UPDATES FROM THE BTI, ORTHOPAEDIC AND OPHTHALMIC SIGS

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

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ALSO INSIDE

AN INTERVIEW WITH PETER EDELMAN

LETTER TO THE EDITOR BY LEN PINCHUK

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BIOMATERIALS FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 40, Issue 4

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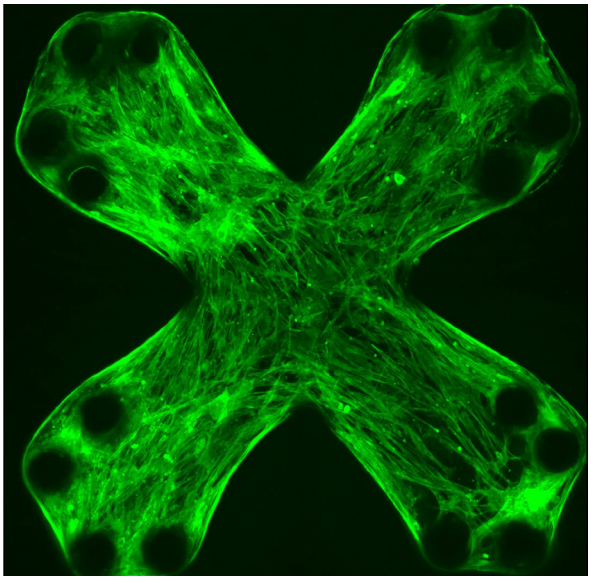

ON THE COVER

The cover image, provided by Prof. Ruogang Zhao of the State University of New York at Buffalo, shows the fluorescence image of F-actin of an engineered four-leaftlet human lung microtissue that mimics the multileaflet, membranous morphology of lung alveolar sac walls. With a diagonal span length of 1380 μm and thickness of 50 μm, this microtissue features a very high span length to thickness ratio of 28:1, corresponding well to alveolar sac geometry.

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NEWS & UPDATES

From the Editor

By Guigen Zhang, Editor, SFB Forum

A POLYMATH SCIENTIST

The term *polymath* is often associated with artists like Leonardo da Vinci. How many of us would associate it with scientists? In his new book *Helmholtz: A Life in Science,* David Cahan calls Hermann von Helmholtz (1821-94) a polymath.

Yes, this is the Helmholtz we are all supposed to know of. For example, in one of the research projects my group is working on concerning the electrical double layer, we often encounter the Helmholtz plane of the double layer structure. Sigmund Freud and Max Planck considered him their idol, and Einstein described him as a free thinker. But for those who may not know of him, his invention, the ophthalmoscope — a ubiquitous medical instrument in the form of a reflective device that shines light into your eye and allows a clinician to examine your retina through a small hole in the reflector — may ring a bell.

Helmholtz's childhood dream was to become a physicist, but life's course led him to become an army surgeon. But physics never left him. In his mid-20s, he came up with an early description of the conservation of energy before it was recognized as a fundamental principle of physics. He was the first to measure the speed of the conduction of nerve impulses. His *Handbook of Physiological Optics* laid the groundwork for understanding of vision.

Helmholtz also made contributions to physical chemistry by describing chemical reactions using the concept of free energy. His work on electrodynamics confirmed the formulation by James Clerk Maxwell. His research on vision and hearing led him to think about the foundations of geometry, and his idea of "non-Euclidean" geometry associated with the appearance of curvature in space inspired Einstein to conceive his theory of relativity. Without Helmholtz "the formulation of relativity theory would have been practically impossible," as Einstein put it.

He was a polymath steeped in music, art, literature and science. He played the piano and brought to the study of sound his passion for music, producing the book *On the Sensations of Tone as a Physiological Basis for the Theory of Music*. His holistic understanding of physics and physiology offered scientific explanations for why certain musical combinations we hear are related to the degree of clashing between the overtones of the various pitches. The Steinway piano company considered Helmholtz's discoveries so useful in improving its instruments that they gave him a grand piano in gratitude.

"THE STEINWAY PIANO COMPANY CONSIDERED HELMHOLTZ'S DISCOVERIES SO USEFUL IN IMPROVING ITS INSTRUMENTS THAT THEY GAVE HIM A GRAND PIANO IN GRATITUDE."

After spending half of his career as a professor of physiology, he arrived in Berlin in 1871 and became a professor of physics. Alongside his teaching and scientific work, Helmholtz was also a visionary leader: he was the founding president of a new kind of research center that bridged *applied* and *basic* science, building the institutional infrastructure that supported experiments that led to Planck's introduction of the quantum.

In closing, I want to briefly tell you what we have prepared for you in this issue. You will hear from SFB President Andrés García on his year-end summary of the state of the SFB, and read about member news and staff update. In our regular columns, your will read student news, SIG update, education news, industry news, government news, and a book review. This issue also features a "Letter to the Editor" from Len Pinchuk discussing his stimulating thoughts on how improved biomedical products could be developed and translated to the market place to benefit patients. Additionally, we bring to you an interview with Peter Edelman by Rebecca Carrier.

With best wishes,

Guigen Zhang

From the President

By Andres Garcia

DEAR SFB COLLEAGUES,

This has been a great year for SFB, comprising the outstanding Annual Meeting in Atlanta, *Biomaterials Day* local events and continued impactful contributions from our members. The SFB Council met in November to approve next year's budget and discuss and plan new initiatives to increase the value added for our members. We continue to focus on fiscal responsibility in prioritizing funding to maximize SFB impact and value. The measures proposed by the Finance Committee last year worked as planned, and I am happy to report that our Society is in good financial standing. We continue to support the *Biomaterials Day* events organized by local student chapters. These events provide excellent opportunities for scientific exchanges and networking and further extend the impact and brand of our Society. *Biomaterials Day* events will be hosted by the MidWest (Case Western Reserve University, University of Michigan Ann Arbor, Carnegie Mellon University and University of Pittsburgh), University of Florida, University of Washington, Texas Collaborative (Rice University, Texas A&M University, University of Texas at Austin, University of Texas Health Sciences and University of Texas at San Antonio), MidAtlantic (University of Maryland College Park, Johns Hopkins University, Penn State University), UC Davis, University of South Dakota, and North Carolina State University chapters.

By the time this letter is published, the final planning for the 2019 Annual Meeting in Seattle will be completed. The theme for this meeting is *The Pinnacle of Biomaterials Innovation and Excellence*. SFB has been the hub for excellence in biomaterials by bringing together an international community of academic researchers, industry scientists, clinicians, regulatory professionals and entrepreneurs to share knowledge on recent developments in basic and applied biomaterials research. I anticipate that this year's meeting will be a pinnacle of biomaterials innovation and excellence to educate, learn and collaborate across various scientific disciplines for improving human health. The Program Committee, working with SIGs, session organizers and reviewers, has organized an exciting cutting-edge scientific program. The Education & Professional Development Committee has again partnered with the Young Scientists Group to develop a track titled "Career Catalysis: Strategies for Biomaterials Education and Professional Development." The track consists of a group of sessions, social events and networking opportunities that relate to career development for SFB members at all stages of their career. The conference will provide many opportunities for networking and community building for all members — make sure that you take full advantage of everything that SFB offers. The meeting website can be found at https://2019.biomaterials.org/. As part of our contract with the hotel, SFB conference attendees are responsible for covering a minimum number of nights, so please consider staying there so we avoid any financial penalties.

"WE ENCOURAGE YOU TO FOLLOW US ON TWITTER AT @SFBIOMATERIALS AND TO RETWEET OUR POSTS, AND TO SHARE SFB POSTS ON FACEBOOK AND LINKEDIN!"

A point of emphasis for this year is to increase SFB's presence in social media to increase communication and networking among members and to disseminate the broad impact and contributions of our Society. The Social Media Task Force is increasing social media presence. We encourage you to follow us on Twitter at @SFBiomaterials and to retweet our posts, and to share SFB posts on Facebook and LinkedIn!

I congratulate Dan Lemyre on his 15-year anniversary working with SFB. Dan is an outstanding advocate and partner with our Society. I extend a personal note of thanks for all his hard work, dedication and patience throughout these years.

In closing, our Society is a thriving and nurturing community at the forefront of scientific excellence and societal impact. I challenge and encourage each of you to be engaged in the diverse activities that we support and to continue enhancing and increasing our impact. I welcome your ideas, suggestions and criticism — please email me at andres.garcia@me.gatech.edu.

Letter to the Editor

By Leonard Pinchuk, PhD, DSc, NAE, President and CEO, Innovia LLC, Miami, FL

Well, it finally hit close to home… My engineer's father died at only 76 years old from pulling out his urinary drainage catheter (often referred to as a Foley catheter) without deflating the balloon. This "pullout" injury occurs too frequently and continues to be a significant problem for patients in all age groups.

There are about 60 million urinary drainage catheters used per year worldwide. These catheters are threaded up the urethra to the urinary bladder. A balloon on the bladder end of the catheter is inflated in the urinary bladder to prevent it from slipping out. Urine flows through a drainage channel in the catheter to a urine collection bag, or the drainage end is shut off with a stopcock to allow for patient mobility.

A pullout injury occurs when the patient pulls out the drainage catheter without deflating the balloon; the inflated balloon rips the urothelium, causing bleeding and allowing urine to enter the bloodstream, causing sepsis, which can be fatal. Pullout injuries most frequently occur in elderly patients awakening from anesthesia, patients with dementia, or patients with confusion as a result of medication or trauma. It has been reported that up to 5 percent of ICU patients have Foley catheter pullout injuries. The cost to hospitals can be measured in the hundreds of millions of dollars, while the aggravation and burden for the urologists who have to clean up the mess and treat the patient, at all hours of the day and night, are immeasurable.

"TO AVOID ALLERGIES TO LATEX, WE USE AN INEXPENSIVE PROPRIETARY POLYURETHANE THAT CAN BE EXTRUDED, RATHER THAN DIP-COATED LIKE THE LATEX CATHETERS. WE ALSO INSERT-MOLDED THE DISTAL TIP AND THE PROXIMAL END TO CONSIDERABLY REDUCE THE COST OF GOODS. AS A RESULT, WE NOW HAVE A HYPOALLERGENIC, PULLOUT-SAFE, INEXPENSIVE URINARY DRAINAGE CATHETER."

There are two very frustrating problems to the biomedical engineer associated with these pullout injuries: (1) a very simple redesign of the urinary drainage catheter can prevent these injuries; and (2) it appears that the manufacturers of the current catheters simply do not care and therefore have no interest in resolving the problem.

Ironically, the engineer mentioned above has been working with me and a very concerned urologist to prevent pullout injuries by redesigning the current state-of-the-art urinary drainage catheters. The traditional urinary drainage catheter is a double-lumen catheter where one lumen drains urine and the other lumen is used to inflate or deflate the balloon with saline. The balloon is attached to the catheter at the bladder end.

Our new and improved catheter that can prevent these pullout injuries includes a slack thread that is tethered within the catheter. One end is attached to the hub that remains outside the patient, and the other end is connected to a plug located in the balloon. When the catheter is elongated by pulling the catheter a predetermined distance (the pullout), the thread tightens and pulls the plug out of the balloon, instantaneously deflating the balloon before the balloon has a chance to lodge within the urethra, thereby preventing the pullout injury. Many patents have been issued on this technology.

As we began to make prototypes of this catheter, we decided to upgrade other features of this age-old technology. For example, to avoid allergies to latex, we use an inexpensive proprietary polyurethane that can be extruded, rather than dip-coated like the latex catheters. We also insert-molded the distal tip and the proximal end to considerably reduce the cost of goods. As a result, we now have a hypoallergenic, pullout-safe, inexpensive urinary drainage catheter.

Despite our success in developing an improved product that can benefit the patient and the patient care facilities, and, importantly, save lives, sales and marketing of a commodity product like a urinary catheter are very difficult for a small company. Even if one can significantly differentiate the product, which we can, the multinational suppliers of commodity items

THEY REFUSED TO SIGN AND PROCEEDED TO INFORM US THAT, ALTHOUGH THEY ARE AWARE OF PULLOUT INJURIES, THEY DID NOT WANT TO FIX THE PROBLEM DUE TO THEIR PERCEIVED INCREASE IN MANUFACTURING COST.

such as urinary catheters usually bundle the product with other items. In addition, there are longstanding and very strong relationships between these vendors and the companies who own/run the hospitals. It makes more sense to sell the technology or provide the catheter to a large company, who then sells it to the doctor or hospital.

With this in mind, our team approached the business development personnel of market leaders to determine their level of interest in improving their product line or their market share by introducing this safety catheter. In view of our new technology and proprietary materials, I asked the market leader to sign a confidentiality agreement to protect us against reverse engineering the material. They refused to sign and proceeded to inform us that, although they are aware of pullout injuries, they did not want to fix the problem due to their perceived increase in manufacturing cost. The second in line also rejected us with the ridiculous assertion that, if the market leader was not interested in pursuing this technology, then why should they be interested. (This attitude is probably why this particular company is not the market leader.) The third in line, after repeated solicitations, never returned our calls. And so, the product is not available to the public while more patients are suffering and dying from these pullout injuries.

"AS NEWER AND BETTER PRODUCTS ARE DEVELOPED TO ADVANCE THE HEALTHCARE OF THE PATIENT, COMPANIES MUST BE ACCOUNTABLE AND TAKE THE NECESSARY MEASURES TO ADOPT THE LATEST STATE OF THE ART."

Solvable medical device injuries are rampant in our industry. In the niche where I work, I have watched several frustrating examples of this problem. For 40 years, I have seen the cracking and deterioration of polyurethane pacer lead insulators; we have a fix, but the latest excuse for not fixing this problem is that the new materials are too expensive. In ophthalmology, I have spent the last 15 years observing intraocular lenses glisten and become hazy with patients complaining of losing contrast sensitivity at night. We have fixes, but the market leaders of these commodity products, once again, do not want to address these issues. Devices that come into contact with blood can be thrombogenic. There are now surface-modifying additives that can be blended into materials interfacing blood to minimize these clots; unfortunately, this fix is not widely adopted. Finally, we are all aware of the problem with infections in hospitals, but the remedies are rarely implemented.

I propose the following idea to help solve this frustrating and disturbing problem. Knowing that insurance companies and Medicare bear the multibillion-dollar cost of treating the patient when the deficient products fail, they must take on the task of establishing standards with which the medical device industry must timely comply. This is similar to the government setting emission standards for automobiles by certain specified dates. As newer and better products are developed to advance the healthcare of the patient, companies must be accountable and take the necessary measures to adopt the latest state of the art. Companies that do not comply should be fined at levels higher than the cost of the fix to render the fix the less expensive alternative. Better still, penalties collected can be used to help finance companies and universities to find solutions for these problems as needed. Providing financial help to the academic or industrial entrepreneur will solve problems, save lives and keep the money in the biomedical community rather than pay for late night advertisements that read "Do you or your loved ones suffer from pullout injuries? If so, please contact the law firm of ….."

Member News

By Rebecca Carrier, Member-at-Large

Society for Biomaterials members,
I am honored to serve as your 2018-2019 Member-at-Large. I aim to work with you to give SFB membership a clear voice for SFB's direction, so together we can help SFB grow and maximize the value of your SFB membership — please email me at r.carrier@northeastern.edu with any ideas and feedback you would like to share!

This quarter's exciting member news and accomplishments include the following:

Prof. Ramille Shah and **Dr. Adam Jakus** recently founded a company, Dimension Inx, to commercialize and translate advanced material 3D-Painting technology they have developed at Northwestern University over the past eight years. This work has been presented at multiple SFB events over that time period. Dimension Inx develops and manufactures medical and nonmedical materials that can enable other companies and industries to develop new technologies and products. Dimension Inx's cofounders believe that the primary challenge to date in advanced manufacturing for applications in regenerative medicine and tissue engineering is not hardware, software or processes, but rather the limited types of existing materials. With its advanced and proprietary materials design and manufacturing platforms, including 3D-Painting, Dimension Inx has introduced an extensive range of highly functional, room-temperature 3D-printable, tissue and organ regenerative materials, including but not limited to Hyperelastic Bone™ (regenerates hard biological tissues), 3D-Graphene (for bioelectronics and nerve, muscle, and cardiac repair and regeneration), Tissue Papers, and Fluffy-X™ (Universal biofabrication material) as well as nonmedical metals, alloys, ceramics and even extraterrestrial materials. 3D-Painting is a manufacturing technology that permits nearly any material, from biological tissues to ceramics, metals, alloys, and more to be 3D-printed (or formed into fibers, used as coatings, foamed, etc.) via simple room-temperature extrusion. Dimension Inx offers an extensive array of products and services including a variety of 3D-Paints, custom 3D-painted products, custom material design service and advanced end-product codevelopment services.

Michael Mitchell, the Skirkanich Assistant Professor of Innovation in the Department of Bioengineering at the University of Pennsylvania, was recently awarded the National Institutes of Health (NIH) Director's New Innovator Award (Grant ID: DP2-TR002776). This highly competitive award is from the NIH Common Fund's High-Risk, High-Reward Research Program, which supports innovative research proposals that might not succeed in conventional peer-review processes despite their promise for medical advancement. The $2.4 million grant awarded to Dr. Mitchell supports his novel approach to design drug delivery systems, a 4D platform: data-driven drug delivery. This approach uses machine learning and data to aid in identification of which physical and chemical properties of a drug delivery technology allow targeting of diseased cells in the body. Dr. Mitchell is working toward enabling testing of many delivery systems at a time for identifying molecular parameters key to efficacy, and ultimately enabling prediction, prior to dosing in humans, of which delivery technology would be best for delivery to specific tissues or even subsets of cells. The New Innovator award will be instrumental in allowing Dr. Mitchell to advance his lab's work integrating cellular engineering, biomaterials science, and drug delivery to understand and therapeutically target complex biological barriers in the body.

Lijie Grace Zhang's lab in the Department of Mechanical & Aerospace Engineering at the George Washington University has discovered a reprogrammable multiresponsive architecture through 4D bioprinting a smart natural polymer. A unique laser-induced graded internal stress followed by a subsequent solvent-induced relaxation, driving a reversible and autonomous change of the programmed configuration after bioprinting, was employed for the first time. Moreover, the naturally derived shape memory polymer is able to trigger an additional "thermomechanical programming" shape transformation over the 4D effect. Using this unique dual 4D technique, a proof-of-concept smart nerve guidance conduit was demonstrated on a graphene hybrid 4D construct, providing outstanding multifunctional characteristics for nerve regeneration, including physical guidance, chemical cues, dynamic self-entubulation and seamless integration. The developed 4D process can elicit proper biological responses that not only mimic the dynamic growth process of native tissues/organs but also achieve a more complicated, dynamic architecture for tissue implants that meet the criteria of multiple variations with precisely controlled stimuli processes. This work also paves the way for the initiation of 4D bioprinting in various high-value research fields such as soft biorobots and intelligent biomanufacturing. This study was featured as the cover image of the September issue of *Advanced Biosystems*.

Staff Update

By Pam Gleason, Assistant Executive Director

Greetings from the Society For Biomaterials headquarters! The Society's Board of Directors and governing Council met on November 5 at SFB headquarters in Mount Laurel, New Jersey. They reviewed the 2019 budget and continued their work implementing the strategic plan for the Society. Following is a summary of the actions and plans for the Board, Council, Committee and Task Forces:

BOARD / COUNCIL

President, Andrés García, PhD

The Board previously added two task forces, one to increase the Society's social media presence, and the other to consider the development of a new Fellows designation for SFB members that would be distinct from the IUSBSE Fellows program. The Fellows designation would recognize long-standing members who have contributed to and impacted the Society.

AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE

Chair: Thomas Webster, PhD

The Awards, Ceremonies and Nominations Committee received a total of 40 award nominations and a full plate of officers to stand for election in 2019. As of this writing, Council has ratified the award recipients and the slate of officers. Officer candidate information is featured in this issue for your review. Award announcements will be featured in the next issue of the Forum. Thank you to all who made nominations, and please start thinking about possible nominations for next year — especially those who may have interest in serving on the Society's Board of Directors as President-Elect and Member-At-Large.

BYLAWS

Chair: Ben Keselowsky, PhD

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

EDUCATION & PROFESSIONAL DEVELOPMENT

Chair: Jan Stegemann, PhD

The Committee reviewed submissions for 2019 Biomaterials Days Grants. All the applications were excellent, and eight applications were accepted for funding.

Biomaterials Days organizers will receive a package that includes retractable banners, swag items, flyers, promotional slides and a promotion code. Students and post-docs who register for a Biomaterials Day event can use the promotion code for a $50 discount off their membership dues.

The mentor/mentee initiative at the 2018 Annual Meeting was successful. Anyone interested in becoming a volunteer mentor for 2019 should send a letter of interest to info@biomaterials.org.

The Young Scientist Career Catalysis group is planning some interactive challenges at the Annual Meeting to engage young scientists. Additionally, student and mentoring and professional development sessions are in the works to be held at the Annual Meeting.

FINANCE

Chair: Elizabeth Cosgriff-Hernandez, PhD

The Society assets are up, and projections indicate a healthy net income for 2018. The Society made a transfer back to reserves bringing the Society back to its chartered fund distributions. The SFB 2019 budget was approved. Please continue your support by booking your accommodations for the 2019 Annual Meeting at the headquarters hotel.

INDUSTRIAL AFFAIRS

Chair: Peter Edelman, PhD

The Committee will be reviewing matters of particular concern to the manufacture of biomaterials and have been developing content for the Annual Meeting Program as directed and requested by the Program Committee.

LIAISON

Chair: Tim Topeski, PhD

The Committee has finalized plans for a 2020 Fall Symposium with the Japanese Society For Biomaterials to be held in Honolulu, Hawaii, December 13-15, 2020.

The Committee is progressing with a revised Endorsement Request Form for joint cosponsored efforts. These opportunities provide helpful selection of keynote speakers for future sessions, and support in organizing sessions at future Annual Meetings.

MEMBERSHIP

Anirban Sen Gupta, PhD

Current membership stands at 1,404 with 699 active, 101 post-grad, 49 retired, and 555 students, and continues to trend upward; this time last year, we were at 1,182, and 1,055 in 2016. The Committee continues to develop strategies to increase membership, especially focusing on industry and clinical sectors. Specifically, the Committee has finalized a plan to offer industry membership subscription packages, which will roll out in the 2019 membership year. The Committee has also developed a

[CONTINUED ON PAGE 8]

member exit survey to collect information on why a member may choose not to renew. The results of this survey will be used to create a strong retention plan. A main target area of focus will be on Student to Post-Grad conversion.

PROGRAM

Chairs: Gopinath Mani, PhD and William Murphy, PhD

The 2019 Society for Biomaterials Annual Meeting & Exposition will take place in Seattle, WA, April 3-6, 2019. The call for abstracts has ended and was successful, with the submission of 942 abstracts. The Committee met December 10-11 to make the final selections, and announcement of poster and oral presentations will be made by the end of the year.

SPECIAL INTEREST GROUPS

Representative: Sarah Stabenfeldt, PhD

The SIGs who have submitted proposals for the 2019 meeting in Seattle and planned their budgets for 2019 were approved. Those SIGs who did not submit a budget proposal will receive no funding for 2019. SIG members are strongly encouraged to attend the Annual Meeting. The SIGnal newsletter continues to be published monthly.

If you have any questions,

need any information or have suggestions for improved services, please feel free to contact the Society's Headquarters office:

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ATTENTION MEMBERS!

WE WOULD LOVE TO HEAR FROM YOU.

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

Student Chapter News

By Margaret Fettis, Student Chapter President

The national officers of the Society For Biomaterials worked together to prepare possible session ideas aimed at early-career and student researchers. The collaborative effort included incoming and current officers: Marc Thompson, Jason Guo, James Shamul, Michaela McCrary and Maggie Fettis. We are already excited for the 2019 Annual Meeting in Seattle! SFB will host the Biomaterials Education Challenge again this year. I highly encourage student chapters to start brainstorming outreach activity ideas to implement and present at our Annual Meeting.

INCREASING STUDENT INVOLVEMENT IN LOCAL SFB CHAPTERS

As a graduate student, I am acutely aware of how important it is to devote time to research, writing and reading. Both graduate and undergraduate students can relate to the feeling of being too busy to add extracurricular activities to their schedules. However, all university student groups have these challenges. Some of our strongest learning experiences and personal growth can happen outside of the lab or classroom walls. Getting involved in local student chapters allows students to build their resume by developing soft skills, conflict management, and leadership skills and by networking. Below is some advice to improve student engagement in local chapters.

Hold regular meetings scheduled ahead of time

Hosting student meetings on a recurring schedule allows students to make time for meetings. Scheduling meetings a couple weeks ahead of time also allows students to schedule around meetings.

Offer valuable experiences at the meetings

Seminars featuring invited speakers are excellent ways to invite students to learn about biomaterials in a relaxed environment. Speakers can include professors, postdoctoral associates and senior graduate students who specialize in biomaterials research. Other possible meeting topics could include career development workshops, preconference presentation practice and advice for undergraduates applying to graduate school. After the meetings, try to send out a brief newsletter or minutes of what happened at the meeting to keep students unable to attend engaged.

Form committees to foster engagement

Form formal committees within student chapters to help with events or develop themes within the chapter. Examples include Outreach/Community Involvement Committee, Biomaterials Education Challenge Committee, Social Events Committee and Biomaterials Day Development Committee. Allowing student members to engage directly with chapter officers will help them feel like included and accountable members of a community.

Sprinkle in some fun

While biomaterials is always fun, including social activities in the student chapter calendar gives students a chance to network with each other. The University of Florida chapter started a "Pop Sci Fri" event where students gather together in an informal setting on a Friday afternoon to discuss a recent biomaterials-related paper. Other ideas include starting an SFB intramural team, attending a university sports event or hosting a coffee break.

Advertise!

Advertising is the single most important thing you can do to get students to meetings and to let them know about chapter events. Contact any department at your university that conducts biomaterials-related research. Post flyers advertising meetings and events on your department bulletin board or in other relevant places. If there are biomaterials courses or courses that have biomaterials modules, ask the professor teaching the course if you can make a quick announcement before class encouraging students to attend an upcoming SFB meeting. Create social media outlets for your chapter. Create chapter events on Facebook, and encourage Twitter followers to get the word out with retweets. Advertise these meetings and events well in advance. Ask students to sign in during meetings, and encourage them to sign up to receive email updates and reminders from the chapter. Email the students who signed up for updates every time an SFB meeting or event is taking place.

We would also like to congratulate our newest student chapter at the University of California, Davis!

WELCOME, UC DAVIS!

Advisor: Kent Leach, PhD
President: Amir Bolandparvaz
Vice President (President-Elect): Riley Allen
Secretary/Treasurer: Noah Pacifici
Secretary/Treasurer-Elect: Kevin Campbell
Biomaterials Chair: Dustin Hadley
Publicity Chair: Marcus Deloney
Bylaws Chair: Rian Harriman

Highlight of the Biomaterials Day at NC State University

The Society for Biomaterials Student Chapter at North Carolina State University organized the second annual Biomaterials Day on Friday, October 19th, 2018 at the James B. Hunt Library located on the University's Centennial Campus. There were 131 people registered online before the event and more than 90 people showed up to attend.

This year Dr. Jeffrey Jones, the Department Head and Professor of Textile Engineering, Chemistry and Science, gave us the welcome address in the opening session. Like last year, there were four invited speakers. Drs. Ke Cheng and Zhenhua Li from Molecular Biomedical Science, NC State, talked about biomaterial and biomimetic approaches for cardiac cell therapy. Dr. Edwin R. Cadet, MD, from Raleigh Orthopaedic Clinic, who was recognized in 2013 by the New York Times Magazine as one of the Super Doctors® New York Rising Stars, gave a lecture on the topic of "Innovations in Rotator Cuff Repair", leading us through the causes, surgical principles, and clinical procedures for repairing a torn rotator cuff.

Dr. Jason Cramer from the NC State Graduate School joined us at lunch to talk about the current job landscape, the required skills for finding employment, as well as introducing us to the "Accelerate to Industry" (A2i) program founded at the NC State Graduate School and now being franchised to other universities across the country.

Dr. Barbara Nsiah, a senior scientist at United Therapeutics Corporation, delivered the first lecture in the afternoon focused on the manufacturing process required for a tissue engineered lung. She gave us a clear sense of the differences in the R&D approach between academia and industry. Dr. Thomas H. LaBean, Professor from Materials Science and Engineering at NCSU, shared his research focus on the design, construction, testing and application of self-assembled DNA nanostructures and their biomimetic fabric of nano-electronics.

This year Biomaterials Day attracted 20 student speakers from different departments and universities who gave either oral or poster presentations. Awards were given to the following winners: Ria D. Corder from Chemical and Biomolecular Engineering (CBE) at NCSU, and Emily P. Mihalko from Biomedical Engineering (BME) at NCSU & UNC Chapel Hill won the first and second prize in the oral presentation competition.

Dr. Jason Cramer introduced A2i™ program

Dr. Martin W. King with oral presenters

Ke Huang from Molecular Biomedical Science and the Comparative Medicine Institute (NCSU), Seema Nandi (BME), and Bgaradwaha S.T.P. (CBE) stood out in the poster competition and won the first, second and third prizes, respectively.

SFB Student Chapter officers at NC State

Dr. Martin W. King made the closing remarks and presented the awards to the student winners. A sincere "Thank you" was expressed for our five judges (Dr. Susan H. Bernacki, Dr. Martin W. King, Dr. Wendy Krause, Dr. Kavita Mathur, and Dr. Gisela Umbuzeiro) who were able to evaluate the student's research work and presentations from a multidisciplinary perspective.

The whole event could not have been such a big success without our outstanding invited speakers who gave us four amazing lectures, and the generous sponsors whose financial support provided us with registration kits, rental of the library space, student awards, lunch and refreshments. The sponsors were Atex Technologies Inc., NC State College of Textiles, NC State Student Government, North Carolina Biotech Center, North Carolina Textile Foundation, Novozymes Inc., Terumo Aortic Inc. and the Society for Biomaterials. The officers of the Student Chapter: Yihan Huang, Dan Chester, Sherry Xie and Monica Deshpande, wish to thank all the volunteers whose commitment of time and effort insured the event's success. The Society for Biomaterials Student Chapter at NC State University looks forward to continued growth and prosperity in the coming year, and plans to organize another Biomaterials Day event in 2019.

Education

IMPROVING THE EXPERIENCES OF ENGINEERING GRADUATE STUDENTS

By LaShan Simpson, Educations Editor

Contributors: Cheryl Cass (North Carolina State University), Adam Kirn (University of Nevada, Reno) Marissa Tsugawa (University of Nevada, Reno), Heather Perkins (North Carolina State University), Matthew Bahnson (North Carolina State University), Blanca Miller (University of Nevada, Reno), Derrick Satterfield (University of Nevada, Reno)

Researchers from North Carolina State University (NCSU) and the University of Nevada, Reno (UNR) have teamed up to study the ways in which engineering students experience their doctoral-level training. The paucity of research on this topic has led to wide-reaching, systemic problems in engineering graduate education (e.g., underrepresentation of female and minority students[1], high attrition rates[2] and degradation of mental health[3]). Only through a systematic examination of graduate education can changes occur that improve the graduate experience. To begin addressing these issues and providing tools for change, a National Science Foundation-supported project has explored the ways graduate student experiences influence engineering identity formation and goal-setting processes, which are attitudinal characteristics that influence academic performance[4], participation[5] and retention[6] in engineering communities of practice. Here, engineering identity is used to describe *how students see themselves as engineers*.

In the qualitative phase of this mixed-methods project, PhD students (n=46) in engineering programs were recruited to participate in focus groups and interviews about their graduate-level academic and research experiences. The goal of the analysis of this data was to understand the lived engineering experiences of the students and the meaning found in these experiences within the context of the project's focus on identity and motivation. In brief, results of this phase indicated that engineering graduate students draw on a higher number of social identities (e.g., gender, race/ethnicity, parental) and role identities (e.g., engineer, scientist, researcher) when navigating their doctoral experiences when compared with undergraduates[7], leverage the past and the future when making decisions for the present[8], and seek ways to integrate their identities into their research projects and graduate experiences[9].

A quantitative phase followed, during which a survey on graduate school experiences was administered to a nationally representative sample of engineering graduate students enrolled in 527 doctoral degree-granting programs.

"It is one of the largest-scale surveys on graduate engineering education to date, with nearly 2,300 student participants," says Cheryl Cass, teaching associate professor and director of Undergraduate Programs in the Department of Materials Science and Engineering at NCSU. "One interesting finding in terms of response rate is that roughly 25 percent of students dropped out of the survey in the demographics section when we asked them to share their university and academic program. This shows that we have diffuse problems in graduate engineering education, and students are afraid to talk about them."

Additional results indicate that engineering graduate students enter their graduate programs with myriad future career goals and identities. We can help students persist through difficulties in their graduate programs by re-examining how we mentor and advise our students and relate and connect their research outside of the lab.

"From the beginning of this project, our goal has been to focus on how our results can inform evidence-based programmatic change in Colleges of Engineering and doctoral degree-granting programs across the United States that will lead to improved engineering identity development and student motivation," says Adam Kirn, assistant professor of Engineering Education at UNR. "Far too often, graduate school interventions focus on how the student can adapt to fit the culture of an engineering program, and this has served to marginalize students, particularly those from groups traditionally underrepresented in engineering doctoral programs."

The researchers have thus made some practical interpretations of their work that can be applied by graduate advisors and administrators.

TIPS FOR FACULTY WHO ARE MENTORING AND ADVISING GRADUATE STUDENTS

1. Allow and develop students to explore their own research ideas and solutions.
2. Discuss students' future career plans, goals and steps required to achieve these goals.

3. Create distributed mentoring networks that address a breadth of students' needs and interests throughout their graduate experience.
4. Graduate students are not necessarily academics in training, therefore students' career options outside of academia need to be supported.

TIPS FOR FACULTY AND ADMINISTRATORS TO HELP CONNECT AND RELATE RESEARCH OBJECTIVES

1. Design graduate courses to explicitly integrate research practices alongside student knowledge building to better foster student identity development.
2. Create videos with senior graduate students explaining how present research tasks relate to future tasks, and assign self-reflection writing tasks to help students connect present tasks with future goals.
3. Integrate non-research tasks with research tasks to increase productivity and knowledge development.
4. Demonstrate how engineering skills and knowledge are used in the research process.

"IN BRIEF, RESULTS OF THIS PHASE INDICATED THAT ENGINEERING GRADUATE STUDENTS DRAW ON A HIGHER NUMBER OF SOCIAL IDENTITIES (E.G., GENDER, RACE/ETHNICITY, PARENTAL) AND ROLE IDENTITIES (E.G., ENGINEER, SCIENTIST, RESEARCHER) WHEN NAVIGATING THEIR DOCTORAL EXPERIENCES."

While the results of this study speak to graduate students holistically, further work is needed to understand how members of the different subpopulations (e.g., underrepresented minorities, international students) that exist within engineering graduate programs experience graduate education. Work that began during the fall 2018 semester will use the quantitative survey data to cluster students into various attitudinal profiles, and follow-up interviews will be conducted with graduate students who fall into the various clusters so that researchers can determine how and why specific graduate experiences impact identity and motivation in engineering disciplines.

ACKNOWLEDGMENTS

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Orthopaedic Biomaterials SIG Update

DESIGN OF ORTHOPAEDIC DEVICES WITH AUTODESK INVENTOR

By Roche C. de Guzman, PhD, Assistant Professor, Department of Engineering, Hofstra University

The majority of clinical orthopaedic devices and hardware are solid and rigid metallic, ceramic, and polymeric biomaterials with distinct but defined geometries and shapes.[1] Prior to manufacturing, these devices are initially conceptualized in the designer's mind, then sketched, prototyped and evaluated using three-dimensional 3D models. In today's technological landscape, computer-aided design (CAD) programs [2, 3] are widely used, particularly for the design and modeling of these mechanical parts and assemblies. Parametric modeling software employs dimensional and geometric relationships and constraints to lines, curves, vertices, edges, faces, and multiple other features that consequently make the iterative design process and design intent easier to accomplish. Inventor (Autodesk, San Rafael, CA) is a popular CAD parametric modeler.[4] Individuals with educational affiliations (students, teachers and design mentors) can register for a free Inventor license for three years! Now, you just need to know how to use it.

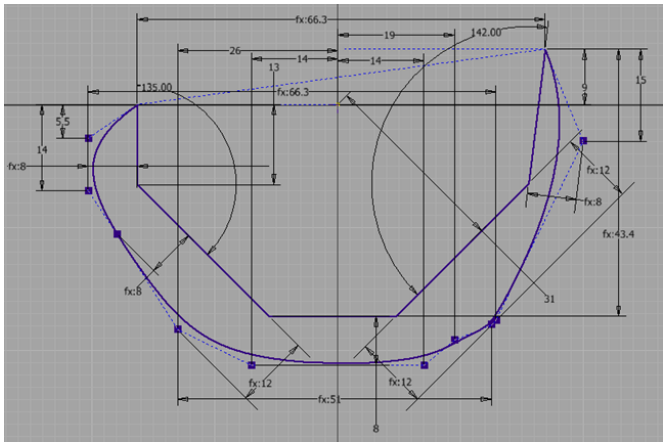

Figure 1. A fully constrained 2D sketch using line and spline tools with defined dimension and geometric parameters used for extrusion of the femoral component 3D model.

Bioengineering and biomedical engineering undergraduates enrolled in capstone senior design courses are often tasked with developing and designing various medical devices. Common examples include orthopaedic implants such as the major artificial joints: hips, knees, shoulders and elbows.[1] This article describes the implementation of Inventor for the bottom-up[5] design approach of a three-part total knee arthroplasty (TKA) implant assembly, which can serve as a learning instruction for students and faculty members unfamiliar with basic CAD operations. The femoral component, tibial tray and spacer TKA parts were modeled as separate part files (*.ipt), organized and adjusted into an assembly (*.iam), converted into a presentation (*.ipn), then shown as two-dimensional 2D) projections and images in a drawing file (*.idw).

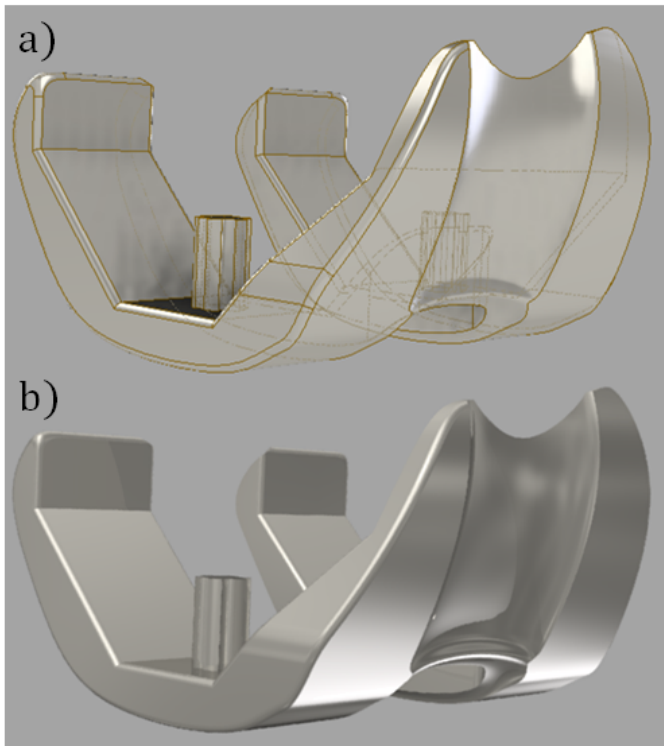

Figure 2. The designed femoral component assigned with titanium material and viewed as (a) shaded with hidden edges, and (b) realistic with activated ray tracing.

The titanium femoral component model was initiated by creating a closed-loop 2D sketch (Fig. 1) on a selected origin plane (XY, XX or YZ) using line and spline tools and fully constrained with defined dimensions and geometric relationships like perpendicular, coincident and horizontal constraints. The boat-shaped sketch was symmetrically extruded to form a solid body. A closed spline sketch was made on a new work plane in front of the object, cut swept backward, creating the distinct irregular front shape, and cut swept again using a partial ellipse with a curved path to carve out the medial depression (Fig. 2). Femoral lugs (for femoral bone insertion) were formed by extruding a circle, cut extruding a smaller semicircle, generating a circular pattern with six features to create grooves and mirroring on the medial plane. Cut extrusion using a rectangle sketch was done to trim the middle third of the material, then finally fillets were added to smoothen the edges and vertices of the component (Fig. 2). Titanium was selected under physical material iProperties and project information updated.

The titanium (iProperties selected material) tibial tray or plate component was designed next starting from an extruded bean-shaped 2D sketch of arcs and lines. Project geometry and offset tools were employed to sketch the inner perimeter and

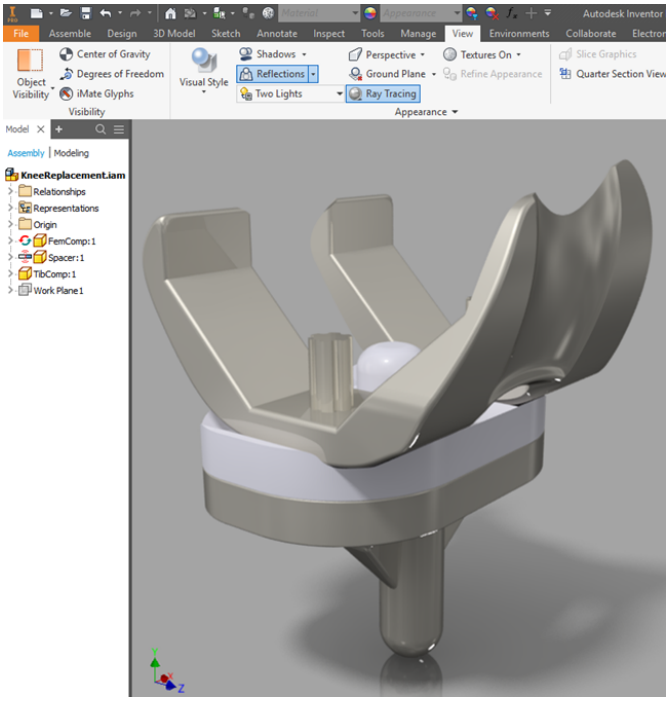

Figure 3. The assembled TKA model composed of three parts: femoral component, spacer and tibial tray, with added contact sets, and mate, flush, tangent, and angle constraint relationships.

cut extruded to produce a shallow depression for supporting the spacer component. The stem was extruded from a circle and filleted to round its end. A trapezoidal sketch in the corner of the stem and underplate was made on the long-axis work plane, revolved symmetrically to 25°, then mirrored to create the posterior keel. Grooves were introduced via sweep and mirror functions. A support keel arc was revolved at the bottom of the plate. External edges were rounded and softened using fillet and chamfer tools.

The final CAD-modeled part was the high-density poly(ethylene) (PE) spacer to provide articulation to the femoral component, mimicking the normal knee joint structure. The project geometry feature was used to copy the inner perimeter of the tibial plate into a new 2D sketch to ensure proper match. Extrusion was used to generate the 3D body, offset anterior plate and cylindrical stabilizer at the center. An inverted trapezoid was sketched using an offset plane, cut swept to remove materials for the external femoral convex surfaces to fit, symmetrically mirrored and fillets applied to smoothen the edges including the stabilizer. High-density PE was assigned as the part material.

The three TKA components were put together in an assembly file (Fig. 3) and checked for dimension consistency and fit. After

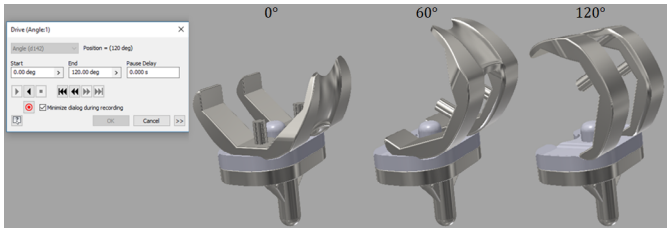

Figure 4. Kinematic simulation of the femoral component articulation with the spacer surface evaluated at 0 to 120° using the drive function of the applied angle relationship.

design corrections and verifications, mate constraints were placed between the posterior surface of the spacer and the anterior tibial tray. The tibial tray orientation was normalized to the three origin planes using mate and flush relationships, and subsequently grounded to prevent motion to this reference component during the assembly process. Both spacer and tibial tray were converted to contact sets, and the activate contact solver was turned on to engage and immobilize the spacer onto the tibial plate. The articulating femoral component and spacer surfaces were formed into a tangent relationship, and their respective medial planes were flushed constraint for alignment. Construction lines were created in their central axis, and angle constraint was applied with a maximum value set to 120°, similar to the native knee range of motion (ROM).[6] The analyze interference inspector confirmed that the three pieces associated without solid-body interference. The TKA bending ROM was investigated using the drive command to the angle constraint, and the result (Fig. 4) exhibited realistically feasible rotational dynamics.

To produce an exploded view of the components, a presentation file was made, assembly rotated in a projected angle, then tweak components were added by moving the femoral component and the spacer sequentially away from the tibial tray. Create drawing view was activated afterwards. In the drawing file, the exploded view was labeled with balloons and parts list of the bill of materials (BOM) incorporated with their appropriate descriptions (Fig. 5, page 16). Base (front), projected (top and side), auxiliary (isometric), section, and detailed views were also included from the assembly for additional 2D representations of the TKA medical device.

For further design improvement toward product development, simulation tools such as stress analysis, dynamic simulation, and frame analysis and modification of physical properties can be used. Particularly in stress analysis, the shape generator function (with the principles of finite element analysis) can be used to

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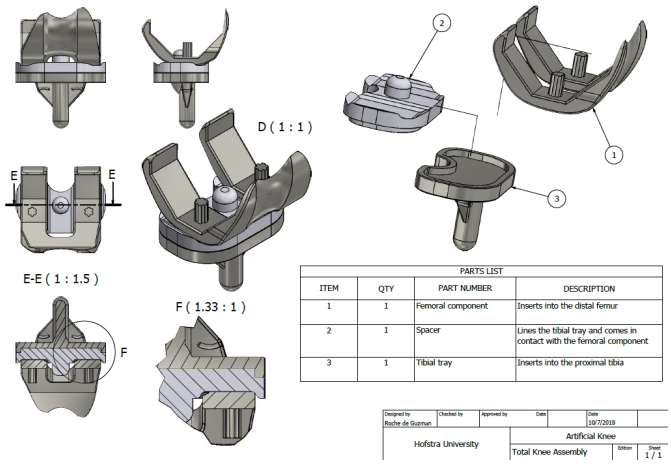

Figure 5. A 2D drawing sheet of the designed artificial knee assembly with representative base, projected, auxiliary, section, detailed, and exploded views, BOM parts list, and project information annotations.

create alternative designs by trimming unnecessary materials, but still sustain the specified loads. This design and modeling exercise demonstrated that relatively simple structures can be made using Autodesk Inventor employing different 2D and 3D functionalities for sketches and 3D models. Learning the fundamentals of Inventor (and other CAD softwares) will definitely enhance the skillset of engineers and scientist working in the field of orthopaedic biomaterials, specifically toward the development of various orthopaedic devices.

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Ophthalmic Biomaterials SIG Update

UPDATE FROM THE OPHTHALMIC BIOMATERIALS SIG: PROGRESS IN BIOMATERIAL-BASED APPROACHES FOR IMPROVED TREATMENT OF OCULAR TRAUMA

By Michael A. Washington and Morgan V. Fedorchak, University of Pittsburgh, Department of Ophthalmology, Pittsburgh, Pennsylvania, USA

INTRODUCTION

According to the U.S. Eye Injury Registry (University of Alabama at Birmingham), more than 2.4 million eye injuries occur each year in the United States alone, an estimated 1 million of which result in permanent, significant visual impairment. Nearly 75% of individuals who suffer permanent impairment become monocularly blind, making eye injury the second most common cause of visual impairment behind cataracts.[1] The majority of these cases occur in individuals under 30 years old, thus greatly increasing the economic and emotional impact of such trauma. This is compounded due to the high rate of such injuries in military personnel, with an estimated 13% of individuals in active combat zones sustaining an ocular injury. Ocular trauma statistics from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) reveal that the most frequent ocular injuries are open-globe and adnexal laceration. Approximately 75% of open-globe injuries in OIF and OEF resulted in a best-corrected visual acuity of 20/200 or worse (currently defined in the United States as legal blindness), increasing to 85% when oculoplastic or neuro-ophthalmic injury occurred concurrently with globe injury.[2,3]

The immediate post-injury needs are numerous and are absolutely critical to the proper healing and function of the eye and its supporting structures. Among these primary needs are identification and sealing of open globe injuries, wound coverage and hydration, infection prophylaxis, and inflammation control. Secondary to these needs are the structural support around the globe, including both soft tissue and bony structure, as ocular injuries tend to be quite complex, commonly involving the bony orbit and/or surrounding periocular tissues (i.e., eyelids, muscles, tarsus and glands).

This update aims to describe current investigational biomaterials-based approaches to managing the myriad injuries associated with ocular trauma. This includes ocular drug delivery, novel glues and tissue-engineered scaffolds to support proper aesthetic and functional outcomes in and around the eyes after trauma.

PROGRESS IN OPHTHALMIC DRUG DELIVERY

During the immediate time period following ocular injury, the primary focus is on sequestering the injury site and mitigating pain via systemic administration of opioids and, less commonly, antibiotics. At all times, intraocular pressure spikes must be avoided to prevent damage to retinal tissues or loss of intraocular contents if the globe is compromised. However, open globe injury in particular provides a unique opportunity to deliver drugs into the anterior and posterior chamber prior to wound closure.

Two key classes of drugs to consider are anti-infectives and anti-inflammatory drugs. Local administration via sustained or controlled release vehicles can minimize systemic exposure to drugs while increasing overall drug bioavailability. This effect has been demonstrated for a wide variety of ophthalmic diseases using a range of minimally invasive systems. Such systems include drug-loaded contact lenses, mucoadhesive or nanoparticle-laden eye drops, microneedle arrays, polymer thin films, hydrogels and more[4]. The recent reviews by Dubald et al and Diebold et al highlight several such methods for delivering anti-infective and anti-inflammatory drugs, respectively, that may also be candidates for use following trauma.[5,6] Particularly in military applications, where the time to surgery can be significantly delayed, long-term autonomous drug delivery may offer substantial benefits to patients. Further, the increased storage life typical of many controlled release systems would be attractive for use in active combat zones.

PROGRESS IN OPHTHALMIC GLUES

Stabilization of open-globe injuries is typically achieved by conventional suturing with standard 10-0 nylon sutures and/or application of a tissue glue. Tissue glues have been successfully used for numerous ophthalmic procedures involving conjunctival and corneal closure and management of ocular wound leaks; however, many are contraindicated for ophthalmic use by the U.S. Food and Drug Administration (FDA). Ophthalmic glues can be divided into subcategories on the basis of their function: blood clot formation (hemostat), barrier formation (sealant) or binding of interfaces (adhesive). The most commonly used glues for ophthalmic applications are hemostatic fibrin-based glues and cyanoacrylate adhesives. While these glues offer improvements compared to suturing alone, significant progress has been made in developing new glues for various tissue engineering applications, including trauma-induced wounds.[7-9]

Hydrogel-based adhesives are a unique class of glues that undergo in situ gelation via chemical cross-linking after photo-induced (e.g., UV, visible light) or mild nucleophilic substitution reactions or via physical cross-linking after exposure to an external stimulus (e.g., pH, temperature, ion concentration). Berdahl et al evaluated the performance of a poly(ethylene glycol) (PEG)-based biodendrimer adhesive hydrogel for repair of central full-thickness 4.1 mm linear lacerations using an *in vivo* leghorn chicken model. After one day, both test groups, traditional 10-0 nylon sutures and photocrosslinked biodendrimer, exhibited reformation of the anterior chamber with no evidence of a toxic response. By day 14, the biodendrimer had degraded and exhibited less inflammation after 28 days compared to sutured corneas.[10] Two component adhesives compromising multifunctional amine-terminated PEG and PEG-succinimide derivatives have also been successfully implemented in *in vitro* and *in vivo* rabbit models.[11,12]

Temporary gel sealants have also been used for management of posterior scleral ruptures. Thompson and coworkers recently developed a stimuli responsive gel sealant that forms a rivet-like occlusion upon application.[13] This strategy was used to seal 3 mm full-thickness scleral incisions in a rabbit model. Improvements in intraocular pressure were observed after 72 hours, and there was no evidence of neurotoxicity or chronic inflammation after 30 days. Clinical user feedback was collected to evaluate the translational feasibility of this device for military applications. The positive results of the survey demonstrate the translational opportunity for such materials.

PROGRESS IN OPHTHALMIC SCAFFOLDS

Synthetic tarsal (eyelid) substitutes are currently being developed to complement surgical techniques and for reconstruction of large full-thickness lacerations to the eyelids.[14] Post-surgical manipulations of the periorbital tissue are critical to restoring form and function after the acute phase of injury. Gao et al recently implemented a biodegradable porous poly(propylene fumarate)-*co*-2-hydroxyethyl methacrylate scaffold (PPF-HEMA) for repair of tarsal plate defects using an *in vivo* rabbit model.[15] Adequate structural and mechanical support of the posterior lamella after tarsal defection (5.0 x 3.0 mm) was observed for PPF-HEMA matrices after implantation. Postoperative evaluation of PPF-HEMA after eight weeks showed good wound healing and satisfactory histocompatibility compared to commonly used acellular dermal matrix. Similar mechanical support was observed by Zhuo et al with a biodegradable scaffold comprising poly(3-hydroxybutyrate-*co*-2-hydroxyhexanoate) (PHBHHx) in a rat model.[16] However, high-density inflammatory cell infiltrate was observed for PHBHHx scaffolds eight weeks postoperative.

[CONTINUED ON PAGE 18]

The unique nature of the tarsus (i.e., the lack of underlying fat and proximity to delicate intraocular tissues) presents an opportunity for tissue engineering approaches to support proper healing and restoration of lid form and function. This is particularly important because homologous grafts and xenogeneic substitutes may result in allergic or immunologic rejection, leading to long-term sequelae.

TRANSLATIONAL CONSIDERATIONS

The FDA regulatory submission process for the devices can differ depending on their mechanism of action. The regulatory pathway for translating previously approved drugs into reformulated versions, including the aforementioned biomaterial-based systems, is the 505(b)(2) new drug application. This is an attractive option, as it seeks to avoid unnecessary duplication of previously performed studies, potentially resulting in a decreased burden to demonstrate new data for the active ingredient. Certain sealants and wound dressings would follow simpler device pathways, such as a direct *de novo* or 510(k) submission, allowing for maximization of commercial potential through decreased premarket testing. The 510(k) submission is typically used for Class I, II and III devices that exhibit comparable safety and effectiveness as legally marketed devices. In contrast, the more recently implemented direct *de novo* pathway is for novel devices that (1) lack any predicates and (2) should be classified as Class I or II devices.

Ocular trauma remains an area of great clinical need and as such, the U.S. Department of Defense uses mechanisms like the Vision Research Program to support the development of novel materials for ocular trauma. Despite the fact that the unique needs of biomaterials for ocular trauma may differ slightly between civilian and military populations, the focus on rapid translation can help bridge the gap between preclinical development and clinical use.

"NEARLY 75% OF INDIVIDUALS WHO SUFFER PERMANENT IMPAIRMENT BECOME MONOCULARLY BLIND, MAKING EYE INJURY THE SECOND MOST COMMON CAUSE OF VISUAL IMPAIRMENT BEHIND CATARACTS."

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Biomaterial-Tissue Interaction SIG Update

By Antonio Merolli, New Jersey Center for Biomaterials, Rutgers, The State University of New Jersey

The good memories of our very successful meeting in Atlanta are still fresh in mind. We had many positive social interactions during the poster sessions where our "skeleton-finger pen" with "Biomaterial-Tissue Interaction SIG" printed on it was distributed in large numbers. We had a BTI-SIG technical presentations session with high-quality and engaging talks where people were standing because they could not find a seat (it happened in Minneapolis too — should we ask for a larger room, or should we decrease the quality of our presentations?). Finally, we had our Best Paper and Best Poster awards announced during the SFB general assembly.

We are very much looking forward our next meeting in Seattle. We want to do even better. So, the news is that we added a tutorial to our usual BTI-SIG technical presentations session. The tutorial topic will be "Best Practices for Immunohistochemistry and Foreign Body Tracking/Measurements." One important behavior of biomaterials is how the human body responds to the particular material once exposed to the tissue. However, the common approaches, such as immunohistochemistry, to characterizing the host response can be experimentally tricky to apply, resulting in artifacts that can be highly misleading. In this tutorial, experts in the field present an in-depth review on immunohistochemistry and foreign body tracking, sharing their experiences on techniques, pitfalls to avoid and experimental instrumentation that can improve outcomes. The BTI-SIG board unanimously agreed that it was worthwhile for our group to provide such an opportunity to all SFB members. We first had to win the SFB meeting organizer's approval, who had a high rejection rate.

Now, we are waiting for the abstracts for the BTI-SIG technical presentations session; we are also look for high-quality posters (…remember to submit to our BTI: Biomaterial-Tissue Interaction session … there is another BTI acronym for the Biomaterials Technology in Industry… it is not us). We hope to again have a "problem" to select the best paper and best poster for 2019, as we had in 2018. So, this is the right point to acknowledge the winners of the BTI 2018 Best Paper and Best Poster awards. The Best Paper award went to Hui Cong from North Carolina State University, Raleigh, North Carolina, for the research "In Vivo Comparison of Polydioxanone and Polyhydroxy-alkanoate Barbed Surgical Sutures in a Rat Model." Since approved by the U.S. FDA in 2004, barbed surgical sutures have been applied to various fields in surgery. Hui compared two polymer formulations in an interesting and well-conducted study. The Best Poster award went to Stephanie Fung from Rutgers University, New Jersey Center for Biomaterials, Piscataway, New Jersey, for the research "Ruffled Border Formation on a CaP-free Substrate: a First Step Towards Osteoclast-Recruiting Bone-Grafts Materials Able to Re-Establish Bone Turn-Over." While the majority of bone regeneration efforts have focused on maximizing bone deposition, the novelty in the approach presented by Stephanie is to focus on osteoclastic resorption as the starter for bone turnover process and its concurrent vascularized bone formation.

We look forward to meeting you in beautiful Seattle! Please take the opportunity to arrive early and enjoy a preconference morning tour of the biomaterials labs at the University of Washington. Floyd Karp, will be your guides!

"WE ARE VERY MUCH LOOKING FORWARD OUR NEXT MEETING IN SEATTLE!"

Industry News

By Steve Lin, Industry News Editor

Stryker (Kalamazoo, Michigan) announced a definitive merger agreement to acquire all of the issued and outstanding shares of common stock of K2M Group Holdings, Inc. (KTWO) for $27.50 per share, or a total equity value of approximately $1.4 billion. K2M, founded in 2004, has annual sales approaching $300 million. It brings to Stryker's Spine division a highly complementary and innovative portfolio. Additionally, K2M's broad portfolio will strengthen Stryker's Spine offering in the core spinal segment, including an attractive minimally invasive spine portfolio, further Stryker's capabilities in additive manufacturing and expand the company's global footprint.

Wright Medical Group N.V. (Amsterdam, The Netherlands) announced it has entered into a definitive agreement to acquire Cartiva, Inc. The transaction will add a differentiated FDA Premarket Approval (PMA)-approved technology for a high-volume foot and ankle procedure and further accelerates growth opportunities in Wright's global Extremities business. Wright will acquire 100 percent of Cartiva's outstanding equity on a fully diluted basis for a total price of $435 million in cash. Cartiva's lead product, a synthetic cartilage implant (SCI) for treating arthritis at the base of the great toe, received U.S. PMA in July 2016. The SCI is composed of a biocompatible, durable, low-friction organic polymer that functions similarly to natural cartilage and can be implanted in about 35 minutes. Wright expects full-year 2018 Cartiva revenues to be approximately $35 million.

Global spine biologics market was valued at $1,644 million in 2015, and is projected to reach $2,214 million by 2022, growing at a compound annual growth rate (CAGR) of 4.3 percent during the forecast period 2014-2022, according to a new report published by Allied Market Research. The bone graft substitutes segment generated the highest revenue in the global market, accounting for more than half of the total spine biologics market. In addition, the cell-based matrices segment is projected to grow rapidly, registering a CAGR of 5.9 percent during the forecast period. The demineralized bone matrix segment is expected to grow at a CAGR of 3.4 percent, owing to its ability to stimulate bone formation.

A market research report by **Future Market Insights (FMI)** has estimated that the demand in the global hip and knee reconstructive market will translate into a revenue of $28.0 billion by the end of 2027, expanding at a notable CAGR of 6.4 percent during the forecast period of 2017 to 2027. Rapid escalation in the percentage of geriatrics in the world's population is the primary driver of the global hip and knee reconstructive market. On the basis of fixation type, the FMI report has segmented the global hips and knees reconstructive market into hybrid, cement and cementless fixations. In 2016, the hybrid segment provided for the maximum demand at 28.1 percent, and the demand for the same is projected to increment at a CAGR of 6.4 percent during the said forecast period. By 2027, this segment will be providing for a demand share of 29.9 percent in the global market for hips and knees replacement.

According to a report by **Zion Market Research**, global implantable drug delivery devices market was valued at around $11.6 billion in 2015 and is expected to generate revenue of around $17.5 billion by end of 2021, growing at a CAGR of around 7.1 percent between 2016 and 2021. The implantable drug delivery devices market is segmented on the basis of different products, including drug infusion pumps, drug delivery devices, bio-absorbable stents, coronary drug eluting stents, brachytherapy seeds, contraceptive drug delivery implants and others. Global implantable drug delivery devices market is primarily driven by growing aging population and prevalence of target diseases such as diabetic retinopathy and chronic diseases.

InDX, a new thumb implant from Galway, UK-based medical devices startup Loci Orthopaedics, has the potential to completely disrupt how painful thumb joint arthritis is treated, according to its founders, Dr. Brendan Boland and engineer Gerry Clarke. Approximately 140,000 surgeries a year take place to try to fix thumb base arthritis. However, Boland says this could rise exponentially if patients could be assured of the same positive outcomes seen with hip and knee implants. Boland says the current value of the treatment market for thumb base arthritis in the United States and the European Union combined is an estimated $600 million per year. However, due to aging populations, this is expected to grow to $1.2 billion over the next 15 years.

The global spinal implants and spinal devices market is growing, due to increasing demand for minimally invasive surgeries, increasing number of hospitals and surgical centers, and commercial applications in areas such as nucleus arthroplasty, stem cell technology and artificial disk replacement. Geographically, North America is expected to dominate the global spinal implants and spinal devices market in the coming years, due to increasing incidence of spinal disorders, increasing awareness of newly developed treatment technologies, well-established healthcare infrastructure, and increasing government funding and support for research and development of advanced

spine treatment devices. Asia-Pacific is expected to be the fastest-growing region in the market, due to the huge pool of patients and increasing geriatric population in the region.

The U.S. Food and Drug Administration (FDA) has issued a warning stating that energy-based devices for "vaginal rejuvenation" can be unsafe and their use should be avoided. Some energy-based devices have previously received FDA clearance for general gynecologic tool indications, including, the destruction of abnormal or precancerous cervical or vaginal tissue and condylomas (genital warts). But using such devices to treat "symptoms related to menopause, urinary incontinence or sexual function can cause serious adverse events," emphasized the FDA. These adverse events include vaginal burns, scarring, pain during sex and recurring pain.

Workshop on Characterization of Fiber-Based Scaffolds

By Carl Simon, Government News Editor

A workshop called Characterization of Fiber-Based Scaffolds was held on August 10, 2018, in Manchester, New Hampshire.[1] The event was jointly sponsored by ASTM and ARMI | BioFabUSA[2], with participation from the Standards Coordinating Body (SCB).[3] The meeting was held at the ARMI facilities in Manchester. The event drew 50 attendees, including representatives from most of the companies that manufacture fiber-based scaffolds for tissue engineering applications. Discussion focused on fiber-based scaffold characterization, batch-to-batch variability, measurement validation and release criteria. As follow-up, a workshop report is being drafted by the organizers to summarize the findings. There was strong interest in drafting an "ASTM Standard Guide for Characterizing Fiber-Based Scaffolds," and an ASTM working group is being formed to address this need. This standard may focus on fiber-based scaffolds made by methods such as electrospinning, forcespinning, meltspinning and pneumatospinning, with typical fiber diameter ranges of 100 nm to 5 µm. Discussions at the workshop were dominated by porosity measurements, and a working group may also be formed to discuss ways to improve porosity measurements for fiber-based scaffolds. Anyone interested in these activities is welcome to join the working groups — please contact Carl Simon at carl.simon@nist.gov.

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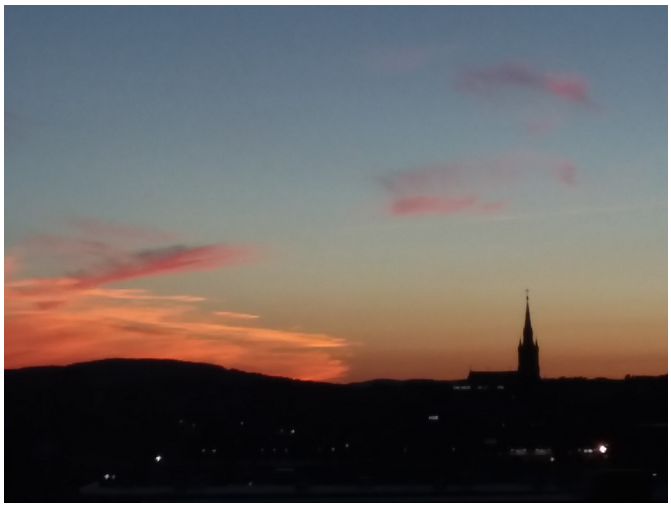


Sunset overlooking the ARMI facilities in Manchester, NH.

An Interview with Peter Edelman

By Rebecca L. Carrier

Editor's Note: Recently, Rebecca Carrier, the SFB Member-at-Large, interviewed Peter Edelman, a Manager, Principal Scientist and Fellow at the Boston Scientific, on Peter's career path and the impact the SFB has had along the way.

Rebecca Carrier (RC): In what subject area did you get your undergraduate and graduate degrees?

Peter Edelman (PE): I got my undergraduate degree in Chemistry from Bates College in Maine. My graduate degree was in Polymer Chemistry at the University of Connecticut.

RC: What made you choose those subjects and places?

PE: Bates was great for me academically. It had a NCAA Division I ski team. I made the team all 4 years, as the #5 man on the 5 man travel team. We trained and raced fall, winter and spring. It was inspirational to compete against the top New England teams (University of Vermont, Dartmouth, Middlebury, etc). When asked what my major was in college, I jokingly reply skiing with a minor in Chemistry.

RC: What did you do after graduation?

PE: With freshly minted degree in hand, I decided to pursue higher education in the mountains of Colorado (a.k.a. be a ski bum!). I moved there in the fall. By the start of the season I had an ideal set-up with a fully paid season pass at Vail, part time jobs at a ski shop and a restaurant and a trailer home for sleeping. Then tragedy struck. I tore a ligament in my knee, shattering my dreams of first tracks in back bowls. I went back east, had surgery, and recuperated with mom and dad. There was no "minimally invasive" back in 1978! My first job as a chemist was at Pitney Bowes Copier Systems Division. We were developing electrophotographic coatings, the heart of the modern copy/scan/fax machine. My boss and mentor was a polymer chemist. Coming from a small, somewhat sheltered liberal arts college, I did not have a great sense of what a chemist did for work. I thought it was cool. Also during that period I went to night school at the University of Bridgeport to improve my GPA. I loved the polymer class. Not only was I fascinated with polymer science, but it was an area where I could get a job.

That 3-year gap was great for me to get some perspective and motivation for grad school. I chose University of Connecticut for its proximity and the strong polymer science program. Prof. Sam Huang was my thesis advisor.

RC: Did you do a postdoc?

PE: Yes. I had my Bachelors degree in hand in 1986, and the economy was at a low point. Job interviews were scarce (I had always intended to work in industry). I had 2 invitations to postdoc. One with Professor Michel Vert in France. He is a pioneer in the area of synthesis and characterization of polymers of lactic and glycolic acid. The second was with Professor Buddy Ratner working in the area of surface modification/characterization of polymers for understanding biological response. I accepted the position to work with Dr. Ratner. Doing a post doc was the best thing I have ever done.

RC: Can you give examples of the kinds of things you learned after your formal education was over?

PE: On the technology side, my career has been pretty evenly split between diagnostics and therapeutics. Working is largely about interfacing with people. I've learned it takes clarity of communication and ability to share a vision to get stuff done in a corporate world. I learned that having passion in what I do is contagious. It is a good source of motivation and makes work not like work. I've learned about differences between large multinational corporations versus small start-ups. I currently work at a very large company; all large companies have a significant amount of bureaucracy. At a startup company, people are keenly aware of the concept of a dry well date – a date you can project when you will run out of money – this creates a sense of urgency that does not exist at large companies. The need to wear many hats at a start-up company does not exist at a larger company, where there is a department for just about everything. In my large company Materials Science R&D role, I get to see a variety of problems and challenges. Our devices are utilized in the brain, cardiothoracic region, abdominal, gynecological, lower extremities, just about everywhere.

RC: When did you first take your first real job? Can you describe your career path that led to your current position?

PE: My first real job was from 1979-81 at Pitney Bowes, working on reprographic coatings. After my postdoc, I worked at Ciba Corning diagnostics for 10 years ('88-'98). We developed a next-gen platform technology for the ER and bedside monitoring of blood gases and electrolytes. The system measured more than 10 analytes on 70 microliters of whole blood with 60 second time to result (sodium, potassium, calcium, chloride, oxygen, CO2, pH, glucose, lactate, etc.). In those 10 years I transitioned from a "lab rat" to R&D manager.

I then went to a startup company called Confluent Surgical in the Boston area for 3 years, working on implantable hydrogels. It was a great experience – I was employee number 4.
Next, I went to CombiMatrix in Mukilteo WA to work on DNA microarrays. The company was not very stable, and I learned some good life lessons. After a year and a half, I worked as a consultant, and then at a startup called Nanostring™ and then as a contractor at Therus™, a start-up developing therapeutic ultrasound, financed by Boston Scientific. which gave me the introduction for the current job I have at Boston Scientific, where I have been for the past 14 years.

RC: What particular research directions are of high priority or profile at your place of work?

PE: To provide best value to hospital systems requires a broad portfolio. This is the underlying driver for our growth. It is about being more of a one-stop shop for everything a physician needs for interventional cardiology or peripheral vascular.

We are active in heart disease therapies - we have two different transcatheter aortic valve replacement devices, and the Watchman™ Left Atrial Appendage Closure device to prevent stroke associated with atrial fibrillation as well as other heart disease technologies under development.

Interventional oncology is seen as a growth area for the business where we can apply our expertise in an adjacent area. We're developing microsphere technology. We are improving hydrophilic coatings on catheters and wires with improved lubricity to enable physicians to get to where they need to get to in the body, and reduced risk of coating shedding. Size reduction for access to more tortuous anatomy, but with the same level of safety. There's a lot of straightforward materials science that goes into meeting this challenge. For example, how do you optimize bond strength for adhesives? We are watching what's going on in the tissue engineering space, but have not yet worked on tissue engineered products.

RC: What do you do in a typical week? How do you divide your time between those activities?

PE: My time is divided between materials science characterization for new and existing projects and problem failure analysis of returns from the field or test failures for products under development. I am part of a department called Materials Testing and Analytical Chemistry (MTAC). We have teams in different analytical areas including corrosion, chromatography, spectroscopy, thermal analysis, imaging etc. I'm a senior member of the spectroscopy team. I work with our analysts but also our clients. I get called into a lot of subject matter expert meetings, where I am helping find solutions. I also write white papers and memos to justify decisions to notified bodies. Significant time has been sent in recent weeks preparing a strategy to comply with the new European Union Medical Device Requirements.

FIGURE OUT HOW TO CONCENTRATE AND FOCUS ON THE *IMPORTANT* (LARGE ROCKS), DON'T BE DISTRACTED BY THE *URGENT* (ANKLE BITERS)

RC: What do you like about the Society for Biomaterials?

PE: SFB keeps me informed of new technology developments, as well as ensuring I don't forget lessons in history and fundamentals. What I really find especially valuable is interactions with and access to from thought leaders. These thought leaders are often helpful in answering questions or helping with projects at work when we need someone with experience who can help guide our activities.

RC: Do you set your own priorities and deadlines and if so, how do you do that?

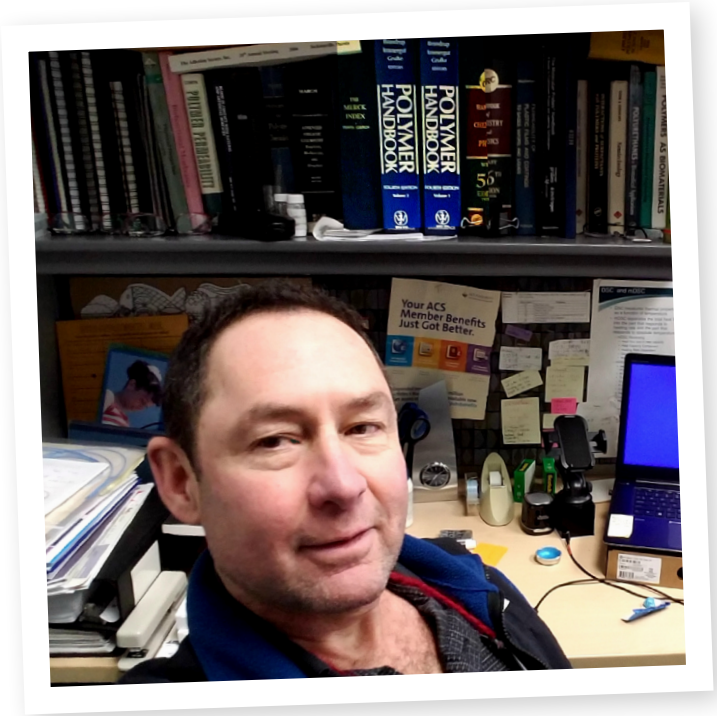
PE: I usually do. Priority setting requires knowing the behind the scenes story of a particular request, and details about how it ties to the business. We are faced with urgent, high pressure situations such as manufacturing line-down, stock-out, customer complaint, regulatory response. These are closer to the money. Less urgent projects might be associated with material change assessment after 2x sterilization and accelerate aging as part of a new product development activity.

RC: Any advice for young biomaterials scientists about time management?

PE: Figure out how to concentrate and focus on the *important* (large rocks), don't be distracted by the *urgent* (ankle biters).

[CONTINUED ON PAGE 24]

Interview with Peter Edelman (continued from page 23)



RC: How did your education prepare you for the job you do today?

PE: I'm a strong believer in going deep so that later you can go broad. I did a deep dive into polymers. Polymer chemistry, physics, rheology, thermal properties, analysis. This has prepared me well. Most all of our products contain some polymers.

RC: What are some of your favorite aspects about working at your company?

PE: It is a good place to work. Very people oriented.

RC: What courses or activities would you recommend that college students take to be prepared for a job like yours?

PE: I think that whole concept is changing. It is not as important what you know, as what you can learn quickly.

RC: What is some of the best career advice you've been given?

PE: Find passion in what you do.

RC: Please share where you think the future of biomaterials/ tissue regeneration is going.

PE: I don't know where it's going Rebecca. What I find exciting is looking around at these meetings and thinking these are the innovators who are taking us there.

RC: What influence has the Society for Biomaterials had on your life and career?

PE: I've gotten to know some very smart people that I can call on from work when we need an expert.

RC: What different positions have you held at the company you currently work for?

PE: My position titles have been Manager, Principal Scientist and Fellow.

RC: Can you provide a website that others can read to find out more about your corporation, including job openings?

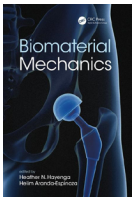
PE: www.bostonscientific.com, http://www.bostonscientific.com/en-US/careers.html

RC: What is the relationship between basic science and applied science?

PE: Basic Science is the idea. Applied science is reducing it to practice.

Book Review

By Lynne Jones, Book Review Editor



Biomaterials Mechanics
Edited by Heather N Hayenga and Helim Aranda-Espinoza
Boca Raton: CRC Press
2017
ISBN 9781498752688

Are you looking for an introductory textbook to share with undergraduate students or other individuals with diverse educational backgrounds? In the search for such a book, I came across ***Biomaterial Mechanics*** by HN Hayenga and H Aranda-Espinoza. Borrowing from the title of Chapter 4, the topics in this book range from a basic understanding to applications. There are 11 chapters separated into four parts:

Part I: Principles of Biomaterial Mechanics

- Chapter 1. Overview of Mechanical Behavior of Materials (R Reit, M Di Prima, WE Voit)
- Chapter 2. Nonlinear Mechanics of Soft Biological Materials (JF Eberth, T Shazly)

Part II: Biomaterials in Devices and Medicine

- Chapter 3. Biomaterials in Devices (DC Rodrigues, IM Gindri, S Sridhar, L Rodriguez, S Aghyarian)
- Chapter 4. Biomaterials in Cancer Research: From Basic Understanding to Applications (E George, S Sen)
- Chapter 5. The Cell as an Inspiration in Biomaterial Design (A Aranda-Espinoza, K Adlerz)
- Chapter 6. Interactions of Carbon Nanostructures with Lipid Membranes: A Nano–Bio Interface (M Quintana, S Aranda)

Part III: Modeling in Biomaterials

- Chapter 7. Computational Model-Driven Design of Tissue-Engineered Vascular Grafts (R Khosravi, CK Breuer, JD Humphrey, KS Miller)
- Chapter 8. Biomolecular Modeling in Biomaterials (SJ Ganesan, S Matysiak)
- Chapter 9. Finite Element Analysis in Biomaterials (CA Meyer)

Part IV: Biomaterial Perspectives

- Chapter 10. Perspectives on the Mechanics of Biomaterials in Medical Devices (HA Hayenga, KL Hayenga)
- Chapter 11. A Perspective on the Impact of Additive Manufacturing on Future Biomaterials (JK Placone and JP Fisher)

The first three chapters of this book set the foundation for understanding biomaterials and biomaterial mechanics. Chapter 1 also discusses the use of universal testing machines to test uniaxial compression (1.4.1.1) or tensile (1.4.1.2) loads with additional information about dynamic mechanical analysis (1.4.2). Meanwhile, Chapter 2 introduces the utility of constitutive formulations to predict mechanical behavior and provides this in the context of vascular mechanics. Chapter 3 is an overview of most of the biomaterials used in medical implants, followed by a discussion of applications used in orthopaedics (total joint replacement, fracture fixation) and dental implants.

The next three chapters introduce us to some of the biological aspects of biomaterial implants. Chapter 4, Biomaterials in Cancer Research, presents diverse applications of biomaterials used to study cancer invasion, tumor imaging and cancer therapeutics. I particularly enjoyed Chapter 5, The Cell as an Inspiration in Biomaterial Design. It tells us that there is much that we can learn from understanding how cells self-assemble, self-heal and tolerate or adapt to external stimuli. It provides this context while discussing cell membranes, the cytoskeleton and DNA. While Chapter 6 provides the reader with the basics of carbon nanostructures with potential applications, it also issues the challenge for more research, especially regarding the balance between function and potential toxicity of carbon nanotubes.

Chapters 7, 8 and 9 relate to the use of computational modeling to develop biomaterials. With increasing knowledge regarding the importance of mechanical behavior in tissue-engineered constructs, computational models have been developed to optimize the scaffolds; vascular tissue engineering is used to illustrate this (Chapter 7). Chapter 8 describes a generic, minimalistic water-explicit polarizable protein model, which can be used to characterize the driving forces behind protein folding and aggregation within specific assumptions and can be used to help design bioinspired fibrous materials. The chapter on finite element analysis (Chapter 9) provides an explanation of the principles and use of finite element analysis for modeling anatomy and physiology as well as device evaluation.

The last two chapters provide perspectives on the mechanics of biomaterials used in medical devices and the impact of additive manufacturing on the field. Both chapters provide a great jumping-off point to discuss how future biomaterials can be designed to address the limitations of today's biomaterials.

The strength and weakness of *Biomaterial Biomechanics* are the same — its concise discussion of topics. The major strength of *Biomaterial Mechanics* is that it provides key concepts in the field in an easy-to-understand text. Several chapters are unique and can be used to stimulate thought-provoking classroom discussion. The weakness of this text is that it is not a comprehensive tome on biomaterial mechanics, and additional supplemental reading materials will likely be needed to delve deeper into each topic.

While *Biomaterial Mechanics* can be used as a textbook for undergraduate and graduate courses, I also see other potential uses. The book can serve as an adjunct to other texts either to introduce or tie together specific topics. Another application would be to assign different chapters for students to present to the class as a project. I will definitely use this book to introduce students or young investigators who do not have a background in biomaterials science to the mechanics of biomaterials.

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