UNCONVENTIONAL BIOMATERIALS

TO IMPROVE HUMAN HEALTH

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

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ALSO INSIDE

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BIOMATERIALS FORUM

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SPECIAL INTEREST GROUP REPORTERS

BioInterfaces	TBD
Biomaterials & Medical Products Commercialization	Subramanian Gunasekaran • guna@encoll.com
Biomaterials Education	Jeremy Mercuri • jmercur@g.clemson.edu
Biomaterial-Tissue Interaction	TBD
Cardiovascular Biomaterials	Astha Khanna • akhanna@gravertech.com
Dental/Craniofacial Biomaterials	TBD
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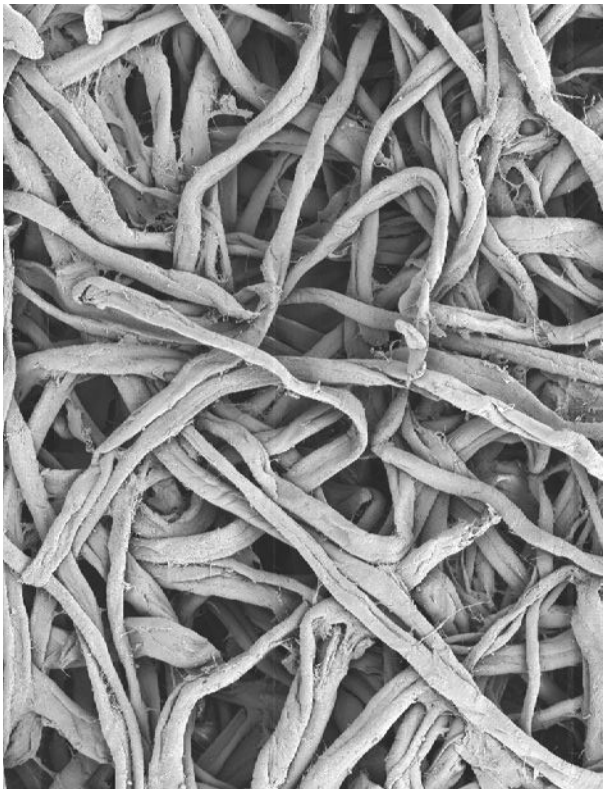
Surface Characterization & Modifications	TBD
Tissue Engineering	Jessica M. Gluck • jmgluck@ncsu.edu

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**.



ON THE COVER

High magnification SEM image illustrates the cellulose fibers in filter paper. Due to its highly porous, tunable and cytocompatible nature, paper can be a suitable biomaterial for culturing cells.

Contents

From the Editor

By Roger Narayan, MD, PhD, Biomaterials Forum Executive Editor

Welcome to the third quarter issue of *Biomaterials Forum*! The feature of this issue is an article from Gulden Camci-Unal on the use of biomaterials such as chicken eggshell microparticles to create tissue scaffolds. The issue also contains a letter from our president, William R. Wagner, on the role of the society in the rapidly changing biomaterials field.

The letter also mentions that the society is seeking greater engagement and representation from clinicians, industry researchers, and government researchers. Natalie Artzi shares member news from Katharina Maisel, Vishal Thomas, and Katelyn Swindle-Reilly. In Industry News, Subramanian Gunasekaran shares information on the approach used to evaluate and code medical devices, including the roles of the Food & Drug Administration and the Center for Medicare and Medicaid Services.

Carl Simon describes the activities of the Roundtable on Biomedical Engineering Materials and Applications (BEMA) initiative of the National Academies of Engineering, Science and Medicine, which provides a venue for topics of national significance involving biomaterials and medical devices such as the use of polyfluoroalkyl substances (PFAS) in medical devices. He also discussed some of the news from the inaugural Gordon Conference on Advanced Cell and Tissue Biomanufacturing. The recent approval of Vowst, a microbial cell therapy to prevent recurrent infections by Clostridioides difficile bacteria, by the US Food & Drug Administration is also described. The approval of Lantidra, a pancreatic islet cell therapy for Type 1 diabetes patients to achieve insulin independence, is also considered.

The issue also features updates from Mary Beth B. Monroe and Grant Scull related to the BioInterfaces SIG and Student Chapter News, respectively. I want to thank the members, society leaders, and staff who supported in the preparation of this issue.

As always, please do not hesitate to contact me at roger_narayan@ncsu.edu if you are interested in sharing articles and news for inclusion in an upcoming issue of Biomaterials Forum.

Yours truly,
Roger Narayan

From the President

By William R. Wagner, PhD, SFB President

Are you a "book person"? Someone who can get lost exploring the stacks of a library or who searches out local bookstores when in a new town? In our professional lives, the need for visiting and exploring libraries has been greatly diminished. We can call up so much of what we need in seconds on our screens. The scientific literature sought is usually fairly recent, and for many journals, scanned archives are available. What's diminished with our powerful electronic interface is the experience of wandering through the archives, pulling out dusty old journal volumes and seeing what was published in that selected time. What perceived problems were being addressed? How was the available technology leveraged?

One of my personal favorites to explore the history of our field is the *Transactions of the American Society for Artificial Internal Organs*, later *ASAIO Journal*, which reaches back to the mid-1950s. There you will find the pioneers of medical devices and biomaterials, and my guess is that you may be amazed at how similar the thinking is with respect to the challenges and needs being addressed. Biomaterials and biocompatibility are at center stage, both opening up new ideas for organ and tissue support and dashing those visions with morbidity and mortality. Our current literature does not quite repeat this history, but it rhymes and samples. So many of our modern tools of inquiry were not available, but most often, one finds those authors making significant insights that helped advance the early versions of today's medical devices.

Moving closer to our present time, the breadth and depth of the literature expands greatly, the tools become more powerful and the rhyming and sampling become more extensive. In teaching a biomaterials class I may pull up a table of contents from a leading biomaterials journal circa 1999. Here, one can look at the abstracts and concluding paragraphs and quickly become cynical — why are the authors' perspectives about the clinical translation of their work so positive, and why did so little of this work actually translate in the next 25 years? We know the major risks: successful preclinical models, navigating the regulatory pathway, manufacturability, sterilization/packaging, compelling business model, clinical adoption, etc.

However, it seems that if the authors had a better understanding of the pathway to the stated application, the report might be better framed in realism. This is not to negate the value of exploratory work, but to emphasize the value in considering how to best position the technology for future translation. And this leads me to our Society for Biomaterials and its mission:

The Society for Biomaterials is a multidisciplinary society of academic, healthcare, governmental and business professionals dedicated to promoting advancements in all aspects of biomaterial science, education and professional standards to enhance human health and quality of life.

Notice that last part about human health and quality of life, and how the opening notes the diverse skill sets we want to engage in our society and its mission. I think it is a fair assessment that our meetings reflect terrific innovation and scientific inquiry. I think it is also fair to say that we could do better in engaging our clinical, industrial and governmental colleagues who represent critical steps towards the patients we want to help. The Society can best accomplish its mission of enhancing human health and quality of life when we have engaged participation across the pathway to the clinic. We have an Industrial Affairs committee that works to engage industry and provide critical industrial perspective in our meetings. We have a Biomaterials and Medical Products Commercialization special interest group focused on translation. You will find in our Biomaterials Forum articles from industry and government views. However, we need more representation and engagement in these areas. I would request that you consider recruiting colleagues, collaborators, consultants to engage with the Society. Many who attended Society meetings as students or fellows, have moved into these targeted areas, but have not continued to participate. We need those voices of the clinic, industry and government to be expanded for our Society to provide greater value to its membership in terms of networking, programming and service.

The mid-20th century pioneers of our field faced a very different pathway to the clinic in terms of economics and regulation. Their efforts are worth uncovering to inspire and guide us. While there are commonalities to appreciate, the landscape beyond the science has evolved tremendously. In today's world the investment and time needed to achieve clinical adoption are great, and safety and efficacy must be rigorously demonstrated at a high level. Our Society's mission demands that we bring together the skillsets required to translate technology with an eye towards the mid-21st century.

Warm regards

Warm regards,
William Wagner, SFB President

Member News

By Natalie Artzi, PhD, SFB Member-at-Large

Katharina Maisel, PhD, Assistant Professor, University of Maryland, Department of Bioengineering, University of Maryland

Dr. Katharina Maisel's lab demonstrated that nanoparticle transport is governed by multiple cellular transport processes and have now developed a simple computational model to extrapolate the dominant pathways.

Vishal Thomas, PhD student, Department of Bioengineering, Clemson University

Mr. Thomas recently authored a review paper, titled "In vitro and in vivo efficacy of naturally derived scaffolds for cartilage repair and regeneration," in the esteemed journal Acta Biomaterialia. At present, he is deeply engaged in the development of an innovative cartilage repair construct utilizing decellularized bovine spinal tissue. His research presentation on this topic earned him the first-place accolade in the 3-Minute Thesis competition (3MT) at the SFB 2023 Annual Meeting and Exposition held in San Diego, California. Furthermore, his paper on this subject is currently under review with the Journal of Biomedical Materials Research Part A, entitled "The Development of a Nucleus Pulposus-Derived Cartilage Analog Scaffold for Chondral Repair and Regeneration."

Beyond his academic pursuits, Mr. Thomas has recently secured five patents in the specialized realm of customized wrist implants, encompassing inventions such as the "Patient-specific carpal implant," "Implant for total wrist replacement," "Prosthetic implant caps," "Intercarpal surgical implant," and "Contralateral image orthopedic implant." Presently, he is diligently working towards their commercialization.

Vishal Thomas (pictured second from left) with other winners and the organizers of the 2023 SFB 3MT competition

Katelyn Swindle-Reilly, PhD, Associate Professor and Innovation Scholar, Biomedical Engineering, Chemical and Biomolecular Engineering, The Ohio State University

Dr. Katelyn Swindle-Reilly, SFB Ophthalmic SIG Chair, has recently received several grants to advance ocular biomaterials research. This includes funding from NEI to evaluate new anti-inflammatory therapeutic strategies to treat dry age-related macular degeneration (AMD), NIBIB to predict and evaluate tunable therapeutic release from a drug delivery capsule, and DOD to evaluate a new therapeutic and delivery system for treatment of vision-threatening ocular injuries.

CALL FOR COVER ART

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Deadline: Accepted on a rolling basis.

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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.

Unconventional Biomaterials to Improve Human Health

By Gulden Camci-Unal, PhD

Envision the challenging task of growing different types of tissues outside the human body. How can one effectively guide and connect the cells to ensure their seamless adhesion and create the desired tissue structure? Tissue engineering and regenerative medicine are making strides in addressing this challenging question and aiding in the improvement of the damaged tissues and organs. Often, we rely on biomaterial scaffolds to guide the tissue growth. However, laborious procedures, meticulous optimization steps, specialized hardware requirements and costly processes are often involved in engineering new biomaterials that can foster the growth of tissue mimetics. Moreover, these procedures frequently use synthetic starting materials that may not necessarily biodegrade.

To address these limitations, materials from nature, everyday life, or even routinely discarded waste items can be utilized (Figure 1, next page).[1,2] We may not have fully realized their biomedical potential because simple and abundant items often go unnoticed and are not thoroughly studied. One of the goals in my lab is to develop multifunctional biomaterials for repairing and regenerating tissues. Given the challenges of fabricating transplantable tissues, one of our strategies involves using naturally derived materials from everyday life. Why do we use this approach? Simply put, we want to make engineering tissues and organs simple, straightforward, sustainable, and inexpensive so that our platforms can be accessible to anyone in the world. Given the potential biological, economic, and environmental benefits, unconventional biomaterials hold great promise across a wide spectrum of applications, from developing personalized disease models to creating implantable scaffolds and targeted delivery approaches. Harnessing unconventional biomaterials with unique properties that are readily available and affordable can help democratize access to scientific advancements worldwide.

An example from our lab is the use of chicken eggshell microparticles to reinforce polymeric materials, such as hydrogels and thermoplastics, in order to fabricate scaffolds for bone repair and regeneration.[3,4] Eggshells contain minerals that are also present in our bones. We have demonstrated that eggshell microparticle-reinforced composites are osteoinductive and improve mechanical properties and bioactivity. They have also been successful in regenerating critical-size bone defects ***in vivo***.[4] Repurposing global waste to create biomedically useful products is a promising approach to also addressing sustainability. Another unconventional biomaterial we work with is paper, which we utilize as a scaffold for cell culture.[5-10] Paper has been used for various applications for about two thousand years, however, it was not until the late 2000s that we began using it for cell cultures. In our lab, we have crafted origami-inspired scaffolds and developed implantable constructs with shape-transforming capabilities as well as multilayered compartmentalized tissue mimetics. Paper is a flexible material that can be easily cut, creased, folded, and manipulated to create three-dimensional (3D) free-standing structures. The resulting scaffolds can be customized in terms of shape, size, and configuration. We also work with plant components to fabricate building blocks for tissue templates. These materials, which are considered unconventional in tissue engineering, are versatile, highly porous and flexible. They can be conveniently modified and tuned to mimic the desired mechanical, chemical or biological properties of the targeted tissue. To address potential limitations with batch-to-batch variations in naturally derived products, the source will need to be closely monitored and controlled.

Unconventional Biomaterials to Improve Human Health (Continued)

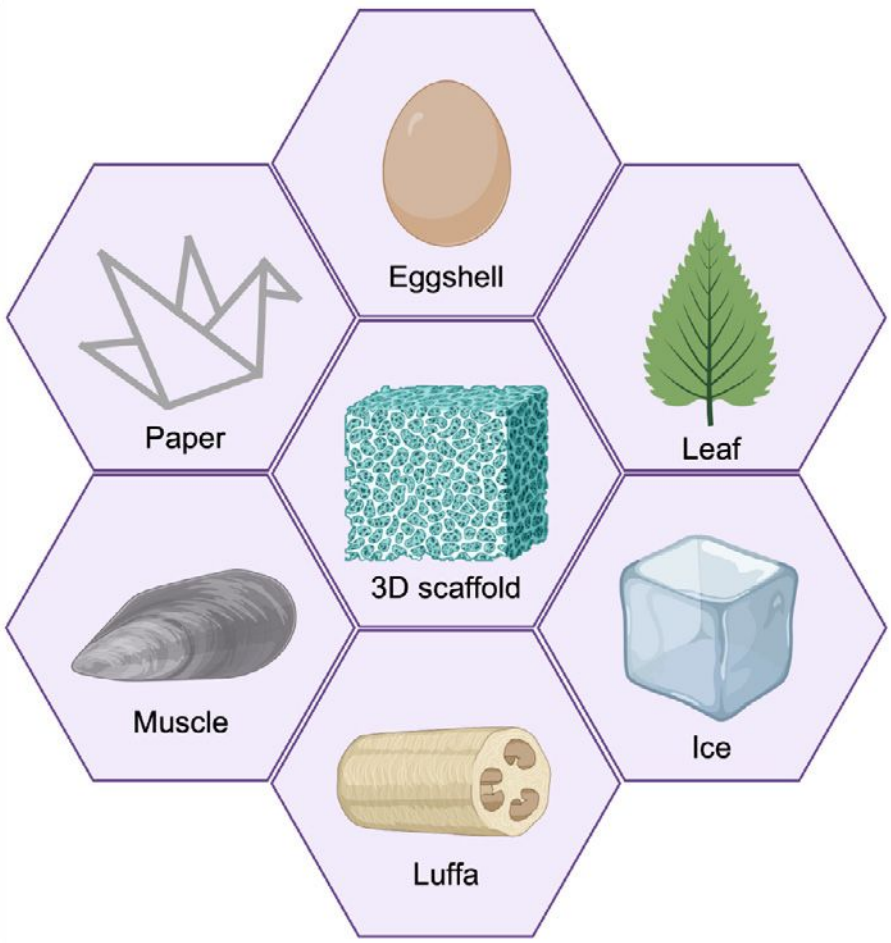

Figure 1. Examples of unconventional biomaterials that can be used to fabricate 3D tissue scaffolds (Image created with BioRender.com.)

An important take away from our approach is that we offer affordable tissue technologies. In the pursuit of addressing healthcare disparities, our lab aims to develop biomaterials for all. Democratizing tissue engineering technologies depends on the development of affordable and widely accessible platforms, both for resource-limited settings and equipped regions with ample access to cutting-edge resources. So, the next time, when you take a walk in nature, peel an apple, cook an omelet, use yarn, or throw away piece of paper, imagine repurposing these items for tissue engineering and regenerative medicine. We can use them to construct molds for crafting implantable scaffolds, generate disease models or study biological interactions in intricate structures. There are no limits to innovation, and the possibilities of what we can achieve are endless.

REFERENCES

1. 1. Nguyen MA, Camci-Unal G. Unconventional tissue engineering materials in disguise. *Trends Biotechnol*. 2020;38(2):178-190.
2. 2. Morrison E, Suvarnapathaki S, Blake L, Camci-Unal G. Unconventional biomaterials for cardiovascular tissue engineering. *Curr Opin Biomed Eng*. 2021;17:100263.
3. 3. Wu X, Stroll SI, Lantigua D, Suvarnapathaki S, Camci-Unal G. Eggshell particle-reinforced hydrogels for bone tissue engineering: An orthogonal approach. *Biomat Sci*. 2019;7:2675-2685.
4. 4. Wu X, Gauntlett O, Zhang T, Suvarnapathaki S, McCarthy C, Wu B, Camci-Unal G. Eggshell microparticle reinforced scaffolds for regeneration of critical sized cranial defects. *ACS Appl Mat Inter.* 2021;13(51):60921-60932.
5. 5. Wu X, Walsh K, Suvarnapathaki S, Lantigua D, McCarthy C, Camci-Unal G. Mineralized paper scaffolds for bone tissue engineering. *Biotechnol Bioeng*. 2020;118:1411-1418.
6. 6. Ahmed AR, Gauntlett O, Camci-Unal G. Origami-inspired approaches for biomedical applications. *ACS Omega*. 2021;6(1):46-54.
7. 7. Wu X, Suvarnapathaki S, Walsh K, Camci-Unal G. Paper as a scaffold for cell cultures: teaching an old material new tricks. *MRS Communicat*. 2018:1-14.
8. 8. Lantigua D, Kelly YN, Unal B, Camci-Unal G. Engineered paper-based cell culture platforms. *Adv Healthc Mater*. 2017;6(22):1700619.
9. 9. Camci-Unal G, Laromaine A, Hong E, Derda R, Whitesides GM. Biomineralization guided by paper templates. *Sci Rep*. 2016;6:27693.
10. 10. Camci-Unal G, Newsome D, Eustace B, Whitesides GM. Fibroblasts enhance migration of human lung cancer cells in a paper-based co-culture system. *Adv Healthc Mater*. 2016;5(6):641-647.

Industry News

By Subramanian Gunasekaran, PhD

In this article, we delve into the dynamics of the federal agencies and their interactions, shedding light on how medical devices are evaluated, valued and coded within complex healthcare systems.

Product Clearance through the FDA, Guardian of Safety and Efficacy: First and foremost in the process of commercialization of a medical device, is its clearance through FDA, the federal agency responsible for approving and overseeing the safety and efficacy of such products.

Commercial Valuation by CMS: The journey of commercializing a product begins with the submission of the product description, indications and clinical data to the Center for Medicare and Medicaid Services (CMS). This is followed by CMS assigning the commercial value along with an HCPCS Code to the product.

Medical Billing & Coding: It is a highly complicated but essential process for every manufacturer to learn and understand how the method of coding and billing is to be accomplished by a Provider who uses the product as per the instructions of the manufacturer.

Medical coding software companies like Codify, AAPC and Supercoder.com are likely to be influenced by major pharma company products and ignore the small company products even if such products are clinically more effective. Accordingly, the manufacturer should face the reality of highly biased medical coding & billing software for proper recognition to ensure fair reimbursement for their products.

The role of billing agents is extremely important for the proper submission of the CMS-1500 form by the Provider/Doctor and waiting for a few weeks for the payment from the insurance.

The Influence of the American Medical Association (AMA): Currently, the commercial valuation of a medical device is performed thrice annually by the Relative Value Update Committee (RUC) comprised of 31 physicians from the societies affiliated with the AMA. Unfortunately, the most powerful RUC committee that assigns the commercial value of advanced medical devices does not consist of any expertise from the field of biomaterial science.

Payment to the Providers: Providers upon the usage of a product get the payment for the product from Payors such as the government insurance agencies like CMS & its MACs (Medicare Administrative Contractors) or private insurance payors either PPOs (Preferred Provider Organizations) or HMOs (Health Maintenance Organizations).

Hospital Supplies: Selling the product through the hospitals has to go through another complicated system of supply chain management mostly managed by the Purchasing/Materials Management departments of the hospital. Added to the complication, most hospitals will have their own confidential Group Purchase Organizations (GPOs) through which the manufacturer should strike a purchase deal after convincing their Value Analysis Committee (VAC). Nobody knows how this committee is framed to value advanced medical devices. Most of the time it is governed by inadequately skilled purchase managers and nurse practitioners. Unfortunately, there is no logical scientific approach to get a proper valuation of a product.

Conclusion: Lack of proper communication between the FDA and CMS makes the latter agency assign the medical products' commercial valuation mainly through the influence of the clinical society namely AMA and its affiliate societies. This often undermines the real valuation of technically advanced tissue regenerative medical devices which need more input from the FDA and other scientific expertise from biological & biomaterial science.

Government News

By Carl G. Simon, Jr., PhD

NASEM ROUNDTABLE ON BIOMEDICAL ENGINEERING MATERIALS AND APPLICATIONS (BEMA)

BEMA is a "Roundtable" initiative of the National Academies of Engineering, Science and Medicine (NASEM) that is administered by both the National Materials and Manufacturing Board and the Board on Life Sciences.[1-3] BEMA held a meeting in Washington DC on July 25, 2023. BEMA's value is to provide a setting for industry, academic, government and nonprofit stakeholders to hold focused discussions of pressing national significance in the field of biomaterials and medical devices. The first goal of the meeting was to reformulate BEMA's goals and select topics for future meetings. Many important topics for potential future discussion were identified: alternatives to ethylene oxide sterilization, polyethylene glycol toxicity, use of animal-derived materials, nickel allergy and conflict minerals. The second part of the meeting discussed the use of polyfluoroalkyl substances (PFAS), broadly defined as molecules with a carbon-fluorine bond, in biomedical devices. Health concerns related to PFAS have resulted in numerous high-profile litigations that are leading to legislation proposals broadly banning all PFAS in US and Europe. PFAS are used to manufacture tens of thousands of biomedical devices, such as pacemakers, guidewires and catheters, as well as cell phones, computer chips, drugs (Prozac) and military equipment. The devastating effects PFAS bans could have on medical treatment in the US were presented. Many options to alleviate the situation were discussed, such as specifically banning the problematic PFAS, such as those used in fire retardant foams, instead of broadly banning all PFAS.

INAUGURAL GORDON RESEARCH CONFERENCE ON 'ADVANCED CELL AND TISSUE BIOMANUFACTURING'

A new series of GRC meetings entitled "Advanced Cell and Tissue Biomanufacturing" was kicked off in Newry, Maine on June 25-30, 2023.[4] The meeting was chaired by Kaiming Ye (SUNY Binghamton) and Paul Carlyle Goodwin (Cytiva). Stakeholders from industry, academia, government and non-profits convened to discuss the development of robust, reliable, scalable manufacturing processes for cell and tissue therapies. ARMI|BioFabUSA announced that they are setting up a new 100,000 square foot GMP-space where they will build fully automated manufacturing lines for 5 new tissues including bone with Epi-Bone, retinal pigment epithelium with Regenerative Patch Technologies and pancreatic islets with Juvenile Diabetes Research Fund (JDRF). A scientist from Humacyte, Inc. unwrapped one of their sterile human blood vessel replacements (42 cm long with a 6 mm diameter lumen) for everyone to handle where the crowd exclaimed that it "looks and feels like calamari!" A team from Carnegie Mellon described a new ice-based approach for 3D printing that enables large overhangs and hollows at 0.2 mm resolution. Research on improved tissue thawing mechanisms using iron nanoparticles and radio frequency coils enabled, for the first time, the successful transplant of a frozen organ: a rat kidney cryopreserved for 100 days that was implanted into a rat. The next installment of this new line of GRC meetings will be held in summer 2025 and will be chaired by Gang Bao (Rice Univ.) and Jay Hoying (Advanced Solutions).

FIRST MICROBIAL CELL THERAPY APPROVED BY FDA: REBYOTA

The first microbial cell therapy, Rebyota, was approved by FDA in November 2022.[5-7] The product is a fecal microbiota suspension for rectal administration for the prevention of recurrence of *Clostridioides difficile* infection (CDI) following antibiotic treatment for recurrent CDI. The product is manufactured from human fecal matter derived from qualified donors. Donor material is filtered and suspended in a solution of polyethylene glycol (PEG) 3350 and saline. Each dose contains between $1x10^8$ and $5x10^{10}$ colony forming units (CFU) per mL of fecal microbes, including $>1x10^5$ CFU/mL of the genus *Bacteroides*. The primary efficacy endpoint in the clinical trials was defined as the absence of CDI diarrhea within eight weeks of treatment. Treatment success was 70.6% in the Rebyota group and 57.5% in the Placebo, corresponding to a 99.1% posterior probability that REBYOTA is superior to Placebo. Although the mechanism of action of Rebyota has not been established, it is a live biotherapeutic product that is intended to restore the gut microbiome diversity and counter antibiotic-induced dysbiosis.

SECOND MICROBIAL CELL THERAPY APPROVED BY FDA: VOWST

Vowst is a bacterial spore suspension in capsules for oral administration which was approved by FDA in April 2023.[8-10] It is similar to Rebyota in several regards: it is indicated for the prevention of recurrence of *Clostridioides difficile* (*C. difficile*) infection (CDI) following antibiotic treatment for recurrent CDI and is manufactured from human fecal matter sourced from qualified donors. The spore suspension is made by using ethanol to treat fecal matter to kill organisms that are not spores, followed by filtration to remove solids and ethanol. Each capsule contains between 1×10^6 and 3×10^7 of phylum Firmicutes spore colony forming units in 92% glycerol in saline. The primary efficacy endpoint in the clinical trials was defined as the absence of CDI diarrhea within eight weeks of treatment. CDI recurrence in Vowst-treated patients was 12.4% compared to 39.8% in placebo-treated participants. Although the mechanism of action of Vowst has not been established, it is hypothesized that the

Government News (Continued)

spore-forming bacteria can compete metabolically with *C. difficile* for essential nutrients, modulate bile-acid profiles to reestablish resistance to *C. difficile* colonization, or have both of these effects.

FIRST PANCREATIC ISLET CELL THERAPY APPROVED BY FDA: LANTIDRA

The first pancreatic islet cell therapy was approved by FDA for treatment of Type 1 diabetes patients "who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education."[11-14] It is an allogeneic product made from deceased donor pancreatic islets of Langerhans and is delivered via hepatic portal vein. "Islets regulate blood glucose levels through secretion of multiple hormones in response to increases and decreases in blood glucose. Endocrine cells within pancreatic islets release insulin, glucagon, somatostatin, pancreatic peptide, and ghrelin. Insulin stimulates glucose uptake by peripheral tissues; glucagon mobilizes glucose from the liver into circulation; somatostatin inhibits both α- and β-cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion. The primary mechanism of action of Lantidra is believed to be secretion of insulin by transplanted β- cells." Efficacy was assessed in two single arm clinical trials, and the primary clinical endpoint was insulin independence, defined as not requiring exogenous insulin to achieve adequate glycemic control. Of thirty patients treated, twenty-five achieved insulin independence: four subjects (13.3%) were insulin independent for <1 year, twelve subjects (36.7%) for 1 to 5 years, and nine subjects (33.3%) for >5 years.

REFERENCES

1. National Academies. "Roundtable on Biomedical Engineering Materials and Applications." https://www.nationalacademies.org/our-work/roundtable-on-biomedical-engineering-materials-and-applications
2. National Academies. "About NMMB." https://www.nationalacademies.org/nmmb/about
3. National Academies. "Board on Life Sciences." https://www.nationalacademies.org/bls/board-on-life-sciences
4. GRC. "Advanced Cell and Tissue Biomanufacturing Conference." https://www.grc.org/advanced-cell-and-tissue-biomanufacturing-conference/2023/
5. FDA. "Package Insert – Rebyota." Accessed August 30, 2023. https://www.fda.gov/media/163587/download
6. FDA. "Summary Basis for Regulatory Action – Rebyota." Accessed August 30, 2023. https://www.fda.gov/media/163879/download
7. Feuerstadt P, Harvey A, Yoho DS, Garcia-Diaz JB, Knapple WL, Bancke L. "Retrospective analysis of the safety and efficacy of fecal microbiota, Live-jslm (REBYOTATM) administered under enforcement discretion to patients with clostridioides difficile infection." Open Forum Infect Dis. 2023;10(5):ofad171. https://doi.org/10.1093/ofid/ofad171
8. FDA. "Package Insert – Vowst." Accessed August 30, 2023. https://www.fda.gov/media/167579/download
9. FDA. "Summary Basis for Regulatory Action - Vowst." Accessed August 30, 2023. https://www.fda.gov/media/168002/download
10. Feuerstadt P, Louie TJ, Lashner B, Wang EEL, Diao L, Bryant JA, Sims M, Kraft CS, Cohen SH, Berenson CS, Korman LY, Ford CB, Litcofsky KD, Lombardo MJ, Wortman JR, Wu H, Auniņš JG, McChalicher CWJ, Winkler JA, McGovern BH, Trucksis M, Henn MR, von Moltke L. "SER-109, an oral microbiome therapy for recurrent clostridioides difficile infection." N Engl J Med. 2022;386(3):220-229. https://doi.org/10.1056/NEJMoa2106516
11. FDA. "Package Insert - Lantidra." Accessed July 14, 2023. https://www.fda.gov/vaccines-blood-biologics/lantidra
12. FDA. "Summary Basis for Regulatory Action – Lantidra." Accessed August 9, 2023. https://www.fda.gov/vaccines-blood-biologics/lantidra
13. FDA Cellular, Tissue and Gene Therapies Advisory Committee. "AM Session Product Characterization - BLA 125734 (Lantidral; donislecel)." Published April 15, 2021. https://www.fda.gov/advisory-committees/advisory-committee-calendar/cellular-tissue-and-gene-therapies-advisory-committee-april-15-2021-meeting-announcement-04152021
14. Qi M, Kinzer K, Danielson KK, Martellotto J, Barbaro B, Wang Y, Bui JT, Gaba RC, Knuttinen G, Garcia-Roca R, Tzvetanov I, Heitman A, Davis M, McGarrigle JJ, Benedetti E, Oberholzer J. "Five-year follow-up of patients with type 1 diabetes transplanted with allogeneic islets: the UIC experience." *Acta Diabetol*. 2014;51(5):833-843. https://doi.org/10.1007/s00592-014-0627-6

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Update from BioInterfaces SIG

By Mary Beth B. Monroe, PhD, BioInterfaces SIG Chair

The BioInterfaces SIG was founded with a focus on improving our understanding of proteins and cells at biomaterial interfaces with biological environments. As our understanding of 'biocompatibility' and the development of biologically active synthetic materials has evolved, these interfaces have become part of biomaterial design rather than a passive process that occurs after implantation. Thus, the BioInterfaces SIG has evolved with the biomaterials field to reflect these changes, and we support research that ranges from fundamental mechanobiological processes on biomaterials to applied biomaterials that elicit specific clinical functions. Furthermore, the definition of "cells" at these interfaces include not only mammalian cells, but also bacterial, viral and fungal cells and studies of how these different cell types interact to affect biomaterial function.

Our new 2023 leadership includes:

Chair: Dr. Mary Beth B. Monroe, Assistant Professor of Biomedical and Chemical Engineering at Syracuse University

Vice-Chair: Dr. Jouha Min, Assistant Professor of Chemical Engineering at University of Michigan

Secretary/Treasurer: Dr. Adam Gormley, Assistant Professor of Biomedical Engineering at Rutgers University

Program Chair: Claudia Loebel, Assistant Professor of Materials Science and Engineering at University of Michigan

Past Chair: Felipe Quiroz, Assistant Professor of Biomedical Engineering at Emory/Georgia Tech

If you would like to join our leadership team as the Biomaterials Forum reporter, please reach out to Mary Beth Monroe (mbmonroe@syr.edu)!

One of our most successful programs is our awards, which include the Burroughs Wellcome Fund (BWF) BioInterfaces Rising Star Award and the Rena Bizios Poster Awards. **We highlighted our awardees at our SIG webinar on October 19 from 3-4 PM ET, where each scholar presented their research.**

The BWF BioInterfaces Rising Star Award is given annually to recognize outstanding BioInterfaces research by postdoc-level scientists. This award seeks to stimulate and highlight research that advances a biomaterials lens to cutting-edge research in protein and cell biology along with research that translates progress in molecular and cell biology into innovative biomaterials. The 2023 BWF BioInterfaces Rising Star Awardee is **Dr. Robert "Smitty" Oakes**, a postdoctoral fellow in the Fischell Department of Bioengineering at the University of Maryland-College Park. His research advances immune cell interfaces to monitor and modulate innate and adaptive immunity. Dr. Oakes webinar talk is entitled "Electrostatic Self-Assembly of Biomolecules for Antigen-Specific Immunotherapies."

The Dr. Rena Bizios Poster Award was set up by a founding and active member of the BIoInterfaces SIG, Dr. Rena Bizios. These awards recognize outstanding BioInterfaces research by graduate students who present at the annual SFB meeting. This year's awardees include:

1st Place: Madeline Eiken, PhD candidate in the Department of Biomedical Engineering at the University of Michigan. Madeline is a third year PhD student and NSF GRFP Fellow in the Loebel and Spence labs at the University of Michigan. She graduated from Santa Clara University in 2019, and worked at EssentBiologics, a biologics start-up company, for two years prior to graduate school. Her research interests are in hydrogels for cell culture, and utilizing organoids for disease modeling. Madeline's webinar talk is entitled **"Engineered 3D Hydrogels to Probe Cell-Material Interactions of Lung Alveolar Epithelial Organoids."**

2nd Place: Natalie Petryk, PhD candidate in the Department of Biomedical and Chemical Engineering at Syracuse University. Natalie is a second-year Bioengineering Ph.D. student and NSF GRFP Fellow studying shape memory polymer foams for improved wound healing in Dr. Mary Beth Monroe's lab. Her research explores the effect of foam pore structure in (i) stopping uncontrolled bleeding in traumatic wounds and (ii) promoting angiogenesis for tissue repair. Natalie's webinar talk is entitled **"Degradable Polyurethane Foams for Trauma Wound Healing."**

Honorable Mention: Natalie Mueller, PhD candidate in the Department of Biomedical Engineering at Case Western Reserve University. Natalie graduated from Louisiana Tech University with a BS in biomedical engineering. She is currently a fifth-year PhD candidate and DoD NDSEG Fellow at Case Western Reserve University, where she is working to improve neural interfaces with a combination of biomaterials and drug delivery. Natalie's webinar talk is entitled **"Mechanically-Adaptive, Resveratrol-Eluting Probes for Neural Interfacing."**

Student Chapter News

By Grant Scull, SFB National Student Section President

The National Student Chapter kicked off its annual programming with a meeting in early October. We welcomed several new members to the team and discussed plans and priorities for the 2023-2024 cohort. While Grant Scull and Arian Veyssi were promoted to President and Secretary/Treasurer, some new faces joined the team in Leonor Teles (President-Elect), Natasha Claxton (Secretary/Treasurer-Elect), and Bhuvana Lakkasetter Chandrashekar (Bylaws Chair). We very much appreciate their service for the upcoming year!

Planning is still underway as we determine how to best approach the Regional Society Meetings scheduled for Fall 2024, and we hope to work hand-in-hand with the student chapters local to each of the meeting locations to ensure that they are fully prepared and supported. We will be reaching out to the local chapter leaders in the near future. Additionally, we plan to host a webinar for these Regional Meetings and how to make the most of your time at them, as well as a whole slate of webinars on various other topics. Be on the lookout for these! Finally, you can expect the continuation of the Three-Minute Thesis event at these meetings as well. We're always looking for volunteers to host these competitions, and this will be even more important at our six Regional Meetings!

Finally, we are looking to highlight Student Chapter members from around the country who are planning to attend the World Biomaterials Congress in Daegu, South Korea this upcoming Spring. We'll reach out for more information after the abstract acceptance period.

Be well and take care!

2023 - 2024 STUDENT SECTION OFFICERS

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

PRESIDENT-ELECT: Leonor Teles, University of Miami

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

SECRETARY/TREASURER-ELECT: Natasha Claxton, University of Virginia

BYLAWS CHAIR: Bhuvana Lakkasetter Chandrashekar, The University of Texas at Dallas

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» Notification of Abstract Acceptance : Jan. 1, 2024
» Early-bird Registration : Apr. 30, 2023 ~ Jan. 31, 2024

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