A New Silicone Carbonate Polyurethane Copolymer

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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[1]. Silicones are known to be extremely biostable and biocompatible, making silicone segments an ideal replacement for the polyether soft segments of polyurethanes. As a result, a new silicone polyurethane copolymer, Elast-Eon™ 2A, was developed by AorTech Biomaterials in Australia[2]. St. Jude Medical Cardiac Rhythm Management Division (SJM-CRMD) began marketing this material as Optim® insulation (Optim) in its pacemaker and defibrillator leads in 2006. Optim combines the toughness of polyurethane with the biostability of silicone into a single material. Optim has a hardness of ~90A while silicones used as insulation can have hardnesses in the range of 60~80A. AorTech recently developed a silicone carbonate polyurethane copolymer called EcSil™ which has a hardness of ~74A. This study compared several mechanical properties useful in establishing the appropriateness of a material for use in pacing and defibrillation leads. Additionally, the biostability of EcSil to Optim was compared using both an accelerated *in vitro* metal ion oxidation (MIO) and *in vivo* environmental stress cracking (ESC) methods.

Materials and Methods: EcSil (AorTech Biomaterials) is a silicone carbonate polyurethane copolymer. Optim (Elast-Eon 2A, AorTech Biomaterials) is a silicone polyurethane copolymer. Both are thermoplastic elastomers.

Mechanical Properties: Mechanical properties were determined according to ASTM standards. Two different lots of EcSil and three different lots of Optim materials were evaluated and results were averaged. One lot of silicone (Dow Corning Q7-4780) was determined.

Environmental Stress Cracking: Single lumen tubing was used for the *in vivo* ESC and *in vitro* MIO studies. EcSil, Optim, and Pellethane 2363 80A (positive control) tubing had the same inner diameter and wall thickness. The tubing was cut to 3 inch lengths. The short tube was then strained to 200% elongation over a solid mandrel within its lumen. Once stretched, the two ends of the tube were tied with non-absorbable polyester sutures in order to hold the tubing in the stretched configuration. All test articles were subcutaneously implanted in rabbits for six months. The test articles were then retrieved, washed, and dried for surface analysis. The sample size was 12 for each material.

Metal Ion Induced Oxidation: A MP35NLT (low titanium nickel-cobalt alloy, Fort Wayne Metals) coil was inserted into the 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 treatment solution was refreshed once a week. 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 SEM (FEI Quanta 200).

Results and Discussion: The mechanical properties are listed in Table 1. EcSil had a hardness of 74A compared to 90A and 80A for Optim and silicone. Stresses at 100% strain were 4.4 and 9.1, 4.5 MPa for EcSil, Optim, and silicone respectively. Both hardness and stress at 100% showed that EcSil is more flexible than both Optim and silicone. Unlike stresses at low elongations, the ultimate tensile strength of EcSil was higher than those of Optim and silicone.

Table 1. Mechanical properties

Property	EcSil	Optim	Silicone
Durometer, Shore A	74	90	80
Stress at 100%, Mpa	4.4	9.1	4.5
Ultimate Tensile Strength, Mpa	30	26	8
Ultimate Elongation, %	588	496	653
Tear Strength, kN/m	66	81	49

All ESC samples were stretched to 200% elongation to accelerate *in vivo* ESC. SEM analysis of all samples was performed to assess the level of surface degradation of each sample. No degradation was observed on either EcSil or Optim samples. In contrast, Pellethane 2363 80A showed significant cracking. Thus both *in vivo* ESC and *in vitro* MIO suggest that the biostability of EcSil is similar to that of Optim, which has been marketed as an implantable material for several years.

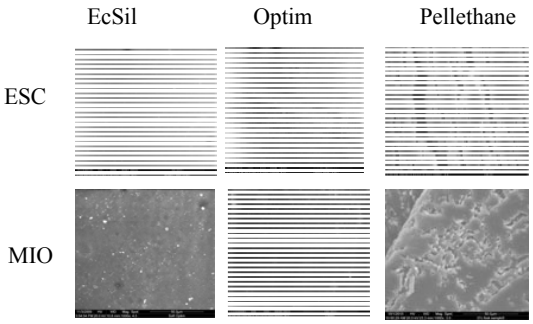

Figure1. SEM images after 6 months implantation and 12 weeks MIO treatment.

In conclusion, mechanical analyses demonstrated that EcSil is more flexible than Optim. Accelerated ESC and MIO showed that EcSil is as biostable as Optim. Therefore it has been demonstrated that by replacing the polyether segments found in Optim by carbonate segments flexibility has been increased without sacrificing biostability.

Reference: 1. Wiggins MJ, Wilkoff B, Anderson JM, Hiltner A. J Biomed Mater Res 58: 302-307, 2001
2. Simmons A, Hyvarinen J, Odell RA, Martin DJ, Gunatillake PA, Noble KR, Poole-Warren LA. Biomaterials 2004; 25:4887-4900