Biostability of a New Cardiovascular Material

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Introduction: Polyurethanes (PU) have long been used for biomedical applications due to their excellent mechanical properties and reasonable biocompatibility. However, polyether urethane elastomers are susceptible to biodegradation. Silicones are known to be biostable and biocompatible, making them an ideal replacement for the polyether soft segment of polyurethanes. As a result, a new silicone-polyurethane copolymer, Elast-Eon 2A®, has been developed by AorTech Biomaterials in Australia[1]. St. Jude Medical began marketing this material as Optim® insulation in its pacemaker and defibrillator leads in 2006. This study compared the biostability of Elast-Eon2A® material to Pellethane 2363-55D (55D) which is clinically acceptable, industry standard polyurethane using both an accelerated *in vitro* metal ion oxidation (MIO) and *in vivo* environmental stress cracking (ESC) methods. Surface degradation was investigated using Optical microscope, SEM, and ATR-FTIR spectroscopy.

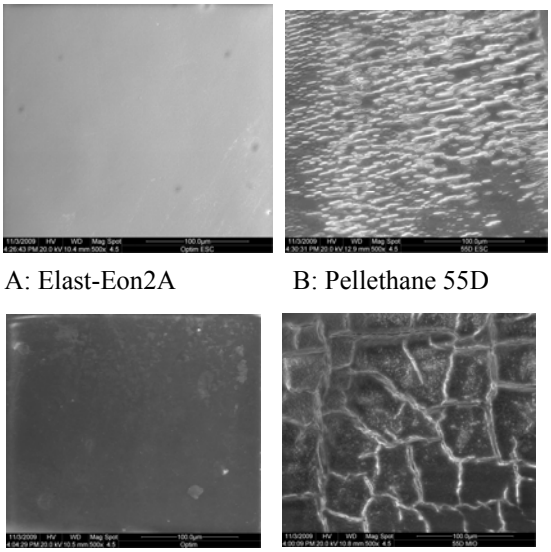
Materials and Methods: Elast-Eon™ 2A® (AorTech Biomaterials) is a silicone-polyurethane copolymer containing 60% of a novel silicone-rich macrodiol blend. The macrodiol consists of 80% bis-hydroxy-ethoxy-propyl polydimethylsiloxane and 20% polyhexamethylene oxide (PHMO). Pellethane 2363-55D (Dow Plastics) contains polytetramethylene glycol (PTMG) as a soft segment.

Polymer films with a thickness of 0.5 mm were prepared for *in vivo* ESC study. The test articles (n=5) were cut from the annealed films using a cutting die (38mm long). All test articles were subcutaneously implanted in rabbits for one year. The test articles were retrieved, washed, and dried for surface analysis.

Single lumen tubing was used for MIO study. Both Elast-Eon 2A and Pellethane 2363 55D tubing had the same ID and wall thickness. MP35N (cobalt alloy) coil was inserted into tubing lumen. All samples (n=6) were treated with a 10% hydrogen peroxide and 0.9% sodium chloride solution at 37°C to simulate an accelerated *in vivo* oxidative environment. The samples were washed, and dried after 12 weeks MIO treatment.

The samples from both MIO and ESC were subjected to surface degradation analysis by optical microscope, SEM (FEI Quanta 200), and ATR-FTIR spectroscopy. The level of degradation was qualitatively assessed using Optical microscope and SEM. ATR-FTIR analysis was used to quantify the extent of degradation. The degradation was monitored by the decrease in the ether peak at 1108 cm^{-1}, normalized to the aromatic peak at 1597cm^{-1}.

Results and Discussion: SEM analysis of all samples was done to assess the level of surface degradation. Figure 1 shows micro-cracking on the Pellethane 2363 55D surface (B) after one-year implantation. No cracking was observed on Elast-Eon 2A (A) samples. MIO results showed similar trend of degradation. The Elast-Eon 2A surfaces (C) still exhibited no degradation while Pellethane 2363 55D (D) heavy cracks. Thus SEM analysis suggested that surface degradation of Elast-Eon 2A® was much less than that of Pellethane 2363 55D control.



A: Elast-Eon2A B: Pellethane 55D

C: Elast-Eon 2A D: Pellethane 55D

Figure 1. SEM images (500X). A and B: after 1-year implantation; C and D: after 12 weeks MIO treatment.

Ether loss percentage with respect to the controls without implantation or MIO treatment was calculated and summarized in Table 1. The ether peak ratios of explanted Elast-Eon 2A and Pellethane 2363 55D decreased by 0% and 32%, respectively. 12 weeks MIO treatment resulted in ether loss percentage of Elast-Eon 2A and Pellethane 55D by 5% and 50%, respectively. The peak at 1015 cm^{-1} assigned to the Si-O-Si stretch of polysiloxane soft segment did not reveal any significant loss after 1 year *in vivo* ESC or 12 weeks of MIO treatment, suggesting that the polysiloxane was stable. The ATR-FTIR data were consistent with the SEM results.

Table 1. Ether loss % (1108 cm^{-1}/1597 cm^{-1})

Material	After ESC	After MIO
Elast-Eon 2A	0%	5± 1%
Pellethane 55D	32± 7%	50 ± 8%

Both SEM analysis and ATR-FTIR data showed that Elast-Eon 2A® was more resistant to accelerated *in vitro* MIO and *in vivo* ESC than Pellethane 2363 55D. This study suggests that Elast-Eon 2A® exhibited superior biostability as a result of the biostable polysiloxane incorporation.

[1] Simmons A, Hyvarinen J, Odell RA, Martin DJ, Gunatillake PA, Noble KR, Poole-Warren LA. Biomaterials 2004; 25:4887-4900.