Performance of Cardiac Lead Insulation Siloxane-Based Multiblock Polyurethanes under Various Mechanical Stresses up to 2 Years in Rabbit

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Statement of Purpose: The in vivo performance of polymeric materials utilized within permanent cardiac lead implants to provide electrical isolation is critical. Finding appropriate testing conditions to model the complex in vivo environment to predict material behavior is a challenge. Materials under internal or external stress are generally more susceptible to failure in environments which do not affect the un-stressed state; environmental stress cracking (ESC) is one such failure mechanism [1]. In vivo conditions, where oxidative agents generated by inflammatory cells are present, is often a contributing factor to degradation of polyurethanes by ESC [2,2]. Hence, minimizing mechanical stress concentrations in the material by appropriate device design is important to promote biostability of polyurethanes. In this study we investigated the material performance of Elast-Eon 2A, a siloxane-based multiblock polyurethane (SPU), exposed to various stress conditions in rabbit. More specifically, the effect of tight bends or stretching of the material, causing areas of high compressional and/or extensional stress, has been analyzed.

Methods: Elast-Eon 2A extruded tubing samples were mounted onto five different bend fixture designs, introducing device (implantable cardiac lead) relevant loading. The stress levels were simulated using Finite Element Analysis (FEA) to compare expected load distribution on samples for the different fixtures. One set of Elast-Eon 2A samples stressed 200% were implanted, to represent a control for ESC in this type of materials and environment [3]. Stressed Pellethane 80A samples were used as positive controls to verify the validity of the method. Samples from each design were implanted subcutaneously in albino rabbits and explanted after 1 (n=6) and 2 (n=6) years. The surface morphology of the samples was analyzed by optical microscope, SEM, and AFM. Techniques such as FTIR, DSC, GPC, and EDS were used to further characterize changes in the material after implantation. When possible, the samples were analyzed at definite areas to identify stress specific effects, e.g. in compression zones and stretched zones.

Results: The positive control Pellethane 80A samples were severely degraded already after 1 year of implantation, displaying severe cracking and fragmentation as a result of ESC. After 1 and 2 years implantation, the surface of the 200% stretched Elast-Eon 2A samples (n=12) were essentially free from significant surface defects. After 2 years implantation, the surface appeared slightly rougher at elevated magnification (over 2000x) compared to after 1 year implantation, indicating at least some slow surface degradation process to be present.

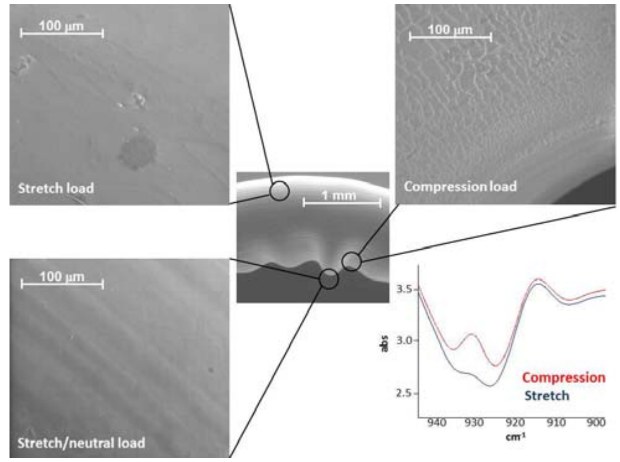

Figure 1. SEM and FTIR result of areas of Elast-Eon 2A samples subjected to different load after 2 years implantation in rabbit.

SEM images showing areas of different applied stresses on the bent Elast-Eon 2A samples can be seen in figure 1. The stretched and neutral loaded areas of the samples displayed no significant surface defects or signs of degradation. In areas subjected to high compressive loads, a type of superficial defects (characterized as netting) was observed. AFM analysis showed that these microscopic cracks were approximately 200 nm deep, which is less than 0.2% of the material thickness. FTIR spectra of stretched and neutral loaded areas showed no sign of surface oxidation or hydrolysis. A small peak at 930 cm^{-1} was observed in areas subjected to compressive load. This indicates some small levels of surface oxidation which occur predominantly under compressive load.

Conclusions: The development of superficial defects and oxidation on Elast-Eon 2A is strongly correlated to the type of stress acting on the material. 200% stretching of the samples did not induce ESC degradation, while compression load areas showed small levels of oxidation. In our study Elast-Eon 2A presented excellent resistance to biodegradation under stress compared to control Pellethane 80A samples. Preventing mechanical stress concentration through design can promote biostability of Elast-Eon 2A in clinical use.

References:
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