basophilic (A) to eosinophilic (B, C, D) foreign material with associated peri-arterial inflammatory cells in sections of 30-day porcine right midbrain (A, B), and 180-day forebrain (C) and cerebellum (D). Reproduced from Stanley et al[8] with permission from Europa Digital & Publishing.

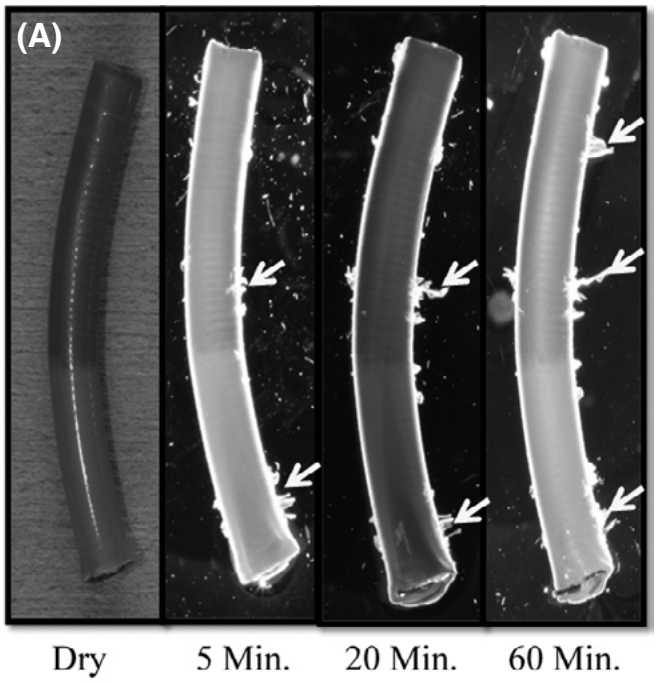

Figure 2. *In vitro* correlate. Coating avulsion and shedding from a saline incubated tip of a PVP coated guiding sheath (A). Representative histology of a tissue embedded sample of coating after one hour of incubation in saline (B). Reproduced from Stanley et al[8] with permission from Europa Digital & Publishing.

The risk for hydrophilic coating shedding from guidewires and sheaths had not been limited to the radial artery or coronary artery catherization, and is expected to increase for interventions that track through tortuous vessels of varying sizes, and complex interventions within and across aneurysms, bifurcations, valves and ventricles. This is particularly concerning for neurovascular and valve replacement interventions where coating particles can embolize into sensitive organs such as the heart or brain.[7,12-13]

Coating Embolization after Angioplasty and Stenting of Animals

Animal studies are used routinely to evaluate catheter torquability and biocompatibility, yet typically neglect to examine downstream organs for the presence of coating emboli.[14] Two recent reports of hydrophilic emboli in animal hearts and brains post catheterization suggest that such added scrutiny may be warranted.

Babcock performed a territory-based downstream analysis of end organs subsequent to coronary angioplasty in swine with coated balloon catheters as part of an integrated *in vitro/ in vivo* coating optimization study.[1] Two PVP-based coatings of similar lubricity, but different thickness (submicron and micron) were evaluated. When tested in an *in vitro* tortuous path model the submicron coating generated an approximate five-fold lower number of particulates ≥10 μm per catheter than the micron coating. Myocardial tissues examined 28 days post angioplasty revealed no visible particulates in the animals treated with the submicron-coated catheters, while 3 of 40 sections from micron-coated catheters contained amorphous foreign material, and 1 of 40 sections from tissue treated with uncoated catheters had amorphous foreign material. In all cases examined, Raman spectroscopic analysis confirmed that the material was PVP. This study illustrates that animal studies can recapitulate clinical observations of coating embolization during coronary interventions and can be used to design safer devices.

We recently tested the safety of a new self-expanding peripheral stent and delivery system (SDS) that was deployed through a PVP-coated Cook guiding sheath into the iliac and/ or carotid arteries of 23 miniswine.[8] In an additional control animal, the guiding sheath was advanced, but no SDS was deployed. Advancement of the coated guiding sheath, with or without the SDS, was associated with frequent foreign material in the arterioles of the brain (Figure 1). Material was observed at 30, 90 and 180 days, involving 54 percent of all study animals (test and control).

To characterize the foreign material, distal portions of hydrophilic-coated guiding sheaths were placed in 0.9 percent saline for 60 minutes. Coating began avulsing from the sheath after 15 minutes and gradually separated and shed from the surface with further incubation (Figure 2A). Notably, the histomorphologic appearance of tissue embedded material that was scraped off the 60-minute incubated catheter (Figure 2B), was consistent with observed emboli in brain sections. Though none of the affected animals exhibited abnormal signs indicative of central neurologic impairment, distribution to the brain in experimental animals raises another potential clinical concern around the use of coated catheters, thus warranting further documentation of effect and monitoring in clinical scenarios

Conclusion

Hydrophilically coated guidewires, sheaths and catheters facilitate the treatment of otherwise challenging anatomies, yet increase the risk for intravascular shedding and embolization to the brain and heart in a manner that has been underappreciated. Yet, this is not a class effect as coating composition, thickness and underlying substrate all affect the risk of delamination, and the risk posed by emboli varies with particulate size, composition and lifetime.

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Herty Advanced Materials Center Launches Advanced Chemical Processing Unit

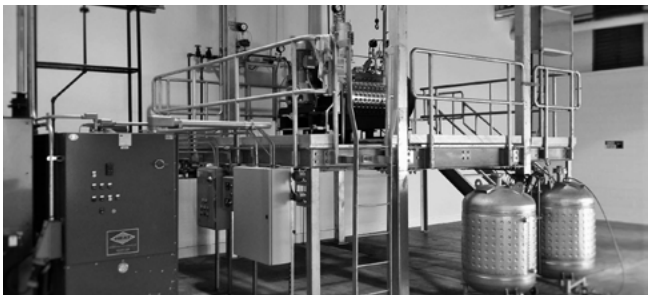
Herty Advanced Materials Development Center (Herty), an applied research center of Georgia Southern University, launched a new Advanced Chemical Processing (ACP) pilot facility.

This new pilot facility allows Herty to expand its research programs and client services to those companies seeking to develop and test new advanced materials required in today's international and increasingly competitive markets. Applications range from the development of protein-specific fibers for pharmaceutical purification to the production of biomaterials for automotive parts.

"The scale and flexibility of this system is second-to-none and it integrates well with our extensive in-place capabilities," said Dr. Alexander A. Koukoulas, President and CEO of Herty. "It provides our partners and clients with a unique platform for accelerating the pace of new product development."

The new ACP allows the development, testing and production of a wide range of advanced, specialty and high-performance materials, like nanocrystalline cellulose — an exceptionally strong, low-cost, renewable composite material that has multiple applications in the automotive and aerospace industries and one is of the most promising renewable biomaterials for this industry. It also enables Herty to process a wide variety of materials, including minerals and polymers for industrial, nutraceutical and pharmaceutical applications.

"This new reactor system offers a powerful platform for giving U.S. industry new and innovative materials, from new plastics to specialized coatings that are otherwise impossible," said Dr. Walter Chappas, Director of Herty's Advanced Materials Group.



Student Chapter Update

BY EVELYN BRACHO-SANCHEZ, NATIONAL STUDENT CHAPTER PRESIDENT, UNIVERSITY OF FLORIDA; CHRISTOPHER "TOPHER" GEHRMANN, NATIONAL STUDENT CHAPTER PRESIDENT-ELECT, UNIVERSITY OF MEMPHIS AND UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER; AND AMANDA CHEN, NATIONAL STUDENT CHAPTER SECRETARY TREASURER-ELECT, UNIVERSITY OF CAMBRIDGE

Welcome to the student section of the Society For Biomaterials (SFB)! We are excited for the new academic year and look forward to working with the entire SFB community. We would like to kick off the year by introducing ourselves and some of the ideas we have for this upcoming year.

My name is Evelyn Bracho-Sanchez and I will serve as your student chapter president for the 2015-2016 term. I am a PhD candidate at the University of Florida (UF) working on controlled-release systems for vaccines and immunotherapies under the guidance of Dr. Benjamin Keselowsky. I have previously served as the historian, vice-president and president of the SFB chapter at UF and have dedicated many of my efforts to the successful planning and implementation of Biomaterials Day for four consecutive years. I have also organized outreach activities to local grade schools, industry tours and academic seminars for our members. I plan on sharing what I learned as an executive board member at UF with other student chapters across the country and abroad, particularly those recently established or looking to organize similar events. I will be the student representative at all council meetings SFB will hold, and will share any concerns and suggestions you might have with our academic leaders and staff.

My name is Christopher "Topher" Gehrmann and I am the president-elect for the 2015-2016 term and second-year PhD student at the University of Memphis (UM) and University of Tennessee Health Science Center (UTHSC) Joint Program in Biomedical Engineering. Currently, I am working under Dr. Bowlin with research focused on the electrospinning of proteins and polymers to create scaffolds, which promote regenerative immune responses. Previous appointments include academic chair for our SFB chapter. In California, I founded an organization that assesses pedagogy using student feedback in universities. In Memphis, our SFB chapter is working with middle school students using these methods to improve biomaterials education in our community. Throughout the next year, I will be assisting Evelyn in her duties. I hope to initialize a focus on educating local communities at each of our institutions so that we can increase the value of SFB membership and the opportunities our organization can provide to its members. I am excited to hear what members of SFB would like to see from our organization, and I eagerly await to see what we can accomplish together.

My name is Amanda Chen and I am secretary-treasurer elect for the 2015-2016 term. I am currently a Whitaker International Fellow and M.Phil. (by research) student at the Churchill College and Department of Chemical Engineering and Biotechnology at the University of Cambridge working on the development of adjuvant cationic liposome vaccine therapeutics under the supervision of Professor Nigel Slater. As an undergraduate at the University of Rochester, I participated in educational outreach projects organized by Professor Danielle Benoit. Although my experience with SFB has just started, I was fortunate to be awarded the 2015 Student Award for Outstanding Research (Undergraduate Category), and I am eager to share my experiences from leadership roles in Tau Beta Pi, the Biomedical Engineering Society, Phi Beta Kappa and Churchill College with the national SFB student chapter. I also plan to be involved in the MIT SFB student chapter when I start my doctorate in biological engineering in fall 2015. I hope to make meaningful professional connections nationally and globally, which, through a common interest in biomaterials, can proactively promote cutting-edge research and education in the field.

You have elected a great team of leaders eager to work with you! Our overall goal is to promote student research, education and professional development in biomaterials and related disciplines. Currently, only the following schools have registered active chapters: Case Western Reserve University, Clemson University, Columbia University, North Carolina State University, Northeastern University, Texas A&M University, University of Florida, University of Memphis, University of Rochester, University of South Dakota, University of Washington, University of Wisconsin-Madison and Vanderbilt University.

If you do not see your school listed and would like to start a chapter or register an existing chapter, or need help in another way, feel free to contact us. We look forward to this new academic year and working with all of you!

You can reach Evelyn Bracho-Sanchez at e.bracho@ufl.edu, Christopher Gehrmann at cjghrmnn@memphis.edu, and Amanda Chen at axchen@mit.edu.

BY STEVE LIN, INDUSTRIAL NEWS CONTRIBUTING EDITOR

Frost and Sullivan Healthcare experts predict that **Amazon**, along with **Chinese e-commerce firm Alibaba**, will launch dedicated services targeting the healthcare sector, serving a range of customers in 2015 — from facilities to individual customers. The initial offering won't be necessarily healthcare products per se, but everything from supplies to toiletries or other ancillary things to care. In the future, more complicated products, like implants, will be sold by the e-tailer. Amazon, by its very structure, is a natural fit in a healthcare world that is demanding price transparency, lower cost and greater value. Amazon is more capable than group purchasing organizations and large medical equipment distributors to serve the needs of non-traditional, out-of-hospital care settings, such as a home care-set up.

On April 24, 2015, Senators Richard Burr (R-NC), Michael Bennet (D-CO) and Orrin Hatch (R-UT) introduced the **Advancing Breakthrough Devices for Patients Act** (ABDP Act). As written, the law is heavily based on the "breakthrough therapies" section (Section 902) of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA), which created the breakthrough therapies designation now being used by dozens of companies. In short, breakthrough therapy designation afford a company wider access to U.S. Food and Drug Administration (FDA) regulators earlier on in the product's lifecycle. The hope is that the earlier advice and access will "expedite the development and review of drugs for serious or life-threatening conditions." The ABDP Act would apply to all medical devices that represent breakthrough technologies; are intended for conditions for which no approved alternatives exist; offer significant advantages over existing approved or cleared alternatives; and should be made available based on the best interest of patients.

Senators Dick Durbin (D-IL) and Lindsey Graham (R-SC) will co-chair a **new National Institutes of Health (NIH) Congressional Caucus** to promote bipartisan strategies that will restore the purchasing power and return predictable growth for NIH biomedical research. NIH Director Francis Collins addressed the first meeting of the new caucus by expressing hope this might be the year to turn around the funding woes of recent years. The NIH budget has lost 23 percent purchasing power in the last decade. The initial members of caucus are: Senators Baldwin (D-WI), Blumenthal (D-CT), Casey (D-PA), Cardin (D-MD), Donnelly (D-IN), Durbin (D-IL), Graham (R-SC), Markey (D-MA) Moran (R-KS), Peters (D-MI), Franken (D-MN), Kaine (D-VA), Klobuchar (D-MN) and Wicker (R-MS).

Japanese electronics maker's **Panasonic Healthcare** (Panasonic's healthcare business) is buying **Bayer AG's** diabetes care business for 1.02 billion euros (about $1.15 billion USD). Private equity firm, Kohlberg Kravis Roberts (KKR) owns 80 percent of Panasonic Healthcare**,** according to EPVantage, the publishing arm of market intelligence firm Evaluate Group. The sale will include the Contour portfolio of blood glucose monitoring meters and strips, as well as other products, including its lancing devices. The deal is expected to close in the first quarter of next year per closing conditions and antitrust clearance. Bayer's diabetes business accounted for 909 million euros (about $1.02 billion USD) in sales in 2014, which suggests that KKR and Panasonic picked up the medtech asset quite cheap.

The **China Food and Drug Administration** (CFDA) recently announced a major step up in registration fees for drugs and devices. According to a CFDA press release, the fee for a domestic drug application is now 624,000 yuan (about $100,000 USD), an almost 20-fold increase from the previous fee of 35,000 yuan (about $5,000 USD). The Chinese fees will differ depending on whether the product is a drug or device, generic, domestic or imported. Though this may seem like a sharp increase, the new fee is still significantly lower than many other countries.

Medtronic recently announced FDA clearance for its MiniMed Connect technology, which enables smartphone users to view data from the firm's CGM and insulin pumps. The company will be working with Samsung to develop new applications for the MiniMed Connect platform, which is a roughly a thumb-sized unit that harvests data from Medtronic's MiniMed insulin pump and select CGM devices. Once the data is gathered, the platform can deliver it to a mobile app or an online portal where patients and caregivers can access it. Alarms can be triggered when glucose levels are out of range.

Johnson & Johnson Innovation will work with **WuXiApp Tec**, a CRO with a venture arm, to identify entrepreneurs and match them with relevant assets, assisting them to get incorporated and funded, and develop novel technologies. WuXi App Tec, which will also invest in these early-stage startups, will provide broad research and development support and do feasibility studies to assess viability of technologies for a fee to these entrepreneurial firms. The collaboration with WuXi is intended to focus on stimulating company formation in China focused on biopharmaceuticals, consumer health products and medical devices and diagnostics.

One of the patent reform bills introduced in a Congressional session — **the Innovation Act (H.R. 9)** — is set to advance to the House floor after a 24-8 positive vote by the House Judiciary Committee, which occurred on June 11. While the bill won bipartisan support, the Medical Device Manufacturers Association (MDMA) expressed their disappointment in the legislation. There is concern it will allow large market-dominant firms to infringe with impunity. The vote on the Innovation Act comes just a week after the Senate Judiciary Committee decided to move the Protecting American Talent and Entrepreneurship (PATENT) Act (S. 1137) on for consideration by the Senate. With both bills moving forward, patent reform is clearly a key priority for Congress.

Government News

NIST WORKSHOP ON MEASUREMENT ASSURANCE STRATEGIES FOR CELL THERAPY PRODUCTS

BY CARL G SIMON JR., GOVERNMENT NEWS CONTRIBUTING EDITOR

Product consistency and lack of standards has been identified as possibly the largest challenge facing the field of regenerative medicine.[1-2] In order to begin to address these issues, a workshop, "Strategies to Achieve Measurement Assurance for Cell Therapy Products," was convened at the National Institutes of Standards & Technology (NIST) May 11–12, 2015.[3]

One hundred cell therapy stakeholders, representing 24 companies, four United States government agencies — The National Institutes of Health (NIH), Federal Drug Administration (FDA), U.S. Department of Defense (DOD) and NIST— three nonprofit organizations and five academic institutions participated. Common cell assays were analyzed with a formal analytical process that revealed a lack of confidence in the most fundamental cell measurements, including cell counting, cell viability and *in vitro* cell functional tests. The need to collect supporting data to validate cell measurements was highlighted, including the establishment of assay performance specifications that must be met before using data to make decisions (e.g., dosing).

Other strategies for achieving measurement assurance were discussed, including the use of appropriate reference materials, assessing sources of uncertainty in a measurement process, "design of experiments" to assess assay ruggedness, inter-laboratory comparisons for establishing reproducible protocols and use of orthogonal measurements to verify results. Slides and materials from the workshop have been posted online,[3] and a white paper to summarize the findings has been submitted.

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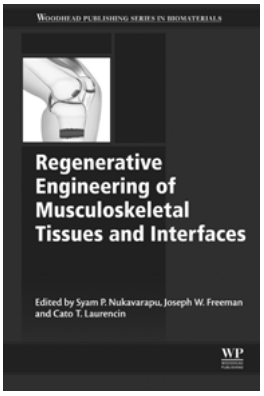
Regenerative Engineering of Musculoskeletal Tissues and Interfaces

Book Review

REVIEWED BY LIISA KUHN, EXECUTIVE EDITOR, BIOMATERIALS FORUM

Edited By Syam Nukavarapu, Joseph Freeman and Cato Laurencin
Publisher: Woodhead Publishing Series in Biomaterials: Number 98
2015 Edition. Elsevier Ltd., Waltham, MA
ISBN 978-1-78242-301-0
Pages: 462 pages



There's a new book about regenerative engineering of musculoskeletal tissues that I'd like to recommend for several reasons. For starters, it is edited and written by a powerhouse team of top scientists in this broad area. It is a nice looking book printed on high-quality paper and contains many images both in black-and-white and in color. The writing is clear and informative and the content is up-to-date. It is divided into three parts: Part I Basic Elements Of Musculoskeletal Tissue Engineering; Part II Individual Musculoskeletal Tissue; and Part III Musculoskeletal Tissue Interfaces. Part I covers biomaterials, cells, growth factors and mechanical forces, while Part II covers bone, cartilage, ligament, tendon, meniscus, muscle, vascularization and neural innervation. Importantly, Part III covers interfaces between all of the individual tissues, e.g., bone to cartilage, bone to tendon, muscle to tendon, etc.

Part I's basic elements chapters are more than just basic. They offer a complex analysis of the existing knowledge in each of the fundamental areas. For example, Chapter 3 on growth factors, written by SFB member Esmaiel Jabbari and colleagues, describes growth factors set in the context of tissue development. There are detailed explanations of the stage-specific profiles of growth factors. Embryonic development events are broken down by individual musculoskeletal tissue type. Examples are given about how combinations of growth factors have been used to preserve multipotency and lineage control of stem cells, and why new paradigms should be considered based on how growth factors are presented during development. There's a strong chapter on bone tissue engineering, by MB Lyles, JC Hu, VG Varanasi, JO Hollinger and KA Athanasiou. They discuss lessons learned from efforts to heal wounded warriors, and explain why additive manufacturing may one day produce implants with the desired level of complexity capable of tissue regeneration, rather than the limited repair seen with current scaffold fabrication techniques.

Just when I thought journal articles were all I needed to stay up to date in the field, this book came across my desk, and I once again realized the benefit of reading a book — expert editors filter through the mass of information available through the Web and provide a focused interpretation, which is worth the couple of hundred dollars cost of the book. Therefore, I conclude that this book would be a valuable addition to your personal or institutional/corporate library.

Happy reading!

Upcoming 2015 Events

EVENT	DETAILS	WHEN & WHERE
International Seminar on Biomaterials & Regenerative Medicine BIOREMED 2015	The aim of this event is to connect scientists from biomaterials and tissue engineering research field with clinicians from different areas of expertise (dentistry, orthopaedics, neurosurgery, ophthalmology, cardiovascular surgery, general and aesthetic surgery and pharmaceutical science).	Sept. 17–20, 2015 Felix Spa Resort — International Hotel 1 Oradea Romania
BioInterface Conference	The Surfaces in Biomaterials Foundation is dedicated to exploring creative solutions to technical challenges at the BioInterface by fostering education and multidisciplinary cooperation among industrial, academic, clinical and regulatory communities.	Sept. 21–23 Scottsdale, Arizona 7575 East Princess Drive
Joint Biomaterials Day — Clemson University and Georgia Tech	More details to come in the future on biomaterials.org.	Sept. 26 The Conference Center and Inn at Clemson University Clemson, South Carolina 230 Madren Center Drive
Drug Delivery Conference	The purpose of the 2015 Drug Delivery Conference is to bridge the gap between basic science and unmet clinical needs in drug delivery. There are five key sessions distributed across a three-day program.	Sept. 28–Oct. 1 Hilton Tucson El Conquistador Golf & Tennis Resort Tucson, Arizona 10000 North Oracle Road
Safety Pharmacology Society's 15th Annual Meeting	The annual meeting will provide a dynamic forum for sharing the latest in safety pharmacology, and will feature a diverse range of scientific sessions organized into two tracks, covering issues on topics, such as cardiovascular, central nervous system, translational, integrative pharmacology and novel *in vitro* models, as well as sessions covering updates on the comprehensive *in vitro* proarrhythmia assay (CIPA) and an NC3Rs workshop on group housing.	Sept. 28–Oct. 1 Corinthia Hotel Prague Czech Republic Kongresova 1
University of South Dakota Biomaterials Day	More details to come in the future on biomaterials.org.	Oct. 2 University Center Sioux Falls, North Dakota 4801 North Career Avenue
9th European Symposium on Vascular Biomaterials (ESVB)	The meeting has been organized every two years since 2001 by the GEPROVAS organization, a non-profit organization that promotes transdisciplinary research in the field of cardiovascular biomaterials. The 2015 ESVB symposium will focus on technologies for thora-coabdominal aneurysms, infra-inguinal therapies and debulking technologies.	Oct. 16–17 Palais de la Musique et des Congres Place de Bordeaux Strasbourg, France
7th UHMWPE International Meeting	The meeting is being organized by the Implant Research Center of Drexel University and Exponent in collaboration with the University of Torino.	Oct. 22–23 Union League Philadelphia Philadelphia, Pennsylvania 40 South Broad Street
AAPS Workshop: Nanotechnology in Personalized Medicine	The AAPS Workshop on Nanotechnology in Personalized Medicine will assemble the leading experts to address the latest advances in nanotechnology for personalized medicine application.	Oct. 25 Orange County Convention Center Orlando, Florida 9400 Universal Boulevard
New Jersey Center for Biomaterials Symposium on Biomaterials Science	The goal of the symposium is to exchange information and ideas across the full spectrum of scientists working in the biomaterials field by focusing on selected research and development topics that represent the most promising directions for ultimate medical application.	Nov. 9 Heldrich Hotel New Brunswick, New Jersey 10 Livingston Avenue
6th International Conference on the Mechanics of Biomaterials and Tissues	ICMOBT provides a unique international forum for researchers and practicing engineers from different disciplines to interact and exchange their latest results.	Dec. 6–10 Waikoloa Village, Hawaii Marriott Waikoloa 69-275 Waikoloa Beach Drive
The Science of Pain and its Management	This international event will discuss the latest research relating to the physiology, psychology and pharmacology of pain; the psychosocial aspects of pain; and the assessment and management of pain.	Dec. 8 London, United Kingdom Cineworld: The O2

Nomination deadline: September 11, 2015

Required Supplemental Documents:

- Resume
- Certification of Status Form (Due Sept.11, 2015)
- Manuscript (Due Oct. 16, 2015)
- Abstract of Manuscript submitted to World Congress (Due Oct. 16, 2015)
- Three Supporting Letters of Recommendation (Due Sept. 11, 2015)

Award recipients receive:

- Certification of Award
- Travel support up to $500 for the World Biomaterials Congress.
- Consideration for publication of paper in Journal of Biomedical Materials Research or Applied Biomaterials
- Complimentary meeting registration

NOTE: Manuscripts and abstracts for the Outstanding Research Awards (Student and Intern) will be accepted until October 16, 2015

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