SurFACTS in Biomaterials

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INSIDE THIS ISSUE

From President Angela DiCiccio

It is with humble admiration and gratitude that I open this note to our community and close our Winter edition of SURFACTs. The end of 2019 into the beginning of 2020 has presented unique challenges across the globe that impact each country, community, family and individual in profound and often unprecedented ways.

As we embark on a unified effort to contain and manage the spread of COVID-19 and its subsequent economic impacts, a resurfacing theme resonates as we strive for global success: how can we better understand what's happening at the surface of all materials that we and the infectious diseases come in contact with, how can we improve diagnostics used to detect these vectors, and how can we provide enough equipment to both protect and care for those exposed working the frontline of healthcare and those infected?

Familiar concepts of biocompatibility, sterilization/disinfection, material compositions of devices, and user safety are common conversations and focuses within our community, but now the significance and impact of these concepts and questions are magnified under the lens of our collective global efforts. What does this mean for us?

This is a time when our strong network of experts, incredible collaborative nature, and ability to mobilize quickly will change the outcome of our global history. The Surfaces in Biomaterials Foundation was seeded with an intention to instill and empower a diverse community of technical experts spanning industry, academia, clinical and regulatory with the fundamentals of open-communication, empowered collaboration and inspired partnerships. For me, the incredible magic of this mission and group couldn't be any more real as I collaborate with on a non-profit effort to design, manufacture, test and distribute personal protective equipment and protocols across the nation to health care providers and patients in need. Many of the key contributors to this project I was able to recruit because of my participation in the Surfaces community and I couldn't be

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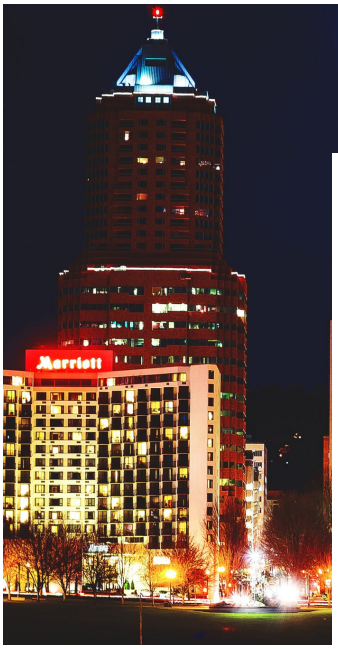
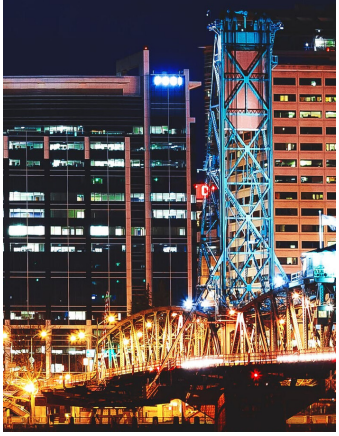


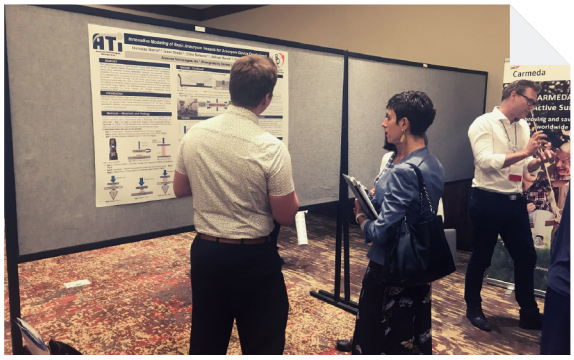
BioInterface 2020
Workshop & Symposium

Surfaces in Biomaterials Foundation
October 21-23, 2020
Portland, Oregon



Call for Abstracts

The 30th Annual BioInterface Workshop & Symposium will be held at the Hilton Portland Downtown in Portland, Oregon, October 21-23, 2020. During our event you will be enriched by the science and the high quality of interaction that is fostered by the unique blend of industry, academic, regulatory and clinical attendees. The moderate size of the event allows you to connect, share and learn by mingling with your fellow attendees and event sponsors.



A critical part of this program is the content presented by our distinguished colleagues. We invite you to submit an abstract online for consideration by the Program Committee at:

https://www.surfaces.org/page/2020AbstractForm

We have very broad program which accommodates nearly all medical device-related topics from academia, government, and industry. We ask that all abstracts are submitted no later than

April 30, 2020

Event Highlights

- Full Day Workshop on Wednesday, October 21 on Entrepreneurship in surface science
- Seven technical sessions and point counterpoint session:
    1. Analytical chemistry
    2. Surface modifications and coatings
    3. Tissue engineering and regenerative medicine
    4. Point counterpoint session
    5. Cell-based and electronic hybrid medical devices
    6. Interface of biomaterials and wound healing/infection
    7. Drug delivery
    8. Imaging advanced technology
- Student town hall meeting & student pitch competition
- Exhibit hall
- Multiple networking receptions, including social mixer on the first day

Become a Part of SIBF

Explore Creative Solutions to Technical Challenges

The Surfaces in Biomaterials Foundation brings together a group of passionate individuals focused on developing new technologies in the surface biomedical community. As a raw material supplier it's important we stay active in the community to be at the forefront of new materials, ideas and products. Every year the foundation connects science leaders together for three days to share breakthrough ideas with multiple networking opportunities. As a member we have an opportunity to shape the BioInterface annual conference sessions by providing input on topics and speakers. There are also opportunities to communicate with key board members daily to develop the vision for the foundation. For the BioInterface conference in Portland this year I'm excited to support the foundation with 2020 planning and look forward to a successful event! — ***Courtney Kay, Elkem***

My first SIBF workshop and symposium experience transformed my understanding and aspirations for industry collaborations and truly highlighted the power of bringing together technical experts with a passion for transparent communication and intense problem solving. SIBF is a passionate collection of fantastic engineers, experts, scientists and deep thinkers dedicated to changing the biomedical field. I am constantly learning, laughing and growing my network of friends and colleagues through my participation with SIBF.
— ***Angela DiCiccio, Verily Life Sciences***

Hello friends! I am a Principal Scientist at Medtronic Corporate in the Microscopy and Surface Analysis Group specializing in surface and interface analysis of materials. I attended my first BioInterface Symposium in 2011 and immediately enjoyed the smaller, more intimate setting that encouraged interaction between attendees, presenters, and exhibitors. Since then, I became an active member and held various leadership roles including chairing technical sessions and board positions (Treasurer, President). The industry focused topics are directly relevant to my career and offers a fun and exciting way to stay informed of new technologies and current challenges in the medical device industry.

SIBF offers many opportunities for eager and energetic individuals. Please contact me or Ingrid for more information. We look forward to hearing from you! — ***Bill Theilacker, Medtronic Corporate***

I was invited by a colleague to attend my very first Bio Interface a few years ago. I discovered that it had a lot to offer for personal growth, learning and was beneficial for the business, relationships as well. Surfaces in Biomaterials Foundation members and attendees represent a good balance of academic, industry research excellence with consistent participation from regulatory experts. The annual Bio Interface Conference covers current industry topics of interest such as advances in wearables, 3D printing and drug delivery devices among several others. Due to its intimate set up and great agenda setting Conference provides excellent networking opportunities. Participating in various committees and the Foundation board helps develop leadership and team building skills.
— ***Chander Chawla, DSM***

Significance and Methods of Creating Anti-microbial Coatings

Covalon Technologies Ltd.

Hospital Acquired Infections, or HAIs, are complications that occur at healthcare facilities or as a result of treatment and are often associated with high morbidity and mortality[1]. Despite efforts to reduce the number of infections, the Centre for Disease Control estimates that "each year, 1 in 25 US hospital patients is diagnosed with at least one infection related to hospital care alone."[1] Of the many contractable hospital infections, 4 of the 5 most common HAIs can be traced back to the use of medical devices, including central-line blood stream infections (CLASBI), ventilator-associated pneumonia (VAP), surgical-site infections (SSIs) and catheter-associated urinary tract infections (CAUTI)[2]. In particular, catheters and the process of catherization account for many HAIs, with urinary tract infections accounting for more than 30% of infections and bloodstream infections accounting for an additional 14%[3]. US hospitals are burdened by the economic costs associated with detecting and treating these complications, estimated at up to $45 billion annually[4]. To mitigate the costly consequences of HAIs, healthcare providers utilize a variety of infection prevention strategies, including devices that offer antimicrobial protection.

How Devices Increase Infection Risk

While invasive medical devices are developed to meet specific clinical needs (e.g. a central venous catheter (CVC) for long term use in an oncology patient), they will increase the patients' risk of infection because they bypass the body's first defense mechanism- the skin. Invasive devices often leave open routes of entry for bacteria wherever the device is present (urinary tract, peritoneum, or vasculature).

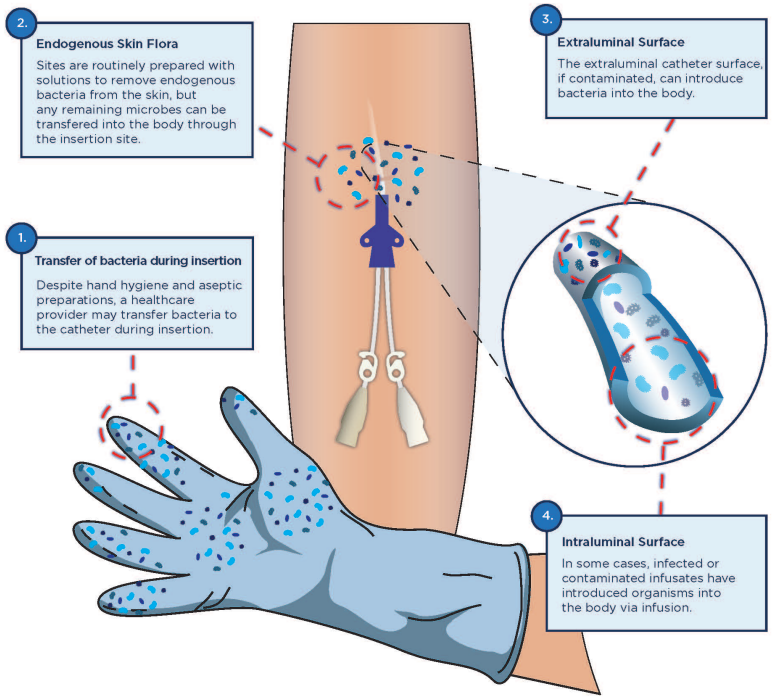


Figure 1: Routes of entry for bacteria during catheter use.

Developing Infection Prevention Devices

According to the CDC's Guidelines for the Prevention of Intravascular Catheter-Related Infections (2017), antimicrobial/antiseptic impregnated catheters are suggested strategies to further reduce the risk of device related infections, particularly when expected use is longer than 5 days[5]. The effort to create solutions for device associated infections can be categorized in two main groups: antifouling and antimicrobial. Antifouling techniques prevent the initial adhesion of bacteria on the device surface, while antimicrobial solutions use antimicrobial agents to kill bacteria before proliferation on the device surface.

Antifouling efforts prevent infection by limiting the formation of conditioning films which enable bacteria to attach and form biofilms.[6] For instance, hydrophilic surfaces can form a tightly bound water layer creating a thermodynamically unfavourable environment for hydrophobic bacteria and other biofilm forming components, and as such, reduce the risk of infection.[6,7,8] While antifouling techniques do not rely on interactions between microbes and the active, these solutions are only effective until a conditioning film forms on the surface.[7]

In addition to antifouling efforts, several techniques exist to modify the surface of a device with an antimicrobial agent. For example, a blending process can be used to embed the active component

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directly into the catheter material during catheter formation.[9] However, when blending bioactives through the material of the device, careful consideration of compatibility between the active and material is important to maintain mechanical integrity.[7]

There exists a wide range of antimicrobial coated medical devices both in development and available for clinical use. Many polymeric coating solutions aim to extend the delivery of an antimicrobial or agents to avoid systemic doses of antibiotics.[11] For instance, the Teleflex® Arrowg+ard® CVC uses eluting chlorhexidine and silver sulfadiazine for broad spectrum antimicrobial activity.[12] Further, many coatings in development deliver liposomes or nanoparticles containing the active ingredient to further extend the release.[13] To extend the lifetime of the active further, direct covalent linkages have been used to attach the antimicrobial to the surface of the device thereby limiting depletion over time. Commercialized products, such as B. Braun's non-eluting antimicrobial CVC, offer antimicrobial efficacy over 30 days.[14] However, if biofilms form over these surfaces, a physical separation between the active and any circulating bacteria exists, inhibiting the antimicrobial effects.[7]

Why CovaCoat®?

While there are multiple methods to coat devices, each can present different challenges. One commonly noted concern of coatings focuses on the delamination of the coating from the device. This delamination occurs because many coatings are simply deposited onto the device surface, leaving it weakly bound and susceptible to removal.

CovaCoat® is a unique surface modification process in which hydrophilic polymer chains are physically grafted from the surface of a medical device. This photopolymerized method results in an interpenetrating network between the surface and the coating resulting in a durable layer that resists shear forces, unlike those of a traditional surface deposited hydrophilic coating. Simulated-use particulate data shows decreased particulate formation on CovaCoat® peripherally inserted central catheters (PICCs) when compared with uncoated controls (Figure 2). The surface modification technology allows for tunability of coating formulations making it possible to change the surface properties for desired lubricity, hydrophilicity and charge.

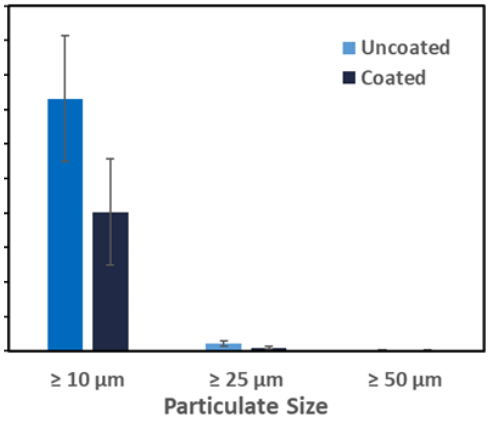

Figure 2: Particulate generation of PICCs in a simulated use model following ASTM F2743 and USP <788> show decreased particulate generation of CovaCoat® samples in comparison to uncoated controls.

With its hydrophilic nature and water-bound surface, CovaCoat® has been shown to reduce the accumulation of proteins on the surface of a device, such as thrombin in a blood loop assay[14], in addition to the delivery of active pharmaceutical ingredients (APIs), including antimicrobials, anti-inflammatories, analgesics and others. A significant advantage to this coating technology is its capacity to load various antimicrobials and combinations

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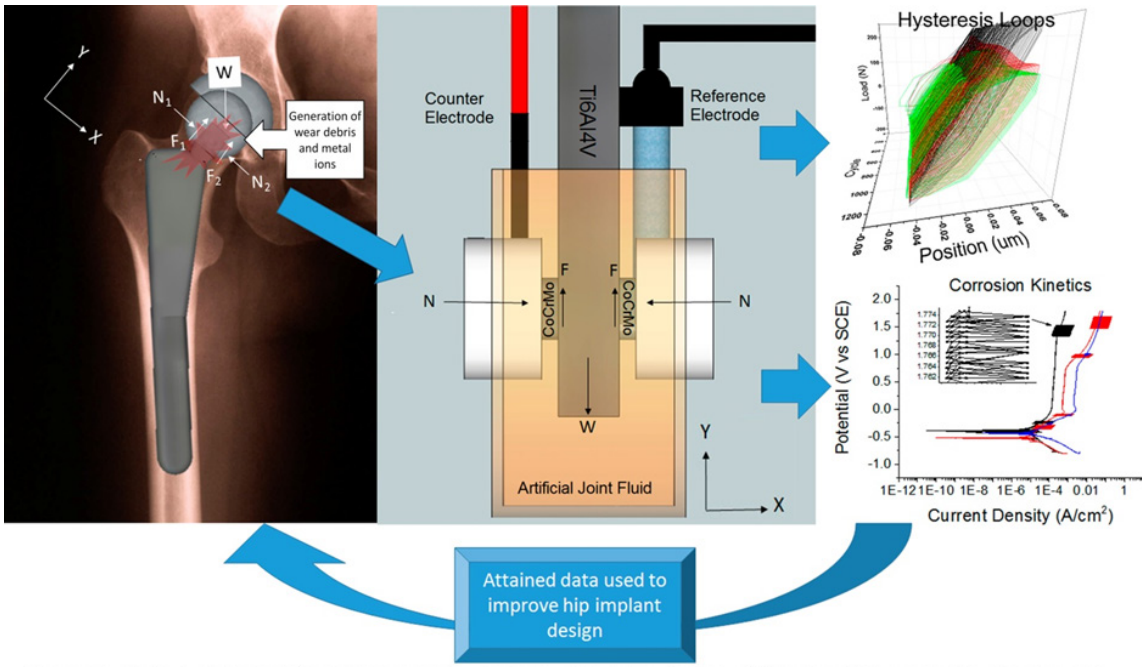
Bio-tribocorrosion Research Related to Total Hip Replacement (THR): Current Perspectives

D. Royhman, M. Runa, D. Bijukumar, MT. Mathew, Department of Biomedical Science, University of Illinois College of Medicine at Rockford, 1601 Parkview Avenue, Rockford, IL 61107, Ph: 815-395-5883, Institute of Biomaterials, Tribocrrosion and Nanomedicine (IBTN), Regenerative Medicine and Disability Research Lab (RMDR); M. Barba,Ortho-illinois, Rockford, IL-61107

In orthopedic clinical management, total hip replacements (THR) have been an effective treatment choice for the end stage of arthritis and other disorders for over a century. The first attempt at a hip replacement occurred in Germany in 1891. The modern, low friction arthroplasty, on which current devices are based, was invented by Sir John Charnley in the early 1960's (Knight et al., 2011). As more knowledge and experience was gained, there have been modifications to improve the functionality and lifespan of hip implants. This involved the use of ceramics in the femoral head and acetabular polymer liner. However, hip modular junctions are still under concern of early failures and possible source of metal particle/ion release to the surround tissue environment.

Modern hip prostheses feature a modular implant design with at least one tapered junction that gives the surgeon flexibility in implant assembly and reduces inventory. Modular junction operates in a challenging environment with several variable parameters, such as load, micro-motion, and a changing local chemical environment. Such complex operating conditions may lead to bio-tribocorrosion (fretting-corrosion) and release of wear debris and metal ions. Bio-tribocorrosion is defined as the scientific investigation of the synergistic interaction of wear and corrosion in a biological and health system. The patient may then experience adverse tissue reactions, pain, and subsequent device failure. Further, any existing crevice provides favorable conditions for corrosion. Hence it is important to understand the influence of such variable parameters on the degradation mechanisms, to mitigate the fretting damage at modular junctions.

Our lab at UIC school of medicine focused on the tribocorrosion research, which involved electrochemical and fretting- corrosion behavior of various hip implant modular junction couples. Collaborative projects are progressing with Department of Orthopedic Surgery, Rush University Medical Center, Chicago and Department of Bioengineering at UIC, Chicago. Our new fretting-corrosion apparatus was successful in simulating the taper degradation related to a combination of mechanical wear (fretting) and chemical attack (corrosion) of a multiple taper implant system (see the figure below). The results indicate that synergistic interaction of wear and corrosion leads to mechanistic transitions at modular junctions of THR, which eventually accelerate the degradations process. The findings could assist in improving the current limitations of the hip modular junctions.



Representation of translational research whereby the knowledge of the loading and chemical conditions in hip implants is translated into a simulator in order to study the wear and corrosion mechanisms that occur at hip implant modular interfaces. The resultant knowledge is then used to improve hip implant design. *Artwork by D. Royhman and M.T. Mathew (Funded by R03 AR064005).*

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thereof to offer broader spectrum activity and extend the lifetime of the efficacious properties.

Alternatively, variations on the CovaCoat® technology elicit contact-kill antimicrobial efficacy through surface activation. This enables regeneration of the surface activation with subsequent dips of the device in the activation solution.

CovaCoat® offers a highly tunable and robust solution for improving patient outcomes and infection prevention strategies. The durability of the grafted hydrophilic coating makes it ideally suited for inserted devices, like catheters, and the sustained delivery of antimicrobial agents aids in the effort to combat hospital acquired infections.

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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.

From President Angela DiCiccio

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more grateful or proud of the progress we're making. The lessons we learn from this accelerated practice of medical device development will surely plant seeds for fruitful discussions at our next annual symposium—we are still looking towards Portland 2020 in October but like the rest of the world, let's approach all plans with nimble flexibility, respectful awareness of health, and hope.

I hope this issue inspires each of you to think about the network you have cultivated through your participation with SIBF, know that you are appreciated, and please don't hesitate to reach out to either get more involved, call on a favor, or learn something new.

With sincere appreciation,

Angela

WANTED: Section Editors for *SurFACTS* Contributions!

Why:

Section editors are critical to the success and quality of our *SurFACTs* quarterly publication, responsible for upkeep of the caliber of submissions and content.

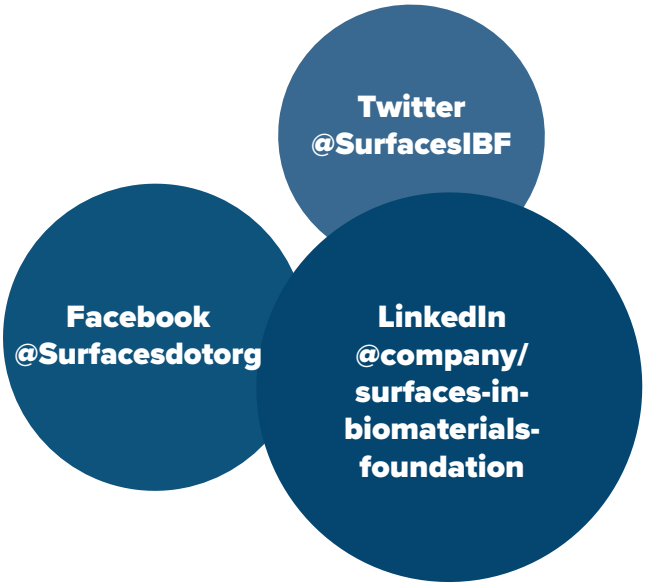
Who:

YOU! Any active member of our foundation, interested member in our community, especially new members and student.

Contributions:

- Renew commitment each quarter
- Collaboration calls for content planning and strategy (< 1 hr/month)
- Source and review articles related to your subject area
- Author and contribute perspectives and highlights

To participate in this key role and learn more please reach out to Melissa Reynolds (Melissa.Reynolds@colostate.edu) or Angie DiCiccio (diciccio@verily.com).



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