Comparison of Sterilization Methods for Resorbable Polymers

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Statement of Purpose:

The purpose of this study was to investigate an alternative sterilization method for resorbable polymer medical devices, such as LactoSorb® (PLA/PGA). Typically, most resorbable polymeric medical devices are sterilized via Ethylene Oxide Gas (EtO) or Gamma Irradiation (Gamma). Currently, LactoSorb® is sterilized via EtO because Gamma causes chain scission which influences the degradation behavior of resorbable devices[1]. While EtO does not impact the degradation behavior, it does have some drawbacks – lengthy processing time for sterile product release due to the dependence on transport to external sterilization facilities as well as the culturing of the biological indicators (3-7 days). Hydrogen Peroxide Gas Plasma Sterilization (HPGP) offers shorter processing time – in house sterilization capabilities as well as shorter incubation time requirements for the biological indicator (48 hours). Additionally, the bi-products of HPGP sterilization (H_2O and O) are non-toxic and non-carcinogenic. The purpose of this evaluation is to determine if HPGP sterilization is a feasible method of sterilizing LactoSorb® (82/18) and (85/15) products by verifying the degradation profile of HPGP sterilized material to demonstrate that HPGP does not cause a significant loss of mechanical strength or reduction in viscosity. The 82/18 formulation design requirements state that 70% of initial strength is maintained to 6-8 weeks whereas the 85/15 formulation requires that initial strength is maintained to 6-8 months.

Methods:

Compression molded test coupons(1" x 0.25" x 0.04") of two PLA/PGA formulations were sterilized via either EtO or HPGP(Table 2) and then exposed to *in vitro* conditions (Sorrenson's buffer at 37 °C and 47°C) over clinically relevant time points. Following *in vitro* aging, the samples were mechanically tested under 3 point bend conditions. Following mechanical evaluation, inherent viscosity (at 30°C, 0.25g/dL) measurements were also conducted on the *in vitro* samples.

Results:

Initial results (t=0) for viscosity(IV) and mechanical strength for both formulations of LactoSorb are comparable between the two sterilization methods(Table 1) and meet the minimum IV design requirements.

PLA/ PGA	Sterilization Method	Initial IV (dL/g)	Initial Strength (psi)
82/18	EtO	1.12	19,296+/-227
	HPGP	1.04	18,557+/-302
85/15	EtO	1.81825	17985+/-234
	HPGP	2.026	18,302+/-365

Table 1: Initial viscosity and mechanical strength

The Inherent Viscosity and Strength Retention Profiles for the 2 LactoSorb formulations for the EtO sterilized condition are presented in Figures 1 & 2.

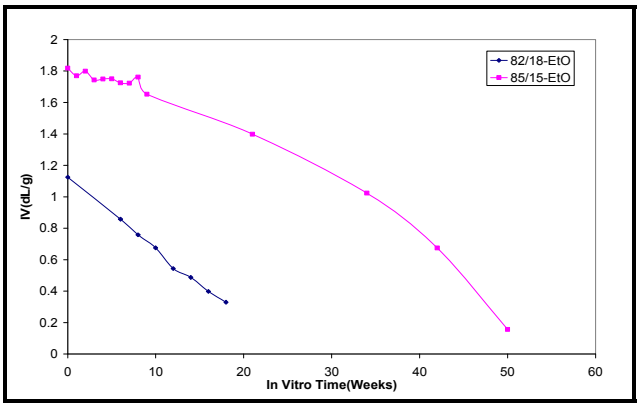

Figure 1: Inherent Viscosity of EtO sterilized LactoSorb

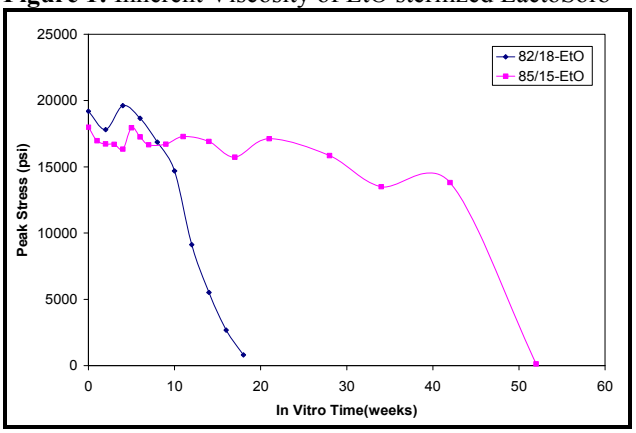

Figure 2: Peak Stress of EtO sterilized LactoSorb

The strength retention profile for both LactoSorb® formulations sterilized via HPGP fall within the range of EtO sterilized for both the mechanical and inherent viscosity profiles of EtO sterilized LactoSorb®. (The mechanical strength and inherent viscosity profiles for the HPGP sterilized material will be presented at a later time.)

Conclusions:

The results of this study support the equivalency of the material degradation profile of both LactoSorb® formulations (82/18 and 85/15) under EtO and HPGP sterilization conditions. The feasibility of HPGP as a method for sterilizing LactoSorb provides a more efficient sterilization method for resorbable polymers which does not impact the degradation behavior and expedites the release of product to the field.

References:

[1] Nuutinen JP, et.al., J Biomater. Sci. Polym Ed. 13(2), 1325-36, 2002.