# BIOMATERIALS FOR BIOMATERIALS OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Third Quarter 2014 • Volume 38, Issue 3

Biomaterials Forum, the official news magazine of the Society For Biomaterials, is published quarterly to serve the biomaterials community. Society members receive *Biomaterials Forum* as a benefit of membership. Non-members may subscribe to the magazine at the annual rate of \$48. For subscription information or membership inquiries, contact the Membership Department at the Society office (e-mail: info@biomaterials.org) or visit the Society's Website, www.biomaterials.org.

It is the policy of the Society For Biomaterials that all articles reflect only the views of the authors. Publication of articles or advertisements within *Biomaterials Forum* does not constitute endorsement by the Society or its agents of products, services or views expressed herein. No representation is made to the accuracy hereof, and the publication is printed subject to errors and omissions. Articles that do not have an author byline may originate from press releases. The Society For Biomaterials retains press releases on file for a period of one year from the date of publication.

Editorial contributions to *Biomaterials Forum* are always welcome. Contributions should be sent to the Executive Editor and are subject to the terms and conditions of the Editorial and Publication Release. Authors should refer to the Author Guidelines, which are available on the Society's website, when writing submissions. The publisher accepts no responsibility for return or safety of artwork, photographs or manuscripts. Submission of editorial content does not guarantee acceptance or publication.

Address corrections should be sent to *Biomaterials Forum*, 1120 Route 73, Suite 200 Mt. Laurel, NJ 08054.

Requests for advertising information should be directed to Sarah Black at sblack@ahint.com or (856) 439-0500, ext. 4240. Information is also available on the Society's website, www.biomaterials.org.

Unauthorized reproduction of this magazine in whole or in part is prohibited without the permission of the publisher. Requests for permission should be directed to the Managing Editor.

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

Copyright© 2014 • ISSN 1527-6031 Society For Biomaterials All rights reserved

# BIOMATERIALS FORUSALS. Volume 38, Issue 3

**Executive Editor** 

Liisa T. Kuhn, University of Connecticut Health Center, Reconstructive Sciences, Biomaterials and Skeletal Development 236 Farmington Ave. MC1615, Farmington, CT 06030-1615 Phone: (860) 679-3922 • Fax: (860) 679-1370 E-mail: lkuhn@uchc.edu

Managing Editor

**Government News** 

**Contributing Editor** 

**Contributing Editor** 

**Contributing Editor** 

**Book Review Editor** 

Society Business & Membership

**News Contributing Editor** 

**Special Interest Group News** 

**AIMBE News Contributing Editor** 

**Education News Contributing Editor** 

**Historical Flashback Editor** 

Student News Contributing Editor

**Industrial News** 

Sarah Black, Society For Biomaterials 1120 Route 73, Suite 200, Mt. Laurel, NJ 08054 Phone: (856) 642-4240 • Fax: (856) 439-0525 E-mail: sblack@ahint.com

Carl G. Simon Jr, NIST Biosystems & Biomaterials Division E-mail: carl.simon@nist.gov

Steve T. Lin, Exactech Inc. E-mail: steve.lin@exac.com

Horst von Recum, Case Western Reserve University Department of Biomedical Engineering E-mail: horst.vonrecum@case.edu

Steve Little, University of Pittsburgh Department of Chemical Engineering E-mail: slittle@engr.pitt.edu

Lynne Jones, Johns Hopkins University Department of Orthopaedic Surgery E-mail: ljones3@jhmi.edu

Lynne Jones, Johns Hopkins University Department of Orthopaedic Surgery E-mail: ljones3@jhmi.edu

Yusef Khan, University of Connecticut Department of Chemical, Materials and Biomolecular Engineering E-mail: ykhan@uchc.edu

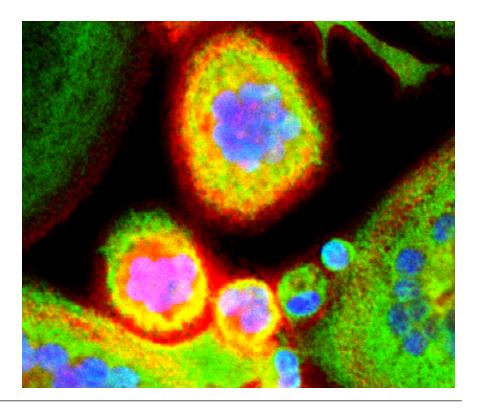
Guigen Zhang, Clemson University Department of Bioengineering E-mail: guigen@clemson.edu

Jordan Gilmore E-mail: jagilmo@clemson.edu

### Special Interest Group Reporters

Biomaterials & Medical Products Commercialization Biomaterials Education Biomaterial-Tissue Interaction Cardiovascular Biomaterials Dental/Craniofacial Biomaterials Drug Delivery Engineering Cells & Their Microenvironments Immune Engineering Nanomaterials Ophthalmic Biomaterial Orthopaedic Biomaterial Protein & Cells at Interfaces Surface Characterization & Modifications Tissue Engineering

Nihar Shah • nihar.shah@uky.edu Greg Hudalla • ghudalla@bme.ufl.edu Floyd Karp • floyd@u.washington.edu Natalie Artzi • nartzi@mit.edu Sachin Mamidwar • smamidwar@orthogencorp.com Scott Guelcher • scott.guelcher@vanderbilt.edu Adam Feinberg • feinberg@andrew.cmu.edu Julie Stenken • jstenken@uark.edu Steven Eppell • sje@case.edu Morgan Fedorchak • mod8@pitt.edu Jessica Amber Jennings • jjnnings@memphis.edu Sumona Sarkar • Sumona.sarkar@nist.gov Nihar Shah, PhD • nihar.shah@uky.edu Abby Whittington • awhit@mse.vt.edu



## Departments

#### **The Torch**

- 2 From the Editor
- 3 From the President
- 4 Staff Update

### **News & Updates**

- 6 Member News
- 8 Historical Flashback
- 8 SIG News
- 19 Government News
- 20 Industrial News
- 21 Education News
- 23 Student News
- 24 Book Review

**On the cover:** Confocal microscopic image of fusing human macrophages and foreign body giant cells stained for nuclei (blue), actin (red) and calnexin (green). Photomicrograph courtesy of Drs. James M. Anderson and Amy K. McNally, Department of Pathology, Case Western Reserve University, Cleveland, Ohio.



#### GREETINGS FELLOW BIOMATERIALS SCIENTISTS,

A core group of Society For Biomaterials (SFB) members who serve as editors of this news magazine have compiled the latest news in the field of biomaterials for you! I hope you enjoy it.

This issue is particularly hefty because the Special Interest Groups (SIGs) were asked to provide an update on their activities or to write a short technical article of particular interest to their members. Seven of the 14 SIGs have responded in time for this issue. I'd like to draw your attention to the article from the Ophthalmic SIG about problems with intraocular lenses under SIG News. If you're like me, it's hard to attend all the sessions of interest at the annual meeting, but I hope that now you may have time to take a quick peek and learn about a core issue in this specialty. The additional SIG updates received after this issue deadline will be included in future issues.

Our SFB members continue to receive prestigious professional awards, advancements and move on to other new opportunities. Read the Member News column to find out more and be inspired by what your colleagues have achieved.

One noteworthy news item, not mentioned in the column, is that Buddy Ratner was interviewed for a TED blog in which he provided a summary of extraordinary biomaterial advances in the past millennia. It's part of the "Questions Worth Asking" series, *Should We Redesign Humans?* Read it here: http://ideas.ted.com/2014/02/18/a-history-of-biomaterials/.

The Government News article in this issue highlights the Alliance for Regenerative Medicine (ARM), which is an industry consortium and advocacy organization that "promotes legislative, regulatory, reimbursement, investment, technical and other initiatives to accelerate the development of safe and effective regenerative medicine technologies." They report that standardization efforts in the area of tissue engineering and regenerative medicine must become a priority because they can streamline regulatory approval through the use of standardized materials and techniques to demonstrate biological activity.

The Historical Flashback describes the long-lasting positive effects of being recognized with the Clemson Award from SFB. When one member was recognized in 1983 it changed his career path for the better.

Also, be sure to read Industrial News for an overview of the latest mergers and acquisitions and other notable corporate product releases.

Please help us to make sure this publication reflects news of interest to you within the diverse and fascinating field of biomaterials. I'm particularly searching for opinion pieces or cover art for the upcoming issues. Please send them to me at <u>Lkuhn@uchc.edu</u> for consideration.

Best wishes,

fisa Kuhn

LIISA KUHN Biomaterials Forum Executive Editor Associate Professor University of Connecticut Health Center



In this issue of *Biomaterials Forum* there are a few articles related to our Special Interest Groups (SIGs). How did these SIGs come about and what is the current state of the SIGs?

To get a better understanding of how things came about, I had a recent

conversation with Dr. Buddy Ratner from the University of Washington. I believe that much of the impetus for the conception and implementation of our SIGs is attributed to Dr. Ratner's efforts. Certainly there was work by others, but Buddy's vision and idea "to get members more engaged as well as open more leadership positions in our Society" led to their formation and petitions that were put forth at the Scottsdale meeting in 1991. At this meeting, there were 22 different names or groups suggested, and, eventually, 10 were approved by council at the meeting in Birmingham in 1993:

- Biomolecular Engineering
- Biotechnology
- Dental Materials
- Drug Delivery
- Hybrid Artificial Organs
- Implant Pathology
- Ophthalmology
- Orthopaedic Biomaterials
- Proteins and Cells at Interfaces
- Surface Characterization

Some of these SIGS are gone, rolled into other SIGs or have changed names. For example, Dental Materials changed to Dental/Craniofacial Biomaterials, whereas others simply added Biomaterials (Ophthalmic) to their name. The Implant Pathology SIG changed its name last year to Biomaterial-Tissue Interaction, and a new SIG, Immune Engineering, was added this year.

From their inception, there were SIG chairs but the first SIG representative to council, David Grainger, was elected in 1996 for a one-year term followed by a bylaws change in 1998 to make this a two-year term, and then again in 2003 to have this position on the Board. Other SIG reps were Cato Laurencin, Jean Jacob, Lynne Jones, Elaine Duncan, Andres Garcia, Lisa Friis, Chris Siedlecki, Jeff Schwartz and, now, Steven Little, the current SIG Rep. How are the SIGs doing in 2014? I believe our SIGs are stronger than ever and at our most recent meeting in Denver, Colo., our SIG meetings were well attended and significantly contributed to the program content. In recent years our SIGs have had much input into the plenary sessions, symposia and tutorials and I hope they continue to be engaged. I am aware of discussions in many of the SIG meetings I attended in Denver that indicate they will continue to submit ideas for our meeting in 2015 in Charlotte.

*The SIGnal*, the newsletter developed three years ago, provides our members with the latest information regarding our SIGs and is a welcome addition to our Society. In addition, to help promote our SIGS as well as offer some value to joining and maintaining membership in our Society, we implemented a change to this year's registration/membership fees that allows members to join one SIG free of charge. I believe this increased the appeal of SIGs for those who did not have an idea what a SIG was about, and gave members an opportunity to try something different and become more engaged in our Society–Buddy's vision coming back again 25 years later!

So, I believe our SIGs are doing quite well, their interest among our members is strong and their actions within our Society are integral to its overall success. Next year we will celebrate the 25th anniversary of our SIGs and it is worth thanking Dr. Ratner and everyone who had the vision to start these groups, as well as SFB members for their hard work in keeping our SIGs engaged in our Society.

Nichl P. Zet

NICHOLAS P. ZIATS, PH.D. Case Western Reserve University President, Society For Biomaterials

# <u>Staff Update</u>

#### BY LESLIE CLARK, ASSISTANT EXECUTIVE DIRECTOR



Hello from Society For Biomaterials headquarters! The big news from headquarters is the recent move to new office space for Association Headquarters, Inc. As of the first week in August we relocated a short distance down the road to a building better suited to the staff and service

departments AH is proud to provide to help SFB and all our client partners as they grow and thrive. Our phone numbers, fax number and email addresses all remain unchanged. See the end of this update for headquarters' new street address.

All SFB committees have spent the last several months reorganizing and beginning work on the charges presented to them by the Council at its meeting in Denver.

#### AWARDS, CEREMONIES AND NOMINATIONS

{ CHAIR JAMES ANDERSON }

The committee has spent the summer reviewing the materials for all candidates whose nominations were eligible to be carried over for consideration in 2015. New nominations have been received throughout the summer. Anyone planning to make a nomination is reminded that the deadline is September 15. In addition, nominations for President-elect, Secretary/Treasurer-elect and Member-at-Large are due to the committee by September 22.

#### BYLAWS

#### { CHAIR ANN SALAMONE }

Several meetings have been held to discuss possible amendments to the bylaws extending the term of the Presidency or adding an additional Member-at-Large. The committee's recommendations will be submitted to Council when deliberations are concluded.

#### **DEVICES & MATERIALS COMMITTEE**

#### { CHAIR SHROJAL DESAI }

The committee will be working on the second annual business competition for the 2015 annual meeting and a third joint workshop with the Chinese Society, which is to be hosted in China.

### EDUCATION AND PROFESSIONAL DEVELOPMENT

{ CHAIR TIM TOPOLESKI }

Requests for SFB's endorsement of other meetings have continued to be received and evaluated by the E&PD over the summer. An Education Task Force is being created to consider new initiatives. Later in the fall the committee will be reviewing submissions for Biomaterials Days grants.

#### FINANCE

#### { CHAIR LISA FRIIS }

A call with SFB's investment advisor was held to review the Society's investments and discuss future plans. The committee agreed to some reallocation of SFB investments in order to bring them into line with the asset allocation outlined in the investment policy. Another meeting will be held in January 2015 to re-evaluate the investments and ratios.

#### LIAISON

#### { CHAIR DAVID PULEO }

Two key areas of focus in the coming year include 2016 workshops and symposia and the China workshop.

#### LONG RANGE PLANNING

{ CHAIR THOMAS WEBSTER }

The Long Range Planning Committee is charged with increasing membership, especially from industry and clinical sectors; furthering international collaborations; increasing the visibility of SFB through public relations efforts; governmental/policy issues; and potential collaborations with other organizations.

#### MEETINGS

{ CHAIR NICHOLAS ZIATS }

Over the next months the Meetings Committee will begin considering potential sites for the 2017 and 2018 annual meetings, the 2015 Bash in Charlotte and work with the SIGs and Liaison Committee on workshops and symposia ideas for 2016.

#### MEMBERSHIP

#### { CHAIR KURTIS KASPER }

This year, the committee will be gathering information and reviewing marketing strategies for societies similar to SFB in order to discover best practices that could be adopted by SFB. Their findings will be presented to Council at its fall meeting.

#### PROGRAM

#### { CO-CHAIRS HELEN LU AND PETER EDELMAN }

The call for abstracts will be going out in early September, with a November deadline. The committee will meet to finalize the 2015 program in December this year, a month earlier than usual, in order to provide more time to notify invited speakers and for international attendees to acquire the necessary visas. Because of this accelerated time line, the program chairs are asking that all abstract reviewers complete their reviews on time.

#### PUBLICATIONS

#### { CHAIR ALAN LITSKY }

The committee is in the process of reorganizing and making plans for the coming year.

#### SPECIAL INTEREST GROUPS

#### { REPRESENTATIVE STEVE LITTLE }

The SIGs were tasked with providing content for this SIG highlight issue of the *Forum*. They have spent the summer submitting proposals for the 2015 meeting in Charlotte, planning their budgets for 2015 and preparing ideas to submit to Council for regional targeted workshops or meetings during the World Biomaterials Congress year 2016. This is a new approach to the WBC year that Council believes would give added value to the SFB membership.

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

#### SOCIETY FOR BIOMATERIALS

1120 Route 73, Suite 200 Mount Laurel, NJ 08054 Phone: 856-439-0826 Fax: 856-439-0525 Email: info@biomaterials.org URL: www.biomaterials.org

#### BY HORST VAN RECUM, 2014-15 MEMBER-AT-LARGE



Greetings to the members of the Society For Biomaterials (SFB). Thank you for electing me as Member-at-Large for the Society for the 2014-2015 year. I am honored to serve you, and I would like to thank Jan Stegemann for his excellent service in this role last year, as well as the help and advice he has given me.

I thought it would be helpful to begin my term by reminding our readers of the functions of this position in the SFB. The role of the Member-at-Large is to represent the overall members of the Society. In this capacity, I serve as an unencumbered representative of the members on both the Board of Directors and the Council of the Society. In addition, the Member-at-Large, in this representative role, is frequently selected to be a member of other committees (e.g. Long Range Planning Committee, Bylaws Committee, Membership Committee, Program Committee). These arrangements are made so the members always have a clear voice in the direction of the Society, and my participation in these committees and governing bodies ensures all voices can be heard. I encourage all members to bring forth ideas about the Society, meetings and anything else relevant to making the Society better.

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

**Dr. Suzie Pun** received 2014 Controlled Release Society Young Investigator Award, inaugural Biomaterials Science Lectureship. Dr. Pun, the Robert F. Rushmer Associate Professor in the Bioengineering Department at the University of Washington, will receive public recognition of this award at the 2014 CRS Annual Meeting & Exposition in Chicago. Dr. Pun is also the first-ever recipient of the Biomaterials Science Lectureship award. The lectureship honors a younger scientist who has made significant contributions to the biomaterials field. In recognition of this award, Dr. Pun will present a lecture three times (with one lecture to take place in the U.S.), receive a travel award, contribute a lead article to the journal *Biomaterials Science* and have her work showcased on the back cover of the issue in which her article is published. **Dr. Rebecca Bader**, Assistant Professor in the Department of Biomedical and Chemical Engineering, and Syracuse Biomaterials Institute at Syracuse University, was awarded tenure and promotion to Associate Professor. Her research is on the elucidation of rheumatoid arthritis pathogenesis using a physiologically relevant in vitro model and development of new treatment strategies based upon dendrimers with orthogonally reactive tethers.

**Dr. Nathan D. Gallant**, Assistant Professor in the Department of Mechanical Engineering at the University of South Florida, was awarded tenure and promotion to Associate Professor. Further, he won the Outstanding Faculty Award at the University of South Florida earlier this year. His research interest is in adhesion receptor-mediated processes and developing novel tools and strategies to investigate how cells interface with native and engineered extracellular matrices.

**Dr. Anirban Sen Gupta**, Assistant Professor in the Department of Biomedical Engineering at Case Western Reserve University, was awarded tenure with promotion to Associate Professor. His research interest is on understanding the complex pathophysiological mechanisms of cardiovascular diseases and cancer, and then on using this insight to develop disease-targeted therapeutic strategies by integrating critical physical, chemical and biological components at nano-to-micro scales.

Two SFB members recently participated in the ELATE program at Drexel University (Executive Leadership in Academic Technology and Engineering). ELATE at Drexel<sup>®</sup> is a national leadership development program designed to advance senior women faculty in academic engineering, computer science, and related fields into effective institutional leadership roles within their schools and universities. Congratulations to **Drs. Julie Hasenwinkel** and **Kristi Kiick** for completing their 2014 fellowships. And congratulations to **Dr. Shelly Sakiyama-Elbert** for being selected to participate in the 2014-15 program.

**Dr. Monty Reichert**, the Alan L. Kaganov Professor of Biomedical Engineering at Duke University, was awarded a Fulbright Award to work with Makerere University in Kampala, Uganda. He will be teaching a class called "Biomaterials for the Developing World" and will be building a MOOC in collaboration with faculty and students at Makerere University. Makerere is recognized for having started the first BME degree in sub-Saharan Africa. He will also be helping them with curriculum development. The Fulbright Award also provides a powerful opportunity for building research and educational alliances between the BME programs at Duke and Makerere. This will be accomplished by building upon existing collaborations between the Duke Global Health Institute and Kampala's Mulago Hospital and Makerere University. A central focus of BME alliance building will be Makerere University's USAIDfunded Development Lab coined ResilientAfrica that intends to improve community resilience against natural and political disasters in 16 African countries through the application of science and technology.

**Dr. Joyce Y. Wong**, Professor of Biomedical Engineering at Boston University, was recently appointed director of a Provost Initiative to promote women in STEM fields at Boston University. The name of the effort is ARROWS: Advance, Recruit, Retain & Organize Women in STEM. They are planning a launch in September 2014, and ARROWS will focus on the organization and alignment of existing and future programs related to women in STEM fields through vertical integration of all levels at Boston University.

**Dr. Erin Lavik**, Elmer Lincoln Lindseth Associate Professor in Biomedical Engineering at Case Western Reserve University, was selected to the Editorial Board of the *Journal* of *Bioconjugate Chemistry*. Her research interest is in developing translatable approaches to treat injuries to and diseases of the central nervous system, including spinal cord injury, glaucoma, and retinal degeneration. Her lab's tools involve polymer science, drug delivery, and cellular therapy approaches.

**Dr. Laura Suggs**, Associate Professor at the University of Texas at Austin, was selected for the Editorial Board for the *Journal of Materials Chemistry B*, a new journal formed from splitting off the applications in biology and medicine from the *Journal of Materials Chemistry*. Her research is primarily focused on the development of biologically active materials and their use and behavior in cardiovascular tissue engineering.

**Dr. Horst von Recum**, Associate Professor in the Department of Biomedical Engineering at Case Western Reserve University, was selected for the Editorial Board of the *Experimental Biology and Medicine* journal and named Associate Editor for biomedical engineering applications. His research interests are in tailoring molecular affinities into polymeric substrates to obtain additional handles to control drug loading and release rate as well as cell behavior. His lab has used this in applications ranging from preventing medical device infection to preventing cardiovascular graft failure and treating cancer. **Dr. David Kaplan**, the Stern Family Endowed Professor of Engineering and chair of the Department of Biomedical Engineering at Tufts University, has been named Editor-in-Chief of the brand-new, web-only journal *ACS Biomaterials Science & Engineering.* The first issue is scheduled to be published in January 2015. This new monthly publication will feature papers in the areas of new and modified biomaterials, as well as bioinspired and biomimetic approaches to biomaterials, biomaterial interfaces for biology and health, manufacturing, technology and tissues in the context of biomaterials, and modeling and informatics tools.

# Winning the Clemson Award Changes One's Career Path

### **Historical Flashback**

#### BY GUIGEN ZHANG, CLEMSON UNIVERSITY



Robert E. Baier, PhD, PE, in 1983 when he received the Clemson Award for Basic Research from the Society For Biomaterials.

For this edition of Historical Flashback, I contacted one of the SFB charter members, Robert E. Baier, Distinguished Professor, State University of New York at Buffalo, and asked him to share with us his personal experience of what it meant to his career development with his winning of the 1983 Clemson Award for Basic Research from the Society For Biomaterials. It turns out it meant a lot. At the time of his winning the Clemson Award for Basic Research, he was a researcher at a contract R&D firm.

The award not only changed his career path from an industry researcher to a distinguished professor, but also led to his acceptance and recognition by his peers and his SFB presidency from 1992 to 1993.

"As a young and brash biophysicist, I had become convinced that blood compatibility is dictated 'where the rubber meets the road', at the true interface," said Dr. Baier. "There was, at

that time, an emerging group of also true zealots — led by Sam Hulbert as he migrated from the New York State College of Ceramics to a leadership post at Clemson University - that was beginning to refer to all such blood, bone, and tissue-friendly substances as biomaterials. Invited to Clemson to present my work, as I heard the squeaking bamboo rapidly growing outside the window, I was cajoled into joining them as a founding member of the Society For Biomaterials (SFB). Then, as an employee of a contract R&D firm, it was crucial to my continuing in this field that I was accepted by academic peers and honored with the 1983 Clemson Award for Basic Research. Such early and flattering notice was key to my subsequent efforts, and led to my SFB presidency in 1992-3. It has been amazing to see how a 'bunch of young revolutionaries' could create a new and productive field of science, and major economic enterprises!"

This part of the SFB history is truly inspiring, especially to many young and new members – the future of the SFB.

### Biomaterials Outreach Design and Assessment: Pioneering Future Biomaterials Scientists and Engineers SIG News BY LISA C. BENSON, ASSOCIATE PROFESSOR, ENGINEERING AND SCIENCE EDUCATION, CLEMSON UNIVERSITY

### FROM THE EDUCATION SIG

Great ideas for outreach projects typically bubble up out of a desire to share your passion for biomaterials research, and to get kids really excited about science, technology, engineering and math (STEM). You may organize one or more fun handson activities, prepare handouts, recruit students, and have a blast on a Saturday afternoon (or maybe several Saturdays). Photos are taken of the happy, smiling faces of your participants. Who can argue with happy? So it was a success, right? But how do you really know if that activity had any effect on your original goal of getting kids excited about science and engineering in a sustained and meaningful way? And how do you define excited? Is it students' interest, or changing their behavior (like participating in science fairs and clubs), or is it just changing their attitudes about science class? It is important to consider assessment as part of the design and development of educational programs and courses, just as in biomaterials research. An investigator wouldn't dream of testing a biomaterial without some idea of the material's likely effect on cells, or its degradation profile. That investigator would carefully research methods to study the material, planning what types of data will be collected at what time points. The same is true for assessing an outreach program. But often assessment is *ad hoc*, and is considered only days before an outreach activity takes place, or worse, afterwards, when the leftover gelatin is being cleaned up or scattered Legos are being gathered, and the question is asked, "What did we really accomplish?" Outreach projects are more likely to be impactful and successful if they are developed intentionally, similar to the way a research proposal itself is designed: Determine the background and interests of your **audience**, choose **objectives** based on these backgrounds (as well as your own expertise and interest), **design** activities to achieve your objectives and **assess** the success of the project through assessments.

#### AUDIENCE

Who we target for our outreach activities depends in part on our objectives. If we are hoping to recruit more students into STEM disciplines, then research has shown that students, especially females, typically lose interest in science in middle school.<sup>1,2</sup> However, recent research is showing that it is not too late to affect students' decisions about college majors in high school.<sup>3</sup>

#### **OBJECTIVES**

Why do we do biomaterials outreach? It is surely part of our jobs as researchers to engage with the community, particularly for those of us at land grant institutions, or at corporations in which community partnership and public service are part of our missions. We also need to fulfill broader impacts requirements for our funded projects. But perhaps the most compelling reason to do outreach is for building infrastructure – recruiting and retaining future biomaterials scientists and engineers. Biomaterials outreach can be considered to be the real pioneering effort in our field!

Similar to learning objectives for a class, statements of what students should be able to do after participating in an outreach activity should be specific and measurable.<sup>4</sup> Especially if the point of an activity is to recruit more students into STEM fields, our objectives should include both knowledge-related outcomes (the cognitive domain) as well as attributes like interest, attitudes, beliefs, and motivation towards pursuing degrees and/or careers in STEM (the affective domain). Objectives in the cognitive and affective domains are not necessarily unrelated. For example, intentionally linking outreach topics to classroom science curricula can increase the relevance of what students are learning and boost their motivation to learn.<sup>5</sup> There are few engineering role models in mass media to expose prospective students to our field; outreach activities have the potential to give more realistic perspectives on what engineers actually do. Activities that boost students' confidence in choosing a science or engineering major can have long term effects, even into college.<sup>6</sup> Thus outreach activities should be designed with both cognitive and affective domains in mind.

#### DESIGN

As pioneers, biomaterials educators open up new areas of thought and create new paths for students to follow. Logic models can be applied, similar to a research proposal, starting with desired outcomes. What do you want to accomplish in terms of learning, actions, or long term effects within the community? What follows is an "if-then" dialog within the logic model: If we get these resources (inputs) and conduct these activities to reach these people, then we will accomplish our outcomes. A logic model helps align the target audience, desired outcomes, activities and assessments.

Inputs	Activities Column 1	Activities Column 2	Outcomes Column 1	Outcomes Column 2	Outcomes Column 3
What we invest	What we do	Who we reach	Why we do it: Short-term results	Why we do it: Intermediate results	Why we do it: Long-Term results
•Staff •Volunteers •Time •Money •Research findings •Materials •Equipment •Technology •Partners	•Conduct workshops, camps and programs •Develop lessons, resources •Facilitate access to information •Work with media	•Students •Teachers •Parents •Agencies and community- based organizations (CBOs)	Learning •Knowledge •Skills •Awareness •Attitudes •Opinions •Goals •Motivations	Action •Behavior •Practice •Decision- making •Social Action	Conditions •Educational environments •Social environments

Table 1. Logic model template for designing outreach activities.<sup>7</sup>

#### ASSESSMENT

Now comes the hard part. We can't rely on anecdotal evidence or photos of happy children to demonstrate the effectiveness of our trailblazing activities. First and foremost, the assessment should match the desired outcomes. If the point of the outreach activity is to teach students about a specific content area such as tissue engineering, then pre- and post-content quizzes that show relative gains in understanding would be appropriate assessments. But if the objective is to increase students' interest in STEM disciplines, content quizzes will not show how well the program met that objective. Attributes in the affective domain that could be assessed include attitudes, beliefs, and views on the nature of science. Both cognitive and affective domains are needed to fully tell the story of what is happening in our outreach programs.

Our stories can be told using quantitative measures, such as grades on quizzes or responses to surveys asking about students' interest in STEM. But much like lab assays for specific reactions, assessments must be proven as valid and reliable before we use them to gauge effectiveness of our programs. Results from valid and reliable assessments can be used to produce solid data as evidence of success of outreach activities, which can be leveraged to obtain funding for such endeavors and to improve and refine activities to achieve desired objectives.

The process of developing a valid, reliable survey is an arduous one and can take years to complete.<sup>8</sup> There are many available assessments that target desired outcomes for an outreach activity, and they eliminate the need to develop

"home grown" surveys. Resources for finding appropriate assessments are listed in Table 2. Surveys are available to assess attributes that are relevant to outreach activities beyond student interest. One example is students' views on the nature of science (VNOS). Validated and reliable surveys that assess changes in VNOS include questions such as:

- What, in your view, is science?
- What makes science (or a scientific discipline such as physics, biology, etc.) different from other disciplines of inquiry (e.g., religion, philosophy)?
- What is an experiment?
- Does the development of scientific knowledge require experiments?
  - » If yes, explain why. Give an example to defend your position.
  - » If no, explain why. Give an example to defend your position.

RESOURCE	TYPES OF ASSESSMENTS	
Field-tested Learning Assessment Guide (FLAG): <u>http://www.flaguide.org/intro/intro.php</u>	Classroom Assessment Tools (CATs), appropriate for classroom-based outreach projects	
NC State MISO: Maximizing the Impact of STEM Outreach: <u>http://miso.ncsu.edu/</u>	Surveys of student and teacher attitudes towards STEM (elementary and middle grades)	
NC State Assessment Instrument Information Page: <u>http://www.ncsu.edu/per/TestInfo.html</u>	Concept inventories on topics in the physical sciences and mathematics; Surveys related to attitudes, motivation, VNOS and interest	
University of Maryland list of Concept Surveys: http://www.physics.umd.edu/perg/tools/diags.htm	Concept inventories on topics in the physical sciences and laboratory concepts	
Florida State Research into RET's: <u>http://ret.fsu.edu/Research_Tools.htm</u>	Database of assessment tools for outreach focused on teachers and students, such as VNOS, interest and attitudes towards STEM	

**Table 2.** Resources for finding appropriate assessment tools for measuring desired outcomes of outreach activities.

Beyond quantitative methods, qualitative research methods can be applied to analyze student written reflections on their experiences. Such reflections can provide rich descriptions that reflect reasons behind quantitative results, and can really get to the crux of what is going on as students make decisions about their futures. It takes training and practice to analyze qualitative data, however. Training is available through resources such as the annual conference of the American Society for Engineering Education (ASEE); several pre-conference workshops were offered this year, for example, focusing on assessment methods that go beyond surveys. ASEE also has an ASEE-K-12 Division that regularly addresses innovative ways to design and assess outreach to pre-college students.

#### CONCLUSIONS

Designing and assessing outreach programs and activities can be daunting and overwhelming when added to an already full research agenda. Consider having students (undergraduate and graduate) involved in data collection and analysis. This provides the additional benefit of exposing these future biomaterials scientists, engineers and researchers to education research in addition to technical biomaterials research. Another benefit is effectively expanding the broader impacts of our funded projects to include students as researchers, as well as outreach to K-12 students.

Finally, as you design and develop an outreach activity, partner with a teacher, evaluation expert and/or education researcher through engineering and/or science education centers and departments at universities. Professional evaluators can be found through the American Evaluation Association.

The bottom line is that our education system needs help. Students may think science is just memorizing facts because that is how their competency in science is tested in school. Albert Einstein once said, "Everybody is a genius. But if you judge a fish by its ability to climb a tree, it will live its whole life believing that it is stupid." There is an entire generation of innovators and deep thinkers who may not consider pursuing careers in STEM because they think they don't have the right stuff. Exciting outreach activities that integrate biomaterials with the science and mathematics students are learning in school can show students what the real "right stuff" is. And effective outreach design and assessment can provide evidence that they indeed have it!

#### REFERENCES

- Miller JA. The Science and Engineering Workforce: Realizing America's Potential. National Science Foundation; 2003: NSB 03-79.
- Tai RH, Liu CQ, Maltese AV, Fan X. Planning early for careers in science. Science. May 26, 2006: 312.
- Godwin A. Understanding Female Engineering Enrollment: Explaining Choice with Critical Engineering Agency [Doctoral dissertation]. Clemson, SC: Clemson University; 2014: 137-140.
- Nilson LB. Teaching at Its Best: A Research-Based Resource for College Instructors, 3rd Ed. San Francisco, CA: Jossey-Bass; 2010.
- Wigfield A, Cambria J. Students' achievement values, goal orientations, and interest: Definitions, development, and relations to achievement outcomes. *Developmental Review*. 2010; 30:1-35.
- Simmons D, Martin J. Developing Effective Engineering Fictive Kin to Support Undergraduate First Generation College Students. *Journal of Women and Minorities in Science and Engineering*. 2014; in press.
- Outreach Evaluation Resource Center. Planning Outcomes-Based Outreach Projects. 2013. Available at <u>http://nnlm.gov/ evaluation/booklets508/bookletTwo508.html;</u>
- 8. DeVaus D. *Surveys in Social Research*, 5th Ed. Abingdon, Oxon: Routledge; 2002: 52-55.
- Olney CA, Barnes SJ. Planning outcomes-based outreach projects. Seattle, WA: National Network of Libraries of Medicine, Outreach Evaluation Resource Center; 2013.

## Immune Engineering SIG

#### BY JULIE STENKEN, PhD, PROFESSOR, UNIVERSITY OF ARKANSAS

The Immune Engineering SIG is the newest SIG in the Society For Biomaterials (SFB) and met for the first time at the April 2014 meeting in Denver. There are currently 54 members in this important SIG that intersects with the interests of many other long-standing SIGs. Our SIG is working on notifying members of the Society as well as other researchers outside the Society of our presence and activities. As we are a new SIG, we are still in the active organizational stage.

A number of initiatives for scientific exchanges and interactions have been created. We have a group set up on LinkedIn (Immune Engineering Society For Biomaterials). Vice-Chair, Susan Thomas, reports that Georgia Tech has launched the Georgia Tech Center for ImmunoEngineering and the Georgia ImmunoEngineering Consortium, a joint venture currently between Georgia Tech and Emory University. This center has successfully held its first annual symposium.

We discussed ways that we could connect with other societies, including those that are predominantly focused on immunology. Different ideas were discussed, including a potential interaction with the Federation of Clinical Immunology Societies (FOCIS). Programming for the 2015 meeting as well as the 2016 World Congress is ongoing. All are encouraged to send us their ideas and their recent successes.

# Engineering Cell and Their Microenvironments (ECTM) SIG SIG News

#### BY ADAM W. FEINBERG, PhD, ASSISTANT PROFESSOR, CARNEGIE MELLON UNIVERSITY

Over the past year the ECTM SIG has enjoyed growth both in membership numbers and in scientific contribution to the annual SFB meeting. Previously known as the Cell and Organ Therapies (COT) SIG, the name change in 2013 to the Engineering Cell and Their Microenvironments (ECTM) SIG has seen membership rise from 108 to 190 people, a more than 75 percent increase. With the inclusion of one free SIG membership with SFB membership, we expect the numbers to grow even more by the 2015 meeting.

At the 2014 meeting in Denver, the ECTM SIG sponsored nine sessions, plus one invited session on surgical meshes. This is very high representation for a SIG across the meeting. Highlights included sessions focused on Cell-Cell Interactions within Biomaterials, Bio-Inspired Cellular Microenvironments, Stimuli-Responsive Cues and Temporal Properties in Biomaterials, Mechanobiology and the SFB Business Plan Competition. Sessions for the 2015 meeting in Charlotte, N.C., promise to be just as exciting, with focuses on advanced hydrogels, high-throughput methods, clinical translation and multiscale biomaterials design as just some of the topics under consideration.

With growth in overall SIG membership there was also growth in student research submitted to the 2014 meeting. ECTM recognized students with three STAR awards and four honorable mentions. A goal of the SIG at the 2015 meeting and beyond is to continue to increase student participation and provide expanded recognition of exceptionable student work in the ECTM area.

# Novel Biomaterials to Improve Orthopaedic Implant Function, Biocompatibility, and Infection Prevention SIG News

#### BY JESSICA AMBER JENNINGS, PHD, UNIVERSITY OF MEMPHIS

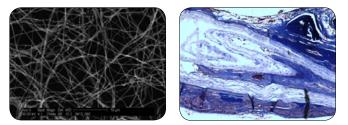
### FROM THE ORTHOPAEDIC BIOMATERIALS SIG

In the field of orthopaedic biomaterials, implants have been engineered to meet requirements for their purposes in reconstruction, replacement, or healing of orthopaedic defects. These materials are often modified to improve their effects on restoring function, encouraging growth of host tissue and preventing or treating infection. Novel methods to modify biomaterial composition, mechanical properties, coatings and drug delivery properties to optimize orthopaedic performance have recently been explored by biomaterials researchers.

In fracture healing and other reconstruction applications, fixation devices such as plates and screws have traditionally been made from permanent metal implants. These longterm implants may lead to later complications and may require removal surgeries. Magnesium biomaterials are being investigated as orthopaedic biomaterials due to their mechanical properties, biocompatibility, and degradability over time.<sup>1</sup> While methods to control and accurately assess corrosion rate, hydrogen gas development, and biocompatibility with tissue are needed,<sup>2</sup> orthopaedic applications of degradable magnesium biomaterials are supported by recent findings that extracts from magnesium alloys promote proliferation of mesenchymal stem cells as well as their differentiation into osteoblasts.<sup>1,3</sup> Porous magnesium materials as well as amorphous tri-magnesium phosphate materials may also have advantages for use as degradable bone scaffolding material.4,5

Nanotechnology approaches to improve implant performance are a growing field for orthopaedic applications. Electrospun nanofibers can guide tissue regeneration, form barriers, deliver drugs, or enhance mechanical or biological properties of orthopaedic implants (Figure 1).<sup>6-8</sup> When enriched with nanoclay particles, electrospun fibers of polycaprolactone degraded faster, supported cell attachment and proliferation, and promoted osteogenic differentiation of mesenchymal stem cells.9 Nanotubes of titanium dioxide attached to implant surfaces not only improve osseointegration, but may also be used to deliver drugs such as pain relievers, antimicrobials, or growth factors.<sup>10,11</sup> Scaffolds of hydroxyapatite that mimic natural bone by creating porosity in the nanoscale as well as macroscale have been shown to improve performance of implants designed to improve healing of large segmental defects.12

Stimuli-responsive release of therapeutic agents or changes in material structural properties can be enabled through incorporation of various types of nanoscale particles or fibers to composite systems.<sup>13-15</sup>



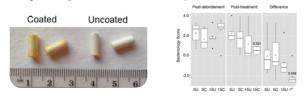
**FIGURE 1.** Left: Scanning electron micrograph of novel aqueous stable chitosan nanofiber membrane. Right: histological section of chitosan nanofiber membrane in rat calvarial defect showing new bone forming in contact with nanofibers.<sup>5</sup>

Because biomaterial implants are at high risk of attachment of bacteria, a process known to lead to the formation of biofilm, there are many targeted strategies being pursued to improve orthopaedic biomaterials and their surfaces to prevent or treat infection. A particular threat in orthopaedics is infection with the common pathogen Staphylococcus aureus, since it has been found to be localized internally within osteoblasts.<sup>16</sup> These internalized bacteria can reemerge and lead to osteomyelitis even after successful initial antibiotic therapy. Novel therapies directed at preventing and treating infection include local drug delivery, surface modification of biomaterials and anti-biofilm strategies. Platelet rich-plasma, rich in factors that promote bone growth, also contains thrombin, which inhibits infection by Gram-positive microorganisms like S. aureus.<sup>17</sup> A cationic peptide, LL-37, kills S. aureus colonies in vitro at nanomolar concentrations and further has also been shown to cross the osteoblast membrane to clear intracellular infection as well as extracellular infection.<sup>18</sup> Targeting the biofilm bacteria through delivery of anti-biofilm signaling molecules, such as D-amino acids or cis-2 decenoic acid, in conjunction with antibiotics is another approach to prevent implant-associated infection.<sup>19-21</sup> If locally delivered in a sustained fashion to infected bone, these antimicrobials could help prevent or resolve chronic orthopaedic infection. Once osteomyelitis develops, orthopaedic implants are usually removed and various methods to resolve the infection are employed prior to revision or reconstruction of defects. Implantation of antibiotic-loaded PMMA beads is a common strategy

to augment systemic antibiotic therapy to clear infection, but clinical results vary due to a wide variety of antibiotic loading levels and implantation methods. The effects of antibiotic loading level and implantation parameters on release of drug from PMMA have been modeled using an antibiotic surrogate that can be imaged using MRI.<sup>22,23</sup> Calcium sulfate implants have also been used clinically as a local antibiotic delivery system, with the advantage of degradability and osteoconductivity. In a recent study, chitosan-coated calcium sulfate implants loaded with the antibiotic daptomycin were shown to improve clearance rate of S. aureus and improve osteomyelitic symptoms in a challenging model of osteomyelitis with minimal debridement (Figure 2).24 Release of various drugs, including hydrophobic molecules, antibiotics and growth factors can be enhanced by creating composites of calcium sulfate with polymeric materials, such as poly(beta-amino ester) or chitosan.25,26

These discoveries demonstrate how multiple biomaterial approaches are being used to optimize orthopaedic healing

and clinical performance of devices. Biomaterial scientists are combining basic, clinical and translational science to improve therapeutic options for the challenging task of treating orthopaedic diseases and injuries.



**FIGURE 2.** a) Photograph of chitosan coated calcium sulfate implants. b) Analysis of chitosan-coated calcium sulfate in a rabbit osteomyelitis model based on average bacteriological scores. Results are shown for each experimental group immediately following debridement, after treatment, and as the change between these two time points. OU and OC refer to uncoated and coated pellets, respectively, while 15U and 15C refer to uncoated and coated pellets containing 15% daptomycin. Boxes indicate the 25th and 75th percentiles for each group and define the IQR, with the horizontal line indicating the median. Vertical lines define the lowest and highest data points within 1.5 IQR of the lower and higher quartiles, respectively, with individual dots representing single data points outside this range. Numbers within the graph are p values determined using ANOVA with Tukey's posth-hoc analysis. IQR: interquartile range.<sup>24</sup>

#### REFERENCES

- Li RW, Kirkland NT, Truong J, Wang J, Smith PN, Birbilis N, Nisbet DR. The influence of biodegradable magnesium alloys on the osteogenic differentiation of human mesenchymal stem cells. *Journal of Biomedical Materials Research*, Part A. 2014.
- Walker J, Shadanbaz S, Woodfield TB, Staiger MP, Dias GJ. Magnesium biomaterials for orthopedic application: A review from a biological perspective. *Journal of Biomedical Materials Research*, Part B. 2014; 102(6):1316-31.
- Yoshizawa S, Brown A, Barchowsky A, Sfeir C. Magnesium ion stimulation of bone marrow stromal cells enhances osteogenic activity, simulating the effect of magnesium alloy degradation. *Acta Biomaterialia*. 2014; 10(6):2834-42.
- Kang MH, Jung HD, Kim SW, et al. Production and bio-corrosion resistance of porous magnesium with hydroxyapatite coating for biomedical applications. *Materials Letters*. 2013; 108:122-124.
- Ostrowski NJ, Lee B, Enick N, Roy A, Kumta P. Amorphous tri-magnesium phosphate (ATMP) as a novel bone scaffolding material. Denver, CO; 2014.
- 6. Wu C, Su H, Tang S, Haggard W, Bumgardner J. Aqueous stable chitosan electrospun nanofibers for tissue engineering. Denver, CO; 2014.
- McCool JM, Rodriguez IA, Sell SA, Han Y, Bowlin GL. A preliminary study on amelogenin-loaded electrospun scaffolds. *Journal of Bioactive and Compatible Polymers*. 2014; 29(1):32-49.
- Gaharwar AK, Mihaila SM, Kulkarni AA, et al. Amphiphilic beads as depots for sustained drug release integrated into fibrillar scaffolds. *Journal of Controlled Release*. 2014; 187:66-73.
- Gaharwar AK, Mukundan S, Karaca E, et al. Nanoclay-Enriched Poly(varepsilon-caprolactone) Electrospun Scaffolds for Osteogenic Differentiation of Human Mesenchymal Stem Cells. *Tissue Engineering*, Part A. 2014.
- Shokuhfar T, Sinha-Ray S, Sukotjo C, Yarin AL. Intercalation of antiinflammatory drug molecules within TiO2 nanotubes. *Rsc Advances*. 2013; 3(38):17380-17386.
- Liu W, Su P, Chen S, et al. Synthesis of TiO nanotubes with ZnO nanoparticles to achieve antibacterial properties and stem cell compatibility. *Nanoscale*. 2014.
- Guda T, Walker JA, Singleton B, et al. Hydroxyapatite scaffold pore architecture effects in large bone defects in vivo. *Journal of Biomaterials Applications*. 2014; 28(7):1016-27.
- Hoban A, McGraw G, Mohapatra A, et al. Preliminary Results for the Addition of Fe3O4 Nanoparticle Impregnated Chitosan Microspheres to the Chitosan Sponge for Stimuli Responsive Antibiotic Delivery. Denver, CO; 2014.

- Kim YJ, Ebara M, Aoyagi T. A Smart Hyperthermia Nanofiber with Switchable Drug Release for Inducing Cancer Apoptosis. *Advanced Functional Materials*. 2013; 23(46):5753-5761.
- Fusco S, Sakar MS, Kennedy S, et al. An Integrated Microrobotic Platform for On-Demand, Targeted Therapeutic Interventions. *Advanced Materials*. 2014; 26(6):952-957.
- Hamza T, Dietz M, Pham D, Clovis N, Danley S, Li B. Intra-cellular Staphylococcus aureus alone causes infection in vivo. *European Cells & Materials*. 2013; 25:341-50; discussion 350.
- Li H, Hamza T, Tidwell JE, Clovis N, Li B. Unique antimicrobial effects of platelet-rich plasma and its efficacy as a prophylaxis to prevent implantassociated spinal infection. Advanced Healthcare Materials. 2013; 2(9):1277-84.
- Noore J, Noore A, Li B. Cationic antimicrobial peptide LL-37 is effective against both extra- and intracellular Staphylococcus aureus. *Antimicrobial Agents and Chemotherapy*. 2013; 57(3):1283-90.
- Sanchez CJ, Jr., Prieto EM, Krueger CA, et al. Effects of local delivery of D-amino acids from biofilm-dispersive scaffolds on infection in contaminated rat segmental defects. *Biomaterials*. 2013; 34(30):7533-43.
- Sanchez CJ, Jr., Akers KS, Romano DR, et al. D-Amino Acids Enhance the Activity of Antimicrobials Against Biofilms of Clinical Wound Isolates of Staphylococcus aureus and Pseudomonas aeruginosa. *Antimicrobial Agents* and Chemotherapy. 2014.
- Jennings JA, Courtney HS, Haggard WO. Cis-2-decenoic acid inhibits S. aureus growth and biofilm in vitro: a pilot study. *Clinical Orthopaedics and Related Research*. 2012; 470(10):2663-70.
- Giers MB, McLaren AC, Schmidt KJ, Caplan MR, McLemore R. Distribution of molecules locally delivered from bone cement. *Journal of Biomedical Materials Research*, Part B. 2014;102(4):806-14.
- McLaren A, Giers MB, Fraser J, Hosack L, Caplan MR, McLemore R. Antimicrobial Distribution From Local Delivery Depends on Dose: A Pilot Study With MRI. *Clinical Orthopaedics and Related Research*. 2014.
- Beenken K, Smith J, Skinner R, et al. Chitosan Coating to Enhance the Therapeutic Efficacy of Calcium Sulfate-Based Antibiotic Therapy in the Treatment of Chronic Osteomyelitis. *Journal of Biomaterials Applications*. 2014; in press.
- Doty HA, Leedy MR, Courtney HS, Haggard WO, Bumgardner JD. Composite chitosan and calcium sulfate scaffold for dual delivery of vancomycin and recombinant human bone morphogenetic protein-2. Journal of materials science. *Materials in Medicine*. 2014.
- Orellana BR, Hilt JZ, Puleo DA. Drug release from calcium sulfate-based composites. Journal of biomedical materials research. *Applied Biomaterials*, Part B. 2014.

## 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

### FROM THE OPHTHALMIC BIOMATERIALS SIG

Intraocular lenses (IOLs) are the most commonly implanted biodevices in the world, with approximately 6 million cataract surgeries with IOL implantation performed per year. A significant number of IOL explantations performed in this past decade were due to a process related to lens opacification and/or discoloration.<sup>1</sup> This article reviews some of the causes of this complication.

#### **SNOWFLAKE DEGENERATION OF PMMA IOLS**

Snowflake degeneration is a slowly 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 represent a breakdown in the PMMA material. Threepiece 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.<sup>2</sup>

#### DISCOLORATION OF SILICONE IOLS ASSOCIATED WITH SYSTEMIC MEDICATION

Katai et al. reported on a patient who was treated with amiodarone for three years and developed brown discoloration of the silicone lenses in both eyes.<sup>3</sup> 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.<sup>4</sup>

#### COATING OF SILICONE IOLS WITH SILICONE OIL

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.<sup>5</sup>

#### COATING OF SILICONE IOLS WITH OPHTHALMIC OINTMENT

We have reported eight cases of toxic anterior segment syndrome (TASS) related to an oily material within the anterior chamber of the patients' eyes. The eight patients had undergone 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; 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 placement of ointment.<sup>6</sup>

### CALCIFICATION OF SILICONE IOLS IN ASTEROID HYALOSIS

Four cases were initially reported in the literature, all with silicone plate lenses in patients with unilateral asteroid hyalosis.<sup>1,7</sup> Whitish deposits appeared only on the posterior optic surface of the lens late postoperatively. Later we described the first similar case related to a three-piece silicone lens, in a patient with bilateral asteroid hyalosis. The contralateral eye had also undergone cataract surgery. The acrylic lens implanted in this eye developed no opacities after six years.<sup>1,7</sup>

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). 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. We have more recently reported on 16 new cases with different silicone lenses.<sup>1,7</sup>

#### 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.<sup>8</sup> Different studies using histopathological, histochemical, 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. Although in many cases it was difficult to determine the time at which 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 to date the only possible treatment.

#### GLISTENINGS AND NANOGLISTENINGS OF HYDROPHOBIC ACRYLIC IOLS

Two hydration-related phenomena have been described in the literature in IOLs made of different materials, particularly in hydrophobic acrylic lenses: glistenings, and surface light scattering.<sup>9</sup> 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 change in the equilibrium water content caused by temperature changes between 30 C and 40 C 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.

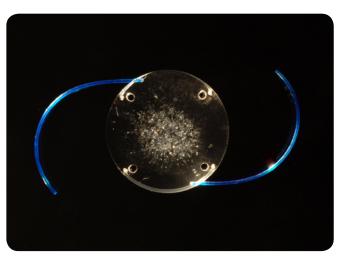


FIGURE 1. Gross photograph of a PMMA IOL explanted because of snowflake degeneration.



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

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.

#### 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 patient's 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

- Werner L. Causes of intraocular lens opacification or discoloration. J. Cataract Refract. Surg. 2007; 33:713-726 (Review).
- 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.
- 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.
- Jones DF, Irwin AE. Discoloration of intraocular lens subsequent to rifabutin use. Arch. Ophthalmol. 2002; 120:1211-1212.
- Apple DJ, Federman JL, Krolicki TJ, et al. Irreversible silicone oil adhesion to silicone intraocular lenses. A clinicopathologic analysis. *Ophthalmology*. 1996; 103:1555-1561.
- 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.
- 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.
- Werner L. Calcification of hydrophilic acrylic intraocular lenses. Am. J. Ophthalmol. 2008; 146:341-343 (Editorial).
- Werner L. Glistenings and surface light scattering in intraocular lenses. J. Cataract Refract. Surg. 2010; 36:1398-1420 (Review).

### From the Tissue Engineering SIG

**SIG News** 

#### BY ABBY R WHITTINGTON, PHD, DEPARTMENTS OF CHEMICAL ENGINEERING AND MATERIALS SCIENCE AND ENGINEERING, VIRGINIA TECH



{ PARTICIPANTS IN THE FIRST ANNUAL RM IGEP RETREAT 2014 } Photo courtesy of Megan Quesenberry.

#### VIRGINIA TECH'S INTERDISCIPLINARY APPROACH TO REGENERATIVE MEDICINE

Launched in August 2012, the Interdisciplinary Graduate Education Program (IGEP) in Regenerative Medicine (RM) brought together the Colleges of Engineering, Veterinary Medicine, Liberal Arts and Human Sciences and Business to address regenerative medicine from scientific inquiry to product feasibility to the clinic. One of 14 interdisciplinary programs offered at Virginia Tech, the IGEPs are designed to train graduate students to fully tackle society's major problems including healthcare, water, and energy. These programs are at the heart of Virginia Tech's approach to graduate education by "transcending traditional disciplinary perspectives and promoting collaborations across colleges, departments, and academic units." Co-led by Dr. Willard Eyestone (Veterinary Medicine) and Dr. Abby Whittington (Chemical Engineering/Materials Science and Engineering), this program's participants are from varied disciplines that include biomaterials, stem cell biology, biomedical engineering, science and technology in society, business development and many more.

In regenerative medicine, a variety of players (industry, government, regulators, scientists, clinicians, patients) must be engaged to make step changes in this field, and to accomplish this we need to work across disciplines. The new RM IGEP at Virginia Tech exposes graduate students to the jargon and thought processes of these different areas, thus preparing them for interactions at all levels of clients from the regulators to the clinicians and, ultimately, the patients. This program also encourages step change now as the faculty are involved in the research and education portions, thus generating natural collaboration efforts within their current research.

#### INTERDISCIPLINARY EDUCATIONAL APPROACH

The RM IGEP is first and foremost a graduate training program. We seek to train the next generation of doctoral scholars to be aware of the multifaceted needs of RM to produce future leaders in academia, industry and regulatory oversight. The interdisciplinary approach requires participants to not only excel in their chosen area but to also delve into the broader aspects of RM as a whole. Students fulfill the requirements from their home department while participating in interdisciplinary activities such as:

- Interactive seminar series
- Cross-disciplinary education, including new and established courses
- Interdisciplinary research experience
- Regular programmatic activities to foster a greater understanding of how the participating academic units can work together for optimal productivity and advancement of goals

A new course was developed and taught in spring 2013 specifically for this program entitled "Regenerative Medicine: Science and Society." Co-developed by Dr. Linda Dahlgren (Veterinary Medicine), Dr. Ashley Shew (Science and Technology in Society) and Dr. Abby Whittington (Chemical Engineering/ Materials Science and Engineering), this course offers students insight into the broader implications of regenerative medicine such as how regulatory and ethical issues influence the scientific development and marketing of new products within the area. Example discussions ranged from what are the arguments against embryonic stem cell research to how do other countries regulate regenerative medicine approaches to what would insurance companies need to know in order to cover RM therapies in the U.S.? Offered every other spring, this course encourages the students to explore how their individual discipline fits within the bigger picture and how they may contribute to the advancement of regenerative medicine as a whole.

#### **INTERDISCIPLINARY RESEARCH**

By bringing seemingly disparate programs together, the research conducted through the RM IGEP is able to reach beyond the traditional programmatic boundaries. Scientific investigations within the Colleges of Engineering and Veterinary Medicine share a biomedical focus and include biomaterials, nanoscience, biomedical engineering, tissue engineering, drug delivery, polymer chemistry, stem cell biology, neuroscience, cardiology, vascular biology and musculoskeletal biology. Parallel pursuits exploring the societal impacts and public perceptions of regenerative medicine discoveries and therapies as well as the business needs and challenges associated with the development of clinical therapies are found within the Colleges of Business and Liberal Arts and Human Sciences. The program seeks to create a global understanding of the field of regenerative medicine through such cross-disciplinary research.

At the close of its second year, RM IGEP hosted its first annual research retreat highlighting the current research being performed by its nearly 40 IGEP students from the Colleges of Engineering, Business, Liberal Arts and Human Sciences and Veterinary Medicine. Held May 19, 2014 at Mountain Lake Lodge in nearby Giles County, the aim of the retreat was to foster expanded research collaborations among faculty working in the various aspects of biology, engineering, business and ethics, and to strengthen the identity of regenerative medicine as a discipline at Virginia Tech. The day included a series of presentations from each lab and ended with a student poster session and an informal opportunity to discuss research and explore possible collaborations. IGEP faculty welcomed several guests, including Matt Hull of the Virginia Tech Institute for Creative Technologies and Applied Sciences, Dr. Jean Clarke of the Fralin Life Sciences Institute, Dr. David Clark of Materials Science and Engineering and Dr. David Hodgson, Dr. Roger Avery and Dr. Cyril Clarke from the veterinary college.

By *educating* and *collaborating across specialized fields of medicine,* our IGEP imparts a thorough understanding of the cross-disciplinary approach and collaborative network needed to conduct transformative research, how to commercialize discoveries in regenerative medicine, and how to develop new strategies for integrating scientific discoveries into real world applications.

Starting its third year this fall 2014, the RM IGEP will be open to new applicants in all of the areas described here. Interested in learning more? Visit http://interdisciplinary.graduateschool. vt.edu/?q=node/281 or email igepregenmed@vt.edu.

# News from the Proteins and Cells at Interfaces SIG



The Proteins and Cells at Interfaces (PCI) SIG is focused on promoting a better understanding of cell and protein interactions with biomaterials interfaces. Topics addressed here can be broadly applied to all aspects of biomaterials, from drug delivery and tissue engineering

to immunomodulation. This interdisciplinary vision is well represented by our diverse group of PCI SIG officers who belong to a broad range of research, academic and government institutions. To learn more about your PCI SIG officers, check out our "This or That" interviews on our SIG page at **www.biomaterials.org**.

To promote awareness of research and ideas related to proteins and cells at interfaces, our group has been engaging in some exciting new activities. This year at SFB we hosted the First Annual PCI Student Poster Competition. We are very happy to announce our winners who presented outstanding posters in the PCI SIG sessions:

First Place: Mark D. Swartzlander, University of Colorado Second Place: Prathamesh M. Kharkar, University of Delaware Honorable Mention: David A. Cantu, University of Wisconsin Honorable Mention: Stacie M. Gutowski, Georgia Institute of Technology

Each winner received a certificate and cash award.



Dr. Rena Bizios, 2014 recipient of the SFB Founders Award and generous supporter of the PCI SIG.

This year's SFB Founders Award winner, Dr. Rena Bizios (University of Texas at San Antonio), has donated her \$1,000 award to the PCI SIG for student competitions and presentations! Dr. Bizios is a former chair of the PCI SIG and we are extremely grateful for her continued support and generous gift. In her honor, next year's student poster competition awards will be given in her name, and in the spirit of her gift, we

hope to host enrichment activities for the professional and personal development of students at future SFB meetings.

Our SIG has been very active on social media with a new Facebook page and Twitter feed. This year we've shared news on new research advancements and upcoming events, and highlighted major accomplishments by our PCI SIG members. Please join us on Twitter (search for @SFBPCI) and on our Facebook page.

PCI was also very involved in the SFB meeting this year, sponsoring and co-sponsoring several sessions including:

- Biomaterial Strategies for Innervation, Nerve Repair and Integration
- Engineering Stimuli-Responsive Cues into Biomaterials
- Material/Tissue Interfacial Phenomena: Lessons Learned from Dental/Craniofacial Reconstructions
- Biomaterials for Immunomodulation
- Effect of Scaffold Properties on 3D Cell Shape
- Advances and Challenges in Biomaterial-Associated Infection and Pathogenesis
- Cellular and Molecular Responses of Biomaterials at the Biomaterial-Tissue Interface I
- Molecular Mechanisms Governing Protein-Surface and Cell-Surface Interactions

There were several exceptional student presentations in these sessions that were recognized by PCI-sponsored STAR Awards:

- Emily A. Morin, University of Tennessee Knoxville
- John K. Hermann, Case Western Reserve University
- Daniel D. McKinnon, University of Colorado
- Kelan A. Hlavaty, Northwestern University
- Elizabeth J. Brisbois, University of Michigan
- Efrain. A. Cermeno, Georgia Institute of Technology
- Karin C. Wang (Honorable Mention), Cornell University

Our focus this past year has been to not only promote research activities related to the interface between proteins, cells and biomaterials, but to also foster the next generation of leading scientists in the field. We hope to continue these activities in the future, expanding our interactions with the biomaterials community by co-sponsoring SFB sessions, hosting workshops and offering more student and junior investigator development activities.

### Government News

BY CARL G. SIMON JR., GOVERNMENT NEWS CONTRIBUTING EDITOR

### ALLIANCE FOR REGENERATIVE MEDICINE PUBLISHES RESULTS OF BIG PHARMA SURVEY



In March 2014, the Alliance for Regenerative Medicine (ARM) published the results of a survey of the research and development leadership of "top pharma and biotech companies regarding their strategic perspectives of regenerative medicine."<sup>1</sup>

ARM is an industry consortium and advocacy organization based in Washington, D.C., that "promotes legislative, regulatory, reimbursement, investment, technical and other initiatives to accelerate the development of safe and effective regenerative medicine technologies."<sup>2</sup> The objective of the survey was to engage pharma and biotech executives to speak candidly "about their views of the sector – highlighting opportunities and the therapeutic potential of the technologies while also addressing concerns regarding major regulatory and commercial hurdles yet to be overcome." There were 16 survey respondents: Allergan, Amgen, Baxter, Biogen Idec, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Johnson & Johnson, Merck Serone, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi Genzyme and Shire.

#### Participants were surveyed about challenges in 10 areas:

- 1. regulation
- 2. manufacturing and scale-up
- 3. cost of goods
- 4. product consistency and standards
- 5. potency assay validation
- 6. supply chain logistics
- **7.** clinical adoption/medical experience
- 8. uncertain reimbursement environment
- 9. uncertain financing environment
- **10.** intellectual property protection

According to the report, "of the 10 areas examined, the lack of predictable and clear regulatory guidance received the lowest amount of concern from the participants, indicating that these companies feel that regenerative medicine products have the ability to succeed within current regulatory constructs." Results "revealed that product consistency and lack of standards is possibly the single greatest challenge facing the field" with 15 of the 16 companies interviewed rating this to be an area of moderate-to-significant concern. The report makes it clear that large pharma and large-cap biotechs are actively building their knowledge base in regenerative medicine.

### PROPOSED REFERENCE MATERIAL MESENCHYMAL STEM CELLS

A group of prominent mesenchymal stem cell scientists have published an opinion article that calls for the development of reference material mesenchymal stem cells (RM MSCs).<sup>1</sup> They "propose using a reference material to *establish methods of comparability amongst MSC preparations*." A search of "mesenchymal stem cells" on clinicaltrials.gov identifies 400 clinical trials worldwide while a pubmed. gov search yields 17,000 scientific publications. Despite this large investment, advancement of the field is being slowed by the inability to compare data.

"This is because of inherent cell heterogeneity, the absence of markers that are unique to MSCs, and the difficulty in precisely defining them by developmental origin. Differences in the properties of MSCs also depend on the site of tissue harvest, phenotypic and genotypic characteristics of the donor and the isolation, and storage and expansion methods used."

Thus standards and reference materials to enable comparability are badly needed and discussions are underway to plan the path forward.

#### REFERENCES

 Viswanathan S, Keating A, Deans R, et al. Soliciting Strategies for Developing Cell-Based Reference Materials to Advance MSC Research and Clinical Translation. Stem Cells & Development. 2014; 23(11):1157-67.

#### CONTACT:

Carl G. Simon Jr., <u>carl.simon@nist.gov</u>, 301-975-8574

### Industrial News

#### BY STEVE LIN, INDUSTRIAL NEWS CONTRIBUTING EDITOR



**Boston Scientific Corp.** said it has agreed to pay \$415 million to buy a division of German drug maker **Bayer AG** that makes interventional products for treating vascular disease. The buy would expand the "breadth and scale" of Boston Scientific's product portfolio, said Jeff Mirviss, peripheral

interventions unit chief. In 2013, Bayer Interventional, based in Minnesota, generated sales of \$120 million, Boston Scientific said. The deal is expected to close in the second half of 2014.

**Medtronic Inc.** and **Covidien plc** have entered into a definitive agreement under which Medtronic has agreed to acquire Covidien. The cash-and-stock transaction is valued at \$93.22 per Covidien share, or a total of approximately \$42.9 billion, based on Medtronic's closing stock price of \$60.70 per share on June 13. After the completion of the transaction, Medtronic and Covidien will be combined under a new entity to be called Medtronic plc. The principal executive offices will be held in Ireland, where both companies have a longstanding presence, while its operational headquarters will continue to be held in Minneapolis and led by Omar Ishrak, chairman and chief executive officer of Medtronic.

**Stryker Corporation** (NYSE: SYK) announced today a definitive agreement to acquire assets of **Small Bone Innovations, Inc.** ("SBi") in an all-cash transaction for up to \$375 million. The net cost to Stryker after taking into account the present value of the tax benefits as a result of the asset purchase structure will be up to \$285 million. Founded in 2004, SBi is a privately held business headquartered in Morrisville, Penn., with facilities in France and Germany. SBi products are designed and promoted for upper and lower extremity small bone indications, with a focus on small joint replacement.

**The Cooper Companies** (Pleasanton, Calif.) said it would acquire British contact lens company **Sauflon Pharmaceuticals**. The medical device company used offshore cash, in part, to finance the \$1.2 billion deal. The acquisition will give Cooper a bigger European footprint and expand its oneday contact lens offerings, which it noted are the fastest growing segment of the soft contact lens market. The deal would put Cooper in third place in the one-day contact lens market with roughly 20 percent market share, behind heavyweights Johnson & Johnson and Novartis' Alcon unit. In Europe, Cooper would have a market share of 24 percent to 30 percent, the company estimated, which would put it in second place behind Alcon.

The ReWalk Personal System, developed by **Argo Medical Technologies** (Marlborough, Mass.), has become the first

FDA-cleared wearable, motorized device to aid paraplegics. The device was cleared via the de novo 510(k) classification process. The device was originally invented by an Israeli researcher named Amit Goffer who has been paralyzed since 1997. The ReWalk had already been on the market in Europe since 2012, and costs approximately \$70,000. ReWalk includes a fitted, metal brace that supports the legs and part of the upper body; motors that provide movement at the hips, knees and ankles; a tilt sensor; and a backpack containing a computer and power supply. According to FDA, the device is intended for patients paralyzed from spinal cord injuries ranging from the seventh thoracic vertebra to the fifth lumbar vertebra when it is used in conjunction with a trained caregiver. In rehabilitation clinics, it can be used for patients with spinal cord injuries ranging from the fourth thoracic vertebra to the sixth thoracic vertebra.

Surgical Theater (Mayfield Village, Ohio) scored FDA clearance for its 3D, augmented reality surgical navigation advanced platform (SNAP) for operating room procedures. SNAP builds on the company's existing surgical rehearsal platform and provides new access to operating room technology. The new device combines flight simulation technology and advanced CT/MRI imaging to allow physicians to perform a real-life "fly through" of surgery, and provides virtual reality guidance to help determine the best way to remove tumors or treat heart defects. Surgeons can rotate images from a patient's CT/MRI scan or make them semi-transparent to see behind arteries and other critical structures, increasing accuracy during complex procedures. SNAP's virtual reality element also helps physicians run through potential scenarios prior to making the first incision.

**Apple** has announced HealthKit, a glorified healthcare and fitness app bundled into iOS8 that can potentially communicate patient health data to hospitals. The company also announced a partnership with the Mayo Clinic, which is exploring the integration of HealthKit, potentially enabling the app to share health information with clinicians. For instance, clinicians can use HealthKit to define custom ranges for metrics like heart rate and blood pressure for the patient. If a reading falls out of that range, HealthKit can contact the hospital proactively. A doctor could then contact the patient to provide them with medical advice.

**FDA** has issued a public call for research proposals to help it stay abreast of health and safety threats from rapidly evolving product technologies and soaring medical product imports. Its notice says that expected funding for the program, not per contract or award, may range from \$200,000 to \$50 million, depending on congressional appropriations. Of likely interest to medical device

**News & Updates** 

marketers are the program's request research proposals that would develop and apply simulation models for product life cycles, risk assessment, and other regulatory science uses such as electromagnetic energy and biomaterials, data mining of spontaneous reports and analysis of electronic health records from large healthcare databases.

The federal **Agency for Healthcare Research and Quality** (AHRO) said in a draft version of its recent technology assessment that it could not determine the safety and efficacy of negative pressure wound therapy (NPWT) technologies in home healthcare settings. Nevertheless, the assessment offers insight into the concerns of healthcare policymakers and will have an impact on federal reimbursement decisions because it will be discussed at an upcoming Medicare Evidence Development & Coverage Advisory Committee meeting. AHRQ says that chronic wounds impose a growing burden on the healthcare system due

to the aging population; almost 2 percent of those older than age 65 suffer a venous leg ulcer over the course of a year. NPWT consists of a foam, gauze or other wound dressing that is applied over the wound and then exposed to negative pressure via a vacuum pump. Key players in the multimillion dollar industry include **Smith & Nephew**, wound care specialists **Kinetic Concepts** and **Prospera**.

Three regulations that life sciences companies find to be most burdensome in 2013, according to a report by Deloitte and Compliance Week, are (1) the Sunshine Act, (2) the Foreign Corrupt Practices Act and (3) the Good Clinical Practices. Do you agree? Let us know.

# Education News

#### BY YUSEF KHAN, EDUCATION NEWS CONTRIBUTING EDITOR

# THE FLIPPED CLASSROOM AND ACTIVE LEARNING: A NEW WAY TO LECTURE



About six months ago this column discussed the rising prevalence and popularity of massive open online courses, or MOOCs. At the core of MOOCs is the course content made widely available on the Internet as video-recorded lectures showing PowerPoint-like slide presentations,

video captures of lecturers lecturing or solving problems in real time, or some combination of these. The idea was that course content from the best educators and/or the best institutions could be available to anyone with the technological capability to receive them. Students could view lectures either during assigned class time or on their own outside of class, as they preferred. The freedom to view these online lectures whenever the student wanted and the ability to view them as often as desired were seen as important advantages over the traditional class lecture structure. In the mid-2000s, when technology became more readily available to record PowerPoint-like presentations with accompanying audio, schoolteachers began recording their lectures to allow students to access them after class. This left valuable time *in class* for the students and teachers to interact, to work on problem sets, to develop interactive methods of reinforcing the lecture material and to evaluate how well the students were grasping the information. These ideas were presented at national conferences and the flipped classroom was born.<sup>1</sup> In truth, the idea of having students gain exposure to class material *prior* to the class so they could analyze and problem-solve *during* the class goes back at least to the late 1990s (and probably before that), but the full utilization of the flipped classroom, as we refer to it today, required modern technology that wasn't available until more recently. So what exactly is a flipped classroom?

A flipped classroom is a method of teaching in which the content that would typically be delivered during the class lecture is viewed online as a video presentation by the student prior to coming to class. This exposure to the course content prior to class gives the student the opportunity to become familiar with the content on his/her own time, and reserves the class time for interactive learning, problem solving, quizzes to enforce the lessons within the lecture or any other strategy the instructor may use to reinforce the content. This allows the instructor to interact with the students more closely and deliberately during class rather than as a talking head at the front of the classroom with little to no time to interact with the students. Cynthia Brame from Vanderbilt University summarized a few of the key elements of a flipped classroom as follows:<sup>2</sup>

- Provide an opportunity for students to gain first exposure prior to class
- Provide an incentive for students to prepare for class
- Provide a mechanism to assess student understanding
- Provide in-class activities that focus on higher level cognitive activities

Traditionally the instructor would create the video using available tools (see below) or in conjunction with a video team, but making these videos can be time consuming, require some specialized equipment or software or have some degree of a learning curve, all of which may discourage one from trying it. MOOCs, however, can help with this because of the wide availability of lectures already online. The instructor can choose the particular lecture from those available online, assign the lecture to the students, and spend the next class session in a more productive way. This approach works well for more traditional disciplines like introductory level math, economics, physics etc. where the curriculum from one institution to another may be very similar. Relying on publicly available course material may not be as reliable for more nuanced courses like biomaterials and tissue engineering, where the specific content may vary from institution to institution.

The literal flipping of the classroom, however, isn't the whole story. A key element of the flipped classroom is how the time is spent in the classroom. Incorporating active learning during class time is an important piece of the flipped classroom approach. Active learning is, as it sounds, the use of methods to engage the students, foster group learning, enhance critical thinking skills and monitor how well the students are grasping the information in real time. This stands in contrast to passive learning, the traditional lecture format, where students sit and listen and absorb as

### **EDUCATION QUOTE OF THE QUARTER:**

*"The main part of intellectual education is not the acquisition of facts but learning how to make facts live."* 

—Oliver Wendell Holmes

best they can during the lecture. There are many strategies to incorporating active learning into the classroom, usually only limited by one's creativity.

While in theory one can imagine the benefits of such a class structure the question remains: is it effective? Eric Mazur at Harvard University has been an active proponent of the flipped classroom for many years now and has incorporated it into his physics lectures.3 He and others have also evaluated the effectiveness of the method and noted considerable improvement in performance of students. Richard Hake in 1998 studied the benefits of flipped classrooms for introductory physics courses and showed almost two standard deviations worth of learning improvement compared to traditional course structure.<sup>2</sup> Carl Wieman introduced flipped classrooms in large physics lectures and noted increases in student engagement and an increase in test scores of almost 35 points.<sup>2</sup> While isolated, these data (and others available in the literature) support the efficacy of the flipped classroom as a tool to increase student understanding and performance.

So the benefit seems intuitively obvious and it appears to be backed up by data, but it's not a panacea. There are challenges associated with this approach. While the value of this strategy can be seen for classes where problem sets make up the homework and can be worked in groups in class, it is less clear how beneficial the format would be for topics that are less based on solving problem sets that require repetition and practice. Perhaps the active learning component of such courses just requires more creativity. It's also less clear if this approach is applicable to all levels. Would this work as well at the graduate level as it would at the high school level? And how will it be received by the student who has learned to perform in a traditional lecture setting? Will the student understand how he/she can benefit from this experience or will it just seem like added work to adjust to the new approach?

The process is also very time consuming and labor intensive. Developing a course from scratch using this model may take far longer than developing traditional lectures. One estimate suggested that for every 10 minute video 10 hours of prep time was required. While this seems extreme, consider that fact that not only does one have to develop the lecture material, but now the instructor has to develop the class-time activity as well. If one is considering changing a preexisting class to a flipped classroom these factors may get in the way, but it may not be necessary to completely flip an entire class. There is a concept referred to as micro-flipping.<sup>4</sup> Rather than deliver the entire lecture to the students prior to class, one can provide a shorter lecture to the students before class, initiate the in-class activity based on that lecture, and the provide short lectures during class to prepare the student for the next in-class activity. This process ensures that students

that did not view the course material prior to class will not be completely left behind, and also allows the instructor to phase in the flipped classroom slowly over time. This approach may be the most appealing for those curious about the idea but unable or unwilling to fully adopt it outright.

So the flipped classroom is here. It's hot. It's new. Is it the best approach? How well does it serve students in a traditional biomaterials or tissue engineering curriculum? Let me know if you have any experience flipping classrooms and if you're willing to share your experiences here in a future column.

#### REFERENCES

- Bergmann J, Sams A. How the Flipped Classroom Is Radically Transforming Learning. http://www.thedailyriff.com/articles/how-the-flipped-classroom-is-radicallytransforming-learning-536.php. 2012.
- Brame C. Flipping the classroom. <u>http://cft.vanderbilt.edu/guides-sub-pages/flipping-the-classroom/</u>. 2013. Accessed July 10, 2014.
- 3. Mazur E. Farewell, Lecture? Science. 2009:323, 50-51.
- Buemi S. Microflipping: a Modest Twist on the 'Flipped' Classroom. Chronicle of Higher Education. 2014; 60(32):p6-6

### Student Chapter Update

#### **News & Updates**

#### BY JORDAN GILMORE, CLEMSON UNIVERSITY, NATIONAL STUDENT CHAPTER PRESIDENT

### THE BENEFITS OF SUMMER



The summer months provide student chapter members the opportunity for uninterrupted research without the added burdens of coursework or teaching responsibilities, and more importantly, a chance for students to relax and have some fun! Many student chapters plan events during

the summer that allow members to socialize and relax together in hopes of both growing the chapter and building a stronger, more engaged group of student members. After speaking with several student chapter representatives across the country, social activities have three major advantages.

#### **1: NEW MEMBERS**

Many of these events are seen as icebreakers for student chapters where people are encouraged to engage with someone they normally wouldn't otherwise. The nontechnical nature of the events provides a natural buffer for students that may feel intimidated by more senior members of the chapter. Discussions about research interests or other academics happen more organically and students have reported feeling less pressured to meet people for social purposes and for future research help. One of the common venues for these events has been local or university sporting events. Student chapter leaders from Clemson University report using local professional baseball games or university football games as early opportunities for student interaction. These events are particularly popular for international students who have the additional benefit of experiencing popular aspects of the university culture.

#### 2: CHAPTER DEVELOPMENT

Many students have voiced the desire for their student chapters to be something more than "just another academic club." Members see the social events and informal networking opportunities as important reasons for joining and maintaining active membership. In addition to the scholarly activities provided by academic departments, such as journal clubs or seminars, students look forward to the mental break provided by these social activities and the chance to see a different side of their lab and classmates. The Society as a whole has confirmed this benefit through the annual promotion of the very popular Biomaterials Bash at the annual meeting.

#### **3: INCREASED MEMBER PARTICIPATION**

The primary focus of many student chapters is the presentation of an annual Biomaterials Day and attendance at the annual meeting. However, most student chapters offer beneficial professional development and scholarship enhancing activities all year. Unfortunately, many student members become too busy to participate in these other activities. Social activities provide student chapter leaders the opportunity to promote other chapter events to a captive audience. Those students in attendance are more likely to attend subsequent events because of the fun they had at the social event.

It is important that all of our student chapters work to integrate social activities into their chapter plans. I think we can all agree that these events offer much more than just fun and games. If used strategically, these events can be a great asset to chapters looking to develop further this year.

#### BY LAURA VILLADA, STUDENT CHAPTER VICE PRESIDENT

### **UNIVERSITY OF FLORIDA: BIOMATERIALS DAY 2014**



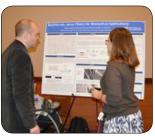
{ UF SFB CHAPTER OFFICERS } (I-r): Jimmy Taylor (webmaster), Carlos Gordian (BEC Rep), Emily Hester (Secretary), Evelyn Bracho (President), Laura Villada (Vice President, Annabelle Woodruff, (Historian), Cary Kuliasha (Treasurer).

The student chapter of the SFB at the University of Florida held its third annual Biomaterials Day, entitled "Engineering the Future of Medicine," March 28, 2014. The one-day symposium included a keynote address and speaker presentations from academia, as well as industry representatives, a student poster session featuring the work of graduate and undergraduate

students from the University of Florida and other regional universities and, last, an industrial information session about career opportunities in the field of biomaterials. Biomaterials Day 2014 had 202 registered attendees including students, professors and industrial professionals from Florida International University, University of Central Florida, Florida Institute of Technology and Gainesville High School in addition to the host, University of Florida. The goal of Biomaterials Day 2014 was to create a network with regional universities and companies actively involved in the biomaterials field.



Keynote speaker Dr. Cato Laurencin giving his speech, "Regenerative Engineering: The Theory and Practice of a Next Generation Field."



The student poster session promoted the interaction between students and leading scientists and developers to move the field forward.

The highlight of the event was having Dr. Cato T. Laurencin from UConn give the keynote address, during which he emphasized the importance of biomaterials in the regenerative engineering field and how it will dictate the future of biomedical engineering. He highlighted the importance of biomaterials in the medical fields, quoting the event's theme, "Engineering the Future of Medicine." Dr. Laurencin is an elected member of the Institute of Medicine of the National Academy of Sciences and an elected member of the National Academy of Engineering.

# Introduction to Biomaterials. Basic Theory with Engineering Applications **Book Review**

#### BY LYNNE JONES, BOOK REVIEW EDITOR



For the members of the Society For Biomaterials who teach basic biomaterials courses, there is an ongoing search for the optimal textbook for your class. Textbooks are selected based upon the level of the class (undergraduate, upper level undergraduate/early graduate,

graduate), the topics you would like to cover and how deeply you want to cover them, whether the class is one or two semesters and whether it is an improvement over the current textbook that you are using. The format is also of interest. Do you want a textbook with problems to solve? Do you want a textbook that will serve as an in-depth resource later in the student's career? There is also an increasing effort to minimize the textbook's costs for the students as much as is possible without compromising the level of teaching. If you are still searching for that optimal textbook, *Introduction to Biomaterials. Basic Theory with Engineering Applications* is a textbook worth evaluating.



\*Mauli Agrawal C, \*Ong JL, Appleford MR, \*Mani G New York: Cambridge University Press, 2014 ISBN: 978-0-521-11690-9

\*Members of the Society For Biomaterials

#### DESCRIPTION

This book does a great job of introducing biomaterial science, from the basic properties of materials to biological systems to specific applications. It begins by introducing us to the very basics of material science (types of bonds, types of materials) and their applications to medical implants (Chapter 1). It then addresses the mechanical, electrochemical and surface properties of materials (Chapter 2).

Chapter 4 takes a practical approach to the characterization of biomaterials. I have already recommended the reading of this chapter to medical students who are trying to read journal articles that use these methodologies (especially in the *Journal of Biomedical Materials Science*). Chapters 5 through 8 address the materials used in the construct of medical implants. I appreciate the equal stature given to natural biomaterials, a category of biomaterials sometimes overlooked in introductory textbooks.

In Chapter 9, the authors identify the significant role that surface modification plays in tissue-biomaterial interactions. This is one of the more in-depth chapters included in the book. Its emphasis indicates how important surface modification has been and is likely to be in the future manufacture of implants. The book also addresses the sterilization of medical implants (Chapter 10). Implantassociated infection has frequently contributed to the failure of medical procedures involving implants. There is renewed interest in this topic as combination products are developed and introduced to the medical community.

Chapters 12, 13 and 14 are focused on different applications of implant materials (drug delivery, tissue engineering and specific clinical applications). This will bring home the utility of biomaterials science to the students.

I believe that future biomaterials scientists need to be educated equally regarding biology and materials. Therefore, I am biased toward textbooks – especially introductory textbooks – that provide more than a cursory page or two about biological principles and their applications to biological implants. While the authors suggest that an introductory course to biology should be a perquisite, I found Chapter 3, "Biological Systems," easy to follow, beginning with the basics of cell biology and advancing to cell junctions and cell signaling pathways. I also appreciated the inclusion of biological testing techniques.

The authors revisit biological principles in Chapter 11, "Cell-biomaterial interactions." This is important for an understanding of adverse events implicating the host response to materials as well as for the exploration of surface modification methodologies to utilize biology to enhance the integration of the implant into the host. Chapter 13, "Tissue Engineering," also addresses the selection of cells for cell-based therapies, including those using cell-seeded scaffolds.

#### CONTENTS

The book addresses the following topics:

- Introduction (Chapter 1)
- Basic materials
  - Chapter 2. Basic Properties of Materials
  - Chapter 4. Characterization of Biomaterials
- Specific Materials
  - Chapter 5. Metals; Structure and Properties
  - Chapter 6. Polymers
  - Chapter 7. Ceramics
  - Chapter 8. Natural Biomaterials
- Surface Modification (Chapter 9)
- Sterilization of Biomedical Implants (Chapter 10)
- Biological Systems
  - Chapter 3. Biological Systems
  - Chapter 11 Cell-Biomaterial Interactions
- Applications
  - Chapter 12. Drug Delivery Systems
  - Chapter 13. Tissue Engineering
  - Chapter 14. Clinical Applications

#### AUDIENCE

#### As described in the preface:

"This book has been written as an introduction to biomaterials for college students. It can be used either at the junior/senior levels of undergraduate education or at the graduate level for biomedical engineering students. It is best suited for students who have already taken an introductory course in biology. We have felt the need for a textbook that caters to all students interested in biomaterials and does not assume that every student intends to become a biomaterials scientist. This book is a balance between science and engineering, and presents both scientific principles and engineering applications."

After reviewing this book, I think that the authors hit the nail on the head. This book is appropriate for an introductory undergraduate course. The text is clearly written and illustrated well. There are relevant problems included at the end of each chapter to reinforce the lessons learned. The inclusion of various techniques/methodologies is also of value to students. I believe the text presented each topic in enough depth to provide a student with an adequate background for future higher-level courses.

#### { OTHER TEXTBOOKS TO CONSIDER }

Biomaterials Science, Comprehensive Biomaterials, and Biomaterials : The Intersection of Biology and Materials Science. Temenoff JS, Mikos AG Prentice Hall, 2008

Biomaterials Science. An Introduction to Materials in Science. Editors: Ratner B, Hoffman A, Schoen F, Lemons J Elsevier Science, 2012 Reviewed: Q 1, 2013

*Comprehensive Biomaterials.* Editor in Chief: Duchyene P Elsevier Science, 2011 Reviewed: Q 2, 2012

# SOCIETY FOR BOMALERIALS Charlotte, NC April 15-18, 2015 2015 ANNUAL MEETING & EXPOSITION



### Driving Biomaterial Innovation and THE RACE TO TRANSLATION

