THE DEVELOPMENT AND APPLICATION OF EXTRUDED SILICONE TUBING WITH OPTIMIZED PRECISION AND CONSISTENCY FOR FLUID MANAGEMENT APPLICATIONS

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PROCESS TECH R&D MGR.
WHO IS SAINT-GOBAIN?

- Founded in 1665
- Corporate Headquarters is located in Paris, France
- Over 1000 Consolidated Companies
- Sales €40 Billion – Publicly held
- 170,000 Employees in 66 Countries
- Materials-based Company – Three Sectors
  - **Performance Plastics** is under the Innovative Materials sector
- **Fluid Systems division of Performance Plastics** is dedicated to Life Sciences Industries
  - Medical Components, Bioprocess Solutions, Filtration Technologies
  - Strong focus on Fluid Management (Fluid Systems division)
- **Key Medical Segments Served include:**
  - Cardiology
  - Nephrology
  - Nutrition
  - Ophthalmic
  - Surgical
  - IV therapy
AGENDA

1) Problem Statement
2) Development of a Solution
3) Three Key Aspects to Optimization
4) Final Case Study
PROBLEM STATEMENT

With rapidly advancing technologies and increasing regulatory requirements, today’s health care providers demand value-based medical devices that deliver enhanced patient outcomes while minimizing patient risk.

- Silicone tubing is well known as a high performing pump tubing

- Material knowledge & consistent processes are critical to minimize variation and improve performance
SOLUTION DEVELOPMENT
Understanding of the Process – Silicone Pump Tubing

Silica Ore → Silicone Gum Stock → Silicone Base → Silicone Compound

Final Product ← Secondary Processing Steps ← Extrusion ← Mix Final Compound

Silica
Compound

Ore

Silicone
Gum Stock

Silicone
Base

Silicone
Compound

Final Product

Secondary Processing Steps

Extrusion

Mix Final Compound

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SOLUTION DEVELOPMENT
Identifying the Factors of Influence

Material Variation
- Lot-to-lot Variability & Varying Formulations
- Catalyst Type
- Material Hardness
- Rheology / Viscosity
- Filler Type/Content
- Other Additives

Process Variation
- Extruder/Former Type
- Cure Oven Type/Design
- Die Design
- Process Conditions
- Measurement Systems
- Automation/Controls
- Recipe Management

Impact to Product
- Quality
- Consistency
- Performance
- Dimensions
- Properties
SOLUTION DEVELOPMENT
Research and Optimization of Inputs

Lab built at Saint-Gobain R&D Center (Northboro, MA)

Varied Equipment for Testing
- Two extruders
- Die/head designs
- Various cure oven types
- Inline measurement systems
- Inline cutting
- Automation/closed loop control
- Recipe management & historian

- 1,000+ ft² “White Room”
- 70° +/-2°F with Controlled Humidity
- Positive Pressure
- $1.2 million investment
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3 Critical Aspects to Silicone Tube Performance Optimization

- Formulation Optimization
- Extrusion Consistency & Precision
- Application Knowledge

Result of Testing = Compass Technology
Patent Pending
AGENDA

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ASPECT #1: MODELING SIMULATION & APPLICATION KNOWLEDGE

Key Benefits
- Provide quantitative understanding of the intrinsic operation of the pump mechanism
- Understand the effect on flow rate by the geometrical and physical properties of tubing through virtual DOEs to design the pumping device

Technical Challenge
- Strong solid (tube deformation) & fluid interaction (FSI) – a challenging task for simulation; new capability in last 5-10 years

Fluid domain changes shape but maintains topology (non-occluded)
Fluid domain has topology change (occluded)
Common FSI approach is Coupled Eulerian Lagrangian (CEL) method

- Given the extreme geometry distortion + high internal pressure (atm), CEL can not resolve the fluid/solid boundary

Smoothed Particle Hydrodynamics (SPH)

- New meshless technique uses discretize space with collection of points instead of grid
  - Capable of handling extreme deformation
- Invented by astronomers in 1970’s; gained acceptance in Mech. Eng. In last 20 years
- Available in top tier Explicit Finite Element Software within the last decade
  - Abaqus/Explicit, LS-Dyna, AutoDyan

Modeling presented at MD&M East, 2012

- R. Schwenker and H. Huang, PhD.
**ASPECT #1: APPLICATION KNOWLEDGE / MODELING SIMULATION**

Example of What Modeling Can Provide

Modeling can define optimal occlusion for a given material/geometry.

One can accurately model the impact of material and dimensional variation on flow rate.

*cartridge gap translates to an occlusion % as noted*

Normalized to 5 RPM

**OC% = 22.5%**

**OC% = 12.2%**

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ASPECT #2: OPTIMIZED FORMULATION
What Goes into a Silicone Formulation?

Many Ingredients = Room for Variation

Spec. Example of Pt Silicone
- Off-the-shelf, Class VI

<table>
<thead>
<tr>
<th>Property</th>
<th>Spec</th>
<th>% of Nominal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore A</td>
<td>50 ± 5</td>
<td>10%</td>
</tr>
<tr>
<td>Modulus (psi)</td>
<td>250 ± 75</td>
<td>30%</td>
</tr>
</tbody>
</table>

When final pump accuracy needs <10%, need to drive out material variation
ASPECT #2: OPTIMIZED FORMULATION
How Can Variation Be Driven Out?

Custom Compounding

- Control over ingredients = reduced variation
- Customize properties based on application
- Resulting in better accuracy & consistency of tube and device
ASPECT #2: OPTIMIZED FORMULATION

Case Study

**Scenario**

- Optimizing current enteral feeding pump
- Need to drive out material variation to improve pump consistency/accuracy
- Need to match physical properties/performance of the legacy tubing used to program the pump

**Action**

- Define critical material properties and lower batch to batch specification/variation
Problem #2: Matching Pump Performance

Strong correlation to flow rate accuracy over time
($R^2 = 0.88$)

Problem #1: Minimizing Variation

Durometer (Shore A)

Modulus (psi)

ASPECT #2: OPTIMIZED FORMULATION

Case Study

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ASPECT #3: CONSISTENT & PRECISE DIMENSIONAL CONTROL

What Impacts Dimensional Variation?

- Equipment Design
- Inline vs. Crosshead
- Equipment Condition
- Material Properties
- Cure Rate
- Viscosity

Long Term Variation
- Material Changes; Screen Pack Cleanliness; Operator Influence
ASPECT #3: CONSISTENT & PRECISE DIMENSIONAL CONTROL
Long Term Variation

How to Eliminate Variation from…
- Lot to Lot Material Changes
- Screen Cleanliness
- Operator Influence
- Equipment Wear

… Implement Automation!
- Closed Loop Control (w/ Historian)
- Recipe Management
- Limits on User Inputs
- Automated PM Schedules

Extruder

Cure Oven

Pulling/Cutting /Packaging

Inline Measurements

Complete SCADA Control System
ASPECT #3: CONSISTENT & PRECISE DIMENSIONAL CONTROL
Short Term Variation

Significant Short Term Factors

- Die/Head Design
- Line/Oven Configuration
  - Vertical-up, Vertical-down, Horizontal
- Cure Technology Type
  - Hot Air, Short Wave IR, Long Wave IR, UV, Salt Bath, Microwave
- Downstream Handling/Processes
  - Cutting, Printing, Measurement
- Loss of feed pressure
- Screw pulsation

How to Reduce Variation?

- Case by Case...
  - Material Viscosity
  - Cure Rate
  - ID Size
  - Aspect Ratio
Scenario

- Looking to reduce variation in an infusion pump
- Lower dimensional variation = lower dosing variation

<table>
<thead>
<tr>
<th></th>
<th>Target (inch)</th>
<th>Tol. (inch)</th>
<th>% of Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID</td>
<td>0.062</td>
<td>± 0.004</td>
<td>6%</td>
</tr>
<tr>
<td>Wall</td>
<td>0.031</td>
<td>± 0.003</td>
<td>10%</td>
</tr>
</tbody>
</table>

Action

1.) Optimize process conditions & equipment to address short term variation
2.) Implement closed loop control w/ SCADA to address long term variation
ASPECT #3: CONSISTENT & PRECISE DIMENSIONAL CONTROL

Case Study

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~50%↓
OVERALL/FINAL CASE STUDY

Scenario
- Developing a new infusion pump
- Study all factors to understand influence on pump performance
- Optimize performance through most cost effective factors

Action
1.) Apply modeling: Identify major factors & define DOE limits
2.) Develop a Custom Compound
   - Study material variation vs. pump performance
3.) Optimize process and equipment to match tubing and formulation
   - Study limits vs. pump performance
Influence of Occlusion

- Min occlusion = +0.3mm

Influence of Back-Pressure

- Little influence from back-pressure
FINAL CASE STUDY
Studying Material and Dimensional Influence

Problem #1: Material Influence

Custom Compound
- Tested & Identified most critical physical property
- But how important considering all factors?

3 Lot Testing

<table>
<thead>
<tr>
<th>Lot #</th>
<th>“Elasticity”</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-10%</td>
</tr>
<tr>
<td>2</td>
<td>Nominal</td>
</tr>
<tr>
<td>3</td>
<td>+10%</td>
</tr>
</tbody>
</table>

Run Joint DOE
15 Distinct Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>ID (inch)</th>
<th>WT (inch)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>2</td>
<td>L</td>
<td>H</td>
</tr>
<tr>
<td>3</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>4</td>
<td>H</td>
<td>L</td>
</tr>
<tr>
<td>5</td>
<td>H</td>
<td>H</td>
</tr>
</tbody>
</table>

Problem #2: Dimensional Influence

ID and Wall Thickness

Lower Limit
Nominal Target
High Limit

Tested & Identified most critical physical property
But how important considering all factors?

Run Joint DOE
15 Distinct Groups
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FINAL CASE STUDY
DOE Results

- **Tested 15 groups measuring pump performance**
- **Tube Factors Analyzed**
  - Inner Diameter
  - Wall Thickness
  - Elasticity/Modulus
- **Pump Factors Analyzed**
  - Fluid Type
  - Operating Temperature
  - Occlusion Distance
  - Pump Speed
- **Studied Main Effects and A x B Interactions**

Many non-significant terms identified. Focus on 2nd order only.
FINAL CASE STUDY
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### Pareto Chart of the Standardized Effects
(responses is Flow_31min[mL/hr], Alpha = 0.05)

Significant Terms:
1.) Operating Temp.
2.) Occlusion x Wall
3.) Wall x Operating Temp.
4.) Occlusion
CONCLUSION / SUMMARY

- Variation Comes from Many Places
- Application Knowledge is Critical
- Modeling can be a Powerful Tool and Reduce Development Time (Speed-to-Market)
- Customized Formulations can Improve Performance and Reduce Variation
- Many Process Factors to Consider per Product

- Saint-Gobain Compass Technology® addresses key problem statements
  - Intravenous pump consistency and accuracy
  - Speed-to-Market