Novel Polyisobutylene-Based Nanocomposites as Promising Biomaterials

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Statement of Purpose: Arborescent poly(isobutylene-*b*-styrene) (*arb*IBS) block copolymers belong to a class of high performance thermoplastic elastomers with an excellent profile of properties, such as exceptional gas and fluid impermeability, elasticity, tear strength and flexural fatigue resistance.[1] *arb*IBS can be processed readily by established polymer processing techniques (e.g. injection molding), to develop a variety of medical devices. *arb*IBS is chemically similar to the linear poly(styrene-*b*-isobutylene-*b*-styrene) (L_SIBS) triblock copolymer and was FDA-approved as the polymer coating on the drug eluting TAXUS Express2™ stent in 2004.[2] As part of an ongoing program on the development and characterization of novel biocompatible nanocomposites for medical device applications, this paper focuses on the mechanical reinforcement and cytotoxicity performance of novel *arb*IBS-clay nanocomposites.

Materials and Methods: *arb*IB-MS with poly(*p*-methylstyrene) (PMS) hard phases (*arb*IB-MS10, M_n = 291,600 g/mol, M_w/M_n = 1.94 and PMS content = 9.5 wt%, and *arb*IB-MS16, M_n = 317,000 g/mol, M_w/M_n = 1.62 and PMS content = 16.4 wt%) were synthesized as reported.[1] Cloisite®-20A montmorillonite nanoclay from Southern Clay Products, Inc. was used to prepare the nanocomposites by solution blending.[3] Upon drying, flat polymer sheets and thin films were compression molded at 170 °C for evaluation. A medical-grade silicone rubber (MED-4050) from NuSil Technology was considered as a benchmark material. Tensile testing of various materials was performed with an Instron 5567 at a testing rate of 500 mm/min. Neat polymer and nanocomposite sheets were sterilized by ethylene oxide and tested for their cytotoxicity using a leachate test with fibroblast cells (NCTC Clone 929 from Lonza Inc.). Polymer sheets were soaked in Eagle's Minimum Essential Medium (from Lonza Inc.), which was then used to culture cells over 11 days. A longer leachate study was necessary to specifically consider the high barrier nature of *arb*IB-MS – residual solvents started to leach only after 5 days in an earlier study.[3]

Results: The reinforcement of *arb*IB-MS10 by Cloisite®-20A has been reported.[4] Optimum reinforcement (from 6 to 9 MPa) was found at 20wt% nanoclay. Fig. 1(a) shows the tensile plots of *arb*IB-MS16-clay nanocomposites. Increasing the hard phase content increased the tensile strength of the neat polymer to 8.8 ± 1.0 MPa. Optimum nanoclay reinforcement was found at 10 wt% – the tensile strength remarkably increased to 13.2 ± 0.8 MPa, with substantial increase of the 100% modulus and marginal loss of elongation. The cytotoxicity of these novel materials was investigated by a leachate test described above using the nanocomposite with the 20wt% of nanoclay. Fig. 1(b) shows similar cell growth behavior for the leachates of neat *arb*IB-MS10, its 20 wt% clay composite, a blank (culture dish) and silicone rubber over 11 days. Repeatable over two runs, this demonstrates that the clay nanocomposite has comparable cytotoxicity to silicone rubber. Earlier promising *in vivo* testing of similar *arb*IBS materials[1] and promising preliminary fatigue data predict a bright future for *arb*IBS-clay nanocomposites.

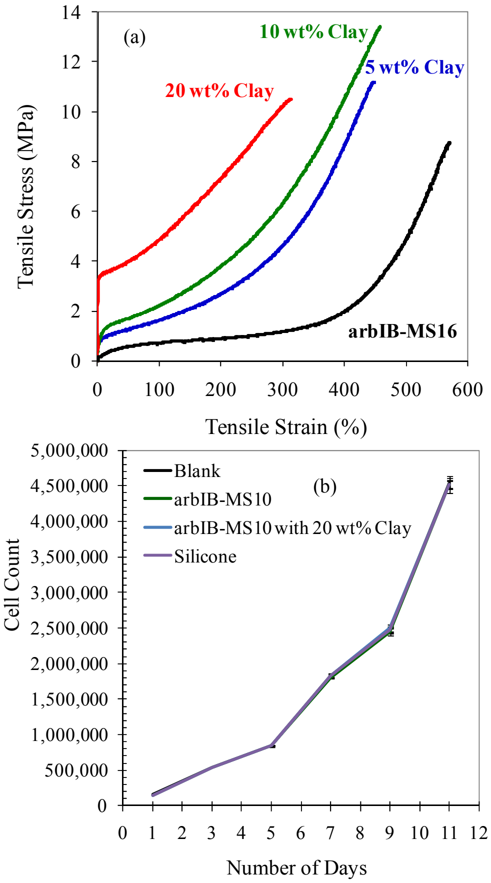

Figure 1. (a) Tensile stress-strain data, and (b) leachate study.

Conclusions: Based on a biopolymer platform, *arb*IB-MS-clay nanocomposites were shown to possess superior mechanical properties and no cytotoxicity as promising biomaterials to many medical devices in the future.

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References:

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