SurFACTS in Biomaterials

May–June 2009 Volume 14 Issue 3

Fracture Putty for Bone Injuries Gets Government Backing

From Northwestern University

Northwestern University is part of a multi-institution initiative to produce "fracture putty," a biocompatible compound designed to mend serious leg fractures, such as those suffered by soldiers.

The two-year research project is funded by the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense.

The research team's goal is to develop a putty-like material that could be used to regenerate bones shattered by roadside bombs or other explosive devices. This type of injury, called a non-union fracture, generally will not heal in a timely manner and can lead to amputation.

Samuel Stupp, director of the Institute for BioNanotechnology in Medicine at Northwestern (IBNAM), is leading the University's portion of the research. He and Ramille Capito, a research assistant professor in Stupp's lab, will use bioactive peptide amphiphile (PA) molecules developed at IBNAM as the major bioactive component of this fracture putty to make bone regenerate.

"New technology is needed to treat in the field the devastating tissue injuries sustained by soldiers that often lead to amputation," said Stupp, Board of Trustees Professor of Materials Science and Engineering, Chemistry and Medicine. "The extremely demanding requirements of such technology could revolutionize many aspects of regenerative medicine in the civilian population."

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From the Editor

Government Support of Technology Development, Stimulus Funding through the Valley of Death, and Academic/Industrial Partnerships

In the last issue of SurFacts I discussed the importance of the SBIR re-authorization bill. The SBIR or Small Business Innovation Research program is a federal grants program that directs a small percentage of funding from all federal granting agencies, including the National Institutes of Health, the Department of Defense and the National Science Foundation, to support small business R&D. As discussed therein, the SBIR, and the related small business technology transfer (STTR) program, have been extremely important to medical device businesses by supporting the R&D efforts of many of our early stage member companies, and indirectly many of our large companies since many of our large companies have acquired SBIR-developed technologies through acquisition or license. As also discussed in this prior editorial, the current reauthorization of the SBIR bill will end July 31, 2009. As I am writing this in mid June, the House is now actively considering the reauthorization of the SBIR program. If you have not yet contacted your elected representatives in support of 2009 S. 177, now is an excellent time to do so now.

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What's Inside

From the Editor
Continued

By Steven L. Goodman, Ph.D., 10H Technology Corporation

In addition to SBIR funding for small business innovation, the 2009 American Recovery & Reinvestment Act (ARRA) provides funds for many "Stimulus" grant programs that are suitable for our members. Many of these are especially suitable for our US owned small businesses, which are as defined by the government as <500 employees. However, if you are from a larger firm, or from academia, you should also take note of these programs since, 1) you pay for them through your taxes, and 2) the companies that apply for and better yet receive these funds are an excellent source of innovative new technologies for your collaborative R&D efforts, commercialization partnering, licensing and/or for acquisition.

The National Institutes of Health through its funding support of biomedical research and technology is, of course, highly relevant to our membership. The American Recovery & Reinvestment Act recently provided $8.2 billion in extramural funding to the NIH. (ARRA also provided lesser levels of stimulus money to other federal agencies that support medical device and instrumentation development including the Department of Defense and the National Science Foundation.) Certainly this kind of money has the potential to stimulate at least a few firms developing new medical devices, materials and instruments of relevance to SurFacts readers.

The first NIH program funded by ARRA was a spectacular success – or at least the interest in this program was spectacular. This was the Challenge Grant program that is intended to "support US institutions and organizations proposing novel research in areas that address specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods that would benefit from an influx of funds to quickly advance the area in significant ways." The good news was that NIH received some 20,000 proposals to this program by its 27 April submission deadline. Raynard S. Kington, acting NIH director stated, "We issued the Challenge Grant Request for Applications and received the largest response in our history…" The submission volume, in fact, overwhelmed the Grants.gov online submission system. The bad news, if you submitted, is that this program will only fund about 200 proposals. Thus, the odds of receiving funding are 200/20,000, or only 1%. This is more like the lottery than other NIH funding programs where the statistical probability is generally in the 10% to 20% range. This is indeed bad news for many medical device firms, including several I worked with that submitted proposals.

Clearly, there is substantial demand for government funding for technology innovation. This certainly also tells us something about the nature of innovation. Innovation requires money! Recognizing this need, and with ARRA funding in hand, the NIH has recently announced some additional programs. One that is especially relevant to our membership addresses the funding gap between promising research and development and transitioning to the market, or as some call it, including the NIH, "The Valley of Death." This new initiative—with quite a name—is the Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) program, and "is intended to provide funding for projects that have demonstrated proof-of-principle, and that now need to scale up toward ultimate commercialization of products or services that will improve human health." Of particular note to the raison d'être of the Surfaces in Biomaterials Foundation and the spirit of our BioInterface meetings, this NIH program explicitly "aims to foster partnerships among a variety of research and development (R&D) collaborators working toward these aims."

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SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

Art Coury Honored as Distinguished Member of Surfaces in Biomaterials Foundation

By Carl Turnquist, Genzyme; Past President, SIBF

On April 26, 2009, Arthur J. Coury (Genzyme, retired) joined a small, select group of Surfaces in Biomaterials Foundation members when he was elevated to Distinguished Member status. The presentation was made in the South End at a lovely restaurant near Art's home in Boston. Attending were Judy Howie (Art's wife), Jan Turnquist (my wife), Peg Palmer (Surfaces Solutions Laboratories Inc., and Chair of the Applied Technology Workshop session at BioInterface 2009), Art and myself. It was a festive evening and offered a wonderful opportunity for each of us to "catch up" on the latest news from the others. The evening was capped by Art conducting a brief historic tour of the South End.

There are two others who also hold this special membership (based upon their special contributions to the Surfaces group). The first awardee is Paul Valint (formerly of Bausch and Lomb) and the second is Jim Powell (formerly of SurModics). The purpose of this special membership class is to encourage continued participation in Surfaces by waiving registration fees for these members. As a member of the Surfaces Board of Directors, I hope to continue the strong relationships that we have all had with these members.

A plaque will be displayed at the Foundation's annual BioInterface Symposia to appropriately honor these special members.

Art Coury and Carl Turnquist

Judy Howie and Art Coury

L to R: Jan Turnquist, Carl, Art, Judy and Peg Palmer

First Use in Coronary Patients of a Combined Near-Infrared Spectroscopy and Ultrasound Imaging Catheter

From InfraReDx, Inc.

InfraReDx, Inc. announced the first use in patients of a novel coronary catheter that uses both light and sound to image coronary plaques. Working on a team led by Dr. Patrick Serruys, Dr. Martin van der Ent performed the procedures on May 11, 2009 in patients undergoing coronary angiography at the Thoraxcenter.

The combination catheter provides the benefits of both IVUS and NIRS imaging in a single study of the artery. IVUS is a well-established technique that is in common use to quantify the degree of narrowing produced by a plaque, the size of the artery and the adequacy of stent expansion. NIRS is a novel technique recently cleared by the FDA for the identification of lipid core plaques, the structures suspected to cause most heart attacks and complicate stenting procedures.

Prof. Serruys stated that, "The composition of atherosclerotic plaques is important in assessing the likelihood that they will cause cardiovascular events. This novel device provides composition on top of anatomy and will play a pivotal role in interventional cardiology, first in clinical trials and further on in treatment planning in individual patients."

The Biomedical Engineering Department of the Thoraxcenter, led by Prof. Dr. Ton van der Steen, provided expertise essential to the addition of IVUS to the NIRS system.

"In order to determine both composition and structure of an atherosclerotic plaque, a combination catheter is necessary," says van der Steen.

James E. Muller, M.D., cardiologist, co-founder and CEO of InfraReDx stated that, "The addition of IVUS to our FDA cleared LipiScan(TM) catheter provides a novel tool that we believe will assist physicians with the complex decisions they face in the management of patients with coronary artery disease."

Defining a Structure Activity Relationship Between Material Composition and Biological Response: Utility in Combination Device Development

By Carol Sullivan, Medtronic CardioVascular

It is well established that biomedical devices serve to alleviate conditions for which they are implanted. Complications potentially arise post implant from adverse reactions to biomaterial of an inflammatory and/or thrombotic nature. In order to minimize these complications, analysis of the surface properties of biomedical materials and the biological effect they elicit pre-implantation is of paramount importance for successful combination device development.

In the case of drug eluting stents (DES), the polymer coating plays an essential role in controlling local delivery of drug from the stent platform. However, these synthetic coatings have been postulated to elicit inflammatory and/or thrombotic responses in the arterial wall. Therefore, we are developing a portfolio of cell based in vitro assays to measure these adverse events in an attempt to provide a rational scientific basis for the development of next generation combination devices. Additionally, we are looking at a number of analytical methods ranging from detailed and elegant Raman spectroscopy to more simplistic contact angle measurements to understand the correlation between biomaterial surface properties and the resulting biologic responses. Herein we provide a brief description of our approach to identify links between polymer chemical composition and biocompatibility as measured in vitro, by cellular inflammatory response to various polymers and polymer blends.

Polymer induced inflammation was evaluated in a novel in vitro assay system developed by Medtronic in which activated inflammatory cells were exposed to polymer and determinations of cell adhesion were taken. Monocyte adhesion has been shown to induce local inflammation as well as promote vascular cell proliferation factors contributing to in stent restenosis in vivo (Rogers et al, Arter.Thromb.Vasc. Biol. 1996). Additionally, we evaluated polymers and their potential to initiate the Tissue Factor (TF) coagulation pathway implicated in late stent thrombosis. Tissue factor, a transmembrane glycoprotein, is the principal initiator of the extrinsic coagulation pathway and is considered to play an important role in mediating arterial thrombosis. Under non-stimulated conditions, the arterial walls express negligible or low levels of TF. However, levels of TF are greatly increased in sites of inflammation or vascular injury.

A key consideration for biomaterial sample analysis is that the material mimics as closely as possible that which is utilized on the device being implanted. For the purpose of this discussion, surface is defined as the area of material which interfaces with cells such as polymer coatings utilized in DES. We developed a number of methods to assess inflammatory cell interactions with polymer surfaces, cell mediated inflammatory cell adhesion, and the effects of polymer coatings on vascular cell activation (Fig. 1).

Various polymers, chemical compositions of which are similar to commercially available DES, were coated onto 96-well microplates or onto bare metal stents. Relative hydrophilicities of polymer surfaces were determined through contact angle measurements and surface analyses. The polymeric surfaces were incubated with human monocytic (PMA treated U937) and their inflammatory activation and adhesion was evaluated via Real-time-based gene profiling and inflammatory cell adhesion assays. In addition, the expression and activation of the pro-thrombotic gene, Tissue Factor, was assessed.

Within the polymeric surfaces that have been evaluated, we have observed a consistent correlation between polymer relative hydrophobicity, as measured via contact angle, and the inflammatory

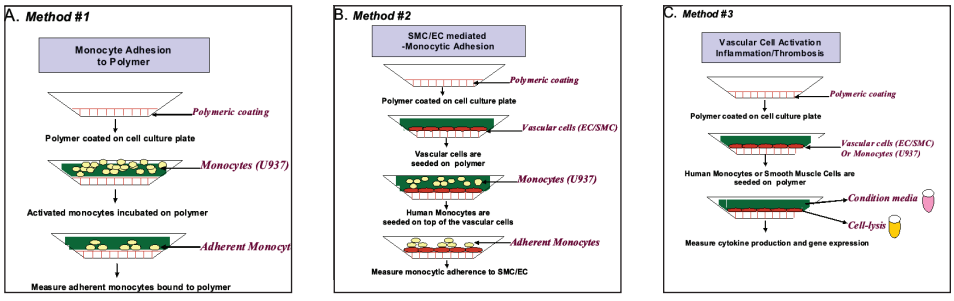

Figure 1 Design of polymer biocompatibility screening
A. Method no. 1, evaluation of monocytic adhesion to polymeric surfaces. B. Method no. 2, evaluation of vascular cell-mediated monocytic adhesion on polymeric surfaces. C. Method no. 3, evaluating the effects of polymeric coatings on vascular cell activation.

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Structure Relationship Continued from Page 4

response they elicit. Specifically, an increase in monocytic adhesion (Fig. 2) was observed to increase as a function of an increase in contact angle. Similarly, Tissue Factor activation increased 2-3 fold as surfaces switched from hydrophilic (≤95º) to hydrophobic (≥112º) contact angles. We then went on to vary the ratio of C10, C19, and PVP constituents in our Biolinx polymer blends. Interestingly, as we moved from more hydrophobic C10-rich materials to hydrophilic C19 and PVP-based materials, we observed a linear decrease in inflammatory cell adhesion, suggesting a more biocompatible polymer blend.

Recently we have adapted our in vitro evaluation methods to characterize coating biocompatibility directly on stent platforms through the use of flow cytometry (FACS) analysis techniques (Fig. 3). By testing stents directly, one can eliminate the possibility that factors related to the coating process would influence the surface properties of the materials. Furthermore, we are also able to characterize surfaces in the presence of drugs and after the drug has been eluted.

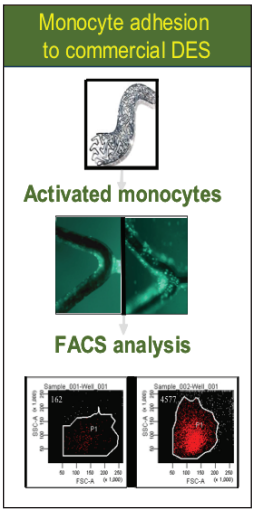
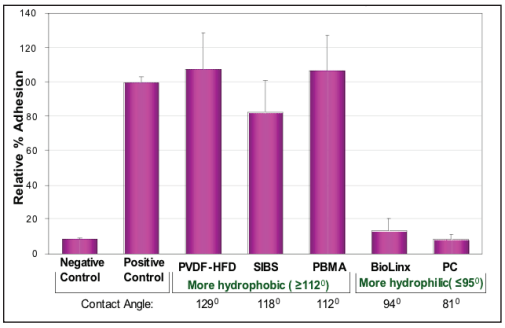


Figure 3 Monocytic adhesion to commercial DES as determined quantitatively via FACS analysis.

Our findings support the view that specific polymer formulations may promote differential inflammatory responses, mediated in part, by differences in the ability of cells to adhere and respond to variations in the hydrophobicity of DES polymeric coatings. Such interactions can trigger differential monocytic inflammatory activation resulting in increased potential for restenosis and thrombosis. The contribution of in vitro studies described previously is to design more biocompatible combination products utilizing a sound scientific rationale. In our hands, defining structure activity relationships between material composition and biological responses has proven to be invaluable in understanding our product and in the design of next generation technologies. We are continuing development efforts to include additional surface characterization techniques to identify additional factors that may also predict biologic responses to coating materials. Additionally, we are continuing to develop our understanding of how these clear in vitro study trends translate into potential clinical outcomes.



Monocyte Adhesion
Figure 2 Inflammatory cell adhesion to commercially available polymers. Polymers with higher surface hydrophobicity (contact angle ≥ 112°) exhibited enhanced adhesion of inflammatory cells. Polymers with more hydrophilic surface (contact angle ≤ 94°) show reduced inflammatory adhesion.

FDA Approves Medtronic Heart Wire

By Chris Newmarker, Minneapolis / St. Paul Business Journal

Medtronic Inc. received federal approval for a heart wire that's out of this world.

The Attain Ability wire uses insulation material developed by NASA Langley Research Center that was previously evaluated for space applications, high-performance engines and harsh environments. Medtronic said this is the first time a NASA-developed material has been used in this kind of implantable medical device. Langley Research Center is located in Hampton, Va.

The wire, called a lead, delivers electrical impulses directly to the heart from a pacing device implanted in a patient's chest. The U.S. Food and Drug Administration has cleared Attain Ability wire for treatment of heart failure.

Fridley-based Medtronic (NYSE: MDT) said Attain Ability is especially thin, making it easier for surgeons to navigate the lead through the intricate curves of the heart's anatomy to place the lead in the ideal location on the left ventricle.

"Attain Ability is the latest innovation in our long-term strategy to provide physicians with a broad portfolio of leads and delivery systems to meet the unique needs of their patients," Pat Mackin, a senior vice president at Medtronic, said in a news release.

Surfaces in Biomaterials Foundation Open House

The Foundation thanks all of our members who attended the Spring Open House held at our co-sponsor's location at Boston Scientific in Maple Grove, Minnesota in April. The event had record attendance and an outstanding presentation by SIBF's Treasurer and Board Member Victoria Carr-Brendel, Vice President of Research & Development Electrophysiology for Boston Scientific. Thanks to Boston Scientific for providing the outstanding location and support for an evening of networking and science.

Presentation at Boston Scientific in Maple Grove.

Joe Chinn and Victoria Carr-Brendel

Klaus Wormuth and Marc Hendriks

Biocoat and Agion to Develop and Co-market Coatings for Medical Devices

From BioCoat, Inc.

Biocoat, Inc., maker of lubricious Hydak® hydrophilic coatings, and Agion Technologies, the worldwide leader in natural silver-based antimicrobial solutions, have announced a co-marketing agreement to develop and promote a coatings product line featuring Agion's antimicrobial protection for medical devices.

This agreement utilizes technology co-owned and patented by Agion and Biocoat for hyaluronan coatings that incorporate silver-based antimicrobial properties. Coatings that take advantage of this synergistic combination of non-thrombogenicity and antimicrobial properties are now available to device makers for immediate evaluation in their products.

"We believe that Agion's silver zeolite technology and the unique properties of coatings based on hyaluronic acid will be a major advance in medical coatings," said Djoerd Hoekstra, CEO of Biocoat. Dr. Josh Simon, Senior Product Manager for Coating Technologies adds, "This is an exciting development not only because it allows us to produce a lubricious coating with antimicrobial properties, but also because of the market timing and prospects for further development of advanced medical coatings."

"Medical devices that incorporate Agion's natural antimicrobial technology actively inhibit the growth of microbes on the device's surface for the life of the product," said Paul Ford, CEO of Agion Technologies. "This partnership will allow us to extend our antimicrobial protection to medical devices that choose Biocoat as their coatings provider."

Coatings that release silver are used on catheters, particularly central venous and urological catheters, where they have been shown to reduce the amount of microbes found on their surfaces. Recently, Medicare declared it will no longer reimburse hospitals for the treatment of some preventable conditions. This is a strong incentive for companies to develop antimicrobial protected devices for prophylactic and therapeutic use.

Biocoat's Hydak product line of lubricious hydrophilic coatings are based on hyaluronic acid, which occurs naturally in the body and has non-thrombogenic properties. The hyaluronic acid in the coating can be crosslinked or non-crosslinked on a surface to varying degrees in order to control durability in applications where abrasion may occur.

The cornerstone of Agion technology is silver, a naturally occurring and highly effective antimicrobial agent. Silver has long been known for its antimicrobial properties and Agion's zeolite carrier provides many benefits over other antimicrobials that are alcohol-, chlorine-, or ammonium-based. Silver is proven to be safe with no toxic affects on people, plants or animals. Agion technology operates at the surface of a product through the controlled release of silver ions which attack microbes and inhibit their growth in three different ways. They offer a variety of silver-based technologies to suit various manufacturing and product requirements.

Brookwood Pharmaceuticals is Now SurModics Pharmaceuticals

From SurModics Pharmaceuticals

SurModics, Inc announced that Brookwood Pharmaceuticals, which SurModics acquired in July 2007, has been renamed SurModics Pharmaceuticals.

"Renaming our Brookwood Pharmaceuticals business unit to SurModics Pharmaceuticals reflects the successful integration of our two organizations, reinforces our plan to leverage the strengths that each location brings to the combined entity, and provides greater clarity to our medtech, pharma, and life sciences customers," said Bruce Barclay, President and CEO of SurModics.

Earlier in SurModics' history, the company was focused on local drug delivery, but the successful execution of its corporate strategy has accelerated technology leadership well beyond local drug delivery. With the acquisition of Brookwood Pharmaceuticals, now SurModics Pharmaceuticals, the company is a a world leader in local and systemic drug delivery with proprietary drug delivery solutions for medical device, pharmaceutical and biotech companies. An important part of the business of Brookwood was the production and sale of biodegradable polymers in the Lakeshore Biomaterials™ Division. This production and sale of biodegradable polymers will continue within SurModics Pharmaceuticals and the polymers will be sold under the Lakeshore Biomaterials™ brand name.

The synergies of the combined businesses are many. SurModics brings exceptional surface modification and characterization expertise, deep experience creating strategically sound patents, strong clinical knowledge in ophthalmology and cardiovascular disease, and an overall reputation as one of the leading coatings companies in the world.

Brookwood brings a considerable level of expertise in parenteral drug delivery, especially in biodegradable polymers, strong relationships in the pharmaceutical industry, experience in multiple clinical areas, and exceptional capability in cGMP manufacturing, both of polymers and drug delivery products.

These core capabilities and the ability to leverage the combined drug delivery technologies have allowed for expansion into new markets. The diversification strategy has also extended clinical reach beyond SurModics' historical strength in cardiovascular to ophthalmology, orthopedics, oncology, neurology, diabetes, dermatology, central nervous system, pain and in vitro diagnostics, among others.

"Since 2007, SurModics Pharmaceuticals has continued to expand its offerings to customers, including expanded manufacturing facilities and expertise. The combined capabilities and resources under SurModics is enabling us to be uniquely poised to provide development and manufacturing links between discovery-level entities and clinical sites. We are excited to be a fully-integrated part of SurModics, a technology rich company, with an incredibly talented group of committed employees, and a dedicated, experienced management team that is more focused than ever on improving the health of patients around the world," said Art Tipton, President, SurModics Pharmaceuticals, and Vice President, SurModics, Inc.

Med-Tech Firm NeuroVasX Gets OK to Sell Device in Europe

By Kathy Grayson, Minneapolis / St. Paul Business Journal

Medical-technology firm NeuroVasX Inc. has received regulatory approval to begin marketing a device used to treat brain aneurysms.

The company's device uses a polymer material designed to fill an aneurysm, preventing it from bursting and causing damage to the brain.

Such aneurysms now are often filled with tiny coils. NeuroVasX reported its device is superior to that treatment, as it uses a simpler process and fills the aneurysm more completely.

Maple Grove-based NeuroVasX already has applied for regulatory approval to sell the device in the United States.

The firm has raised more than $13 million in financing since its founding in 1997. In December 2007, it raised $8.5 million through a private placement.

Lifecore Biomedical Announces Commercial Launch of Corgel™ Biohydrogel

From Lifecore Biomedical, LLC

Lifecore Biomedical, LLC announced the commercial launch of its proprietary Corgel™ BioHydrogel research kits. Corgel is a hyaluronan (hyaluronic acid) based biocompatible hydrogel. It was initially conceived and developed by scientists at Cleveland Clinic as a tissue bulking agent and drug delivery matrix. The tunability of the matrix and the biocompatibility also allows for the direct inclusion of cells or bioactive agents.

Lifecore procured an exclusive license agreement with Cleveland Clinic in 2007 and has been actively developing the technology by completing ISO 10993 Safety and Toxicity studies, as well as exploring modifications and variables to the technology. Lifecore now looks forward to collaborative development for use in surgical and transcatheter applications in vascular surgery, cardiology, ophthalmology, orthopedics, aesthetics, ENT, drug delivery, tissue engineering and regenerative medicine and several other medical fields.

Fracture Putty Continued from Page 1

Biomedical engineers at The University of Texas Health Science Center at Houston (UTHSC-H) are leading the overall effort, which also includes Harvard University. The total value of the UTHSC-H effort, if all phases of the development program are completed, could be up to $7.9 million with subcontract to Northwestern up to $1.2 million.

Serious injuries typically are repaired with bone grafts. Pins, plates or screws hold the grafts to healthy bone and external fixators provide support. Soldiers may require multiple surgeries and long recuperation periods, and they may not recoup full use of the injured leg.

If fracture putty proves successful, injured soldiers could regain full use of their legs in a much shorter period of time. It could also be used in emergency rooms to treat civilians injured in traffic accidents and other traumatic events.

Northwestern investigators at IBNAM are developing the new materials based on nanotechnology to make bone regenerate quickly; the Houston group will focus on mechanical properties; and the Harvard team, led by George Whitesides, will focus on adhesion of the putty to bone.

The entire research team is being led by principal investigator Mauro Ferrari, director of the division of nanomedicine and deputy chairman of the department of biomedical engineering, a joint venture among the UT Health Science Center at Houston, The University of Texas at Austin and The University of Texas M. D. Anderson Cancer Center.

The Ferrari team will begin the preclinical study by testing the mechanical and biological properties of candidate compounds in mathematical models and in vitro systems. Afterward, the compounds designed in Stupp's laboratory will be tested in several animal models. If the fracture putty works in an animal model, the next step would involve patients.

"The fracture putty will serve as a bioactive scaffold and will be able to substitute for the damaged bone," said Ferrari. "At the same time, the putty will facilitate the formation of natural bone and self-healing in the surrounding soft tissue through the attraction of the patient's own stem cells. The putty will have the texture of modeling clay so that it can be molded in any shape in order to be used in many different surgical applications, including the reconnection of separated bones and the replacement of missing bones."

The research project, "BioNanoScaffolds for Post-Traumatic OsteoRegeneration," runs through December 2010. The site leaders at the other collaborating institutions are Antonios Mikos, Rice University; Bradley Weiner, The Methodist Hospital; Philip Nobel, Baylor College of Medicine; and Raffaella Righetti and Theresa Fossum, Texas A & M University.

DARPA sponsors revolutionary high-risk, high-payoff research that bridges the gap between fundamental discoveries and their military use.

"This undertaking represents the ultimate convergence of materials science, mechanics and orthopedics," said DARPA Program Manager Mitchell Zakin. "I look forward to the first results, which should present themselves in about a year or so."

Nanowires Sense Blood Anti-Bodies

By Steve Bush, Electronics Weekly

The University of Southampton will develop a bio-medical sensor based on silicon nanowires.

"You can functionalise the wire by coating it with a chemical that will attract a particular anti-body," Professor Peter Ashburn told Electronics Weekly. "Anti-bodies are usually charged, so they alter conduction in the nanowire, which you can detect." A simple version might involve a 1µm wide silicon track on the surface of a chip, said Ashburn, but this might not be sensitive enough.

"To get high sensitivity, you need a large surface to volume ratio, so there are advantages in a 50nm wire," he explained.

Beyond thinning the wire, to further increase sensitivity the University proposes to expose not just the top, but the sides of the wire as well to anti-bodies—the bio equivalent of a finFET—or even expose the whole wire by suspending it in space.

(Editor's note – a FinFET is a type of non-planar, double-gate transistor where the conducting channel is wrapped around a thin silicon "fin," which forms the body of the device.)

"We are going to look at a polysilicon finFET structure made on oxide or nitride using techniques that are used to make displays," said Ashburn. "This is probably the most straightforward method to get anti-bodies on three sides."

By exploiting anisotropic etching "spacer" techniques used in chip-making, the team aims to construct 50nm wide wires using 1µm lithography. The fully-exposed wire approach may be examined by forming the sensor across a 2µm wide gap.

This is intrinsically more sensitive but, said Ashburn, free-standing nanowires may be too fragile to withstand normal liquid processing, and the jury is still out on the safety of free nanowires that escape into the environment.

Beyond the sensing structure, which the team aims to have prototyped in between 12 and 18 months, the three-year plan includes integrating electronics and micro-fluidics to produce a self-contained device that allows routine blood tests to be completed in a doctor's surgery. Ashburn feels that chemical coating technology is sufficiently developed to allow a single chip to have wires that detect different anti-bodies. "I can envisage three, four or five nanowires 100µm apart to identify different biomarkers."

The chip will probably be disposable. "We could make it re-usable, but the doctor will somehow have to sterilise it," he explained. Towards the cost of the programme, Ashburn's nanotechnology group and the University's schools of medicine have been awarded £1,330,346 by the Government's Nano Grand Challenge in Healthcare.

From the Editor Continued from Page 2

As those of us who have developed promising technologies in our business or academic lab have discovered, The Valley of Death is very real. One can demonstrate that a new medical device (or material, or instrument) works on the bench top for a pittance compared to the money, time, and other resources needed to get this technology to patients or other customers. Product refinement, production scale-up, patent costs, reproducibility, ISO/GLP processes, animal testing, clinical testing, regulatory approval, sales and marketing... These all too often get in the way. What is the solution? Partnering.

Partnerships are central to this Foundation and to our industry as a whole. Through partnerships and related business relationships, the Valley of Death can be bridged. A small business with a promising technology may work with an academic lab for small animal testing. An academic lab may work with a small or large business for product refinement or scale-up of their novel technology. A large business may, in contrast, seek specialized capabilities within an academic lab or a small company. And of course, a large business may support the considerable costs of scale-up, clinical testing, and meeting the regulations to get a product to the market. Engendering these relationships is critical to our industry, and in fact developing these relationships through networking is largely why we attend meetings. This coming fall at BioInterface 2009 I will chair the Academic/Industrial Partnership session. The intent of this session is to enable promising new technologies available for partnership to be showcased by academics and small businesses, and for those presenting to discuss their partnership needs. This session can also enable large industry to express what they seek, be it new technologies or capabilities, and to explain their criteria for generating partnerships. At this time I would like to learn your needs, hear your suggestions, and read your abstracts (note the call for abstracts on page 16). Through partnering we can make this a stronger session. Call or email!

Drug Delivery With Nanotechnology: Capsules Encapsulated

From ScienceDaily

When cells cannot carry out the tasks required of them by our bodies, the result is disease. Nanobiotechnology researchers are looking for ways to allow synthetic systems to take over simple cellular activities when they are absent from the cell. This requires transport systems that can encapsulate medications and other substances and release them in a controlled fashion at the right moment.

The transporter must be able to interact with the surroundings in order to receive the signal to unload its cargo. A team led by Frank Caruso at the University of Melbourne has now developed a microcontainer that can hold thousands of individual "carrier units"—a "capsosome." These are polymer capsules in which liposomes have been embedded to form subcompartments.

Currently, the primary type of nanotransporter used for drugs is the capsule: Polymer capsules form stable containers that are semipermeable, which allows for communication with the surrounding medium. However, these are not suitable for the transport of small molecules because they can escape. Liposomes are good at protecting small drug molecules; however, they are often unstable and impermeable to substances from the environment. The Australian researchers have now combined the advantages of both systems in their capsosomes.

Capsosomes are produced by several steps. First, a layer of polymer is deposited onto small silica spheres. This polymer contains building blocks modified with cholesterol. Liposomes that have been loaded with an enzyme can be securely anchored to the cholesterol units and thus attached to the polymer film. Subsequently, more polymer layers are added and then cross-linked by disulfide bridges into a gel by means of a specially developed, very gentle cross-linking reaction. In the final step, the silica core is etched away without damaging the sensitive cargo.

Experiments with an enzyme as model cargo demonstrated that the liposomes remain intact and the cargo does not escape. Addition of a detergent releases the enzyme in a functional state. By means of the enzymatic reaction, which causes a color change of the solution, it was possible to determine the number of liposome compartments to be about 8000 per polymer capsule.

"Because the capsosomes are biodegradable and nontoxic," says Brigitte Staedler, a senior researcher in the group, "they would also be suitable for use as resorbable synthetic cell organelles and for the transport of drugs." In addition, the scientists are planning to encapsulate liposomes filled with different enzymes together and to equip them with specific "receivers" which would allow the individual cargo to be released in a targeted fashion. This would make it possible to use enzymatic reaction cascades for catalytic reaction processes.

Long-Term Study Shows Drug-Coated Stents Safe

By Gene Emery, Reuters

Heart stents coated with drugs are just as safe as uncoated ones and appear to keep blood flowing to the heart muscle longer, dispelling earlier concerns about their safety, Swedish researchers said recently. A study by the same researchers in December 2006 found people who got the so-called drug-eluting stents were 18 percent more likely to die within three years.

That sent sales of the devices, made by Boston Scientific (BSX.N) and Johnson & Johnson (JNJ.N), into a tailspin. In September 2007, the Swedish team reported the safety difference between drug-eluting and bare-metal stents had evaporated. But the damage had been done as sales had slumped by $1 billion.

Now, long-term results from the study, led by Dr. Stefan James of Uppsala University Hospital in Sweden and published in the New England Journal of Medicine, confirm that the risk of death or heart attack is no greater among those who got drug-eluting stents or older, bare-metal stents.

Stents are tiny mesh tubes used to prop open diseased heart arteries. Drug-eluting stents have medicine added to them to prevent scar tissue from clogging up the device, a common problem with the older, bare-metal variety.

Stents Safe Continued on Page 13

New Tissue Scaffold Regrows Cartilage and Bone

From ScienceDaily

MIT engineers and colleagues have built a new tissue scaffold that can stimulate bone and cartilage growth when transplanted into the knees and other joints.

The scaffold could offer a potential new treatment for sports injuries and other cartilage damage, such as arthritis, says Lorna Gibson, the Matoula S. Salapatas Professor of Materials Science and Engineering and co-leader of the research team with Professor William Bonfield of Cambridge University. "If someone had a damaged region in the cartilage, you could remove the cartilage and the bone below it and put our scaffold in the hole," said Gibson. The researchers describe their scaffold in a recent series of articles in the Journal of Biomedical Materials Research.

The technology has been licensed to Orthomimetics, a British company launched by one of Gibson's collaborators, Andrew Lynn of Cambridge University. The company recently started clinical trials in Europe.

The scaffold has two layers, one that mimics bone and one that mimics cartilage. When implanted into a joint, the scaffold can stimulate mesenchymal stem cells in the bone marrow to produce new bone and cartilage. The technology is currently limited to small defects, using scaffolds roughly 8 mm in diameter.

The researchers demonstrated the scaffold's effectiveness in a 16-week study involving goats. In that study, the scaffold successfully stimulated bone and cartilage growth after being implanted in the goats' knees.

The project, a collaboration enabled by the Cambridge-MIT Institute, began when the team decided to build a scaffold for bone growth. They started with an existing method to produce a skin scaffold, made of collagen (from bovine tendon) and glycosaminoglycan, a long polysaccharide chain. To mimic the structure of bone, they developed a technique to mineralize the collagen scaffold by adding sources of calcium and phosphate.

Once that was done, the team decided to try to create a two-layer scaffold to regenerate both bone and cartilage (known as an osteochondral scaffold). Their method produces two layers with a gradual transition between the bone and cartilage layers.

"We tried to design it so it's similar to the transition in the body. That's one of the unique things about it," said Gibson.

There are currently a few different ways to treat cartilage injuries, including stimulating the bone marrow to release stem cells by drilling a hole through the cartilage into the bone; transplanting cartilage and the underlying bone from another, less highly loaded part of the joint; or removing cartilage cells from the body, stimulating them to grow in the lab and re-implanting them.

The new scaffold could offer a more effective, less expensive, easier and less painful substitute for those therapies, said Gibson.

MIT collaborators on the project are Professor Ioannis Yannas, of mechanical engineering and biological engineering; Myron Spector of the Harvard-MIT Division of Health Sciences and Technology (HST); Biraja Kanungo, a graduate student in materials science and engineering; recent MIT Ph.D. recipients Brendan Harley (now at the University of Illinois) and Scott Vickers; and Zachary Wissner-Gross, a graduate student in HST. Dr. Hu-Ping Hsu of Harvard Medical School also worked on the project.

Cambridge University researchers involved in the project are Professor William Bonfield, Andrew Lynn, now CEO of Orthomimetics, Dr. Neil Rushton, Serena Best and Ruth Cameron.

The research was funded by the Cambridge-MIT Institute, the Whitaker-MIT Health Science Fund, Universities UK, Cambridge Commonwealth Trust and St. John's College Cambridge.

Medical Tech Firms Say Prices OK, but Wall Street Disagrees

By Debra Sherman, Reuters

If US medical device makers had one message they want to deliver to investors these days, it would be that their products are not commodities and are not facing significant price pressures. Historically a safe haven during recessions, shares of companies that make heart devices and orthopedic implants have been under a dark cloud in recent months amid concerns of price pressure resulting from a weak hospital sector and probable US healthcare reform.

The recession has already taken its toll as more people lose employer-provided insurance and put off medical procedures. Concerns of looming price pressure on medical devices have kept investors at bay, even with price-earnings ratios of top manufacturers holding near their lowest levels in about two decades.

"These stocks are pretty fairly valued right now because of concerns around pricing," said Raj Denhoy, director of equity research at Thomas Weisel Partners. "These concerns are not misplaced."

According to a recent report by the American Hospital Association, nearly all of the 1,078 hospitals surveyed said their capital situation had not improved or was still getting worse since December. The pricing environment in the United States is deteriorating, said Wachovia analyst Michael Matson.

"Indications are that it could get worse still," he said. "(Hospitals are) trying to wring costs from every area, so they're taking more desperate measures to force surgeons to use lower-cost implants."

But that's not what medical device company executives are saying. Jim Crines, chief financial officer of Zimmer Holdings (ZMH.N), acknowledged that the pricing environment was "challenging," but no more so than it was during the past couple of years.

Zimmer's first-quarter financial statement showed pricing in the Americas fell 0.3 percent, turning negative for the first time since the late 1990s, noted JPMorgan analyst Michael Weinstein. With new agreements will come additional pressures to reduce prices, he said.

But on a conference call after Zimmer reported earnings last week, Crines told analysts he saw an opportunity for pricing of its products, including hip and knee implants, to improve going into the balance of the year.

It's Stabilizing

Zimmer management used the words "stabilize," "stabilized," "stabilizing," "stabilization" or "stability" to describe pricing and the company's markets 14 times during the one-hour conference call.

Meanwhile, Medtronic Inc (MDT.N) Chief Financial Officer Gary Ellis said in a recent interview that pressure on hospitals had not put pressure on the prices of the world's largest stand-alone medical device maker's products, which include implantable heart defibrillators, heart stents, and spinal implants.

St. Jude Medical (STJ.N) Chief Executive Dan Starks said he had not seen pressure on prices in the company's key market for implantable heart defibrillators, better known as ICDs. Starks told a conference call that hospital administrators tended to characterize medical devices as commodities. "(They are) part of a discussion of why prices ought to be lower," he added.

But such devices are only commodities if all are state-of-the-art, he said. "In the real world, that's not how it is," Starks said. "So the service is a significant differentiating factor. The device reliability is a nontrivial issue."

Price pressures have been most acute on big expensive capital equipment, like MRI scanners, for more than a year. But Oppenheimer analyst Amit Hazan said he expected that pressure to spill over to orthopedic and cardiovascular devices. Matson said results from Wachovia's hospital purchasing managers survey, which was conducted at the end of the first quarter, suggest that price pressure on orthopedics was likely to increase.

For instance, the survey found that respondents expected the average joint implant cost to decline by 4.5 percent over the next 12 months, with spine implant costs down 4.7 percent. Matson said he did not expect prices to match steep forecasts of the hospital purchasing managers, but maintains those responses signal intensified pressure. Many analysts contend that problems faced by hospitals and uncertainty surrounding healthcare reform will keep a lid on all healthcare stocks.

Until the shape of that reform becomes clearer, JPMorgan's Weinstein said, portfolio managers are rotating out of the sector and into beaten-down financials.

"Your big concern is missing a rebound," he said. "That's the biggest fear driving all markets right now."

Meeting/Conference/Trade Show Calendar

Meeting/Conference/Trade Show	Dates	Place	Web Address
AAPS National Biotechnology Conference	June 21-24	Seattle, WA	aapspharmaceutica.com/meetings/biotec/bt09/index.asp
Controlled Release Society (CRS) - 36th Annual Meeting & Exhibition	July 18-22	Copenhagen, Denmark	controlledreleasesociety.org/meeting/default.cfm
International Conference of the IEEE Engineering in Medicine and Biology Society	Sept 2-6	Minneapolis, MN	embc09.org/
22nd European Conference on Biomaterials	Sept 7-11	Lausanne, Switzerland	esb2009.org
MEDTEC China	Sept 8-10	Shanghai, China	devicelink.com/expo/shanghai08/
Transcatheter Cardiovascular Therapeutics (TCT)	Sept 21-26	San Francisco, CA	tctmd.com
Orthopedic Design & Technology (2nd annual)	Oct 6-8	Fort Wayne, IN	odtexpo.com/
American Neurological Assoc (ANA)	Oct 11-14	Baltimore, MD	aneuroa.org/index.php?src=gendocs&ref=2008SLC__Home
VIVA (Vascular Interventional Advances)	Oct 19-23	Las Vegas, NV	vivapvd.com/index.cfm
Medical Device & Manufacturing Minneapolis	Oct 21-22	Minneapolis, MN	devicelink.com/expo/minn08/
BioInterface 2009	**Oct 26-28**	**San Mateo, CA**	**surfaces.org**
American Association of Pharmaceutical Scientists (AAPS)	Nov 8-12	Los Angeles, CA	aapspharmaceutica.com/meetings/futuremeetings/index.asp
American Heart Association (AHA)	Nov 14-18	Orlando, FL	scientificsessions.americanheart.org/portal/scientificsessions/ss/seeyounextyear2009
Medica	Nov 18-21	Dusseldorf, Germany	medica.de
BIOMEDevice 2009	Dec 9-10	San Jose, CA	devicelink.com/expo/biomed08/

Stents Safe Continued from Page 10

Results from the Swedish study of nearly 48,000 patients now suggest the devices work as promised, especially in high-risk patients, who had a 74% lower risk of having a clogged stent compared with similar patients who got a bare metal stent. Professor Franz Eberli from the University Hospital Zurich in Switzerland said the original study caused "a huge firestorm" when it was first presented at a cardiology meeting in Barcelona in 2006.

"The immediate impact was a decrease in the use of drug-eluting stents and a lot of scrutiny on safety," he said in a statement. Eberli said the latest paper looking at the same group of patients "provides a lot of reassurance."

Real-World Study

A smaller study in the same journal looking at how the devices performed in heart attack patients showed no difference in the risk of death or heart attack.

That study found the drug-eluting stent did a better job than bare-metal stents of keeping blood vessels flowing freely.

"Our study is in the highest-risk patients and it's a randomized trial. The Swedish study is important because it's a 'real-world' study that included all comers," Dr. Gregg Stone of Columbia University Medical Center said in a telephone interview.

Stone's study, supported in part by a grant from Boston Scientific, involved 3,602 people at 123 medical centers in 11 countries who used the company's Taxus-brand stents.

At the 13-month mark, 10% of the blood vessels held open by the Taxus stents had clogged up by at least 50%, compared with 23% of the instances where the bare stents were used.

The drug-eluting stents cost significantly more than the older uncoated stents, even though they do not seem to help people live longer, at least not in the short run.

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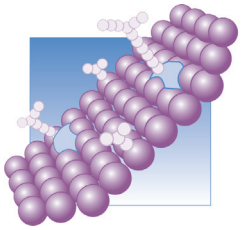

Surfaces in ***Biomaterials*** Foundation

BioInterface 2009

Call for Abstracts

Explore the creative solutions and technical challenges that BioInterface 2009 offers!

The Surfaces in Biomaterials Foundation presents one of the best technical conferences in 2009! Please join us for the upcoming BioInterface 2009 Symposium and Workshop in San Mateo, CA on October 26 – 28, 2009. Plan to attend and to contribute to the conference by submitting your technical abstract now! The deadline for abstract submission is July 15, 2009.

Conference highlights include our *Advances in Thermoplastic Elastomers and Biodegradable Polymers: Analysis and Applications* workshop on Monday, October 26, followed by these special events: Student Poster competition and lively Point-Counterpoint session on Tuesday, October 27; the prestigious Excellence in Surface Science Award and luncheon on Wednesday, October 28; two full days of solid technical sessions (October 27-28).

This year our Monday workshop will feature a comprehensive ensemble of renowned academic and industrial speakers known for their respective work in Thermoplastic Elastomers and Biodegradable Polymers. The technical sessions on Tuesday and Wednesday will have presentations covering these diverse topics: *Recent Advances in Biodegradable Polymer Systems, Next-Generation Drug-Eluting Stents, Surface Interaction Designs for Controlled Biological Responses, Recent Advances in Tissue Engineering and Cell Communicating Surfaces, Stability of Biomaterials in Clinical Applications* and *Coming Innovations in Medical Devices and Therapies*.

Please plan to attend this conference. You will be enriched by: the science, the venue (the San Francisco Bay area), and the unique blend of industry, academic, regulatory and clinical attendees. Our conference is purposely kept small (approximately 150 registrants) to allow you to connect, share and learn by relaxed contact with your fellow attendees.

On Tuesday we will host our popular Student Town Hall where students have the opportunity to meet industry representatives during a special luncheon. For more information on BioInterface 2009, please contact Ashley Crunstedt at ashleyc@surfaces.org or call her directly at 651-203-7248. For updates, please visit our Website at www.surfaces.org.

BioInterface 2009

The venue for BioInterface 2009 is the beautiful San Mateo Marriott in San Mateo, CA, just outside San Francisco. Our conference offers a unique opportunity for participants to meet top thought leaders from the industry, academia and the medical community. BioInterface 2009 incorporates the successful format that worked well last year at our meeting in Minneapolis, MN. You will find your participation enlightening and enlivening as you are able to directly interact with the speakers and other conferees.

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Workshops/Sessions

Monday, October 26

Workshop: Advances in Thermoplastic Elastomers and Biodegradable Polymers: Analysis and Applications
For workshop information contact:
Chair: Marc Hendriks, DSM Biomedical

Applied Technology Workshops
For ATW information contact:
Chair: Peg Palmer, Surface Solutions Labs, Inc.

Reception

Keynote Presentation:
James Barry, Vice President of Corporate Research and Advanced Technology Development at Boston Scientific Corp.

Tuesday, October 27

Student Poster Judging
Carl Turnquist
Genzyme

Morning Poster Sessions
This will be a brief session of 5-minute introductions by poster presenters about the topic of their posters. Once the presenters finish, you will be given a chance to discuss the presenters' topics with them at their poster.

Recent Advances in Biodegradable Polymer Systems
Co-Chairs: John Middleton, SurModics Pharmaceuticals
Jim Arps, SurModics, Inc.

Next-Generation Drug-Eluting Stents
Chair: Mikael Trollsas, Abbott Vascular

Student Town Hall Meeting

Luncheon

Surfaces in Biomaterials Foundation Business Meeting

Afternoon Sessions

Surface Interaction Designs for Controlled Biological Responses
Co-chairs: Joseph Berglund, Medtronic CardioVascular
Susan Rea Peterson, Medtronic CardioVascular

Point-Counterpoint Session
Chair: Carl Turnquist, Genzyme

Exhibits

Wednesday, October 28

Morning Poster Sessions
This will be a brief session of 5-minute introductions by poster presenters about the topic of their posters. Once the presenters finish, you will be given a chance to discuss the presenters' topics with them at their poster.

Recent Advances in Tissue Engineering and Cell Communicating Surfaces and Structures
Chair: Gene Boland, University of Louisville and Jewish Hospital, Cardiovascular Innovation Institute

Stability of Biomaterials in Clinical Applications
Chair: Jeremy L. Gilbert, University of Syracuse

Luncheon

Excellence in Surface Science Award
Chair: Marc Hendriks, DSM Biomedical

Student Poster Award Winner Presentation

Afternoon Sessions

Coming Innovations in Medical Devices and Therapies
Chair: Zhengrong Zhou, St. Jude Medical

Academic/Industrial Partnerships
Chair: Steve Goodman, 10H Technology Inc.

NOTE: Exhibits will be available to participants throughout the workshop and conference days. Posters will be on display during the technical sessions (Tuesday and Wednesday).

Awards & Visibility

Excellence in Surface Science Award This award honors an outstanding researcher for significant contributions to surface science at the biointerface or an entrepreneur for practical application of surface science in the development of medical devices. The winner will present his or her work at the symposium Awards session.

Student Award This award recognizes excellence in student research. The award winner will be selected from student poster presentations at the meeting and will be recognized at the Awards luncheon.

Visibility Gain a voice in the surface science community by supporting the Surfaces in Biomaterials Foundation!

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Contact Ashley Crunstedt, at 651-203-7248 or by email at ashleyc@surfaces.org to choose a visibility opportunity that best fits your corporate goals and budget!

Abstract Guidelines

Electronic Abstract Submission

Authors are encouraged to submit abstracts as an email attachment addressed to ashleyc@surfaces.org by July 15, 2009.

Submitted abstracts are considered final when submitted. Your email message will serve as your abstract submission form and should identify one topical session from the session list on page 3, and keywords for each abstract submitted. Send one email per abstract submission.

Submit only ONE abstract for each presentation; do NOT submit multiple copies of the same abstract, do NOT submit in blinded format, and do include your name, your address and e-mail address on any submitted abstract.

Failure to Present

The presenting author is expected to present the paper. Should an emergency situation occur at the time of your presentation at BioInterface 2009, please notify the Chair of your session as well as the Overall Program Committee Chair (Joe Chinn), as soon as possible. It is the presenting author's obligation to ensure that the abstract is presented.

Notification

Notification of acceptance or rejection will be e-mailed in early July. The final selection of abstracts for presentation and placement of accepted abstracts in the program format will be made by the Program Committee.

Abstract Format

Abstract must be submitted in Microsoft Word format. All information must fit on one page (800 word maximum). Figures are allowed and do not count against the word limit. Go to www.surfaces.org to find a sample abstract.

Title

Type the abstract title in upper and lower case letters. Use a short and concise title. Title should be centered on the page.

Authors

The presenting author's name must be underlined. This person is expected to present the paper. Type name(s) of author(s) and institution with complete mailing and email addresses, including country. Do not use titles, i.e., MD, Ph.D., etc. Use upper and lower case type. If the affiliations of the other authors are different from the first author, use superscript to note differing affiliations.

Abstract Body

Text must be typed single-spaced. Do not skip a line between paragraphs. Type should be 8 to 10 points using Times New Roman font or equivalent. The abstract needs to address how the work described relates to the biointerface.

Abstracts accepted for podium presentation will be provided 15 minutes for didactic presentation, followed by 5 minutes for discussion. The nature of the multiple session format makes it imperative that these time limits be strictly observed by all participants. Audio-visual is a single LCD projector. Your presentation must not include animation or sublinks to other programs. No laptop or wireless mouse will be provided. You must provide your own laptop for LCD presentation.

Poster Presentations

Abstracts accepted for poster presentation will be provided an easel designed for a board that is 4 ft. high x 8 ft. wide (1.22m high x 2.44m wide). The presenting authors must be at their panels during the scheduled Poster Session listed in the Final Program and adhere to Set-Up/Tear-Down instructions included in the acceptance notification.

Outside Support

Support from outside sources must be listed in the abstract. In adherence with standards of the Accreditation Council for Continuing Medical Education, and guidelines of the Food and Drug Administration as endorsed by the American Medical Association, any conflict of interest must be clearly recognizable. Make note if a potential conflict of interest exists. The indication of outside support does not affect the decision of abstract for acceptance or rejection.

All abstracts are due by July 15, 2009.