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Visually significant opacification of hydrophilic acrylic intraocular lenses – a clinico-pathological analysis

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PURPOSE. *To describe the clinic-pathological analysis of the visually significant opacification of the Cirrus International Hydroflex™ foldable hydrophilic acrylic intraocular lens (IOL) (model SC600-2, Medical Developmental Research Inc., Clearwater, Florida) and to highlight that this IOL is the same model as the Acryflex™ SC600-2 IOL, by the same manufacturer.*
METHODS. *Retrospective review of five eyes of four patients with opacification of their Cirrus International Hydroflex™ foldable hydrophilic acrylic IOLs (model SC600-2) after uncomplicated phacoemulsification and IOL implantation. Two IOLs were explanted from two patients 14 to 24 months after initial implantation. Each explanted lens was divided into equal halves, one half for scanning electron microscopy (SEM) study and the other half for transmission electron microscopy (TEM) examination. SEM and TEM samples were also subjected to energy dispersive X-ray analysis (EDX).*
RESULTS. *The IOL opacification was detected 14 to 24 months after uncomplicated phacoemulsification and IOL implantation. EDX analysis showed that the crystals contained calcium and phosphorus, presumably calcium phosphate.*
CONCLUSIONS. *The Cirrus International Hydroflex™ foldable hydrophilic acrylic IOL (model SC600-2) is associated with opacification, that appeared worse centrally than peripherally. This is the same model as the Acryflex™ SC600-2 IOL, made by the same manufacturer. The opacification consists of calcium and phosphate. (Eur J Ophthalmol 2003; 13: 147-50)*

KEY WORDS. *Acrylic intraocular lens, Hydrophilic, Opacification, Phacoemulsification*

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INTRODUCTION

Many types of intraocular lenses (IOL) are constantly being introduced for use in cataract operations. Various materials have been employed in the manufacture of such lenses. Polymethylmethacrylate (PMMA), silicone, acrylic and hydrogels are the main ones currently used. There have been reports of opacification of hydrophilic acrylic IOLs (1-5), calcifications of hydrogel IOLs (6) and glistening of acrylic IOLs (7). We describe five eyes of four patients with hydrophilic acrylic IOL opacification detected 14 to 24 months after uncomplicated phacoemulsification and IOL implantation. In all five cases, the IOL involved was the Cirrus International Hydroflex™ foldable hydrophilic acrylic IOL (model SC600-2). Two opacified IOLs were explanted and underwent pathological analysis which showed that the opacification consisted of calcium and phosphate.

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PATIENTS

Five eyes of four patients underwent uneventful phacoemulsification and implantation of Cirrus International Hydroflex™ foldable hydrophilic acrylic IOLs (model SC600-2). All patients were prescribed Spersadexoline® (chloramphenicol 5 mg/ml and dexamethasone 1 mg/ml, CIBA Vision, Hettlingen, Switzerland) eye drops four times a day for one month. One month post-operatively, the patients' best-corrected visual acuity (BCVA) ranged from 6/6 to 6/7.5.

IOL opacification was detected 14 to 24 months after the phacoemulsification and IOL implantation. The patients complained of decreased vision but did not have any other visual symptoms. The opacification was evident clinically, was centrally located (Fig. 1) and was visually significant in all cases, with an associated decrease of 2-4 Snellen lines of BCVA compared with the early post-operative period. Two patients had successful IOL exchange with visual improvement to the same level as the early post-operative period.

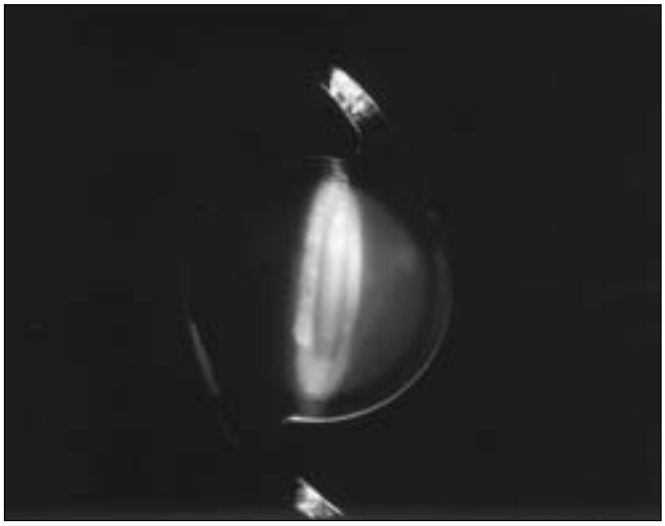

Fig. 1 - *Slitlamp photograph of the explanted IOL showing significant central opacification of the optic portion of the IOL.*

Pathological analysis

Each explanted lens was divided into equal halves, one half for transmission electron Microscopy (TEM) and the other for scanning electron Microscopy (SEM). All the specimens were fixed for 4 hours in 3% buffered glutaraldehyde, post-fixed in 1% buffered osmium tetraoxide for 2 hours, then dehydrated with a series of gradually increasing concentrations of ethanol, starting with 25% up to 100%.

The SEM samples were examined using the Philips XL30-FEG SEM (Philips Electron Optics, Einhoven, The Netherlands) at 20kV from 300X to 4,800X magnification. Energy dispersive X-ray analysis (EDX) was then done with the EDAX system (EDAX International, Mahwah, NJ), with a super UTW+ detector attached to the SEM.

The TEM samples were examined using the JEOL JEM-1220 TEM (JEOL Ltd., Tokyo, Japan) at 80kV at 5,000X and 10,000X magnification. EDX was carried out with the EDAX system with a super UTW detector attached to the Philips CM BioTwin STEM (Philips Electron Optics, Einhoven, The Netherlands).

Fig. 2 - *Transmission electron micrograph of the opacities (x 5000) in the explanted IOLs.*

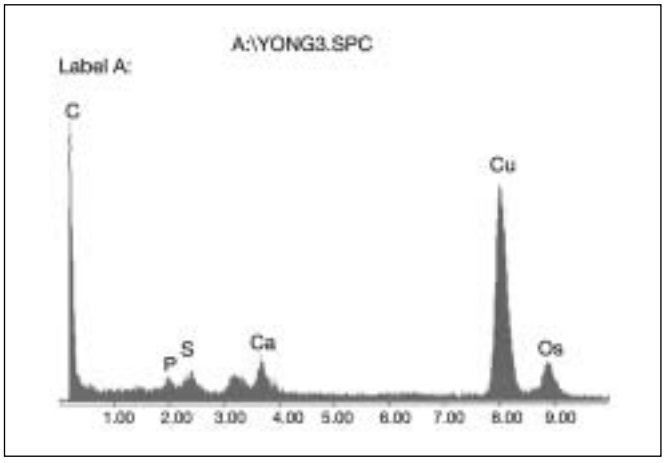

Fig. 3 - *EDX showing peaks of calcium and phosphorus in explanted IOL 1.*

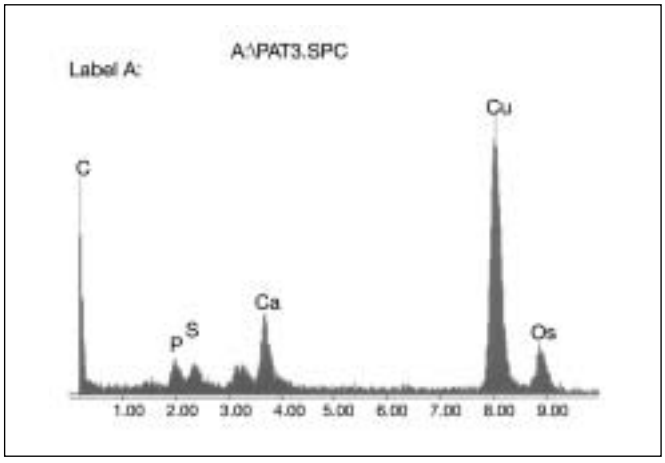

Fig. 4 - *EDX showing peaks of calcium and phosphorus in explanted IOL 2.*

DISCUSSION

The five IOLs described are Cirrus International Hydroflex™ hydrophilic acrylic foldable IOLs (model SC600-2, Medical Developmental Research Inc., Clearwater, Florida). This is a single-piece IOL with a haptic-to-haptic length of 12.5 mm and an optic size of 6.0 mm. Water absorption is 27.4% (w) at saturation and the refractive index is 1.46. Optical transmission is >95%.

Opacification occurred 14 to 24 months after implantation. It was evident clinically and was visually significant in all cases, with a decrease of 2-4 Snellen lines of visual acuity from the early post-operative period. In two cases, IOL exchange led to an improvement of 1-3 Snellen lines. None of the eyes had any co-existing ocular pathology other than pseudophakia. None of the IOLs had cells or deposits on them clinically.

SEM analysis of the two explanted IOLs found deposits within the substance of the optic. TEM (Fig. 2) showed crystalline opacities ranging from 5-20 µm in size. EDX analysis (Figs. 3, 4) showed that the crystals contained calcium and phosphorus, presumably calcium phosphate.

There have been recent reports of similar opacification in acrylic IOLs (1-5). In three reports, the IOL in question was the SC60B-OUV (Medical Developmental Research Inc., Clearwater, Florida) (2, 3, 5). Werner et al reported dense opacification of the optic of the SC60B-OUV IOL (5). Most patients in that study became symptomatic 24 months after uneventful phacoemulsification and IOL implantation. Our patients also became symptomatic 14 to 24 months after uncomplicated phacoemulsification and IOL implantation.

Pathological analysis has been done on the SC60B-OUV IOL. Pavlovic et al, (3) Shek et al (4) and Werner et al (5) performed EDX microanalysis of the explanted IOLs. The deposits were shown to contain calcium, phosphorus and oxygen, presumably calcium phosphate or calcium hydroxyapatite. Calcium has also been reported to deposit on the surface of IOLs. Fernando and Crayford described two cases of visually significant calcification of hydrogel intraocular lenses (6). Analysis of the explanted lenses revealed deposits of calcium phosphate (hydroxyapatite) on the IOL surface.

Other forms of IOL optic opacities have been reported in PMMA (7) and foldable acrylic IOLs (8). Silicone IOLs have become discoloured (9). Both discolouration and glistening have been attributed to changes in the IOL optic material due to the hydration (3).

The Medical Devices Agency (MDA) in the United Kingdom has published a hazard warning to all ophthalmologists regarding increased lens clouding of Acryflex™ SC60B-OUV and SC600-2 IOLs (Medical Developmental Research Inc., Clearwater, Florida). [Medical Devices Agency (MDA) Hazard Warning. HN 2000(04) – AcryflexTM SC60B-OUV and SC600-2 and Orion IFP3D6 intraocular lenses – Increased lens clouding. Date published 17/09/2001 (MDA website)]. In all our five cases, the IOL involved was the Cirrus International Hydroflex™ foldable hydrophilic acrylic IOL

(model SC600-2). This is the same model as the Acryflex™ SC600-2, manufactured by Medical Developmental Research Inc. but the IOL is marketed as a different brand in different countries.

CONCLUSIONS

The Cirrus International Hydroflex™ foldable hydrophilic acrylic IOL (model SC600-2) is associated with opacification and is the same model as the Acryflex™ SC600-2, made by the same manufacturer. Opacification was confined to the IOL optic and involved the substance of the IOLs. The patients complained of decreased vision but did not have any other visual symptoms. Pathological analysis showed the opacities to contain calcium and phosphorus, presumably calcium phosphate. The source of the opacification may be in the manufacturing process of the IOL or a change in the IOL material itself over time. In symptomatic patients, IOL exchange provides a means of improving BCVA.

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