Irradiated experimental and control groups were statistically indistinguishable with respect to the measured variables. However, the results of this study show that there is no significant effect of therapeutic doses of such irradiation on this copolymer.

**Materials/Methods**

LactoSorb® (Biomet, Inc., Warsaw, IN) is an absorbable copolymer synthesized from L-lactic acid and glycolic acid in an 82:18 ratio. Unoriented wafer specimens (25.4 x 10 x 1 mm) were machined. There were eight groups of six irradiated wafers, each, and nine groups of six non-irradiated (control) wafers, each. After initial measurements were made on one of the control groups, the balance (eight groups each) were placed in pH 7.4, 37°C, phosphate buffer. For five consecutive days of every week, up to eight weeks, each specimen was removed from the bath and exposed to 200 rad of irradiation using a Therapax Series 7: HF 150 (Oselet Corporation, Fairfax, Virginia). All but one group were then returned to the bath. This was repeated each week, increasing the cumulative dosage to the remaining groups to a maximum of 8,000 rad for the last group by the eighth week. These radiation levels have been shown to be very effective in head and neck cancer. In a given week, the group not returned to the bath was destructively tested.

Inherent viscosity, in chloroform at 30°C, was tested using a Ubbelohde Type OC viscometer. Three-point bend testing was performed using a Sintech 1/S test system (Sintech, Inc., Research Triangle Park, NC). The test fixture consisted of two support noses and one central load nose, all with radii of curvature of 1.27 mm. The support nose span (center to center) was 16 times the wafer thickness. The load nose movement was 12.7 mm/min. Elastic modulus and energy to break (defined as the area under the force-displacement curve when the load decreased to 60% of its peak developed value) were computed by the software package. Polymer mass decrease over time was measured as the difference between the end-point weight of the vacuum dried specimens and their initial desiccated mass. Statistical significance was determined using the Student-Newman-Keuls test at p < 0.05.

**Results**

A one-time exposure of specimens to 0.5 Mrad confirmed that gamma irradiation, at a sufficiently high level, does degrade LactoSorb® copolymer (data not shown). However, the results of this study show that there is no significant effect of therapeutic doses of such irradiation on this copolymer. Figures 1-3 (ave±S.D.) show the inherent viscosity, flexural modulus, and energy-to-break profiles of the experimental and control groups, respectively. After the first week, the inherent viscosity values decreased linearly with time. Overall, there was only a slight decrease in flexural modulus vs. time. The energy to break decreased slightly after the sixth week, with the decrease accelerating after the sixth week. Final dry mass of the specimens was identical to the initial value, or differed by no more than 0.001g, showing that there was no appreciable mass loss during this in vitro period. Overall, the experimental and control groups were statistically indistinguishable with respect to the measured variables.

**Discussion**

LactoSorb® unoriented copolymer has previously been shown to retain at least 70% of its strength, in vitro, by eight weeks. This study provides strong evidence that this material can withstand gamma irradiation, administered in a clinical manner, without effect on its eight week in vitro properties. This suggests that it is an appropriate absorbable internal fixation material when the subsequent irradiation of tumors is a consideration. Many other absorbable polymers used in clinical practice are similar to LactoSorb®, i.e., based on alpha-hydroxy acids, e.g., PLLA homopolymer, other PLLA/PGA ratios, and formulations containing D-lactic acid. Further testing will be required to determine their stability to therapeutic gamma irradiation.

**Conclusions**

LactoSorb® copolymer was shown to withstand therapeutic doses of gamma irradiation by a variety of mechanical and physiochemical criteria. As such, there should be little concern that irradiation treatment of *in situ* tumors near the location of LactoSorb® implants will prematurely cause their degradation.

**References**


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