SurFACTS in Biomaterials

November–December 2009 Volume 14 Issue 6

Novel Polymer Coatings for Prevention of Biofilms in Dental Unit Waterlines and on Urinary Stent and Catheter Materials

By Nerites Corporation, Madison, WI

Bacterial fouling of medical devices continues to be a persistent problem in multiple areas of medicine, and has a significant impact on healthcare costs annually. Nerites Corporation has focused its efforts on reducing biofilm formation on devices in two specific arenas: dentistry and urology. We have developed a biomimetic strategy to inhibit microbial fouling of the lumen of dental unit waterlines (DUWL) as well as bacterial contamination and encrustation of urinary stents and catheters.

Nerites' antifouling coatings are inspired by the unique protein glues secreted by marine mussels for adhesion to underwater substrates (Figure 1). These adhesive proteins solidify rapidly and enable the mussel to anchor itself to various surfaces in a wet, turbulent, and saline environment. One of the key components identified in mussel adhesive proteins (MAPs) is 3, 4-dihydroxyphenylalanine (DOPA), an amino acid that is believed to be responsible for both the adhesive and cohesive properties of MAPs. We have coupled DOPA and DOPA-like moieties to well-known antifouling polymers such as poly (ethylene glycol) (PEG). These new polymer constructs have been applied to both dental unit waterline tubing and urinary stent and catheter materials through a simple dip-coat process to reduce the adhesion of multiple microbial species.

Polymer Coatings Continued on Page 6

From the Editor

Ultimate Networking at BioInterface 2009

In my last editorial I wrote about the upcoming October BioInterface meeting, and in particular about my upcoming session on Academic and Industrial Partnerships. The overall intent of this session was two fold: The first was to provide information on how to engender and prepare for Partnerships such as those between Academia and Industry, and the second was to enable academic and industrial partnerships as well as similar relationships between large and small firms, or with consultants. The reason for such is that our discipline, however we define it, is a complex one. We need teams to conceive, hypothesize, develop, engineer, test, evaluate, manufacture, get approvals, and more, in order to get new and better medical devices to physicians and their patients.

Despite the Academic and Industrial Partnership Session being the last one at BioInterface 2009, and then despite a delayed start due to very extensive Q&A in the prior days' sessions, attendance at this ultimate session was still quite respectable. Thanks to all for staying to the sweet end. For those

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What's Inside

From the Editor
Continued

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

of you who did not remain, or were unable to attend any of BioInterface 2009, please read on.

The Ultimate Session began with two invited presentations. The first addressed patents and the management of patent portfolios (presented by Colin Farman, JD, PhD of Fulbright and Jaworski, LLP, Minneapolis). This was followed by the second invited presentation on the role of academic technology transfer offices (presented by Jeanine Burmania, MS, of the Wisconsin Alumni Research Foundation). Both presentations were excellent, and like most of the BioInterface 2009 presentations, these are available at www.surfaces.org. This will be especially beneficial for those who were unable to stay to the end of the meeting. (Note that this is only available to those who registered for the meeting.)

The second half of the session is where the "Ultimate Networking" experiment began. When the ultimate networking session was conceived, I had hoped it would provide the opportunity for attendees to accelerate their networking by letting everyone know what they had to offer, be it an academic technology for licensing, novel materials, specialized consulting or analysis capabilities, or the potential to be some company's next star employee.

As a recap of this session, I announced at the opening of BioInterface 2009 that any registered attendee could make a 5 minute/5 PowerPoint slide "Pitch." As stated in the Meeting Program:

> *Any registered attendees may present, "I am seeking partners…" or a similar message at the final session of BioInterface 2009 on Wednesday October 28 at 3:30 PM. Presenters will be allotted a maximum of 5 minutes, including any questions. Submissions will be accepted on a first-come, first-served, time-available basis, at the discretion of the session chair. To enable last minute discussions, submissions may be received up until 3 PM on the day of the session.*

At the close of the meeting, I was very pleased to judge this concept was a success. There were six "seeking partners" presentations, plus there were several more that could not be accommodated due to time constraints. (My apologies to those that we couldn't fit.) The presenters and their titles were:

1. Jeanine Burmania of the Wisconsin Alumni Research Foundation was seeking commercialization partners for licensing of patents that included: Wound Healing Using Patterned Gradients of Immobilized Bimolecular; Bioactive and Biocompatible Implantable Copolymers; Protein-Based, PEG-Modified, Multi-Functional Hydrogels; Orthopedic Implant Coating for Enhanced Bone Growth; Biologically Active Sutures for Regenerative Medicine.
2. Trevor Johnson of Flagship Biosciences was seeking to provide Histology and Digital Histology Pathology Evaluation and Archival Services.
3. Jun Yang of the University of Michigan-Ann Arbor was seeking employment opportunities following her degree completion, with expertise in Nitric Oxide Generating Anti-throm-

From the Editor Continued on Page 3

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.

BioInterface 2009: A Student's Perspective

By Colby James, Cal Poly, San Luis Obispo

I knew a little about what to expect at the 2009 BioInterface conference since I had attended the 2008 conference, and just as last year, the trip was well worth it. In 2008, at the conference in Minneapolis, I presented the proposed research plan for my Master's thesis work in the student poster competition. My return in 2009 was meant to present the results and conclusions of the actual research that I conducted, again during the student poster competition. But the poster competition itself is just a part of the BioInterface experience. Sure, it was great to get a chance to talk about my work with intelligent, passionate people from both industry and academia. But I also got the chance to talk with those same people about their work, and then debate with them over the value of in vitro device testing methods, which is at the heart and soul of my project. Like most students who attend the conference, I came from a background of academia, so a chance to get advice from people who had been in industry for 10, 20, 30, and even 40 years was amazing. Plus, the opportunity to meet students and faculty from schools around the country is always rewarding.

For students attending future BioInterface conferences, I have two bits of advice. First, have fun during the competition itself. This year the judges came around one by one to talk to each of the students, and every judge had a different approach. To one judge I explained my entire thesis from introduction to conclusions; to another I answered specific questions concerning electrospun scaffolding; and to another I simply introduced myself and let my poster do the talking. The whole process was very low pressure, and I found myself really enjoying fielding some tough questions. Because I had fun during the competition, I had no expectations about winning, which made my eventual first place finish even better! My second piece of advice is to ask as many questions as you can. Everyone attending was extremely friendly, and excited to talk about their work to anyone interested. I also got some great practical advice concerning working in industry versus pursuing a PhD from people who had faced the same decision.

Overall, I highly recommend BioInterface to students who want to experience a conference without feeling lost in the crowd. The quality of the presentations and ease of approaching the presenters makes BioInterface a unique and fulfilling experience. I hope to see you there!

From the Editor Continued From Page 2

botic Surface via Layer-by-Layer Assembly.

4. Norman Munroe of the Applied Research Center at Florida International University was seeking to provide Corrosion and Biocompatibility Assessment services that included: In-vitro corrosion testing in accordance with ASTM standards; SEM/EDS, TEM, AFM, XRD, Raman Spectroscopy, XPS, ICPMS; Osseointegration and Endothelialization of Alloys; and Cytotoxicity Assessments.
5. Howard Killilea of Valspar, a very large coatings company, was seeking to assist firms with their broad technology platforms that include coatings that are widely used in Food and Pharmaceutical applications.
6. Steven Goodman of 10H Technology and the University of Wisconsin-Madison (and this Editor) was seeking to assist industrial partners with analytical and microscopic characterization for R&D, QA/QC, and for Regulatory purposes; and to provide services related to the evaluation and development of new technologies and business opportunities.

One measure of success was that there were six seeking partners presentations, with four of these provided by BioInterface attendees at the meeting, and more that could not be accommodated. A second measure was that the audience stuck around. But, by far the greatest measure of success was that several of the presenters were contacted for follow-up detailed discussions that may lead to exactly the type of partnerships this session was created to engender.

I hope this opportunity was interesting and possibly beneficial to you all. This was an experiment, and I believe it was successful. But, as always, I would appreciate hearing from my readers. Was this of benefit to you? Shall we repeat this in future meetings, such as a next year's meeting in Atlanta? Drop me a line (sgoodman@10htech.com).

Nanoindentation Based Techniques for Characterization of Biomedical Devices and Materials

By Dehua Yang, Ph. D, Ebatco, Eden Prairie, MN

Stents, catheters, guide wires, lead wires, balloons and dental screws are implantable devices made of various materials such as stainless steel, metal alloy, polymer or ceramic, and which often have surface thin films, coatings, or are in the format of a composite. These devices need to be characterized for the purposes of new material and product development, and must meet product specifications, quality control, failure analysis or biocompatibility. Researchers, developers and manufacturers are enthusiastically looking for great tools, instruments and equipment that can visualize, characterize, measure, and manipulate materials at atomic and nanometer level. To support at least a part of the above mentioned needs, here we will briefly introduce nanoindentation based techniques for characterization of biomedical devices and materials at the nanoscale.

Nanoindentation, sometimes referred to as instrumented or depth-sensing indentation, is a promising technology for measuring mechanical and tribological properties of materials and devices at the nano- and microscales. Nanoindentation was initially developed as an alternative approach to conventional hardness measurement techniques for determination of the hardness of small volumes. For thin films, coatings and material interfaces the indentation imprints are so small that accurate observation and/or measurement of the indents using an optical microscope becomes extremely difficult. Depth-sensing indentation was thus introduced in order to eliminate observation and measurement the indentation marks. Nanoindentation relies on simultaneous measurement and/or control of the load and displacement of an indenter probe during indentation process. The indentation load-displacement curve (as shown in Figure 1) characterizes the mechanical deformation of the tested materials. Based on an established and widely-accepted Oliver and Pharr model and method, nanohardness and elastic modulus of materials can be derived from the curve. Nanoindentation has found many more applications over the last decade since the method has improved dramatically, benefiting from improvements in transducer technology and computer hardware and software. Obviously, precise measurement of displacement in nanometer resolution and loads in nano-Newton resolution is very important to the success of the nanoindentation technique.

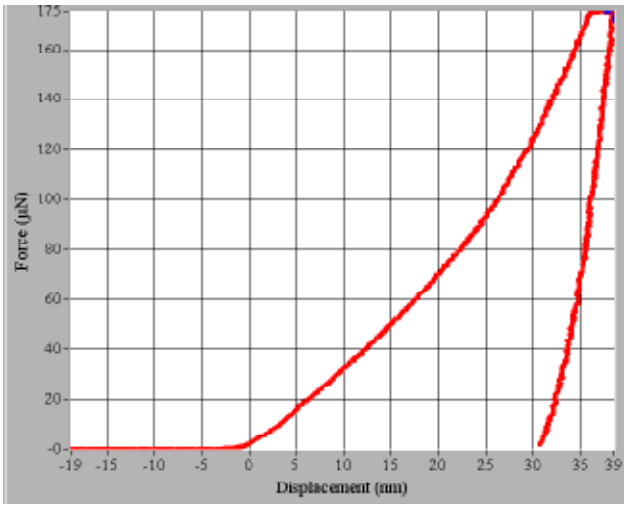

Figure 1. A load-controlled nanoindentation load-displacement curve.

To date, nanoindentation has been expanded to encompass a whole spectrum of testing techniques, well beyond the narrow indication of its name. For instance, while quasi-static nanoindentation, the core technique of nanoindentation, has been broadly accepted as a method for determination of nanohardness and elastic modulus of materials, dynamic mechanical analysis of visco-elastic materials at nanoscale has been steadily gaining more interest. In addition, many other testing methods and techniques have been developed and commercialized to broaden the nanoindentation technique and enable customers to study physical phenomena associated with probing the surface under controlled load or displacement, such as nanoscratch, nanofriction, nanowear, nanocompression, nanotensile, and coating interfacial adhesion measurement. When nanoindentation based techniques are combined with in-situ scanning probe microscopy (in-situ SPM), the power of the technique is greatly enhanced.

With such combined techniques, researchers can not only position the probe over spots of interest, but can also observe and study the surfaces immediately before and after the tests with nanometer accuracy (see Figure 2 for a nano indent with material piling up).

Nanoindentation Continued on Page 9

Surgical Scalpel Sniffs Out Cancer

By Katherine Bourzac, Technology Review

In the hope of helping oncologists remove every piece of tumor tissue during surgery, researchers are developing new imaging tools that work in real time in the operating room. European researchers have now demonstrated that a chemical analysis instrument called a mass spectrometer can be coupled with an electroscalpel to create a molecular profile of tissue during surgery. The researchers have shown that the method can be used to map out different tissue types and distinguish cancerous tissue. The device will begin clinical trials this month.

"When a surgeon is performing cancer surgery, he doesn't have any direct information on where the tumor is," says Zoltán Takáts, a professor at Justus-Liebig University in Giessen, Germany. Instead, surgeons rely on preoperative imaging scans and on feedback from pathologists examining tissue biopsies under a microscope. "We want to provide a tool that's right in their hands, so that if they think a structure looks suspicious, they can just test it," says Takáts.

Mass spectrometry, a very precise method for identifying molecules by analyzing the ratio between their mass and charge, is already being used by a handful of research groups to study biological samples. Researchers have known for many years that tumor tissue and healthy tissue have different molecular profiles and that this can be used to tell them apart, or even to determine how aggressive a particular tumor is. Other research groups have used mass spectrometry to analyze biopsied tissue and have shown that it can make these differentiations. The problem with using mass spectrometry in the operating room is sample collection. Before molecules can be analyzed, they have to be ionized and sucked up into the machine. Creating ions requires bombarding a sample with a stream of charged particles, often a gas, and these methods aren't suitable for the operating room. "A high-voltage nitrogen jet is not compatible with the human body," says Takáts.

Takáts realized that some surgical cutting tools, including electroscalpels, produce gaseous ions as a kind of waste product that are suitable for analysis with mass spectrometry. And these fumes, often called "surgical smoke," are already collected during surgery because they're harmful to the lungs. Takáts and his collaborators found that mass spectrometry of surgical smoke can be used to make a molecular map of a tumor. After the fumes are sucked into the mass spectrometer, the chemicals in the sample are identified and checked against a database to give the surgeon a readout. Gathering and analyzing a chemical sample takes a few hundred milliseconds. "We can draw a map and say this part is healthy liver, that is connective tissue, this is adipose tissue, that is cancer," says Takáts.

Mass spectrometry is just one of many imaging techniques being evaluated for use during surgery. Another approach is to inject a patient with fluorescent dyes that bind to tumor molecules and are visible under infrared light. But mass spectrometry can provide more comprehensive information about tissues' molecular profiles. The new system not only provides real-time information, but also produces an image of the tumor, using chemical information, which could also help guide postoperative care. The imager could, for example, reveal a particularly aggressive form of cancer, and this information could guide oncologists in prescribing the right drug.

So far, the German researchers have tested the surgical mass-spectrometry system in several animals, including rodents, with cancer. The group is also working with veterinarians to use the scalpel during tumor-removal surgeries in dogs with naturally occurring tumors. Next month the device will go into human clinical trials, and Takáts is working with Meyer-Haake, a German electrosurgical device company, to develop the machinery.

The most important remaining hurdle to getting mass spectrometry into the operating room may be the expense. An electrosurgery system typically costs $8,000, while a commercial mass-spectrometry system starts at $120,000. Takáts notes that the market for mass spectrometry is currently very small, but opening up the surgical market may help bring costs down. By using instruments tailored to the kind of analysis relevant to biological tissue, which doesn't need to be as high-performance as that in chemistry labs, Takáts hopes to make a machine that costs about $20,000.

Polymer Coatings Continued from Page 1

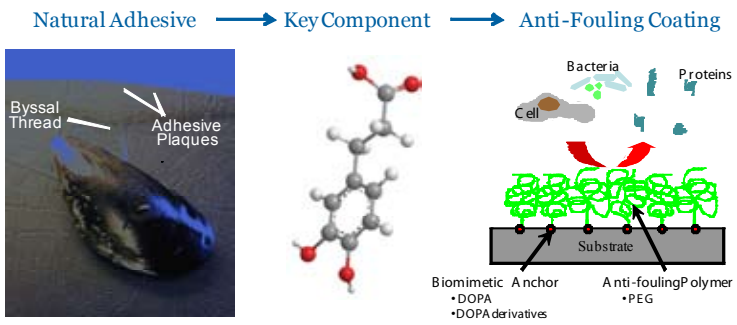

Figure 1: Nerites' mussel-inspired antifouling coatings.

Dubbed Surphys™, our first-generation antifouling polymers comprised simple constructs of linear conjugates of PEG and DOPA. In recent advances in our chemistry and experimentation, it was found that using a branched PEG polymer increases the effectiveness of the antifouling coatings, presumably by making them more robustly attached to substrate materials. The molecular weight of the PEG segments can also be varied for different applications. Our extensive library of Surphys™ polymers has been evaluated on materials used in both dentistry and urology. For DUWL applications, we have investigated the ability of Nerites' coatings to reduce the attachment of common DUWL pathogens and the compatibility of Nerites coatings with several existing antimicrobial DUWL treatments. For urological applications, we evaluated the performance of Nerites coatings against both bacterial adhesion and encrustation in urine.

Staphylococcus aureus and Pseudomonas aeruginosa are two common DUWL pathogens which dental workers and patients may come in contact with via the spray of water from waterlines. We have indentified four polymer coatings that demonstrate strong resistance against S. aureus attachment on DUWL polyurethane (PU) tubing, with reductions of 90% or greater compared to control surfaces (Figure 2). However, very little, if any, reduction was observed against P. aeruginosa. We hypothesize that in the nutrient-poor environment of the DUWL, P. aeruginosa can use PEG as a carbon source to survive.

The selected antifouling coatings for DUWL were also evaluated in conjunction with common cleansers used to remove biofilm build-up. Coated DUWL polyurethane (PU) substrates were subjected to typical cleaning regimens of four common DUWL cleansers and subsequently challenged with bacterial suspensions of S. aureus and P. aeruginosa to test coating integrity. DUWL cleansers did not appear to disturb the DOPA-substrate interaction, and in some cases, even improved antifouling ability over the coated substrates not subjected to any treatment (Table 1). This suggests a synergistic effect between the coating and the active ingredient in the cleansers and a possible association between the two.

Adhesion of six common uropathogens (Staphylococcus epidermidis, Escherichia coli, Proteus mirabilis, Pseudomonas aeruginosa, Streptococcus pneumonia and Enterococcus faecalis) was evaluated on coated and uncoated urinary stent (PU) and catheter (polydimethylsiloxane; PDMS) materials. Among all the coatings tested, Surphys-035 and Surphys-037 were found to be the best performers on both PU and PDMS surfaces. On PU surfaces, Surphys-035 and Surphys-037 exhibited significant antifouling activity against the attachment of all six uropathogens, with >90% reduction frequently observed (Figure 3). On PDMS surfaces, although not inhibitory to either K. pneumonia or P. aeruginosa, Surphys-035 and Surphys-037 demonstrated excellent reduction on the adhesion of the other tested bacterial species, particularly S. epidermidis and P. mirabilis, two principal organisms associated with urinary tract infections (Figure 4).

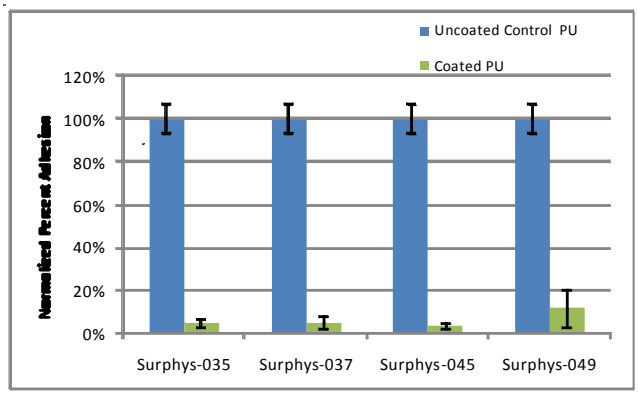

Figure 2: S. aureus attachment on uncoated and coated DUWL PU surfaces.

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	% Reduction Compared to Uncoated PU							
	Surphys-035		***Surphys-037***		***Surphys-045***		***Surphys-049***	
	S. aureus	*P. aerug.*	*S. aureus*	*P. aerug.*	*S. aureus*	*P. aerug.*	*S. aureus*	*P. aerug.*
No Treatment	85.5%	none	85.3%	none	88.1%	48.3%	93.9%	54.4%
Cleanser A	95.1%	none	94.9%	none	78.6%	65.0%	87.3%	93.6%
Cleanser B	90.2%	none	97.0%	57.0%	89.3%	78.7%	95.4%	89.8%
Cleanser C	89.4%	none	80.8%	6.9%	89.5%	74.4%	92.6%	70.9%
Cleanser D	92.1%	none	86.7%	17.1%	91.4%	84.0%	97.7%	72.4%

Table 1: Reduction in attachment of DUWL pathogens on coated DUWL PU substrates after treatment with various DUWL cleansers.

Coated and uncoated urinary stent segments were immersed into artificial urine for 7 days for encrustation evaluation. Encrustation was physically removed from each stent segment and weighed. The preliminary results showed that stents coated with Surphys-035 and Surphys-037 demonstrated modest reduction of encrustation in the urine (data not shown).

Nerites Corporation has developed a series of polymer coatings designed reduce microbial contamination to surfaces. We have recently demonstrated that by coupling biomimetic anchoring groups to antifouling polymers we can significantly reduce bacterial attachment to medical devices. Future work includes investigation into the durability and longevity of the coatings, including methods to reapply coatings as needed.

Nerites Corporation is actively seeking corporate partnerships for opportunities to develop innovative medical device technologies. For additional information please contact Jediah White, Senior Director of Business Development, at jwhite@nerites.com.

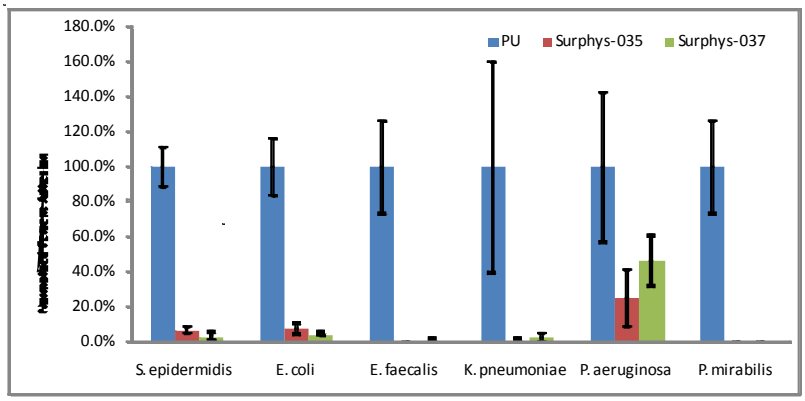

Figure 3: Bacterial attachment on uncoated and coated stent material (PU) surfaces.

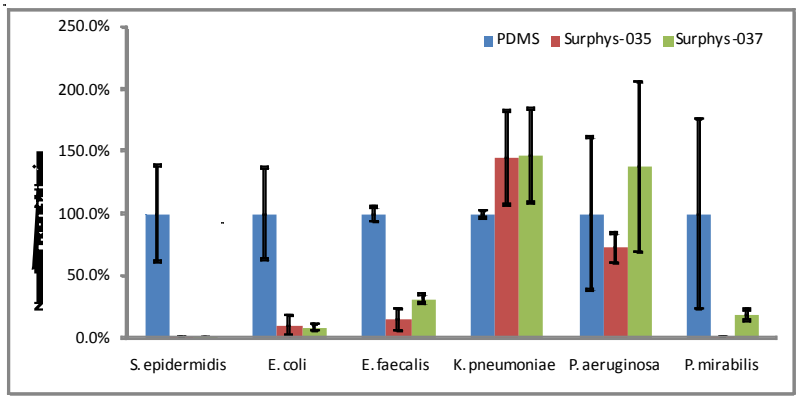

Figure 4: Bacterial attachment on uncoated and coated catheter material (PDMS) surfaces.

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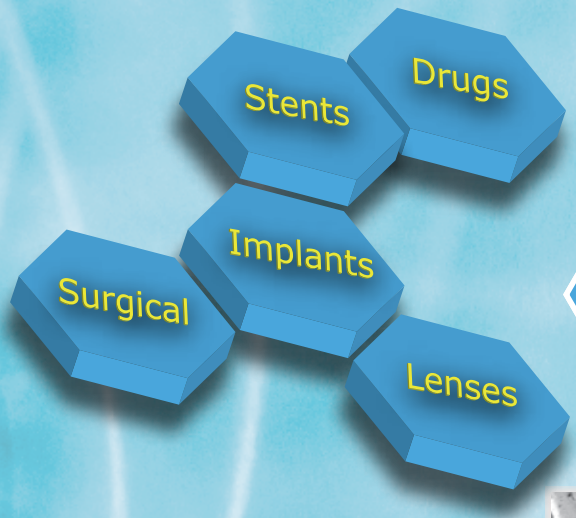

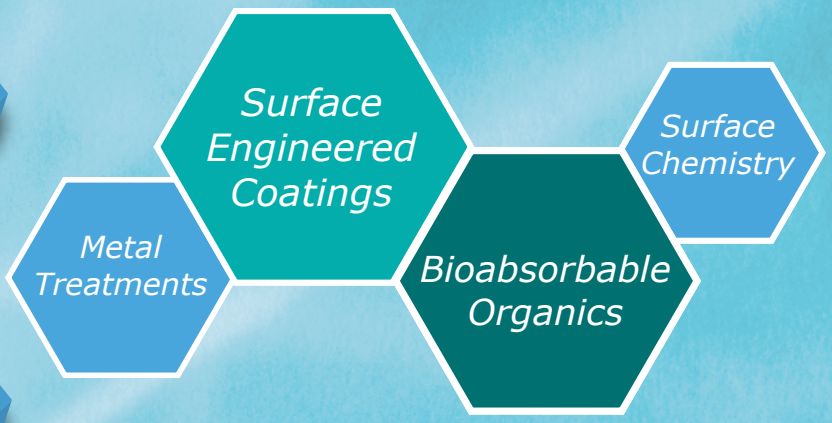

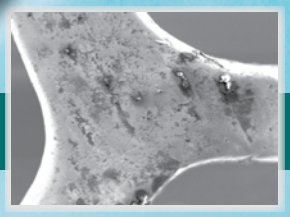

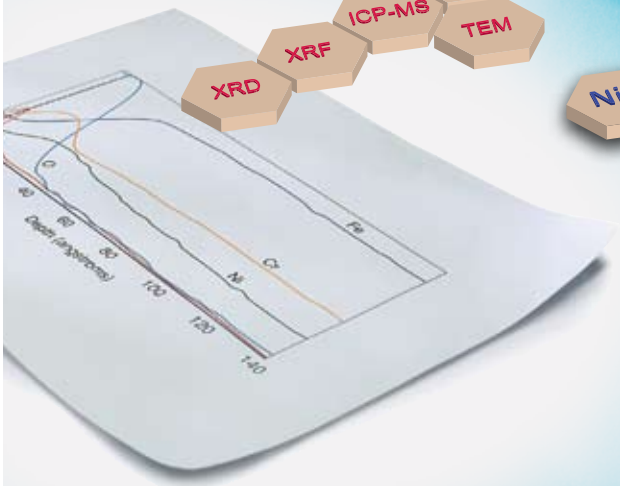

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Nanoindentation Continued from Page 4

Although challenging, nanoindentation with temperature and/or environmental controls is possible. These controls significantly increase the usefulness of the nanoindentation techniques. Figure 3 presents the nanohardness and reduced elastic modulus of polycarbonate obtained as a function of temperature. As can be seen from the figure, a dramatic softening of polycarbonate has occurred around 150ºC.

One of the common questions asked when using nanoindentation is: can we compare nanohardness to Vickers hardness? The answer is yes, but with caution. The nanoindentation hardness may be converted into Vickers hardness for comparison purposes. The ideal Berkovich indenter tip commonly used in nanoindentation has the same projected cross-sectional area as a function of depth as the Vickers indenter probe does.

The nanohardness values determined with a nanoindenter are based on the ratio of load to projected contact area, which is determined by carefully characterizing the geometry of the indenter tip. Since the indenter face contact area is used in the definition of conventional Vickers hardness, to convert the nanohardness values into Vickers hardness one can use the ratio of projected to face contact area (0.927 for a perfect Berkovich tip). Certainly the hardness units have to be converted as well.

H (in GPa) = Hv (in kgf/mm2) × 9.807 N/m2 × 106 × 10-9 / 0.927 = 0.01058Hv (in kgf/mm2)

Nanoindentation based techniques have proven to be useful tools for characterization of medical materials and devices at nano and micro scales. Ready access to and broad applications of these techniques will help to improve product and aid the design of next generation biomedical materials and devices for diagnostic, therapeutic and interventional applications. More information on these techniques may be found at www.ebatco.com. Questions and interests may be addressed to Ebatco's Nano Analytical and Testing Lab at natlab@ebatco.com.

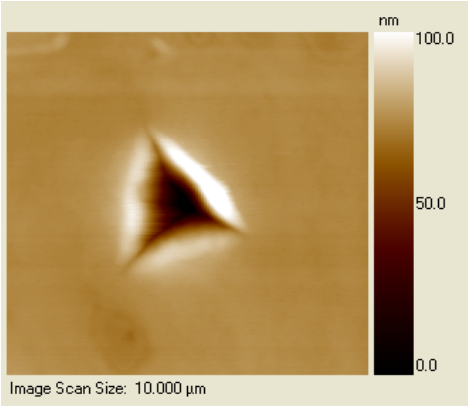
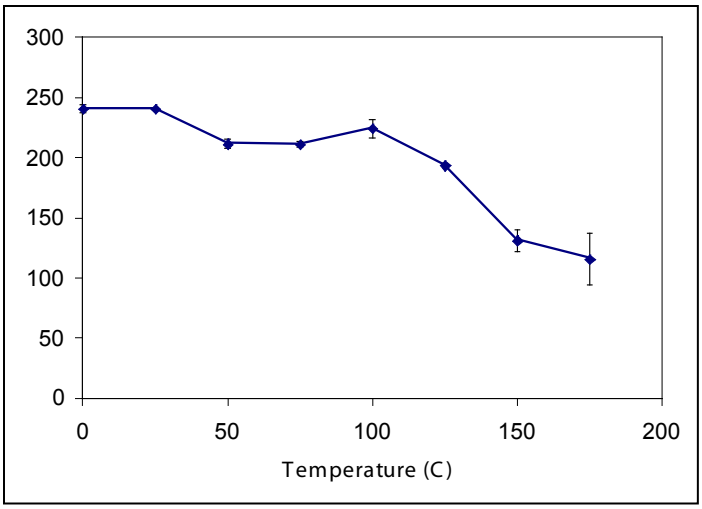


Figure 2. An in-situ SPM image of a nanoindent made on an optical CD.



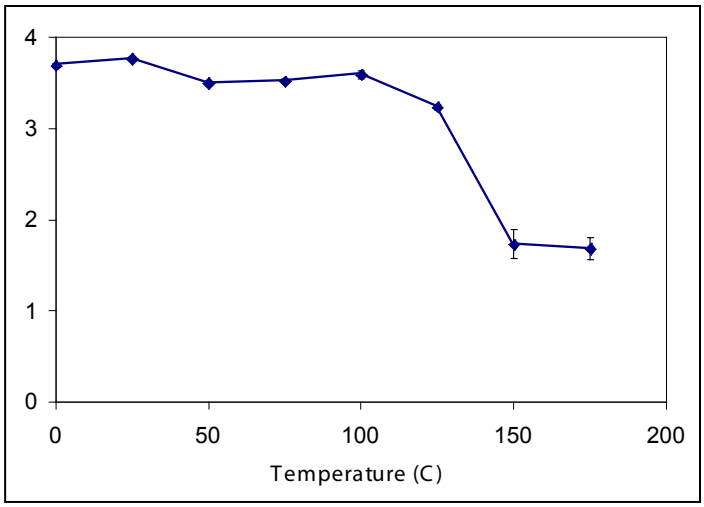


Figure 3. Nanohardenss and reduced elastic modulus of polycarbonate as a function of temperature.

DSM Unveils VitroStealth™ Coating Technology

From Business Wire

DSM Biomedical announced the development of VitroStealth™, a breakthrough non-biofouling (NBF) coating technology. Specifically developed to combine state of the art non-biofouling properties with high durability and fast processing, VitroStealth™ coating is scratch resistant and reduces unwanted protein absorption and cellular adhesion on surfaces.

"While the main application focus at this time for VitroStealth™ coating is in life science consumables, pre-analytics, and point of care diagnostics, we are excited about the many other areas that the technology can significantly impact," said Steve Hartig, President of DSM Biomedical. "We currently are investigating the scope of this technology for in-vivo medical applications and see a future for this coating technology in several other markets."

To develop the medical coating technology, DSM Biomedical leveraged advances in scratch resistant coatings developed by its parent organization DSM for use in displays and other non-medical applications. By extending DSM's leading hard coat technology to medical applications, DSM is aiming to offer the medical device and pharmaceutical industry the ability to decrease the likelihood of surface contamination and improve assay sensitivity, reproducibility and ultimately the reliability of medical consumables and point of care diagnostic tools. Application includes pre-analytical blood collection devices where VitroStealth™ coating eliminates surface mediated hemolysis and leads to clean, reproducible and thus reliable serum or plasma samples for the clinical laboratory. In diagnostics, VitroStealth™ coating increases signal to noise ratio as the analyte is not partially lost by adsorption to the surface of the device. Furthermore, due to its highly hydrophilic character the coating increases the capillary flow of analytes in microfluidic point of care devices.

"Medical experts do not leave much to chance. They need analytical and diagnostic tools that are reliable and leave no doubts regarding their efficacy," said John Marugg, Business Director for Medical Coatings, DSM Biomedical. "It was critical that we expand upon DSM's existing technology to provide the medical community with a coating technology whose durability and reliability are unparalleled."

Although coatings and surface treatments that reduce the accumulation of biological species have been on the market for some time, they often suffer from high levels of extractables and leachables, as well as poor scratch resistance. In some cases, these extractables have interfered with subsequent in-vitro assays and this potential for interference has limited the application success of current non-biofouling solutions.

Comparatively, VitroStealth™ coatings are solvent based and cured by exposure to UV light. This crosslinking chemistry leads to remarkably low levels of extractables and leachables, thereby greatly enhancing device reliability. VitroStealth™ coatings can be processed at high speeds and applied using a variety of liquid coating techniques, including dip-coating, spin coating and spray coating, among others. The fast processing is suitable for high throughput manufacturing of large numbers of coated parts.

Medtronic to Study Stent in Erectile Dysfunction

By Susan Kelly, Reuters

Medical device maker Medtronic Inc has begun a feasibility study for a treatment for erectile dysfunction that uses a specially designed drug-eluting stent.

The study, called Zen, is expected to enroll 50 subjects at up to 10 U.S. medical centers over the next year.

"The link between erectile dysfunction and coronary artery disease has been well established. Based on this evidence, we are investigating the use of stents in pelvic arteries to determine whether it may provide a new treatment approach and enable better response to drug therapies," Dr. Jason Rogers, director of interventional cardiology at UC Davis Medical Center in Sacramento and a lead investigator for the study, said in a statement.

The study is intended for men who have not responded well to PDE5 inhibitors such as Viagra, Cialis and Levitra. The study will evaluate the safety and improved erectile function of pelvic artery stenting. Results are expected in 2011.

DSM PTG Unveils Bionate® II PCU

From Business Wire

DSM PTG, part of DSM Biomedical, a global leader in biomedical materials science, announced the availability of Bionate® II PCU, a versatile medical polymer with built-in surface technology designed for chronic implants.

Bionate® II PCU is a line extension of the well known Bionate® Polycarbonate Urethane family, one of the industry's leading medical polymers for long-term implants, and is backed by an established FDA Master File. The new polymer offers improved performance and processing characteristics for medical devices. It includes patented SAME® technology, a built-in surface modification utilizing surface activity and self assembly of chemical groups attached to the ends of each polymer molecule during synthesis. This breakthrough technology enables medical devices to be equipped with permanent surface modification while maintaining excellent mechanical properties. It can also eliminate the need for secondary surface treatments once a device is made.

Cincinnati-based PMC Medical, a contract manufacturer delivering solutions in complex polymer molding and assembly, evaluated the processability of Bionate® PCU versus Bionate® II PCU. "Upon the conclusion of our experiments, we determined that DSM PTG's Bionate® II PCU is more easily processed for injection molding applications," said Bob Langlois, Executive Director of Applied Technology.

In addition to providing controlled surface chemistry and better processing, Bionate® II PCU also offers improved oxidative stability and greater strength than the first generation Bionate® PCU.

"We believe Bionate® II PCU with SAME® technology offers a performance breakthrough in high-strength, biostable polymers for medical device designers. It is the next step in the continuous improvement of our biomedical thermoplastics, offering customizable surface chemistry for unique medical device designs," said Bob Ward, President and CEO of DSM PTG. "In the case of Bionate® II PCU, we have made minor changes to a proven polymer family that improve the polymer's processability and oxidative resistance, and significantly increase its strength."

The Bionate® PCU family has been extensively tested and is used in many commercially-available long term implants, including pacemaker leads, ventricular assist devices, catheters, stents, spinal discs, neurostimulation devices, hip and knee joints, and spinal fixation systems.

FDA Approves CryoLife BioFoam Trial

From Atlanta Business Chronicle

The U.S. Food and Drug Administration (FDA) gave its OK for Kennesaw, Ga.-based CryoLife Inc. to start human trials for its BioFoam Surgical Matrix protein hydrogel technology.

The product will be used to help seal liver parenchymal tissue when halting bleeding by ligature or other conventional methods is ineffective or impractical, CryoLife said. BioFoam is a protein hydrogel biomaterial that has an expansion agent that generates a mixed-cell foam. The foam creates a mechanical barrier to decrease blood flow and pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis.

The study will evaluate safety outcomes of BioFoam compared with a standard topical blood-stopping agent. The feasibility investigation will be conducted at two investigational sites and will enroll 20 eligible subjects with 10 subjects in each treatment group. CryoLife (NYSE: CRY) now will ask for approval from the U.S. Department of Defense, which will be the final step necessary to begin this trial.

"Following our July 2009 CE Mark approval to distribute BioFoam in the EU, we now have approval to begin a clinical trial, a critical step forward in the process to gain FDA approval of BioFoam in the U.S.," said Steven G. Anderson, CryoLife president and CEO, in a statement. "We believe that BioFoam may hold tremendous promise for surgeons around the world and are excited by the early data published thus far."

BioMimetic Therapeutics Receives First Orthopedic Marketing Approval for Augment™ Bone Graft

From Business Wire

BioMimetic Therapeutics, Inc. received approval from Health Canada to begin the marketing of its lead orthopedic product, Augment™ Bone Graft, as an alternative to the use of autograft in midfoot, hindfoot and ankle fusion indications in Canada.

"After rigorous pre-clinical and clinical evaluation of the product, BioMimetic is now ready to introduce this novel, implantable biologic to the marketplace," commented Dr. Samuel E. Lynch, president and chief executive officer of BioMimetic. "In the Canadian clinical study, we observed 90% clinical success without the morbidity and extra operating room time required to harvest autograft. We are proud to offer this safe and effective product to Canadian surgeons, who will now be able to offer their patients an alternative to the previous method of cutting bone out of one site of their body and transplanting it to another site."

Augment is a completely synthetic grafting system for bone regeneration and is composed of a purified recombinant growth factor, recombinant human platelet derived growth factor (rhPDGF-BB), and a synthetic calcium phosphate matrix, beta-tricalcium phosphate (Î²-TCP). The combination of the two components of Augment is key to the overall effectiveness of the product. The rhPDGF-BB provides the biological stimulus for tissue repair by stimulating the recruitment and proliferation of new bone forming cells and blood vessels, while the Î²-TCP provides the framework or scaffold for new bone growth to occur.

Augment is the company's second product to receive marketing approval in Canada. GEM 21S®, a grafting material for bone and periodontal regeneration, was approved for use by the U.S. Food and Drug Administration (FDA) and Health Canada in 2005 and 2006, respectively. Augment and GEM 21S are both based on the company's platform regenerative technology.

Joint Solutions Alliance Corporation (JSAC), a sales and distribution company for orthopedic products headquartered in Burlington, Ontario, Canada is the exclusive distributor of BioMimetic's Augment Bone Graft product in Canada. BioMimetic will also deploy product specialists in the Canadian market to work collaboratively with the Joint Solutions Team. The company expects the product will be available to customers in Canada within 30 days.

Augment Bone Graft Clinical Trial Results

Health Canada approval of Augment was based on results from a three center, 60 patient open label trial in which all individuals were treated with Augment. Patients were studied for nine months following implantation of the product and were assessed for healing using clinical and radiographic endpoints. Patients requiring fusions involving the midfoot, hindfoot and ankle were all eligible for enrollment in the study.

The results of the study demonstrated that 90% of the patients, which included a large percentage of high risk individuals, achieved a successful outcome based upon return to full weight-bearing and lack of need for revision surgery. The radiographic fusion rate was 87% at nine months after surgery. Based on a literature meta-analysis, the high level of success achieved in the study is consistent with results expected using autograft, the current gold standard for bone grafting materials, but without the morbidity and extra operating room time required to harvest autograft. The data from GEM 21S showing periodontal bone regeneration was also included as supplementary information demonstrating that the product does re-grow bone.

Clinicians are referred to the Augment package insert for additional information on the use of this product.

Meeting/Conference/Trade Show Calendar

Meeting/Conference/Trade Show	Dates	Place	Web Address
Therapeutic Breakfast: Planning for Success: The Balance Between Clinical Trial Design and Implementation	Jan 28	Redwood City, CA	baybio.org/wt/page/Clinical_Trials_Domestic
Medical Device Breakfast Series: Company Valuation for M&A	Feb 9	Palo Alto, CA	baybio.org/wt/page/Company_Valuation_For_M_A
International Symposium on Surface Science Aspects of Pharmaceutical Science, Pharmacology, Cosmetics and Bio-Technology	Apr 19-21	Danbury, CT	mstconf.com/SurfSciPharm.htm

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