2022 AWARD RECIPIENTS

SFB OFFICER NOMINEES

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

FIRST QUARTER 2022 • VOLUME 44, ISSUE 1

ALSO INSIDE

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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 44, Issue 1

SPECIAL INTEREST GROUP REPORTERS

BioInterfaces	TBD
Biomaterials & Medical Products Commercialization	Subramanian Gunasekaran • guna@encoll.com
Biomaterials Education	Sarah Rowlinson • sarcorow@gmail.com
Biomaterial-Tissue Interaction	Antonio Merolli • antonio.merolli@rutgers.edu
Cardiovascular Biomaterials	Astha Khanna • akhanna@gravertech.com
Dental/Craniofacial Biomaterials	TBD
Drug Delivery	Eun Ji Chung • eunchung@usc.edu
Engineering Cells & Their Microenvironments	Silviya Zustiak • silviya.zustiak@slu.edu
Immune Engineering	Yaoying Wu • yw195@duke.edu
Nanomaterials	Mahboubeh Nabavinia • NABAVINIAM20@ecu.edu
Ophthalmic Biomaterials	Frances Lasowski • lasowsfj@mcmaster.ca
Orthopaedic Biomaterials	Roche C. de Guzman • roche.c.deguzman@hosftra.edu
Surface Characterization & Modifications	TBD
Tissue Engineering	Jessica M. Gluck • jmgluck@ncsu.edu

If interested in filling a vacancy above, please reach out to your SIG Chair.
Contact information can be found on individual SIG pages as found **here**.

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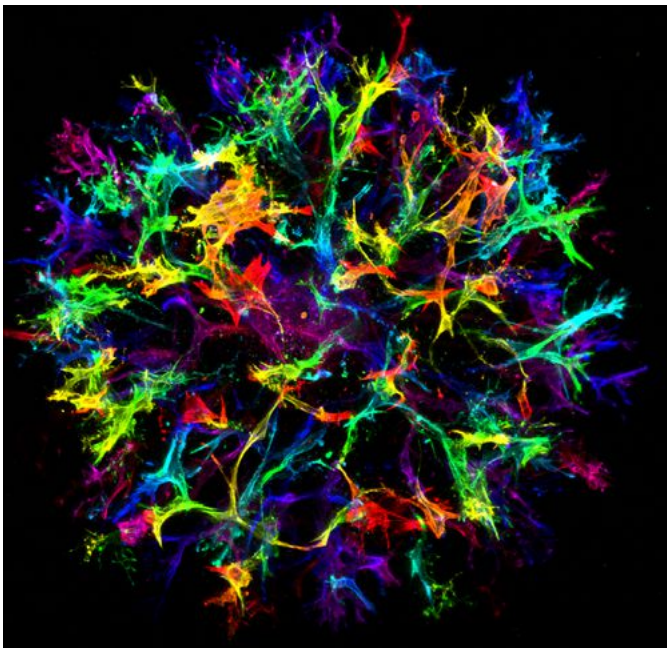

ON THE COVER

Endothelial cells sprouting from a multicellular spheroid embedded within a porous hydrogel are imaged in this depth color-coded maximum projection of a stack of confocal images. (Courtesy of Dr. Taimoor Qazi)

From the Editor

By Roger Narayan, Biomaterials Forum Executive Editor

It is my great pleasure to share the first quarter issue of Biomaterials Forum with you. The cover of this issue was provided by Taimoor Qazi, a postdoctoral research fellow at University of Pennsylvania. I encourage you to take advantage of the opportunity to have an image from your biomaterials research featured on a cover of an upcoming issue of Biomaterials Forum. This issue recognizes the Society's 2022 awardees- their achievements are truly inspiring. In addition, this issue includes statements from candidates for our society's leadership positions. These statements provide a unique insight into opportunities for growth of the society's activities over the coming years. We are fortunate to share three feature articles in this issue. SuPing Lyu considers the timely issue of supply challenges in the medical device industry. As noted in the article, sustained efforts are needed to address the parameters that lead to these supply challenges. Otto C. Wilson, Jr. shares his insights related to biomaterials education through several vignettes and images. I am grateful to Janet Kar and her colleagues at Women in 3D Printing for sharing examples of Kristie Snodderly's and Stephanie Willerth's efforts to clinically translate and commercialize their expertise in the growing field of bioprinting. I hope to share additional articles on this topic in upcoming issues. As always, I look forward to your feedback related to these articles and welcome your ideas for upcoming issues.

Yours truly,
Roger Narayan

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.

From the President

By Guigen Zhang, SFB President

First of all, I am delighted to report that the joint symposium cohosted by the Society For Biomaterials (SFB) and the Japanese Society for Biomaterials (JSB) was a blast. Over 150 people attended this memorable symposium in person in Hawaii in January, plus an additional 158 attended virtually, to celebrate the seminal contributions by James Anderson and Art Coury on the SFB side and Tadashi Kokubo and Teruo Okano on the JSB side. The success is also highlighted by the well-organized and well-attended Women in Biomaterials session. What's more to say about this blast? Despite numerous financial and logistic challenges amidst this seemingly never-ending pandemic, we anticipate being very close to breaking even on the event financially, many thanks to Dan, Shena and Ashton for their hard work and creative thinking.

We are one step closer to executing the MOU for SFB/FDA partnership to promote enhanced communication and collaboration to include joint workshops, webinars, annual meeting invited speakers and/or sessions, etc. We are also in the process of developing another MOU for SFB/MS&T Partnership to cosponsor the annual Materials Science & Technology Technical Meeting and Exhibition in 2022. The SFB/MS&T collaboration entails up to three symposia for MS&T22. At this stage, we are in the process of forming a program committee, chaired by Roger Narayan, to spearhead the SFB contribution to the joint MS&T22 symposium(s).

In the coming year, SFB will be undergoing a website redesign this year. Our current website is built on a Drupal 7 platform which will no longer be supported in 2023. As such, we're upgrading to a Drupal 9 platform, and this will require an overhaul of the current website. We'd like to take the opportunity to make some improvements, address some functionality issues and enhance member benefits. To facilitate this, we are assembling a task force of volunteers to help us gather opinions and insight about the website and member engagement needs.

The planning of the 2022 SFB Annual Meeting and Exposition is also making great strides after two half-day sessions in January, which laid out the scientific program filled with workshops, panel sessions, keynote sessions, awards sessions, as well as many parallel oral and poster sessions, among other special events.

Finally, I have something exciting update to report. On December 17, 2021, Dr. Tina Morrison, director of the Office of Regulatory Science and Innovation in the Food and Drug Administration's (FDA) Office of the Chief Scientist, and I co-organized a two-hour long brainstorming session bringing together a group of 18 thought leaders representing key stakeholders from leading biomedical companies, government agencies and academia including Depuy Synthes, Johnson and Johnson, Medtronic, Zimmer, Ansys, NIH, DOD, University of Rochester, King's College of London and other national and international companies and consultancies. This brainstorming session was a prelude to a workshop that Dr. Morrison and I are planning at the SFB 2022 Annual Meeting. At the brainstorming session, the group sketched out a rough framework with several focus areas identified, including 1) reducing friction between industry and regulatory agency by heeding not only what the agency needs but what the industry/user needs as well; 2) unpacking the life cycle of product development and clinical translation to facilitate, and/or lower the barriers to, effective transition from bench to clinic for researchers and innovators; and 3) showcasing what successes are like in these areas, as well as lessons learned.

WE ARE EXCITED ABOUT THE PROSPECT THAT A JOINT EFFORT BY THE SFB AND FDA LIKE THIS WILL HELP MAKE A DIFFERENCE IN ACCELERATING BIOMEDICAL INNOVATION.

In a follow-up call in late January, Dr. Morrison and I further condensed these focus areas into three key topics: 1) showcasing success stories on regulatory science collaborations that involved industry, academia and FDA; 2) unpacking the lifecycle of from the perspective of the stakeholder; and 3) heeding the needs of regulatory agency, industry/users for reducing regulatory frictions. These topic areas will help define the theme of the workshop with an end goal of identifying efficient ways to integrate translational science and regulatory science toward developing better regulatory tools and facilitating effective regulatory processes to accelerate medical technology innovation. We are excited about the prospect that a joint effort by the SFB and FDA like this will help make a difference in accelerating biomedical innovation. Hope to see many of you at the workshop during the SFB annual meeting in Baltimore in April 2022.

Thank you again for your devotions and contributions to the SFB!

Best wishes!

Officer Nominees

PRESIDENT-ELECT

The President-Elect shall become familiar with the duties of the President and shall, at all times, cooperate and assist with the duties of that office. In the absence of the President, the President-Elect shall preside at the meetings of the Society, the Council and the Board of Directors, and perform the duties and exercise the powers of President. The term of office is for a period of one year without succession. The President-Elect shall coordinate the duties of Council regarding the long-range direction and future of the Society.

Gopinath Mani, PhD
Abbott

Biographical Sketch: Dr. Gopinath Mani is currently a Staff Biocompatibility Scientist in the Division of Science and Technology at Abbott. He joined Abbott in 2016 as a Senior Biocompatibility Scientist prior to his promotion to the current role in 2020. Previously, he worked as an Assistant Professor in the Department of Biomedical Engineering at the University of South Dakota (USD) from 2010 to 2016. Prior to that, he worked as a Research Assistant Professor (2008-2010) and as a Postdoctoral Fellow (2007-2008) in the Department of Biomedical Engineering at the University of Texas at San Antonio (UTSA). He received his Ph.D. in Biomedical Engineering from UTSA in 2007 under the mentorship of Prof. C. Mauli Agrawal. His research was focused on surface modification/characterization of biomaterials for developing local drug delivery systems for cardiovascular implants and devices. He has published 30 peer-reviewed research articles, 3 book chapters, and has made 40 conference presentations. He has co-authored a biomaterials textbook "An Introduction to Biomaterials: Basic Theory with Engineering Applications". He also has an issued patent in the area of drug-coated balloons. He was a recipient of National Scientist Development Grant from the American Heart Association and USD President's Award for Research Innovation & Entrepreneurship. Currently, he represents the Science and Technology Division at Abbott and serves as a subject matter expert for materials and biological characterizations ensuring the medical devices of Class I to Class III are in compliance with ISO 10993 biocompatibility standards as per the global regulatory requirements (e.g. FDA).

Dr. Mani has been active in the Society for Biomaterials (SFB) for over 15 years since he attended his first SFB annual conference in Pittsburgh as a graduate student in 2006. Over the course of years, he has served in various positions and committees of the SFB including Industry News Contributing Editor for the Biomaterials Forum (2020-present), Industry Affairs Committee Member (2019-present), Program Co-Chair for the SFB 2019 Annual Meeting in Seattle, Council Member (2018-2019), Program Committee Member (2014, 2018 and 2019), Membership Committee Member (2014-2015), Education & Professional Development Committee Member (2011-2014), and Chair (2015-2017), Vice Chair (2013-2015), Program Chair (2011-2013), and Forum Reporter (2015-2019) of the Surface Characterization and Modification SIG. In addition, Dr. Mani has organized over 20 general sessions, symposia, and panel discussion in the SFB Annual Meetings. He has also served as a Faculty Advisor for the University of South Dakota (USD)–SFB Student Chapter for five years from 2011-2016 and USD Biomaterials Day Meetings in 2013, 2014, and 2015.

Vision Statement: It is an honor to be nominated for the President-Elect position of the SFB. If elected, I will specifically focus my efforts on the following three areas:

Improving Academia-Industry Interaction and Collaboration: We need to develop and provide opportunities to improve the interaction and collaboration between academia and industry. The industry members need to know all the fascinating biomaterials research that is currently being carried out in academia while the members from academia need to know what it really takes to translate a product from lab to clinic. Unfortunately, I believe there is a gap in this area, and the knowledge and information are not very well shared between these two entities. Since the ultimate goal of both the Academic and Industry researchers is to develop products that goes to clinics and benefit patients, it is imperative that we need to provide ample opportunities for such interactions/collaborations to happen. SFB would be a perfect platform to take initiatives on this and build a bridge of knowledge exchange between academia and industry. This could be accomplished by collaborating with industry-based societies to co-organize/co-sponsor meetings, events, sessions, symposia and webinars.

Improving the value for student community: Students today will be leaders tomorrow. SFB does an outstanding job in recognizing students participation and achievements through various events, positions and awards. One area that the student community always enquires and looking forward in the meetings is potential job opportunities. Conducting events such as Career Fair would provide such opportunities. I understand that we have tried organizing Career Fair in the past SFB meetings and met with limited success. We need to develop new strategies to work with HR teams in the companies to bring them to our annual meetings to showcase the enormous young talents that we have in our society. If the students are getting jobs because of SFB's

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initiatives, the impact will be huge for the society. In addition, sessions organized on elucidating the nature of work in different divisions (Quality, Regulatory, R&D, Manufacturing, Clinical and Operations) in industry would greatly benefit the student community. This would be helpful for the students to decide what division in industry might be a fit for them considering their interests and goals.

Improving International Community Participation in SFB: Considering the recent travel challenges and financial crisis brought to the world by the pandemic, many international members may not be able to participate in the in-person SFB meetings in future. Hence, allowing the annual meetings to be organized through virtual option as well for the international community would open up opportunities for members from various countries to participate in our meetings. Such participation not only helps our members with international collaboration but also provides financial stability to the society through their registration (and membership) fees to help run our society successfully for a long-term.

In summary, if elected, I will enthusiastically work with the SFB Board, Council, Committees and Members and do everything in my capacity for the betterment of the society.

William R. Wagner, PhD
McGowan Institute for Regenerative Medicine

Biographical Sketch: Dr. William R. Wagner is the Director of the McGowan Institute for Regenerative Medicine and a Distinguished Professor of Surgery, Bioengineering and Chemical Engineering at the University of Pittsburgh. He has served as Scientific Director of the NSF Engineering Research Center on "Revolutionizing Metallic Biomaterials" and Chief Science Officer for the Armed Forces Institute of Regenerative Medicine. He holds a B.S. (Johns Hopkins Univ.) and Ph.D. (Univ. of Texas) in Chemical Engineering.

Dr. Wagner is the Founding Editor and Editor-in-Chief of one of the leading biomaterials journals, Acta Biomaterialia. He has been an active member of the Society for Biomaterials since 1992, having organized programming, served on committees, and acted as SFB representative to the International Union of Societies for Biomaterials Science and Engineering (IUSBSE). He has past leadership experience as president of the American Society for Artificial Internal Organs (ASAIO) and Chairman for the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Americas region. William is a fellow and former vice president of the American Institute for Medical and Biological Engineering (AIMBE), where he chaired the Fellows Selection Committee. In addition, he has been elected a fellow of the IUSBSE, Biomedical Engineering Society, TERMIS, International Academy of Medical and Biological Engineering and American Heart Association. In 2006 he was selected to the "Scientific American 50", the magazine's annual list recognizing leaders in science and technology from the research, business and policy fields.

Dr. Wagner's research has generated numerous patents (40 issued to date) and patent filings that have resulted in licensing and University of Pittsburgh Innovator Awards in 2007, 2008, 2009, 2010, 2014, 2017 and 2018. With a colleague and former students, he co-founded a cardiovascular disease focused company that raised $42M and initiated clinical trials in 2014 and 2016. In 2020, he co-founded a company focused on cardiac valve technology. In his directorship of the McGowan Institute, he has successfully championed and facilitated the formation of spin-out companies to complete the Institute's mission of delivering solutions to patients suffering from tissue and organ failure. To date 35 companies have been launched from the Institute. In recent years he has been awarded the Society for Biomaterials Founders Award and the Clemson Award for Applied Research, the Chancellor's Distinguished Research Award by the University of Pittsburgh, the Zhu Kezhen Distinguished Lectureship from Zhejiang University and the Senior Investigator Award by TERMIS-Americas. In 2017 he was inducted into the National Academy of Inventors and in 2018 was named Inventor of the Year by the Pittsburgh Intellectual Property Law Association. In 2019 he was appointed to the rank of distinguished professor of surgery at University of Pittsburgh, the highest recognition available to the faculty. In 2020 the 4th edition of the best-selling biomaterials textbook, "Biomaterials Science" was published with Dr. Wagner taking over the role of lead editor in partnership with a new generation editorial team. Dr. Wagner's research interests are in cardiovascular engineering with projects that address medical device biocompatibility and design, biomaterial development, tissue engineering and targeted imaging.

Vision Statement: I am deeply indebted to the Society for Biomaterials (SFB) for the tremendous opportunities it has provided to me over the past three decades. My personal experience with SFB was possible because it has always been a society that listens to its membership and reaches out to its youngest and newest members. When other societies were not providing engagement opportunities for a young assistant professor, I was provided the chance to co-chair sessions, serve as an officer in a SIG, and develop symposia programming by SFB. These roles provided the experience, built the

Officer Nominees (continued)

relationships, and refined my perspective - greatly enhancing my career in biomaterials. A core motivation for seeking this leadership role is to ensure that SFB continues to actively engage its membership, particularly junior members and those that bring diverse backgrounds and professional skills.

SFB's activities ultimately seek to enhance human health and quality of life. Keeping focused on this mission and the patient benefactors of our work should continue to guide Society activities. A clear value proposition must exist to new and current members that SFB better equips them to achieve their specific goals. As we know, the biomaterials expert must not only partner across academic disciplines, but also understand the pathway to the patient with clinical, governmental, and business experts contributing to the team. Given that multiple, risk-laden steps must occur beyond laboratory proof-of-concept, I have been encouraged to see SFB engage partners along the commercialization pathway. Current efforts with the FDA and standards organizations need to be built upon so that our society is increasingly seen as the prime location for such expertise, and so that our researchers can readily establish contacts and partnerships. Related to this, a growing emphasis on entrepreneurial activity from academic members and the challenges faced by smaller companies can be further developed. I have served as a leader of several consortia that have the mission of delivering technology to the patient and helping to navigate the commercialization pathway. Through these leadership roles, I have gained connections and perspective that can help to grow SFB's reach and impact into this translational pathway.

For SFB to effectively provide value to its membership and impact the broader community, the organization must itself be healthy. The past two years have been difficult ones for scientific societies. I would focus efforts on strengthening the Society's financial position and bring to bear broad experience in managing organizations through challenging times. In addition to directing a major research institute for the past decade, I have previously guided organizations that have faced challenges with membership growth and fiscal sustainability. New growth often sprouts in these times. In today's shrinking world, communications advances open new opportunities for international partnerships. Economically developing regions can be connected with new outreach efforts and become future partners in fulfilling our mission on a global scale.

I appreciate your consideration and hope to have the chance to serve as President-Elect, helping to build and enhance this society to the best of my ability.

MEMBER-AT-LARGE

The Member-at-Large shall serve as an unencumbered representative of the membership at meetings of both the Board of Directors and Council. The Member-at-Large shall serve for a period of one year.

Gulden Camci-Unal, PhD
University of Massachusetts Lowell

Biographical Sketch: I am an Assistant Professor in the Department of Chemical Engineering at the University of Massachusetts Lowell. In Fall 2016, I joined the faculty of UML after completing my post-doc training at Harvard Medical School and Harvard University. I also hold an adjunct appointment in the Department of Surgery at the University of Massachusetts Chan Medical School.

My research at the interface of biomaterials, regenerative engineering, and point-of-care diagnostics has made important contributions in generation of engineered platforms for cardiovascular and bone repair, wound healing, and disease detection including bacterial and viral conditions. My interdisciplinary research projects cover a broad range of applications including understanding fundamental biology to developing disease models for personalized medicine, tissue repair and regeneration, and rapid POC diagnostics. The ultimate goal of my research is to improve human health and quality of life. My research has been funded by the NIH, ONR, US Army, DOD, NSF, DHA, and AHA. I have significantly contributed to translating technology from benchtop to patient care. In the next steps, I am taking leadership in commercialization of engineered products in collaboration with industry partners. I have collaborated with companies through Phase 1 and Phase 2 SBIR and STTR grants.

I have supervised a diverse group of 2 post-doctoral researchers, 6 Ph.D. students, 2 M.Sc. students, 21 graduate researchers, and 32 undergraduates who carried out research in my lab in five years. My students have gone to graduate schools, medical schools, veterinary schools, and excellent engineering positions working in industry. The research experience in my lab led my students to receive distinct honors and fellowships. My research and teaching achievements include various awards such as the Robert and Gail Ward Endowed Professorship, UMass Lowell Teaching Excellence Award, Iowa State University Teaching Excellence Award, Runner-Up for Massachusetts Medical Device Development Center $200K Challenge, Wakonse Fellowship, Chevron-Phillips Award, Procter&Gamble Fellowship, and finalist for BioFlux Innovation Award. My research has resulted

Officer Nominees (continued)

in 83+ published manuscripts, 75+ conference abstracts, and 10+ patent applications. I am an Editorial Board member of Scientific Reports, PLoS One, Journal of Biomaterials and Tissue Engineering, International Journal of Bioprinting, and Regenerative Engineering and Translational Medicine.

I have been an active member of professional societies including SFB, BMES, AIChE, and MRS. I have served these societies in different roles by organizing conferences, symposia and sessions, contributing to programming, chairing sessions, and presenting my research findings. I have served as an Awards Committee Member to BMES for 4 years. I have been working diligently to put together a diverse range of sessions for conferences and annual meetings in the scientific community. In addition to scientific fundamentals and practical applications, I include discussions for development and commercialization of medical devices in the conference and meetings. My interdisciplinary sessions have been of great significance to the clinicians, scientists, engineers, industry members, regulatory groups, and members from academia. I also fundraised for the sessions and symposia that I organized. My approach has been encouraging networking opportunities between different professions, promoting mentoring, education, and research.

Vision Statement: I am truly honored to be nominated for the Member-at-Large position for the SFB. The SFB has been my professional home since I became a member in 2011. I have been an active member in the past decade and have served the society in different roles by reviewing abstracts, organizing symposia and sessions (2014-2022), contributing to programming of the organized sessions, chairing sessions (2014-2021), and presenting my research findings regularly. I am currently serving as the Program Chair of the Tissue Engineering Special Interest Group (SIG) at the SFB.

If elected as the Member-at-Large, I will work diligently with the Board, Council, Membership Committee, and the SIGs to increase membership efforts. I had incredible opportunities for my professional development at the SFB. To give back to the Society and increase engagement of the younger generation, I will work to support students, pre- and post-grad trainees, early career professionals, and young investigators at the SFB. I will also work with the Programming Committee towards increasing the quality and value of the scientific sessions at the annual meeting, which will include presentations and discussions about cutting edge research and emerging strategies in biomaterials science and engineering. This will help increase the visibility, facilitate exchange of knowledge, and promote valuable networking opportunities to all members.

I will emphasize diversity, inclusion, and scientific excellency in the membership, leadership, and programming efforts. I would like to advocate for members from diverse backgrounds and contribute to the activities within the Society including annual meeting, leadership, and awards. It is important to incorporate diversity, equity, and inclusion into the office and leadership roles, different awards, initiatives, and programs. I have been actively involved in promoting and supporting diversity in my professional community and beyond. I have served as a faculty advisor to the Society of Women Engineers (SWE) chapter and the Women in Science and Engineering (WISE) program at the UML. I have also served as the Awards Committee Chair of the Women in Chemical Engineering (WIC) at the American Institute of Chemical Engineers (AIChE). Having been involved in groups to increase diversity and continuously hosted students from various backgrounds in my research group, I am committed to continue pursuing efforts to cultivate and promote a diverse and inclusive Society as the Member-at-Large, and ensure that the SFB will continue to be welcoming for all members. This goal will be achieved by enhancing the access and opportunities in the SFB.

Furthermore, I plan to reach out to companies and increase engagement of industry members in the Society. I will use my experience from working with industry partners on grant agreements and STTR and SBIR projects to facilitate more participation by companies in SFB. Participation in SFB by the clinicians, scientists, engineers, industry members, regulatory groups, and members from academia will encourage networking opportunities between different professions working in the biomaterials field, promote mentoring, education, research, and increase the visibility of the SFB.

I would be honored to continue my service to the SFB as the Member-at-Large.

Officer Nominees (continued)

Stephanie Seidlits, PhD
University of Texas at Austin

Biographical Sketch: Stephanie Seidlits is an Associate Professor in the Department of Biomedical Engineered at the University Texas at Austin. Dr. Seidlits' research seeks to develop multifaceted therapies for the central nervous system that utilize biomaterial platforms to both model and directly alter the pathological microenvironment. She obtained a B.S. in Bioengineering from Rice University and went on to receive both M.S. and Ph.D. degrees in Biomedical Engineering from the UT-Austin under the mentorship of Dr. Christine Schmidt and Dr. Jason Shear. Dr. Seidlits then trained as an NIH NRSA post-doctoral fellow in Chemical and Biological Engineering at Northwestern University under the mentorship of Dr. Lonnie Shea. As an Assistant Professor in Bioengineering at the University of California, Los Angeles, Dr. Seidlits was honored, among other awards, with an NSF CAREER Award, the 2019 Society for Biomaterials Young Investigator Award, and a 2020 Rising Star in Cellular and Molecular Bioengineering Award from the Biomedical Engineering Society. While she has yet to serve in a position with more responsibility within SfB, Dr. Seidlits has a proven track record of dedication and success in positions of more responsibility within the biomedical engineering community, as evidenced by her previous service as Neural Engineering Track Chair for the 2018 Biomedical Engineering Society (BMES) Annual Meeting, current membership on the BMES Ethics Subcommittee, and a recent 3-year term as co-chair of the Neural and Spine TWIG (Thematic Working Interest Group) with TERMIS-AM (Tissue Engineering and Regenerative Medicine International Society-Americas).

Vision Statement: I am honored to be considered for the Member-at-Large position for the 2022-2023 term. The Society for Biomaterials (SfB) has been a huge part of my professional development. I joined SfB in 2009 as a graduate student and have consistently participated in the SfB Annual Meetings over the past decade through abstract submissions, reviewing submitted abstracts, and chairing scientific sessions. I am eager to increase my own involvement in the Society, working to ensure that we continually provide rich opportunities for scientists from all walks of life to make new discoveries, professional connections, thrive in their individual professional goals. As a Member-at-Large, I will engage in frequent communication with members, in particular young scientists still establishing their careers, to provide Society Leadership with the diverse perspectives and experiences that can inform in-person and virtual programming as well as larger priorities, such as addressing member-identified barriers to participation. I believe that frequent and inclusive communication, followed by appropriate actions, among leaders and members will be key to helping SfB continue to evolve as a scientific community that brings together researchers with a diversity of ideas and perspectives to advance biomaterial science.

Anita Shukla, PhD
Brown University

Biographical Sketch: Anita Shukla is an Associate Professor of Engineering and member of the Center for Biomedical Engineering at Brown University. Prior to joining Brown in 2013, Dr. Shukla was an NIH Ruth Kirschstein postdoctoral fellow in Bioengineering at Rice University. She received her Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology in 2011 as an NSF Graduate Research Fellow. She also received an M.S. in Chemical Engineering Practice from MIT. Dr. Shukla received her B.S. at Carnegie Mellon University in 2006 with majors in chemical engineering and biomedical engineering.

Dr. Shukla is deeply committed to service in the biomaterials community. She has been an active member of the Society for Biomaterials over the last decade, attending her first SFB Annual meeting in 2010, and organizing sessions and reviewing abstracts since 2014. Dr. Shukla served as the secretary/treasurer of the Surface Characterization and Modification Special Interest Group (SC&M SIG) (2017-2019), chair of the SC&M SIG (2019-2021), and is currently vice chair of the SC&M SIG. She has worked with the SIG officers to increase involvement of the SIG in scientific programming at the annual conferences and promote the achievements of the SC&M SIG community. Dr. Shukla also currently serves on the SFB Finance Committee. In addition to SFB, she is an active member of the Biomedical Engineering Society (serving as session chair and abstract reviewer) and the American Institute of Chemical Engineers (AIChE). She was co-chair and chair of fall programming for the Women in Chemical Engineering group for the 2019 and 2020 AIChE annual meetings and has been a director in the Materials Engineering and Sciences Division of AIChE since 2020.

Dr. Shukla's research group develops nano- to macro-scale responsive and targeted biomaterials for applications in drug delivery and regenerative medicine, focusing on treatments for infectious diseases. Her research has been funded by the NSF, DOD, NIH, the Rhode Island Foundation, the Falk Medical Research Trust, and industry-sponsored research. She is the recipient of several national and University honors for both her research and teaching, including a National Academy of

Officer Nominees (continued)

Engineering Grainger Grant (2021), a Presidential Early Career Award for Scientists and Engineers (PECASE) (2019), an NSF CAREER award (2020), an Office of Naval Research Director of Research Early Career Grant (2017), and a Brown University Early Career Research Achievement Award (2020) and Dean's Award for Excellence in Teaching (2017). Dr. Shukla has mentored 11 Ph.D. students, 7 postdoctoral researchers, 10 Sc.M. students, and more than 35 undergraduate researchers. Her commitment to diversity is evident in the demographics of her research group (>80% underrepresented individuals and women), with graduate students and postdocs with backgrounds in biomedical engineering, chemistry, chemical engineering, pathobiology, and immunobiology. Dr. Shukla's students and postdocs have successfully secured positions in industry (medical devices, pharmaceuticals, start-ups), academia (4 tenure-track faculty), and government. Her dedication to providing undergraduate research opportunities and mentorship were recognized by a Tau Beta Pi Research Excellence Award (Rhode Island Alpha Chapter, 2019).

Vision Statement: It is an honor to be nominated for the position of member-at-large for the Society for Biomaterials. I have been an active member of the SFB community over the last decade and recognize this Society as an exemplary space for both intellectual development and academic community. I am honored to have an opportunity to contribute the learnings from my own experiences to further the growth of a scientific community that has been so instrumental in the evolution of my own career.

It is my goal, if elected, to advocate for our members and serve as a liaison between the SFB membership and the board. I believe the Society will benefit from growth in two primary areas: (1) strengthening our commitment to diversity, equity, and inclusion and (2) increasing professional development opportunities for trainees and young professionals. For this to happen, I feel that it is very important to increase involvement of the diverse members of our scientific community in SFB at all different career stages and to provide continued support to our membership. I am deeply committed to working closely with the special interest groups (SIGs) and membership committee to increase the number of SFB members from underrepresented backgrounds at all levels, from undergraduate students to academics and industry professionals. This effort will include working with our student chapters and SIG student representatives as well, to involve individuals early in their training. I also believe that it is critical to increase recognition of the scientific achievements of our underrepresented members. I plan to work on this by ensuring that these members receive more spotlighted positions, such as nominations for awards both within SFB and externally; leadership roles in SFB (e.g., nominations for SIG officer positions, invitations to chair sessions and workshops at our annual meetings); and invited speaker opportunities. It is my goal to ensure that the SFB membership understands the value and need for these opportunities within the scientific community and collaboratively works towards making this vision a reality.

While working closely with SFB leadership, I will prioritize increasing awareness of and providing more opportunities for professional development and scientific exchange within the Society and the greater biomaterials field. I will focus on facilitating and connecting members to more networking and mentorship opportunities. An example of a current effort underway that I have proposed is the development of the first ever Future Biomaterials Faculty Workshop. This workshop will be held during the SFB 2022 annual meeting with the goal of providing early insights into academic careers and the faculty application and interview process, along with opportunities to network and engage with future colleagues.

I am truly excited by the potential to contribute further to this wonderful scientific community and look forward to continuing to serve SFB in the coming years.

ATTENTION MEMBERS!

WE WOULD LOVE TO HEAR FROM YOU.

IF YOU HAVE NEWS TO SHARE WITH FORUM READERS, LET US KNOW. EMAIL YOUR NEWS AND ANY PHOTOS TO INFO@BIOMATERIALS.ORG AND YOU COULD BE FEATURED IN THE NEXT ISSUE.

Society For Biomaterials Announces its 2022 Award Recipients

SFB'S PRESTIGIOUS INDUSTRY AWARDS RECOGNIZE OUTSTANDING ACHIEVEMENTS IN AND CONTRIBUTIONS TO THE BIOMATERIALS FIELD

SOCIETY *for* BIOMATERIALS

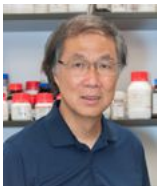
The Society For Biomaterials (SFB), a multidisciplinary society of academic, healthcare, governmental and business professionals dedicated to promoting advancements in all aspects of biomaterials science, education and professional standards to enhance human health and quality of life, recently announced its slate of 2022 award recipients.

SFB's members include professionals who have experience in numerous sectors of the biomaterials field, ranging from clinicians and researchers to medical device manufacturers and students studying biomaterials.

One of the defining aspects of SFB is its commitment to bridging the gap between academic research and its application within an industry setting to advance the biomaterials field and lead to innovations in research, patient care and policy. SFB is proud to present the following awards:

FOUNDERS AWARD

This is awarded to an individual who has made a long-term, landmark contribution to the biomaterials discipline.



Kam Leong, PhD, Columbia University

Fellow SFB member, Arthur J. Coury, PhD, shared, "Kam is one of the significant leaders of our field of Biomaterials, making seminal contributions to the development of biodegradable polymers for drug and gene delivery and regenerative medicine, educating a large number of biomaterials researchers with his mentorship, and servicing the biomaterials community with his editorship of the top journal in the field. His ongoing support of many government, academic and industrial organizations, makes him a leading emissary for advancement of our Biomaterials field for the benefit of Society, worldwide."

SOCIETY FOR BIOMATERIALS AWARD FOR SERVICE

This award honors significant service to the SFB in establishing, developing, maintaining and promoting its objectives and goals.

Elaine Duncan, Paladin Medical, Inc.

"Elaine's contributions to the SFB have been as an individual AND as a corporate entity through her company, Paladin Medical, so Elaine is unique in the respect that she has been a champion of the objectives and goals of the Society For Biomaterials, both as an individual and as a corporate entity" wrote nominator, John (Jack) L. Ricci, PhD. Also stating, that Elaine is "a passionate and bold advocate for all that the Society For Biomaterials stands for."

TECHNOLOGY INNOVATION AND DEVELOPMENT AWARD

This award recognizes an individual's (or a team's) successful application of basic and applied biomaterials research in the development of a novel medical product or technology that significantly benefits the health and well-being of medical and surgical patients.

Guillermo Ameer, ScD, Northwestern University

"His research group at Northwestern University was the first to describe the synthesis of bioresorbable biomaterials that are based on citric acid. These biomaterials are used for 3D printing medical devices such as stents, drug and protein delivery, and the regeneration several tissues including blood vessels, cartilage, bone, bladder, and skin." wrote Robert S. Langer, Sc.D. "Dr. Ameer has co-authored numerous publications in high impact journals, book chapters, patents, and conference proceedings and has received several awards for his research." His research and patents are the foundation for the Citregen biomaterial technology, which has been further expanded by Jian Yang, PhD (Penn State University) and Richard

Society For Biomaterials Announces its 2022 Award Recipients

T. Tran, PhD (Acuitive Technologies, Inc). Citregen is now used in implantable medical devices for musculoskeletal surgery through a proprietary manufacturing process developed by Acuitive Technologies and commercialized by Stryker Corporation.

Allen Y. Wang, Ph.D. and ETHICON SURGICEL® Powder cross-functional Team

"… I am very impressed by SURGICEL® Powder performance, the product that Allen and the ETHICON team developed, and by Allen's ability and persistence as a technology and solution-driven technical lead in developing, driving and delivering SURGICEL® Powder to the market. During the early development stage, Allen worked with surgeons and his team to identify the unmet needs and to scope out the target product profile for SURGICEL® Powder. He further optimized the performance of powder prototypes by changing its structure and interaction with blood. He collaborated with the device team on the concept of an ease-of-use delivery applicator. This has led to the development of combined product of SURGICEL® Powder with its delivery device (SURGICEL® Powder Applicator), which allows to achieve complete and sustained hemostasis when used as an adjunctive topical hemostat, resulting in better clinical outcomes," wrote Richard Kocharian, MD, PhD, Senior Franchise Medical Director, Biosurgery & Wound Closure, Ethicon, Inc., a Johnson & Johnson company.

CLEMSON AWARD FOR APPLIED RESEARCH

This is awarded to an individual whose accomplishments include significant utilization or application of basic knowledge in science to achieve a specific goal in the field of biomaterials.

David Kohn, PhD, University of Michigan

Nominator Paul Ducheyne, PhD, shares, "David's fundamentally thorough approach to applied questions can be found in his tissue engineering work. A limitation in translating tissue engineering to the clinic (an applied question) is the` inability to reproducibly synthesize a significant volume of tissue. He tackles this issue fundamentally: to better control cells' response to biomaterials, he mimicked aspects of nature's biomineralization strategies as a basis for biomaterials design."

CLEMSON AWARD FOR BASIC RESEARCH

This is awarded to an individual who has made an original contribution to the basic knowledge and understanding of the interaction between materials and tissue.

Julia Babensee, PhD, Georgia Institute of Technology and Emory University

"Dr. Babensee is a pioneer in the field of immunology of biomaterials. She was one of the first researchers to recognize, define, and tackle problems in this field of biomaterials immunoengineering and is internationally recognized for her leadership," wrote James M. Anderson. MD, PhD. "Dr. Babensee's outstanding contributions have significantly advanced thinking about how biomaterials can influence key cells of the immune cells and design strategies using biomaterials for immunomodulation."

CLEMSON AWARD FOR CONTRIBUTIONS TO THE LITERATURE

This is awarded to an individual who has made a significant contribution to the literature on the science or technology of biomaterials.

Laura Suggs, PhD, The University of Texas at Austin

"Laura's first broad impact on the biomaterials community was with her work designing and applying poly(ethylene glycol) (PEG) modified fibrin gels for a variety of applications. These materials, often referred to as PEGylated fibrin, provided a ready means to manipulate fibrin gel mechanical properties as well as to covalently link active biomolecules into the fibrin scaffold. Laura established herself as the leading researcher in this field and she contributed both excellent scholarship and innovation with her many publications on this topic," wrote William R. Wagner, PhD.

MID-CAREER AWARD

This award recognizes an individual SFB member who has demonstrated outstanding achievements in and/or contributions to the field of biomaterials research.

Ashley Brown, PhD, North Carolina State University and the University of North Carolina at Chapel Hill

"Dr. Brown has established a strong reputation for her research program, as evidenced by both her outstanding extramural support record and her remarkable publication record. Dr. Brown's research spans both translational and fundamental efforts and draws from multiple scientific disciplines to develop creative and effective solutions to both address critical clinical needs and to elucidate novel fundamental biological mechanisms," wrote nominator

Society For Biomaterials Announces its 2022 Award Recipients

Christopher A. Siedlecki, PhD. "Altogether, more than 10 million people suffer from conditions addressed by Dr. Brown's research program, with more than $100 billion in health care costs spent on these problems. It's clear that Dr. Brown's work has the potential to dramatically improve healthcare worldwide.

Ankur Singh, PhD, Georgia Institute of Technology

"Professor Singh is an exceptional mid-career stage investigator engaged in basic biomedical research, whose research program can significantly advance the understanding, diagnosis, or treatment of cancer and immune diseases," wrote nominator Kam W. Leong, PhD. "Professor Singh has combined synthetic and natural hydrogels with multi-dimensional nanoengineering to generate ex vivo immune tissues. There are few biomaterials researchers or biomedical engineers in the world who can match the creativity of Ankur in the areas of immune-biomaterials and immune-engineering."

YOUNG INVESTIGATORS AWARD

This award recognizes an individual who has demonstrated outstanding achievements in the field of biomaterials research.

Michael J. Mitchell, PhD, University of Pennsylvania

"Mike has employed this biomaterials platform to identify drug carriers that induce targeted delivery of genes to the bone marrow microenvironment. Using these carriers, Mike developed the first nanoparticle RNAi therapy to treat multiple myeloma, an incurable hematologic cancer that colonizes in bone marrow. Before this, no one in the drug delivery field has developed an effective gene delivery system to target bone marrow," wrote Robert S. Langer, ScD. "Mike is a standout young investigator and leader that intimately understands the importance of research and collaboration at the interface of nanotechnology and medicine."

STUDENT AWARDS FOR OUTSTANDING RESEARCH

This is awarded to undergraduate, graduate and/or PhD students who have shown outstanding achievement in biomaterials research.

Recipients in the PhD Candidate Category:

Henry Beaman, Syracuse University

Anujan Ramesh, University of Massachusetts Amherst

Recipient in the Masters Candidate Category:

Natalie Petryk, Syracuse University

C. WILLIAM HALL SCHOLARSHIP

This award honors the memory of the Society's first president, Dr. C. William Hall. This student scholarship is awarded to a junior or senior undergraduate pursuing a bachelor's degree in bioengineering or a related discipline.

Savan Patel, University of Pennsylvania

CATO T. LAURENCIN TRAVEL FELLOWSHIP

Named in honor of a distinguished member of the Society For Biomaterials, Cato T. Laurencin, MD, PhD, the travel fellowship will support undergraduate students who are disproportionally underrepresented in the fields of science, technology, engineering and math (STEM).

Andres J. Miramontes, The University of Texas at Dallas
Briana Cristal Martin-Villa, Stanford University

Staff Updates

By Shena Seppanen, Assistant Executive Director

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

BOARD/COUNCIL - PRESIDENT: GUIGEN ZHANG, PHD

SFB is thankful to the Japanese Society for Biomaterials for co-hosting the recent 2022 Joint Symposium in Hawaii this past January. We look forward to maintaining a collaborative relationship in the future.

AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE – CHAIR: ANDRÉS J. GARCÍA, PHD

Officer candidate information and award announcements are being featured in this issue of the Forum. All active and retired members are eligible to vote. The deadline to vote is Thursday, April 8, 2022.

Please start thinking about possible nominations for next year – especially those who may have interest in serving on the Society's Board of Directors as President-Elect, Secretary-Treasurer-Elect, and Member-At-Large.

BYLAWS COMMITTEE – CHAIR: C. LASHAN SIMPSON, PHD

The Committee has recently reviewed the entirety of the Society's bylaws. They are making a recommendation to the Board that an amendment be put forth for membership vote to further separate Board and Council issues so that fiduciary and content decisions are decided on by the appropriate decision makers.

DIVERSITY, EQUITY, & INCLUSION COMMITTEE – CHAIR: EDWARD A. BOTCHWEY, PHD

The DEI Committee developed and presented to Council five proposals, which all received approval. The Committee now works to ensure all five are implemented, while keeping an eye out for new opportunities to continue the Society's progress forward.

EDUCATION & PROFESSIONAL DEVELOPMENT COMMITTEE – CHAIR: THOMAS DZIUBLA, PHD

The Committee plans to host the Biomaterials Education Challenge at this year's 2022 Annual Meeting.

FINANCE COMMITTEE – CHAIR: DANIELLE BENOIT, PHD

The Society is currently undergoing its annual audit, anticipating another year of revenue loss due to the continued effects of the pandemic. Please share your support by renewing your membership and booking your accommodations for the 2022 Annual Meeting at the headquarters hotel – the Baltimore Marriott Waterfront.

INDUSTRIAL AFFAIRS COMMITTEE – CHAIR: SUPING LYU, PHD

The IAC is focused on creating awareness and education around supply chain issues and shortages for suppliers of medical devices so that potential solutions may be identified.

LIAISON COMMITTEE – CHAIR: BINGYUN LI, PHD

SFB is currently pursuing the opportunity of co-hosting the Materials Science & Technology (MS&T) Annual Meeting in October 2022. If all proves successful, SFB may become an annual partner. The Committee is also sending out quarterly surveys to gather information from members on potential collaborative opportunities where SFB may be able to partner with other associations for symposia, conferences, webinars, etc.

MEMBERSHIP COMMITTEE – CHAIR: NATALIE ARTZI, PHD

The Committee continues to consider ways to expand the Society's reach to industry and clinicians. This year, their plan included ensuring that Annual Meeting program content was attractive to the two audiences, as well as made targeted speaker invitations to renowned experts in specific disciplines.

2022 ANNUAL MEETING PROGRAM COMMITTEE – CHAIRS: CARL G. SIMON, JR., PHD, AND CHERIE STABLER, PHD

The 2022 Society For Biomaterials Annual Meeting & Exposition will held in Baltimore, MD, April 27-30, 2022, with more than 290 technical presentations, over 300 poster presentations, six workshops, eight panel discussions, and four plenary sessions. We look forward to getting back to our first in-person meeting since 2019!

PUBLICATIONS COMMITTEE – CHAIR: JAN P. STEGEMANN, PHD

The Publications Committee continues their efforts to work closely with Wiley to consider ways to leverage cross promotion through the publications' platform. They are also continually considering

Staff Updates (continued)

the opportunity for additional journals and publications as well as innovative ideas that may benefit the Society.

SPECIAL INTEREST GROUPS – REPRESENTATIVE: ASHLEY BROWN, PHD

An ALL SIG social event will be held during the 2022 Annual Meeting at Power Plant Live! in Baltimore, MD. All SFB members are welcome to attend.

National Student Chapter: The National Student Chapter hosted the following webinars, "How to Host a Biomaterials Day;" "Career Opportunities in Biomaterials for HBCU Students" and "Creating Impactful Figures for Papers, Websites and Beyond". Stay tuned for announcements on the future webinar opportunities.

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

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

CALLING ALL BOOKWORMS!

If you'd like to contribute a review of your recent favorite read to the ***Biomaterials Forum***, send it for consideration to the Editor at ***Roger_narayan@ncsu.edu***. If it's approved, it will be published in a future Forum Book Review column!

Member News

By John P. Fisher, PhD, Member-at-Large

Rena Bizios, University of Texas, San Antonio, was elected to the National Academy of Engineering. Academy membership honors those who have made outstanding contributions to engineering research, practice, or education.

Karen Burg, University of Georgia, was selected for the Presidential Award for Excellence in Science, Mathematics and Engineering Mentoring (PAESMEM).

Martine LaBerge, Clemson University, has been named to the South Carolina Life Sciences Hall of Fame.

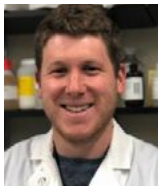
Shaochen Chen, University of California, San Diego, was elected to the US National Academy of Inventors in December 2021.

Narayan Bhattarai, North Carolina A&T State University, will be the Program Chair of the 38th Annual Southern Biomedical Engineering Conference (sbec18.org/38th-sbec-2022)

Astha Khanna, Graver Technologies and **Ngan Huan, Stanford University** have published a review article on the applications of extracellular matrix-based biomaterials in cardiovascular tissue engineering (Journal of Cardiovascular Development and Disease 2021, 8, 137).

Nathan Richbourg, University of Texas at Austin recently published hydrogeldesign.com, an accessible guide and reference tool for designing structurally optimized hydrogels for a broad range of biomedical applications.

Howard Winet, University of California Los Angeles recently published "Ethics for Bioengineering Scientists: Treating Data as Clients", a text suitable both for a course or for individual reading.



Michael Blatchley, University of Colorado Boulder launched a new open-access, interactive journal club covering recent papers in tissue engineering / regenerative medicine (thepapertrailjc.squarespace.com) streaming on Twitch.

Congratulations to the following SFB Members who were named Fellows of the American Institute for Medical and Biological Engineering:

- **Emily Day, University of Delaware**
- **Akhilesh K. Gaharwar, Texas A&M University**
- **Monica Hinds, Oregon Health & Science University**
- **Ana Jaklenec, Massachusetts Institute of Technology**
- **Susan P. James, Colorado State University**
- **Wendy Liu, University of California, Irvine**
- **Christopher Loose, Frequency Therapeutics**
- **Brenda Mann, Kiora Pharmaceuticals**
- **George D. Pins, Worcester Polytechnic Institute**
- **Krishanu Saha, University of Wisconsin, Madison**
- **Evan Scott, Northwestern University**
- **Daniel J. Siegwart, University of Texas Southwestern Medical Center**
- **Ankur Singh, Georgia Institute of Technology**
- **Sarah E. Stabenfeldt, Arizona State University**
- **Jeanne C. Stachowiak, University of Texas, Austin**
- **Kelly R. Stevens, University of Washington**
- **Amy Wagoner Johnson, University of Illinois, Urbana Champaign**

Challenges in Supply for the Medical Device Industry

By SuPing Lyu

Semiconductor shortage, automobile shortage and many more things are in supply shortage now. Shortage has been seen in supply and technical service for medical device industry too. Back to 2019, several major sterilization facilities were closed, leaving many companies rushing to figure out where they could sterilize their products and ship to the patients whose lives depend on them. But the shortage in the medical device industry has some differences, when compared to other industries.

Let's start with a simple thing, pandas' food. Pandas eat bamboo. They also eat other things, but 99% of their diets is bamboo. There are many bamboo species in the world. However only a few bamboo species grow at the high altitudes where pandas typically live. So, pandas face a food shortage. Human beings' activities make this problem worse!

The medical device industry shares a similar situation. There are many materials, but medical device manufacturers have only used limited number of special materials such that the products are biologically safe and functionally effective. There are multiple suppliers for each of those special materials, but only few of them have been willing to sell their materials for making medical devices, especially implantable ones. So, the medical device industry has been facing an inherent shortage as well! Ever-tightening regulatory environments and patients' expectations make the problem worse.

Medical devices are used to diagnose, treat, and manage diseases of the patients. When patients' health is involved, the products must meet high standards and broad requirements. Consider a cardiac pacemaker as an example. The products must have high reliability to sense the hearts' conditions and deliver therapies when needed; they must be biologically safe for the patients (biocompatible), and they must last for the intended duration (biostable). On top of that, manufacturers must consider other restrictions such as lead free, bisphenol free, Go-Green, etc. For these reasons, many materials and process technologies are excluded in the first place. Only a small number of materials end up being considered.

People may think making a medical device is similar to building a bridge: the engineers design it, the construction workers build it, then it opens to the public. In other words, people may think a comprehensive transfer function or technical "cookbook" exists. The design engineers input the materials and process properties into the transfer function, the manufacturing workers make the product by following the blueprints, then the product can be used for the patients in the next days. Unfortunately, such comprehensive transfer functions do not exist for most medical products. There are very few cases where engineers can predict the product performance by using first principles. For most products, the process is to design, build, and test. Then the feedback, redesign, rebuild, and retest cycle continues, until it meets the requirements. This process is not only expensive but also takes a long time, yet there is no guarantee for success. After one material or technology has been demonstrated to be acceptable for a product, there really is not much incentive to consider additional materials for the same application.

Practically, qualifying a material is to qualify the supplier that supplies the material (often under a brand name). The supplier and its materials are equally critical. When multiple suppliers make the same material (i.e., same CAS number), there are always some differences in the materials from each supplier, e.g. additives, process conditions, etc. Even if they use the same additives, its percentage composition may be different. These differences are usually a secret-sauce that the suppliers do not disclose to the public. However, these seemingly minute differences matter for the medical devices. For example, biocompatibility of the finished products can fail if there are a few parts per million of certain additives. For this reason, qualifying a material from one supplier typically does not apply to the same material made by another supplier. Furthermore, when a qualified supplier changes its own ingredient suppliers, equipment, or processes, the changes must be evaluated. Thus, similar to material qualification, after qualifying one supplier, it is not financially favorable to qualify a second one.

When engineers develop other products later, the previously qualified suppliers and their materials are the first candidates to consider. The result is, over time, more and more products have been designed and made on a small number of materials and suppliers that were introduced to the industry many decades ago. Silicone rubber, polyether polyurethane, polyethyleneoxide polyamide copolymers, stainless steel, titanium, and parylene are a few examples. Certainly, engineers have accumulated more knowledge on how to use these special materials and gained higher confidence on product quality. The downside of this, however, is that the engineers are approaching the design limits of the relatively small number of now the old materials. This not only delays innovation but also puts billion dollars of products on supply risks.

Challenges in Supply for the Medical Device Industry

While it is desirable to stay with the existing materials and suppliers, there is a contrary desire from the patients, suppliers, and medical device manufacturers to have more materials and suppliers. In the early days of the medical device industry, most patients were physically less active and they did not expect the products to work for them for very long. Now, more and more patients receiving devices are young and active. They apply much more mechanical load on the devices. Yet, they expect the devices to work for them for the rest of their lives. The material science says that a material will last less time if under a more intensive load. Our patients expect the opposite, which means we must develop new materials to satisfy the patients' needs.

In the past decades, regulation has become tighter and tighter. Not only the criteria for proving the safety and effectiveness have been significantly increased, but also many other things have been added in (e.g., RoHS, Animal Tissue Derived Materials, Go-Green, etc.). Those trends together are pushing away some of the old materials and technologies (e.g., lead solder, plasticized polyvinyl chloride). Alternative materials are needed.

From device manufacturers' perspectives, the longer they stayed with a limited number of current suppliers, the more revenue they are building on them. Given that their suppliers may exit the business for any reason and at any time (e.g., pandemic, wildfire, portfolio rationalization, etc.), the revenue stack the device manufacturers hold continues to increase if they do not have alternative options.

These contrary issues of supply have already accumulated to a painful degree. This is clearly seen when several major ETO sterilization facilities in the US were shut down in 2019.[1] The current pandemic-induced supply shortage across the world may make the issue worse. To prevent the worst to come, people need to look into a strategy moving forward.

It is hard to predict the future. But the future should retain some of today's basics. That is, the patient safety must be at the top priority, every sector should make fair profits, and regulations are to be followed. On top of these, the future must address some of today's supply challenges. Regardless how special this industry is, it is within the global material market and regulatory environment that are ever changing. So, the future medical device industry must adapt to manage changes in supply to keep up with the accelerating world. Specifically,

- There must be a systematic approach at the industrial level for all the companies to quickly and comprehensively address changes, instead of continuing to fight endless individual supply battles.
- Material composition must be standardized to all the parties. Secret sauce formulation should be avoided.
- There must be quick and inexpensive qualification process, just like today's bridge design process, for the medical device industry to introduce new materials. This capability should be a property of the entire industry.

To achieve goals, a first thing is to promote cooperation of material suppliers. The industry may consider forming a trade organization among suppliers and device companies (users). Today, the supply relationships are considered confidential business information. Some device companies may be luckier than others in sustaining their supply relationships. However, if one looks at the entire industry, the luck may be only temporary because everyone is in the same struggling boat. It would be a strategic benefit if all the suppliers belong to a consortium such that every device company know the suppliers of the consortium, what materials they make, and what medical devices are made of the materials. Doing so not only allows the device manufacturers to access more suppliers but also the suppliers to access more customers.

It is important to encourage large material companies to join the consortium. Those suppliers have typically invested in advanced technologies. But they may worry that they could bear unproportionally greater liability than the profits they could get by selling their materials to medical device industry. Encouraging those suppliers to prioritize medical device industry should be a part of the strategy. In addition to cooperation, legal environments should reform so there is a clear boundary between liability and right for various parties in the fields. Materials suppliers should not fear being sued for the things they have no liability.

A second thing is to develop a more informative material standards for all the materials being used for medical devices. When we talk about metal materials, there are relatively well developed codes that specifies the composition, key properties, and typical applications (e.g., stainless steel is coded in the Society of Automotive Engineers) from "2xx" to "9xx." One of commonly used grade is 316L (Austenitic) contains (wt%) Cr at 16-18, Ni at 10-14, C at 0.08, Mn at 2, Si at 0.75, P at 0.045, S at 0.03, N at 0.10, Mo at 2-3 and balance with Fe. This coding information, combined with the long use history of the materials, is valuable for the designers to assess the product performance.

When we talk about polymers, most time one will see brand names, e.g. Pellethane® (Lubrizol), Pebax® (Arkema), Makrolon® (formerly Bayer and now Covestro), etc. These names do not tell anything about the chemistry or composition.

Challenges in Supply for the Medical Device Industry

If a new device developer wants to pick a polymer for develop an implantable product, no chemical information means it has to take more effort to burn down risks. This suppliers' secret sauce is one of the main reasons why it takes so long to introduce a new polymer material and why it is so expensive. A common code system should be developed for all the materials used for the medical device industry. In addition, process technologies and their impacts on the material composition should be included as well. A successful coding system of this type is expected to significantly simplify biological safety and biostability testing needed for finished device products, which is addressed today by repeatedly testing even the products are made of similar materials and processes.

A third thing is to develop a method for the designers and developers to predict the product performance based on accelerated evaluation, existing data, and scientific rationale. This is especially necessary for long term implantable devices made of new materials. For example, to develop a product to serve the patient for ten years, it is not practical to conduct ten years' clinical study or even animal study. Although the research has been conducted for decades, accelerated in vitro testing find success only in simple things, (e.g., some mechanical performance). Reliability related to chemical changes of materials due to biological response of the patients are not being understood well enough for predicting the performance of products in the real world. Today, to introduce a new product with new materials, bench testing, animal studies, and clinical studies are needed to demonstrate satisfactory and consistent safety and effectiveness of the products. After getting regulatory approval, a long-term surveillance on the performance of the products used in the patients are needed for continuously monitoring the product performance. There are no standard methods existing.

If a new product shares some materials or processes with existing products, then the testing can be to "compare and leverage." Starting with the products that have been used for the patients for many years with acceptable reliability, introduce a material that is considered to be equivalent to the current one. Then the products made of the new material are assumed to have comparable performance, which is confirmed with extensive testing. One also applies the same argument for using the same material to make a product having a slight change in design. Baby-step by baby-step, the industry has been introducing new materials or new product design. But such incremental approach not only has been too slow but also it simply does not work if the changes in materials, design, or use conditions are big enough that the equivalence argument is no longer valid.

To develop useful accelerated evaluation methods, a few things have to be understood: one is quantitative understanding of the biological environments. For example, oxidative chemicals produced by the tissue as a result of the foreign body reactions are one key driver for materials to degrade. But it is heterogenous and not well quantified. For example, looking at an explanted pacemaker lead, the chemical composition and geometry are the same from one end of the lead to the other. But some areas of the lead had a substantial amount of cracking, the other areas were pristine. Another one is the kinetics of degradation of the materials in the products implanted in the patients where there are water, oxidants, all the chemicals in patient body, and mechanical load due to the patient' activities. Translating this complicated environment into an executable study problem is a key. The challenges are not lack of knowledge of elementary physics or chemistry. It is to identify what physical or chemical process take place and at what rates. The last one is correlate the material breakdown with the reliability of products. After understanding these questions, one might be better prepared to develop relevant evaluation methods to predict product performance faster and more accurately.

Advancing toward the three areas above, (i.e., industrial consortium, common grades, and accelerated material evaluation methods) is expected to address some of the supply challenges the industry faces today. It is believed to be a good starting point at the industrial level.

REFERENCES

1. FDA. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates. downloaded on Nov 10, 2019.

This article reflects the personal opinions of the ***author only.***

The ABC's of Biomaterials Education: Through the Looking BioGlass of Idioms and Analogies – Part 2

By Otto C. Wilson, Jr.
Catholic University of America

Read part one.

"SIMPLE, CLEAR PURPOSE AND PRINCIPLES GIVE RISE TO COMPLEX INTELLIGENT BEHAVIOR. COMPLEX RULES AND REGULATIONS GIVE RISE TO SIMPLE STUPID BEHAVIOR."
— DEE HOCK, FOUNDER OF VISA

Idioms and analogies provide unique opportunities to reflect on the simpler things in life which tend to hold the most value. The quote from Dee Hock regarding the benefits of simple clear purpose and principles reverberates even more loudly in today's society where the rate of information transfer can easily boggle the mind. Fostering an appreciation for the simple lessons in life can lead to transformative learning experiences. In the first part of this article, we focused on famous idioms related to apples, honeybees and curiosity inspired cats. Our next series of idioms and analogies admonish us to avoid self-sabotage and to aim high by taking advantage of great opportunities that are presented to us and expecting great outcomes.

D IS FOR DISASTER AVOIDANCE: DON'T SHOOT YOURSELF IN THE FOOT

The epitome of self-sabotage involves shooting yourself in the foot. This has been portrayed in many Wild West comedies where someone draws their gun and accidentally pulls the trigger and shoots themselves in the foot. The figurative meaning for this idiom involves engaging in activities that impede your personal pathway to success. I have shot myself in the foot on a number of occasions during my career. I have even managed to shot myself in both feet simultaneously at times! My most memorable experiences in shooting myself in the foot involve times that my career path intersected with Dr. Cato Laurencin. Dr. Laurencin is a bona fide Rock Star in the world of biomaterials and medicine and mentoring! He is featured in the 2021 third quarter edition of Biomaterials Forum. Dr. Laurencin has envisioned, pioneered and championed the field of Regenerative Engineering. He is blazing an inspirational trail that has helped to guide many scholars along amazing career pathways and this inspiration will continue as his career further unfolds. His recently released book *Success is What You Leave Behind: Fostering Leadership and Innovation* chronicles his learning path in achieving great things and sets a very high standard of achievement.[1] He has received many prestigious awards including an NSF Presidential Mentoring Award. One of my other inspirational mentors, Dr. Winston Anderson from Howard University, also received this award. They have both set a very high standard for me to strive for in my research, mentoring, and outreach activities.

I first met Dr. Laurencin at a Ford Foundation Conference in the late 1980s. I was a new Pre-doctoral Fellow and Dr. Laurencin introduced himself and started to talk about research. He asked if I had access to a differential scanning calorimeter at Rutgers. I responded that I did and he invited me to collaborate with his research team and analyze some samples and write a paper together. I did not follow up on this wonderful opportunity. It is sad to say that I did not learn from this missed opportunity and I still had to learn how not to shoot myself in the foot. I had a chance to talk with Dr. Laurencin a few years later and he invited me to write a Ford Foundation Postdoctoral Fellowship to work in his lab at Drexel University. Let's just say that I dropped the ball again. I finally came to my senses and holstered my idiomatic "gun" and reached out to Dr. Laurencin and asked him to serve as my mentor for a Whitaker Foundation Fellowship and he graciously agreed. I travelled to Drexel University and received a tour of his amazing research facility and met some his phenomenal research team and students. Our application made it through the initial screen and we were invited to submit a full proposal. Unfortunately, my family experienced a serious health challenge at the time which hindered my ability to complete the proposal and I dropped the ball again. As I look back on key points in my career, I would like to share this thought with young scholars. Don't drag your feet to take advantage of special opportunities to broaden your horizons when they cross your pathway. Carpe Diem! Seize the day and the opportunity and see where the journey takes you.

E IS FOR ELEVATE: SHOOT FOR THE STARS

There is a much better alternative to shooting yourself in the foot that is highlighted in our next idiom. If you are going to shoot something, why not shoot for the stars! Let's encourage

The ABC's of Biomaterials Education: Through the Looking BioGlass of Idioms and Analogies – Part 2 (continued)

our young scholars to shoot for the stars. Shooting for the stars is a phenomenal goal because stars provide a rich source of inspiration. Stars achieve great things by taking hydrogen (H), the simplest atomic building block in nature and transforming it into helium (He). In the fusion reaction process, enormous amounts of energy are produced and this energy is vitally important for supporting life on earth. This fusion analogy played an integral role in a Teacher Quality Improvement (TQI) grant that we received from the Department of Education and the DC Office of the State Superintendent for Education (OSSE) in 2017 called the DC Focused Universe of STREAM Inspiration and Ongoing Nurture (FUSION) Professional Development (PD) Project. Our DC FUSION PD Team consisted of faculty members from four DC Universities (Catholic, Howard, Trinity, and George Washington) and a number of DC schools and partners with a shared passion for STREAM Education. The goal of the DC FUSION PD Project is to develop multidimensional PD resources for teachers and student focused learning modules, curriculum and books to inspire deeper level learning. The DC FUSION Team collaborations recapitulate the stages of star formation and progress through key stages including stellar gas cloud initiation, gravitational condensation, and rotation. Under the proper conditions, the critical mass spontaneously ignites and a new star is born that provides enormous energy. The DC FUSION PD Project seeks to learn about and model fusion processes that are integral to star formation and harness this process to provide unlimited inspiration energy for our teachers and student scholars to dream and achieve great things.

FUSION CONSTELLATION MAPS FOR LEARNING INSPIRATION

Fusion can be viewed as a multi-level process which encompasses inspired learning at the individual teacher/student level within the classroom as well as higher level interactions at the school, district, state, national and international levels. The education system in the Washington, DC and other school districts can be viewed as an interstellar map with patterns that we observe as local clusters of stars and constellations. Each point of light represents a school. At higher magnification, individual teachers and students are the spectral features which are observed within the school. Within individual school classrooms, teachers shine brightly by presenting lessons that harness their STREAM passions and release waves of inspiration. Student scholars can reflect the light generated by the teachers and also be inspired and equipped to generate their own bright illumination for learning. There is great hope that collaborative efforts such as DC FUSION PD can be harnessed to help all schools achieve sustainable fusion. A key element for achieving this dream goal involves long term support for designing and implementing enhanced Teacher PD that effectively impacts student achievement and success.

In addition to the fusion reactions that power the stars and drives the creation of elements in the universe, there are other aspects of fusion that are integrated into the DC FUSION PD Project including cell fusion, the fusion of spices to elevate cuisines, and the fusion of music genres. Dr. Laurencin tells a very interesting story in his book about how he met Earth Wind and Fire on a trip to Europe. Earth, Wind and Fire (EWF) just happens to be one of my favorite musical groups! Phillip Bailey, one of the lead singers for EWF, wrote the Afterword section for Dr. Laurencin's book. EWF has a number of great hits including *September* which is featured in the final dance scene in the movie Night at the Museum where a mystical tablet brings the Museum attractions to life at night. One of EWF's most insightful songs is *Shining Star*. The inspirational lyrics of the song's chorus are

"YOU ARE A SHINING STAR, NO MATTER WHO YOU ARE, SHINING BRIGHT TO SEE, WHAT YOU CAN TRULY BE."

Our young scholars are indeed shining stars and we need to redouble our efforts to inspire them to visualize and achieve their full potential in learning.

SIMPLE BUILDING BLOCKS FOR INSPIRATION: POST IT NOTE ORIGAMI, PENCILS AND SPRINGS

The FUSION project provided us with opportunities to build on the theme of how simple building blocks of inspiration can be used to construct wonderful multi-scale structures that support higher level learning. In my quest to make my life simpler and less cluttered both mentally and physically, I have found much enjoyment in focusing on the simple inspiration that has been cultivated through paper, the pencil, and springs. Paper has been an integral tool in transforming society because it serves as a medium to record transformative thoughts, inspiring ideas, and aspirational artwork through drawing and painting. Paper can exhibit an additional dimension of creativity through the creative wrinkle and folding of origami. It is amazing to see how simple things can be transformed into intricate works of art that stimulate

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and activate our brains to think deeply. The structure that is highlighted in Figure 1 was created from simple building blocks paper post it notes. The Post-It Note revolutionized note taking and incorporates the addition of a weak adhesive to give paper more-sticky appeal. The post it notes were folded into Pentagon Hexagon Zig Zag (PHiZZ) units (created by Mathematics Professor Dr. Thomas Hull) and used to create a modular origami model of a carbon 60 (C60) buckyball molecule.

While the pen is indeed mightier than the sword, the pencil has played a key role in recording information over history.[2] Carbon in the form of graphite was used to transform writing through the creation of the pencil in 1561 in England. The modern day pencil is a marvelous extension of graphite that is mixed with clay, sintered and encased in wood. The pencils in Figure 2 have been "woven" together into a hexastick model. I was first introduced to this structure while visiting my son Otto III at his school during a Parent visitation weekend at Rochester Institute of Technology (RIT) in 2019. We were looking at exhibits at the Math Department and a pencil hexastick model was on display as a prize for solving a series of puzzles. My mind was immediately inspired to figure out how to make one of these hexastick models on my own.

Simple things can be used in extraordinary fashion to solve problems and also transform learning. One of my favorite examples of this principle involves the use of pencils and scotch tape to creatively solve a problem in graphene research related to how to separate single atomic layer graphene sheets for analysis. This ingenious idea contributed to the Nobel Prize in Physics awarded to Andre Geim and Konstatin Novoselov in 2010. This simple technique has opened up great opportunities for probing the amazing properties of single atom thick graphene sheets. A recent discovery highlights how moire patterns can be generated from two single atom graphene sheets. When the angle between the adjacent graphene sheets is 1.1°, the graphene sheets undergo a phase transition and exhibit superconductivity at a temperature of 1.7 K.[3]

WHILE THE PEN IS INDEED MIGHTIER THAN THE SWORD, THE PENCIL HAS PLAYED A KEY ROLE IN RECORDING INFORMATION OVER HISTORY. CARBON IN THE FORM OF GRAPHITE WAS USED TO TRANSFORM WRITING THROUGH THE CREATION OF THE PENCIL IN 1561 IN ENGLAND.

Springs are another relatively simple structure that plays a key role in nature and technology. Springs and coiled structures are ubiquitously used in nature with the double helix in nucleic acids serving as the basis for genetic encoding. Spiral structures are also adapted into functional devices in many areas of technology based on the characteristic features of springs. The

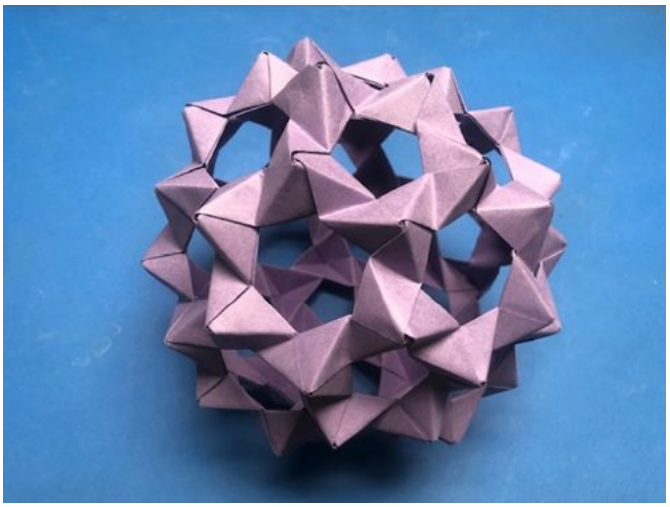

Figure 1. Pentagon Hexagon Zig Zag (PHiZZ) Unit Modular Origami Buckyball Model Made From 3" x 3" Squares of Paper

Figure 2. Simple Pencil Building Blocks Assembled to Make Extraordinary Structures to Illustrate the Power of Creativity in Transformative Learning b) Hexastick Model Made from Pencils

The ABC's of Biomaterials Education: Through the Looking BioGlass of Idioms and Analogies – Part 2 (continued)

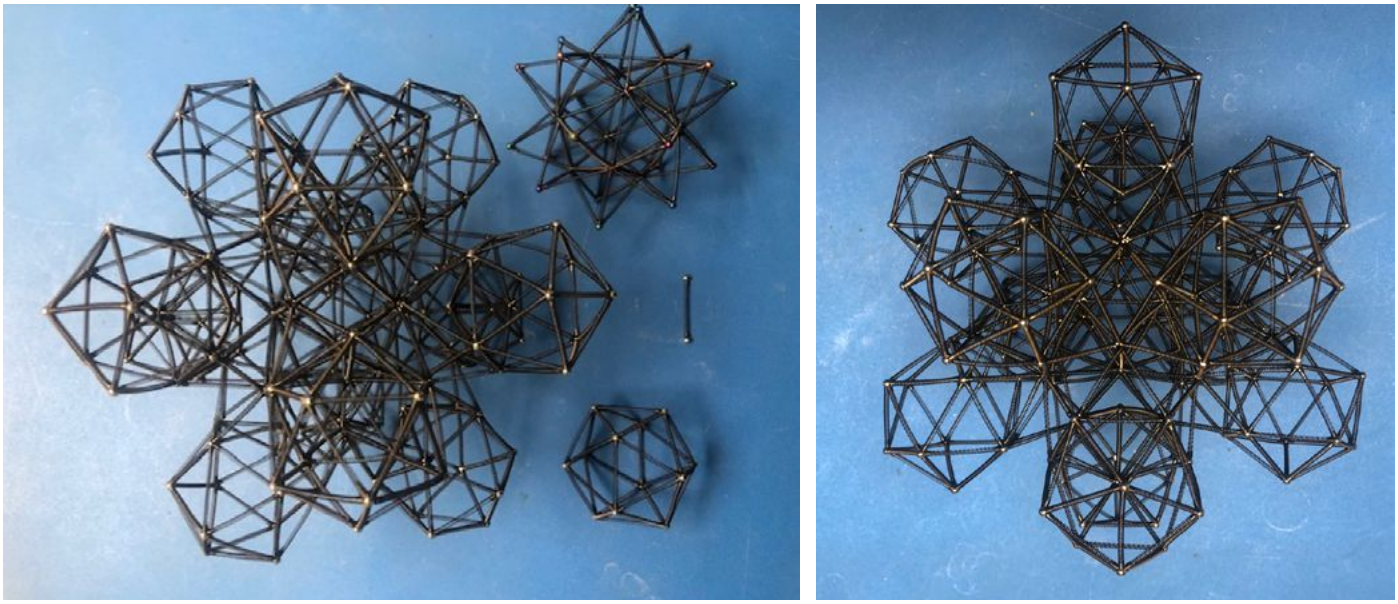

Figure 3. Spring Magnet (SPRAGNET) Structures Assembled from Springs (1") with Magnetic Attachment Joints

spring structure displayed in Figure 3 is made from 1 inch springs and small magnet bead connectors. The base unit shape is an icosahedral building block that can be assembled into larger scale structures. I used SPRAGNETS as part of the Medgar Evers TIPS PD training for preservice teachers and two participants made the comment that if they had this resource during chemistry, it would have been a different story.

The larger scale structure has fractal characteristics and is reminiscent of quasicrystal structures. The five-fold symmetry contributes to the star-like appearance. Quasi crystals (QC) were discovered by Dr. Daniel Shechtman in 1984 and he was awarded a Nobel Prize for his discovery in 2012. They are called quasicrystals because they have unique symmetry elements that prevent them from filling three dimensional space efficiently. They can be thought of as 3D analogues of Penrose tiles. There are a number of biological systems that display quasicrystal characteristics. Microtubules are one of the most exciting and surprisingly simple yet extremely versatile organic quasicrystal systems that occur in all cells as an integral part of the cell cytoskeleton. Microtubules are hollow tubes approximately 25 nm in diameter that are constructed from a and b tubulin dimer units that have spiral characteristics. The tubulin dimer units assemble and disassemble in a dynamic fashion to coordinate important cell processes related to cell motility, intercellular transport of proteins, and cell division. There are a number of fascinating theories which also implicate microtubules associated with neurons and axons with playing unique roles in consciousness, memory, and how we learn. This is a concrete example of how simple building blocks at the cellular and subcellular level are actually linked with how our brains learn, process and store new information.[4]

REFERENCES

1. Laurencin CT. (2022). *Success is What You Leave Behind: Fostering Leadership and Innovation*. Academic Press.
2. Petroski H. (2010). *The Pencil: A History of Design and Circumstance*. Alfred A Knopf.
3. Mutalik P. (2019). When Magic is Seen in Twisted Graphene That's a Moire. Quanta Magazine. https://www.quantamagazine.org/when-magic-is-seen-in-twisted-graphene-thats-a-moire-20190620/
4. Priel A, Tuszynski JA, Woolf NJ. Neural cytoskeleton capabilities for learning and memory. *J Biol Phys*. 2010;36:3-21.

How Academia Can Be a Launch Pad for Bioprinting Careers by Wi3DP

By Janet Kar, Women in 3D Printing

If it weren't for universities having 3D printing facilities — both Kristie Snodderly, Additive Manufacturing R&D Project Engineer at ASTM and Stephanie Willerth, CEO of Axolotl Biosciences and Canada Research Chair and Full Professor of Biomedical Engineering at University of Victoria may have not easily entered the bioprinting sector.

There are many interesting applications that are being explored in academia and industry. Unfortunately, many challenges still exist — and solutions must evolve to ensure commercial success of bioprinting applications and affordably improve patient care. Academia can be a great stage to support industry progression.

GETTING STARTED WITH THE SUPPORT OF ACADEMIA

Kristie Snodderly, Additive Manufacturing R&D Project Engineer at ASTM

"I started out as a lab manager for tissue engineering at the University of Maryland. At the time, they had two 3D printers — one was extrusion-based bioprinter and other, a DLP (Digital Light Processing) printer they used to create bioreactors." shares Kristie Snodderly. "At the time, I was required to figure out how these machines worked and how to maintain them."

As part of Snodderly's daily operations, she supported grad students who were experimenting in the lab. As she became a super user of the bioprinters, she soon started helping them with their projects, "I was doing all the fun parts of grad school without having to do all the administrative work!".

Stephanie Willerth, CEO of Axolotl Biosciences

On the other hand, Stephanie Willerth started her journey when she was completing her PhD in biomaterial sciences at Texas A&M (TAMU). "At the time, TAMU built their own bioprinters and they lacked quality bio-inks." Willerth was able to apply for grants, and they were able to secure their first bioprinter. Today, she is also the Research Chair and Full Professor of Biomedical Engineering at the University of Victoria and through the support of the government, she was able to develop new bio-inks and commercialize it via Axolotl Biosciences.

"We waited a long time before launching Axolotl Biosciences. When we incorporated we had lots of pull from the academic sector to use our inks. Currently, our patents have been covered

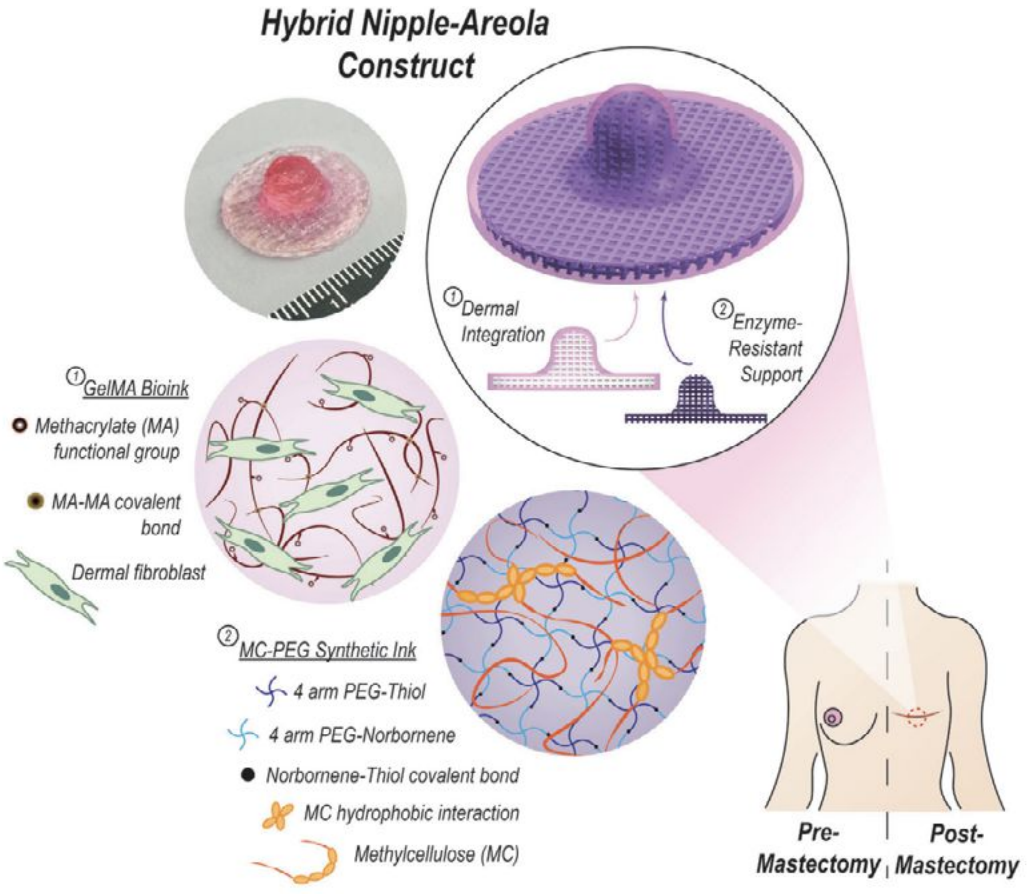

Figure 1. Dual Extrusion Pattering Drives Tissue Development Aesthetics and Shape Retention in 3D Printed Nipple-Areola Constructs research article (https://pubmed.ncbi.nlm.nih.gov/34617414/)

How Academia can be a launch pad for Bioprinting Careers by Wi3DP (continued)

by grant mechanisms." she shares, "When the lab was shut down due to the coronavirus pandemic, it was frustrating. We had a mature technology, and started to officially sell our first bio-inks. Throughout the pandemic, we had government funding to hire new students to support product development."

However, there are still challenges when it comes to accessing bioprinting labs with GMP (Goods Manufacturing Practice) compliance. "In Victoria, there were no GMP compliant facilities. We had to partner with beta testers that had access to GMP compliant labs. One of which, Humanobiologics Inc. tested our bio-inks for collagen production." shares Willerth.

INTERESTING PROJECTS COMING OUT OF ACADEMIA AND INDUSTRY

Snodderly recounts the work she did with nipple aerial construction using two materials, a synthetic material to help the nipple construct maintain its shape, and a biomaterial seeded with patient cells to remodel it (Figure 1). Other projects include cartilage-based tissue engineering and pattern testing. "We were trying to figure out with pattern testing, if we print a material with one cell type next to another material cell type – would they cross talk? Would the spacing improve how cells communicate?"

"We've also worked with Bioprosthetics where they used bio-ink to print human bones and got great results. A fertility clinic bioprinted organoids that support sperm production. It would be interesting to see if they achieve their end goal of supporting IVF treatment. There are too few people working on fertility treatment from stem cells, embryonic cells and sperm cells." shares Willerth.

If you visit the Axolotl Biosciences website (axolotlbiosciences.com)—you can learn more about fibrin-based bioinks for 3D printing of neural tissues derived from human induced pluripotent stem cells, bioprinting a novel glioblastoma tumor model for drug screening, 3D Bioprinting Mesenchymal Stem Cell-Derived Neural Tissues and much more.

NEAR-TERM WINS WITH BIOPRINTING

Snodderly shares, "In the short-term, bioprinting can be used as diagnostic tools. Imagine, printing small coupons with relevant cell types of orientation, we can use these for disease diagnosis and drug tests. I believe in the short term, bioprinting can remove a lot of the need for preliminary animal testing and evaluate drugs. Instead of using an in vivo rat model, we can use a bioprinted construct on a chip.

We still have a long way to go for scaling up bioprinting at a commercial level. There are many great applications, however challenges arise when dealing with complex tissues – especially those that require multiple cell types, stick constructs and vascularization. Testing out one aspect of the human body is simpler than focussing on how a solution is impacted by the entire body — which is complex.

Today, many academic labs are working heavily on creating bioprinted constructs on a chip, to represent the liver, kidney and other body parts."

CHALLENGES WE MUST OVERCOME

Some key challenges Snodderly and Willerth shared regarding what industry must overcome to scale up bioprinting applications include:

1) **Increasing cell numbers with bioreactors** — if we want to print brain tissue, we need to increase the number of cells/ml. Today, academic institutions are exploring tissue culturing, producing and printing cells. Access to quality bioreactors is important to achieve this.
2) **Access to more GMP compliant labs and clinical grade printers** — we need reliable manufacturing process to produce clinical grade materials for bioprinting. Otherwise, one day you may get 75 tissues and on a bad day, 10.
3) **More clinical grade bio-inks** — there's still a narrow range of printable and biocompatible materials. There's a need for ECM-based materials, multi-material and stimuli-responsive materials.

To date, academia continues to become a launchpad for bioprinting innovations. Most recently, University of Maryland has published research on 3D printing scaffolds for dynamic stem cell coculture, hybrid materials for vascular remodeling, 3D printed bioengineering placenta model to study preeclampsia, articular cartilage — and much more. We look forward to next generation researchers, inventors and scientists developing that can help push humanity forward in the right direction.

Industry News

By Gopinath Mani, Industry News Editor

KILI Carrier is a patented post-operative tool designed to reduce discomfort and improve healing for cancer patients who require Jackson Pratt (JP) drains.[1] JP drains are common for patients to live with, sometimes up to five weeks after surgery.[1] They allow fluid to collect outside of the body, reducing the risk of infection.[1] JP drains attach to the body with sutures can easily tangle in clothing, cause pain, and potentially rip skin or sutures, requiring medical attention.[1] Cinde Dolphin, a four-time cancer survivor, created KILI Carrier to manage four medical drains after her breast cancer surgery.[1] The apron-like mesh pouch, known as a KILI Carrier, is designed to reduce suture tears and the number of post-surgical readmissions.[1] With over 100,000 breast cancer surgeries performed annually in the U.S., a cancer patient took on the challenge and invented an alternative to holding the drains in place.[1] Reducing hospital visits for immune-compromised people, such as those living with cancer, is paramount during the pandemic.[1] "Often patients aren't informed about JP drains before surgery," says Dolphin, "and it's a harsh awakening after the procedure that octopus-like drains are attached to their bodies for a period of time," she said.[1] "How do you even bathe?" Products and procedures for healing need to be developed with patient input.[1] "Walk a mile in your patients' shoes," urges Dolphin.[1] "Spend a night or two with a drain attached to your hospital gown using safety pins, and then try to shower.[1] You'll find it's not the best experience to aid in the healing process."[1] As World Cancer Day is on February 4, oncologists and cancer centers are encouraged to collaborate with patients, listen to feedback, and find better solutions to outdated medical protocols.[1]

The U.S. Food and Drug Administration (FDA) recently authorized marketing of the laser-based device, called the **Philips CavaClear Laser Sheath**, for the removal of Inferior Vena Cava (IVC) filters.[2] The device is designed for patients who have an IVC filter, a small cage-like device inserted into the largest vein in the body to capture blood clots and prevent them from traveling to the lungs.[2] IVC filters are commonly used to treat patients who are at risk for pulmonary embolism when treatment with blood thinners cannot be used or is ineffective.[2] While some IVC filters are left in place permanently, the FDA issued a safety communication in 2014 based on reports of adverse events associated with IVC filters and recommended that implanting physicians consider removing the filter as soon as blood clots are no longer a risk for the patient.[2] During removal, the Philips CavaClear Laser Sheath device is designed to facilitate detachment of firmly adherent IVC filters from the IVC wall using ultraviolet laser energy to remove a small amount of the tissue.[2] The device is designed for use in conjunction with conventional snare devices to assist in IVC filter removal.[2] The Philips CavaClear Laser Sheath was granted a Breakthrough Device Designation for the removal of IVC filters.[2] The Breakthrough Devices Program is a process designed to expedite the development and review of devices that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and that otherwise meet the statutory criteria for Breakthrough Device Designation.[2]

Urotronic, Inc., a medical device company, recently announced that the U.S. FDA has approved the **Optilume® Urethral Drug Coated Balloon** for use in male urethral strictures.[3] A urethral stricture is a scar in or around the urethra that can restrict the flow of urine from the bladder and can result in a painful, frustrating slowing of the urinary stream.[3] Strictures can be caused by infections, trauma, and other medical procedures that injure the lining of the urethra and can significantly impact patients' quality of life.[3] If left untreated, strictures can lead to serious complications, including bladder and kidney damage, infections, and poor ejaculation in men.[3] Multiple endoscopic treatments of the same stricture are proven to lead to progressively worsening outcomes, recurrence, and retreatment.[3] Optilume works by inhibiting new scar tissue growth that often recurs after endoscopic dilations.[3] Patients who suffer from urethral stricture undergo millions of dilations per year in the U.S.[3]

Insulet Corporation, the leader in tubeless insulin pump technology, recently announced that it has received FDA clearance for its **Omnipod® 5 Automated Insulin Delivery System** (Omnipod 5) for individuals aged six years and older with type 1 diabetes.[4] Omnipod 5 is a tubeless automated insulin delivery (AID) system that integrates with the Dexcom G6 Continuous Glucose Monitoring (CGM) System and a compatible smartphone to automatically adjust insulin and help protect against highs and lows.[4] Omnipod 5 is designed to make it easier than ever to manage glucose with no multiple daily injections, no tubes, and zero fingersticks to help simplify life with diabetes.[4] The Omnipod 5 System consists of the tubeless Pod enhanced with SmartAdjust™ technology, the Dexcom G6 CGM, and the Omnipod 5 mobile app with its integrated SmartBolus Calculator.[4] The user has the option to download this app onto a compatible personal smartphone or to use the Omnipod 5 Controller.[4] Every five minutes, SmartAdjust receives a Dexcom CGM value and trend, and predicts where glucose will be 60 minutes into the future.[4] The system then increases, decreases, or pauses insulin delivery using the user's desired and customized glucose target, helping to protect against highs and lows.[4]

Industry News (continued)

Chemence Medical, Inc., a manufacturer of adhesive-based medical devices, recently announced that it has received FDA clearance for the **Exofin® Precision Pen** as a new medical device for wound closure.[5] The Exofin Precision Pen will enable medical providers with great versatility and precision in closing wounds.[5] The Exofin Precision Pen is the pen-style applicator with an adjustable tip that allows the user to control the adhesive width by supporting three different application methods in a single device: a micro-bristle brush for wide coverage, an inverted brush for narrow lines, and an angle precision tip for micro lines.[5] The Exofin Precision Pen also includes an ergonomic design with a grooved non-slip surface, a pressure-controlled variable adhesive flow rate, a see through activation chamber for easily viewing the adhesive flow, and contains up to 152% more usable adhesive than other products in the industry.[5] The Exofin Precision Pen also provides a 14 day microbial barrier to improve recovery and allow patients to resume normal activities faster, including showering without special coverings or dressings.[5]

AliveCor, a medical device and artificial intelligence (AI) company, recently announced the launch of **KardiaMobile Card**, the slimmest and most convenient personal ECG device.[6] At the size of a standard credit card, KardiaMobile Card fits easily into any wallet and delivers a medical-grade, single-lead ECG in 30 seconds.[6] KardiaMobile Card is the first credit-card-sized ECG cleared by the FDA.[6] KardiaMobile Card pairs with a smartphone using Bluetooth technology to detect six of the most common arrhythmias.[6] KardiaMobile Card users also have access to cardiologist analyses of ECGs, monthly heart health reports, and automatic sharing of ECG recordings.[6] The device's algorithm is based on AliveCor's AI-enabled Kardia technology.[6] KardiaMobile Card allows users to take an ECG recording anytime, anywhere.[6] KardiaMobile Card comes at a moment when both heart arrhythmias and hypertension, a risk factor for atrial fibrillation and other arrhythmias, are becoming more common.[6] These cardiac conditions have significant economic impact.[6] Hypertension costs the U.S. healthcare system an estimated $316 billion annually. Also, it is estimated that 80% of all cardiovascular disease is preventable, which highlights the importance of putting real-time data within reach of patients.[6]

Rousselot® Biomedical recently launched **Quali-Pure™**, a range of gelatins for biomedical applications with controlled endotoxin levels.[7] The Quali-Pure has been specifically designed for a variety of applications including embolization, wound healing, drug delivery, vaccines and hemostatics.[7] Quali-Pure delivers biocompatibility, biodegradability, controlled endotoxin levels, and batch-to-batch consistency, and fully supports medical device compliance with ISO 22442 and the new EU Medical Device Regulation (MDR) standards.[7] Also, the results of a new study demonstrates that Rousselot's ultra-pure GMP-grade gelatins outperformed standard non-endotoxin purified research grade gelatins and other coating materials in 2D cell culturing.[8] The data demonstrate that endotoxin (lipopolysaccharide, LPS) levels and the nature of biomaterials used in cell coating have a significant impact on cell morphology and proliferation.[8]

Polynoma LLC recently announced that it has reached an agreement with the FDA under a Special Protocol Assessment (SPA) on a pivotal Phase 3 clinical study of **seviprotimut-L, Polynoma's melanoma cancer vaccine**.[9] The SPA process is a procedure by which the FDA provides a clinical trial sponsor with an official evaluation and written guidance on the design of a proposed protocol intended to form the basis for a new drug application.[9] A SPA does not ensure the receipt of marketing approval or that the approval process will be faster than conventional regulatory procedures.[9] Final marketing approval depends on efficacy and safety results and an evaluation of the overall benefits and risks of treatment after review of the data from the development program in its totality.[9] Seviprotimut-L is an allogeneic, polyvalent, partially purified shed melanoma antigen vaccine derived from three proprietary human melanoma cell lines.[9] Seviprotimut-L stimulates humoral and cellular immune responses.[9] Melanoma-associated antigens (MAAs) found in seviprotimut-L are taken up by antigen-presenting cells (e.g., dendritic cells) which then activate the production of antigen-specific cytotoxic T-lymphocytes (CTLs) as well as develop antibody responses against MAAs.[9] These CTLs and antibodies then recognize and act on tumor cells expressing the MAAs on their surfaces, causing cell death.[9] Seviprotimut-L is currently in development for the adjuvant treatment of patients with Stages IIB and IIC melanoma, following definitive resection.[9]

REFERENCES

1. KILI Medical Drain Carrier Reduces Post-Op Hospital Visits for Cancer Patients, Receives Patent. Accessed February 4, 2022 https://www.prnewswire.com/news-releases/kili-medical-drain-carrier-reduces-post-op-hospital-visits-for-cancer-patients-receives-patent-301460928.html
2. FDA Grants Marketing Authorization for Inferior Vena Cava Filter Removal Device. Accessed February 4, 2022. https://www.prnewswire.com/news-releases/fda-grants-marketing-authorization-for-inferior-vena-cava-filter-removal-device-301449191.html
3. FDA Approves Optilume® Urethral Drug Coated Balloon, a breakthrough treatment for urethral strictures. Accessed February 4, 2022. https://www.prnewswire.com/news-releases/fda-approves-optilume-urethral-drug-coated-balloon-a-breakthrough-treatment-for-urethral-strictures-301442655.html
4. Insulet Announces FDA Clearance of its Omnipod® 5 Automated Insulin Delivery System, First Tubeless System with Smartphone Control. Accessed February 4, 2022. https://www.businesswire.com/news/home/20220127006047/en/
5. Chemence Medical Receives FDA Clearance for new Exofin® Precision Pen. Accessed February 4, 2022. https://www.businesswire.com/news/home/20220131005076/en/
6. FDA Clears World's First Credit-Card-Sized Personal ECG. Accessed February 4, 2022 https://www.prnewswire.com/news-releases/fda-clears-worlds-first-credit-card-sized-personal-ecg-301472260.html

References continued on page 30

Government News

RETHYMIC APPROVED BY FDA FOR TREATMENT OF ATHYMIA IN CHILDREN

By Carl Simon, Government News Editor

Rethymic is "allogeneic processed thymus tissue" for "immune reconstitution in pediatric patients with congenital athymia."2 Rethymic was approved by the Food and Drug Administration (FDA) in October 2021 and is marketed by Enzyvant Therapeutics, Inc. Congenital athymia is a rare condition where children are born without a thymus, have severely reduced numbers of T cells and are susceptible to infection.2 It is considered fatal by 3 years of age due to infection.

Rethymic is manufactured on demand from thymus tissue collected from donors undergoing heart surgery that are under nine months of age. The tissue is collected in slices that are cultured on filter membranes for 12-21 days. The slices are yellow to brown in color and of variable shape and size. The primary purpose of manufacturing is to reduce allogeneic thymocyte levels for safety, while maintaining tissue organization and viability and the retention of cell types believed to be important for function.

Dosing is based on the surface area of the implant (mm2) versus the surface area of the patient. The recommend dose range is 5000 to 22,000 mm2 of Rethymic per square meter of surface area of the patient. During implantation surgery, Rethymic is removed from the membranes and implanted in the quadriceps muscle of the patient approximately 1 cm in depth and 1 cm apart in between the muscle fibers.3 Up to 42 Rethymic slices can be implanted per patient, preferably into a single leg, but into both legs if necessary. Rethymic is intended to function as a normal thymus by recruiting host T cells (thymocytes) into the slices where the T cells mature, undergo positive and negative selection, and are released into circulation as immunocompetent naïve T cells to provide protection from infection.

Rethymic was tested clinically at a single center, Duke University, over 28 years, from 1993 to 2020, including implantation into 105 children. The data were collected in single-arm clinical trials, and results were compared to historical data. The primary endpoint was survival at one year. Other endpoints included survival at two years and survival of patients that lived at least one year after treatment. The patients were assessed for evidence of thymic function by measuring the presence of naïve T-cells in peripheral blood. Infections and other adverse events were also assessed. Efficacy analysis included 95 patients that were diagnosed with congenital athymia and their median age was 298 days.

Of the 95 patients, 21 died in the first year before developing T cell function and one died in the second year, yielding one-year and two-year survival rates of 77% and 76%, respectively.2 For comparison, in a natural history population of 49 children with athymia, the one-year and two-year survival rates were 6% and 0%, respectively.1 For children alive one year after treatment, survival was 93% with a median follow up time of 10.9 years. Deaths were from a variety of causes, including many different types of infections. Thymic function was assessed by measuring the presence of T cells in the peripheral blood. Results demonstrated that T cells were not present at three months, first appeared at six months, and approached their maximum at 12 months after treatment. The maximum T cell levels in the treated patients approached the 10th percentile of the normal range.

Historically, children with congenital athymia died within the first few years of life. With Rethymic treatment, there is hope that their immune system may be reconstituted and they may be able to live a fuller life. Mary Louise Markert, a pediatric immunologist at Duke University, dedicated her 30-year career to developing a cure for athymia.4 She began working on the project in 1991, and Rethymic was approved by FDA on October 8, 2021. Dr. Markert retired on October 15, 2021.

REFERENCES

1. Summary Basis for Regulatory Action – Rethymic. FDA. 2021. Accessed February 2, 2022. https://www.fda.gov/vaccines-blood-biologics/rethymic
2. Markert ML, Gupton SE, McCarthy EA. Experience with cultured thymus tissue in 105 children. *J Allergy Clin Immunol*. 2022;149:747-57. https://doi.org/10.1016/j.jaci.2021.06.028
3. Package Insert – Rethymic. FDA. 2021. Accessed February 2, 2022. https://www.fda.gov/vaccines-blood-biologics/rethymic
4. Wang V. Duke researcher Louise Markert receives FDA approval for groundbreaking treatment of pediatric immune disorder. *The Chronicle*. Accessed February 3, 2022. https://www.dukechronicle.com/article/2021/11/pediatric-congenital-athymia-drug-mary-louise-markert-immune-disorder-food-drug-administration-thymus-t-cells-immune-gland

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Student Chapter News

By Gerry Koons

On October 27, 2021, we held a webinar on Career Opportunities in Biomaterials for Historically Black Colleges and Universities (HBCU) Students. Our six accomplished panelists shared about and inspired us with their career pathways in academia, industry and regulatory agencies:

- Dr. Gregg Duncan (University of Maryland)
- Dr. Cheryl Gomillion (University of Georgia)
- Dr. Antentor Hinton (Vanderbilt University)
- Dr. Catherine Faye Whittington (Worcester Polytechnic Institute)
- Dr. Jamal Lewis (University of California-Davis)
- Dr. Pumtiwitt McCarthy (Morgan State University)

On February 25, 2022, we hosted a panel on creating figures for publications and presentations, featuring professional experts in illustration, website development, and other valuable backgrounds.

In March, we teamed up with TERMIS Student and Young Investigators Section to host a virtual international mixer about the similarities and differences among training environments in North America and Europe.

During the SFB Annual Meeting in April, we are looking forward to hosting our popular 3-Minute Thesis Competition!

Follow us on our new Instagram *@sfbstudents* and expanded Twitter *@sfb_students* – or contact us through our new Gmail address: **sfbstudents@gmail.com**

Industry News (continued from page 28)

7. Darling Ingredients' health branRousselot® launches Quali-Pure™, a range of gelatins with controlled purity, supporting full compliance with new EU Medical Device Regulations and ISO 22442. Accessed February 4, 2022 https://www.prnewswire.com/news-releases/darling-ingredients-health-brand-rousselot-launches-quali-pure-a-range-of-gelatins-with-controlled-purity-supporting-full-compliance-with-new-eu-medical-device-regulations-and-iso-22442-301402589.html
8. New study confirms that purity and type of coating biomaterials used in 2D cell culturing are crucial for efficient stem cell proliferation. Accessed February 4, 2022 https://www.sciadnewswire.com/news/693/new-study-confirms-purity-and-type-coating-biomaterials-used-2d-cell-culturing-are-crucial
9. Polynoma Receives Special Protocol Assessment (SPA) Agreement from the U.S. FDA for a Pivotal Phase 3 Clinical Study of Seviprotimut-L, a Melanoma Cancer Vaccine. Accessed February 4, 2022. https://www.biospace.com/article/releases/polynoma-receives-special-protocol-assessment-spa-agreement-from-the-u-s-fda-for-a-pivotal-phase-3-clinical-study-of-seviprotimut-l-a-melanoma-cancer-vaccine/?keywords=Cancer+vaccine+FDA

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