Novel Translucent/Transparent Thermoplastic Elastomeric Nanocomposites for Breast Prosthesis

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Statement of Purpose: Breast cancer strikes one in every eight American women. Almost all these women will be candidates to undergo breast reconstruction who would consider prostheses made of a silicone rubber shell, filled with saline or silicone gel. Unfortunately, medical researchers have reported a high incidence of prosthetic failure (12 – 53 %), such as gel bleed, implant rupture, capsular contracture, and others, to cause inflammatory reactions and infections in patients [1]. These health problems clearly necessitate improvements in the safety and reliability of breast prostheses. Dendritic poly(isobutylene-*b*-styrene) (D_IBS) block copolymers belong to a class of high performance thermoplastic elastomers (TPEs) to exhibit exceptional gas and fluid impermeabiltiy, elasticity, tear strength and flexural fatigue properties [2,3]. This paper presents the development of novel biocompatible TPE nanocomposites for breast implant shell using the D_IBS copolymers with montmorillonite nanoclays and the evaluation of their tensile properties and morphology.

Materials and Methods: In this study, D_IBS had a molecular weight (M_n) of 291,600 g/mol, a polydispersity index of 1.94 and a polystyrene content of 9.5 wt%. The nanoclay filler used in this study was Cloisite®-20A montmorillonite nanoclay by Southern Clay Products, Inc, at three different loadings (10, 20 and 30 wt%).

Solution blending was employed to prepare nanocomposites by first dissolving specific amounts of the polymer in a solvent mixture of tetrahydrofuran and methylcyclohexane at 20:80 (w/w) to yield a polymer concentration of 25 wt%. The solutions were shaken on a shaker at a speed of 1000 rpm for 8 hrs. Specified amounts of Cloisite®-20A were added, and the mixtures were first sonicated for 3 hrs, shaken for another 8 hrs at 1000 rpm and again sonicated for 15 min to remove any bubbles formed during shaking. Finally, the solutions were dried at room temperature to a constant weight. After that, polymer sheets with a good flat surface were compression molded at 170 °C and cut into micro-dumbbells using a hydraulic press for tensile testing and morphological studies.

Results: Fig. 1(a) provides the stress-strain plots of filled and unfilled D_IBS. One can observe from the figure that the rubbery plateau of the neat D_IBS (between 100 and 200 % strain) gradually disappears with an increasing amount of clays. This suggests that the nanoclay platelets were effective to "restrict" the mobility of polymer chains, thereby increasing the initial modulus at 100 % and 200 % strain by nearly four-fold at 30 wt% nanoclay. Dispersing Cloisite®-20A well in D_IBS also brings the benefit of strengthening the material, but reduces the elongation at break. It is to mention that during the preparation of clay nanocomposites, small amounts of polymer-clay agglomerates were observed at 30 wt% nanoclay. As a result, the tensile strength of D_IBS appears to maximize at 20 wt% nanoclays, with an overall increase of 50 %. The material remained translucent even at 30 wt% clay content. Fig. 1(b) shows the excellent intercalation of nanoclay platelets (20 wt%) in the D_IBS matrix.

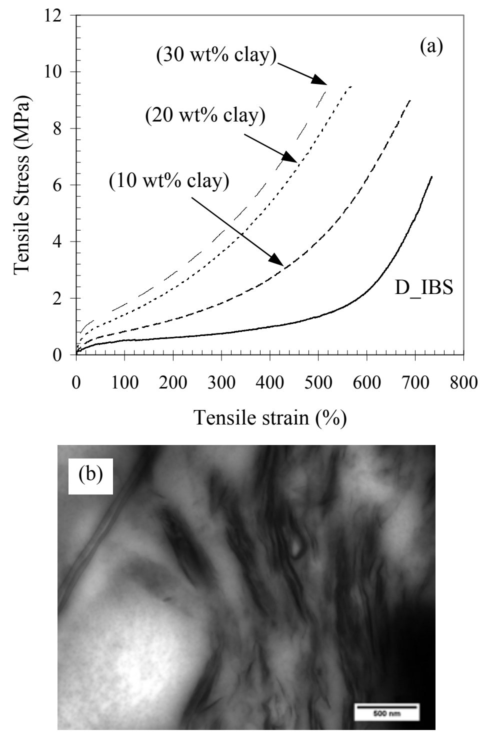

Figure 1. (a) Tensile stress-strain plots of neat and D_IBS clay nanocomposites, (b) clay dispersion at 20 wt% in D_IBS.

Conclusions: This work presents the effectiveness of using nanoclays to provide significant mechanical reinforcement, and provides a foundation for our team to explore this nanotechnology to improve the fluid (e.g. silicone gel) barrier property and long-term fatigue performance of the D_IBS polymer in the development of a new and safer biomaterial for breast implant shells.

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