Modulation of Degradation Profile in Biphasic Polymer Systems

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Statement of Purpose: Absorbable medical devices generally fall into one of three categories: short, medium, and long term strength retention profile. As the strength retention profile is increased, device absorption time also increases. With devices exhibiting long-lasting strength retention profiles, particularly those prepared from polylactic acid, absorption is measured in years rather than months. This extended degradation profile can lead to complications, such as foreign body reactions, extrusion of the implanted device, and residual fragments that can persist for many years after loss of functionality. This prompted Poly-Med, Inc. to initiate a broad-based study to develop material(s) that exhibit strength retention similar to currently-available PLLA implants, but with an accelerated mass loss profile.

Methods: S7 is a copolymer prepared from *l*-lactide and trimethylene carbonate, having molecular weight suitable for injection molding and fiber extrusion. M2 is a copolymer prepared from glycolide and *l*-lactide, also having sufficiently high molecular weight to allow for fiber formation and injection molding.
S7, M2, and a blend of the two components were formed by (1) injection molding into ASTM Type V tensile bars and (2) melt extrusion and orientation into monofilaments. Injection molding was performed using a 33-1/2 Ton injection molding unit (Arburg, Germany). Melt extrusion was performed using a custom built ¾" single screw extruder (Alex James and Associates, Greenville, SC).
Formed articles (tensile bars and monofilaments) were analyzed for bending and tensile strength using an MTS Synergie load frame with various grips. Real time and accelerated *in vitro* performances were analyzed by soaking test specimen in 7.2pH or 12pH phosphate buffer at 37°C and 50°C for predefined times. Mass loss was determined by removing samples from buffered solution, drying to a constant weight, and comparing with initial measurements. Samples designated for strength testing were tested immediately after removal from their respective buffer.

Results: Injection molded articles and monofilaments were analyzed for initial properties and strength retention profile, with example results indicated in Figure 1. Injection molded articles exhibited initial yield strengths, in both tensile and bending modes, between 70 and 85 MPA, and monofilaments exhibited bending yield strengths between 160 and 180 MPa. Figure 2 describes the accelerated mass loss profile of S7 and S7/M2 monofilaments, indicating the S7/M2 loses mass at more than twice the rate of S7.

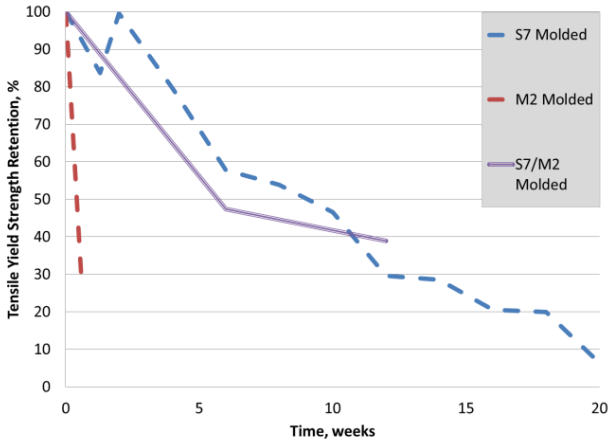

Figure 1. *In vitro* Strength retention profile of injection molded articles after incubation in 7.2pH PBS at 37°C

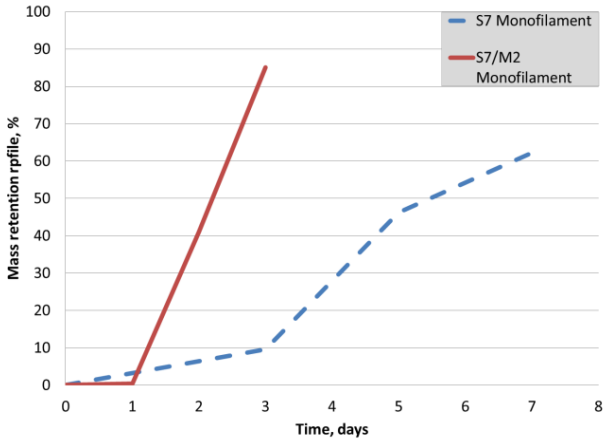

Figure 2. Accelerated *in vitro* mass loss profile of monofilaments after incubation in 12pH PBS at 50°C

Conclusion: Initial development indicates that this technology can be leveraged for fibrous constructs, as well as in molded articles. Advantages of this biphasic composite include less risk of complications associated with the long term degradation profile of lactide-based implants. By creating biphasic constructs, *e.g.* S7/M2, a novel material was generated exhibiting a long-lasting strength retention profile that displays accelerated absorption characteristics.

References

1. Shalaby, S.W. et al, U.S. Pat app. 2009204116 (2009).