

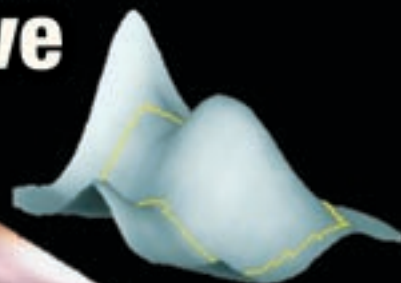
BIOMATERIALS FORUM



Second Quarter 2004 • Volume 26, Issue 2

**Special Interest Group
Officers Serving Another Term**

**Role of Cell
Printing in
Regenerative
Medicine**



**World
Congress
Update**





TO DELIVER BETTER HEALTH WITH SILICONES . . .

RELY ON PEOPLE WHO KNOW YOUR NEEDS . . . Quality experts like Tom Banigan and his dedicated QA team at NuSil Technology. Their familiarity with healthcare regulatory bodies, policies and testing requirements can help you bring new products to market sooner . . .

COUNT ON A VENDOR WITH SUPERIOR FACILITIES . . . NuSil's ISO-certified, environmentally controlled production and technical centers in the U.S. and France are unparalleled in the healthcare materials industry . . . as immaculate as the healthcare facilities they serve . . .

WHO CAN GIVE YOU THE RIGHT PROPERTIES . . . NuSil offers 200+ healthcare silicones, all supported by FDA Master Access Files and tested to ISO 10993 and USP Class 6 standards to expedite product approval by regulatory bodies. Or we will formulate and document to meet your needs . . .

WITH GLOBAL REACH AND REPUTATION . . . Tom and his NuSil colleagues will provide you with silicones known for consistency and cost-effectiveness – from adhesives and gels to elastomers and encapsulants – fully traceable and backed by solid regulatory experience . . . Let us prove how we can be your . . . **CREATIVE PARTNER IN A MATERIAL WORLD.**

NuSil Technology 1050 Cindy Lane, Carpinteria, CA 93013
Telephone: (805) 684-8780 Fax: (805) 566-9905

NuSil Technology - Europe - Technical Services Center
2740 route des Crêtes BP 325, 06906 SOPHIA ANTIPOLIS cedex, France
Telephone: +33 (0)4 92 96 93 31 Fax +33 (0)4 92 96 06 37

NuSil SILICONE
TECHNOLOGY

www.nusil.com/ddt

Biomaterials Forum, the official news magazine of the Society For Biomaterials, is published quarterly to serve the biomaterials community. Society members receive *Biomaterials Forum* as a benefit of membership. Non-members may subscribe to the magazine at the annual rate of \$48. For subscription information, or membership inquiries, contact the Membership Department at the Society office (e-mail: info@biomaterials.org) or visit the Society's Web site, www.biomaterials.org.

It is the policy of the Society For Biomaterials that all articles reflect only the views of the authors and that publication of articles or advertisements within *Biomaterials Forum* does not constitute endorsement by the Society or its agents of products, services, or views expressed herein. No representation is made as to the accuracy hereof and the publication is printed subject to errors and omissions. Articles that do not have an author byline may originate from press releases. The Society For Biomaterials retains press releases on file for a period of one year from the date of publication.

Editorial contributions to *Biomaterials Forum* are always welcome. Contributions should be sent to the Executive Editor, and are subject to the terms and conditions of the Editorial and Publication Release. Authors should refer to the Author Guidelines, which are available on the Society's Web site, when writing submissions. The publisher accepts no responsibility for return or safety of artwork, photographs, or manuscripts. Submission of editorial content does not guarantee acceptance or publication.

Address corrections should be sent to *Biomaterials Forum*, 17000 Commerce Parkway, Mt. Laurel, NJ 08054.

Requests for advertising information should be directed to Frank Scussa at fscussa@ahint.com or (856) 439-0500, ext. 3064. Information is also available on the Society's Web site, www.biomaterials.org.

Unauthorized reproduction of this magazine in whole or in part is prohibited without the permission of the publisher. Requests for permission should be directed to the Managing Editor.

Scientific photos may be submitted for cover consideration in future issues. Submit color photo no larger than 4" x 6", along with credit information and scientific description, to the Executive Editor.

Copyright© 2004 ISSN 1527-6031
Society For Biomaterials
All rights reserved

BIOMATERIALS FORUM



The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 26, Issue 2

Executive Editor

Martine LaBerge, Clemson University
501 Rhodes Research Center, Clemson, SC 29634-0905
Phone: (864) 656-5557 • Fax: (864) 656-4466
E-mail: martine.laberge@ces.clemson.edu

Managing Editor

Frank Scussa, Society For Biomaterials
17000 Commerce Parkway, Mt. Laurel, NJ 08054
Phone: (856) 439-0500 • Fax: (856) 439-0525
E-mail: fscussa@ahint.com

Government News Contributing Editor

John A. Tesk, National Institute of Standards and Technology
Industrial Liaison Office
100 Bureau Dr., Stop 1005, Gaithersburg, MD 20899-1005
Phone: (301) 975-6799 • Fax: (301) 963-9143
E-mail: john.tesk@nist.gov

Government News Contributing Co-Editor

Christine A. Kelley, National Heart, Lung and Blood Institute
National Institutes of Health
6701 Rockledge Dr., Suite 9180, Bethesda, MD 20892-7940
Phone: (301) 435-0513 • Fax: (301) 480-1336
E-mail: ck53r@nih.gov

Industrial News Contributing Editor

Steve T. Lin, Exactech Inc.
2320 NW 66th Court, Gainesville, FL 32653
Phone: (352) 377-1140 • Fax: (352) 378-2617
E-mail: steve.lin@exac.com

Society Business & Membership News Contributing Editor

Jennifer L. West, Rice University
6100 Main Street
Department of Bioengineering - MS 142
Houston, TX 77005
Phone: (713) 348-5955 • Fax: (713) 737-5877
E-mail: jwest@rice.edu

Special Interest Group News Contributing Editor

Elaine Duncan, Paladin Medical Inc.
PO Box 560, Stillwater, MN 55082-0560
Phone: (715) 549-6035 • Fax: (715) 549-5380
E-mail: duncan@paladinmedical.com

University and Research Institution News Contributing Editor

Dave Puleo, University of Kentucky
Center for Biomedical Engineering
205 Wenner-Gren Lab, Lexington, KY 40506-0070
Phone: (859) 257-2405 • Fax: (859) 257-1856
E-mail: puleo@uky.edu

Book Review

Liisa Kuhn, University of Connecticut Health Center
Center for Biomaterials
263 Farmington Avenue, Farmington, CT 06030-1715
Phone: (860) 679-3922 • Fax: (860) 679-4889
E-mail: Lkuhn@uchc.edu

Special interest Group Reporters

Biomaterials Availability & Policy
Biomaterials-Cell/Organ Therapies
Biomaterials Education
Cardiovascular Biomaterials
Dental/Craniofacial Biomaterials

Karen Masterson, kbmaster@pacbell.net
Judy Ulreich, ulreich@u.arizona.edu
Jeffrey Karp, Jeffrey_m_karp18@hotmail.com
Daniel L. Mooradian, d.mooradian@biovascular.com
TBA

Drug Delivery
Implant Pathology
Ophthalmologic Biomaterials
Orthopedic Biomaterials
Proteins & Cells at Interfaces
Surface Characterization & Modification
Tissue Engineered Products

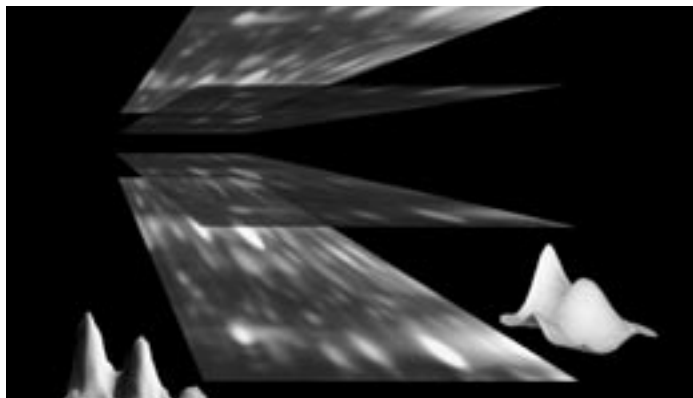
James Marotta, james.marotta@smith-nephew.com
Michelle Tucci, mtucci@orthopedics.umsmc.edu
Mutlu Karakelle, mutlu.karakelle@alconlabs.com
TBA
TBA
David Castner, castner@nb.engr.washington.edu
Karen Burg, kbarg@clmson.edu
Sarina Kay, latinasarina@rocketmail.com

Next Issue Deadline: June 2, 2004

Second Quarter 2004 • Volume 26, Issue 2

Features

- 6 **Award Winners**
Society announces 2004 award winners, including Founders Award, Clemson Awards, Young Investigator Award, and Student Award for Outstanding Research (PhD).
- 8 **SIG Officers to Serve Another Year**
Special Interest Group officers and appointees are serving another year after a special election determines that one more year of service is fair for the volunteers.
- 10 **Role of Cell Printing in Regenerative Medicine**
This article examines advances in cell printing, which is allowing viable cells to be delivered to precise target positions on scaffold materials like a printer arranges droplets of ink on flat pieces of paper.



Differential in-gel 2-D electrophoresis (DIGE) of proteins from human umbilical vein endothelial cells (HUVEC). The red channel shows proteins from HUVEC activated with TNF- α for six hours (labeled with Cy5 dye). The green channel shows proteins from normal HUVEC (labeled with Cy3 dye). The blue channel accounts for differences in the amounts of protein loaded on the gel (proteins from both samples are labeled with Cy2 dye). The combined image is shown on the bottom - spots in red are proteins present in higher amounts in the stimulated cells. The images were produced by Brad Wacker in the laboratory of Donald L. Elbert (Department of Biomedical Engineering, Washington University, St. Louis), in collaboration with R. Reid Townsend (Dept. of Internal Medicine, Washington University, St. Louis).

Departments

The Torch

- 3 From the Editor
- 4 Seventh World Congress Preview
- 5 Education & Professional Development Committee: Career Development and Resources on the Web

University News

- 12 Rensselaer Awarded NIH Grant

Special Interest Group News

- 13 Biomaterials-Cell/Organ Therapies Special Interest Group News

Government News

- 14 Report on Medical Implant Information, Performance, and Policies Workshop Available
- 15 High-Throughput Biomaterial Screening

Industry News

- 16 Industry Insights: NuSil Technology
- 17 BioInk

Book Review

- 18 Tissue Engineering

Biomaterials Community

- 22 Faster, Easier Online Submission and Peer Review System for JBMR Authors
- 24 Community Calendar

From the Editor

World Congress in Perspective



Once every four years, there is a World Biomaterials Congress—a venue without frontiers and borders aimed at gathering scientists from around the world who share biomaterials science and engineering as a passion. A World Congress is organized by the International Union of Societies for Biomaterials Science and Engineering, also known as the IUS-BSE. The IUS-BSE is composed of two members from each of the

constituent societies representing the international biomaterials community. This community currently consists of the Society For Biomaterials (U.S.), European Society for Biomaterials, Canadian Biomaterials Society, Japanese Society for Biomaterials, Australian Society for Biomaterials, Chinese Society for Biomaterials (People's Republic of China), Korean Society for Biomaterials, and the Society for Biomaterials & Artificial Organs (India). The first World Congress was held in 1980 in Vienna, Austria, followed by Washington D.C.; Kyoto, Japan; Berlin; Toronto; and Hawaii.

This year, the Australian Society for Biomaterials is hosting the 7th World Congress in Sydney, Australia. Every sponsoring society hopes for success, which translates into the number of attendants and exhibitors, the number of abstracts submitted and accepted, and enough revenue to at least break even. It is also a fact that the success of the World Congress is highly dependent on the dedication, motivation, and commitment of the sponsoring society. However, one would also believe that success is dependent on location, despite the cost involved in travel. There might be some truth to that. In fact, as of March 3, 2004, pre-registration at the Sydney meeting indicated that the United States accounted for the most registrants per country, totaling 26 percent of all registration.

Sydney is, without any doubt, an exotic venue. *Biomaterials Forum* published a series of letters from Rolfe Howlett, program chair of the 7th World Congress, for the past two years; letters providing information on the culture change (and shock!) to expect, social activities that Ozzies are found of, and many more. In this issue of the *Forum*, Rolfe addresses the World Congress as a venue for sharing and exchanging biomaterials research. In essence, this is what a Congress is all about—science and research at a mega scale. Therefore, the Society For Biomaterials is looking forward to participating in the World Congress as a member of the IUS-BSE, but also as a contributor and shaker of science and research in biomaterials.

A great trip to all members of the Society and friends of *Biomaterials Forum*!

You Design
and (we will help)
Distribute...
(we will do the rest for you)

We **M**old,
We **A**ssemble,
We **P**ackage &
Do **S**terilization
Management

Our ISO 9002 and EN46002/ISO 13488 Certifications and FDA Device Manufacturer Registration assures world-class quality.

Call 952-929-3312
and ask for Kyle Nevala or
Visit our website at www.mpc-mn.com

MIDWEST
PLASTIC COMPONENTS

7309 West 27th Street
Minneapolis, MN 55426

Seventh World Biomaterials Congress – A Preview

The Torch
By Rolfe Howlett

G'day

Many thanks to all of you who are supporting the 7th World Biomaterials Congress in Sydney. We are now into the final stages of all the planning and are looking forward to an exciting and stimulating Congress.

Many people around the world have helped in the organization of this Congress. These include the groups who have been organizing the symposia. They have taken a significant load in relation to refereeing and making decisions on how to best integrate the various submitted abstracts into the program. They have been supported by a large number of other referees as well, and by many who kindly offered to help with refereeing. Overall, about 180 international referees were used; most looked at around 20 abstracts, but some examined significantly more. Again, many thanks to all.

Overall, around 2,000 abstracts were received, and following the U.S. approach, were blinded before being sent for evaluation. Of the submitted abstracts, around 1,300 requested consideration for oral presentation, while the other 700 requested consideration for poster presentations.

The Program was developed from the referee's suggestions by an international panel. This panel included delegates representing each of the eight member societies of the IUSBSE (www.worldbiomaterials.org). This panel met for a week in New Jersey in early December 2003. Many thanks are due to the New Jersey Center for Biomaterials for their generous sponsorship of this meeting.

The draft Program includes 120 oral sessions, including three plenary addresses (by George Whitesides, Magdi Yacoub, and Graeme Clark), and also poster sessions each day. Overall, we expect around 740 oral presentations, (about a 15 percent increase from the Hawaii meeting) including almost 60 symposium or international keynote talks.

For a Congress of this size, necessarily the majority of papers will be poster presentations. With around 680 slots for submitted abstracts, unfortunately this means that about 50 percent of those requesting oral presentations could not be allocated to this category by the referees and international panel.

For us, posters are an equally important part of the Congress. We have awarded one of the two student travel awards that were provided by Resmed specifically to a poster request, and the other to an oral request – both are equally important parts of the Congress. Indeed, for many, the extra visibility that can be achieved by a poster is seen as very valuable, and there will be several hours of scheduled viewing each day. On the other hand, with nine concurrent sessions, the visibility of oral presentations will on average often be low.

We have been trying to keep the costs and budget for the Congress under control, while still providing a balance between

the science and the social and networking opportunities. The Program will start with an opening ceremony on Monday afternoon, during which all the Society awards will be made, followed by an opening reception. On Tuesday, there will be an exhibition reception, while on Thursday we will have the Congress dinner on Sydney Harbour.

A very important aspect of the budget is the support from all our sponsors, exhibitors, and advertisers. We would like to thank them all, and in particular our principal sponsor, Dow Corning, and our gold sponsors, Johnson & Johnson and Stryker Howmedica Osteonics. Unfortunately, to date, we have not been able to secure any financial support from our Federal government, nor from any state government, which is very disappointing to us.

Several people have inquired about the cost structure for the Congress. Unfortunately, certain items for a Congress in Australia are very expensive, for example the Congress venue and the audio-visual equipment. And, as a small Society, we do not have the financial backing that is available to the larger Societies. The one major point that we cannot control is the exchange rate—recent U.S. issues have led to a drop in the U.S. dollar to a significant low compared to the Aussie dollar. The fall during the last year has been close to 25 percent, so those who registered early have saved considerably. The fall is even more if you go back around two to three years. During this time, the running costs for the Congress have not changed (except upwards) and certain items here remain very expensive.

Finally, we wish you all a safe journey. It is a long way to travel—we know as we do it regularly! But, if you relax, read, watch a movie or two, or sleep, it is over quite quickly! We hope that you enjoy Sydney. And for those who are touring, we hope that you enjoy the other parts of our continent as well. And remember, if you have any questions or need advice, please contact the Congress organizers.

Important SFB Events at World Congress

Monday, May 17, 2004

5:15 p.m. – 6:30 p.m. • Opening Ceremony
6:30 p.m. – 8:00 p.m. • Welcome Reception

Wednesday, May 19, 2004

12:00 p.m. – 2:00 p.m. • SIG Chairs Meeting,
Harbourside Meeting Room 5
6:00 p.m. – 7:00 p.m. • SFB Annual Business
Meeting, Harbourside Meeting Room 5

Education and Professional Development Committee:

Career Development and Resources on the Web

There are many options to choose from in trying to plan a career in biomaterials. Options include what level of education is needed, how to match interests with a career path, and what skills (technical and interpersonal) are needed. After visiting the career center, consulting books,¹ and looking at Web sites of the professional organizations and private foundations in a general area of interest, one may find himself or herself seeking more information to launch a broader job search. This article, as part of a series of articles on career and professional development sponsored by the Education and Professional Development committee, reviews three Web sites that can provide valuable information and resources to those just beginning their careers, as well as those who may be interested in changing career paths. It is hoped that these resources will be of value and be included in discussions in student chapter or lab meetings, and in special courses, seminars, or workshops. Please feel free to make comments and/or suggest other resources to Joel D. Bumgardner (jbumgard@abe.msstate.edu), chair, or any of the other members of the Education and Professional Development committee.

Before beginning a job search, one of the first sites that should be visited is the **NIH Virtual Career Center** (www.training.nih.gov/careers/careercenter). This is a remarkable site developed by the Office of Education. There is much information regarding career options, educational levels, employment opportunities, search strategies, and tips on negotiating job offers. The Web site also highlights biomedical careers in the context of the larger world of employment opportunities. Under the 'Exploring Career Options' section are links that allow one to do self-assessment with respect to job conditions and environments, as well as important career skills such as publishing and presenting papers and ethical considerations. This section also provides links to sites discussing careers in science and research as a physician scientist, and in choosing a career in industry vs. academe or government. Under the 'Employment Options and Opportunities' are links to sites for researching employers, as well as an extensive list of job resources covering government/federal and non-profit positions, national and international job banks, and recruiters. The 'Job Search Process' section has a wealth of advice on job search strategies, including tips on things to look out for like privacy issues and employment scams. This section also provides tips on networking online and at meetings, interviewing skills, writing cover letters, resumes and CV's, and negotiating job offers. In particular, the link to Colorado College career center provides easy forms and checklists for evaluating worker satisfaction, benefits packages,

and salaries. In general, the site is very flexible, easy to navigate, and might be considered the one-stop-shop in preparation for a dream position. Note, however, that while many of the self assessment sites and job resources are free, some do charge fees.

For non-academic positions, one resource that may be useful is **www.careerbuilder.com**. Without requiring registration, this site allows access to a database (searchable by factors like type of job, type of industry, and location) of many thousands of jobs across a wide range of fields. A recent quick search for "engineering" pulled up 4,000 postings, and a search using the keyword "biotechnology" turned up 273 postings, all posted within the previous 30 days. The 'Advice and Resources' feature of this site does not compare to the advice and information available at the NIH Virtual Career Center, but if one is looking for information on a wide variety of non-academic job openings, careerbuilder.com should help out.

If currently in an academic job or considering applying for academic jobs, an essential Web site is **The Chronicle of Higher Education's** www.chronicle.com. News content on this page is generally very good, but is restricted to subscribers (\$82.50/year in the United States and \$135/year in Canada, with or without postal mail delivery of the 49 issues/year of the Chronicle newspaper). However, from the main Chronicle page, if you click on "Chronicle Careers" or go directly to <http://chronicle.com/jobs> you can, without a subscription, access a great deal of information and a wide variety of academic-related job postings. The "News & Advice" section provides links to books and job-hunting resources as well as articles and regularly-updated columns (including the fabulous Ms. Mentor advice column, which is always entertaining and shockingly truthful). This portion of the Web site also provides a searchable database that allows you to learn what the average faculty salaries (by rank) are at more than 1,400 schools and campus systems (figures compiled by the American Association of University Professors). Finally, the "Find a Job" section allows one to search for job postings including faculty, administrative, executive, and positions outside academe at a wide variety of campuses, colleges, and universities. The Chronicle's site will provide readers with a much broader view of issues, jobs, and careers in academe than previously thought possible.

1. Education and Professional Development Committee: Resources for Building Your Professional Career, Joel D. Bumgardner and Kay C. Dee, *Biomaterials Forum*, 1st Quarter 2004.

2004 Society For Biomaterials Award Winners

Founders Award

Founders Award is given for long-term, landmark contributions to the discipline of biomaterials.

Buddy D. Ratner
Professor & Director, UW
Engineering Biomaterials
University of Washington



Student Award for Outstanding Research (PhD)

Award is given to student researchers who have demonstrated outstanding achievement in biomaterials research.

Xuanhong Cheng
University of Washington



Clemson Award for Contributions to Literature

Award is given for significant contributions to the literature on the science or technology of biomaterials.

John Jansen, PhD
Professor
University of Nijmegen
Nijmegen, The Netherlands



Clemson Award for Basic Research

Award is given for significant contributions to the basic knowledge and understanding of the interaction of materials with tissue.

David G. Castner, PhD
Professor, Chemical Engineering
Director, NESAC/BIO
University of Washington



Young Investigator Award

Award recognizes an individual who has demonstrated outstanding achievements in the field of biomaterials research within five years following his/her terminal degree or formal training.

Andres J. Garcia, PhD
Assistant Professor
Woodruff School of Mechanical
Engineering
Georgia Institute of Technology



**Awards will be given
to winners during
Opening Ceremony
of World Congress**



Request for Proposals

Society For Biomaterials • 2005 Annual Meeting • Memphis, TN

Deadline: June 04, 2004

Your proposals are requested for Symposia & Workshops

The 2005 Program Committee and Meetings Committee would like your proposals and recommendations for symposia and workshops for the Society's 2005 annual meeting. Please submit a brief proposal (no more than two pages) containing the following information:

- objective of the symposium (or) workshop
- justification
- target audience (please be specific)
- preferred format (e.g. multiple speakers/podium presentations; panel; multiple speakers/poster discussion; other recommendation)
- estimated session time required
- proposed speaker support; number of speakers
- proposed organizer(s) for the symposium or workshop
- contact information for the proposed organizer(s)

Please submit your proposals to BOTH of the following committee chairs:

Joel Bumgardner • *Chair, 2005 Program Committee*
jbumgard@abe.msstate.edu

Anne Meyer • *Chair, 2005 Meetings Committee*
aemeyer@acsu.buffalo.edu

The Society's 2005 Annual Meeting will take place in late April 2005 at the Memphis Cook Convention Center.



Special Interest Groups Regroup for Challenging Year

Feature

By Elaine Duncan,
Special Interest Group Representative to Council

Before discussing upcoming events, it is important to make sure everyone got the word about this year's Special Interest Group (SIG) officer elections. Based on recommendations from the current SIG officers, the Society For Biomaterials Board of Directors approved the headquarter office's solicitation of votes from all SIG members on the question of whether the Society should hold SIG officer elections this year or forego new elections for the officers and the SIG representative to the Council. A motion to forego a new election was overwhelming approved. Therefore, the current SIG officers (elected in Reno in 2003) will remain in office until 2005. If any current officer determines through the course of the coming year that he or she cannot serve the full term, the officer should contact the chair (or vice-chair) of their SIG and discuss the options for fulfilling any ongoing responsibilities. The additional service of these fine volunteers is greatly appreciated. It is anticipated that their continued service will help assure a smooth transition to the 2005 annual meeting in Memphis.

The year since the Reno annual meeting has not been all that productive for the SIGs. But, after a solid run since the World Congress in Toronto in 1996, maybe we needed a breather.

One reason for the SIGs' inactivity has been the Society's preoccupation with the successful transition from one professional management company to another since right after the Reno meeting. This transition was the first for the Society. Our previous management group, Ardel, had assumed responsibilities very slowly after the 1986 meeting in Minneapolis, taking over advertising and exhibit sales first, then the office from Rachel Sellers of UAB in Birmingham. No other group before Association Headquarters Inc., our new management company, had been asked to jump onto a galloping horse from a rowboat tied to a floating dock in a raging thunderstorm.

In addition, there is no annual meeting this year, as the 2004 World Biomaterials Congress is being held in Australia. SIGs have traditionally been heavily involved in the regular annual meetings. Many SIG members don't recall the formative years of the SIGs and the launching of this great experiment around the time of the annual meeting in Toronto. That may be one reason the 2004 Congress caught so many SIGs off guard. The 2000 World Congress in Hawaii was hosted by the U.S. Society, so the management of that Congress was pretty much business as usual for SIGs. The World Congress in Australia, however, is the first Congress since 1992 (Germany) to be off the continent or not hosted by the U.S. Society.

So now, just as sleeping bears emerge from hibernation, SIGs are awakening, hungry and raring to go. We have a lot of work to do and a short time to get it done.

All SIG program chairs should be aware that the 2005 Program and Meetings Committees would like your proposals and recommendations for symposia and workshops for the Society's 2005 annual meeting. A detailed announcement is included in this issue of the Forum. Notice that the deadline is June 4, 2004, so plan to finish your proposal on the flight back from Sydney! (Please also send a copy to the Chair or the sponsoring SIG and the SIG representative to Council).

But SIGs are now in hot demand! SIGs have been invited to participate in the Society's upcoming meeting, Biomaterials in Regenerative Medicine: The Advent of Combination Products, to be held in Philadelphia October 16-18, 2004, immediately after the annual meeting of the Biomedical Engineering Society. Dr. Michael

Sefton, the meeting chair, has invited SIGs to participate as "co-sponsors" of selected sessions of the symposium and provide co-chairs for those sessions. The exact session will depend on the call for abstracts and the program committee's assessment of sessions. Please let Elaine Duncan or Michael Sefton know if there is an interest in SIG sponsorship of a portion of this meeting.

In addition to participation in this meeting, the SIGs have received an invitation to sponsor a session in an upcoming ASAIO meeting. The exact nature of this collaboration is still in the discussion phase, but any interested SIG should let its interest be known.

SIGs have also been invited by Cannon Communications to "test market" one or more conference "tracks" containing six presentations of interest to our attendees within the cardiovascular and orthopedic device sectors or device retrieval. Canon is also interested in a similar agreement for MD&M West 2005, January 10-12, in Anaheim, Calif., and based on a successful experience at MD&M Minneapolis 2004, an expanded program for MD&M Minneapolis 2005. More than 500 medical manufacturers attended the MD&M West conference and more than 10,000 attended the exhibition. The predominant job function for our attendees is R&D, and Canon Communications hopes to continue to evolve both the conference and exhibit to serve the most rapidly growing areas of the medical device industry. This would be a "win-win" situation for the SIGs and the Society For Biomaterials, as Canon seeks the expertise of our members to organize these highly sought after technical programs. Please contact Elaine Duncan, SIG representative to Council, with any interest in participation.

The World Congress meeting in Sydney will be an important time for organization of all SIGs, so please consider the following carefully:

- You may have the opportunity to submit a proxy for the Annual Meeting. Please execute the proxy. Don't throw it in the trash. If you cannot come to the meeting, give your proxy to someone who will be going. The SIG Rep has an early-registration list of the U.S. attendees.
- The SIG meeting on Wednesday, May 19, will be an ALL-SIG meeting and a box lunch will be served. The agenda for this meeting will be sent to all SIG members, so even if you cannot come, you can participate by making sure the key delegate from your SIG knows your thoughts. Please contact one of your SIG officers to pass along your issues or contact the SIG Representative to Council.
- After a general session, each SIG will have time in the meeting room for breakouts to meet together and work on programs and organizational issues.

Although this has been a stressful year for some members and groups, the upcoming year will be one of varied opportunities, and every SIG member plays an important role in their group. Even if a member does not actively participate in meetings, the act of paying dues sends a message that the topic and programs of the group are important! This counts more than some may realize. If a member has not renewed their dues for the Society or the SIG there is plenty of time to do so without loss of membership benefits and to help support the SIG through the coming year.

Your SIG needs you, all the way to Memphis!

2004 Special Interest Group Officers

Biomaterials Availability and Policy Chair

Phil Triolo
Phil Triolo & Associates
Salt Lake City, UT
Phone: (801) 328-1996
Fax: (801) 328-2399
philt@philt.com

Vice Chair

Carl McMillin
Synthetic Body Parts
Brecksville, OH
Phone: (440) 838-0985
Fax: (440) 838-4516
docmac9582@aol.com

Secretary-Treasurer

Kathleen White
Polymer Tech Group
Berkeley, CA
Phone: (510) 841-8800
Fax: (510) 841-7800
kwhite@polymertech.com

Program Chair

Karen Masterson
Thoratec Corp.
Rancho Cordova, CA
Phone: (916) 852-2847
Fax: (916) 638-3216
karen.masterson@thoratec.com

Biomaterials Education Chair

Lisa Friis
University of Kansas
Dept. of Mechanical Engineering
Lawrence, KS
Phone: (785) 864-2104
Fax: (785) 864-5254
lfriis@ku.edu

Vice-Chair

Thomas Webster
Purdue University
West Lafayette, IN
Phone: (765) 494-2995
Fax: (765) 494-1193
twebster@ecn.purdue.edu

Secretary-Treasurer

Dr. Lon Mathias
University of Southern Mississippi
Hattiesburg, MS
Phone: (601) 266-4871
Fax: (601) 266-5635
lon.mathias@usm.edu

Program Chair

Dr. Abhay Pandit
National University of Ireland, Galway
Nun's Island, Galway Ireland
Phone: 353 91 512395
Fax: 353 91 563991
abhay.pandit@nuigalway.ie

Cardiovascular Biomaterials Chair

Narendra R. Vyavahare
Clemson University
Bioengineering Research Center
Clemson, SC
Phone: (864) 656-5558
Fax: (864) 656-4466
narenv@clemson.edu

Vice-Chair

Mark Moore
Sulzer Carbomedics
Austin, TX
Phone: (512) 435-3252
Fax: (512) 435-1793
mmoore@carbomedics.com

Secretary-Treasurer

Michael S. Sacks
University of Pittsburgh
Department of Bioengineering
Pittsburgh, PA
Phone: 412 624 8985
Fax: 412 624 4732
msacks@pitt.edu

Program Chair

Dr. Christopher Widenhouse
Cordis Corp.
Pembroke Pines, FL
Phone: (954) 441-5012
Fax: (786) 313-2830
cwidenho@crdus.jnj.com

Cell/Organ Therapies Chair

Donald Elbert
Washington University
St. Louis, MO
Phone: (314) 935-7519
Fax: (314) 935-7448
elbert@biomed.wustl.edu

Vice-Chair

Laura Suggs
University of Minnesota
Minneapolis, MN
Phone: (612) 624-7541
suggs001@umn.edu

Secretary-Treasurer

Brenda Mann
Keck Graduate Institute
Claremont, CA
Phone: (909) 607-8565
Fax: (909) 607-9826
bmann@kgi.edu

Program Chair

Karen Burg
Clemson University
Department of Bioengineering
Clemson, SC
Phone: (864) 656-6462
Fax: (864) 656-4466
kburg@clemson.edu

Dental/Craniofacial Materials Chair

Joel D. Bumgardner
Mississippi State University
Dept. of Agriculture & Biological Engineering
Mississippi State, MS
Phone: (662) 325-3282
Fax: (662) 325-3853
jbumgard@abe.msstate.edu

Vice-Chair/Program Chair

Spiro Megremis
American Dental Association
Chicago, IL
Phone: (312) 440-3546
Fax: (312) 440-2536
megremis@ada.org

Secretary-Treasurer

John Ricci
New York University
College of Dentistry
New York, NY
Phone: (212) 998-9623
Fax: (212) 995-4244
john.ricci@nyu.edu

Drug Delivery Chair

Jeffery Joseph
Thomas Jefferson University
Philadelphia, PA
Phone: (215) 955-6161
Fax: (215) 933-5507
jeffrey.l.joseph@mail.tju.edu

Vice-Chair

Dhirendra Katti
University of Virginia
Charlottesville, VA
Phone: (434) 924-5989
Fax: (434) 924-1691
dsk2n@virginia.edu

Secretary-Treasurer

Hamad Benghuzzi
University of Mississippi
Department of Health Science
Jackson, MS
Phone: (601) 984-6324
Fax: (601) 984-6324
hbenghuzzi@shrp.umsmed.edu

Program Chair

Lisa Kuhn
University of Connecticut Health Center
Biostructure & Function Department
Farmington, CT
Phone: (860) 679-3922
Fax: (860) 679-1370
lkuhn@uchc.edu

Implant Pathology Chair

Howard Winet
University of California Los Angeles
Bone Chamber Lab
Los Angeles, CA
Phone: (213) 742-1007 ext. 1459
Fax: (213) 742-1515
hwinet@laoh.ucla.edu

Vice-Chair

Tim Muench
NAMSA
Northwood, OH
Phone: (419) 662-4346
Fax: (419) 666-2954
tim-m@NAMSA.com

Secretary-Treasurer

Michelle A. Tucci
University of Mississippi
Medical Center
Jackson, MS
Phone: (601) 815-1043
Fax: (601) 984-5062
mtucci@orthopedics.umsmed.edu

Program Chair

Jason Emmanual
WL Gore Associates
Flagstaff, AZ
Phone: (928) 864-3855
Fax: (928) 864-3860
jemmanua@wlgore.com

Ophthalmologic Biomaterials Chair

Pericles Calias
Eyeteck Pharmaceuticals
Woburn, MA
Phone: (339) 927-0711
Fax: (781) 935-9083
pcalias@eyetk.com

Vice-Chair

Yoseph Yaacobi
Alcon Laboratories
Fort Worth, TX
Phone: (817) 551-3047
Fax: (817) 568-6994
yoseph.yaacobi@alconlabs.com

Secretary-Treasurer

Chi-Chun Tsai
Alcon Laboratories
Fort Worth, TX
Phone: (817) 568-6320
Fax: (817) 568-7570
chi-chun.tsai@alconlabs.com

Program Chair

Jean Jacob
Louisiana State University Eye Center
New Orleans, LA
Phone: (504) 412-1326
Fax: (504) 412-1315
jjacob@LSUHSC.edu

Orthopaedic Biomaterials Chair

Bob Hastings
Depuy Inc.
Warsaw, IN
Phone: (574) 372-7438
BHastin2@dpyu.jnj.com

Vice-Chair

Michele Marcolongo
Drexel University
Dept. of Materials Engineering
Philadelphia, PA
Phone: (215) 895-2329
marcolms@drexel.edu

Continued on page 23

The Role of Cell Printing in Regenerative Medicine

All vertebrates exhibit multiple levels of structural organization and function, which is beautifully executed during development. Much understanding of how to engineer tissues with complexity may therefore be derived from studying the principles of biological self-organization. Although our understanding of these self-assembly processes is still in its infancy, some cues are already being used to develop efficient strategies for assembling simple tissues.

For example, the physical properties of embryonic tissues have yielded surface and interfacial tensions,¹ these properties have been exploited to create two dimensional cell assemblies that fused into coherent structures over time,² and mathematical modeling has been successfully applied to these systems to predict the conditions for which fusion will take place.³ Moreover, the process has been automated using customized inkjet printers, which can deliver cells suspended in their cartridges as sort of “bioink.” To survive, the cells are printed on hydrogel “biopapers,” which maintain hydration and allow nutrients to reach the cells.⁴ Viable cells can be delivered to precise target positions on scaffold materials, just as a printer arranges droplets of ink on a flat piece of paper. Furthermore, using different cell types as different bioinks, which are then delivered to exact positions to mimic tissue structures of the original tissue, can be envisioned by using multiple nozzles. Thus, the printing of dissociated human or animal cells onto specific patterns, and their subsequent fusion, may allow the development of replacement tissue or even whole organ substitutes. In recent studies, viable bacteria were directly printed using an off-the-shelf thermal inkjet printer,³ significantly expanding the capabilities of inkjet printing in the direction of creating living tissue substitutes.

In addition, suspensions of Chinese Hamster Ovary (CHO) and embryonic rat motoneurons were printed directly using modified Hewlett Packard (HP) 550C printers with high viability. Soy agar and collagen hydrogels were used as bio-paper. The CHO cells proliferated as expected, while the motoneurons grew processes that were somewhat smaller than in traditional 2D culture.⁵ This exciting combination of off-the-shelf inkjet printing and viable biomaterials was demonstrated for bacterial patterning and now could be adapted for tissue engineering. With the obvious advantages of high throughput and flexibility, this bottom-up technology potentially offers researchers an applicable and cost-effective tool to rapidly fabricate cell patterns and tissue-like structures.

Figure 1 shows patterns that were fabricated using the inkjet method. Much more interesting findings are surely to result from perusing this developmental biology-based engineering approach.

Although developmental biology may provide cues, rules, and possibly a framework for hierarchical self-assembly, the timeframes involved are too slow for effective tissue regrowth. It is necessary to develop efficient strategies for assembling tissue-



Figure 1. Precision placement of *E. coli* bacteria onto biopaper. Photograph of cartoon tiger paw generated by printing viable cells, according to a pre-designed pattern, onto an agar-hydrogel.

like constructs in “real-time.” Since tissues and organs exhibit distinct shapes and functions nurtured by vascular connectivity, these strategies must include efficient methods of vascularizing large, living, three-dimensional (3D) tissue-engineered constructs. Many of the top-down fabrication techniques used to build microelectromechanical systems, including photolithography, are more attractive due to the similar feature sizes than cellular networks, but are often unsuitable for delicate biological systems or aqueous environments.⁶ A bottom-up approach inspired by the success of soft lithography and self-assembly to construct hierarchical non-living structures has been proposed by us to pattern functional cell structures in three dimensions. Using this approach, free-form cell structures of a variety of forms, including tubes and vascular branches, can be built.

Adapting bottom-up approaches to tissue engineering is a genuine challenge. Since the first application of fused-deposition modeling for tissue engineering scaffolds,⁷ considerable effort has been focused on printing synthetic biodegradable scaffolds.⁸ Concurrently, a variety of rapid prototyping techniques have been developed to define macroscopically the shapes of deposited biomaterials, including photolithography,^{9,10} syringe-based gel deposition,¹¹ and solid freeform fabrication.¹² That these approaches have not yet led to the construction of harmonically organized complex tissues may be due to the difficulty to embed the various cell types within the intricate designs. A proposed tissue engineering approach combines rapid prototyping procedures with microencapsulation to print viable freeform structures using custom modified inkjet printers.^{5,13} The cell printing is expanded into a layer-by-layer method of tissue construction in an attempt to verify our new paradigm that the balance between cell growth, maturation, and fusion can be manipulated using engineering principles, thus potentially leading to the “real time” tissue construction.

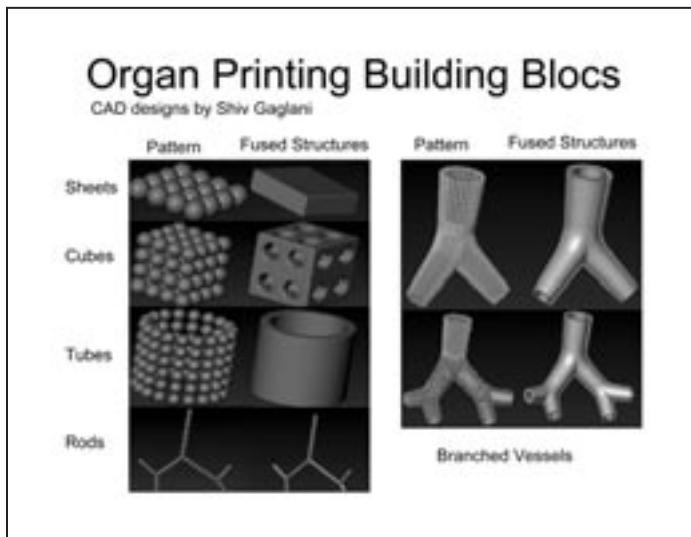


Figure 2. Schematic roadmap for organ printing. Local micron size droplet delivery of a cell mixture causes gelling of a polymer solution at the air/solution interface. The gelled drops fuse and are submerged into fresh uncrosslinked solution thus maintaining hydration of the constructs. The procedure can be repeated until the desired shape is obtained. To help in the fabrication of freeform structures, computer aided designs were made with VX CAD by Shiv Gaglani. Structures such as a tissue cube, a branching vessel, and a branching vessel inside a tissue cube can be printed using several different nozzles filled with the cell types of interest. Cell sheets fuse to form nonvascularized cubes. Cell tubes fuse to form functional vessels. Gelling and maturation of vessels inside a cube are expected to lead to vascularized tissue blocks.

The model that may be used as a macroscopic building block for assembly of more complex tissues is schematically shown in Figure 2. Local micron-size droplet delivery of a cell mixture causes gelling of a polymer solution at the air/solution interface. The gelled drops fuse and are submerged into fresh uncrosslinked solution, thus maintaining hydration of the constructs. The procedure can be repeated until the desired shape is obtained (Figure 3). Cell viability is maintained by choosing biocompatible polymers dissolved in isotonic buffer solution or culture media, and noncytotoxic crosslinkers. To help in the fabrication of free-form structures, computer aided designs (CAD) can be created using a variety of commercial CAD software.

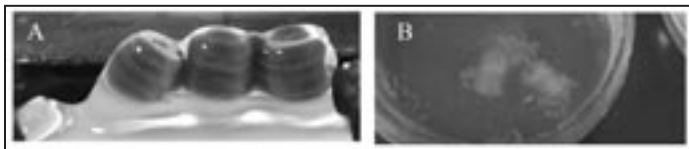


Figure 3. Macroscopic images of printed endothelial cell tubes. Cell tubes with endothelial cells as seen on day 0 immediately after printing. The different layers can clearly be seen (A). After several days of *in vitro* culture, the cells have fused into tubes. Some cells are seeing migrating out of the gels (B).

Figure 3 shows printed tube constructs of endothelial cells using customized printers. These cells were cultured for seven days prior to the experiment, trypsinized, and resuspended in isotonic

phosphate buffered saline solution. The inkjet cartridges were filled with 1.5 ml of crosslinker solution and the BAEC cells were added to form a bioink at a concentration of 2×10^6 cells/ml. Positively charged nylon membranes were placed on a z-stage, which was immersed just below the surface of an ungelled polymer hydrogel solution. After every print action, a recoating procedure was performed by lowering the elevator platform into the chamber and bringing it back 100 microns below its original position utilizing a stepper motor assembly. The stacked rings gelled onto each other to create a cylindrical tube of the cells. The tubes were carefully detached from the

Thus, the printing of dissociated human or animal cells onto specific patterns, and their subsequent fusion, may allow the development of replacement tissue or even whole organ substitutes. In recent studies, viable bacteria were directly printed using an off-the-self thermal inkjet printer,³ significantly expanding the capabilities of inkjet printing in the direction of creating living tissue substitutes.

paper and individually placed in small polystyrene dishes filled with 3 ml culture media, which was changed every 24 hours.

Tubes of many cell types have been printed using this method, including CHO cells, endothelial cells, smooth muscle cells, osteoblasts, bone marrow derived stem cells, and primary cardiac cells. Initial studies focused on viability, reducing bacterial contaminations, and optimizing conditions of *in vitro* culture. Dense fused structures that can exhibit function when challenged with agonists in simple *in vitro* experiments have also been printed. These include vasoconstriction properties of printed smooth muscle cell tubes, and the potential of printed stem cells to differentiate into multiple lines, although the control of this differentiation is not yet understood.

Vital to cell patterning procedures is the use of stable, aqueous noncytotoxic bioinks that act as crosslinking agents delivered using the inkjet method into a rapid prototyping chamber. There is a need to develop biomaterials that can be used as bioinks; current strategies for bioinks include natural and

Continued on page 21

Rensselaer Awarded \$2.7 Million Grant to Improve Drug Development Process

The National Institutes of Health (NIH) has awarded Rensselaer Polytechnic Institute a \$2.7 million, four-year grant to develop new tools for drug discovery. The grant, awarded in partnership with the University of California, Berkeley, Massachusetts Institute of Technology (MIT), and Oak Ridge National Laboratory, will support basic research intended to produce effective pharmaceuticals faster and more economically.

Jonathan Dordick, the Howard P. Isermann '42 Professor of Chemical and Biological Engineering at Rensselaer, leads the research team that includes Shekhar Garde, assistant professor of chemical and biological engineering at Rensselaer; Alexander Klibanov, professor of chemistry and bioengineering at MIT; Douglas Clark and Jeffrey Reimer, professors of chemical engineering at U.C. Berkeley; and Brian Davison, director of life sciences at Oak Ridge.

"This is a stellar partnership that relies on many different skill sets to complete the research," Dordick says. "Our goal is to develop a key set of tools to synthesize and screen promising compounds rapidly, and identify those most suitable for further development as potential new drugs." The current process of developing a single new therapeutic drug can take many years and cost up to \$1.7 billion, according to a recent report in *Chemical & Engineering News*.

Recent advances in chemistry and screening techniques make it possible to identify large numbers of promising compounds, known as derivative libraries. Yet the subsequent testing required to evaluate each compound is expensive and slow. The resulting bottleneck in drug development has attracted considerable attention among researchers seeking to advance more efficient and affordable processes.

Dordick and the team are proposing a novel set of techniques that will, if successful, remove this bottleneck. "With this research," Dordick says, "we will be able to generate completely new compounds, accessing a whole new range of molecules and expanding molecular libraries."

To produce the derivative libraries, the researchers will use enzymes to react with promising compounds attached to small beads or soluble polymer supports. Because the products of the enzymatic reactions remain on the bead or polymer, further derivatization is possible by simply washing away the initial reagents and adding in new ones. It is hoped this will enable rapid and repeated synthesis of compound derivatives. However, to achieve this novel synthetic strategy, Dordick and the research team will need to obtain a fundamental understanding of how enzymes function with their reactants attached to a

bead, and then identify ways to coax enzymes into working better under such conditions. "Successful completion of this research program will result in a powerful new tool that biomedical investigators can use to speed the search for new, more potent therapeutics," Dordick says.

The researchers will begin work with a series of simple compounds and progress to complex natural products, including the flavonoid bergenin, and current pharmaceuticals, including the current HIV-1 protease inhibitor indinavir.

This award represents Rensselaer's first Bioengineering Research Partnership Grant from NIH. Rensselaer currently has 30 active grants from the NIH totaling \$24 million, an increase in five years from three active NIH grants totaling \$600,000. The basic research supported by this grant will be carried out in the new Rensselaer Center for Biotechnology and Interdisciplinary Studies, a state-of-the-art facility scheduled to open in September 2004.

About Biotechnology at Rensselaer

Biotechnology research at Rensselaer comprises multidisciplinary work, combining life sciences, information science, applied mathematics, engineering, and physics. Areas of research include biocatalysis and metabolic engineering (application of enzymes and manipulated metabolic pathways); functional tissue engineering (creating replacement tissues and organs that can augment or replace damaged tissue); integrated systems biology (systems-based, experimental methods of gaining insight into the function of complex biosystems); and computational biology and bioinformatics (using information technology tools to search massive databases, such as those generated by the Human Genome project, to efficiently correlate relevant facts).

About Rensselaer

Rensselaer Polytechnic Institute, founded in 1824, is the nation's oldest technological university. The school offers degrees in engineering, the sciences, information technology, architecture, management, and the humanities and social sciences. Institute programs serve undergraduates, graduate students, and working professionals around the world. Rensselaer faculty are known for pre-eminence in research conducted in a wide range of research centers that are characterized by strong industry partnerships. The Institute is especially well known for its success in the transfer of technology from the laboratory to the marketplace so that new discoveries and inventions benefit human life, protect the environment, and strengthen economic development.

Biomaterials–Cell/Organ Therapies Special Interest Group News

Special Interest Group News

By Shelly E. Sakiyama-Elbert

The Biomaterials-Cell/Organ Therapies Special Interest Group (SIG) is comprised of about 40 members from both industry and academia, including a significant number of student members. The goal of this SIG is to facilitate the education of biomaterials community members with regards to new technological developments that may enhance their research or product development. Towards this goal, the SIG has helped organize a workshop and several symposia at recent annual meetings. At the 2002 annual meeting, the SIG organized a workshop titled, "Practical Aspects of Genomics and Proteomics," which was chaired by Donald Elbert and Jennifer West. The workshop described the benefits and limitations of traditional biochemical techniques as well as new high-throughput techniques in the study of biomaterials/tissue engineering, with a special focus on DNA arrays and proteomics. The SIG also sponsored a symposium on stem cell-based therapies at the 2002 meeting focusing on the use of stem cells for tissue regeneration and repair with Arnold Caplan as the lead speaker. At the 2003

annual meeting, the SIG sponsored two sessions: a symposium (co-sponsored with the Tissue Engineering SIG) titled, "Stem Cells in Tissue Engineering," with lead speaker Johnny Huard, and a podium session titled, "Functionalized Materials: Cell Interactions." The SIG also presented two student travel awards to outstanding student presenters from the "Functionalized Materials: Cell Interactions" session, which were presented to Andrea Gobin, from Rice University, and Stephanie Martin, from the University of Washington.

For more information about membership and activities of the Biomaterials-Cell/Organ Therapies Special Interest Group, please contact Shelly E. Sakiyama-Elbert at sakiyama@biomed.wustl.edu, or by mail at Department of Biomedical Engineering, Washington University, 1 Brookings Drive, Campus Box 1097, St. Louis, MO 63130.

17th Annual Meeting of the International Society for Ceramics in Medicine

Bioceramics 17

www.bioceramics17.com

info@bioceramics17.com

December 8-12, 2004

Wyndham New Orleans Hotel at Canal Place,
New Orleans, Louisiana 70130, USA, Tel 504-553-5003

President: Panjian Li, PhD
DePuy Inc, Warsaw, IN 46581
Tel 574-372-7445, Fax 574-372-7128
PLi@dpuyus.jnj.com

Chairman: Cliff Colwell, MD
Scripps Clinic, La Jolla, CA 92037
Tel 858-332-0166, Fax 858-332-0127
Colwell@scripps.edu

Topics include (but not limited to)

Biological ceramics
Biomimetic ceramics/coatings
Bioceramics chemistry
Ceramic/surface-body fluid interactions
Bioceramics-bone interactions
Materials-cells interactions
Ceramics/surfaces in delivery system

Clinical application -fixation
Clinical application - bone replacement
Clinical application - bearing surfaces
Novel biomaterials and their synthesis
Biomaterials for minimum invasive surgery
Bioactive coatings for fixation of osteoporotic bone
Academia-Industry-Clinic forum

Deadline of abstract submission: May 15, 2004

Please send your abstract to info@bioceramics17.com and visit www.bioceramics17.com for the guideline on abstract preparation.

Report Issued on Medical Implant Information, Performance, and Policies Workshop

The final report has been issued for the Medical Implant Information, Performance, and Policies workshop that was coordinated by the Biomaterials and Medical Implant Science (BMIS) committee. The BMIS Coordinating Committee was formed by Dr. Harold Varmus, former NIH Director, in 1997 to serve as a trans-NIH technical committee that would coordinate agency research programs and develop joint initiatives and workshops in the areas of biomaterials and medical implant science research. The committee also includes representatives from other federal agencies and public organizations that bring additional perspectives on biomaterials and medical implant research as well as the public good. The executive summary of the workshop is given below. The final report can be accessed at www.nibib.nih.gov/events/BMIS/BMIS2002.htm.

Executive Summary

The Biomaterials and Medical Implant Science (BMIS) Coordinating Committee convened a workshop titled, "Medical Implant Information, Performance, and Policies," September 19-20, 2002, at the University of Maryland at Shady Grove in Rockville, Md. The purpose of the workshop was to evaluate the role of the Federal government in obtaining and disseminating data gained from medical implants to ensure safer health care. Workshop participants included representatives from clinical medicine, biomedical research, information technology, law, ethics, patient advocacy, and Federal program development. For the purpose of this workshop, implants were defined as "having a minimum lifespan of three months, as penetrating living tissue, as having a physiologic interaction, and as being retrievable." This definition was used to exclude short-term devices that may be considered implants according to the FDA definition (i.e., catheters).

The following recommendations outline the most important

areas where the Federal government can impact the acquisition and dissemination of data related to medical implants to ensure safer health care:

- Establish Internet-based medical implant information and data resources for patients, clinicians, researchers, designers, manufacturers, and other interested persons.
- Develop standard definitions and practices for recovering implants, conducting research, evaluating outcomes, and reporting results.
- Catalyze a scientific team approach involving stakeholders of the health care enterprise, including researchers, health care providers and payers, industry, and government.
- Educate stakeholders about research on retrieved implants.
- Publish a peer-reviewed law article that clarifies the medical implant property rights of patients, manufacturers, hospitals, insurers, and other interested parties.
- Create a central source of general information regarding the medical value, safety, lifetime, and adverse events associated with medical implants.

The final report serves as a synopsis of the workshop proceedings and documentation of the resulting recommendations. Abstracts of each of the plenary presentations, a summary of the discussion and subsequent recommendations from each breakout session, and a description of the broad recommendations obtained from the workshop deliberations are included in this report. The Federal government will use these recommendations to evaluate and develop future programs.

Submit Your University News

The Editors of *Biomaterials Forum* would like your input for enhancing the University News section of the magazine. As a member of the Society For Biomaterials and a reader of the Forum, what do you want to see in the University News section? Do you have any information about your institution that other SFB members may find informative? Has your department/center/program recently hired in the area of biomaterials? Do you plan additions in the near future?

Although we cannot guarantee publication of the information, please submit news for consideration for inclusion in the University News section. News items can be submitted to the Executive Editor, Martine LaBerge, via e-mail at lalberge@clemsun.edu. The submission deadline for the next issue (July-September 2004) is July 2. Other deadlines for 2004 are: Sept. 1 (October-December issue).

We thank you for your help.

High-Throughput Biomaterial Screening

Polymers are frequently blended to optimize material properties such as strength, flexibility, morphology, and crystallinity. This includes polymers used for biomedical applications. For instance, Vicryl (Ethicon Inc.) is a degradable suture made of Polyglactin 910 that is a blend of poly(L-lactide) (PLLA) and poly(lactide-co-glycolide). To speed the development of new biomaterials, we are developing high-throughput methods for characterizing the biocompatibility of polymer blends.

Preparation of individual polymer specimens of discrete compositions that systematically span a significant range of properties can be tedious and time-consuming. To address this, a high-throughput technique that involves the creation of a gradient of polymer composition in the form of a film to examine cell response to blends of two polymers was used. Cell responses such as adhesion, morphology, proliferation, and

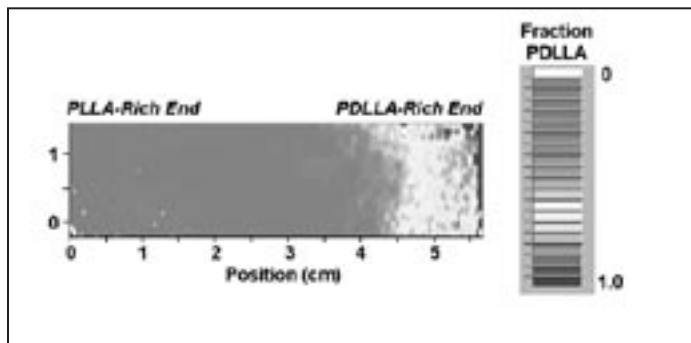


Figure 1: FTIR map of a PLLA-PDLLA composition gradient.

differentiation can be evaluated after culture of cells on the polymer composition gradients. Compositions that support cell function can be rapidly identified to provide an optimal blend composition for use in tissue engineered medical products.

A composition gradient of two biodegradable polymers, PLLA and poly(D,L-lactide) (PDLLA), was made. The pure polymer solutions are separately and simultaneously infused into and withdrawn from a mixing vial such that the composition of the resulting mixture changes over time. A syringe then samples the solution during mixing, which results in a composition gradient along the barrel of the syringe. The gradient solution is then quickly deposited in a line on a flat substrate and spread into a film using a knife.

The gradients are characterized with microspectroscopic fourier transform infrared (FTIR) spectroscopy to map composition of

the entire gradient library (Fig. 1) and atomic force microscopy (AFM) to map surface topology. FTIR reveals that the technique is feasible and makes consistent gradients. AFM demonstrates that the surface roughness varies with composition. The PLLA-rich end of the gradient (RMS = ~10 nm) is about 10 times rougher than the PDLLA-rich end (RMS = ~1 nm).

Cellular response is characterized on the library as a function of local material parameters. Automated fluorescence microscopy is

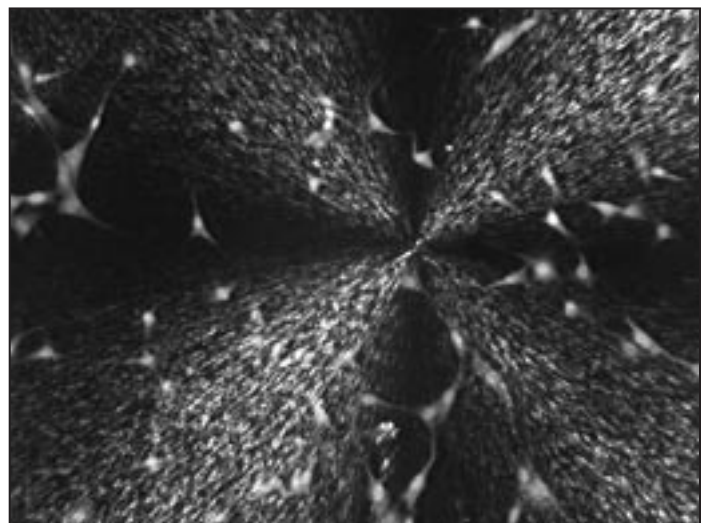


Figure 2: Osteoblasts growing on a PLLA spherulite.

used to correlate changes in cell shape, cytoskeleton development, focal adhesions, and proliferation and correlating these with substrate topography. Preliminary studies with osteoblastic cells (MC3T3-E1) suggest that they proliferate faster on PDLLA (Fig. 2). This technique should accelerate materials research for tissue engineering by providing a rapid technique for investigators to screen polymer blends for their ability to support cell function.

Contributors and collaborators are E. J. Amis, L. O. Bailey, M. L. Becker, C. G. Simon, N. R. Washburn (Polymers Division, NIST) and N. Eidelman (American Dental Association). For more information, please contact newell.washburn@nist.gov.

NuSil Technology

About NuSil Technology

NuSil Technology is a leading formulator of silicone compounds for aerospace, healthcare, electronics, and other applications requiring precise, predictable, cost-effective materials performance. ISO-9001 certified since 1994, NuSil Technology operates state-of-the-art laboratories and processing facilities in North America and Europe and provides on-site, in-person application engineering support worldwide. NuSil Technology can be reached at 805-684-8780, or on the web at www.nusil.com.



Last year NuSil Technology announced the acquisition of Rhodia Silicones' long-term implantable silicones business. Long-term implantable silicones are used in medical device products implanted for 29 days or more.

NuSil Technology and Healthcare

NuSil Technology has a history in health-care related materials that spans well over two decades. In 1992, NuSil assisted many of its customers in the health-care industry by rapidly developing replacement products for materials discontinued by Dow Corning. By quickly establishing material master access files with the FDA, NuSil provided those customers affected by the withdrawn products with the materials and regulatory support they needed for success. These products were primarily used in long-term implantable medical device applications such as pacemaker leads, hydrocephalus shunts, and intra-ocular lenses. NuSil then established an entire "unrestricted" product line, incorporating all the products that are not restricted for use in any application. Its unrestricted product line has since expanded to include fluids, gels, elastomers, and dispersions for a broad range of health-care related applications.

NuSil Technology understands the various regulatory issues facing the long-term implantable medical device industry, and therefore NuSil can many times find, develop, and manufacture the answers to its customers' design challenges. Many of NuSil's

silicone materials meet ISO 10993 and U.S./European Pharmacopoeia testing requirements, have master access files filed with the FDA, and are manufactured in its ISO 9001-2000 certified facilities. Companies that approach NuSil for novel materials and technologies will benefit from its regulatory knowledge because NuSil applies this knowledge appropriately and therefore doesn't spend time needlessly pursuing options that will not work further down the road. The result is that customers save time and money because of NuSil's experience and willingness to work with their customers' needs.

NuSil Technology has developed an understanding of excipient standards facing many pharmaceutical/health-care companies. The excellent reputation that NuSil's R & D services have for finding solutions appeals to many start-up or experimental types of projects. Many of these smaller and developmental applications have grown to significant levels over the past few years. By working closely with its customers and providing a high degree of success at smaller production levels, NuSil is finding that developing what are small applications today can be an area of strong growth in the future.



Providing Custom Materials Based on Properties

NuSil Technology is unique because it establishes a partnership-style relationship with its customers. NuSil realizes that its success is invariably tied directly to the success of its customers, and because of that, NuSil takes a very adaptive role and tries to provide solutions to the problems that its customers face. NuSil Technology shares research and development responsibilities to supply custom silicone materials for very specific applications. NuSil even works with its customers to address all regulatory concerns before a product is sent to market.

NuSil Technology's goal is to supply silicone materials with unparalleled customer service to a variety of companies throughout the health-care industry. NuSil has been providing custom solutions to design challenges within the drug delivery

Continued on page 19

EnduraTec Testing Services, an international provider of test services for the medical device industry, announced that it has successfully completed an essential fatigue life test of MIV Therapeutics Inc.'s proprietary **hydroxyapatite (HAp) stent coating**. The test was conducted to evaluate the mechanical integrity and bonding properties of MIV Therapeutics ultra-thin biocompatible coating. The test simulated the radial strain produced by heartbeats in a coronary artery. Stents were coated with the HAp coating and subjected to 40 million cardiovascular cycles representing over one year of implantation life at an average of 72 heartbeats per minute. EnduraTec recorded zero failures of the stent structure during visual inspection. According to Dr. Tom Troczynski, MIV Therapeutics' VP of coatings, test results confirm the company preliminary assessment of the bonding properties of the HAp coating. The results are rewarding for the company and validate its earlier expectations about the durability of the coating.

Medtronic Inc. (Minneapolis, Minn.) has started U.S. clinical trials for its Intercept™ epilepsy control system, the company's brain stimulation therapy that may reduce seizure rates in patients with epilepsy. Epilepsy is a condition that affects 2.3 million Americans. About one-third of these patients continue to experience seizures despite a wide range of treatment options. The trial uses existing technology to test whether bilateral stimulation of the anterior nucleus of the thalamus can safely and effectively reduce seizure frequency in patients with epilepsy. All patients in the trial will be implanted and monitored for 13 months following implant, with long-term follow-up until the device is approved. Patients in the active group, who will receive neurostimulation, will be monitored for a reduction in seizure rates compared to the control group, who will not receive neurostimulation during the double-blind phase. After the double-blind phase, all patients will receive neurostimulation. The therapy is designed to disrupt the circuits suspected of influencing epileptic seizures. The system provides bilateral brain stimulation using three implantable components: a neurostimulator (implanted in the chest), extensions (two small, insulated wires that are threaded from the neurostimulator to the head) and leads (electrodes that are implanted in the thalamus). The neurostimulator generates electrical pulses that are delivered directly to the brain by the extensions and leads. These pulses can be non-invasively adjusted by a clinician from a physician programmer and transmitted via telemetry to the implanted device. In addition, patients can activate additional stimulation when they sense an oncoming seizure through a hand-held programmer that resembles a remote control.

Exactech Inc. (Gainesville, Fla.) announced that it has received clearance from the Food and Drug Administration (FDA) to produce and market a new demineralized bone matrix (DBM) based human allograft bone paste that will enable the company to enter the spinal market. The material is based on a synthetic bioabsorbable polymer carrier technology previously licensed from **Genzyme Corp.** The company plans to begin marketing the new bone paste material, which it plans to manufacture and distribute, before the end of 2004.

Stryker Corp. (Kalamazoo, Mich.) was granted from the U.S. Food and Drug Administration (FDA) a Humanitarian Device Exemption (HDE) for the use of its patented human protein osteogenic protein-1 (OP-1) in revision spine surgery. The approved product, OP-1 Putty, is a combination of the OP-1 protein, a collagen carrier, and a handling excipient, which is wetted and then surgically implanted across the transverse processes of the posterior spine to promote fusion. OP-1 Putty is indicated for use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are

not feasible or are not expected to promote fusion. Examples of compromising factors include osteoporosis, smoking, and diabetes. This approval marks the second regulatory clearance for OP-1 in the United States following approval in 2001 of an HDE for difficult-to-heal fractures. HDE devices are defined by the FDA as those intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals per year in the United States. Commercial shipments of the OP-1 Putty are expected to begin in third-quarter 2004. Stryker is focused on the commercialization of OP-1, which, in addition to the U.S. approvals, is approved for the treatment of difficult-to-heal fractures in Australia, Europe, and Canada. For more information, please visit www.stryker.com.

Boston Scientific Corp. (Natick, Mass.) announced that it has received approval from the U.S. Food and Drug Administration (FDA) to market its Taxus™ Express2™ paclitaxel-eluting coronary stent system. The company plans to launch the product in the United States immediately. The company launched the Taxus system in Europe and other international markets in February of 2003, and is the leader in those markets today. The Express2 coronary stent system is known for its excellent deliverability and conformability.

South Korean Ministry of Health and Welfare said it will invest a total of 95 billion won (US\$80.75 million) this year for further development of the local biotechnology industry, an increase of 14 percent from 83.2 billion won in 2003. The announcement follows a recent scientific breakthrough by a Seoul National University team, which succeeded in creating human embryos through cloning and extracting embryonic stem cells for the first time in the world.

Driven by both personal and humane concerns, **Doug Melton**, Thomas Dudley Cabot Professor of Natural Sciences at Harvard and Howard Hughes Medical Institute, has derived 17 new lines of embryonic stem cells, which can, in theory, be coaxed into becoming any type of adult tissue from kidneys to spinal cords. He isolated the cells from excess fertilized eggs obtained from *in vitro* fertilization clinics with their owners' permission. The eggs are grown into embryos from which the stem cells are extracted before the embryos show any signs of life. The work was done with private funds because the U.S. government limits federal funding for such research to 64 lines of frozen cells already in existence.

During the past three years, **Duke** researchers exposed cells taken from human liposuction procedures to different cocktails of nutrients and vitamins and "reprogrammed" them to grow into bone, cartilage, fat, and nerve cells. At the time, they termed these cells adipose-derived stromal cells. However, as a result of the latest set of experiments, researchers are now confident that the majority of these cells are indeed truly adult stem cells that have the potential to be reprogrammed into traveling down multiple developmental paths. This is important, they said, because these cells could be a single, readily available source for creating new cells and tissues to treat disease. The results of the Duke study were presented March 8, 2004, at the 50th annual scientific meeting of the Orthopedic Research Society.

Continued on page 22

“Tissue Engineering”

Book Review

By Liisa Kuhn

Bernhard Palsson and Sangeeta Bhatia

Copyright 2004, Pearson Education, Inc., Pearson Prentice Hall, Upper Saddle River, NJ. 407 pages.

Cell-based therapies hold the promise to become major therapeutic modalities in the 21st century. To educate upcoming tissue engineers that will design and develop cell-based therapies, the authors have written one of the first tissue engineering textbooks specifically for undergraduate and graduate students. The authors provide a conceptual framework that covers the broad, wide spectrum of scientific engineering fundamentals inherent in tissue engineering. This includes basic biological sciences (cell biology, physiology, embryology, and wound healing); engineering fundamentals (fluid dynamics, transport phenomena, materials science, mechanics, and chemical kinetics); many clinical aspects (surgery and transplantation, immunology, pathology, radiology, and medicine); and various relevant biotechnologies (cell culture, cell separation, and gene transfer). Instructors will find this text to be a useful framework since it is amenable to augmentation based on their area of expertise and desired focus of a course in tissue engineering. The text is written primarily for senior bioengineering students or first-year graduate students, and it assumes a working knowledge of engineering fundamentals. In this spirit, the authors have provided a series of engineering-style homework problems and solutions to allow students to work through the concepts presented.

Tissue engineering is focused on the manipulation and design of human tissues to meet clinical needs. To facilitate the education of future tissue engineers, the authors have identified four basic areas that should be studied: quantitative cell and tissue biology, cell and tissue characterization, engineering methods and design, and clinical implementation. The text is correspondingly divided into these four parts. Tissue organization and the processes by which tissues develop and reorganize are introduced. The way in which cells interact with each other and the extracellular matrix are discussed. The basics of cell culture and cell and tissue characterization are covered. Genomic technologies are included along with conventional characterization tools. Approaches to cell separation and scale-up of cultivation processes are included. The basics of biomaterials are covered; however, since much material is available elsewhere on the use of biomaterials in tissue engineering, this text only covers the bare minimum on this topic. Conventional clinical approaches to tissue dysfunction are introduced to provide a comparison for novel tissue engineered medical products (TEMPs). Wound healing, immunology, and angiogenesis are also covered. Throughout the text, relevant time and length scales of physicochemical processes in cell biology and medicine are emphasized.

As a faculty member teaching a new course titled, “Biomaterials in Tissue Engineering,” the reviewer chose this textbook from among those available to use for the course. It has been easy to create course lectures from the book chapters. The abbreviated treatment of biomaterials made it easy to supplement by including journal club readings from the *Journal of Biomedical Materials Research* and a term project on biomaterial design. While initially excited to see that homework problems were included, it was found that the mathematics involved in most of

the problem solutions are far beyond the typical undergraduate biomedical engineer. The solution manual does not provide detailed enough solutions for these types of problems to use in class. However, this shortcoming with regards to the homework problems is small in comparison to the benefits of having a complete textbook for a tissue engineering course. To summarize, the authors have done an excellent job in writing a textbook on a diverse subject. Key subject areas within tissue engineering have been identified and are made student accessible.

Audience

Senior bioengineering students or first-year graduate students, medical students, traditional engineering students, faculty or students from biomedical engineering, material science, and biology.

Contents

Introduction

Part I Quantitative Cell and Tissue Biology

2. Tissue Organization

3. Tissue Dynamics

4. Morphogenesis

5. Stem Cells

6. Cellular Fate Processes

7. Coordination of Cellular-Fate Processes

Part II Cell and Tissue Characterization

8. High-Throughput Biological Data

9. Cell and Tissue Properties

10. Cell and Tissue Culture

11. Gene Transfer

Part III Engineering Methods and Design

12. Time Constants

13. Scaling up for Ex Vivo Cultivation

14. Cell Separation

15. Biomaterial Scaffolds

16. Tailoring Biomaterials

Part IV Clinical Implementation

17. Conventional Clinical Approaches to Tissue Dysfunction

18. Host Integration: Interacting Cell-Fate Processes

19. Producing Tissue-Engineered Therapies

Appendix A: Tissue Engineering Study Problems

Chapter 15. The Development of Coralline Porous Ceramic Bone Graft Substitutes

Chapter 16. Clinical Issues in the Development of Bone Graft Substitutes in Orthopedic Trauma Care

Chapter 17. Issues Involving Standards Development for Synthetic Material Bone Graft Substitutes

Industry Insights

(Continued from page 16)

industry by developing silicone materials such as pressure sensitive adhesives and gels for transdermal drug delivery systems, coatings and lubricants for needle and syringe applications, and elastomer systems that can be extruded or molded to elute or deliver drugs to locations within the body. NuSil is committed to being a unique company that focuses on developing custom materials for our customer's exact applications, no matter how demanding or different they may be.

In fact, NuSil Technology recently underwent a large renovation to its facilities to expand its ability and capacity to perform research and development projects for next generation silicone materials in the healthcare industry.

Expanding to Suit Customer Needs

NuSil Technology has recently added new offices in the marketing and sales department to improve communication with its customers so it can properly identify what customer needs are and effectively provide innovative material solutions essential to the customer's success. In addition, expansion to NuSil's research and development and product development departments improves its operations and modernizes its manufacturing capabilities. This expansion includes the addition of more laboratories, mixing and packaging areas, and controlled environment areas for clean-room type manufacturing. NuSil also doubled the power in its building to support new, advanced manufacturing equipment. In the end, what this expansion means is NuSil can provide material solutions for its customers as their problems arise. Not only can NuSil rapidly develop new products on short notice, but its facilities allow it to address even the smallest of customers' needs.

Expertise with Silicone Technology

NuSil Technology is focused on silicone technology. It has spent over twenty years developing and optimizing silicone formulations for various applications for different industries. During this time, NuSil has amassed a formidable knowledge of silicone chemistry and can therefore produce silicone materials that can be customized to very specific applications. For example, cure chemistries can vary from addition cure systems to room temperature vulcanization cure systems. Polymer functionalities can include dimethyl, trifluoropropylmethyl, and diphenyl, which offer substantially different material properties. Reinforcing filler functionalities can also affect the performance of an elastomer in certain applications. NuSil Technology can utilize this knowledge quickly and efficiently to provide materials that respond and interact differently with various agents.

The range of products available to the health-care industry, including polymers, gels, foams, and elastomers, can address many design configurations. When combining these factors with NuSil's recent R&D expansion, it adds up to the ability to rapidly prototype materials for even the most challenging application. This has been the reason that leading health-care companies choose to do business with NuSil Technology.

Advances in Tissue Engineering

Rice University

**Center for Excellence in Tissue Engineering
Institute of Biosciences and Bioengineering,
Department of Bioengineering
Houston, Texas**

August 11-14, 2004

Twelfth annual conference with leading scientists from Rice University, the Texas Medical Center, industry and other institutions on advances in the science and technology of tissue engineering. Be informed on the latest technology in the world of patient-specific therapeutics, from transplantation of cells and tissues to artificial organs.

For biomaterialists, biomedical engineers, physicians, technical managers and others involved in research in the areas of:

- **Vascular surgery and medicine**
- **Drug delivery and targeting**
- **Organ and cell transplants**
- **Artificial internal organs**
- **Applied immunology**
- **Orthopaedic surgery**
- **Plastic surgery**
- **Reconstructive surgery**
- **Cell and tissue culture**
- **Gene Therapy**



RICE

CONTACT: Carol Lofton

**Rice University
Center for Excellence in Tissue
Engineering, MS-142**

P.O. Box 1892

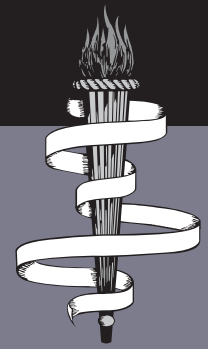
Houston, Texas 77251-1892

713/348-4204; Fax: 713/348-4244

E-mail: cdl@rice.edu

Internet: <http://tissue.rice.edu/>

Biomaterials in Regenerative Medicine: The Advent of Combination Products



PRELIMINARY PROGRAM

Abstracts for oral and poster presentations highlight important advances in fundamental and applied biomaterials science and clinical research in biomaterials in the context of regenerative medicine. Sessions will be organized from the Program Topics listed below .

PRELIMINARY SCHEDULE OF EVENTS

SATURDAY, OCTOBER 16, 2004

1:30 PM - 3:00 PM	Plenary Session
3:00 PM - 4:00 PM	Poster Session
4:00 PM - 5:30 PM	Oral presentations (4 concurrent sessions)

SUNDAY, OCTOBER 17, 2004

8:00 AM - 10:00 AM	Plenary Session
10:00 AM - 11:00 AM	Poster Session
11:00 AM - 12:00 PM	Oral presentations (4 concurrent sessions)
12:00 PM - 1:30 PM	Lunch
1:30 PM - 3:00 PM	Oral Presentations (4 concurrent sessions)
3:00 PM - 4:00 PM	Poster Session
4:00 PM - 5:30 PM	Oral Presentations (4 concurrent sessions)

MONDAY, OCTOBER 18, 2004

8:00 AM - 9:30 AM	Plenary Session
9:30 AM - 10:30 AM	Poster Session
10:30 AM - 12:00 AM	Plenary Session

Program Topics

- 1. Frontiers in Combination Products**
 - Combination products in specific clinical areas (e.g., neural, cardiovascular, orthopaedic, ophthalmic, etc.)
 - Biology of regeneration, repair, healing
 - Nanotechnology in regenerative medicine
 - Regulatory issues associated with combination products
- 2. Novel Materials**
 - Synthesis strategies of nanostructures
 - Self-assembled nanostructures and materials
 - Protein-biopolymer nanodevices
 - Biomimetic materials
- 3. Material-Cell Interactions**
 - Biomaterial and soluble/insoluble cues for cell phenotype
 - Stem and progenitor cell delivery in regenerative medicine
- 4. Material-Drug/DNA Interactions**
 - Materials for DNA delivery
 - Drug/DNA/material interactions
 - Drug delivery systems in regenerative medicine
 - Material processing strategies to preserve protein/DNA structure/function
- 5. Host Response**
 - Validation of biological models
 - In vitro/in vivo/clinical correlations
 - Materials as agonists of biological response
 - Functional integration of combination products
 - Minimally and noninvasive assessment

Industry/FDA Forum

“Translation from Discovery to Development”
David Feigl
Director, Centre for Devices and Radiological Health, FDA

Invited Speakers

- Julia Babensee** • Georgia Institute of Technology
- Chris Chen** • John Hopkins University
- David Feigl** • Centre for Devices and Radiological Health, FDA
- Jeffrey Hubbell** • Ecole Polytechnique Federale Lausanne
- Bob Langer** • Massachusetts Institute of Technology
- Ann Marie Schmidt** • Columbia University
- Duncan Stewart** • St. Michael's Hospital, Toronto
- Sam Stupp** • Northwestern University

The Role...

(Continued from page 11)

synthetic physical hydrogels,^{3,5} concentrated cell pellets,¹⁴ and collagen solutions.¹⁵ Clearly, much improvement of the current biomaterials used as bioinks is still needed. Optimizing the rheological and surface properties of inks, and designing printers optimized for these properties, will improve cell density of the printed constructs and the speed at which tissues may be manufactured. Incorporating controlled-release particles loaded with growth factors or signaling molecules into bioinks opens interesting avenues for combining stem cell therapies with cell printing. Combining minimally invasive approaches with cell printing may also lead to *in vivo* tissue repair.¹⁶ Many of these avenues still remain to be explored and may lead to many interesting findings along the way.

The combined approach, using free-form fabrication techniques aided by the inherent ability of cells and tissues to self-assemble, is an excitingly new method to construct tissues layer-by-layer. The success of this method may call for a paradigm shift towards the generation of functional tissue by manipulating the balance between cell growth, maturation, and fusion using engineering principles. Most of all, the continued joint efforts of developmental biologists, material scientists, and engineers in the area of cell printing may lead to “real-time” tissue construction, a cornerstone to making the dream of regenerative medicine come true.

1. R. A. Foty, *et al. Development* 122, 1611-1620 (1996).
2. Bhatia, S.N. (1999) *Microfabrication in Tissue Engineering and Bioartificial Organs*. Kluwer.
3. T. Boland, *et al. Anat. Rec.* 272A, 497–502 (2003).
4. Forgacs *et al. Proc. Natl. Acad. Sci. USA* 101, 2864-2869 (2004)
5. T. Xu *et al. Biotechnol. Bioeng.* 85(1), 29-33 (2004).
6. T. Xu, J. Jin, C. Gregory, J. J. Hickman, T. Boland *Biomaterials submitted*
7. D.W. Hutmacher *Biomaterials* 21, 2529-2543 (2000).
8. S. Yang *et al. Tissue Eng.* 8, 1-11. (2002).
9. M. N. Cooke *et al. J. Biomed. Mater. Res.* 64B, 65-69 (2003).
10. G. Vozzi *et al. Biomaterials* 24, 2533-2540 (2003).
11. R. Landers *et al. Biomaterials* 23, 4437-4447 (2002).
12. E. Sachlos, *et al. Biomaterials* 24, 1487-1497 (2003).
13. C. Wilson, T. Boland *Anat. Rec.* 272A, 491 -496 (2003).
14. V. Mironov *et al. Trends Biotechnol.* 21, 157-161 (2003)
15. E. A. Roth *et al. Biomaterials* 25, 3707-3715 (2004).
16. K. J. L. Burg, T. Boland *IEEE Engineering in Medicine and Biology*, 22, 84-91 (2003)



LET US LEAD THE WAY.

Why struggle through unfamiliar territory trying to discover the right surface modification pathway for your medical device? At SurModics we've been there before—many times.

We can guide you through the product development cycle more quickly, from concept, through regulatory, to launch—and beyond.

SurModics is the leader with the know-how, the experience, and the track record:

Products PhotoLink® surface modification and our other technology platforms provide simplicity, flexibility, and performance.

People Our experts in a variety of disciplines can help steer you down the quickest path to market success. From chemistry through surface characterization and regulatory assistance, SurModics leads the way.

Partners Our capabilities and proven performance make us the best partner for all your coating needs. With SurModics you can rest assured that we will be there for you now and in the future.

It just makes sense to let SurModics lead the way.

**SurModics®**

SurModics, Inc., 9924 West 74th Street,
Eden Prairie, MN 55344
952/829-2701
www.surmodics.com

PhotoLink® is a registered trademark of SurModics, Inc.
© 2001 SurModics, Inc.

Faster, Easier Online Submission and Peer Review System for JBMR Authors

Journal of Biomedical Materials Research, Part A (JBMR) is pleased to offer a web-based system for manuscript submission and peer review. JBMR's online submission site can be found at: <http://jbmr-wiley.manuscriptcentral.com/>

Online submission and peer review is beneficial for authors not only because it expedites publication, but because it allows authors to monitor the progress of their manuscripts throughout the review process simply by logging onto the system. Submitting your manuscript to the JBMR is now easier than ever!

Online help is available to you at all times during the process. If you have any questions, do not hesitate to contact us at edsupport@wiley.com

Online submission was launched for *Part B: Applied Biomaterials* in June 2003, which has resulted in almost a four-month reduction in editorial processing time. The acceptance-to-online-publication time for

JBMR articles has been reduced by four months between 2003 and 2004. With the introduction of online submission, we expect the editorial processing time to be reduced further. We continue to endeavor to further decrease the publication time of your articles online.

REMINDER TO ALL SFB MEMBERS!

Members of the Society For Biomaterials can access the Journals online with registration at www.interscience.wiley.com/societies/sbm. Please contact Lucy Woo at Lwoo@wiley.com for registration instructions. SFB members also receive a discounted rate on article reprints.

JBMR BACK CONTENT AVAILABLE ONLINE SOON!

Content going back to Volume 1, Issue 1, 1967 of *Journal of Biomedical Materials Research, Part A* and Volume 1, Issue 1, 1990 of *Part B: Applied Biomaterials* will be available as part of the Materials Science Backfile Collection, to be launched online in October 2004 via Wiley InterScience, or <http://www.interscience.wiley.com>

BioInk

(Continued from page 17)

Enzo Biochem Inc. (Farmingdale, N.Y.), a leading biotechnology company specializing in gene identification and genetic and immune regulation technologies for diagnostic and therapeutic applications, announced early interim results of its Phase II randomized double-blind study of Alequel™, the company's investigational therapeutic modality for the management of Crohn's disease. Seventy-one percent of treated subjects achieved clinical remission, compared with 25 percent of subjects who received the placebo. Alequel, a complex of autologous colon-derived antigens administered orally, was developed by Enzo based on the company's proprietary immune regulation platform. Crohn's disease is a chronic, serious inflammatory disease of the gastrointestinal tract that affects at least one-half million Americans, according to the Crohn's & Colitis Foundation of America.

A new technology, called **electroperturbation**, which exposes cells to electric pulses just tens of nanoseconds long, may lead to improved methods of treating diseases such as cancer and leukemia, according to researchers in the USC Viterbi School of Engineering. The pulses are so brief and intense that they pass virtually undetected through the outer membrane of the cell without damaging it. But these fast-rising pulses pack such a powerful punch to the intracellular structures of the cell that they can dramatically change its biochemical balance, or trigger apoptosis. Initial observations have shown that the nanosecond pulses produce bursts of calcium inside cells within milliseconds after the pulse is delivered. Calcium ions serve as regulatory messengers that can alter specific intracellular structures.

Researchers at **New York University School of Medicine** have found that a protein called APC plays a role in controlling a web of molecular interactions that can transform normal cells into cancerous ones. The finding may provide new possibilities for devising cancer therapies that target this protein. APC puts the brake on cell growth. The study sheds light on the relationship between APC and two other proteins involved in the development of cancer—Skp2 and p27. APC controls the abundance of Skp2, according to the study. Skp2 determines whether a cell will begin the process of making copies of itself, and it was previously tied to p27.

Advanced Medical Technology Association (AdvaMed) commends the House and Senate for passing the Medical Devices Technical Corrections of 2003 (S. 1881), which makes technical and clarifying corrections to ensure that the landmark Medical Device User Fee Modernization Act (MDUFMA) operates as intended. The bill goes to President Bush for signing.

Two of the key changes are:

- A critical amendment to the third party inspection program that if unchanged would render the program inoperable. Existing MDUFMA language requires companies to certify that foreign countries recognize a Food and Drug Administration inspection and market their products in a foreign country that recognizes the third party inspector. The correction permits companies to meet one or both of these requirements.
- The legislation also creates an 18-month moratorium on implementation of section 301 of MDUFMA. Section 301 of MDUFMA requires all manufacturers to place their name or brand on their device, if feasible. The moratorium provides the Congress and FDA more time to consider the implications of 301 and any possible change in policy.

In one of the largest randomized studies to assess the effectiveness of **acupuncture**, the ancient Chinese treatment, scientists found it worked better than conventional treatment alone. The scientists compared acupuncture plus standard treatment to normal therapy alone in 401 patients in England and Wales who suffered from headaches several days each week. Initially there was not much difference between the two groups, but at the end of the year-long trial the scientist noticed a big change. Patients receiving acupuncture had 22 fewer days of headaches per year, used 15 percent less medication, made 25 percent fewer visits to their family doctors, and took fewer days off sick than the other group. Their research is published online by the British Medical Journal.

2004 Special Interest Group Officers

(Continued from page 9)

Secretary-Treasurer

Debra Wright
Michigan Technological University
Department of Biomedical Engineering
Houghton, MI
Phone: (906) 487-1989
Fax: (906) 487-1717
wright@mtu.edu

Program Chair

Jeremy Gilbert
Syracuse University
Department of Bioengineering
Syracuse, NY
Phone: (315) 443-2105
Fax: (315) 443-9175
gilbert@ecs.syr.edu

Protein and Cells at Interfaces Chair

Andres Garcia
Georgia Institute of Technology
Atlanta, GA
Phone: (404) 894-9384
Fax: (404) 385-1397
andres.garcia@me.gatech.edu

Vice Chair

Thomas Webster
Purdue University
West Lafayette, IN
Phone: (765) 494-2995
Fax: (765) 494-1193
twebster@ecn.purdue.edu

Secretary/Treasurer

Christopher Siedlecki
Pennsylvania State University
College of Medicine
Hershey, PA
Phone: (717) 531-5716
Fax: (717) 531-4464
csiedlecki@psu.edu

Surface Characterization and Modification Chair

Erika Johnston
Genzyme Corp.
Cambridge, MA
Phone: (617) 591-7180
Fax: (617) 374-7225
erika.johnston@genzyme.com

Secretary Treasurer

Anna M. Belu, PhD
Surface Characterization Specialist
Medtronic Inc.
Minneapolis, MN
Phone: (763) 505-4586
Fax: (763) 505-4712
anna.belu@medtronic.com

Tissue Engineering Chair

Ann Schmierer
Georgia Institute of Technology
Atlanta, GA
Phone: (404) 385-2259
Fax: (404) 894-2291
ann.schmierer@ibb.gatech.edu

Vice-Chair

Diane Hoffman-Kim
Brown University
Providence, RI
Phone: (401) 863-9395
Fax: (401) 863-1753
diane_hoffman-kim@brown.edu

Secretary-Treasurer

Harihara Baskaran
Case Western Reserve University
Cleveland, OH
Phone: (216) 368-1029
hari@cwru.edu

Program Chair

Dale Feldman
University of Alabama at Birmingham
Dept. of Biomedical Engineering
Birmingham, AL
Phone: (205) 934-8426
Fax: (205) 975-4919
dfeldman@eng.uab.edu

Forum Reporters and Appointees

Biomaterials Availability and Policy

Forum Reporter
Karen Masterson
Thoratec Corp.
Rancho Cordova, CA
Phone: (916) 852-2847
Fax: (916) 638-3216
karen.masterson@thoratec.com

Biomaterials Education Assistant Program Chair

Mike Shaw
Rockwell Scientific
Thousand Oaks, CA
Phone: (805) 493-3296
mshaw@clunet.edu

Forum Reporter

Jeffrey M. Karp
Institute of Biomaterials & Biomedical Engineering
University of Toronto
Ontario, Canada
Phone: (416) 952-3981
Fax: (416) 978-4317
jeff.karp@utoronto.ca

Cardiovascular Biomaterials

Forum Reporter
Julie Trudel
Medtronic Vascular
Santa Rosa, CA
Phone: (707) 543-0209
Fax: (707) 566-1408
julie.trudel@medtronic.com

Web Master

Nijesh Ingle
North Carolina State University
College of Textiles
2401 Rea Dr
Raleigh, NC
Phone: (919) 601-2026
nplinge@unity.ncsu.edu

Cell/Organ Therapies

Forum Reporter
Shelly Sakiyama-Elbert
Washington University
Department of Biomedical Engineering
St. Louis, MO
Phone: (314) 935-7556
Fax: (314) 935-7448
sakiyama@biomed.wustl.edu

Implant Pathology

Forum Reporter
Jason Emmanuel
WL Gore Associates
Flagstaff, AZ
Phone: (928) 864-3855
Fax: (928) 864-3860
jemmanua@wlgore.com

Ophthalmologic Biomaterials

Forum Reporter
Yoseph Yaacobi
Alcon Laboratories
Fort Worth, TX
Phone: (817) 551-3047
Fax: (817) 568-6994
yoseph.yaacobi@alconlabs.com

Student Program Chair

Margaret Kayo
University of Florida
Gainesville, FL
Phone: (352) 392-7661
Fax: (352) 392-3771
mkayo@mse.ufl.edu

Orthopaedic Biomaterials Student Recognition Coordinator

Debra Wright
Michigan Technological University
Department of Biomedical Engineering
Houghton, MI
Phone: (906) 487-1989
Fax: (906) 487-1717
wright@mtu.edu

Student Recognition Coordinator

Jeremy Gilbert
Syracuse University
Department of Bioengineering
Syracuse, NY
Phone: (315) 443-2105
Fax: (315) 443-9175
gilbert@ecs.syr.edu

Forum Reporter

Brunda Ray Kattakola
University of Kansas
Lawrence, KS
Phone: (785) 841-9212
kattakol@ku.edu

Student Officer

Ayyana Chakravartula
University of California, Berkeley
Berkeley, CA
Phone: (510) 643-9095
Fax: (510) 642-5599
ayyanac@newton.berkeley.edu

Surface Characterization and Modification

Forum Reporter
Lara J. Gamble, PhD
NESAC/BIO Research Coordinator
University of Washington
Seattle, WA
Phone: (206) 616-4173
gamble@nb.engr.washington.edu

Tissue Engineering Assistant Program Chair

Subramanian Gunasekaran
Encoll Corp.
Fremont, CA
Phone: (510) 795-8581
Fax: (510) 795-7571
guna@encoll.com

Forum Reporter

Ranee Stile
Baxter Healthcare
Round Lake, IL
Phone: (847) 270-5176
Fax: (847) 270-3969
anee_stile@baxter.com

Forum Reporter

Guigen Zhang
University of Georgia
Driftmier Engineering Center
Athens, GA
Phone: (706) 583-0994
Fax: (706) 542-8806
gzhang@engr.uga.edu

Community Calendar

Regenerate 2004: Tissue Engineering the Human Body

June 9-12, 2004
Westin Seattle
Seattle, WA
(412) 235-5128
pcantini@ptei.org

Controlled Release Society 31st Annual Meeting & Exhibition

June 12-16, 2004
Hawaii Convention Center & Hilton
Hawaiian Village
Honolulu, Hawaii
www.controlledrelease.org

AO Research Institute ECM V: The Cell Biomaterial Reaction

June 28-30, 2004
Congress Centre
Davos, Switzerland
www.aofoundation.org

Materials & Processes for Medical Devices Conference & Exposition

August 23-25, 2004
Radisson Riverfront Hotel
St. Paul, Minnesota
www.asminternational.org

American Society for Bone and Mineral Research 26th Annual Meeting

October 1-5, 2004
Washington State Convention and
Trade Center
Seattle, WA
(202) 367-1161
asbmr@dc.sba.com
www.asbmr.org

BMES 2004 Annual Fall Meeting

October 13-16, 2004
Wyndham Franklin Plaza Hotel
Philadelphia, PA
(301) 459-1999
www.bmes.org

Society For Biomaterials Symposium on Biomaterials in Regenerative Medicine

October 16-18, 2004
Wyndham Franklin Plaza Hotel
Philadelphia, PA
www.biomaterials.org

The 7th New Jersey Symposium on Biomaterials Science

October 20-22, 2004
Hyatt Regency
New Brunswick, NJ
www.njbiomaterials.org

Surfaces in Biomaterials Foundation Annual Symposium & Exhibition

October 27-29, 2004
Wyndham Baltimore Inner Harbor
Baltimore, MD
www.surfaces.org

Osteoarthritis Research Society International 2004 World Congress

December 2-5, 2004
Hyatt Regency Chicago
Chicago, IL
www.oarsi.org



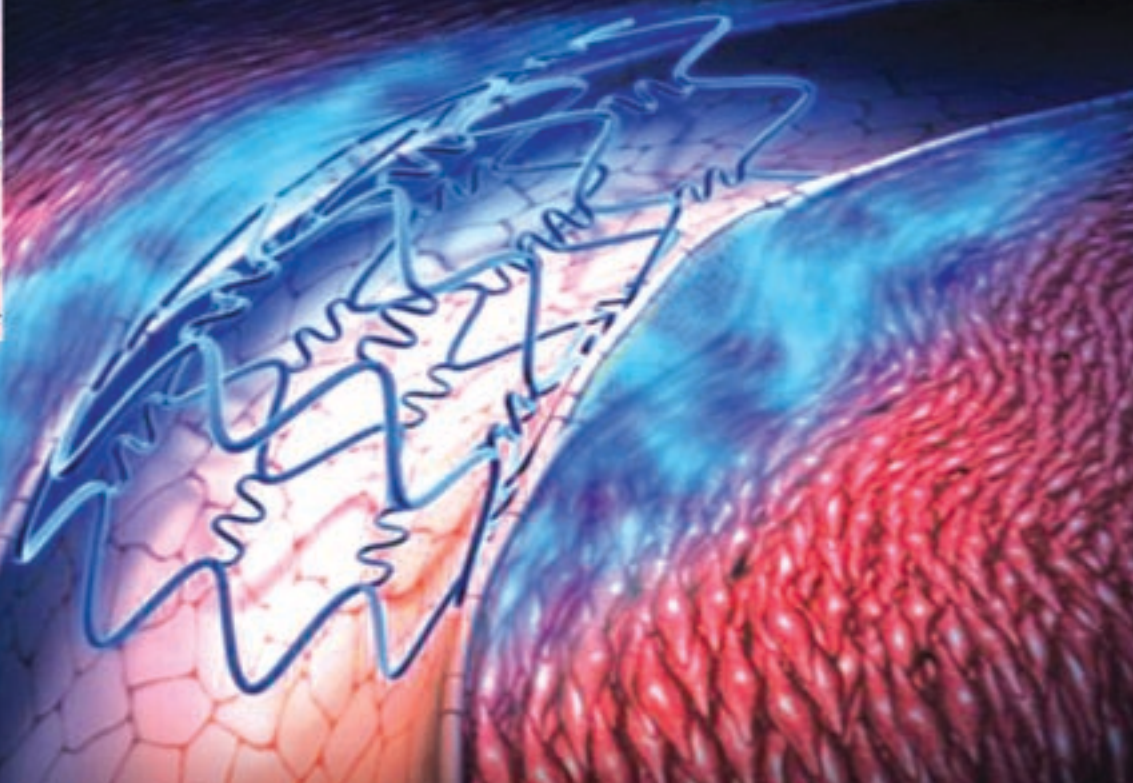
October 16-18, 2004 • Wyndham Philadelphia at Franklin Plaza • Philadelphia, PA



Society for Biomaterials

Biomaterials in Regenerative Medicine: The Advent of Combination Products

A special symposium held in conjunction with the Biomedical Engineering Society 2004 Fall Meeting



Deadline for Abstracts: June 4, 2004

Abstract categories include:

- Frontiers in combination products
 - Material-Cell interactions
 - Material-drug/DNA interactions
- Host Response
- Novel materials
- Industry/FDA forum "Translation from Discovery to Development" (Chair: Robert Nerem)

Invited speakers include:

- Julia Babensee
- Chris Chen
- Jeffrey Hubbell
- Bob Langer
- Ann Marie Schmidt
- Duncan Stewart
- Sam Stupp

Log on to **www.biomaterials.org** for information about submitting your abstract;

Or contact SFB office at:

Society for Biomaterials • 17000 Commerce Parkway, Suite C • Mount Laurel, NJ 08054

Phone: 856-439-0826 • Fax: 856-439-0525

Form Follows Function

In the past, biomedical researchers have been forced to use testing machines that were oversized for their needs and designed for other industries. Now, with ElectroForce® technology, EnduraTEC gives you a new performance standard for the demanding requirements of biomedical research. You just plug it in and go. Form does follow function.

7th World Biomaterials Congress
Sydney - May 2004
Stop by our Booth #6
and Register to Win a
BOSE
Wave Radio!



Tissue Testing



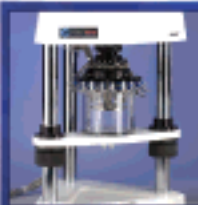
Spinal Disk Wear



Stent/Graft Testing



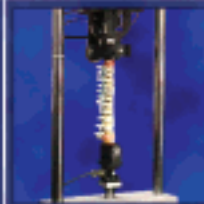
Bone Screw Testing



Multi-wire Fatigue Testing



Restorative Dentistry



Spinal Simulation



Prosthetic Limb Testing



The EnduraTEC ITEMS BioReactor™ Series
Introducing the first intelligent, commercial
BioReactor for Functional Tissue Engineering



5610 Rowland Road, Minnetonka, Minnesota 55343 USA • 952.278.3070
Koelnerstrasse 10, 65760 Eschborn, Germany • 49 6196 400.943
www.enduratec.com • electroforce@enduratec.com