

Intraocular Lens Calcification in a Subcutaneous Model

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Statement of Purpose: In recent years, there have been numerous peer-reviewed publications that have described calcification of hydrophilic intraocular lenses (IOLs) clinically. (Apple 2001, Izak 2003, Saeed 2004, Werner 2006, Yu 2001). It is recognized that IOL calcification may take years to develop in the human eye. (Buchen 2001) The study of Buchen et. al. demonstrated that material calcification is similar in nature but is more aggressive in the intramuscular or subcutaneous implantation models than in the intraocular implantation model. Subcutaneous implantation in the rabbit model is a useful screening tool for calcification of IOL materials. There is a need to assess biocompatibility and, furthermore, calcification across lens materials in one model. This is evident by the numerous studies that discuss the calcification of one or two explanted IOLs in a case report of a single patient from a given material or lens type. The purpose of the current study was to examine the biocompatibility of three classes of IOL material (hydrophilic acrylic, hydrophobic acrylic, and silicone) in one model by determining their propensity to calcify in the subcutaneous environment of the rabbit.

Methods: Seven different commercial IOLs were implanted subcutaneously in 14 New Zealand White rabbits for 70 ± 2 days. Among the lenses, 5 were hydrophilic (Akreos Adapt and Fit, Acri.Smart, ThinOptX, Rayner 570C, and Hydroview IOLs); 1 was hydrophobic acrylic (AR40e IOL); and 1 was silicone (Clariflex IOL). Upon explantation, half of the specimens in each IOL group were subjected to histological analysis. The other half was subjected to scanning electron microscopy (SEM) to determine surface morphology and energy dispersive spectroscopy (EDX) to determine elemental composition at 3 to 5 randomly selected, representative sites per sample. Samples were then subjected to atomic force microscopy (AFM) to determine the surface profile and topography.

Results: Macrophages and giant cells were more prevalent at the tissue-implant interface of the hydrophilic materials compared to the hydrophobic materials. In SEM analysis, all 3 samples of the following lenses exhibited signs of material degradation and pitting: Akreos Adapt and Fit, Acri.Smart, ThinOptX, and Rayner 570C IOLs (Fig. 1). These samples showed distinct calcium and phosphorus peaks with EDX analysis (Fig. 2). AFM analysis of selected hydrophilic IOLs demonstrated a change in surface topography of up to $2.55 \mu\text{m}$ in depth with “multi-nucleated” calcium and phosphorus structures ranging in diameter from 5 to $60 \mu\text{m}$. The Hydroview IOLs showed signs of material degradation and the presence of calcium and phosphorus in 1 of the 3 samples. The AR40e and Clariflex IOLs

exhibited no signs of material degradation; nor was there evidence of calcium or phosphorus.

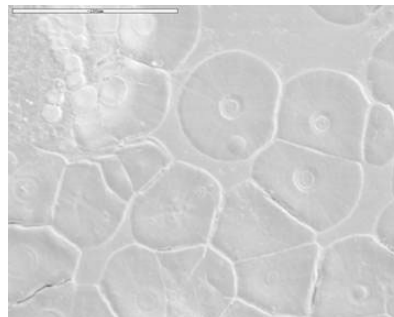


Fig. 1: SEM photomicrograph of explanted Akreos Fit IOL demonstrating surface pitting (500x).

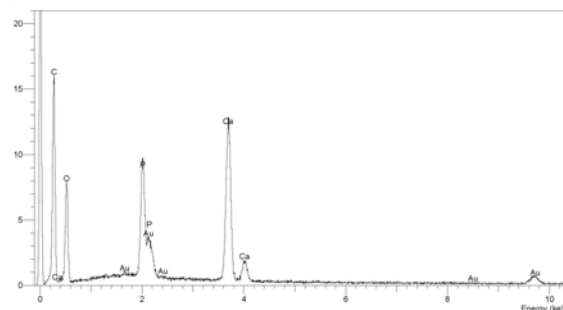


Fig. 2: EDX spectra of explanted Akreos Fit IOL showing the presence of calcium and phosphorus (200x).

Conclusions: SEM and EDX analysis showed obvious signs of calcification in 5 of 6 hydrophilic IOLs. There were no signs of calcification in the hydrophobic acrylic or silicone IOLs. Furthermore, the AFM analysis demonstrates that the presence of calcium and phosphorus in the hydrophilic IOLs is not only a surface phenomenon and that the calcium and phosphorus structures are embedded in the IOLs. Clinically, hydrophobic acrylic or silicone may be better choices for ocular biomaterials for intraocular lenses.

References:

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