SurFACTS in Biomaterials

WINTER 2019
VOLUME 24, ISSUE 1

INSIDE THIS ISSUE

Excellence in Biomaterials Science Award Presented by SIBF

The Excellence in Biomaterials Science Award presented by the Surfaces in Biomaterials Foundation (formerly known as the Excellence in Surface Science Award) recognizes an individual who has made significant contributions to the biomaterials science field. It is the highest award given by the Foundation. The first award was presented in 1991 to Buddy Ratner, University of Washington. The award is presented anually at the BioInterface Symposium.

The winner is notified before BioInterface and is invited to speak about the advancements made at the symposium.

If you would like to nominate someone for an Excellence in Biomaterials Science Award, please complete the **Award Nomination Form** by April 30, 2019.

Find past Award Recipients at: **https://www.surfaces.org/page/ExcellenceinBiomaterialsScienceAward.**

The Benefits of Thinking Out Loud

From Colonoscopy Prep Alternatives to Examining Cosmetic Makeup Sponges

Benjamin T. Matheson and Heather E. Canavan
Biomedical Engineering, University of New Mexico, Albuquerque, New Mexico

The gap between the benefit of a medical research project and true improvement in a clinical setting can be quite large. Heather Canavan, an Associate Professor in Biomedical Engineering at the University of New Mexico, works with her students to reduce that gap. Through her efforts of promoting human-centered design, she and her students are embracing a spirit of collaboration and creative thinking to ascertain better healthcare-related solutions.

Inspiration can strike anywhere at any time! Whether it be while watching make-up tutorials on YouTube or while enjoying a refreshing bubble tea. Unfortunately, most people tend to drop their ideas that have potential to

The Benefits of Thinking Out Loud ... continues on pg. 5

Surfaces in *Biomaterials* Foundation

BioInterface 2019
Workshop & Symposium

Surfaces in Biomaterials Foundation
September 4-6, 2019
Park City, Utah

Workshops/Sessions

WEDNESDAY
September 4
BIOINTERFACE WORKSHOP

Theme:
Implantable Sensors

THURSDAY
September 5
BIOINTERFACE SYMPOSIUM

Session 1 Topic:
Surface Modifications and Coatings

Session 2 Topic:
Tissue Engineering and Regenerative Medicine

Session 3 Topic:
Ophthalmic

Session 4 Topic:
Point Counterpoint Debate

FRIDAY
September 6
BIOINTERFACE SYMPOSIUM

Session 5 Topic:
Neurovascular-Neuro Devices

Session 6 Topic:
Cardiovascular

Session 7 Topic:
Imaging

Session 8 Topic:
Analytical Characterization of Medical Devices

2019 Call for Abstracts

Abstract Guidelines

ELECTRONIC ABSTRACT SUBMISSION

Submit your abstract online at https://www.surfaces.org/page/2019_Abstract_Form

Unlike most Academic symposia, full disclosure of materials, methods, and funding sources is encouraged, but NOT required so that presenters may speak about their latest work before it is published in full detail elsewhere.

Abstracts will be published on the BioInterface 2019 website that is only accessible to registered attendees. Please submit one form per abstract submission.

Submit only ONE abstract for each presentation; do NOT submit multiple copies of the same abstract, do NOT submit in blinded format, and do include your name, your address and e-mail address on any submitted abstract.

FAILURE TO PRESENT

The presenting author is expected to present the paper. Should an emergency situation occur at the time of your presentation at BioInterface 2019, please notify the Chair of your session as soon as possible. It is the presenting author's obligation to ensure that the abstract is presented.

All abstracts are due by April 30, 2019

PRESENTER REGISTRATION

Presenting authors MUST register and pay to attend the event. If registration is not received by July 30, 2019, the presentation will be removed from the program. Online registration will be available on the Surfaces in Biomaterials Foundation website soon.

NOTIFICATION

Notification of acceptance or rejection will be e-mailed in April. The final selection of abstracts for presentation and placement of accepted abstracts in the program format will be made by the Program Committee.

TITLE

Type the abstract title in upper and lower case letters. Use a concise and descriptive title.

ABSTRACT BODY

The one-page abstract needs to address how the work described relates to the biointerface. Abstracts accepted for podium presentation will be provided 15 minutes for didactic presentation, followed by 5 minutes for discussion. The nature of the multiple session format makes it imperative that these times limits by strictly observed by all participants. Audio-visual includes a single LCD projector, screen, podium and laptop. Your presentation must not include animation or sublinks to other programs.

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Surfaces in *Biomaterials* Foundation

APS and SIBF Presents
What's New in ISO 10993-1:2018

APS is teaming up with Surfaces in Biomaterials Foundation to put together a night of networking and discussions surrounding the new release of ISO 10993-1:2018 . Two industry professionals will provide insights into biological evaluation, chemical characterization testing, FDA Guidance documents, submission requirements, and MDR requirements.

Thursday, April 11, 2019
4:30-6 p.m.: Registration & Networking
6-7:30 p.m.: Program

Registration is FREE at www.surfaces.org
Food and beverages provided

American Preclinical Services
9055 Evergreen Blvd., Coon Rapids, MN

Speakers:
Mac McKeen, MBA, RAC, Fellow-Regulatory Science at Boston Scientific
Ed Rankin, Sr. Scientist at Medtronic Physiological Research Laboratories

Mac McKeen has over 30 years of experience in the medical device industry in regulatory and quality roles focused on the development, clinical study, and regulatory approvals of cardiovascular devices and is currently a Fellow at Boston Scientific with previous leadership roles at Guidant, Medtronic, St. Jude Medical, Cardiac Science and Phillips Medisize. He also serves as an Adjunct Professor at the University of Minnesota instructing a 4000 level course on medical device development and is also a Faculty Director within the college of Continuing and Applied Professional Studies and is a member of the UMN Medical Device Innovation Graduate Degree program. He is actively involved in advocacy and collaboration with the FDA through industry associations including AdvaMed, MDIC and Medical Alley. He holds a BS in Industrial Technology from Iowa State University and an MBA from the University of Dallas and is RAC certified.

Ed Rankin is a Senior Scientist at Medtronic with 18 years' experience using ISO 10993 to write biological evaluations, perform biocompatibility testing, and coordinate regulatory submission information for a wide variety of medical device applications. He holds a BA in Biology from Taylor University and a Master of Biological Sciences degree from the University of Minnesota.

continued from pg. 1

be something great. Alternatively, people in the Canavan lab group are encouraged to not only hold on to their ideas but establish a way of seeing their ideas come to life. For instance, one of the most promising research projects gathering momentum in the group started off by the simple act of drinking a bubble tea. Bubble tea contains chewy tapioca balls that can be peculiar to some people, but inspired a group of engineers to use it as a platform to create an alternative to colonoscopy preparation.

The Bubblyte™ Project

Although the screening for colorectal cancer is capable of catching the disease in an easily treatable early stage, only about half of patients comply with the preparation for colonoscopy screening. One reason for this lack of patient compliance is that the preparation is difficult for patients due to the viscosity and taste of the preparation. As a result, many patients will not finish what is asked before the colonoscopy, or will put off scheduling follow-up exams. What if there was an alternative? It was from this focus on redesigning the patient experience that "Bubblyte™" was born, making preparation for gastrointestinal imaging easier and more likely to be completed.

The Bubblyte™ project in many ways follows traditional experimental design followed in academic labs. By varying concentrations and formulations of the active ingredients in the preparation, hydrogel "Bubble" carriers were designed in the lab (Figure 1). Next, the ability of the gels to correctly release their

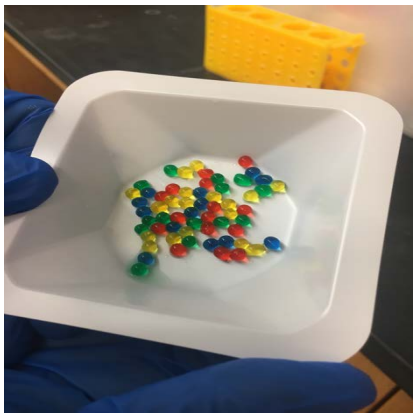

Figure 1. A sample prototype of the hydrogels developed in the lab

cargo in response to the pH of the gastrointestinal system was verified using techniques common to academic labs, such as NMR and spectrophotometry. The ability of the gels to withstand long-term storage (similar to gummy vitamins) is currently being tested to ascertain shelf life. Also, in contrast to the current "one dose fits all" paradigm for current treatments, the dosage of the Bubbles is being determined using biocompatibility testing with cells from the human gut.

Our group has applied for two patents related to this project (4685. WO2018222947 BUBBLYTE) including undergraduate and graduate students who have worked on the surface analysis and mammalian cell work showing its proof-of-concept. While the group ultimately envisions the product going to market through partnerships with industry or licensing, in the meantime, undergraduate student, Darnell Cuylear, and graduate student, Phuong Nguyen, have presented their research at scientific conferences, including the recent Surfaces in Biomaterials conference in Boulder. It was also the subject of Ms. Nguyen's recent presentation at the International AVS Symposium in Long Beach, for which she was awarded the Dorothy Hoffman Award. When asked about working on this type of project, Cuylear said, "Being able to work on a project that includes licensing, patenting, and an industry crossover has made me a better scientist because I have had an educational experience that sets me apart from my peers."

The Genius Beauty Queen™ Project

Another project was inspired by observing the growing number of tutorial videos that test or demonstrate products on YouTube. For instance, YouTube has 14.9 billion beauty-related video views and 75+ hours of new beauty-related content uploaded on a daily basis, reflecting a $445B market share in the U.S. alone. After watching only a few makeup tutorial videos, it becomes obvious the use of cosmetic sponges, tools designed to apply cosmetics onto the face in a way that evenly distributes the perfect amount into the skin, is ubiquitous. Furthermore, although the hygiene of eye shadow, foundation, lipstick and other cosmetics are carefully regulated, through oversight by the FDA, makeup brushes, sponges, and other tools, are not. As a result, members of the group started to wonder how clean cosmetic sponges really are after multiple makeup applications. Could cosmetic sponges harbor opportunistic bacteria that can cause problems for the user?

This project, coined the "Genius Beauty Queen™" project, has focused on how hospitable commer-

The Benefits of Thinking Out Loud ... continues on pg. 7

Medtronic is Exploring the Next Frontier in Healthcare: Regenerative Medicine

Medical researchers envision a day when a sick person with a diseased heart or other organ can get a new one, designed on a computer, made specifically for their personal anatomy and created from stem cells, or perhaps even their own cells, on a 3D printer. This concept is known as regenerative medicine and researchers, governments, and industries all over the world are trying to make it a reality.

"It's not science fiction, it's not a matter of if this happens. It's a matter of when," said Michael Hill, Ph.D., vice president of corporate science, technology and innovation at Medtronic. "Regenerative medicine will play an incredibly important role in the future of medical technology, and Medtronic intends to be part of it. Proof of concept in humans has been demonstrated in several areas such as cartilage replacement, vascular vessels for bypass surgery, trachea reconstruction, and others. The task at hand is to develop the capability to move from creating one vascular vessel to producing hundreds of thousands of these each year in a consistent high quality and reliable manner and transport these all over the world in sterile and functional condition. This capability stills needs to be created."

D. Kamen, R. McFarland, M. Hill & M. O'Connor at ARMI Winter Summit (Jan 4, 2018, Manchester, NH)

That is why Medtronic has agreed to a seven-year strategic partnership with the Advanced Regenerative Manufacturing Institute (ARMI), which was established in 2016 with an $80 million grant from the U.S. Department of Defense. The collaborative effort is intended to figure out how to create, and manufacture on a large-scale, patient-specific tissue and perhaps someday even working organs.

Many of the applications have been proven on a small scale that these things can be done. Then the question becomes how to get that work out of the lab and mass produced to help the most people.

The first devices from regenerative medicine (also known as biofabrication) could be products such as ligaments and cartilage for knees, bio-fabricated skin, bone or spine devices such as discs or vertebrae. And many of these devices may someday be custom-made for individual patients, to specifically match the needs of their anatomy or pathophysiology. Functioning organs, such as hearts or pancreases, are much further down the road. Besides the technical and clinical difficulties, regulatory and reimbursement challenges need to be overcome as well for successful market introduction of regenerative medicine products. ARMI will address these issues as well.

Michael Hill, Ph.D., vice president of Corporate Science, Technology, and Innovation

The Benefits of Thinking Out Loud
continued from pg. 5

cially-available cosmetic sponges are to opportunistic bacteria after exposure to liquid makeup (Figure 2). Even though the subject of this experiment is unusual, the techniques used (e.g., culture of bacteria on agar plates, SEM, XPS, and other analyses of the sponges themselves) are common to most students in the biomedical and chemical engineering areas.

Figure 2. Infected cosmetic sponge after only 4 days of use. Mold is indicated by a blue asterisk.

As said before, inspiration is all around us. Therefore, the lab group has developed a presence of thinking differently by creating research projects that originate from moments that impact the individual which then grow into something spectacular. Through this type of environment, the team continues to push the boundaries in developing better products by embracing the value of thinking out loud.

Interested in finding out more about what the lab group is working on? Visit the Heather Canavan Lab website at **https://canavanlabs.com**

The Canavan Group uses creative, diverse and interdisciplinary methods to explore both fundamental science and new research. All with the goal of creating practical, real-world.

Visit the Adaptive Biomedical Design website at **https://adaptivebiomedicaldesign.com**

Adaptive Biomedical Design connects idea generators with students, teachers, engineers, marketing and patent experts. And the technology and resources to design, prototype and patent their ideas to create solutions-new advances, innovations and inventions-in the biomedical and medical fields.

Follow the Surfaces in Biomaterials Foundation on social media!

Like us on Facebook: click here

Visit our LinkedIn page here

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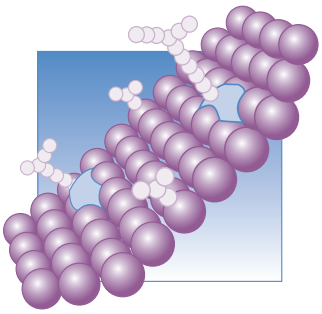
Members are encouraged to submit articles for future editions of SurFACTS. Please email your report (with all appropriate figures and graphics) to Newsletter Committee Chair Melissa Reynolds at melissa.reynolds@colostate.edu for consideration in a future issue. Deadlines for upcoming issues are posted on surfaces.org.



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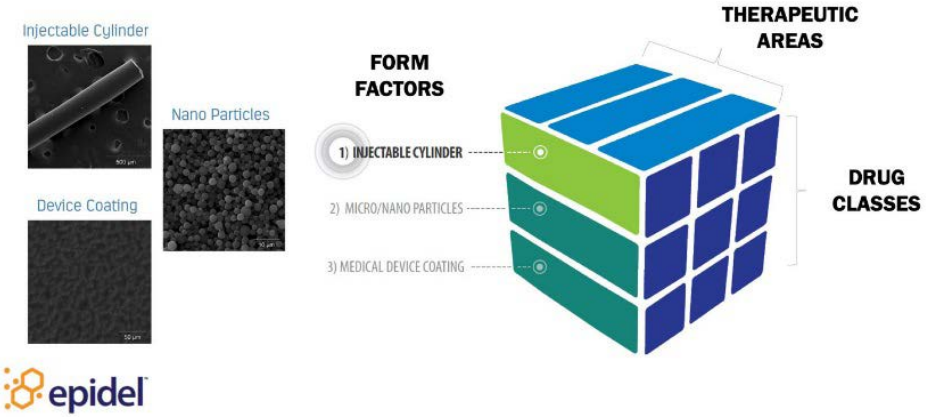
Epidel®— A Non-Polymeric Surface Erosion Based Sustained Drug Delivery Technology

Interface Biologics' Endexo® Anti-Thrombogenic Surface Modification Technology is used commercially in medical devices for vascular access and neurosurgery. It is also in clinical trials for use in hemodialysis. The Endexo family of fluorinated oligomers are designed as additives that are blended into base resins prior to device fabrication. Surface energy driven, the oligomers bloom to the device surface creating a uniform, durable passivating layer that is resistant to thrombus formation and bacterial adhesion. The ease of manufacturing in combination with benefits observed in clinical studies and more than 800,000 patient exposures, highlights the strength and safety of the Endexo technology.

Interface is leveraging the team's expertise in chemistry, material science and product development to focus on their own local drug delivery products. The company has discovered a new class of materials that are uniquely designed for controlled and sustainable drug delivery to target tissues. The Epidel technology, is a non-polymeric highly engineerable drug delivery platform with significant advantages over current polymeric materials. It can be manufactured in an array of custom design implants with indication-tailored drug dosing, release kinetics and implant duration. Epidel has broad applications across a range of therapeutic areas and drug classes. The Epidel chemistry's polymer-like properties enables the material to be formulated into a wide array of forms including cylindrical implants, micro-and nanoparticles and coatings for pharmaceutical and medical



device applications. Drug release is controlled via surface erosion with concurrent degradation of matrix and drug without acidic byproducts. A high drug ratio enables smaller implant size.

Epidel's lead candidate is a dexamethasone surface eroding intravitreal implant, IBE-814, aimed at being a best in class therapy for the treatment of posterior inflammatory eye diseases, including diabetic macular edema (DME), retinal vein occlusion (RVO) and non-infectious uveitis (NIU).

The IBE-814 implant is minimally invasive, delivered through a thin 30-gauge needle, which is significantly smaller than currently marketed intravitreal sustained-release steroid therapies (i.e. 22-25 gauge needle delivery). IBE-814 is designed to deliver a low, consistent, efficacious dose for approximately nine-to-12 months. The extended clinical effect paired with the potential to avoid common steroid-induced adverse events (i.e. increased intraocular pressure, cataract formation), positions IBE-814 to be class-leading in both safety and efficacy. Clinical opinion leaders believe this could potentially expand the number of patients suitable for extended release steroid products.

Interface Biologics held a positive pre-IND meeting with the FDA in October 2018, securing agreement on a 505(b)(2) regulatory pathway, including an accelerated clinical plan. Interface plans to spend most of 2019 confirming the chemistry and manufacturing and completing pre-clinical studies for IBE-814, enabling initiation of a Phase 2 clinical trial in 2020.

Axolotl Biologix Launches New DualGraft™ For Faster Healing

Regenerative Medicine Patch Advances Wound Repair

Phoenix, AZ (January 23, 2018) – To help physicians facilitate wound healing, Axolotl Biologix, a biotechnology leader in regenerative medicine, is proud to announce the launch of Axolotl DualGraft™, a bi-layered human amnion membrane patch that serves as a barrier to protect wounds while advancing skin repair and reconstruction.

Axolotl's DualGraft promotes healing of damaged tissue by using amniotic components to create a biological scaffolding which stimulates cells to repair themselves. This 3-dimensional extracellular matrix scaffold encourages cell migration and proliferation needed for healing.

DualGraft™ also helps to establish an environment in the wound to lower the growth of bacteria and reduce the rate of infection in chronic wounds, such as diabetic ulcers. Since it is conveniently packaged as a terminally irradiated, dehydrated allograft, it can be stored at room temperature and applied in a clinical setting.

"We our proud to offer physicians our new Axolotl DualGraft to help promote healing in wounds and improve patient outcomes in a number of clinical applications," said Dr. Robert Kellar, Chief Science Officer of Axolotl Biologix. "DualGraft is the newest addition to our line of products in the space of regenerative medicine."

"Research has demonstrated amniotic membrane products, like DualGraft, have clinical benefits that will help physicians and wound care specialists," said Dr. Robert Diller, Senior Director of Research. "This is only the beginning as we research and develop new technologies to help people age without losing their ability to stay active."

Amnion membrane used in DualGraft™ are derived from the amniotic lining of the placenta following a scheduled cesarean section. The donated amniotic membrane is recovered and processed aseptically in accordance with all FDA guidelines and quality assurance standards in a controlled environment.

About Axolotl Biologix:
Axolotl Biologix, Inc. is an innovative biotechnology leader in regenerative medicine through research, technology and clinical application. Axolotl Biologix is expanding the human body's ability to regenerate by developing and manufacturing regenerative human cell and tissue medical technologies that are disrupting traditional, more invasive, painful and expensive treatment protocols.

New Social Medial Coordinator

We are happy to announce Hailey Hibbard will be the Foundation's social media coordinator. This newly formed position in the Foundation is to assist with keeping our Foundation relevant in today's news and media age. This position helps to create continuous information flow about the Surface in Biomaterials Foundation, its members, and its member companies. Hailey's research focuses on developing solutions to the growing problem of antibiotic resistant bacterial infections. She is currently working on creating a new enzyme-activated antibiotic that will release an antibacterial agent site-specifically only when bacteria are present. This compound will have applications in treating antibiotic resistant bacterial infections both systematically or on surfaces. Hailey is currently a fourth-year Chemistry PhD candidate in the Therapeutic Materials & Biointerfacial Research (TMBR) group at Colorado State University (advisor: Melissa Reynolds). Kristen Metcalf assists with the development of social media content. If you have information that you would like to share on social media, please contact Kristen at **Kristen@surfaces.org**.

SurFACTS in Biomaterials is the official publication of the Foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

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