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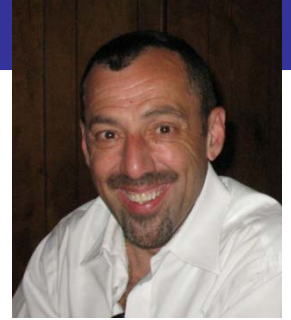
Jodie Laughlin
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Ed Fewkes
Paul German
Michael Wallick
Vipul Dave

SOCIETY OF PLASTICS ENGINEERS

Medical Plastics Division

2013 – Third Quarter



Letter from the Chair:

Dear Friends and MPD Members,

With so much to say in my first newsletter as Chair, it is hard to pick a topic to begin - and be brief at the same time.

I guess I'll start in the past and move to the future. First and foremost, our division had a very successful ANTEC 2013 with some great sessions in Cincinnati. This was followed by our first meeting as a new MPD Board. I would like to welcome all new and returning and current board members and of course thank everyone in advance for volunteering their time and talents. These are very exciting and pivotal times for MPD and our Global Healthcare systems in general.

For the really exciting stuff in the future, the 2013-2014 calendar is action filled for the SPE Medical Plastics Division. We are co-sponsoring a full day Medical Plastics MiniTec with the Chicago and Milwaukee sections on 09 SEP 2013, followed by a keynote session and dinner. You should be getting some additional information on this event in the upcoming months.

We then end 2013 with a BANG! The first-ever SPE TOPCON in China will be held on 11-12 DEC 2013 at the Marriott Hotel City Center in Shanghai. The Medical Plastics Division and the Injection Molding Division are cosponsoring the International Medical Device and Packaging Conference with MPD providing content for the "Global Advances in Plastics for Medical Devices and Packaging" portion of the program. The call for papers already has been out there and the program is shaping up to be one of the best TOPCONs in recent memory. This will be a world class conference with sponsors and presenters from Europe, USA, and China with complete real time translations (Chinese and English) and some great networking opportunities. If you or your company is interested in presenting, sponsorship, or attending please do not hesitate to contact me.

Thanks again, for your interest in MPD and for making our division the best it can be.

Have a great summer everyone. I look forward to continuing to grow the best Division in SPE and look forward to hearing from you and working with all of our members to continue to improve our group.

Sincerely,

Mark Bonifacio
2013 – 2014 Chair

Inside

*Upcoming Conferences
Eurotec 2013 and TOPCON China*

*Goals and Objectives
2013 - 2014*

Technical Presentation

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From The Editor:

I am proud to say that I have been a SPE member since 1985. I am less proud to say that I drifted in and out of the Medical Plastics Division for many years. Early in my career, I went to ANTEC each year for the technical papers, looking for ideas and data that would help me with my projects. About eight years ago, I decided to get involved. Almost immediately, I was elected to the Board of Directors. I begin my fourth year as newsletter editor this year of 2013-2014 and look forward with anticipation.

At ANTEC this year, I learned the most from keynote speakers. One keynote was about measuring biocompatibility of plastics and dealing with regulatory agencies, another on managing innovation (hint: you have to practice creativity and innovation to become good at it, just like a sport or a musical instrument). I attended several interesting and useful technical talks but I had my "A-ha" moments at the keynotes.

I have gotten a great deal from MPD by participating. I invite you to see how much you can get by becoming involved. Volunteer to help the Board of Directors to set up a technical conference, to increase membership, to sponsor the MPD through advertisement, or to work on a MPD education initiative. If you have ideas, call a Board member to chat. Just do it.



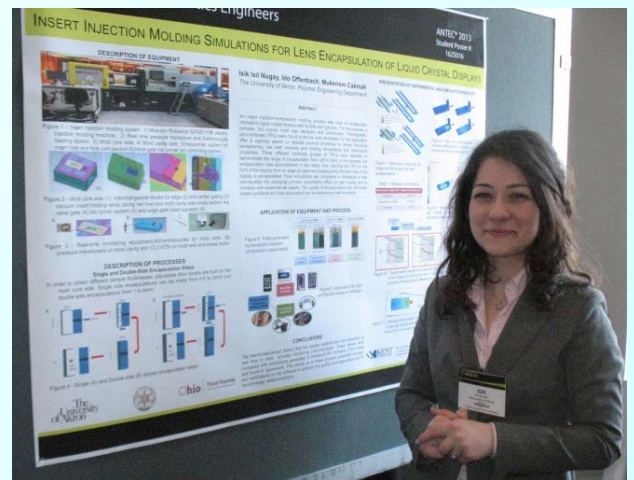
Duke Energy Convention Center
Cincinnati, Ohio, USA April 22-24

Medical Plastics Division

Activities and Programs

Monday Afternoon	M33	Joint Panel with Marketing and Management
Monday Evening	5:30 – 7:00	Medical Plastics Division Board of Directors Meeting
Monday Evening		Medical Plastics Division Dinner at <i>Campanello's</i>
Tuesday Morning	T31	MPD Session – sponsored papers and presentations
Tuesday Morning		Medical Plastics Division Business Meeting Following T31 session
Wednesday Morning	W12	MPD Session – sponsored papers and presentations
Wednesday Noon	12:15 – 2:00	Student Awards Luncheon Junior Ballroom D – 3 rd Floor Duke Energy Center
Wednesday Afternoon		Polymer Applications in Health New Technology Forum
Wednesday Afternoon		Reception jointly sponsored by MPD and EPSDIV Following New Technology Forum

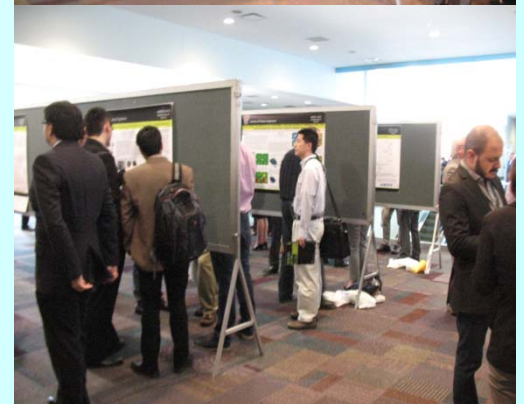
Monday, 22 Apr 2013



Isik Nugay was one of the many student presenters of the Interactive sessions on Monday and Tuesday afternoon.



A joint panel discussion with Marketing and Management was arranged by Vipul Dave of the Medical Plastics Division, which included Jean-Paul Tres (ETS), Michael Devereux (Mueller Prost PC), Maggie Baumman (G. H. Associates), Vipul Davé (Johnson & Johnson) and António Baptista (CENTIMFE).



Medical Plastics Division

ANTEC 2013

Monday, 22 Apr 2013

Board of Directors Meeting



Back Row: Glenn Beall, Margie Hanna, Ben Poon, Vipul Dave, Ed Fewkes, Maureen Reitman, Ali Asher, Jim Oberhauser, Michael Wallick, Len Czuba.

Front Row: Jill Martin, Norris Tollefson, Dan Fuccella, John Thomas, Mark Bonifacio, Steve McCarthy, Harrison Yu

Division Dinner

At a tiny Italian restaurant in Cincinnati



Medical Plastics Division

ANTEC 2013

Tuesday, 23 Apr 2014

It was another busy day in the halls of ANTEC. The plenary speaker, Dwight Tozer from ExxonMobil lit up the crowd by talking about shale gas and its revitalization of the plastics industry. Tuesday was also the second day of the student interactive session, held in the conference area. Judging for best poster presentations was also completed with results compiled and awards given at the Wednesday Student Awards Luncheon. For evening activities, both the UMass Lowell reunion dinner and a dinner for the CASPE (Chinese American SPE) members capped off the second day of ANTEC 2013.



“Past Presidents’ Breakfast.” Current Chair Mark Bonifacio (l) with previous holders of that responsibility; Len Czuba, Glenn Beall, and Steve McCarthy.

T31 - Tuesday Afternoon

1592047	Cold Gas Plasma in the Surface Modification of Medical Plastics	Sahagian, Khoren; Larner, Mikki; Kaplan, Stephen L
1590412	Developing Polymer/Ceramic Scaffolds via Thermally Induced Phase Separation for Bone Tissue Engineering	<u>Akbarzadeh, Rosa</u> ; Hagen, Matthew; Yousefi, Amy
1590211	Design and Fabrication of Polymer/Ceramic Scaffolds for Bone Tissue Engineering	<u>Minton, Joshua</u> ; Janney, Cara; Focke, Carlie; Yousefi, Amy
1474685	New Scientific Approaches for the Integration of the Statistical Design of Experiments for the Validation of Injection Molding Processes in Medical Technology	Mueller, Andrea; Seul, Thomas
1592149	The Effects of Type and Loading of Radiopaque Fillers on the Properties of Polyether Block Amide Compounds	Boyden, Breanna G.; Nilajkar, Amar; O'Neil, Charles
1589897	Synthesis and characterization of PVA/SBMA crosslinked hydrogels with low fouling property	Xu, Shouping; Zeng, Renchang; Lin, Changpeng; Pan, Huichan; Cai, Zhiqi; Wen, Xiufang; Pi, Pihui; Cheng, Jiang
1583498	Thermoplastic Polycarbonate Based Polyurethanes	Walder, Anthony; Makal, Umit; Kulkarni, Pallavi
1591384	An Electroactive Activator made with cellulose/Gamma ferric Oxide/Polypyrrole	Chowdhury, Nargis A.



**Duke Energy Center
Cincinnati, OH**

Medical Plastics Division

ANTEC 2013

Wednesday, 24 Apr 2013



Dr. James Anderson from Case Western Reserve University began the Wednesday MPD session with his keynote speech "New Challenges in Evaluating the Safety of Medical Devices and TEMPs: Beyond ISO 10993".



TEMP stands for tissue engineered medical product. Dr. Anderson discussed the safety and efficacy of medical devices made from plastics and emphasized that regulatory agencies approve the final medical device, not the components from which it was made. It is necessary to understand local interactions of materials in order to predict systemic interactions – if a material does not elicit a biological or toxicological response in direct contact, then indirect contact will not also.

There is often a lack of agreement or recognition between different regulatory bodies and standardization agencies such as FDA, USP, ASTM, ISO, or BSI. The FDA does not accept ISO 10993 as a ruling document but discussions with the FDA are possible. Risk assessment using ISO guidelines does not provide a way to express benefits.

Evaluation of risk must be made based on many different sources of information. Changes in raw materials, in formulation, in processing, in primary packaging, in sterilization, or in product over time must be addressed with the appropriate level of due diligence. If you know your system, do your homework, and document it, challenges in evaluating medical devices become easier.

N.M. Tollefson

W12 – Wednesday Morning

	New Challenges in Evaluating the Safety of Medical Devices and TEMPs: Beyond ISO 10993 Keynote Speaker	James M. Anderson, MD, PhD <i>Ed. Note:</i> TEMP = Tissue Engineered Medical Product
1592193	Performance Evaluation and Morphology Observation of PET/PP Blends in Injection Molding	Otsuka, Tadashi
1592030	The Mechanical Properties and Degree of Crystallinity of Biomedical Grade PEEK	Yakacki, Christopher M
1591720	Fracture Toughness Of A Medical Grade Ultra High Molecular Weight Polyethylene Using A Single Specimen Method	Brignola, Christopher; Shabeer, Ahamed; Guthorn, Paul; Zamiski, Gerald
1579791	A Nanoscaled Three Dimensional Structure Created By Using Electrospun Poly(ϵ Caprolactone) (PCL) Nanofibers and Induced PCL Crystallization	Wang, Xiaofeng; Han, Wenjuan; Salick, Max R.; Wang, Xiaodong; Cui, Zhixiang; Peng, Yiyang; Han, Jian; Turng, Lih Sheng; Li, Qian

Medical Plastics Division

ANTEC 2013

Wednesday, 24 Apr 2013

New Technology Forum

Polymer Applications in Health

Wednesday Afternoon

Putting Electrospun Nanofibers to Work for Biomedical Research	Younan Xia Georgia Institute of Technology
Resorbable Polymers: Melt Processing	Larry Thatcher TESco Associates
Differentiating Biological Response to DES polymers	Barbara Huijbregtse Boston Scientific Corp.
The Application of Bioresorbable Polymers to Vascular Medical Devices	James Oberhauser Abbot Vascular
Value-driven Engineering and U.S. Global Competitiveness	Frank Douglas Austen Bio-Innovation Institute
Global Regulatory Guidelines for the Design and Development of Medical Devices	Jizhong Jin 3M Health Care



Student Awards Luncheon

The Medical Plastics Division and the Engineering Properties and Structure Division co-sponsored this year's NTF, "Polymers Applications in Health". It featured leading scientists and representatives from renowned institutions and companies who shared the latest technology advancements for products either recently introduced or in development for future new products.

Bioresorbable materials was the theme for three of the presentations which covered novel processing technologies and the structure / property dependence, nano-fiber electro-spinning for tissue scaffolding and resorbables for cardiovascular stents. Presentations on testing for critical improvements in DES (drug eluting stent) technology, assessment of global regulatory challenges and the expanding role of global competitiveness completed the program.

Attendees engaged the speakers in a lively question and answer session before all adjourned for the cocktail reception hosted by the sponsor divisions.

Younan Xia – Georgia Institute of Technology **Putting Electrospun Nanofibers to Work for Biomedical Research**

This talk discussed how the conventional setup for electrospinning can be modified to control the composition, structure and alignment of nanofibers. The focus was on the use of aligned nanofibers to control the differentiation of embryonic stem cells into different types of neural lineages and to guide the outgrowth of neurites for peripheral nerve repair, nanofiber scaffolds can be designed for injury repair at the insertion site between tendon and bone, and as substitutes for dura mater in brain surgery.

G. Lawrence Thatcher – TESco Associates **Resorbable polymers: Melt Processing**

This presentation provided an overview of bioabsorbable polymer melt processing including the interplay of the clinical objectives, such as mechanical performance, degradation kinetics, and healing response with the material processing. Some of the critical factors in melt processing, as well as trends, and challenges confronting commercial product realization were offered. Attention to details for sterilization were discussed as well as the potential for the undoing of even well processed materials. An outlook on new materials and processing and comments on the importance of the processor partnership on clinical utility concluded the presentation.

Medical Plastics Division

ANTEC 2013

Barbara Huibregtse – Boston Scientific

Differentiating Biological Response to DES polymers

This presentation described in vitro and in vivo assays that can be performed to evaluate the biological performance of different stent coatings compared to uncoated stents. Evaluation of the biological response can be performed in a series of experiments to assess components of the response to stent when placed for a clinical indication to better understand the individual drivers for the healing response. Protein deposition, platelet adhesion, inflammation, endothelial cell coverage can be assessed through in vitro testing whereas local tissue response can be evaluated at multiple time points in either rabbit or porcine models. The methods and results for different configurations of polymer-coated and bare coronary artery stents were presented.

James Oberhauser – Abbott Vascular

The Application of Bioresorbable Polymers to Vascular Medical Devices

Bioresorbable polymers are increasingly prevalent in medical device applications. One of the more vigorous areas is vascular implants used to treat arterial occlusions, because the disease state lends itself to the transient scaffolding properties of bioresorbable polymers. This presentation used the bioresorbable vascular scaffold (BVS), in development to treat coronary artery occlusions, as a case study of the design requirements and their relationship to polymer processing and characterization. The translation of these concepts to other disease states was discussed.

Frank Douglas (substitute) – Austen BioInnovation Institute

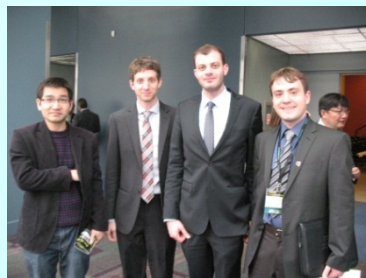
Value-driven Engineering and U.S. Global Competitiveness

The barriers of the U.S. maintaining its lead in the medical technologies and devices industry are not only in the area of R&D spending, but also in the education approaches, regulatory and reimbursement regulations, and patient-centricity. The Austen BioInnovation Institute in Akron and colleagues from several universities and industry have developed an approach that, if adopted, could become a catalyst to further energize U.S. innovation in the medical device space. This approach is called Value-driven Engineering and consists of considering simultaneously, the clinical utility, complexity and healthcare system savings in the design through manufacture of any device. A white paper on the topic details recommendations for educating the next generations of engineers, FDA regulators, and the use of an equation to assess Value of an innovation.

Scott Sardeson – 3M Health Care

Global Regulatory Guidelines for the Design and Development of Medical Devices

Global trends in medical device regulations were discussed. The information provided gave a brief history of medical device regulations, current trends from a manufacturer's point of view and future considerations that need to be monitored by the industry. Also presented were some things to consider in the design and development of medical devices to help manage this increasingly complex area.



The Wednesday evening reception sponsored by both the Medical Plastics Division and the Engineering Properties and Structure Division (EPSDIV) was a great way to follow the New Technology Forum and bring the conference to a close.

Recent Conferences



*Duke Energy Convention Center
Cincinnati, OH April 22-24, 2013*



Exposition: **June 18-20, 2013**
Conference: **June 17-20, 2013**
Pennsylvania Convention Center
Philadelphia, PA



MDMeast.com

*MD&M East will be reported in the next issue
of the Medical Plastics Division newsletter.*

Upcoming Conferences and Activities



See the Advanced Program for *Medical Plastics and Polymers* on the following page.

Upcoming Conferences and Activities

MINITEC 2013



Technology Advances in Plastic Materials and Processing for Medical Devices

Presented by the SPE Medical Plastics Division
with the Chicago and Milwaukee Regional Sections of SPE.

**Monday,
September 9, 2013**

**Holiday Inn Gurnee
6161 West Grand Ave
Gurnee, IL 60031**

See Registration details in this newsletter.

Call for Papers

SPE TOPCON 2013 China Plastics Conference Medical Devices & Packaging 2013

The Medical Plastics Division of SPE invites you to present topics of interest which may include but not limited to the following categories:

Products- Devices for Medical, Biomedical, Drug Delivery, One Time Use, etc.
•Research and Development
•Design
•Application
•Patents, Regulations, Standards, Certifications, and Approvals
•Technical and Financial Merits, Partnership, Funds and Investments

Advanced Manufacture
•Process and Bioprocess
•Equipment
•Materials (Polymers, Biopolymers, Additives, and Biopharma Additives)
•Analytical Testing and Compliance

Speaker Requirements and Deadlines

- July 15, 2013:** Author's name, paper title and abstract (250 words maximum)
- September 15, 2013:** Full paper submission (to be published)
- December 1, 2013:** PowerPoint presentation

Shanghai Marriott City Centre

No. 555 Xizang Middle Road
Huangpu District, Shanghai 200003, China
Phone: +86 800 228 9290

Go to the SPE website www.4spe.org and search on "TOPCON 2013 in China" for complete information.

Polymers in Medicine and Biology 2013

October 9 - 12, 2013
Hilton Sonoma Wine Country
Santa Rosa, California USA

**Division of Polymer Chemistry
AMERICAN CHEMICAL SOCIETY**

<http://www.polyacs.net/workshops/13biomed/home.htm>



Society of Plastics Engineers

EUROTEC® 2013

*Cite Congress Exhibition Center
July 4-5, 2013
Lyon, France*

Medical Plastics and Polymers

Session T15 – Thursday, 04 July 2013

9:00 Microstructural Changes in Polylactides During an Initial 7 Day Degradation Period in PBS

1595517 | Jose-Ramon Sarasua, University of the Basque Country (UPV/EHU)

9:30 New Application for Plastic in Medical Devices

1652144 | Radoni Mario, Politechnic University of Marche

10:30 Development of Contact Lenses for Ocular Drug Delivery

1625215 | David Phelan, Waterford Institute Of Technology

11:00 Evaluation of Shape Memory of a PLGA Glassy Copolymer

1625172 | Jose-Ramon Sarasua, University of the Basque Country (UPV/EHU)

14:30 Innovative Material Solutions for High Heat Autoclaving of Medical Devices

1625222 | Mark van der Mee, SABIC

15:00 Controlling Biodegradable Polymer Thermal and Degradation Properties Through Molecular Design

1579281 | Dan Lewitus, Shenkar College of Engineering and Design

Session T15 – Thursday, 04 July 2013

8:30 Influence of Ag Nanoparticles on Polymer Composite Optical Properties

1625251 | Jovita Pudlauskaitė, Kaunas University of Technology

9:00 Effects of Thermo-Mechanical Treatments on Mechanical Properties of Lactide Derived (Co)Polymers

1652345 | Susana Petisco, UPV-EHU

9:30 Radiopaque Filler Considerations When Designing a Medical Device

1636277 | Brian LaBrec, Foster Corporation

9:30 Effects of Thermo-Mechanical Treatments on Mechanical Properties of Lactide Derived (Co)Polymers

1652345 | Susana Petisco, UPV-EHU

10:30 Soft Contact Lens Development Using UV Curing

1630663 | Austin Coffey, Waterford Institute of Technology

11:00 The Effects of Electron Beam and Gamma Irradiation on the Properties of Poly (Ether-Block-Amide) Compounded with Various Stabilisers

1649960 | Kieran Murray, Athlone Institute of Technology



Technology Advances in Plastic Materials and Processing for Medical Devices

**Monday,
September 9, 2013**

**Holiday Inn Gurnee
6161 West Grand Ave
Gurnee, IL 60031**

Schedule of Events:

7am – 8am
Registration & Continental
Breakfast

8am – 9pm (all day & evening)
Tabletop Exhibition

8am – 5pm
All Day MiniTec
(Lunch and Breaks Included)

5pm – 6pm
Reception & Networking

6pm – 9pm
Dinner & Keynote Speaker

Register to Attend:

Early Registration before July 22
MiniTec Only: \$125
MiniTec and Dinner: \$150
Dinner Only: \$35

Late Registration after July 22
MiniTec Only: \$150
MiniTec and Dinner: \$175
Dinner Only: \$35

Info & Online Registration:

<http://tinyurl.com/medicalminitec>

Contact Information:

Kimberly Rush
Phone: 224-659-0708
E-mail: cspeef@gmail.com

A one day conference where 14 presentations from the industry will discuss the latest developments in the area of medical plastics.

Morning Session on New Materials

High Performance Polymers
Maureen Reitman – Exponent

**Silicone Biomaterial Applications:
Past, Present and Future**
Alexis Proper – PolyOne Corporation

**Specialty Polymer Solutions for a
Changing Healthcare Landscape**
Dane Waund – Solvay Specialty Polymers

PEEK in Medical Implant Applications
Kenneth Ross – Evonik Cyro

Morning Break

**PET: A Sustainable Material for Medical
Packaging Applications**
Scott Steele – Plastics Technologies Inc.

Fluoropolymers in Healthcare Applications
John Felton – Daikin – America

**Polycarbonate Resins for Medical
Applications: Today and Tomorrow**
Pierre Moulinie – Bayer Material Science LLC

**A Multi-pronged Approach to Meeting HAI
Challenges with Specialty Engineered
Thermoplastics**
Lynn Collucci Mizenko/Manish Nandi – SABIC

Lunch

Afternoon Session on New Processing Technologies

**Exciting, New Extruded Tubing Materials
for Medical Applications**
Ed Boarini – Teleflex Medical OEM

**Advantages of Co-extrusion for Use in
Medical Tubing**
Tom Thompson – Teel Plastics

**Openair® Plasma Improves Adhesion of
LSR to Medical Grade Polymer Substrate
Materials**
Jeff Leighty – Plasmatreat

Afternoon Break

**Why Your Perfect Mold and Process
Produces Imperfect Parts**
Kevin Rottinghaus – Beaumont

**Advanced Process Controls for Injection
Molding**
Susan Montgomery – Priamus Systems
Umberto Catignani – Orbital Plastics

**Seeing Beyond the Surface: How CT
Scanning Redefines Industrial Metrology**
Jennifer Raymond/Tom Casali – NyproMold, Inc.

Q & A Discussion *program subject to change

**Reception and Dinner with Keynote
Speaker – Steve Goreham**

TABLETOP EXHIBITOR OPPORTUNITIES AVAILABLE

Showcase Your Company

- Early registration before July 22 - \$450, after July 22 - \$500
- Registration includes 2 admissions
- Company Name Recognition published in promotions and on event signage!
- Booth Setup 7am-8am; requests for electricity accepted

SPONSOR OPPORTUNITIES AVAILABLE – CHOOSE YOUR LEVEL:

Company Name Recognition published in promotions and displayed on signage!

Corporate: \$1000 (includes 2 admissions)
Lunch Sponsor: \$500 (2 available)
Breakfast Sponsor: \$400 (2 available)

Reception Sponsor: \$300 (2 available)
Break Sponsor: \$100 (5 available)

**SPE Medical Plastics Division and
Chicago & Milwaukee Sections Present
MEDICAL PLASTICS MINITEC 2013**



Society of Plastics Engineers

Technology Advances in Plastic Materials and Processing for Medical Devices

**Monday,
September 9, 2013**

**Holiday Inn Gurnee
6161 West Grand Ave
Gurnee, IL 60031**

Schedule of Events:

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8am – 9pm (all day & evening)
Tabletop Exhibition

8am – 5pm
All Day MiniTec
(Lunch and Breaks Included)

5pm – 6pm
Reception & Networking

6pm – 9pm
Dinner & Keynote Speaker

A one day conference where 14 presentations from the industry will discuss topics relating to trends, performance materials, application testing and latest developments in the area of medical plastics. Engineers and management personnel will benefit by attending this MiniTec!

Special Hotel Accommodations at the Holiday Inn Gurnee

- **Room Rate: \$99**
- **Contact hotel directly at 847-336-6300**
- **Mention *MEDICAL PLASTICS MINITEC 2013* for special rate**



**Dinner with Keynote Speaker
Steve Goreham**

**Environmental Researcher & Author of
*The Mad, Mad, Mad World of Climatism***



www.heartland.org/steve-goreham

**For more information and
to register online:
<http://tinyurl.com/medicalminitec>**

Registration Form

Early Registration before July 22

MiniTec Only: \$ 125
MiniTec and Dinner: \$ 150
Dinner Only: \$ 35
Tabletop Exhibit: \$ 450

Late Registration after July 22

MiniTec Only: \$ 150
MiniTec and Dinner: \$ 175
Dinner Only: \$ 35
Tabletop Exhibit: \$ 500

Sponsorship Opportunities

Corporate: \$ 1000
Lunch: \$ 500
Breakfast: \$ 400
Reception: \$ 300
Break: \$ 100

Mail to: Attn. Kimberly Rush, Polyform Products Company, 1901 Estes Avenue, Elk Grove Village, IL 60007
Check payable to: SPE Chicago Email with credit card information to: cspeef@gmail.com

Please charge my Credit Card \$ _____

Enclosed is my Check for \$ _____

Card #: (AmEx/Visa/MC) _____

Exp. Date: ____/____/____

Authorized Signature: _____

Security Code: _____

Name: _____

Company: _____

Address: _____

City/State/Zip: _____

Phone: _____ Fax: _____

Email: (please print legibly) _____

Questions? Contact Kimberly Rush at
224-659-0708 or Email: cspeef@gmail.com

Medical Plastics Division



Mission Statement

To promote the Medical Plastics Division of the Society of Plastics Engineers through outreach, networking, and education about our fascinating and vital industry. To encourage participation of everyone from the MPD Board and from the Division to help shape our message and to encourage others to join us in this mission.

Goals and Objectives 2013 - 2014

Leadership Development

Communicate about our industry through outreach, education, and networking. Encourage MPD Board members and division members to actively participate in the Division and SPE. Identify new board prospects, mentor those new to the board. Initiating new MPD programs to benefit members and prospective members of SPE. Be respectful of everyone's opinions.

- Fill all positions on board.
- Have each BOD member identify a successor and mentor that person.
- Hold 6 Conference Calls as a Board during MPD 2013-2014 Calendar year.

Technical Programming

Maintain or increase MPD level of participation at ANTEC, including joint sessions with other divisions.

Continue to partnership with UBM Canon for MDM shows.

Develop a speakers list for division.

Continue support of TopCon for 2013.

Support and participate in the EuroTec and AsiaTec conferencing efforts.

Communications Program

Publish at least three issues of the Medical Plastics Division newsletter of high quality content with news of activities and interest to our members.

Use the website for better communication about MPD activities and volunteers.

Utilize SPE monthly email blasts to reach out to members with news and to promote activities.

Finance Committee

Determine effective use of MPD funds to support an operating budget as well as member programs, benefits, and student support.

Develop long-range plans for use of funds including annual budget and to raise income.

Membership

Appoint a membership chair to develop a communication program, to recognize new members, and to reach out to potential new members. Increase division membership by 5%.

Recognition

Use Awards program to recognize contributions from conference speakers and student papers. Work with programming committee to identify and recognize best speaker at each conference.

Nominate and sponsor at least one member for either Honored Service Member or Fellow from our division.

Use division awards to recognize significant contributions.



SOCIETY OF PLASTICS ENGINEERS INC.
MEDICAL PLASTICS DIVISION

Sponsors...

We are now seeking Sponsor Display Ads for our Award-winning Division Newsletter! To show your support of the Society of Plastics Engineers and in particular, the Medical Plastics Division Newsletter, please consider taking part in this important communication effort.

Sizes Available (Full year amount, i.e. 3 issues)

Full page (8½" X 11")	\$3,000
Half page	\$1,600
Quarter page	\$900
Eighth page	\$500

The newsletter is published electronically at least **three times per year**. Every Medical Plastics Division member, about **1,000**, receives a copy mailed directly to their listed address. And additional copies are also circulated in our continuing effort to reach new and prospective members and other interested individuals.

To show your support please contact Norris M. Tollefson (newsletter editor) at 678-415-3784 (Internet: Norris.tollefson@cibavision.com) with your copy (jpg preferred) and payment.

Or contact MPD Chair Mark Bonifacio at 310-683-3257 (Internet: mark@bonifacioconsulting.com) for more information.

Thank you for your support!

Medical Plastics Division - SPE Board of Directors for 2013 - 2014

Name	2012-2013 Position	Company
Officers		
Mark Bonifacio	Chair	Bonifacio Consulting
open	Vice Chair	
John Thomas	Secretary	Bonifacio Consulting
Paul German	Treasurer	Kruger Plastics
Margie Hanna	Councilor (2012 - 2015)	Czuba Enterprises, Inc.
Jill Martin	Past Chair (2012 - 2013)	Dow Chemical
Board Members		
Class ending ANTEC 2014		
Norris Tollefson	Newsletter Editor	Alcon Laboratories, Inc.
Jim Madenjian	Membership	J.M. Engineering Associates
Harrison Yu	Website Communications / Pinnacle	Bondable Biopolymers
Jordan Freedman	Technical Program Committee	Biomet Orthopedics
Class ending ANTEC 2015		
Jodie Laughlin	Marketing - To be chartered	GE Healthcare
Maureen Reitman	Awards / Technical Program	Exponent
Ken Breeding	Marketing - To be chartered	Eastman Chemical Company
James Oberhauser	Technical Program Committee	Abbott Vascular
Ali Ashter	Technical Program Committee	EMD Millipore
Class ending ANTEC 2016		
John Thomas	Secretary	Bonifacio Consulting
Ed Fewkes	Technical Program ANTEC	Corning Inc
Ben Poon	Technical Program Committee	Baxter Healthcare
Len Czuba	Technical Program Committee	Czuba Enterprises Inc
Michael Wallick	Awards Committee	Invibio Biomaterial Solutions
Vipul Dave	Technical Program Committee	McNeil Consumer Healthcare
ex officio		
Glenn Beall	Historian (Appointed)	Glenn Beall Plastics
Sarah Sullinger	SPE Liaison (Appointed)	SPE
Vijay Boolani	EC Liaison (Appointed)	Boolani Engineering Corporation
Gerry McNally	EMPD TPC	McNally Associates
Austin Coffey	EMPD Chair & Councilor	Waterford Institute of Technology

If you would like to get in touch with a member of the board, contact information may be found in the SPE Membership Directory.

Board of Directors for the Medical Plastics Division

New and Returning Board Members for 2013 – 2014.



John Thomas is the Managing Director for Technical Services at Bonifacio Consulting Services. He has been an engineer, manager, or consultant in medical device manufacturing, consumer goods, and other plastics related industries since graduating from UMass Lowell in 1993. John has held positions in R&D, product development, management, and engineering. With an MBA from the University of Southern California, John brings a wide variety of experience and a unique and well rounded perspective.



Ben Poon is a Senior Principal Engineer in the Materials Science group at Baxter Healthcare Corporation. He is responsible for design, selection, and support for materials used in new medical devices as well as current products. Prior to Baxter, Ben worked at Dow Chemical to develop XLA™ Elastic fibers and INFUSE™ Olefin block Copolymers. He graduated from Cornell with a BS in Materials Science and from Case Western Reserve with a PhD in Macromolecular Science.



Len Czuba is president of Czuba Enterprises, Inc., a Chicago-based product development firm. He works with clients to take products from concept to market. His primary focus is selection and processing of plastics and biomedical polymers for medical devices. In 2004, Len was recognized as one of the 100 MD&DI Notable Persons in the medical device industry. He has been a member of SPE since 1975 and is a Distinguished Honored Service Member.



Paul German is currently the marketing / quality manager at Kruger Plastics in Benton Harbor, MI. He has worked in the plastics industry for over 30 years. Paul has been treasurer of the Medical Plastics Division of SPE for 30 years, providing the membership with concise reports on finances and communicating with SPE on tax reporting measures.



Michael Wallick is the US Technical Support Manager for Invivo Biomaterial Solutions. Previously, Michael was a Polymer Research Scientist and injection molding subject matter expert with a leading medical device manufacturer. Magna cum laude graduate from Huntington University, Michael is a member of SPE and ASTM.



Vipul Dave has been at Johnson & Johnson for over 16 years and is currently a Research Director in the Global Technology group at McNeil Consumer Healthcare, a J&J company. His technical expertise is in biomaterials, medical plastics, and drug delivery, with applications to oral care, wound care, skin care, and personal care products. Vipul received his BS from the University of Baroda, India in Textile Engineering and his PhD from Virginia Tech in Materials Engineering.



Ed Fewkes started his career with GE Plastics working in materials chemistry, reactive extrusion, and PC/ABS blends. He continued with Corning Inc where he has held positions as a scientist and as a manager in all of Corning's major businesses, especially Corning Optical Fiber, Corning Cable Systems, and Corning Life Sciences. Ed received his undergraduate degree in chemistry from Rensselaer Polytechnic Institute and his PhD in organometallic chemistry from Princeton. He has been an SPE member since 1990.

Requirements and Responsibilities of Board Members for the Medical Plastics Division

- ▶ Candidates for the SPE Medical Plastics Division Board of Directors must be active members of the Society of Plastics Engineers and of the Medical Plastics Division.
- ▶ Members of the Board should be involved in or have interest in some aspect of the Medical Plastics Business or a related academic field.
- ▶ Board members are expected to participate in monthly 1-hour teleconference meetings and annual in-person Board of Directors and Business meetings at SPE's Annual Technical Conference (ANTEC).
- ▶ Board members are expected to assume responsibility for specific duties, such as Secretary, Newsletter, Web-Site, Social Activities, Technical Program Chair, Membership, Student Activities, Treasurer and SPE-Council Representative.
- ▶ Board members are expected to participate in committees in some capacity to support activities such as Technical Conferences, Membership Group Activities, Financial oversight, BOD nominations, etc.
- ▶ We encourage an active membership so any one individual doesn't carry too much of a load.

Board of Directors Meeting of the Medical Plastics Division of the Society of Plastics Engineers
Meeting Minutes

Date: April 20, 2013 5pm, ANTEC 2013 Duke Energy Convention Center, Room 250

In attendance:

Mark Bonifacio, Margie Hanna, Dan Fuccella, Jill Martin, Ali Ashter, Ed Fewkes, Glenn Beall, Harrison Yu, Jim Oberhauser, John Thomas, Len Czuba, Maureen Reitman, Norris Tollefson, Steve McCarthy, Vipul Dave, Benjamin Poon, Michael Wallick, Sarah Sullinger

Call to order

Roll Call, Introductions , Welcome new BOD members and officers

Brief Intro – Incoming Chair – Mark Bonifacio Goals for 2013-2014

1. Approval of meeting minutes from March 7, 2013: Moved John Thomas; second Norris Tollefson
2. Treasurer's report
 - a. Schedule of next finance committee meeting: Paul German, Mark Bonifacio, Steve McCarthy, John Thomas will attend
 - b. Schedule for remainder of 13-14? 2-3 weeks before each BoD meeting.
 - c. \$32,504 balance, \$1,037 SPE rebate. Paul German to provide report
3. Technical program
 - a. MD&M Anaheim, CA – had 8 speakers, 40 attendees, high quality and diversity of talks ~\$3,500 revenue. Next year will seek more OEM speakers, think about selling sponsorships, watch for too much commercialism.
 - d. MD&M in Philly (June 2013)
 - i. Vipul Dave: All set with 8 speakers, 4 from Anaheim and 4 new, in process of getting bios etc.
 - ii. Len Czuba: Time to decide on doing 2014
 - iii. \$10K sponsorships including a speaker spot
 - iv. Concern that sponsorship spot will become marketing talks. SPE MPD does not want to compromise the quality of the content.
 - e. ANTEC 2013/2014
 - i. Jim Anderson is the Keynote speaker for the Wednesday am session.
 - ii. Need to write up job descriptions for the Committee Chair positions.
 - iii. Need paper reviewers.
 - f. TOPCON China – Marriott City Center, Shanghai 12/11/13 thru 12/12/13
 - i. Harrison Vu, Steve McCarthy, Ali Ashter and Vipul Dave
 - ii. MPD will co-sponsor with Injection Molding Division and SPE headquarters. Profit breakdown: 25% MPD, 25% IMD, 50% SPE; currently have 6 speakers lined up from MPD. They are looking for 20 MPD speakers; expecting 300 attendees.
 - g. MiniTec (no paper submissions required vs. TOPCON)
 - i. MiniTec committee Vipul Dave, Len Czuba. Jim Madenjian, Ben Poon
 - ii. Much interest by sections in doing a MiniTec with MPD
 1. Chicago section is doing a MPD MiniTec 9/9/2013
 2. Minneapolis section wants a MiniTec Spring or Fall of 2014
 3. Piedmont – Coastal Section (eastern NC) wants Fall of 2014
4. Membership
 - a. 24% New Memberships are outside of the US
5. SPE Leadership Update – Sarah Sullinger
 - a. SPE update
 - b. Vijay Boolani President-elect
6. Communications
 - a. Newsletter update – Norris T
 - b. Content , request for assistance

1. Councilor Report – Margie Hanna
 - a. 24% New Memberships are outside of the US
 - b. ANTEC 2014: Las Vegas, 2015: Orlando, 2016: Indianapolis
2. Liaisons – EMPD, EC, SPE Sarah Sullinger’s Report:
 - a. Instituting new Customer Management System May 31, 2013
 - i. Will be able to choose two groups (sections, divisions, etc.)
 - ii. Will be daily updates
 - b. New more user friendly website coming in December 2013
 - c. SPE Events app coming end of summer
 - d. Looking at a new paper review system
 - e. European Medical Polymers is proposing a TOPCON next year
3. Unfinished business
4. New business
 - a. Conference Calls Schedule
 - b. Other Sub Committee Calls (ex- Finance)
 - c. Other : Need to work on Pinnacle award and nominations for Fellow and Honored Service Member nominations.
5. Closing Remarks – Next Meeting – Thank You to everyone for your time, talent and efforts.
 - b. NEXT MEETING 5/20/13 Mon 11 a.m. EST, 8 a.m PST Call in INFO TBD Will EMAIL TO ALL and send MEETING NOTICE.
 - c. Meeting was adjourned 6:27pm Moved Steve McCarthy, second Ali Ashter

Technical Presentation

Cold Gas Plasma in Surface Modification of Medical Plastics

Khoren Sahagian, Mikki Lerner, and Stephen L. Kaplan. Plasma Technology Systems, Belmont, CA

Abstract

Cold gas plasma may be applied to medical and life science material surfaces for the permanent re-engineering of polymers, elastomers, metals and ceramics to provide unique surface properties without affecting the bulk properties. Examples of applications include: surface amination, coating and/or ink adhesion, biocompatibility, or wettability to fluids or reagents. Plasma is an excited gas comprised of metastable molecular fragments that are able to polymerize or covalently graft to a surface. Considerations in creating a plasma include power delivery, gas or vapor composition, or unique chamber configuration and design. Plasma systems exist that enable both facile batch processing or in-line treatment of sheet and fiber.

Introduction

Surface interactions play a critical role in biological and polymeric systems. It is at these interfaces that chemistries will undergo reaction or elicit a specific environmental response. Plasma is a means by which to modify the chemistry at a surface. This allows for greater versatility with a substrate and less emphasis on the material selection. The plasma is used as a catalyst for the modification of a wide range of materials. In their energized state, molecular fragments will effectively restructure the topmost layer of a solid.

A myriad gases or vapor may be used independently or in concert with other gases or liquid species to create specific modifications to a surface (Table 1). Careful consideration is made to select chemistry that will yield a desired property for a specific application or function.

Table 1. Sample gases and liquids used to create plasmas in low pressure

Gas Chemistry	Liquid Chemistry
Oxygen	Methanol
Argon	Water
Helium	Allyl Amine
Nitrogen	Ethylenediamine
Ammonia	Acrylic Acid
Hydrogen	Acetone
Nitrous Oxide	Hydroxyethylmethacrylate
Carbon Dioxide	Polyethylene glycols
Air	Hexamethyldisiloxane
Ethylene	Diaminopropane
Hexafluoropropylene	Diglymes
	Silanes (Amino, Carboxy, Hydroxyl, Mercapto, Vinyl)

As practiced, cold gas plasma modifications are achieved via a vacuum process. The components to be treated are placed in a vacuum compatible chamber that is vacated to a base pressure of on average 35 to 100 mtorr. Process gas(es) are then introduced into the chamber to a desired system equilibrium.

Radio-frequency energy supplied to electrodes within the chamber excites the gas(es) into plasma. Plasma, the fourth state of matter, is a gas comprised of modest concentrations of electrons, ions, as well as other excited meta-stables. These excited species have sufficient energy to rupture chemical bonds of the component (substrate). These ruptured bonds are thermodynamically unstable and reach out into the plasma to combine with gas fragments to normalize their energy, thereby molecularly re-engineering the surface of the material placed into the plasma.

Cold gas plasma processes are low energy processes and the species created have little penetrating energy, thus the modification is limited to the surface of solid materials. This is typically no deeper than a few molecular layer. Porous media, such as sintered polyethylene membranes, polyolefin non-wovens, & foams are readily modified as the species sustain enough energy for modification of the interstitial surfaces. Temperature sensitive materials such as low molecular weight olefins, and individual fibers may be easily modified in cold gas plasma without deteriorating the bulk properties of the material being treated. As practiced in non-semiconductor applications, cold gas plasma is recognized as both a worker and safe workplace clean air technology.¹

Applications in Medical Plastics

Surface Functionalization

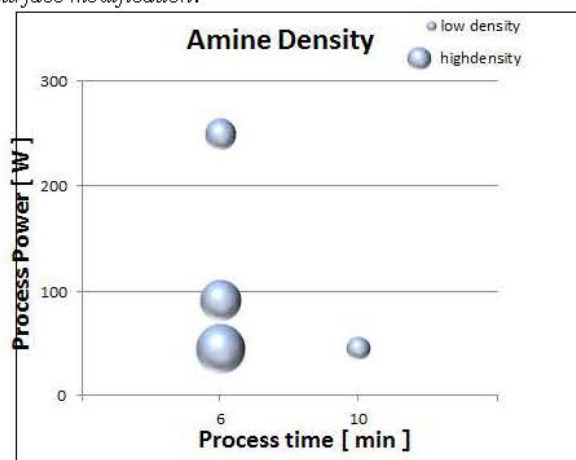
Cyclo olefin, glass, methyl methacrylate or lower cost polypropylene, polyethylene and polyester micro fluidic devices and sensor surfaces may require a specific binding property or a capacity to react with a fluid. Functional groups such as amine, hydroxyl and carboxyl (to name a few) will evoke system specific responses such as binding to proteins, nucleotides, or adhesives. Plasma begins by removing organic surface contaminants by reducing them to volatile compounds. The nascent surface is subsequently reacted to process specific plasma chemistry. The intensity and duration of a plasma process is deterministic in the surface functionality and density that result. If the density of a functional moiety is either too high or too low this may hinder an intended surface reactivity. Table 2 illustrates the percentage of elemental

nitrogen detected on a gold surface as measured by XPS before and after plasma functionalization.² This amine is covalently bound to the surface meaning it is permanently incorporated onto the surface. This is exemplified by the persisting nitrogen composition post solvent wash. Figure 1 demonstrates different amine densities resulting from varying plasma process intensity and exposure. It is noteworthy that plasma processing isn't a linear phenomenon and therefore judicious selection of power, pressure, and time may be necessary. More power and more time does not always translate to denser species loading. Plasma operates within regimes that may be either addition or ablation dominant.

Table 2. XPS measurement of amine incorporation onto a gold surface. The modification is permanently bound to the surface and persists after a solvent wash

Sample	C	N	O	Cu	Zn	Au	F
Control	46.5	-	10.8	1.6	-	39.7	-
Amine	72.9	16.5	8.1	0.1	-	2.2	-
Amine washed	73.6	15.7	10.0	-	0.4	0.2	0.1

Figure 1. The relative amine density on a surface as related to process power and duration of a plasma surface modification.



Device Hydrophilization

As markets improve the accessibility of medical and diagnostic devices to their consumers, product evolution drives material selection towards the use of commodity polymers such as polypropylene and polyethylene. Many of these plastics however lack the surface polarity that typically makes a surface compatible with an aqueous solution or biological reagents.

In industry there is often confusion relating wetting, surface energy, and chemical functionality. One general misconception is that 70 dynes/cm is synonymous with a hydrophilic surface. Dyne solutions are not water. They are solvent mixtures. Functional groups of the plasma treated samples may interact with the hydroxyl, ether, and amine groups of the solvents.³ A study was conducted on polyethylene (a hydrophobic polymer) by varying exposures of power and pressure using three plasma chemistries known to add oxygen moieties to a surface. Figure 2a and 2b present measurement made over a 48 hour interval on the polyethylene surface using both a surface dyne solution and a contact angle using distilled water. In most cases greater hydrophilicity is accompanied by a high surface dyne level, however, samples 9 and 12 exhibit poor hydrophilicity yet the dyne values are still high. Reliance on the contact angle or dyne solution alone is not an accurate guide for wettability.

Figure 2a. Contact angle measurements conducted on polyethylene after exposure to various plasma processes.

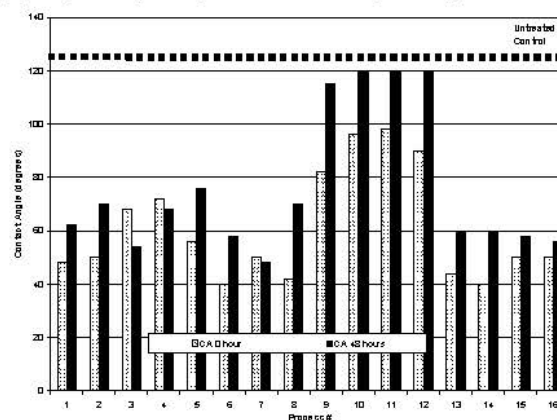
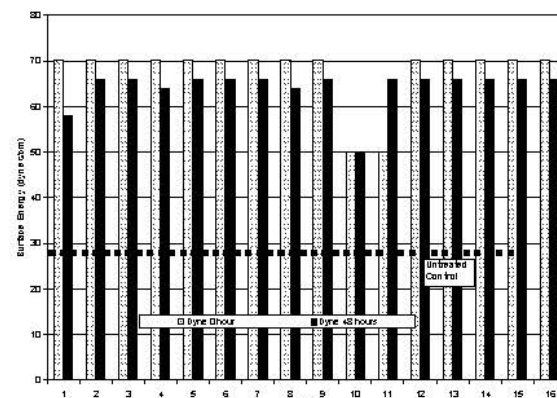


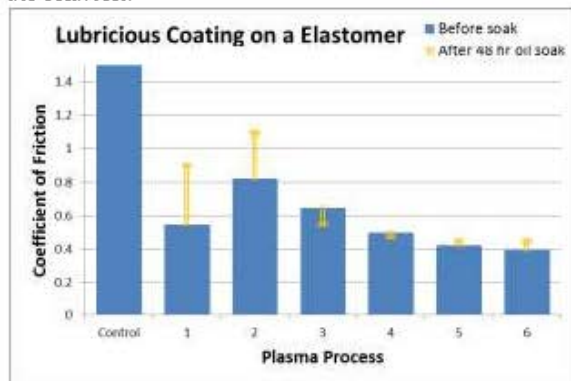
Figure 2b. Surface dyne level as measured on polyethylene after exposure to various plasma processes.



Lubricious Coatings and Anti-blocking

Without a surface treatment many categories of elastomers adhere to themselves or another surface when exposed to pressure, temperature, or humidity. Anti-blocking refers to the ability of a surface to not stick. In the medical device arena, anti-blocking agents such as waxes and oils are often unacceptable solutions in the management of adhesion. Such modifiers may be unapproved for device use due to the potential for elution into a working fluid or the disruption of organism function. Various low coefficient of friction surface treatments are available for deposition on polymeric substrates such as those used in seals, caps, catheters, and syringe plungers. These materials include but are not limited to silicones and thermoplastic elastomers such as Polyether block amide or polyurethanes. Plasma polymerized coatings form densely crosslinked polymer networks that are covalently bound to a surface. Some of these coating chemistries have also been optimized for performance as flexible gas and/or liquid barriers⁴. Figure 3 demonstrates plasma processes which reduce static friction as deposited on a fluoroelastomer surface. Plasma treated components were then soaked in oil for 48 hours and the change in coefficient of friction was noted in orange. In particular process 4, 5, and 6 exhibit a threefold decrease in the coefficient of friction and minimal change after the oil exposure.

Figure 3. Friction reducing plasma surface treatments before/after oil soak. The coatings are leach free and some exhibit good compatibility in oil as demonstrated by the soak test.

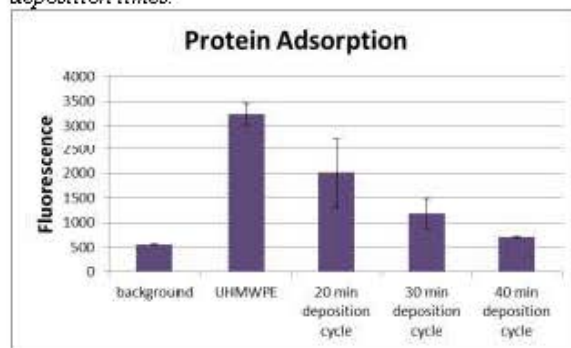


Bioactive Surface

Dynamic interactions exist between surfaces and living organisms. Biocompatibility is loosely achieved if a device functions without eliciting an unfavorable response in a living system. Surface energy, ionic interaction, and intermolecular forces all play a role in the adsorption of proteins. In one example when a foreign object becomes

implanted in the body the immune system may respond by marking the surface with communicative molecules. It has been demonstrated that cell attachment may be inhibited through protein resistant coatings. S. Kane *et al.* demonstrates the feasibility of plasma polymerized polyethylene glycol (PEG)-like hydrogels on the surfaces of implantable ultra high molecular weight polyethylene (UHMWPE) components⁵. Plasma introduces a streamlined controlled approach to functionalize and coat the surface without a time intensive or multi-step wet chemistry. Figure 4 compares the protein adsorption via optical fluorescence on a few variations of plasma deposition thicknesses. A positive correlation can be seen relating plasma coating thickness and protein resistance. The ether (C-O) content in the plasma coated hydrogel was measured between 82.1-83.2%. This nearly matches the 100% ether content of conventional bulk polymerized polyethylene glycol. Additionally the mechanical properties of the ultra-thin coating were assessed using atomic force microscopy. Unlike alternative hydrogels, the plasma deposited coating is covalently coupled to the polymeric surface and demonstrates improved pressure and wear resistance. The time required for processing a batch of parts is on average less than 20 minutes using a 5 cubic feet PTS 0500 plasma reactor.

Figure 4. Protein adsorption on the surface of PEG-like plasma polymerized coatings as related to increasing deposition times.



Conclusion

Plasma is a versatile tool that is capable of solving many surface modification challenges. This includes streamlining approaches where conventional multi-step wet chemistries are employed. Examples show that there is no universal process for like and dissimilar materials. Screening studies are warranted to understand optimum conditions for the desired surface modification. Plasma gives the design engineer the freedom to separate mechanical, optical, and fabrication techniques from the surface requirements. Freedom of choice usually results in significant cost savings. It is important to note that presenting a comprehensive overview of plasma's potential in a brief presentation minimizes the true

capabilities of the technology. With plasma surface treatment, the choices and capabilities are expansive. Plasma surface treatment is not one process, but an entire chemistry tool box.

References

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