



SOCIETY OF PLASTICS ENGINEERS

Medical Plastics Division

2014 – Second Quarter

2013 – 2014 OFFICERS

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Bonifacio Consulting

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TBD

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Vipul Dave

Letter from the Chair:



Hello fellow colleagues and MPD members:

2014 is in full swing and our division has already gotten off to a great start for the year and with much more in store. I want to first start out by thanking all of our Board members for volunteering their time and talents to make our division one of the best and most active divisions in SPE. We are about to have our Board elections for our next year which begins at ANTEC 2014 in Las Vegas this April. We welcome any member to join our board or send us email; we would be glad to have you as an observer to our Board conference calls held every other month.

We just finished a very successful sponsorship at the MDM West in Anaheim with a great turnout and even better speakers. Content ranged from processing to advanced materials, as well as business trends in medical plastics. I would like to give a special thanks to our Program Chair Vipul Dave, as well Len Czuba, for helping to organize the successful session. WE have already started planning our next Speaker sessions for MDM East in NYC this June. STAY TUNED for more - we may have a two day program due to popular demand!

The SPE Medical Plastics Division along with the Upper Midwest Section presented MEDICAL PLASTICS MiniTec 2014 in Brooklyn Park, MN on March 27, 2014. This was a one day conference where 14 presentations from the industry discussed topics relating to trends, performance materials, application testing, and latest developments in the area of medical plastics. Engineers, management personnel, purchasing, quality, and production staff all benefited by attending this MiniTec conference. As always, this was a great networking opportunity to meet some of your fellow Medical Device professionals from a wide variety of therapeutic disciplines and technical and non-technical disciplines.

The final event I would like to talk about is ANTEC 2014 in Las Vegas. At the Rio All-Suite Hotel & Casino on April 28–30. ANTEC® is the largest conference in the USA dedicated specifically to plastics. Join SPE and accomplished expert speakers from around the globe as we present the latest practices and trends currently influencing the plastics industry. This year, the expanded program will include our premier Global Parts Competition! Don't miss this opportunity to learn and to network with representatives from some of the largest and varied industry segments. This year there will be over 600+ technical presentations and 100+ Exhibitors, along with a Business of Plastics, presented by SPI as well as Student and young professional Sessions and Program for the next generation and the upcoming stars of our field.

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As you can see we have an exciting Q2 coming up for our Division, with opportunities for you participate and to continue to learn. We hope to hear from you on ways you would like to get involved or participate. Do not hesitate to contact me directly at Mark@bonifacioconsulting.com or any other board member.

We are an all-volunteer board and organization and always invite our members to participate. There is truly a role for whatever you like to do. I also encourage all MPD members to recruit a friend or colleague you join our division this year.

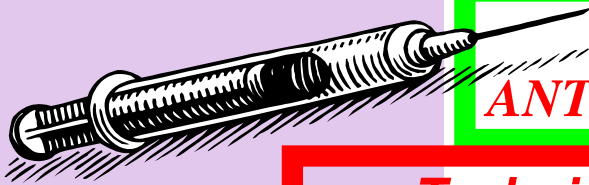
In today's global economy, it is more important to stay abreast of the latest technologies and trends AND grow your influence and network. The Medical Plastics Division does both of those. You can't beat that value proposition.

In closing, I always like to remind everyone that among our busy days and responsibilities, we sometimes forget the impact we all have in our world. All of you in this profession and field should take a great pride and satisfaction in the work that you do. Whether you are in the field of medical polymers, medical devices, or any other related Healthcare field that represent our membership, without the work that we do every day, the great benefits to our global population that get delivered every minute of every day, around the world would not be possible. Keep up the good work and feel good about contributing to our society in such a powerful and meaningful way.

One final thanks, before I sign off to the man who puts all this together, our dedicated Newsletter Chair Norris Tollefson. If anyone has ever organized any kind of publication large or small, I think you will understand the effort, time and dedication it takes. (not to mention having to get on the Chairman to write this column, four times a year). Norris, thanks for all that you do!

I hope to see you at one of our upcoming events or hear from you via email.

Mark Bonifacio
2013 – 2014 Chair



Upcoming:
ANTEC 2014 in Las Vegas

**Technical
Presentation**

**Reports from Three
Recent Conferences**

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Upcoming Conferences and Activities



SOCIETY OF PLASTICS ENGINEERS
ANTEC 2014

Rio All-Suites Hotel & Casino
April 28–30, 2014
Las Vegas, Nevada, USA

FINAL PROGRAM FOR THE MEDICAL PLASTICS DIVISION

29 APR 2014

T13 Medical Plastics I (am)

Plenary Speaker – Title to be Announced

Steve McCarthy
UMASS Lowell

POLYURETHANES IN CARDIAC DEVICE LEADS: EFFECT OF MORPHOLOGY ON PERFORMANCE

Ajay Padsalgikar
St Jude Medical

Implantable polyurethanes have been utilized in the medical industry for decades due to the combination of biocompatibility and toughness, abrasion resistance properties and advantages of thermoplastic processability. The long term stability of these materials in the body has been a topic much research and scrutiny. Several in-vitro and in-vivo studies on implantable polyurethanes have demonstrated the main degradation modes in the body are oxidation and hydrolysis. The susceptibility of polyurethanes to these degradation modes depends on the morphology of the material. Multiple studies are reviewed here in an attempt to characterize different degradation pathways and assess material properties that affect biostability.

POLYPROPYLENE AND POLYPROPYLENE-SEBS BLENDS FOR MEDICAL FILMS

Martina Sandholzer
Borealis Polyolefine GmbH

Due to the negative publicity of PVC, polypropylene is attracting increasing attention as an alternative material for flexible medical packaging. Propylene-ethylene random copolymers (PP-R) are usually the materials of choice as they are suitable for the preparation of retortable transparent films and transparent molded items. External elastomers such as styrene ethylene/butylene styrene triblock-copolymers (SEBS) usually need to be added to achieve the desired softness of the final item. In the current study, it was demonstrated that modifying PP-Rs with SEBS also improves the toughness and the transparency of films. The second part of this study showed that random heterophasic polypropylenes (PP-R/B) containing a significantly reduced (30%) amount of SEBS or even containing no SEBS at all can in fact achieve the same performance as SEBS modified PP-Rs. These results illustrate that PPR/ Bs are an attractive alternative to PP-Rs as they allow for a reduction of costly SEBS.

CHEMICAL RESISTANCE ADVANTAGES OF TRITAN™ COPOLYESTERS FOR MEDICAL APPLICATIONS - ONCOLOGY DRUG CASE STUDY

Yubiao Liu
Eastman Chemical Company

Changing fitness for use requirements for the next generation of medical devices have significantly increased the need for higher performing plastics with improved chemical resistance. For example, heightened awareness of hospital-acquired infections (HAIs) has resulted in the increased use of medical disinfectants which can cause cracking or discoloration of plastic medical devices. In addition, the continual effort to advance medicine has led to the development of new oncology drugs and oncology drug delivery devices. These oncology drugs have been found to cause cracking, crazing and hazing in certain plastics. With these trends in mind, the chemical resistance of common medical grade thermoplastics was tested against various disinfectants, oncology drug carrier solvents and actual oncology drugs. These studies illustrate that Eastman Tritan™ copolyesters exhibit excellent chemical resistance to meet the changing needs of the medical device market.

HIGH FLOW POLYCARBONATE COPOLYMERS FOR MEDICAL APPLICATIONS

Malvika Bihari
SABIC- SBU Innovative Plastics

High-flow polycarbonate (PC) copolymer derived from bisphenol-A (BPA) and a specific bio-sourced monomer derived from castor bean oil for medical applications available in two melt flow ranges is reported. This copolymer belongs to the class of Lexan™ HFD resins known for their improved melt flow and ductility balance compared to standard polycarbonate yet with similar high optical clarity and light transmission properties. These high flow HFD copolymers for the healthcare industry are designed to have all attributes of the Lexan™ HFD resins such as lower temperature processing capability, longer injection molding flow lengths and improved low temperature ductility versus a standard polycarbonate and ISO10993 biocompatibility. The superior flow enables molding of thinner parts with similar practical impact to standard healthcare PC.

30 APR 2014

W11 Medical Plastics II (am)

THE INFLUENCE OF ATMOSPHERIC PRESSURE PLASMA SURFACE-MODIFIED POLYMERS PVDF, ECTFE, AND PEEK ON PRIMARY MESENCHYMAL STEM CELL RESPONSE

Trevor Spence
New York University

Three plastics, polyvinylidenedifluoride (PVDF), ethylene-chlorotrifluoroethylene (ECTFE), and polyetheretherketone (PEEK), are known for their chemical resistance, thermal stability, and low surface energy, a great combination for low biological activity and, thus long-term stability, but very little integration with surrounding tissue. Atmospheric pressure plasma (APP) a clinically-safe plasma method, was applied to the substrates to functionalize the plastic surfaces and successfully increased integration of mesenchymal stem cells to the substrates in vitro for implications of enhanced bone growth.

RADIATION-STERILIZATION OF NEW MEDICAL RESINS IN OXYGEN-FREE PACKAGING

Pierre Moulinie
Bayer MaterialScience LLC

In this work, several medical-grade resins were studied for their color-recovery behavior after sterilization by radiation. Plastic parts irradiated in oxygen-free packaging showed that exclusion of oxygen significantly lengthened the time required for color-recovery, although the final color of samples sterilized in air and oxygen-free atmospheres were almost identical after both were exposed to ambient atmosphere for sufficient time. Newly-introduced MakrolonR Rx2440, a high-flow polycarbonate formulated for radiation-sterilization in oxygen-free packaging completed its color recovery after 14 days when stored in O₂-free packaging in the dark.

BENEFITS OF SERVO-DRIVEN ULTRASONIC WELDING FOR CRITICAL ASSEMBLIES

Kenneth Holt
Dukane Corporation

Complex part designs and ever more stringent requirements require more controlled and consistent ultrasonic welding processes. Dukane has addressed this demand through the development of the iQ series Servo-Driven Ultrasonic Welder with Melt-MatchR technology (matching welding speed with the melt flow rate of the plastic. This study explores the potential benefits of these features solely available with Dukane's servo-driven welders. A full scale Design of Experiments has been undertaken to identify the relational effects of these speed and distance control features, quantify the improvement to the weld joint, and outline how they can be used to optimize the welding process.

MOISTURE DETERMINATION OF SPECIALTY RESINS USING RELATIVE HUMIDITY SENSOR TECHNOLOGY; A SOLVENT-FREE ALTERNATIVE TO KARL FISCHER TITRATION

James Moore
Arizona Instrument LLC

The Health Care industry has increased its needs for specialized devices over the past decade, which has led to a new frontier of resin and polymer development designed to keep the quality of care high while minimizing cost. With these goals in mind, the resins being used for medical devices are scrutinized more thoroughly than other resins that require less regulatory compliance. The development of an alternative to Karl Fischer moisture analyzer, which uses a relative humidity (RH) sensor for quantifying water content has been achieved, and can be used for moisture specific analysis of medical device grade resins. The results between the two methods of detection of H₂O content in TPU strongly correlate with the KF, with the KF measuring an average of 62ppm of water in the resin and the RH sensor instrument measuring 65ppm.

THERMO-SENSITIVE COPOLYMERS FOR THE TREATMENT OF ARTERIAL ANEURYSMS

Austin Coffey
Waterford Institute of Technology

Aneurysms are among the most common of all lethal cardiovascular conditions. While open surgery and minimally invasive techniques can be used to treat the condition, treatment efficacy is often hindered leakage into the aneurysm sack after endovascular repair. Accessing specific treatment sites located in regions of complex tortuosity remains extremely challenging. This paper looks at the feasibility of deploying smart, thermo-responsive hydrogels as 'filler' materials which can be applied to the affected site using a novel, minimally invasive, catheter delivery technique; with a particular focus on the mechanical and thermo-responsive properties of hydrogel materials. Results show that specific solute-solvent concentrations have potential for use when coupled with a temperature controlled catheter delivery system. However, optimal temperature control remains challenging.

MODIFIED PEBA FOR DIRECT ADHESION TO EFEP

Sabine Fleming
Evonik

New modified (Polyether Block Amides) offer tubing manufacturers a means of producing multi-layer fluoropolymer catheters via a co-extrusion method instead of the traditional manner of hand building a catheter. The ability to manufacture catheters without the need of etching or an adhesive layer provides for ease in manufacturing, reduction in costs, and improved adhesion between the different layers. In providing a modified PEBA which adheres directly to EFEP increases the catheter manufacturers the opportunity to produce safe, durable products.



30 APR 2014

W17 Medical Plastics III (pm)

HYDROGELS FOR ARTERIAL MODELLING AND TISSUE SCAFFOLDING

Austin Coffey
Waterford Institute of Technology

Models of human blood vessels have potential application as aids in research on new medical devices. These vessels have the advantage that they can be accurately tested in an in-vitro setting and obviate the need for early animal testing. Artificial materials that match both the physical and mechanical properties of biological blood vessels may also be useful in biomedical simulation experiments. Consequently, a research gap was identified to obtain viscoelastic properties of a hydrogel material comparable to that of arterial vessels. Therefore, the main purpose of this research was to attain the storage modulus (G') of the thoracic and abdominal aorta in the region of 43kPa and 64kPa respectively.

RADIOPAQUE FILLER ENHANCES NANOCOMPOSITE CATHETER SHAFT PERFORMANCE

Amar Nilajkar
Foster Corporation

Nylon 12 and polyether block amide nanocomposites are being used to stiffen catheter shafts. Montmorillonite clay is the filler of choice to make the nanocomposite. Typically the construction is a dual layer where one layer is the nanocomposite and the second layer is a radiopaque layer. We are evaluating the possibility of combining radiopaque properties along with the nano fillers to enhance strength as well be visible under fluoroscopy. Our study is also aimed at looking at the effect of particle shape of the radiopaque filler on the final properties of the material. We want to evaluate if synergy exists between the nano particles and radiopaque fillers to further enhance the physical properties of the material.

MAXIMIZATION OF HYDRAULIC FLOW IN SMALL FLEXIBLE POLYMER TUBING BY STIFFNESS AND WALL THICKNESS OPTIMIZATION UTILIZING HARDNESS AND GLASS & CARBON NANO TUBES FILLERS

Alan Boardman
Brigham Young University

As medical infusion treatments increase, better and faster fluid delivery is greatly needed. Advancements in polymers may provide increased flow while maintaining outer dimensions, stiffness and burst resistance. A current CVC polyurethane with glass beads of 4% by weight, PU with CNTs of 1% by weight and PU of 10% increased durometer, were tested per ISO 10555-1; tensile strength, stiffness, flex fatigue, vacuum lumen collapse and hydraulic burst. Each structure also having wall thickness of 0.010", 0.015" and 0.020". Structure C1, increased hardness and wall thickness 0.020" passed all ISO 10555-1 requirements. C1 had a tensile strength 13.4% less than current PU and was 52.7% stiffer. C1 had no wear or defects at flex fatigue testing. C1 had average tensile strengths 14.8% less than the current PU post flex fatigue tensile testing. And no burst failures (150 psi for 5 seconds). C1 had a 43% higher flow rate capacity, providing for significantly higher infusion treatment rates.

DEVELOPMENT OF AN ABSORBABLE MAGNESIUM-POLYMER FUSION CAGE FOR THE CERVICAL SPINE

Theresa Kauth
Institute of Plastics Processing at
RWTH Aachen University (IKV)

Conventional fusion devices ("cages") are often used to join two vertebrae of the human spine and generally remain in the body for a lifetime and can theoretically lead to any complications. Therefore, an absorbable hybrid fusion cage consisting of a magnesium skeleton infiltrated with absorbable polymer (poly- ϵ -caprolactone, PCL) has been developed. The primary objective of the cage is to ensure an adequate stiffness of the disc space directly after the operation and to encourage the ingrowth of new bone tissue to secure long life stability. Once a sufficiently rigid bone connection is formed, the implant should be absorbed. Within this paper results of in vitro investigations of the mechanical properties and of in vivo investigation in blackcap sheep are presented.

29 APR 2014

New Technology Forum (pm)- Plastics in the Hospital and the Human Body

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| NOVEL PLATFORMS FOR TARGETED DRUG DELIVERY USING MICRO-CAPSULES | Stephen McCarthy UMASS Lowell |
| HELICAL PROTEINS FOR MATERIALS APPLICATION: FROM PIEZOELECTRIC NANOFIBERS | Michael Yu University of Utah |
| SOFT MATTER PHYSICS TO DESIGN NOVEL LIGHT TRANSMISSION POLYMERS FOR HEALTHCARE | Daniel Ou-Yang Lehigh University |
| ADVANCEMENTS IN 100% SOLIDS PRESSURE SENSITIVE ADHESIVES FOR USE IN THE MEDICAL INDUSTRY | Steve Schroff MacTac (Bemis) |
| GLOBAL REGULATORY HARMONIZATION EFFORTS FOR REVIEW AND APPROVALS OF COMBINATION MEDICAL DEVICES | David Eakers Becton Dickinson |

Business and Social Events

| | |
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| MPD BOARD OF DIRECTORS Room COCO-B (Rio) | 28 APR 2014 4:30 - 6:00 pm |
| ANTEC 2014 WELCOME RECEPTION | 28 APR 2014 6:00 – 7:30 pm |
| MEDICAL PLASTICS DIVISION DINNER | 28 APR 2014 8:00 - ??? |
| MPD BUSINESS MEETING | TBD |

Please join the Medical Plastics Division in its support of education at the Students Awards Luncheon on 30 APR 2014 at 12:15 pm. Non-Student tickets are \$20 in advance and \$40 onsite.



Recent Conferences

SOCIETY OF PLASTICS ENGINEERS

ANTEC DUBAI 2014

21-22 January, 2014
JW Marriott Marquis Hotel
Dubai, UAE

Advances in Processing – Materials (Room 1 Day 1 / am)

| | | |
|---|---------------------------|---|
| The Impact of Plug Material Selection on Overall Part Cost | Mr. Conor Carlin | CMT Materials, Inc. |
| New generation of potable water certified NorylTM grades for Water Management | Mr. Christ Koevoets | SABIC Innovative Plastics |
| Thermoplastic Prepreg Fabrication Technology Using Induced Vibration Techniques | Dr. Mohammed Alghamdi | Yanbu Industrial College |
| Development of Superhydrophobic Surface using Ultrasonic Imprinting | Dr. Keun Park | Seoul National University of Technology |
| FAILURE ANALYSIS OF PVC AFTER EXPOSURE TO HEAT | Dr. Christian Stapfer | Metrastat |
| Importance of Electron Beam Radiation Technology for Polymer Industry | Dr. Subhendu RayChowdhury | Bhabha Atomic Research Centre |
| Thermoplastic Prepreg Fabrication Technology Using Induced Vibration Techniques | Dr. Mohammed Alghamdi | Yanbu Industrial College |

Advances in Materials - New Materials (Room 2 Day 1 / am)

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|---|-------------------------|-------------------------|
| Inorganic additives for Laser applications in the Plastics Industry. | Mr. Gordon Ernest Price | Merck KGaA |
| High Performance Nanocomposites using Ionic Liquid as Novel and Efficient Dispersion-Curing Agent | Mr. Nishar Hameed | Deakin University |
| A New High Clarity Peel Seal Resin | Dr. Rajen M. Patel | Dow Chemical Company |
| Influence of melt viscosity on the properties of polypropylene/carbon nanotube nanocomposites obtained by melt mixing process | Alessandra Lorezetti | University of Padova |
| Effect of Amphiphilic Surfactants on the Properties of Polyethylene – Graphene Oxide Nanocomposites | Dr. Vikas Mittal | The Petroleum Institute |
| Accurate simulation for multi-phase materials in the Industries | Dr. Roger Assaker | E-Xstream Engineering |
| Developments in the Global Polyolefin Business | Sheth Utpal | I H S Inc. |

Advances in Machinery (Room 3 Day 1 / am)

| | | |
|---|------------------------|-------------------|
| Plastics Food Global Regulations and Packaging Compliance | Dr. Naeem Mady | Intertek |
| Advanced Material Preparation with Co-rotating Twin-Screw Extruders | Rob Roden | SteerAmerica Inc. |
| The Co-Rotating Twin Screw Extruder ZSK Mc18 for Compounding of Polyolefins | Mr. Frank Lechner | Coperion Werner |
| Comparing High-Tech Twin Screw Extruders with 1.5 and 1.66 OD/ID Ratios | Mr. Michael Thummert | Leistritz Group |
| USE OF MODERN PRE-HARDENED TOOL STEEL IN MOULDING APPLICATIONS | Dr. Per Hansson, Ph.D. | SSAB |

SPE held their premier ANTEC conference in Dubai this year at the JW Marriott Hotel on January 21 - 22, 2014. There were approximately 170 delegates and approximately 60 technical presentations and workshops. Topics covered Injection Molding, Thermoforming and Medical plastics. Plenary Sessions and Technical Program speakers from SPE worldwide participated in this first ever ANTEC in this important polymer producing region of the world. Tutorials and exhibitors were enthusiastically received during SPE's initial venture into the Middle East.
Margie Hanna – MPD Councilor

Advances in Materials - Sustainability I (Room 4 Day 1 / am)

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| New resources from waste recovery: synthesis and properties polymer based composites containing innovative inertized fly ash from municipal solid waste incineration | Stefano Besco | University of Padova |
| Investigation of feasibility of Compounding and Processing Lignin as Additive and Colorant with Polypropylene | Mr. Kevon Tabrizi | University of Wisconsin-Platteville |
| Strain hardening: Fast test for long term properties | Mr. Abdulaziz Alsayyari | SABIC, Saudi Basic Industries Corporation |
| Preparation and Biocompatibility Evaluation of Compatibilized blends of Thermoplastic Polyurethane (TPU) and Polydimethyl Siloxane Rubber (PDMS) | Mr. Krishnaprasad Rajan | Yanbu Industrial College |

Plenary Session (Ballroom Day 1 / pm)

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| Welcome and Introduction | Willem De Vos | CEO, Society of Plastics Engineers |
| KEYNOTE | Dr. Abdulwahab Al-Sadoun | Secretary General, Gulf Petrochemicals & Chemicals Association (GPCA) |
| Impact of Shale Gas on US Plastic Resin Producers and Converters | William Carteaux | President & CEO, Society of Plastic Industry Trade Association |
| To be announced | | Tasnee |
| Enabling Down Stream Plastic Conversion: the PCC Integrated Industrial Park Model | Dr. Raed Al Zu'bi | Petrochemical Conversion Company |
| How the Composite Industry Approaches the Automotive Challenge | Prof. Jan-Anders Manson | Ecole Polytechnique Fédérale de Lausanne (EPFL) |
| Challenges for a Local Converter | Geert Haentjens | Director New Businesses, Mattex Group |
| Closing Remarks | Jon Ratzlaff, President | Society of Plastics Engineers |





Advances in Materials - Sustainability II (Room 1 Day 2 / am)

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| Cyclised Soyabean Oil as Plasticizer for PVC for replacing Di- octyl phthalate | Mr. Bhakti Mehta | Institute of Chemical Technology |
| IMPROVING FIRE BEHAVIOR OF POLYURETHANE RIGID FOAMS BASED ON POLYOLS FROM RENEWABLE RESOURCES | Mr. Michele Modesti | University of Padova |
| Novel nanoblends prepared from simultaneous in-situ polymerization and compatibilization of bio-based plant oils and thermoplastic polymer | Professor Samy A Madbouly | Iowa State University |
| Oxo-biodegradable plastics | Mr. Michael Frederick Stephens | Symphony |

Advances in Materials Performance - Resins I (Room 2 Day 2 / am)

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| New generation of potable Noryl resin grades for Fluid Engineering | Mr. Christ Koevoets | SABIC Innovative Plastics |
| STANDARDIZATION OF GEL/DEFECT MEASUREMENT BY RIBBON TEST METHOD | Tariq Syed | SABIC |
| EFFECT OF OCTENE CONTENT ON THERMAL AND MECHANICAL PROPERTIES OF CROSSLINKED ETHYLENE-OCTENE COPOLYMERS | Dr. Rajesh Theravalappil | King Fahd University of Petroleum and Minerals |
| The New Frontier of Z-N Catalysts for PP polymerization: CONSISTA(tm) catalyst. Commercial status and fundamentals | Mr. Jose M. Rego | W.R. Grace & Company |
| Hydroxyapatite reinforced chitosan composites: Preparation and characterization | Dr. Selvin Palakattukunnel Thomas | Yanbu Industrial College |
| Developing High Melt Flow Polystyrene Grade for Extruded Polystyrene foams with Carbon Dioxide Blowing Agent | Dr. Ghurmallah H Al-Ghamdi | SABIC |
| Biaxial deformation behavior of PP films | Dr. Vassilios Gallatsatos | Borouge Pvt Ltd |

Advances in Processing - Extrusion, Injection Molding, and Thermoforming (Room 3 Day 2 / am)

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| Plastic Recycling on Co-Rotating Twin Screw Extruders | Mr. Noah Grade | Krauss Maffei Berstorff |
| Perfect injection molding with fluid assisted technologies | Mr. Ulrich Stieler | Stieler Kunststoff Service GMBH |
| SANDWICH MATERIAL FROM PP BLENDS SKIN AND X-HDPE CORE MANUFACTURED BY CO-INJECTION MOLDING | Dr. Utai Meekum | Schooll of Polymer Engineering, Suranaree University of Technology |
| Flowability of Bulk Solids during the Extrusion Process | Dr. Jaime Gomez | Coperion |
| 3rd Generation Thermoforming | Mr. Ralph Mayer | ILLIG Maschinenbau GmbH & Co. KG |

Advances in Rheology, Modeling & Simulation – I (Room 4 Day 2 / am)

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|---|--------------------------|--|
| Reactivity Ratios Estimation Model and Parameter Uncertainty Quantification | Dr. Mohammad A. Al-Saleh | Kuwait Institute for Scientific Research |
| Effects of Rheological Behaviour on Colour Matching of Two Polycarbonate Resin Blends | Dr. Ghaus M. Rizvi | University of Ontario Institute of Tech |
| Melt Flow Rate, Molecular Weight and Rheological properties | Tariq Syed | SABIC |

Advances in Materials - New Applications (Room 1 Day 2 / pm)

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| SABIC SOLUTIONS FOR RAIL INTERIOR APPLICATIONS MEETING THE REQUIREMENTS OF THE NEW EUROPEAN EN 45545 RAIL STANDARD | Mr. Mark van der Mee | SABIC |
| Advances in Microcellular Plastics | Mr. Vipin Kumar | University of Washington |
| New paradigm of space exploitation: large size space constructions | Dr. Alexey V. Kondyurin, Ph.D. | University of Sydney |
| Mucell(R) Foamed Film Applications | Mr. Luis Zalamea | Dow Europe GmbH |
| The reports on the adverse effects of BPA are greatly exaggerated and Polycarbonate does not need to be eliminated from medical devices | Len Czuba | Czuba Enterprises Inc |
| Development of resins and specialty film types for high performance biax-film machines – practical approaches and available solutions | Mr. Andreas Blin | Bruckner Group |
| Accelerate Innovation of Advanced Polymer Materials | Mr. Frank Huijnen | Intertek Polychemlab BV |

Advances in Materials Performance - Resins II (Room 2 Day 2 / pm)

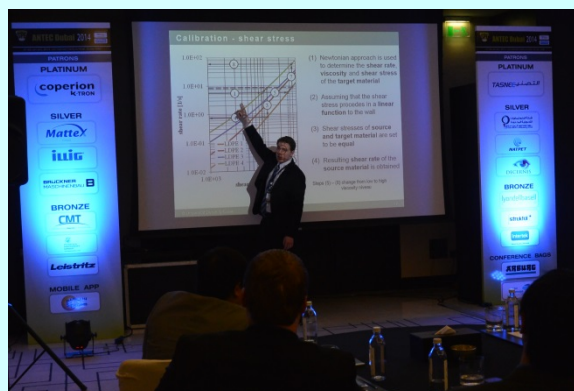
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| Metal replacement: A holistic look at the entire process | Mr. Marc Mezailles | PolyOne Corporation |
| Ultrahigh Performance Pigments & IR Reflectivity | Mr. Tom Mestdag | The Shepherd Color Company |
| EFFECT OF MATRIX AND PROCESSING METHOD ON PROPERTIES OF POLYMER GRAPHENE NANOCOMPOSITE | Dr. Ahmed A. Abdala | The Petroleum Institute |
| TECHNICAL PERSPECTIVES OF PLASTICIZERS PERFORMANCE FOR DIFFERENT PVC APPLICATIONS | Dr. Abdulhadi Saeed Alshehri | SABIC |
| Mineral Modifiers for Polyolefin Applications | Dr. Michael Tinkl | Omya International AG |
| XPS Alternative foaming agent study | Mr. Muteip Bin Saif | SABIC |
| Polyactic Acid for Durable Applications | Dr. Sushant Agarwal | West Virginia University |
| Surface Damage Behaviors of Urethane-Acrylate Coatings for Aesthetic Assessment | Mr. Jongil Weon | Dongguk University |

Advances in Materials Performance - Composites and Blends (Room 3 Day 2 / pm)

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|---|---------------------------|--|
| New Push-up to Water Business with Components of Blow Moulding and Composites Technology | Mr. Jukka E. Silén | Acqua Plastica - R&D and Business Consultancy |
| Superior Properties and Sophisticated Design to Industrial Applications with Plastics and Composites | Mrs. Karita Silén | abc-Acqua Business Consulting |
| Biopolymer – Graphene Oxide Nanocomposites: Structural Characterization and Properties | Dr. Vikas Mittal | The Petroleum Institute |
| Preparation of Polypropylene/Montmorillonite (MMT) nanocomposites for food packaging applications | Dr. Abdirahman A. Yussuf | Kuwait Institute for Scientific Research |
| Studies on the Properties of Polypropylene Composites with Modified Bio-Filler (Wood Fiber& Wheat Husk) by using Modified Surface Treating Agents | Dr. Pradeep Upadhyaya | CENTRAL INSTITUTE OF PLASTICS ENGINEERING ANN TECHNOLOGY |
| Sustainable Composite: High Strength Polypropylene Fiber Composite for Metal to Plastic Conversion for Automotive Application | Mr. Brajesh Kumar Singh | Mahindra & Mahindra |
| ELECTRICALLY CONDUCTIVE AND MECHANICALLY ENHANCED BIOPOLYMER-GRAPHENE NANOCOMPOSITES | Dr. Ahmed A. Abdala | The Petroleum Institute |
| Does Graphene Increase Tg of Polymer Nanocomposites? | Dr. Christopher W Macosko | University of Minnesota |

Advances in Rheology, Modeling & Simulation – II (Room 4 Day 2 / pm)

| | | |
|--|-----------------------|-------------------------------------|
| Using Design through Moldex3D Simulation to understand Flow Ability | Mr. Teng Yang | University Of Wisconsin Platteville |
| CALIBRATED CFD-BASED CALCULATION OF COLOR AND MATERIAL CHANGES IN EXTRUSION DIES | Levente Szöke | University of Duisburg-essen |
| An Alternate Method to OIT for Determination of Thermal Stability in HDPE Resin" | Dr. Poondi Srinivasan | Equate Petrochemical Company |



Recent Conferences



Exposition: February 11-13, 2014
Anaheim Convention Center

Anaheim, CA

Conference: February 10-13, 2014



The Medical Plastics Division (MPD) of the Society of Plastics Engineers sponsored a one day **Medical Device and Plastics Session** (Track D) on February 11 in collaboration with UBM Canon during the MD&M West Conference in Anaheim, CA. The session was organized and chaired by Dr. Vipul Davé, a Research Director and Fellow at Johnson & Johnson and a Board Member of MPD. There were six presentations in the session which were delivered by experts in the medical plastics field. The topics of the talks included drug delivery from absorbable polymers, polycarbonate and BPA, medical applications of ultrahigh molecular weight polyethylene and textile fabrics, laser micromachining of polymers and challenges of medical device manufacturing. Presentation titles and speaker names are shown in the table (next page).

A exclusive guided tour was led by Mark Bonifacio for the conference delegates of the most innovative companies in new polymer technology on the trade show floor.

Slides of the presentations for the MD&M West Conference are available to the attendees on the UBM Cannon Conference website. 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 30 conference attendees

A similar one day session will be held at the MD&M East Conference in New York in June, 2014. We look forward to seeing all of you at this conference to enjoy and learn about innovations in Medical Plastics!

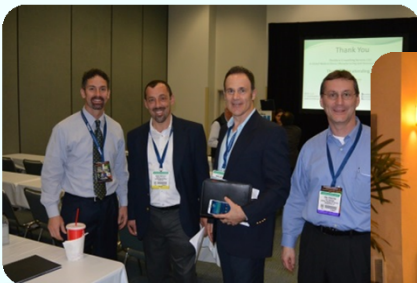
Vipul Davé



DAY 2 - Tuesday, February 11th

MEDICAL DEVICE POLYMERS AND PLASTICS

| | |
|----------|--|
| 9:00 AM | The entrepreneurial journey Rudy Mazzochi, CEO, Elenza |
| 10:15 AM | Absorbable polymers for drug delivery Vipul Davé, Ph.D. , Research Director, Fellow Global OTC Technology, McNeil Consumer Healthcare , Johnson & Johnson |
| 10:50 AM | New research on Polycarbonate and BPA: Safe for continued use in medical disposables Len Czuba, President, Czuba Enterprises, Inc. |
| 11:30 AM | Ultra high molecular weight polyethylene: Material properties and applications Anthony Verrocchi, Celanese Textile Fibers and Medical Fabrics |
| 1:00 PM | Textile fibers and medical fabrics Todd Blair, Director of Marketing, Biomedical Structures |
| 1:45 PM | Conference VIP exhibition tour: Polymers |
| 3:00 PM | Laser micromachining of polymer based medical devices Glenn Ogura, Executive Vice President, Business Development, Resonetics |
| 3:45 PM | Challenges of medical device contract manufacturing Mark Bonifacio, Principle and Owner, Bonifacio Consulting Services |



See the previous issue of the MDP newsletter for the complete program presented at MD&M West.

Recent Conferences



International Polyolefins Conference 2014 "The Polyolefin Renaissance" at Hilton Houston North February 23 - February 26, 2014, Houston, Texas

The 2014 SPE International Polyolefins Conference was held at the Hilton Houston North Hotel in Houston, Texas on Feb 23 – 26, 2014. With this year's theme of "The Polyolefin Renaissance", there were about 700 registered guests, 12 sponsors, 60+ exhibitors, 20+ student posters, and 80+ presentations over 14 sessions. The conference covered virtually everything on polyolefins with topics including state of business, horizontal drilling / shale oil and gas, chemistry, characterization, processing, advances in materials, and end use. This was the inaugural year for Medical Plastics participation in the conference with a dedicated session of 5 presentations and another talk was given at the Innovation Session. The presentations covered a breadth of areas including regulatory requirements, needs of medical industry, challenges and innovation opportunities, applications of polyolefins, and modeling. Interests in medical plastics was strong based on numerous questions and interactions that followed the talks. In addition to the presentations, there were plenty of networking opportunities with various sponsored lunches, breaks, and receptions. Attendees were treated with Texas hospitality with a blues band playing at the Monday reception and a mariachi band during one of the breaks.



Ben Poon, Jose Reyes, Barbara Canale, Mark Perry, James Stern

Ben Poon

Medical Plastics Division sponsored session:

| | | |
|----------------|-------------------------|---|
| James Stern | Borealis UK | How Polyolefin Polymer Producers Can Support the Healthcare Industry |
| Ben Poon | Baxter Healthcare | Pharmacopeia Requirements for Polyolefins |
| Jose Reyes | Celanese Corp. | Innovative Uses of Ethylene Vinyl Acetate Polymers for Advancing Healthcare |
| Barbara Canale | TOPAS Advanced Polymers | Meeting Today's Medical Device Challenges with Cyclic Olefin Copolymer |
| Mark Perry | Baxter Healthcare | Multi-Purpose Modeling of Dropping Flexible Polyolefin Drug Containers |

Recent Conferences

SPE Medical Plastics Division and
Upper Midwest Section Present
MEDICAL PLASTICS MINITEC 2014



Technology Advances in Plastic Materials and Processing for Medical Devices

27 MAR 2014

Keynote Speaker



Arthur G. Erdman – University of Minnesota, Medical Devices Center

Arthur G. Erdman, P.E., is the Richard C. Jordan Professor and a Morse Alumni Distinguished Teaching Professor of Mechanical Engineering at the University of Minnesota, specializing in mechanical design, bioengineering and product design. In July 2007 he was selected as the Director of the Medical Devices Center at the U of M and is also the Co-Editor of the ASME Journal of Medical Devices.

He received his BS degree at Rutgers University, his MS and Ph.D. at RPI. Dr. Erdman has published over 370 technical papers, 3 books, holds 35 patents (plus 10 pending), and shares with his former students 9 Best Paper Awards at international conferences. Dr. Erdman has had research collaborations with numerous health sciences faculty including those in Ophthalmology, Neuroscience, Epidemiology, Cardiology, Urology, Orthopedics, Surgery, Dentistry, Otolaryngology, Veterinary Medicine and Sports Biomechanics.

New Materials

Manuel Garcia-Leiner – Exponent

Dr. Manuel Garcia-Leiner is a Manager in Exponent's Polymer Science and Materials Chemistry practice. His research and professional interests include structure-property relationships and processing of polymeric systems. His areas of focus include melt processing, polymer composites, nanocomposite systems, high-performance polymers, polymer rheology, polymeric foams and solvent assisted polymer processing.

Before joining Exponent, Manuel was with Arkema for almost 9 years. He has a BS and MS in ChemE from Universidad Nacional Autonoma de Mexico, an MS and PhD from in UMass Amherst.



Steven Givens – Eastman Chemical Company

Dr. Steven Givens is a Senior Polymer Application Scientist for Eastman Chemical Company. He has responsibility for new application development, market focused product research and product performance.

He holds a Bachelor's degree in chemistry from the University of Virginia at Wise, a Doctor of Philosophy degree in Material Science and Engineering from the University of Delaware.

He has 20 years' experience in polymer R&D and processing in various positions in R&D, application development and technical marketing with Corning and duPont.



Alexis Proper – PolyOne Corporation

Alexis Proper graduated from Michigan State University with a degree in Mechanical Engineering. When working at Dow Corning, Alexis had multiple roles in application engineering and sales supporting medical industries including pharmaceutical manufacturing, medical devices, topical products, and wound care. In her current role at PolyOne, Alexis is in a Business

Development role providing technical support for customers using silicone and polyisoprene within the medical device market.



John Felton – Daikin – America

John Felton joined Daikin America in November 2005 as a Senior Market Development Representative and in his current role is responsible for developing applications in both Medical and Aerospace Markets. Globally headquartered in Osaka, Japan, Daikin Industries Ltd. is a worldwide leader in airconditioning systems, in which fluorine chemistry is key. The fluoropolymers and fluorochemicals division has annual sales exceeding \$1.2 billion. Before joining Daikin America, John worked as an account manager for Ticona Engineering Polymers where he was responsible for customer program development, material recommendations and design assistance. Prior to Ticona, John spent many years working for injection molding companies as well as Electronic OEMs providing design and development support.

John is a graduate of Western Washington University, holds a Bachelor of Science Degree in Manufacturing Engineering Technology and has been active in the plastics industry for over 25 years.

Pierre Moulinié – Bayer Material Science LLC

Pierre Moulinié obtained a PhD in Polymer Chemistry at Carleton University in Ottawa in 1996. He joined Bayer in 1999 and has occupied various technical functions related to polycarbonate and polycarbonate blends. Pierre worked in Bayer's Global Innovation Blends group in Germany from 2004-2008 and since 2008 has been a scientist supporting Polycarbonate products for medical applications.



Christian Herrid – Teel Plastics

Christian Herrid joined Teel in 2012 as the Director of Business Development and In-House Counsel. Currently the Director of Sales and Marketing, Christian manages Teel's sales force as well as market research, branding, and marketing activities. He also serves as in-house counsel for Teel and handles their agreements and legal matters. Chris graduated cum laude from UW-Madison Law School in 2012 and earned his MBA from UW, with a specialization in Entrepreneurial Management. Chris worked for a few other companies in Wisconsin before joining Teel full time. He has a strong technical background with undergraduate degrees in both Mathematics and Chemistry from Marquette University, where he won several awards for his chemistry work as an undergraduate. Prior to his advanced schooling, he spent almost two years as an industrial synthetic chemist working primarily with polynucleotides.



Len Czuba – Czuba Enterprises, Inc.

Len is president of Czuba Enterprises, Inc. a Chicago area medical device product development company, where he serves as the materials expert. He works with clients to take products, especially medical devices, from concept to production. His primary focus is in the selection and processing of plastics and biomedical polymers used in medical devices.

He holds 15 US patents including several for PVC replacement materials.

In 2004, Mr. Czuba was one of the 100 MD&DI Notable Persons in the medical device industry. He is a frequent conference speaker, moderator and instructor and has given presentations and seminars around the globe.

A member of the Society of Plastics Engineers since 1975, Mr. Czuba is past chairman of the Medical Plastics Division, was Councilor for the European Medical Polymers Division and was President of SPE during the 2005 – 2006 year. He is now a Distinguished Honored Service Member of SPE.

Jeff Leighty – Plasmatreteat

Jeff Leighty has been with Plasmatreteat since 2009 when the German parent company opened their first United States technical center in Elgin, Illinois. He serves as Sales and Business Development Manager with a focus on applications for the life sciences market using atmospheric pressure plasma technology. Jeff has a 15-year background in surface finishing.



Roger Pearson – Aspen Research Corp.

Dr. Roger Pearson is Vice President of Technology Development at Aspen Research where he is responsible for management of the analytical lab operations along with oversight for the R&D of new material technologies. Dr. Pearson is instrumental in the formulation, process development and Intellectual Property for all new materials. Dr. Pearson received his BS in Chemistry from Montana State University and his MS and PhD from the University of Minnesota.



Kevin Rottinghaus – Beaumont Technologies, Inc.

Kevin Rottinghaus is the Regional Account Manager for Beaumont Technologies responsible for this area of the country which includes Minnesota, Wisconsin, Illinois, Nebraska, Iowa and the Upper Peninsula. Kevin has been with Beaumont over 3 years and before this position, worked with a small injection molding company in nearby Wisconsin. His strong knowledge of materials, additives, secondary operations and tooling coupled with his understanding the basics of plastic injection molding allowed him to provide consulting for some clients on how to improve part and tooling design to reduce costs and lead-times.



Susan Montgomery – Priamus System Technologies

Susan Montgomery has been President of Priamus System Technologies, Brunswick, OH, since 2002. She has been in the plastic processing field for 19 years, most of this time spent in plastics process instrumentation and injection molding process controls. Ms. Montgomery holds a BS in Chemical Engineering from Cleveland State University (Ohio) and has done Master's coursework at SUNY Buffalo in Surface Chemistry and Engineering. She holds a Six Sigma Green Belt (from GE Plastics). Susan also served as Chair of SPE's Injection Molding Division from 2011-2012 and 2012-2013. She was Injection Molding Division Technical Program Chair for ANTEC 2011.



New Processing Technologies

Dave Kupiecki – Teleflex Medical OEM



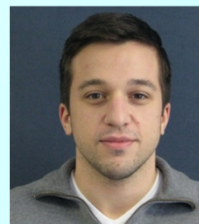
David Kupiecki is a Technical Sales Manager for Teleflex Medical OEM, a global provider of product development and production services for OEMs. The business specializes in custom-engineered extrusions, complex catheters, performance fibers and medical devices. He joined Teleflex Medical OEM during 2010.

Mr. Kupiecki is a medtech industry veteran with almost 20 years of experience in managing the research and development of innovative products and leading infrastructure improvement initiatives, most recently as a Program Manager for American Medical Systems and Operations Manager for iScience Interventional. He also served as the Director of Engineering at Vasconnect, R&D Manager at Lumend and a Project Engineer at Prolifix Medical. He began his career as an Engineer at Target Therapeutics.

David has a BS in Chemical Engineering from the University of California, Berkley and an MBA from the University of San Francisco.

Visent Avxgu – 3D ProScan, a division Nypromold, Inc.

Visent Avxhi is the business development manager for 3D ProScan, a division of Nypromold. He was named to this position in July 2013. Visent is responsible for the development of the CT scanning division of Nypromold and supports the company's continued market growth in this area.



Visent received a bachelor's degree in biochemistry and molecular biology from UMASS Amherst where he had an integral part of creating two organizations, the Eta Mu Chapter of the Fraternity of Phi Gamma Delta and the Albanian Student Union.

Notes and News



SOCIETY OF PLASTICS ENGINEERS INC. **MEDICAL PLASTICS DIVISION**

Sponsorship – Advertise in the MDP Newsletter

The Medical Plastics Division of the Society of Plastics Engineers is seeking Sponsor Display Ads for our Award-winning division newsletter. The newsletter is published quarterly and reaches the nearly 1000 members of the Medical Plastics Division.

Sizes Available (Full year amount, 4 issues)

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

Please support the Medical Plastics Division and its newsletter by advertising your company or product in the MPD newsletter. Contact the newsletter editor (norris.tollefson@alcon.com) or the division chair (mbonifacio123@gmail.com) for details.

Thank you for your support!

How would you like to reprint your Technical Presentation in the Medical Plastics Division Newsletter?

I would like to invite any member of the Medical Plastics Division to submit an article or paper that has been published or presented elsewhere for reprint in the MPD newsletter.

The intention is to provide a diverse selection of subjects over the year that are interesting to our members and important to our medical plastics industry.

Please submit an article or paper in a pdf format to the newsletter editor Norris M. Tollefson (norris.tollefson@alcon.com). At your discretion, you may also include a brief biography (less than 50 words) and a photo. Not all submissions may be used.

Please make submission to the newsletter editor
Norris M. Tollefson (norris.tollefson@alcon.com)

Board of Directors for the Medical Plastics Division

Selected Board Members for 2013 – 2014.



Margie Hanna



Ali Ashter



Austin Coffey



Ben Poon



Vijay Boolani



Norris Tollefson

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 bimonthly 1-hour teleconference meetings and annual in-person Board of Directors and Business meetings at SPE's Annual Technical Conference (ANTEC).
- ▶ Willing Board members will assume specific roles in leadership positions, 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 for the Medical Plastics Division

The Board of Directors is the governing body of the Medical Plastics Division. Its responsibilities include election of MPD officers, establishing division rules and operating procedures, appointing committee chairs, establishing a budget, and fundraising, as well as authorizing, negotiating, and planning topical conferences (TOPCONs).

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 while also a member of the Board. Our Councilor to the SPE serves a three year term.

Elections to fill five vacancies were held in March 2014. New and returning members will be welcomed at the Board meeting to be held at ANTEC 2014 in Las Vegas.

From The Editor:

This year, the meeting at ANTEC 2014 will herald a bit of change with the directors of the Medical Plastics Division.

After more than 30 years, Paul German has decided to retire as *ex officio* Treasurer for the SPE Medical Plastics Division and from our Board of Directors. We wish him well in the future.

Ali Ashter will be assuming the duties of MPD Treasurer.

After four years, I am passing the newsletter on to Jordan Freeman, who will be starting his second term on the Board with this ANTEC meeting. I expect Jordan will do a great job with the future newsletter.

But I do not plan on going anywhere. I am hoping to be re-elected to the Board (at this time, election results are still pending) so that I can take on other responsibilities within the Medical Plastics Division and try something new.

There is an advertising slogan "What happens in Vegas, stays in Vegas." My hope is that "what happens in Vegas, starts in Vegas," because that would mean that the things we learn, the goals we set, and the connections we make will go with us into the future and not end when we all go home.

Let's start something in Vegas.

Norris M. Tollefson

March 2014

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.

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 - 2014) | 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 |
| <i>ex officio</i> | | |
| 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.

Meeting Minutes

Meeting Minutes for MPD BOD Conference Call

Date: 1-13-14 11 am EST

1. Call to order
2. Roll Call: Attendees: Mark Bonifacio, John Thomas, Margie Hanna, Jodie Laughlin, Len Czuba, Steve McCarthy, Michael Wallick, Ken Breeding, Ben Poon, Ali Ashter, Norris Tollefson, Ed Fewkes, Glenn Beale, Maureen Reitman, Vipul Dave, Ben Poon
3. Meeting minutes from 11/20/13 Norris motion to approve, Ali 2nd: approved
4. Treasurer/Finance Committee Report – Paul German not on call – Brief review MPD BOD Finance Committee conf call tomorrow
5. Technical program
 - a. Medial Plastics Papers – Ed Fewkes reviewed spreadsheet
 - b. MD&M West Anaheim – Len: Vipul heading up, email promo with UBS Cannon Presentations set. Len suggests that we organize a luncheon/networking event – JT to set up, Margie set it up last year.
 - c. TOPCON China Update – Very successful – Ali will write up review for the Newsletter – nice write up in the Plastics News – send Norris pdf and photos. Over booked the room block and lost profit, but Positive feedback and were told that we would have attendees and sponsorship if we do another TOPCON in China in the future
 - d. Polyolefins Conference – Ben: 5 presenters 2/25/14 afternoon session, no issues
 - e. MiniTec Minneapolis, Wed. March 26, 2014 call for papers, publicize in Anaheim & newsletter
 - f. ANTEC 2014 Las Vegas
 - i. Motion approved to Host reception up to \$2,000
 1. Len to ask other division to co-sponsor
 2. JT to contact Barbara & set up
 - g. Potential Medical Plastics Event with Philadelphia SPE
 - h. Ben – send requests for speaker gifts
6. Membership Committee – Jim Madenjian (not on call) – Mark will follow up
7. Councilor Report – Margie Hanna – no new updates other than we will be represented in Dubai – Margie will send something for the newsletter
8. Newsletter update – Norris needs everything as soon as possible so he can publish next week. Wants to publish Q2 newsletter before ANTEC
9. SPE Sections and Divisions liaison – Kathy Schacht (She took Tricia McKnights place. Sarah did the job for a while but is now only part time.)
10. Award Nominations Committee – Mike Wallick
 - a. Mike wants suggestions/advice from SPE veterans
 - b. Best Papers
 - c. Pinnacle – requirements, paperwork
 - d. We recommended honor & fellow for ANTEC 2014
11. BOD Officers for 2014 – Changes?
 - a. Call for open nominees
 - b. Norris – 4 positions open
 - c. JT nominates Ben for Secretary, Len 2nd

- a. Close nominations & vote next meeting 3/5/14
 - b. Call for Board Member nominations for Newsletter
- 2. Unfinished business
- 3. New business - elections – via email ballot, nominations due 2/14/14
- 4. Next meeting & 2014 meeting schedule
 - a. BOD meeting – Monday 4/28 reserve room after reception
 - b. MPD Business meeting – TBD
 - c. Tentative dates for Newsletter
- 5. Motion to adjourn – Len, 2nd Margie

Meeting Minutes for MPD BOD Conference Call

Date: 3-5-14 11 am EST

- 1. Call to order
- 2. Roll Call: Mark Bonifacio, John Thomas, Margie Hanna, Len Czuba, Steve McCarthy, Michael Wallick, Ken Breeding, Benjamin Poon, Ali Ashter, Norris Tollefson, Ed Fewkes, Glenn Beale, Maureen Reitman, Vipul Dave, Jim Madenjian, Jordan Freeman
- 3. Approval of meeting minutes from 1/13/14 Jim M motion to approve, 2nd
- 4. Treasurer/Finance Committee Report
 - a. Loan to MPD from Glenn Beale
 - b. Ali Ashter – new treasurer
 - c. Wim Devos know the financial situation and can wait on MDP commitments to SPE (approx. \$6K)
 - d. Summary of finance situation for benefit of people not on the call
- 5. Technical program
 - a. MD&M West Anaheim – Vipul 3 MPD board members presented, 20+ people well attended good mix of materials and processing. MD&M did not recognize SPE as putting on the program
 - b. Polyolefins Conference – Ben
 - i. 6 talks total
 - ii. 700 registered attendees, 20-25 people in the session many questions & interest
 - iii. Invited back for next year
 - iv. Will follow up on finances (est. \$3K)
 - v. Will provide photos and write up for the newsletter
 - c. MiniTec Minneapolis, March, 27 2014 – Len
 - i. ½ hour talks morning materials, afternoon processing
 - ii. Looking to reach out and encourage attendance
 - d. ANTEC 2014 Las Vegas – Ed Fewkes
 - i. 3 full sessions plus a few additional papers, someone from the FDA wanted to submit a paper, Keynote speaker 1 hour.
 - ii. Sessions: Tues morning T13, Wed am & Wed pm.
 - iii. Ben & Ali moderators – Jim M volunteered to be 3rd moderator
 - e. Medical Plastics Event with Philadelphia SPE
 - i. we won't be able to do anything until after March MiniTec
 - f. MD&M East – June 9-12, Javits Center, New York, NY
 - i. Technical Program – Working on topics
 - ii. Joint networking reception with Québec Government Office on June 11th between 4pm and 6pm
 - g. Additional programs are encouraged

1. Membership Committee – Jim Madenjian
 - a. 6 new members,
 - b. Welcome email and note in newsletter
2. Ben: Committee meeting – new website & divisions can have sub-website, New SPE logo
3. Councilor Report – Margie Hanna
 - a. ANTEC Dubai
 - b. April 26-28 next council meeting
4. Newsletter update – Norris T
 - a. 1st issue, out in Jan
 - b. 2nd 1st week of April (approx.) Before ANTEC
5. Liaisons – Kathy Schacht – could not attend call
6. Award Nominations Committee – Mike Wallick
 - a. We did not make the cut for the Pinnacle award, but are working on next year
 - b. Looking for historical #'s on membership, acceptable rate of growth – Jim (Len 3-5%)
 - c. Len to send prior successful submittal
7. ANTEC – awards for best paper – off line follow up
8. BOD for 2014
 - a. Officers Changes
 - b. Nominees
 - c. Annual Meeting at ANTEC Monday, April 28, 5:30-7pm – JT to send out calendar item upon confirmation
Welcome reception 6-7:30pm Can we move the BOD meeting to 5pm?
 - d. BOD dinner – after reception – JT send invite
 - e. Business meeting?
 - f. Elections – will get ballot out in the next week of so
 - i. How many running
 - ii. Board member elections during board meeting
 - g. Len Nominate Norris as Vice Chair for next year, Margie 2nd
 - h. MVP for the division – Margie: schedule a call before ANTEC, or can be done by email vote
9. Unfinished business
10. New business
11. Next meeting will be scheduled for elections before ANTEC
12. Motion to adjourn (Norris) 2nd. Meeting adjourned.

Technical Presentation

INNOVATIVE USES OF ETHYLENE VINYL ACETATE POLYMERS FOR ADVANCING HEALTHCARE

Jose D. Reyes

Celanese Corporation, Irving, TX, USA

Abstract

Ethylene vinyl acetate (EVA) has a long and successful history of innovation in medical packaging, medical devices, and pharmaceutical applications. In fact, EVA has been an innovative force in those applications for over 35 years and continues its innovation legacy through enablement of solutions in areas of ever increasing challenges. New solutions are required for continually improving patient healthcare. This paper will examine the evolutionary role of EVA innovation in diverse applications ranging from its early use in parenteral applications for delivery of life saving medications to cryogenic storage bags for stem cells used in the emerging field of cell therapy to controlled release of small molecule active pharmaceutical ingredients (API) and finally as an innovative gastroretentive delivery vehicle for controlled release of large molecule therapeutics for the high growth field of biologics and personalized medicine. It is the simplicity of the molecular architecture of EVA which leads to its ability to create innovative solutions to some of healthcare's most challenging and complex problems. Case studies will provide an illustration of each of these applications.

Introduction

We are living at a time when healthcare is undergoing exciting new developments and

innovations. The medical device industry and the pharmaceutical industry are developing innovative products which provide for better patient care and improved quality of life. Also, and of no surprise, the two industries have applications in common as well as areas of uniqueness. For example, an intravenous (IV) bag containing drugs illustrates where a medical device and pharmaceutical product work together in support of patient needs. For an application where a medical device and a pharma product work independent of one another, one may consider a sleep apnea device versus a tablet containing an API. Here, the sleep apnea device does not contain a pharma product and the tablet (pharma product) is not part of a medical device.

Ethylene vinyl acetate (EVA) has been used for many years in both industries and has historically been an important enabler of innovation. Today and going into the future, EVA is enabling innovation in emerging fields like cell therapy and controlled release of biologics. In the following sections, this paper provides an overview of EVA polymers followed by three case studies demonstrating EVA's innovative use for advancing healthcare.

Introduction to EVA Polymers

Ethylene vinyl acetate copolymers are made using two monomers: ethylene and vinyl acetate (VA). The polymerization may take

place by either autoclave or tubular reactors. Figure 1 illustrates the polymerization (1).

Polymerization of Ethylene and Vinyl Acetate

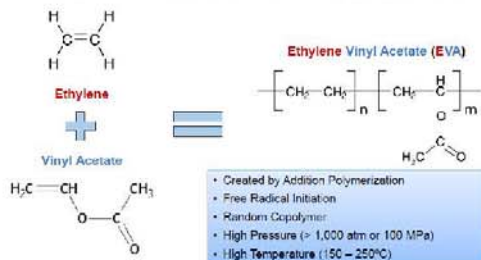


Figure 1. Polymerization of EVA

The percent of VA incorporated into the polymer backbone can vary from 0 to 40. At 0% the polymer is essentially low density polyethylene. As VA content is increased, the polymer becomes more flexible and transparent. EVA polymers with VA content higher than 40 percent tend to become a handling challenge from a commercial pelletized perspective. The melting point of the EVA is influenced by the vinyl acetate content. As VA content increases, melting point decreases. Figure 2 illustrates the linear relationship (2).

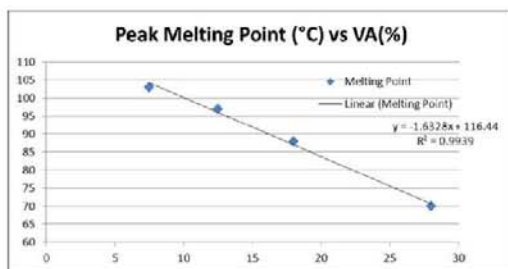


Figure 2. Melting point versus VA%

EVA has been commercially used for over 35 years in medical device applications. Figure 3 illustrates some examples

following the commercial launch of EVA in 1960.

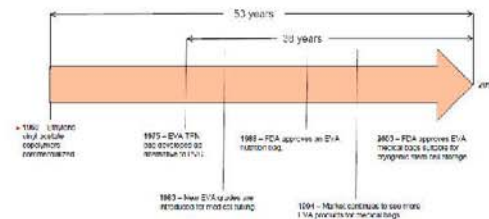


Figure 3. Timeline of EVA in Healthcare

Case Study 1: IV Therapy and EVA

IV therapy is when medicine or fluids are infused directly into a vein. The majority of IV therapy is for delivery of nutrition, sodium chloride, potassium chloride or sucrose. Approximately 80% of hospitalized patients receive some form of IV therapy. In 1950 Dr. Carl Walter, a Harvard surgeon and pioneer in kidney transplants invented the plastic medical bag (3). This enabled plastic bags to replace glass bottles thereby reducing breakage, less weight during shipment and safer handling during dangerous but urgent situations such as a battlefield or natural disaster where patients need immediate attention and are often being carried away with IV lines in. It is difficult to estimate how many soldiers' lives have been saved through the use of rapidly available plastic IV bags and their contents. In 1969 Dr. Stanley Dudrick at the University of Pennsylvania (4) conducted work that ultimately led to the foundation for total parenteral nutrition (TPN). In the 1970's and 1980's alternatives to PVC plastic IV bags were sought because the phthalate plasticizer, commonly used in PVC, was leaching into nutrition fluids including the lipid components.

Case Study 1 – EVA Innovation

EVA was found to be an excellent solution for TPN bags. EVA offered the ability to have high flexibility without having to incorporate plasticizers. The simplicity of the molecular architecture enabled said flexibility by increasing the content of vinyl acetate comonomer. The higher VA content, e.g. 18 to 28 percent, also provides excellent transparency. Film of high quality was possible due to EVA's excellent rheology. Of additional importance was EVA's ability to be welded for construction of the bags. For IV nutrition bags, EVA provides excellent biocompatibility as measured by USP Class VI testing.

Case Study 2 – Cell Therapy and EVA

This case study will be limited to the area of stem cell therapy. It is a very large and promising area for treating diseases such as: Parkinson's, diabetes, ALS, and heart disease. Successful therapies for these diseases enable treatment of between 100 million to 150 million Americans (5). Consider the untapped power of an embryonic stem cell. This is a cell that can differentiate into any type of body tissue. Researchers and medical professionals store stem cells at cryogenic conditions so that they are available when needed. Consider the lifesaving situation in a 2 year old toddler from the UK who received frozen stem cells. She was facing a rare life threatening form of acute myeloid leukemia having a 30% life expectancy. She was given a transplant of frozen stem cells which were originally located in Tokyo. She made a complete recovery. Which type of medical packaging is used for storage of these

precious cells? EVA is used as a polymer for these storage containers.

Case Study 2 – EVA Innovation

Stem cells are stored at temperatures of -156C to -196C (6). Various materials have been used for storage bags. They include EVA and fluorinated ethylene propylene (FEP) or polytetrafluoroethylene (PTFE). In the USA, EVA is the material most commonly used for cryocontainers (7). FDA 510K clearances illustrate EVA's use. If one looks at the simple molecular structure of EVA it is observed that EVA can achieve remarkable diversity of properties due to its two monomer design, ethylene and vinyl acetate. The reactivity of each monomer is such that the overall composition of ethylene to VA content in the final copolymer is approximately the respective feed ratios. Therefore, one can vary flexibility and glass transition temperature, T_g by varying the vinyl acetate content. For high VA content grades, e.g. 28%, a glass transition temperature of -30C is achievable. This provides good low temperature performance with a high clarity of the container. Furthermore, because of the designable nature of properties by varying solely the VA content, one does not need to add additives such as plasticizers which can leach into the storage contents. EVA is easily sterilized by gamma radiation which is commonly used for sterilization of cryo storage bags. Gamma sterilization is not recommended for FEP due to its low tolerance level of 50 kGY. Polytetrafluoroethylene (PTFE) has a tolerance level of 5 kGY and may disintegrate into powder with gamma

radiation. Also PTFE may liberate fluorine gas during gamma sterilization.

The innovative nature of EVA and its simplicity of molecular architecture have positioned it to be the leading material in the field of cryogenic stem cell storage materials.

Case Study 3 – Controlled Release of Low or High Molecular Weight Active Pharmaceutical Ingredients

Folkman and Long are believed to be the first to have reported the use of polymers for controlled release of APIs. They investigated the use of silicone tubing (7). The early work with silicone polymers demonstrated that certain drugs could release in a sustained manner but they had to be low molecular weight drugs, e.g. less than 1000, and of non polar nature. Drugs higher than 1000 molecular weight and possessing polarity would not diffuse out. Molecular motion is possible through amorphous regions. Over time other polymers were introduced as excipients for drug delivery. Hydrophobic polymers include ethylcellulose and EVA. Ethylcellulose is combined with a solvent and plasticizer to create a film. Some solvents used include acetone, chloroform, ethanol, toluene and blends. Controlled release of APIs can be designed by the thickness of the ethylcellulose film which alters the diffusion path.

EVA is a hydrophobic polymer which does not require the use of solvents or plasticizers for drug delivery. EVA has been used in a wide variety of applications and administration routes. Anderson et.al. (8)

conducted a study examining the release characteristics of two, but different, low molecular weight APIs. A hormone, etonogestrel MW = 324, was compared to cyclosporine A, MW = 1203 for release characteristics based on molecular considerations of the EVA and the APIs. Two EVA polymers were used in the study. One containing 18% VA and the other containing 28% VA. As the VA content increased, it created higher amorphous content which should offer greater release rates as amorphous content goes up. As expected, the higher amorphous content EVA released API faster. Another important finding was that as VA content increases, polarity increases which offers the drug delivery designer the capability of tailoring polarities between EVA and APIs to improve API solubility with the excipient. Recall in the early work of Folkman it was found that polar APIs would not diffuse from their silicone tubing excipient. Table 1 illustrates Anderson's results (9).

| Polymer VA content (wt %) | Cyclosporine loading (mg) | % Released in 30 days |
|---------------------------|---------------------------|-----------------------|
| 18 | 5 | 18 |
| 18 | 25 | 12 |
| 28 | 5 | 29 |
| 28 | 25 | 26 |

Table 1. Release rate as a function of VA Content for Cyclosporine A in EVA

In 2012, 8 of the top 15 selling drugs were biologics. These are high molecular weight molecules, e.g. 40,000 to 2 million Daltons. Some biologic examples are proteins, monoclonal antibodies, peptides, etc. Biologics are becoming a very promising field of therapeutics. All of the top selling biologics are administered through injection. It would be of value to have an oral dosage

administration route for improving patient compliance. Because biologics are large molecules (e.g. polymers), they require more space for diffusion than what an excipient can offer via traditional amorphous content. To that end, Reyes et.al. propose drug delivery vehicle technology to accomplish this (10) using microcellular foaming in combination with a rheologically engineered EVA copolymer. During microcellular foaming a supercritical fluid is injected. This process enables the design of highly symmetrical microstructure of closed or open cell foam delivery vehicles. The symmetry is used for engineering a uniform diffusion path. The biologics are then seeded into the EVA foam core. Tablets can be manufactured such that they have coatings for enabling passage of the biologics through the stomach for delivery to the lower intestine.

Case Study 3 – EVA Innovation

In Case Study 3 it was observed that various polymers have been used as excipients. Ethylcellulose polymers provide controlled release but can require harsh solvents like chloroform as part of the application process. Silicone was shown to offer controlled release. However those polymers require curing steps which can contain harsh curing agents and take long processing times for achieving proper cure state. Also, silicone is polarity limited as found by Folkman et.al.

EVA provides an excellent approach for engineering polarity and amorphous content owing to its simple two monomer structure. Furthermore, because EVA is a thermoplastic, it does not require curing

steps like silicone. EVA has been used in various administration routes including, dermal patches, subcutaneous implants, and intravaginal rings. Going forward, as healthcare enters into the growing area of biologics and individual medicine, EVA is innovating the field for controlled release drug delivery. EVA's ability to have engineered rheology in combination with supercritical fluid microcellular foaming for open or closed cell foam advances its value as an excipient for the multibillion dollar field of biologics.

Conclusion

This paper has examined the evolution of EVA's innovation in healthcare. EVA has experienced a long successful history in advancing healthcare. From its leading role in nutrition bags and expanding the field of IV therapy, to its importance in the storage of critical products like stem cells and into its emerging role as a controlled release excipient for biologics, EVA has been at the forefront of innovation in healthcare for decades.

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