SCIENTIFIC DATA SERIES IN RESORBABLE FIXATION

Strength Retention of 70:30 Poly(L-lactide-co-D,L-lactide) Adhesion Barrier Film and Surgical Mesh Following Real Time Ageing

Introduction

Various biomaterials have been evaluated for soft tissue support (surgical mesh), and to prevent or minimize postsurgical adhesions. Polymeric solutions, gels, and membranes have been studied for these applications. Adhesions are believed to form in the very early postoperative time period (1 to 2 weeks), and therefore a successful barrier may not require significant strength retention beyond this time.[1] Similarly, surgical mesh may not require prolonged strength as an aid in the healing of various tissues.[2] The purpose of this investigation was to determine the tensile properties of 70:30 Poly(L-lactide-co-D,L-lactide), following *in vitro* real time ageing, as a potential surgical mesh or as a barrier for the control of postsurgical adhesions.

Materials and Methods

Films were fabricated from commercially available 70:30 Poly(L-lactide-co-D,L-lactide) raw material. The fabricated forms included melt processed films and sheets - films to a nominal thickness of 0.02 mm and 0.05 mm and sheets to a nominal thickness of 0.2 mm. Samples of the 0.02 mm and 0.05 mm films included three replicate lots. From the films or sheets, standard tensile specimens were die cut (ASTM D638, type V).[2] All samples were sterilized by e-beam irradiation. The actual thickness of every sample was measured by micrometer prior to ageing, and later used to convert tensile load data to tensile strength.

Real time ageing was performed following ASTM F1635.[3] All samples were placed in phosphate buffered saline (PBS) and incubated at 37 °C; the temperature of the incubators was monitored daily. The ratio of the volume of the PBS to the mass of the samples exceeded 20:1 and the pH of the solution was regularly monitored. At no time did the pH of any sample drift out of the range of 7.4 ± 0.2.

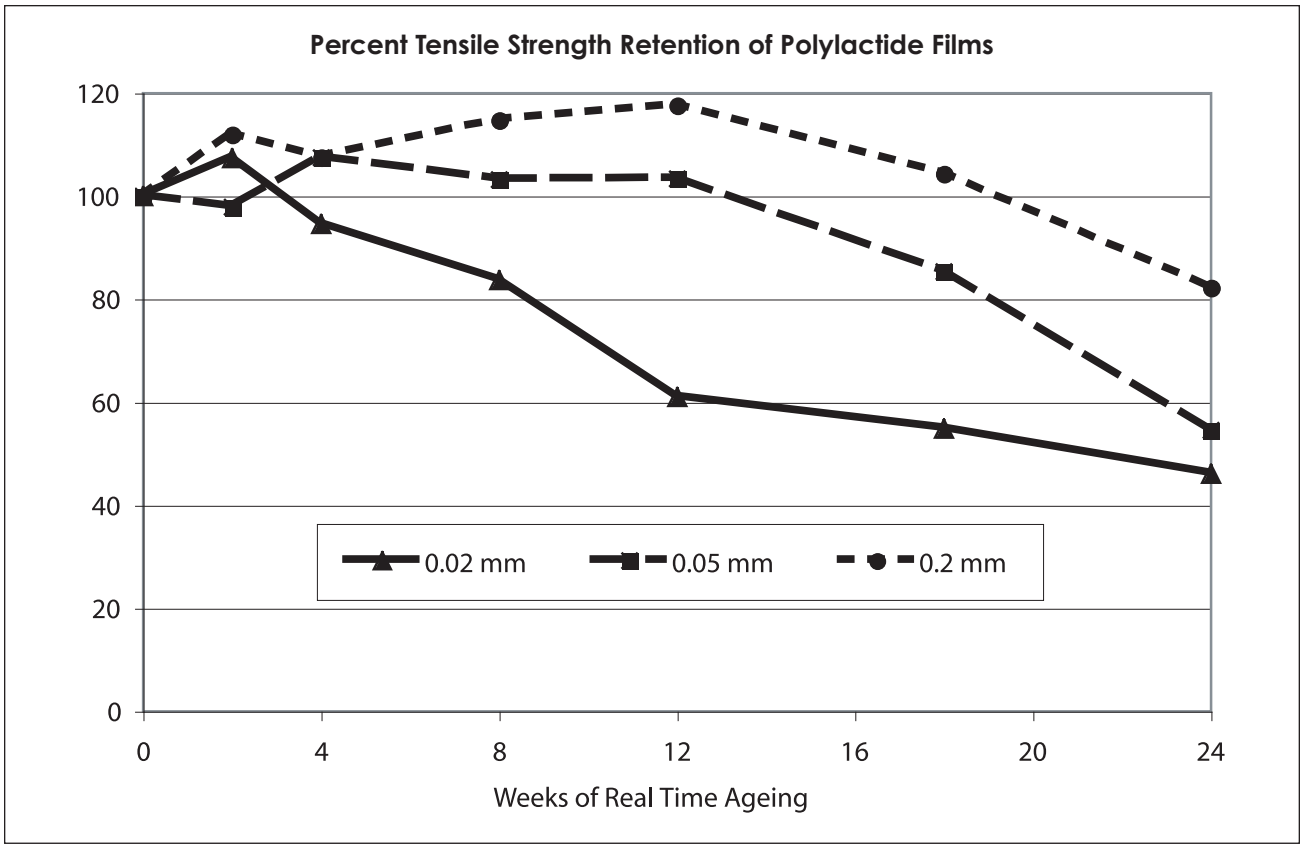
After ageing for various time periods (2, 4, 8, 12, 18, 24, and 39 weeks), samples were subjected to tensile testing to failure. Sterilized samples not aged (time zero) were also tested to obtain initial or baseline strength values. Testing was performed with appropriate fixtures for the various sample configurations at a rate of 0.085 mm/second (ASTM D638), using a servo-hydraulic test system (MTS Systems Corp., Minneapolis MN). For all samples the maximum tensile load was determined and converted to strength values. At each time point five samples were tested.

Time zero and aged samples also were analyzed for changes in the polymer. The properties measured included inherent viscosity (dilute solution viscometry), thermal properties and crystallinity (differential scanning calorimetry), and molecular weight (gel permeation chromatography).

Results

The tensile testing results are summarized in the figure shown, with the average at each time point normalized to the time zero results. For the 0.02 mm and 0.05 mm films, the results shown are the average from three replicate lots of material.

The 0.02 mm film exceeded 100% of initial strength at two weeks, 60% at twelve weeks, 50% at eighteen weeks, and 45% at 24 weeks of ageing. The 0.05 mm film retained over 100% of initial strength through 12 weeks of ageing, and exceeded 80% of initial strength at 18 weeks and 50% at 24 weeks of ageing. Additional samples of the



0.02 mm and 0.05 mm films are currently ageing for testing at time points of 39 weeks and longer.

The 0.2 mm sheet samples demonstrated 100% of initial strength retention through 18 weeks, and 85% strength retention at 24 weeks. At 39 weeks the samples had become brittle and could not be handled and gripped for testing. The initial tensile strength values for these samples were consistent with other forms of the 70:30 Poly(L-lactide-co-D,L-lactide) material (approximately 55 MPa).

The initial increase in strength following ageing (above the time zero value) has been demonstrated with this material in various loading modes.

Polymer analysis demonstrated decreases in molecular weight (Mw) and inherent viscosity of approximately 35% after 12 weeks. No crystallinity was detected in any samples (0 to 24 weeks), confirming the amorphous nature of the processed material.

Discussion and Summary

These results demonstrate that thin films and sheets of 70:30 Poly(L-lactide-co-D,L-lactide) can retain 100% of initial tensile strength for up to 18 weeks under *in vitro* real time ageing conditions. Since it is believed that adhesions form in the very early postoperative time period, the demonstrated strength retention may indicate the suitability of these forms of the material for use in the control of adhesions. Similarly this strength retention may be appropriate for soft tissue support in the form of a surgical mesh. Based upon these results, and the documented biocompatibility of the material, thin films or sheets fabricated from 70:30 Poly(L-lactide-co-D,L-lactide) material may be appropriate for use as a barrier to control postsurgical adhesions, or as a surgical mesh for soft tissue reinforcement.

References

1. Cuono, C. in Jurkiewicz, M. et al., eds., Plastic Surgery Principles and Practice, St. Louis, Mosby, 1990.
2. ASTM D638, Standard Test Method for Tensile Properties of Plastics.
3. ASTM F1635, Standard Test Method for In Vitro Degradation Testing of Poly(L-lactic Acid) Resin and Fabricated Form for Surgical Implants