Statement of Purpose: Post-operative adhesions are a significant problem, especially in the case of gastrointestinal surgery where they can lead to complications such as bowel obstruction. A limited number of products exist to prevent adhesions, usually in the form of barrier films or gels. Lactide copolymers, such as 70:30 poly (L-lactide-co-D, L-lactide) (PLDL), have been approved for use as separation films. However, these polymers remain in the body a substantial amount of time after the wound has healed and offer moderate conformance around soft tissue. This prompted Poly-Med to further investigate the use of high compliance, faster-absorbing materials as a barrier film.

The novel absorbable polymer Glycoprene® RD7, a 25:20:55 poly (TMC-co-caprolactone-co-glycolide) copolymer, shows promise as a more compliant, faster absorbing alternative.

Methods: Films were created from RD7 and PLDL (Poly-Med, Inc) using a custom built ¾” single screw extruder (Alex James and Associates) with a cast film die to an approximate thickness of 25 µm. In vitro performance of the films was characterized by conditioning test specimens in 7.4 pH phosphate buffer at 37°C. Mass loss was determined by removing samples at predetermined time points, drying to a constant weight, and comparing to initial weight according to ASTM F1635-11. Tensile strength retention was measured by removing sample from the buffer and immediate testing to failure on an MTS Synergie according to ASTM D882-10. Sterilized films (n=1) were implanted in a porcine model along the abdominal wall where they were secured by a central anchoring suture. Prior to implantation, the tissue surface of the sites was slightly abraded by 30 manual strokes with surgical gauze. Following a 1 month implantation period, samples were explanted. Representative tissue specimens from each implant site were collected in 10% neutral-buffered formalin and subsequently processed into hematoxylin and eosin-stained microslides for evaluation of histology.

Results: Tensile testing of film at the time zero point revealed RD7 films to have roughly a tenth the modulus of PLDL (149.2 MPa versus 1943 MPa for PLDL). In vitro analysis shown the absorption profile of RD7 showed 20% strength retention at 30 days and over 40% mass loss at 4 months. Histological evaluation of explanted films is exhibited in Table 1 and demonstrated similar composite scores. RD7 a higher degree of encapsulation compared to PLDL and was explanted as a balled mass, mostly likely related to the use of a single anchoring suture. RD7 had a lower score for neovascularity, macrophage presence, and necrotic debris.

Conclusion: The data suggests that Glycoprene™ RD7 exhibits beneficial materials properties to the PLDL control, such as faster degradation and lower modulus allowing for better compliance at the wound site. Since both materials produced similar histological results, RD7 is a likely candidate for continued research as a tissue separation film.

References: