

LETTER FROM THE NEW PRESIDENT
UPDATES FROM THE SC&M AND PCI SIGs

BIOMATERIALS FORUM

A stylized white graphic of a pen nib with a decorative flourish at the top, positioned to the right of the word 'FORUM'.

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

SECOND QUARTER 2019 • VOLUME 41, ISSUE 2

ALSO INSIDE

AN INTERVIEW WITH STEVE LIN

IN MEMORIAM: BOB BAIER AND RUSS PARSONS

BIOMATERIALS FORUM!

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

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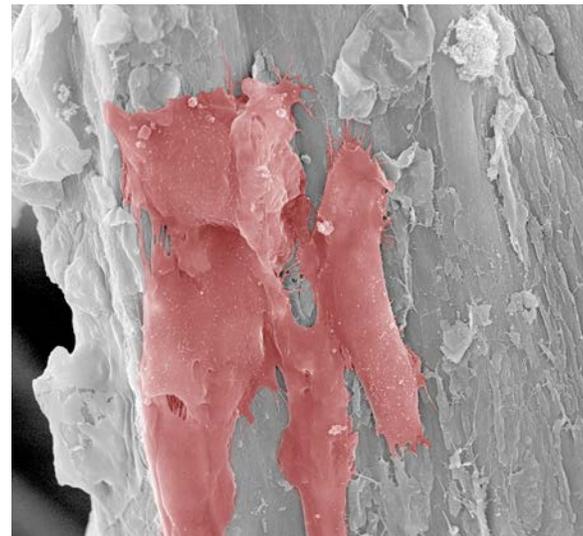
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ON THE COVER

By Fan Zhang

The cover image, provided by Fan Zhang, of Prof. Martin W. King's lab in the Department of Textiles Engineering at North Carolina State University, shows human umbilical vein endothelial cells on a collagen filament (some cells are pseudo-colored).

From the Editor

By Guigen Zhang, Editor, SFB Forum



OUR RESPONSIBILITY TO KEEP THE TORCH BURNING

At the business meeting at the 2019 Society for Biomaterials (SFB) Annual Meeting in Seattle, Washington, Elaine Duncan's comment on her feelings when she sees students standing at their posters, waiting and hoping for someone to stop by to talk to them about their research, got me — big time. Earlier at the meeting, colleagues had come to tell me how much they appreciated my questioning and challenging the student/trainee presenters in the sessions I was chairing. When I heard Elaine's comment, the two events collided in my head, and it brought me back to the 1990s, when I was a student attending the SFB meeting. Presenting at the SFB meeting was about showcasing our research, of course, but it was also about getting expert critiques of our work, methods, results, conclusions — the whole nine yards.

I often ask myself: what keeps bringing me back to the SFB meetings all these years, from being a student member to an active member of the SFB? It is true that it is about being connected in the network of our peers and friends in the SFB family, but it is also about getting feedback from peers, sometimes, it could mean critiquing and challenges before being repudiated, or accepted and recognized, for our works by our peers in the fields.

We often talk about value proposition to current and future members, and these students are certainly future members, like many of us. Here comes the value proposition question: what is the value we could create for them to benefit from? Of course, under the leaderships of many generations of SFB presidents and leadership teams, many valuable activities and events have been created over the years. But this one area that Elaine brought to our attention seems to be a low-hanging-fruit — one of the cost-free things that would bring tremendous dividends

we may have missed. Here is an idea for us to do something about it, for example: if each of our active members takes on the "challenge" of examining 5 or 10 posters and questioning the presenters during the poster sessions, we could create priceless value to these students and the resulting impact may last a lifetime. Therefore, I would think that this little thing we all could do might just be what the SFB needs to keep the torch burning for the next 50 years.

In closing, let me briefly tell you what we have prepared for you in this issue. You will hear from our new president, Dr. Horst von Recum, about his vision for SFB in the coming year. You will catch up with Members in the News, Staff Update, Student News, Events at the SFB Meeting in Seattle, and update from the Surface Characterization and Modification and Protein and Cells at Interfaces SIGs. We also congratulate our student travel awards recipients by providing a list of names. In our regular columns, you will read industry news, government news, education news and book reviews. In Memoriam shares a reflection piece by Jack Lemons in memory of Robert Baier, a past-president of SFB and Clemson Award recipient, and a reflection piece by Jack Ricci in memory of Russ Parsons. In this issue, we also feature an interview with Steve Lin on his unique industry research and development and entrepreneurial career path. Finally, I want to bring to your attention for the upcoming deadlines for the various SFB Awards for 2019-2020 and Officer Nominations for various leadership positions.

With best wishes,

Guigen Zhang

From the President

By Horst von Recum, SFB President



DEAR FRIENDS AND COLLEAGUES

It is my honor to take on the role of president of our Society For Biomaterials. Fortunately, I've been passed the wheel of a ship that has been well maintained and set on an excellent course by our

Past President, Andres Garcia. Let's all thank Andres and the rest of the Board and Council for a job well done. I hope I can serve the society in this coming year as well as he and our past-presidents have. Many of us have recently returned from another great SFB meeting, the 2019 SFB Annual Meeting held in Seattle, Washington. Program Committee Chairs, Bill Murphy and Gopi Mani, and the rest of the committee put together a fantastic meeting, with great keynotes, excellent scientific talks and a strong program. In addition, we should thank our many sponsors and exhibitors, whose support helped make the meeting great. Finally, I want to thank our Executive Director, Dan Lemyre, and his staff at Association Headquarters for the enormous amount of behind-the-scenes work they did in planning and keeping the meeting running smoothly.

I don't have all the numbers yet, but it looks to have been successful both for our finances and for our community. Personal comments I received at the meeting from many of you indicated that it was one of your favorite meetings of recent memory.

A strong financial and societal performance is an excellent point on which to end 2019, since this coming year we will not be holding our national meeting in the United States. Lack of a US meeting affects both our income (national meetings are the single largest income generator in a typical year) and the continuity of member participation. We expect that the financial successes of the past couple of years, combined with some belt-tightening measures, will see us through this next year so that we can emerge on the other side with (hopefully) another great US national meeting, held in Chicago, Illinois, in 2021.

This is not to say that we will be idle this coming year. In fact, I hope to see you all at the Biomaterials World Congress, from May 19 – 24, 2020, in Glasgow, Scotland, hosted by the European Society for Biomaterials. I expect to see an excellent program there, as well, and encourage you to contribute as you would in one of our national meetings (wbc2020.org). It's not too late to help!

In fall 2020, our society will also hold a joint workshop with the Japanese Society for Biomaterials, from December 11 – 12, 2020, in Hawaii.

I expect other aspects of the society, such as local Biomaterials Days, *Biomaterials Forum*, Council, committees and local chapter activity to continue as they would in any other year.

If you had the luck/misfortune to hear my address at the Business Meeting in Seattle, Washington, you know that I further urge all of you to use this year as a period of self-reflection and renewal. Specifically, I would like each of you to ask yourself two questions: (1) "What is my Biomaterials Community?" and (2) "Have I passed on my legacy to others?" I will explain in a little more detail.

What Is My Biomaterials Community?

As the Society For Biomaterials, it is our mission to promote advancements in all aspects of biomaterial science, education and professional standards to enhance human health and quality of life. This endeavor can often be challenging because there are few well-defined "biomaterials" educational programs. In addition, although the broader educational field (e.g., biomedical engineering) has seen strong growth over the past 10 years, the number of individuals who identify themselves with the term "biomaterials" has at best remained constant but could possibly even be decreasing. In asking yourself, "What is my biomaterials community?" you should identify things such as:

- Is there a group of individuals within my institution/company/organization who identify with the term "biomaterials," and are they visible to the outside world (e.g., a web page)?
- Are those folks coming to our SFB meetings? If not, why not?
- Are there individuals who do biomaterials-related work but do not identify themselves with the term "biomaterials"? Why not?

Have I Passed on My Legacy to Others?

We all love our society. If we didn't, we wouldn't keep coming to our meetings. I hear many versions of a story similar to mine, where I started coming to our meetings early in my training and have been coming continuously since then, partially because of excellent colleagues and science but also because I could see a path for me to grow in the society. However, we should ask ourselves, "Have I passed on that legacy?" Are my trainees, five years out, as enamored with the society as I was/am? Are they even coming to our meetings once they are on their own? If not, why not? Has the society changed such that the value I found is no longer there or no longer needed? Or, is it simply that others have risen up in the meantime and are (better?) able to provide what our trainees need?

Throughout the course of this next year, I hope to reach out to all of you through a number of different means. I will be curious as to the results of your internal reflection. In the meantime, never hesitate to reach out to me. You can always reach me at horst@case.edu. I look forward to hearing from you and to serving you and our society for the coming year.

Member News

By Rebecca Carrier, Member-at-Large



Society for Biomaterials members, It has been an honor to serve as your 2018-2019 Member-at-Large. I am excited to see this role being taken over by Cherie Stabler, who I am confident will do a great job representing the membership of SFB!

This quarter's exciting member news and accomplishments includes the following:

Sidi Bencherif, an Assistant Professor of Chemical Engineering at Northeastern University, recently received a CAREER award from the National Science Foundation to support his research on "Modulating Local Tumor Hypoxia using Cryogel Scaffolds to Regulate Dendritic Cell Function and Activity". Bencherif has designed a porous, gel-like material that gives off oxygen, allowing the study of how low-oxygen environments alter the function of immune cells, and providing a potential platform for reversing the effects of hypoxia. These materials could potentially be used to supply oxygen to help train immune cells to fight cancer. For more information, please see: <https://news.northeastern.edu/2019/04/04/northeastern-professor-sidi-bencherif-receives-national-science-foundation-career-award-to-develop-oxygen-producing-biomaterials-to-help-fight-cancer/>

Danielle Benoit, Associate Professor of Biomedical Engineering at the University of Rochester, was awarded the College Award for Undergraduate Teaching and Research Mentorship. This award recognizes tenured faculty members in Arts, Sciences & Engineering who "teach large, introductory classes as well as advanced seminars and independent study projects, and who mentor research experiences, especially those that involve laboratory training in the sciences and engineering." Dr. Benoit has mentored research experiences for more than 80 undergraduates in her lab, which focuses on developing therapeutic biomaterials for tissue regeneration and targeted drug delivery. Benoit "embodies the spirit of this award through her dedication to undergraduate learning through classroom teaching, research experiences, and mentoring," says Diane Dalecki, chair of the Department of Biomedical Engineering. "The research training and mentoring that undergraduates receive from Professor Benoit primes them for continued success as graduate students and throughout their professional careers." For more information, please see: <https://www.rochester.edu/newscenter/danielle-benoit-college-award-undergraduate-teaching-research-mentorship-373122/>

Adam Jakus, Co-Founder & Chief Technology Officer of Dimension Inx LLC, recently shared that Dimension Inx's 3D-Painted Hyperelastic Bone Biomaterials will be featured as part of a year-long exhibitions at the Cooper Hewitt Smithsonian

Design Museum (in NYC) and CUBE Design Museum (Netherlands). The Exhibits open May 9th, and Hyperelastic Bone was specifically selected to represent the future of regenerative biomaterials. The exhibits will feature numerous 3D-Painted Hyperelastic Bone objects as well as Hyperelastic Bone art pieces on canvas. More information on the exhibit can be found at: <https://www.cooperhewitt.org/2019/01/31/cooper-hewitt-and-cube-announce-projects-for-the-2019-design-triennial/>

Dimension Inx will also be 1 of 2 hosts on an upcoming webinar hosted by ASME and the Advanced Regenerative Manufacturing Institute (ARMI). The webinar will be highly educational in nature and be a major kickoff of the broad efforts of industrialization, standardization, and quality control efforts going on in biofabrication and 3D-printed biomaterials. More information on this webinar can be found at: <https://www.armiusa.org/events/2019/5/15/bioprinting-bioinks-and-biomaterials-for-tissue-engineering-webinar>

More information about Dimension Inx can be found at: <https://www.dimensioninx.com>

Amol Janorkar, Professor and Graduate Program Director in the Biomedical Materials Science Department of the School of Dentistry at the University of Mississippi Medical Center, was awarded the "Outstanding Young Alumni Award" from the Clemson University College of Engineering, Computing, and Applied Sciences. At the Award ceremony at Clemson University, Honorees walked down an orange carpet to the field of Memorial Stadium, where they were greeted by a bluegrass band and a congratulatory message on the scoreboard. The Outstanding Young Alumni award recognizes graduates of the college who are 40 years old or younger and have made significant achievements to their profession or the welfare of society. Dr. Janorkar has been successful in supporting his flourishing research program in cell-biomaterials interactions, tissue engineering, and drug delivery, securing grants from governmental and corporate partners exceeding \$2.2 million. He has also published over 45 scientific papers, one of which has been cited 1400 times. For more information, please see: <http://newsstand.clemson.edu/top-alumni-light-up-scoreboard-at-memorial-stadium/>

Jeff Karp, Professor of Medicine at Brigham and Women's Hospital, Harvard Medical School, Principal Faculty at the Harvard Stem Cell Institute, and an affiliate faculty at the Broad Institute and at the Harvard-MIT Division of Health Sciences and Technology, was named a fellow of the Royal Society of Chemistry. This designation, a senior category of membership, recognizes individuals who hold positions of influence in the

Member News (continued)

scientific community and have invaluable experience, expertise and commitment to promoting the value of chemical science. Karp's work crosses the fields of drug delivery, medical devices, stem cell therapeutics and tissue adhesives. He serves as a mentor to the next generation of bioengineers working at the forefront of regenerative medicine. For more information, please see: <https://www.brighamandwomens.org/about-bwh/newsroom/awards-honors-grants-detail?id=3298>

Technology from Dr. Karp's lab has also recently shown promise in treatment of hearing loss in clinical trials. **Frequency Therapeutics** announced that its lead candidate, FX-322, a cocktail of small-molecule drugs designed to activate the body's healing abilities, showed no adverse events in a phase 1/2 study following a single injection given through the eardrum. Further, some patients with hearing loss showed improvements in hearing tests compared to placebo. The treatment is aimed at triggering dormant cells in the ear to spur the growth of fine hairs that sense and translate sound waves. For more information, please see: <https://www.fiercebiotech.com/biotech/frequency-shows-early-positive-results-for-small-molecule-hearing-loss-therapy>

David Mills, Professor of Biological Sciences at Louisiana Tech University, is PI of a team that received an Interdisciplinary Translational Project (ITP) teams grant award from the Center for Dental, Oral, & Craniofacial Tissue and Organ Regeneration (C-DOCTOR) for "3D Printed Nanoclay Enhanced Calcium Phosphate Ceramic Composite." This project is focused on developing a 3D printed, calcium phosphate microbead with tunable properties, increased material strength, and sustained release of drugs, specifically antimicrobials and osteogenic agents designed to induce osteogenesis, control infection and produce a reparative tissue. C-DOCTOR is funded by the National Institute of Dental & Craniofacial Research and represents a partnership among several California institutions serving as a national resource for the clinical translation of innovative technologies to regenerate dental and craniofacial tissues and organs. C-DOCTOR announced their latest ITP teams after a nationwide competition from universities and industry.

Dr. Mills also received the Outstanding Research Publication award from the Institute for Micromanufacturing. The annual award is an all-college (College of Engineering and Science) competition that crosses across all engineering disciplines. Dr. Mills also received this award in 2018.

Richard Terry, Principal Research Scientist in the Laboratory for Drug Delivery led by Professor Mark Prausnitz in the School of Chemical and Biomolecular Engineering at Georgia Institute of Technology, was a contributing author on a manuscript describing

a new long-acting contraceptive based on a microneedle-containing patch and designed to be self-administered by women. The manuscript was recently published in the journal *Nature Biomedical Engineering*. The work was supported by Family Health International (FHI 360), funded under a contract with the U.S. Agency for International Development (USAID). The device described in the manuscript is based on polymeric microneedles that have been engineered to break off, and thus remain embedded in the skin, after application of a patch. The device may provide a new self-administered, long-acting (e.g., monthly administration) family planning option, particularly in developing nations where access to health care can be limited. The citation for the article follows: Wei Li, et al., "Rapidly separable microneedle patch for the sustained release of a contraceptive," (*Nature Biomedical Engineering*, 2019). <https://dx.doi.org/10.1038/s41551-018-0337-4>

Nanovis, a company co-founded by Professor **Thomas Webster** of the Department of Chemical Engineering at Northeastern University, was selected as a Top 10 Orthopedic Solution Provider, 2019 by a panel of analysts, company executives, and the editorial panel of *Med Tech Outlook*. Nanovis uses nanotechnology in fixation devices and infection prevention. Alex D'souza, Managing Editor of *Med Tech Outlook*, noted "We congratulate Nanovis for being at the forefront of providing cutting-edge infection technology solutions; the value these solutions offer to surgeons and hospitals is evident. We anticipate hearing more about the success of Nanovis in the years to come."

Pittsburgh's inaugural joint Biomaterials Day was held on November 9th, 2018, including an outstanding attendance of 165 participants, filling the University Club Ballroom on the campus of University of Pittsburgh. Attendees included high school students, undergraduate and graduate students, trainees, postdoctoral fellows and faculty representing 9 Universities. The event included 2 Workshops, 9 Talks, and 53 Posters. The student chapters at University of Pittsburgh and Carnegie Mellon University successfully raised funds for this collaborative event, which also involved collaboration with University of Michigan and Case Western University. Keynote speakers included Dr. Lola Eniola Adefeso, Professor from University of Michigan, Dr. Eben Alsberg, Professor at Case Western University, Dr. Adam Feinberg, Professor at Carnegie Mellon University, and Dr. Charles Sfeir, Professor at the University of Pittsburgh.

One workshop, led by Dr. William Wagner, Director of the McGowan Institute of Regenerative Medicine and Editor-in-Chief of *Acta Biomaterialia*, included discussion of the peer review process and avoidance of common mistakes when communicating data. Dr. Andrew Brown, Senior Program Manager for Commercial Translation at Pitt's sciVelo, conducted

Member News (continued)

an engaging workshop about approaching research with a focus on clinical translation. In addition to the Society For Biomaterials Grant, Biomaterials Day 2018 was supported by the Biomedical Engineering Department of Carnegie Mellon University, the Department of Bioengineering, SciVelo and the Innovation Institute, McGowan Institute of Regenerative Medicine (MIRM), Center for Medical Innovation (CMI), School of Pharmacy, and School of Dental Medicine at University of Pittsburgh.

Induction into the 2018 AIMBE Class of Fellows

Congratulations to the SFB members who were inducted as American Institute for Medical and Biological Engineering (AIMBE) Fellows: **Danielle Benoit, PhD**, University of Rochester; **Rebecca Carrier, PhD**, Northeastern University;

Elaine Duncan, MS, RAC, Paladin Medical, Inc.; **Thomas Dean Dziubla, PhD**, University of Kentucky; **Lisa Friis, PhD**, University of Kansas; **Scott Guelcher, PhD**, Vanderbilt University; **Zhen Gu, PhD**, University of California, Los Angeles; **Brendan Harley, ScD**, University of Illinois at Urbana-Champaign; **Christopher Jewell, PhD**, University of Maryland; **Bingyun Li, PhD**, West Virginia University; **Chuanbin Mao, PhD**, University of Oklahoma; **Ebru Oral, PhD**, Massachusetts General Hospital / Harvard Medical School; **Heather Sheardown, PhD, PEng, FCAE**, McMaster University; and **Lijie Grace Zhang, PhD**, The George Washington University.

Staff Update

By *Brittany Noll, Assistant Executive Director*



Hello from Society For Biomaterials Headquarters! Our thanks and appreciation to Seattle, Washington, for hosting the 2019 Annual Meeting! With the beginning of a new program year, the Society's Board of Directors, Governing Council, committees, task forces and

special interest groups (SIGs) will be working to advance the Society's mission, as described below.

ANNUAL BUSINESS MEETING

The Society's Annual Business Meeting took place on April 5, 2019, in Seattle. Results of the spring election were announced, and the following people have been elected as officers for the SFB Board of Directors:

- **2019 – 2020 President-Elect:** Shelly Sakiyama Elbert, PhD, University of Texas at Austin
- **2019 – 2020 Secretary/Treasurer-Elect:** Sarah Stabenfeldt, PhD, Arizona State University
- **2019 – 2020 Member-At-Large:** Cherie Stabler, PhD, University of Florida
- **2019 – 2020 SIG Representative:** Danielle Benoit, PhD, University of Rochester

BYLAWS VOTE RESULTS

Incoming President Horst von Recum reported the results of the bylaws amendment vote. The amendment received 85 "yes" votes and 33 "no" votes, with nine abstentions. At the time of the meeting, it was assumed that this meant the motion had passed, but a closer review of the bylaws indicated that a 75 percent affirmative vote is required to pass an amendment to the bylaws; therefore, the measure will not be adopted.

ELECTION OF 2019 – 2020 AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE

The following were elected by the members present: Rena Bizios, PhD; Peter Edelman, PhD; Bob Hastings, PhD; and Susan Thomas, PhD.

NEW COUNCIL

The following members will make up the 2019 – 2020 Council, serving alongside the elected board as committee chairs:

Awards, Ceremonies and Nominations	Liisa Kuhn, PhD
Bylaws	Ashley Brown, PhD
Industrial Affairs (f/k/a Devices and Materials)	SuPing Lyu, PhD
Education & Professional Development	Anirban Sen Gupta, PhD
Finance	Sarah Stabenfeldt, PhD
Liaison	Tim Topoleski, PhD
Membership	LaShan Simpson, PhD
President's Advisory	Andres J. Garcia, PhD
Program	Elizabeth Cosgriff Hernandez, PhD Nick Ziats, PhD
Publications	Sachin Mamidwar, MBBS, MS
Student Chapter president	Jason Guo

Staff Update (continued)

The committees advanced the SFB mission in the following ways in the first quarter of 2019.

AWARDS, CEREMONIES AND NOMINATIONS

Chair: Tom Webster, PhD

The following awards were presented during the Annual Meeting in Seattle:

- **Founders Award:** Joachim Kohn, PhD, Rutgers, The State University of New Jersey
- **SFB Award for Service:** James M. Anderson, MD, PhD, Case Western Reserve University
- **C. William Hall Award:** Peter Edelman, PhD
- **Technology Innovation and Development Award:** Ann Beal Salamone, MS, Rochal Industries
- **Clemson Award for Applied Research:** Christine Schmidt, PhD, University of Florida
- **Clemson Award for Basic Research:** Paulette Spencer, DDS, PhD, University of Kansas
- **Clemson Award for Contributions to the Literature:** Balaji Narasimha, PhD, Iowa State University
- **Mid-Career Award:** Edward Botchwey, PhD, Georgia Institute of Technology
- **Young Investigator Award:** Stephanie Seidlits, PhD, University of California, Los Angeles
- **Student Award for Outstanding Research — Hospital Intern:** Alexander Tatara, MD, PhD, Massachusetts General Hospital
- **Student Award for Outstanding Research — PhD:** Priyadarshini Singha, University of Georgia
- **Student Award for Outstanding Research — PhD:** Kathryn Wofford, Drexel University
- **Student Award for Outstanding Research — Masters:** Rebecca Haley, Case Western Reserve University
- **C. William Hall Scholarship:** Evan Haas, University of Kansas
- **Cato T. Laurencin Travel Fellowship:** Kai Adeb Clarke, Florida Institute of Technology, and Sydney Wimberley, University of Connecticut

BYLAWS

Chair: Ben Keselowsky, PhD

The Bylaws Committee presented an amendment to the membership to create a new "Fellow" category of membership, but the measure was not adopted at the Annual Business Meeting, as noted above.

EDUCATION & PROFESSIONAL DEVELOPMENT

Chair: Jan Stegemann, PhD

Since the 2018 fall council meeting, the Education & Professional Development (E&PD) Committee evaluated nominations for the C. William Hall Award, the Cato T. Laurencin Travel Fellowship and Student Chapter travel grants.

FINANCE

Chair: Elizabeth Cosgriff-Hernandez, PhD

Income and expenses are in line with projections for 2019. SFB received an unqualified opinion ("clean") audit report for 2018. The financial position of the Society For Biomaterials as of Dec. 31, 2018, and the changes in its net assets and its cash flows for the year were prepared in accordance with U.S. generally accepted accounting principles.

MEMBERSHIP

Anirban Sen Gupta, PhD

Current membership stands at 1,302, which is up from the past two years! This time last year, total membership was 1,246; in 2017, it was 1,055.

PROGRAM

Chairs: Gopinath Mani, PhD, and William Murphy, PhD

The 2019 Society for Biomaterials Annual Meeting closed on April 6 after three and half days of active meetings and interactions in the Washington State Conference Center in Seattle. In total, 1,355 people registered for the conference, with 538 posters, 120 Rapid Fire presentations and 425 oral presentations. Thanks to the 2019 SFB Program Committee, especially Gopi Mani and Bill Murphy, for putting this program together. Abstracts from the meeting have been posted online and can be viewed at <https://2019.biomaterials.org/program>.

The following meeting locations have been approved by council:

- **2020:** Hilton Waikiki Beach, Honolulu, Hawaii; Dec. 11–13, 2020
- **2021:** Hilton Chicago, Chicago, Illinois; April 21–24, 2021
- **2022:** Marriott Waterfront, Baltimore, Maryland; April 27–30
- **2023:** Site selection for 2023 will be underway shortly

PUBLICATIONS

Chair: Sachin Mamidwar, MBBS, MS

The next edition of the preeminent textbook in the field, *Biomaterials Science* (published by Elsevier) is in the works, with a new team of editors. Updates are expected in the near future. The journals continue to do well in electronic format.

Advances in Tissue Engineering 27th Annual Short Course

Rice University
Houston, Texas

Center for Engineering Complex Tissues
Center for Excellence in Tissue Engineering
Department of Bioengineering

August 14-17, 2019

Twenty-seventh annual short course including a hands-on bioprinting workshop with leading scientists from Rice University, the Texas Medical Center, industry, and other institutions on advances in the science and technology of tissue engineering. Be informed on the latest technology in the world of patient-specific therapeutics, from transplantation of cells and tissues to artificial organs.

For biomaterialists, biomedical engineers, physicians, technical managers, and others involved in research in the areas of:

- Regenerative Medicine
- Stem Cell Biology
- Cell & Tissue Culture
- Applied Immunology
- Drug Discovery, Delivery & Targeting
- Organ & Cell transplantation
- Vascular Surgery
- Plastic Surgery
- Reconstructive Surgery
- Gene Therapy
- Nanobiotechnology

Rice University
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NATIONAL STUDENT CHAPTERS

President: Margaret Fettis

The 2019 Student Luncheon in Seattle was joined by a panel whose members focused their talks on putting your best foot forward in the competitive application process for grants and employment. Students who join SFB continue to receive complementary membership to all SIGs they choose.

SPECIAL INTEREST GROUPS

Representative: Sarah Stabenfeldt, PhD

The officers for the 2019 – 2021 term held an all-SIG officers meeting at the annual meeting led by outgoing SIG Representative Sarah Stabenfeldt and incoming SIG Representative Danielle Benoit. They discussed the following priorities for the SIGs:

- Submit budget proposals by Aug. 15, 2019.
- Submit session ideas for the 2020 World Biomaterials Congress by June 1, 2019.
- All SIGs are expected to appoint student, web, forum and industry representatives.

*If you have
any questions,*

need any information or have suggestions for improved services, please feel free to contact the Society's Headquarters office:

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Student Chapter News

By Margaret Fettis, Student Chapter President



The Student Chapter had a successful 2019 Society For Biomaterials Annual Conference and Exposition. The student luncheon was chaired by Michaela McCrary, the outgoing Bylaws Committee chair, and Maggie Fettis, the outgoing Student Chapter president. The luncheon was titled, "Becoming a Competitive Applicant in a Competitive World," and focused on students positioning themselves to be competitive applicants for awards, grants and life after PhD. The invited panelists were Dr. Cherie Stabler (University of Florida), Dr. C. LaShan Simpson (Mississippi State University), Dr. Julianne Holloway (Arizona State University) and Megan Schroeder (University of Colorado Boulder) and included a rich discussion driven by student questions.

Throughout the conference, many students were involved in chairing and planning sessions this year, including Michaela McCrary, James Shamul, Deanna Bousalis and Maggie Fettis. Marvin Mecwan helped plan and facilitate a well-received student trivia event held in conjunction with the Young Scientist Group's (YSG) Happy Hour at Pike Brewing Company. Many student chapters participated in the Biomaterials Education Challenge, and the top three finishers were University of Florida, Texas A&M University and Vanderbilt University.

The outgoing and incoming student officers held a business meeting during the conference. The meeting welcomed two new student chapters: University of California, Davis, and University of Maryland. The student society continues to grow, and we are excited to have more than 30 student chapters! Michaela McCrary (Bylaws Committee chair), together with a bylaws review committee (Sabrina Freeman, Deanna Bousalis and Maggie Fettis), reviewed and proposed changes to the bylaws that were discussed, voted on and approved.

The results of the elections were announced, and three new officers were elected: President-Elect Deanna Bousalis, Secretary/Treasurer-Elect Sabrina Freeman and Bylaws Committee Chair Zahra Davoudi. These officers will join President Jason Guo and Secretary/Treasurer James Shamul for the 2019 – 2020 term. Jason Guo is a bioengineering PhD student at Rice University, where he has excelled in his research and as a leader, serving as president of the graduate student association. James Shamul is a bioengineering PhD student at the University of Maryland and has a strong aptitude for entrepreneurship; he is co-founder of Biomaterials Day at his student chapter.

Each year, student chapters submit applications for financial support to host Biomaterials Day. I am thankful that the Society For Biomaterials continues to value these student events and supports our student chapters. These events are regional celebrations of biomaterials research that can include student presentations, invited speakers from various fields, panel discussions and

networking opportunities in friendly, collaborative environments. Students dedicate time and talents to bring these days to fruition, and we commend their efforts on these successful events!

RECENT BIOMATERIALS DAY EVENTS:

- Sept. 21, 2018: University of South Dakota
- Oct. 19, 2018: North Carolina State University
- Nov. 9, 2018: Carnegie Mellon University, University of Pittsburgh, University of Michigan and Case Western University
- Nov. 9, 2018: Southeast Biomaterials Day: Clemson University, Georgia Institute of Technology and Vanderbilt University
- Jan. 11, 2019: University of California, Davis
- Feb. 23, 2019: MidAtlantic Biomaterials Day: University of Maryland, College Park, and Johns Hopkins University
- March 18, 2019: University of Florida

For details on these events, please visit the SFB website.

UPCOMING EVENTS:

- May 31, 2019: Texas Collaborative: Rice University, Texas A&M University, University of Texas at Austin, University of Texas Health Sciences and University of Texas at San Antonio
- Sept. 12, 2019: University of South Dakota
- Sept. 27, 2019: North Carolina State University
- Summer/Fall 2019: University of Washington
- Fall 2019: Midwest Biomaterials Day: Case Western Reserve University, University of Michigan, Carnegie Mellon University and University of Pittsburgh

As my presidency term comes to a close, I would like to thank the entire SFB council, the Education & Professional Development Committee and YSG for their guidance and encouragement. I would also like to acknowledge the other Student Chapter officers I've collaborated with in the past year — James Shamul, Marc Thompson, Jason Guo and Michaela McCrary — for their enthusiasm and tireless involvement in the society. The Student Chapter will be in good hands, and I'm excited to see what the future Student Chapter officers will accomplish!

Student leaders.



Right to left: James Shamul, Sabrina Freeman, Deanna Bousalis, Jason Guo, Michaela McCrary and Maggie Fettis. (Not pictured: Marc Thompson and Zahra Davoudi)

Events at the 2019 SFB Meeting

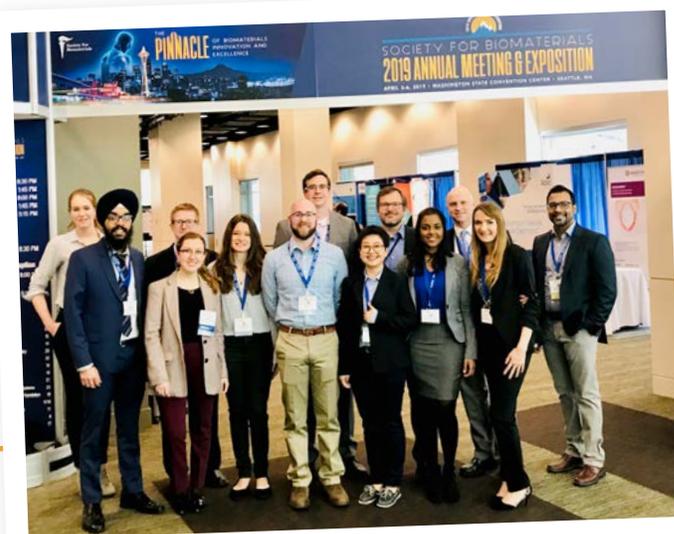
EDUCATION CHALLENGE

The Biomaterials Education Challenge encourages and challenges Society For Biomaterials student chapters and other student clubs or groups to develop innovative and practical approaches to biomaterials education for middle school (grades 6 to 8) science classes. Teams are challenged to develop an educational module that will both improve widespread understanding of biomaterials-related science and expose students to potential career opportunities. Modules are expected to be engaging, hands-on learning experiences that demonstrate fundamental biomaterials concepts, easily completed within a 45-minute class period; learning objectives should be clearly understood and materials easily obtained.

Winners will have emphasized innovation, practicality and the likelihood of widespread adoption and dissemination through demonstration of educational impact. Finalists are selected based on the submitted abstracts to present a poster to the panel of judges, which consists of Dr. Daniel Alge, Dr. Joel Bumgardner, Dr. Bill Murphy, Dr. Jan Stegemann and Dr. Anirban Sen Gupta.

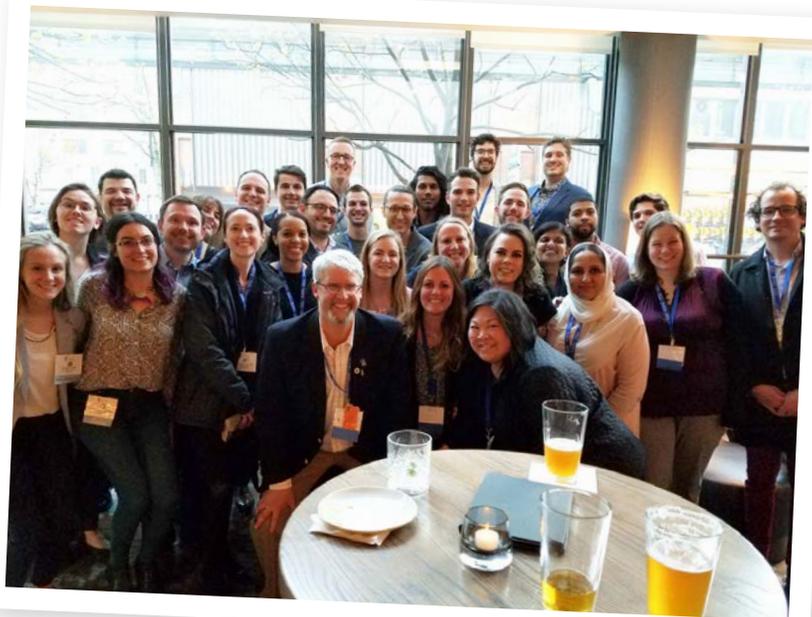
This year's Biomaterials Education Challenge was held at SFB's 2019 Annual Meeting and Exposition in Seattle, Washington. Below are the results of the challenge:

- First Place: University of Florida, Gainesville, Florida
- Second Place: Texas A & M University, College Station, Texas
- Third Place: Vanderbilt University, Nashville, Tennessee



SECOND LGBTQI MIXER

The second SFB LGBTQI and friends mixer was held during the 2019 annual meeting. It was a great time reconnecting with many friends from our first mixer at the 2018 annual meeting in Atlanta, Georgia, as well as making many new friends. Everyone enjoyed relaxing from the activities and sessions of the meeting while enjoying some wonderful appetizers and beverages. We look forward to getting together again at future meetings. Anyone who wants to find additional information about the group, please contact Joel D. Bumgardner, (jbmgrdnr@memphis.edu).





Remembering **ROBERT BAIER**

*By Jack Lemons, University Professor Emeritus,
University of Alabama at Birmingham*

Robert (Bob) Baier, PhD, my friend and professional associate for five decades, passed away on March 2, 2019. This brief remembrance is intended to recognize an individual who made significant contributions to the evolution and continued development of the discipline and associated Society For Biomaterials (SFB).

Bob will be remembered as one of the “academic fathers.” He was always professional, focused, willing to interact and friendly. The detailed record of his multiple contributions to biomaterial sciences and technologies, which extend from the late 1960s through 2019, are available on websites. This record clearly demonstrates the wide range of studies he conducted and published, focused mostly on the characterization of surfaces and interactions with biologic and other environments.

Bob was always willing to discuss biomaterials science and especially cardiovascular applications. He would always share all types of information, often including humorous events among the multidisciplinary stakeholder participants. This humor extended to worldwide professional meetings.

As one example of his willingness to share information and time, my teenaged son attended some of the SFB and associated meetings. Each time I would look for my son, he would be talking with Bob. Those discussions and one-on-one mentoring was “what Bob did,” and my family and I were greatly appreciative.

As mentioned, one central focus was specific to the initial events and related interactions at environment-to-biomaterial interfaces and how best to characterize events using quantitative measurements such as surface tension and energy. Many of the methods and measurements developed have been routinely used over the decades. This topic, in part, was one part of a session at the 2019 SFB meeting in Seattle, Washington.

Bob’s contributions to the science, technology, teaching and “the academic family” of SFB have supported the discipline since the initial days of development and subsequent expansion. The approach Bob took represents a template for the future. It is sad to realize that some of the younger professionals will not have the opportunity to interact with him. On a personal note, Bob, we will miss ya!



Remembering RUSS PARSONS

By John (Jack) Ricci, New York University School of Dentistry

Russ (John Russell) Parsons died on March 27, 2019. On this sad occasion, I wanted to offer a few memories and observations of someone who was a great mentor and a close friend.

Russ was Jonathan Black's first graduate student at the University of Pennsylvania. Jonathan sent me the following information on Russ' thesis work:

Thesis Title: The Viscoelastic Mechanical Properties of Articular Cartilage, Completed/PhD. Awarded: 1977 (The degree was awarded in metallurgy/materials science because the Department of Bioengineering had not yet been formed.)

"He made a major contribution to the (then) early modern understanding of the mechanical properties of intact cartilage in joints: His doctoral research demonstrated, in part, that intact healthy articular cartilage, in situ on supporting bone, at least in animal models, behaves as a simple, linear viscoelastic solid while disease and disuse produces non-linear properties (*J Biomech.* 1979;12:765-773)."

Russ spent his career concentrating on the repair of the musculoskeletal system. His work concentrated on biomaterials technology for bone and soft tissue implants, tendon and ligament repair, spinal biomechanics, fracture mechanics, bone healing and remodeling, and other musculoskeletal areas of research.

I met Russ in 1979 at what was then the College of Medicine and Dentistry of New Jersey (; I was Russ' first graduate student. In those days, working in Russ' lab meant two things: You became involved in the Society For Biomaterials, and you were sailboat-racing crew for Russ and his wife, Janey. Since then, I have only missed a handful of SFB meetings, and I participated in well over 1000 races with Russ and Janey. Because of Russ, SFB became an important part of my professional life.

Over time, I came to know Russ as a dedicated mentor to master's and PhD students, medical students and orthopedic residents. He accomplished a great many things in his career, but I won't go into those in detail here because that wasn't his style. He was proud of having been president of the Society For Biomaterials from 2000 to 2001. He spent 31 years at the University of Medicine and Dentistry of New Jersey and was the director of orthopedic research for most of that time. He was a Fellow of Biomaterials Science and Engineering and a Fellow of the American Institute for Medical and Biological Engineering.

Russ was an excellent mentor to a lot of people. He shaped a lot of minds and influenced a lot of careers. I know I'm not alone in saying that I will miss his wisdom, his modesty, his sense of humor and his friendship. It was Russ' dedication to training the next generation of scientists and clinicians that he was most proud of. That is how many of us will remember him, and that is how he would want it.

Update from the SC&M SIG

By Gopinath Mani, Abbott; Anita Shukla, Brown University; and Guigen Zhang, University of Kentucky

The main goal of the Surface Characterization and Modification (SC&M) Special Interest Group (SIG) is to promote educational and networking opportunities for Society For Biomaterials members in areas related to any aspect of SC&M in biomaterials and medical devices and to develop compelling scientific programs in SC&M for the SFB annual meetings. The two major research topics that the SC&M SIG emphasized are (1) improving understanding of biomaterial surface structure and its relationship to biological performance and (2) developing surface modification strategies for biomaterials.

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 2019 – 2021 term: Dr. Anita Shukla (Brown University) as chair, Dr. Hitesh Handa (University of Georgia) as vice-chair, Dr. Elizabeth Brisbois (University of Central Florida) as secretary/treasurer and Dr. Hongli Sun (University of Iowa) as program chair. We thank the previous board, which did an amazing job enhancing the SC&M SIG's activities, including Chair Dr. Guigen Zhang, Vice-Chair Dr. Balakrishnan Sivaraman, Secretary/Treasurer Dr. Anita Shukla and Program Chair Dr. Hitesh Handa.

We currently have more than 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 or co-sponsored by the 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 2019 Annual Meeting, the SC&M SIG sponsored or co-sponsored 10 sessions, including:

- Cardiovascular Biomaterials and Blood Compatibility
- Developing Better Biomaterials: Advances in Technologies and Understanding of Surface Modification
- Multifunctional Biomaterials: Recent Developments and Future Directions
- New Directions in Biomedical Surface Analysis
- Recent Developments in ISO 10993 Series of Standards for Biocompatibility Testing and Evaluation
- Recent Advances in Antimicrobial and Antimicrobial and Antibiofilm Materials 1
- Recent Advances in Antimicrobial and Antimicrobial and Antibiofilm Materials 2

- Regulatory Translational Science Focused on Commercialization Challenges for Surface Modification and their Characterization: SIG-SQUARED
- Surface Characterization and Modification SIG
- Targeted and Stimuli Responsive Biomaterials

The SC&M members played a vital role in organizing or co-organizing these sessions by reviewing abstracts for them and chairing or co-chairing the sessions. All these sessions were well received at the meeting, some with standing room only.

The SC&M SIG undertook several new initiatives for this year's program, as well:

- We initiated the SFB SC&M SIG Trainee Travel Awards. This year, three awards were provided to outstanding abstracts submitted by students and trainees in SC&M SIG-sponsored sessions. The students and trainees were recognized during their presentations in respective sessions.
- Congratulations to Vaishali Inamdar of Children's Hospital of Philadelphia, James Wroe of Georgia Institute of Technology, Shang-Lin Yeh of National Taiwan University and Megan Douglass of University of Georgia for receiving the 2019 SFB SC&M SIG Travel Awards!
- We congratulate SC&M-nominated STAR awardee Xiaoyu Chen (the Chinese University of Hong Kong) and honorable mentions Megan Douglass (University of Georgia) and Shang-Lin Yeh (Taiwan University).
- We featured three invited 30-minute lead talks in three SC&M-sponsored symposiums. To recognize and acknowledge their outstanding scientific contribution to the field, we presented these speakers with plaques.
- Dr. Jeremy Gilbert, Dr. Vincent Rotello and Dr. Horst von Recum received the plaques this year during their presentations in respective symposia. The SC&M SIG thanks the invited speakers for providing outstanding talks in their respective symposiums.

The SC&M SIG plans to continue these activities, motivate students and trainees, and recognize outstanding contributions by leaders in the field. In addition, the SIG plans to continue organizing general sessions, symposiums, panel discussions, workshops and tutorials that would be of great interest to the SC&M SIG community in future meetings. Discussions on enhancing our web presence as a SIG have also begun, bringing news or our members' accomplishments and activities within the SC&M field to the broader scientific community and enabling us to share career and professional development opportunities with our members (stay tuned!). With all these excellent initiatives and a wonderful team of SIG officers, the future looks very bright for the SC&M SIG.

Update from the PCI SIG

By Stephen J. Florczyk, Rafael Ramos, and Pranav Soman

BIOELECTRICITY CONSIDERATIONS IN BIOMATERIALS RESEARCH

Bone as an Electrically Dynamic Material

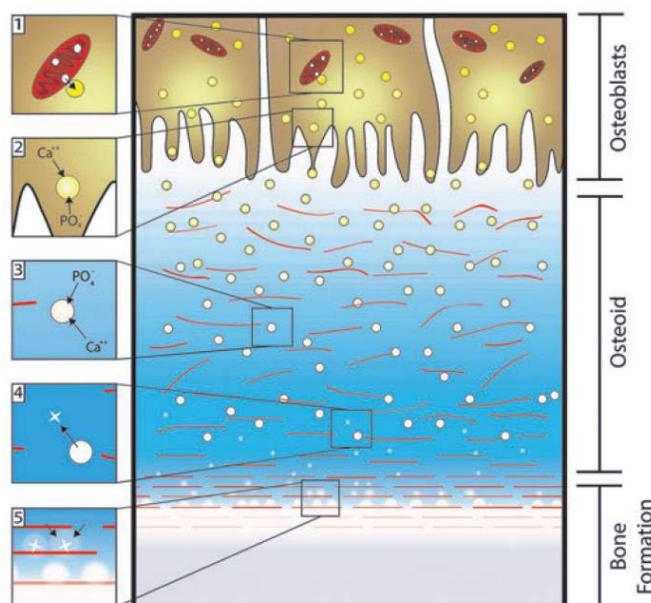
Native bone is a composite material that consists of highly ordered organic collagen fibrils and inorganic hydroxyapatite (HA) and calcium phosphate mineral.¹ Based on physiologic loading, age and several other parameters, bone is continuously remodeled throughout our lifespan to maintain homeostasis through an intricate process that involves bone resorption by osteoclasts and mineral deposition by osteoblasts. The process of mineral deposition by osteoblasts begins with the aggregation of amorphous calcium phosphate within intracellular vesicles, followed by exocytosis of the vesicles into the extracellular space, where they begin to deposit crystalline apatite mineral within and along aligned collagen fibrils before crystalizing into HA.^{2,3}

Understanding the properties of cell-deposited mineral is important because a loss in mineral is often associated with an increased risk of osteoporotic fracture and a reduced rate of bone healing. As a result, several research groups have used cell-laden hydrogels as model *in vitro* systems to investigate the process of mineral deposition.^{4,5} In a typical study, osteogenic cells are encapsulated within a hydrogel matrix using cell-friendly cross-linking conditions and chemically induced to facilitate cell-mediated mineral deposition within the hydrogel matrix. For these studies, model cells lines such as human osteogenic sarcoma cells MC3T3-E1 murine osteoblasts, mesenchymal and adipose stem cells, embryonic stem cells and human induced pluripotent stem cells have been encapsulated within model natural hydrogels (collagen, fibrin, alginate), synthetic hydrogels (polyethylene glycol) and semisynthetic hydrogels.^{5,6} Although studies have investigated the changes in morphology and material composition of mineral deposited by the encapsulated cells, no study has succinctly summarized their range in electrical properties.

Electrical properties have been measured in native bone tissue using a range of approaches.⁷ In fact, clinical therapies based on electric stimulation have been shown to enhance bone regeneration.⁸ The origins of electrical properties have been linked to both the organic (type I collagen) and the inorganic (HA) components of bone tissue, although the exact mechanisms are not known, and are the focus of many *in vitro* and *in silico* studies.⁷ This inorganic component makes up 50 – 70% of the bone mass and is responsible for the bone's structural rigidity, resistance to loading, and electroconductive and piezoelectric properties.^{9,10} To mimic the inorganic component of bone tissue for potential clinical and tissue engineering applications,

synthetic biomaterials such as polymer and hydrogel-based scaffolds are often coated with HA or calcium phosphate-like materials. To do so, numerous approaches, such as sputter coating, thermal spraying and pulsed laser deposition, have been applied. However, these conventional methods suffer several drawbacks. For example, thermal spraying requires high temperatures that could induce HA decomposition, while sputter coating and thermal pulsed laser deposition are capable of coating only flat substrates. Incorporation of apatite elements into the bulk of these scaffolds could serve as a alternative, though it does present the additional issue of the aggregation of these ionic elements through stochastic interactions, making it difficult to replicate these tailored scaffolds and perhaps introducing a limiting variable concerning total construct size and complexity of both micro- and macro-architecture.

Fig 1.



Osteoblast-mediated mineralization in native bone.¹¹ Original image adapted from Mescher 2013. Twenty-eight color images are available online at www.liebertpub.com/tea.

Simulated Body Fluid

As an alternative approach to creating biomimetic bone-like surfaces, surface coating using simulated body fluid (SBF) has been widely used.¹² In the SBF approach, flat substrates or 3D scaffolds are incubated in a solution containing ionic elements with an equal or similar ion concentration compared with the blood plasma. By controlling the incubation time, surface properties and SBF composition, bone-like apatite can be precipitated on surfaces to create mineralized constructs. The

Update from the PCI SIG (continued)

calcium-binding properties and the resulting bioactivity of mineralized substrates have previously been investigated.¹³ SBF-induced mineralized surfaces have also been used as in vitro mineralized templates for studying the behavior of cells found within bone tissue. These studies typically involve SBF-mediated deposition of mineral within naturally derived hydrogels such as collagen and gelatin. Use of porous, protein-based hydrogels has been shown to facilitate the deposition of mineral on the exposed surfaces as well as in the interior of the scaffolds.¹⁴ Recent studies have demonstrated that SBF mineralized collagen scaffolds can trigger migration of osteoblasts as well as their transition into an osteocyte phenotype.¹⁵ Another study showed that SBF-mediated mineralized gelatin methacrylate composite was able to drive induced pluripotent stem cell differentiation into osteogenic cell lineages without chemical induction.¹⁶ Although SBF-mineralized hydrogels have been increasingly used to mimic the inorganic component of bone tissue, little is known about the electrical properties of these mineralized constructs.¹⁷ Considering the importance of bioelectricity within bone tissue, an important future step will center on identifying the electrical properties of SBF-induced mineralized constructs.

Limitations and Future Considerations

The most pressing limitation for identifying either native bone or in vitro construct conductive properties is the lack of a standardized testing protocols for the easy comparison of samples of equitable size and shape. These approaches are commonplace in much of material science, particularly when studying metals and ceramics, but there is a difficulty when introducing the organic elements so critical to bone's structure. Four-probe conductivity measurements and electrochemical impedance spectroscopy are probable candidates, but work by Durand, Christel and Assailly showed that inner-probe distances result in significant variations in measurements, even within similar samples of cortical bone — a fact reflected by the dual nature of bone as a hierarchical and anisotropic structure.¹⁸⁻²⁰ These complications can be further compounded by the difficulties that arise when testing hydrated samples such as the hydrogel constructs. The ability to normalize these approaches will go a long way in the development of replicable bone-mimicking constructs as well as providing further insight into the conductive nature of native bone.

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Education News

By LaShan Simpson, Education News Editor



At the Society For Biomaterials 2019 Annual Meeting, held in Seattle, Washington, the Biomaterials Education Special Interest Group (SIG) organized a session titled, “Strategies for Effective and Engaged Teaching.” The Biomaterials Education SIG officers who organized the event are J. Amber Jennings, PhD, assistant professor, University of Memphis; Cheryl Gomillion, PhD, assistant professor, University of Georgia; and C. LaShan Simpson, PhD, assistant professor, Mississippi State University. Invited panelists for the session included Aileen Huang-Saad, PhD, University of Michigan; Karen Burg, PhD, University of Georgia; and Dale Feldman, PhD, University of Alabama at Birmingham.

Biomaterials educators bridge the gap between theory and practice in biomaterials science. As science, technology, engineering and mathematics (STEM) education continues to evolve, innovative approaches for engaging all categories of student learners are widely sought. For faculty, the introduction of novel approaches in the classroom is often a missed opportunity for integration of their teaching and outreach into their traditional scholarship and thus, a missed opportunity for potential funding. The invited panelists discussed many academic development matters, including active learning activities, instructional laboratories and conversion of educational innovations to scholarship. Topics included project ideas for cooperative problem-based lab instruction, course innovations, academic – industry collaborative projects, outreach and assessment methods. Our experienced panelists in engineering education outlined the education theories most commonly used and broke down the stigma associated with theory. Panelists also provided participants with a thorough introduction to active learning strategies and resources, gave an overview of best practices for incorporating active learning into biomaterials courses and highlighted success stories for integrating such educational activities into technical research and scholarship. This panel discussion outlined a framework for incorporation of innovative educational strategies into biomaterials curricula, outreach and educational publications.

Dr. Huang-Saad spoke of her journey from biomedical engineering to engineering education. Her presentation, titled “Engineering Education Research: Incorporating it into Your BME Research Portfolio,” outlined techniques and methods to convert active learning practices in the classroom into scholarship. She explained the difference between quantitative and qualitative research in engineering education, then provided a blueprint for using these techniques to assess classroom innovation for publishing and funding. Dr. Huang-Saad also provided suggestions for journals in which to publish active learning or course innovation techniques, which include *International Journal of STEM Education*, *Advances in Engineering Education*, *Journal of Engineering Education* and *American Society for Engineering Education Conference Proceedings*. Funding opportunities that Dr. Huang-Saad outlined from the National Science Foundation were PFE: Research Initiation in Engineering Formation (PFE: RIEF); Improving Undergraduate STEM



Pictured from left to right: panelists Aileen Huang-Saad, Karen Burg and Dale Feldman; moderator Cheryl Gomillion

Education: Education and Human Resources (IUSE: EHR); and Research in the Formation of Engineers (RFE). For those interested in learning more, she offers a list of engineering education hacks on her web page (<https://teel.bme.umich.edu/engineering-education/>).

Dr. Karen Burg spoke on creating sustainable outreach efforts, acquiring funding for outreach and publishing data obtained through outreach. She discussed her extensive experience with outreach activities at numerous levels, from K – 12 classroom visits and special events to museum teacher workshops and camps. Dr. Burg encouraged audience members to include outreach in their “business plan” for sustainability; she also offered lessons learned for the audience:

- Avoid the one-off: sustainability and impact.
- Mentor students.
- Engage partners.
- Develop partners.
- Plan for publication.
- Relate technical work to broader impacts.

Dr. Dale Feldman gave an overview of his experience with team-based learning in training students for entrepreneurship. Courses included pedagogy on design theory, the regulatory process (product to market) through a 510(k) U.S. Food and Drug Administration submission and effective group work. Dr. Feldman explained how these course innovations develop useful skill sets to make students more marketable for job opportunities in industry. He also detailed his modified team-based learning (TBL) course structure, which includes factual knowledge assessed through individual and group quizzes and application demonstrated through case studies and outside speakers. Dr. Feldman recommended the book titled *Quiet* by Susan Cain as a resource to encourage student teams to work together effectively and divide tasks.

The Biomaterials Education SIG aims to continue providing programming to help faculty develop innovative course initiatives and sustainable outreach efforts, then translate them into scholarship and funding. If you have any ideas for future topics, feel free to contact any officers of the Biomaterials Education SIG.

Industry News

By Steve Lin, Industry News Editor



Nordic Capital Fund IX agreed to acquire a majority holding in Orchid Orthopedic Solutions from Altor Fund III, which will retain a significant minority holding. Orchid's current management team will remain in place. Orchid provides contract design and manufacturing

services, from concept through launch, serving its global customer base from 12 manufacturing sites in the United States, the United Kingdom, Switzerland and China. Markets include joint reconstruction, spine, trauma, sports medicine, extremities, dental and cardiovascular. Orchid's annual orthopedic-related revenue is in the range of \$315 million to \$325 million, holding 6 percent of a more than \$5 billion global orthopedic contract manufacturing market.

Charles River Laboratories (CRL) signed a binding offer to acquire Citoxlab, an early-stage contract research organization, for €448 million in cash (~510 million USD). The proposed transaction is expected to close in the second quarter of 2019. Citoxlab specializes in regulated safety assessment, nonregulated discovery and medical device testing. It operates six sites across Eastern and Western Europe and three in the United States and Canada, including AccellAB, which Citoxlab acquired in 2016. The transaction would further expand CRL's small and mid-sized biotechnology client base, which is its fastest-growing client segment per leadership comments. Of note, the acquisition doubles CRL's medical device testing capabilities.

Smith & Nephew entered into an agreement to acquire Osiris Therapeutics for ~\$660 million. The deal is expected to close in the second quarter of 2019. Although the transaction is primarily complementary to Smith & Nephew's wound management business, Osiris brings BIO4™ viable bone matrix, an alternative to autograft, and Cartiform® cryopreserved viable osteochondral allograft for articular cartilage repair. Cartiform is exclusively distributed by Arthrex; BIO4 is exclusively distributed by Stryker. Analysts report that the Arthrex agreement is not expected to change, with no comment on BIO4 reported. This is Smith & Nephew's second purchase of 2019, following closure of the Ceterix Orthopaedics acquisition early in the first quarter of 2019.

Corin acquired **OMNIBotics Robotic Assisted Knee Replacement** from OMNI. This acquisition gives Corin a greater foothold in the United States, where robotics is growing rapidly. OMNIBotics combines a robotic cutting guide with what is billed

as "the world's first robotic tool to measure ligament function." Combined with the Optimized Positioning System for hips, OMNIBotics gives Corin flagship technologies across multiple segments as the company strives to create a connected digital ecosystem throughout a patient's episode of care.

Procter & Gamble (P&G) has agreed to acquire **Merck KGaA's** consumer health unit for €3.4 billion (4.2 billion USD), giving it vitamin brands such as Seven Seas and greater exposure to Latin American and Asian markets. The deal would help P&G expand its portfolio of consumer healthcare products, which includes Vicks cold relief. The Merck unit includes vitamin brands Femibion and Neurobion. Based in the United States, P&G derived 12 percent of group sales, or \$7.5 billion, from healthcare products last year, including Oral-B toothbrushes and toothpastes.

The U.S. Food and Drug Administration has awarded breakthrough device designation to a **BioDirection's Tbit™ Testing Platform**, which has been developed to predict positive computerized tomography (CT) scans after traumatic brain injury. The device consists of a nanotechnology biosensor to quickly and accurately identify protein biomarkers released from the brain immediately after a trauma to the head. Results can be delivered within 90 seconds. Because the device is portable, it could be used in hospital emergency departments, with potential for future use at the point of injury. The ability to diagnose brain injuries at an earlier stage could facilitate more appropriate treatment decisions while minimizing unnecessary head CT scans.

Neuroengineers from the Mortimer B. Zuckerman Mind Brain Behavior Institute at Columbia University in the United States have developed a brain – computer interface that can directly translate thoughts into intelligible, recognizable speech. The new system offers hope for people with little to no ability to speak, such as patients with amyotrophic lateral sclerosis or those recovering from a stroke. Approximately one-third of people who have had a stroke have some kind of problem with speech. The interface is based on speech synthesizers and artificial intelligence that track brain activity and reconstructs that activity as words. The researchers believe that the new system has the potential to be used in computers that can communicate directly with the brain.

The Global Medical Device Nomenclature (GMDN), the de facto global standard for identifying the world's millions

Industry News (continued)

of medical devices, has been made freely available to all manufacturers for the first time this week. The GMDN is currently used by more than 7000 medical device manufacturers around the world, and it is hoped that the move will encourage smaller and start-up manufacturers to use the standard, as well. The GMDN covers all equipment and devices used in hospitals, from sterile wipes to pacemakers, from scalpels to magnetic resonance imaging scanners. Currently, it lists more than 25,000

categories of medical devices, with about 700 new categories created in 2018. New categories that identify breast implants with different surface textures, a sensory-neuron simulator to aid muscular rehabilitation and tumour-therapy magnetic nanoparticles are examples of the diverse nature of new medical device technology that need to be described.

HAVE A *LETTER TO THE EDITOR*, *BOOK RECOMMENDATION* OR *COVER ART* TO SHARE WITH FORUM READERS?

PLEASE CONTACT
Guigen Zhang at
guigen.bme@uky.edu.

Government News

By Carl Simon, Government News Editor



STANDARDS WORKSHOP

The Standards Coordinating Body (SCB), US Food and Drug Administration (FDA), National Institute of Standards and Technology and Nexight Group held a workshop titled

“Realizing the Benefit of the 21st-Century Cures

Through Standards Development” on March 18 – 19, 2019, in Gaithersburg, Maryland. The goal was to expose stakeholders to the standards development process so that they can better appreciate the benefits and limitations of standards. Sessions focused on reference materials, demystifying standards development, cell characterization, rapid microbial testing, cell viability testing and scaffold characterization. Speaker slides, a workshop summary and other workshop materials are available at the link. <https://www.standardscoordinatingbody.org/march2019workshop>

FDA DRAFT GUIDANCE

FDA has issued a “draft” Guidance for Industry titled “Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research: Guidance for Industry,” which is open for comment. The guidance outlines the value of standards for streamlining the regulatory process and describes why FDA encourages sponsors to use appropriate standards, when available. The draft guidance can be downloaded at the link.

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM589416.pdf>

DEMYSTIFYING STANDARDS

SCB has issued a set of flyers that describe the different types of standards and their value in a quick, easy-to-read format. These flyers may be helpful to anyone, from industry experts to undergraduate students, interested in quickly learning the basics of standards. The titles of these 1- to 2-page PDFs are listed here:

- “Benefits of Standards Fact Sheet”
- “Guide to Standards Terminology”
- “Strengthening Standards Development Process Brochure”
- “Documentary Standards Brochure”
- “Reference Materials Brochure”
- “ASTM Regenerative Medicine Standards Development Efforts Fact Sheet”
- “ISO Regenerative Medicine Standards Development Efforts Fact Sheet”
- “About SCB Fact Sheet”

The flyers can be downloaded at the link.

<https://www.standardscoordinatingbody.org/publications>

REGULATORY CONSULTING

The Advanced Regenerative Manufacturing Institute (BioFabUSA) is now offering regulatory and preclinical consulting services.

The services are free to members (fee for nonmembers) and provided by staff with FDA experience in reviewing biologics, devices, drugs and combination products. See link for more information. <https://www.armiusa.org/biofabconsulting>

"FDA HAS ISSUED A "DRAFT"

GUIDANCE FOR INDUSTRY TITLED

"STANDARDS DEVELOPMENT AND THE

USE OF STANDARDS IN REGULATORY

SUBMISSIONS REVIEWED IN THE CENTER

FOR BIOLOGICS EVALUATION AND

RESEARCH: GUIDANCE FOR INDUSTRY,"

WHICH IS OPEN FOR COMMENT."

CURRENT NATIONAL INSTITUTE FOR INNOVATION IN MANUFACTURING BIOPHARMACEUTICALS PROJECTS

The current project portfolio for the National Institute for Innovation in Manufacturing Biopharmaceuticals is online. These exciting projects are aimed at improving the quality of manufactured biologics and focus on topics such as line detection of contaminants, automation training, improving readiness of new hires, quantitative differentiation assays for MSCs, training of cell therapy manufacturing personnel and low-cost production of cytokines. <https://niimbl.force.com/s/current-projects>

Contact: Carl Simon (carl.simon@nist.gov)

An Interview with Steve Lin

By Guigen Zhang, *Biomaterials Forum* Editor



Editor's note: Dr. Steve Lin is a longtime contributor to the Forum as the industry news editor. He is not only a productive biomaterials researcher but an entrepreneur and industry leader, working at the forefront of biomaterials translation. If you are regular readers of the Industry News Column he compiles for us, you probably have already benefited from

his unique insight, which is built on his extensive research and development experience. In this interview, I give you a closer view of his career path. I hope that trainees and students who aspire to an entrepreneurial or industry career may get some useful hints from reading it.

Guigen Zhang (GZ): In what subject area did you get your undergraduate and graduate degrees?

Steve Lin (SL): I have a BS and an MS in chemical engineering. I also have graduate degrees in biomedical engineering: a MS from Drexel University and a DSc from Washington University.

GZ: What made you choose those subjects and places?

SL: When I was doing my chemical engineering graduate study at South Dakota School of Mines and Technology, I took a biochemical engineering course. The professor gave the class a list of topics to research and write a term paper. I was attracted to the topic, "artificial kidney." I went to the library and found a lot of research papers on this subject published by Prof. Robert Sparks' group at Washington University. As a chemical engineer, I found artificial kidney so intriguing because we could apply engineering principals to solve an unmet clinical problem.

The following summer, I went to work in Philadelphia to earn money to pay for my last semester of graduate study. One day I accidentally learned that Drexel University had a biomedical engineering program. I was curious, so I took a day off from my work and went to visit. I met Prof. Richard Beard and had an excellent tour and education from him about various research that his and other professors' labs were doing. The visit helped me solidify a clear direction for continuing my graduate study. I got a job as a resin chemist in a chemical company after I received my MS in chemical engineering. Since my mind was set on biomedical engineering, I contacted Prof. Beard and started applying for Drexel's biomedical engineering graduate program. I was admitted to Drexel and did a master research project under Prof. Beard to develop new power sources to extend the pacemaker battery life. The two years of graduate study at Drexel helped me understand what a chemical engineer could really contribute in the biomedical engineering field. I then decided to pursue a doctoral degree in biomedical engineering under Prof. Sparks at Washington University. I had

a great opportunity to work on a new research in regenerative engineering which was to develop a small artificial blood vessel that he had just started. I learned in my research the synthesis of biodegradable polymers and various processing techniques to make polymeric films, tubings and filaments impregnated with anticoagulant compounds.

GZ: What did you do after graduation?

SL: As I was finishing my doctoral study and beginning to search for a job, my professor suggested that I join Prof. Robert Langer at the Massachusetts Institute of Technology as a postdoc. Coincidentally, I was offered an industrial position as a research engineer at Hexcel Corporation, where the company was developing an artificial ligament for anterior cruciate ligament (ACL) reconstruction. The company had had an investigational device exemption (IDE) approval and had just started a human clinical trial. The opportunity to participate in an IDE project to develop an implantable device that could regenerate an ACL was too exciting to pass up. It was an easy decision for me to head to California to join a young implant research and development (R&D) team at Hexcel Corporate Research Center. Soon after I was on board, I found out our team was facing a serious challenge to solve a critical implant design flaw that was causing the implant to develop defects of grave concern during the surgery. During my interview, our team leader had been impressed with my expertise on biodegradable polymers. He hired me to help solve this critical implant design problem that was about to derail the clinical trial.

GZ: Did you do a postdoc?

SL: No.

GZ: Can you give examples of the kinds of things you learned after your formal education was complete?

SL: I encountered many difficult technical challenges in my doctoral research to develop a small artificial blood vessel, and I gained many problem-solving skills. Those problem-solving skills helped me do my job as a research engineer in an emerging implant industry.

I was so excited to join a young implant team to develop an artificial ligament. But, my excitement was quickly replaced by high anxiety and stress when the trial was put on hold temporarily until we could solve the implant design flaw. The implant was basically a long carbon-fiber flat tow coated with a thin L-poly(lactic acid) (PLA) with two large needles attached at both ends. A significant number of carbon fibers were breaking during the surgery. Apparently, the PLA coating seemed to degrade substantially after dry heat sterilization, which rendered it too weak to act as a protective coating for fibers. I quickly identified that the residual moisture carried over from the glycerol that was added to plasticize the rigid PLA was the culprit causing the polymer to

An Interview with Steve Lin (continued)

thermally degrade. I was able to quickly apply the technique that I learned in my doctoral research to remove residual moisture from glycerol. Although the thermal degradation problem was stopped, the PLA coating at the maximum thickness allowed was still inherently too weak to protect the fibers. It became clear that we needed a biodegradable elastomer that was highly elastic, soft and tough to protect fibers during the surgery.

"I ENCOUNTERED MANY DIFFICULT TECHNICAL CHALLENGES IN MY DOCTORAL RESEARCH TO DEVELOP A SMALL ARTIFICIAL BLOOD VESSEL, AND I GAINED MANY PROBLEM-SOLVING SKILLS. THOSE PROBLEM-SOLVING SKILLS HELPED ME DO MY JOB AS A RESEARCH ENGINEER IN AN EMERGING IMPLANT INDUSTRY."

For the next six months, I searched the literature, including many relevant patents, and discussed the problems with many people. I was in the lab every night after dinner and every weekend. I was distilling ϵ -caprolactone to make an extremely pure monomer, using a distillation setup and a technique that one of the group leaders in the Corporate Research Center had taught me. I still remembered how excited I was when I made a copolymer of lactide and ϵ -caprolactone (25:75) in a weekend. This copolymer was a perfect elastomer, highly elastic and very tough, to protect the fragile carbon fibers. Poly ϵ -caprolactone was being used as a controlled-release device in a worldwide contraceptive clinical trial sponsored by World Health Organization at that time. After presenting the safety data for the copolymer of lactide and ϵ -caprolactone to the U.S. Food and Drug Administration (FDA), the ligament clinical trial was permitted to restart, and the company was able to complete the trial successfully, and submitted a PMA to the FDA.

I learned two lessons in my early industrial career : (1) There is always an answer to a problem, no matter how serious that problem is, and (2) there must be a person who holds an answer to your problem. You just need to find that person.

GZ: When did you first take your first real job? Can you describe the career path that led to your current position?

SL: I started working at Hexcel in 1981 after I received my doctoral degree from Washington University. My early industrial career at Hexcel was quite successful. I invented a patented elastomeric polyester copolymer system that saved the artificial ligament project and enabled us to complete the clinical trial. I was also involved in a carbon-fiber-reinforced composite hip implant project. I was given responsibility for composite material design and testing of the hip. I found and worked with a world-renowned composite design engineer in the aerospace industry and finalized

the composite design for the hip implant. I worked with a testing equipment company to build a multistation fatigue-testing machine and successfully characterized and verified the fatigue property of the composite hip implant. I worked with my teammates to develop and optimize a process for making the composite hip, which was successfully implanted in a dog by our clinical research collaborators from Keck School of Medicine of USC.

The director of R&D at the Corporate Research Center was so impressed with my performance that when he left Hexcel in 1984 to start his own medical device company, he invited me to join him. I was manager of Advanced Composite Research. I had all kinds of opportunities to get a startup company up and running. I built R&D laboratories, hired staff, negotiated with vendors to purchase equipment and supplies, interacted with relevant government agencies (e.g., FDA, OSHO), on regulatory issues and collaborated with an academic orthopedic research center for clinical feedback on composite hip and fracture management implants. Our young company was able to obtain a FDA 510(k) cleared dental hydroxyapatite implant and launch the product in the dental market within 12 months. We also completed a composite hip design and put the implant in a dog for a preclinical evaluation. We made good progress in developing a bioresorbable glass fiber as a reinforcement for a totally bioabsorbable composite. While we were making impressive technical advancement, however, our young startup was quickly burning through the cash. Although our two dental implant products were generating revenue, it was not sufficient to support the other two development projects. The investors were reluctant to continue funding the company, and it was later acquired by a more established medical device company. I took the opportunity to interview several orthopedic companies and decided to join Zimmer, the largest orthopedic company in the world. I thought the experience I would gain from working in a large corporation would be beneficial to my career, which proved to be correct as I looked back many years later. My professional career developed nicely at Zimmer, and I was given more responsibilities. I advanced from a manager to a group manager, a director and finally a vice president. I ran Zimmer's worldwide research and was responsible for more than 60 research staff and a \$10 million annual budget. I had many opportunities to meet and work with leading researchers in academia and industry here and outside the United States. I became a key member when Zimmer set up an Asia-Pacific Task Force Team to develop the Chinese market. The team brought modern orthopedic implant technology to China, offered training to key Chinese orthopedic surgeons and started opening the Chinese market in 1994.

After 13 years with Zimmer, I joined Exactech in 1999, a small, young orthopedic company that designed surgeon-friendly and patient-focused hip and knee implants. The company had an ambition to expand into China and a vision to develop orthobiologic solutions for bone and joint restoration — two areas in which I could make real contributions. I had a successful

An Interview with Steve Lin (continued)

career working as vice president of business development, vice president of biologics R&D and chief technology officer. I developed a high-performance bone graft product line based on human allograft demineralized bone matrix (DBM). I also brought in several synthetic bone graft products and the platelet-rich plasma and bone marrow concentrate systems that formed the basis, with the DBM bone grafts, on which to grow Exactech's orthobiologic business. In 2006, I came across a novel and elegant regenerative technology to repair articular cartilage defects; it had been developed in Taiwan by researchers in the Industrial Technology Research Institute and orthopedic surgeons at National Taiwan University Hospital. Exactech established a wholly owned subsidiary in Taiwan the following year and licensed the intellectual properties. A human clinical trial was commenced in late 2012, which was just finished this past March after 6 years. I went to work full time for Exactech Taiwan as chief executive officer (CEO) in 2017 and merged the company with a local regenerative company in early 2018 that is developing a recombinant human bone morphogenetic protein-2 bone graft licensed from a Japanese pharmaceutical company. I retired from Exactech after 18 years of employment, and now serve as CEO for the combined regenerative company. We anticipate receiving approval for the cartilage repair implant from the Taiwan Food and Drug Administration by the end of this year. The company is also preparing to go public in the Taipei stock exchange in near future.

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

SL: My current company is focusing on the development of regenerative orthobiologic products for bone and cartilage repair. Our cartilage repair technology is the one-step technology that does not require in vitro cell culture, so it simplifies the whole surgical procedure. We believe that it is a game-changing technology for articular cartilage repair.

GZ: What do you do in a typical week? How do you divide your time between those activities?

SL: My main focus is on the long-term business development strategy. I spend most of my time in the development of external collaboration and also devote time to various technical, clinical and regulatory issues.

GZ: What do you like about the Society For Biomaterials.

SL: Networking is the most important for me. Of course, the annual conference provides an opportunity to learn about new research, which always excites me. I have been the editor for *Industrial News of Biomaterials Forum*. I enjoy sharing interesting industrial news with our members and helping them keep abreast of new developments in the medical device industry.

GZ: Do you set your own priorities and deadlines? If so, how do you do that?

SL: As a CEO of my company, I set my own priorities based on

the need of the company and the status of various development projects.

GZ: Any advice for young biomaterials scientists about time management?

SL: To manage time efficiently, you must prioritize various tasks and know what not to do.

GZ: How did your education prepare you for the job you do today?

SL: Be honest to the people that you interact and the job that you do, and always offer to help when an opportunity presents so that you can gradually establish a reliable network of contacts over time.

GZ: What are some of your favorite aspects of working at your company?

SL: I get an opportunity to work alongside many talented and passionate young professionals who have a common goal to succeed.

GZ: What courses or activities would you recommend that college students take to be prepared for a job like yours?

SL: I think participating in civil activities to develop interpersonal skills will help you a lot in your future career.

GZ: What is some of the best career advice you've been given?

SL: Always be honest and helpful to others.

GZ: Please share where you think the future of biomaterials/tissue regeneration is going.

SL: I believe that the total joint replacement that we know today will disappear in the future.

GZ: What influence has the Society For Biomaterials had on your life and career?

SL: I have met many wonderful friends who have been helpful in my career.

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

SL: I serve as a CEO of my company and also as a member of the board of directors.

GZ: Can you provide a website that others can read to find out more about your corporation, including job openings?

SL: www.biogend.com.tw

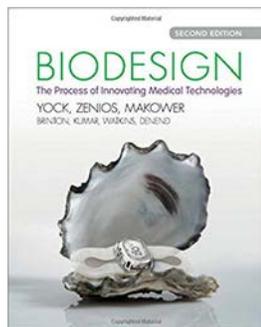
GZ: What is the relationship between basic science and applied science?

SL: Basic science tries to help answer "why"; applied science helps you come up with solutions using the knowledge that you have gained from basic science.

Book Review

BIODESIGN. THE PROCESS OF INNOVATING MEDICAL TECHNOLOGIES. 2ND EDITION

By Lynne Jones, Book Review Editor



Biodesign: The Process of Innovating Medical Technologies, 2nd Edition
 Editors: Paul G. Yock, Stefanos Zenios, Josh Makower, Todd J. Brinton, Uday N. Kumar, F.T. Watkins
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They say that there is no substitute for experience. This is certainly true for innovation in biomaterials and medical technology. Another piece of advice is that an experienced advisor — a person who can help you navigate the process — is invaluable. Yet, as the book reviewer for *Biomaterials Forum*, I can also say that a good textbook on the subject of innovation can be a constructive first step in the process to establish a foundation on this challenging subject. Such a book is the second edition of *Biodesign: The Process of Innovating Medical Technologies*.

Before I discuss the book, let me make a comment about the editors, because they provide a particularly high level of credibility to the book. The Stanford Byers Center for Biodesign is a partnership between academia and the health technology industry that is truly an example of what synergy can bring to innovation. The editorial team includes Paul Yock (Stanford University; founder and director of Biodesign), Stefanos Zenios (Stanford University; co-director of the Center for Entrepreneurial Studies), Josh Makower (founder and executive chair, ExploraMed), Todd J. Brinton (Stanford University; clinical professor of medicine), Uday N. Kumar (founder, president and chief executive officer of Element Science), F.T. Jay Watkins (managing director, De Novo Ventures); the principal writer is Lyn Denend (Stanford University; director of academic programs for Biodesign). Thomas M. Krummel is the specialty editor, and Christine Q. Kurihara is the web editor.

This book is now in its second edition, which is important to note because the book begins by telling you that this edition has been modified to address value orientation, going global, and better ways to teach and learn. The first 46 pages of the book address these focus points, a preamble that provides valuable insight

into current issues that are especially relevant to innovation today. Medical innovation cannot be undertaken without an appreciation for “value,” or cost-benefit analysis. This fact is particularly true today, with concentrated efforts by the Centers for Medicare & Medicaid Services to lower healthcare costs while providing better care to patients. The next section provides a discussion of global perspectives related to Africa, China, Europe, India, Japan and Latin America. Each region provides its own opportunities and challenges regarding innovation. The following section describes how the book is organized and why. Don’t skip this section: It will actually help you better understand the flow of information contained within this book. The book has been separated into three parts consisting of six stages (subsections). In total, 29 chapters describe the path from idea to translation. Logically, the book begins with Part I: Identify, followed by Part II: Invent, and then Part III: Implement. Each stage is followed by a case study from Acclarent, Inc, a company that develops technology for the ear, nose and throat medical field, to illustrate the different steps of the innovation process.

PART I. IDENTIFY

This section literally begins at the beginning — namely, identify the unmet medical need. This undertaking is particularly challenging for students new to medical innovation. In fact, it can even be challenging to individuals established in the field. For those already working in industry or within a specific academic discipline, the medical needs will be circumscribed by the specific specialty or subspecialty. Part I. Section 1 describes processes that include determining the strategic focus; examining the strengths and weaknesses; conducting background research, including observation; and developing a need statement. Section 2 continues, with a focus on research and analysis. As our interest is in medical innovation, it is important to understand the fundamentals of the disease state and the medical research in the field. What existing and emerging solutions exist or are under development? The chapter on stakeholder analysis provides important insights regarding identification and appreciation of the different stakeholders that may have a vested interest in your project. I felt that the chapter on market analysis was useful to me as someone without a business background. It presented the material in such a manner that I was able to understand the basic concepts. The last chapter in Part I examines the development of a needs ranking system and the utility of creating a need specification based on this ranking. This chapter brings together the elements discussed in the preceding chapters, with examples to illustrate the needs selection process.

Book Review (continued)

PART II. INVENT. CONCEPT GENERATION AND CONCEPT SCREENING

As the authors state, "it's time to have some fun." This is the stage (i.e., activity) in which students and inventors like to engage. However, this stage also requires the same diligence and perseverance that the previous stage required. The first section discusses *ideation*, the process of creating new concepts or ideas, and initial concept selection. I particularly liked the discussion of the team approach to brainstorming. Techniques for organizing and objective comparison of ideas are provided, with a pragmatic illustration on how to accomplish it. Many individuals may have an urge to skip right to Section 4, Concept Screening, because it reviews the basics of intellectual property (IP), regulatory and reimbursement; business models; concept exploration and testing; and final concept. (Resist the urge: You will be skipping useful information.) I do believe that this is an important section to read before reaching out to your technology transfer office or a patent attorney, especially if you are new to the process. Again, the chapters on IP and regulatory underscore the importance of doing your homework and documentation.

PART III. IMPLEMENTATION. STRATEGY DEVELOPMENT AND BUSINESS PLANNING

This part is invaluable for academic innovators. It reviews strategy development relating to IP (e.g., filing provisional and utility patent applications, hiring a patent attorney, understanding ongoing patent management), R&D (e.g., pragmatics — what is involved; milestones), clinical studies (preclinical studies and clinical trials), regulatory as related to your specific idea (one size does not fit all), quality management, reimbursement, marketing and stakeholders, sales and distribution, and competitive advantage and business. I felt that these chapters truly captured the essence of these topics, based on my experience. For those of you unfamiliar with quality systems, the discussion of implementation, in addition to a discussion of common mistakes made and regulations regarding quality systems, may be beneficial. Students who may not appreciate the importance of reimbursement processes in the ultimate success of a product should pay particular attention to the chapter on reimbursement strategy. The last section of the book relates to business planning: operating plan and financial model, strategy integration and communication, funding approaches and alternate pathways. The introduction to Section 6.1 explains that engineers, clinicians, statisticians, executives, reimbursement consultants, sales people and key opinion leaders are "essential to the development and commercialization of a medical device," but a "carefully integrated plan that captures and coordinates

these complex, interdependent efforts" is essential. Of particular utility to individuals not working in the medical industry, the chapter on alternate pathways explains licensing, partnering and sale/acquisition.

"IT PROVIDES A COMPREHENSIVE REVIEW OF THE PROCESS OF INNOVATING MEDICAL TECHNOLOGIES, BUT IT DOES SO IN AN EASY-TO-READ, ALMOST CONVERSATIONAL MANNER. IN FACT, AS I WAS READING I FELT AS THOUGH I WAS SITTING IN A COLLEAGUE'S OFFICE DISCUSSING THE PROCESS ONE ON ONE."

enjoyed reading this book. It provides a comprehensive review of the process of innovating medical technologies, but it does so in an easy-to-read, almost conversational manner. In fact, as I was reading I felt as though I was sitting in a colleague's office discussing the process one on one. Another strength of the book is that the supplementary material is unparalleled. Its multimedia collateral includes access to an extensive library of 300 videos to illustrate the points being made, active links to external websites and resources, supplementary appendices and timely updates. The only weakness that I could find was that the book does not openly discuss how lengthy and difficult this process can be and the likelihood of failure (e.g., the "Valley of Death"). Perhaps this was intentional, as the tone of the book was more positive — more like a coach or a teacher guiding a pupil along the path. I recommend this book to all students and new employees in the medical industry. There is even value for more established innovators in reading different points of view provided by the diverse team of editors from academics and industry about the process of medical technology innovation.

Call for Nominations

SFB 2020 AWARD AND OFFICER NOMINATIONS — LETTER OF INTENT — JULY 15

The Awards, Ceremonies and Nominations Committee is soliciting nominations for the 2020 awards (biomaterials.org/awards/awards-descriptions) listed below and for the positions of president-elect and member-at-large for the 2020–2021 term.

2020 Awards

- C. William Hall Award
- Clemson Award for Applied Research
- Clemson Award for Basic Research
- Clemson Award for Contributions to the Literature
- Founders Award
- Mid-Career Award*
- Outstanding Research by a Hospital Intern, Resident or Clinical Fellow Award
- SFB Award for Service
- Student Award for Outstanding Research (PhD, Masters and Undergraduate)*
- Technology Innovation and Development Award
- Young Investigator Award*

2020 Student Travel Programs

Applications will be accepted for the following student travel programs beginning in August:

- C. William Hall Scholarship (biomaterials.org/awards/c-william-hall-scholarship) (applications due Nov. 29, 2019)
- Cato T. Laurencin Travel Fellowship (biomaterials.org/awards/cato-t-laurencin-travel-fellowship) (applications due Nov. 29, 2019)

Deadlines

The 2020 award nominations deadline is Friday, Sept. 13, 2019; however, nominators are encouraged to submit a letter of intent to nominate to Headquarters by July 15, 2019. Although a letter of intent is not required and is not binding, the information it contains will permit the Awards, Ceremonies and Nominations Committee to identify awards and positions for which apparent nominations are not forthcoming and to solicit specific nominations as needed. Nominations will be accepted in September regardless of receipt of a letter of intent.

*NOTE: Manuscripts and abstracts for the Outstanding Research by a Hospital Intern, Resident or Clinical Fellow Award; the Young Investigator Award; and the Mid-Career Award will be accepted until Oct. 14, 2019.

To submit a letter of intent to nominate, please include your contact information, the name of the candidate and the award or position for which the nomination will be made in an email to info@biomaterials.org.

Please contact SFB Headquarters at 856-642-4201 or info@biomaterials.org with any questions or concerns.



Student Travel Achievement Recognitions

The Student Travel Achievement Recognitions (STARs) acknowledge research excellence and develop future leaders within the Society. The STAR recipients are selected according to the following requirements:

Special Interest Group (SIG) officers review a list of the STAR applicants who applied for the STAR Awards when submitting their meeting abstracts, along with their abstract titles and

scores. Each SIG will then nominate several students to the Society's Education and Professional Development Committee for consideration. The SIG Chair Committee reviews the nominations and selects the STAR recipients, who each receive a monetary award of \$250. Those abstracts recommended by the SIGs, but not selected by the SIG Chair Committee receive honorable mentions.

2019 STUDENT TRAVEL AWARD (STAR) RECIPIENTS

Riley Allen University of California, Davis	Yu Dang Washington University, St. Louis	Michael Gower University of South Carolina	Yan Luo Soochow University Prarthana Patil Vanderbilt University	Stephanie Smith Clemson University
Rukhsana Awais University of Memphis	Yuxi Dong University of Pennsylvania	Iman Hassani Auburn University	Michaela Pfau Texas A&M University	Eri Takematsu University of Texas at Austin
Vimala Bharadwaj Arizona State University	Shaheen Farhadi University of Florida	Pengfei Jiang The Ohio State University	Matthew Remy University of Iowa	Rachel Wilmoth University of Colorado
Eunice Chee University of North Carolina and NC State University	Nicole Friend University of Michigan	Andrea Jones University of Michigan	Jared Shadish University of Washington	
Xiaoyu Chen The Chinese University of Hong Kong	Jonathan Galarraga University of South Carolina	Heng-Wen Liu Johns Hopkins University	Kenneth Sims University of Rochester	

2019 HONORABLE MENTION STUDENT TRAVEL AWARD (STAR) RECIPIENTS

Marian Ackun-Farmmer University of Rochester	Morgan Ellis Auburn University	Nada Haq-Siddiqi City College of New York	Qian Pang Zhejiang University	Tibra Wheeler Cornell University
Gillie Agmon Stanford University	Ashley Farris Johns Hopkins University	Mi Kwon University of Pennsylvania	Seung Hyun Park Yonsei University	James Wroe Georgia Institute of Technology
Grace Bushnell University of Michigan	Sabrina Freeman University of Florida	Jiapu Liang University of Florida	Siavash Parkhidesh Rice University	Shangjing Xin Texas A&M University
Daniel Chester North Caroline State University & University of North Carolina	Jordana Gilbert-Honick Johns Hopkins School of Medicine	Seema Nandi North Carolina State University & University of North Carolina	Hunter Rogers Northwestern University	Shang-Lin Yeh National Taiwan University
Lars Crawford University of Washington	Aidan Gilchrist University of Illinois, Unrbana-Champaign	Dang Nguyen Nanyang Technical University	Ujjal Didar Singh Sekhon Case Western Reserve University	Xuwei Zhao Tufts University
Megan Douglass University of Georgia	Bhuvanewari Gurumurthy University of Mississippi Medical Center	Clyde Overby University of Rochester	Shashank Shukla Brown University	Le Zhen University of Washington
Ian Dry University of Washington			Laura Smith University of Toronto	