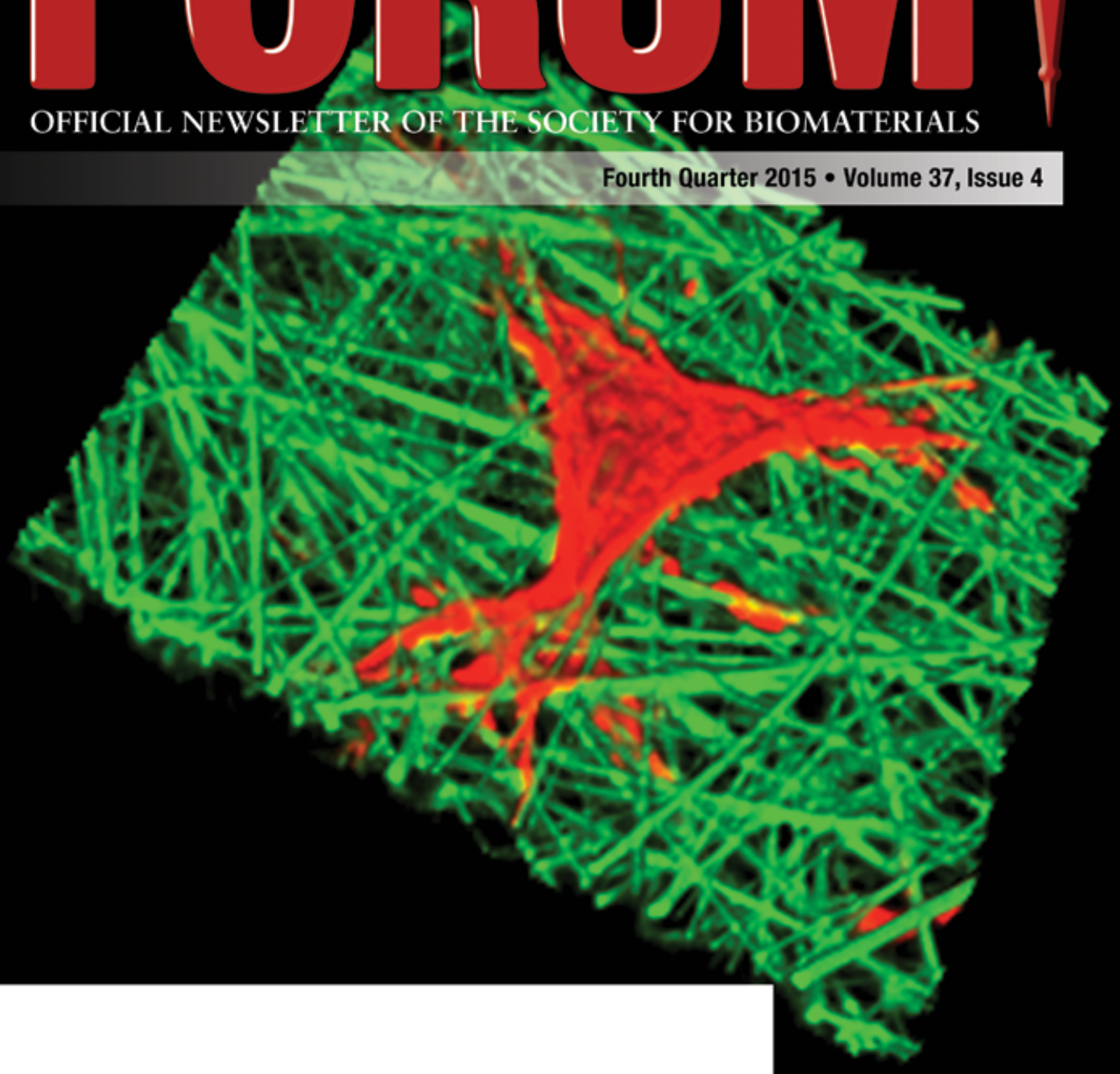
NEW: CATO T. LAURENCIN, MD, PhD, STUDENT TRAVEL FELLOWSHIP

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Fourth Quarter 2015 • Volume 37, Issue 4



Also Inside:

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BIOMATERIALS
FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 37, Issue 4

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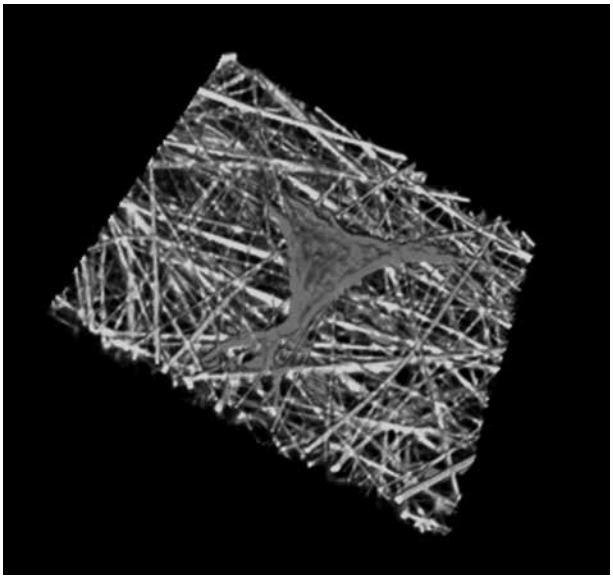

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The Torch

News & Updates

On the cover: Primary human bone marrow stromal cell (hBMSC) cultured one day on a polymer fiber scaffold. The image was captured by confocal fluorescence microscopy. Nanofibers were electrospun from poly(D,L-lactic acid), spiked with rhodamine-123 to make them fluorescent and had a diameter of approximately 1 μm. The hBMSC was stained with Alexa Fluor 633 phalloidin, which is an actin stain. The image cube is 123 by 123 by 14 μm (length by width by depth).

Image submitted by Carl G Simon Jr., National Institutes of Standards and Technology.

Liisa Kuhn

Greetings Fellow Biomaterials Scientists,

Congratulations are due to many Society For Biomaterials (SFB) colleagues who have recently managed the acquisition of their companies, received prestigious professional awards and grants or have been promoted. Read the **Member News** column and be inspired by what your colleagues have achieved. Member-At-Large Elizabeth Cosgriff-Hernandez edits the Member News column, so please let her know your news and she'll make sure you are appropriately honored in the next issue.

The Forum is also a place to pay respects to our recently deceased members. In this issue there's an **In Memorium** article about Dr. John Autian, founding SFB member, who recently passed away at the age of 91 after a long, productive career in the area of plastics toxicology.

Find out about two recently reported phenomena in bacterial adhesion and biofilm formation in the **SIG News** section, kindly reported to us by Dino Di Carlo, professor at the University of California, Los Angeles (UCLA).

Learn more about the early activities within SFB by reading the interview with SFB member Art Coury, retired VP of Genzyme, in the **Historical Flashback** column.

Gaining classroom teaching experience is an encouraged and mandated activity in a new program at the University of Alabama, which accelerates the graduation of certified high school STEM teachers while they get their primary scientific or engineering degree. Read more about this program in the **Educational News** column.

Concerned about job cuts? The **Industry News** column reports the top five medical technical firms with the most layoffs last year. On a positive note, the *in vitro* diagnostics industry continues to grow at a steady clip. This reminds me of the advice that Dr. Tony Atala gave us during his talk at the last SFB Annual Meeting — it is much quicker to get a new diagnostic into human use than a new therapy. His advice is something to consider as you decide how to best make use of your special set of skills and motivation to impact human health.

Find out how students are helping students in the **Student News** column. Two women student members have developed a blog "She Does Science" to provide relatable role models to younger women interested in a STEM career.

In case you missed it, SFB President Tom Webster has started to offer webinars free for SFB members on a variety of topics. I watched one and found it thought provoking and packed with important information. You can watch them by visiting **biomaterials.org/webinars.**

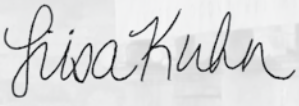
Did you know that the National Institutes of Standards and Technology (NIST) can help validate methods and characterization of cells and materials for your future product? NIST is able to participate in public-private partnerships to help accelerate regenerative medicine/tissue engineering clinical trials. Find out more in the **Government News** column, edited by Carl Simon (NIST employee).

Past President Lynne Jones and SFB member Cato Laurencin have successfully created a new travel fellowship for under-represented minorities that will support student travel expenses and membership to attend a World Biomaterials Congress or an SFB Annual Meeting. No abstract is required! Applications are due in December. You might remember that Lynne proposed this activity at the last Annual Meeting. I'm pleased to report that it's already a reality thanks to their efforts. If you know of an undergraduate student that would be eligible, please encourage them to send in an application (**biomaterials.org/awards/cato-laurencin-travel-fellowship)**. You can show your support for this program by making a tax deductible donation to it on the SFB website.

There's a new book, reviewed by Lynne Jones in the **Book Review** column, about the impact of infection on the long-term outcome of medical devices. This book complements the outstanding material found in our society's key publication, "An Introduction to Materials in Medicine" by Buddy D. Ratner and others, which no member should be without.

I, and the many volunteers that work to make this Forum possible, thank you for taking the time to browse through this issue. We hope it's been useful to you.

Until next time, I wish you much success with your biomaterials experiments!



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

HAVE YOU SEEN US LATELY (AROUND THE GLOBE, ON THE NEWS OR ON THE WEB)?

Thomas J. Webster

In case you have not noticed, we have been very busy. Earlier this year, we made a commitment to increase the value of being a Society For Biomaterials (SFB) member. Among other things, we promised increased SFB events, one webinar a month, greater global presence and promotion of member news.

Our efforts are paying off. For example, at the time I am writing this (September), we have had over 180 registrants for our first-ever summer webinar series. We have had a record number of entrees for our SFB awards, which will be recognized at the World Biomaterials Congress (WBC) in Montreal, Canada. We are about to run a joint workshop with the SFB in China and are even in the final conversation to start the first-ever Latin American Society for Biomaterials. And, we have hired a public relations firm to publicize all of the wonderful biomaterials research and educational advances our members are making. Everyone in our society is stepping up and contributing their time and energy to advance all aspects of our mission. But, by no means are we done yet.

"Everyone in our society is stepping up and contributing their time and energy to advance all aspects of our mission. But, by no means are we done yet."

As I hit the halfway point of my presidency, I continue to be inspired by the number of our members who volunteer countless hours for the love of SFB — members who are ready to drop whatever they are working on during their "day jobs" to promote SFB, debate future directions and nominate a colleague for an award. Our membership is strong and deep in its mission to help spread the biomaterials word to an ever-increasing number of people. In this tradition, our society is unlike any other, as time-and-time again we continue to be innovative not only in research and education, but also as a society.

"We have had over 180 registrants for our first-ever summer webinar series."

And in this manner, we turn to our membership again. We want your ideas for how we can serve you better. What additional webinars would you want made available? What other events can we hold? What parts of the globe can we promote biomaterials education and research in? How can we increase the value of your membership?

Please keep your ideas coming because we will act on them. We count on you to engage and continue to think of creative ways we can elevate SFB. I know we are all up to it because I have seen SFB meet numerous challenges in the past. So, don't wait until WBC to talk to us again, catch us around the globe, in the news or on the Web! Tell us what you think and lend your ideas.

"I continue to be inspired by the number of our members who volunteer countless hours for the love of SFB." We want your ideas for how we can serve you better.

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

Staff Update

BY DEB DUPNIK, ASSISTANT EXECUTIVE DIRECTOR

Hello from Society For Biomaterials (SFB) headquarters! SFB's Board of Directors and governing council will be meeting in November here at headquarters in beautiful Mount Laurel, New Jersey. They will be reviewing the 2016 budget and continuing their work on the strategic plan for the society. Here is a brief rundown on some of the things being done on behalf of the membership.

AWARDS, CEREMONIES AND NOMINATIONS

CHAIR JOEL D. BUMGARDNER, PhD

The Awards, Ceremonies and Nominations Committee has received a record 57 award nominations and six nominations for the two open officer positions. Pending the council's ratification to the proposed slate, award winners and officer candidates will be announced in November. Thank you to all those who made nominations, and please start thinking about possible nominations for next year!

BYLAWS

CHAIR BENJAMIN G. KESELOWSKY, PhD

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

DEVICES & MATERIALS

CHAIR PETER G. EDELMAN, PhD

The committee is working on its third workshop in collaboration with the Chinese Society For Biomaterials (CSB) in conjunction with the CSB 2015 meeting in Haikou, China, Nov. 19–22, 2015. The workshop will be presented on Nov. 19 at the meeting with invited speakers from regulatory agencies (such as the China Food and Drug Administration and the Federal Drug Administration), leading Chinese and global companies, clinical research institutes and academia. The invited speakers will present their experience and lessons learned through case studies. The second part is a panel discussion to address the questions from the audience.

EDUCATION & PROFESSIONAL DEVELOPMENT

CHAIR HUINAN LIU, PhD

The committee received nine grant applications for the 2016 Biomaterials Day program and is in the process of reviewing these. In addition, the monthly webinar initiative continues. Four webinars have been offered by SFB this year. For information on any of the webinars, or to view those that have been archived, please visit **biomaterials.org/webinars**. The webinars are free for members. The Education & Professional Development Committee also has been working on soliciting applications for the 2016 C. William Hall Scholarship and has created a new travel fellowship, the Cato T. Laurencin, MD, PhD, Travel Fellowship.

This C. William Hall Scholarship honors the memory of the society's first president, Dr. C. William Hall. Any undergraduate students interested in attending the World Biomaterials Congress (WBC) in Montreal, Canada should apply for the 2016 C. William Hall Scholarship. The scholarship covers the entire expense of the event. For more information, please visit **biomaterials.org/students/c-william-hall-scholarship.**

The Cato T. Laurencin, MD, PhD, Travel Fellowship was named in honor of a distinguished member of SFB and the travel fellowship will support under-represented minorities in the field of biomaterials by providing an undergraduate student the resources to attend the SFB Annual Meeting (or the WBC in 2016), and a complementary membership to SFB. The goal of this initiative is to stimulate and encourage recipients to pursue a career in biomaterials. For more information about this fellowship, please visit **biomaterials.org/awards/cato-laurencin-travel-fellowship.**

Applications for the Cato T. Laurencin, MD, PhD, Travel Fellowship and the C. William Hall Scholarship are due by Dec. 1, 2015.

FINANCE

CHAIR SHELLY SAKIYAMA-ELBERT, PhD

Development of the 2016 budget is underway. In 2015, SFB expanded the Biomaterials Day grant program to include even more institutions. Reserves remain healthy, and the Finance Committee is looking to invest in increasing membership services to align with the strategic plan.

LIAISON

CHAIR DAVID PULEO, PhD

The Liaison Committee continues its efforts to coordinate and collaborate with other societies for the 2016 WBC. A concerted effort is being made to develop joint programming in hopes that we can bring the tremendous experience of the SFB membership together with other organizations. The committee has solicited nine proposals to this end, and will be making final recommendations to the council for opportunities to pursue in 2016.

LONG RANGE PLANNING

CHAIR LIISA KUHN, PhD

The committee is working to develop a globalization strategy and increase SFB involvement with standard organizations.

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

MEMBERSHIP
CHAIR LIJIE GRACE ZHANG, PhD
The committee is working to develop strategies to increase membership, especially in the industry and clinical sectors.

PRESIDENT'S ADVISORY
CHAIR NICK ZIATS, PhD
The committee will review the code of ethics for SFB and advise the council about any matter requested by the president.

PROGRAM
CO-CHAIRS CHRIS SIEDLECKI, PhD AND SUPING LYU, PhD
The committee is working with the Liaison Committee to identify and finalize the 2016 symposia that will best serve the society's members. The committee will also be exploring ways to improve SFB's Annual Meeting. The 2016 WBC Organizing Committee is happy to report that they received 3,590 abstracts submissions. This sets the stage for the 2016 WBC event to be one of the largest scientific gatherings of biomaterials scientists ever. The largest amount of abstract submissions came from North America with 805 abstracts submitted. Europe and Asia followed with 926 and 1,015 abstracts respectively. In addition, there were submissions from Puerto Rico (1), Canada (416) and Mexico (57).

PUBLICATIONS
CHAIR ALAN LITSKY, MD, ScD
The Publications Committee continues its work with the bi-weekly e-newsletter, *Biomaterials Bulletin*. In addition, the committee will be working to expand services available on the website, and will look to maintain SFB's partnership with Wiley in the publication of the *Journal of Biomedical Materials Research*. Committee members are currently reviewing proposals for Web and Forum editors and will make recommendations to the council.

NATIONAL STUDENT CHAPTERS
PRESIDENT EVELYN BRACHO-SANCHEZ
National student chapter officers will be working with the Education and Professional Development Committee to refine the Biomaterials Days grant program with an eye on converting participants to SFB members.

SPECIAL INTEREST GROUPS
REPRESENTATIVE BRENDON HARLEY, PhD
The Special Interest Groups (SIGs) are looking forward to celebrating their 25th anniversary at the 2016 WBC. Proposed budgets have been submitted and will be reviewed by the board in November.

Please consider the SIGs as a great place to get more involved with the society and grow your personal and professional networks!

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

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Biomaterials Forum Cover Contest

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

6th International Conference on the Mechanics of Biomaterials and Tissues

Dec. 6–10 • Waikoloa Village, Hawaii • Marriott Waikoloa

The International Conference on the Mechanics of Biomaterials and Tissues (ICMOBT) provides a unique international forum for researchers and practicing engineers from different disciplines to interact and exchange their latest results.

Member in the News

BY ELIZABETH COSGRIFF-HERNANDEZ, MEMBER-AT-LARGE

Greetings to the members of the Society For Biomaterials (SFB). As a brief overview of my role as your 2015-2016 Member-at-Large, I serve as an unencumbered representative of the members on both the Board of Directors and the council of the society. In addition, I also serve as your representative on other committees (e.g., Long Range Planning Committee) so that members have a clear voice in the direction of the society. I would like to encourage all members to send me your ideas and feedback about the society. With your help, we can continue to improve SFB and increase value for all of our members. Another duty of the Member-at-Large is to write this column, which highlights member news and accomplishments. 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. I would love to hear from you so please take a moment to send me news for future issues.

Paiyz Mikael, University of Connecticut, was awarded the Outstanding Woman Scholar of the Graduate School. Her dissertation research, "Hybrid Matrix Design for Cartilage-Mediated Segmental Bone Tissue Engineering," focused on the development of improved scaffolds for segmental bone defects. The outstanding senior women academic achievement award was established in 1993 and recognizes outstanding female undergraduates and graduate students for their academic excellence and dedication to research and service within the university community.

Stuart L. Cooper, a past president of SFB, was selected as the winner for the 2014 Founders Award winner from the American Institute of Chemical Engineers (AICE). Dr. Cooper received the same distinction from SFB in 2010.

Buddy D. Ratner, professor of bioengineering and chemical engineering at the University of Washington, was awarded the prestigious Langmuir Lecture by the Colloid Division of the American Chemical Society (ACS). Dr. Ratner presented the award lecture at the ACS Boston meeting on Aug. 18. At the same meeting, Dr. Ratner also received the Distinguished Service Award from the Polymer Division of ACS.

Suzie Pun, Robert F. Rushmer Professor of Bioengineering at the University of Washington, was selected as a 2015-16 AAAS-Lemelson Invention Ambassador in recognition of her contributions to, and innovation in, the field of biomaterials and drug delivery. Dr. Pun's research focuses on door-opening technologies in drug delivery, including macromolecule delivery to the central nervous system, injectable hemostatic polymers and materials for controlled modulation of the immune system for cancer treatment. Recently, bioengineers in Dr. Pun's research group developed PolySTAT, an injectable polymer that helps strengthen blood clots to stop uncontrolled bleeding. The researchers published their findings in the March 4, 2015 issue of *Science Translational Medicine.*

The following members were selected as **2015 Young Innovators of Cellular and Molecular Bioengineering (CMBE)** by the Biomedical Engineering Society (BMES). This award honors tenure-track assistant professors working in the field of cellular and molecular bioengineering. Honorees submitted full-length manuscripts for publication in the journal, *Cellular and Molecular Bioengineering*, and will present in a special two-part platform session at the BMES 2015 Annual Meeting in Tampa, Florida.

Danielle Benoit, University of Rochester
Akhilesh Gaharwar, Texas A&M University
Zhen Gu, University of North Carolina and North Carolina State University
Deok-Ho Kim, University of Washington
Lijie Grace Zhang, George Washington University

Rich Payne has accepted a new position as the associate director of process development in the Regenerative Medicine Clinical Center (RMCC) of Wake Forest Institute for Regenerative Medicine (WFIRM). The goal of the RMCC is to develop products coming out of WFIRM from proof-of-concept through early-stage clinical trials.

Eric Sussman has been promoted to staff fellow at the Federal Drug Administration (FDA). This position in the Center for Devices and Radiological Health's Biology, Chemistry, and Materials Science Division in the Science and Engineering Laboratories office involves regulatory consults, as well as the continuation of research in the area of biocompatibility.

Anirban Sen Gupta, associate professor of biomedical engineering at Case Western Reserve University, has received two R01 grants (in 2014 and in 2015) to carry out research in platelet-inspired biomedical technologies. Specifically, one grant is focused on development and mechanistic validation of platelet-mimetic synthetic hemostats that integrate platelet's injury site-selective adhesion and aggregation functionalities on synthetic biomaterials-based particle platforms to leverage and amplify endogenous clotting mechanisms for treatment of bleeding disorders. The other grant is focused on platelet-inspired bioengineering of targeted drug-delivery systems

that can actively anchor onto thrombus sites under vascular flow environment and deliver clot-busting drugs, as well as other therapeutic payloads. These platelet-inspired technologies have also been issued two patents, US 9107845 and US 9107963. Furthermore, Sen Gupta and his clinical collaborators at the Cleveland Clinic and University Hospitals of Cleveland have recently received additional funding from National Center for Accelerated Innovations-Cleveland Clinic and Case Coulter Translational Research Partnership to evaluate the hemostatic efficacy the synthetic platelet technology (SynthoPlate) in pig models of traumatic bleeding.

Joo Ong, who has served for several years as the chairman of the Biomedical Engineering Department at the University of Texas at San Antonio (UTSA), has been promoted to the role of associate dean in the College of Engineering. Dr. Ong will continue to stay active in research and teaching in the field of biomaterials.

This summer the McGowan Institute for Regenerative Medicine held its **Second Annual Regenerative Medicine Summer School program**. Twenty national and international undergraduate students participated in a hands-on learning program in regenerative medicine. Students interacted with McGowan Institute faculty, staff and students through lectures and research activities in the McGowan Institute laboratories. The activities highlighted cell-based therapies, biomaterials, tissue engineering and medical devices with a focus on clinical translation. Students also participated in networking and career-building activities throughout the week. The summer school program was endorsed by SFB and multiple participating faculty presenters and students are SFB members. The program was rated as being highly successful and engaging. The Third Annual Regenerative Medicine Summer School program is scheduled to run June 20–24, 2016. Students entering their third or fourth year of undergraduate study are encouraged to apply.

SFB member and former chair of the Device & Materials Committee, **Andy Doraiswamy** recently managed the acquisition of his company, Oculeve by Allergan Plc. (AGN).

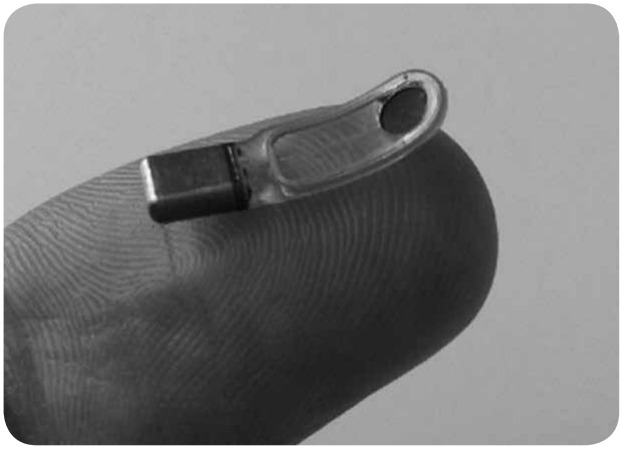


Figure 1. Oculeve's miniature implantable neurostimulator

Oculeve is a start-up medical device company with a first-in-class treatment for Keratoconjunctivitis Sicca or Dry Eye Syndrome (DES).[1] Chronic dry eye is a disease that can be caused by advanced age, contact lens wear, certain medications, eye diseases and other medical conditions or environmental factors. Without enough tears, the film protecting the eye can break down, creating dry spots on the cornea. Chronic dry eye is estimated to affect 25 million patients in the U.S.[2]

Oculeve developed a disruptive neurostimulation technology to stimulate the lacrimal gland in producing tears to treat DES. The technology is one of the smallest implantable neurostimulators in the world with a novel biomaterial. The device also features a connected therapeutic to capture compliance. The company was founded out of Stanford and funded by Kleiner Perkins Caufield & Byers (KPCB), New Enterprise Associates (NEA) and Versant Ventures. According to the Security Exchange Commission (SEC) filings, Oculeve raised $26 million and took about four years to reach this exit. Under the terms of the agreement, Allergan acquired Oculeve for a $125 million upfront payment and commercialization milestone payments.[3] The agreement also includes the acquisition of an additional earlier-stage dry eye device development program.

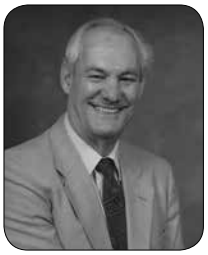
Additional information for McGowan Institute for Regenerative Medicine's Summer School program can be found at mcgowan.pitt.edu/professional-development/summer-school. Email inquiries to Allyson LaCovey at lacoveya2@upmc.edu.

REFERENCES

1. Company Overview of Oculeve, Inc. Bloomberg Business website. http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=142253744. October 7, 2015.
2. Market Scope. 2011 Report on the Global Market for Dry Eye Products. 2011;1-148.
3. Allergan plc. PR Newswire website. http://www.prnewswire.com/news-releases/allergan-successfully-completes-oculeve-acquisition-300126314.html. October 7, 2015.

In Memoriam: Dr. John Autian

BY JOHN KAPEGHIAN, TOXICOLOGIST



Dr. John Autian

Dr. John Autian, former Dean of the University of Tennessee College of Pharmacy and renowned materials science toxicologist, passed away on Sept. 4, 2015 at the age of 91.

Dr. Autian, born Aug. 20, 1924, was of Armenian descent, and his parents Armenouhi Khastian, sole family survivor of the 1915 Armenian Genocide, and Zaker Autian (last name believed to have been Haroutunian, but it was mistakenly recorded as Autian during United States Immigration processing), settled in Philadelphia, Pennsylvania.

Dr. Autian grew up in the Wissinoming district of northeast Philadelphia, attended Frankford High School and was outstanding in track. During World War II, at the age of 17, he enlisted in the U.S. Army and served on active duty for a period of three years. Two of those years were served in the Pacific Theater of Operations and his unit was one of the first to land in Japan at the end of the war.

In 1950, after returning home, he received his bachelor's degree in pharmacy from Temple University. He received both his master's degree (1952) and doctorate (1954) in pharmacology and pharmaceutical sciences from the University of Maryland. After receiving his doctorate, he served as a faculty member at Temple, the University of Maryland and the University of Michigan. Then Dr. Autian moved on to become associate professor at the University of Texas.

While at the University of Texas, Dr. Autian established and directed the Drug-Plastic Research Laboratory, focusing on the safety evaluation of plastics in pharmacy practice. This research center was the first of its kind in the United States. In 1967, he was appointed as a professor at the University of Tennessee in the medical center in Memphis, Tennessee. During this time he founded the Materials Science Toxicology Research Laboratory within the University of Texas Medical Center and served as its director, while also serving on the faculty of the pharmacy and dentistry colleges. He was later appointed dean of the College of Pharmacy, dean of the graduate school and vice chancellor for research.

Dr. Autian retired from the university in 1986, but remained active as a toxicology consultant in biomaterials research and as a proponent of toxicology education in undergraduate and graduate training programs worldwide. He accepted a professorship at Texas A&M University in 1986, and, in 1987, Dr. Autian became a senior science advisor to a joint U.S.-Saudi Arabian program to help enhance research and graduate training. As a result of this collaboration, he helped establish an environmental toxicology laboratory in Saudi Arabia.

During his career, he authored or coauthored over 200 scientific publications in the fields of pharmacology, toxicology and biomedical materials, and contributed to 18 textbooks, including chapters about plastics toxicology in the early editions of Casarett & Doull's *Toxicology, the Basic Science of Poisons*.

He is considered the "Father of Plastics Toxicology" for his pioneering work with phthalate esters and polymers, and, in 1978, he became a founding member of the Society For Biomaterials (SFB), receiving the highest honor, The Clemson Award.

Dr. Autian also established an annual "Toxicology Education Award" through his Forum for the Advancement of Toxicology consortium. The Society of Toxicology took over the award after several years and, very fittingly, recognized Dr. Autian's efforts in toxicology education by presenting him the award in 1988. The award was a special recognition for Dr. Autian, who after 31 years in academia had mentored countless students, postdoctoral associates and junior collaborators in the art and science of toxicology.

In later years, Dr. Autian spent his time and resources helping bring biomedical research, as well as inner-city community service, to Memphis, Tennessee. He traveled extensively to promote education and science, and made several trips to Armenia to help in relief efforts after devastating earthquakes and regional conflicts. Dr. Autian was known for his boundless energy and enthusiasm for helping those less fortunate. All who knew him appreciated his quick wit, humor and self-deprecating antics, which often surfaced unexpectedly during his technical presentations and, quite expectedly, at family gatherings. He was an avid runner and fitness enthusiast, who loved boxing, wrestling and football. Most of all, he was treasured by his family as an inspirational figure who never lost sight of his humble beginnings. Dr. Autian cared deeply for his family, his Armenian heritage and humanity.

Dr. Autian was married to Ginny Langford. In addition to Ginny, he is survived by their son John "Zak" Zaker, daughter-in law Jennifer and grandson Tyler Christian. Other family members include nieces Karen Swartz and Jamie Ward, nephews John Kapeghian and Jerry Sweeney and several great nieces and nephews.

Society For Biomaterials: Service and Benefits, Optimal Synergy

Historical Flashback

BY GUIGEN ZHANG, CLEMSON UNIVERSITY

The successes of the Society For Biomaterials (SFB) can be attributed to many things. One in particular, in my view, is the active scientific and service contributions from not only academic researchers, but also clinical and industrial researchers. Art Coury, a widely recognized leader in the field of biomaterials, personifies the industrial involvement. Mr. Coury was president of SFB from 1999 to 2000, and was the recipient of SFB's 2007 Innovation and Technology Development Award. As a retired vice president of biomaterials research at Genzyme Corporation, he is now the university distinguished professor of chemical engineering at Northeastern University. In response to my request for some historical flashback, Mr. Coury was kind of enough to give some reflection on his involvement with SFB. Here in his own words:

"My industrial career began in 1965, right after receiving my doctorate in organic chemistry, with my employment by General Mills, Chemicals, Inc. In my 10-plus years there, I had wonderful mentors in learning polymer science from the ground floor, but generated no commercial product. I then joined Medtronic, Inc. in 1976 when it was small, but still the largest implantable device company, and started its polymer group. Quickly, in this setting, exploiting my polymer background and that of my group, we began to generate numerous products and components. For example, in 1978, we introduced the first synthetic, adhesive, conductive, solid hydrogel to the field of medical electrodes. This composition, to this day, continues to play a part in sensing and stimulating electrodes, such as in an electrocardiogram (EKG). Subsequently, we contributed multiple components to pacemaker devices and to other medical products at Medtronic.

I don't recall exactly when I joined SFB, but I imagine it was among the excitement of the Clemson years of the early 1970s. Although a member, I had to wait my turn at Medtronic to attend an Annual Meeting. I attended the 1983 Annual Meeting in Birmingham, Alabama. What a revelation that was! Then, and subsequently, it has been my main immersion into the progress and evolution of our field. Although my inaugural society was the American Chemical Society (ACS), which I have been a member of for over 50 years, my attendance at that Annual Meeting then confirmed SFB as my main society.

In 1986, I began my official service to SFB by assembling the historical medical device exhibit for the Minneapolis meeting. In 1991, President Buddy D. Ratner asked me to head the Devices and Materials Committee of SFB. This committee, chartered to serve the translation interests of corporate and individual members, had the drafting, review and recommendation for approval of the first ISO 10993 Standards: "Biological Evaluation of Medical Devices" as its main service at the time. As the SFB representative to the working group, I was one of the nine plenary reviewers of the first 12 of these documents. Overall, there now are 20 issued ISO 10993 documents. Professor Jim Anderson was the initial chair and continues to be the overall coordinator of the working group (ISO TC-194) for ISO 10993-1, the document responsible for specifying the test standards for "Biological Evaluation of Medical Devices."

After serving about eight years as chair of the SFB Devices and Materials Committee, I became president-elect, and president of SFB (1999–2000). During my term, SFB was host to the 2000 World Biomaterials Congress (WBC) in Hawaii, which is remembered as a very successful meeting.

Subsequent to my service on the SFB Council (1991–2001), I have continuously served, as all former presidents, on the President-Elect's Long Range Planning Committee, Finance Committees and Awards, Ceremonies and Nominations Committee, as well as in various special interest groups (SIGs), etc. Throughout my service in three companies, various universities, during my "retirement," and to this day, I have been privileged to be associated with SFB. I hope to continue my membership and service indefinitely to the society and to my profession."

From left to right, Art Coury with Howard Winet of the University of California, Los Angeles (UCLA) and Jeffrey Hollinger of Carnegie Mellon at the 7th World Congress of Biomaterials in Hawaii in 2000, during which Art served as president for SFB (note: Art's wife, Judy, is in the background behind Art's right shoulder).

MANUFACTURING INNOVATION AND ITS IMPACT ON DEVELOPING HEALTHCARE MONITORING SYSTEMS

BY RAHIM JINDANI, PhD STUDENT: FIBER AND POLYMER SCIENCES (FPS) WITH MINOR IN BIOMEDICAL ENGINEERING (BME), NORTH CAROLINA STATE UNIVERSITY

Google Inc., the provider of the world's leading Internet search engine, announced a project, titled "Jacquard," on June 5, 2015 in collaboration with Levi Strauss & Co., one of the largest manufacturers of denim garments in the fashion industry. The goal of Jacquard is to weave technology into traditional clothing and day-to-day wear to allow for a more interactive experience with clothing and expansion of its use in conjunction with communicating devices.

Electronics, such as smart phones, can then be utilized without the need for direct-device contact. Various functions can be completed without touching the phone screen or even without removing the phone from one's pocket. For example, calls can be answered, volume adjusted and peripheral controls can be performed via clothing. These concepts are currently being explored by Google in collaboration with textile manufacturers around the world. Ideas like these help ensure that limitless possibilities for innovation are being explored consistent with Google's emerging refined mission statement. The integration of metallic wires and conductively coated fibers — such as silver nanowires and copper, silver or polyaniline conductive coatings — will make this integration possible. These materials are just the starting point, and are expected to lead to innovations that will become integrated into everyday life.

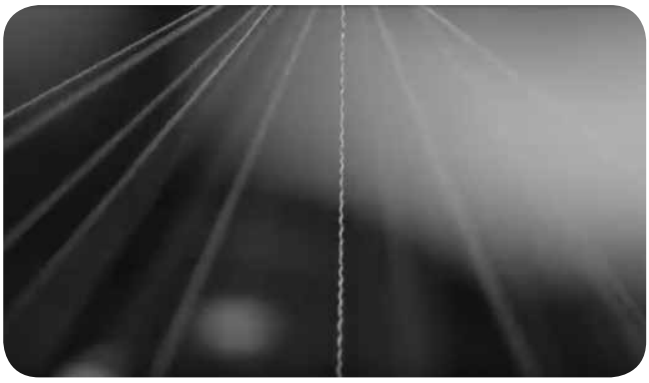


Figure 1. Image of a Maypole braiding with metallic yarn as core yarn and yarns around the core yarn (taken from Google Project Jacquard).

In a similar effort last year, President Obama announced the Next Generation Power Electronics Innovation Institute, which will be headquartered in Raleigh, North Carolina. It is a $140 million-initiative that included a $70-million grant from the U.S. Department of Energy, which is the largest grant in North Carolina State University history. The grant allowed for the development and expansion of the Center for Advanced Self-Powered Systems of Integrated Sensors and Technologies (ASSIST), which is sponsored by National Science Foundation (NSF). The aim of this center is to develop various technologies that are self-powered, avoiding reliance on external batteries.

Currently, concepts like the commercially available Nike+ FuelBand, as well as other similar devices that can measure vital signs, are popular with the public. These devices allow people to better understand their health condition and manage routine activities, including eating habits, in a better way. However, these devices all run on battery power and, thus, monitoring of vital signs and calories is limited to the power source.

The ASSIST center aims to harness and develop collaboration between various research and industry institutes to develop technologies for healthcare monitoring and other devices for day-to-day activities. The center plans to exploit the power generated from the range of motion that the human body performs during day-to-day tasks, such as walking, jogging and flexing of muscles, as well as ambient sources such as solar, vibrational, wind and various other energy forms that, although small, can eventually power monitoring devices. Additionally, the institute plans to harness the potential of previous technological advances whilst ensuring that the shortcomings of those ideas are being further studied to develop better models and improved ideas with greater efficiencies or more sustainable outcomes.

One such example is the nonwoven-based dry electrocardiogram (ECG) and electromyography (EMG) monitoring electrodes with silver nano-wires, which are currently being researched. The higher surface area available with the use of nonwovens allows for better efficiency. The electrodes can enable better and efficient measurements of heart rate and QRS graphing as compared to wet electrodes, which are inefficient under the different skin micro flora conditions and varying environment conditions often encountered in everyday use.

Self-monitoring devices and sensors developed by the ASSIST center are providing solutions to deliver drugs and nanoparticles in a controlled manner. The group of researchers collaborated to develop micro, needle-based, self-powered glucose sensors. The electrochemistry utilized allows for sub-dermal monitoring of glucose in a sustained fashion without the need for other monitoring devices. These technologies can allow for sustained insulin delivery, cancer drug release and treatments for various genetic ailments in the future.

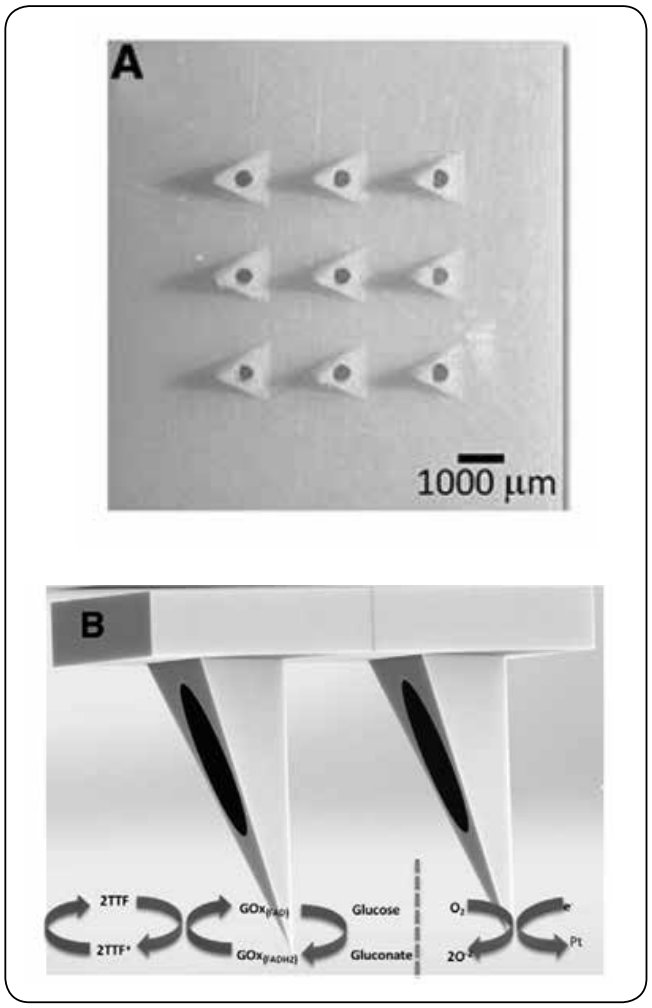


Figure 2.
A). Optical micrograph of the micro needle array. B). Scheme of the carbon paste bio anode and cathode electrodes mated on two of the hollow micro-needles located within the array. Schematic relation delineating the operational principle of the self-powered sensor device using a GOX/TTF-based bio anode and Pt-based cathode.[1]

Although not yet in wide commercial use, smart and efficient health monitoring systems like these are envisioned to be self-powered in the future, harnessing unexploited energies. The amount of data generated through the use of such devices is expected to eventually enable better health data management systems, as well as continuous monitoring for hospitals and healthcare providers. This could ultimately cut the cost of expensive clinical trials and other studies, such as those conducted in preparation for the Federal Drug Administration (FDA) 510(k) submissions, where a number of variables would otherwise be difficult to control and would be time-consuming to monitor.

With these developments and further improvements, crucial data should be reliable and effortlessly available. The time required for qualitative and quantitative analysis of medical conditions will be reduced with the development of such advanced devices, perhaps even shortened to less than real time as computer modeling provides another way of examining, diagnosing and predicting patients' medical conditions to supplement continuous contemporaneous monitoring.

It is hoped that healthcare monitoring using sensors and nano devices will eventually allow for higher standards of living, permitting people to adapt to emerging medical issues by acting accordingly to take the preventive measures needed. The potential of self-powered systems being explored on the one hand, and the weaving of technology as envisioned by Google on the other hand, will eventually bring a number of breakthroughs that could benefit in a sustained manner for both the developed and third worlds alike. Ideas such as these are yet to be fully explored and will require massive collaboration between industry and academia in the coming years.

REFERENCE

Valdés-Ramírez G, et al. Micro needle-based self-powered glucose sensor. *Electrochemistry Communications*. 2014;47:58-62.

THE ROLE OF CATHETER FLUID FLOW IN BIOFILM FORMATION

BY DINO DI CARLO, PhD, PROFESSOR OF BIOENGINEERING, CALIFORNIA NANOSYSTEMS INSTITUTE AND JONSSON COMPREHENSIVE CANCER CENTER, UNIVERSITY OF CALIFORNIA, LOS ANGELES

Of interest to the Biomaterials Tissue Interaction SIG, and other Society For Biomaterials (SFB) members, are the results concerning the effect of fluid flow on the development and growth of bacterial biofilms. Flow corresponding to shear stresses present in catheters during normal clinical operation can unexpectedly enhance adhesion and biofilm formation in some strains of *S. epidermidis*.

According to the Centers for Disease Control and Prevention (CDC), more than 15 million central venous catheter (CVC) days and 80,000 cases of catheter-related bloodstream infection (CRBSI) occur in intensive care units annually,[1] while hospital-wide a total of 250,000 cases have been estimated to occur annually in the United States.[2] The infections are associated with substantial morbidity, mortality and financial cost. Infectious syndromes, including septic shock, infective endocarditis or suppurative thrombophlebitis, may result from CRSBIs.

CRBSIs can be caused by breaks in sterile technique during catheter insertion, improper catheter maintenance and care or by contaminated solutions administered through the catheter. Organisms commonly causing CRBSIs include *Staphylococcus aureus* (including methicillin-resistant *S. aureus* or MRSA), coagulase-negative staphylococci (e.g., *S. epidermidis*), Gram-negative organisms, and *Candida* species. Critical pathogenic determinants of CRBSI include 1) the material of which the device is made; 2) the host factors, such as fibrin, fibrinogen and fibronectin, which form a sheath around the inner catheter lumen and to which bacteria have specific binding proteins targeted against; and 3) the intrinsic virulence factors of the infecting organism, including the extracellular polymeric substance (EPS) produced by the adherent organisms. Microbial adherence is promoted through the production of a biofilm "slime" layer in which organisms can embed themselves. The biofilm facilitates evasion of host defense mechanisms and makes the organism less susceptible to antimicrobial agents.[3-5]

Due to the presence of the biofilm, treatment without catheter removal results in unacceptably high-failure rates. Bloodstream infection recurs in the majority of patients once the course of antibiotics is completed. Depending on the catheter type, however, removal is frequently a management challenge, as many of these patients require the catheter emergently (such as for administration of vasoactive medications or fluids) or long term (hemodialysis or nutritional needs for short-gut syndrome). Long-term CVCs

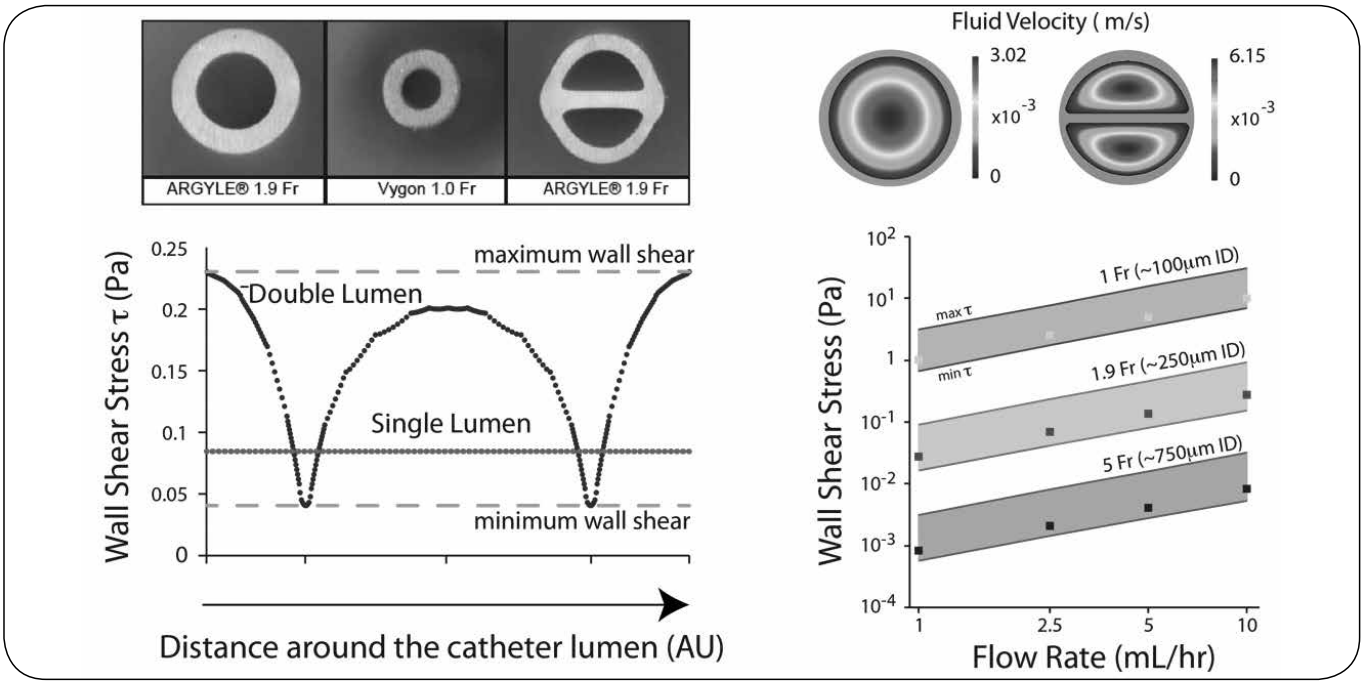


Figure 1. Normal operating shear stresses within commonly used catheters. Single lumen catheters have uniform shear stress on all walls while double lumen catheters have high and low shear stress regions. Common operating flow rates in the clinic are shown for three catheter types (100, 250 and 300 μm inner diameter), and the corresponding wall shear stresses (or shear stress range for double lumen catheters – shaded region) are shown.

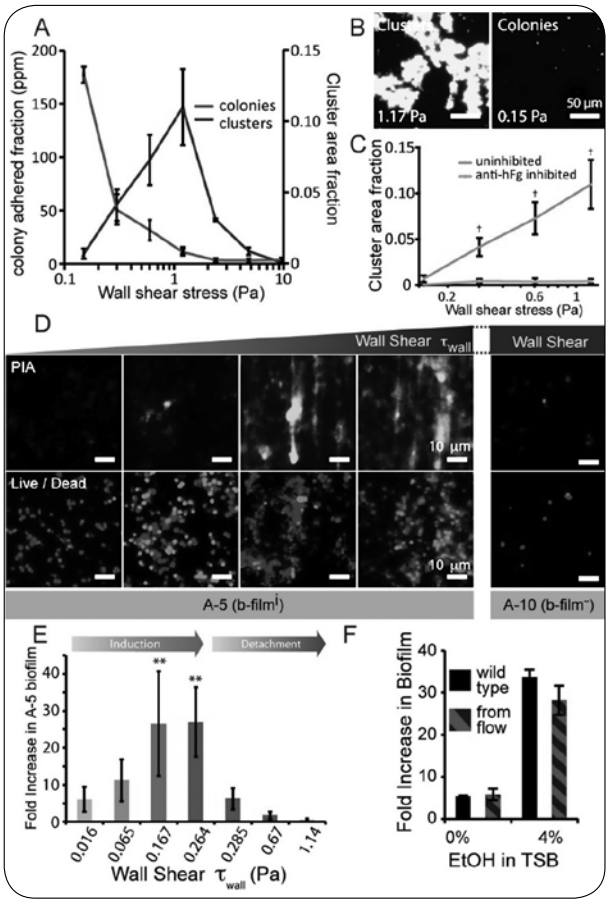


Figure 2. Mechanical forces from fluid flow increase the pathogenic potential of S. *epidermidis*.
A. Cell clustering increases with fluid shear and results in higher adhesion efficiency. B. Examples of large clusters and single colonies. C. Cluster adhesion requires exposed fibrinogen epitopes. D. Clinical isolate A-5 does not form biofilm in static culture, but secretes PIA biofilm matrix with increasing wall shear. E. Total biofilm in A-5 is biphasic with wall shear. F. Cells collected from A-5 flow biofilms revert to wild type when cultured without flow, indicating this is an inducible phenotype. Please see the online version for a higher magnification image of Panels B and D.

are typically placed surgically and tunneled subcutaneously, and removal requires a second surgical procedure. Among patients undergoing hemodialysis who have CRBSI involving long-term catheters, the catheter is not only the source of the infection, but also the sole vascular access for ongoing dialysis. Because the majority of infections involving catheters are intraluminal,[6] understanding how fluids flow under normal operating conditions affect biofilm formation and development is critical to develop new materials and protocols to address the challenge of clinical management of CRBSIs without catheter removal.

We have developed a microfluidic assay to study both adhesion and biofilm formation on well-defined surfaces under physiological flow conditions (Figure 1). We have used this assay to characterize two previously unreported phenomena in *S. epidermidis*, which appear to be mediated significantly by fluidic forces. First, increasing fluidic shear results in increased clustering of free flowing cells leading to increased binding efficiency to immobilized fibrinogen under high shear stresses (Figure 2A-C).[7]

Secondly, we have shown that a subset of clinical isolates harboring the ica operon are induced to secrete elevated levels of polysaccharide intracellular adhesin and form more biofilm structure simply by exposure to fluid flow (Figure 2D-F).[8] Importantly, the shear stresses implicated in improved adhesion and stimulation of biofilm formation are within the range observed during normal catheter operation (Figure 1). Together, these results strongly implicate the fluidic environment as a regulator of pathogenic potential in *S. epidermidis* and indicate further investigation into mechanism and response of other pathogenic species is warranted. Furthermore, these unexpected findings indicate that fluid flow rates and lumen shape and size should be taken into consideration in catheter design to mitigate the potential to enhance pathogenicity.

REFERENCES

1. Guidelines for the Prevention of Intravascular Catheter-Related Infections.
2. DG Maki, DM Kluger, CJ Crnich. The risk of bloodstream infection in adults with different intravascular devices: a systematic review of 200 published prospective studies. *Mayo Clin Proc.* 2006;81(9):1159–1171.
3. JL Gaillard, R Merlino, N Pajot, et al. Conventional and nonconventional modes of vancomycin administration to decontaminate the internal surface of catheters colonized with coagulase-negative staphylococci. *J Parenter Enteral Nutr* 1990;14(6):593–597.
4. Pascual A, Ramirez de Arellano E, Martínez Martínez L, Perea EJ. Effect of polyurethane catheters and bacterial biofilms on the in vitro activity of antimicrobials against Staphylococcus epidermidis. *J Hosp Infect*. 1993;24(3):211–218.
5. Raad I, Davis S, Khan A, et al. Impact of central venous catheter removal on the recurrence of catheter-related coagulase-negative staphylococcal bacteremia. *Infect Control Hosp Epidemiol.* 1992;13(4):215–221.
6. Raad I, Costerton W, Sabharwal U, et al. Ultrastructural analysis of indwelling vascular catheters: a quantitative relationship between luminal colonization and duration of placement. *J Infect Dis*. 1993;168(2):400–407.
7. Weaver WM, Dharmaraja S, Milisavljevic V, Di Carlo D. The effects of shear stress on isolated receptor-ligand interactions of Staphylococcus epidermidis and human plasma fibrinogen using molecularly patterned microfluidics. *Lab Chip*. 2011;11(5):883–889.
8. Weaver WM, Milisavljevic V, Miller JF, Di Carlo D. Fluid flow induces biofilm formation in Staphylococcus epidermidis polysaccharide intracellular adhesin-positive clinical isolates. *Appl Environ Microbiol.* 2012;78(16): 5890–5896.

POSTOPERATIVE OPACIFICATION OF INTRAOCULAR LENSES

BY LILIANA WERNER, MD, PhD, ASSOCIATE PROFESSOR OF OPHTHALMOLOGY AND VISUAL SCIENCES, AND CO-DIRECTOR, INTERMOUNTAIN OCULAR RESEARCH CENTER, JOHN A. MORAN EYE CENTER, UNIVERSITY OF UTAH

A significant number of intraocular lens (IOL) explantations performed in this past decade were due to a process related to lens opacification and/or discoloration.[1] The inability to recognize such a process may prompt surgeons to perform unnecessary surgical procedures, such as Nd:YAG posterior capsulotomies or vitrectomies, in eyes where the opacification is actually in the IOL itself and not at the level of the posterior capsule or the vitreous. This may jeopardize subsequent implantation of a new IOL in the capsular bag, among other complications. There are a few causes of IOL opacification/discoloration.

Snowflake Degeneration of PMMA IOLs

Snowflake degeneration is slow, progressive opacification of poly(methyl methacrylate) (PMMA) IOLs, occurring sometimes 10 years or more after implantation (Figure 1). It has been hypothesized that this degeneration is a result of long-term ultraviolet (UV) exposure. The dry snowflake lesions, which represent a breakdown in the PMMA material, should be differentiated from glistenings, which are fluid-filled, intra-optical vacuoles. Three-piece PMMA lenses implanted between the early 1980s and the mid-1990s were generally manufactured by injection molding. The lenses explanted because of this condition and analyzed in our laboratory generally had lesions clustered in the central zone and midperipheral portion of the optic. This led to the hypothesis that the central optic was exposed to UV light over an extended period, whereas the peripheral optic may be protected by the iris.[2]

Discoloration of Silicone IOLs Associated with Systemic Medication

Katai et al reported about a patient who received treatment with amiodarone for three years and developed brown discoloration of the silicone lenses in both eyes.[3] Jones and Irwin described the case of a patient who developed a rose discoloration of the silicone lenses in both eyes after receiving rifabutin for 10 months.[4]

Coating of Silicone IOLs with Silicone Oil

The interaction of silicone oil, used in vitreoretinal surgery, with standard silicone IOLs in a given patient is a well-documented clinical complication. Patients with vitreoretinal problems that may require use of silicone oil should not be implanted with silicone lenses, as the oil will attach to the lens surfaces, causing optical irregularities. This irreversible adherence of silicone oil to the IOL optic may lead to different sequelae, including visual disturbances and visual loss for the patient, as well as obstruction of the vitreoretinal surgeon's view into the eye. This is a complication not generally seen by the implanting cataract surgeon, but, rather, at a later stage in a patient's postoperative course, by a vitreoretinal surgeon.[5]

Coating of Silicone IOLs with Ophthalmic Ointment

There have been eight cases reported of toxic anterior segment syndrome (TASS) related to an oily material within the anterior chamber of patients' eyes. The eight patients underwent uneventful phacoemulsification by the same surgeon via clear corneal incisions, with implantation of three-piece silicone lens designs. Postoperative medications included antibiotic/steroid ointment and pilocarpine gel, and each eye was firmly patched at the end of the procedure. On the first postoperative day, some patients presented with diffuse corneal edema, increased intraocular pressure (IOP) and an oily, film-like material within the anterior chamber, coating the corneal endothelium. The others presented with an oily bubble floating inside the anterior chamber, which was later seen coating the IOL.

Gas chromatography-mass spectrometry (GC-MS) of the IOL extracts identified a mixed chain hydrocarbon compound, which was also found in the GC-MS analyses of the ointment used postoperatively. Therefore, the results indicated that the ointment gained access to the eye, causing the postoperative complications described. These cases highlight the importance of appropriate wound construction and integrity, as well as the risks of tight eye patching following the placement of ointment.[6]

Calcification of Silicone IOLs in Asteroid Hyalosis

Four cases were initially reported in literature, all with silicone plate lenses in patients with unilateral asteroid hyalosis. Whitish deposits appeared only on the posterior optic surface of the lens late postoperatively. In two of the cases, the deposits were noted before Nd:YAG laser capsulotomy was performed. Fast re-accumulation of the deposits on the posterior surface of the lenses was described after the procedure. There was also a similar case related to a three-piece silicone lens in a patient with bilateral asteroid hyalosis. The contralateral eye also underwent cataract surgery. The acrylic lens implanted in this eye developed no

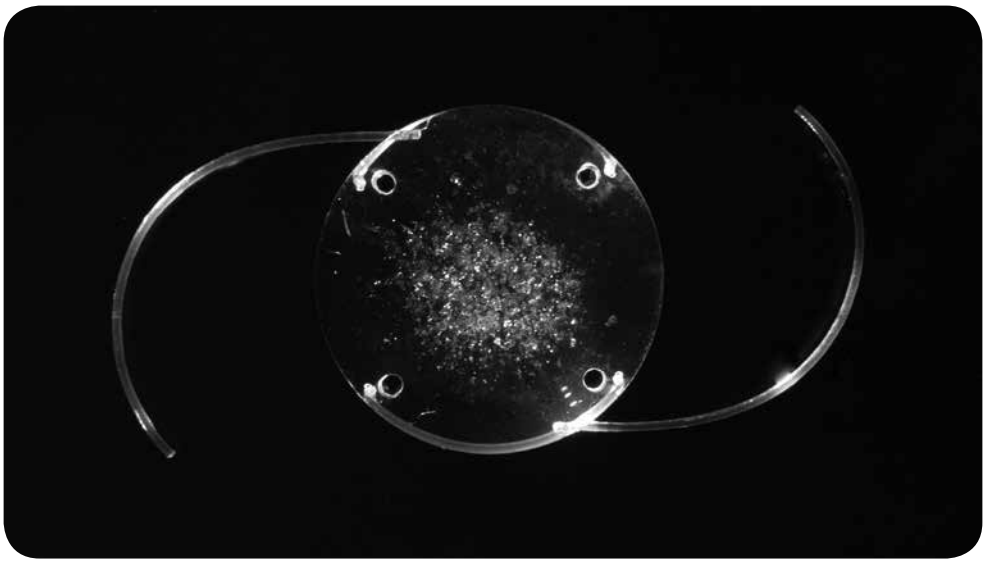


Figure 1. Gross photograph of a PMMA IOL explanted because of snowflake degeneration.

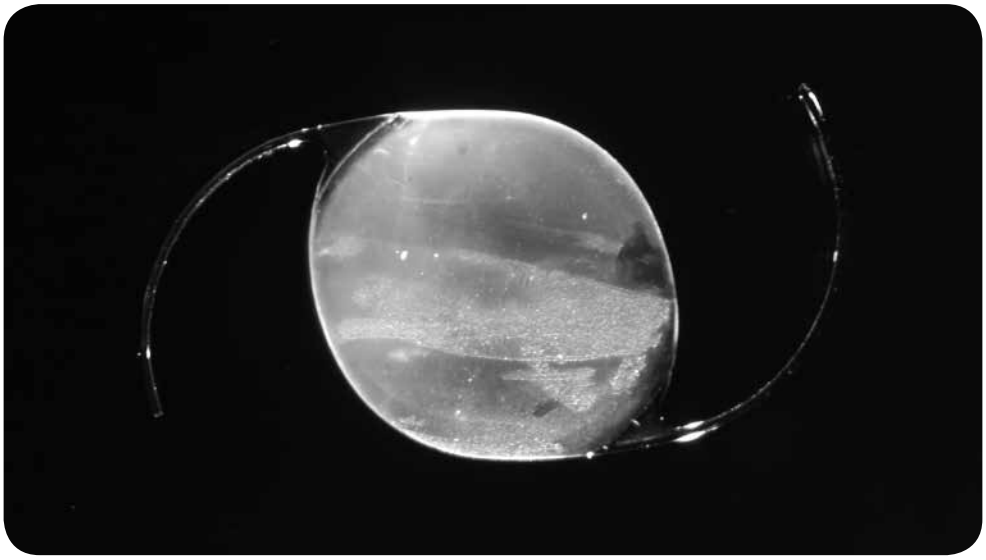


Figure 2. Gross photograph of a hydrophilic acrylic IOL explanted because of calcification.

opacities after six years. In the absence of asteroid hyalosis, long-term calcified deposits were previously observed only on the surface or within the substance of some hydrophilic acrylic IOL designs. There is, therefore, increasing evidence that the material opacifying the silicone lenses is derived from the asteroid bodies or derived from a similar process that results in this vitreous condition, as its composition was found to be similar to that of hydroxyapatite (calcium and phosphate). The latter is more likely the case because the asteroid calcium is already "out of solution." It is, however, still unclear why only a relatively few number of cases have been observed, while there have probably been many implantations of silicone lenses of various designs in patients with asteroid hyalosis. More recently, 16 new cases were reported with different silicone lenses.[7]

Calcification of Hydrophilic Acrylic IOLs

Postoperative optic opacification of modern hydrophilic acrylic IOL designs has been a significant complication leading to IOL explantation since 1999.[8] Different studies using histopathological, histochemical and electron microscopic, as well as elemental or molecular surface

analytical techniques, demonstrated that the opacification was related to calcium/phosphate precipitation on and/or within the lenses. The four major designs manufactured in the United States involved in the problem were the Hydroview (Bausch & Lomb) (Figure 2), the MemoryLens (Ciba Vision), the SC60B-OUV (Medical Developmental Research) and the Aqua-Sense (Ophthalmic Innovations International). Sporadic cases involving hydrophilic acrylic lenses manufactured in Europe were also described. Although in many cases it was difficult to determine the time optic opacification was first observed, the lenses involved in the problem were in average explanted during the second year post implantation. The opacification was not associated with anterior segment inflammatory reaction and Nd:YAG laser was ineffective in removing the calcified deposits from the lenses. Calcification of hydrophilic acrylic lenses appears to be a multifactorial problem, and factors related to IOL manufacture, IOL packaging, surgical techniques and adjuvants, as well as patient metabolic conditions, among others, may be implicated. As the exact combination of factors and sequence of events ultimately leading to calcification of the lenses is still unknown, continuous research on this complication is warranted. This requires a multidisciplinary approach, which is further complicated by the fact that detailed manufacturing procedures are considered proprietary information, and some IOL designs are distributed in different countries with different commercial names. To date, explantation/exchange of the opacified/calcified IOL is the only possible treatment.

Glistenings and Nanoglistenings of Hydrophobic Acrylic IOLs

Two hydration-related phenomena have been described in literature in IOLs made of different materials, particularly in hydrophobic acrylic lenses — glistenings and surface-light scattering.[9] Glistenings are fluid-filled microvacuoles (1 to 20 microns in diameter) that form within the IOL optic when the lens is in an aqueous environment. Although they are largely described in association with hydrophobic acrylic IOLs, they can actually be observed with different IOL materials, including PMMA. The majority of peer-reviewed articles on glistenings available in literature describe them in relation to the AcrySof material (Alcon). The change in the equilibrium water content caused by temperature changes between 30 and 40 degrees Celsius was found to be an important factor in glistening formation, and IOL materials featuring less temperature-dependent water absorption would be less likely to form glistenings. There is still controversy on whether or not glistenings have any impact on the visual function of the patient and if they progress over time. Surface-light scattering is a "whitening" appearance of the lens surface when the light is directed at the IOL at an angle of incidence of 30 degrees or greater during slit lamp examination or during image capture at an angle of 45 degrees at Scheimpflug photography. Studies analyzing explanted lenses in dry and hydrated states, as well as analyses under cryo-focused ion beam SEM, showed that scattering was predominantly caused by phase separation of water (from aqueous humor) as subsurface nanoglistenings. Surface-light scattering/nanoglistenings have also been studied and described in IOLs made of the AcrySof material.

Summary

Different pathologic processes may lead to clinically significant opacification or discoloration of the optic component of IOLs manufactured from different biomaterials and in different designs. Factors such as patients' associated conditions, IOL manufacture, IOL storage, surgical techniques and adjuvants, among others, may be involved in different combinations. With the increasing number of new lenses in the market every year, constant vigilance regarding overall IOL biocompatibility is warranted.

REFERENCES

1. Werner L. Causes of intraocular lens opacification or discoloration. *J Cataract Refract Surg.* 2007;33:713-726.
2. Dahle N, Werner L, Fry L, Mamalis N. Localized, central optic snowflake degeneration of a PMMA intraocular lens: Clinical report with pathological correlation. *Arch Ophthalmol.* 2006;124:1350-1353.
3. Katai N, Yokoyama R, Yoshimura N. Progressive brown discoloration of silicone intraocular lenses after vitrectomy in a patient on amiodarone. *J Cataract Refract Surg.* 1999;25:451-452.
4. Jones DF, Irwin AE. Discoloration of intraocular lens subsequent to rifabutin use. *Arch Ophthalmol.* 2002;120:1211-1212.
5. Apple DJ, Federman JL, Krolicki TJ, et al. Irreversible silicone oil adhesion to silicone intraocular lenses. A clinicopathologic analysis. *Ophthalmology.* 1996;103:1555-1561.
6. Werner L, Sher JH, Taylor JR, et al. Toxic anterior segment syndrome and possible association with ointment in the anterior chamber following cataract surgery. *J Cataract Refract Surg.* 2006;32:227-235.
7. Stringham J, Werner L, Monson B, Theodosis R, Mamalis N. Calcification of different designs of silicone intraocular lenses in eyes with asteroid hyalosis. *Ophthalmology.* 2010;117:1486-1492.
8. Werner L. Calcification of hydrophilic acrylic intraocular lenses. *Am J Ophthalmol.* 2008;146:341-343.
9. Werner L. Glistenings and surface light scattering in intraocular lenses. *J Cataract Refract Surg.* 2010;36:1398-1420.

Student News

Student Chapter Update

BY EVELYN BRACHO-SANCHEZ, NATIONAL STUDENT CHAPTER PRESIDENT, UNIVERSITY OF FLORIDA

As student members of the Society For Biomaterials (SFB) we have had the great fortune of accelerating ourselves toward independent research through the engagement of an active scientific community. To ensure the success of an upcoming generation of researchers, we can employ methods like early exposure to opportunities and mentors, early engagement with scientists in our field, and the establishment of relatable role models. Reflecting on how these experiences have shaped the early stages of our own careers, students within SFB have been working to make engaging experiences more accessible for those who will come behind us.

One way that students have been reaching out is through providing relatable role models to young women interested in a career in the science, technology, engineering and mathematics (STEM) fields. Earlier this year, student members Caroline Addington and Brittany Haselwood at Arizona State University developed the blog "She Does Science," featuring informal interviews with women working in STEM roles/careers. Studies have found that providing students with relatable, stereotype-defying role models can counteract the negative effects of the stereotype itself.[1] Therefore, the goal of "She Does Science" is to provide an informal database of women in STEM roles, which illustrates that a career in STEM is attainable for young women.

Our student section has also become more proactive in reaching students through social media outlets. For those interested in participating and contributing to the SFB community we have developed Facebook and LinkedIn groups specifically targeting student members. We are excited to promote greater student engagement within the society and we look forward to the growth of our student membership. For more information regarding SFB's student social media presence, please visit **facebook.com/groups/SocietyForBiomaterials.StudentSection** and **linkedin.com/grp/home?gid=8305945.**

REFERENCE

Marx, et al. Girls Do Science. *J Exp Soc Psych*. 2009; 45(4):953-6.

For more information about women in STEM fields or to contribute an interview, visit shedoesscience.wix.com/home or contact shedoesscience@gmail.com or caroline.addington@asu.edu.

Government News

News & Updates

NATIONAL EYE INSTITUTE WORKING TOWARD FIRST iPSC CLINICAL TRIAL IN THE U.S.

BY CARL G SIMON JR., GOVERNMENT NEWS CONTRIBUTING EDITOR

Scientists at the National Eye Institute (NEI) and National Institutes of Health (NIH) are developing a cell therapy for age-related macular degeneration (AMD), the leading cause of vision loss.[1,2] AMD is caused by degeneration of the supportive layer of cells in the back of the eye (retinal pigment epithelium or RPE). Lead by Dr. Kapil Bharti, the team is manufacturing healthy RPE in the lab for implantation into AMD patients. Their strategy circumvents the immune system by using the patient's own blood cells to make healthy RPE through induced-pluripotent stem cell technology (iPSC). The mature RPE cells are being cultured on a fibrous scaffold to facilitate handling and implantation. The vitreoretinal surgical team is designing new surgical tools that can lift and implant the delicate constructs without damaging them. It is important to conduct trials such as these in the public domain so that a behind-the-scenes view of the development and manufacturing process can benefit other cell-therapy stakeholders. This is key since the cell therapy industry has identified a lack of reliable methods for characterizing cell-based products as possibly the single greatest challenge for the field.[3,4] The project forged a public-private partnership, where Cellular Dynamics,[5] a pioneer in translating iPSC-tech-

If you have any questions or comments, contact Carl Simon at 301-975-8574 or carl.simon@nist.gov.

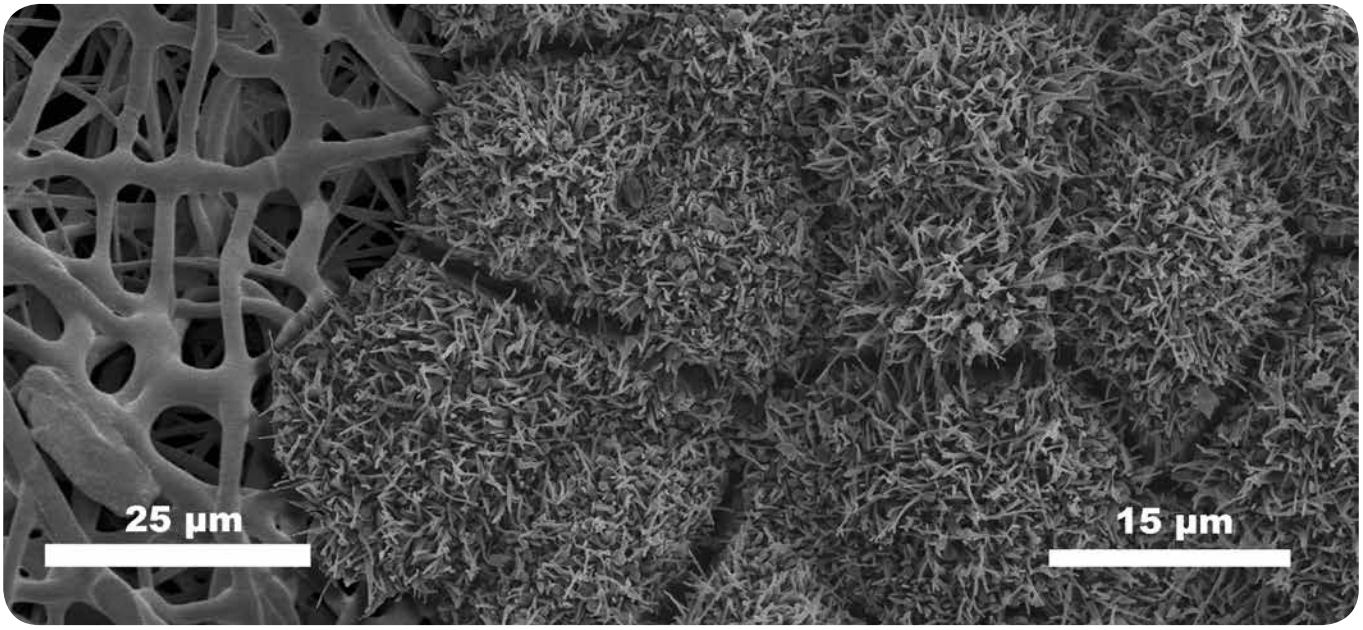
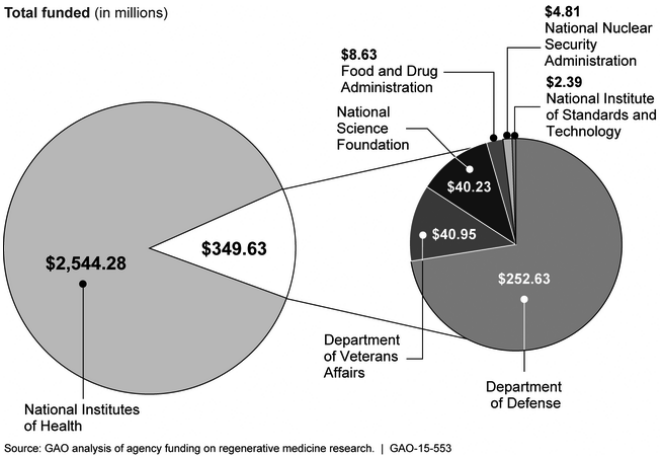


Image: Scanning electron micrograph of RPE cultured on a nanofiber scaffold (image prepared by Nathan Hotaling, NIST). RPE and nanofibers were imaged separately and two images were combined to create the image. There are two scale bars on the image, since RPE and nanofibers were imaged at different magnifications. Shadowing was added to the RPE.

nology, won a contract to develop the cell manufacturing process, which will be used in the trial. The National Institutes of Standards and Technology (NIST) worked with the team to validate methods and characterize the scaffolds and cells. The team held a two-year project review at NIH on Sept. 18, 2015 and is on track for a 2017 trial, which would be the first iPSC clinical trial in the United States.

GAO REPORT ON FEDERAL INVESTMENT IN REGENERATIVE MEDICINE

The United States Government Accountability Office (GAO) published a report on federal investment in regenerative medicine.[6] They found that seven federal agencies invested approximately $2.89 billion in regenerative medicine research in fiscal years 2012, 2013 and 2014, the three most recent years for which full funding data was available. Most of the investment (88 percent) came from the National Institutes of Health (NIG). To conduct the study, GAO reviewed agency documents, reports, strategic plans and an interagency working group's meeting agendas and minutes. GAO also interviewed officials from the seven agencies, non-federal stakeholders, patient advocacy groups and trade organizations. Challenges identified in the report included recruiting regenerative medicine scientists to join the federal workforce, navigating the product review process, insurance coverage and reimbursement and communication between stakeholders from a wide array of disciplines and agencies.



REFERENCES

1. National Institutes of Health website. https://commonfund.nih.gov/stemcells/index. October 26, 2015.
2. Intramural Research Program. National Institutes of Health website http://irp.nih.gov/our-research/research-in-action/visionary-scientist-mentor-ceo. October 26, 2015.
3. Pharma and Biotech Survey. Alliance for Regenerative Medicine website. http://alliancerm.org/sites/default/files/ARM_Pharma_SurveyRept_Mar2014_e.pdf. October 26, 2015.
4. Hunsberger J, Harrysson O, Shirwaiker R, et al. Manufacturing road map for tissue engineering and regenerative medicine technologies. *Stem Cells Translational Medicine*. 2015;4:130-135.
5. Cellular Dynamics International website. www.cellulardynamics.com. October 26, 2015.
6. Report to Congressional Requesters: Regenerative Medicine — Federal Investment, Information Sharing, and Challenges in an Evolving Field. United States Government Accountability Office. GAO-15-553 website. http://www.gao.gov/assets/680/670930.pdf. October 26, 2015.

Researchers Use DNA 'Clews' to Shuttle CRISPR-Cas9 Gene-Editing Tool Into Cells

BY MATT SHIPMAN, NORTH CAROLINA STATE UNIVERSITY

For the first time, researchers from North Carolina State University and the University of North Carolina at Chapel Hill have created and used a nanoscale vehicle made of DNA to deliver a CRISPR-Cas9 gene-editing tool into cells in both cell culture and an animal model.

The CRISPR-Cas system, which is found in bacteria and archaea, protects bacteria from invaders such as viruses. It does this by creating small strands of RNA called CRISPR RNAs, which match DNA sequences specific to a given invader. When those CRISPR RNAs find a match, they unleash Cas9 proteins that cut the DNA. In recent years, the CRISPR-Cas system has garnered a great deal of attention in the research community for its potential use as a gene editing tool — with the CRISPR RNA identifying the targeted portion of the relevant DNA, and the Cas protein cleaving it. But for Cas9 to do its work, it must first find its way into the cell.

This work focused on demonstrating the potential of a new vehicle for directly introducing the CRISPR-Cas9 complex — the entire gene-editing tool — into a cell.

"Traditionally, researchers deliver DNA into a targeted cell to make the CRISPR RNA and Cas9 inside the cell itself — but that limits control over its dosage," says Chase Beisel, co-senior author of the paper and an assistant professor in the department of chemical and biomolecular engineering at North Carolina State. "By directly delivering the Cas9 protein itself, instead of turning the cell into a Cas9 factory, we can ensure that the cell receives the active editing system and can reduce problems with unintended editing."

The nanoclews are made of a single, tightly wound strand of DNA. The DNA is engineered to partially complement the relevant CRISPR RNA it will carry, allowing the CRISPR-Cas9 complex — a CRISPR RNA bound to a Cas9 protein — to loosely attach itself to the nanoclew. "Multiple CRISPR-Cas complexes can be attached to a single nanoclew," says Wujin Sun, lead author of the study and doctorate student in Zhen Gu's lab.

When the nanoclew comes into contact with a cell, the cell absorbs the nanoclew completely — swallowing it and wrapping it in a protective sheath called an endosome. But the nanoclews are coated with a positively charged polymer that breaks down the endosome, setting the nanoclew free inside the cell. The CRISPR-Cas9 complexes can then free themselves from the nanoclew to make their way to the nucleus. And once a CRISPR-Cas9 complex reaches the nucleus, gene editing begins.

To test the nanoclew CRISPR-Cas delivery system, the researchers treated cancer cell cultures and tumors in mice. The relevant cancer cells had been modified to express a fluorescent protein. In short, they glowed. The CRISPR RNAs on the nanoclews were designed to target the DNA in the cancer cell that was responsible for making the fluorescent proteins. If the glowing stopped, the nanoclews worked. "And they did work. More than a third of cancer cells stopped expressing the fluorescent protein," says Beisel. "This study is a proof of concept, and additional work needs to be done — but it's very promising," says Zhen Gu, co-senior author of the paper and an assistant professor in the joint biomedical engineering program at North Carolina State and University of North Carolina at Chapel Hill.

** The paper, "Self-Assembled DNA Nanoclews for the Efficient Delivery of CRISPR–Cas9 for Genome Editing," is published in the journal* Angewandte Chemie. *Co-authors include Jordan Hall, an undergraduate at North Carolina State and Wenyan Ji, Quanyin Hu and Chao Wang of the joint biomedical engineering program. The work was supported by the North Carolina TraCS,National Institue of Health's (NIH) Clinical and Translational Science Awards at University of North Carolina at Chapel Hill, grant number 1UL1TR001111 and by National Science Foundation (NSF) under grant MCB-1452902.*

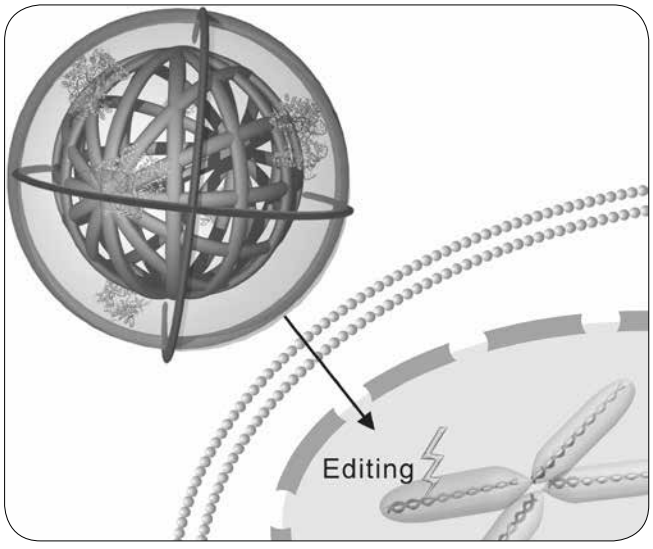


Image courtesy Wujin Sun

UABTEACH: ENCOURAGING UNDERGRADUATES TO PURSUE A CAREER IN STEM EDUCATION

BY YUSUF KHAN, EDUCATION NEWS CONTRIBUTING EDITOR

The last Education News column discussed programs that encouraged undergraduate science, technology, engineering and mathematic (STEM) students to pursue STEM education after graduation. One of the programs discussed was the UTeach program, a program originating at the University of Texas, Austin that prepares undergraduate students for careers teaching STEM courses at the high school level. Here we focus on one of the 44 programs in 21 states (and Washington DC) nationwide that have grown from the original University of Texas, Austin program.

The University of Alabama at Birmingham Teach (UABTeach) program was launched in the fall of 2014 with funding from the Howard Hughes Medical Institute and UAB. Run by Co-Directors John Mayer and Lee Meadows, with Program Coordinator Lawrence Moose, the UABTeach program was patterned after the original UTeach program in Austin. I was able to chat with Dr. Mayer, the professor and director of the undergraduate program in the Mathematics Department at UAB, and he provided some more details about their program.

The UABTeach program began in 2014 and anticipates having its first cohort of graduates in 2017. Prior to 2014, an undergraduate UAB student interested in certification as a high school STEM teacher would have been required to undertake a double major, one in the STEM field of their choice and the other in the education program. The existing education major provided limited interaction with practicing STEM teachers and few opportunities to gain classroom-teaching experience until the junior year of study. UAB noticed that the prospect of pursuing a double major was dissuading students from entering the program and the numbers of math and science teachers becoming certified was low, prompting the development of UABTeach.

The introduction of UABTeach brought many changes to the existing STEM education and certification process, three of which stand out prominently.

1) An entirely new curriculum, based on the original UTeach program, which provides inquiry-based approaches to learning and lesson design, knowledge of the chosen STEM field, classroom interactions, project-based instruction and apprentice teaching.

2) Updated program requirements for STEM field teaching certification, including the completion of a full undergraduate curriculum in a STEM field while completing a minor concentration in education (versus a full double major), reducing the required education credit hours by almost 50 percent.

3) New requirements for students to both observe and actively participate in classroom teaching as early as their freshman year, versus the previous program structure that did not require this until junior year. This new emphasis in early and sustained field experience was thought to compensate, in part, for the reduction in required education credit hours, while still providing a more intense-focused, hands-on, educational experience. This emphasis on early and sustained interaction would be partly accomplished by including clinical faculty made up of formerly practicing high school science teachers, referred to in the program as "master teachers," in the program, giving the students extensive one-on-one interaction with individuals who have extensive field experience.

The program is rigorous and demanding as students must simultaneously complete the full curriculum of their chosen STEM field and the UABTeach curriculum, but upon graduation the student receives a bachelor's degree in a STEM field and teacher certification.

Since the UABTeach program is only in its second year there is no data to assess its success, but the UTeach program in Austin has been collecting data from its own and other satellite programs, and the UTeach program produces students with higher graduation rates and higher GPA scores than the general pool of STEM graduates. After graduation students from the UTeach program show better retention within the teaching profession, with 80 percent of graduates still in the field after five years, compared to the national trend of 65-70 percent.

This may be due to the curriculum, the early and intensive immersion in field experience or the Post-Graduate

Induction Support program that the curriculum provides for its recent graduates. This program follows recent graduates for the first two years of their career and provides mentorship by the program's master teachers. This continued mentorship can take many forms and is largely up to the developers of the program. At this time, the UABTeach post-graduate induction support is still under development, but it will provide a continued connection between the graduates from the program and the program itself. The motivation for this is two-fold — it eases the transition of the recent graduate into his/her career, but also ensures retention within the field. Clearly, judging by the retention rate, it is working.

While the UTeach model and the UABTeach program are currently directed at undergraduate students interested in teaching high school STEM courses, it serves as an interesting model that may be applicable to graduate studies as well.

Are you part of a UTeach offshoot program? If so, and you'd like to share your experiences, please feel free to contact me at ykhan@uchc.edu and perhaps we can feature your program in the future.

"The function of education… is to teach one to think intensively and to think critically… Intelligence plus character — that is the goal of true education."

— Martin Luther King Jr.

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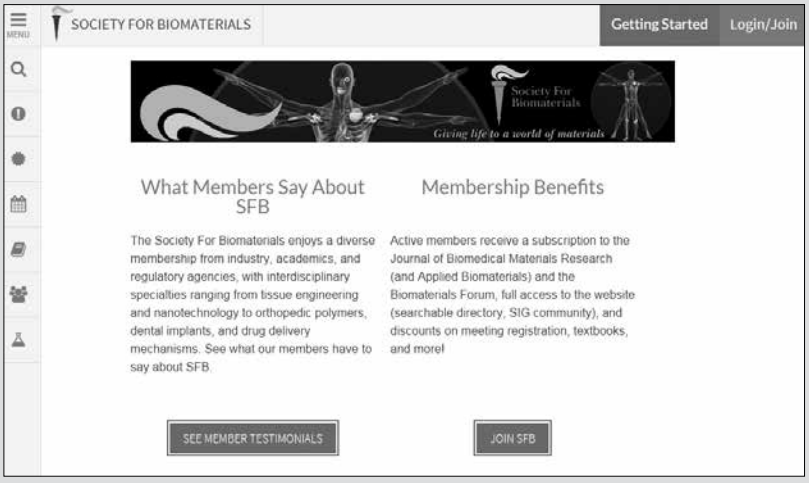


Industry News

BY STEVE LIN, INDUSTRIAL NEWS CONTRIBUTING EDITOR

India's Federal Department of Pharmaceuticals has proposed new regulations that include price controls for many devices, such as surgical instruments and implants. The structure, outlined in a document titled, "National Medical Device Policy, 2015," would charge a National Medical Devices authority to oversee the prices of medical devices. The draft regulations propose that the Indian government has the right to identify classes of medical devices that require pricing controls, which would trigger the creation of an additional medical devices control order. In addition, the draft calls for efficacy and safety testing, and would seek to ensure that products made in India would be produced according to internationally recognized standards. When it comes to medical devices, India still relies heavily on imports — about 70 percent of which are imported — yet, the nation is the largest consumer of pharmaceuticals internationally.

Stryker Orthopaedics has notified courts in New Jersey and Minnesota that it is ready to disburse $1.4 billion in a product-liability settlement over metal-on-metal artificial hips. Stryker recalled its Rejuvenate and ABG II artificial hips in July 2012, warning surgeons they could harm tissue around the hip and cause other health problems. About 95 percent of people who had revision surgery to replace the company's Rejuvenate Modular-Neck hip stem or ABG II Modular-Neck hip stem signed up for the settlement. New Jersey had more than 2,100 cases and there are another 1,500-plus federal suits centralized in the U.S. District Court of Minnesota, according to a report in the New Jersey Law Journal. The patient portion of this expensive saga may be winding down, but the hospital portion has just begun. A northern Arkansas hospital recently filed suit against Stryker, claiming it lost revenue on metal-on-metal hip implant issues.

It is striking to look at the **five medical technology firms** with the biggest job cuts (as a percentage) in 2014. All of the companies in the list are involved in diagnostics. Meanwhile, the *in vitro* diagnostics industry continues to grow at a steady clip overall. Below are the five medical technology firms with the most layoffs last year, relying on data drawn from the recent VantageEP report from Evaluate MedTech.

- BG Medicine (Cut staff by 70 percent)
- Alere (Handed pink slips to 44 percent of its staff)
- Cytori Therapeutics (Downsized nearly 40 percent of its workers)
- Sequenom (Trimmed 21 percent of its staff — about 122 people)
- Chembio (Cut 19 percent of its workforce)

Pioneer entrants into new device categories spend more than a third more time (more than seven months longer) getting their devices approved with the Federal Drug Administration (FDA), according to new research by Ariel Dora Stern, an assistant professor at Harvard Business School. Stern, who analyzed regulatory approvals spanning from 1977 to 2007, estimated that a delay of such length can produce 7 percent of the research and development (R&D) costs involved with bringing a new high-risk medical device to market. Problems with approval delays appear to occur when "evaluation criteria have not been formally articulated or informally established by precedent." One ray of hope is that the FDA may have already started to work with the medical device community through groups, such as the Medical Device Innovation Consortium, to reverse such trends.

Recently, major left ventricular assist device (LVAD) makers **Thoratec** and **HeartWare** were dealt a setback when the FDA issued safety communication reporting problems with the two companies' U.S.-approved devices. With the HeartMate II, scientific studies have found a pump thrombosis rate as high as 8.4 percent of implanted devices at three months and 6 percent at six months. That's higher than the 1.6-percent rate found after one year during the clinical trial to support bridge-to-transplant approval in 2008, and the 3.8-percent rate found after two years in the clinical trial for destination therapy approval in 2010. During a clinical trial to evaluate the HeartWare HVAD as a destination therapy, 28.7 percent of HVAD patients experienced one or more strokes over two years, versus 12.1 percent among patients implanted with the HeartMate II. The FDA also became aware of bleeding complications related to both the Thoratec and HeartWare devices. The

cause of the bleeding complications — mentioned in adverse event reports and a variety of other sources — is not fully understood and likely due to many different factors, according to the FDA.

The **FDA** announced **FY16 fee rates** and payment procedures for medical device user fees, which apply from Oct. 1, 2015 through Sept. 30, 2016. The collected fees are intended to support the FDA's endeavors to conduct efficient, timely, and transparent reviews. The fee for establishment registration is $3,845, which is up from $3,646 for FY15. Fees for 510(k) submissions increased by $210 standard and $105 for a small business, and PMA fees increased by $10,493 and $2,623, respectively. There is no fee reduction for small businesses, but they do qualify for lower user fees on certain application types. If a business has gross sales or receipts of no more than $30 million, it may qualify for a waiver of the fee for the first premarket-approval application, product-development protocol, biologics-license application, or premarket report.

The FDA announced the launch of a new crowd-sourced, cloud-based platform**, precisionFDA**, to enable developers of genomic sequencing diagnostics to share data and methodologies. The new platform is being jointly developed by the FDA's recently formed Office of Health Informatics, which was also behind the highly successful openFDA initiative and DNAnexus, a California-based company that specializes in data sharing for genomic sequencing. Additionally, the platform is intended to serve the president's recently announced Precision Medicine initiative. The FDA says it is building this platform to help accelerate the development of diagnostics that use next-generation sequencing (NGS) to test for wide ranges of genetic disorders. Because these tests generate so much data and can be used for multiple conditions, they do not fit within the confines of the agency's existing approach for evaluating diagnostics.

Cambridge-based **Editas Medicine** announced a $120 million Series B round led by Bill Gates's chief advisor for science and technology, Boris Nikolic. Editas is developing a gene-editing technique based on clustered, regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated protein 9 (Cas9) and transcription activator-like effector nucleases (TALENs). CRISPR-Cas9 is a two-part system derived from a defense mechanism that bacteria use to fend off viruses. Think of it as a pair of molecular scissors (Cas9) being carried into a cell's nucleus by a strand of RNA that serves as a guide (CRISPR). Once there, the scissors may be able to snip out a defective gene and, perhaps, replace it with a new, functioning one. CRISPR/Cas9 and TALENs uniquely enable highly efficient knock-out, knock-down or selective editing of defective genes in the context of their natural promoters, unlocking the ability to treat the root cause of a broad range of diseases.

The **FDA** issued public letters informing scope makers **Olympus, Pentax** and **Fujifilm** that it found several inadequacies during inspections in March and April at the companies' factories in Japan and the United States. The agency said the manufacturers failed to report trouble with the complex scopes and, in some cases, did not make sure that the devices could be sufficiently cleaned. The FDA specifically cited Olympus and Pentax for failing to report to the agency that their devices "may have caused or contributed to a death or serious injury" within the required 30 days when they learned of the events. The FDA also cited Pentax and Fujifilm for failing to ensure that their scopes' cleaning instructions were valid. The agency gave each company 15 days to respond to its letters.

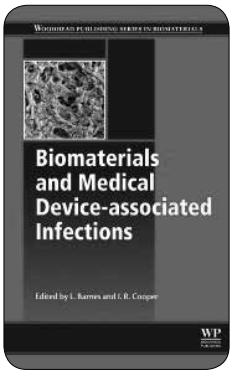
Moody's Investors Service is predicting that medtech companies will experience a solid earnings growth of 4 to 5 percent over the next 12 to 18 months, prompting the ratings agency to upgrade its outlook for the industry from "stable" to "positive." The ratings agency expects that cost savings due to major mergers and acquisitions that closed in 2015 — Medtronic/Covidien, Becton Dickinson/CareFusion and Zimmer/Biomet — will contribute 1 to 2 percent of the sector's aggregate earnings growth during 2015–16. Without these saving measures, the negative effects of foreign exchange would be more noticeable during 2015. The ratings agency cited a few other factors for its rosy earnings outlook, including expansion in emerging markets and new cardiac and orthopaedic products that could reduce hospital readmission rates and improve patient outcomes, which could boost earnings.

Biomaterials and Medical Device-Associated Infections

Book Review

BY LYNNE JONES, BOOK REVIEW EDITOR

Edited by: L. Barnes and I.R. Cooper
Publisher: Elsevier/Woodhead Publishing
ISBN: 978-0-85709-597-8



Infection is one of the factors that may contribute to decreased survivorship of medical devices. With the introduction of antibiotics and aseptic technique to the operating theater, the rate of infection dramatically decreased and research was refocused on other issues (e.g., wear). There has been a resurgence of interest driven by payers, providers and policymakers who are focused on quality improvement and cost-reduction — especially reducing readmissions and postoperative complications. The approach to reducing infection rates is multidisciplinary and includes the selection of biomaterials and device design, improved diagnostics and innovative treatment strategies. The book, "Biomaterials and Medical Device-Associated Infections," seeks to address each of these issues. Each chapter is written by an established researcher who is an expert in their field. They provide a review of what is known, but also add what they believe the future trends will be.

Part One: Introduction to Biomaterials and Medical Device-Related Infections

This section contains five chapters that provide the clinical context for the book. Chapter 1 begins with the requisite history of biomaterials and then transitions into their application to medical devices. The chapter, titled "Overview of Problems Associated with Medical Devices," is focused on implant-associated infections and includes a brief description of the principle pathogens that have been identified. The second chapter provides us with a characterization of biofilms and the pathogenesis of biofilm infection. Chapter 3 is a good resource for those who want to learn more about animal models that have been used. I especially appreciate the section on the pros and cons of the different models. Improved diagnosis of infections at the implant interface is paramount to our ability to understand the pathogenesis of the tissue response, as well as in developing interventions. Therefore, two chapters have been dedicated to this topic. Chapter 4 focuses on the detection of biofilms at the interface and Chapter 5 addresses prophylaxis, diagnosis and treatment.

Part Two: Technologies and Materials for Controlling Biofilms

Part two contains six chapters that describe different strategies for reducing medical device-associated infections. Chapter 6 is a thorough monograph on the use of surface modification to prevent or control biofilm formation. I would strongly suggest having your students read this chapter to provide them with the background for surface modification as it relates to infection. Chapter 7 builds on this to introduce us to surface nanoengineering strategies. Both of these chapters address anti-adhesives, as well as antibiotics. Chapter 8 is a stand-alone chapter that provides the overview of biomaterials and devices, a description of device-associated infections and biofilm formation and then a review of conventional antimicrobial biomaterials. Chapter 9 describes the specific application of antibiotic-loaded bone cement for hip and knee arthroplasty and Chapter 10 focuses on restorative materials and dental applications. Chapter 11 introduces us to infection-resistant biomaterials, including drug-releasing antimicrobial systems, antimicrobial cationic systems, antifouling surfaces and naturally occurring antifouling surfaces, and silver ions and silver-containing surfaces.

The strength of this book is its focus — biomaterials. This is a 360-degree view of the impact of infection on the long-term outcome of medical devices. It addresses how biomaterials are associated with infection and how biomaterials can be used to combat infection. It provides the reader with an excellent review of the past, a picture of the present and a snapshot into the future regarding many of the issues concerning medical device-associated infections. I would, however, suggest that the reader supplement the reading of this book with publications regarding the biological responses to biomaterials that can be found in textbooks (such as Inflammation and Infection In: An Introduction to Tissue-Biomaterial Interactions[1] or Biomaterials Science: An Introduction to Materials in Medicine, 3rd ed.[2]), as well as in the medical literature. This is a good book to have as a resource for topics relating to medical device-associated infections and can easily be used for upper-level undergraduate courses.

REFERENCES

1. Dee KC, Puleo DA, Bizios R. Inflammation and Infection In: *An Introduction to Tissue-Biomaterial Interactions*. Hoboken, NJ: Wiley & Sons; 2002.
2. Ratner B, Hoffman AS, Schoen FJ, Jack E. Lemons JE, eds. *An Introduction to Materials in Medicine* (3rd Edition). Biomaterials Science. Waltham, Massachusetts: Elsevier; 2013.

Upcoming 2015 – 2016 Events

EVENT	DETAILS	WHEN & WHERE
6th International Conference on the Mechanics of Biomaterials and Tissues	ICMOBT provides a unique international forum for researchers and practicing engineers from different disciplines to interact and exchange their latest results.	Dec. 6–10 Waikoloa Village, Hawaii Marriott Waikoloa 69-275 Waikoloa Beach Drive
The Science of Pain and its Management	This international event will discuss the latest research relating to the physiology, psychology and pharmacology of pain; the psychosocial aspects of pain; and the assessment and management of pain.	Dec. 8 London, United Kingdom Cineworld: The O2
Biobanking 2016	This three-day event brings together biomedical and biopharmaceutical researchers, regulators, biorepository managers and practitioners to discuss current practices regarding the banking of biospecimens used for basic research through clinical trials.	Jan. 5 London, United Kingdom Cineworld: The O2
Keystone Symposia: Molecular and Cellular Basis of Growth and Regeneration	The regulation of scale and proportion is a fundamental attribute of life. Yet, the molecular, cellular and systems-level mechanisms regulating these processes remain largely unknown. This meeting aims to delineate the molecular and cellular basis of growth and regeneration by highlighting, comparing and contrasting the differences and similarities in scale and proportion mechanisms and stem cell management among diverse animal species.	Jan. 10–14 Breckenridge, Colorado Beaver Run Resort 620 Village Road
9th Symposium on Biologic Scaffolds for Regenerative Medicine	This symposium is designed to advance the use of biologic scaffolds for regenerative medicine and all general surgery applications via a series of objective presentations describing the potential benefits and risks associated with the use of such materials, factors that affect performance and the clinical applications that may benefit most from their use. Topics range from the most basic science of scaffold remodeling at the molecular level through the preclinical and clinical level.	April 28–30 Napa California Silverado Resort and Spa 1600 Atlas Peak Road
10th World Biomaterials Congress	The conference program will consist of plenary lectures, symposia, workshops and invited sessions of the latest significant findings and developments in all the major fields of biomaterials and related disciplines. Submitted abstracts will be peer reviewed for quality and impact. Accepted abstracts will be assigned to oral and poster sessions and will appear in the Conference Proceedings.	May 17–22 Montreal, Quebec City, Canada Palais des Congres de Montreal 159 Saint-Antoine St. West
ASAIO 62nd Annual Conference	A Unique Scientific Forum: The ASAIO Journal and Annual Conference promote excellence in basic and clinical research. In contrast to other organizations, preference is given to outside-the-box ideas and approaches to organ assist or replacement therapy. The annual conference is a uniquely open and vibrant forum for the discussion of current and future work.	June 15–18 San Francisco, California Hyatt Regency San Francisco 5 Embarcadero Center

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