Mechanical Evaluation of Medical Grade Bioresorbable Materials for Additive Manufacturing Scaffolds

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Statement of Purpose: The ability to produce medical devices composed of resorbable materials through additive manufacturing could lead the way to incorporating tissue engineering into personalized and targeted medicine. Bioresorbable materials are strong candidates for integrative medical devices based on their ability to degrade by bulk hydrolysis and eventually being resorbed by the patients' body after fulfilling a temporary function as an implant. Such devices eliminate the need for secondary surgeries (e.g. explant) and significantly enhance a patient's post-operative quality of life. When combined with the innovation and technological advances of layer-by-layer manufacturing processes, such as fused filament printing and electrospinning modes of additive manufacturing (AM), the use of bioresorbable polymers could prove tremendous to the development of novel bioresorbable implants. However, a key question for the use of thermoplastic-based bioresorbable polymers lies in the potential for changes in the material properties during manufacturing, and thus the effect of processing parameters on the products is of critical importance to the final device. Specific bioresorbable materials are selected for mechanical and resorption-rate properties based on bulk assessments, but the final mechanical properties of a device are the first to be affected by processing parameters and are the first to be discussed with surgeons during development of a new device.

Methods: Medical-grade polymer granules of Lactoprene® 100M (linear homopolymer of poly (*l*-lactide)), Caproprene® 100M (linear homopolymer of poly (ε-caprolactone)) and Lactoflex® 7415 (linear segmented copolymer of *l*-lactide, trimethylene carbonate, and ε-caprolactone) were supplied by Poly-Med, Inc. (Anderson, SC). The medical grade polymers and copolymers of *l*-lactide, ε-caprolactone were extruded into 1.75 mm diameter filaments and 3D printed by fused filament fabrication (FFF). Gcode was generated from a Solidworks® drawing within Repetrel software via Slic3r® software for Type V tensile test samples (ASTM D638). The printing method was programmed to generate parts comprised of four layers of 0.4 mm layer height and a single outline perimeter at a raster speed of 5 mm per second. Gcode was regenerated for each infill setting of 25%, 50% and 75% with alternating laydown angles of 45° and 135° to produce the parts shown in Figure 1. To complete the set and confirm the mechanical property trends, 100% infill samples were produced by extruding a single layer height in linear fashion to generate a fiber sample. Nozzle temperatures of 150 ºC, 170 ºC, and 200 ºC, respectively, were used to 3D print the Caproprene, Lactoflex, and Lactoprene materials. The molecular, thermal, and mechanical properties of the resulting samples from the bioresorbable polymers were evaluated within 48 hours of production to characterize processing effects on molecular weight, melting temperature, relative crystallinity, tensile strength, and tensile modulus.

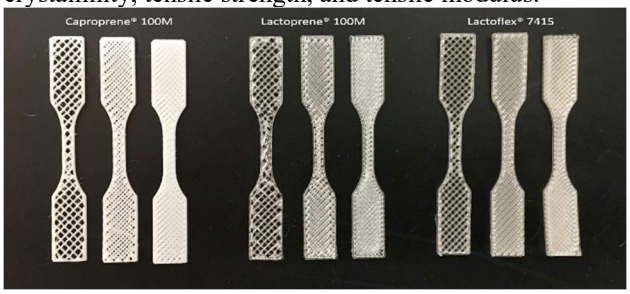

Figure 1: Macroscopic Image of 3DP Tensile Bars

Electrospinning each of the medical grade polymers was conducted by dissolving in hexafluoroisopropanol (HFIP). The polymer solution was dispensed through a 20G blunt needle and an electrical potential was applied. Randomly aligned fibers were collected in a layer-by-layer fashion forming a nonwoven fabric on the collector drum. The fabric was also characterized for molecular, thermal, and mechanical properties.

Results: Homopolymers of *l*-lactide and ε-caprolactone experienced a decrease in thermal properties due to melt processing but were able to maintain molecular properties. Varying degrees of tensile modulus and ultimate tensile strength (UTS) were observed for each material, mode and range of infill, shown in Figure 2 (n = 5).

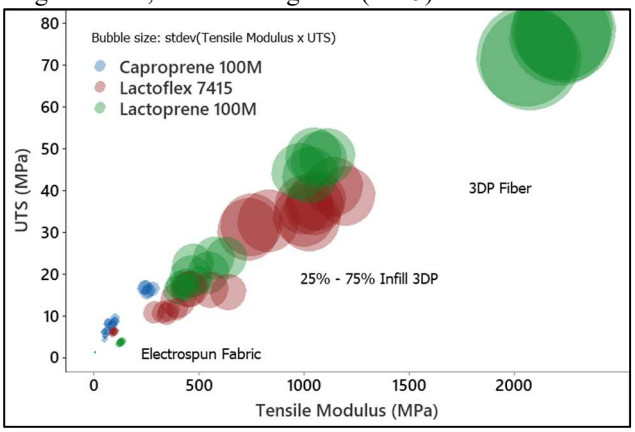

Figure 2: Ashby Plot of Tensile Mechanics

A unique copolymer of *l*-lactide, ε-caprolactone, and trimethylene carbonate, Lactoflex® 7415, was evaluated and demonstrated a crossover between both *l*-lactide and ε-caprolactone homopolymers with its intermediate mechanical properties.

Conclusions: Lactoflex® 7415 provides a unique alternative to homopolymers of *l*-lactide or ε-caprolactone. With just these three materials and ranging the AM parameter of infill, an order of magnitude range in tensile strength and modulus properties were observed to be feasible and optimizable.