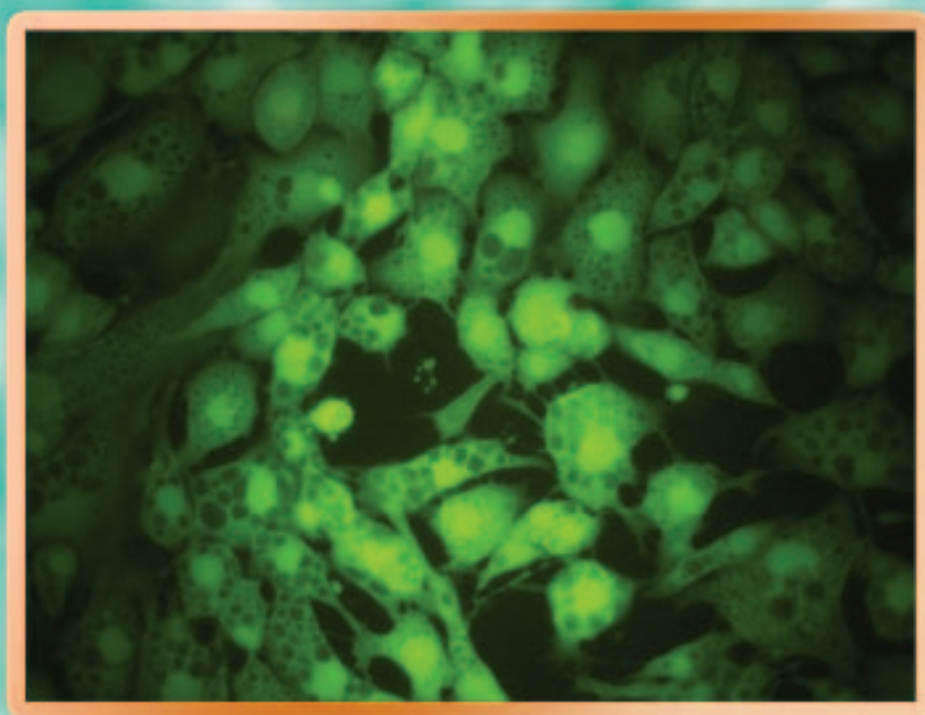


Encompassing a Biomaterial's Tradition

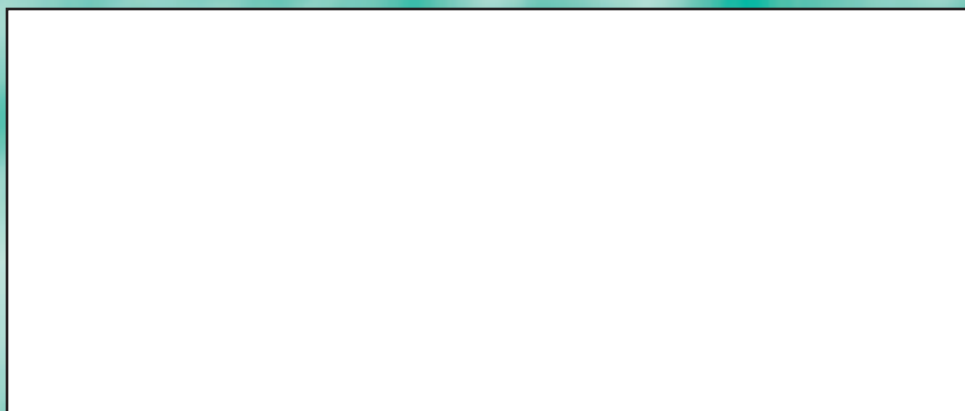
BIOMATERIALS FORUM



Second Quarter 2008 • Volume 30, Issue 2



**NIST Reference Materials are
“Gold Standard” for Bio-Nanotech Research**



**Invention
vs.
Innovation**

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BIOMATERIALS FORUM



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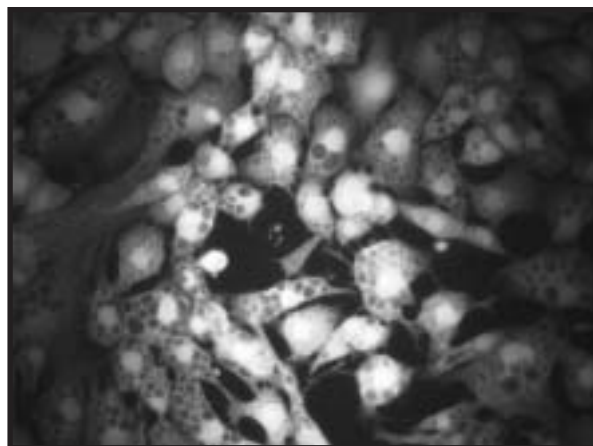
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Oxygen nanosensors engulfed in mesenchymal stem cells. Photo courtesy of Erik Bland and Karen Burg of Clemson University; the nanosensors were developed for cancer research through funding provided by a National Science Foundation Emerging Frontiers in Research & Innovation grant.

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The cover photo on the previous issue (30(1); 2008) denoted an SEM wet mode image of bone cells and their mineralized matrix on chitosan scaffolds after 4 weeks in a rotary bioreactor.

Photo was courtesy of Dr. Joel Bumgardner of the University of Memphis.



From the Editor The Torch

By Karen J.L. Burg



I recently attended the American Council on Education (ACE) Council of Fellows meeting in Washington, D.C. I love the meeting because it is an opportunity to ponder the complicated issues and opportunities in the world of higher education and, in my case, in research administration. Of interest and discussion was the topic of disciplinary.

I remember as a student learning that my home department was founded by a multidisciplinary group of individuals in the early 1960s as a Clemson University program, evolved into the Department of Interdisciplinary Studies, and subsequently into the Department of Bioengineering. This history is engrained in my mind, so it was amusing watching the ACE meeting participants wrestle with the concept of something beyond a discipline. But as the discussion evolved, I appreciated that even we as biomaterialists, whether in industry, clinical, or academic environments, must carefully consider short-term and long-term potential and implications of interdisciplinarity, particularly as we develop new training programs.

Terms are still being formalized (or perhaps popularized)—disciplinarity, multidisciplinary, crossdisciplinarity, interdisciplinarity, transdisciplinarity, and postdisciplinarity. “Multidisciplinary” implies the simple juxtaposition of disciplines through, for example, the enrollment in courses of different disciplines. “Crossdisciplinarity” suggests the study of one discipline from the perspective of another, e.g., the physics of music. “Interdisciplinarity” describes the integration of discipline-specific perspectives or ideas to form a new method or approach toward a problem, whereas “transdisciplinarity” is perceived as the melding of disciplines while broad perspectives of a field (i.e., “engineering” or “humanities”) are maintained. Proposed at the ACE meeting was the concept of postdisciplinarity—i.e., the absence of disciplines in even the most basic courses. We see this trend with “just-in-time” math modules superceding the traditional prerequisite course system (“must have calculus before biomechanics”). As I synthesize these concepts as a research administrator, several questions spring to mind about biomaterials education, research, and training. Should a biomaterialist be a “transdisciplinarian” or even a “post-disciplinarian,” or should a biomaterialist be a “disciplinarian” with excellent communication skills and specific transdisciplinary skill sets? Industry colleagues frequently ask me for names of students who are bioengineers by graduate training, but who have a classical engineering undergraduate training. Will our ability to advance the field be lost if we lose experts of the discipline? Will we all have technical breadth but no depth? Is it the logical thought patterns or the specific facts of the discipline that are more important? And when does an interdisciplinary study become a discipline in the eyes of the funding agencies that have special monies for interdisciplinary team play? This discussion is by no means limited to the ACE—in fact SFB members have an advantage in being comfortable with the concept of complementary, integrated technical concepts and perspectives. Will we, the SFB membership, proactively develop a functional disciplinary model, i.e. the optimal combination of multi-, cross-, inter-, trans-, or post-, for the non-biomaterials community? I would suggest that we should.

*Best wishes from Clemson,
Karen J.L. Burg*

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Passing the Torch!



C. William Hall had a vision where an exclusive group of scientists would come together to network and learn from each other—a home without borders where everyone shares biomaterials as a passion. This vision became the Society For Biomaterials. More than 30 years later, the SFB has kept its leadership position as the premier professional society in the

world that promotes advances in all phases of materials research and development in the biomaterials field. The SFB membership has more than tripled! Still, from generation to generation, not only is the SFB considered the ultimate platform for sharing, learning, and discovering the science behind the building blocks of medical devices, it is a culture that exemplifies collegiality. In 1986, Elaine Duncan, as Editor of the *Torch Newsletter*, clearly emphasized the role of members and volunteers in the success of the Society: “A match can light a torch, but will never blaze as long or as brightly.” Every year, the torch flame is being invigorated through the dedicated commitment of members. During the past months, I have been amazed and delighted by the energy and leadership skills of Council and Board members. Many activities have

been pursued by committees with the goal of increasing membership value while fulfilling the mission of the Society. A report card highlighting accomplishments and setting the stage for growth and enhancement will be presented to members at the annual business meeting and published soon thereafter. A new look for SFB is coming!

This letter is my last as President of the SFB. And as such, I would like to leave office by thanking all of you for your support and encouragement, and for considering the SFB your home. A very dear friend of mine and past-president of the Society For Biomaterials once said: “Biomaterials became my academic home, my passion, and my life’s accomplishments. I had found my true professional calling.” SFB is all about passion. This is indeed contagious! Like all my predecessors, I have been privileged to serve you and hopefully met your expectations. In passing the Torch to our incoming President, Jeffrey Hubbell, I would like to leave with a charge to all young biomaterials scientists and engineers, to carry and share the Torch, lighting the path for science and discovery to become safe and effective clinically used technology.

Martine LaBerge, PhD
President

Letter to the Editor



I enjoyed the recent editorial (*Biomaterials Forum*, 29(4), 2008) on the topic of open access. This is an important issue for SFB, especially considering that a substantial fraction of the Society’s income derives from a contract with Wiley regarding royalty sharing. You are right to raise this issue in the *Forum* and sensitize the membership to this issue. I suspect that

open access will only change how we pay to publish our work but it will not fundamentally challenge how we work.

What if the print system becomes irrelevant? The new generation of SFB scientists is more Internet-oriented than the previous generation. As a result, blogs, webcasts, online publications, etc. are likely to become more important mediums of scientific communication than they are now. Print-based journals may become obsolete forms of scientific publication. The Internet as a distribution system will replace (eventually) the publisher, especially as Google and Wikipedia (and wikis more generally—see for example, <http://openwetware.org/wiki/>) become more sophisticated. If you want to see a vision of the future of newspapers, check out <http://epic.makingithappen.co.uk/>.

Think about the current system. The volunteer, unpaid editor, combined with volunteer reviewers, working with a for-profit

publisher, is an unstable situation. We write the articles, we review them, and the publisher makes money because we want to see the paper in print and they have a distribution system. University libraries are having a hard time affording print journals and the publisher’s fees for online access.

Would we be willing to give up the aesthetically pleasing reformatting of the paper that the publisher now provides? Would we be willing to forego the editing and attention to detail (all those author queries) that the publisher pays for? Would we care if the publisher didn’t market the journal and by inference our own work or the field we are in? And who would be responsible for maintaining the electronic archive if not the publisher?

But the big question is do we really need refereeing? The physics community apparently doesn’t. Do we? Will we even have a vote?

Michael Sefton
Institute of Biomaterials and Biomedical Engineering
University of Toronto

Editor’s note: Royalties from John Wiley & Sons Inc. account for approximately 20-25 percent of the Society For Biomaterials’ income; subscription fees account for approximately 10-15 percent of the Society’s expenses.

SFB 2008 Activities

The Society For Biomaterials annual business meeting will be held May 29, 2008, at noon at the RAI Conference Centre in Amsterdam. In addition to the 2008 World Biomaterials Congress (May 28-June 1), the Society will be hosting a Fall Symposium in Atlanta, GA, on Translational Biomaterial Research (Sept. 11-13). The Society is also developing a webinar series to provide ongoing educational opportunities throughout the year.

Committee Reporting

Following up on the Committee reports from the last issue of the *Forum*, each of the Society's committees are listed below with an update on their activities during the past quarter toward their published goals.

Awards, Ceremonies and Nominations Committee

Award presentations and announcements concerning the 2008 officer election results were made at the Society's annual business meeting during the World Biomaterials Congress in Amsterdam on May 29, 2008. The annual business meeting was held at the RAI Conference Centre at noon and lunch was provided for all SFB Members!

Bylaws Committee

The Bylaws Committee has drafted a bylaws amendment to correct an inconsistency with regard to the election process. The amendment, distributed to the membership in mid-March, was discussed and voted upon at the Society's annual business meeting.

Devices and Materials Committee

The Devices and Materials Committee has begun negotiations with the ASM to collaborate on the next module of their materials database. They have already launched the Cardiovascular Materials Database and the Orthopedic Materials Database online. They have come to SFB for help in developing content on the research materials database, and it is the committee's goal to provide this content in exchange for SFB member access to these tools. Once an agreement between these two organizations has been reached, the committee will seek Council's approval prior to soliciting volunteers for content development.

Education and Professional Development Committee

The Education and Professional Development Committee had a conference call on Feb. 8. The main item discussed was the webinar series to be initiated in April/May. It was decided that this experience would be piloted with a webinar aimed at the student members, on a topic possibly touching career options after graduation. The second webinar will be targeted to all members and will cover a technical topic, most likely cell therapy for cardiac regeneration. More information regarding these webinars will be found shortly in your inbox.

Finance Committee

The Finance Committee is overseeing the implementation of the Board-approved investment and reserve policies, and developing a draft policy on the solicitation of funds on the Society's behalf. No report has been received from this committee for this period.

Liaison Committee

The Liaison Committee continues to interact and discuss possible joint meetings with other societies.

Long Range Planning Committee

The Long Range Planning Committee continues to focus its activities on analysis of the ranking and perception of the journals of the Society, namely the *Journal of Biomedical Materials Research Part A and B*, relative to other peer journals in the field of biomaterials and related disciplines. Recommendations for improvements in visibility of the journal and enhancing attraction of high visibility articles are being formulated.

Meetings Committee

The members of the Meetings Committee, including Martine LaBerge, Dan Lemyre, Karen J.L. Burg, Timmie L.D. Topoleski, Antonios G. Mikos, Alan S. Litsky, and Lynne C. Jones, have addressed the remaining committee goals established in May 2007: "the assessment of the funding and sponsorship revenue of our annual meetings and to provide recommendations for

Hansjörg Wyss Endowed Chair

Clemson University's Department of Bioengineering is seeking applications for the Hansjörg Wyss Endowed Chair. This prestigious position is supported by a \$4M endowment established by The Hansjörg Wyss Medical Foundation and the State of South Carolina, and is an integral part of the South Carolina Regenerative Medicine Research Center of Economic Excellence. Applicants with expertise in the area of orthopaedic biomaterials, as related to trauma, spine, craniofacial, and maxillofacial applications are sought to complement Clemson University's pioneering research and education program in biomaterials. The tenure-track appointment will be at the Associate Professor or Professor level. Candidates should have a Ph.D. in biomedical or materials engineering or a related discipline, and a strong record of research accomplishments and leadership in the field, high-quality publications and presentations, extramural research funding, meaningful outreach activities, and government and industry contacts. The candidate should have demonstrated leadership skills, the ability to work across scientific disciplines and organizations, and a commitment to teaching at the undergraduate and graduate levels. The Wyss Chair will be expected to play a key role in the development of state-wide programs in bioengineering research and education and in the development of the Clemson University - Medical University of South Carolina Bioengineering Program. Clemson University is located on Lake Hartwell in scenic upstate South Carolina, is a four hour drive from Charleston, SC, and enjoys a mild 4-season climate with a low-cost-of-living. The Medical University of South Carolina is located in Charleston, a beautifully preserved architectural and historic city, with a rich, 300 year heritage.

Applicants should send their CV, a statement of research and teaching interests, and the names of at least three references to Ms. Sherri Morrison, Wyss Search Committee, Department of Bioengineering, 501 Rhodes Engineering Research Center, Clemson University, Clemson, SC 29634-0905. E-mail inquiries may be sent to: msherri@clemson.edu. Applications will be evaluated until the position is filled; however, to be assured full consideration, applications must be received by August 15, 2008. Clemson University is an Affirmative Action/Equal Employment Opportunity employer and does not discriminate against any individual or group of individuals on the basis of age, color, disability, gender, national origin, race, religion, sexual

increasing these sources of revenue to better offset meeting attendee registration costs.” The committee met through conference calls and is now working on securing sponsorship for the 2008 Fall Symposium to be held in Atlanta and the associated bash that will be held at the Georgia Aquarium. The committee is confident that its effort will lead to the development of a standard operating procedure and an increased contact list of sponsors and exhibitors that can be used to assure the success of future annual meetings.

Membership Committee

The Membership Committee had conference calls in October 2007 and in late-January 2008. The committee is continuing to address issues of recruiting new members into the Society as well as a retention plan for current, active members. In October, Chair Ziats attended the SFB Board/Council Meeting held in Philadelphia and gave an update on the committee activities. Staff from SFB headquarters managed recruitment booths at the Orthopedic Research Society and Biomedical Engineering Society meetings in 2007 to explore the possibilities of increasing our membership by reaching out to a wider audience, and have begun to track how new members are hearing about SFB. The Board felt that, in lieu of staffing an exhibit booth at other meetings, it was beneficial to partner with other societies for more programmatic and/or workshop type events. New and continuing members in the Society have the option of more than one year of renewal, that is, up to three years. So far, this option has met with modest success, although this is the first year for this membership option. The Membership Committee is also working with other committees to enhance recruitment, for example, with the Education and Professional Development Committee to increase the number of student chapters. Some new chapters being formed include those at Drexel University, University of Texas, Rice University, and Georgia Institute of Technology. The Membership Committee is distributing postcards to various institutions as an additional method to recruit new and old members. Finally, the committee had representation at the World Congress in May.

Presidents Advisory Committee

The Presidents Advisory Committee is evaluating how the SFB may interact with other professional societies in the future. This includes forming alliances or even mergers. Also, the committee is considering how the Annual Meeting can be made more attractive and useful to attendees. No report has been received from this committee for this period.

Program Committee

The Program Committee has spent considerable time in the planning and organization of the 2008 Fall meeting focusing on “Translational Biomaterials.” The following milestones have been accomplished:

1. The general program for the meeting has been finalized and consists of seven clinical application sessions (90 min), four technology rapid fire sessions (60 min), two panel discussions, and two workshops. Requests have been made to session chairs for abstract reviewers.
2. Dr. Nicholas L’Heureux (Cytograft) has agreed to be the fourth keynote speaker.
3. Advertisement materials with March 15 abstract deadline date have been distributed.

4. The program planning meeting was held on Wednesday, May 14, from 9:00 am to 5:00 pm at the Grand Hyatt Atlanta in Buckhead.

Publications Committee

In addition to continuing efforts already reported, the committee is in the process of developing a survey of the effectiveness and quality of all publications of the Society. The survey will be used to set future goals for our publications. Any suggestions and comments can be sent directly to the Committee Chair, Professor Rick Gemeinhart (rag@uic.edu). No report has been received from this committee for this period.

Special Interest Groups

The Special Interest Groups (SIGs) continue to be very active in this World Congress year. As always, the SIGs are very involved in the programs of both the World Congress and the upcoming SFB Fall Symposium, which is focused on translational biomaterials research. The SIGs have taken a major role in identifying topics and developing content for this symposium. We are continuing to make inroads to improved communication throughout the SIGs. This task is being accomplished through more frequent conference calls, newsletters, reports to the *Biomaterials Forum*, emails, and the SIG Web sites. A task force has been formed to work with the Bylaws Committee to revise the bylaws with respect to the SIG structure and operation. The SIGs are working with the Membership Committee in the development of a postcard campaign to recruit lapsed members back to the Society. If you are interested in knowing more about a particular issue, policy, or committee activity, or if you have any suggestions for improved membership services, please contact me directly at the SFB headquarters office.

Sincerely,



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From the time that SIGs were first formed, we have continuously asked, “What can SIGs do for the Society For Biomaterials?” In the past few issues of the *Biomaterials Forum* we have described the impact of the SIGs on the education of, communication with, and networking between the SFB members. The SIGs have experienced a resurgence of activity through the efforts of a resourceful leadership and they are empowered to accomplish more than they ever have before.

It is now time to ask, “What can the Society For Biomaterials do for the SIGs?” Of course, the first response that comes to mind is to support the SIGs. But what does this actually mean? I have a few suggestions for where to begin.

First, choose dates to hold the Annual Meeting and symposia that are not in conflict with the members’ other professional society meetings. The SIGs will provide a list of the dates of the major meetings for their areas of focus. Second, provide

the SIGs with opportunities for networking. The schedule for the Annual Meeting is so tight the SIGs have had to hold their meetings before the day’s events (at 7:00 am) or during lunch. One suggestion is for one evening to be set aside for SIGs to hold meetings and/or networking events. Networking events may include guest speakers. Third, empower the SIGs to have a bigger role in the program of the Annual Meeting. Through the years, the SIGs have mostly been reactive regarding the program content, whether it is the review and selection processes concerning the abstracts or the submission of ideas for workshops, symposia, tutorials, or panel discussions. Allow the SIG leaders to be more proactive. They should identify the current issues facing their members and encourage them to recruit scientists who can present cutting-edge research to the Society. And last, the most important suggestion, encourage the SIG leaders and members to think outside the box. There is so much more that they can do, you need only ask.

Invention vs. Innovation

I used to equate invention with innovation. Every chance I had, I would use these two words synonymously to show off my vocabulary. In case you are wondering if there is indeed any difference between them, I just looked them up for you: to invent is to create a novel object, process, or technique; to innovate is to introduce something new. Confused? That is how we usually define these words.

Lately, I tend to look at these words more in the terms of Peter Drucker. While invention is the act of creating something new, innovation is the act of converting something new (a new form of thing or knowledge) or something old (an existing natural material or knowledge) into a new wealth-producing resource, a resource with economic and social value. So, innovation puts more emphasis on the social and economic value of the act of creating something new, and it does not necessarily have to be based on a high-tech invention. In Drucker’s words, innovation is “an economic and social rather than a technical term.” To innovate, you must “use both the right and left sides of your brain” to first work out the technical aspects of your creation and then go out to “look at potential users to study their expectations, their values, and their needs.” Once your creation meets their expectations, values, and needs, you can have an innovation—a wealth-producing resource that helps push societies forward.

Seeing the difference between these two words may help sharpen our objective in re-engineering engineering education. It urges us to prepare future engineers as knowledge workers with technical competence and humanistic consciousness so they will not just create something new for the sake of newness, but something new with economic and social value and responsibility.

“
Seeing the difference
between these two words
may help sharpen our
objective in re-engineering
engineering education.”

If you are still in doubt of such an engineering education approach, let me make another point. General George Marshall once complained that he did not receive a good education at Virginia Military Institute because there was no training in history. He knew that to be a leader one must have a sense of history, for history is the human story. The same can be said for an engineer: to be able to innovate, the engineer must have a sense of humanistic appreciation of our society, for innovation is not just a technical endeavor, but a human one.

NIST Reference Materials are “Gold Standard” for Bio-Nanotech Research

Feature

Joy Dunkers, Government News Contributing Editor
By Andras Vladar and Vincent Hackley

The National Institute of Standards and Technology (NIST) has issued its first reference standards for nanoscale particles targeted for the biomedical research community—literally “gold standards” for labs studying the biological effects of nanoparticles. The three new materials, gold spheres nominally 10, 30, and 60 nanometers in diameter, were developed in cooperation with the National Cancer Institute’s Nanotechnology Characterization Laboratory (NCL). Nanosized particles are the subject of a great deal of biological research, in part because of concerns that in addition to having unique physical properties due to their size, they also may have unique biological properties. On the negative side, nanoparticles may have special toxicity issues. On the positive side, they also are being studied as vehicles for targeted drug delivery that has the potential to revolutionize cancer treatments. Research in the field has suffered from a lack of reliable nanoscale measurement standards, both to ensure consistency of data from one lab to the next and to verify the performance of measurement instruments and analytic techniques.

The new NIST reference materials are citrate-stabilized nanosized gold particles in a colloidal suspension in water. They have been extensively analyzed by NIST scientists to assess particle size and size distribution by multiple techniques for dry-deposited, aerosol, and liquid-borne forms of the material. Dimensions were measured using six independent methods—including atomic force microscopy (AFM), transmission electron microscopy (TEM), scanning electron microscopy (SEM), differential mobility analysis (DMA), dynamic light scattering (DLS), and small-angle X-ray scattering (SAXS). At the nanoscale in particular, different measurement techniques can and will produce different types of values for the same particles.

In addition to average size and size distributions, the new materials have been chemically analyzed for the concentrations of gold, chloride ion, sodium, and citrate, as well as pH, electrical conductivity, and zeta potential (a measure of the stability of the colloidal solution). They have been sterilized with gamma radiation and tested for sterility and endotoxins. Details of the measurement procedures and data are included in a report of investigation accompanying each sample.



False color scanning electron micrograph (250,000 times magnification) showing the gold nanoparticles created by NIST and the National Cancer Institute’s Nanotechnology Characterization Laboratory (NCL) for use as reference standards in biomedical research laboratories.

Credit: Andras Vladar, NIST

NCL examines candidate nanotech cancer drugs developed by biotech firms and academic labs. NCL and the NCI’s Alliance for Nanotechnology in Cancer sponsored the NIST work. Additional technical and ordering information for the new NIST nanoparticle reference materials is available at:

- RM 8011, Gold Nanoparticles, Nominal 10 nm Diameter
https://srmors.nist.gov/view_detail.cfm?srm=8011
- RM 8012, Gold Nanoparticles, Nominal 30 nm Diameter
https://srmors.nist.gov/view_detail.cfm?srm=8012
- RM 8013, Gold Nanoparticles, Nominal 60 nm Diameter
https://srmors.nist.gov/view_detail.cfm?srm=8013

Polymers Division,
National Institute of Standards and Technology
First published in NIST Techbeat, January 8, 2008.

Encompassing a Biomaterial's Tradition: The Materials for Medical Devices Database

The ability to access appropriate biomaterials information can have significant utility in increasing the speed and efficiency of design of new medical devices. Not only will this impact the productivity of engineers and designers, this information on specific materials and predicate use impact numerous functions within the medical device industry, including preclinical, clinical, quality, regulatory, and supply chain. There have been previous attempts at creating a biomaterials database, without success. I began to get a sense of the difficulty of such an undertaking when in the early 1990s NIH decided to upgrade the NIH guidelines on biomaterials testing, originally developed a decade earlier. Paul Didisheim asked Jeff Hubbell and me to write the chapter on "Materials Selection" (Helmus, M., Hubbell, J. 1993). This article had extensive tables on biomaterials and properties. It became clear that the categorization of these properties in order to facilitate comparison of different materials, particularly across different classes of materials, was exceptionally difficult. Stan Brown at FDA worked on developing a database and a software package was developed. However, this effort, as well as others, was not successful due to political, proprietary, and cost reasons. A few years ago, I had the good fortune to reconnect with ASM International and their effort at developing a materials database for clinically approved devices. The Database Committee, which I chair, in collaboration with ASM International and Granta Design Limited, the developer of the database, has identified the material data—physical, chemical, and biological—that would be of need to medical device designers.

This relational database is an extensive resource, containing the engineering and biological performance of materials used in medical devices, as well as information about compatible coatings and drugs, manufacturing processes, and an extensive database of relevant published literature. The data is comprehensively cross-referenced and fully traceable to original sources. The database can be used for information retrieval and selection of materials, drugs, and coatings for combination devices. Using the polymer carrier of the Taxus drug-eluting stent as an example, the following information can be extracted from the database: styrene-isobutylene-styrene triblock copolymer, carrier for drug-eluting stent; ISO



Tests performed 3, 4, 5, 6, 10, 11; Citations - Gallocher et al. (2006), Silber (2003), Ranade et al. (2004). Figure 1 is an example of some of the data that is contained for the styrene-isobutylene-styrene triblock copolymer. Links to drugs used with the polymer, in this case Paclitaxel, are also contained in the database.

The Cardiovascular Implant Module has more than 1,600 device records that include mechanical, physical, biological response, and drug compatibility properties for the materials and coatings used in cardiovascular device applications. The new Orthopaedic Module initially focuses on spinal implants. The module establishes records for nearly 1,200 devices for spinal interlaminar fixation orthosis, spinal intervertebral body fixation orthosis, and pedicle screw spinal systems. Records are being continuously extended to include information on device applications and constituent materials, drugs, and coatings. Each material, drug, or coating is linked to further records providing data on mechanical and engineering properties, materials producers, and specific material grades, enabling device designers to rapidly acquire information to support device design, materials screening, and various regulatory filings. Future releases will extend coverage into other orthopaedic applications.

The database encompasses the traditions of the field of biomaterials. The members of Database Committee

demonstrate the depth and connections with biomaterials and the Society For Biomaterials (see below). As the database grows to encompass the full extent of medical devices, the participation of biomaterial and medical device researchers and experts will be welcome and necessary.

ASM Medical Devices Database Committee

- Michael Helmus, Committee Chair and Consultant: Medical Devices, Biomaterials, Drug Delivery, and Nanotechnology
- Kelvin Brockbank, Senior Vice President, Organ Recovery Systems
- Art Coury, Vice President of Research, Genzyme Corp.
- Lawrence Eiselstein, Principal Engineer, Exponent Failure Analysis Associates
- Howard Freese, Manager, Business Development, ATI Allvac
- Keith Foy, Assistant to the Chief Engineer, FDA, Office of Orphan Products Development
- Don Gibbons, Corporate Scientist (Retired), 3M Biosciences Laboratory
- Jennifer Hoffman, Managing Engineer, Exponent Failure Analysis Associates
- Gordon Hunter, Senior Research Project Manager, Smith & Nephew Orthopaedic
- Frederick Lisy, President, Orbital Research Inc.
- Neil Morgan, Consultant
- George Pins, Associate Professor of Biomedical Engineering, Worcester Polytechnic Institute
- Oludele Popoola, Manager, Zimmer Inc., Research Lab
- Charles Sturrock, Consultant
- Ray Taylor, Director, Houston Biomaterials Research Center
- Karen Warden, Case Western Reserve University

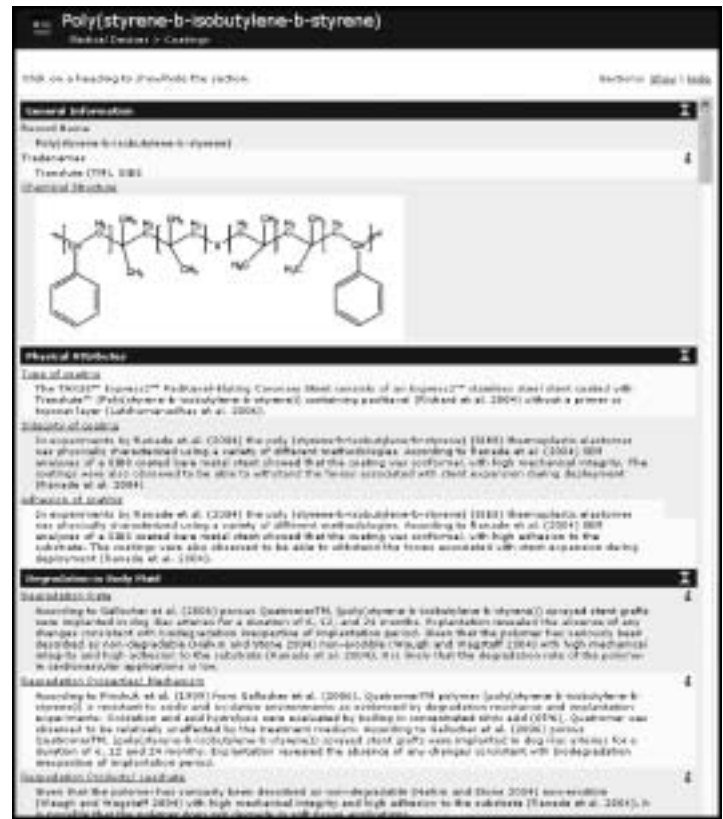


Figure 1. SIBS Polymer Data from Materials for Medical Devices Database ¹

¹ASM International and Granta Design Limited (2007), Materials for Medical Devices Database (MMD), <http://products.asminternational.org/meddev/index.aspx>

Reflecting on Our Founders

Student News

By Sarina Kay, Bioengineering Doctoral Candidate, Clemson University

The SFB History Summit was recently organized in order to capture the spirit and experiences of the beginning of the Society through the personal recollections of its founding members. When offering to help with the Summit I didn't know what to expect; as the first session began I quickly realized that it was going to be a very valuable experience.

With stories told about people showing off implants they tested on themselves, very heated discussions between friends, and early bashes with barrels of shrimp and beer on the lake, the Summit proved to be both entertaining and informative. These recollections of initial meetings by our founders were so numerous they struggled to move past 1969 in the allotted amount of time. What struck me most when listening was the obvious camaraderie that existed between these men when they began having historic meetings in the basement of an old campus building. This sense of a scientific community continues to exist between them today. Their original purpose was not to be credited with establishing a major professional society, but to simply share their latest findings and thoughts for the betterment of society, and have fun while doing it.

Their enthusiasm for their work was not driven by a desire for personal gain. All were careful to include the names of graduate students, clinicians, and others that contributed to their early work for the record. This commitment to sharing credit and ideas, I believe, is what helped establish the field of biomaterials and allowed it to thrive.

As a society that has grown by leaps and bounds from basement meetings and barrels of beer on the lake, we strive to better engage our members—our students, in particular. We can take some important lessons away from our humble beginnings. Take advantage of meetings as a time to really engage with other members both professionally and socially. Reestablishing the sense of community that began the Society may renew the enthusiasm of our members and ultimately improve upon the important work that we do in our field.

Congratulations to:

James Anderson, Case Western Reserve University Professor of Pathology, Macromolecular Science, and Biomedical Engineering, and Editor of *JBMR, Part A*, who was elected to the Association of American Physicians (AAP). The Association of American Physicians is a nonprofit, professional organization founded in 1885 by seven physicians for “the advancement of scientific and practical medicine.” Currently the Association is composed of about 1,000 active members and approximately 550 emeritus and honorary members from the United States, Canada, and other countries. The goals of the AAP members include the pursuit of medical knowledge, and the advancement through experimentation and discovery of basic and clinical science, and their application to clinical medicine. Each year, 55 individuals, having attained excellence in achieving these goals, are recognized by nomination for membership by the Council of the Association.

Barbara Boyan, Professor of Biomedical Engineering and Price Gilbert, Jr., Chair in Tissue Engineering at the Georgia Institute of Technology, who received one of four 2008 Rice University Distinguished Alumni Awards. The award is presented to alumni who have advanced the interests and standards of excellence of Rice University through distinctive professional or volunteer careers. Dr. Boyan was cited as an internationally recognized scientific leader of orthopaedic and dental regenerative medicine and tissue engineering.

Johnna S. Temenoff, Assistant Professor of Biomedical Engineering at the Georgia Institute of Technology, and **Antonios G. Mikos**, J.W. Cox Professor of Bioengineering at Rice University, for publication of their biomaterials text, *The Intersection of Biology and Materials Science*. The new book is a fundamental textbook designed to cover basic principles of biomaterials science and engineering, address complex issues associated with the structure and biocompatibility of synthetic materials, and cite in-depth applications for new medical devices.

Nicholas Peppas, the Fletcher Stuckey Pratt Chair and Professor of Chemical Engineering at the University of Texas at Austin, who was elected in the inaugural class of Materials Research Society Fellows. Dr. Peppas was recognized “for seminal and pioneering contributions to the field of biomaterials and especially for the development of hydrogels as biomaterials” at the 2008 MRS Spring Meeting in San Francisco. The title of MRS Fellow honors members who are notable for their distinguished research accomplishments and their outstanding contributions to the advancement of materials research worldwide.

Michael Sefton, Director of the Institute of Biomaterials and Biomedical Engineering at the University of Toronto, who is one of five Canadian scholars who will be honored with the 2008 Killam Prize, Canada’s most distinguished annual award for outstanding career achievements in engineering, natural sciences, humanities, social sciences, and health sciences. The Killam Prizes were inaugurated in 1981 and financed through funds donated to the Canada Council by Mrs. Dorothy J. Killam, in memory of her husband, Izaak Walton Killam. The Prizes were created to honor eminent Canadian scholars and scientists actively engaged in research, whether in industry, government agencies, or universities.

Patrick Stayton and **Allan Hoffman**, Professors of Bioengineering from the University of Washington, who co-founded PhaseRx Inc., a new Seattle biotechnology startup company focused on developing novel approaches to the delivery of siRNA and other macromolecules.

Tim Topoleski, Professor of Mechanical Engineering at the University of Maryland, Baltimore County, who was honored with the University of Maryland Baltimore County (UMBC) Presidential Award. Named a UMBC Presidential Teaching Professor, Dr. Topoleski was cited as an outstanding scholar and educator whose engaging teaching has touched and inspired many students at UMBC. Because of his vision and hard work, the UMBC Department of Mechanical Engineering received two prestigious Graduate Assistance in Areas of National Need awards from the U.S. Department of Education.

For a change of pace, the two books reviewed in this issue of the *Forum* are light reading about fictional scientific research. They are not textbooks or reference books.

Intuition

By Allegra Goodman

The Dial Press. Copyright 2006.

Paperback, 344 pages. \$2 used on Amazon.com.

Description and Critique

Set in a research lab at a prestigious institute in Cambridge, MA, the story begins with a postdoctoral fellow that suddenly has a major breakthrough in his research. One of his fellow postdocs suspects the unthinkable: that his findings are fraudulent. She goes public with this suspicion (to the NIH) and the ensuing controversy makes for compelling reading. How the relationships between the postdoc that performed the experiments and the two professors mentoring him evolve through the initial success to the subsequent investigation by the government is thought provoking. The relationship between the two PIs may resonate with academics reading the book. The description of lab life is astonishingly accurate. The extreme joy of an experiment that worked correctly, the grueling long hours, the ambition, the intense competitiveness, the relationship between a professor and postdoc, postdoc and postdoc, scientist and their family—all are conveyed with the intimacy of reality TV. The writing is smooth and seamless and doesn't get in the way of the story. Maybe when you leave work, you want to leave it all behind. In that case, this is not the book for you. Reading this book is like looking in a mirror. You may or may not like what you see!

Audience/Recommendation

For scientists of all types. For your significant other to read so they understand your life at work. Highly recommended.

The Sixth Cow

By Michael Wright

iUniverse. Copyright 2007.

Paperback, 253 pages. \$12 on Amazon.com.

Description and Critique

Sloan is a medical researcher determined to find a cure for cancer. To be able to follow his dream involving stem cells, he starts his own company and receives funding from a large venture capital group that, unbeknownst to him, has secret ties to the pharmaceuticals industry and the Food and Drug Administration. He makes a breakthrough around the same time he learns his wife, Ally, has melanoma and is pregnant with their first child. Ally is told she must have an abortion, followed by traditional chemotherapy and radiation in order to live. Rather than give up their long sought after child, the two decide Ally will be Sloan's first patient and receive his new, yet unproven in humans, cancer therapy. Meanwhile, the venture capital group learns that Sloan has made a breakthrough and demands full disclosure, which Sloan will not give. The greed and politics of venture firms, big Pharma, and the FDA drive the story to a crescendo and ultimate resolution.

This book is written like a cheap thriller or spy novel and is just too unbelievable and technically unsupported to really connect to it. The female characters are shallow and theatrical. The government monitoring of animal research is not accurately presented. For what the backcover promised, I thought there would be more depth to this book. Moral and ethical decisions are glossed over.

Audience/Recommendation

Not recommended.

**Community
Calendar**

European Society of Biomechanics

Lucerne, Switzerland
July 6-9, 2008
www.esb2008.org

International Fibrinogen Workshop

Venice, Italy
July 10-13, 2008
<http://alisf1.univpm.it/XXifw/>

Society For Biomaterials Fall Translational Research Symposium

Atlanta, GA
September 11-13, 2008
www.biomaterials.org

34th Annual National Society for Histotechnology Symposium/Convention

Pittsburgh, PA
September 12-18, 2008
www.nsh.org

2008 Biomedical Engineering Society Annual Fall Meeting

St. Louis, MO
October 2-4, 2008
<http://bme.wustl.edu/BMES2008/> and <http://www.bmes.org>

2008 Materials Research Society Fall Meeting

Boston, MA
December 1-5, 2008
www.mrs.org

Alphatec Holdings Inc. (Carlsbad, CA), a medical technology company focused on the design, development, manufacturing, and marketing of products for the surgical treatment of spinal disorders, announced that the company and **Progressive Spinal Technologies** LP have entered into an exclusive worldwide license agreement that provides Alphatec Spine the right to commercialize Progressive's dynamic anterior cervical plate technologies. The technologies incorporate a unique self-ratcheting mechanism that enables the dynamic anterior cervical plate to allow for axial settling in order to increase load sharing with the graft and thereby improve fusion rates.

B. Braun (Melsungen, Germany), an international medical device manufacturer, launched its latest breakthrough in Malaysia—a drug-eluting balloon catheter, SeQuent Please. The device combines a coronary balloon with a bioabsorbable, polymer-free drug carrier matrix. The device is a potential alternative to drug elution stents for selected heart patients.

Exactech (Gainesville, FL) announced that it has signed an exclusive license deal with the Industrial Technology Research Institute and the National Taiwan University Hospital for the rights to technology and patents related to the repair of cartilage lesions. The company noted that it expects the projects would proceed through the completion of human clinical trials under the guidance of the Food and Drug Administration in order to obtain pre-market approval for the device in the United States.

ROBODOC (Sacramento, CA), a company that develops, manufactures, and markets a fully automated surgical robotic system for use in orthopaedic surgery, and **IBM** announced that they have entered into a major patent cross-licensing agreement. In addition to its current surgical robotics patents, this agreement gives ROBODOC access to more than 40,000 patents in IBM's global portfolio, particularly IBM's surgical robotics patents.

On February 20, the U.S. Supreme Court handed **Medtronic** Inc. (Minneapolis, MN) a victory in a much-watched and long-fought product liability dispute. In issuing their landmark decision, the justices established a new level of legal protection for medical devices cleared to market via the premarket approval (PMA) path. In an 8–1 decision in the case of *Riegel v. Medtronic Inc.*, the justices ruled that the preemption provision of the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act overrides most state-law claims seeking damages for injuries caused by medical devices approved by FDA under the PMA process. While the decision was widely lauded by the medical device community, many consumer advocate groups have expressed outrage over the decision, which they view as significantly limiting the legal recourse of patients injured by medical devices.

PhaseRx (Seattle, WA), a biotech startup company, was formed to develop technologies for delivery of siRNA and other macromolecules. The company was formed by Robert Overell, of Foundation BioVentures, along with co-founders Professors Patrick Stayton and Allan Hoffman from the University of Washington's Department of Bioengineering; Professor Oliver Press of the Fred Hutchinson Cancer Research Center's Clinical Research Division; and Dr. Paul H. Johnson, the company's Chief Scientific Officer. PhaseRx has exclusively licensed novel polymer technology from the University of Washington that was developed by the Stayton and Hoffman laboratories, in collaboration with the Press laboratory. This technology enables the effective intracellular delivery of siRNA.

Regeneration Technologies Inc. (Alachua, FL) and **Tutogen Medical** Inc. (Alachua, FL), two companies specialized in allograft products processing and distribution, announced that the merger of the two companies is completed. Shareholders of both Regeneration Technologies and Tutogen Medical approved the merger at separate special shareholder meetings. The total value of the transaction is about \$205 million. Effective immediately, the name of the newly combined company is RTI Biologics Inc.

TENURE TRACK POSITION Department of Biomaterials and Biomimetics COLLEGE OF DENTISTRY

The New York University College of Dentistry seeks applicants for a full-time tenure track position in the Department of Biomaterials and Biomimetics. The tenure-track junior position is open to individuals with a materials science and engineering or physical science background (minimum PhD) applicable to Biomaterials and Biomimetics research and teaching programs. Capabilities permitting collaborations with NYU initiatives in soft condensed matter, molecular design and bioengineering are considerations. Evidence of the potential for significant contributions to research is required. The individual would have responsibility for limited teaching in the College of Dentistry D.D.S. Program as well as the Graduate School of Arts and Science including the Biomaterials Science Master's Degree Program. Candidates must indicate how their background could contribute to at least one of the departments' ongoing research efforts in: calcium phosphate formulations, inks and coatings, scaffolds for engineering tissue response, novel ceramics and tooth enamel fatigue and fracture, imaging, and clinical research.

NYU offers competitive compensation and excellent benefits. Applicants should submit a letter of interest and curriculum vitae to: Dr. Louis Terracio, Associate Dean for Research, c/o Carmen Chisholm, NYU College of Dentistry, 345 East 24th Street, Room 8045, New York, NY 10010-4086. The search will continue until an appropriate candidate has been selected.



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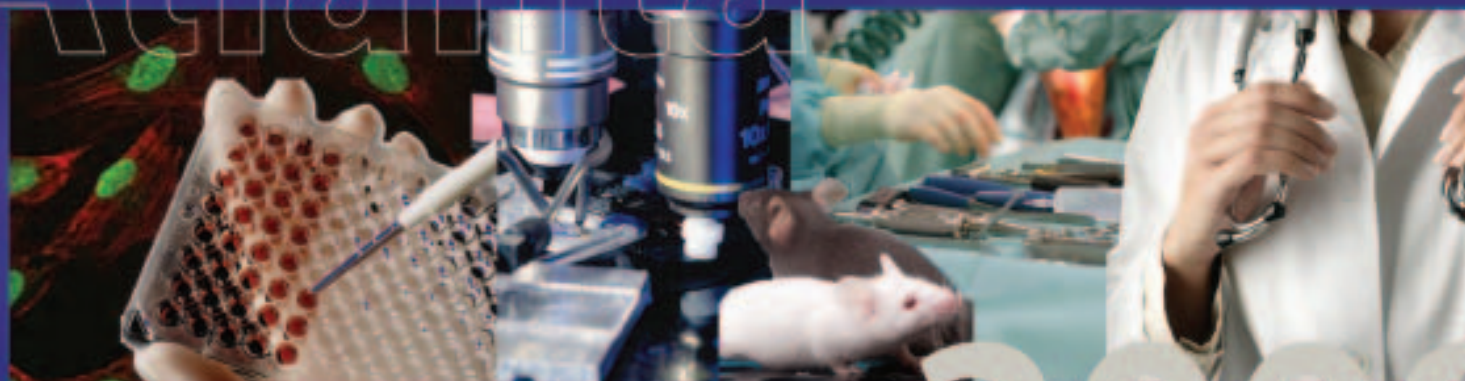
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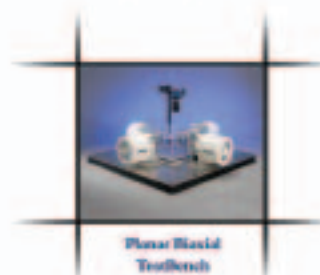
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