

BIOMATERIALS

FORUM

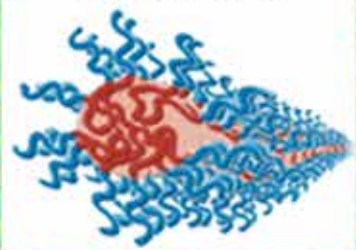
OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS



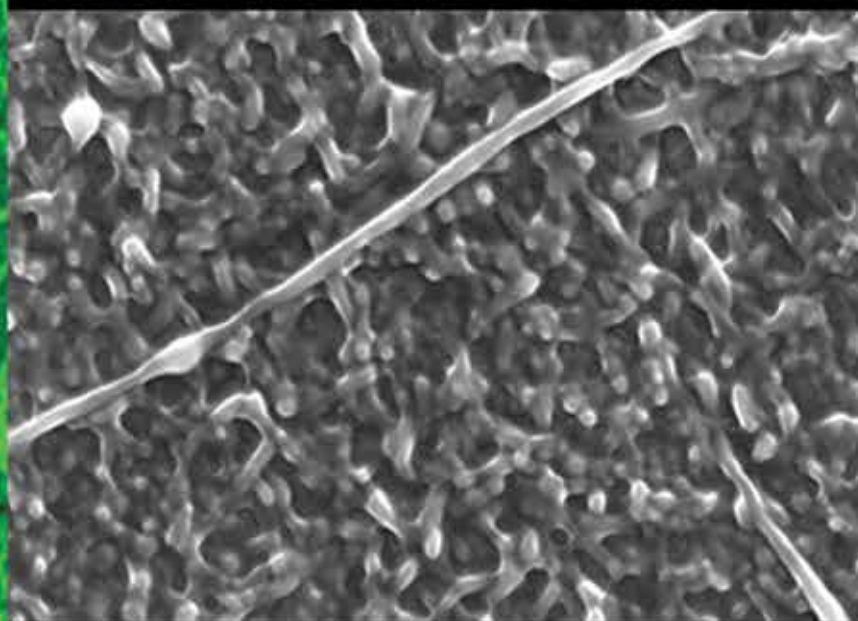
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Third Quarter 2013 • Volume 35, Issue 3

Filomicelle



Layer-by-Layer Filomicelle Self-Assembly



1 μm



50 μm

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BIOMATERIALS FORUM



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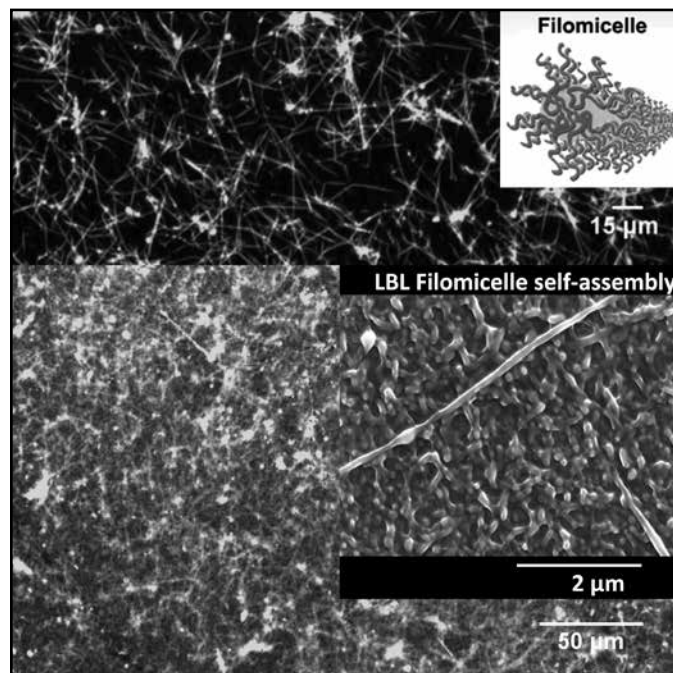
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On the cover: Layer-by-layer networks of methoxy-poly (ethylene glycol)-b-poly(lactic acid) filomicelles(FM). Networks were formed by the alternate deposition of biotinylated-FM and streptavidin. (Top image - one layer, Bottom image and SEM - seven layers) The resulting layers form a mucin-like network that can be loaded with hydrophobic drugs or surface-decorated with active proteins, serving as an artificial replacement of a mucosal surface. Fluorescence imaging was obtained by the naturally fluorescent antioxidant, curcumin, loaded into the FM as a model drug. This material was developed by Sundar Authimoolam in the research group of Thomas Dziubla in the Department of Chemical and Materials Engineering at the University of Kentucky.



Greetings fellow biomaterials scientists,

Welcome to the news magazine of the Society For Biomaterials. Our goal is to keep members up to date on some of the latest happenings in biomaterials. Here's a sampling of what you'll find within this issue:

- Interview with a corporate research scientist, page 6. Each of us has a story to tell about our career paths, and Dr. Aart Molenberg shares his story in this issue. Please contact me if you've got a few gray hairs and you're willing to be interviewed for a future issue.
- Announcements of prestigious professional awards, advancements and relocations of SFB members can be found on page 8.
- Highlights of the student activities at the SFB Annual Meeting, page 19.
- Making sure we maintain a steady stream of short technical articles from members, Special Interest Group Representative Steve Little has created a timetable for submission of articles to the *Forum*. Please see page 7 to find out when yours is due. It's the responsibility of the SIG chair to make sure the article is submitted on time, but contributions can come from any SIG member.
- A technical article about computer modeling to predict biomaterials degradation and drug release, which may be of special interest to Cardiovascular SIG members, can be found on page 11.
- Industrial news (page 15)—investments in the medical device industry continue to fall while corporate acquisitions continue. Wearable medical technology will soon be the rage—think about how biomaterials fit into that sector, and maybe your good idea will lead to a start-up or corporate success. A company in Korea reports carbon nanotubes lead to the creation of an artificial nose with a sense of smell comparable to a human nose. There's also a commentary on the medical device tax from one of the SIGs.
- Assistant Professor Yusef Khan reviews topics of interest to those involved with biomaterials education on page 16.
- In the book review corner: A textbook suitable for graduate education— *Polymeric and Self Assembled Hydrogels: From Fundamental Understanding to Applications* (page 18).

This magazine is one of several venues to share important news and views with the wider biomaterials community. If you've got something to say about biomaterials, I invite you to submit a contribution for publication in the next issue of the *Forum*. Please send it to me at Lkuhn@uchc.edu.

Best wishes,

A handwritten signature in black ink that reads "Lisa Kuhn". The signature is written in a cursive, flowing style.

Biomaterials Forum Executive Editor
University of Connecticut Health Center



The Growth of Student Chapters

There has been a quietly dramatic change in the number of student chapters in the Society. Before 2010, the Society had seven student chapters. The last count indicates the Society now has 23 student chapters, an increase of more than 220 percent. It is also worth noting that new chapters are forming at universities all over the country. The newest chapters are at Johns Hopkins University, North Carolina State University, Northeastern University, Syracuse University, University of California Los Angeles, University of Connecticut Health Center, University of Michigan, University of Rochester, University of South Dakota and Vanderbilt University.

I was startled when I learned about the increase in the number of student chapters. This is a clear confirmation of the vitality of the Society! Looking back at what may have contributed to such an increase, I cannot help but congratulate our previous leaders on a number of forward-looking initiatives that have helped SFB embrace student members.

Consider the Biomaterials Days. Since 2009, SFB has been awarding substantial grants—each in the order of \$5,000—to universities or groups of universities for organizing a day of presentations and discussions on biomaterials-related topics and invite local researchers and students to join the fun. For example in 2012, four Biomaterials Days were organized by the University of Memphis, University of Florida, Duke University and Rice University in collaboration with Texas A&M University and University of Texas at Austin involving a total of 460 participants. Students are invited to join these meetings, and many of these

students find a renewed interest in biomaterials and become active participants in Society activities. Although many factors contribute to the formation of a student chapter, it is worth noting that 15 of the 23 chapters originated in locations sponsoring a Biomaterials Day since 2009.

We also need to pay great tribute to the efforts of our Education and Professional Development Committee. The Chapter Improvement Grant Application allows student chapters to request funds for projects related to the overall goals and objectives of the Society. Innovative projects have been approved with a variety of activities ranging from company tours to outreach events. Importantly, such projects keep the chapters strong and active and attract new students to their memberships.

Engaging students early in their careers in the Society should be one of the primary goals of the Society, as it will ensure its future growth and health. Currently, SFB's finances are in excellent shape. This is the right time for all of us to engage in the formation of new student chapters and other activities, such as Biomaterials Days, that can be partially supported by the Society. Students are the future of this field. The technical and organizational skills we can offer them through the formation of student chapters can be transformative for them and the Society For Biomaterials.

Antonios G. Mikos
President, Society For Biomaterials

Hello from Society For Biomaterials headquarters! As we gear up for 2014, the annual meeting and budget preparation, we are looking through a new lens: the long-range plan adopted by Council in April 2013. Thank you to the members who took the time to provide input on the long-range plan through a series of surveys distributed to all members, committees and Special Interest Groups. In 2014, the Society's board of directors, governing council, committees, task forces and SIGs will be working to advance the Society's mission in new ways as described below.

Awards, Ceremonies and Nominations – Chair Nicholas Peppas

The Awards, Ceremonies and Nominations Committee is soliciting nominations for the 2014 awards and the President-Elect and Member-At-Large position for the 2014-2015 program year. The deadline for award nominations has been changed to September 20, 2013. The deadline for officer nominations is September 20, 2013.

Bylaws – Chair Jiro Nagatomi

The Bylaws Committee is focusing on methods to further engage industry members and reviewing the bylaws for any inconsistencies created by past amendments.

Devices and Materials – Chair Andy Doraiswamy

The committee is exploring ways to further engage industry members and to re-invigorate the award nominations being solicited for the Society's industry awards. In addition, the committee submitted three proposals for the 2014 annual meeting program focused specifically on delivering content for industry members.

Education and Professional Development – Chair William Murphy

The EPD Committee is soliciting grant applications for the 2014 Biomaterials Days grant program and the 2014 C. William Hall Scholarship. All student chapters are invited to submit Biomaterials Day grant applications by September 16, 2013. Notifications will be made by October 31, 2013. Each grant winner will receive \$5,000 toward the cost of hosting an educational event. This program has grown tremendously over the last four years, and we encourage all student chapters to apply! For more details about the program and an application, visit http://www.biomaterials.org/biomaterials_day_grantinfo.cfm.

Undergraduate students interested in attending the SFB annual meeting should apply for the C. William Hall scholarship. This award honors the memory of the Society's first president, Dr. C. William Hall. The recipient of the C. William Hall Scholarship will enjoy all-expenses-paid participation in the Society For Biomaterials 2014 annual meeting. This includes airfare, hotel, transfers, registration and meals. (Some limitations apply.)

Finance – Chair Lisa Friis

Development of the 2014 budget is underway. With the Society in great shape financially, the committee will focus on funding programs that deliver value to our members, expand membership and reduce dues and registration costs.

Liaison – Chair Dave Puleo

The Liaison Committee continues its efforts to coordinate and collaborate with other societies. We are pursuing interactions with domestic and international organizations encompassing engineering, life and clinical sciences. Initiatives under consideration at the moment include collaboration with the World Biomechanics Congress and the Materials Research Society. If you are interested in furthering collaborations with another society, please contact headquarters.

Long-Range Planning – Chair Nicholas Ziats

The committee has prioritized the objectives in the long-range plan adopted by Council in April. The complete plan is available by request—please contact SFB headquarters for more information. Charges have been distributed to pertinent committees, and budget requirements are being outlined for the 2014 budget.

Meetings – Chair Antonios Mikos

The 2014 meeting will take place in Denver, April 16-19, 2014, and the 2015 meeting will take place in Charlotte, N.C., April 15-18, 2015. The committee will begin planning for the 2014 Bash and site selections for 2016 and 2017 in the near future. The 2015 annual meeting will be co-chaired by Peter Edelman, PhD, Boston Scientific, and Helen Lu, PhD, Columbia University.

Membership – Chair Horst von Recum

The committee will be focused on promoting membership, marketing and the continued development of student chapters.

Program – Chair Joo Ong

The 2014 Program Committee received 92 ideas for sessions for the 2014 meeting in Denver. For the first time, SIGs reviewed the Program Committee's recommended combinations prior to the request for full proposals. It is hoped this will avoid content overlap and enable more appropriate distribution of the abstracts that are received. Proposals will be requested in early August, and the call for abstracts will be published by Labor Day. The abstract deadline will be in early November. Additional details will be made available on www.biomaterials.org as they become available.

Publications – Chair Alan Litsky

The Publications Committee continues its work with the bi-weekly e-newsletter the *Biomaterials Bulletin*. In addition, the Committee will be working with the website redesign task force on a complete overhaul of the Society's website in the months ahead. Please send any suggestions for website services or functionality to webeditor@biomaterials.org.

National Student Chapters – President Beth Pollot

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

Special Interest Groups – Representative Steve Little

The priorities for the SIGs in 2014 are to: increase the value of the SIGs, grow the SIGs and develop content for the 2014 meeting. SIGs are budgeting for 2014 accordingly, and the publication of the *SIGnal* newsletter continues on a monthly basis.

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

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Biomaterials Community

BMES Annual Meeting
September 25-28, 2013
Seattle
www.bmes.org

TERMIS-AM Conference
November 10-13, 2013
Atlanta
www.termis.org

ASTM International F04 Fall meeting
November 12-15, 2013
Jacksonville, Fla.
www.astm.org

Interview with Aart Molenberg, Corporate Research Scientist

Degrees held: PhD, MS in Chemical Engineering

Job affiliation: Institut Straumann AG, Research department, Basel, Switzerland

Q: In what subject area did you get your undergraduate and graduate degrees, and where did you get those degrees?

A: MS in chemical engineering with a specialization in organic materials science (i.e. polymers) and PhD in polymer chemistry and physics.

Q: Did you do a post-doc?

A: Yes, in industry (Novartis, Ciba Vision).

Q: What jobs have you held throughout your career?

A: After my post-doc year, I was offered a position at Ciba Vision, where I worked on novel contact lens materials. After that, I moved to a start-up company, Kuros Therapeutics, where I worked on the development of hydrogels for hard- and soft-tissue augmentation. When Kuros was bought by the dental implant manufacturer Institut Straumann AG, I moved there and worked on further developing the hydrogel technology for dental applications.

Presently, I hold the position of Head of Biomaterials and Surfaces Research within Straumann's Research department, and I am responsible for a group of researchers focusing on implant surfaces as well as dental bone and soft tissue regeneration.

Q: What attracted you to a position at your present institution/corporation/regulatory agency?

A: I was attracted to working in a medium-sized organization where one can realize many of their ideas. Working on medical devices is rewarding because one works on challenging products relevant to peoples' lives, and the time between product idea to market launch takes a number of years (versus decades in pharma).

Q: When did you first take your job? How long have you been working there?

A: I took my first job in October 1997 and stayed there for 3.5 years at Ciba Vision (including the post-doc year), then worked about a year and a half at Kuros. After the company was sold to Straumann, I gradually transferred to the latter. At Straumann, I've been working here for about 11 years with about eight years as a group leader.

Q: What different positions have you held at your corporation?

A: R&D scientist, group head.

Q: How is the line drawn between basic science and applied science at your organization?

A: Within the company, we only do applied research, such as aiming at new or improved products. We do, however, support basic research, done by external partners, that is more focused on understanding the interaction of tissue with biomaterials.

Q: What are some of your favorite aspects about working at your organization?

A: The possibility to realize my own ideas and, in cooperation with others, to find solutions to problems.

Q: What do you do in a typical week?

A: I keep track of the progress the members of my team make and advise them as needed, and I plan experiments to be performed by our lab team. Furthermore, many discussions take place within multi-disciplinary project teams on how to proceed with the various research and development projects for our group. Also, everybody in the research department acts as a specialist in her/his own field and is often asked for advice. Last but not least, I manage a number of external collaborations (e.g. with university groups) in terms of obtaining regular updates and assisting with contract negotiations.

Q: How did your college education and postdoctoral training (if relevant) prepare you for the job you do today?

A: The chemical engineering education taught me the approach to problem solving, and my PhD project taught me how to be successful in a complicated project. An internship in Amoco's research laboratories in Naperville, Ill., gave me my first valuable insights in industrial research and helped me to decide to pursue a career in industry. During my post-doc year in Switzerland, I learned a lot about working in a large medical device/pharmaceutical company.

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

A: A broad spectrum ranging from (cell) biology over chemistry and materials science to physics in order to be able to grasp all aspects of the job. Also some knowledge of psychology is a big help in most jobs.

Q: What are the websites where interested readers can find out more about your company and check for job openings?

A: www.straumann.com and <http://www.straumann.com/en/home/jobs-and-careers.html>

Q: What are key qualifications or job expectations for someone seeking employment at your organization?

A: It depends of course very much on the specific vacancy to be filled, but important are in all cases the ability to work in a team. A solid background in materials science is certainly helpful for those who seek employment in research, development or regulatory affairs.

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

A: Go to Switzerland, because it turned out to be a place with many opportunities in the biomaterials field.

Q: Please share what you think are the most exciting new biomaterials/tissue regeneration developments as of today and where you think the future of biomaterials/tissue regeneration is going?

A: In my eyes, some of the most promising biomaterials for drug delivery and many other applications are in situ formed hydrogels, because of their generally excellent biocompatibility and the many possibilities to adjust their properties. The future of biomaterials will go to ever-smarter materials that adjust better and better to their hosts' needs.



SIG Schedule For *Forum* Article Submission

SIG News
Steve Little
SIG Representative

ISSUE	DEADLINE*	SIG	REPORTER	EMAIL
4Q 2013	Oct. 9, 2013	Biomaterials Education SIG	Gregory Hudalla	ghudalla@uchicago.edu
4Q 2013	Oct. 9, 2013	Biomaterials and Medical Products Commercialization SIG	Nihar Shah	nihar.shah@uky.edu
1Q 2014	Jan. 10, 2014	Dental/Craniofacial Biomaterials SIG	Sachin Mamidwar	smamidwar@orthogencorp.com
1Q 2014	Jan. 10, 2014	Drug Delivery SIG	Scott Guelcher	scott.guelcher@vanderbilt.edu
2Q 2014	April 30, 2014	Engineering Cells and Their Microenvironments SIG	Adam Feinberg	feinberg@andrew.cmu.ed
2Q 2014	April 30, 2014	Nanomaterials SIG	Steven Eppel	sje@case.edu
3Q 2014	July 10, 2014	Ophthalmic Biomaterials SIG	Morgan Fedorchak	mod8@pitt.edu
3Q 2014	July 10, 2014	Orthopaedic Biomaterials SIG	Jessica Amber Jennings	jjnning@memphis.edu
4Q 2014	Oct. 3, 2014	Surface Characterization and Modification SIG	Nihar Shah	nihar.shah@uky.edu
4Q 2014	Oct. 3, 2014	Tissue Engineering SIG	Abby Whittington	awhit@mse.vt.edu
1Q 2015	Jan. X, 2015 (TBD)	Implant Pathology SIG	Floyd Karp	floyd@u.washington.edu
1Q 2015	Jan. X, 2015 (TBD)	Proteins and Cells at Interfaces SIG	Sumona Sarkar	Sumona.sarkar@nist.gov
2Q 2015	March X, 2015 (TBD)	Cardiovascular Biomaterials SIG	Natalie Artzi	nartzi@mit.edu

*Articles due in to Editor Liisa Kuhn lkuhn@uchc.edu

THEMES: 1st quarter – Pre-meeting issue, awardees featured; 2nd quarter – Letter from new President, annual meeting recap; 3rd quarter – SIG highlight issue; 4th quarter – officer nominees for upcoming election



Greetings to all Society members! I am honored to serve as the Member-at-Large for 2013-14, and I would like to thank Nick Ziats for his excellent service in this role last year, as well as the help and advice he has given me. I thought it would be helpful to begin my term by reminding our readers of the functions of this position in the Society For

Biomaterials. The role of the Member-at-Large is to represent the overall members of the Society. In this capacity, I serve as an unencumbered representative of the members on both the Board of Directors and the Council of the Society. In addition, the Member-at-Large is a standing member of the Long Range Planning Committee and the Program Committee of the Society. These arrangements are made so the members always have a clear voice in the direction of the Society, and my participation in these committees and governing bodies ensures all voices can be heard. I encourage all members to bring forth ideas about the Society, meetings and anything else relevant to making the Society better.

It is also part of my duty to write this column, which highlights recent accomplishments and news about SFB members. This forum is a great way to catch up on what is happening in our community and see how SFB members are impacting the field. Please send news for future issues! As usual, SFB members have been very active and productive in the past quarter.

Dr. Susmita Bose was inducted as a Fellow of the American Ceramic Society (ACerS). Fellows are honored for “outstanding contributions to the ceramic arts or sciences; through broad and productive scholarship in ceramic science and technology, by conspicuous achievement in ceramic industry or by outstanding service to ACerS.” Dr. Bose’s research on 3D-printed resorbable ceramic scaffolds for bone tissue engineering was featured by a number of news media outlets in the past year, including the AP, BBC, NPR, MSNBC, ABC and CBS. Dr. Bose is a Professor in the School of Mechanical and Materials Engineering at Washington State University.

Dr. Stuart L. Cooper won the 2013 American Chemical Society Rubber Division Chemistry of Thermoplastic Elastomers Award. The award acknowledges Professor Cooper’s research on the chemistry and microphase morphology of polyurethane multi-block polymers, as well as his contributions in evaluating these polyurethanes as biomaterials. Dr. Cooper is Professor and Chair of the William G. Lowrie Department of Chemical and Biomolecular Engineering at Ohio State University.

ASTM International has honored **Dr. Warren Haggard** with an Award of Merit from Committee F04 on Medical and Surgical Materials and Devices. He was simultaneously inducted as an ASTM International Fellow. Dr. Haggard was cited for his

“outstanding leadership and high productivity in fostering the development and promulgation of surgical implant standards.” The Award of Merit and its accompanying title of Fellow is ASTM’s highest organizational recognition for individual contributions to standards activities. Dr. Haggard has been active in both the industrial and academic spheres biomaterials science. Dr. Haggard is a Professor and Herff Chair of Excellence in the Department of Biomedical Engineering at the University of Memphis.

Dr. Gregory Hudalla has joined the J. Crayton Pruitt Family Department of Biomedical Engineering at the University of Florida as an Assistant Professor. Dr. Hudalla’s research is focused on the development of biomedical technologies that harness the immunomodulatory potential of mesenchymal stem cells, or functional features thereof, for transplant- or implant-based therapeutics.

Dr. Ali Khademhosseini received the 2013 Owens Corning Early Career Award of the American Institute for Chemical Engineers (AIChE). Dr. Khademhosseini was cited for “outstanding contributions in applying micro/nanoscale technologies to engineer functional biomaterials for regenerative medicine.” Professor Khademhosseini was also awarded the 2013 IEEE Engineering in Medicine and Biology Society’s Technical Achievement Award to recognize outstanding achievement, contribution and/or innovation in a technical area of biomedical engineering. In addition, Dr. Khademhosseini received the 2013 Young Investigator Award from the Controlled Release Society (CRS), which recognizes a CRS member who has made outstanding contributions in the science of controlled release and is 40 years of age or younger. Dr. Khademhosseini is an Associate Professor at the Harvard-MIT Division of Health Sciences and Technology, Brigham and Women’s Hospital and Harvard Medical School as well as an Associate Faculty at the Wyss Institute for Biologically Inspired engineering.

Dr. Bob Langer received the very prestigious 2013 Wolf Prize in Chemistry in a ceremony at the Israeli Knesset in Jerusalem. He was cited “for conceiving and implementing advances in polymer chemistry that provide both controlled drug-release systems and new biomaterials”, and his award was presented by Israeli President Shimon Peres. Wolf Prizes are awarded to living scientists and artists for “achievements in the interest of mankind and friendly relations among peoples... irrespective of nationality, race, color, religion, sex or political views.” Dr. Langer is a long-standing member of SFB and has received numerous national and international awards, including the 2013 Founders Award from SFB. Dr. Langer is the David H. Koch Institute Professor in Chemical Engineering at MIT.

Dr. Grayson W. (Bill) Marshall received the 2013 Distinguished Faculty Award from the Northern California Section of the American College of Dentists. Dr. Marshall is Distinguished Professor Emeritus and Chair of the Division of Biomaterials and Bioengineering in the Department of



Dr. Warren Haggard (center) receives the ASTM International Award of Merit from Committee F04 on Medical and Surgical Materials and Devices.



Dr. Nicholas Peppas, recipient of the 2013 Benjamin Garver Lamme Award for Excellence in Engineering Education from the American Society for Engineering Education

Preventive and Restorative Dental Sciences at the University of California, San Francisco.

Dr. Jack Parr was the recipient of the 2013 William T. Cavanaugh Memorial Award from ASTM International. Dr. Parr was cited for his long-standing and distinguished leadership in promoting national and international standards for medical and surgical implants and materials. Dr. Parr has been a leader in the field of biomaterials and their clinical application, and he is a past President of SFB. Dr. Parr is Chairman and CEO at Extremity Innovations and President of the consulting firm Medical Technology Development.

Dr. Nicholas Peppas received the Benjamin Garver Lamme Award for Excellence in Engineering Education from the American Society for Engineering Education (ASEE). This award reflects Dr. Peppas' excellence in teaching, his contributions to the research and technical literature and his achievements advancing engineering college administration. Dr. Peppas is a long-standing SFB member and leader in the biomaterials community. He is recognized for his research accomplishments in biomaterials, controlled drug delivery, biomaterials and bionanotechnology. Dr. Peppas is current President of the International Union of Societies for Biomaterials Science and Engineering. He is also a past President of SFB, and he has received numerous awards from the Society. Dr. Peppas is the Fletcher Pratt Chaired Professor and Department Chair in Biomedical Engineering at the University of Texas at Austin.

Dr. Christine E. Schmidt was named Pruitt Family Professor and new Chair of the Biomedical Engineering Department at the University of Florida effective January 2013. Dr. Schmidt was also recently named a Fellow of the American Association for the Advancement of Science. In addition, she was honored with an appointment as Deputy Editor-in-Chief of the new Journal of Materials Chemistry B and member of the Executive Board for Journal of Materials Chemistry A, B and C. Her research is focused on engineering novel materials and therapeutic

systems to stimulate damaged peripheral and spinal neurons to regenerate.

Dr. Qiaobing Xu was named a Pew Scholar in Biomedical Sciences by the Pew Charitable Trusts. Dr. Xu's research is in the area of tissue engineering and nanomedicine, and he will use the Pew award to repurpose tendon fibers to create tubular vascular grafts. Dr. Xu is an Assistant Professor of Biomedical Engineering at Tufts University.

A number of SFB members contributed to a National Science Foundation report on the "NSF Biomaterials Workshop: Important Areas for Future Investments" held June 19-20, 2012. This 123-page report provides an up-to-date description of the biomaterials and identifies scientific themes, challenges and opportunities facing the field. The Workshop Organizing Committee included Dr. David Tirrell (Chair, California Institute of Technology), Dr. Kristi Anseth (University of Colorado), Dr. Dennis Discher (University of Pennsylvania), Dr. Lara Estroff (Cornell University) and Dr. Paula Hammond (Massachusetts Institute of Technology). A copy of the report may be downloaded from <http://nsfbiomatworkshop2012.caltech.edu/report/>.

In Memoriam:

We note with sadness the passing of Joseph "Joe" A. Persivale, Jr in May. Mr. Persivale was a senior research pathologist supervisor of histopathology for many years at Ethicon, Inc. in Bridgewater, N.J., until his retirement in 1995. He then worked a short time for Bristol-Myers Squibb.

The US Senate's recent vote of 79-20 to end the medical device tax made many manufacturers and patients excited. However, considering the vote was on a budget resolution, it may just be a feel-good (symbolic) vote. The medical device tax, which had gone into effect on January 1, 2013, was designed to generate about \$30 billion over 10 years to partly fund the large expenses of the Affordable Care Act (ACA). Although manufacturers and many Congress people across party lines prefer it be repealed, they do not know how to plug the resultant revenue loss. Dean Zerbe at Forbes best captured the message sent by the Senators as follows: "Yes, I'd like to replace this stupid tax by raising some unknown tax on unknown persons at an unknown time." There is certainly a possibility the medical device tax would be removed (or at least modified) in the future, but that path is undoubtedly going to be longer and more convoluted.

The industry contends the
tax will suppress innovation
and make U.S. manufacturers
globally uncompetitive.

As a reminder, this tax is a 2.3 percent excise tax on the gross sales of almost any FDA-registered "device" intended for human use—this includes almost everything from multi-million dollar MRI machines to cardiac defibrillators, stents, ultrasound equipment and relatively inexpensive items like tongue depressors. However, certain devices directly provided to patients, such as eyeglasses, hearing aids, sterile bandages and wheelchairs, have been exempted from this tax. The included exemptions will ensure industry accountants and legal teams stay busy trying to bring more and more products within these exemptions without inviting wrath from the government or the Internal Revenue Service (IRS).

There were two main ideas used to justify the levying of this tax. First, according to the government, the device industry is positioned to reap higher revenues from the ACA because it would add as many as 30 million Americans to the list of the medically insured while encouraging the use of technology to increase the efficiency of healthcare delivery. Additionally, Congress was under pressure to make the ACA "revenue-neutral," by offsetting the costs using a balance of taxes and cost reductions elsewhere in order to keep the federal budget unaffected.

However, the medical device industry feels Congress is isolating and uniquely burdening it to pay for the act. Its primary argument, as mentioned on the Medical Device Manufacturers Association (MDMA) website, is "...this tax will stifle innovation, harm patient care and weaken the position of the United States as the global leader in medical device innovation." MDMA also notes "...there is no data or studies that show the costs of this 'innovation tax' will be offset due to an increased pool of insured beneficiaries receiving treatment." In addition, the medical device industry, which is already subject to more regulations than most others, now has to deal with yet another point of reporting and compliance which brings no value to the healthcare consumer.

Scrutiny of the complete ACA will reveal that many of these arguments are not completely true. For one, the "device" tax is just one of many levied on the entire healthcare sector, not just the device industry. Congress imposed new taxes on more generous high-end health insurance policies, new annual fees on health insurers and pharmaceutical manufacturers, even a tax on indoor tanning services. Medicare taxes paid by the wealthy were increased, and flexible spending plans, which reduce taxes for middle-class workers, were pared back. Thus, there is a high probability that physicians and hospitals serving Medicare patients will see their reimbursements reduced.

Because this tax applies to both domestically produced devices as well as imported ones, there is no tax incentive for companies move manufacturing offshore. In fact, proponents believe the tax will only spur innovation as companies to come up with more cost-effective ways of manufacturing, marketing and delivering care to patients. For example, lean manufacturing practices successfully adopted by other large manufacturing industries to offset costs, such as cars and plastics, are largely absent in the medical device and other healthcare sectors.

The industry contends the tax will suppress innovation and make U.S. manufacturers globally uncompetitive. However, it is unable to cite any independent and objective study in support. When Michael Hiltzik with the *LA Times* posed this question to the Advanced Medical Technology Association (AdvaMed), the association's response included two studies commissioned by AdvaMed itself and four from libertarian or anti-tax organizations (the Pacific Research Institute, the National Center for Policy Analysis, the Business Roundtable and the Heritage Foundation). Although these cannot be claimed to be completely independent or objective, the industry continues to cite and use them.

Looking at the most recent figures, since the recent implementation of the medical device tax, manufacturers have already paid an estimated \$388,000,000 to the IRS so far this year. One may imagine this amount of money could have otherwise been directed towards investment in the development of the nation's economy, for example, via creation of jobs in

Computational Modeling of Biomaterial Degradation and Local Drug Release Facilitates Rapid Device Development, Enhanced Performance and Regulatory Evaluation

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Introduction

Biodegradable materials are popular platforms for biocompatible and tunable local drug release. However, controlling and predicting material degradation dynamics, and the associated drug release kinetics in the complex *in vivo* environment often proves challenging. Commonly, *in vivo* performance is governed by unforeseen processes that do not present in the artificial *in vitro* environment used to evaluate device performance. While experimental techniques might provide clues as to dominance of emergent *in vivo* processes, definitive identification of the mechanisms governing *in vivo* performance is limited by spatial resolution of *in vivo* imaging systems, or by the destructive, invasive nature of the assay (e.g. histology) that makes it impossible to follow the same area at multiple time points.

Computational approaches can fill experimental voids and have emerged as a crucial tool for modeling *in vivo* device performance, understanding device tissue interactions, exploring the impact of biophysical design modifications, and driving innovation beyond our intuition. The ability of computational models to parse the independent influence of each variable through the simulation of virtual experiments makes it easier to identify the determinant factors controlling material performance for a given *in vivo* setting. Modeling helps define experimental design, leading to a rapid and cheaper device development. Realizing the potential of computational modeling to foster innovation and streamline regulatory evaluation has been defined as a strategic priority of the FDA's Center of Devices and Radiological Health (CDRH),¹ and has already led to a series of collaborations between the FDA, industry and academia. The current article draws upon examples from published works to illustrate how the combination of modeling and experimental studies can provide mechanistic insight onto material fate, drug release and distribution- facilitating rapid device development and evaluation. Cardiovascular devices serve as prime examples, due to the complex dependence of their *in vivo* performance on multiple device and local physiological factors, and the lengthy and costly preclinical evaluations that they typically undergo.

Continued from previous page.

manufacturing, sales and research and development. If the industry's arguments turn out to be true, the industry has to choose from either absorbing this financial burden into its profit margins or simply passing it on to the customers. This choice, unfortunately, is not so simple. According to Bryan Wampler, a life sciences sales executive at Kronos, the impact on company margins is going to be far greater than 2.3 percent. He says "... because this is a revenue tax, not a profit tax, the margin impact is closer to 20-40 percent in most medical device companies." He speculated companies would have to focus on operational efficiency, which may include layoffs, elimination of 401k match and other measures.

However, looking at the bigger picture of the entire nation's healthcare system, repealing the tax would cost the nation \$29 billion over the 2013-2022 period. Repealing this tax would force

Congress to levy other taxes or reduce healthcare spending, and a likely target would be reduction in coverage for Americans. Additionally, repealing this particular tax may set the precedent for all other healthcare sectors to demand repeal of other revenue generation provisions in the ACA, again snowballing into more offsets or adding to the already massive budget deficit.

The media is littered with numerous realistic and many exaggerated arguments from both sides of this issue. Only time will tell whether the impact of the medical device tax, and the ACA as a whole, will benefit the nation and its citizens, or push us closer to an unsustainable healthcare system.

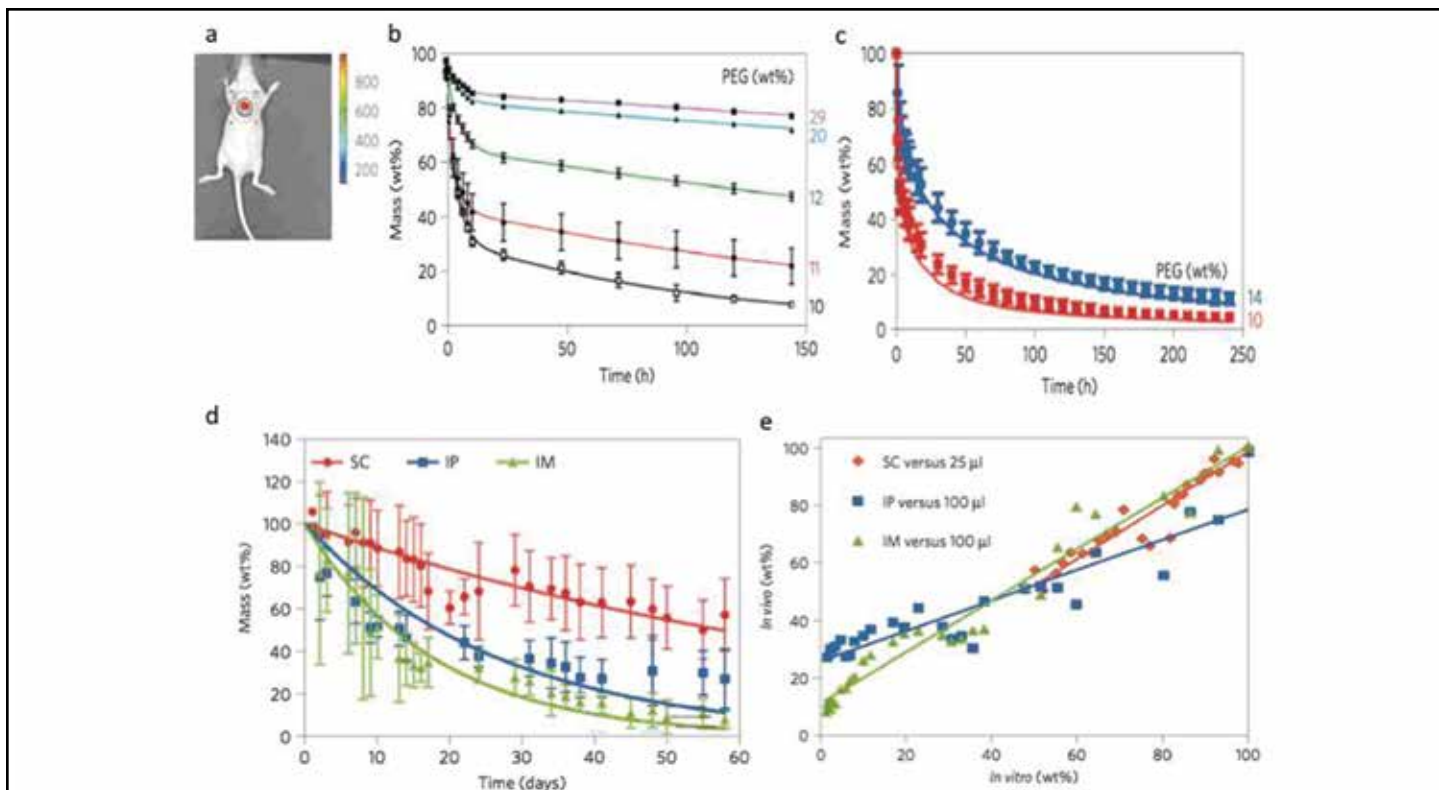


Figure 1: (a) In vivo imaging was used to follow material mass loss by tracking the loss of fluorescence signal with time. (b) Variation in PEG solid content was used to control material degradation. Degradation adhered to a dual exponential decay model. (c) The linear relationship attained between in vitro and in vivo erosion was used to predict in vivo erosion profile for two PEG compositions from their in vitro curves successfully. (d) In vivo erosion of compressed denatured type II collagen is mono-exponential but with site-dependent rate constants (Subcutaneous (SC), intraperitoneal (IP) and intramuscular (IM)). (e) Under specific conditions the in vitro erosion profile linearly correlated with the in vivo erosion; for SC implantation when in vitro erosion was performed in 25 l of PBS solution and for IM and IP when 100 l of PBS was used. Adapted from Artzi et al 2 with permission.

Modeling biodegradation kinetics measured by noninvasive optical imaging

As medical devices and coatings are increasingly designed to degrade with time, material fate in *in vivo* becomes a critical parameter determining device efficacy, integrity, mechanical properties, healing capacity, and potentially drug release kinetics and bioavailability. However, in *in vivo* performance rarely coincides with erosion *in vitro*. Material fate *in vitro* varies with material dimensions, crosslinking and composition, but also with environmental conditions and stresses that are not necessarily present in *in vivo*. Pathophysiologic conditions such as inflammation cannot be recapitulated *in vitro*, raising the question whether erosion or loss of mass in one domain can predict performance in the other. Our group addressed this concern through the development of noninvasive optical imaging to track material degradation in real time and facilitate the mathematical modeling of this process (Fig 1a).

This paradigm can be used *in vitro* and *in vivo* and in that way facilitates the examination of one factor at a time in a controlled *in vitro* environment while seeking for correlative *in vivo* behavior. This approach was applied to model hydrolytically degradable adhesive materials based on polyethylene glycol (PEG) amine and dextran aldehyde that react at body temperature in a Schiff base reaction to form adhesive materials as aldehydes bind to tissue amines.² The reaction is reversible and the material hydrolyzes to its polymeric components. We have shown that formulation protocols control erosion profiles, as network formation dictates fluid uptake and depends on the aldehyde:amine ratio (Fig. 1b). In *in vivo* and *in vitro* degradation both adhered to a dual

exponential decay model, but with different parameter values.

The kinetic model was then used to predict *in vivo* erosion kinetics of newly synthesized materials from *in vitro* data, thus minimizing the number of animals used (Fig. 1c).

In a model of enzymatically degradable materials, we quantified the erosion kinetics of compressed collagen matrices, materials increasingly used in tissue engineering applications. Erosion kinetics *in vitro* correlated best with *in vivo* behavior for specific immersion volumes that varied with implant site. A linear relationship was obtained for intramuscular and intraperitoneal erosions when 100 μ l diluent volume was used *in vitro*. In a most intriguing manner the inferred volumes and concentration align remarkably with empirically obtained values reported in the literature. The method presented in this work can be extended to include the incorporation of multiple concomitant tags for independent tracking and correlation of drug release and material loss from a polymer drug-eluting scaffold.

Computational models for drug release kinetics

In addition to the physicochemical properties and fate of the drug-containing scaffold, drug characteristics add another layer of complexity determining drug release kinetics and bioavailability. First generation and many current drug eluting stents employ durable polymer coatings to release anti-restenotic drugs. *In vitro* and computational modeling studies have revealed that drug release from such durable coatings is predominantly governed by diffusion of the drug through the polymer, though polymer hydration and drug dissolution can also influence release kinetics. Imaging studies of spray-coated stents³ reveal complex micro-distributions of drug and polymer within the coating

that depend not only on drug and polymer chemistry but also on processing conditions. Understanding the determinants of these microstructural variations, how they can be controlled and their influence on drug release has been the focus of a range of computational studies. One category of models uses percolation concepts to relate the connectivity of the drug phase in the coating to the drug load. Well below the percolation threshold drug particles are embedded in a polymer continuum so that drug release is a slow diffusion limited process. As the drug load rises, larger and larger surface connecting networks of drug emerge and lead to the observed burst release. While percolation type models have successfully modeled *in vitro* and *in vivo* drug release kinetics from coated stents^{4,5} and can be generalized to biodegradable coatings, these models are not designed to predict the dependence of drug and polymer micro-distributions on chemical properties and processing conditions. To achieve this latter goal, David Saylor and co-workers have been developing a comprehensive modeling approach using the mathematical framework of diffuse-interface theory of nucleation processes.⁶

Regardless of the actual modeling framework, most studies assume that *in vitro* and *in vivo* drug release from stents is unimpeded by the surrounding medium. While perfect sink conditions can be contrived *in vitro*, and release from certain stents is rate limiting relative to tissue transport, computational simulations illustrate that tissue transport will influence drug release kinetics from fast eluting stents and drug coated balloons.⁷ Moreover, some novel drug eluting stents⁸ (Fig. 2) and balloons⁹ incorporate the drug into an *in vivo* deployable coating. *In vitro* drug release may still be governed by diffusion,

but is then not representative of the *in vivo* release, which is tightly coupled to tissue distribution. Computational modeling offers a novel framework for understanding such coupled problems.

Mathematical modeling of tissue distribution of drug

The transformative influence of drug eluting stents on vascular medicine belies the difficulty of locally delivering drug to the arterial wall. Early failures of endovascular drug delivery devices such as catheters and stents were frequently attributed to inadequate distribution of drug into the arterial wall or to short residence times in arterial tissue. Mathematical modeling has played a pivotal role in quantifying the factors governing drug distribution and residence time in arterial tissue through the analysis of dedicated diffusion chamber and flow loop experiments with excised tissue samples. Such studies have supported the development of a computational model of drug convection, diffusion and binding to extracellular and intracellular proteins, and elucidated the dependence of transport and binding parameters on drug physicochemical properties such as molecular weight, shape and charge, as well as on tissue composition.¹⁰

The coupling of computational models of drug release kinetics and tissue transport has provided an integrated quantitative framework by which to consider the dependence of drug distribution and retention on device geometry, placement site, and release kinetics.^{7, 10} Yet total drug concentrations, as determined for example by fluorescent microscopy, are not directly predictive of local effects. Thus, only models that

resolve drug binding to intracellular receptors are able to predict the dependence of *in vivo* effects on drug load and release kinetics. Simulations using relevant parameter values for two sirolimus eluting stents predicted that intracellular receptors were fully saturated one-day post stent implantation.¹¹ At early times, only a small fraction of tissue residing drug is predicted to be receptor bound, but this fraction increases as the rate of drug release declines, eventually dominating drug retention. Moreover, parametric sensitivity analysis predicts that receptor binding is more sensitive to the rate of drug release rather than to nominal drug load, consistent with pre-clinical and

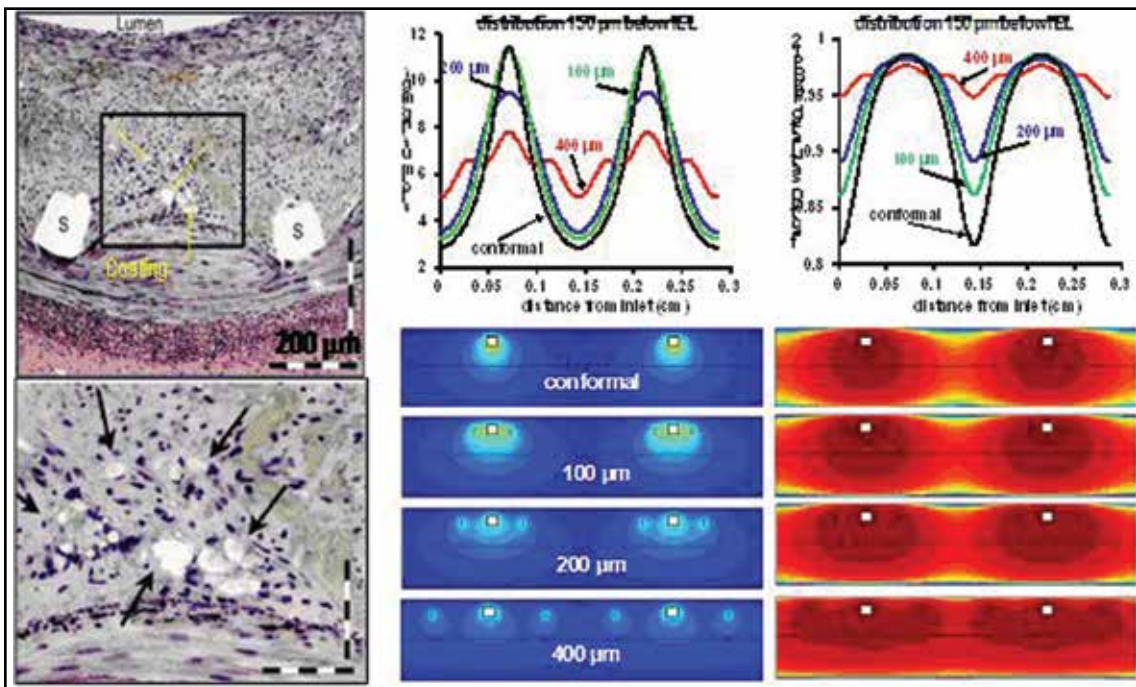


Figure 2: Flow of drug loaded coating can minimize drug gradients between struts. (Left) Histology micrographs 30 days post implantation in porcine coronary arteries. The square-shaped clear spaces represent the stent strut (S) location though the actual strut was lost during processing of the histology slides. Distinct, irregularly shaped clear spaces (black arrows) represent areas previously occupied by coating that has been lost during processing. Modeling predicted total drug (Center) and receptor-bound drug (Right) based on the assumptions that the coating moves lateral relative to the stent strut, that both struts have the same amount of coating migration and that (in this example) approximately 30% of the coating migrates. All color schemes are uniform (0–1 for bound receptors; 0–40 ng/mg for deposited drug). “Conformal” refers to strut-adherent coating and the numbers 35, 100 and 350 represent relative distances from the stent strut. Adapted from Carlyle et al 8 with permission.

clinical experience. This modeling framework is helping device companies predict how changes in release kinetics will alter device performance. It can also be used for model based prediction of drug elimination kinetics, instead of the prevailing and costly practice of extending *in vivo* studies until the lower level of quantitation is reached. Moreover, when drug release and tissue distribution are fully coupled, modeling offers the only way by which to understand device performance. For example, when crystalline drug is incorporated within a flowable stent coating, standard experimental methods cannot discern between coating-residing and interstitial or intracellular drug, and can only quantify the total amount of delivered drug. We used histology to identify the deployed polymer coatings in the arterial wall (Fig. 2 Left) and computational modeling to understand the dependence of drug distribution on the migration of flowable coating relative to the struts (Fig 2. Center). Modeling demonstrates that at small migration distances drug deposition is enhanced due to greater surface area of elution. Above some threshold distance, deposition is also enhanced by saturation of binding sites that are otherwise free in the strut-adherent case (Fig 2. Right). Thus, computational modeling can help streamline device development when the mechanisms of action are well characterized, or support the development of innovative technologies where experimental methods only provide partial insight.

Summary

Modeling and simulation increase engineering and scientific understanding of medical devices through evaluation of design variations, simulation of a multitude of use conditions, or visualization of complex processes and data at relatively low cost. Advances in the fields of medical imaging and computational modeling have revolutionized the way medical outcomes and medical devices are understood. Noninvasive imaging now enables tracking material fate *in vivo* continuously. Correlations between *in vitro* and *in vivo* domains infer on the factors controlling *in vivo* material fate, and help identify *in vitro* clinically relevant conditions that can be used to predict *in vivo* performance. Similarly, modeling and imaging along with conventional analytical techniques can be used to understand the factors controlling drug release, tissue distribution and mechanism for *in vivo* drug retention.

References:

- ¹ Regulatory science in FDA's Center for Devices and Radiological Health: A vital framework for protecting and promoting public health; 2012.
- ² Artzi N, Oliva N, Puron C, et al. *In vivo* and *in vitro* tracking of erosion in biodegradable materials using non-invasive fluorescence imaging. *Nat Mater*. Sep 2011;10(9):704-709.
- ³ Balss KM, Llanos G, Papandreou G, et al. Quantitative spatial distribution of sirolimus and polymers in drug-eluting stents using confocal Raman microscopy. *J Biomed Mater Res A*. Apr 2008;85(1):258-270.
- ⁴ Barocas V, Drasler W, 2nd, Girton T, et al. A dissolution-diffusion model for the TAXUS drug-eluting stent with surface burst estimated from continuum percolation. *J Biomed Mater Res B Appl Biomater*. Jul 2009;90(1):267-274.
- ⁵ Hossainy S, Prabhu S. A mathematical model for predicting drug release from a biodegradable drug-eluting stent coating. *J Biomed Mater Res A*. Nov 2008;87(2):487-493.
- ⁶ Saylor DM, Guyer JE, Wheeler D, et al. Predicting microstructure development during casting of drug-eluting coatings. *Acta Biomater*. Feb 2011;7(2):604-613.
- ⁷ Balakrishnan B, Dooley JF, Kopia G, et al. Intravascular drug release kinetics dictate arterial drug deposition, retention, and distribution. *J Control Release*. Nov 6 2007;123(2):100-108.
- ⁸ Carlyle WC, McClain JB, Tzafirri AR, et al. Enhanced drug delivery capabilities from stents coated with absorbable polymer and crystalline drug. *J Control Release*. Sep 28 2012;162(3):561-567.
- ⁹ Kolachalama VB, Pacetti SD, Franses JW, et al. Mechanisms of Tissue Uptake and Retention in Zotarolimus-Coated Balloon Therapy. *Circulation*. Apr 12 2013.
- ¹⁰ Hwang CW, Wu D, Edelman ER. Impact of transport and drug properties on the local pharmacology of drug-eluting stents. *Int J Cardiovasc Intervent*. 2003;5(1):7-12.
- ¹¹ Tzafirri AR, Groothuis A, Price GS, et al. Stent elution rate determines drug deposition and receptor-mediated effects. *J Control Release*. May 26 2012;161(3):918-926.



Venture investing in the medical device industry continues to be on the decline, according to a report from PricewaterhouseCoopers/National Venture Capital Association report using data compiled from Thomson Reuters. During the first quarter, venture investing was down 20 percent in terms of dollars invested. In

addition, there was a 10 percent decrease in the total number of venture-investing deals compared to the previous quarter. For 2012 Q1, medical equipment and device investment dropped by \$409 million. While there were 71 closed venture investment deals, this is approximately 10 percent less than the previous year. Less money is now going into capital-intensive sectors like the life sciences and clean technology. In particular, first-time deals are on the decrease.

UK-based orthopaedic implant manufacturer **Smith & Nephew** has announced the acquisition of Pune-based **Adler Mediequip Pvt Ltd**, including the brands and assets of **Sushrut Surgicals Pvt Ltd**, a leader in mid-tier, orthopedic trauma products for India. The transaction was made for an undisclosed sum to the Pitre family. The announcement stunned some in the industry, as Sushrut-Adler Group Managing Director Ajay Pitre has been an outspoken champion of domestic medical manufacturing. The acquisition will give Smith & Nephew a well-established platform to develop products for India's mid-tier market and for export. In particular, it gives Smith & Nephew an entry point to India's fast-growing trauma segment. The news sent shock waves through India's device industry, as Pitre is Chairman of the **Confederation of Indian Industries, Medical Equipment Div.** and member of a core committee advising Indian regulators on medical device regulations and implementation strategies.

Wearable technology such as smart watches, fitness monitors, shoes and headsets, is the next big trend, says Credit Suisse analysts in a report published recently. Companies need to pay attention to this field because it will have a "significant and pervasive impact on the economy." The market will grow rapidly in the next three to five years, from about US \$3 billion to US \$5 billion today to US \$30 billion to US \$50 billion. Many of these devices will be fitness and wellness gadgets, but wearable devices have great potential in medical technology as well. Examples of wearable medical technology for patients include T-shirts that track patients' location and vital signs, headsets that track EEG and knitted fetal monitors. Medical wearable devices have complex hurdles to overcome, however. One challenge is the difficulty of securely storing and transferring electronic health records.

The Supreme Court unanimously ruled normal human genes cannot be patented. Writing for the court, Justice Clarence Thomas explained, "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated." In *Association for Molecular Pathology v. Myriad Genetics*, No. 12-398, the Court ruled manipulating a gene to create a synthetic version, however, makes it eligible for patent protection. The genes at the heart of the case were BRCA1 and BRCA2, which have been linked to an increased risk of breast and ovarian cancers. While Myriad did isolate a useful gene, the act of isolating it from "surrounding genetic material is not an act of invention," explained Justice Clarence Thomas. Over the past three decades, U.S. patents have been granted to more than 4000 human genes. Before the ruling, the biotechnology industry predicted a decision against Myriad would put in jeopardy billions of dollars in investment.

Medical superglue was used to halt brain bleeding in an infant, named Ashlyn Julian, according to Channel 5 in Kansas City. Physicians discovered the three-week-old baby had an aneurysm in her brain. This aneurysm had reached the size of an almond. Since Ashlyn's brain had already gone through two periods of bleeding, cutting through her skull wasn't considered an ideal choice. Since infant brain bleeding is very rare, there aren't many tools available to help physicians with this type of case. To save the child, the doctor threaded a hair-thin microcatheter through Ashlyn's hip and into her brain. This microcatheter was then threaded directly into the aneurysm. This is the first time that surgical superglue has been injected into an infant's brain. Biomaterials to the rescue!

Stratasys (Eden Prairie, Minn.), makers of 3-D printers for healthcare applications including rapid prototyping and R&D, has made a power play in the 3-D printer market by acquiring **MakerBot**. The merger, which is expected to be finalized in third-quarter 2013, will expand Stratasys's already wide range of industrial 3-D printers to include desktop 3D printers produced by MakerBot. MakerBot's brand of small 3-D printers intended for home use have become a staple among 3-D printing enthusiasts and have gathered a loyal following among prosumers including engineers, designers, architects, manufacturers, entrepreneurs and individuals, for professional purposes, as well as for personal applications. MakerBot's Thingiverse.com, is the largest collection of downloadable digital designs for making physical objects, including some medical devices and prototypes.

Wright Medical Group (Arlington, Tenn.) announced it will sell its **OrthoRecon** business to **MicroPort Medical BV** for \$290 million. The company plans to refocus its core business on biologics and extremities. In 2012, Wright's OrthoRecon

(Continued on page 16)

Biomaterials Education: New Challenges and New Opportunities



Three-and-a-half years ago this column was introduced to the *Biomaterials Forum* by Jan Stegemann as a place to highlight news and information related to biomaterials education, and since then it has been faithfully and expertly maintained by him. The column has featured articles discussing teaching strategies within

the classroom, examples of successful educational programs, integration of new technologies and the relevance of biomaterials education to a stronger workforce, to name a few. With his appointment as Member-at-Large for SFB, he has stepped down as Education Editor and given me the opportunity to take over the position as editor of this column. I'm very appreciative of this opportunity, and I hope to provide as stimulating a forum as he has. Obeying the mantra "If it ain't broke, don't fix it," I plan to use the original format as a template and to solicit SFB members and education experts beyond SFB for contributions. I welcome ideas and submissions from students, faculty, administrators and members of industry alike, and occasionally I will interject my own thoughts on a particular topic. Above all, this is your column, your place to share ideas, concerns and knowledge related to biomaterials education. I encourage and look forward to your participation.

I am currently an Assistant Professor at the University of Connecticut Health Center and the UCONN Engineering School, and I have been teaching Introductory Biomaterials for the last eight years. I've also been active in NSF-funded Research Experience for Undergraduates (REU) programs, mentored undergraduates, graduates and post-doctoral fellows, and I'm a member of the SFB Biomaterials Education SIG. During these years I've become acquainted with the challenges associated with teaching biomaterials, a truly multi-disciplinary course, to undergraduates and new graduate students who come to the discipline with varied background knowledge. I've also seen how the teaching

landscape has and continues to evolve with both the advent of new technologies and the development of novel pedagogical approaches to teaching. With these thoughts in mind, I've listed a few areas of my particular interest related to biomaterials education I hope to cover in this column. Perhaps these topics will spark an interest in you as well. If so, and you are interested in submitting an article on these topics or if you have other topic areas you think would be of interest please do contact me (ykhan@uchc.edu), and I will facilitate the process.

STEM Education

This is an important time for Science, Technology, Engineering and Mathematics (STEM) education, an arena within which biomaterials education is firmly seated. Recruiting students to STEM fields, retaining these students throughout their education, and understanding when to start reinforcing an interest in STEM fields in pre-college education are important, timely topics that will hopefully find an audience here. I encourage those with an interest and/or knowledge in this area to consider providing input.

MOOCs

Massive Open Online Courses (MOOCs) are here. These open-access, web-based courses, initially centered around individual educational institutions like Harvard and MIT, have blossomed over the past two years, and through companies like Coursera, Inc., are attracting the attention of higher education institutions around the country. The concept isn't confined to higher education either. The Khan Academy has been around since 2006 and has amassed more than 4,000 educational, web-based videos directed towards K-12 education. Are MOOCs good? Are they bad? Are they the future of higher education or a passing fad? We will discuss MOOCs in this forum, and I look forward to input from stakeholders in web-based education or perhaps those already using this approach for their classroom.

Continued from previous page.

pulled in \$269 million. A significant part of this haul came from sales of knee and hip reconstruction implants. Wright expects the deal to be completed by the end of this year. Once it has sold off OrthoRecon, Wright will refocus on its foot-and-ankle business, a fast-growing division. Last year, Wright Medical's extremities segment landed \$214 million in total sales. For 2013, the company expects growth of 12 percent. With the extra funds from the sale, the company can also improve its biologics implant product line. In March of this year, Wright landed a \$190 million deal for **BioMimetic Therapeutics**, a regenerative medicine company.

Chemical engineers in South Korea have successfully created an artificial nose with a sense of smell comparable to a highly trained human expert's nose. The nose, called a nanobioelectronic nose (nbe-nose), was able to detect smells at concentrations of as low as 0.02 parts-per-million (ppt)-equivalent to human levels. The nbe-nose was also able to detect odors in gas form, which more closely mimics how the human nose works. Mimicking the human sense of smell, or olfaction, has a wide variety of current and potential benefits including health, security and environmental. Currently, "artificial noses" are used in laboratories and industry to monitor quality control and prevent problems such as contamination and spoilage.

Novel Teaching Methods

Styles of teaching and lecturing are changing, partly via the technology available to professors. Effective teaching methods are becoming more and more important as top institutions begin hiring faculty solely to teach STEM-related courses rather than in addition to developing research programs. As new undergraduates enter higher education, they arrive with a different educational experience than many of us had at the pre-college level. What new teaching methods and strategies are being implemented? How do we harness new technology, social media and novel teaching styles to improve biomaterials education? This column will examine these new tools and how they are being utilized at all levels of STEM education.

Curriculum and Program Development

While many universities have long-established biomaterials programs with well-developed curricula, there are many still in the midst of establishing themselves. A biomaterials curriculum is truly multi-disciplinary, and can be challenging to develop at the undergraduate level given the required background in both the biological and materials-based sciences. What lessons have been learned by the established programs? What would they do differently if they could start from scratch? What input would students offer based on their experiences in biomaterials undergraduate education to a newly founded program? This column will discuss biomaterials curriculum development, course content, the ideal textbook and associated challenges, to name a few.

SFB and Biomaterials Education

How can SFB nurture discussion of these topics? The Biomaterials Education SIG organizes sessions at the annual meeting pertaining to aspects of biomaterials education. Past sessions have discussed curriculum development and other related topics to biomaterials education. Do you have ideas for future annual meeting sessions? Any thoughts about how the Society can be better integrated into biomaterials education? Do you have some SFB-related teaching activities to tell us about? Let me know.

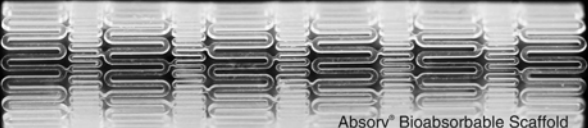
Once again, I would like to thank Jan Stegemann for his contribution to establishing, maintaining and growing this column, and I congratulate him on his appointment as Member-at-Large. I am excited to carry the torch for him and continue populating this column with timely, relevant and informative topics related to biomaterials education. I look forward to working with the greater SFB community and encourage participation. In keeping with the column's traditional closing, I leave you with this:

Education Quote of the Quarter:

"The best teacher is the one who suggests rather than dogmatizes and inspires his listener with the wish to teach himself."


- Edward Bulwer-Lytton

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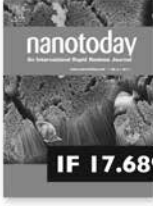
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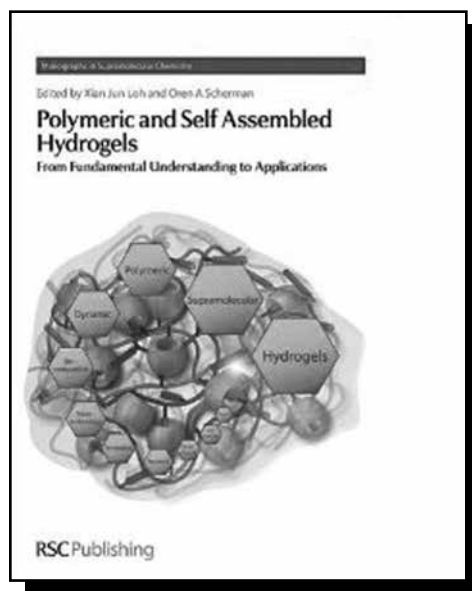
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Materials Science



Polymeric and Self Assembled Hydrogels: From Fundamental Understanding to Applications
By Loh, Xian Jun; Scherman, Oren A.; Gale, Philip
(RSC Publishing, 2012).
Retrieved from <http://www.ebilib.com>
Print ISBN: 9781849735612
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The interest in the use of hydrogels for medical applications has grown exponentially over the past decade. Hydrogels are now being explored for use for drug delivery and tissue engineering in cardiovascular, dental and craniofacial, ophthalmology, orthopaedics, and skin and other organ applications. It is then imperative that in our curriculum for future bioengineers as well as others in the field to address the basic science of hydrogels for medical applications. The book, *Polymeric and Self Assembled Hydrogels: From Fundamental Understanding to Applications*, provides an excellent resource for teaching about hydrogels.



The chapters include the following topics:

- Chapter 1. Introduction. Xian Jun Loh and Oren A. Scherman
- Chapter 2. Fabrication, Structure, Mechanical Properties and Applications of Tetra-PEG Hydrogels. Mitsuhiro Shibayama and Takamasa Sakai
- Chapter 3. Supramolecular Hydrogels. Jesús del Barrio, Eric A. Appel, Xian Jun Loh and Oren A. Scherman

- Chapter 4. Synthesis and Properties of Slide-Ring Gels. Kazuaki Kato and Kohzo Ito
- Chapter 5. Peptide and Protein Hydrogels. Lawrence J. Dooling and David A. Tirrell
- Chapter 6. Chemomechanical Hydrogels: Selective Response towards External Effector Molecules. Hans-Jörg Schneider
- Chapter 7. Injectable Temperature- and pH/ Temperature-Sensitive Block Copolymer Hydrogels. Cong Truc Huynh and Doo Sung Lee
- Chapter 8. Hydrogels for Biomedical Applications. Xian Jun Loh, Tung-Chun Lee and Yoshihiro Ito
- Chapter 9. ReGel™ Hydrogels for In Vivo Applications. Kirk Flowers
- Chapter 10. Biomedical Applications for Hydrogels: Poly(vinyl alcohol)-Based Hydrogels for Embolotherapy and Drug Delivery. Andy Lewis and Clare Heaysman
- Chapter 11. Outlook. Xian Jun Loh and Oren A. Scherman

The introduction provides the groundwork for the remainder of the book. Chapters two through seven present the context for different hydrogels, including fabrication and materials and mechanical properties of various hydrogels. Chapter eight is a very good review of the biomedical applications currently of interest to the medical community. In addition to providing a description of ReGel™ Hydrogels, chapter nine illustrates many of the issues regarding the translation of the use of hydrogels to the medical setting.

This text provides the appropriate material to augment the teaching of hydrogels to an upper-level undergraduate class. The text is easy to follow with appropriate illustrations. However, this is not a superficial treatment of the included topics. Each chapter can be read individually—containing enough material to provide a basic understanding of the principles involved. Each of the chapters reviews the historical context of its topic while providing a current review (as current as a book can be) of the literature. This text is also a resource for academics and industrial scientists—especially with the extensive bibliographies provided for each chapter.

Student News from the Annual SFB Meeting and Exposition



This year at the SFB conference there was a great turnout of members at both the student luncheon as well as the National Student Chapter meeting. The student luncheon had more than 200 students in attendance as well as 15 mentors. The invited speaker was Joel Corbett from Poly-Med, Inc. He gave a wonderful

talk about the finer points of job seeking and helped prepare students for life after completing their degrees. As he spoke about cautionary tales from job interviews, highlighting skill sets required on the job-hunting trail and the importance of knowing the market, the venue provided a platform for each table mentor to share their experiences and trials while finding their own positions as well as offering advice to the students around them.

The National Student Chapter meeting saw student organizations from University of Rochester, University of Texas at San Antonio, Clemson University, North Carolina State University, and University of Connecticut Health Center, just to name a few. These groups really helped facilitate spirited discussion. Discussions included the strategies each organization was employing for greater member outreach, how these plans were succeeding and the needs of students across the country. The University of Rochester chapter, for example, has been supporting access to biomaterials and bioengineering education for students in elementary, junior and senior high schools through hands-on activities as well as teaching them about the path to become a researcher. The most prominent topic discussed was how to utilize the resources available to each student group on the Society For Biomaterials webpage. Under the "Students" section, there are chapter meeting ideas, chapter fund-raising ideas, textbook discounts, an SFB Career Center as well as information available to students who would like to start a chapter at their own institution.

After the meeting was concluded, students were able to stick



University of Rochester students demonstrate gas volume and temperature principles to 4th graders.

around and participate in mock interviews with Joel Corbett and Paul Attar from Bridge PTS, Inc. These mock interviews lasted

about 10-15 minutes, with feedback provided on resumes, CVs and their interview skills. Hopefully, we will be able to find a way to include mock interviews and resume workshops at next year's conference for students, since this was an extremely popular portion of the meeting.



Students await their turn with Joel Corbett from Poly-Med, Inc. for a mock interview.

Over the past year, the student organizations have had tremendous support from the Society. There are more activities and resources put on by the Society at the annual meeting and throughout the year. This year, student organizations were invited to submit an outreach project for middle school science classes to teach them about biomaterials. Case Western Reserve University took home first prize for its work involving Jell-O, along with a \$2,500 prize from the Society. The student luncheon and mock interviews would not have been as successful without mentors from the Society supporting each event. Throughout the year, the Society supports student groups with travel awards to conferences as well as support for Biomaterial Days conferences. As our numbers continue to grow, it is imperative to the success of every student chapter this support continues. Increasing involvement from students within the Society is also vital to success of student organizations and the Society itself. Students are strongly encouraged to join the Society's Special Interest Groups (SIGs). These groups provide a smaller network within the Society for collaborations and sponsored events through the year and program content for the annual meeting. In every SIG, there are student positions available, since having a student perspective is felt to be extremely helpful and therefore supported by members of the Society. With greater student involvement within the Society, more support from the Society comes back to the students and the student chapters. The next year is upon us, and preparations for the 2014 annual meeting are already underway and will provide a new frontier for the Society and student chapters to grow together to increase collaborations, mentorships and outreach of the world of biomaterials.

Immune Engineering: New Special Interest Group Proposed

We are proposing formation of a new SIG for Immune Engineering in the Society For Biomaterials. For many years, the field of biomaterials has involved immunology considerations in context of implants, tissues, and reaction against synthetic/natural materials. However, over the past decade, the focus of many bioengineers and clinicians has been continually shifting towards “immune engineering” approaches, including, but is not limited to, engineered biomaterials for vaccines, immunotherapy (immune-modulation), cell and gene therapy, immune microenvironment engineering and systems immunology. These research areas embrace a comprehensive list of translational immunology-associated problems including chronic infections, autoimmune diseases, aggressive cancers, allergies, etc.

We are seeking support from active SFB members for the formation of this Immune-engineering SIG. If you are interested and support the proposal, please send an email to Ankur Singh (as2833@cornell.edu) saying, “I support the petition for Immune-engineering SIG, and, if possible, would be willing to participate.”

Sincerely,
Ankur Singh, Ph.D.
Assistant Professor
Sibley School of Mechanical and Aerospace Engineering
Cornell University
233 Thurston
Ithaca, NY
14853-7501
Phone: (607) 255-2194
E-mail: as2833@cornell.edu

Call for SIG Book Reviewers

Dear SIG Members:

We would like to make you aware of a new opportunity for our SFB members.

In each issue of the *SFB Biomaterials Forum*, a review of a book we believe is relevant to our members is included. As the *Biomaterials Forum* is published only four times a year, this limits the number of books we can review. We would like to offer a listing of books (un-reviewed) where the members of the SFB have played a part (authors of books and/or chapters and editors). This list would be published in the *Biomaterials Forum* and published on the Society’s website.

Members of SFB may always suggest titles of books for us to review. However, as mentioned, the list is growing, and we try to review the books in a timely fashion (within a year of publication). In addition, we occasionally will review books considered classics or timeless in their content.

We ask for volunteers from each of the SIGs who would be willing to review books in their field. (No reviews will be accepted from authors or editors of the book under review.)

If you have a book you would like listed, or if you are willing to volunteer as a reviewer, please contact us as soon as possible. The next deadline for the *Forum* is October 9, 2013.

We look forward to hearing from you.

Sincerely,

Lynne Jones, Book Review Editor (ljones3@jhmi.edu)
Liisa Kuhn, Editor-in-Chief (lkuhn@uchc.edu)
Steven Little, SIG Chair Representative (slittle@engr.pitt.edu)



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 fax: 856-439-0525
 email: info@biomaterials.org

Special Interest Group Application

Please note: You must be a member of SFB to join a SIG

First Name: _____ Last Name: _____ Suffix: _____

Highest Degree: _____ Title: _____

Company/Affiliation: _____

Department: _____

Address: _____

City, State, ZIP, Country: _____

Telephone: _____ Fax: _____

E-mail: _____

Special Interest Groups (Optional)

Each Special Interest Group is \$10 per year (free for Student Members)

- | | |
|----------------------------------------------------------------------------|-------------------------------------------------------------------|
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| <input type="checkbox"/> Biomaterials Education | <input type="checkbox"/> Orthopedic Biomaterials |
| <input type="checkbox"/> Cardiovascular Biomaterials | <input type="checkbox"/> Protein & Cells at Interfaces |
| <input type="checkbox"/> Dental/Craniofacial Biomaterials | <input type="checkbox"/> Surface Characterization & Modifications |
| <input type="checkbox"/> Drug Delivery | <input type="checkbox"/> Tissue Engineering |
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