Thin Films Prepared from Novel Absorbable Polymers for Use as Compliant Wrap

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Statement of Purpose: Commercially available surgical wraps such as Seprafilm®, SurgiWrap® and OrthoWrap™ are simple barrier devices that are made from sheets of stiff, strong and brittle materials. These devices are designed to minimize adhesion formation after surgery. To date, the only true barriers are based on inert, permanent implants. Furthermore, absorbable materials such as Seprafilm® lack the physical properties or efficacy to be used in minimally invasive laparoscopic or robotic assisted surgeries. In certain cases, such materials have been reported to increase the incidence of abdominal abscesses and anastomotic leaks when used as protective wraps[1]. In the cases of OrthoWrap™ and SurgiWrap®, an amorphous 70:30 poly(L-lactide-co-D,L-Lactide) is used for device manufacture. While this polymer is completely bioresorbable and may provide a barrier to adhesion, it offers little benefit in the way of flexibility. As such, the main drawback to these devices is their stiffness and noncompliant properties. Absorbable adhesion-prevention materials could be engineered with improved flexibility and compliance for optimal use in laparoscopic, robotic-assisted, or open surgical procedures. Poly-Med has recently developed strong, flexible and highly elastic films from a high molecular weight polyaxial co-polyester that is completely bioresorbable to prevent adhesions. As a first step, the synthesis and mechanical characterization of these resorbable films is presented.

Methods: Polymer solutions were prepared by dissolving 2.5 grams of the polyaxial co-polyester (SVG) in 50 mL acetone. Solutions were placed on a shaker at room temperature until complete dissolution was reached within approximately two hours. Films were cast in 7”x5”x1” (L x W x H) trays that were fashioned from release paper. 50 mL solutions were poured into trays and allowed to dry in a laminar flow hood overnight. Air-dried films were subsequently dried at room temperature under reduced pressure for 24 hours. Polymeric films were tested on an MTS Synergie 200, fitted with a 1 kN load cell, to determine tensile properties. For comparison, a SurgiWrap® Bioresorbable Protective Sheet was also tested with the MTS Synergie under similar conditions. Tensile tests were performed using an extension rate of 2.33 mm/sec and a grip separation of 0.750 in.

Results: Film-casting produced SVG films of approximately 0.190 mm in thickness, on average. These films were completely amorphous, fully transparent, and did not contain air bubble defects. In addition, SVG films demonstrated a high degree of flexibility and elasticity. Thus, these films easily assume the shape of surfaces to which they are applied. Additionally, mechanical tensile testing of SVG films and PLA-containing SurgiWrap® samples indicates that the modulus values for these two materials differ by nearly two orders of magnitude (see Table I). SurgiWrap® tested as a very stiff material that lacked a significant ability to plastically deform; these samples failed by crack propagation immediately upon the onset of failure. SVG, on the other hand, demonstrated a high degree of extension prior to rupture (see Figure 1). These SVG films have a yield strain of approximately 41.5% and an ultimate strain of 1000%. Furthermore, SurgiWrap® demonstrated a high stress at break, but did not exhibit a stress at yield, and SVG had a stress at yield that was an order of magnitude lower than the stress at break (see Table II).

Table I. Average tensile properties for SurgiWrap® and SVG films. Ultimate strain and yield strain are reported for SurgiWrap® and SVG, respectively.

Film Type	Modulus (MPa)	Strain (%)
SurgiWrap®	890.1	5.5
SVG	8.5	41.5

Table II. Comparison of yield stress vs. break stress for SVG and SurgiWrap®.

Film Type	Stress at Yield (MPa)	Stress at Break (MPa)
SurgiWrap®	NONE	48.0 ± 8.0
SVG	2.2 ± 0.3	21.1 ± 1.4

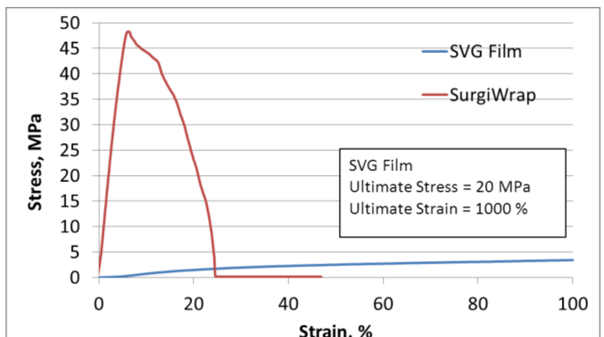

Figure 1. Stress vs. strain plot for SVG and SurgiWrap®.

Conclusions: The two materials tested here, SVG and SurgiWrap®, demonstrated marked differences in mechanical tensile behavior. Whereas SurgiWrap® performed as a brittle, stiff material with practically no yielding prior to failure, SVG is very much the opposite, demonstrating approximately 41.5% strain at the yield point and 1000% ultimate. The flexibility of SVG makes this a versatile material that should conform readily to the surfaces of soft tissues and be able to withstand flexing of anatomical surfaces once the film has been sutured into place. Thus, highly compliant SVG films could show significant promise as an adhesion prevention surgical wrap, especially in dynamic *in vivo* environments.

References:

1. Zeng, Q. et al. *World J Surg*, 31, 2125 (2007).