Delayed postoperative opacification of three hydrophobic acrylic intraocular lens: A scanning electron microscopic and energy dispersive spectroscopic study

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Purpose: The aim of this study was to report scanning electron microscopic (SEM) and energy dispersive spectroscopic (EDS) findings of three specimens of opaque hydrophobic acrylic intraocular lens (IOL) explanted in delayed postoperative period for visual indications. **Methods:** Clinical data and photographs from each subject were obtained. Explanted IOLs were examined under gross and light microscopy followed by SEM coupled with EDS. **Results:** All three subjects underwent IOL implantation following senile cataract extraction at an average age of 64.3 ± 0.3 years, and the IOLs were *in situ* for a duration of 11.3 ± 4.04 years. The IOL explantation and exchange were done due to late postoperative opacification of the IOL and significant visual deterioration. The milky iridescent opacity affected the full thickness of IOL optics in the first two specimens and in the third only two surfaces were involved. SEM detected surface cracks in the first specimen, typical conglumated surface, pores and accumulation of crystals with surface deposit of nano-particles on the second specimen and uneven surface erosion in the third specimen. SEM detected mainly sodium (Na) and chloride (Cl) spikes. All patients recovered normal vision following IOL exchange. **Conclusion:** SEM features of the IOL optics and absence of calcium and phosphate spikes in EDS and other findings were consistent and suggestive of hydrolytic biodegradation of hydrophobic acrylic IOL polymer in ocular media and was responsible for delayed postoperative opacification of the hydrophobic IOLs and visual loss.

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Cataract surgery and IOL implantation is one of the most frequent, safe, cost-effective and universally performed surgical procedures and its demand is ever increasing.[1] The estimated incidence of IOL exchange is 2 per 1000 surgeries[1-4] Nowadays, the leading cause of IOL explantation is opacification or discoloration of IOL,[5-9] whereas two decades ago the major indication of IOL exchange was dislocation, incorrect IOL power and inflammation.[10] The changing trend behind IOL explantation is mainly due to continuous evolution of surgical techniques, advances in pharmacotherapeutics and introduction of newer IOL materials and design.[7] Opacification of IOL was first reported in the '90s[11] but the diagnosis of IOL opacification remains a challenge and misdiagnosis as posterior capsule opacification prompts the surgeon to perform unnecessary surgical procedures.[9,12] IOL exchange also bears a potential risk of subnormal visual recovery.[4] Any IOL biomaterial may develop opacity but such a complication is mostly reported with hydrophilic or hydrophobic surface coated hydrophilic IOLs.[7,10,12-19] Primary calcification is mainly responsible for late postoperative visually significant opacification of hydrophobic IOL and is inherent to its biomaterial.[7,9] Scanning electron microscopy (SEM), energy dispersive spectroscopy (EDS) and special staining have confirmed the deposition of calcium and phosphate on the surface and in the substance of opaque lens.[12,14,15] Cross-sectional studies suggest this secondary complex phenomenon that is seen selectively in some patients, may result from the interaction between unknown biological variables of the patient and the IOL itself.[9,15-19] The assessment of the IOL performance and factors causing its slow degradation[20] is thorough and at multiple points manufacturers have had to issue field safety notice and withdraw their much-acclaimed product from the market.[11,20]

Single piece hydrophobic IOL is the most popular implant nowadays. Late postoperative opacification of hydrophobic IOL has not yet been reported. Cochrane database search using search strategy 'postoperative hydrophobic IOL opacification', found only two cases of secondary IOL opacification following vitrectomy,[21,22] three cases of reversible IOL opacity due to ocular inflammation in the immediate postoperative period,[23,24] some cases of intralenticular cell growth in piggy bag IOL[25] and glistening formation.[7]

The present report is on SEM material characterization of three opaque explanted specimens of hydrophobic IOLs which had spontaneously turned opaque *in vivo*, causing loss of visual function and IOL exchange at the terminal age of life. Considering the rarity and seriousness of the complication, this report has been submitted to the Indian literature.

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Methods

The study was approved by the institutional review board and protocol adhered to the declaration of Helsinki. Informed consent was obtained from the participants. Only three patients (3 eyes) who underwent explantation of hydrophobic IOLs due to a significant decrease of visual function after having developed late postoperative opacification of the IOLs optics were included in this study.

Medical records, history and clinical findings were registered in each case. All the IOLs were of the same model and had a common manufacturer. Preoperative slit-lamp photograph of the IOLs *in situ* were recorded using Kodak easy-share M200 micro camera. Immediately after explantation, photographs of the IOLs were documented using an operating microscope (visu OPMI 150, Zeiss, Germany), condensed fiber-optic light and the above mentioned Kodak camera. Care was taken to avoid any damage during manipulation of IOL optics with the grasping forceps. The IOLs were subsequently transferred to the Centre of Nano Technology of the Indian Institute of Technology (IIT), Guwahati, in sterile containers in a dry state. In the laboratory, IOLs were air-dried for three days at normal room temperature after bi-section. For contrast enhancement and accurate measurement of surface deposits, the samples were gold coated (sputtered), 30 minutes before microscopy. Specimens were stabilized with adhesive carbon tape and mounted on round aluminum stabs for imaging. The samples were prepared properly to avoid any beam or specimen drift and minimum beam energy had been used to avoid breaking of chemical bond, mass loss, reduction of crystallinity and creation of volatile material from the polymer during the SEM process. For characterization of the surface and quantitative analysis of the material, scanning electron microscope (Hitachi S 3000 N EXAX Genesis VP SEM) and energy dispersive spectroscope (SEM-EDS) was used. Field emission scanning electron microscope (FESEM) was used for observation of small structures in the biological cells and materials on the polymer. Serial microphotographic images of the IOLs were captured in various magnifications, ranging from 500× to 80000× till the appropriate images were captured. Similarly, electron microscopic photographs were obtained from a virgin hydrophobic single-piece acrylic IOL immediately after its removal from the wagon wheel pack as a control specimen for comparison. The IOLs in the fellow eye were optically clear and without any obvious abnormalities, however, the make and model of the IOL couldn't be determined even after thorough reviewing of the old medical records of the patients.

Results

All three patients were male and underwent senile cataract surgery at the mean age of 64.3 ± 0.3 years. Planned ultrasonic phacoemulsification was performed and single-piece acrylic hydrophobic IOL was implanted using injector in each of them. Opacification of IOL and deterioration of vision was the common indication for IOL explantation and exchange. The mean age at the time of explantation was 75.7 ± 4.5 years and the average duration of the IOL *in situ* was 11.3 ± 4.04 years. Duration of visual symptoms which led to IOL explantation ranged between 3 to 5 years. At the time of explantation, visual acuity of the affected eyes of the patient ranged from 20/40 to 20/80 (Snellen's chart) with complaints of glare. On slit-lamp examination, opacity in the IOL optics was evident in all cases [Figs. 1a, 2a and 3a]. In case 1 both the surfaces of the IOL were involved and in the remaining two, the entire lens substance was affected by the opacity. The IOLs were in the bag and stable. The pupils showed resistance to pharmacological dilation and pseudo-exfoliation was noted in case no. 2. The third case had raised intraocular pressure (IOP) and open angles on gonioscopy. Otherwise, all ocular fundi were normal and the eyes were quiet in all cases. Medical history of the patients was also unremarkable [Table 1].

Light and electron microscopic findings were as follows:

All explanted specimens were that of a single piece hydrophobic IOL. Sample 1 - Light microscopy detected opacification of the entire IOL optic, except for a circular peripheral ring which was overlapped by the anterior capsule while the IOL was *in situ* [Fig. 1b]. SEM microphotograph of the surface structure of the IOL in 200× and 500× magnification captured cracks, erosion and the roughened surface of the IOL [Fig. 1c and d]. The surface appeared scaly.

Sample 2 - Light microscopy demonstrated brownish-white discoloration of the IOL optics and it was more evident when the photograph was taken keeping the IOL in an oblique position with fiber optic condensed xenon light focused at right angle to the optics [Fig. 2b and c]. The opacity involved both the surfaces only. SEM photograph of the surface structure captured a conglumated structure and pores in the polymer of the IOL optics [Fig. 2d and e]. FESEM photograph detected isolated areas of clumps of aggregated crystals of different sizes, mostly in hexagonal configuration. A magnification of 80000× demonstrated nanoparticles of about 10 nanometers in size, on the surface of the crystal [Fig. 2f and g]. EDS elemental analysis of the crystal detected sodium (Na), chloride (Cl), Sulphur (S), Silicon (Si) and Tantalum (Ta) and absence of calcium and phosphate peaks [Fig. 2h].

Sample 3– light microscopy detected opacification of the entire IOL optics which was not uniform in distribution [Fig. 3b]. SEM photograph in different magnifications demonstrated non-homogeneous licking and erosion of the surface. The advancing edge of erosion was also evident [Fig. 3c and d].

Discussion

Intraocular lens material should ideally be biocompatible and stable because host reaction to it, is important for IOL performance and lifelong transparency.[26] IOL biomaterials of various water contents, chemical composition, refractive indices and tensile strength are under constant evaluation, intending to minimize host cell response, reduce the incision size and obtaining a better refractive outcome. Presently, there is a progressive increase in the demand for IOL implantation in younger age groups due to an increase in refractive lens exchange and treatment of pediatric cataract.[27,28] The IOLs will, therefore, remain in the ocular environment for a much longer time in the future, in which case, though rare, this particular complication, especially because of its undetermined nature will always bear the risk of visual loss and IOL exchange at any point in the patient's life post-implantation.

Degradation of a polymer in a biological environment is universal and results either from hydrolysis or enzymatic attack (produced by microorganisms). In aqueous media, water gets absorbed and induces simple chemical hydrolysis of the hydrostatically unstable polymer bond. As a result, cleaving or hydrolytic chain scission occurs and the long polymer chain converts into water-soluble fragments with polymer dissolution and surface erosion. Both, absorption of water and erosion, together or alone can produce cracks and pores in the polymer. Locally produced acids catalyze the degradation process and the polymer inside the pores further dissolves. Rate of erosion is determined by the chemical stability of the polymer bond, the hydrophilic/hydrophobic balance, morphology,

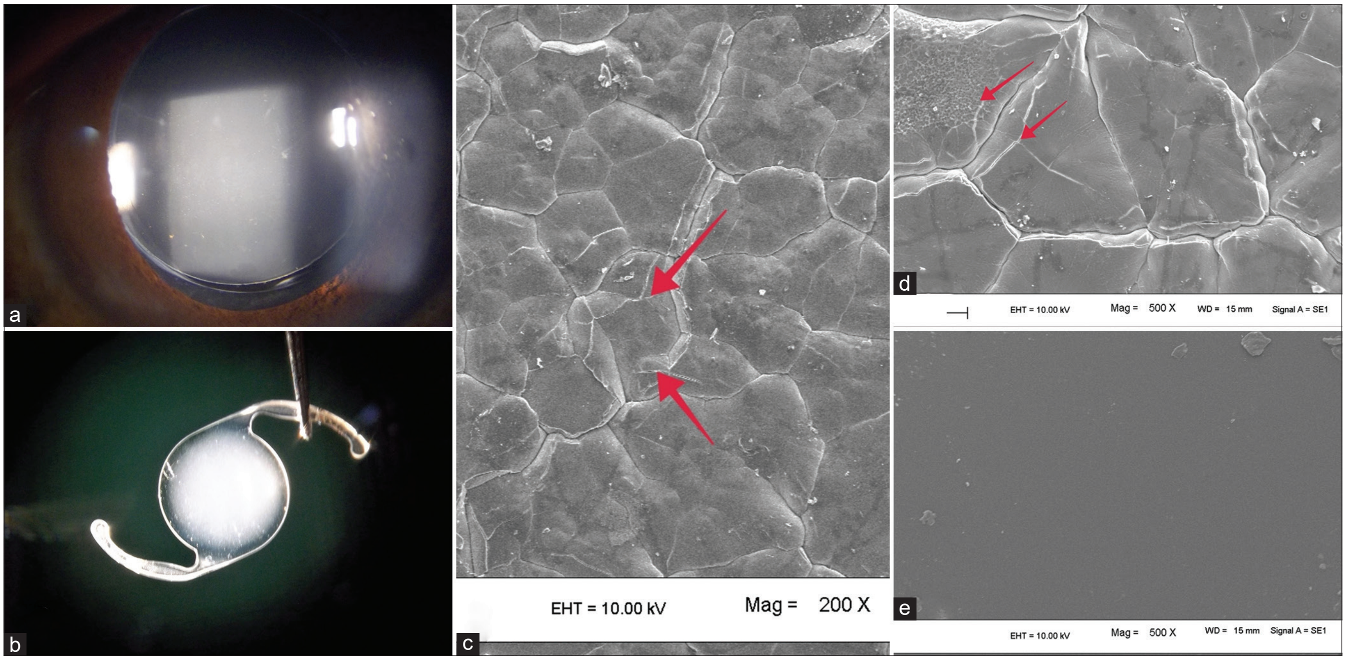

Figure 1: (a) Slit-lamp photograph showing cloudiness of the IOL. (b) Light microscopic photograph of the explanted single-piece hydrophobic IOL (Case 1, Sample 1). Note the opacification of the IOL optics except in the area which was undercover of the anterior lens capsule while the IOL was in vivo. (c and d) SEM photograph of surface structure of the explanted IOL in 200× and 500× magnification. Note erosion and cracks (arrow) and the rough surface of the IOL. (e) Control specimen. SEM photograph of the surface structure of a virgin acrylic hydrophobic IOL. Note fairly flat, smooth and homogenous surface

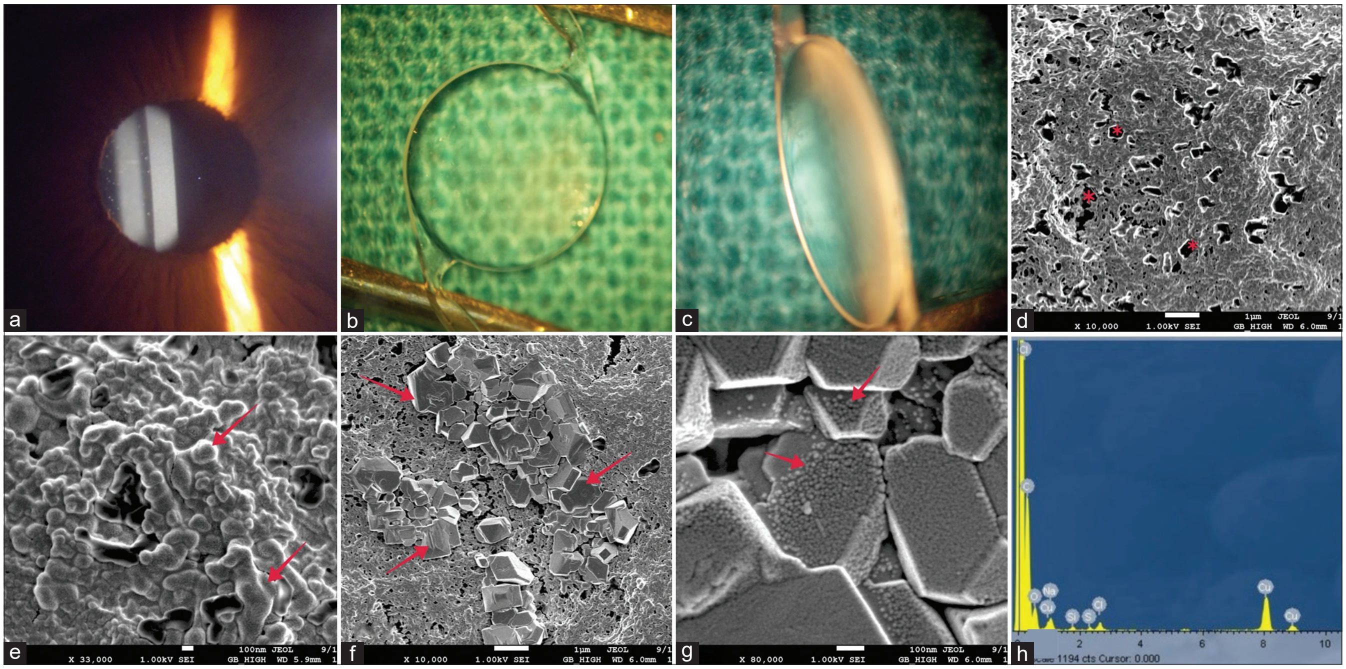

Figure 2: (a) – Slitlamp photograph showing cloudiness of the IOL (b and c) - Light microscopic photograph showing brownish-white discoloration of the IOL optics. (d and e) – SEM photograph of the surface structure. Note conglumated structure (arrow) and pores (asteric) in the IOL polymer. (f and g) – FESEM photograph. Note aggregated crystals deposited on the surface (arrow). In 80000× magnification (g) nano particles of 10 nm covering the crystals (arrow). (h) – EDS elimental analysis of the crystals and nano particles of the specimen. Note Na, Cl, S, Si and Ta. Note the absence of calcium and phosphate peaks

molecular weight and molecular distribution of the polymer and solubility of the low molar mass degradation product.[26,29-32] Ultraviolet absorbing compounds, low molecular weight additives, bland or co-monomer are covalently integrated into the polymeric backbone of IOL polymer. Electromagnetic wave, which presents in the visible light or ultraviolet light can degrade the bond and change the property of IOL polymer. The chemical and physical changes due to the biodegradation processes are reflected on the surface of the polymer and can be easily characterized by electron microscopy. The only

Table 1: Characteristics of the patients and explanted IOLs

Sample and Case no.	Age (years)	Gender	Age at Implantation (years)	Duration of Pseudophakia (years)	Slit lamp findings	IOL status	Indication of Explantation	Vision at the time of explantation	Light microscopy	SEM findings
1	80	Male	65	15	Quiet eye	Diffuse, dusty, hazy IOL optics	Blurring of vision	20/60	Single piece IOL. Homogenously hazy IOL optics	Surface cracks. Evidence of hydrolytic degeneration in aqueous media
2	76	Male	64	12	Quiet eye Resistant pupil. Pseudo exfoliation	Diffuse, dusty, hazy IOL optics	Blurring of vision, diplopia	20/40	Single piece IOL. Homogenously hazy IOL optics involving mainly both surfaces	Conglumated structure and pore on the IOL surface Crystals over the surface Nano particles over the surface (TEM, AFESEM, TEM-EDS) Evidence of low-molar-mass hydrolytic degradation in aqueous media Nano particles consistent of IOL polymer
3	71	Male	64	7	Quiet eye. IOP 28 mm Hg (Applan)	Diffuse, dusty, hazy IOL optics	Gross visual impairment	20/80	Single piece IOL. Homogenously hazy IOL optics involving mainly both surfaces	Non homogenous licking and uneven erosion of IOL surface suggestive of water-enzyme- catalyst chemical hydrolysis in biological environment due to random scission of polymer chain.

*Medical history of all cases was unremarkable. *Duration of onset of progressive visual deterioration and visual symptoms ranged from 3-5 years

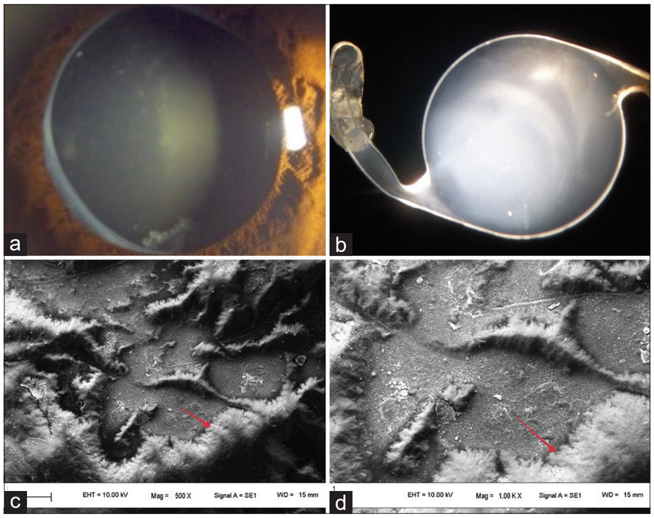

Figure 3: (a) – Clinical slit-lamp photograph. Note the cloudiness of the IOL. (b) – Light microscopy of the explanted single piece hydrophobic IOL (Sample 3). Note dense opacification of the IOL optics as seen by fiber optic guided condensed xenon light. (c and d) – SEM photograph of IOL surface topography in two different magnifications. Note homogenous licking and uneven erosion of the IOL surface and deeper layers. Erroding edges are evident (arrow)

drawback is that the beam damage may destroy the polymer specimen.[29,32] Reduction in optical quality and image contrast has been documented in opacified IOLs. In polymer science, electron microscopic techniques are in conventional use to study the morphology, composition, physical properties and dynamic behavior of a polymer.[29] Hydrophobic foldable IOL is a copolymer of phenyl ethyl acrylate and phenyl ethyl methacrylate cross-linked with butyrate diacrylate.[33]

In our study surface erosion and cracks in specimen 1 are suggestive of hydrolytic degradation of IOL polymer in an aqueous medium. In specimen 2, typical "conglumated" structures and pores on the surface suggest low molar mass degradation and absorption of polymer in aqueous media and in specimen 3, non-homogenous licking and erosion of surface and deeper layers indicates water–enzyme-catalyzed hydrolysis in biological environment due to random chain scission of the polymer. The electron microscopy of the control specimen detected a flat and homogenous structure without any cracks and pores on the surface [Fig. 1e]. In all the cases IOL was *in vivo* for an average of 11.3 ± 4.04 years. Co-morbid eye disease present in case 2 and 3 were pseudoexfoliation and glaucoma, respectively. On EDS analysis one of the samples detected carbon, oxygen and silicon peaks which are the normal composition of IOL.[34] Absence of calcium and phosphate peaks in the specimen and any other known factors and observing the electron microscopic findings and on comparing with the control specimen, we believe late postoperative opacification of the IOL is due to its slow biodegradation in the ocular media. In the degraded polymer, incident light gets scattered within the material at every point of refractive index inhomogeneities. Thus the once transparent IOL polymer following degradation looks opaque without any deposition of material in it and produces haze in the transmitted image.[35] However selective nature of biodegradation could not be explained in our cases.

There were a few limitations of the study, one of them being the limited number of specimens and the wide variation in the duration of pseudophakia among them. We would have benefitted from studying more specimens, however, obtaining a large number of samples with specifically primary type of biodegradation of IOLs, was difficult. Secondly, the presence of pseudoexfoliation in the second specimen could have had an influence in the biodegradation process and this needs to be studied in the future. Thirdly, further analysis of the nanoparticles and the cut-section of the specimens could not be done as after undergoing scanning electron microscopy (SEM), the specimens got burnt and charred and could not be utilized further.

Conclusion

To conclude, SEM features of the opaque IOL optics and absence of calcium and phosphate spikes in EDS and other findings were consistent and suggestive of hydrolytic biodegradation of hydrophobic acrylic IOL polymer in ocular media, responsible for delayed postoperative opacification of those IOLs and visual loss. No biomaterial used at present seems to be free from this process of biodegradation. This report demonstrates that other than secondary and tertiary opacification, primary opacification of the hydrophobic IOL is possible due to the inherent structure of the IOL polymer. Further research on this subject is essential and encouraged, safe prospective human application of IOLs, particularly with regards to the pediatric population, in whom a longer pseudophakic life is expected, making them more at risk for an IOL exchange, owning to the biodegradation of the IOL.

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Conflicts of interest

There are no conflicts of interest.

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