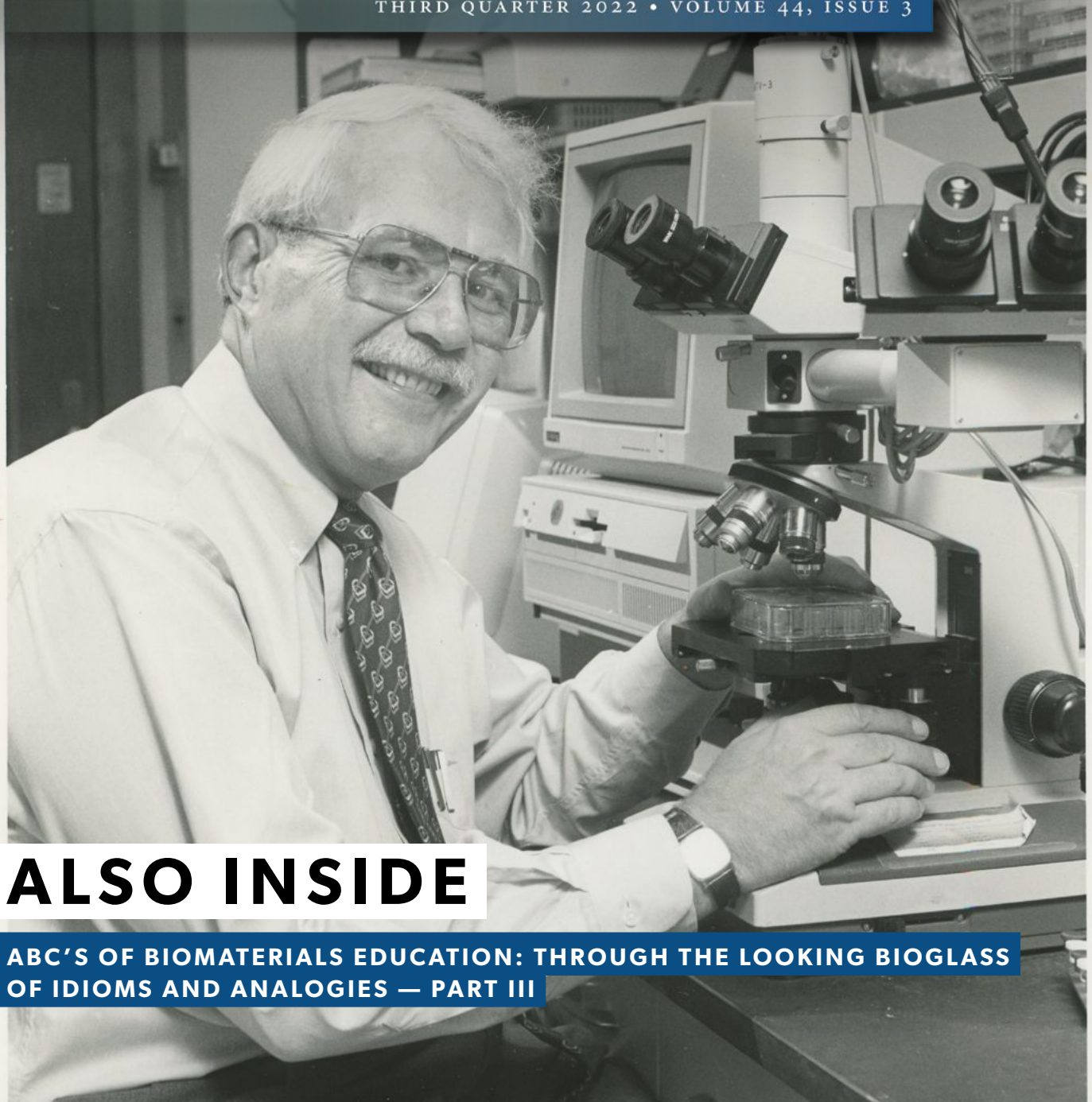
BIOMATERIALS AT CWRU: THE FIRST 30+ YEARS

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

THIRD QUARTER 2022 • VOLUME 44, ISSUE 3



ALSO INSIDE

ABC'S OF BIOMATERIALS EDUCATION: THROUGH THE LOOKING BIOGLASS OF IDIOMS AND ANALOGIES — PART III

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

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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 2

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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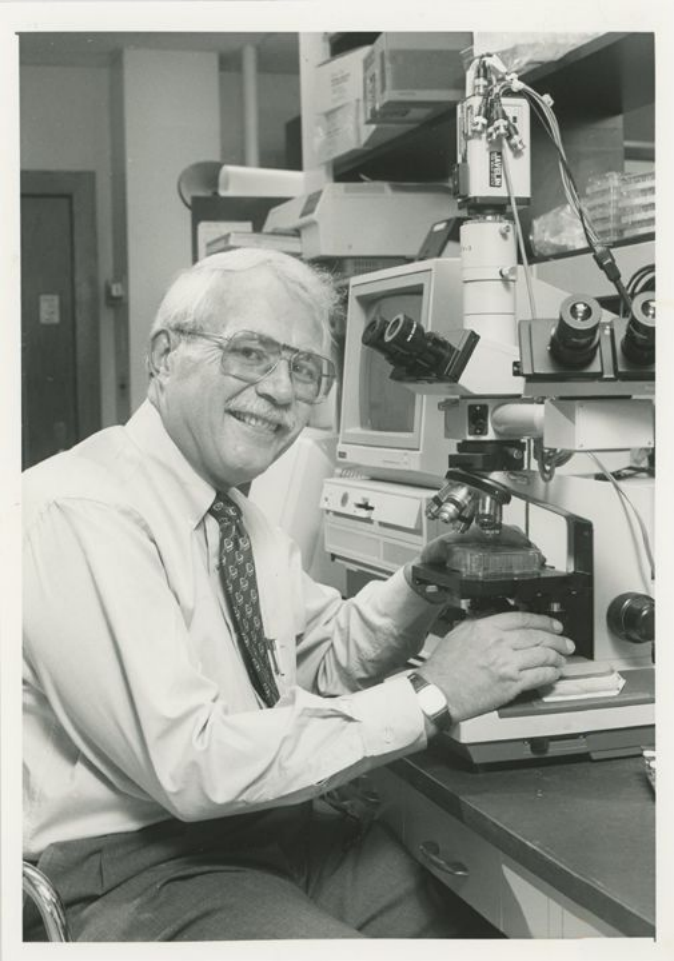


ON THE COVER

James Anderson at his microscope

From the Editor

By Roger Narayan, Biomaterials Forum Executive Editor

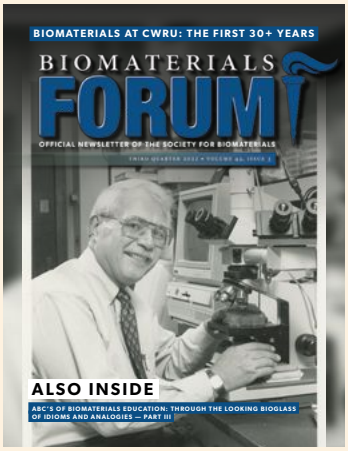
I am glad to share this third quarter issue of *Biomaterials Forum* with you! This issue features a brief history of biomaterials research activities at Case Western Reserve University, one of the pioneering institutions in our field. The article, from James Anderson, contains details about the role of case researchers in biomaterials innovation over recent decades. Another feature is the third installment by Otto C. Wilson, Jr. in his "ABC's of Biomaterials Education series"; this article considers "Through the Looking BioGlass of Idioms and Analogies." Like the previous articles in this series, this article provides insight into Dr. Wilson's views of biomaterials in a broader context. This issue also includes a letter from our president, Elizabeth Cosgriff-Hernandez, regarding the upcoming 2023 Annual Meeting and other upcoming meetings that the society is supporting. Shena Seppanen provides details on the activities of the society's board, council, and committees in the staff updates section. Stephanie K. Seidlits, the Society's Member-at-Large, reviews recent achievements by James Anderson, Nicholas Peppas, Guillermo Ameer and other leaders of our field.

A summary of the activities that will take place at the upcoming Materials Science & Technology 2022 Meeting, including three Society For Biomaterials-sponsored symposia as well as a student poster contest and rapid fire event, is found in this issue. Gopinath Mani considers recently advances in the commercialization of biomaterials research by Immunicom, Inc., Palette Life Sciences, Eliaz Therapeutics Inc., Spectral Medical Inc., SoniVie, Apyx Medical Corporation, VenoStent, Inc., Accelus and Invictus Sterilization LLC. Carl Simon, our Government News Editor, reviews the activities of the Advanced Regenerative Manufacturing Institute (ARMI), a nonprofit that supports advances in the manufacturing of cells, tissues, and organs. ARMI's development of a Deep Tissue Characterization Center (DTCC) and support of extramural research are described in the article. Karen J.L. Burg and Anirban Sen Gupta provide us with an overview of AIMBE News; recent legislation to improve funding for science & technology research and the development of a new Advanced Research Projects Agency for Health (ARPA-H) are described. David Eduardo Flores-Prieto, the National Student Chapter President, shares recent student chapter news, including information about the 2022-2023 national student chapter officers and details on upcoming activities. Silviya P. Zustiak has prepared an update from the Engineering Cells & Their Microenvironments (ECTM) Special Interest Group (SIG), including SIG member news and activities by the SIG at the recent annual meeting. Howard Winet provides an overview of "Ethics for Bioengineering Scientists — Treating Data as Clients," a new book from Taylor & Francis that can serve as a textbook or reference for bioengineers who are considering ethics as it related to their field.

It was a pleasure to work with the members, volunteer leadership and staff to prepare this issue. I hope that this issue provides you and your colleagues with useful information about the society's activities and recent advances in the field. Please do not hesitate to reach out to me at roger_narayan@ncsu.edu if you would like to prepare an article for inclusion in an upcoming issue of the Forum.

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 Elizabeth Cosgriff-Hernandez, SFB President

Dear friends and colleagues,

As summer 2022 comes to an end, I hope this message finds you well and you were able to find some rest and relaxation. There has been a lot happening in our biomaterials community as we prepare for an exciting year. I would like to wish a warm welcome to our new President-Elect, Bill Wagner and our new Member-at-Large, Stephanie Seidlits. New Council appointments are complete, and committee chairs have populated their committees — thank you to all of our volunteers! Each committee is hard at work developing their agenda for the year, and the Council met at the end of July for our strategic planning session. Please feel free to reach out if you have suggestions for activities or action for the Board and Council — we would love to hear from you!

Planning for the 2023 Annual Meeting in beautiful San Diego on April 19-22, 2023 is in full swing. The theme is "Riding the Translational Waves to the Future!" and I am looking forward to an exciting meeting. The Program Committee has been busy reviewing applications for Symposia, Workshop and Special Events — thank you to everyone for submitting wonderful ideas for the meeting. The call for abstracts will come out later this month, so be prepared to submit! I expect the San Diego meeting to be a huge success and offer diverse opportunities to our members. In addition to outstanding scientific and technical sessions, professional development, outreach and networking opportunities are being developed and incorporated to increase value to our members. There are also a myriad of sponsorship opportunities that can be found on our meeting website.

It's award nomination time! Awards recognizing the exceptional scientific, professional and service contributions of our members at all professional stages, including the new Diversity Award, are offered. The deadline was September 16, 2022 and more information can be found here. Thank you to all those who submitted their nominations!

There are several exciting biomaterials meeting this fall. The 32nd Annual Conference of the European Society of Biomaterials took place from September 4-8, 2022 in Bordeaux, France. SFB will be sponsoring one of the keynote speakers, and we encourage you to attend to hear their talk! SFB is also co-sponsoring the 2022 Materials Science & Technology Technical Meeting and Exhibition October 9-12, 2022 in Pittsburgh, Pennsylvania, as well as programming three new symposia. Finally, the Call for Symposium is open for the 12th World Biomaterials Congress (WBC), which will be held in Daegu, South Korea, May 26-31, 2024. This is a great opportunity for SFB members to be involved in WBC programming.

In an effort to increase member value, I will be holding a series of listening sessions throughout the year to hear from you about how the Society can better serve your needs. Please join me! I also encourage you to share your ideas and suggestions with me directly at cosgriff.hernandez@utexas.edu.

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: ELIZABETH COSGRIFF-HERNANDEZ, PHD

The Governing Council recently held a full day strategic planning meeting to discuss the charges and goals of the 2023 membership year.

AWARDS, CEREMONIES, AND NOMINATIONS COMMITTEE — CHAIR: HORST VON RECUM, PHD

The Committee recently solicited awards and officer nominations which closed on September 16, 2022. Award nominations are currently under review for announcement of selected recipients to be made in late November. Officer nominations, once formalized by the Committee, will be forwarded to Council for ratification and the approved candidates will stand for election in early 2023.

BYLAWS COMMITTEE — CHAIR: C. LASHAN SIMPSON, PHD

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

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

The DEI Committee has been working to develop a leadership succession plan for organizers of the Annual Meeting identity mixers, have identified liaisons to serve on the current ACN and Program Committees, and developed a rubric for the new DEI Award providing guidance for the ACN Committee to review and evaluate. They also worked to create clear charges for each member so that their individual roles are better defined.

EDUCATION & PROFESSIONAL DEVELOPMENT COMMITTEE — CHAIR: BRENDAN A. HARLEY, SCD

The Committee plans to host the Biomaterials Education Challenge again at this year's 2023 Annual Meeting. They are also working with the National Student Chapter to re-engage student chapter participation and increase engagement at the meeting and throughout the year.

FINANCE COMMITTEE — CHAIR: DANIELLE BENOIT, PHD

The Society is reviewing and revising the current financial model to ensure long-term financial solvency.

INDUSTRIAL AFFAIRS COMMITTEE — CHAIR: GOPINATH MANI, PHD

The IAC is focused on new initiatives that will help expand SFB's industry connections and participation, as well as enhance SFB's involvements in biomaterials-related policy advocacy concerning not only basic and applied research but material supplies and supply chain.

LIAISON COMMITTEE — CHAIR: BINGYUN LI, PHD

SFB is co-sponsoring this year's Materials Science & Technology (MS&T) Annual Meeting in October 2022. If all proves successful, SFB may become an annual partner. The Committee is also continuing to send 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: GULDEN CAMCI-UNAL, PHD

The Committee continue to work toward increased membership, as well as the overall engagement of current members and support of younger members. They are considering ways to better recognize and highlight member accomplishments and innovative work, and are making an increased effort on industry outreach, engagement and inclusion.

2023 ANNUAL MEETING PROGRAM COMMITTEE — CHAIRS: KAREN L. CHRISTMAN, PHD AND JENNIFER WOODELL-MAY, PHD

The 2023 SFB Annual Meeting & Exposition will be held in San Diego, California, April 19-22, 2023. The call for abstracts early bird deadline will be October 14 with the extended deadline as November 1.

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

SPECIAL INTEREST GROUPS — REPRESENTATIVE: ASHLEY BROWN, PHD

All 14 SIGs are committed to increasing student and member engagement and will be doing so with their fall/spring webinar series, which you will receive notice about via email. Stay tuned for more details!

Member News

By Stephanie K. Seidlits, PhD, Member-at-Large

James Anderson, Case Western University, was awarded the 2022 Professional Impact Award for Leadership, American Institute for Medical and Biomedical Engineering (AIMBE) "for outstanding leadership through activities involving impactful research, journal editorship, professional society governance and guidance, and regulatory standards development."

Nicholas A. Peppas is honored at the 35th Anniversary Ellis Island Medals of Honor at Ellis Island on May 14, 2022 in New York City. (Photo by Noam Galai/Getty Images for Ellis Island Honors Society)

Nicholas Peppas, University of Texas at Austin, is a 2022 recipient of the Ellis Island Medals of Honor, which have been presented to inspiring Americans who are selflessly working for the betterment of the US and its citizens since 1986. A highly prestigious award, recipients are read into the Congressional Record each year. Since the medal was founded, we have honored distinguished and diverse Americans including Presidents Ronald Reagan and Joe Biden, as well as six other Presidents of the United States. Past Medalists include former Apple CEO John Sculley, Google Chairman and CEO Eric Schmidt, Mastercard CEO Ajay Banga, IBM CEO Ginni Rometty, former PepsiCo CEO Indra Nooyi, Nobel Prize laureates Elie Wiesel and Malala Yousufzai, Sen. John McCain, Muhammad Ali and Lee Iacocca, among others.

In addition, Peppas was elected a Member of the Academy of Romanian Scientists. The nominator wrote: "In the past, some elected members have included Louis de Broglie, Max Born, Paul Sabatier, George Emil Palade, all members of the Academy of Romanian Scientists." The induction event held at the Academy in Bucharest.

Guillermo Ameer, Northwestern University, was awarded the 2022 Innovation Commercialization Award by the Tissue Engineering and Regenerative Medicine International Society-Americas (TERMIS-AM) for his translation of tissue engineering and regenerative medicine research to benefit patients.

Lawrence Gettleman, University of Louisville, was elected a Fellow of Sigma Xi, the prestigious Scientific Research Honor Society.

Ngan Huang, Stanford University, was recently promoted to Associate Professor in the Department of Cardiothoracic Surgery.

Lesley Chow, Lehigh University, has been promoted to Associate Professor with tenure in the Departments of Bioengineering and Materials Science & Engineering.

Kyle Lampe, University of Virginia, was promoted to Associate Professor of Chemical Engineering, with tenure, effective August 25, 2022.

Member News (Continued)

Bryan James, Woods Hole Oceanographic Institution, recently published in the journal *Environmental Science & Technology* on the valuable, interdisciplinary role that biomaterials science and engineering can play in addressing the existential threat of plastic.

Ritu Raman, Massachusetts Institute of Technology, recently published a book aimed at introducing general audiences to the emerging discipline of Biofabrication. It offers an accessible introduction (high school+) to how engineers can use biological materials to replace damaged tissues in our bodies, make sustainable lab-grown meat and leather, power robots and more. The book also discusses the ethics, economics, and sustainability of building with biology. It has an easily digestible introduction to a field that helps us appreciate the beauty, adaptiveness, and persistence of the biological machinery that drives our bodies and our world.

Astha Khanna, Graver Technologies, and researchers from Stanford University have been recognized for outstanding contribution to the biomaterials field and their recent publication on three-dimensional stem-cell based bioprinting engineering techniques for cardiovascular regeneration. This work was published recently in the *Journal of Molecular and Cellular Cardiology*.

Narayan Bhattarai, North Carolina A&T State University, served as the program chair of 38th Southern Biomedical Engineering Conference held August 25-28, 2022 in New Orleans, Louisiana.

Verena Scheper, Hannover Medical School, and an interdisciplinary team of the research consortium RESPONSE have developed a technique to additively manufacture patient individualized, mechanically flexible, drug delivery implants. The results of an individual healing attempt using this new generation of implants were recently published. This is the first time such a 3D printed device was successfully implanted into a patient. The technique can be adapted to multiple applications.

pharmaceutics

MDPI

Article

Individualized, Additively Manufactured Drug-Releasing External Ear Canal Implant for Prevention of Postoperative Restenosis: Development, In Vitro Testing, and Proof of Concept in an Individual Curative Trial

Farnaz Matin-Mann [1,*,†], Ziwen Gao [1,2,†], Jana Schwieger [1,2], Martin Ulbricht [3], Vanessa Domsta [3], Stefan Senekowitsch [3], Werner Weitschies [3], Anne Seidlitz [3,4], Katharina Doll [5], Meike Stiesch [5], Thomas Lenarz [1,2] and Verena Scheper [1,2]

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!

MS&T22 takes place in Pittsburgh, PA, USA October 9-12, 2022 at the David L. Lawrence Convention Center

MS&T22 Welcomes Society for Biomaterials Members

In October, the Society for Biomaterials (SFB) joins the long-standing Materials Science & Technology 2022 Technical Meeting & Exhibition (MS&T22) as a programming partner. MS&T22 fosters technical innovation at the intersection of materials science, engineering and application. SFB members can register for the conference at the discounted member rate and join their colleagues at MS&T22, October 9-12, 2022, in Pittsburgh, Pennsylvania.

More than 80 symposia on materials science-related topics are planned in 15 topic areas at MS&T22. SFB will sponsor the following three symposia as part of the Biomaterials topic track:

- Biological Response to Materials and Material's Response to Biological Environments
- Biomaterial Applications
- Biomaterial Applications in Today's Industry: Development, Translation & Commercialization

Each year, MS&T brings together scientists, engineers, students, suppliers and business leaders to discuss current research and technical applications and to shape the future of materials science and technology.

The event's unmatched technical program addresses structure, properties, processing, and performance across the materials community. Its exhibition showcases a wide variety of equipment and services to the automotive, aerospace, instrumentation, medical, oilfield and energy industries.

MS&T is organized by a joint partnership of leading materials science-related societies: the American Ceramic Society (ACerS), the Association for Iron and Steel Technology (AIST) and The Minerals, Metals & Materials Society (TMS). Learn more about the organizing societies.

The partnership between the three societies allows for a wide variety of topics which are sure to cross over within your industry. Below are the topics for this year's programming:

- Additive Manufacturing
- Artificial Intelligence
- Biomaterials
- Ceramic and Glass Materials
- Education
- Fundamentals and Characterization
- Iron and Steel (Ferrous Alloys)
- Lightweight Alloys
- Materials-Environment Interactions
- Modeling
- Nanomaterials
- Nuclear Energy
- Processing and Manufacturing
- Sustainability, Energy, and the Environment
- Special Topics

The MS&T22 technical program is developed by a Program Coordinating Committee consisting of representatives from the three organizing societies: **Jessica Rimsza,** Sandia National Laboratory (Chair and ACerS Representative); **Siddhartha Biswas,** Big River Steel (AIST Representative); **John Carpenter,** Los Alamos National Laboratory (TMS Representative); and **Eric Lass,** University of Tennessee, Knoxville (TMS Representative).

MS&T22 (Continued)

Each year, MS&T features the following events:

- **ACerS Annual Meeting:** Advancing the industry with the latest research in ceramics and glass
- **AIST Steel Properties & Applications:** Technical developments related to ferrous metallurgy and the steelmaking process
- **TMS Fall Meeting:** Exploring the intersections of development, synthesis and application

Materials science's next generation is always a vital part of MS&T. We have many annual student events that ensure students are involved and exposed to the networking, learning and fun that the conference provides!

See below for the student events this year:

- Student Social Media Contest
- 2022 Undergraduate Student Speaking Contest
- Student Networking Reception
- NEW! Professional Student Headshots
- 2022 Undergraduate Student Poster Contest
- 2022 Graduate Student Poster Contest
- AIST Student Plant Tour
- AIST Foundation Steel to Students Recruiting Reception
- Ceramic Mug Drop Contest
- Ceramic Disc Golf Contest
- ACerS Student Tour at Almatis

There are also many networking and social events at the conference.

See below for the events happening at MS&T22:

- Lift & Thermo-Calc "ICME for Ceramics" Kick-Off Event at MS&T22
- MS&T Women in Materials Science Reception
- ACerS 124th Annual Membership Meeting
- Welcome and General Poster Reception Hosted by the MS&T Partners
- AIST Steel to Students Recruiting Reception
- ACerS Annual Honor and Awards Banquet
- ACerS Basic Science Division Ceramographic Exhibit & Competition
- TMS Emerging Professionals Tutorial Luncheon & Lecture
- ACerS Basic Science Division Ceramographic Exhibit & Competition
- ACerS Basic Science Division Ceramographic Exhibit & Competition

MS&T's exhibit also creates unique materials science networking opportunities. For MS&T22, we are pleased to also announce that **Event Partners** will co-locate the following two commercial exhibitions with MS&T22:

- **The Advanced Materials Show,** showcasing the very latest in high-performance materials technology for applications including aerospace, automotive, electronics, energy and medical technology
- **The Nanotechnology Show,** focused on the development and integration of nanotechnology within a range of applications including chemicals, life sciences, pharmaceutical, energy, electronics, automotive and aerospace

The two new co-located shows will showcase the very latest in high-performance materials technology for applications including aerospace, automotive, electronics, energy, medical technology, chemicals, life sciences and pharmaceutical.

- Tuesday October 11: 9:00 am – 6:00 pm
  (Networking Reception 4:00 pm – 6:00 pm)
- Wednesday October 12: 9:00 am – 5:00 pm

Established in 2003, the MS&T conference series has been bringing together the materials science and engineering community for 20 years with support from leading materials-related societies. More than 46,000 attendees have participated in MS&T since 2005, with approximately 25,000 oral and poster presentations delivered during that time.

Learn more about the conference series at matscitech.org.

To register and book housing for MS&T22, visit matscitech.org/MST22.

Below is a list of every past conference of MS&T:

YEAR LOCATION PARTNERS (SFB is not currently a "partner")

2003 Chicago, IL: ISS-TMS

2004 New Orleans, LA: ISS-TMS

2005 Pittsburgh, PA: ACerS-AIST-ASM-TMS

2006 Cincinnati, OH: ACerS-AIST-ASM-TMS

2007 Detroit, MI: ACerS-AIST-ASM-TMS

2008 Pittsburgh, PA: ACerS-AIST-ASM-TMS

2009 Pittsburgh, PA: ACerS-AIST-ASM-TMS

2010 Houston, TX: ACerS-AIST-ASM-TMS

2011 Columbus, OH: ACerS-AIST-ASM-TMS

2012 Pittsburgh, PA: ACerS-AIST-ASM-TMS

2013 Montreal, QC: ACerS-AIST-ASM-MetSoc-TMS

2014 Pittsburgh, PA: ACerS-AIST-ASM-TMS

2015 Columbus, OH: ACerS-AIST-ASM-TMS

2016 Salt Lake City, UT: ACerS-AIST-ASM-TMS

2017 Pittsburgh, PA: ACerS-AIST-ASM-TMS

MS&T22 (Continued)

2018 Columbus, OH: ACerS-AIST-ASM-MetSoc-TMS

2019 Portland, OR: ACerS-AIST-ASM-TMS

2020 Pittsburgh, PA: ACerS-AIST-TMS

2021 Columbus, OH: ACerS-AIST-TMS

2022 Pittsburgh, PA: ACerS-AIST-TMS

The objective of the partners is to conduct the premier annual worldwide fall event for the broad metals and materials science and engineering community. The event is to feature robust participation by metals and materials professionals (from industry, academia and government), university students and businesses/ suppliers that serve the metals and materials community and that employ metals and materials professionals. The event will comprise individually as well as collectively organized technical programming, an exhibition, social functions and tours. Since 2020, the event annual comprises:

Advancing the industry with the latest research in ceramics and glass

Technical developments related to ferrous metallurgy and the steelmaking process

Exploring the intersections of development, synthesis, and application

Biomaterials at CWRU: The First 30+ Years

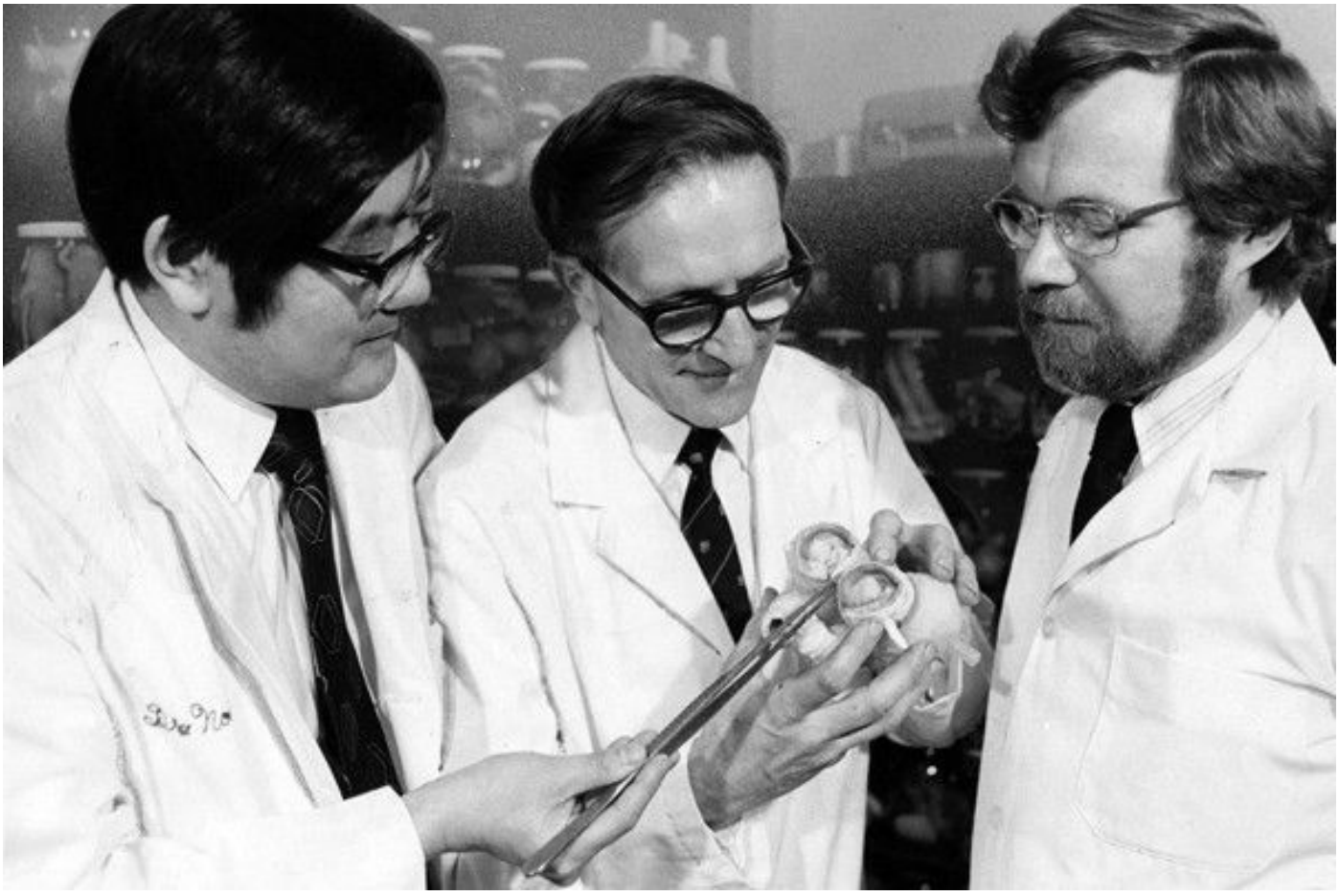
By James Anderson

This brief history of biomaterials research at Case Western Reserve University (CWRU) covers the years from 1962 to the mid-1990s. It is based on the author's best recollection of people and their students who made significant contributions to biomaterials science and engineering over this period of time. The author apologizes in advance for any errors or omissions. As will be seen, many people contributed to biomaterials research over the first 30+ years and not all were from the Case Western Reserve University School of Engineering or the Department of Biomedical Engineering. Even some 60 years ago, collaboration was the name of the game for biomaterials research.

Biomaterials research at the Case Institute of Technology (CIT) began in 1962 when Donald F. Gibbons, PhD, DSc, joined the School of Engineering as Director of the Center for the Study of Materials. Don together with Dave Fleming, Bob Plonsey, Jim Reswick and others worked to develop the Department of Biomedical Engineering (BME) that was formally recognized in 1968. In 1967, I came to CIT for post-doctoral work on metal ion oxidations of organic acids, following my PhD in physical organic chemistry in 1967 from Oregon State University.

In 1969, I joined the Division of Polymer Science to synthesize sequential polyamino acids as collagen and silk models. By 1970, I was also developing anesthetic-loaded silicon rubber nerve cuffs, steroid-loaded pHEMA and polymers for enhanced cell culture for use by colleagues in the Department of Anatomy for nerve blockers, developmental biology and chromosomal defect studies, respectively. In the early 1970s, Don and I developed a course entitled "Polymers in Medicine" for the Biomedical Engineering curriculum.

By 1970, Don had developed interactions with colleagues in our Medical School, Dental School, VA Hospital, University Hospitals of Cleveland, the Cleveland Clinic, and St. Lukes Hospital. At this time, Don and I were also attending and presenting at the "Clemson" Meetings, precursor to the formation of the Society For Biomaterials (SFB) in 1974. Don



Yuki Nose, Don Gibbons and Jim Anderson inspecting a Total Artificial Heart.

Biomaterials at CWRU: The First 30+ Years (Continued)

and I were considered founding members of SFB. My original work on the synthetic scaleup of random copolymers of amino acids eventuated in a large NIH funded Program Project.focused on the synthesis, characterization, and evaluation of random copolypeptides as biomedical polymers. This Program Project involved faculty in the Departments of Polymer Science, Anne Hiltner, Alan Walton, Eric Baer; Biomedical Engineering, Don Gibbons; Pathology, Jack Carter, Bob Martin, Oscar Sudilovsky, Om Malhotra and Bob Cook; Medicine-Hematology, Oscar Ratnoff and Dale Cowan; and Cellular and Molecular Biology, Lloyd Culp; at CWRU and University Hospitals. Students involved included Sumner Barenberg (with Phil Geil) and Carl McMillan and Don Solomon (with Alan Walton). Sumner Barenberg also collaborated with scientists at the Cleveland Clinic.

Over the 1970s Don Gibbons had a superb group of BME graduate students including Craig van Kampen, George Picha, Patrick Parks, Mike Helmus, Jonathan Rosen, S. Ray Taylor and Jean Goggins. Don and his students had strong collaborations with the Cleveland Clinic (Yuki Nose), St. Luke's Hospital (Richard Jones) and NASA Glenn Research Center (Bruce Banks). Don and his students carried out research studies in blood/material and tissue/material interactions. In 1981, George Winter, a principle scientist at 3M, passed away suddenly, creating an open position in biomaterials biocompatibility that Don Gibbons took in 1984. CWRU lost an outstanding teacher, mentor and scientist when Don moved to St. Paul, Minnesota.

For a young guy just getting started, the "Clemson" Meetings were phenomenal; the opportunity to interact and receive encouragement from individuals such as Sam Hulbert, Bill Hall, Larry Hench, Adam Weslowski, John Autian, Bob Leininger, Fred Leonard, Leo Vroman, Tom Salthouse, Allan Hoffman, Jonathan Black and many others was priceless. I also met future collaborators such as Bob Langer, Jan Feijen, and Sung Wan Kim at these meetings. In 1970-71, I was exploring other opportunities and had job offers from the E.I duPont Central Research Department and the School of Engineering at the University of Florida (Larry Hench's Department); I elected to go to medical school at Case Western Reserve in 1972 and that added another seven years (four years medical school and three years pathology residency) onto my educational experience.

From 1969 to 1979, I was a Senior Research Associate and not able to have graduate students. My research efforts were carried out with dedicated undergraduate students and postdoctoral associates who wanted an experience in biomedical polymers. In 1979 I finally became an Assistant Professor at the age of 39 and was able to be the Research Advisor for graduate students from the Departments of Biomedical Engineering, Macromolecular Science, and Pathology. At this time, I had been looking at the human tissue responses to retrieved implants as a Surgical Pathologist. The common finding of the foreign body reaction at retrieved implant surfaces formed the basis of our subsequent research as well as an internal implant retrieval and evaluation program that I carried out for over 30 years with over 20,000 implants.

By 1979, my research group had expanded to include my first graduate students; Larry Olanoff (MD/PhD), Roger Marchant (PhD) and Kandace Kottke (MD/PhD). Larry's research focused on Drug-Polymer sustained release systems, Roger developed in vitro and in vivo biocompatibility tests and the cage implant system, and Kandace worked on blood/material interactions utilizing human blood. In Kandace's research on the in vitro complement and platelet interactions with clinically relevant biomedical polymers, we used human blood. The utilization of human blood and its cellular components in our research was to be a constant theme for over 30 years. The reasons for the use of human material, when possible, was simple. We are developing biomaterials, medical devices and prostheses for human use, why not use human material as it is most relevant. Human diagnostic assays such as PF-4 and Beta-TG for platelets and complement component assays were being developed and were available; similar assays for animal blood and its components were not available. This theme carried over to our extensive in vitro cell culture work on monocyte/macrophage/foreign body giant cell interactions in the tissue response continuum. As monocytes are the first blood-bourne cells to interact with biomaterials in vivo, why not isolate and use these cells in cell cultures on different biomaterials. Underlying this concept is a more profound question relating to the origin and use of different cells in cell culture. In the 1980s, as it is today, studies commonly use so-called rodent "macrophage" immortalized cell lines derived from various tumors, for example, the RAW 264.7 cell line. The RAW 264.7 cell line is derived from a mouse transformed lymphoma. What are the genetic and phenotypic similarities and differences between cells derived from a mouse transformed lymphoma and human blood-bourne monocytes that differentiate into macrophages and form foreign body giant cells on biomaterial surfaces? As we did not and do not know the answer to this question, we have always elected to use human blood and human cells in our studies.

Larry, Roger and Kandace taught me a very important lesson in guiding and mentoring students, that is, "get out of the way and let me do my thing." That advice proved invaluable to me for the next 35 years. Roger and Kandace were married in 1981 and continued their PhD research without interruption, a measure of their commitment to their education and future.

Biomaterials at CWRU: The First 30+ Years (Continued)

In his PhD research, Roger and I developed the in vivo cage implant system which enabled us to quantitatively evaluate the cellular and humoral responses in the in vivo inflammatory, foreign body reaction and wound healing responses to biomaterials. The cage implant system was subsequently used by my students for over 30 years to investigate the time-dependent monocyte/macrophage/lymphocyte/foreign body giant cell interactions (the tissue-response continuum) at polymer surfaces.

The exceptional productivity of Roger, Kandace and Larry enabled me to become a full professor in 1984. Roger joined the Department of Biomedical Engineering in 1988 and developed biomaterial research programs in the development and characterization of plasma-polymerized biomedical polymer surfaces and blood compatible surfaces for cardiovascular devices. In 1990, Roger founded the Center for Cardiovascular Biomaterials and Roger, Kandace and I were able to obtain $1.2 million dollars from the Ohio Board of Regents Fund for equipment for the Center. I was able to obtain a confocal microscope for immunofluorescence studies of surface adherent macrophages and foreign body giant cells on different polymers and substrates. Roger obtained an Atomic Force Microscope and a FTIR for surface analysis of modified biomedical polymers.

In 1980, I became a member of the NIH Surgery and Bioengineering Study Section under the NHLBI, at that time the only study section reviewing biomaterials grants. I was only an assistant professor at that time but the combination of pathology and polymer science was unique and provided this opportunity. This was an exceptional opportunity to interact with surgeons who utilized medical devices and prostheses in their daily clinical practice as well as engineers who were developing new devices and prostheses.

In the early 1980s, Tom Hering and I investigated the healing response to human vascular grafts in an effort to understand why human vascular grafts do not endothelialize but yet remain relatively non-thrombogenic. While this question is still an enigma today, it appears that there is insufficient deposition of circulating human stem cells for the development of an endothelial surface on the collagen deposited in the healing response of human vascular grafts. Ernesto Castillo, under the direction of Jack Koenig (Polymers) and myself, carried out FTIR studies on the fouling mechanisms of soft contact lenses and hydrogels.

In 1984, Katherine Merritt (immune reactions to metallic implants) and Stanley Brown (corrosion and failure mechanisms of orthopedic implants) joined the faculty of BME; they subsequently moved to the CDRH division of the Food and Drug Administration (FDA) in 1994. Kristine Kieswetter and Jill Kawalic were BME students with Drs. Merritt and Brown. In the 1980s, collaborative biomaterials research was also being carried out by other researchers in the Chemistry, Microbiology and Materials Science Departments at CWRU. Chaim Sukenik in Chemistry, an early pioneer in the development of self-assembled monolayer surface modification of polymers, metals, and ceramics, collaborated with Lloyd Culp, Microbiology, to determine cell-type-specific adhesion mechanisms at surface-modified polymers; Kathleen Merritt, BME, surface modification of titanium implants; Arthur Heuer, Materials, surface modification of ceramic biomaterials; and Jim Zull, Biology, biosensors. These collaborations were focused on the identification of different cellular adhesion mechanisms controlled by protein deposition, fibronectin in particular, to different surface chemistries and the development of anti-fouling surfaces.

In the early 1990s, Kaz Yamaguchi and I carried out in vivo studies on the biodegradation of poly(lactic-glycolic acid) beads and microcapsules. Kaz Yamaguchi's work is still cited today in drug delivery system applications to the FDA as well as other original research papers. Kaz's work provided the foundation for the review article on PLA and PGA by Matt Shive and myself, which was published in 1997 and again in 2012 as one of the most cited papers in *Advanced Drug Delivery Reviews*. In the early 1990s, I developed a productive collaboration with Robert Gurny and his students at the University of Geneva, Switzerland. This collaboration focused on biocompatibility studies of biodegradable drug delivery systems.

In the mid-1980s, Kathleen Miller and Tracey Bonfield joined my research group and studied the response of activated human monocytes and macrophages on various polymer surfaces.

At the same time, we began investigating the possible biodegradation of polyurethanes utilized in medical devices clinically. Beginning in 1980, our collaboration with Nick Ziats and Oscar Ratnoff focused on the adsorption of blood proteins on polymer surfaces. We were the first to clearly identify the adsorption of Hageman Factor (FXII), the first reaction in the intrinsic coagulation pathway, from human blood on ePTFE surfaces in 1990. Our studies on the biocompatibility and potential biodegradation of polyurethanes was a project that continued for over 30 years. We had collaborations with scientists and engineers at Medtronic (Ken Stokes, Art Coury, Pat and Linda Cahalan, Rick McVenes, Peter Urbansky Mike Ebert and Mike Wolf), E.I. duPont de Nemours (Gary Lodoen and Bob Payet) and Polymer Technology Group (Bob Ward and Kathy White). Students who worked with myself and Anne Hiltner in

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Polymer Science on various projects related to the foreign body reaction and polyurethane degradation included Hugh Q. Zhao, Y. Wu, C. Selletti, Mike Brunstedt, Mark Schubert, W. John Kao, Terry Collier, Michael Wiggins and Elizabeth Cosgriff-Hernandez.

Hugh Zhao, in a series of papers, identified and characterized the macrophage and FBGC mediated oxidative chain cleavage of poly(ether urethanes) (PEUUs) as the principle mechanism of biodegradation of these types of polymers. Y. Wu and Carlo Selletti confirmed these findings with excellent ATR-FTIR depth profiling studies of biodegraded PEUUs. Mike Brunstedt and Mark Schubert continued the PEUU studies with duPont's Lycra-Spandex PEUU and various anti-oxidants and their various effects on in vitro and in vivo biodegradation. It should be noted that J&J Ethicon's "Biomer" PEUU was a "cleaned up" version of duPont's Lycra-Spandex PEUU. In 1993, Hugh Zhao and Amy McNally identified the adsorbed blood protein alpha-2 macroglobulin as a co-catalyst in the free radical oxidative degradation of PEUUs.

Amy McNally developed our in vitro human monocyte Interleukin-4 mediated cell culture system for studying the temporal sequence of human monocyte to macrophage to foreign body giant cell differentiation and fusion in the early 1990s. Further studies by Amy McNally and Kristin Defife identified the complement mediated adhesion mechanism of human monocytes and macrophages to biomedical polymers and the integrin receptors on macrophages and giant cells that were upregulated with time. Amy also studied the inhibition of foreign body giant cell development on surfaces using agents that pharmacologically inhibited the synthesis of the macrophage mannose receptor as well as antibodies which blocked engagement of the monocyte/macrophage receptor to protein coated biomedical polymers. Kristin Defife further extended our knowledge of macrophage fusion with her studies of IL-13 cytoskeletal and adhesive structural polarization of macrophages and FBGC and the spatial regulation and surface chemistry control of monocyte/macrophage adhesion and FBGC formation. Further studies by Amy McNally identified the time dependent Beta1 and Beta2 integrin receptors and their alpha subunit partners during macrophage adhesion and fusion. Utilizing polymer surfaces provided by Taki Matsuda, Osaka University, Japan, Jacqueline Jones studied the time dependent phenotypic expression of cytokines and other biomarkers from macrophages and FBGCs in vitro.

Biomaterials research activity expanded in BME with the addition of Roger Marchant in 1988. Roger's productivity is best exemplified by the fact that he achieved full professorship with tenure in 1998, only 10 years after joining BME. Roger's early research interests were directed to molecular scale imaging and nanoscale measurements of plasma protein and vascular cells on biomaterials, design and engineering of biomimetic materials, interfacial studies at the molecular and cellular levels, and cell-responsive surface coatings and hydrogel polymers for vascular tissue engineering. Roger's most significant collaborator was his wife, Kandace Kottke-Marchant, MD, PhD, who was an outstanding hematopathologist in the Department of Pathology and Laboratory Medicine at the Cleveland Clinic. Kandace would go on to become Chairperson of that Department from 2007 to 2017. Roger's students over the early period included Chris Siedlecki, Mike Danilich, S. Yuan, I-wen Wang, Julie Higashi, Nolan Holland, Robert Tucker and Mark Ruegsegger.

Gabriela Voskercian and I, in collaboration with Bob Langer and Michael Cima at MIT, studied the in vitro and in vivo biocompatibility of MEMS micro-reservoir drug delivery devices. The cage implant system proved invaluable in these studies. These studies led to a first-in-man study of a wireless controlled drug delivery microchip. Students who used our in vitro human monocyte/macrophage/FBGC cell culture system and the in vivo cage implant system (rats and mice) for biocompatibility studies also included Mahrokh Dasetan, Karen Spilizewski, Laura Bigby, Rick Huskey, Mary Agger, Ahmad Azeez, Terry Collier, Michael Wiggins, Elizabeth Cosgriff-Hernandez, David Chang and Analiz Rodriquez.

Our studies of blood/bacteria/material interactions were initiated by Mike Brunstedt and further expanded by Suneeti Sapatnekar, Jasmine Patel and Matthew Shive. Roger Marchant's creativity was once again displayed by his development of a spinning disc apparatus with I-wen Wang and Julie Higashi (both MD/PhD students in BME) for the study of material and shear dependent bacteria and blood component adhesion to different materials. This spinning disc apparatus was used extensively by Suneeti Sapatnekar, Jasmine Patel and Matt Shive in our laboratory in collaboration with Roger Marchant and his students. Matt Shive and Bill Brodbeck studied the shear dependent nature of leukocyte apoptosis (programmed cell death) as a mitigating factor in the development of vascular device infections. All of these studies used human blood and its components.

Beyond the late 1990s, we continued our efforts to better understand mechanisms involved in blood/material/bacteria interactions with Jasmine Patel and Matt Shive; different surface chemistries to control the foreign body reaction, Chris Jenney, Jacqueline Jones and Jasmine Patel; and the in vitro and in vivo biodegradation of poly(ether urethanes), Mike Wiggins, Mark Schubert and Elizabeth Cosgriff-Hernandez. Chris Jenney investigated over 20 different silanated glass surfaces with different surface chemistries in our IL-4 monocyte cell culture

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system to better understand adhesion and fusion properties of the respective surfaces.

Our studies of controlling factors in the biodegradation of biomedical polyurethanes continued with the use of an accelerated in vitro system utilizing cobalt ions and hydrogen peroxide to simulate the reactive oxygen free radicals identified from our previous in vivo studies, and the reactivity of poly(carbonate urethanes) and various end-group modified poly(ether urethanes) and poly(carbonate urethanes). Mike Wiggins studied the effect of fatigue and novel anti-oxidants on the in vitro and in vivo biodegradation of polyurethanes. Elizabeth Cosgriff-Hernandez investigated modulation of polyurethane biodegradation by the use of polycarbonate soft segments and the capping of polyurethane chain end groups with various non-reactive oligomers. These studies utilized both ATR-FTIR and SEM to identify distinct changes in the surface chemistry and structure of various polyurethanes.

After 2000, our focus on the cellular components of the transient in vivo inflammatory response involved in the foreign body reaction turned to the study of possible involvement of lymphocytes. Utilizing our different in vitro and in vivo systems, Amy McNally, Analiz Rodriquez and David Chang carried out these investigations. Analiz Rodriquez investigated biomedical polymer-dependent macrophage/lymphocyte reactivity and memory and David Chang studied biomaterial surface chemistry modulation of monocyte/lymphocyte interactions. Analiz, in an extensive in vivo study with "knock out" mice, discovered that a normal foreign body reaction with foreign body giant cell formation and fibrous capsule formation was present with SCID(Th1/Th2), Mast Cell, NK, NKT and IL-4alpha deficient mice.

In the mid to late 1990s, biomaterials research in the BME Department was further expanded with the addition of Ravi Bellamkonda in 1995, Steve Eppell in 1997 and Jinming Gao in 1998 (Table 1). J. Lawrence Katz joined BME in 1989 but was actually Dean of Engineering from 1989-2002. Further additions to the biomaterials faculty in BME came later with Horst von Recum in 2005, Eben Alsberg in 2005 and Anirban Sen Gupta in 2006. Unfortunately, BME, CWRU, SFB and the national and international biomaterials community lost an outstanding scientist, collaborator, mentor and teacher with the untimely passing of Roger Marchant in 2014.

Table 1. Transient Biomaterials Faculty in BME at CWRU

Donald F. Gibbons	1962 – 1984	3M
Katherine Merritt	1984 – 1994	FDA
Stanley Brown	1984 – 1994	FDA
J. Lawrence Katz	1989 – 2002	Retired
Ravi Bellamkonda	1995 – 2003	Georgia Tech
Jinming Gao	1998 – 2005	UTexas-Southwestern

The ABC's of Biomaterials Education: Through the Looking BioGlass of Idioms and Analogies – Part 3

By Otto C. Wilson, Jr.
Catholic University of America, Department of Biomedical Engineering, BONE/CRAB Lab

Parts 1 and 2 can be found in Issue 43, Quarter 4 and Issue 44, Quarter 1, respectively.

"AN OUNCE OF PREVENTION IS WORTH A POUND OF CURE" — BENJAMIN FRANKLIN, 1736

While this famous idiom was originally coined to remind the citizens of Philadelphia about fire safety, these wise words have additional value in relation to personal health and worldwide healthcare. It can be much more economically prudent to take precautions to prevent illness rather than treatment. Unfortunately, economic drivers in healthcare dictate that more money is made from treating illnesses rather than prevention. However, we have power to tip the scales to favor prevention of serious medical conditions. This can be accomplished as we develop strategies and education resources to explore and expand the field of Biomaterials Education to encompass the prescient concept of prehabilitation. Instead of retroactively treating preventable medical conditions, why not beat illness to the punch and proactively take preventative measures to stop treatable conditions from spreading before they happen? This gets at the heart of the famous quote "For every thousand striking at the leaves of a problem, there is one striking at the root."

For Part three of this series, I would like to provide a brief introduction to our Biomedical Engineering Department at the Catholic University and highlight the origins of ideas related to prehabilitation engineering. This will serve as an introduction into my personal wake up experience with prehabilitation in terms of diabetes. Diabetes is a surging medical challenge that affects over 20 million US citizens, and over 450 million people worldwide based on World Health Organization (WHO) data (WHO, 2020). WHO has the ambitious goal of halting the rise of diabetes by 2025.

WHEN REHABILITATION MEETS PREHABILITATION

The Biomedical Engineering Department (BE) at the Catholic University of America (CUA) has grown substantially in many areas of academic and scholarly pursuits. BE sprang out of the Mechanical Engineering Department in the early 1990s and was historically built on strengths related to Robotic Assisted Rehabilitation Engineering. This expertise has culminated in the $4.6 Million Rehabilitation Engineering Research Center (RERC)[1] led by Dr. Peter Lum. Dr. Sang Wook Lee and Dr. Lin Chin Chang provide research support on the grant while I help with K-12 education and community outreach. The RERC team includes collaborators from Georgetown University (Dr. Barbara Bregman) and the Children's National Hospital (Dr. Kevin Cleary). Our BE Faculty team has expertise in Tissue Engineering and Biomaterials through the efforts of Dr. Chris Raub and myself. New areas of research include gut microbiome engineering to help develop long term solutions to health challenges related to immune disorders, mental health, athletic performance, and even cancer through tailoring the composition of intestinal flora. Our faculty team is rounded out by Dr. Greg Behrmann who brings a wealth of insight and experience related to biomedical engineering design. Dr. Behrmann has coached our students in developing a host of extremely innovative projects including sports safety devices for prevention of neck injuries in football (please access this address for additional information - https://communications.catholic.edu/news/spotlight/football-helmets.html), devices to help blind athletes run unassisted, physically impaired athletes to golf, and honeybee hive monitoring systems to improve hive health. The BE Faculty at CUA have the privilege of working with some of the brightest students who learn with us as we help them prepare to impact world health in a substantial way through leadership, compassion, empathy, and exemplary ethical character.

We are excited about our future opportunities to continue to serve by addressing health and education needs in our local community and beyond. The three focus areas for our Biomedical Engineering Department are 1) ***Prehabilitation*** — Proactively develop health interventions and a message based on healthy habits and practices to prevent future crises. 2) ***K-16 Education Outreach and Professional Development*** — Building shared partnerships in the DC and neighboring areas to enhance the level of STREAM achievement that we can achieve in all scholars through enriched learning experiences. 3) ***Empathy Training*** — This can be a powerful tool to help enhance our student's passion for addressing the high level of human needs that are expressed in the myriad of challenges that we face. We plan to design and develop safe resources that help our students to understand at a deeper level what it

[1]This work was supported in part by the Department of Health and Human Services (Administration for Community Living, NIDILRR RERC) under Grant 90REGE0004.

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means to have a health challenge through first-hand experience, catalog the process, and then use this experience to gain an unprecedented level of dynamic familiarity with the challenges that they previously learned about in class in a static manner. This directly links with the idiom related to how we do not know a person's challenges and should not unfairly judge until we walk a mile in their shoes. This will be augmented through the integration of real life "temporary handicaps" with virtual reality, augmented and mixed reality (AR, VR) based learning resource tools. As the new BE Department Chair, I see my role as a shepherd to help our team of faculty, staff and students help develop tools and resources related to transform our DC Metro Area, nation and world one heart and mind at a time.

FROM PROCRASTINATION TO PRECRASTINATION TO PREHABILITATION

A more serious obstacle related to prehabilitation recently surfaced for me personally in regards to diabetes. My Father passed away in 2009 due to kidney malfunction from complications due to diabetes, I was well aware that my sweet tooth was a literal Sword of Damocles that precariously dangled above my head on the thinnest of threads. I had been warned on many occasions in life. I remember as a young child being admonished by my Great Aunt Dr. Mariah Vassal to use less sugar on my breakfast cereal to help prevent diabetes later in life because of our family history. I love to bake cakes and cookies and have been doing so since my wonderful Mom showed me how to bake chocolate chip cookies and cakes when I was about 10 years old. These lessons from Mom helped develop my passion for chemistry and feed my sweet tooth. Unfortunately for me, my family members (Daniel, Otto and Debbie) don't eat as many sweets as I do. I often found myself eating the whole cake or batch of cookies myself and used the idiom "Waste not, want not" and "A penny saved is a penny earned" to justify my actions. I needed to exercise moderation and not eat the whole batch of home baked chocolate chip cookies.

Additional warnings came across my path with from good friends Dr. Greg and Marcy Clark. I love fruit juice and love mixing different combinations and enjoying the flavor profiles that develop. I could easily drink a liter or more at a time and I was making a more healthy choice in comparison to sugary soft drinks or alcohol. Greg and Marcy are great advocates for healthy living and they gave me a better framework to think of my fruit juice consumption. They asked me to think about the number of oranges needed to make a liter of orange juice in comparison to the number of oranges you can eat in one sitting. Being an engineer who loves math challenges, I did a little research and was surprised by the results. Depending on the size of the orange, estimates range from 8-16 oranges needed to produce one liter of fresh squeezed orange juice. My ingesting large quantities of fruit juice was spiking my blood sugar levels without the benefits of the fiber.

This summer I experienced my Day of Reckoning and Great Awakening when my sweet-tooth decisions finally caught up with me. While a spoonful of sugar may help the medicine go down as sung by Mary Poppins in the classic movie, I was way past my sugar quota. I noticed a more frequent need to urinate with a peak frequency of every two hours and 3:00 am like clockwork. This made me take pause and consider my sweet tooth more seriously. I invested in a blood glucose monitor. The first numbers that came back were a real wakeup call. To put this in perspective, a normal blood glucose level taken after fasting for eight hours is around 100 mg/dL. Prediabetes is indicated by a fasting blood glucose level of 100-125 mg/dL and above 125 mg/dL indicates diabetes. My first reading was 449 mg/dL. First I was in denial and just knew the instrument was faulty, so I purchased another monitor. The new monitor confirmed my fears and I could no longer ignore the fact that my blood glucose levels were way too high. I needed to take immediate and drastic action by initiating a divorce from sugar by seriously limiting my sugar intake coupled with reinitiating my daily walk habit.

HEALTH IS WEALTH

A number of years ago, my youngest Son Daniel made a statement that shook me to my core like a bowl full of jelly. "Daddy, you have a poochy belly!" These were words that I did not want to hear or admit. In my mind I was still frozen in time in high school but the harsh reality was I was on the wrong side of 40 years and 45 extra pounds. Like the emperor and his "clothes" in the classic children's fable, I was shocked into the truth and forced to take a look at the man in the mirror without my blinders. That statement was a key catalyst that started me on an epic journey to improve my health and fitness through walking. Walking is wonderful and probably the greatest tool in our arsenal for promoting health through prehabilitation. I walked all over DC and MD and cut way down on my commuting costs. I even started to make excuses to walk to places to get in more steps. A few years ago, Terry Shields from our CUA Human Resources Department organized a team based walking competition. Our team from the School of Engineering at CUA placed second to the team from Facilities and Maintenance. We are waiting for the next opportunity for a rematch. I won a fitbit watch for placing second overall and was just shy of reaching a million steps for the two-month time period of the competition. I noticed a great benefit for thinking, strength, stamina, and productivity. I was able to do more with my time even though I was walking a few hours each day. Sadly, my practice of walking was curtailed over the last two years. However, within the last

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month, I have started to get back into this great healthy habit. This is largely in part due to taking daily walks with Rocky, our Border Collie puppy. I get great joy from asking him in the morning, "Do you want to take a walk?" He springs to life with great joy in his eyes when he hears the word "Walk" and he literally bounces off the walls. Most other times, he has selective hearing and only hears what he wants to hear. When we are about to embark on a walking adventure, however, he listens intently and obeys instantly. Figure 1 shows an animated picture of Rocky interacting with our Curious Cat, Busy Bees and Appetizing Apple that were featured in part I of the ABC's of Biomaterials Education Article.

I have been challenging myself to fully experience the health benefits of walking and walk a minimum of 10,000 steps daily. I have noticed that walking is the single most important activity in my personal quest to lower my blood glucose levels. Values are trending downward currently and they are below 200 mg/dL for my daily average. Recently, I passed the 30,000 steps a day threshold and at this level, my blood glucose level reached a low of 116 mg/dL. I am thankful to God that I survived my recent encounter with extremely high blood glucose levels. Each step I take puts me further ahead of the grim reaper. I would like to leave him in the dust and put as much distance between us as possible. In this case, parting is ***not*** such sweet sorrow (Shakespeare pun intended).

BUCKET LIST

After the blood glucose level scare and revelation of diabetes, I am taking a more conscientious view of diet and exercise and I have added one very important goal to my bucket list. I want to run on a relay team with my Sons Otto III and Daniel. I was pretty good as a Track and Field runner in High School in the early 1980s. Otto III and Daniel are phenomenal runners and have far surpassed me on the track. Otto runs the 400-meter dash and the mile relay (4 x 400 m) for the Rochester Institute of Technology (RIT) Track and Field Team while studying Biomedical Engineering. He will finish next year (May, 2023) with his Bachelor of Science and Masters Degree. Daniel runs for Aberdeen High School in MD and is a standout Cross Country and Track and Field Scholar Athlete. He will return this year for his Senior Year after anchoring his two-mile relay team (4 x 800 m) to a second place finish at the Maryland State Track and Field Championship Meet in May 2022 with a school record time of 7:59. Daniel's team qualified to run in the New Balance National Track and Field Championships for the Rising Stars division on June 18, 2022. Unfortunately, Daniel fractured his ankle halfway through the race yet still managed to finish running the anchor leg and placed first in their heat. They were second place overall and broke the school record again with a time of 7:57. He was in a cast all summer but he is recovering well and will be back running in mid-September to catch up on his training.

TEMPUS FUGITS

It is true that time does fly, especially when you are having fun and asking the right questions. It has been a privilege to write this three-part article. It has been a wonderful experience to reflect on the decisions and circumstances that have allowed me to reach this point in my career. I have made a lot of miscalculations and mistakes, but I thank God that I have learned some important lessons from those mistakes. In life, we all make mistakes and it is an important part of the learning process. Just don't keep making the same mistake and learn as much as you can from the adventure. My next big adventure involves how to reverse procrastination and convert it to "precrastination" and get my work done consistently in a timely fashion before it is due. I remember that it did happen at least one time in my life. The research paper that I wrote for Dr. George Sigel's class on the topic of Bioglass (highlighted in Q1 2022 *Biomaterials Forum*) that paved the way for a fascinating career was actually completed before it was due. I do believe that the lighting of inspiration can strike twice in the same place, so I look forward to connecting prehabilitation with precrastination and seeing where it can lead in enhancing health, learning and inspiration for our current and future biomaterials education scholars.

Figure 1. A cartoon version of Rocky, our family Border Collie interacting with our Curious Cat, Busy Bees, and an Adorably Appetizing Apple before embarking on a walking adventure with me. (illustration created by Mary Luongo Weyrick)

Industry News

By Gopinath Mani, Industry News Editor

Immunicom, Inc., a privately held clinical-stage biotechnology company with a transformative immuno-oncology platform, has been awarded $2 million by the National Cancer Institute (NCI) and National Institutes of Health (NIH) to initiate its first US-based clinical trial at the Baylor College of Medicine in Houston, Texas.[1] The trial will evaluate the safety, tolerability, and efficacy of the Food and Drug Administration (FDA) Breakthrough Immunopheresis® LW-02 Molecular Ligand-Capture Column for treating refractory, **hormone-resistant breast cancers**.[1] Immunicom employs a proprietary, high-affinity, molecular capture-ligand binding matrix within the LW-02 Column to remove specific cytokine receptors, soluble TNF-Receptors 1 and 2 (sTNFR-1/2), that are shed by cancer cells into the extracellular tumor microenvironment.[1] sTNF-Rs serve as decoys, binding to tumor necrosis factor alpha (TNF-α) before it can bind to its membrane-embedded sTNF-R receptors to trigger several cell death pathways, as well as modulate antitumor cytotoxic T-cells and macrophage activity.[1] The selective removal of decoy sTNF-Rs by the LW-02 Column allows the patient's immune system to identify and aggressively attack the cancer.[1] **Immunopheresis**, like dialysis, is a subtractive therapy that occurs outside the body, in contrast to conventional drugs and biologics that are infused into the patient.[1] Immunopheresis is thus intended to be much better tolerated than chemo- and immunotherapies, allowing for its use as an adjunct with these therapies, possibly in lower doses to reduce their toxicity.[1] The Immunopheresis platform is a targeted removal therapy that can selectively remove any soluble factor.[1] Immunicom has multiple cytokine and soluble targets under development, including IL-6, VEGF, IL-1 beta, and soluble PD-L1, with others to follow.[1]

Palette Life Sciences, a global life sciences company, recently announced the U.S. Food and Drug Administration (FDA) 510(k) clearance of Barrigel®, the **hyaluronic acid rectal spacer** that separates the prostate from the rectum to protect it during radiation therapy treatment for **prostate cancer**.[2] The Barrigel clearance is based on the data from the FDA-reviewed randomized controlled trial using hypofractionated radiotherapy for treating prostate cancer with a rectal spacer.[2] Barrigel is indicated for prostate cancer patients with T1-T3b disease.[2] Barrigel is made from Non-Animal Stabilized Hyaluronic Acid (NASHA®).[2] NASHA has a long history of safety, efficacy and biocompatibility in a wide variety of medical applications, including pediatrics.[2] NASHA can withstand high levels of radiation without any compromise to its functional capabilities.[2] Further, NASHA will decompose and disappear in a natural way following radiation therapy.[2] Barrigel has previously been approved for rectal spacing in Australia and Europe and is being developed for future market introduction in Japan.[2]

Eliaz Therapeutics Inc (ETI), a therapeutic apheresis company, was awarded its second NIH grant, an SBIR phase 2 grant for $1.7 million.[3] ETI has developed a unique, patented medical device to remove Galectin-3 (Gal-3) from human blood.[3] XGAL3® removes both bound and free Gal-3 from circulation, offering new and effective treatment options for life threatening common conditions where viable treatments are currently not available.[3] The initial focus of ETI is on **sepsis and sepsis-induced acute kidney injury** (S-AKI).[3] Despite extensive efforts to develop effective treatments, sepsis remains the leading cause of death in intensive care units (ICUs) worldwide.[3] Sepsis is often complicated by S-AKI.[3] Sepsis and S-AKI are associated with significant morbidity and mortality.[3] In a series of separate studies, Gal-3 was identified as a biomarker and therapeutic target for sepsis and acute kidney injury (AKI), thus offering a novel approach to treating the two leading causes of ICU death.[3] Gal-3 inhibition was shown to reduce inflammation and protect kidneys from the development of fibrosis.[3] Gal-3 depletion by an extracorporeal apheresis treatment is hypothesized to have a combined therapeutic effect for sepsis and S-AKI.[3] By attenuating the inflammatory response, it protects against immune dysregulation, organ dysfunction, kidney injury and renal fibrosis.[3] **Apheresis** is a well-established procedure that has been in use for decades.[3] Therapeutic apheresis involves removing the patient's blood and separating from it the plasma.[3] The plasma is then run through different filtration columns and unwanted compounds are removed, while the remaining blood components, including filtered plasma and blood cells, are reintroduced back into the patient's bloodstream.[3] The award will enable ETI to continue developing its XGAL3® device, establish its biocompatibility, and conduct a regulatory compliant large animal safety trial.[3]

Spectral Medical Inc., a late-stage theranostic company, recently announced that the FDA has granted Breakthrough Device designation for the Company's Toraymyxin™ ("PMX") device, a therapeutic **hemoperfusion device** that removes endotoxin, which can cause **septic shock**.[4] The Breakthrough Devices Program was established to expedite the development and prioritize the review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.[4] This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.[4]

SoniVie, a company developing a novel proprietary Therapeutic Intra-Vascular Ultrasound System (TIVUS™) to treat a variety of hypertensive disorders, recently announced that the U.S FDA granted IDE approval for its «REDUCED1» Pilot study to treat **Resistant Hypertension** Patients with **Renal Artery Denervation** using TIVUS™.[5] Renal Denervation using TIVUS™ is a minimally invasive procedure that uses high-frequency non-focused Ultra-Sound energy to ablate nerves in the renal artery.[5] This causes a reduction in the nerve activity, which may decrease

Industry News (continued)

blood pressure.[5] This procedure is designed for patients who suffer from resistant hypertension, which is defined as the blood pressure higher than 140/90 mmHg despite the use of three antihypertensive medications of different classes at the best tolerated doses, one of which must be a diuretic.[5] Millions of people world-wide suffer from resistant hypertension which substantially increases the risk of heart attack, stroke and kidney failure.[5]

Apyx Medical Corporation, a maker of medical devices and supplies and the developer of Helium Plasma Technology, marketed and sold as Renuvion® and J-Plasma® in surgical markets, recently announced that it has received 510(k) clearance from the FDA for the use of the Renuvion Dermal Handpiece for specific **dermal resurfacing procedures**.[6] The Renuvion Dermal Handpiece is indicated for dermatological procedures for the treatment of moderate to severe wrinkles and rhytids, limited to patients with Fitzpatrick skin types I, II or III.[6]

VenoStent, Inc., a clinical-stage tissue engineering company developing **bioabsorbable perivascular wraps**, recently announced that the Center for Devices and Radiological Health (CDRH) at the **FDA** has granted its novel technology, the SelfWrap® Bioabsorbable Perivascular Wrap, Breakthrough Device Designation (BDD).[7] For millions of patients every year, **vein grafting** offers the best opportunity for survival.[7] These procedures, such as arteriovenous fistula (AVF) creation and coronary artery bypass grafting (CABG), use a vein as a replacement artery.[7] Unfortunately, as veins are not built like arteries, these surgeries can have extremely high failure rates — some more than 50% — greatly increasing morbidity and mortality.[7] VenoStent's device, SelfWrap, is a macroporous, bioabsorbable polymer wrap that provides scaffolding for these veins, helping them to arterialize and potentially saving thousands of lives in the process.[7] This BDD is an official recognition from the FDA that the SelfWrap technology may provide for more effective treatment of a life-threatening or irreversibly debilitating human disease or condition, with no approved or cleared alternative available to patients.[7]

Accelus, a medical technology company, recently announced that it has received 510(k) clearance from the FDA for its FlareHawk TiHawk™11 Interbody Fusion System.[8] TiHawk11 is the latest addition to Accelus's flagship FlareHawk® portfolio of **spinal fusion cages**, which are now available in a larger footprint with titanium at the bony interface.[8] TiHawk11 cages are manufactured using an innovative titanium and PEEK bonding process that deposits a uniform, 0.5-micron-thick layer of titanium at the bonding interface.[8] This provides strong adhesion between the PEEK and titanium without the loss of fluoroscopic visualization often associated with titanium implants.[8] The combination of PEEK and titanium may also permit a modulus more similar to bone.[8] TiHawk11 features an 11mm-wide insertion profile and expands to 17mm in width and 14mm in height, providing 70% more footprint than a 10mm-wide interbody device of identical length.[8] This larger interbody footprint is designed to increase stability and provide the ability to post-pack bone graft after expanding to increase graft volume.[8]

Invictus Sterilization LLC., a provider of Hospital-Grade UV-C based surface and air sterilization products, recently announced today that the FDA cleared its Aura Storm as a Class II ultraviolet medical **air purifier**.[9] The Aura Storm air purifier is a free standing, air purification device utilizing ultraviolet light and a multi-stage filtration system for the inactivation of bacteria and viruses in hospitals and other medical related facilities.[9] With this clearance, the Aura Storm will now be offered as a medical device to hospitals, nursing homes, hospice facilities, and other medical and dental offices to mitigate risks associated with airborne threats such as the coronavirus, monkeypox, and HAI (Hospital Acquired Infections).[9] Invictus utilizes its expertise to develop comprehensive hospital-grade UV-C solutions for a wide array of environments to capture and kill dangerous microorganisms (including COVID-19) without producing harmful residue.[9]

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Government News

ADVANCED REGENERATIVE MANUFACTURING INSTITUTE (ARMI)

By Carl Simon, Government News Editor

ARMI is a non-profit research institute that was started in 2017 with $80 million in seed money from Department of Defense. ARMI's goal is to develop next-generation manufacturing techniques for repairing and replacing cells, tissues and organs. ARMI is located in Manchester, New Hampshire and is directed by Dean Kamen, the inventor of the insulin pump and the Segway (two-wheeled self-balancing personal transporter. ARMI currently has 179 member organizations and hundreds of millions of dollars in matching industry funds that are being using to reach its goals.

ARMI has an intramural research program where they built a prototype closed and automated manufacturing line that is called the "Tissue Foundry" (Figure 1). The Tissue Foundry sits on a 20-foot benchtop and a vial of frozen mesenchymal stem cells goes in one end and ten ligament tissue constructs emerge from the other end. One of the main obstacles in building the foundry was getting the separate unit manufacturing components to work with one another. Due to the success and impact of the ligament Tissue Foundry, five more foundries are being planned: islets, skin, retina, muscle and bone.

ARMI built a Deep Tissue Characterization Center (DTCC) to link multiomics approaches, including metabolome, proteome and lipidome, with product quality attributes. The DTCC is lead by Maciej Kukula. One of the aims is to use spent medium as a way to compare quality of manually fabricated tissues to tissues fabricated by automated approaches. Another goal is to link omics results to clinical outcomes. The overall goals of the DTCC are to identify steps in a manufacturing process that need to be controlled and to shed light on what needs to be measured and when it should be measured.

ARMI has a regulatory consulting arm that is lead by ARMI's Chief Regulatory Officer, Richard McFarland, who worked 16 years in FDA's Center for Biologics Evaluation and Research (CBER). They offer a two-day "Regulatory Bootcamp" that is a course for learning the basics of regulatory science for tissue engineered medical devices. They also offer one-on-one regulatory consulting services for ARMI members.

ARMI funds many extramural research projects, a few of which will be highlighted. One is a project lead by Advanced Solutions to automate fabrication of a 1 cm-thick 3D human liver model that includes built-in vascularization.[1] Another is a design of experiment approach from Trailhead Biosystems to improve pluripotent stem cell manufacturing where multiple developmental signalling pathways were probed in a combinatorial fashion to identify better temporal combinations of differentiation factors.[2] A final highlight is a project on flexible manufacturing where computer models are being developed to adapt the manufacturing process to the variable attributes of the input patient cells.

ARMI hosts public meetings on their campus several times per year, which are called the "Meeting in the Millyard," and the next one is October 25-27, 2022.

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Contact: Carl Simon, carl.simon@nist.gov

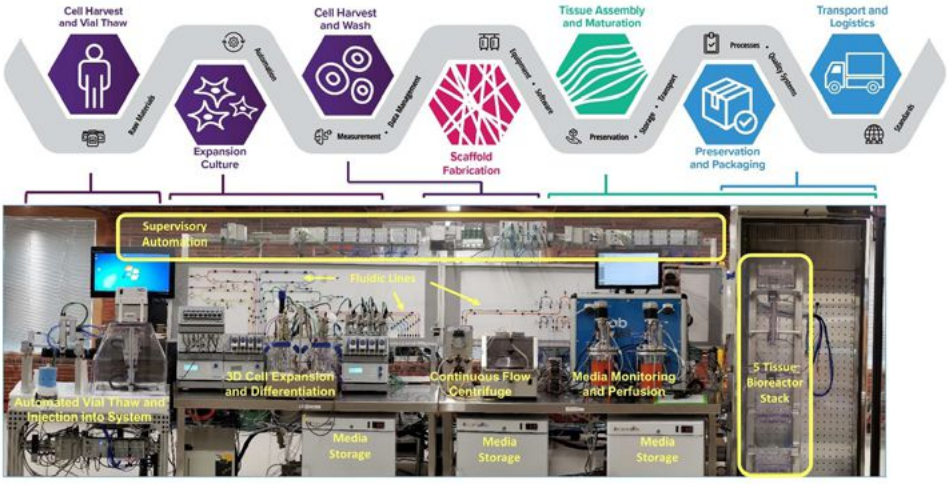

Figure 1. ARMI|BioFabUSA tissue foundry that was designed for closed and automated ligament manufacturing. (Used with permission of ARMI|BioFabUSA)

AIMBE News

By Karen J.L. Burg, PhD and Anirban Sen Gupta, PhD

STRENGTHENING US COMPETITIVENESS AND INNOVATION

AIMBE, along with many leading science, engineering and higher education groups has long supported HR 4521, the America Creating Opportunities for Manufacturing, Pre-Eminence in Technology and Economic Strength, commonly known as COMPETES Act and approved by the House of Representatives in June. A similar proposal called the US Innovation and Competition Act, S. 1260, was recently approved by the US Senate. Both measures strengthen the nation's competitive advances in science and innovation and are very similar, but now require a Conference Committee to resolve minor differences. Key among the areas of agreement is language that creates a new Directorate at NSF to fund research aimed at specific competitive goals, increased funding authorization for NSF, the creation of a network of regional tech hubs, the establishments of a National Engineering Biology Research Development Institute to build a diverse bio-workforce, and strategies to expand STEM research Fellowships and traineeship grants. Like many important issues that require increased focus by Members of Congress it is likely the differences might not get resolved until the closing hours of this Congress later this fall.

SLOW BUT STEADY PROGRESS FOR ARPA-H

Congress has taken another step to establish the Advanced Research Projects Agency for Health (ARPA-H), a key priority for the Biden Administration. However, legislation advanced in the House of Representatives establishes the new agency in HHS and not under the umbrella of the NIH where Biden had proposed the new initiative. Many in Congress felt the new agency needed greater independence and an independent vision more along the line of DARPA at the Department of Defense, from those of other institutes at NIH. AIMBE has supported creation of ARPA-H and focused its advocacy efforts on how the new agency would be funded. AIMBE urged Congress to establish the agency with new funding and not borrow funding from existing medical and biological research funding programs.

NEW FISCAL YEAR ALWAYS BEGINS OCTOBER 1

While it comes as no surprise to Members of Congress the government's fiscal year begins October 1, seldom in the last 20 years has Congress passed all 12 spending bills on time. With the summer recess around the corner and fall Congressional elections in November, there remain very few legislative days left to finish all budget measures before the start of the new fiscal year. Before their recess for the July 4 district work sessions, the House Appropriation Committee finished work on, and passed, the last of the 12 appropriations measures. AIMBE took strong positions urging Congress to dramatically increase funding for the NIH. The House spending bills coming out of committee increased funding for NIH to $47.5 billion, an increase of 6% over current year appropriations. Similarly, the House has approved a 9% increase for NSF to $9.6 billion. These strong increases are being challenged in the Senate where AIMBE and other national science and biomedical advocacy groups now turn their focus.

Student Chapter News

By David Eduardo Flores-Prieto, National Student Chapter President

Greetings SFB student members and all! It is my honor to introduce you to the 2022-2023 National Student Chapter Officers:

PRESIDENT: David Eduardo Flores-Prieto, Arizona State University

PRESIDENT-ELECT: Grant Scull, UNC-Chapel Hill and NC State University

SECRETARY/TREASURER: Nicholas Fischer, DDS/PhD, University of Minnesota

SECRETARY/TREASURER-ELECT: Arian Veyssi, the University of Texas at Austin

BYLAWS CHAIR: Amberlyn Simmons, Arizona State University

We are currently developing a new set of student-focused webinars which you will receive details about shortly. Additionally, we plan to continue offering the 3-Minute Thesis Competition at the 2023 Annual Meeting and hope you will apply. Have any other ideas for us? Please feel free to reach out!

CONNECT WITH US!

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Update from the Engineering Cells & Their Microenvironments (ECTM) SIG

By Silviya P. Zustiak, Biomedical Engineering, Saint Louis University

The Engineering Cells & Their Microenvironments (ECTM) Special Interest Group (SIG) concentrates on technologies and approaches focused at the single cell level and encompassing engineering cell microenvironments, biomaterial-induced cell signaling, stem cell manufacturing and differentiation, immunoengineering, and biomaterials for cell-based detection and diagnosis. The main goals of our SIG are to: 1) engage members at the annual Society For Biomaterials meeting by guiding and sponsoring forums, 2) promote networking through social events held at the annual meeting, and 3) share resources to support students and members. We currently have over 470 members from various academic, industrial, business and government organizations.

The current SIG Officers are Dr. Daniel Alge (Texas A&M) as Chair; Dr. Janet Zoldan (University of Texas, Austin) as Vice-Chair; Dr. Chelsea M. Magin (University of Colorado) as Treasurer and Secretary; Dr. Sara Pedron Haba (University of Illinois Urbana-Champaign) as Program Chair; Dr. Chris Highley (University of Virginia) as Web Contact; Dr. Daniel Harrington (University of Texas Health Science Center at Houston) as Industry Representative; Dr. Silviya Zustiak (Saint Louis University) as Reporter; and Ashley Brown (North Carolina State University) as Past Chair. New initiatives undertaken by the officers over the past year include a virtual summer webinar series focused on trainees (initiated in summer 2022), developing policies for and soliciting industry sponsorships, launching a new Sci-Art competition for trainees in 2021, and growing our social media presence. We have given several Sci-Art awards and the picture from one of our winners — **Taimoor Qazi** (University of Pennsylvania; starting as an Assistant Professor at Purdue University in fall 2022) — was featured on the cover of the *Biomaterials Forum* 2022, first quarter issue. Another winning image by **Pouria Fattahi** (University of Pennsylvania) is shown in Figure 1. Winners of our Sci-Art competition, which was generously sponsored by Ronawk, received canvas prints of their images. The competition will continue this year, so trainees interested in submitting scientific images for the Sci-Art competition should email Daniel Alge at dalge@tamu.edu.

Figure 1. Secretory organelles garden: Ultrastructural analysis using transmission electron microscopy reveals the presence of lamellar body-like inclusions in iPSC-derived alveolospheres.

The ECTM SIG sponsored or co-sponsored 17 symposiums and sessions at the 2022 Society for Biomaterials Annual Meeting on diverse topics such as tumor models for drug screening and diagnostics, the lung microenvironment, and biomaterials for neural applications. This was the first in-person meeting after two long years of the COVID-19 pandemic and we saw excellent attendance in all sessions. Our officers and members were actively engaged in organizing and chairing the SIG-sponsored sessions or presenting podium or poster presentations. Two of our SIG member trainees received STAR awards — **Saurdeep Sinha** and **Mohammadjafar Hashemi** for their submissions, and three members received an honorable mention — **Tracy Chung, Liana Kramer** and **Mona Mansouri**. In addition, **Suting Cai** and **Vanessa Doulames** received best oral presentation awards while **Indranil Joshi**, **Xuelin Wang** and **Raven El Khoury** received best poster presentation awards for the work they presented at the conference. These awards were also sponsored by Ronawk.

In other SIG news, multiple SIG members were recently honored with prestigious awards and fellowships for their contributions to science.

- **Brendan Harley**, a Robert W. Schaefer Professor of Bioengineering at the University of Illinois Urbana-Champaign, was elected as a 2021 Fellow of the Biomedical Engineering Society and has recently taken a leadership role as Program Leader for the Cancer Center at Illinois.

Continued on page 26

Ethics for Bioengineering Scientists – Treating Data as Clients

By Howard Winet, Ph.D.

CRC Press: Taylor & Francis Group, 2022
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978-1-032-05354-7 (paperback)
978-1-003-19721-8 (ebook)

"Bioengineers … handle nothing more important than data produced by scientific research" (xix). The central message of this text is that our handling of data is "owed care equivalent to biological subjects" (xix). As expressed in the subtitle, we must treat the data as clients. Bioengineers may be responsible *for* the data; we are always responsible *to* the data.

Howard Winet has written an interesting book that can be used as a textbook for an introductory course in ethics and as a reference book for those with more familiarity with the subject. For students new to the subject, it provides a thorough introduction to ethical thought (without requiring a long slog through 800 pages of moral philosophy), including numerous actual and theoretical case studies, and examples of ethics applied to various subdisciplines within the broader scope of bioengineering. Experienced investigators will also find references to resources for further exploration, and useful information about ethical aspects of animal and human subject research, the Food and Drug Administration (FDA) and the handling of academic misconduct.

The first section of the book begins with an introduction to the development of bioengineering as a data-based discipline and contrasts this with the subjectivity that is inherent in morality and philosophy. Subsequent chapters discuss five significant moral theories and the process of moral analysis. Utilitarianism, Deontological Theory, Contractarian Values, Virtue Ethics and Feminist Ethics are introduced. The important terms and concepts are succinctly defined and examples throughout the chapters give the reader a chance to see how different moral theories can be applied to the same case study, often resulting in different conclusions. Several cases are presented but not analyzed in the text allowing the reader the opportunity to think through the moral analysis on their own.

The second section of the book deals with professional ethics as distinct from lay ethics and then explores in greater depth engineering ethics (chapter 6), medical ethics (chapter 7) and bioengineering science ethics (chapter 8). The bioengineering science chapter is the most directly applicable to many Society for Biomaterials members and is where the author returns to the central concept that "bioengineering scientists are defined by the integrity of the data they gather."

"THE PRODUCTS OF A SCIENTIST'S WORK ARE THE RESEARCH DATA; THESE ARE ALSO HIS/HER CLIENTS, WHOSE INTEGRITY HE/SHE MUST PRESERVE" (141).

The sanctity of data gathering, data handling, and data reporting are essential to the validity of any conclusions and applications that result from that data. Chapter 8 proceeds to outline the scientific method and presents a "Scientists' Code of Ethics" proposed by Woodward and Goodstein and published in *American Scientist*.[1] This is an excellent general code of conduct applicable to all scientific endeavors. Key aspects of scientific misconduct — fabrication, falsification, plagiarism — are briefly presented followed by a delineation of the types of misconduct that must be explicitly avoided by each of the various groups that participate in the data gathering, review and publication processes. One interesting addition to this is a brief warning about predatory publishers and conference organizers. A few classic scientific misconduct cases are summarized.

The next three chapters focus on research involving non-human animals and human subjects. The animal rights movement and the regulation of animal research are included along with some cases involved in the evolution of the regulations governing research with non-human animal subjects. Chapter 10 focus on some well-known cases of abusive human subject "research." Several Nazi experiments with prisoners, the Japanese army's research on the effectiveness of chemical and biological weaponry on humans, and Tuskegee Syphilis Study conducted in the United States with support of the US Public Health Service are presented. The regulations that were enacted as a result of these, and similar, abuses include the Nuremberg Code, the Helsinki Declaration and Belmont Report. A valuable historical chronology

Ethics for Bioengineering Scientists – Treating Data as Clients (Continued)

of major events in human subject research is presented in Appendix E. This list begins with King George I offering pardons to inmates agreeing to be inoculated with smallpox in 1718 and includes event up to 2003 when the FDA reported that cancer patients at a Veterans Administration Medical Center had been subjected to experimental protocols by an "investigator" who did not have a valid medical license.

Chapters 12 and 13 explore the ethics of medical product development and the ethics of product failure including the role of the FDA and the legal system. A useful summary of medical device classification, the stages of preclinical and clinical trials, and the protections available for intellectual property is given.

In addition to the listing of noteworthy events in the history of human subject research presented in Appendix E, the other appendices offer a suggested format for classroom debates, a sample informed consent document, an advanced health care directive, UCLA's research misconduct policy document, and examples of medical device incident reports.

The text itself is clearly organized and extensively referenced, enhancing its utility as a resource for those wishing to explore a specific subset of its content. The large glossary will be useful to readers new to some of the topics presented. The index is comprehensive will be helpful for those looking for a specific topic.

Winet, an adjunct professor of Orthopaedic Surgery and Bioengineering at UCLA, has developed this book from ten years of experience teaching Bioengineering Ethics. The text can serve as a textbook for an introductory exploration to the discipline or as a useful desk reference for investigators wanting to review or expand their understanding of the concepts covered. This book is does not comprehensively cover the foundations or the practice of bioengineering ethics but serves well as a basis for more in-depth explorations of any of the topics included.

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Update from the Engineering Cells & Their Microenvironments (ECTM) SIG (Continued)

- **Kristi Anseth**, a Distinguished Professor in Chemical and Biological Engineering at the University of Colorado Boulder, was honored with the 2021 American Institute of Chemical Engineers Founder's award for her seminal work in the design of advanced biomaterials, hybrid medical devices, and bionanoscale-based processes.
- **Akhilesh Gaharwar**, an Associate Professor in the Department of Biomedical Engineering at Texas A&M University, was elected to the 2022 Class of the American Institute for Medical and Biological Engineering (AIMBE) College of Fellows for his seminal contributions in designing bio-instructive materials towards regenerative medicine, drug delivery and 3D bioprinting applications.
- **Sarah Stabenfeldt**, an Associate Professor in the School of Biological and Health Systems Engineering at Arizona State University, was elected to the 2022 Class of the AIMBE College of Fellows for outstanding contributions to advancing neural tissue engineering and regenerative medicine, nanoparticle therapeutics, and biomarker discovery for the injured brain.
- **Alison McGuigan**, an Erwin Edward Hart Professor of Chemical Engineering at the University of Toronto, Canada, was elected as a 2022 fellow of the Canadian Academy of Engineering. Dr. McGuigan is a leader in the field of tissue engineering and disease modelling. Her group applies methods from materials and chemical engineering to assemble artificial tissues in a dish to accelerate drug discovery and the development of next-generation regenerative therapies.
- **Scott Wood**, an Assistant Professor in the Department of Nanoscience and Nanoengineering at South Dakota School of Mines and technology received an NSF CAREER Award that was enabled by his work in the development of a micropatterned biomaterial-based scaffold to maintain articular chondrocyte phenotype in vitro.
- **Shantanu Pradhan**, an Assistant Professor at the Department of Biotechnology at IIT Madras, India was awarded the DBT Ramalingaswami Fellowship. This is a fellowship for Indian nationals who have returned to India from abroad to pursue research careers in academic institutions.
- **Ke Huang**, an Assistant Research Professor in the Department of Molecular Biomedical Sciences at North Carolina State University, received an American Heart Association Career Development Award: A Minimal-Invasively Injectable SynCSC Adhesive (MISA) for Aging Rats with Heart Failure.

Above is just a sampling of the many accomplishments of our SIG members, which are too numerous to list in this publication. The ECTM SIG is considering additional ideas to better promote its members and increase their visibility. Those include enhancing the SIG LinkedIn presence, using the SIG Twitter account (@SFB_ECTM_SIG) to follow more members, and holding quarterly industry-sponsored meetings with integrated mentoring and networking activities. We are aiming to build a vibrant and supportive community and we always welcome ideas and engagement from our members.


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