Biocompatibility of a Silicone-polycarbonate- urethane Used in a Prosthetic Lumbar Spinal Disc

Kathleen White[1], Robert Ward[1], Kari Zimmers[2], Sallie Coviello[1], Tai Ngo[1], Rob Ward[1], Yuan Tian[1]
[1]The Polymer Technology Group Inc, Berkeley, CA, 94710, [2]AxioMed Spine Corporation, Garfield Heights, OH, 44125

Statement of Purpose: There has been considerable interest in recent years in developing *compliant* prosthetic joints and stabilization devices. Novel polymers are being used that differ from the rigid materials typically used in orthopedic implants: UHMWPE, PEEK, metals and ceramics. The specification of an elastomeric polymer for use in load-bearing orthopedic device must consider processability, bulk and surface properties, biostability, and biocompatibility. Previous work has shown that optimizing the silicone content of thermoplastic polycarbonate-silicone-urethane results in a beneficial combination of physical properties and *in vitro* biostability [1, 2]. Based on this work, a Lumbar Spinal Disc was developed incorporating a silicone-polycarbonate-urethane (SPCU) with 20 wt% silicone and a Shore hardness of 80A: CarboSil® 20 80A SPCU, as the elastomeric core contained between two titanium plates, Figure 1. The Freedom™ Lumbar Disc is intended to replicate the geometry, motion, deformability, inherent stiffness, and damping necessary to restore normal function to the spinal segment. The polymer's viscoelastic properties allow compression, rotation and translation, while providing load transfer and damping. The one-piece design restores disc height and lordotic angle. Here we present the test results conducted to evaluate the biocompatibility of the CarboSil SPCU core used in this novel Lumbar Spinal Disc.

Methods: Biocompatibility test specimens were prepared by compression molding "sandwiches" of CarboSil 20 80A SPCU and the titanium primer used in manufacturing the Lumbar Spinal Disc. Tests were performed using either test specimen extracts or the test specimens, as recommended in ISO 10993. A lipid uptake analysis was performed using compression molded samples in the shape of the same dog bones used for tensile testing. Specimen weight, dimensions, surface damage, and tensile properties were evaluated after exposing the samples to a lipid solution under cyclic compressive loading for up to 100 days. A particulate study was conducted to evaluate the effects of wear debris percutaneously injected in rabbit spines at 3 and 6 month intervals. Due to the novel combination of polymer and design features in this Spinal Lumbar Disc, wear particles are not generated under normal use. To allow evaluation of the response to 'wear debris', particles were generated by cryogenically grinding the CarboSil 20 80A SPCU. High doses of 13 million particles and low doses of 1.3 million particles were injected.

Results/Discussion: Exposure of material samples to lipid solution confirmed that there was no lipid uptake and no significant changes in mechanical properties.

The particulate study showed no evidence of neurotoxicity, systemic toxicity or local effects associated with the treatment of wear debris. There was also no evidence of trans-location of the wear debris.

The results of the biocompatibility tests are summarized in Table 1.

Figure 1. AxioMed Freedom™ Lumbar Disc

Test/ISO 10993 Part	Result
Cytotoxicity Part 5	No evidence of cell lysis or toxicity
Sensitization Part 10	No evidence of dermal contact sensitization
Irritation Part 10	No evidence of irritation
Acute Systemic Toxicity Part 11	No evidence of systemic toxicity
Pyrogen Part 11	Nonpyrogenic
Genotoxicity Part 3 Bacterial reverse mutation	Nonmutagenic
Genotoxicity Part 3 In vitro chromosomal aberration	Not genotoxic
Genotoxicity Part 3 Mouse bone marrow micronucleus	Not genotoxic
Muscle Implantation Part 6	2 week: nonirritant 12 week: nonirritant
Sub-Chronic Toxicity	4 week: No evidence of systemic toxicity
Chronic Toxicity	26 week: No evidence of systemic toxicity

Table 1. CarboSil 20 80A Biocompatibility Test Results

Conclusions: This thermoplastic silicone-polycarbonate-urethane has a unique combination of strength, viscoelastic properties and biocompatibility which make it a serious candidate for use in well-designed orthopedic implants.

References:

1. Ward R, et al, Abstract Number: 162, Trans. SFB 30th Annual Mtg, 2005, Memphis, TN

2. Christenson E M, et al, Abstract Number: 46, Trans. 7th World Biomaterials Congress, 2004, Sydney, Australia