

Establishing the Biocompatibility of Intraocular Lens Surfaces Using X-Ray Photoelectron Spectroscopy and Time of Flight Secondary Ion Mass Spectrometry

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Statement of Purpose: Calcification of polymeric medical devices has frequently been reported in the literature. Calcification of devices such as heart valves and catheters along with cerebrospinal fluid shunts and contact lenses have been reported earlier.¹⁻³ Calcification of intraocular lens implants has also been observed and reported previously.⁴ Given the disruptive nature of intraocular lens calcification it is desirable to understand the factors associated with this process. An in vitro model has been developed to evaluate and understand the biocompatibility of intraocular lens surface calcification. This model used in conjunction with X-ray Photoelectron Spectroscopy and Time of Flight Secondary Ion Mass Spectrometry on IOL surfaces provides a potential explanation for the formation of calcified deposits.

Methods: Low water content intraocular lenses composed mainly of poly (hydroxyethyl methacrylate) were used for this investigation. The lenses and haptics were manufactured via a lathing process to render the finished product and all lenses were evaluated post sterilization. All intraocular lens samples were calcified via the process identified by Wu.⁵ Pre and post calcified lenses were analyzed using a Physical Electronics (PHI) Quantera X-ray Photoelectron Spectrometer (XPS) and a PHI model 7200 Time of Flight Secondary Ion Mass Spectrometer (TOF-SIMS). Detection and location of species on the lens surface were achieved using stage driven Scanned X-ray Images (SXI). A sample positioning station with calibrated coordinates to the XPS system was used to collect optical images of the IOL optic/haptic junction.

Results: Stage driven SXI images, collected on pre-calcified test lenses, were used to identify localized areas of contamination across the IOL. The maximum field of view of the SXI was 1.5mm² and as such 25 SXI images were digitally pieced together to construct a chemical image of the entire IOL surface (Figure 1). XPS analysis was used to evaluate the chemistry and atomic concentration of these contaminant areas identified by the stage driven SXI's. XPS analysis revealed that the main component of these moieties were silicone based. Once identified and characterized, the location of these silicone moieties were referenced to the microscopic image of the optic/haptic junction collected on the optical microscope outside the XPS system. This referencing was necessary so that the exact location of the silicone contamination could be established before un-mounting the IOL sample. Upon removal of the sample from the XPS, the IOL was then processed using an octacalcium phosphate (OCP) calcification model in conjunction with behenic acid. Post calcified lenses were subsequently reanalyzed using the XPS and TOF-SIMS. The location of the original silicone contamination was driven to the sample analysis

position in the XPS and the chemistry was once again evaluated. Pre-calcified areas of silicone contamination were found to contain calcium and phosphorous. The atomic concentrations and ratios established that OCP precipitated at the location of the original silicone contamination. Lenses were then analyzed using TOF-SIMS in the same areas where OCP had precipitated on the surface. In addition to measuring characteristic silicone fragments on the calcified areas, peaks associated with behenic acid were also detected at the same locations.

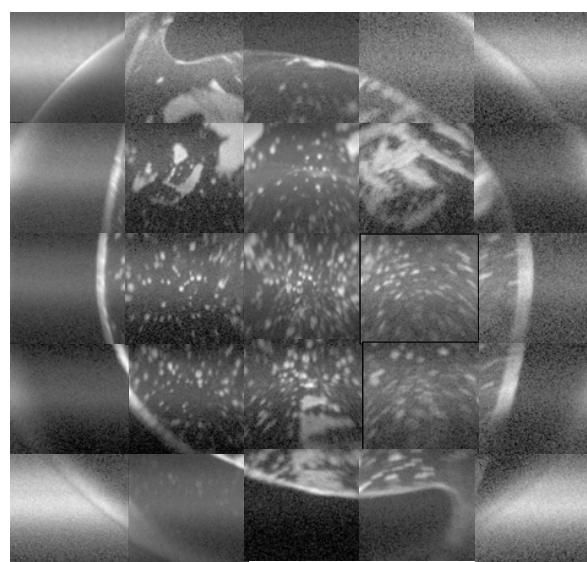


Figure 1. SXI images of an IOL surface

Conclusions: Surface analysis of pre and post calcified IOL's indicate that silicone and certain fatty acids play an important role in the precipitation of octacalcium phosphate. The analysis suggests that the hydrophobic head of behenic acid adsorbs to the silicone moieties present on the lens surface thereby exposing the hydrophilic tail in solution. Areas absent of silicone contamination were found not to induce calcification.

References:

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