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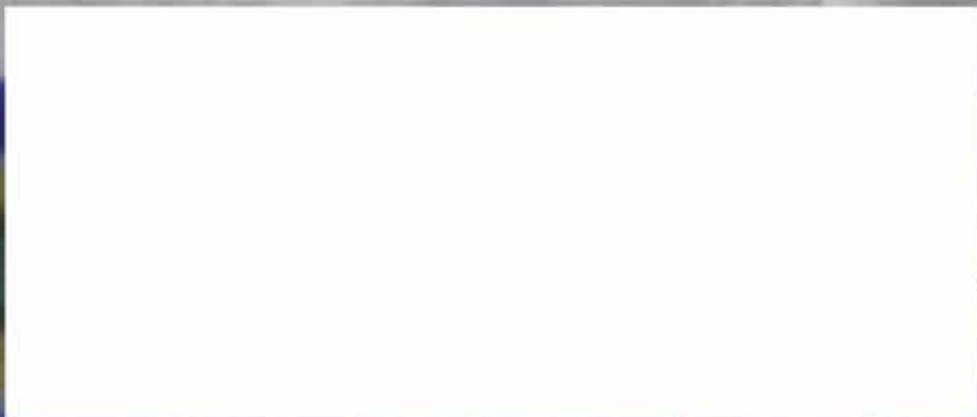
B I O M A T E R I A L S

FORUM



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BIOMATERIALS FORUM



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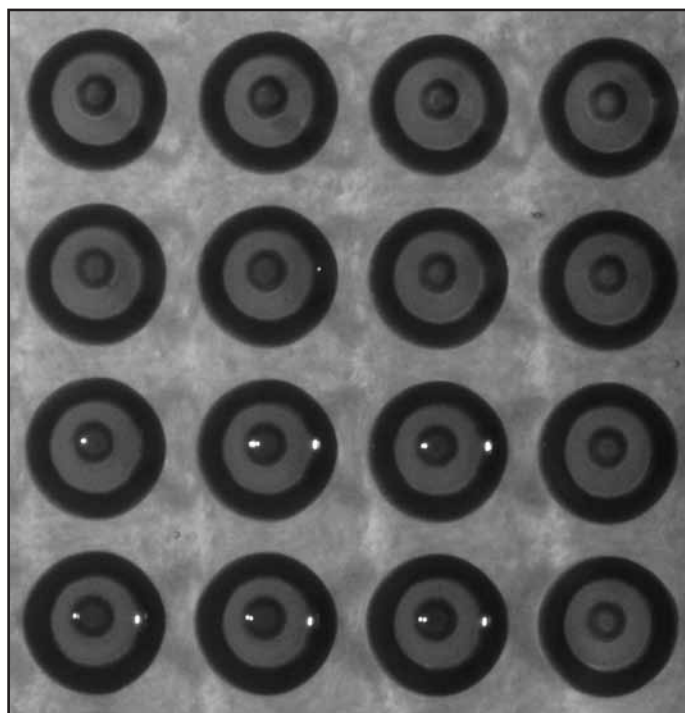
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On the cover: Microgel multi-compartment eye-bead: This figure shows microfabricated photo-cross-linkable polyethylene glycol hydrogels in concentric circles for vascularized tissue engineering applications. Each color within the ring represents a sub-compartment with different cellular and extracellular composition.

Umut A. Gurkan¹, Burcu Erkmen¹, Emel Sokullu Urkac¹, Gunes Parlakgul¹, Jacob G. Bernstein², Edward S. Boyden² and Utkan Demirci^{1,3}

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Greetings fellow biomaterials scientists,

In this issue you'll find:

- **Member news:** An interesting article by Anne Meyers about the accomplishments of past Society For Biomaterials awardees, as well as announcements of new awards to our members.
- **Chapter news:** Some highlights of the World Biomaterials Congress held in Chengdu, China, in early June 2012.
- **Industry news:** Investments in the medical device industry are down, regulation of devices in Japan may get easier due to new regulations that will separate devices from drugs and acquisition news are featured in this section.
- **Technology news:** This issue's cover art and the technology article describe advances in the fabrication of multi-layer hydrogels for culture and regeneration of complex tissues.

- **Book reviews:** If you are interested in orthopaedic implant design, the book review column features an introductory book that's ideal for teaching the subject to residents and graduate students—*Mechanics of Biomaterials: Fundamental Principles for Implant Design*. For those of you interested in dental materials, there's a review of a new book on Amelogenins and their function in tooth biomineralization and their application in tooth regeneration in this issue.

I hope you enjoy the content in this issue of the *Biomaterials Forum*! If you have suggestions for content to be used in an upcoming issue, please send it to me at Lkuhn@uchc.edu. The deadline for the next issue is mid-October.

Lisa Kuhn



I am honored and privileged to have been elected as president of the Society For Biomaterials. I have grown up in the Society, attending my first meeting in 1986, and I have attended just about every meeting since. Reading the journals, attending the meetings, listening to talks and presentations and networking with many other researchers allowed me to grow from a young, naïve graduate student into an independent

biomaterials researcher. The Society has grown and evolved, too, not only in scope of meetings and topics, but also as an organization with the evolution of the student groups, the SIGs and management organization. As I started my year as president-elect and as chair of the Long-Range Planning Committee, I considered what I would add. As I thought about this, I found that the Society had not reviewed and updated its long-range plan in many years. I was struck by this, as there are many exciting and dynamic activities of the Society evolving at present—the launch of the SFB book series, redevelopment of the website, ongoing development of student and SIG activities and moving the Society's abstracts to a on-line accessible format. However, without some sort of plan, I felt that it would be hard to continue to steer the Society as it continues to grow and evolve in its role as a leading professional organization. With this in mind, I worked with the Long-Range Planning Committee towards re-developing a long range plan that will be able to be used, evaluated, revised and updated as the Society continues to grow as a professional organization. I realized this was a rather ambitious task, but it was one that I was encouraged by the committee to embrace.

In brief, much effort was placed on the review of the mission statement and development of a vision statement, since the Society did not have a vision statement. A mission statement explains the overall purpose of the Society and what the Society does in a general sense, while, by comparison, the vision statement articulates the future of the Society and the community it serves. By implying what the Society still needs to accomplish, it provides credibility and motivation to the mission statement. The revised mission and vision statements considered by the Society are:

Mission:

The SFB is a multidisciplinary society of academic, medical, governmental and business professionals dedicated to promoting advancements in biomedical material discoveries, education and professional standards to enhance human health and quality of life.

Vision:

The vision of the SFB is to serve as the world's preeminent interactive global community of professionals and individuals committed to advancing excellence in all aspects of biomedical materials science, engineering and technology for promoting human health and well-being.

After extensive discussion of the current state of the Society and its issues, four broad goals were identified:

1. SFB will raise visibility, impact and stature of Society and membership on national/international and regional/local levels for advancing biomaterials science/ engineering research and development, education and professional development.

This is important for the Society to be recognized as a dynamic organization and a source for growth, innovation and development for its members, constituents and the field.

2. SFB will promote professional development, education and networking scientists/researchers, clinicians, industry and governmental agency personnel.

This is important for articulating the unique skills and knowledge base of individuals in biomaterials careers, for developing future biomaterials professionals and to meet the ongoing industrial, clinical and technological needs

3. SFB will continue to develop and support a diverse membership, including clinical and industrial members, as well as basic and applied science/engineering researchers and students.

The Society has had a long and productive history in providing a unique space for basic and applied scientists, industry, clinical and governmental representatives to interact and network to advance the biomaterials field. This has been a major strength, and perhaps this unique aspect of the Society needs to continue in order to help inspire and advance the next generation of biomaterials professionals and innovations.

4. SFB will increase value and quality of annual meetings and extend accessibility of annual meeting information beyond meeting dates and locations.

In the current economic environment, it is critical we continue to offer high quality scientific/technical meetings at an affordable price and that we extend accessibility of the meeting information beyond actual meeting dates and physical locations to provide a lasting and large impact on our community. There are already many activities underway to achieve these goals—website redevelopment, book publishing, liaison activities with other organizations and innovative meeting programs. Additional goals to be pursued will include developing a public relations plan to further raise the profile and awareness of the Society, its value and contributions to biomaterials science and technology, developing and continuing to offer programs at the meetings and via web-based platforms to advance educational and professional development activities of particular value to biomaterials industry and clinicians, becoming a resource of biomaterials career

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Hello from Society For Biomaterials headquarters! Your headquarters staff is hard at work preparing for the 2012 Fall Symposium, October 4-6 in New Orleans, while simultaneously gearing up for the 2013 Annual Meeting, April 10-13 in Boston. We hope you have plans to attend both!

This year's annual meeting took place at the World Biomaterials Congress in Chengdu, China, June 1-5. For those SFB members able to make the trip, it was an exciting cultural experience and opportunity to meet and hear from colleagues around the world. The Society's normal business was also conducted at WBC.

Annual Business Meeting

The Society's Annual Business meeting took place June 2 in Chengdu, China. Among the items on the agenda were:

Election of Officers—Results of the spring election were announced, and the following people have been elected as officers for the Board of Directors:

Antonios Mikos, PhD, Rice University—President-elect
Nicholas Ziats, PhD, Case Western Reserve University—Member-At-Large

New Council—These members will be serving as chairs of committees, and, along with the board, will comprise the 2012-2013 Council: Lynne Jones, Awards, Ceremonies and Nominations; Jiro Nagatomi, Bylaws; Bruce Anneaux, Devices and Materials; William Murphy, Education and Professional Development; David Kohn, Finance; David Puleo, Liaison; Antonios Mikos, Long-Range Planning, Joel Bumgardner, Meetings; Horst von Recum, Membership; Karen Burg, President's Advisory; Tim Topoleski, Program; Alan Litsky, Publications; Scott Cooper, Student Chapter President. Members elected or appointed to the committees will be posted on the Society For Biomaterials website at www.biomaterials.org.

Election of Awards, Ceremonies and Nominations Committee:

The following members were elected to the 2012-2013 Awards, Ceremonies and Nominations Committee: David Castner, PhD, University of Washington; Claudia Fischbach-Teschl, PhD, Cornell University; Ahmed El-Ghannan, PhD, University of North Carolina at Charlotte; Shrojal Desai, PhD, Hospira Inc.

Election of Membership Committee: The following members were elected to the 2012-2013 Membership Committee: Rebecca Bader, PhD, Syracuse University; Don Elbert, PhD, Washington University; Michelle Tucci, PhD, University of Mississippi Medical Center; Xiaoming Xu, PhD, Louisiana State University School of Dentistry



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hard at work preparing for the
2012 Fall Symposium, October 4-6
in New Orleans, while simultaneously
gearing up for the 2013 Annual Meeting,
April 10-13 in Boston.

2012 Award Recipients: Two of the Society For Biomaterials' 2012 Award Recipients chose to receive their awards in Chengdu:

2012 Founders Award: Arthur Coury, PhD, Genzyme Corporation (ret.)

2012 Student Award for Outstanding Research: Mark Tibbitt, University of Colorado

Committee News

Headquarters Staff is also supporting the following committee activities:

Awards Ceremonies and Nominations—Nominations were sought for 2013 officers and awards. Nominations deadlines were September 14 for awards and September 21 for officers.

Education and Professional Development—The Biomaterials Day grant program continues its success. The 2013 application deadline was September 21, 2012. The committee will be soliciting applications for the 2013 C. William Hall scholarship in the near future.

Finance—Dr. Suggs reported at the 2012 annual business meeting that the Society's finances are healthy. The Finance Committee is preparing the 2013 budget.

Long-Range Planning—Dr. Bumgardner presented the results of this committee's work during the annual business meeting (see p. 3 for details).

Meetings—The 2013 annual business meeting will take place during the 2013 annual meeting in Boston, April 10-13. Locations for the 2014 and 2015 annual meetings are being researched now.

Membership—The Membership Committee will be identifying specific target populations and coordinating with the Program Committee so that programming can be tailored to attract them. Further programmatic direction will be gleaned from the recent Devices and Materials Committee survey of industry members.

Program—The Program Committee issued a call for ideas for the 2013 annual meeting. Abstracts for these proposed sessions will be solicited in the fall of 2012, and the abstract deadline will be in late December 2012. The theme for next year's meeting is "Biomaterials Revolution," in keeping with the historic nature of the location.

Publications—A special issue in celebration of the 100th *Volume of JBMR* is in the works. This will be a "virtual issue" with 20-25 articles compiled from the first 100 volumes. In addition, a new e-newsletter service through Multibriefs has been approved by the board. Finally, three proposals for a new SFB website are being considered by the board. A decision is expected shortly.

Special Interest Groups—SIGs are encouraged to submit items for the Biomaterial of the Month feature on the SFB website. The monthly SIGnal newsletter is now being sent to all SIG members. Some changes to the STAR program process were approved, enabling the SIGs to select from a larger pool of applications and to allow STAR applicants to select more than one SIG on their applications.

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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SFB's Young Investigators and Student Awardees: Where Are They Now?

By Anne Meyer, PhD
University of Buffalo

Recognition of talented individuals—whether they are established leaders or rising stars—is one of the more important activities of a professional organization, including our Society For Biomaterials. All 10 of SFB's 2012 awardees were featured in the previous issue of *Biomaterials Forum* (v34(2):4-5); based on their travel plans, two awardees were recognized at the World Biomaterials Congress in Chengdu, while eight others will be recognized at SFB's Fall Symposium (October 4-6, 2012 in New Orleans).

Most of us know about the contributions of the established leaders in our field, simply because they have developed their excellence, pursued their research and presented their findings and perspectives over several years. But what about the rising stars? What will our 2012 award winners—Anna Blakney (Outstanding Undergraduate Research; University of Colorado), Paschalia Maria Mountziaris (Outstanding MD/PhD Research; Baylor College of Medicine and Rice University), Mark Tibbitt (Outstanding PhD Research; University of Colorado) and Dr. Steven Little (SFB Young Investigator, University of Pittsburgh)—be doing 10 or 20 years from now? If freeze-frame views of some of SFB's prior awardees are any indication, we can expect great things from all of them!

One of SFB's newer awards is the Young Investigator Award, which recognizes scientists and engineers who have already demonstrated excellence in a significant body of research early in their professional careers. Awardees typically have had the rank of assistant professor. Dr. Jennifer West (Rice University) was SFB's first Young Investigator awardee (2000). She now is the Isabel C. Cameron Professor of Bioengineering at Rice University, holds several patents and has received numerous additional awards since SFB recognized her as a rising star. Other SFB Young Investigator awardees also have risen to the rank of full professor on the basis of their research, teaching and service: Liping Tang (2001 awardee), Bioengineering, UT/Austin; W. John Kao (2002), Pharmacy, Surgery and Biomedical Engineering (and Associate Dean of International Studies), UWisc/Madison; Masayuki Yamato (2003), Biomedical Engineering and Science, Tokyo Women's Medical University; and Andres Garcia (2004), School of Mechanical Engineering, Georgia Tech.

Thirteen years before her 2005 Young Investigator award from SFB, Julie Babensee (Georgia Tech) received SFB's 1992 MS candidate award for her research at University of Toronto. This year, Dr. Babensee is the Program Chair for the 2012 BMES annual meeting. Academia has its traditions, of course, and one must usually work through the ranks on a relatively standard timetable. All of SFB's more recent Young Investigator

Most of us know about the contributions of the established leaders in our field, simply because they have developed their excellence, pursued their research and presented their findings and perspectives over several years. But what about the rising stars?

awardees have been promoted to Associate Professor and are working toward full professorships: Richard Gemeinhart (2006), Pharmaceutics and Bioengineering (and Director of Graduate Education for the College of Pharmacy), Univ. Illinois/Chicago; Krishnendu Roy (2007), Biomedical Engineering (and General Dynamics Faculty Fellow), UT/Austin; Helen Lu (2008), Biomedical Engineering, Dental and Craniofacial Engineering, Columbia University; Niren Murthy (2009), Biomedical Engineering, Chemistry and Biochemistry, Georgia Tech; Todd McDevitt (2010), Biomedical Engineering, Georgia Tech; Jeff Karp (2011), Harvard-MIT Division of Health Sciences and Technology; and Ali Khademhosseini (2011), Harvard-MIT Division of Health Sciences and Technology.

And what about prior student awardees? Many of these are more difficult to track, but preparation for this article uncovered some interesting stories. For example, what did we think Joel Bumgardner—the 1989 MS candidate awardee from Univ. Alabama/Birmingham—would be doing now? Did we think that he would become Professor of Biomedical Engineering at The University of Memphis? That he would be SFB's 2012/13 President? He is! In 1984, Michael L. Salgaller received SFB's MS candidate award. He subsequently earned a PhD in pathology at The Ohio State University, was a research scientist at NIH and has more than 20 years experience in the therapeutics industry. In 2008, Dr. Salgaller was appointed Chief

Operating Officer of a biotechnology company in Maryland that specializes in proteomics and applications in personalized medicine. In 2010, he published *Biotechnology Entrepreneurship: From Science to Solutions*. The 1994 MS candidate awardee, Christopher Siedliecki, is now Professor of Surgery and Bioengineering at Pennsylvania State University. Michael C.D. Trindade (1999 MS candidate award) is now an orthopaedic surgeon in California.

When Roger Marchant was recognized as the 1984 PhD candidate awardee, was it clear that he would become Professor of Biomedical Engineering at Case Western Reserve University and the director of Case's Center for Cardiovascular Biomaterials? The first PhD candidate award was given in 1981, to Lea Mor, who currently is a faculty member in the Department of Biotechnology Engineering, ORT Braude College, in Israel. Hasan Uludag (1993 PhD candidate awardee) is Professor of Chemical and Materials Engineering at University of Alberta.

It comes as no surprise that many of SFB's prior awardees in the category for interns, residents and clinical fellows are active, practicing MDs; most of them are surgeons, and most of these surgeons specialize in orthopaedics. This could be a function of the nomination process, but the strong link between biomaterials research and advances in orthopaedics is there for all of us to see in the work of prior awardees. To name just

a few: J. Spence Reid (1985), Division Chief of Orthopaedic Trauma at Pennsylvania State University; Peter Bonutti (1987), director of his own clinic in Effingham, IL and a prolific inventor of surgical instrumentation; and Jack Choueka (1995), currently Chair of Orthopedic Surgery & Musculoskeletal Services at Maimonides Medical Center in Brooklyn. Wouter J.A. Dhert already was an MD when he received the 1991 PhD award. Dr. Dhert now is the Director of Orthopaedic Research at the University Medical Center in Utrecht, The Netherlands. The first MD to be recognized in the clinical category (1984), however, represented the cardiovascular research interests of SFB at the time. The 1984 awardee was Harry B. Kram, currently a cardiovascular surgeon in California and medical director of the "LEGSAVERS" clinic.

These are short reminders of just a few of SFB's rising stars from the past. It is a pleasure to observe the successful career advancement of these SFB award winners. If you were one of our student awardees or Young Investigators, we would like to hear from you! Are you still working in the field of biomaterials in some way? Do you have any advice for our student members? We are planning more articles like this, and possibly an "awards alumni notes" section of SFB's website. Please share your story with *Biomaterials Forum* editor, Liisa Kuhn (lkuhn@uchc.edu) or SFB website editor, Tom Webster (Thomas_Webster@brown.edu).

From the President

Continued from page 3

opportunities and networking and continuing to engage students towards careers in biomaterials. These will be important to our membership and to our discipline.

It is planned that the mission and vision statements as well as the long-range plan will be put on the Society website and in the *Forum* to invite comment and input by the members prior to adoption. As I begin this year, I look forward to advancing many of these goals and objectives and continuing to promote and grow our Society as the leading biomaterials professional organization.

I would like to thank the LRP committee members for volunteering their valuable time, great insights and suggestions in undertaking this task, especially since all the work was conducted via teleconference—they were the best committee ever!

Thank you, and I look forward to working with you over the next year.

Joel Baumgartner

Facile Method to Fabricate Hydrogel Matrices for Culture of Complex Tissues

By Jerome V. Karpik¹, Yogesh Ner^{2*} and Adah Almutairi^{2,3,4}

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Introduction

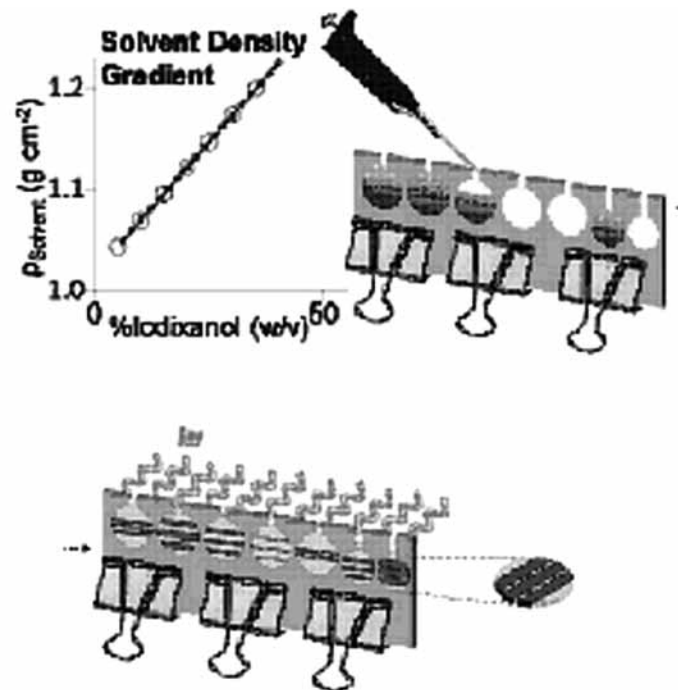
Tissue engineering is a rapidly expanding field with implications for both regenerative medicine and fundamental developmental biology, as tissues cultured *in vitro* could be implanted to replace damaged or injured tissues or could serve as a system where extracellular variables influencing differentiation, migration and adhesion may be easily manipulated. Despite the broad utility of hydrogel matrices where both structural and biochemical properties vary across a gradient¹, few scalable, cost-effective methods yet exist to fabricate them. Current methods, such as additive photopatterning²⁻⁴, laser scanning lithography⁵, printing⁶ and sequential functionalization⁷, are complex, expensive or generate scaffolds with mechanically weak interfaces between layers. Herein we describe our adaptable, facile and economical multi-layer polymer fabrication technique that produces continuous interfaces between layers: density gradient multilayer polymerization (DGMP)⁸. The method exploits sucrose and iodixanol as aqueous density modifiers to keep solutions stratified prior to single-step polymerization; each solution can contain varying concentrations of prepolymer and/or distinct combinations of biological cues (Figure 1).

Method

To separate the layers, hydrogel precursors and other matrix components (e.g. adhesion molecules or growth factors) are co-dissolved in separate fractions of serial dilutions of sucrose or iodixanol. To minimize diffusion of biochemical cues across layers, they may instead be conjugated to acrylated or methacrylated hydrogel precursors prior to layer preparation. Components are mixed according to the desired order of layers; for example, to create a three-layered hyaluronic acid (HA) gel where the bottom layer is stiffest and the top layer is least stiff, the most densely methacrylated HA would be mixed with the most concentrated solution of density modifier (e.g. 15 percent), HA with an intermediate degree of methacrylation with the intermediate concentration (e.g. 10 percent) and the least modified HA with the lowest (e.g. 5 percent).

In a biosafety cabinet, these solutions are filter-sterilized. Trypsinized cells are counted and centrifuged; after removal of media, cells are resuspended at the desired concentration

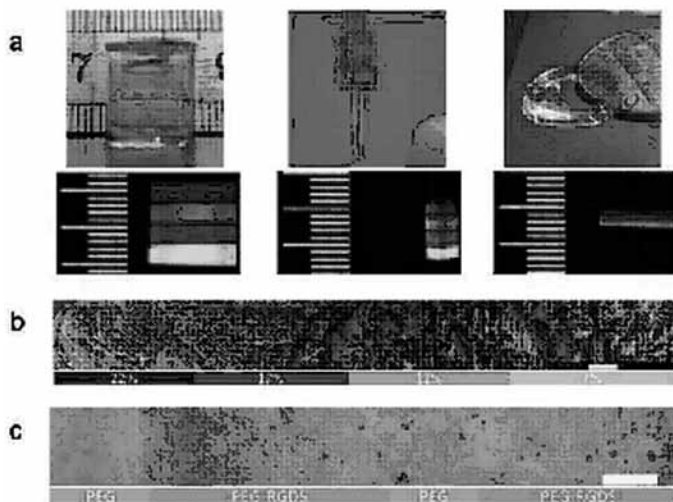
Figure 1. Schematic of DGMP method. Top, solutions containing varying concentrations of a density modifier are layered into a custom-made mold. Below, polymerization yields disc-shaped hydrogels.



in each matrix solution. If radical polymerization will be employed, photoinitiator (e.g. Darocur 2959) is added, then solutions are gently layered in molds created from custom-cut polydimethylsiloxane between silanized glass slides, from high to low solvent density (Figure 1). To create hydrogels attached to slides for easier manipulation, one silanized and one untreated slide can be used.

The layered solutions are polymerized in a single step either immediately or after a brief settling period to create more graduated boundaries between layers. If the hydrogels consist of methacrylated polymers, this requires brief irradiation at 365 nm. The gels are submerged in culture medium and density modifier is removed by several media exchanges over 48 h.

Figure 2. Advantages of DGMP. a, geometric versatility; b, structural coherence; c, separation of a biological cue (the adhesion peptide RGDS).



Results

To demonstrate that DGMP yields scaffolds with discrete layers and can be adapted to multiple scales, polyacrylamide hydrogel scaffolds of different layer thicknesses were fabricated via four-layer sucrose DGMP (50, 40, 30, 15%). Discrete compartments containing bound fluorescein or rhodamine B can be observed in alternate layers (Figure 2a).

We also sought to investigate the continuity between layers, so a four-layer polyethylene glycol diacrylate hydrogel where the polymer concentration varied was examined by scanning electron microscopy. Transitions between regions of varying porosity appear smooth (Figure 2b).

Finally, we evaluated the utility of DGMP for creating scaffolds that direct patterned cell growth. Multilayer PEG discs, where alternating layers incorporate the tagged adhesion peptide RGDS-AlexaFluor 350, were seeded with C2C12 murine myoblasts ($20k \text{ cells cm}^{-2}$) and resulting cell patterns were observed after 24 hrs in culture via epifluorescence and phase-contrast imaging (Figure 2c). Note that cell spreading is restricted.

Conclusions

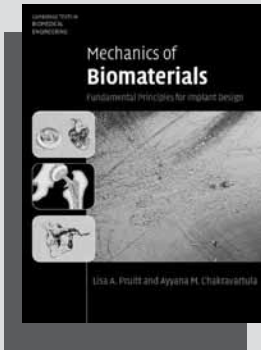
DGMP is a straightforward method for preparing multilayered tissue culture matrices where layers are structurally uninterrupted. Because it uses standard reagents and materials and does not require expensive equipment, it could be adopted in almost any lab. This method can be adapted for creating scaffolds using other biocompatible materials, such as collagen, agarose or engineered peptide-based polymers, multiple geometries and scales, and a range of cell types. We are currently exploring DGMP as a means of creating organized neuronal structures.

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Mechanics of Biomaterials: Fundamental Principles for Implant Design

By Lisa A. Pruitt and Ayyana M. Chakravartula;
Cambridge: Cambridge University Press, 2011
ISBN 978-0-521-76221-2
Review by Lynne Jones

A couple of months ago, an orthopaedic resident approached me regarding the design of total joint prostheses. He was interested in a book that could teach him the basic elements of implant design. To those of us who have spent decades in this field, this question may appear naïve at first blush. Is it possible for one book to contain all the knowledge necessary regarding implant design including biomaterial properties and selection, biocompatibility, kinematics of the joints and mechanics? No, not really. However, there are several outstanding books on the individual subjects. The SFB-endorsed *Biomaterials Science: An Introduction to Materials in Medicine*¹ by Buddy Ratner and colleagues provides a comprehensive look at biomaterials and is a useful resource to those who want to dig deeper. But what about a book focused on the novice or the young graduate student? Is there a resource for them? Something that provides enough detail to be meaningful but can be read by a third-year orthopaedic resident?

Mechanics of Biomaterials: Fundamental Principles for Implant Design is such a book. This book was written with the undergraduate and graduate student in mind. It is well-written and easy to follow. The book contains three parts: materials, mechanics and case studies. Each chapter includes a historical perspective, learning objectives, the primary subject matter, case studies, a summary, problems for consideration, references and a bibliography.

The first five chapters are dedicated to biomaterials. It begins with an introduction to issues regarding biocompatibility, sterilization and materials selection. The strengths of this chapter are that it deals with many of the practical issues facing the decision makers regarding materials selection. It is intended as an introduction to the topic of materials. One of my primary criticisms of this chapter is how superficially it treats biocompatibility (less than one page). This is a concern I have with many “biomaterials” books in print. How can a book be about implant materials, otherwise known as biomaterials, and have so little “bio?” I would recommend that those interested in learning more about biocompatibility, inflammation and repair and adverse biological responses read the chapters dedicated to this topic in the *Biomaterials Science* textbook or in Jonathan Black’s textbook on this subject.² The next three chapters relate to metals, ceramics and polymers. Each chapter describes the characterization of the material, processing, their use in medical implants, and a case study. Again, enough information to provide a basic understanding of the use of these materials as implant materials. Chapter Five covers the mechanical behavior of structural tissues. This chapter is particularly useful as an introduction to tissues for tissue engineering.

Part II can be subdivided into the basics of elasticity and viscoelasticity followed by mechanisms of implant failure. The chapters on elasticity and viscoelasticity provide the basic concepts of stress and strain as well as the behavior of viscoelastic materials (e.g. creep, strain relaxation). These chapters are presented in such a way as to be particularly useful to the orthopaedic resident or young investigator in their desire to understand total joint design. The next chapters then expand on these concepts to discuss failure theories, fracture mechanics, fatigue and wear. Again, each chapter introduces the student to the necessary terminology and concepts required to understand what can go wrong when a specific material’s biomaterial and biomechanical properties are exceeded.

One of the major strengths of this book is the case studies that are included in Part III regarding orthopedics, cardiovascular, oral & maxillofacial devices, and soft tissue replacements. Each of these chapters includes material on the anatomy, functional requirements, material selection, design elements that are included with most of the current implants, types of implants that are currently available, design concerns, as well as a perspective on the future development of implants. These chapters are preceded by a brief description regarding regulatory affairs and testing that touches upon key points every medical device designer needs to know.

I believe this book provides a great starting point for an orthopaedic resident or student to gain insight into the process of implant design. It would serve well as a textbook or as a resource on my bookshelf.

1. Ratner, B.D., et al. *Biomaterials Science : An Introduction to Materials in Medicine*. 2nd ed. 2004, Amsterdam; Boston: Elsevier Academic Press. xii, 851 p.
2. Black, J., *Biological Performance of Materials : Fundamentals of Biocompatibility*. 4th ed. 2006, Boca Raton: CRC Taylor & Francis. 497 p.

Comprehensive texts:

Ratner, B.D., Hoffman A.S., Schoen F.J., and J.E. Lemmons. *Biomaterials Science : An Introduction to Materials in Medicine*. 2nd ed. 2004, Amsterdam; Boston: Elsevier Academic Press. xii, 851 p.
Ducheyne, P., Healy K.E., Huttmacher D.W., Grainger D.W., Kirkpatrick C.J., *Comprehensive Biomaterials*. 1st ed. 2011, Elsevier

For the those interested in total joint replacement, related material can be found in:

Mow, V.C. and R. Huijskes, *Basic Orthopaedic Biomechanics & Mechano-Biology*. 3rd ed. 2005, Philadelphia: Lippincott Williams & Wilkins. p.
Burstein, A.H. and T.M. Wright, *Fundamentals of Orthopaedic Biomechanics*. 2nd ed. 1994, Baltimore: Williams and Wilkins. 226 p.
Radin E.L., Rose, R.M., Blaha J.D. and A.S. Litsky, *Practical Biomechanics for the Orthopaedic Surgeon*. 2nd ed. 1992, New York: Churchill Livingstone Inc. 216 p.



Amelogenins Multifaceted Proteins for Dental and Bone Formation and Repair

*E-Book ISBN-13: 9781608051717
Editor: Michel Goldberg
Part of the series: Frontiers between science
and clinic in odontology
Bentham Science Publishers, 2010, 231
pages, color illustrations.
Review by Liisa Kuhn*

For those studying mineralized tissue formation or biomineralization, this book would make an excellent addition to your library. It is the only book I am aware of that is dedicated to the subject of amelogenins, which are proteins best known for their role in regulating tooth enamel formation. Interestingly, it is a protein that is deliberately resorbed away by two specific proteases after guiding enamel mineral formation, leading to a low 0.6% protein content in the mature tooth. After reading this book, you'll come to appreciate that amelogenin is found in several tissues, not only teeth, and has regenerative properties through specific cell-protein interactions that may help push forward the field of bidentistry, which aims for tooth regeneration.

The book is written by an international team of experts in the field led by Michel Goldberg and includes some familiar names such as Arthur Veis and Sam Stupp. The similarities and differences between enamel, bone and dentin formation are highlighted in a chapter by H. Margolis. For those biomaterials scientists interested in tissue engineering of teeth, there's a chapter about the regenerative role of gene splice fragments of amelogenin in dentin repair. There's also a review of the clinical applications of enamel matrix protein derivative which is now being used for regenerative periodontal therapy.

This book has 17 chapters in total divided into three sections that describe the different roles of amelogenin. Part I: Gene and Cell Regulations, Part II: Amelogenin and Biomineralization, and Part III: Amelogenin Tools for Pulp Capping, Periodontal and Bone Regenerative Therapies. It is available on-line through several different e-book vendors and is the premiere book on this subject.



A Report from the World Biomaterials Congress

By Lynne C. Jones, PhD
Associate Professor, Johns Hopkins University

Welcome back from the World Biomaterials Congress in Chengdu, China. What an incredible venue it was, with plenty of pomp and circumstance, cutting-edge science and networking. You could tell that this was going to be something special just from the banners bordering the streets throughout the city and airport. The opening ceremony really set the stage for this meeting. A number of important Chinese dignitaries spoke, the fellows of the International Union of Societies for Biomaterials Science and Engineering were inducted and numerous individuals were recognized with awards, including members of SFB. The scientific program was packed with scientific presentations in both podium and poster sessions. Of course, we didn't stay inside the entire time. Chengdu was a great city to tour. Many of us visited the Chengdu Research Base of Giant Panda breeding. Other sites included the park and grounds of the Thatched Cottage of Du Fu, a poet from the Tang Dynasty; a night at the Chinese opera and a visit to the Mao Zedong statue on the Tianfu Square. Many of us ate at the local restaurants—the food was fantastic. I fell in love with the Chengdu hot pot, a specialty of Sichuan cuisine wherein a variety of meats and vegetables are cooked in small pots of boiling spicy broth at each table. A special thank you goes out to our wonderful hosts for making this World Biomaterials Congress so memorable.



Updates In Industry

U.S. venture capital funding for the life sciences sector, which includes biotechnology and medical devices, fell during the first quarter of 2012 to its lowest level since the fourth quarter of 2010, according to the MoneyTree™ Report from PwC and the National Venture Capital Association (NVCA) based on data provided by Thomson Reuters. Venture capitalists invested \$1.5 billion in 171 life sciences deals during the quarter. Dollars invested dropped eight percent over the year and 22 percent over the quarter, while the number of deals declined to its lowest point since the first quarter of 2009. The life sciences slowdown reflected that of venture funding for all industries, with 758 deals bringing in \$5.8 billion during the first quarter, a decline of 14 percent in dollars and 12 percent in number of deals year over year. Compared with the previous quarter, dollars invested declined 19 percent; and number of deals, 15 percent. The average deal size for all industries dropped to its lowest since the last quarter of 2010 and stood at \$7.6 million.

The Japanese government will consider revising the **Pharmaceutical Affairs Law (PAL)** and treat medical devices separately, according to a new national strategy drawn up recently by the government council. The move is strongly welcomed by industry, which has long cast the PAL as an obstacle to the development of innovative medical devices. Currently in Japan, medical devices and drugs share the same regulatory rules and regulations. The government's announcement came in response to a petition filed in July 2011 by the Japan Federation of Medical Device Associations (JFMDA) requesting regulations that specifically target the medical device industry. The bill will be submitted to the National Diet, the country's legislative body, next year at the earliest, and it will take at least another couple of years for the revised law to come into force.

Health care giant **Johnson & Johnson** (New Brunswick, N.J.) made its first acquisition in China recently, picking up **Guangzhou Bioseal Biotech** for an undisclosed amount. The company has been doing business in China for more than 25 years, including last year's launch of a medical device and diagnostics innovation center there. Bioseal developed a sealant used to control bleeding during surgery, the only porcine plasma-derived fibrin sealant approved for use in China, according to a press release. The newly acquired company will work alongside Johnson & Johnson's Ethicon subsidiary, which already markets its Surgical and Surgiflow biosurgery products in China.

Kensey Nash Corporation (Exton, Pa.) announced it has entered into a definitive agreement with **Royal DSM** (DSM) (Heerlen, the Netherlands). DSM has agreed to acquire all of the common stock of Kensey Nash through a cash tender offer, followed by a merger with a subsidiary of DSM. DSM is a global Life Sciences and Materials Sciences company with sales around nine billion euros and 22,000 employees worldwide. Under the terms of the merger agreement, DSM will commence an all-cash tender offer to acquire all of the outstanding shares of common stock of Kensey Nash for \$38.50 per share. Kensey Nash's Board of Directors has unanimously approved the tender offer and resolved to recommend Kensey Nash stockholders tender their shares to DSM in the tender offer.

Mindray Medical International Limited (Shenzhen, China) announced a definitive agreement to acquire a controlling stake of **Wuhan Dragonbio Surgical Implant Co., Ltd.** (Dragonbio), a domestic medical orthopedic products provider that specializes in trauma, spine, joint and other surgical products. Under the agreement, Mindray will pay a total purchase price of approximately \$35.5 million, which will be funded through Mindray's existing cash reserves.

A first-generation artificial pancreas by Johnson & Johnson subsidiary, **Animas Corp.**, proved successful in managing insulin levels in patients with Type 1 diabetes in a non-controlled, non-randomized feasibility trial conducted at one trial site in the U.S. involving 13 diabetic patients. Each patient tried the HHM system for about 24 hours. Food and insulin variables were varied to test the limits of the system, finding that the system was able to automatically predict rises and falls in blood glucose and deliver or decrease insulin accordingly. The Hypoglycemia-Hyperglycemia Minimizer system includes a subcutaneous insulin pump, a continuous glucose monitor and software that predicts changes in blood glucose, aiming to prevent dangerous highs and lows in glucose levels.

The Nordic private equity firm **EQT Partners** agreed to buy the German medical supplies company **BSN Medical** for 1.8 billion euros, or \$2.26 billion USD. EQT is acquiring BSN, which reported revenue of 665 million euros last year and currently employs 4,000 people around the world, from the private equity firm Montagu Private Equity, which bought the business in 2005. The transaction is one of the few recent bright spots in the private equity sector, which continues to struggle from a lack of debt financing and mounting concerns about the health of the global economy.

Teleflex Incorporated (Limerick, Pa.), a leading global provider of medical devices for critical care and surgery, announced it has acquired **Semprus BioSciences** (Cambridge, Mass.), a biomedical company and spin out from Massachusetts Institute of Technology (MIT). The acquisition includes the core Semprus Sustain™ Technology. Sustain™ is a long-lasting, covalently bonded, non-leaching polymer that mimics the chemical properties of endothelial cell membrane to reduce the attachment of platelets and blood proteins at the device surface. Teleflex recently received 510(k) cleared antithrombogenic claims on their existing ARROW PICC with Chlorag+ard technology, which is a chlorhexidine-based coating. The transaction brings to Teleflex an innovative and patented platform technology that serves as the basis for next-generation medical devices.

Johnson & Johnson (New Brunswick, N.J.) announced it has received U.S. regulatory clearance for its proposed acquisition of **Synthes, Inc.** This completes all regulatory approvals required to close the transaction. Johnson & Johnson expects to close the transaction with Synthes for a total purchase price

continued on page 15

Nicholas Peppas Elected to Spanish Royal Academy of Pharmacy

Nicholas A. Peppas, past president of the Society For Biomaterials and chair of The University of Texas at Austin's Biomedical Engineering Department, has been elected a Corresponding Member of the Real Academia Nacional de Farmacia (Royal Academy of Pharmacy) of Spain. The RANF is one of the Royal Academies belonging to the Institute of Spain under the reigning king of Spain, Juan Carlos I. The academy is composed of 50 academics and 173 corresponding academics worldwide, representing "...excellence and the highest scientific and intellectual merit in the field." Prof. Peppas was inducted into the Royal Academy and gave an inaugural lecture in Madrid on April 25.

Prof. Peppas is a pioneer in drug delivery and pharmaceutical bioengineering. The citation for this honor notes that his research "...blends modern molecular and cellular biology with engineering to create innovative medical systems and devices for patient treatment." He has had numerous associations with academic institutions in Spain, including collaborative research projects, publications and participation in the education of numerous Ph.D. students.

Peppas is also a member of two U.S. national academies—the National Academy of Engineering and the Institute of Medicine—and the National Academy of France.

ASTM International Committee on Medical and Surgical Materials and Devices Honors Dr. Kenneth St. John with Award of Merit

Kenneth St. John, Ph.D., associate professor at the University of Mississippi Medical Center in Jackson, Miss., has received the Award of Merit from ASTM International Committee F04 on Medical and Surgical Materials and Devices. The

Award of Merit is ASTM International's highest organizational recognition for individual contributions to standards activities.

Prof. St. John works on several F04 subcommittees, including the U.S. Technical Advisory Group to ISO/TC 150 on Implants for Surgery (F04.93). He currently serves as chairman of Subcommittees F04.16 on Biocompatibility Test Methods and F04.92 on Planning. Committee F04 has honored him with several awards, including the Patrick G. Laing Award in 1997, the Manny Horowitz Award in 1992 and the Robert E. Fairer Award in 1987.

A member of ASTM International since 1980, St. John is also a member of Committees E08 on Fatigue and Fracture, E47 on Biological Effects and Environmental Fate, E56 on Nanotechnology and G02 on Wear and Erosion.

Steven Little Named Chair of Chemical and Petroleum Engineering Department at the University of Pittsburgh Swanson School of Engineering

Steven Little, PhD, Associate Professor and Bicentennial Alumni Faculty Fellow of the University of Pittsburgh Swanson School of Engineering, has been appointed Chair of the Department of Chemical and Petroleum Engineering, effective May 1, 2012.

Dr. Little joined the Swanson School of Engineering in 2006, where his research focuses on the controlled release of drugs. He holds the Bicentennial Board of Visitors Endowed Faculty Fellowship and also retains appointments in the McGowan Institute of Regenerative Medicine and in the Swanson School's Department of Bioengineering. Recently, he was elected Chair of the Drug Delivery Special Interest Group in the Society For Biomaterials.

CALL FOR NOMINATIONS



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The Society For Biomaterials is soliciting nominations for the 2013 Awards listed below, and for the following Board of Directors positions:

- President-Elect
- Secretary-Treasurer-Elect
- Member-At-Large

2013 Awards:

- Founders Award
- C. William Hall Award
- SFB Award for Service
- Clemson Award for Applied Research
- Clemson Award for Basic Research
- Clemson Award for Contributions to Literature
- Technology Innovation & Development Award
- Young Investigator Award
- Student Award for Outstanding Research
- Outstanding Research by a Hospital Intern, Resident, or Clinical Fellow Award

Nominations Deadlines

Awards: September 14

Board of Directors: September 21

For more information on any of the awards, or to nominate someone for an award or position on the SFB Board of Directors, please visit:

www.biomaterials.org

Attention Contract Research Organizations:

If you are involved with preclinical testing programs of biomaterials, we'd like you to consider sharing your expertise with our members through a small advertisement. Please contact me for additional information.

-Editor L. Kuhn,
Lkuhn@uchc.edu

Updates in Industry

Continued from page 13

of approximately \$19.7 billion in cash and stock. As previously announced, **DePuy Orthopaedics, Inc.**, a wholly owned subsidiary of Johnson & Johnson, has entered into an agreement to divest its trauma business to **Biomet, Inc.**

Stephen J. Ubl, president and CEO of the **Advanced Medical Technology Association** (AdvaMed), issued the following statement on June 7, 2012 following the U.S. House of Representatives passage of the **Protect Medical Innovation Act of 2011** (H.R. 436), legislation to repeal the nearly \$30 billion excise tax on medical devices set to take effect January 2013:

- "AdvaMed commends the House for voting to repeal the device tax. Today's vote is a vote to protect high-wage American jobs, maintain our global competitive leadership and encourage the research and development needed to find tomorrow's treatments and cures.
- "On behalf of the nearly two million men and women whose jobs are supported by the medical technology industry, we would like to thank Rep. Erik Paulsen (R-Minn.), the author of the bill that passed today, for his tireless leadership in seeking repeal of this onerous tax, as well as all the other members of the House who supported the legislation.
- "Medical technology companies are world leaders in the development of new medical devices and diagnostics for patients worldwide. But American leadership is at risk. Our industry can be a partner in job creation and an engine for growth for our national economic recovery but public policies need to support that growth and allow us to compete on the global stage. Repealing the device tax is an important first step.
- "AdvaMed encourages the U.S. Senate to join the House and act promptly to repeal this counterproductive, job-destroying tax."



Society For Biomaterials

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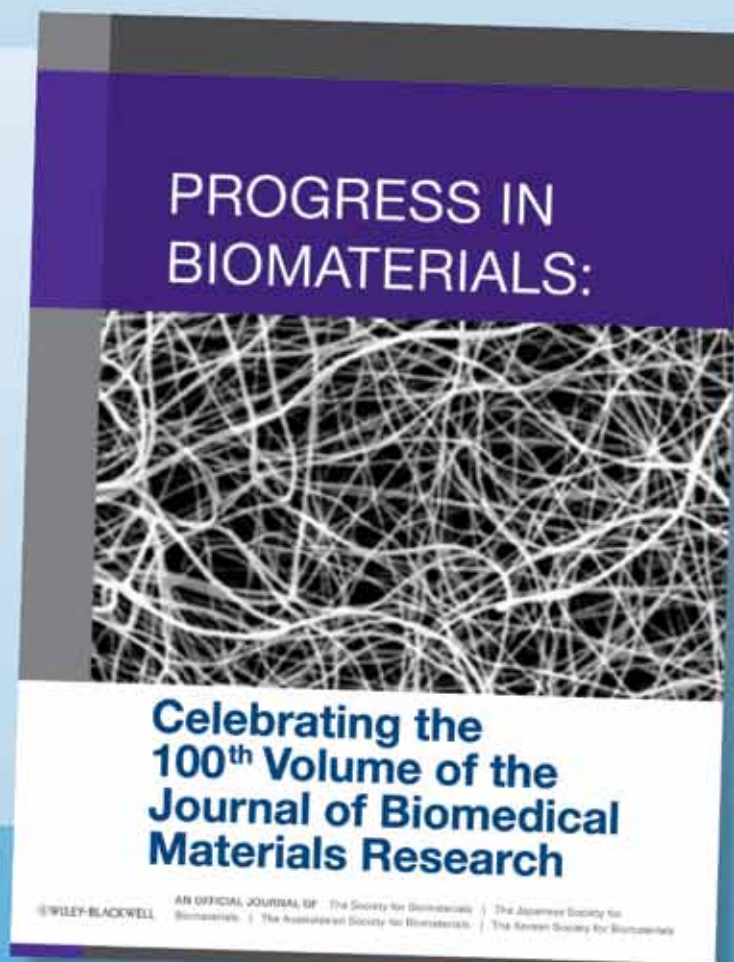
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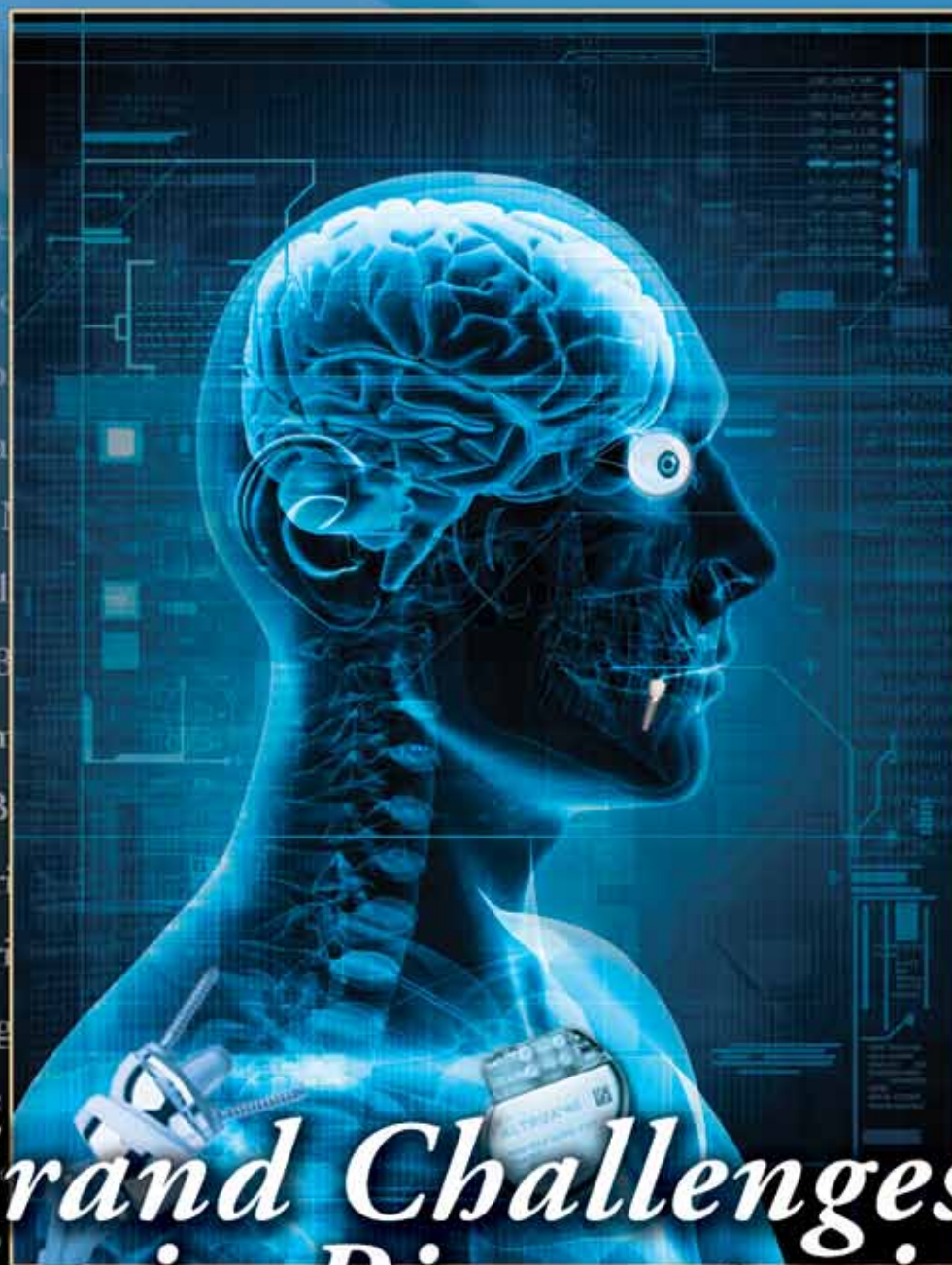
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