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BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

FOURTH QUARTER 2020 • VOLUME 42, ISSUE 4

ALSO INSIDE

NIBIB UPDATES: RESEARCH PROGRAM RESOURCES FOR BIOMATERIALS

REMEMBERING PROFESSOR JAN CHŁOPEK (1952-2020)

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 (email: info@biomaterials.org) or visit the Society's website, biomaterials.org.

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.

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Requests for advertising information should be directed to Lisa Howard-Fusco at lfusco@ahint.com or 856-380-6905. Information is also available on the Society's website, biomaterials.org.

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

BIOMATERIALS FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 42, Issue 4

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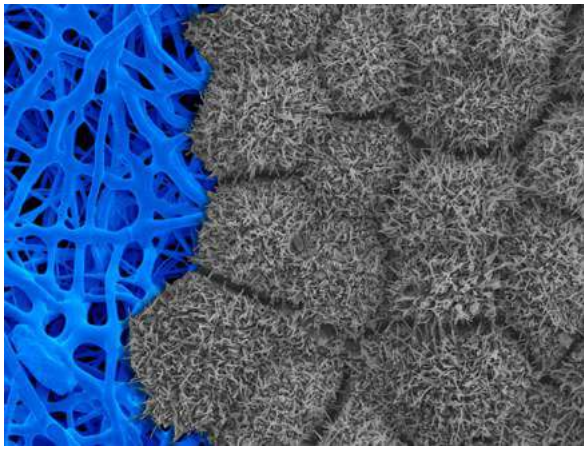

ON THE COVER

Retinal Pigment Epithelium on Fiber-Based Construct

This is a scanning electron micrograph of tissue-engineered retinal pigment epithelium (RPE) cultured on a fiber-based scaffold. Constructs were generated in the lab of Kapil Bharti at the National Eye Institute (NEI/NIH). RPE are derived from induced pluripotent stem cells (iPSCs) that were generated from the cells of patients with age-related macular degeneration (AMD). AMD is a leading cause of adult blindness that affects millions. RPE support the health and integrity of photoreceptor cells, and their degeneration can result in AMD. The RPE constructs are being developed at NEI for a human clinical trial to treat AMD. The hypothesis is that the RPE constructs will implant in the back of the eye to replace the patient's faulty RPE and support the rod cells to prevent further loss of vision. The left side of the image shows the fiber-based construct with blue pseudocoloring. The RPE are grown on a fiber-based scaffold to give the constructs mechanical integrity so that they can be lifted out of a dish and implanted into the back of the patient's eye. The fiber-based constructs are also able to support the in vitro differentiation of iPSCs into RPE during the biomanufacturing process.The right side of the image shows the mature RPE in grey color with their characteristic microvilli visible on their surface. These microvilli integrate in between and interact with the photoreceptor cells.

Photo Credit: Nathan Hotaling

Reference

Schaub NJ, Hotaling NA, Manescu P, et. al. Deep learning predicts function of live retinal pigment epithelium from quantitative microscopy. *J Clin Investig*. 2020;130:1010-1023. doi: https://doi.org/10.1172/JCI131187.

Commentary

Tucker BA, Mullins RF, Stone EM. Autologous cell replacement: a noninvasive AI approach to clinical release testing. *J Clin Investig*. 2020;130: 608-611. doi: https://doi.org/10.1172/JCI133821.

National Eye Institute. NIH, NIST researchers use artificial intelligence for quality control of stem cell-derived tissues.https://www.newswise.com/articles/nih-nist-researchers-use-artificial-intelligence-for-quality-control-of-stem-cell-derived-tissues. Accessed December 1, 2020.

From the Editor

By Roger Narayan, Biomaterials Forum Executive Editor

The ongoing COVID-19 pandemic has had profound effects on the global biomaterials community. I want to take this opportunity to express my sincere thanks to the members of the biomaterials community who are on the front lines of the response to this pandemic as healthcare practitioners, educators and researchers. I also want to give thanks to the researchers who applied their scientific backgrounds to provide solutions to the challenges brought about by this pandemic. At North Carolina State University, Gary Gilleskie and his team at the Biomanufacturing Training and Education Center worked with Novozymes to produce hand sanitizer in large quantities from bioethanol. Behnam Pourdeyhimi and his team at the Nonwovens Institute created a new type of spunbond fabric containing two polymer materials for use in surgical masks; this mask was recently approved for use as personal protective equipment. These two examples show how the research community is applying fundamental scientific knowledge and rapidly scaling up solutions to reduce disease transmission. The activities that advance the prevention, detection and treatment of COVID-19 using scientific innovations appear in the news daily, and serve as a reminder to the wider community about the societal importance of scientific funding.

This issue of *Biomaterials Forum* highlights two important considerations related to how the Society uses funding to support biomaterials research. In the first feature, Professor Daniel Herr and Dean Sherine Obare discuss the importance of using scientific funding to support women, Black, Hispanic and Latino people and differently-abled people, as well as others who have historically faced challenges in their pursuit of scientific careers. Recruitment and retention efforts to obtain individuals from diverse backgrounds must become a larger focus for decision makers in academia and industry. Future issues of the Forum will highlight resources that the biomaterials community can use to connect with students and collaborators from diverse backgrounds.

The second feature highlights recent changes at the National Institute of Biomedical Imaging and Bioengineering that support biomaterials research. It is hoped that this article gives biomaterials scientists in academia and industry some insight into current funding trends. I plan to reach out to the Small Business Innovation Research program, as well as staff at other funding platforms, to provide their insight for upcoming issues of the *Forum*. It is hoped that this issue provides some ideas for the biomaterials community to consider and bring into a brighter, happier and more productive 2021.

Best Regards,

Roger Narayan

From the President

By Shelly Sakiyama-Elbert, SFB President

Dear SFB Colleagues,

As 2020 comes to a welcome end, I hope this message finds you well. It has been a difficult year for all of us in many different ways. But as the year comes to a close, I am optimistic for our future in 2021, thanks to the arrival of not one, but two vaccines based on mRNA and lipid nanoparticles. I am grateful for the tireless work of the scientists, engineers and clinical research teams that helped to develop the COVID-19 vaccines, and I look forward to receiving one of them (hopefully in the spring).

One big change for the Society For Biomaterials is that starting January 1, 2021 we will begin transitioning the Editor-in-Chief role for our flagship journal, *The Journal of Biomedical Materials Research Part A*. Jim Anderson has been an outstanding champion for the field of biomaterials and an exceptional editor for *JBMR Part A*. SFB is grateful for his leadership and mentorship as Editor-in-Chief over the years. We are excited to welcome Kent Leach (of the University of California, Davis) as the new Editor-in-Chief of *JBMR Part A*, and we look forward to working together with him to continue the excellence in biomaterials publications.

In August, SFB voted to amend our Bylaws to add a standing Diversity, Equity & Inclusion Committee to coordinate current diversity activities and expand our ability to highlight the outstanding work of underrepresented scientists in biomaterials. The Diversity, Equity & Inclusion Committee will also work to expand training on mentorship of diverse research groups and increasing the nominations for SFB awards and elected offices. I am pleased to announce that Ed Botchwey from the Georgia Institute of Technology has agreed to serve as the inaugural Chair for the Diversity, Equity & Inclusion Committee. Please feel free to reach out to me or him if you have additional suggestions for activities or action.

We recently made the difficult decision to move the April 2021 SFB Annual Meeting to a virtual format, given the uncertainty of vaccine supplies and travel restrictions in the spring. We are making some exciting changes in the program format, including Rapid-Fire talks for all poster presenters. We will open the call for Late Breaking abstracts in early January, and these abstracts will be eligible for the Rapid-Fire Talks. The Annual Meeting dates have also shifted to April 20-23 to avoid a weekend conference date, which is more challenging for many virtual conference attendees. Registration rates are being reduced to reflect the change in format (and the savings from lack of food, beverage and venue charges). Please see the 2021.biomaterials.org website for the latest information.

Also, mark your calendars for our joint symposium with the Japanese Society for Biomaterials in Hawaii that is now scheduled for July 29-31, 2021 at the Hilton Waikiki Beach.

I challenge you all to continue your involvement with the Society For Biomaterials (including renewing your membership) to enhance the impact of our work improving healthcare through the use of biomaterials, while supporting and continuing to build a diverse community. I welcome your suggestions for ways to engage over the coming year (please email me at sakiyama@utexas.edu).

CALL FOR COVER ART

WE WANT TO FEATURE YOUR EXCITING BIOMATERIALS ARTWORK ON THE COVER OF *BIOMATERIALS FORUM*.

Deadline: Accepted on a rolling basis.

Instructions: Please email artwork (digital images, artistic creations, etc.) to info@biomaterials.org, to the attention of the Executive Editor of the *Biomaterials Forum*. All artwork with biomaterials relevance that have not appeared as a *Forum* cover are welcome. Multiple submissions are permissible.

Description: Selected artwork will appear as the cover of a future issue of *Biomaterials Forum* along with a brief "On the Cover" description of the subject and name/affiliation of the creator.

Format: High-resolution electronic version in .gif, .tiff or .jpeg file format.

Member News

By Joyce Wong, Member-at Large

Thank you to everyone who submitted their news. Please continue to send me your information — I will still need your help to ensure that we spotlight *all* of our members' news and accomplishments. You can submit your own news or amplify other SFB members' work at any time using this form. If you wish, please include your headshot.

News means not only honors and awards but also publications, books, conferences, grants, outreach, diversity equity and inclusion, promotions, new roles, etc. **I am also in the process of collecting patents issued within the past 5 years from our members – please continue to submit your entries.** You can also email me at jywong@bu.edu or help us by tagging "#SFB" in your posts on Twitter (@SFBiomaterials), Facebook and LinkedIn. Please also contact me with suggestions to help me advocate for the broad membership of SFB.

SFB MEMBER NEWS AND ACCOMPLISHMENTS, PAST QUARTER

FUNDING AND GRANTS

Cheryl Gomillion, Assistant Professor, University of Georgia, College of Engineering, was recently awarded a two-year grant from the National Science Foundation for work entitled, "An Investigator Development Plan for Building Capacity to Explore Diverse Microcultures in Graduate Engineering Research Laboratories," with a goal of understanding the best practices, characteristics and functioning of diverse STEM research labs.

Dr. Gomillion is also a recipient of a three-year grant from Venturewell for "Design Achieved with Generosity (DAWG): Integration of Engineering Design and Clinical Immersion for Solving Unmet Medical Needs for Underserved Populations," a project aimed at developing a community-focused, BioDesign-modeled, senior capstone engineering experience in a community clinic environment in the Athens, Georgia community.

Amber Jennings, Assistant Professor, University of Memphis, Department of Biomedical Engineering, has received a 2020 National Science Foundation Faculty Early CAREER Development Award to design materials with a novel, synthetic, biofilm-disrupting molecule bound to their surfaces. The 5-year, $543,551 grant is titled, "Tethered Biofilm Dispersal Signals for Long-Term Protection of Engineering Materials." Biofilms form when bacteria attach to surfaces. Because biofilms protect the bacteria, they are often more resistant to traditional antimicrobial treatments and evade immune systems, making them a serious health risk in the fields of health care, environmental engineering, chemical engineering, food preparation and more.

David Kohn, Natalie C. Roberts Endowed Professor, University of Michigan, is the lead PI on a 5-year, $31.4 million NIH grant to establish a national regenerative medicine resource center geared toward clinical and commercial translation of dental, oral and craniofacial tissues. The center leadership team includes SFB members **William Wagner, David Mooney** and researchers from the University of Michigan, University of Pittsburgh and the Wyss Institute at Harvard University. The Center brings together a multidisciplinary team of scientists, engineers, clinicians, regulatory and commercialization experts to help advance technologies through FDA approval to begin clinical trials.

Ana Maria Porras, Presidential Postdoctoral Fellow, Meinig School of Biomedical Engineering, Cornell University, received funding from @IfThenSheCan to partner with @storycollider to do their *first ever* show in Spanish! They highlighted the immigration of Latinas in STEM on Friday, December 4. Porras will join the faculty at the University of Florida in July 2021.

Cherie Stabler, Professor, J. Crayton Pruitt Family Department of Biomedical Engineering, University of Florida, recently received a $1.7 million RO1 grant from the NIH National Institute of Diabetes and Digestive and Kidney Diseases for her project, "Engineering Immunomodulatory Nanoscale Coatings for Protecting Islet Transplants." Stabler's recently-funded grant seeks to improve cellular implants by encapsulating the cells within protective immunomodulatory biomaterials. Lessons learned from this approach could also be translated to other cell-based therapies to improve their duration and minimize the immunosuppressive drug load to the patient.

Jessica Weaver, Assistant Professor, Arizona State University, School of Biological and Health Systems Engineering, was awarded a JDRF (Juvenile Diabetes Research Foundation) Innovative Grant for work to induce antigen-specific tolerance in islet transplantation. The Innovative Grant program solicits proposals for highly innovative research with significant potential to accelerate the mission of JDRF.

HONORS AND AWARDS

Brian Aguado, NIH and Burroughs Wellcome Fund postdoctoral fellow, University of Colorado, Boulder, received CU-Boulder's 2020 Outstanding Postdoc Award, reserved for postdocs excelling in research productivity and innovation, communication and leadership. Aguado is a recipient of the prestigious NIH K99/R00 Pathway to Independence Award and

Member News (continued)

will assume a faculty position at the University of California San Diego in July 2021. Aguado is also a former President of the Postdoctoral Association of Colorado Boulder (PAC Boulder), a group of CU Boulder postdocs that partners closely with CU Boulder's Office of Postdoctoral Affairs on initiatives to enhance CU Boulder's postdoc community.

Julianne Holloway, Assistant Professor, Arizona State University, received the AIChE 35 Under 35 Award in the Bioengineering category. The AIChE 35 Under 35 Award honors engineers under the age of 35 who have made significant contributions to the Institute and to the chemical engineering profession. Holloway's research group develops biomaterials for tissue engineering applications.

Bryan D. James, NHLBI Predoctoral Fellow/PhD Candidate, University of Florida, Materials Science & Engineering, received from the Foundation for Women's Wellness the Gridley McKim-Smith Women's Health Fellowship Award for research investigating vascular cell sexual dimorphism in complex mechanical microenvironments and career accomplishments. Part of this award is an essay entitled "Let's Talk About Sex – Biological Sex Is Underreported in Biomaterial Studies." This essay is published in *Advanced Healthcare Materials,* which argues for the biomaterials community to report the sex of their cells (https://doi.org/10.1002/adhm.202001034).

Kyle Lampe, Assistant Professor, University of Virginia, Chemical Engineering, recently received the Distinguished Young Alumni Award from his BS alma mater, Missouri University of Science and Technology in Rolla, Missouri during the virtual homecoming celebration. Kyle graduated from MST in 2004 with a BS in Chemical Engineering.

Cato T. Laurencin, Albert and Wilda Van Dusen Distinguished Professor of Orthopedic Surgery and Chemical, Materials and Biomedical Engineering at the University of Connecticut School of Medicine, is the recipient of the 2020 Mike Hogg Award, which is the University of Texas MD Anderson Cancer Center's most prestigious award.

Tao L. Lowe, Frederick G. Smith, MS, DDS and Venice K. Paterakis, DDS Professor of Oral and Maxillofacial Surgery, Professor of Bioengineering, University of Maryland, Department of Oral and Maxillofacial Surgery and Department of Bioengineering, has been selected as a Fellow of the American Association of Pharmaceutical Scientists (https://tinyurl.com/y5rxkt9u). Dr. Lowe is an international expert in pharmaceutical sciences, especially in biomaterials, drug delivery, nanotechnology, transport across biological barriers and regenerative medicine. She was awarded a Coulter Foundation Early Career Award in Translational Research and is the first and only endowed professor in the School of Dentistry at the University of Maryland. She pioneered periocular hydrogel technology for ocular drug delivery, and filled the market gap by offering 6- to 12-month injectable contraceptives.

Christine Schmidt, J. Crayton Pruitt Family Professor and Department Chair, J. Crayton Pruitt Family Department of Biomedical Engineering, University of Florida, has been chosen as a 2020 inductee into the Florida Inventors Hall of Fame. Schmidt is the creator of the decellularization technology that is the basis for AxoGen's AvanceÒ Nerve Graft, which has improved the lives of over 100,000 patients suffering from peripheral nerve damage. Her research is also the foundation for the start-up company, Alafair Biosciences, in Austin, Texas, that focuses on internal wound care management. Alafair's first clinical product, VersaWrap Tendon Protector, was launched in December 2017 and has been used in over 2000 patients. Alafair's VersaWrap Nerve Protector received FDA approval in fall 2020. Schmidt has additional patents licensed to companies such as Smith and Nephew and Siluria Technologies, Inc., and many additional invention disclosures and pending patents.

PROMOTIONS AND APPOINTMENTS

Emily Day, Associate Professor, University of Delaware, Biomedical Engineering, has been promoted to Associate Professor with tenure at the University of Delaware. Dr. Day uses a multidisciplinary approach to engineer nanomaterials with unique physical and chemical properties so that they can be used to transform the study, detection and treatment of cancer.

Ankur Singh, Associate Professor, Georgia Institute of Technology, recently moved from Cornell University as Associate Professor to Georgia Tech and Emory University in July 2020. At Cornell, his laboratory developed "living" immune tissues using biomaterials and pursued the discovery and translation of immunotherapies. At Georgia Tech/Emory, he hopes the new directions in his lab will lead to important discoveries in immunology and cancer and the development of immune-therapeutics to fight a range of disorders.

RETIREMENTS

Joachim Kohn is excited to announce his retirement from Rutgers University effective Nov 1, 2020. "As I retire after a long and successful period of 34 years, I am looking back at so many

Member News (continued)

wonderful achievements. These achievements include the creation of three start-up companies, which over time generated products that are now used by over 500,000 patients worldwide. Perhaps more importantly, these products are credited with having saved thousands of lives. A major highpoint was my leadership in the Armed Forces Institute of Regenerative Medicine (AFIRM) and the face transplants that were conducted at the Cleveland Clinic. I am proud of the over 600 students, postdocs, technicians and faculty who trained and worked in my lab. For more details of my work at Rutgers, there is a nice interview about my 'academic journey' at this site: https://www.controlledreleasesociety.org/publications/crs-inside-track/academic-journey-dr-joachim-kohn-professor-rutgers-university.

"I don't look at retirement as the end of my scientific work. It is more like a 'job change.' I will continue to be very prominently involved in the global biomaterials community and be active in research, consulting, mentorship and entrepreneurship. In particular, I look forward to contributing to the Society For Biomaterials which has played an important role throughout my entire professional life."

RECENT PUBLICATIONS FROM OUR MEMBERS

Hyunjoon Kong, Robert W Schafer Professor, University of Illinois at Urbana-Champaign, Chemical & Biomolecular Engineering, reported a soft manipulator inspired by an octopus's sucker that rapidly transfers delicate cell/tissue or electronic sheets to the patient, overcoming a key barrier to clinical application (https://news.illinois.edu/view/6367/1745853877).

The paper entitled "Electrothermal Soft Manipulator Enabling Safe Transport and Handling of Thin Cell/Tissue Sheets and Bioelectronic Devices" is available online in *Science Advances* (https://advances.sciencemag.org/content/6/42/eabc5630).

Bingyun Li, Professor, Department of Orthopedics, West Virginia University, and Thomas Webster, Professor, Department of Chemical Engineering, Northeastern University, has published two new books on biomaterial-associated infections with colleague Thomas Webster. The books are titled *Racing for the Surface — Pathogenesis of Implant Infection and Advanced Antimicrobial Strategies* and *Racing for the Surface — Antimicrobial and Interface Tissue Engineering*. These two new books have a total of 51 chapters, offer strong input from academia, industry and clinicians and cover the latest research in biofilm, infection, antimicrobial strategies and integration of both antimicrobial and osteoinductive properties in reducing and treating infections.

Carolyn Schutt Ibsen, Assistant Professor, Oregon Health and Science University, Department of Biomedical Engineering and the Knight Cancer Institute, coauthored a new review in which they explore advances using external stimuli (light, ultrasound, electric and magnetic fields) to manipulate biomaterial scaffolds and influence cell behavior with implications for tissue-engineered models of disease progression and personalized medicine.

Schutt CE, et. al. Stimuli-responsive biomaterials: Scaffolds for stem cell control. *Adv Health. Mater.* 2020. https://doi.org/10.1002/adhm.202001125. Accessed November 30, 2020.

Rami Tzafriri, Cardiovascular Biomaterials SIG Chair, Director of Research and Innovation CBSET, Lexington Massachusetts, and colleagues published a study investigating how drug-coated balloons work and might be optimized.

Tzafriri AR, et. al. Balloon-based drug coating delivery to the artery wall is dictated by coating micro-morphology and angioplasty pressure gradients. *Biomaterials*. 2020 Nov;260:120337. doi: 10.1016/j.biomaterials.2020.120337.

See highlight in clinical/industry newsletter: https://evtoday.com/news/cbset-preclinical-study-shows-balloon-based-drug-delivery-is-critically-dependent-on-coating-micromorphology?c4src=news.

Michael F. Wolf, Distinguished Scientist, Medtronic, Core Technologies group, published "In Vitro Methodology for Medical Device Material Thrombogenicity Assessments: A Use Condition and Bioanalytical Proof-of-Concept Approach" in the *Journal of Biomedical Materials Research Part B*. Available free on Open Access. This paper summarizes the basic science behind the in vitro tube and loop models and gives case examples that include comparison to NAVI studies. The take-home message is that these simple in vitro bioanalytical methods give results similar to the in vivo NAVI model.

ENTREPRENEURIAL ACTIVITIES

David K. Mills, Professor, Biomedical Engineering/Biology, Louisiana Tech University, reports that NASA selected their innovative filter technology as one of 10 companies to participate as finalists in the 2020 NASA iTech Cycle II Forum. The organicNANO team included Chris Miller and Antwine McFarland (PhD students at Louisiana Tech University), and Dr. David K. Mills, Professor of Biology/Biomedical Engineering at Louisiana Tech University and President of organicNANO. The Forum, held virtually Oct. 15-16, was the culmination of NASA iTech's search for dual-use technologies from entrepreneurs in 2020.

Member News (continued)

CONFERENCE ORGANIZATION

Scott Taylor, CTO, Poly-Med, Inc., is chair of an upcoming workshop hosted by ASTM regarding the "'Use of Absorbable Polymers for Medical Devices." This virtual workshop is January 20 - 21 and members of SFB are encouraged to attend to learn about current material trends and regulatory challenges within this important product class. Registration is open now, and can be accessed at https://bit.ly/3m3oK8Z

DIVERSITY, EQUITY & INCLUSION

Brian Aguado, and **Ana Maria Porras** recently published an opinion piece on co-founding LatinXinBME which uses a Slack platform and is active on Twitter (@LatinXinBME) with highlights of members and their professional successes, job openings, internship opportunities and professional development workshops, and provides resources to support diversity, equity and inclusion. LatinXinBME co-founders Drs. Aguado and Porras also served on the SFB Diversity Task Force to help establish the new Society For Biomaterials Diversity, Equity & Inclusion Committee.

Aguado BA, **Porras AM**. Building a virtual community to support and celebrate the success of Latinx scientists. *Nat Rev Mater*. 2020;5:862–864. https://doi.org/10.1038/s41578-020-00259-8.

Key points for allyship: What can you do?

- Take an active role in diversifying undergraduate and graduate admissions
  - Eliminate GREs
  - Provide application fee waivers
  - Build meaningful relationships with Hispanic-Serving Institutions, Historically Black Colleges and Universities and Tribal Colleges and Universities
- Commit to bold efforts when hiring faculty
  - Cluster hiring for tenure-track professors
  - Expand recruitment pools
  - Reassess hiring criteria
- Invite underrepresented colleagues to
  - Give departmental seminars/colloquia
  - Collaborate on grants
  - Co-author manuscripts
- Recognize diversity, equity and inclusion efforts in performance evaluations at all levels
- Create welcoming and safe work environments and help stop racist behaviors that infect the STEM community and leave the Latinx community powerless
  - Stop assuming that the Latinx scientist down the hall is the janitor
  - Stop joking that Latinx scientists are good at making cocaine in the lab
  - Stop mentioning that accents are distracting in presentations
  - Stop thinking that Latinx immigrants are stealing jobs
  - Stop saying that Latinx trainees were awarded a fellowship because they are Latinx

HAVE A ***LETTER TO THE EDITOR, REGIONAL BIOMATERIALS EVENT HIGHLIGHTS*** OR ***COVER ART*** TO SHARE WITH FORUM READERS?

PLEASE CONTACT
Roger Naryan at roger_narayan@ncsu.edu.

Staff Updates

By Shena Seppanen, Assistant Executive Director

Hello from the Society For Biomaterials Headquarters! The following is a summary of the actions and plans for the Board, Council, Committees and Task Forces.

BOARD/COUNCIL

President: Shelly Sakiyama-Elbert, PhD

The SFB Board and Governing Council met twice this fall, with another meeting anticipated in December, via Zoom, to discuss 2021 programming, the 2021 budget and efforts to recruit and retain Society members and enhance the value of membership.

AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE

Chair: David Kohn, PhD

The Committee has met on multiple occasions to review and deliberate the final slate of 2021 awardees and Officer nominations; notifications will be made shortly to those selected. Additionally, a representative from the newly-formed Diversity, Equity & Inclusion Committee was added as a member of the ACN Committee.

BYLAWS COMMITTEE

Chair: Ashley Carson Brown, PhD

The recent amendment to the bylaws included the adoption of a Diversity, Equity & Inclusion Committee.

DIVERSITY, EQUITY & INCLUSION COMMITTEE

Chair: Ed Botchwey, PhD

Appointments have been offered and the Committee is currently being compiled. Representatives have been added to both the Awards, Ceremonies and Nominations Committee and the Program Committee. The Committee is in the final stages of developing an action plan and will soon have a dedicated space on the SFB website to increase both awareness and participation.

EDUCATION & PROFESSIONAL DEVELOPMENT COMMITTEE

Chair: Tom Dziubla, PhD

The Committee is currently reviewing the Biomaterials Days Grant applications of two universities who recently became officially-recognized SFB Student Chapters in 2020. Awardees from 2020 who had postponed their events are currently considering hosting them virtually in lieu of in-person events. The E&PD Committee is also continuing to pursue webinar content and encourages all members and student chapters to submit a proposal. Additionally, the Committee plans to begin offering virtual mentor roundtables, based on specific topics.

FINANCE COMMITTEE

Chair: Sarah E. Stabenfeldt, PhD

The 2021 budget is currently being prepared for Board approval, taking into consideration the ways 2020 has seen a decline in membership, as well as the likely change in attendance of SFB's traditional in-person Annual Meeting due to the pandemic. The Finance Committee has worked diligently to reduce overall expenses without affecting membership benefits.

INDUSTRIAL AFFAIRS COMMITTEE

Chair: SuPing Lyu, PhD

The Committee is currently in the process of developing a forum for device companies, suppliers and government agencies to harmonize regulatory efforts and stabilize supply chains at the 2021 Annual Meeting.

LIAISON COMMITTEE

Chair: Bingyun Li, PhD

At the upcoming WBC event, SFB will pitch to the IUSBSE to host the 2028 World Biomaterials Congress. SFB has also co-hosted several webinars with the Materials Research Society (MRS) and plans to continue their relationship with a virtual symposium next fall. If you would like to be involved in the development of this event, please contact Dan Lemyre (dlemyre@biomaterials.org).

MEMBERSHIP COMMITTEE

Chair: C. LaShan Simpson, PhD

The Membership Committee is currently reviewing feedback provided in the two-part member needs assessment survey and this year's member exit survey to better guide recruitment and retention efforts.

PROGRAM COMMITTEE

Chairs: Elizabeth Cosgriff-Hernandez, PhD and Nicholas P. Ziats, PhD

The SFB Joint Symposium with the Japanese Society For Biomaterials is set to take place July 29-31, 2021 in Honolulu, Hawaii. A Call for Abstracts will take place in the first quarter of 2021.

SPECIAL INTEREST GROUPS

Representative: Danielle Benoit, PhD

If your SIG would like to organize a webinar, please contact Dan Lemyre directly (dlemyre@biomoaterials.org) or complete the webinar proposal submission form. To access the webinar archive and recordings, please visit www.biomaterials.org/webinars.

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Student Chapter News

HELLO FROM THE NEW NATIONAL STUDENT CHAPTER OFFICERS!

By Deanna Bousalis, National Student Chapter President

Greetings SFB members! I am happy to introduce our new national student chapter officers for 2020-2021, as well as our newly-elected officers for the 2021-2022 term:

- President: Deanna Bousalis (University of Florida)
- Secretary/Treasurer: Sabrina Freeman (University of Florida)
- Bylaws Chair: Nicholas Fischer (University of Minnesota)
- President-Elect: Gerry Koons (Rice University)
- Secretary/Treasurer-Elect: Bryan James (University of Florida)

NATIONAL STUDENT CHAPTER COUNCIL MEETING RECAP

The SFB National Student Chapter Council meeting was recently held on October 22, 2020. At the meeting, the outgoing president, Jason Guo, gave a recap of the past year and announced the new officer election results, and I introduced myself and my goals for the upcoming year. My priority for the upcoming year is to increase student member involvement. Our team is excited to plan new workshops, networking events and other programming for our student members. We would love to have good attendance at these events and provide a space that fosters communication between members from across the country. Our first endeavor will be to host virtual socials for SFB Student Chapter members. We hope to receive input about what types of events and programming will engage our student members. Stay tuned for further details!

STUDENT WEBINAR SERIES

Bryan James, National Secretary/Treasurer-Elect and President of the University of Florida SFB Chapter, has spearheaded the creation of a student webinar series! This series offers SFB student members the opportunity to present their research in a virtual environment. Each webinar will be hosted by an SFB local student chapter and will highlight the research of one or two of their members, as well as the activities of the chapter itself. There will be a Q&A session in each webinar for attendees to interact with one another. This webinar series will serve as an outlet to learn about chapters from across the country and their members and allow us to share ideas about campus and community engagement and outreach. If you are reading this, whether you are a student or faculty member, please share with your local student chapter and encourage them apply! The application can be found here: https://docs.google.com/forms/d/e/1FAIpQLSeCIe9LsSzRv0TskFUQDqeSkLny7w2hL9w_aFsjtLyMijdWlQ/viewform

UPCOMING PLANS FOR THE 2021 SFB CONFERENCE

Without spoiling too much, we can tell you that we have been planning some exciting and informative panels at SFB 2021. Jason Guo (outgoing president) and I have been working hard to identify panelists for two different sessions. One event is a collaboration with SFB's Young Scientist Group, in which respected seniors in the fields of academia and industry will speculate and provide advice on what they would do if they were students now. The other event we will reveal in the next issue! Attending these panels, as well as the conference as a whole, will be a valuable opportunity for any student member of SFB, and we hope that you can all attend!

CONNECT WITH US!

Another great way to participate in SFB as a student is to connect with us, your student chapter officers. Please reach out to us if you have any ideas for programming that can better serve your needs as young scientists and researchers. We are open to any suggestions — please fill my inbox! You can contact me at dbousalis@ufl.edu with ideas, suggestions or just to introduce yourself or your local chapter. You can also find SFB and its members on social media, including Facebook, LinkedIn and Twitter. More information on these social media outlets can be found here: https://www.biomaterials.org/about-about-society/sfb-social-media.

ATTENTION STUDENTS — AND THEIR ADVISORS — IN THE SOCIETY FOR BIOMATERIALS FAMILY!

The *Biomaterials Forum* invites you to share your biomaterials images with the global biomaterial community through our new SFB Student Art Contest! Please submit your images (in TIFF or JPEG file format) to *Biomaterials Forum* Executive Editor Roger Narayan (roger_narayan@ncsu.edu) for consideration by the Society's publications committee.

The next submissions deadline is January 27, 2021.

AIMBE Report

By Lynne C. Jones, Alan Litsky and Joel Bumgartner

Many members of the Society For Biomaterials go to Washington, D.C. to advocate for you about issues relating to biomaterial research and education, development of innovative biomaterials and technologies and the translation of these advances to healthcare. Yet the voice that your lawmaker wants to hear is YOURS. They are your senators and representatives and they want to know what their constituents think. There are different strategies to use to reach out to your lawmakers, including writing a letter, inviting them to your laboratory, attending a town hall meeting, and meeting with them at their Washington, D.C. or local offices.

AIMBE has created an Advocacy Toolkit that you can use as an SFB member — you do not need to be a member of AIMBE. You can reach the Toolkit from the Advocacy navigation bar on the top of the SFB homepage. This site is rich with information on how to reach out to your representatives and senators. There is a link to identify your lawmaker. This link not only provides you with the addresses and phone numbers for their Washington, D.C. and local offices, but also lists their biography, committee memberships, website, Twitter handle and Facebook page. There is another link for writing a letter, often one of the first steps that a new advocate takes to communicate with their representatives and senators. Currently, there is a template for a letter in support of NIH Funding in the proposed coronavirus stimulus package. This template allows you to personalize your message. It can also be used to create your own letter based on the issue that you want to discuss. You have the option to send this letter by email or by using a traditional letter format to be delivered by the United States Postal Service. Also in the Toolkit is a link to request a meeting in Washington, D.C. Meeting with your lawmakers in their D.C. office is a unique experience and I highly recommend it for everyone. It definitely gives you the feeling that you are an active participant in the governing process. Don't forget, however, that you can also meet with your representatives, senators and their staff at certain times of the year in their local office. Local meetings and town halls are a great way to see your lawmakers up close and hear where they stand on the issues. The section on "Request a Meeting" contains two brief videos explaining why it is important and what to expect from a meeting. The page also includes talking points and provides guidance on things to keep in mind when talking to your senator or congressperson (or, often, a member of their staff).

Regardless of which strategy you choose, maximize your opportunity. Be focused and keep it simple (no scientific or engineering jargon). Be passionate about your personal story — why your research or job is important, how it will ultimately address a critical need and why federal support is needed. But, most importantly, be yourself.

Staff Update (continued from page 10)

STUDENT CHAPTER/YOUNG INVESTIGATORS

Deanna Bousalis (Student Chapter President) and Brian Aguado, PhD

The SFB National Student Chapter will be hosting several virtual socials throughout the year, via Zoom. SFB is currently seeking participation in the Student Webinar Series which offers student members the opportunity to highlight their research in a virtual environment. In addition, students will have the chance to network and learn about the activities of the other SFB Student Chapters. We invite you to help us develop this program by completing the submission form.

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
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In Memoriam
PROFESSOR JAN CHŁOPEK (1952-2020)

Professor Jan Chłopek passed away on Saturday, November 14, 2020. He was Head of the Department of Biomaterials and Composites, former Dean of the Faculty of Materials Science and Ceramics at the AGH University of Science and Technology, former President of the Polish Society for Biomaterials and an academic lecturer and a scientist, but above all a wonderful human being, a leader and an extraordinary mentor of students and younger scientists.

For almost 50 years, Professor Jan Chłopek was associated with the Faculty of Materials Science and Ceramics at the AGH University of Science and Technology – first as a student and then as a faculty member. He graduated in materials science in 1976, received his PhD degree in technical sciences in 1983, habilitation in 1998 and finally became a full professor in 2005.

He was an outstanding scientist working on biomaterials engineering and composite technology. He was the author of over 350 publications, including seven books/book chapters and 25 patents/patent applications. He was a supervisor of nine PhD dissertations and over 200 Bachelor and Masters students' theses.

Professor Jan Chłopek was Dean of the Faculty of Materials Science and Ceramics (2005-2012), Deputy Dean for International Cooperation (2002-2005) and Head of the Department of Biomaterials and Composites (2012-2020). He was a founding member of the Polish Society for Biomaterials where he served as Vice-President (1999-2006, 2010-2013), President (2014-2016) and Council Member (2017-2020). From 2007, he was Editor-in-Chief of the *Engineering of Biomaterials Journal*. He was Chairman of the Biomaterials in Medicine and Veterinary Medicine conferences, which has been organized annually since 1991. Having gained international recognition as a biomaterial scientist, Professor Chłopek chaired organizing committees of such important scientific meetings as the 27th European Conference on Biomaterials (ESB 2015) and the International Conference on Biomedical Polymers and Polymeric Biomaterials (ISBPPB 2018). Professor Jan Chłopek managed a nationwide team which developed teaching standards for biomedical engineering in Poland. He was a co-founder of the Multidisciplinary School of Biomedical Engineering at AGH. He received many awards and distinctions for his scientific and teaching activities. As an accomplished figure in the field of biomaterials science and engineering, Professor Chłopek received the accolade of Fellow, Biomaterials Science and Engineering (FBSE) from the International Union of Societies for Biomaterials Science and Engineering (IUSBSE).

The sudden death of Professor Chłopek has left us all in deep grief. He will be remembered as a scientist, mentor, husband, father, grandfather, football fan, player and coach. We will always cherish his kindness, sense of humor, positive attitude and faith in people.

Toward a Diverse Biomaterials Workforce: A Strategic and High Impact Advantage

By Daniel J. C. Herr and Sherine O. Obare

> *"DIVERSITY IS A STRATEGIC ADVANTAGE IF THERE IS A TRULY VIBRANT COMMUNITY, SUSTAINED BY A WEB OF RELATIONSHIPS."*
>
> **— FRITJOF CAPRA,** *THE WEB OF LIFE.*[1]

Biomaterials research and innovation are the underpinning components of science, technology and engineering. As the field continues to broaden its impact, particularly to address problems faced by global populations, a strategic advantage is to leverage diverse ways of thinking and problem solving that allow researchers to learn from one another and discover new knowledge for transformative solutions. Leveraging inclusivity provides the brainpower and the strategies needed to solve society's most pertinent problems in ways that not one group alone can do. With respect to scholarly impact, Harvard University professor and economist Richard Freeman reported that "papers that got the most citations, the most prestige, were often written by a mix of people with different backgrounds."[2] Collaboration among colleagues with different views and perspectives tend to enhance scientific understanding and to catalyze productivity. The U.S. Census Bureau population data show that the United States is becoming increasingly diverse. Currently, women, underrepresented minorities and persons with disabilities represent more than 50%, 33% and 12%, respectively, of the population.[3] These data suggest a tremendous value opportunity that leverages the expertise, creativity and perspectives of this diverse and growing talent pool.

Strategies to diversify talent in the science, technology, engineering and mathematics (STEM) disciplines, which will consequently support the biomaterials workforce, continue to be undertaken nationally. For example, according to the National Center for Science and Engineering Statistics, there has been an increase in degrees awarded at the bachelors, masters and doctorate levels to women and persons from underrepresented minority groups over the past two decades.[4] However, their representation in the U.S. workforce and in STEM disciplines does not reflect the diversity of the current U.S. demographics. The Metropolitan Policy Program report on census population projections indicates that the percentage of the combined minority population in the United States is expected to exceed 194 million people, or more than 50%, by 2045.[5] As we embark on future research, innovation and discovery, it is important that the biomaterials community develop strategies to train the next generation of domestic STEM researchers to ensure that global issues remain front and center and that solutions are implemented that will be beneficial to all communities. The National Science Board, Vision 2030, highlights a significant misalignment between the U.S. demographics and the current numbers of women, African Americans, Hispanics or Latinx and persons with disabilities in STEM-related careers. This misalignment of STEM expertise diminishes our ability to fully leverage diversity as a creative force. To achieve alignment, the number of women in the STEM workforce will need to double, the number of African Americans and persons with disabilities will need to more than double and the number of Hispanics or Latinx will need to triple.[6] For the biomaterials community to succeed in increasing representation and to fully benefit from this reservoir of diverse perspectives, we offer the following recommendations.

NURTURE HEALTHY AND SAFE EDUCATIONAL AND WORKFORCE ECOSYSTEMS

One of the foundations of cultivating a culture of inclusivity requires that women, underrepresented minorities and persons with disabilities work in an environment that allows them to contribute successfully by ensuring that they have a strong sense of belonging within the ecosystem where they work. How can we best build such a welcoming and inclusive culture?

This may be the hardest aspect of building communities with strong support structures to support diversity. It requires bias training so that participants to feel safe and respected around one another and that their contributions and ideas are taken seriously and appreciated by all members. Each of us can nurture this sense of belonging by celebrating the rich diversity of our students, post-doctoral researchers and faculty, as well as outreach to the next generation of biomaterials scientists and engineers. Collectively, we can provide a safe and healthy research community, one that strengthens collaborative and supportive networks, reenforces foundational understanding and technical skills, rewards critical and creative thinking and builds individual and collective resilience.

Dr. Suzanne Simard describes forests as a community of trees

Toward a Diverse Biomaterials Workforce: A Strategic and High Impact Advantage (continued)

"widely linked to other trees in the forest through their fungal-root connections[7,8] and very much interdependent upon the local microbiome." In *The Hidden Life of Trees*, Peter Wohlleben shares how elder trees within a forest ecosystem, such as those shown in Figure 1, share resources and establish safe environments for the diverse community of mature and young trees, as well as its microbiome. The elder trees also nurture and enable younger trees to find their own growth path over tens or hundreds of years.[9]

Like a forest, successful educational ecosystems leverage synergistic relationships and interdependencies that support the next generation of biomaterials scientists and engineers to discover and leverage their strengths, cultivate ideas and critical thinking, and learn from their experiences.[10] In this regard, role models and formal and informal hands-on STEM training opportunities (that also holistically engage their families) may be two of the most impactful ways to nurture and sustain interest in biomaterials science and engineering. For example, Dr. Gertrude Elion, biochemist and Nobel laureate, often made time to share her passion for science with thousands of young students around the globe. Each year, she also met regularly with, listened to and nurtured 12 middle school girls who exhibited an interest in STEM. Looking back over her career, she believed that establishing these long-term mentoring relationships were some of her most rewarding endeavors.[11]

RECRUIT TO ACHIEVE DIVERSITY ALIGNMENT

We must increase the participation of women, underrepresented minorities and persons with disabilities in the discipline. As in nature, diverse communities that celebrate each other's gifts where individuals can discover and achieve their full potential have a strategic advantage. Additionally, education and research institutions have also launched initiatives that effectively attract, cultivate and channel pools of gifted early career URM researchers into high impact career opportunities. For example, in 1984, the University of California established the University of California President's Postdoctoral Fellowship Program "to encourage outstanding women and minority PhD recipients to pursue academic careers at the University of California. The current program offers postdoctoral research fellowships, professional development and faculty mentoring to outstanding scholars in all fields whose research, teaching and service will contribute to diversity and equal opportunity at UC."[12] Departments throughout the UC system, such as Bioscience and Engineering, recruit from this pool of talented scholars for tenure track positions. "The investment in promising early career post-docs is paying off: Not only does UC attract top-tier PhDs from all over the country each year, but roughly 75% of its fellows have gone on to receive tenure track faculty appointments. Since 2003, more than 100 former fellows have received faculty appointments at a University of California campus. The program is so successful, in fact, that a dozen other colleges

Figure 1. (a) A Forest of Interconnected Trees. (b) A Young Tree Nurtured by the Forest Community.

Toward a Diverse Biomaterials Workforce: A Strategic and High Impact Advantage (continued)

and universities have used the model to create similar programs, including Harvard, MIT and the University of Pennsylvania."[13]

Strategic recruiting strategies must ensure trustful partnerships with organizations that embrace communities from diverse backgrounds. The partnerships must be cultivated to enable mutual understanding of what each community values, such that these values will become integrated and valued by both partners. Several organizations, including the National Science Foundation (NSF) and the National Institutes of Health (NIH), have developed mechanisms to provide funding to increase diversity. Such mechanisms have had success in identifying researchers; however, their entry and retention into careers in the field remains limited.

"STRATEGIC RECRUITING STRATEGIES MUST ENSURE TRUSTFUL PARTNERSHIPS WITH ORGANIZATIONS THAT EMBRACE COMMUNITIES FROM DIVERSE BACKGROUNDS."

RETAIN AND EMPOWER WITH A COMMUNITY OF DIVERSE PERSPECTIVES

Social network theory[14] provides several ways in which the STEM community, and consequently the biomaterials community, can retain researchers and value their contributions such that the future workforce begins to reflect that of U.S. demographics. While social network theory is a huge discipline, some of this work's critical success factors include understanding dynamics surrounding trust, respect, value and knowledge transfer. It is important to appreciate the value of individuals who can serve as allies, influencers, coaches and mentors. Such agents are important in helping emerging researchers toward establishing an identity in STEM and biomaterials research that will lead to integration into the scientific community.

The current trend in producing the biomaterials workforce is not sufficient to ensure leadership that encompasses and engages the talent and takes advantage of the diverse perspectives needed to address global priorities. Consequently, it is imperative that we undertake aggressive efforts to recruit and retain women, underrepresented minorities and persons with disabilities, and ensure that they are able to contribute to successful initiatives and to advance the vision and mission of the biomaterials community.

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Student Perception of the Ultimate Socially-Distanced Cell Culture Lab – A Simulated Virtual Lab Experience

By Cheryl Gomillion, PhD

Since its formation in 2012, the College of Engineering at the University of Georgia (UGA) has experienced significant growth in undergraduate student enrollment. This growth has been coupled with necessary curriculum revisions and updates for the Biological Engineering degree program to better reflect the evolution of our students interests and career goals in the field of biomedical engineering. In particular, an undergraduate course in tissue engineering has been taught annually since 2015 with a focus on the building blocks of tissue engineering (i.e., cells, biomaterials, etc.) and an exploration of research and advances in the field. As this course has been primarily lecture-based, students would consistently note in course evaluations that an accompanying lab would be ideal to help reinforce and solidify many of the concepts presented to students via lectures and research discussions.

Laboratory courses and modules are an important component of science, technology, engineering and mathematics (STEM) education, as they provide students opportunities to observe how concepts taught in the classroom are applied to the physical world. This exposure to real-world applications is important for enhancing student learning and understanding, which further contributes to student professional development. With recent expansion and renovation of instructional lab infrastructure at UGA, a new cell and tissue culture lab was built. However, like many initiatives in the current year, the ongoing COVID-19 pandemic resulted in delayed implementation of the lab, and even if opened, mandated campus social distancing requirements would have significantly restricted feasible use of the physical lab space by students. In addition, like many courses that had to turn to a fully online or hybrid model, the same was true for this tissue engineering course, where online-only options had to also be made available for students that may have had to isolate or quarantine because of COVID-19 exposure, making in-person labs less ideal at this time.

In an effort to integrate real-world, lab-based learning experiences into the course without use of an in-person lab, gamified virtual lab simulations produced by Labster (Somerville, Massachusetts) were selected to provide the most socially-distanced lab experiences available – individual lab experiences that students could complete on their own by computer at any location. Simulated labs help to address logistical challenges associated with hands-on labs, often requiring fewer financial resources and less time for setup and completion.[1,2] In a previous offering of the Tissue Engineering course, a Labster simulated lab module was used for studying motivation in biological engineering students.[3] Here, more intentional coupling of the virtual labs with lecture content was planned to help reinforce student learning, an approach also taken by other college faculty during this COVID-19 era.[4] An informal survey of students was conducted after the first module to assess student perception of the activity and its usefulness for learning.

VIRTUAL LAB IMPLEMENTATION

Class lectures include an overview of requirements for cell culture, aseptic technique and steps for maintenance of cells. Following presentation of the lectures on these topics, students were given a two-part assignment that included first completing the Labster virtual lab simulation on cell culture basics,[5] followed by an instructor-developed problem set. The Labster module takes place in a simulated cell culture lab, "equipped" with all the necessary equipment and supplies needed for aseptically culturing cells under controlled conditions. The simulation environment requires students to perform specific steps to advance to the next steps – appropriate personal protective equipment (PPE) is even required to begin work in the biological safety cabinet. This particular module guides students through the process of preparing media and plating and splitting and freezing fibroblast cells, with the goal of completing the learning objectives shown in Table 1. Quizzes are integrated into the module and scores can be recorded or integrated with the gradebook on various learning management systems. A theory tab provides quick facts and information throughout for learning about specific topics if students need more information to help complete quiz questions.

At the end of this simulation, students will be able to:

- Apply the aseptic technique and other good laboratory practices in a cell culture lab
- Describe the minimum requirements to have an adequate cell environment that supports cell growth
- Describe and perform the key steps when working with mammalian cells in vitro: thawing and plating; cell passaging; cell cryopreservation
- Correctly use a biosafety cabinet and an automated cell counter

Table 1. Learning Objectives for Labster Cell Culture Basics Simulation[5]

Student Perception of the Ultimate Socially-Distanced Cell Culture Lab – A Simulated Virtual Lab Experience (continued)

SURVEY HIGHLIGHTS

Following completion of the virtual lab activity, students were asked to complete a short survey to obtain feedback about the utility of the virtual lab. Of the 38 students enrolled, 37 responses were received. A summary of some of the findings obtained from the survey are shown in Figure 1 and described below.

The majority of students found the virtual lab interesting and noted that their understanding of cell culture concepts was strengthened following completion of the assignment. In addition, a majority of students indicated that if a hands-on lab is not available, virtual labs are a good alternative, although 10.8% of participants either somewhat disagreed or disagreed with this statement. Short answer comments from those that disagreed with this statement noted that the module was "slow moving" and that it was "very tedious to click all of the items," even though they found the activity to be "thorough and accurate" while simulating the real-life experience.

CONCLUSION

Overall, the simulated virtual lab was well-received by students and viewed positively for meeting learning objectives. Additional lab activities are planned for inclusion in the course for providing more learning experiences for students. During this time of the global pandemic, or in low-resource settings where access to physical laboratories may be limited or interrupted, virtual simulated labs offer a means for providing valuable educational experiences while allowing for broad dissemination remotely. With all the negatives experienced during the pandemic, one positive could be the opportunity to redefine biomedical engineering education and training with the technology and creative solutions that reinforce student learning, strengthening technical competency and engaging the students.

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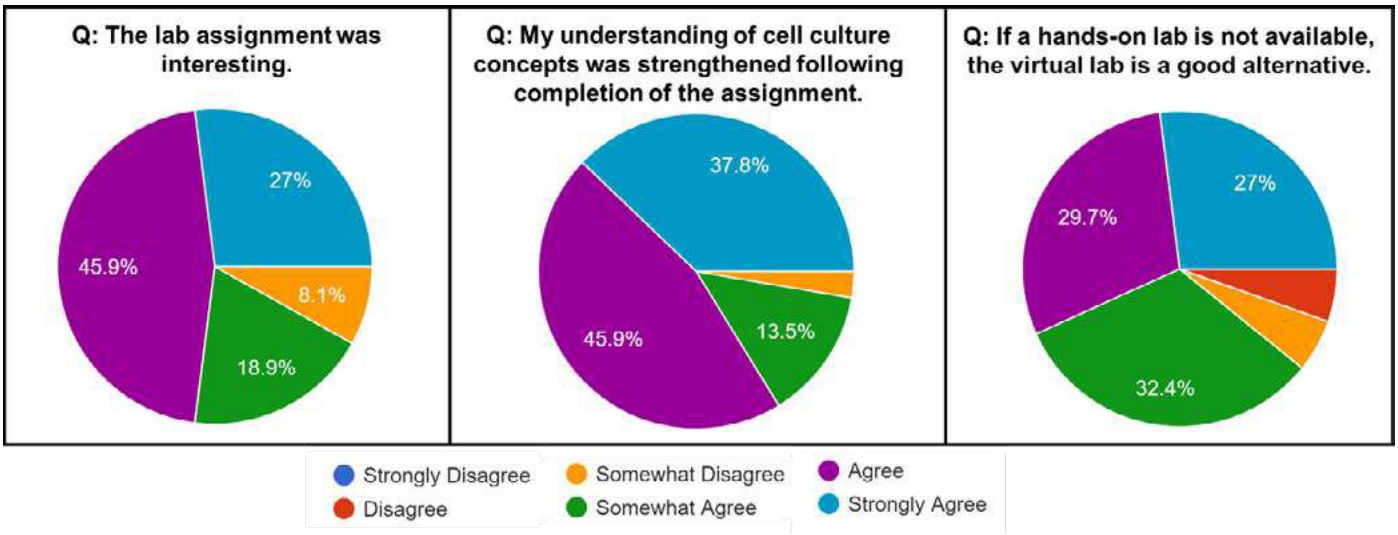

Figure 1. Summary of Student Responses to Survey of Simulated Virtual Lab Activity

NIBIB Offers a Fresh Programmatic Outlook on Biomaterials Research

By Raymond MacDougall

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has updated its research program resources to shine a brighter light on biomaterials research. To reflect and support the breadth of biomaterials innovation in the community, NIBIB has distributed biomaterials research among several programs, which are organized by the method of interplay between engineered and biological elements, or biotransduction.

Biomaterials in their many forms are interspersed among research program portfolios across the National Institutes of Health. Because of this, identifying the best sources of information, funding announcements and the appropriate NIH program officer to pursue regarding your area of biomaterials research requires forethought and navigation to several websites at your target institute.

An investigator who may be developing biomaterials with a focus on type 1 diabetes, for example, might find a good home for that research — and accompanying support — with NIH's National Institute of Diabetes and Digestive and Kidney Diseases. If, on the other hand, the work is development of a nanoparticle for cancer immunotherapy, perhaps NIH's National Cancer Institute is the right home. But if the project is focused on the development of biomaterials in the context of a modular platform biotechnology, then NIBIB might be the best fit.

"We want to call attention to the materials engineers in the community who are designing new materials with emphasis on biomedical applications," said David Rampulla, PhD, Director of the NIBIB Division of Discovery Science & Technology. "NIBIB is technology forward — meaning that in addition to addressing an unmet medical need, we put a premium on engineering innovations, especially for modular platform technologies that can find utility in a broad array of biomedical applications."

In the revised program structure, the Biochemical Engineering program is the home of materials that focus on converting physicochemical energy into biological action. The Biophotonic Engineering program focuses on converting photonic energy into biological action, and the same logic holds for the Biomechanical Engineering program and the Bioelectromagnetic Engineering program. NIBIB hopes to encourage biomaterials development for biomedical application using a wide array of materials innovation.

"A lot of the development of biomaterials for bioengineering will be found within the Biochemical, Bioelectromagnetic, Biomechanical and Biophotonic Engineering programs, where each program is focused on a different method of biotransduction," Rampulla said. "However, biomaterials are found in other NIBIB programs as well, including materials for sensing and biomedical imaging." The relevant program descriptions mentioned by Rampulla can be found online at https://www.nibib.nih.gov/research-funding/division-discovery-science-technology-ddst and at https://www.nibib.nih.gov/research-funding/division-applied-science-technology-dast.

Rampulla advises that the best way to assess which NIH institute(s) and program(s) are the best fit for your project is by communication with the program staff member. "Reach out and ask," he said. "It can save a lot of time and ensure that a submission will go to the right programmatic home at the NIH."

The following is a list of NIBIB programs under which biomaterials is featured, with the contact information for the program staff member who manages each area:

- Biochemical Engineering

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- Bioelectromagnetic Engineering and Biomechanical Engineering

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- Bioanalytical Sensors and Molecular Probes and Imaging Agents

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Biomaterial-Tissue Interaction SIG Update

By Antonio Merolli

I hope you and your families are well.

The COVID-19 pandemic has affected everybody, even those who, like me, did not experience health problems among family members, friends and colleagues (I am surprised but grateful for this).

Let's start talking about our World Biomaterials Congress (WBC) and our BTI-SIG role. With an unprecedent decision, the Congress had been delayed and moved to December 2020, and was fully virtual. I have been to Glasgow in the past, and it is a very nice venue. I know how much effort my friends and colleagues in the U.K. put into organizing this Congress (and, before that, in winning the bid). It must have been very painful for them to accept the new situation. Of course, they know they are not alone in the world. The board of the BTI-SIG and the SFB staff had already started the detailed planning of the scientific and social events that we would have promoted. Our virtual session remained in December, but we missed the "real" fun we were planning for our in-person social events. Because of the postponement of WBC, I can't report on any of the best oral and poster presentations in this issue of the *Forum*, but perhaps I can highlight some outstanding presentations or posters during the Congress. I also have no highlights of breakthroughs or social happenings to report that the usual warm atmosphere in our gatherings, national and international, has always generated.

We all agree, however, that this major change occurred for a very serious reason. Our professional life has been affected in many ways. Online teaching has generated a mix of positive and negative impressions in both mentors and mentees. Most of us have found ourselves deeply involved in COVID-19 research, even if we never imagined this could happen. We often read and heard the question, "What can the biomaterials community contribute to the COVID-19 response?" The answer, as you know, is "a lot." Our interdisciplinary field, so rich in biomedical expertise and leading-edge technology, has contributed in so many sectors: from innovative vaccine delivery, to improved personal protection equipment, to virus-inactivating compounds. We also contributed our routine analytical techniques. I have my personal experience to share with you, on how the Helium-ion Microscopy was redirected to the analysis of SARS-COV-2 samples. By coincidence, this happened the very same day the first patient was hospitalized in New York. A final contribution, but very significant, is that the biomaterials community continued (even with restrictions) in its daily work, supporting biomedical research; COVID-19 has not stopped the requirements for implants and devices for patients who suffer a long list of other conditions (cardiomyopathy, bone fractures, cancer). They did not lock down as non-essential medical procedures.

"WE OFTEN READ AND HEARD THE QUESTION, 'WHAT CAN THE BIOMATERIALS COMMUNITY CONTRIBUTE TO THE COVID-19 RESPONSE?' THE ANSWER, AS YOU KNOW, IS 'A LOT.'"

My final wish is that we will overcome this global challenge soon, but we will not forget its lesson too soon. Please, study the papers of those who worked on SARS and MERS. They give us a clear picture of the risk to come and very good hints on the possible therapies … a decade ago! Their results, buried in the literature, are now appreciated too late.

Best wishes for staying healthy!

Nanomaterials SIG Update

DENDRIMER-BASED NANOMEDICINE: PROPOSED ENDOTHELIAL GLYCOCALYX-TARGETED CANCER METASTASIS TREATMENT

By Chinedu Okorafor, Ronodeep Mitra, and Eno E. Ebong (Corresponding Author)



INTRODUCTION

Cancer metastasis is the main cause of death for cancer patients. In cancer metastasis, cancer cells detach from the primary tumor to invade nearby blood vessels and attach and penetrate through the blood vessels' wall in order to form secondary tumors on distant organs. Although it is not an efficient process (only about 0.1% of disseminating tumor cells metastasize to form new tumors) this process is the deadliest characteristic of cancer.[1] Presently, there is no effective treatment for cancer metastasis, with treatments primarily focusing on eliminating the primary tumor. Here, we summarize endothelial glycocalyx's (eGCX) function of being a protective barrier for the endothelium and its involvement in the metastatic cascade. In addition, we propose a dendrimer nanomedicine-based therapeutic strategy that aims to limit metastasis by restoring the eGCX.

ROLE OF ENDOTHELIAL GLYCOCALYX IN CANCER METASTASIS

In the inner lining of blood vessels lie endothelial cells (ECs) whose surface is covered by the eGCX, a negatively-charged, carbohydrate rich layer. eGCX is a mesh-like layer composed mainly of proteoglycans, which are anchored to the EC membrane, and glycosaminoglycans (GAGs), i.e., heparan sulfate, chondroitin sulfate and hyaluronic acid, which are in the upper part of the eGCX and extend into the vascular lumen. The eGCX also consists of soluble plasma molecules. There are adhesion molecules found in the basal portion of the eGCX, shielded by the aforementioned components. These adhesion molecules (i.e., selectins, integrins and immunoglobin superfamily) are involved in recruiting constituents from the blood circulation to the endothelium by acting as binding receptors to the ligands of circulating elements. In cancer metastasis, the selectins are involved in tethering cancer cells from the blood stream and cancer cells' subsequent rolling along the endothelium layer. The immunoglobin superfamily and integrins are involved in cancer cells' firm adhesion to the endothelium followed by its extravasation to nearby tissues.[2] Thus, eGCX acts as a protective barrier by limiting the interaction between the adhesion molecules of the endothelium and the circulating tumor cells (CTCs) in the bloodstream. The inflammatory cytokines and enzymes secreted by cancer cells and the disturbed flow regions in blood vessels which occur at branched and curved points of the blood vessels degrade eGCX components, exposing the endothelium surface.[3,4] The breakdown of this protective barrier is a main factor in the progression of cancer metastasis.

After cancer cells detach themselves from the primary tumor and penetrate nearby blood vessels, there are two paths they can take: die in circulation or attach themselves to the adhesion molecules of the endothelium in order to survive. Recently, it has been established that the degradation of eGCX increases the amount of cancer cell attachment to the vascular wall. Our lab group showed that neuraminidase-induced degradation of the sialic acid residue, components of the eGCX, increases metastatic cancer attachment to ECs.[5] Rai et al also showed that high levels of E-selectin expression correlated with a significantly degraded eGCX.[4] The degradation uncovered the previously hidden E-selectins, leading to an enhancement of E-selectins' interaction with cancer cells, increasing cancer cell attachment.[5]

From these studies, maintaining the integrity of eGCX may be the key to inhibiting the metastatic cascade. A possible treatment method will have to have a dual effect of reducing interaction between ligands of cancer cells and exposed E-selectin, and restoring eGCX integrity.

STANDARD TREATMENTS FOR CANCER METASTASIS

Once cancer has advanced and spread to different parts of the body, it is difficult to completely remove cancer from the body. Standard treatment methods for patients with advanced cancer target the primary tumor in the body and/or target the different areas of the body where cancer has spread (systemic treatment).[6] To treat the primary tumor, surgery and radiation are common methods. Systemic treatments include chemotherapy, hormone therapy and immunotherapy. Chemotherapy helps to shrink the size of tumors by killing cancer cells. Hormone therapy blocks the action of some hormones that help cancer cells grow. Immunotherapy incites the immune system to target and kill cancer cells. All of these treatment options are sometimes used in combination with each other to try to slow down cancer growth. After a time, however, the treatments stop working due to the patients' body developing a resistance to the treatments. This limits the effectiveness of these treatments. As a consequence, for example, the 5-year survival rate for patients diagnosed with advanced metastatic (stage 4) breast cancer is as low as 27%, as reported by the American Cancer Society.[7] Therefore, more work needs to be done to effectively treat cancer metastasis and increase the survival rate for those diagnosed with advanced cancer.

Nanomaterials SIG Update (continued)

NANOMEDICINE: APPLIED TO TREAT CANCER METASTASIS

Nanomedicine is a growing field and holds great potential as a tool for improving cancer treatment. Engineered nanoparticles can directly and selectively target cancer cells, enhance the therapeutic efficiency of tumor drugs, increase the circulation time of drugs in the body and reduce the toxicity effect of drugs. In the past, when trying to inhibit cancer metastasis, scientists mainly focused on creating nanoparticles that target the primary tumor vessels in order to prevent tumor neovascularization and limit subsequent detachment of cancer cells from primary tumors as they attempt to enter the blood stream to travel to secondary locations.[8,9] Primary tumor vessel targeting methods produced a significant anti-metastatic effect. However, a considerable amount of cancer patients have a late diagnosis in which cancer cells have already detached themselves from the primary tumor and started circulating in blood vessels. Thus, more scientists have tried to therapeutically target CTCs in circulation with nanoparticles. Those studies range from liposomes conjugated with E-selectin that captured and killed CTCs by delivering doxorubicin, a chemotherapeutic drug, and platelet membrane-coated silica nanoparticles conjugated with a tumor necrosis factor-related apoptosis-inducing ligand that targeted and induced apoptosis in CTCs.[10,11] To our knowledge, there has not been a nanomedicine approach that directly targeted eGCX, a potential path to slowing down metastasis.

"CURRENTLY, THERE IS NO ESTABLISHED DRUG THAT CAN PREVENT ITS ENZYMATIC DEGRADATION. HOWEVER, THERE HAVE BEEN COMPOUNDS IDENTIFIED THAT CAN PROTECT OR RESTORE THE COMPROMISED EGCX."

TARGETING ENDOTHELIAL GLYCOCALYX

We propose that therapies be developed to restore degraded eGCX's function and stability. Currently, there is no established drug that can prevent its enzymatic degradation. However, there have been compounds identified that can protect or restore the compromised eGCX. Two compounds are orosomucoid and sulodexide. Orosomucoid is a glycoprotein known to maintain stability of eGCX by enhancing eGCX's negative charge. Cai et al performed a study in which they pre-treated microvessels with orosomucoid and found that the pre-treatment significantly reduced cancer cells' adhesion to vascular wall by strengthening eGCX.[12] Sulodexide is a purified mixture of dermatan sulfate (20%) and heparan sulfate (80%), a major GAG of eGCX, and sulodexide is known to increase GAG content and rebuild the eGCX, as shown in a study by Li et al in which sulodexide stimulated eGCX reconstruction which resulted in the functional recovery of balloon-injured endothelium.[13] Sulodexide also inhibits the release of inflammatory cytokines and downregulates eGCX degrading enzymes. Although both orosomucoid and sulodexide try to either maintain or restore eGCX integrity, we will proceed forward with using sulodexide as our therapeutic due to its ability to recover endothelium function and reduce inflammatory reactions. We believe that restoring eGCX will reduce the adhesion of cancer cells to the endothelium and limit the progression of the metastatic cascade. In addition, eGCX therapy could recover the functional ability of the endothelium (i.e., EC cell-to-cell communication, nitric oxide synthesis).[13,14]

DENDIMER-BASED NANOPARTICLES IN CANCER METASTASIS THERAPY

Sulodexide is typically administered systemically to stabilize the eGCX. We aim to use nanoparticles for targeted administration of sulodexide to specific vascular areas where there is eGCX degeneration.

Since our target is the compromised eGCX, we will first have to decide on an eGCX-appropriate nanocarrier for delivering sulodexide. The intact eGCX is a negatively-charged layer with a porosity of around 7 nm. This pore size is a lot smaller compared to typical nanocarriers that have diameters that range from 50 nm-200 nm. Although eGCX's degradation increases porosity, the size of this structural change is unknown. Thus, for passive targeting our lab has engineered PEGylated gold nanoparticles (10 nm) that were retained by the degraded eGCX.[15] Unfortunately, gold nanoparticles are not therapeutically active or biodegradable. So, we turn our attention to another nanocarrier option: a dendrimer.

There are a variety of advantages associated with dendrimers, from their small diameter size (2 nm-30 nm) to their high drug loading capacity. Dendrimers are highly branched molecules. Interior branched polymer chains are connected to the inner core of the dendrimer. Exterior ends of the polymer chains are capped with functional surface groups that form the external surface of the dendrimer. With this structure, therapeutics can be physically encapsulated within the hydrophobic domains of the dendrimer, covalently conjugated or stably complexed with dendrimers through electrostatic interactions. For example, the dendrimer nanocarrier has been used to encapsulate and control the delivery of chemotherapeutic drugs and the targeted delivery of genetic material to cells.[16] Targeting ligands can be similarly covalently conjugated or stably complexed with dendrimers to engineer the external dendrimer surface to express targeting ligands.

Nanomaterials SIG Update (continued)

We propose a sulodexide-loaded biodegradable polyester-polyamide dendrimer conjugated with surface functionalizing E-selectin monoclonal antibodies, to therapeutically target vascular areas of compromised eGCX. E-selectin antibody is chosen as the targeting ligand because during cancer metastasis, the degraded eGCX exposes the previously hidden E-selectin of the endothelium.[3] Our nanoparticle system is hypothesized to adhere to the exposed E-selectins, blocking the adhesion of cancer cells to the vascular wall, while simultaneously delivering sulodexide to repair eGCX integrity.

Future research is needed to examine drug loading efficiency, drug release, co-localization of the therapeutic with degraded eGCX, dosing needed to therapeutically restore eGCX and the cytotoxicity of the nanoparticle system. This nanoparticle system has the potential to restore eGCX while reducing the inflammatory reaction associated with cancer metastasis, hindering the progression of cancer metastasis. The proposed dendrimer-based nanoparticle system can bring great advancement to the field of cancer metastasis medicine.

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Industry News

By Gopinath Mani, Industry News Editor

Stryker recently announced the global launch of the industry's first completely wireless hospital bed, ProCuity™.[1] This intelligent bed was designed to help reduce in-hospital patient falls at all acuity levels, improve safety and nurse workflow efficiencies and help lower hospital costs. The bed can connect seamlessly to nurse call systems without the use of cables or wires. Research shows that between 700,000 and one million patients experience a fall while being treated in the hospital annually, with 79% of falls occurring on or near a bed while unassisted.[1] Stryker's own research found that 97% of hospital nurses reported having encountered a situation where a patient has had difficulty getting out of a hospital bed, with 75% reporting they have encountered a situation where a patient has hurt him or herself while getting out of a hospital bed.[1] Anywhere from 30 to 51% of in-hospital falls result in injuries.[1] ProCuity is ergonomically designed with the latest technologies to promote safe patient handling and help reduce fall-related injuries, including intuitive patient positioning, bed alarms and ergonomic side rails.[1] Helping to address nurse call cable connectivity issues prevalent in hospitals today, ProCuity can be equipped with fully wireless features. Additionally, the bed's easy-to-use touchscreens and other key components makes the job of caregivers easier and more efficient, while providing for a more enhanced patient experience.[1]

Theranica, a digital therapeutics company developing advanced electroceuticals for migraines and other pain conditions, recently announced that it has been granted a CE mark for its Nerivio® device for acute treatment of migraines, a little more than a year after receiving FDA clearance in the United States.[2] Millions of people suffer from migraines. Far more than just a headache, a migraine can also be accompanied by symptoms such as nausea, numbness, sensitivity to light and sound and confusion.[2] Nerivio is a smartphone-controlled, wearable device for the acute treatment of migraine.[2] Placed on the upper arm at the onset of a migraine attack, the device uses remote electrical neuromodulation to wirelessly stimulate a conditioned pain modulation response to mitigate pain.[2] A corresponding Nerivio app also keeps track of migraine episodes and provides analytics that a patient can share with their doctor, to help monitor and tailor their treatment.[2]

Foldax®, Inc. recently announced that the FDA has granted approval to expand the U.S. clinical study of the Tria™ surgical aortic heart valve.[3] The Tria valve reimagines the heart valve by incorporating a new proprietary biopolymer with an innovative valve design intended to resist calcification, withstand stresses and strains without failure and restore patients' quality of life without the lifelong use of anticoagulants.[3] Tria is also robotically manufactured, reducing variability and enabling high precision, repeatability and quality while substantially improving the economics of heart valve manufacturing.[3]

OSSIO, Inc., an orthopedic fixation technology company, recently announced that its OSSIO*fiber*® Compression Screw Portfolio has received 510(k) market clearance from the FDA for the maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis and bone grafts of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization.[4] OSSIO's Compression Screw Portfolio will initially comprise a 4.0 mm-diameter cannulated, headless, partially-threaded compression screw in lengths ranging from 26 mm to 60 mm.[4] The compression screw combines the necessary strength for bone fixation with the ability to fully integrate into the surrounding anatomy without adverse foreign body reactions and stress shielding, and avoids potential patient discomfort or implant-related complications.[4] Studies show that implants made from OSSIO*fiber*® provide easy insertion and secure fixation with rapid bone attachment in as little as two weeks following surgery, and gradual, safe incorporation and complete integration into the surrounding anatomy within 18 to 24 months.[4]

Orthofix Medical, Inc., a medical device company with a spine and extremities focus, recently announced the FDA 510(k) clearance for the nanotechnology feature of the FIREBIRD™ SI Fusion System.[5] Introduced earlier this year, the FIREBIRD SI Fusion System is the first 3D-printed titanium bone screw with nanotechnology specifically designed to compress and stabilize the sacroiliac joint (SI joint) during fusion.[5] The FIREBIRD SI Fusion System is implanted through a minimally invasive procedure that involves inserting two to four bone screws across the SI joint to stabilize the joint during the fusion process. The system's 3D-printed mid-shaft porous region is designed to allow for bone growth through the device to aid in the fusion process for patients being treated for pain and dysfunction of the SI joint.[5] Featuring a cannulated screw design, the system enables surgeons to pack the device with autograft and/or allografts to help promote bone fusion.[5] Common causes that may lead to SI joint dysfunction and pain include trauma, lifting or twisting, pregnancy, natural childbirth, degeneration from previous lumbar spine surgery, stresses to the joint due to leg length differences, joint replacement or scoliosis, among others.[5] Published clinical literature indicates that sacroiliac joint pain is estimated to affect between 15 and 30% of individuals with chronic lower back pain.[5]

Industry News (continued)

The **National Capital Consortium for Pediatric Device Innovation** (NCC-PDI) announces six awardees chosen for its annual "Make Your Medical Device Pitch for Kids!" competition, to share in $250,000 in grants funded by the FDA to support the advancement of pediatric medical devices.[6] The competition, powered by NCC-PDI partner MedTech Innovator, focused on cardiovascular, NICU and orthopedic and spine devices, which are areas of critical need where innovation can significantly improve children's healthcare.[6] This year's pediatric device innovation awardees are:

- **Adipomics, Inc.** (Cambridge, Massachusetts) for COVI-SPOT, a one-step COVID-19 diagnosis on the spot
- **BioSense** (Beverly Hills, Michigan) for the first working non-contact EKG for constant, non-invasive monitoring
- **Innara Health** (Olathe, Kansas) for a biofeedback device to help newborns and premature infants improve feeding readiness and promote the neuro and physiological aspects of feeding
- **Navi Medical Technologies** (Melbourne, Australia) for a non-invasive device to provide real-time feedback of central line tip location using ECG
- **Novonate** (South San Francisco, California) for a device that secures and protects the umbilical catheter insertion site for neonates in intensive care
- **Renata Medical** (Costa Mesa, California) for a growth stent used in the treatment of congenital narrowed lesions in neonatal patients.[6]

Physicians with the **Texas Cardiac Arrhythmia Institute (TCAI) at St. David's Medical Center** are among the first in the world to participate in a clinical trial to evaluate a new intra-cardiac echocardiography catheter.[7] The NuVision™ ICE Catheter is 4D imaging, which is designed to better guide complex cardiac procedures, improve outcomes and reduce procedure times, all of which are beneficial to the patient.[7] This catheter offers all of the imaging capabilities of previous imaging platforms with the added spatial benefits of real-time intracardiac 3D guidance, giving physicians an advanced view of the heart in motion during complex structural heart surgeries, appendage closures and cardiac ablation procedures.[7] This enhanced visualization allows physicians to better assess complex cardiac structures with the potential to improve patient outcomes, while reducing procedure times and fluoroscopy (X-ray) exposure. It also gives physicians better control of the image generation by allowing them to guide the catheter throughout the procedure.[7] 4D imaging also allows doctors to perform structural heart procedures under conscious sedation, which is associated with a lower risk of complications for patients.[7]

B. Braun Medical, Inc. (B. Braun) recently announced that it has received 510(k) clearance from the U.S. Food and Drug Administration for the SpaceStation MRI to allow Space® infusion pumps to continuously deliver medications to patients within the MRI suite.[8] The SpaceStation MRI is designed to shield Space infusion pumps against 1.5-T and 3.0-T magnetic fields, to protect the MRI scanner and provide interference-free images.[8] Long infusion lines are no longer needed, and hospital-wide Space infusion pumps are now able to safely transition patients into the imaging suite.[8]

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Government News

By Carl Simon, Government News Editor

NIST RAPID MICROBIAL TESTING METHODS CONSORTIUM

The National Institute of Standards and Technology (NIST) launched a Rapid Microbial Testing Methods (RMTM) Consortium "to address the need for measurements and standards, including reference materials, to increase confidence in the use of rapid testing for microbial contaminants in regenerative medicine and advanced therapy products."[1] Traditional testing for microbial contamination can take 14 or more days, which is often longer than the shelf life of an autologous cell-based therapeutic. The RMTM Consortium was launched with a virtual workshop open to all on September 17, 2020. The presentations and discussions were recorded and are accessible on the website.[2] Planning for the goals and next steps of the Consortium are underway with the first meeting for Consortium members scheduled for November 2020. Interested parties can find the contact personnel on the Consortium website.[1]

ANOTHER CLINICAL TRIAL REQUESTED FOR MESOBLAST'S REMESTEMCEL-L

Tissue-specific progenitor cells (mesenchymal stem cells) have been used in hundreds of clinical trials for treatment of a wide range of clinical indications.[3] Mesoblast's remestemcel-L is an investigational allogeneic cell therapy product for intravenous infusion containing "culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor."[4] Mesoblast completed a clinical trial and applied for a Biologics License Application (BLA) for use of remestemcel-L to treat pediatric steroid-refractory acute graft versus host disease (SR-aGVHD). "Remestemcel-L is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues."[4] The FDA held a public Oncologic Drugs Advisory Committee (ODAC) meeting on August 13, 2020 "in order to gain the Committee's insights and opinions regarding the characterization and quality attributes of the proposed drug product for the proposed oncologic indication." Materials from the ODAC meeting are publicly available, including the agenda, roster and slides from both FDA and Mesoblast,[5] providing an opportunity to learn about the regulatory process. The ODAC voted 9-1 in favor "that the available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD."[4] However, the FDA recommended that Mesoblast conduct "at least one additional trial to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD."[4] The FDA also identified a need for further scientific rationale "to demonstrate the relationship of potency measurements to the product's biologic activity." Remestemcel-L is also currently being tested in a randomized, controlled Phase 3 trial "in up to 300 ventilator-dependent adults with moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19."

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The Great Influenza: The Story of the Deadliest Pandemic in History

WRITTEN BY JOHN M. BARRY

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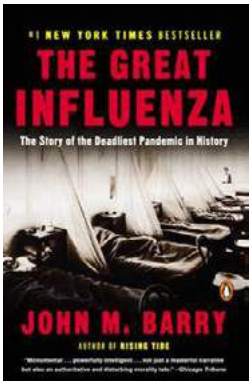

Penguin Random House LLC, New York, 2018

ISBN 9780670894737 (hardcover)
ISBN 9780143036494 (paperback)
ISBN 9781101200971 (e-book)

The COVID-19 pandemic has affected us all. Perhaps you know someone infected with SARS-CoV-2, or maybe you have been infected yourself. Your research laboratory may have restricted access or been closed entirely. For many researchers, progress has slowed to a crawl and deadlines have been missed. All of these disruptions have occurred in tandem with the personal impact on our families and ourselves. When the pandemic first started, a colleague recommended that I read *The Great Influenza* by John M. Barry, describing the 1918 flu pandemic, also known as the Spanish Flu. I was told that it contained many lessons that could be applied today. In many ways, this book is actually three stories in one: a history of the 1918 influenza pandemic, the stories of the medical doctors and researchers trying to combat the disease and a philosophical discussion of how research should be performed.

Barry begins the book by laying out the historical context of the pandemic and the key figures in medical science. He describes the state of medical research at the time, which, in the United States, was just gaining a foothold with the 1893 opening of The Johns Hopkins School of Medicine in Baltimore. This was to be the first medical research university, founded by William Welch, Sir William Osler, William Halstead and William Kelly. Another key figure was Simon Flexner, the first director of the Rockefeller Institute for Medical Research; the institute opened in 1901. Scientists were starting to accept the germ theory of disease — that "minute living organisms invaded the body, multiplied and caused disease, and that a specific germ caused a specific disease" (pg. 49). The study of antibiotics was in its infancy. Antitoxins and vaccines were being developed to prevent diphtheria, tetanus and other diseases. *The Great Influenza* also takes place against the backdrop of World War I (1914–1918), which played a key role in the spread of the Spanish Flu throughout the U.S. and the world.

Much of this book describes the tortuous path of trying to identify the pathogen responsible for the Spanish flu. Most of the effort was spent on investigating *Bacillus influenzae*. Barry explains that this futile focus stemmed partly from researchers being pressured to find a quick solution to the influenza pandemic, finding bacteria present in cultures and not looking "beyond their own work" (pg. 413). These studies were not adhering to Koch's postulates regarding identification in diseased patients, isolation of the pathogen, re-creation of the disease in an experimental animal and re-isolation of the pathogen (pg. 280). In fact, the microbe was not identified until the 1930s, long after the pandemic had ended. It is now understood that the bacilli that many research groups had identified were "secondary invaders" (also called "opportunistic pathogens"). Without a working vaccine or antibiotics to handle the concomitant bacterial infection, infection control revolved around isolation, quarantine (which was difficult to enforce), handwashing, the wearing of face masks and limits on large public gatherings. Does this sound familiar?

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The human toll of the Spanish Flu was immense. Barry writes that it is impossible to determine an accurate death toll, but epidemiologists estimate that 675,000 people died out of a U.S. population of 105 million (0.6%) (pg. 397) and that the pandemic claimed greater than 5% of lives globally. Even beyond these devastating statistics, Barry describes the experiences of individuals, families, cities and military bases in a way that helps readers appreciate the horror and sense of hopelessness that was rampant. He tells the story of government corruption and ineptitude in the Philadelphia government at the time. William Kruser, the public health director in Philadelphia, permitted the "greatest parade in the city's history" — the Liberty Loan parade — to proceed despite concern about the large number of people

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that would attend. Two days after the parade, he conceded that the epidemic was now present in the civilian population. Families were decimated. So many people were sick and dying that hospitals had to close their doors, and coffins and gravesites were unavailable. Bodies were collected in wagons and carts. So many had died that bodies were buried in trenches. After three waves of infection and unanticipated sequelae involving the brain and nervous system, the pandemic eventually ended. As the virus continued to mutate, it became less virulent.

I found the stories of the warriors — the men and women studying the disease in a determined effort to stop it — to be interwoven with facts, as well as compelling. Researchers were just beginning to explore the intricacies of the human body and disease. The work of physicians and scientists brought the nascent medical sciences to life. Barry describes the fascinating paths these figures took with their lives and their research and the ways in which their lives were interwoven. This part of the book reads like a Dan Brown novel, painting portraits of these individuals in all their strengths and weaknesses. Barry describes William Welch as a leader who "inspired a generation of brilliant scientists" in the United States. He portrays Simon Flexner's role in identifying the brightest scientists and supporting their research. Another key person in the story (the book was, in part, dedicated to him) was the researcher Paul Lewis. The prologue and last chapter focus on his work as a researcher, but his personal story is woven throughout the book. He is described as someone who was "born for the laboratory" and had "the full confidence of Welch, Theobald Smith and Flexner" (pg. 200). Although Lewis died before his contributions to influenza research were recognized, Barry postulates that he would have received co-credit with Richard Shope for leading the way to identify the pathogen responsible for the Spanish Flu as a virus. Another interesting fact was that many of the researchers and administrators who were involved were themselves eventually infected.

As a researcher, I enjoyed the sections in which Barry waxes philosophical about research and the search for truth. In Chapter One, he discusses the differences between biologists and engineers who studied physics. He called biology "messy" and physics "logical." Later in Chapter Three, he describes Koch's postulates (pg. 51), setting the stage for the biggest error that occurred when trying to find the Spanish Flu pathogen. He states in the last chapter, "In the midst of the epidemic, under the greatest pressures, many bacteriologists had compromised the quality of their work in the hope of getting quick results" (pg. 413). This is an important lesson, indeed. Barry raises the questions that needed to be answered at the time. What was the epidemiology of influenza? What was the pathology of this disease? What was the pathogen? Ultimately, their approach to identifying the pathogen was the biggest barrier to identifying the cause of the pandemic. Without this knowledge, effective vaccines could not be developed. I recommend reading the Afterword, which summarizes what we have learned from the experience of the Spanish flu. It also discusses the challenges that we have in combating pandemics with pharmaceutical and non-pharmaceutical interventions (including quarantines). I encourage every student pursuing research to reflect on these chapters.

It is important to note that *The Great Infuenza* is history as interpreted by a non-science writer. The book contains several errors regarding characterizations of viral behavior. However, I suggest we overlook these inaccuracies and appreciate the book for its insights into the past and relevance to our current situation. Barry's book makes me wish that I could read the account that will be written about the COVID-19 pandemic 100 years from now. What don't we know about COVID-19? What misguided research and policy paths have we taken? How did we overcome the barriers to understanding the coronavirus called SARS-CoV-2? Who will be the key figures who lead us out of the pandemic?


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