

Effect of Polymer Architecture on Physical and Mechanical Properties of High Glycolide Content Polymers

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Statement of Purpose: Synthetic absorbable polymers are routinely used as medical implants, scaffolds for tissue engineering, and drug delivery devices. Though these materials can have modulated strength and mass profiles based on the use of various monomeric units, current absorbable polymers are limited in their functionality by being largely comprised of linear chains exhibiting low solubility and low mechanical compliance. Poly-Med, Inc. believes that absorbable polymers can be enhanced by displaying a poly-axial architecture which can impart enhanced compliance, lower crystallinity, and result in a new class of absorbable materials. This work demonstrates the benefit of poly-axial absorbable polymer directly compared to a linear absorbable polymer.

Methods: Linear (Max-Prene® 955) and poly-axial (Glycoprene® 935¹) high glycolide polymers (≥ 90 mol%) were synthesized by ring opening polymerization. The polymer was formed after overnight reaction in a stainless steel kettle, ground, and sieved to 0.5-4 mm sized granules. Material was then evaluated for physical properties including inherent viscosity and thermal properties. Mechanical test samples were made by injection molding into Type V tensile bars using an Arburg Allrounder 270°C, 33 ton injection molding machine at 230°C. Polymer granules and tensile bars were degraded in phosphate buffer for up to four (4) months. Mechanical tests were conducted on a MTS Synergie 2000 screw-actuated tester. Tensile tests were conducted with 2.55 cm grip spacing at a test speed of 100 mm/min.

Results: The general structures of Max-Prene® and Glycoprene®¹ are depicted below in Figure 1.

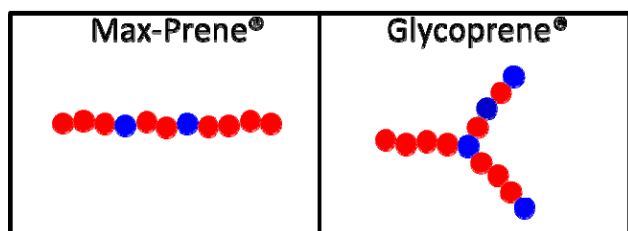


Figure 1: Schematic of the molecular architecture for Max-Prene® and Glycoprene® displaying the linear and poly-axial structure, respectively.

Both Max-Prene® and Glycoprene® exhibited similar physical properties in regards to thermal properties with a high melting temperature $\geq 210^\circ\text{C}$ and high degree of crystallinity based on enthalpy measurement ≥ 65 J/g. Glycoprene® and Max-Prene® also exhibited intermediate molecular weight with inherent viscosities of 1.1 dl/g and 1.6 dl/g respectively. During *in vitro* degradation, both polymers exhibited significant increase in enthalpy over time based on the removal of amorphous sites within each polymer system. Accordingly, the inherent viscosity demonstrated a significant decrease

after three days *in vitro*, illustrating near exponential decay in molecular weight.

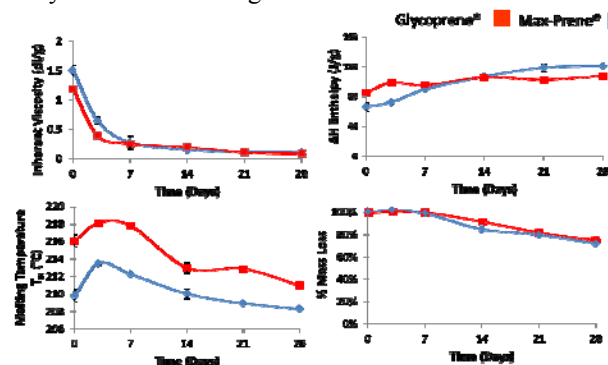


Figure 2: Physical properties of Max-Prene® (BLUE) and Glycoprene® (RED) polymer granules. N = 3 per group; * indicates significant difference compared to control PGLA group.

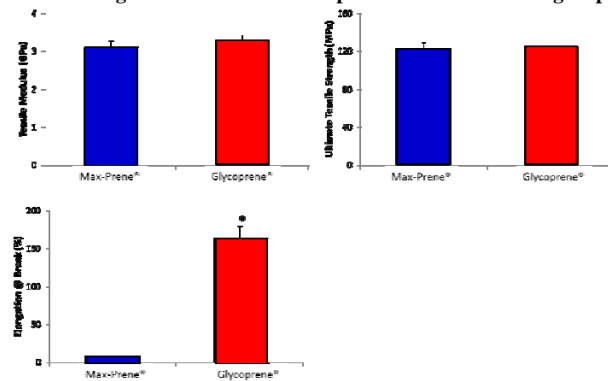


Figure 3: Mechanical properties of Type V tensile bars of Max-Prene® (BLUE) and Glycoprene® (RED). N = 3 per group; * indicates significant difference.

Mass loss of polymers showed lowering in content of 20% after 28 days *in vitro*. Mechanical properties of tensile bars indicated that both Max-Prene® and Glycoprene® had a high tensile modulus and ultimate tensile strength of 3 GPa and 120 MPa, respectively. During tensile loading, it was determined that Glycoprene® was able to undergo upwards of 150% strain before break. This behavior was attributed to the poly-axial nature of the polymer indicating enhanced compliance and molecular reorientation while retaining near identical strength profiles.

Conclusions: This work determined that the use of poly-axial initiators to form absorbable high glycolide polymers (Glycoprene®) retained many of the same features of linear high glycolide polymers (Max-Prene®). The added benefit of poly-axial polymers can be attributed to enhanced compliance owing to enhanced functionality. We foresee the use of varying polymer architecture as a means to not only produce robust, absorbable polymers, but to also influence the mechanical performance producing compliant properties.

References: ¹US Patent No. 6,462,149 B1