Design of Silicone Materials for Ophthalmic Application

Can B Hu, Derek Pham, Mike Lowery, Rakhi Jain
Abbott Medical Optics, Santa Ana, CA 92705

Introduction: The human eye is a highly evolved and complex sensory organ. It is composed of a cornea, which refracts light rays en route to the pupil, an iris which controls the size of the pupil thus regulating the amount of light entering the eye, and a lens which focuses the incoming light through the vitreous fluid in the eye to the retina. The retina converts the incoming light to electrical energy that is transmitted through the brain to the occipital cortex resulting in a visual image.

As the body ages, the effects of oxidative damage caused by environmental exposure and endogenous free radical production accumulate resulting in a loss of lens flexibility and even the clarity of the lens. The clarity of the lens is critical to the vision and flexibility of the lens is essential for focusing light onto the retina by a process referred to as accommodation. Accommodation allows the eye to automatically adjust the field of vision for objects at different distances. Both issues, cataract (opacity of the lens) and presbyopia (rigidity of the lens) are common problems in the aged population. Phacoemulsification is a standard procedure to remove the defective lens. After removing the natural lens, a synthetic intraocular lens (IOL) is implanted. It is desirable to develop a lens that mimics the clarity and natural accommodative mechanism of the healthy eye. Such a lens design consists of a soft optic (low modulus) integrated with a supporting haptic (high modulus) made from a biocompatible material.

Methods: A silicone polymer capable of yielding IOLs with the desired properties was developed. The polymer was synthesized with a typical example as follows. To a 1 L reaction vessel purged with dry nitrogen and pre-heated to 105 ± 10 °C was charged 129.45 grams of octaphenylcyclotetrasiloxane (D^{ph}_4), 666.07 grams of octamethylcyclotetrasiloxane (D_4) and 4.51grams of 1, 3 divinyl tetramethyldisiloxane. Then 2.62 grams tetramethylammonium siloxanolate was added to initiate the polymerization. Stirring was continued for 18 hours at 105 ± 10 °C. Then temperature was raised to 150±20°C for 5 hours. After cooling, a clear silicone fluid was filtered through a 0.5 micron filter. The theoretical vinyl content of this material is 0.06 mmoles per gram.

A wiped-film still was used to remove the volatile components. The efficacy of the wiped-film process was conformed by the removal of the low molecular weight oligomers when monitored using gel permeation chromatography (GPC). The silicone polymer prepared by this process is used in the subsequent formulations. Two different cross-linkers, phenyltris(dimethylsiloxy) silane (**SIP**) and tetrakis-(dimethylsiloxy)silane (**SIT**), and a platinum catalyst, platinum-cyclovinylmethyl siloxane complex, were investigated. Formulation variables included different hydride and vinyl (H/V) ratios and catalyst concentration. In addition, a formulation having a fixed H/V ratio was evaluated to determine the effect of different post-curing periods after a fixed curing temperature.

Discs were cured in Teflon molds at 140°C for 10 minutes. Extraction of disc was performed at room temperature using isopropyl alcohol (IPA). The compression modulus was measured using a Q800 DMA (TA Instruments). After sample loading, the temperature of the system was raised to 35°C and held at equilibrium for 5 minutes before testing. Ramp force applied to the disk from 1 N/min to the 9 N/min. The modulus was determined by the slope of two elongation points (4% and 8%) from the curve.

Results: Table 1 summarizes the compression modulus of silicone materials at 0.3% catalyst concentration with different H/V ratios. As shown in the table, the modulus was sensitive to the H/V ratio for both X-linkers.

Table 1 Modulus at fixed catalyst with different H/V ratio

H/V Ratio	Compression Modulus, KPa			
	SIP Cross-Linker		SIT Cross-Linker	
	Before Extraction	After Extraction	Before Extraction	After Extraction
1.5	104	196	496	631
1.0	588	669	544	635
0.7	64	73	82	121
0.5	Too soft to test		Too soft to test	

Table 2 summarizes the silicone materials with fixed H/V ratio of 0.7 with different catalyst concentrations and post curing periods at 60°C (D=day) after standard curing. Samples with 0.5% catalyst were too soft to test and were not listed in the table.

Table 2 Modulus of silicone gels with different catalyst concentrations and post curing conditions at H/V ratio 0.7

140°C 10 min	0.1% catalyst Modulus (KPa)		0.3% catalyst Modulus (KPa)	
	Before Extraction	After Extraction	Before Extraction	After Extraction
Control	155	157	54	53
60°C 1D	151	135	64	73
60°C 3D	151	162	53	59
60°C 5D	150	154	50	57

Conclusions: By varying the ratio of X-linker and the vinyl fluid, silicone materials with different moduli could be obtained. It was also surprising to find out that modulus of material was also affected by the amount of catalyst. The curing time did not appear to be a factor in the modulus of the cured samples. These parameters allowed us to use the same base fluid to design materials of different moduli for lens application.