Effects of processing on Glycoprene® 6829 Glycolide/Caprolactone/Trimethylene Carbonate polyaxial random copolymer: A preliminary report

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Background: Synthetic absorbable polymers are routinely used as medical implants, scaffolds for tissue engineering and drug delivery devices. These devices are created from fibers, yarns, films, nonwoven fabrics, textile constructs, particles, and injected molded articles. Typically, component materials are selected based on anticipated degradation performance; however, processing of the polymer can affect the final medical device performance regardless of polymer composition. Many devices utilize extruded fibers and textile constructs, particularly for wound healing applications. Alternatively, injection molding is another standard technique for processing synthetic absorbable polymers, most commonly for clips, staples, bone fixation devices or othre temporary barrier devices.

Methods: Glycoprene® 6829, which is comprised of repeat units derived from glycolide, E-caprolactone, and trimethylene carbonate was extruded into a monofilament using a custom ¾" single screw extruder with four temperature zones. During extrusion, the fiber was quenched using a water bath with a temperature range of 30°C - 40°C. The fiber was collected on the take-up spools. Using three subsequent heat rollers, the fiber was drawn to the final diameter and subsequently thermally stabilized. Heat treating the fiber increases the dimensional stability and relieves the internal stresses associated with the previous processing steps. Type V tensile bars were generated using an Arburg Allrounder 270°C, 33 ton injection molding machine.

Specimens were analyzed for *in-vitro* performance by incubating in 7.4pH, 100mM phosphate buffer at 37°C. Mechanical tests were conducted on a MTS Synergie 2000 screw-actuated tester.

Results: Mechanical testing results for the extruded monofilament samples are listed in Figure 1. Data is reported as mean ± 1 standard deviation. The diameter of the monofilament listed in the table below is an average of 0.13 mm.

Figure 2 illustrates the strength retention profile for the two different processed materials. The tensile bar loses strength faster than the monofilament. After 3 days *in-vitro*, the monofilament has strength retention of an average 80 ± .01% while the tensile bar's strength retention is an average 36 ± .05% (difference of 50%). At 7 day *in-vitro*, the monofilament has a strength retention profile of an average 34 ± .01% while the injection molded material has a strength retention profile of an average of 13 ± .03% (difference of 21%).

Table 1: Mechanical properties of Glycoprene® 6829 monofilament and Type V Tensile Bar. N = 5 for monofilament/N = 3 for tensile bar; *indicates statistical difference compared to each data set

Mechanical Test	Monofilament	Tensile Bar
Tensile Strength (MPa)	*322.4 ± 11.7 (MPa)	*90.4 ± 16.9 (MPa)
Tensile Modulus (MPa)	*963.9 ± 131 (MPa)	*277.3 ± 44.8 (MPa)
Elongation (%)	132.2 ± 32.4 (%)	559.6 ± 174.8 %

The data results listed within figure 1 show that the monofilament exhitibs higher tensile strength compared to the injection molded material which means that the same material when extruded and oriented into a monofilament can withstand a significantly greater engineering stress before breaking (3.6 times stronger). Furthermore, the monofilament has a tensile modulus of 686.6 MPa greater and a percent elongation 427.4 % less then the type V tensile bar indicating significant differences in stiffness properties as well as deformation properties, respectively.

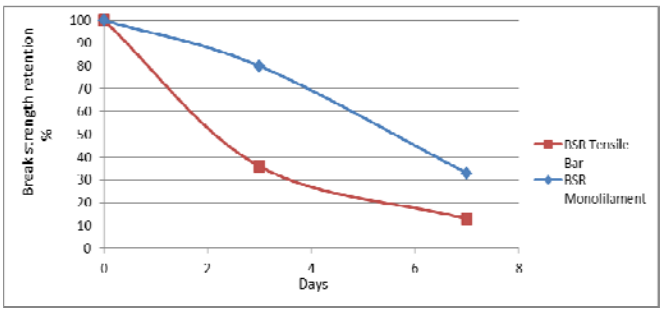

Figure 2: *In-vitro* Break Strength Retention profile of Glycoprene® 6829 processed into a monofilament and Type V Tensile Bar. N = 5 for monofilament/N = 3 for tensile bar

Conclusion: This study has demonstrated that different processes can result in changes to a material's mechanical properties as well materials break strength retention profiles. This results in significantly different *in vitro* response, and likely tissue response, to implants made of the same material but processed differently.

References:

1. US Patent No. 6,462,149
2. Ratner et al. Biomaterial Science (2012) 1010 - 1023