PROFILING EXTRACTABLES FROM 3D PRINTED STRUCTURES PREPARED USING ADDITIVE MANUFACTURING TECHNIQUES

**INTRODUCTION**

Additive manufacturing techniques including fused deposition and stereolithography create an almost limitless opportunity for the fabrication of consumer and biomedical components. For many of these products, especially those intended for skin contact or implantation, the extractable and leachable components of the device must be characterized.

Liquid chromatography coupled with mass spectrometry is one of the first line techniques in these studies. In addition to profiling the materials used in the fabrication process, pre and post fabrication samples are analyzed to determine any changes or new compounds formed during the fabrication process, which might include thermal degradation during extrusion or photodegradation during UV curing.

**METHODS**

A published stereolithographic method was used to create the polyphenyl sulfone component. An automated Elemental Composition Determination, ChemSpider structure search, and theoretical matching of high energy fragment peaks. Use of Progenesis QI for multivariate modeling of precursor identification of polymer additives and initiators. Rapid, confident characterization of polymeric components, across wide dynamic range. Increased analytical peak capacity by incorporating IMS resolved isomeric species. Novel methods for finished component. Peak area for PPO initiator across the sample set.

**RESULTS**

peak area for PPO initiator across the sample set.

**CONCLUSIONS**

- Increased analytical peak capacity by incorporating IMS separation to separate species on the basis of charge and mass. Reduced fragment characterization of polymeric components, identification of polymer additives and initiators. Use of Progenesis QI for multivariate modeling of precursor materials and finished components, including identification of distinguishing components and characterization of their chemistry.Macro. TOF ES FROM 3D PRINTED STRUCTURES PREPARED USING ADDITIVE MANUFACTURING TECHNIQUES

**NOVEL METHODS**

- **UV CURE**
- **FUSED DEPOSITION**

**Figure 1.** Schematic diagrams for fused deposition and stereolithography methods for device fabrication.

**Figure 2.** VSD/MS Q-TOP.

**Figure 3.** Figures of merit for Thermoplastic amine scale. Panel A. Observed (ESI)-UV at 226 or 266 nm, Panel B- mass measured accuracy ±0.1% (RSD) Standard deviation ±0.1%. Panel C. Detector counts (precursor ions).

**Figure 4.** PCA Bi-Plot and Trend Plot for UV cured components. Panel A, Extractables profile for polyurethane, material, bottom, finished component. Panel B top, Extractables profile for transparent precursor material, bottom, fabricated component. Panel C, Extractables profile for flexible precursor material, bottom, fabricated component.

**Figure 5.** Left panel, ATD vs m/z difference plot for extradagles from flexible precursor material (amber) and flexible component (blue). Right panel, inset plot of spectra from precursor (top) and finished component (bottom).

**Figure 6.** Left panel, Raw low and high energy spectra for PPO initiator. High energy, IMS Cleaned low and high energy spectra. Use of Discovery Tool to characterize a photoinitiator across the sample set.


**Figure 8.** Use of Discovery Tools to characterize a photoinitiator used in the SLS and UV cured components. The tool consists of an automated Elemental Composition Determination, ChemSpider structure search, and theoretical matching of high energy fragment peaks.

**Figure 9.** PCA Bi-Plot and Trend Plot for Novel fabrication methods components. Panel A, Extractable profile for polyphenyl sulfone component. Panel B top, Extractable profile for polyphenyl sulfone filament; bottom, ABS A filament. Panel C, Extractable profile for polyphenyl sulfone component. Panel A top, Extractables profile for polyphenyl sulfone; bottom, ABS B component. Panel B top, Extractable profile for extruded polymer material. Panel C, Extractable profile for extruded polymer material.

**Figure 10.** Use of Progenesis QI for multivariate modeling of precursor materials and finished components, including identification of distinguishing components and characterization of their chemistry.