Materials, Medicine & Manufacturing: 
*Materials Awareness and Selection*

Dr. Crystal G. Morrison 
Principal Investigator and Senior Materials Scientist
Dr. Crystal G. Morrison

- Ph.D. – University of Michigan
- Postdoc – Agnew National Security Fellow at Los Alamos National Laboratory (LANL)
- Lead Polymer SME for LANL Nuclear Weapons Program
Dr. Crystal G. Morrison

– Technical Lead for Polymeric Materials
Additive, Military and Medicine?

- Additive Manufacturing Direction
  - Rapid prototyping …
  - Novel designs…

BUT,

- Increasing interest and focus on using AM for high value, high performance, critical parts and assemblies
Materials Emphasis

• AM Trend:
  – High Value and Performance

• AM Focus:
  – Materials \(\rightarrow\) Processes \(\rightarrow\) Product V&V

• Materials understanding across the lifecycle of the product

Awareness of Considerations Unique to the AM Community
Possibilities and Questions

I’ve made a zillion rapid prototypes with this material. I can move forward with production, right?

ABS, ABS “like”, medical grade, food grade… it’s all the same. Or is it?

I have years of data on this device design made with X plastic using injection molding. I’m going to use X plastic with an AM method. Do I really need testing?

I buy my powered raw materials from X, who gets them from Y, who is a distributor for Z. I think it’s good stuff. Right?
Don’t assume or underestimate!

Q: Where do I start when selecting polymeric materials for an AM-produced device?

A: Use systematic materials assessment with focus on Requirements, Materials Screening, and Manufacturability
Moving forward…

• Polymers and Plastics in Medical Devices
  – Emerging Considerations
• Selection Process Overview
• Considerations for Additive Manufacturing
  – Requirements
  – Material Screening
  – Manufacturability
  – Ranking
• Summary
Emerging Considerations
Selection Process Overview

Requirements
- Biocompatibility
- Sterilization
- Physical Properties

Material Screening

Manufacturability
- Injection Molding
- FDM

Ranking
Requirements

Material Screening
- Biocompatibility
- Sterilization
- Physical Properties

Manufacturability
- Injection Molding
- FDM

Ranking
Requirements

• FDA device classification?

• Is the material biocompatible?

• What load will be applied? How long?

• What testing has been done?
Requirements
- Biocompatibility
- Sterilization
- Physical Properties

Material Screening

Manufacturability
- Injection Molding
- FDM

Ranking
Materials Screening

• Biocompatibility
  – USP Class VI
  – ISO 10993
    • Nature of physical contact vs biological risks
    • Cytotoxicity, Sensitization, Irritation

Limited selection of materials for AM now… but not for long.
Materials Screening

- Select VisiJet® clear materials
- Accura ® ClearVue and Y-C 9300R
- Dreve Fototec hearing aid material
- DuraForm® PA and PRO

- Somos® materials
  - Watershed XC11122
  - ProtoGen 18420
  - BioClear

- Select e-Shell materials

- PA 2200

- Fortus®
  - PC-ISO
  - ABS-M30i

- Objet
  - MED610

- OXPEKK®

List compiled by Sam Anson for Medical Plastics News.
Materials Screening

- The first FDA approval for an additively manufactured polymer implant was Oxford Performance Material’s OsteoFab® cranial device made from PEKK.
- FDA 510(k) clearance for its 3D printed OsteoFab® Patient-Specific Facial Device (OPSFD).

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Materials Screening

• Sterilization
  – Radiation (gamma/e-beam)
  – Chemical (EtO)
  – Autoclave (steam)

• Chemical Resistance
  – Isopropyl Alcohol
  – Bleach
  – Peroxides
Materials Screening

• Mechanical Properties
  – Conventional vs. Additive
  – Ultem® amorphous thermoplastic polyetherimide (PEI) resin family from SABIC

Research from Fischer and Josupeit at Direct Manufacturing Research Center (DMRC) in Paderborn Germany
Materials Screening

Tensile strength is much greater in X direction rather than Z build direction.

Research from Fischer and Josupeit at Direct Manufacturing Research Center (DMRC) in Paderborn Germany
Materials Screening

• Wear Resistance
  – Mechanical properties can be different
  – Surface properties and wear debris
  – Other factors
    • Pairs (combination of materials in contact)
    • Conditions (wet or dry)
    • Configurations (rotating, sliding, oscillating)
Materials Screening

- Thermal Properties
  - Filler
  - Orientation
  - Crystallinity
  - Conventional vs. Additive
Requirements
- Material Screening
  - Biocompatibility
  - Sterilization
  - Physical Properties

Manufacturability
- Injection Molding
- FDM

Ranking
Manufacturability

AM Material Options

AM Method ↔ AM Equipment
Impact

Schedule

Testing

Success

Design

Process Improvement

Troubleshooting
Impact – Manufacturer Liability

- Biomaterials Access Assurance Act (BAAA) of 1998
- Responsibility and liability for the device performance
- High quality materials and testing
Summary/Conclusion

• Landscape is exciting… and overwhelming
• Awareness of materials considerations
• Systematic assessment
• Requirements, Materials Screening, Manufacturability
  – Simultaneous, Evolving Dialogue
• Impact
Questions?
Crystal G. Morrison, Ph.D.
Principal Investigator & Senior Materials Scientist

724.325.1776 Office
724.387.1897 Direct
724.710.0974 Mobile

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