SOCIETY OF PLASTICS ENGINEERS

Medical Plastics Division

2013 – Second Quarter

Letter from the Chair:

Dear Members:

It is hard to believe that spring is here already! At least it is in Texas where I'm enjoying the bluebonnets and other spring flowers along with seasonable temperatures. I'm personally taking it all in before the heat of a Texas summer sucks all of my energy away.

Spring also means ANTEC must be right around the corner. For those of you planning on traveling to Cincinnati, our division has a number of activities and sessions planned with a joint session on Monday afternoon with the Marketing & Management SIG, papers on Tuesday afternoon and Wednesday morning, and a New Technology Forum on Wednesday afternoon. If that doesn't keep you busy enough with the rest of your SPE colleagues, we also are having a business meeting right after the Wednesday morning session and a joint reception with EPSDIV on Wednesday after their final session. I think it is important to remind everybody that all division members are welcome to join us for the business meeting. We are in the process of electing new board members and it is an opportunity to both see what we are doing as well as consider running next year!

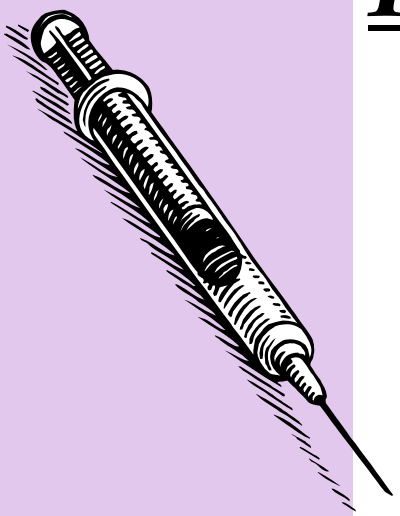
Later this year we will be participating in the TopCon in Shanghai. This is a new initiative for SPE and one that our board agreed would be a good opportunity to both teach and learn from the medical device industry in a dynamic economy. Harrison Yu and Ali Ashter are soliciting papers and the topics can be found in this newsletter. Even if you don't participate in the industry in China today, attendance will enable you to decide if maybe your business strategy should also involve working with companies who understand the intricacies of engagement.

Lastly, I want to informally welcome Mark Bonifacio to the role of Medical Plastic Division board president. Mark is a very dynamic person who will be rapidly engaging with division members at ANTEC to make sure that we continue to grow membership and also address the changing industry.

See you in Cincinnati!

Jill Martin
2012 – 2013 Chair

Inside



Upcoming Conferences
ANTEC 2013 and Eurotec 2013

Goals and Objectives
2012 – 2013

Technical Presentation
from ANTEC Mumbai

In This Issue

From The Editor:

Another year gone by and we are just a few short weeks from ANTEC 2013 in Cincinnati OH. I have always looked forward to attending, eagerly reviewing the advanced program, wondering how I am going to juggle the three talks I want to go to at 10 am, who I will see on the Exposition floor. Over the last few years, my favorite social event has turned out to be the annual MPD dinner.

We are delighted to have Dr. James M. Anderson of Case Western Reserve open the Wednesday morning session of the Medical Plastics Division program as our keynote speaker.

Rumor has it that a mobile app for ANTEC 2013 was announced on Twitter. I must admit that I didn't see it because I don't tweet. The apps ANTEC2013 is supposed to let you see the technical program from your mobile device as well as details of the Exposition and help you schedule your time between the technical presentations and the Expo. Go to your apps store and search for ANTEC2013. I am going to check it out as soon as I can pick up a signal.

There are many things to look forward to at ANTEC 2013. Hope to see you there.

Norris M. Tollefson

ANTEC® 2013

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

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 *Campanello's*
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 – 3rd 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

All events are open to all registered conference members with the exception of the Medical Plastics Division Board of Directors Meeting. The Student Awards Luncheon requires advanced ticket purchase.

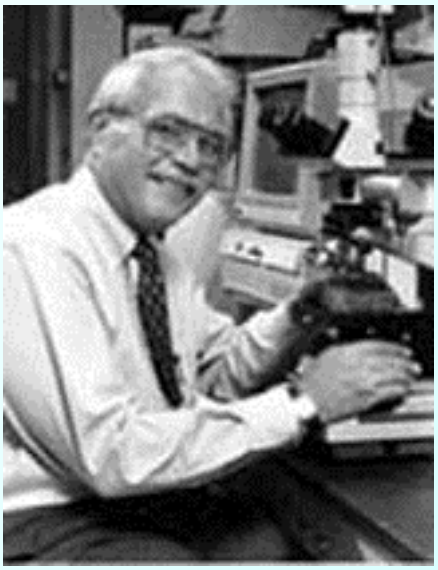
For more information, go to www.4spe.org

Medical Plastics Division

Program for ANTEC 2013

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	Akbarzadeh, Rosa; Hagen, Matthew; Yousefi, Amy
1590211	Design and Fabrication of Polymer/Ceramic Scaffolds for Bone Tissue Engineering	Minton, Joshua; 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.



Our keynote speaker **James M. Anderson** is a Professor of Pathology, Macromolecular Science, and Biomedical Engineering at Case Western Reserve. He has worked in the area of biomaterials, medical devices, and prostheses for 40 years. Current activities include the clinical pathology evaluation of retrieved implants from humans to fundamental studies of cellular interactions with biomaterials, working with *in vivo* and *in vitro* systems.

Dr. Anderson is a founding member of the Society for Biomaterials and of the Controlled Release Society. He serves as a consultant to the NIH Artificial Heart Program, to the FDA, to ISO, and he is Editor-in-Chief for The Journal of Biomedical Materials Research. He has received recognition for accomplishments in both research and in education.

Medical Plastics Division

Program for ANTEC 2013

W12 – Wednesday Morning

	New Challenges in Evaluating the Safety of Medical Devices and TEMPs: Beyond ISO 10993 **Keynote Speaker**	James M. Anderson, MD, PhD *Ed. Note:* 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, Yiyan; Han, Jian; Turng, Lih Sheng; Li, Qian

New Technology Forum

Polymer Applications in Health

Wednesday Afternoon

Putting Electrospun Nanofibers to Work for Biomedical Research	Younan Xia Georgia Institute of Tecnology
Resorbable Polymers: Melt Processing	Larry Thatcher TESco Associates
Differentiating Biological Response to DES polymers	Barbara Huibregtse 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

Recent Conferences

MEDTECH SESSION

The Society of Plastics Engineers Medical Plastics Division (MPD) sponsored a one day **MedTech Polymers** session on February 11, 2013 in collaboration with UBM Canon during the MD&M Conference in Anaheim, CA. The session was organized and chaired by Vipul Davé, an Engineering Fellow at Johnson & Johnson and a Board Member of MPD. There were 10 presentations in the session which were delivered by experts in the medical plastics field. The topics of the talks included implantable devices such as sutures and stents; materials and processes used in catheter technology; innovations in antimicrobial and chemical resistance polymers; and development of stem cell based tissue engineering therapies and MEMS based drug delivery devices. Details of the titles and speakers are provided at right.

All the talks were well attended and at the end of each presentation there was an interactive discussion which exhibited a lot of interest in the educational value that was provided by each speaker. The session was attended by about 40 conference attendees! The accompanying photographs were taken during the session which represents an engaging environment during the presentations.

A similar one day **MedTech Polymer** session will be held at the MD&M East Conference in Philadelphia on June 20, 2013. We look forward to seeing all of you at this conference to enjoy and learn about innovations in Medical Plastics!

1E – MedTech Polymers	
9:00AM	**Plenary Session: Opening Keynote Speech** ***Is there room for innovation in today's medical device industry?*** ***Stanton Rowe*** *Corporate VP, Advanced Technology and CSO* **Edwards Lifesciences**
9:50AM	Networking Coffee Break
10:10AM	**Opening Remarks** Chair: ***Vipul Davé***, *Engineering Fellow - MD&D Global Supply Chain*, **Johnson & Johnson**
10:20AM	**Suture and fiber materials selections for cardiovascular device components** ***Ed Boarini***, *Sr. VP and General Manager*, **Teleflex Medical**
10:55AM	**Using Polymers' Mechanical and Surface Properties in the Development of Stem Cell-Based Tissue Engineering Therapies** ***Byron Deorosan***, *Associate*, **Exponent**
11:30AM	**Meeting the Demands of Medical Device Performance Requirements with Polymeric Bioresorbable Vascular Scaffolds** ***Ashley Kelley***, *Sr. R&D Engineer*, **Abbott Vascular**
12:00PM	Lunch Break
1:00PM	**EFEP co-extrusion technology** ***John Felton***, *Market Development Manager*, **Daikin America**
1:35PM	**Advances in antimicrobial plastics technology** ***Matthew Gande***, *Principal Technology Specialist*, **BASF**
2:10PM	**Comparative radiopacity and mechanical properties of FDA compliant radiopacifiers** ***Jack Frautschi***, *Sr. Biomaterials Scientist*, **PolyOne Corporation**
2:50PM	Networking Coffee Break
3:00PM	**MEMS intraocular drug delivery device** ***Ronalee Mann***, *Senior Associate*, **Exponent**
3:30PM	**Chemical resistance of Eastman Tritan™ copolyesters and engineering polymers used in medical devices - oncology drug case study** ***Yubiao Liu***, *Medical Application Development Manager*, **Eastman Chemical**
4:00PM	Day One Welcome Drinks Reception

Keynote speaker Kim Blickenstaff, President and CEO of Tandem Diabetes Care

MD&M West 2013

Jeremy Fennelly (right) and colleagues from Abbott Vascular

Jim Pike (DSM Engineering Plastics) and Dennis Jamiolkowski (J&J Ethicon)

Upcoming Conferences and Activities

1983-2013 MD&M 30TH ANNIVERSARY EAST

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

UBM Canon

MDMeast.com

The program for MD&M East will be very similar to the recent MD&M West program.

SPE EUROTEC 2013

JULY 4-5
Cité Centre de Congrès
Lyon, France

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

Call for Papers

SPE Medical Plastics TOPCON in Shanghai, China: December 18, 2013

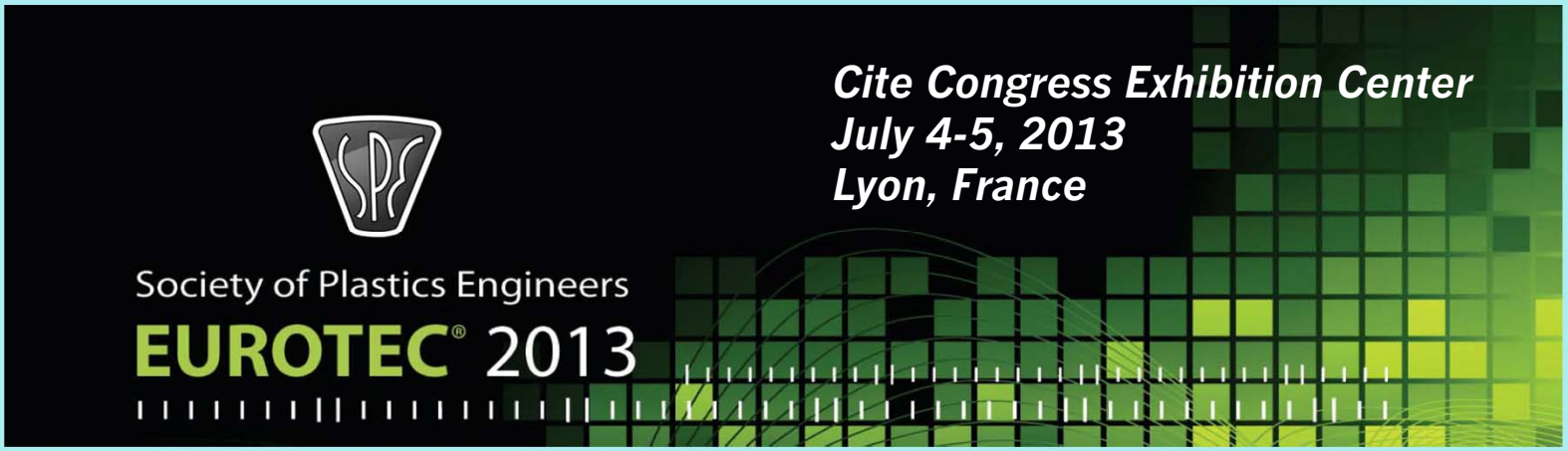
The Medical Plastics Division of SPE invites you to present topics of interest which may include, but not limited to, the following categories

•Products
(The Devices for Medical, Biomedical, Drug Delivery, and 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

- Visit Upcoming Events on the Medical Plastics division webpage at www.4spe.org for more information.
- Email harrisonyu@comcast.net for specific information, Harrison Yu, MPD TOPCON TPC at SPE TOPCON in China 2013.



Medical Plastics and Polymers

Session T15 – Thursday, 04 July 2013

9:00 Microstructural Changes in Polylactides During an Intial 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 Pudlauskaite, 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

Medical Plastics Division

Mission Statement

To provide a forum for technical, quality systems, and regulatory information exchange on polymers and polymer processing for the medical and healthcare industries focusing on new technologies, applications, and delivery methods.

Goals and Objectives 2012 - 2013

Officers

Jill Martin – Chair
Dan Fucella – Secretary
Margie Hanna – Councilor
Mark Bonifaccio – Chair- Elect
Paul German – Treasurer
Steve McCarthy – Past Chair

•The officers are responsible for the MPD board operations to comply with SPE Division guidelines and policies. This includes maintaining an active Board of Directors with appropriate officers and chairs. The officers challenge each member with bringing new enthusiasm to the board and their assigned area of responsibility. This will include identifying new board prospects, mentoring those new to the board and initiating new programs that will make MPD of more benefit to members and to prospective members of SPE. The officers shall be responsible for attendance and active participation at all SPE Council and Division Committee meetings as well as holding an annual business meeting.
•The Medical Plastics Division shall plan to win the Pinnacle Gold and strive to win the Communications Award.
•Board members are expected to attend board meetings or advise chairman when unable.

Technical Program Committee

Ed Fewkes - ANTEC Technical Program Chair
Henk Blom – Member
Jordan Freedman – Member
Jim Oberhauser – Member
Jim Madenjian - Member
Len Czuba – MiniTec Chair
Vipul Dave – Member
Ken Breeding – Member
Ali Ashter – Member

•The ANTEC Technical Program Committee is responsible for our ANTEC involvement with 2 days of papers including joint sessions with other divisions.
•The Technical Program Committee is responsible for managing the partnership with Canon for MDM shows, developing webinars, and managing a traveling MiniTec Road Show which can be offered to Sections interested in partnering with MPD for a medical themed half or full day conference event. The Technical Programming Committee shall provide technical programming that drives diverse member participation and networking opportunities, as well as technical programming that addresses participation in under-represented areas. The Technical Program Committee shall support new SPE technical products and support Student Activities and Programming.
•Other activities include preparing a speakers list, making it available to Sections for monthly dinner type meetings, and supporting the EuroTec and AsiaTec conferencing efforts.

Goals and Objectives 2012 – 2013
(con't.)

Communications Committee

Dan Fuccella – Secretary – Chair
John Thomas – Social Chair
Norris Tollefson - Newsletter
Harrison Yu – Website / Pinnacle

•The Communications Committee is responsible for effectively communicating with members about SPE offerings and events to foster a sense of community and to allow them to respond. This includes providing financial reports and minutes of the Board meetings to membership, offering a social event annually, and providing SPE Headquarters with best practices for member communications. In addition the Communications Committee will prepare and send out at least 3 and possibly 4 newsletters of high quality with news of activities and interest to our members, participate in the Communication Excellence Award contest, effectively use the website for better communication about MPD activities as well as a support mechanism to answer members' technical questions, and to reach out to members with monthly email blasts to promote activities.

Finance Committee

Jill Martin – Finance Committee Chair
Mark Bonifacio – Member
Paul German – Treasurer
Steve McCarthy – Member

•The finance committee is responsible for proposing the effective use of division funds as well as proposing an operating budget for best use of funds for member programs and benefits. The finance committee also develops a long-range plan for the use of funds including an annual budget and plans to raise income, and submission of the SPE Annual Financial Report and IRS 990 Form.

Membership Committee

OPEN – Membership Chair

•The membership committee is responsible for providing SPE Headquarters with names, addresses, phone and email addresses of prospective members acquired by the Medical Plastics Division. In addition the membership committee will develop communication programs and efforts to both recognize new members but to reach out to lapsed members, work with communication tools (newsletter and website) to reach prospective new members through the MDM program, to develop and implement at least one new service that offers member value, and try to increase division membership by 10%.

Recognition Committee

Len Czuba – Nominations
Maureen Reitman – Awards

•The Recognition Committee is responsible for utilizing the awards program to recognize contributions from conference speakers to student papers, working with the programming committee to identify and recognize best speaker at each conference.
•In addition the Recognition Committee will nominate and sponsor at least 1 member for either HSM or Fellow from our division, implement a Medical Plastics Division member recognition program, and use division awards to recognize significant contributions.

Board of Directors for the Medical Plastics Division

New Board members will announced at ANTEC 2013.

The Board of Directors is made up of approximately 20 elected members that generally serve three year terms in a staggered fashion so that each year we elect five new board members. Officers serve one or two year terms with the exception of our Councilor to the SPE who serves a three year term.

Elections will be held in April 2013. Any member of the Medical Plastics Division may nominate another member. Any member may nominate him/herself.

If you are interested in participating in the Medical Plastics division as a member of the Board of Directors, please contact any current Board member for more information.

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.

Medical Plastics Division - SPE
Board of Directors for 2012 - 2013

Name	2012-2013 Position	Company
Officers		
Jill Martin	Chair	Dow Chemical
Mark Bonifacio	Vice Chair / Finance	Bonifacio Consulting
Dan Fuccella	Secretary / Finance	Applied Technologies
Paul German	Treasurer	Kruger Plastics
Margie Hanna	Councilor (2012 - 2015)	Czuba Enterprises, Inc.
Steve McCarthy	Past Chair (2011 - 2012)	UMass Lowell
Board Members		
Class ending ANTEC 2013		
Vipul Dave	ANTEC Technical Program Chair	Cordis J&J
Henk Blom	ANTEC Technical Program Committee	Rollprint
Ed Fewkes	ANTEC Technical Program Committee	Corning
John Thomas	Social Chair	Bonifacio Consulting Services
Class ending ANTEC 2014		
Norris Tollefson	Newsletter Editor	CibaVision Corp./Alcon
Jim Madenjian	Communications / Social Co-chair	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
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
Committee Volunteers		
Len Czuba	MiniTec	Czuba Enterprises, Inc.

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

March 7, 2013 Board of Directors Meeting
Medical Plastics Division of the Society of Plastics Engineers

The teleconference BOD meeting was called to order by MPD Board Chair Jill Martin at 12:34am CT.

Board members in attendance: Jill Martin, Mark Bonifacio, Dan Fuccella, Paul German, Margie Hanna, Vipul Dave, Len Czuba, Norris Tollefson, John Thomas, Jodie Laughlin, and Ali Ashter.

•Treasurer's Report, Paul German Treasurer:

Balance as of October 23, 2012	$32,754.89
INCOME	0
APPROVED EXPENSES (3/7/13 BOD meeting)	
ANTEC-MUMBAI	$250.00
Proposed ANTEC funding for students	$2,500.00
Proposed travel funds for TOPCON 2013	$3,000.00
FUNDS AVAILABLE (as of March 7, 2013)	$27,004.89

•2013 China TOPCON (December 8 -13, 2013, Shanghai)

1. Len Czuba going to China to look at facilities – meeting with people from Exponent.
2. Would like to have the team from Exponent pull together packaging participation.
3. Marriott City Center is the proposed location in Shanghai.
4. Len will be talking to Wim De Vos, CEO SPE to see if there are other needs.
5. Concern over the sharing of technically sensitive information at a TOPCON held in China was discussed. It was expressed that since the information to be presented is to be purely educational and non-proprietary in nature, and since most countries have access to SPE presentations delivered in other countries, there is little reason for concern specific to this event.
6. A motion was presented for the establishment of a travel allowance for two members of MPD to assist with the production of the 2013 China TOPCON. The selected members (Ali Ashter and Harrison Yu) would be expected to coordinate the solicitation papers, assist with the paper selection process, seek event sponsorships, and each present a paper at the event. They are to provide a follow-up trip report. The amount of the travel allowance was proposed to be up to $1,500.00 for each of them.

Moved: Mark Bonifacio, Second: Margie Hanna. Carried unanimously

1. MPD is shooting for 2 sessions of 7 papers each. Jill Martin is to check on the number of Divisions participating.

•2013 ANTEC (April 22-24, 2013, Duke Energy Convention Center in Cincinnati, Ohio)

1. Student Activities Support: Margie Hanna proposed the MPD donate $2,500 to the Student Activities at the 2013 ANTEC. Student activities include; tours, a job fair, and a luncheon at which awards including travel awards are presented. The funds, which are collected from throughout SPE primarily go toward student travel allowances ($200 domestic and $300 international) for which student poster presenters can apply.

Moved: Margie Hanna, Second Norris Tollefson. Carried unanimously.

1. Jill Martin will distribute an updated ANTEC agenda.

•MPD Elections: The BOD decided it would be beneficial to have elections prior to the 2013 ANTEC so that elected officials would be available to ANTEC attendees. Jill Martin plans to have the Call for Candidates distributed by March 8, 2013. Election will be held on-line the week of March 25, 2013.

•MPD Newsletter: Norris Tollefson plans to have another newsletter out before the 2013 ANTEC.

1. Vipul Dave is to write up the MD&M West event where, with his assistance, the paper presentation sessions were very successful. Len Czuba to provide photos.
2. Will be translating substantially all of the MD&M West program to MD&M East (have additional speakers if a couple from West fall out).
3. Norris would like to include one technical papers in each issue of the MPD newsletter. Deadline for submission for the upcoming newsletter is March 22, 2013.

•Adjournment: The BOD meeting was adjourned at 1:05 CT. Moved: Jill Martin, Second: Paul German, Carried unanimously .

Submitted by,
Dan Fuccella, MPD Secretary
March 7, 2013

BIORESORBABLES
A FAMILY OF MATERIALS WITH WIDE POTENTIAL
BUT SIGNIFICANT CHALLENGES TO OVERCOME

Len Czuba, Czuba Enterprises, Inc. Lombard IL, USA
Steve Coulter, Fallbrook Engineering, Grayslake, IL, USA

Abstract

There is a great deal of interest these days in the family of polymers called "Bioresorbables". The unique property of melting away allows a bioresorbable medical device or component to ***be there*** one month and then ***be gone*** the next. This interesting feature or polymer property makes useful medical devices that have been around and in use for almost fifty years. But for a number of reasons, new applications have been long in development and slow to be accepted. However, an explosion of new products based on these materials is expected as indicated by three noticeable trends:

1. A variety of new products applications are continuously being introduced.
2. Improved processing and handling methods are enabling fabrication.
3. In general an increased familiarity and acceptance as viable products.

Introduction

Plastic Medical Devices

One of the first uses for resorbables was for sutures. Bioresorbable sutures have the ability to function like any other suture materials closing a wound, but with bioresorbables, after the healing was done the sutures slowly dissolved and did not need to be removed. This novel material allowed better treatment of post-surgical wounds, resulted in quicker healing and eliminated the need for secondary surgery to remove the inner sutures. Without the second surgery to remove the inner stitches, it also resulted in reduced infection risks.

Simple catgut sutures were the first bioresorbable sutures used as long ago as the first century (AD) Rome by Galen. Sutures from cat intestine completely degrade via proteolytic activity in 90 days, but they lose their tensile strength in only 7 days. Chromic catgut (catgut treated with chromic salts) was developed which extended the tensile properties from 7 days to 18 - 21 days.

Synthetic Sutures

Synthetic bioresorbable sutures were developed more than 40 years ago when Ethicon developed Vicryl sutures. These novel products are based on glycolide-lactide polymers (PGLA). Vicryl sutures degrade via hydrolytic activity and completely resorb in 60 days. But, as with catgut sutures, the tensile properties disappear in much less time (3 - 4 weeks). Since then, many more polymers and copolymers have been developed as suture materials, namely, polycaprolactone (PCL), polydioxanone (PDS or PDO) and polytrimethylene carbonate (TMC). Synthetic suture materials avoid any issues of contamination from animal components and because the bioresorbables can be designed to have slower or faster dissolving times, the sutures can be used based on the speed at which the wound is expected to heal.

Table 1 (below) lists various bioresorbable materials and compares their total resorption time.

There is a difference between when these bioresorbables lose their strength and when they have completely disappeared from the body. Just as an example, **Figures 1 and 2** (below) show the degradation times of a common PGLA system and for a pure PLLA polymer. They lose strength long before the polymer is dissolved or completely bioresorbed. .[1]

Wide Array of Absorbable Products

Other wound closure products soon followed the acceptance of bioresorbable sutures. Staples, clips, hemostatic agents, surgical meshes and slings, tissue repair patches, skin and dural substitutes, guided tissue regeneration devices (nerve repair) and adhesion barriers gave surgeons a wide array of new products all based on the resorbability of these polymers.

The success of the initial products showed the utility of resorbables and stimulated research throughout the world. At many universities, graduate research studies were carried out with the intent of learning how to work with these new materials. In parallel, corporate research into expanding the utility of bioresorbables began to discover newer grades and types of these polymers. Unfortunately, it was not until the 1980s and 1990s that any real progress was made into new processing techniques including working with copolymers and improving the molding effectiveness of bioresorbables. New materials, including polyorthoesters, polyanhydrides and polyhydroxy-alkanoates, were developed but for a number of reasons

these newer bioresorbables are still not commercially available or have only very limited availability.

Research Programs

A partial list of Universities with research programs in this area and the principle investigators:

Aachen University, Aachen, Germany
(Michaelis and Obeloer)
Waterford Institute of Technology, Waterford, Ireland
(Coffey)
University of the Basque Country, Bilbao Spain
(Sarasua and Lizundia)
McMaster University, Hamilton ON Canada
(Takacs)
UMass Lowell, Lowell, MA, USA
(McCarthy)
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New Product Development Areas

Orthopaedics

After the initial success and acceptance in wound closure applications, the bioresorbables began finding popularity as orthopaedic products initially for bone pins, screws, rivets, tacks, rods and plates. Later they were used for meniscus repair devices, tendon repair devices and bone graft devices. These applications required the materials to bring not only an initial resistance to degradability, but required good physicals or mechanical properties of the polymers to allow healing of the slow growing bone structures without premature failure of the bioresorbable product. As the product designers pushed the limits of the materials, polymer engineers responded with the development of newer composites including fibres, hydroxyapatite structures and new polymer chemistries that offered better physical properties. And at the pace of products currently in development and use, it appears that orthopaedic applications are beginning to outpace the tissue and wound repair bioresorbables.

Cardiovascular

The next wave of products that rely on bioresorbables appears to be in cardiovascular applications. The first use is for cardiac stents which are being introduced by Abbott Vascular and other leading multinationals. The advantage over previous stents is that after the stent is deployed and re-establishes normal blood flow in the reopened blocked blood vessel, unlike bare metal stents which often lead to restenosis, which is the re-forming of the blockage in the artery, the bioresorbable stent is digested and it disappears. Patients with metal stents either need to take blood thinners to reduce the potential of clot formation or rely on slowly eluting drugs in drug eluting stents to prevent clots. Bioresorbable stents will maintain their functionality until the re-opened vessel is healed at which point the stent begins the process of resorption. Within a matter of months, the stent will be completely eliminated from the patient and there is no foreign body left behind to cause any additional complication.

Tissue Scaffolding

Looking even further into the future, bioresorbables will be widely used as tissue scaffolding, where cells would be seeded into the bioresorbable. Then as the cells grow to confluence, the biopolymer slowly melts away leaving only living tissue behind in the form of whatever shape was originally formed by the scaffold.[2]

Drug Delivery

In a similar use, bioresorbables will be introduced as drug delivery structures in new applications that need long residence times and long term, slow dose treatment. Much like the function of drug eluting stents, the bioresorbables can be made to mimic the same release process but in addition, they are resorbed after their intended useful life.

Propelled by these successful applications, other products are being developed and the challenge now is to find suppliers for the variety of materials needed.

The Next Steps – Industry Challenges

Cost is Major Barrier to Entry

Creative companies are finding new ways to use the bioresorbables in new medical devices. But in spite of the variety of types and grades currently available, there are sadly few suppliers of commercial quantities with the grades needed to optimize end-use products. One of the barriers to entry both from the product designers point of view as well as for suppliers of the materials is the high cost of the polymers. Bioresorbables can range in price from several thousand dollars (or even Euros) per kilogram to even higher when purchased in smaller quantities. It makes the product development costs a serious factor in any program. The need for extensive testing required by any implantable, prior to its regulatory submission, becomes a substantial cost and represents an additional challenge or barrier to entry.

Limited Number of Suppliers Restrict Access
There has been limited progress in finding new sources for bioresorbables. Compared to the explosion of new products in the pipeline, the sourcing of the resorbables remains a problem. The supply and demand equation is at play here with extremely high material costs keeping out all but the largest players and the reduced volumes being produced are not being made in quantities that will help drive down prices. Regulatory issues also come into play. Companies may not want to risk working with smaller suppliers in case they do not survive throughout the life of the medical device for which they were qualified. Switching to a new vendor requires a repeat of all qualification testing and the added costs are prohibitive. Thus, most companies originally select as their primary supplier, larger, more stable companies, which in effect reduces the opportunity for competition from new suppliers.

For years, the only major bioresorbable materials suppliers were Boehringer Ingelheim from Germany and PURAC from the Netherlands. In 2004, Boehringer Ingelheim licensed its technology to Evotec AG but they no longer produce commercial bioresorbable polymers.

In the U.S. the oldest commercial supplier of bioresorbables was Birmingham Polymers; later know as Absorbable Polymers International. API was merged into the Durect Corp. at the end of 2004 and in total, for more than 25 years, this supplier has been producing high quality biodegradable polymers for drug delivery and medical devices.

In the last 10 years, a new entry into the field was a joint venture between Cargill and Dow Chemical which in 2005 became the stand-alone company, NatureWorks. This Minnesota-based company produces lactides which could be used to make biopolymers but their primary target markets are consumer product applications.

A recent announcement by the Cambridge, Massachusetts based Metabolix describes the partnership with Antibioticos SA for the manufacture of polyhydroxyalkanoate biopolymers at their Leon, Spain manufacturing plant. Although this creates another materials source, most medical device applications of these new materials are in very early stages.[3]

There appears to be limited growth in the number of suppliers of bioresorbable polymers but it is apparent that the demand continues to outstrip the supply.

Processing challenges[4]
Bioresorbables are very sensitive to heat and moisture, making them prone to degradation during typical melt processing such as extrusion, compression molding or injection molding. Micromolding has addressed the design of molds and control of the processing conditions to control much of the lost polymer costs associated with bioresorbables, but this alone is not sufficient to bring down the processing costs. It will be important for new process technologies to be developed around the use of bioresorbables because at traditional melt processing temperatures, these new biopolymers become easily degraded to the point beyond useful life in many cases.

New Technologies
Several examples of processing technology which enables processing of heat and shear sensitive materials include:

SCORIM – Shear Controlled Orientation Injection Molding[5]
This process developed at Brunel University in Uxbridge, UK 1982, reduces the shear on the polymer melt stream by using oscillating dual piston filling to fill the mold.

Saturated CO_2
Another research group from IKV at Aachen University in Aachen Germany developed a method to lower the melt temperature required to melt process heat sensitive materials. This process uses carbon dioxide gas to saturate the materials prior to and during the injection molding process. A dramatic reduction in the temperature required to mold bioresorbables leads to a reduction in heat related degradation of the materials and enables compounding heat sensitive drugs in the molded parts. Certain antibiotics such as Gentamicin will be functional after molding at the lower temperatures but not if processed at the higher temperatures. Another research group at the University of Toronto showed how this process affects the crystallinity.[6]

Compression-Free Heating
A final example of how industry can support the evolution of these materials is the recently announced T-Rex screw assembly having no compression zone in the injection molding machine. In this system designed by Spiral Logic Ltd. of Hong Kong, the heating of the material comes entirely from the heater bands and the screw is designed to minimize compression of the melt. For heat and shear sensitive biopolymers, this can reduce degradation of the polymer, eliminate waste, improve physical properties of the final product and expand the range of products that can be made using resorbables.

Medical Device Sterilization
One final design challenge that bioresorbable materials face is the sterilization process. Any implantable medical device must be sterile before it is placed into the body.

Since most bioresorbable polymers are hydrolytically labile, both high temperatures and high humidity can be problematic. Steam sterilization is obviously the most aggressive. But, ethylene oxide (EO) sterilization also

exposes the polymers to both conditions. EO can be used successfully with bioresorbable polymers, but allowance must be made for the degree of molecular weight loss.[7] The molecular weight of many of the PGLA polymers will decrease by half of its value during EO sterilization.

Irradiation sterilization (also called *gamma* or *beta* irradiation) can also be used with these polymers. But the required dosages needed for sterilization are likely to affect the molecular weight of the polymer so it is important to minimize the exposure and test to determine suitable mechanical properties are maintained post sterilization. As an example, the molecular weight of the same PGLA polymers mentioned above will also decrease by about half of the original value. So the effect of the sterilization methods must be carefully studied to determine the properties of the final medical device.

Additional Considerations

Other influences help drive the interest in bioresorbables including the desire to find material alternatives to petroleum based polymers, the need to help solve the waste and litter problem and the pervasive culture of sustainability also called the "green" movement. Biopolymers can help each of these goals although the cost penalty associated with these materials will continue to restrict rapid growth.

In specialty medical devices, one can imagine new products that couple immunochemistry with bioresorbables to provide specific targeting of cell or tissue antigens. This would allow treatment to be given or delivered to a target organ or part of the body. When the therapy is delivered and when predesigned bioresorption time is reached, the device is resorbed and the polymer is eliminated.

Brainstorming

And beyond implantable applications, what if all sharps used in healthcare from needles to scalpels to trocars and pins were all made of resorbable or erodible polymers? Sharps could be collected after use and put through a wash cycle similar to the dish washer and the sharp edges or points would all dissolve. Is this a possibility? Perhaps!

Summary

We believe that as we begin to better understand these unique materials, more and even wilder ideas will lead to new products.

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Key Words

PLA, PGA, Bioresorbables, Resorbables, Implantables, Medical Devices,

Table 1

Material Name	Abbreviation	Typical Total Bioresorption Time (Months)
Polyglycolic acid	PGA	6 -12
Poly (L) lactic acid	PLLA	> 24
Poly (glycolic-lactic acid) copolymers	PGLA	(typical) 1 - 6
Poly (D,L) lactic acid	P(D,L)LA	12 -16
Poly (glycolic acid-trimethylene carbonate)	PGA-TMC	6 -12
Polydioxanone	PDS or PDO	6 -12
Polycaprolactone	PCL	6 -12

Figure 1

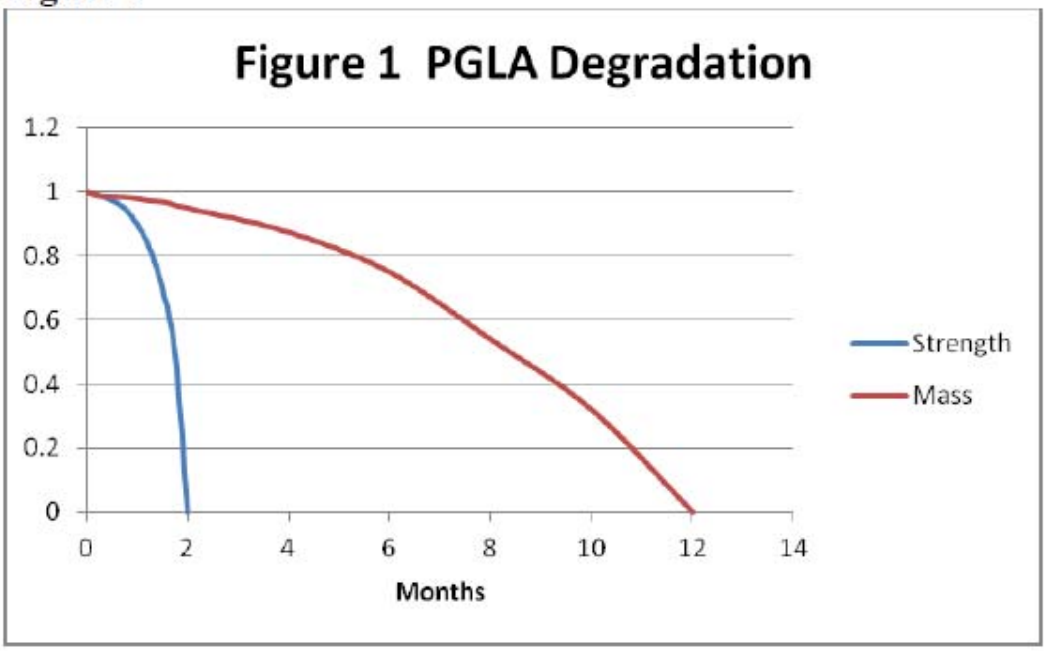

Figure 2