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BIOMATERIALS FORUM

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The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 34, Issue 1

Special Interest Group Reporters

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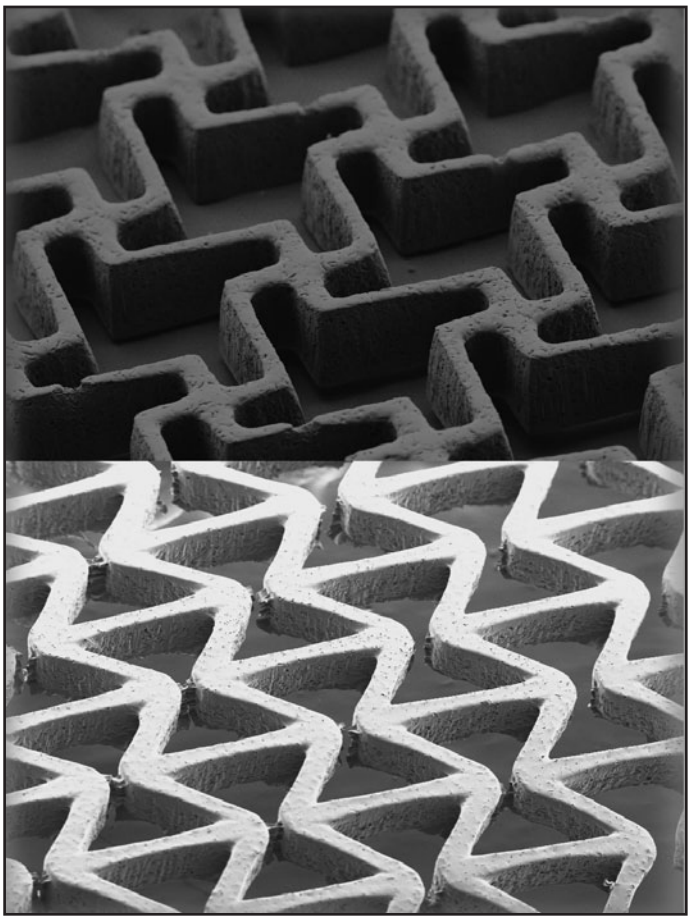
Biomaterials Community



On the cover: While elastic modulus is tunable in tissue engineering scaffolds, it is substantially more challenging to tune the Poisson's ratio, a material property often neglected in the field. In certain biological applications, scaffolds with a negative Poisson's ratio may be more suitable for emulating the behavior of native tissue mechanics. Negative Poisson's ratio (NPR) materials get thicker when they are stretched. Custom-made digital micromirror device stereolithography (DMD-SL) was used to fabricate single- and multiple-layer NPR scaffolds using polyethylene glycol (PEG) biomaterial. The NPR property is a result of pore structures having special geometries, and deformation mechanisms. Cover picture illustrates scanning electron microscopy image of PEG scaffolds with NPR property with reentrant and missing-rib architectures. Photo courtesy of Pranav Soman, David Fozdar and Shaochen Chen at the University of California, San Diego.

Fozdar, D.Y., et al., *Three-Dimensional Polymer Constructs Exhibiting a Tunable Negative Poisson's Ratio.* Advanced Functional Materials, 2011. 21(14): p. 2712-2720.

From the Editor

Greetings fellow biomaterials scientists,

In this issue you'll find –

- ***Member news***: Members of SFB continue to be awarded top honors in the field.
- ***Industry news:*** A quote - "Companies active in life sciences attracted $2.1 billion of venture capital (VC) in the second quarter of 2011. Of that total, $841 million was invested in *medical device applications*, which was 26% more than where it was in the first quarter." Read more about how the medical device industry continues to grow despite the uncertain economy.
- ***Technology news:*** A technical brief about tissue engineered tracheas from one of our special interest groups and another technical brief about antibacterial coatings from our colleagues at the National Institutes of Standards and Technology.
- ***Small business/entrepreneur news:*** A useful article about how to select a contract research organization to help with your small business/commercialization needs.
- ***Educational news:*** A review of a textbook and a perspective from a faculty member in our field about quantifying elements of biomaterials-related course content. He has suggestions for how to prepare quantitative, rather than qualitative, in-class examples, homework questions and test questions.
- ***An interview with a prominent SFB member:*** One of the pioneers in our field, Professor Robert Baier speaks candidly about his career path, the evolution of biomaterials research, real-life clinical problems, his advice to junior faculty today and recommended courses and textbooks for a biomaterials curriculum.

I hope you enjoy the content we've assembled for you. Remember to send me your thoughts about the content you'd like to read about in a future issue to Lkuhn@uchc.edu and we'll work together to make it happen.

Best wishes from Connecticut,

ANNOUNCEMENTS

Attention Small Business Owners and Contract Research Organizations:

If you are involved with corporate preclinical testing programs, please consider sharing your list of contract research organization contacts with our other members. I'd like to start a running list of resources for our small business members that would be featured in every issue.

-Editor L. Kuhn, Lkuhn@uchc.edu

Are there any troubling work issues plaguing you at the moment? There's a group of experienced SFB members willing to provide advice in the form of a "Dear Abby" column in the Biomaterials Forum. **Dear "Labby"** is an American Society For Cell Biology moniker. Do you have any witty suggestions of a biomaterials-themed female name for the *Forum* column? PEGgy? Please email me your suggestions. Regarding confidentiality, names will be de-identified, so no other members will be aware of who has submitted the question. Please send your question directly to Leslie Clark at lclark@ahint.com and she will remove all identifying information and then forward your concern anonymously to me. Please contact me if you'd like to serve on the advice board for this proposed column.

From the President

I hope that you are off to a good start in 2012 and are gearing up to participate in the 9th World Biomaterials Congress in Chengdu, China in June. The program organizing committee met a few months ago to finalize the program, themed "Innovative Biomaterials and Crossing Frontiers in Biomaterials and Regenerative Medicine." If your plans do not include this meeting, perhaps you will sign on for the October 4-6, 2012 New Orleans Society For Biomaterials (SFB) symposium, an exciting Grand Challenges theme based event. The abstract deadline is March 26, 2012. Two of the 14 designated National Academies grand challenges are to "engineer new medicines" and to "engineer the tools of scientific discovery." It will be exciting to see, in Chengdu and in New Orleans, how these challenges are being tackled by the biomaterials community.

Other SFB news, we are in the process of launching an electronic newsletter. Not to worry, this newsletter is not a substitute for *Biomaterials Forum*, but rather will include Society newsflashes, as well as biomaterials related "just-in-time" news and information from around the world. This service will be largely press releases and news feeds provided by a third party and overseen by an editor; however, the choice in content and subscription will be driven by you. Please consider volunteering for this new editorial position or consider nominating a qualified and enthusiastic colleague.

Speaking of publications, this January, we celebrated the 100th issue of the publication that we now know as the *Journal of Biomedical Materials Research A*. The *Journal* was launched with the vision of providing a home for publications that were "too fundamental for the clinical journals and too applied or specialized for the more basic scientific publications." Most importantly the *Journal* was designed to provide stimulus for research in the field of biomaterials. The articles from that 1967 issue however, strike me as being just as relevant today as they were at that time. I wonder how the next 45 years will shape the journal content and format; I hope that the material will be just as pertinent and thought-provoking. By the way, I enviously note the 1967 rate of 1 USD postage per volume for international mailing as the one feature that is time dated. Thank you to all the editors, present and past, of *JBMR A* for keeping us up-to-date and engaged in our field!

Best wishes from Clemson,

Karen J.L. Burg
Hunter Endowed Chair & Professor of Bioengineering
Interim Vice Provost and Dean of the Graduate School
Clemson University

Staff Updates from Headquarters

Hello from Society For Biomaterials headquarters! As we gear up for 2012 with the World Biomaterials Congress in Chengdu, China, and the Fall Symposium in New Orleans, the Society's board of directors, governing council, committees, taskforces and SIGs have been actively engaged in the following activities:

Awards, Ceremonies and Nominations - Chair Anne Meyer

The Awards, Ceremonies and Nominations Committee evaluated all nominations for officers and awards and presented their recommendations to council. Officer candidates are listed on pages 6-9. The committee selected this strong slate of nominees on behalf of the membership to continue the tradition of leadership excellence in SFB. Voting may be done via the website, fax, mail or e-mail. The deadline for receipt of ballots is April 4, 2012.

Please join in congratulating the following 2012 award winners:

- Founder's Award - Art Coury, PhD, Genzyme Corporation (Ret.)
- C. William Hall Award - Dharam Dhindsa, DVM, PhD, National Institute of Health (Ret.)
- SFB Award for Service (new) - Martine LaBerge, PhD, Clemson University
- Young Investigator Award - Steven Little, PhD, University of Pittsburgh
- Clemson Award for Contributions to the Literature - Molly Shoichet, PhD, University of Toronto
- Clemson Award for Basic Research - Andres Garcia, PhD, Georgia Institute of Technology
- Clemson Award for Applied Research - Kam Leong, PhD, Duke University
- Student Award for Outstanding Research, PhD Candidate - Paschalia Maria Mountziaris, Rice University
- Student Award for Outstanding Research, PhD Candidate - Mark Tibbitt, University of Colorado
- Student Award for Outstanding Research, Undergraduate - Anna Blakney, University of Colorado

Full details about the awards and recipients will be provided in the next issue of the *Forum*. More detailed information is also available on the SFB website.

The committee thanks those who took the time to nominate their colleagues for awards and officer candidacy, and sincerely appreciates the officer candidates' willingness to serve the Society For Biomaterials.

Bylaws – Chair Jiro Nagatomi

The Bylaws Committee will recommend to the board of directors that the current officers serve until the annual business meeting which will be held in Chengdu during the World Congress. The bylaws are not specific as to the changeover in terms of officers, and this has been the practice in years past. This committee's recommendation, once approved by the board, will become a matter of policy that will not require a bylaws amendment.

Devices and Materials – Chair Bruce Anneaux

The committee discussed the results of a recent survey and will be suggesting two new session formats for future meetings: one aimed at fostering greater interaction between industry and academia, and the other intended to facilitate more focused networking within areas of specialty. In addition, the committee will be evaluating options for bringing members additional insight into regulatory processes.

Education and Professional Development – Chair William Murphy

A student luncheon and a women's networking luncheon are being planned for the New Orleans symposium. Registrants will indicate their area of interest to facilitate better matching of mentors and mentees. The committee is also pleased to announce the 2012 Biomaterials Days grant recipients:

- February 17, 2012 - University of Memphis / University of Tennessee / Vanderbilt University
- March 16, 2012 - University of Florida
- April 20, 2012 - Duke University
- July 27, 2012 - Rice University / Texas A&M University / University of Texas
- September, 2012 - University of Kentucky / Purdue University / Case Western Reserve University
- October 10, 2012 - Clemson University

Additional information about each Biomaterials Day is provided on the SFB website.

Finance – Chair David Kohn

The Finance Committee has achieved the reserve targets set in 2007, and is evaluating revisions to the Society's investment and reserve policies to insure the stability of the Society's fiscal future and to maximize value to current members.

Liaison – Chair Molly Shoichet

As a result of the Liaison Committee's recent call for volunteers, the committee has formed seven mini-committees that will be spearheading outreach to the following organizations: AADR, ACS, BMES, ISSCR, MRS, ORS, TERMIS. If you are interested in furthering collaborations with another Society, please contact headquarters.

Long Range Planning – Chair Joel Bumgardner

The committee is re-examining the Society's mission statement and crafting a new vision statement that will help to shape the future direction of the Society. The committee is also reviewing some recent books on best practices for associations. Once the new mission and vision statements have been drafted, the committee plans to outline a strategic plan for accomplishing its vision. Each of these components will be discussed with the governing council and approved by the board of directors prior to implementation.

Meetings – Chair Karen Burg

2012 World Biomaterials Congress –In March 2012, the SFB headquarters staff will begin collecting visa applications, passports and other necessary items from those traveling to China who wish to utilize SFB as their agent in obtaining a visa. More information is available on the website.

Membership – Chair Horst von Recum

The Membership Committee is considering a revision to the application process which would streamline application and conversion to active membership. The committee is also reaching out to several universities with significant numbers of student members which do not yet have active student chapters.

Program – Chair William Reichert

The preliminary list of sessions for the 2012 Fall Symposium is posted on the SFB website. The Program Committee is soliciting abstracts in 27 specific categories. The quantity and quality of abstract submissions will determine how many of the proposed sessions will actually be presented in New Orleans, October 4-6, 2012. The abstract submission deadline for the 2012 Fall Symposium is March 26, 2012.

Publications – Chair Ashutosh Chilkoti

Website: Headquarters staff has distributed a request for proposals for the development of the new SFB website. More to come in the months ahead!
Book Series: Two books are in development and a third proposal is being considered. Titles should be available shortly.

National Student Chapters – President Scott Cooper

With the oversight of the Education & Professional Development Committee, the national student chapter has made eight grants for assistance with operating expenses and local activities: Memphis University, Wake Forest University, Syracuse University, Texas A&M University, Case Western Reserve University, Columbia University, Clemson University, and the University of Texas at San Antonio. Additional grants will be made in the fall semester, and planning for the student mentoring luncheon at the Fall Symposium continues.

Special Interest Groups – Representative Jeff Schwartz

Several SIGs are creating Facebook fan pages and LinkedIn sub-groups. Contributions for the Biomaterial of the Month feature on the website have been steady, however the pipeline is clear for more submissions. The SIGs continue their efforts to enhance the scientific quality of SFB events with many of the session proposals, organizers, and abstract reviewers for the Fall Symposium coming from our very active SIGs!

If you have any questions, require any information or have suggestions for improved services, please feel free to contact the Society's headquarters office:

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2012 Officer Nominees

The task of selecting the slate of officer nominees for 2012 has been completed. Following are the nominees for President-elect and Member-at-Large. The Society encourages all members to cast their vote for the candidate of their choice. Ballots may be cast electronically via e-mail to headquarters, via the Members Only section of the Society's website (www.biomaterials.org) or via mail.

Following are descriptions of the responsibilities of each position, along with a brief synopsis of each nominee's biographical background and his vision for the Society's future.

President-elect

The President-elect shall become familiar with the duties of the President and shall, at all times, cooperate and assist with the duties of that office. In the absence of the President, the President-elect shall preside at the meetings of the Society, the Council and the Board of Directors, and perform the duties and exercise the powers of President. The term of office is for a period of one year without succession. The President-elect is the chairperson of the Long Range Planning Committee.

Nominees for President-Elect

Alan S. Litsky, MD, ScD
Associate Professor
Biomedical Engineering and Orthopaedics
Ohio State University

Biographical Sketch: Alan S. Litsky, M.D. Sc.D., is associate professor of Biomedical Engineering and Orthopaedics at Ohio State University. He leads the Orthopaedic BioMaterials Laboratory and serves as Director of Orthopaedic Research. He earned his medical degree from Columbia University's College of Physicians and Surgeons and his Sc.D. in Materials Science and Engineering from M.I.T. His research focus is hard-tissue biomaterials with an emphasis on new materials for orthopaedic and dental applications. Prof. Litsky's teaching includes courses on Hard-Tissue Biomaterials, Tissue Mechanics, and Research Ethics.

Dr. Litsky has served on the Orthopaedic study section at NIH, the Arthritis Foundation's Technology and Biomechanics study section, and on the American Academy of Orthopaedic Surgeons' Basic Science Evaluation subcommittee. He is a member of editorial boards of the *Journal of Biomedical Materials Part B – Applied Biomaterials*, *Veterinary and Comparative Orthopaedics and Traumatology*, the *Journal of Dental Biomechanics*, and the *Annals of Improbable Research*. He is a regular reviewer for these journals and for several granting agencies. Alan is a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) and serves as the OSU faculty representative to the Federal Demonstration Partnership. He is an active participant in the Orthopaedic Research Society and the Society For Biomaterials.

Alan has been a member of the Society For Biomaterials since 1985. His involvement in the Society includes review of abstracts for the annual meetings, service on the Program Committee, the Liaison Committee, and the Awards, Ceremonies, and Nominating Committee. Dr. Litsky has also been an active participant in workshops and plenary sessions at several Society meetings. He has served in leadership roles as a member of the Orthopaedic Special Interest Group (vice chair 1999-2000, chair 2000-2001), and the Biomaterials Education SIG. He has served on Council as chair of the Education and Professional Development Committee (2001-2003), the Membership Committee (2004-2005), and served for four years as Secretary/Treasurer-elect and chair of the Finance Committee (2005-2007) and Secretary/Treasurer (2007-2009). During his tenure as Secretary-Treasurer, he focused on simplifying and clarifying the Society's financial planning, budgeting, and accounting processes and implementing the long-term investment strategies developed to insure the Society's fiscal future. He is currently (2011-2012) serving as Member-at-Large.

Vision Statement: If given the honor and opportunity to serve the Society For Biomaterials as President, I would like to focus on two important areas. The first is improving the value of SFB membership, which I would like to accomplish through a wide array of Society activities. Many members interface with our Society primarily through the annual meeting and I hope to continue and to expand current efforts emphasizing both the breadth and depth of the biomaterials field in our programs. Our meetings should include current research in basic and applied materials science and implant biology; they should also have a strong education component both for our members and to fulfill our position as a resource for knowledge and policy advice in our discipline. Increasing the value of our journals by enhancing their scientific standing (e.g., through the addition of review articles) and by working with our publisher to hold subscription costs in check (electronic subscriptions, etc.) and working to establish year-round SFB activities will also make our Society more useful to our members and better serve the biomaterials community. Expanding and diversifying our membership to re-establish the interactions between members from the academic, industrial, and government communities will make our meetings more valuable to us all.

A second emphasis will be insuring the future of the Society. One approach to this will be the inclusion of students and young members in all Society activities –increasing the number and activities of student chapters, more new member participation in program development and meeting planning, and stronger representation of young member perspective in Council-level decisions. Through this type of mentoring we can improve the SFB and develop our next generation of leadership. Equally important is our financial security. We have

in place a solid fiscal plan but continued close oversight of our investment policy and long-term reserve accounts along with a careful monitoring of all of our expenses will ensure that we not only survive the tight budgets of World Congress years but secure our ability to expand programmatic initiatives and member services.

One new initiative that I would prioritize as president is the reorganization and revitalization of the Society's web presence. This activity, the planning stages of which are just underway, will increase the value of membership by allowing more direct and timely interaction with management services, by facilitating access to the abstracts and presentations from prior meetings, and by making it easier to submit our research to future meetings and Society events. An improved web site will reinforce our leadership role as the "go to" site for biomaterials information and policy for members and non-members, and enable us to adapt our interactions towards more forward-looking, electronics-based interactions.

I am honored to have been nominated to run for President. If elected to this position I look forward to continuing to work for the Society For Biomaterials and its members.

Antonios G. Mikos, PhD
Louis Calder Professor
Bioengineering and Chemical and Biomolecular Engineering
Rice University

Biographical Sketch: Antonios G. Mikos is the Louis Calder Professor of Bioengineering and Chemical and Biomolecular Engineering at Rice University. He is the Director of the J.W. Cox Laboratory for Biomedical Engineering and the Director of the Center for Excellence in Tissue Engineering at Rice University. He received his Dipl.Eng. (1983) from the Aristotle University of Thessaloniki, Greece, and his Ph.D. (1988) in chemical engineering from Purdue University. He was a postdoctoral researcher at the Massachusetts Institute of Technology and the Harvard Medical School before joining the Rice Faculty in 1992 as an assistant professor.

Mikos' research focuses on the synthesis, processing, and evaluation of new biomaterials for use as scaffolds for tissue engineering, as carriers for controlled drug delivery, and as non-viral vectors for gene therapy. His work has led to the development of novel orthopaedic, dental, cardiovascular, neurologic, and ophthalmologic biomaterials. He is the author of over 430 publications and 25 patents. He is the editor of 14 books and the author of one textbook (*Biomaterials: The Intersection of Biology and Materials Science*, Pearson Prentice Hall, 2008). He has been cited over 28,000 times and has an h-index of 91.

Mikos is a Fellow of the American Institute for Medical and Biological Engineering, a Fellow of the International Union of Societies for Biomaterials Science and Engineering, a Fellow of the Biomedical Engineering Society, a Fellow of the Controlled Release Society, and a Fellow of the American Association for the Advancement of Science. He has been recognized by various awards including the *Founders Award* and the *Clemson Award for Contributions to the Literature* of the Society For Biomaterials, the *Robert A. Pritzker Distinguished Lecturer Award* of the Biomedical Engineering Society, the *Alpha Chi Sigma Award for Chemical Engineering Research* and the *Food, Pharmaceutical and Bioengineering Award in Chemical Engineering* of the American Institute of Chemical Engineers, the *Meriam/Wiley Distinguished Author Award* and the *Chemstations Lectureship Award* of the American Society for Engineering Education, the *Edith and Peter O'Donnell Award in Engineering* of The Academy of Medicine, Engineering and Science of Texas, the *Marshall R. Urist Award for Excellence in Tissue Regeneration Research* of the Orthopaedic Research Society, the *Distinguished Scientist Award - Isaac Schour Memorial Award* of the International Association for Dental Research, and the *Outstanding Chemical Engineer Award* of Purdue University.

Mikos has mentored 50 graduate students on their way to completing their doctoral studies, as well as 33 postdoctoral fellows, 21 of whom remain in academia at institutions including Georgia Tech, Hanyang University, Mayo Clinic, Texas A&M University, Tulane University, University of Maryland, University of New Mexico, University of Oklahoma, University of Texas at Austin, Virginia Tech, and Rice University among others. He is organizer of the continuing education course *Advances in Tissue Engineering* offered annually at Rice University since 1993.

Mikos is a founding editor and editor-in-chief of the journals *Tissue Engineering Part A, Tissue Engineering Part B: Reviews, and Tissue Engineering Part C: Methods* and a member of the editorial boards of the journals *Advanced Drug Delivery Reviews*, *Cell Transplantation*, *Journal of Biomaterials Science Polymer Edition*, *Journal of Biomedical Materials Research (Part A and B)*, and *Journal of Controlled Release*.

Vision Statement: The Society For Biomaterials presents a solid history of prominent global leadership in the biomaterials field and upholds an excellent trajectory for continued eminence. I envision that the continued success of the Society will be built upon growth of the current strong foundation of active members to enable the sustained vitality and impact of the existing programs and educational activities of the Society, while supporting expansion into exciting new areas. For example, the investment of focused effort to encourage increased representation and active participation of those engaged in clinical practice and industry will foster the continued interactions necessary for the clinical and commercial translation of biomaterial-based technologies to advance patient care.

As the membership of the Society continues to expand, so too should the commitment of the Society to provide ongoing benefits to the members through programs and activities. The Society has been very effective in providing platforms for dissemination of research and exchange of ideas, as evident

through the success of the Annual Meetings and the various publications of the Society. Clearly, efforts of this scale require a considerable investment of time and resources by the Society, which must be undertaken within the bounds of a sound plan for fiscal responsibility. As Secretary/Treasurer of the Society from 2009-2011, I can state with fullest confidence that the financial state of the Society is excellent, and I plan to leverage my experience from this role to ensure that ongoing fiscal responsibility enables the continued vitality of the Society.

The Society has been very effective in harnessing its financial resources and the volunteer efforts of the membership to maintain a steadfast commitment to education, as demonstrated by the successful and expanding Biomaterials Day programs, the Special Interest Groups (SIGs), and the numerous biomaterials curricula development activities within the Society. As chair of one of the first SIGs to be formed, I observed directly the power of the SIGs to promote active participation in the Society, and I fully support the ongoing prominent role of the SIGs in the success of the Society. Indeed, continued investment in programs that support the interest of students and young investigators in the field and engage them within the Society are of paramount importance to the continued vitality of the organization.

The Society must also continue to seek to interact with other societies, while maintaining a distinct identity and clear prominence within the field. Specifically, as biomaterials continue to play an expanding role in the development of emerging fields, the Society should maintain interest in fostering positive interactions with the societies in those fields through joint meetings and other avenues, while maintaining the focus and unique identity of the Society. As Continental Chair of the Tissue Engineering and Regenerative Medicine International Society – North America (TERMIS-NA) from 2009-2011, I have witnessed directly the positive impact such interactions can have on a society, and I stand committed to promote interactions between the Society For Biomaterials and other organizations to ensure that the Society remains forward looking and maintains a strong presence in emerging fields, such as tissue engineering and regenerative medicine.

I am thrilled and deeply honored by the nomination to serve as President-elect, and I invite the opportunity to expand my service to the Society through this position.

Member-at-Large

The Member-at-Large shall serve as an unencumbered representative of the membership at meetings of both the Board of Directors and Council. The Member-at-Large shall serve for a period of one year.

Nominees for Member-at-Large

Eben Alsberg, PhD

Associate Professor
Biomedical Engineering and Orthopaedic Surgery
Case Western Reserve University

Biographical Sketch: Eben Alsberg, PhD, received his B.S.E. in Mechanical Engineering and Material Science and Biomedical Engineering, *cum laude*, from Duke University in 1994. Eben then went to graduate school at the University of Michigan in Ann Arbor where he received an M.S.E. in Mechanical Engineering (1998), an M.S.E. in Biomedical Engineering (1998), and a Ph.D. in Biomedical Engineering (2002) under the guidance of Dr. David J. Mooney. He began his graduate studies in Dr. Steve Goldstein's Orthopaedic Research Laboratory investigating the roles biomaterials and mechanics play in healing fracture defect and distraction osteogenesis models. He then continued on at Michigan as an NIH-NIDCR Graduate Fellow engineering biomaterial systems for bioactive delivery and tissue engineering applications. The work received several honors including the Biovalley Young Investigator Award for best paper presentation at the 4th International Meeting of the Tissue Engineering Society International (2001), 1st Place in the American Association for Dental Research/ Warner-Lambert Hatton Award Competition (2002), 2nd Place in the International Association for Dental Research/Warner-Lambert Hatton Award Competition (2002), the International Association for Dental Research/Lion Dental Research Award in the Periodontal Research Category (2002), and the American Association for Dental Research William J. Gies Award for the best paper published in the *Journal of Dental Research* (2003). Following his graduate studies, he was a Postdoctoral Research Fellow in the Vascular Biology Program at Harvard Medical School for two years investigating biomaterial and mechanical regulation of lung development and endothelial cell behavior under the guidance of Dr. Donald E. Ingber.

Eben took a faculty position in 2005 at Case Western Reserve University, where he is currently an associate professor of Biomedical Engineering and Orthopaedic Surgery and serves as Director of the Stem Cell and Engineered Novel Therapeutics Laboratory. His lab focuses on the engineering of new technologies to regenerate tissues and treat cancer through the development of novel biomaterials and microenvironments. He's co-authored over 48 peer reviewed papers, in journals such as the *PNAS, Biomaterials, Advanced Functional Materials, JBMR, Nanoletters, and JACS*, and 92 abstracts and conference proceedings. His work has been recognized with the 2008 Ellison Medical Foundation New Scholar in Aging Award and

the Crain's Cleveland Business 2009 Forty Under 40 Award. Biomaterials education is of great importance to Eben, and to that end, he has developed new undergraduate and graduate courses at Case in this area as they relate to regenerative medicine.

Eben believes strongly in giving back to the professional fields that have provided him with extensive opportunities, and has been an active member of the Society For Biomaterials since 2002, and many others over the years including MRS, ACS, TERMIS, IADR, BMES, ORS, and IEEE/EMBS. He's organized and chaired dozens of biomaterials-related sessions and symposia at these meetings, including 13 for SFB and WBC in the last 5 years. As a standing member of several Special Interest Groups, he's served in leadership roles as Program Chair for the Tissue Engineering SIG (2007-2009) and as Vice Chair of the Cell/Organ Therapies SIG (2007-2009). He's reviewed abstracts for the SFB annual meetings and World Congresses for a decade, as well as for the other aforementioned annual meetings. He is on the editorial board for several biomaterials journals and reviews manuscripts for many.

Vision statement: I would be honored to serve the Society For Biomaterials as Member-at-Large, and would take the responsibility of the role with a strong sense of purpose. The primary role of the Member-at-Large is to provide a voice for the SFB membership at annual meetings of both the Board of Directors and Council. Since the term of this position is only for one year, in order to actually understand the ideas, concerns, and suggestions of the SFB membership in time to effectively present them to the Board of Directors and Council in New Orleans in October 2012, I pledge to actively solicit this feedback in advance. I will send out an e-mail survey to all members requesting information regarding their ideas for the Society moving forward, the best things about the Society that should be maintained and built upon, and areas that need improvement and potential ways to implement such change. I will similarly seek such input at the Biomaterials Days meetings to secure the valuable student membership perspective and as a liaison at other society annual meetings with related interests, such as BMES and TERMIS, to determine ways we can continue to increase the SFB membership base. I would see my role in this position as one to represent each individual member of the Society, and provide an accessible avenue for all to be heard by the governing body as we shape the direction of the Society for the coming decade and beyond.

A second objective I'd like to pursue is to initiate programs that will help integrate members of our Society at all levels. At the undergraduate level, SFB might provide opportunities for students to interact with potential graduate school advisors in scientific and/or social settings. For graduate students, I'd like to explore the possibility of additional events to facilitate and coordinate interactions with potential postdoctoral advisors or industrial employers. Borrowing from BMES, a special Meet the Faculty Candidates session could be planned for those seeking academic positions. In addition, sessions for junior faculty could be arranged to provide mentorship in areas of grant writing, laboratory management, becoming more involved in SFB and overall advice for getting off to a strong start in a first independent research position.

Nicholas P. Ziats, PhD

Associate Professor
Pathology, Biomedical Engineering and Anatomy
Case Western University

Biographical Sketch: Nicholas P. Ziats, Ph.D. is an Associate Professor of Pathology, Biomedical Engineering, and Anatomy at Case Western University in Cleveland, Ohio. He received his B.S. in Zoology and Microbiology from Ohio University and his Ph.D. in Pathology from Case Western University. His research has focused on biocompatibility, blood vessel diseases, cardiovascular devices and therapeutic treatments for vascular disorders. He also has been involved in studies concerning drug delivery for treatment of cancer. Finally, he has demonstrated a strong commitment to teaching including teaching biomaterials and biocompatibility courses to Biomedical Engineering students as well as courses for personnel in industry. He has served on numerous study sections including those from the NIH, VA and the Aging Society. He has published extensively and serves on the editorial boards of the *Journal of Biomedical Materials-A*, *Biomaterials*, *Recent Patents in Biomedical Engineering* and the *Journal of Biomedical Science & Engineering*.

Nick has been a member of the Society For Biomaterials since 1989. He has been an active member serving on numerous committees over the past ten years. He has been involved with the Special Interest Groups (SIGs) for many years and has served as Chair of the Proteins and Cells SIG (2007-2009) and co-chair of the Education SIG (2010-2011). He has served on SFB Council as the Membership Committee Chair (2007-2009) and the Program Committee Chair (2010-2011). He was Program Chair for the SFB meeting in Orlando in 2011. Other committees of the Society he has served on include the Membership Committee (2006-2009), Program Committee (2009-2011), Long Range Planning Committee (2011-2012), Education and Professional Development Committee (2010-2012), and the Awards, Ceremonies and Nominations Committee (2005, 2011-2012). Nick has also been instrumental in the organization of three Biomaterials Days: University of Kentucky (2009; Program Co-Chair), Case Western Reserve University (2010; Program Chair), and Purdue University (2011; Program Co-Chair).

Vision Statement: It is an honor to be nominated for the position of Member-at-Large. If elected, I would serve as an active participant on Council and for the Society. Having served on the Council in recent years, I have seen the Member-at-Large position become more important on Council as well as to our Society. Most recent holders of this office have done an excellent job in bringing an active role to this position, particularly in working to engage our Society's members in participation and membership. I believe that this is an extremely important role for this position and, if elected, my major goal will be to improve active participation in the Society as well as help the Society improve its relationship with its membership.

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Technical Briefs
Tissue-Engineered Tracheas

The end goal of tissue engineering is to replace missing or damaged tissues and organs. The recent implantations of synthetic tissue-engineered tracheas into two patients take us one step closer to that goal. Led by Professor Macchiarini, previous surgeries have used decellularized cadaver tracheas to demonstrate proof-of-concept [1]; however, donor availability and possible rejection limits their feasibility. Moving to synthetic scaffolds, Macchiarini led a team that developed a nanocomposite polymer (polyhedral oligomericsilsesquioxane covalently bonded to poly-[carbonate-urea] urethane) via an extrusion-phase inversion method molded into the exact shape of the patient's trachea. Seeded with the patient's stem cells and cultured for 36 h in a bioreactor custom designed by Harvard Biosciences, Inc. (http://www.harvardbioscience.com), the cell-scaffold construct was then transplanted to the 36-year-old male patient in June 2011 [2]. This study was repeated again in November 2011 with a 30-year-old male patient suffering from tracheal cancer. In this study, however, poly(ethylene terephthalate) elctrospun nanofibers molded in the shape of his trachea (Figure 1) designed by Nanofiber Solutions (http://www.nanofibersolutions.com) was used [3]. As before, the scaffold was seeded with the patient's stem cells and cultured prior to implantation. Because the patient's own cells were used, no immunosuppressant drugs were needed. After transplantation, blood vessels grew into the synthetic scaffold integrating the synthetic tissue to the host body. These first human trials demonstrate that biomaterial and bioreactor technology can enable successful growth of synthetic tissue-engineered tissues suitable for transplantation.

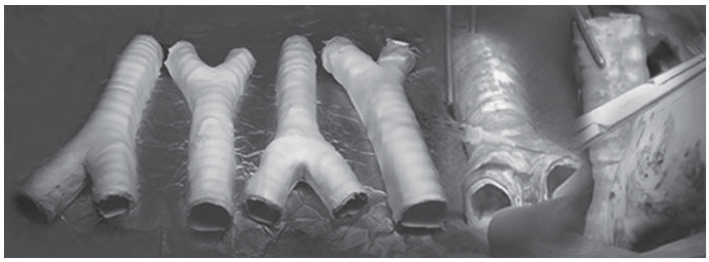

Figure 1. *Synthetic tracheal scaffolds composed of poly(ethylene terephthalate) nanofibers were seeded with the patient's stem cells and cultured prior to implantation.*

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2012 Officer Nominees

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I served as Membership Chair for three years at a time when our membership was declining and we helped develop creative incentives for improvement. We increased our Student Chapters from a few to many and increased their activity within the Society. I believe we can be more creative in reaching out to our members and serving as their voice. Having recently served as Program Chair for the 2011 Orlando meeting, I heard a number of positive and negative comments about the meeting, as well as the Society, and how both can be improved. After seeing the latest survey results (as well as past surveys), I was impressed with how important our Society is to so many of its members, but I am also disappointed in the low level of participation in these important surveys. I believe that in order for our Society to move forward, we need to improve the member participation in our various surveys, perhaps by changing the surveys, providing other incentives or targeting the surveys to our different constituents. If we do so, I believe we can actively respond to their concerns and make changes that are necessary to improve the Society and our meetings. I believe we can be creative in achieving this by working with Council, our SIGs and the various Committees to reach out to all of our membership.

The role of the Member-at-Large should be as an active participant in the Society and I hope to do so if elected to this important position. I would encourage our members to voice their ideas and opinions and hope, in part, that the Member-at-Large officer will be one to aid in disseminating this information to the Society.

In conclusion, I have listened to and read your comments over the past years and would be honored to be an active voice as Member-at-Large on the Council of the Society For Biomaterials.

From the SIG Representative

Jeff Schwartz, Special Interest Group Representative

What Is So Special About a Special Interest Group?

While many Society members are part of a Special Interest Group or SIG, there are some members who have not had the opportunity to learn more or may not even know SIGs exist. I hope to change that by explaining what SIGs are, how they benefit the Society, and most importantly how they can benefit you as a member of the Society For Biomaterials.

SIG History

Back in the late 1970s and early 1980s, the SFB Council was in charge of preparing the annual meeting. Meeting attendance was relatively modest at first, in the several hundreds. However, when the Society experienced significant growth Dr. Buddy Ratner (University of Washington), then part of the Long Range Planning Committee as the Society's President-elect, decided to create a "system to allow the members to focus on their special interest, have a say in organizing meetings, invite keynote speakers, develop social functions, and especially to respond to new and evolving subjects." At the SFB Annual Meeting in Scottsdale in 1991 he posted a sign-up sheet for a few key areas of biomaterials and received 100 or more names for each group. "This demonstration of enthusiasm from the membership was sufficient to convince the Council to begin formally developing a mechanism for SIGs," states Dr. Ratner. SIGs were signed into the SFB bylaws in 1996.

Today's SIGs

SIGs are involved in developing, submitting and organizing sessions for the annual meeting as well as conducting abstract reviews and providing session moderators. Many of the current Society board members belong to one or more SIGs. As of today, we have 13 SIGs:

- Biomaterials and Medical Products Commercialization (formerly Biomaterials Availability and Policy)
- Biomaterials Education
- Cardiovascular Biomaterials
- Dental/Craniofacial Biomaterials
- Drug Delivery
- Engineering Cells & Their Microenvironments (formerly Cell/Organ Therapies)
- Implant Pathology
- Nanomaterials
- Ophthalmic Biomaterials
- Orthopaedic Biomaterials
- Proteins and Cells at Interfaces
- Surface Characterization and Modification
- Tissue Engineering

Each SIG interacts with its members differently and has traditions that make it distinctive. While each SIG has four core officers (Chair, Vice-Chair, Secretary/Treasurer, and Program Chair), there are several non-elected positions volunteers. Most SIGs have a Web Representative, who keeps the SIG webpage up-to-date, and a Student Representative, who acts for the student members of the SIG. SIG members should always feel free to e-mail their SIG officers if they have suggestions or ideas. It is important to remember that SIGs are volunteer driven and how active a SIG is depends on the participation of both the SIG officers and SIG members. Officer contact information is available on the website at: www.biomaterials.org and select Special Interest Groups. You can check out the SIG-specific websites as well.

What Can SIGs Do For Me?

Would you like to meet and talk with the people who are top in their field? Getting involved with a SIG provides the environment for those new to an area to interact with SIG members with more experience. Student members can make contacts and seek advice from academic, industry or government Society members. Besides networking, SIGs have fun such as SIG social events at the Annual Meeting. One SIG took members on a Luau during the 2011 Annual Meeting in Orlando. There are also benefits for student members, such as a Résumé CD that is distributed annually by another SIG. Finally, SIGs connect with other Societies by sponsoring sessions at other meetings, thus promoting cross-society interaction.

Annual SIG meetings are held either in the morning or during the lunch break at the Annual Meeting and Exposition. Food is offered and anyone can attend the meeting, however only members can vote on SIG matters. Check the program for times and rooms of SIG meetings.

How to Join

There are many ways to join a SIG. When you are re-registering for the Society, you can check a box next to the area of interest. Student members are not charged extra, while Active and Associate members are charged a modest fee of $10 per SIG. This money is used by the SIG for events throughout the year as well as for social events, prizes or awards during the Society's annual meeting. A quick and easy way to join is to fill out the form attached to this edition of the *Biomaterials Forum*. Follow the mailing instructions and include your payment.

I hope you learned a little more about Special Interest Groups. SIGs give you the ability to be more involved with the Society For Biomaterials as well as offer networking and special events. The involvement of the SIGs has never been more important to the Society. From helping to shape the annual meeting program to creating grass roots commitment to improve our Society, SIGs are involved. Please consider joining a SIG the next time you renew your membership or by filling out the form at the back of this magazine.

Thanks to all that have been, are currently or are considering becoming a SIG member.

Brett A. Hoover
Vice President, ImageIQ

Selecting an Imaging Contract Research Organization: Important Considerations for Ensuring Success

By Brett A. Hoover
Vice President, ImageIQ

As the use of medical imaging in clinical trials continues to rapidly increase, biotechnology companies, including medical device and pharmaceutical organizations, face an increasing array of complexities. In many cases, imaging technologies (CT, MRI, PET, etc.) can help speed the process of proving the efficacy and safety of drug therapies and medical devices. For most, however, keeping track of the rapidly changing imaging and image analysis technology landscape can be challenging.

To assist with the imaging components of their work, clinical trial sponsors often turn to imaging core laboratories or central imaging laboratories. These organizations help to secure consistent, high-quality imaging data and ensure minimal variability through central image reading and analysis. These organizations guide the sponsor in designing appropriate image acquisition protocols and provide services to manage the imaging and image data management portions of the trial.

A newer option is to utilize an imaging contract research organization (ICRO) that employs a combination of imaging, image analysis, and biomedical expertise along with customizable software for image analysis and data capture and management. Customized image analysis algorithms can be used in lieu of manual processes, thus helping companies reduce the guesswork, cost and time associated with preclinical and clinical studies.

It is important to understand the characteristics that distinguish ICROs. While the following is not an exhaustive list of ICRO critical features, it provides a strong foundation for evaluating an ICRO to support a preclinical or clinical study.

Operational Abilities

ICROs can excel in a number of areas. Some specialize in a specific therapeutic area, or in supporting preclinical versus clinical studies. On-site versus off-site access to professional staff (e.g., radiologists and pathologists) to read and provide or validate image analysis is also an important consideration, as an on-site staff means the sponsor can expect better access to expertise, potentially lower costs, better turnaround time and fewer potential logistical concerns. Further, an on-site professional staff gives the ICRO greater control over the quality of the manually scored image data [1].

One often overlooked aspect of an ICRO's operational prowess is its ability (and willingness) to provide image acquisition and data management consultation to researchers, clinicians and technicians at remote study sites to optimize and standardize imaging equipment across multiple study sites. Since clinical 3-dimensional imaging modalities have such low resolutions (relative to modalities like Micro-CT), an ICRO's ability to help technicians fine-tune and optimize a CT or MRI scanner can mean the difference between "ok" data and exceptional data. As a result of the inherent differences in preclinical and clinical imaging modalities (e.g., resolution, image acquisition time, etc.), an ICRO with expertise in both can add a great deal of value by helping a sponsor successfully translate preclinical efficacy outcomes into subsequent clinical trials efficacy end points.

Out-of-the-Box Thinking

There are few aspects that are more important to the success of biomedical research and development than the ability to identify problems, quickly design solutions, and then implement those solutions efficiently and effectively. Of significant importance is creative thinking nurtured in an environment that promotes problem-solving and innovation.

For example, a common problem in orthopedic studies utilizing CT or MR imaging over multiple time points is that the 3D images are not acquired in the same plane (e.g., sagittal versus axial) due to inconsistent patient or specimen positioning. Unless an ICRO can quickly develop a way to digitally reorient and co-register these image volumes to the same plane and coordinate system, the radiologists will have to manually account for this when they score the images. As a result, additional subjectivity, variability and labor have been introduced into the data set. One possible solution would be to account for this when the team of readers are trained and standardized prior to the study beginning. Alternatively, a technically advanced ICRO would anticipate this and develop study-specific image co-registration algorithms to reorient the images prior to analysis.

Imaging Modality Diversity

If an ICRO offers a particular image acquisition modality, they need to be well versed in the science behind it and the technical aspects of its implementation. What is truly important is the diversity of experience an ICRO has with imaging modalities. For example, an ICRO should be well versed in both 2-dimensional (e.g., ultrasound, X-ray, confocal and scanning electron microscopy) and 3-dimensional (e.g., CT and MRI) imaging modalities. This enables the ICRO to offer the client multiple options (and combinations thereof) for establishing optimal study end point measurements. This also demonstrates

that the ICRO is not beholden to, or limited by, a single imaging technique. As a preclinical example, orthopedic implant histology histology is often a costly and time consuming endeavor. To help mitigate the time/cost burden, an ICRO should offer its sponsor the option to utilized micro-CT in combination with 2D histology. In addition to reducing data turnaround time and cost, this approach should yield data that is more quantitative and comprehensive [2].

Therapeutic Research Diversity

Equally important is an ICRO's breadth of scientific and medical expertise. Having experience in multiple areas of medicine (i.e., orthopedics, cardiology, oncology, etc.) gives an ICRO a broad and valuable perspective from which to draw upon when they help design and execute a study. For example, an orthopedic knee implant clinical trial involving CT and MRI imaging over multiple time points would require very different imaging and image analysis controls than a preclinical study to evaluate an early-stage wound healing drug whose image-based end point measurements take place at the cellular level. Understanding these details and how they can be manipulated and implemented early on in a study, can have a substantial impact on the timeline of a study and the quality of the final data.

Technology Implementation

ICROs utilize many types of technologies to practice their craft. For example, a Picture Archiving and Communication System (PACS), image scoring and data tracking software, and a secure "portal" (i.e., web-based) for managing, transferring and communicating important information (including raw and evaluated image data) among the ICRO, study site(s) and the sponsor, are fairly universal among ICROs. Some ICROs even utilize custom software engineering to custom-tailor image processing, analysis and visualization techniques on a study-by-study basis [3, 4, 5]. This enables the ICRO to quickly generate extremely quantitative data, and offer the study sponsor a wider range of image measurement options. Regardless, what is important for a biotechnology company to consider is how an ICRO uses all of this technology and what it translates into for the sponsor. If the ICRO is particularly technology savvy, they should be able to leverage custom-tailored imaging analytics to reduce both the cost and time associated with a study by either increasing the efficiency of a study, and/or by increasing the precision and accuracy of the end point measurements such that fewer specimens (or patients) are required to meet a study's end points.

Track Record

Finally, it is important to consider the experience of the ICRO as a whole (i.e., what other sponsors have they worked with?), as well as the background (i.e., formal training and experience) of the people involved in evaluating, designing and executing the study. The ICRO should be able to confidently answer specific study questions, and provide references for sponsors who will give an honest account of their experience working with them. An ICRO should have a track record for successfully working with a sponsor to present (and defend) study data to regulatory agencies. For example, in the United States an ICRO should be willing to attend pre- and post-study meetings with the FDA to present, review and defend both study data and their approach to obtaining that data. To this end, an ICRO should have access to regulatory experts with study-specific scientific experience.

When the success of a study is at stake, sponsors want an ICRO that can help accelerate their journey from bench to bedside. A sponsor should be confident that the ICRO can support their imaging-related efforts in every capacity. Investing the time and effort up-front to vet and get to know your ICRO will pay dividend over the long-haul in the form of fewer headaches, better data and shorter timelines.

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About the Author

Brett Hoover has more than 10 years of experience in Biotechnology and Life Science as a researcher, product manager and commercialization specialist ensuring knowledgeable communications and smooth transitions from the needs assessment/sales process to customer utilization. Prior to joining ImageIQ (www.Image-IQ.com) he functioned as a product manager for the Clinical Tissue Engineering Center (CTEC) and as a commercialization specialist for the Armed Forces Institute for Regenerative Medicine (AFIRM), both of which are located at Cleveland Clinic. In 2004 Brett was awarded the National Institutes of Health's Young Investigator Grant Award for his work in with stem cells and tissue engineering, and in 2010 one of his technology projects was awarded $2.2M through the Ohio Third Frontier Commercialization Program. In 2009, one of Brett's early-stage technology start-up companies was a semi-finalist at the Oakridge National Labs Global Venture Challenge. While at Cleveland Clinic, Brett worked with Dr. Amit Vasanji and the Biomedical Imaging Analysis Center for 5+ years on various medical imaging technology development projects. Brett has a BA in Biology, Chemistry and Art History, and a Master's in Cell and Molecular Biology and Entrepreneurial Biotechnology, all from Case Western Reserve University.

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An interview with Dr. Robert E. Baier

Distinguished Professor & Director, Biomaterials Graduate Program, State University of New York at Buffalo

Interviewed by Forum *Editor Liisa Kuhn, PhD, Associate Professor, University of Connecticut.*

Beginning as a surgical technician operating heart-lung machine and dialysis equipment at the Buffalo General Hospital in 1959, Dr. Robert E. Baier progressed through Bachelor of Engineering Science (Physics, Cleveland State University) and Ph.D. (Biophysics) degrees to post-doctoral training as a National Academy of Sciences fellow (Surface Chemistry) in Washington D.C. (1966-68). Dr. Baier spent sixteen years on the professional research staff of Calspan Advanced Technology Center prior to joining SUNYAB full time. He was Executive Director of the New York State Center for Advanced Technology in Health-care Instruments and Devices (1984-1989), and now is Executive Director of the Industry/University Center for Biosurfaces sponsored by the U.S. National Science Foundation. He is extensively published in many areas of biosurface physics, particularly involving dental and medical implant technology. He is past president of the Society For Biomaterials (1992-1993).

Liisa Kuhn: Bob, you were a biomaterials scientist before there was such a thing. What attracted you to the field?

Robert Baier: As a chemical-engineering college dropout, working as a surgical technician at the Buffalo General Hospital, it was my job to spray clean our home-constructed heart-lung machine with boiling lye to get the blood protein deposits off the "plastic" and metal parts, while replacing the sensor's important ping pong ball, condom, and tin-cured tubing between human patients. I thought we could do better, and focused on this goal after returning to finish my degree in Engineering Physics. Seeing the pain and suffering of affected children, their parents, and the dedication of the frustrated hospital professionals trying to save lives with our primitive medical equipment, during my hospital years and follow-up research in the Clinical Building at NIH in Bethesda, I developed a sense of urgency to deliver product to patients not widely shared by academic colleagues.

LK: I see you've been on the editorial board since 1977. Were you one of first members of the Society For Biomaterials?

RB: Yes, at the strong urging of Bill Hall and Sam Hulbert, I was a Founding Member of SFB being formed, in part, in rebellion from ASAIO where I was then on the Executive Board. One of the arguments for SFB was that ASAIO, attending to the dominant needs of dialysis and cardiovascular research, had no room for orthopedic or dental biomaterials in the annual technical meetings.

LK: Describe the evolution of biomaterials research since you've been involved with it.

RB: Biomaterials research was—and should have been—originally most focused on blood compatibility since there is always first blood contact at surgical intervention sites. The orthopedics ceramics team at Clemson, and pioneering percutaneous prosthetic research at Southwest Research Institute, attracted European colleagues in skin and histopathology research as well as military and National Institute of Dental Research Funding to the mission of safely and effectively meeting biomechanical requirements. Emphasis on blood contact receded, orthopedic device testing came to dominate, and now scaffolding to support tissue regeneration represents a mere remnant of the original materials science while cell biology has come to supersede physical and chemical technology. "Conflict of interest" prohibitions have weaned the inventors from the inventions, significantly diminishing the pace of translation of new biomedical devices to clinical care.

LK: How has your understanding of important biomaterials issues (or your research focus) progressed through the years? What has stayed the same?

RB: In my own case, understanding of important biomaterials issues has radically changed from initially expecting that different materials will selectively adsorb different critical proteins from complex biological systems, to the experimentally demonstrated realization that each biological system will selectively deposit its same protein at solid/liquid boundaries that is there differentially retained (or not) as a function of controllable material surface properties. We cannot control the "on" reaction, but we can control the "off" reaction by proper material selection for each biodynamic domain. Some mechanical work is necessary to see these changes, so Petri dish experiments often fail to predict or correlate well with actual clinical outcomes.

What has stayed the same is the reality that Mother Nature has not changed the rules since we crawled from the primeval soup. Interaction of wet, salty, biological systems with non-physiologic boundaries is the same everywhere, in the sea, in the eye, in the blood, in the knee, and in the wine vat. Like Shakespeare's plays, the script remains the same, even though the actors and costumes change from place to place.

LK: What advances in other scientific fields have impacted biomaterials research the most?

RB: The unhappy answer is that dramatic advances in what we call "tissue engineering" have submerged the development of structural and functional Biomaterials to a transient supporting role, as temporary scaffolding for regenerative medicine infusions. Unfortunately, the end products now risk the introduction of infective vectors, cannot be easily sterilized themselves, and carry cells that may progress to tumors rather than the target tissue. On the other hand, "engineered tissue replacements" –such as bioprosthetic heart valves—have

not yet been widely enough applied. Our first prospectively designed Biomaterials-based fully PMA-approved product through the FDA, in January 1979, was the glutaraldehyde-tanned umbilical cord vein graft (the Dardik Biograft), now in manufacturing limbo because of increased costs associated with FDA's new Good Tissue Practices regulations.

LK: Translational research is a hot topic these days. You've been involved with that your entire career. Could you give me some examples of "What does happen (real life), rather than what can happen (futuristic, often university-based research)" as steps to delivering actual patient benefit.

RB: Here are three examples:
[1] We still teach, especially in medical schools, that there is only one possible outcome of the insertion of a non-physiologic material into a living host: the universal "foreign body reaction," walling off every material with a surrounding fibrous scar capsule in a process our Australian friends call "marsupialization". When working with the team of P-I Branemark and P-O Glantz in Gothenburg, Sweden in the early 1970's toward implants of commercially pure titanium (cpTi) into jaw bone, we were chastened by colleagues that such fibrous capsules would not bear loading and our proposed dental implants would be –as were most others—doomed to clinical failure. When the unique surface properties of cpTi allowed the discovery of the capsule-free host acceptance of such implants in a process now called "osseointegration," academic colleagues scoffed that there probably would never be more than a few hundred accepted into clinical practice. This year, it is expected that over 8 million such dental implants will be placed worldwide. Most medical and dental professionals, and many manufacturers, still do not know the materials requirements to obtain an osseointegrated, load-bearing clinical outcome.

[2] It is close to a "holy creed" in Biomaterials Science that highly hydrophilic materials will resist biofouling essentially forever, while hydrophobic materials will sustain biofouling forever, based on laboratory experiments that seldom take over one week. "Forever" in the case of a life-saving implant, or the bottom of a ship, is certainly longer than a week—and it should be instructive to SFB Members that after all our years of preaching this creed there is NO successful hydrophilic bioadhesion-resisting material used in medicine or for ship bottom coatings over longer terms than tested in the lab. But, on the other hand, short-term "terrible" materials like hydrophobic polydimethylsiloxanes have lasted thrombus-free in life-saving Starr-Edwards heart valves for over 40 years, and on the hulls of the world's largest cargo ships are now routinely shedding accumulating biofouling as the no-longer-poison-laden ships move across the Pacific Ocean at 30 knots. Have you ever wondered why it takes such strong chemistry to remove the biofouling layers from your highly hydrophilic soft contact lenses that should not have fouled in the first place? Because of the water molecule's small size and rapid positional exchanges, interphase dehydration inevitably occurs while the same sites once strongly binding the water become the binding sites for the nearby multi-footed protein caterpillars, unlikely to be as easily back-exchanged into solution from these polar surfaces.

..and [3] Shorter, based on university research, it is held that – because albumin is found to dominate the protein deposit layer on some demonstrably thromboresistant implant materials—pre-coating an implant material with an albumin layer will render that material permanently blood compatible. In reality, such albumin layers are quite rapidly displaced by fibrinogen deposited from whole blood and the materials then are usually thrombogenic. Again, the issue is timing. Pre-coating a heart-lung machine circuit with human serum albumin DOES give the system an hour or so of operating time without overt thrombosis before the albumin is replaced by the fibrinogen. So the signature of "dominant albumin" on thromboresistant surfaces results from the intrinsically thromboresistant surfaces –that do NOT strongly retain or denature fibrinogen—having more of the more-abundant albumin in their more rapidly "turning over" interphase films.

LK: You spent many years in industry, did you ever think of going back, and why or why not?

RB: I have not thought of going back, because the challenge that brought me to the University environment in the first place is still not well met: Fostering more effective Technology Transfer –in both directions—from/to Industry/University. The problem to be solved is that the reward systems are so different. In Industry, what accrues to the benefit of one researcher is felt as a gain for all the researchers. The University uses the "finite pie" model: If one faculty member gets a bigger slice of pie, that means it is taken from the others—so there is little to no mutual support and cooperation for fellow Faculty success.

LK: What has kept you in academia given your interests in applied science?

RB: What has kept me in Academia has been the opportunity to "fight this dragon" of inhibited technology transfer, first as Executive Director of a New York State-funded Center for Advanced Technology in Healthcare Devices and Instruments and for the last 20 years as Executive Director of one of the National Science Foundation's family of Industry/University Cooperative Research Centers—ours specializing in biological surface science. Although publication rates in peer-reviewed Journals are diminished in these tech-transfer enterprises, it is amazingly rewarding – a large psychological paycheck to the investigators—to have product actually go to market and advance patient health and well-being. It does not hurt the process that a new "artificial tear" formulation recently developed in cooperation with our Center is now selling at the rate of $100,000,000 per year for the relief of "dry eye" symptoms, and many of our earlier Industry partners have had similar commercial successes, often using faculty/student-derived data sets critical to obtaining regulatory approvals.

LK: Have you had a translational research project funded by NIH? Do you have any suggestions for how to balance translational research pursuits to make a project fundable by both NIH and by industry?

RB: I am close to receiving NIH support for clinical translation of a respiratory relief "device" for biofilm-impacted Cystic Fibrosis sufferers, using a slime-busting compound developed with Swedish colleagues over 30 years ago and now both

EU- and FDA-approved for control of gingivitis. Our bench-to-bedside translational challenge depends on proving safety when the compound –approved as a medical device and not a drug, because of its physical-chemical mechanism of action—is administered directly to the lungs of animals in a pre-clinical setting. Our industry partner will be supplying the cGMP-manufactured reagent at no-cost, along with file records leading to the prior regulatory approvals for intra-oral use. It is a valuable current effort by NIH to offer support for such trials via its new SMARTT program administered by NHLBI (the Institute that supported much of my early research with Vincent Gott, MD of the Johns Hopkins Hospital, on blood compatibility).

LK: How have you cultivated your industry contacts over the years? Did working in industry help you with this?

RB: I have had the good fortune of assisting industry partners to bring many products through regulatory approval and to the medical marketplace over the years, and –yes—prior experience in industry as well as in the surgical suite were very helpful in being accepted as a "realist" and not a traditional academician. It has been important, as well, to respect the old saying "There is no limit to the amount of good people can do in this world, if they do not care who gets the credit." Biomaterial scientists must accept that this is a "physician's game," and be willing to stand in that shadow. Scrupulous attention to maintenance of commercial confidentiality, and the delivery of research results on time, within budget, in accord with a pre-negotiated statement of work are the absolute keys to successful industry collaborations—anathema to academic traditions.

LK: Has your tech transfer office been able to help faculty at SUNY Buffalo get inventions out into industry or has the majority of the responsibility and effort fallen on the faculty members themselves? What is the best way to get inventions to the attention of industry?

RB: As your question correctly supposes, our tech transfer office works hard and sincerely toward protecting university-generated intellectual property (IP) and getting commercial licensees for that new technology, with cumulative costs over the years much in excess of royalty yields, as experienced in most other universities. For only a subfraction of the IP developed, there is the possibility of an exclusive license being negotiated.....but, overall, the complexities are discouraging to faculty attempting technology transfer efforts. One demonstrated successful way to get inventions to the attention of industry—and to public benefit—is to agree in advance that the starting invention is already the IP of the industry partner, and the university faculty/student role will be to provide supporting/validation research and demonstration of results not expected to yield any additional university ownership. We still have inventive technicians lurking in the halls of our affiliated clinical research institutions, offering to "trade" new device ideas to equipment/media sales representatives in return for a "free" case of costly reagent. Only the most entrepreneurial faculty, themselves, have success in getting their inventions commercialized, usually by leaving academia and setting up their own small businesses.

LK: Do you have any advice for junior faculty just starting to set up their research programs in biomaterials?

RB: Yes! "Get thee to the clinic!" Do everything you can to stand table-side or chair-side, properly gowned and gloved, and witness the activities of your clinical colleagues as they cut, coagulate, poke, probe and ultimately place implements made from materials for which they have almost no professional knowledge of the actual compositions or surface properties—beyond tradenames and provisions from their purchasing agents. Realize, through such personal observations, that putting an expected 15-year implant into the bloody environment of an artificial hip surgery is not well-modeled by your 2-day lab studies of isolated, purified osteoblasts in serum-enriched culture medium in lab dishes. Make note of the fact that serum does not contain fibrinogen, which is the major protein Nature first deposits on all implanted materials before final target cells (osteoblasts?) ultimately arrive at those interfaces *in vivo*.

Many years ago, "scrubbed-in" to a vascular graft surgery, the new textile graft I had helped introduce fell to the floor when being lifted from its pan of blood-covered, heparinized saline (who knew that was routine?) and was accidently stepped on by the surgeon. Casually retrieved and re-rinsed in the same pan, the graft was placed and—three days later—closed with a clot. The admonition to me: "Obviously, your graft is not yet good enough." As biomaterials scientists, it is not enough to make a "perfect" product. "Perfect" is not good enough; it must also have a broad range of physiological (and operator) forgiveness.

LK: What courses should be included in an undergraduate biomaterials curriculum and why?

RB: I recommend that every institution consider the specific courses described in "How to Teach Artificial Organs" by Conrad Zapanta, Harvey Borovetz, Michael Lysaght, and Keefe Manning, published in the *ASAIO Journal 2011*; 57:466-469, since they are rich in examples about practical in-use devices that young students will know about from having heard about family members treated by these various modalities.

Adding to that, among many texts that are available, I recommend *Biological Performance of Materials: Fundamentals of Biocompatibility, Fourth Edition, 2006*, by Jonathan Black, Taylor & Francis CRC Publishers, New York. Jonathan's book, designed for a 1 semester undergraduate course, has enough material for at least two entire semesters and has the engaging virtue of single authorship. There are no multi-author "mixed messages," but diversity in viewpoint is respected in Jonathan's welcome "Afterwords" and "Final Comments" at the end of each chapter.

LK: What is one biomaterials research topic that you hope will continue to be investigated for many years in the future because it remains a vexing and important issue?

RB: That topic is the "Oppenheimer Effect," a more than 60-year mystery about why certain biomaterials induce cancers (predominantly fibrosarcomas, in rats and mice) and others do not when implanted in subcutaneous tissues, with different

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Positively-charged Dimethacrylates to Reduce Bacterial Attachment

Nancy J. Lin, Joseph M. Antonucci, Diana N. Zeiger, Kathy Tang, Sheng Lin-Gibson
Polymers Division, National Institute of Standards and Technology, Gaithersburg, MD

Introduction

The widespread incidence of recurrent tooth decay (caries) highlights the need for improved dental restorative materials. Caries are most frequently caused by acid-producing bacterial biofilms. One approach for developing biomaterials with reduced biofouling is to include quaternary ammonium salts, which are known to adversely affect biofilm growth.[1] For instance, cationic, monomethacrylate monomers have been developed to impart antibacterial activity to polymeric dental materials.[2,3] However, with only one methacrylate group per molecule, incorporation of high concentrations of monomethacrylates into dimethacrylate-based dental polymers will likely alter the overall polymer network structures and properties.

We recently utilized a simple approach to synthesize an ionic dimethacrylate (IDMA) monomer containing a quaternary ammonium functionality (IDMA-1).[4] IDMA-1 was designed to be miscible with common dimethacrylate dental monomers while containing two methacrylate groups for improved copolymerization properties. Our objective was to evaluate the effects of IDMA-1 incorporation into dental polymers on the material properties and biological response, including bacterial growth on and cytotoxicity of the modified polymers.

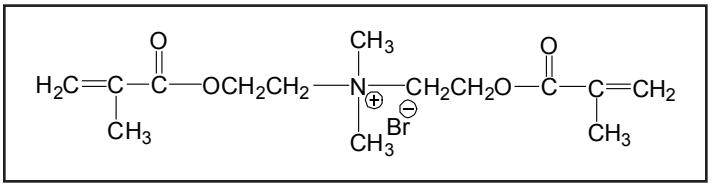

Figure 1: *Structure of bis(2-methacryloyloxyethyl)dimethylammoniumbromide (IDMA-1).*

Methods

Bis(2-methacryloyloxy-ethyl)dimethylammonium bromide (IDMA-1, Fig. 1) was synthesized by the Menschutkin reaction[5] and was incorporated at 0 %, 10 %, 20 %, and 30 % (by mass) into an equal mass ratio of bisphenol-A glycerolate dimethacrylate (bisGMA) and triethyleneglycol dimethacrylate (TEGDMA). The resin viscosity was characterized using a cone and plate rheometer. Resins containing IDMA-1 were activated for blue light (470 nm) photopolymerization with camphorquinone (0.2% by mass) and ethyl 4-N,N-dimethylaminobenzoate (0.8% by mass). Polymer disks were prepared by photo-irradiating the activated resin blends for 1 min per side. The density of quaternary ammonium groups present on the polymer surfaces was quantified using fluorescein sodium salt. For bacterial studies, polymers were inoculated with the oral pathogenic bacteria, *Streptococcus mutans (S. mutans)*, in phosphate buffered saline for 4 h (37°C, 5 % CO_2), fixed, stained (SYTOX Green), and imaged using laser scanning confocal microscopy. To evaluate cytotoxicity, RAW 264.7 murine macrophage-like cells were cultured on the polymers for 24 h and either stained and imaged to evaluate cell density and viability or tested for mitochondrial activity (MTT assay). All images were quantified using Image-Pro Plus.

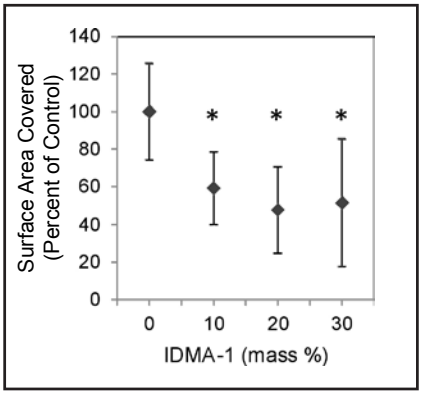

Figure 2: *Fraction of surface covered with S. mutans normalized to 0% IDMA-1 polymer disks. *P-value < 0.05 as compared to 0% IDMA-1. Each error bar represents one standard deviation and serves as the estimate of standard uncertainty.*

Results and Discussion

Synthesis of IDMA-1 was verified using Fourier transform infrared and ^{1}H nuclear magnetic resonance spectroscopies. IDMA-1 was readily miscible with BisGMA:TEGDMA, and the addition of IDMA-1 into BisGMA:TEGDMA (50:50) slightly increased the viscosity of the mixture from (0.25 ± 0.01) Pa s for 0 % IDMA-1 to (0.63 ± 0.01) Pa s for 30 % IDMA-1. The degree of conversion increased from about 68 % with 0 % IDMA-1 to almost 71 % with 30 % IDMA-1. Polymeric surface charge density was not significantly different between 0 % and 10 % IDMA-1. For 20 % and 30 % IDMA-1, surface charge density increased by a factor of 5 and 400, respectively, as compared to 0 % IDMA-1. These data indicate that IDMA-1, with its two methacrylate groups, incorporates into the dimethacrylate dental polymers to increase the surface charge density without large changes in resin viscosity or polymer degree of conversion.

Incorporation of IDMA-1 into BisGMA:TEGDMA reduced bacterial colonization when compared to the 0 % control (Fig. 2). There are no significant differences in bacterial surface coverage between the 10 %, 20 % and 30 % IDMA-1 compositions. These results suggest that 10 % IDMA-1 is effective in decreasing bacterial colonization even though no significant change in surface charge between the 10 % and 0 % samples was detected. In addition, increasing the IDMA-1 concentration above 10 % did not further reduce the bacteria colony size (data not shown).

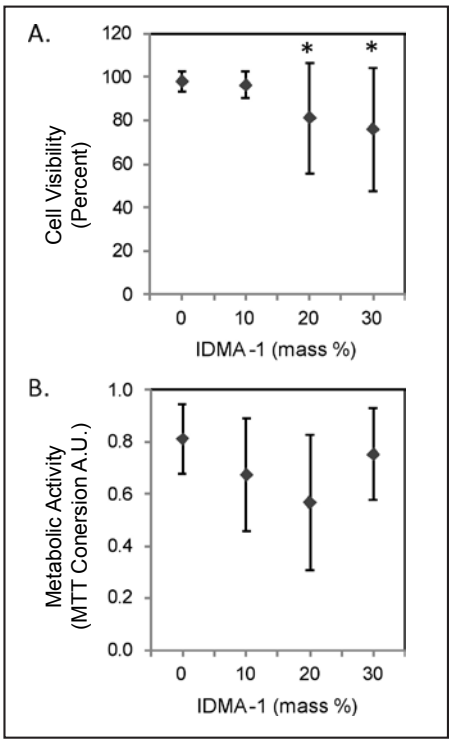

Figure 3: *RAW 264.7 response at 24 h. (A) Viable cell fraction as a function of IDMA-1. *P-value < 0.05 compared to 0% IDMA-1. (B) MTT activity for cells cultured in the same well as the polymer disks but growing on the TCPS well plate. No significant differences were present for TCPS cells (P-value >0.05). Each error bar represents one standard deviation and serves as the estimate of standard uncertainty.*

Cytotoxicity results are shown in Fig. 3. Polymers with 10 % IDMA-1 reduced macrophage density (data not shown) without affecting viability (Fig. 3A) or total metabolic activity (data not shown), indicating that while there are significantly fewer cells, their viability and metabolic activity are unaffected. Cell viability decreases significantly for the 20 % and 30 % compositions, and metabolic activity shows the same trends (data not shown). Macrophages were also cultured on the tissue culture polystyrene (TCPS) wells in the presence of the polymer disks to evaluate effects of small molecules leached from the polymers and into the media on the macrophages. The cell metabolic activity on TCPS was not significantly different between the IDMA-1 loaded polymers and the control (Fig. 3B). Thus, leachables from polymers containing IDMA-1 were not cytotoxic, and changes detected in bacteria and cells adherent to the polymers are due to direct interactions with the surface quaternary ammonium groups, and not to toxic leachables.

Conclusions

IDMA-1, which contains two dimethacrylate groups and a quaternary ammonium functionality, reduces initial bacterial colonization but can also be cytotoxic to mammalian cells. To balance these effects, ≤ 10 % IDMA-1 is suggested for reducing *S. mutans* colonization without altering macrophage viability. These findings highlight the promise of IDMA-1 and other liquid cationic dimethacrylates for use in dental and biomedical applications where biofilm growth is of concern.

Support: NIDCR/NIST Interagency Agreement Y1-DE-7005-01. Contribution of BisGMA and TEGDMA from Esstech, Inc. is acknowledged.

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An interview with Dr. Robert E Baier

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results for smooth and rough versions, and slab vs particulate versions of the same materials, with no easily apparent relationships to material compositions or surface properties. A quick and well-done summary of this issue, with a good early-reference list, appeared as a *Biomaterials Forum* Special Feature, pages 8,10, September-October 1992, Vol 15, no. 4, "The Oppenheimer Effect and Long-Term Medical Device Implant Studies in Rodents," by Robert F. McConnell, DVM.

My own conclusion, predominantly reflecting our continuous and ongoing research with surface-modified implant materials since 1966, is that cancer causation around implanted biomaterials can result from thick, unattached fibrous capsules around the material, within which reactive-oxygen-species (ROS) production by activated macrophages triggers malignant transformation of capsule-potentiated stem-cell-like inclusions. I advocate glow-discharge-treatment of such implant materials to foster macrophage spreading, incapacitating their ROS production, and favoring coverage with thinner, tighter tissue capsules: A step toward "soft tissue integration" that will mimic our already successful osseointegration in hard tissues.

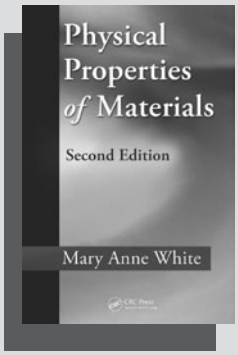
Regarding the lack of malignancies around our now 30-year-plus implants of diverse types, maybe it is true that "we are not just big rats" and we should re-consider the sacrifice of so many animals in our research when *in vitro* bench tests can do as well or better.

LK: Thank you, Bob, for taking the time to share your views with the Society For Biomaterials members.

Is there someone interesting that you'd like to interview on behalf of the Biomaterials Forum*? Please send me an email at Lkuhn@uchc.edu so I can help you get started.*

Book Review

Review by Lynne C. Jones,
Associate Professor, Johns Hopkins University
And Timmie Topoleski,
Professor, University of Maryland, Baltimore County



Physical Properties of Materials

By Mary Ann White
CRC Press, copyright 2012
Hardcover, 452 pages. Cost is $79.95.
ISBN: 978-1-4398-6651-1

Description and Review

Is "Physical Properties of Materials" by Mary Anne White a good resource for lectures on biomaterials given to undergraduates and novices to the field? If you are looking for a brief monograph that presents some basic material science to provide a foundation for a more in-depth discussion of biomedical implant materials, the answer is a qualified yes.

This book is organized into 5 sections: I. Introduction, II. Color and Other Optical Properties of Materials, III. Thermal Properties of Materials, IV. Electrical and Magnetic Properties of Materials, and V. Mechanical Properties of Materials. Each section contains one to six chapters which comprises topical information, with examples and comments from the author, followed by problems and suggestions for further reading. While this book is written more from the perspective of physical chemistry than classical materials science, it may be this difference in perspective that brings a fresh look at traditional materials. The author, Mary Anne White, is the University Research Professor at Dalhousie University in Halifax, Nova Scotia. She is a much decorated academician with a substantive career in research and education regarding materials science, and specifically energetic and thermal properties of materials.

Dr. White's interests and expertise are clearly reflected in the four chapters on Color and Other Optical Properties of Materials and the six chapters dedicated to the Thermal Properties of Materials. This perspective is apparent as she uses the discussion of color and other optical properties of materials to teach about basic atomic transitions, electronic states, and vibrational transitions. The chapter on Surface and Interfacial Phenomena, a topic of relevance to biomaterials, is not usually covered in most traditional materials science texts. This chapter is an excellent reminder that we should expand our teaching beyond bulk properties of materials and include topics of specific relevance to biomaterials, such as surface properties of materials. In contrast, the text does not offer the in-depth discussions of electrical or mechanical properties of materials that are typically found in classic textbooks. The chapters that are included on these topics concentrate on providing basic definitions and provide little on the application and testing of these properties. Instructors will need to supplement the text with additional reading to provide a more thorough presentation of the subject matter.

Audience:

This book is directed toward undergraduate level classes. It is not so much of a reference book as an "Introduction to Materials" book. It is clearly written and accessible to new students in the field. One strength of the book is that there are many basic examples that are useful to illustrate the scientific concepts. One limitation of the book, for our SFB members, is that it does not address biomaterials, per se. To return to the original question of our article, Dr. White's text does a good job of explaining the basics of materials science from a physical chemistry approach. Regarding the use of this book for undergraduate biomaterials classes, we recommend that educators carefully review this book to determine whether the material is complementary to their teaching styles, and whether its content is sufficient to, and is presented in a manner that will, provide their students with the fundamental information to advance their understanding of biomaterials.

If you are looking for a brief monograph that presents some basic material science to provide a foundation for a more in-depth discussion of biomedical implant materials, the answer is a qualified yes.

Putting Numbers in the Biomaterials Curriculum

Brian J. Love, Ph.D.
Professor of Materials Science and Engineering, Biomedical Engineering and Dentistry
University of Michigan

It seems that, from the perspective of both educators and the educated in the field of biomaterials, there are several elements that are increasingly self evident to consider as we anticipate how our discipline evolves that might trigger a larger discussion within the biomaterials community. Common issues we encounter as educators include the fact that many of our educational and other supplementary materials present discussion questions (compare and contrast, discuss, how to improve a design) that often lead to long-winded, verbal and necessarily qualitative answers. So much so that we seem to forget the wealth of mathematical and modeling experience of the students enrolled in our classes. The evaluation of these qualitative problems are often subjective and difficult to grade, take longer to evaluate and ultimately trigger our own optical stress experiments late in the evenings before the homework is returned. We all also have our growing stockpile of quantitative questions we adapt and recycle for examinations, while others revert to teaching biomaterials from a "zoological" perspective where each class of materials and each design environment have their own attributes, constraints, limitations and specific evaluation criteria. Separate constraints on those of us with undergraduate programs include the periodic accreditation reviews that continuously lead to questions about how we should both convey course content and evaluate student performance. Given the landscape we are presented, one might consider whether our own sub-discipline could benefit from a recommitment to quantify elements of related biomaterials course content. I'll provide a few relevant examples, and it would be great to get your own feedback in a larger thread.

Part of the landscape is complicated by the imbalance between biomechanics and biomaterials. Biomechanics focuses on constitutive relationships, tensors and vectors, quantitative constants and establishes regions of linearity and non-linearity, etc. Biomechanicians are born to calculate something. Biomaterial scientists, on the other hand, gain a rather more qualitative feel and are also subject to the practical reality that the haptic interface is a larger unknown design constraint. It is also confusing as materials scientists present biomaterials in a balanced approach (we use metals, ceramics, polymerics and mixtures thereof), interfacing with a variety of hard and soft tissues using materials that can be very much stronger and stiffer than the tissues they connect. It is hard to present steels, other common orthopaedic alloys, and consolidated ceramics as appropriately designed components and solutions to resolve total joint arthroplasties. This suggests that some consideration other than the actual mechanical behavior of the biomaterials is the real rationale for their continued usage. If we presented bone structure and properties as the appropriate design environment, we might be asking larger questions about how we can obtain properties in developmental alloys or porous composites that are more effective in reducing stress shielding, as an example. In the patent literature, there have been some interesting studies to add other co-alloying elements to titanium to reduce modulus by as much as 40%. Mechanical data and phase structure of the formed alloys are included as part of the patents, which reinforces how one might optimize satisfactory mechanical behavior without triggering stress shielding.

Of course, we probably also need to provide the rationale for why this particular alloy isn't being immediately evaluated and deployed as better than what we have on the shelf. This issue of grandfathering certain biomaterial compositions as acceptable has raised the activation energy to qualify any alternative, stifled innovation and presented a series of opaque design constraints almost unrelated to the actual design needs.

Another area where we might quantify more is in the various cell culture studies we also use as tools to help us in understanding cellular response. Often results are presented as blots, bar graphs with various time points, etc. Perhaps other ways to visualize the data as a dynamic concentration graph might lend themselves to more refined ways to calculate material balances, perform differentials, and provide for a more comprehensive quantitative approach. We might look for better datasets and apply more analysis than the visual presentations of the gels, and such

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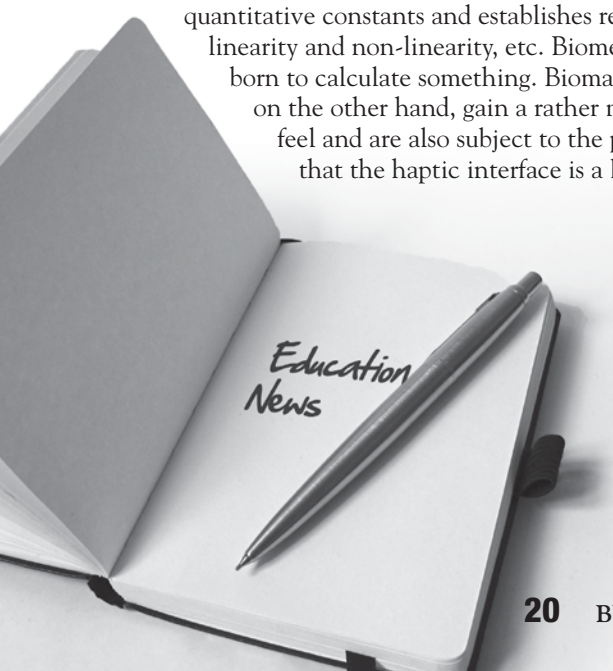

Education Quote of the Quarter:

"If you can't describe what you are doing as a process, you don't know what you are doing."

— W. Edwards Deming

Updates In Industry

More than three-quarters of medical device makers go overseas first when launching new products, according to researchers at Northwestern University. Of 350 medical device company employees reviewed, 22 percent said high costs of FDA review sent them overseas and 14 percent blamed a lengthy and complicated U.S. review process, according to a report by researchers at Northwestern University. Nearly all of the remaining 63 percent of respondents cited unpredictability as the main reason for going abroad before applying for FDA clearance. The study, which was paid for by the Institute for Health Technology Studies, drew responses from employees of small, medium and large med-tech companies recently involved in 510(k) submissions. The institute is a non-profit funded by the medical device industry.

Medical device makers can now have their devices simultaneously evaluated by FDA and CMS, allowing them to know at the same time whether their devices will be approved and covered by Medicare. A pilot program, run jointly by FDA and CMS, will begin accepting submissions from sponsors immediately. It is designed to simplify the process for obtaining device approval and receiving Medicare coverage. The program will review up to five products per year, will run for at least two years, and "will focus on innovative technologies that can benefit from the efficiencies of parallel review," according to the release. The program is meant to prevent device makers from discovering that their products will not receive coverage after they've already gone through FDA's approval process.

Earlier this year, PricewaterhouseCoopers reported that companies active in life sciences attracted $2.1 billion of venture capital (VC) in the second quarter of 2011. Of that total, $841 million was invested in medical device applications, which was 26% more than where it was in the first quarter. After that report was released, there has been a growing amount of evidence that VC funding is trending downward for medtech companies. Just recently, a survey released by the National Venture Capitalists Association's Medical Innovation & Competitiveness Coalition surveyed 156 venture capital firms, and reported that 39% of respondents reported decreased medtech funding over the past three years. The primary reasons for the funding decrease? What you might expect: Regulatory concerns, reimbursement issues, and the down economy. FDA was singled out as being so cautious that many manufacturers have simply given up trying to get their products to the market in the United States.

In February 2011, Mobisante (Redmond, Wash.) got the green light from the FDA for its mobile, smartphone-powered ultrasound device. It took the medical device startup another eight months to meet the various FDA guidelines, but now its MobiUS SP1 Ultrasound System is finally available for commercial sales starting this month. These types of small medical scanning devices with Wi-Fi and cellular connectivity can be taken into the field, are more affordable and easier to operate than full-sized machines, and images can quickly be shared with other medical professionals at far away locations. Captured images are small, a maximum of 480-by-480 pixels — enough for mobile usage but not a replacement for traditional ultrasound machines. The Redmond, Wash.-based startup is going up against much larger manufacturers. GE makes the VScan mobile, a $7,900 portable ultrasound device that looks like a large Motorola Razr flip phone. Siemens sells its Acuson P10 ultrasound system for $8,499.

A group led by London-based private-equity firm Apax Partners acquired Kinetic Concepts Inc. (San Antonio, TX) in a deal valued at about $6.1 billion, including outstanding debt. Shareholders were slated to receive $68.50 a share under terms of the transaction. KCI and an affiliate obtained $2.5 billion of senior secured financing under new credit facilities as part of the acquisition. In addition, the KCI entities issued $1.75 billion in senior secured notes due in 2018 and $750 million in senior notes due in 2019. Participating with Apax in the acquisition were affiliates of Canada Pension Plan Investment Board and the Public Sector Pension Investment Board, also of Canada.

Sen. Dan Coats (R-Ind.) introduced an "FDA Mission Reform Act," aiming to clarify the mission of the federal watchdog agency and clarify the regulatory environment. The federal watchdog agency's new mission would require it to establish a regulatory system that:

- "Advances medical innovation by incorporating modern scientific tools, standards, and approaches to ensure the predictable, consistent and efficient review, clearance, approval and licensing of innovative products (including drugs, devices and biological products);
- "Protects the public health and enables patients to access novel products while promoting economic growth, innovation, competitiveness and job creation among the industries regulated by the FDA;
- "Identifies and uses the most innovative and least burdensome tools for achieving regulatory ends;
- And "Incorporates a patient-focused benefit-risk framework that accounts for varying degrees of risk tolerance."

Rep. Mike Rogers (R-Mich.) introduced a similar bill in the U.S. House of Representatives earlier this year.

The Chinese medical device market is expected to grow 17 percent, according to Citigroup's first hospital survey. Just 11 medical equipment segments are due to grow to $5 billion. That overall growth is based on a projection of 12 percent growth in the medical equipment market and 25 percent growth in medical consumables. Strong demand from Chinese hospitals because of larger purchasing budgets and planned infrastructure upgrades are fueling the growth. The survey also found that while multinational companies currently dominate the Chinese market, they can expect some competition from domestic players, especially inpatient monitors, anesthesia machines and radiography segments. In particular, Mindray, Wandong and Aeon are companies to watch for, according to Citi analysts. GE led the medical equipment market, while in medical

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AIMBE Awards Top Honors to Two SFB Past Presidents

The American Institute for Medical and Biological Engineering (AIMBE) has selected **Arthur Coury, Ph.D.**, as the 2012 recipient of the Pierre Galletti Award. The Galletti Award is the highest honor that AIMBE bestows on an individual.

Dr. Coury, a Fellow of AIMBE and past president of the Society For Biomaterials (1999-2000), was nominated for the award *for seminal contributions to the design and commercialization of pacemakers, biodegradable biomaterials, and implantable devices and for leadership in medical and biological engineering and public policy issues*.

Dr. Coury holds a B.S. degree in chemistry from the University of Delaware (1962), a Ph.D. in organic chemistry (1965) and an M.B.A. (1980) from the University of Minnesota. His industrial career included positions as: Senior Research Chemist at General Mills, Inc. (1965-1976), Director, Polymer Technology and Research Fellow at Medtronic, Inc. (1976-1993), Vice President, Research and Chief Scientific Officer at Focal, Inc. (1993-2000), and Vice President, Biomaterials Research at Genzyme Corporation (2000-2008). His career focus has been polymeric biomaterials for medical products such as implantable electronic devices, hydrogel-based devices, and drug delivery systems. He holds over fifty distinct patents and has published and presented widely in his field.

In addition, **Anne Meyer, Ph.D.**, has been chosen as the 2012 recipient of AIMBE's Fellow Advocate Award. The Fellow Advocate Award recognizes a Fellow who has made outstanding contributions to advancing federal policies assisting the field of medical and biological engineering.

Dr. Meyer, who has served in many leadership roles in SFB including a term as president from 2004-2005, has made an indelible mark on AIMBE over the course of her fifteen years as an AIMBE Fellow, culminating in over five years service on AIMBE's Board of Directors. She has also served as the Chair of the Council of Societies, Chair of the Bylaws Committee, actively participates in the Women in Medical and Biological Engineering (WIMBE) Committee, and is currently finishing a two-year term as AIMBE's treasurer.

Perhaps Dr. Meyer's greatest contribution to AIMBE's public policy efforts was her seminal role in founding AIMBE's Federal Symposium in 2005. At her urging, AIMBE formed this yearly event at which AIMBE Fellows and members of AIMBE's Council of Societies gather to learn about the salient issues affecting the medical and biological engineering community, develop position papers and educational materials, and visit with their respective lawmakers to reinforce the many contributions that the engineering community has made on society. The Federal Symposium has become a hallmark of AIMBE's advocacy efforts. Dr. Meyer continues to participate in the Federal Symposium, and has witnessed how the program has grown to great success over the past six years.

Dr. Meyer is the Director of the Industry/University Center for Biosurfaces and Associate Dean for Research in the School of Dental Medicine at the State University of New York at Buffalo. She holds research and adjunct faculty positions in the schools of medicine, dentistry, and engineering. Her research focuses on biosurfaces, biomaterials, and biomedical implants. In addition, Dr. Meyer's teaching ensures continued advancement in the fields of biological and medical engineering. Most recently, she developed a pre-baccalaureate certificate program on the regulatory environment of medical devices and implants, attracting adult learners from various industries as well as traditional university students. In 2002, Anne received the C. William Hall Award from the Society For Biomaterials.

Dr. Coury and Dr. Meyer were presented with their awards at AIMBE's 21st Annual Event which took place February 19-21, 2012, at the Grand Hyatt in Washington, D.C.

Antonios Mikos, Ph.D., and **Michael Sefton, Ph.D.**, have been elected fellows of the American Association for the Advancement of Science (AAAS), the world's largest general scientific society and the publisher of the journal *Science*. AAAS fellows are elected by their peers for their efforts to advance science or scientific applications that are deemed scientifically or socially distinguished. Prof. Sefton served as president of SFB in 2005-2006; Prof. Mikos served as Secretary-Treasurer of our Society from 2007-2009.

Noam Eliaz, Ph.D., M.B.A., associate professor of mechanical engineering at Tel Aviv University and a new member of the Society For Biomaterials, was inducted as a 2012 Fellow of NACE International. NACE International (originally known as the National Association of Corrosion Engineers) is the largest organization in the world committed to the study of corrosion, with more than 60 years of experience in developing corrosion prevention and control standards. The rank of Fellow was created in 1993 "…to provide recognition of members for distinguished contributions in the fields of corrosion and its prevention …"

Ali Khademhosseini, Ph.D., will be the recipient of two awards at the American Chemical Society meeting in San Diego, CA, March 25-29, 2012. He has won the Division of Biochemical Technology's Young Investigator Award intended to recognize an outstanding young contributor to the field of biochemical technology. Additionally, he has been awarded the Biotechnology & Bioengineering Division's Daniel I.C. Wang Award offered for exceptional research by a young scientist.

AIMBE Honors SFB Members

Alan Litsky, Society Business and Membership News Contributing Editor

AIMBE – the American Institute for Medical and Biological Engineering – recently announced its new inductees and several SFB members are among those honored. AIMBE, a non-profit organization headquartered in Washington, D.C., and comprising "the top 2% of medical and biological engineers," represents academic institutions, private industry and professional engineering societies (including the Society For Biomaterials) and provides leadership and advocacy in medical and biological engineering for the benefit of society.

SFB members inducted in February, and the brief citation describing the reason for their induction, include:

Anthony Atala, M.D., Wake Forest University School of Medicine
- for outstanding contributions to the development of regenerative medicine and the successful translation of tissue engineering principles into clinical practice

Amit Badyopadhyay, Ph.D., Washington State University
- for outstanding contributions in the development and characterization of new biomaterials

Hamed Benghuzzi, Ph.D., University of Mississippi Medical Center
- for fundamental development of drug delivery systems and for critical leadership regarding graduate education of biological and medical scientists

John P. Fisher, Ph.D., University of Maryland, College Park
- for outstanding contributions to the development of engineered tissues based upon the control of paracrine signaling among biomaterial-embedded cell populations

Stuart Goodman, M.D., Ph.D., Stanford University
- for exceptional contributions in the study of biological responses to biomaterials and for excellence, service and leadership in orthopaedic research

Ali Khademhosseini, Ph.D., Brigham & Women's Hospital / Harvard Medical School
- for contributions to novel technologies at the materials science, micro- and nano-engineering and medicine interface, which will enable regenerative therapeutics

Kristi L. Kiick, Ph.D., University of Delaware
- for seminal contributions to the design and synthesis of novel macromolecular biomaterials, including homogeneous glycopolymers and cell-responsive growth-factor crosslinked matrices

Steve T. Lin, Ph.D., Exactech, Inc.
- for significant contributions for developing new orthopaedic biomaterials and implants

Sachin S. Mamidwar, M.B.B.S., M.D., Ostomy Care R&D
- for significant contributions for the development of Bone Graft Materials and its introduction to the market

Howard W.T. Matthew, Ph.D., Wayne State University
- for seminal contributions to the development and application of polysaccharide biomaterials in tissue engineering

Gabriele Niederauer, Ph.D., ENTrigue Surgical, Inc.
- for the development of novel biomedical devices of significant commercial value

Liping Tang, Ph.D., University of Texas at Arlington
- for outstanding contributions to advance the understanding of biocompatibility and to transform the development of medical devices for patient care

Min Wang, Ph.D., University of Hong Kong
- for outstanding contributions to biomedical composites

Thomas J. Webster, Ph.D., Brown University
- for outstanding contributions in nanotechnology and regenerative medicine as well as leadership, education, and community outreach in biomedical engineering

Patrick Stayton,
Ashutosh Chilkoti, Conference Organizers

NanoBio Seattle 2012

NanoBio Seattle 2012
July 23-26, 2012
Seattle, WA

This will be the fourth in this NanoBio series that started as NanoBio Tokyo (Professor Kazunori Kataoka, Chair), then was NanoBio Seoul (Professor Kyung-Hwa Yoo, Chair), and most recently NanoBio Zurich (Professor Marcus Textor, Chair). They have been very successful meetings with 500-1000 attendees and we hope to continue the high standard of these exciting meetings in Seattle. The meetings are special in many regards, e.g. in their breadth and emphasis on cutting edge nanobio research, and the combination of more fundamental nanotechnology research with more applied medical application research. The organizers hope to continue this bringing together of advances in tools, materials, medical devices and translational medical applications will cause attendees to find new connections and find inspiration from this network that crosses between nanoscience and nanotechnology.

Session topics will include NanoBio Sensing; NanoBio Materials; NanoBio Interfaces; NanoBio Devices, Drug Delivery & Nanomedicine; Nanomedical Imaging; Nanotoxicology, Biomimetic and Bioinspired Nano-Structured Materials and Interfaces; and Nano-scale Characterization Techniques and Single Molecule Analysis.

Putting Numbers in the Biomaterials Curriculum

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quantification will likely also require the types of normalizations and reference standards usually included in other quantitative assays.

Finally, we might try to do our part to quantitatively analyze the performance of the innate biomaterials we are already equipped with. The proliferation of inexpensive sensors for strain, temperature, acoustic and electrical signaling, coupled with related instrumentation equipment, might allow us to collect real data to assess biophysical properties, rather than continuously searching for an appropriate dataset. While we need to be aware of the potential liabilities and manage the risks for doing these types of measurements accordingly, the costs of doing real experiments have dropped dramatically.

These are just a couple of examples I see in my own syllabus that would be improved on if we could develop a larger database of relevant quantitative examples. I would be interested in other faculty and student feedback to establish best practices. For that matter, it would be useful if a central repository of quantitative examples and questions could be collected and managed, albeit with the knowledge that they all have their own shelf life.

Industrial News

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consumables, especially in orthopedics and drug-eluting stents, Medtronic, Johnson & Johnson and Stryker were ahead.

The U.S. FDA has expanded approval of an endovascular graft to include ruptures of the aorta, the body's largest artery. The Gore Tag Thoracic Endoprosthesis was first sanctioned in 2005 to treat aortic bulges called aneurysms, the agency said in a news release. Use of the graft to treat aortic tears will spare patients more invasive open chest surgery. The graft, produced by Flagstaff, Arizona-based W.L. Gore and Associates, contains a metal mesh frame surrounded by a fabric tube. Implantation is done via a catheter inserted into a leg artery. Approval for the new use was granted based on clinical studies involving 51 people with aortic tears. Gore will follow patients implanted with the device for five years.

Smith & Nephew plc (London), the global medical technology business, announced that it has, through its subsidiaries ("Smith & Nephew"), agreed to form a joint venture with Essex Woodlands (www.ewhv.com), a specialist healthcare growth equity and venture capital firm, to further develop its Biologics and Clinical Therapies division. The new entity, called Bioventus LLC ("Bioventus"), will be 51 percent owned by Essex Woodlands and 49 percent by Smith & Nephew. In addition to this shareholding, Smith & Nephew will receive approximately $98 million cash, which will be used to pay down debt, and a $160 million five-year note from Bioventus. Smith & Nephew will transfer the vast majority of its US Biologics team and Clinical Therapies business to Bioventus and, for the time being, Smith & Nephew will continue to distribute Clinical Therapies products outside of the US.

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